LBA12000 **Oral Abstract Session**

PRO-ACTIVE: Results of a pragmatic phase IV randomized trial comparing the effectiveness of prophylactic swallow intervention for patients receiving radiotherapy for head and neck cancer.

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12001 Oral Abstract Session

Phase III randomized placebo-controlled trial on repurposing olanzapine for prevention of radiotherapy-induced nausea and vomiting (RINV): CTRI/2022/01/039723.

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Background: Prospective placebo controlled randomized study with or without olanzapine, to evaluate its role in reducing RINV in abdominal-pelvic radiation therapy patients. **Methods:** Phase III, double-blind, placebo-controlled trial in patients undergoing radiotherapy (RT) [Eligibility: >18 yrs, abdominal/pelvic RT, no prior RT history] were randomized to receive 5mg olanzapine or matching placebo daily, along with standard care (ondansetron 4mg twice daily) using simple randomization method. Primary endpoint was nausea prevention. Secondary endpoint was no emesis, no rescue medications, toxicity (CTCAE v5), & QOL. Pearson chi-square test & independent t-test employed for statistical analysis. **Results:** Between Feb 2022 to Aug 2024, 683 patients were screened & 301 randomized [153 placebo, 148 experimental/olanzapine]. In placebo & experimental arm, mean age was 63.8 years (+/- 10.8) & 62.3 years (+/-10.4), female 42% & 37%, rectal cancer 77(50%) & 72 (49%), prostate 47 (31%) & 46 (31%), endometrial cancer 14 (9%) & 14(9.5%), pancreatic cancer 9(6%) & 5(3.4%) (p=NS). In placebo & experimental arm, Image-guided RT done in 89% & 83%(p=NS), concurrent chemotherapy in 57% & 53% (p=NS). During RT, 'no nausea' & 'no vomiting' complain in placebo & experimental arms were 16.3 & 85.8% (p= <0.001); 74.5% & 95.9% (p= <0.001). Total number of vomiting episodes >15 times during RT in placebo & experimental arm were 9.2% & 2% (p=0.002). Rescue therapy during RT required in 7.8% placebo &1.4% in experimental arm (p=0.008). Grade≥2 nausea in placebo & in experimental arm 67% & 7.4% (p=0.001), and vomiting 7.8% & 1.4% (p=0.001). In rectal cancer, nausea grade ≥2 in placebo & experimental arm were 85.7% & 2.8% (p=0.001) & in prostate cancer 19% & 9% (p=0.018). In experimental arm, significant adverse reactions (grade 1) included drowsiness (p<0.001), dysarthria (p=0.003), and orthostatic hypotension (p<0.001). Mean anxiety score before & after RT in placebo was 13.2 (+/-2.5) &14.5 (+/-2.4) (p<0.001); in experimental arm 13.4 (+/-2.3) & 11.1 (+/-2.2) (p<0.001); Mean depression score before & after RT in placebo & experimental arm were 11.9 (+/-1.6) & 13.7 (+/-1.8) (p<0.001); 11.9 (+/-1.6) & 9.7 (+/-1.6) (p<0.001). The olanzapine group had more sleep hours/day (8.4 ±1.7 hours vs. 5.29 ±1.13 hours; p<0.001). QOL score from baseline to end of RT showed improvement in emotional function, nausea/vomiting, insomnia, & loss of appetite (all p<0.001) in olanzapine arm. Mean EORTC GHS QOL score at RT completion was 61.6 (+/- 8.6) in placebo arm and 62.9 (+/-9.2) in experimental arm (p=0.235). **Conclusions:** Adding olanzapine 5mg along with standard antiemetics demonstrated a significant reduction in RINV in patients receiving abdominal-pelvic radiation therapy. Clinical trial information: CTRI NO/2022/01/039723. Research Sponsor: Indian Council of Medical Research; 58/22/2020/PHA/BMS.

12002 Oral Abstract Session

Randomized control trial to validate mitigation of chemotherapy-induced peripheral neuropathy by limb-cooling apparatus in breast cancer patients receiving paclitaxel (CECILIA).

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Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a common adverse event affecting patient quality of life. Limb cooling may help to prevent CIPN, but no phase 3 trials have confirmed its efficacy, and its efficacy and safety remain challenging. This trial determined if temperature-controlled limb cooling could reduce CIPN in patients with breast cancer receiving weekly perioperative paclitaxel (PTX). **Methods:** This multicenter, double-blind, randomized controlled trial (jRCT2032210115) assigned patients with breast cancer scheduled to receive 12 weekly doses of perioperative PTX (60 min 80 mg/m^2 intravenous infusion) chemotherapy randomly (1:1) to limb-cooling therapy at a constant temperature of 13°C (Experimental arm) or 25°C (Control arm). The primary endpoint was the proportion of patients with Patient Neurotoxicity Questionnaire (PNQ) ≥D in their limbs after PTX treatment or at the time of discontinuation. Secondary endpoints were NCI-PRO-CTCAE™, EORTC QOL-QLQ-C30, and CIPN-20, and adverse events of cooling therapy. We assumed primary endpoints of 37% and 15% in the Control and Experimental arms, respectively. The planned sample size was 150 to detect a difference (Fisher's exact test, power 80%, 1-sided alpha 2.5%). **Results:** The study randomized 150 patients (n = 75 each arm). The PTX treatment completion rates (≥80%) were 88.0% (66/75) in the Experimental and 93.3% (70/75) in the Control arm. The proportion of patients with PNQ ≥D by the end of the treatment (primary endpoint) was similar in both arms (13°C vs. 25°C, 33.3% [25/75] vs. 29.3% [22/75], 1-sided p = 0.76). The proportions were higher in the Experimental arm 3 months after the end of PTX and in patients registered from June to September (Table). The proportion of patients with PNQ ≥D was higher in patients with hand epidermal temperature below the mean (21.5°C) at completion of PTX infusion than in the whole population (38.5%, Table). No frostbite or adverse events were reported in either arm. **Conclusions:** The primary endpoint did not meet and the limb cooling therapy using a stable cooling device resulted in lower proportion of PNQ ≥ D than was assumed for the Control arm irrespective of temperature settings, warranting further studies to determine optimal temperature. Clinical trial information: jRCT2032210115. Research Sponsor: Nippon Sigmax Co, Ltd.

Efficacy	13°C cooling (95%CI)	25°C cooling (95%CI)	P value
PNQ ≥D (primary endpoint)	33.3% (22.9–45.2)	29.3 % (19.4–41.0)	0.76
NCI-PRO-CTCAE	48.0% (95%CI 36.3–59.9)	49.3 % (37.6–61.1)	0.87
EORTC QLQ-CIPN20 (% non-worsening scores)	28.1% (95%CI 17.6–40.8)	8.8 % (3.3–18.2)	0.006
PNQ ≥D 3 months after end of PTX	32.0% (95%CI 21.7–43.8)	16.2 % (8.7–26.6)	0.034
PNQ ≥D in pts registered June–September	58.1% (39.1–75.5)	25.8 % (11.9–4.6)	0.020
PNQ ≥D in pts with hand epidermal temperature <21.5°C	38.5% (23.4–55.4)	-	-

12003 Oral Abstract Session

Music therapy versus cognitive behavioral therapy for anxiety in cancer survivors: A telehealth-based randomized clinical trial.

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Background: Anxiety is prevalent, disruptive, and under-treated among cancer survivors. While the pandemic exacerbated the mental health crisis, it also accelerated telehealth adoption, creating opportunities to expand access. Cognitive behavioral therapy (CBT) is the gold standard for anxiety, but not all survivors respond to it, have access, or prefer this option due to stigma. Music therapy (MT) has demonstrated short-term anxiety reduction, but its long-term effectiveness relative to other treatments is unknown. This study evaluated whether MT is noninferior to first-line CBT when both are delivered remotely. **Methods:** In this randomized clinical trial, English- or Spanish-speaking survivors of any cancer type or stage with anxiety lasting ≥1 month were randomized 1:1 to MT or CBT. Participants received 7 weekly sessions of a standardized protocol via Zoom and were followed for 26 weeks. Co-primary endpoints were Hospital Anxiety and Depression Scale (HADS) anxiety subscale changes at weeks 8 and 26. Secondary outcomes included depression, fatigue, insomnia, pain, cognitive function, and quality of life. Data were analyzed with linear mixed-effects models following intention-to-treat. Assuming 15% attrition and 1-sided $p < 0.025$, the trial had 80% power to detect noninferiority within a margin of D = 0.35*standard deviations (SDs). The margin was informed by an expected SD of 4.2 and the minimum clinically important difference (MCID) of 1.7 points for the HADS anxiety subscale. Thus, establishing noninferiority would indicate differences between MT and CBT are not clinically meaningful. **Results:** Among 300 (147 MT; 153 CBT), mean age was 56.9 (SD 13.2) years, 224 (74.7%) were female, 228 (76.5%) were white, and 57 (19.1%) were Hispanic. The most common cancer types were breast (45.3%) and hematologic (15.7%). At week 8, mean change in HADS anxiety score was -3.12 (95% CI -3.59 to -2.65) in MT and -2.97 (95% CI -3.45 to -2.50) in CBT; between-group difference was -0.15 (95% CI -0.78 to 0.49), which was within margin of 1.20 ($P < 0.001$ for noninferiority of MT; calculated from SD of 3.42). At week 26, mean change was -3.31 (95% CI -3.78 to -2.85) in MT and -3.00 (95% CI -3.47, -2.53) in CBT; between-group difference was -0.31 (95% CI -0.95 to 0.32), which was within margin of 1.30 ($P < 0.001$ for noninferiority of MT; calculated from SD of 3.65). Both groups produced anxiety reductions exceeding MCID of 1.7 and showed similar improvements in secondary outcomes. **Conclusions:** MT was non-inferior to CBT for short- and long-term anxiety reduction among diverse survivors of various cancer types. Both treatments produced clinically meaningful, durable anxiety reduction and were delivered remotely using standardized protocols, thereby increasing their reach and scalability. MT should be considered alongside first-line CBT to expand treatment options for anxiety during cancer survivorship. Clinical trial information: NCT05215353. Research Sponsor: Patient-Centered Outcomes Research Institute.

Fear of cancer recurrence in long-term colorectal cancer survivors: A randomized controlled trial of a therapist-guided eHealth intervention.

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Background: Despite the availability of effective interventions, fear of cancer recurrence (FCR) remains a prevalent and significant concern among cancer survivors, underscoring the need for more accessible and scalable approaches. This trial assessed the effectiveness of a therapist-guided eHealth intervention, TG-iConquerFear. **Methods:** This parallel randomized controlled trial (ClinicalTrial.org #NCT04287218) enrolled Danish colorectal cancer survivors (CRCS) who had completed curative-intent primary treatment between March 2014 and December 2018, were aged ≥ 18 years, and reported Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF) scores ≥22 (i.e. clinical FCR). After diagnostic interview, eligible participants were randomized to TG-iConquerFear (intervention) or a webpage with self-help mindfulness exercises (augmented control) in a 1:1 ratio. The 10-week TG-iConquerFear program comprised six modules with written therapist guidance delivered asynchronously. Follow-up questionnaires were administered at two weeks (T1), three months (T2), and six months (T3) post-intervention. The primary outcome was predefined as the difference in the change scores of the total FCRI score at T2, analyzed as intention-to-treat. Secondary outcomes were anxiety, depression, emotional distress, health-related quality of life (HrQoL) and physical symptom burden. Pre- and post-intervention mean within and between groups were pairwise compared using Student's t-test. **Results:** Of 9,946 eligible CRCS, 5,515 (55.4%) completed FCR screening, and 299 (5.4%) CRCS reported clinically significant FCR (FCRI score ≥ 22). Among them, 221 (73.9%) expressed interested in FCR treatment, and 103 (46.6 %) were randomized to TG-iConquerFear (n = 49) or control (n = 54). Main reasons for non-randomization included new cancer diagnoses or FCR not affecting everyday life. Participants completed 4.5 modules on average, and 55% completed the intervention. Baseline total FCRI score was 84.6/168 in both groups. Total FCRI score decreased more from baseline to T2 in the TG-iConquerFear group (mean -21.7, 95% CI [-30.1, -13.3]) compared to the augmented control group (mean -2.6 95% CI [-7.8, 2.6]). This represents a between-group difference at T2 of 19.1 (95% CI [10.0, 28.3], $p < 0.001$) corresponding to a standardized effect size (Cohen's *d*) of 0.62 (95% CI [0.13 - 1.1]). A higher proportion of TG-iConquerFear participants were in the non-clinical range at T2 compared to control participants (81.5% vs. 42.9%, p = 0.002). Statistically significant differences favoring the intervention group were observed across all secondary outcomes. **Conclusions:** The TG-iConquerFear intervention demonstrated a statistical and clinically significant reduction in fear of cancer recurrence in a population of long-term CRCS. The effects were sustained at six months post-intervention. Clinical trial information: NCT04287218. Research Sponsor: Danish Cancer Society; #12781, #16561 and #17152; The Tryg Foundation; #146250 and #152299; Dagmar Marshall Foundation; Fabrikant Einar Willumsen Memorial Fund; Overlæge Jørgen Werner Schou and Wife Else Marie Schou, Born Wonge Fund; Tømrermester Jørgen Holm's Memorial Grant; Region of Southern Denmark; Research Council of Lillebaelt Hospital.

12005 Oral Abstract Session

Results of a multisite randomized trial of Bright IDEAS-Young Adults: Efficacy of problem-solving skills training on distress and health-related quality of life.

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Background: Young adults (YAs) diagnosed with cancer between the ages of 18 and 39 face unique psychosocial challenges and are at risk of experiencing significant emotional distress and poor health-related quality of life (HRQOL). This randomized trial evaluated the efficacy of Bright IDEAS-YA, a problem-solving skills training intervention, on reducing distress and improving HRQOL of YAs newly diagnosed with cancer. A secondary aim examined change in problem-solving ability as a potential mediator of treatment effects. **Methods:** A three-site randomized trial of Bright IDEAS-YA compared with enhanced usual care (EUC) enrolled YA survivors within four months of a first diagnosis of cancer. Participants were randomized 1:1 to Bright IDEAS-YA or EUC (NCT04585269). Bright IDEAS-YA is a 6-session, one-on-one intervention that teaches a systematic approach to overcome personal challenges across any life domain. EUC involved usual psychosocial care plus AYA resources. Participants completed surveys at 0 (baseline), 3, 6, 12, and 24 months, with 6 months as the primary endpoint. Validated measures included the PROMIS Depression Short Form and Anxiety Short Form (primary outcomes), the Functional Assessment of Cancer Therapy – General (FACT-G; primary outcome), and Social Problem-Solving Inventory-Revised Short Form (SPSI-R; mediator). Efficacy was tested using linear mixed effects models, run in R, examining the group x time interaction effects. Mediation was tested using the R multiple mediation analysis. **Results:** 344 YA (34.2% acceptance rate, M_{age} = 30.3 years, SD = 6.3; 63% female, 37% male, < 1% non-binary) participated (100% planned enrollment), with 86% and 81% completing surveys at 3 and 6 months, respectively. Compared to baseline, the intervention arm showed statistically significant improvements in depression, anxiety, and HRQOL relative to the control group at 6 months. The intervention arm demonstrated an average reduction of 3.2 T-score points reduction in depression (95% CI [-4.9, -1.5], $p < 0.001$), 2.4 T-score points in anxiety (95% CI [-4.0, -0.81], $p = 0.003$), and 3.4 points improvement in total FACT-G (95% CI [0.34, 6.5], $p = 0.029$) relative to the control. These differences reflect clinically meaningful changes per published reports. Across all three models, change in total problem-solving ability (SPSI-R) was shown to mediate treatment effects, primarily due to change in the negative problem-orientation subscale. **Conclusions:** Bright IDEAS-YA was efficacious in reducing symptoms of depression and anxiety and improving HRQOL compared with enhanced usual care among YAs with cancer. Improvements are attributable to increased problem-solving ability, particularly by reducing the tendency to view problems as significant threats and doubt one's ability to successfully solve problems. Clinical trial information: NCT04585269. Research Sponsor: National Cancer Institute; R37CA240807.

A multicenter, randomized, controlled, open-label trial to determine the optimal duration of steroid therapy for mild pneumonitis associated with immune checkpoint inhibitors.

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Background: The optimal duration of corticosteroid therapy for pneumonitis associated with immune checkpoint inhibitors is clinically relevant. Several guidelines recommend a duration of 4 to 6 weeks for mild immune-related pneumonitis. However, evidence from clinical trials is limited. We conducted the first randomized trial to evaluate whether short-term corticosteroid therapy can achieve comparable efficacy. **Methods:** In this multicenter, open-label, randomized clinical trial at 22 institutions in Japan, we randomly assigned patients with mild immune-related pneumonitis according to the Common Terminology Criteria for Adverse Events grade 1 or 2, in a 1:1 ratio, to receive either 3-week or 6-week corticosteroid treatment. The primary endpoint was the rate of treatment success 8 weeks after the start of steroid administration, with a non-inferiority margin of 16 percentage points. The major secondary endpoints were safety, percentage of participants with treatment failure, quality of life, and overall survival. The primary hypothesis was that a 3-week treatment would be non-inferior to a 6-week treatment in terms of the primary endpoint. **Results:** Overall, 106 patients were randomized, and after the exclusion of one patient without immune-related pneumonitis, 105 were included in the intention-to-treat (ITT) population: 51 patients in the 3-week group and 54 in the 6-week group. In the ITT population, the patients' median age was 72 years; 81% of the patients were men, and 73% had grade 2 at baseline. The rate of treatment success was 66.7% in the 3-week group and 85.2% in the 6-week group, which did not demonstrate noninferiority in the overall study population (difference, −18.5% percentage points [80% confidence interval {CI}, −29.0% to -7.9%], p = 0.621), and a predefined exploratory superiority analysis indicated superiority of the 6-week regimen (p = 0.013). Over the entire study period, the relapse or exacerbation rates of pneumonitis were 41.1% in the 3-week group and 24.1% in the 6-week group. Grade 3 or higher adverse events occurred in 12% of patients in the 3-week group and 24% of patients in the 6-week group. The absolute mean change in the total QOL using the K-BILD score from baseline was 4.78 in the 3-week group and 6.28 in the 6-week group (between-group difference, -1.50 points; 95% CI, −5.91 to 2.91). **Conclusions:** In patients with mild immune-related pneumonitis, non-inferiority of 3-week corticosteroid treatment compared to that of 6 weeks was not confirmed in the overall population, and the relapse or exacerbation rate of pneumonitis was higher in the 3-week group over the entire study period. Corticosteroid therapy shorter than the duration recommended by the guidelines is not supported. Clinical trial information: jRCTs051220082. Research Sponsor: None.

12007 Oral Abstract Session

Romiplostim for chemotherapy-induced thrombocytopenia (CIT) in colorectal, gastroesophageal, and pancreatic cancers: A global, phase 3, randomized, placebo-controlled trial (RCT).

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Background: CIT is a common consequence of antineoplastic regimens for gastrointestinal (GI) cancers, occurring in >60% of colorectal cancer patients receiving multiagent chemotherapy. CIT can lead to chemotherapy dose reduction, delay, omission, and discontinuation, potentially worsening outcomes. There are no widely available licensed therapies for this unmet need. Aim: To evaluate the safety and efficacy of the thrombopoietin receptor agonist romiplostim (ROMI) in patients with GI cancers to limit chemotherapy dose modifications from CIT. **Methods:** This was a phase 3, placebo (PBO)-controlled RCT of patients receiving oxaliplatin-based multiagent regimens for GI cancers with persistent CIT, ie platelets (Plt) $\leq 85\times10^9$/L on day 1 of a scheduled chemotherapy cycle (NCT03362177). Patients from 55 sites in 14 countries were randomized 2:1 to ROMI or PBO for 3 chemotherapy cycles, stratified by baseline Plt (< or $\geq 50\times10^9$/L) and cancer type. Study drug started at 2 μg/kg subcutaneous weekly, adjusted weekly by 1 μg/kg up to 10 μg/kg to target Plt $\geq 100\times10^9$/L in 12 weeks (≤4 weeks at 10 μg/kg). Chemotherapy started when Plt $\geq 100\times10^9$/L (Plt response) or after week 4 per investigator. The primary endpoint was no CIT-induced dose modification of any myelosuppressive agent in either the second or third chemotherapy cycle per independent adjudication committee. **Results:** Patients (N=165; 109 ROMI, 56 PBO) had colorectal (75%), gastroesophageal (13%), or pancreatic (12%) cancer; 60% were male, 90% White, 4% Black, and 24% Hispanic, with mean (SD) age of 61.4 (11.1) years. Baseline median (range) Plt was 69 $(8–85)\times10^9$/L; 11% had Plt $<50\times10^9$/L. Stage IV disease rates were ROMI 65%, PBO 55%. Most (75%) patients completed study drug; 3% discontinued due to adverse events (AEs). The primary endpoint was achieved in 92/109 (84%) patients receiving ROMI vs 20/56 (36%) receiving PBO (odds ratio 10.2; 95% CI 4.6-22.5; P<0.001). Median (range) Plt nadirs were ROMI 87 $(14–167)\times10^9$/L, PBO 58 $(22–95)\times10^9$/L; P=0.005. For those with Plt responses (ROMI 97%, PBO 77%), median (95% CI) time to first Plt response was ROMI 1.1 (not estimable) weeks, PBO 2.1 (1.1-3.0) weeks; P<0.001. Treatment-related (TR) AE rates were ROMI: 12%, PBO: 7%, most frequently nausea (2%, 2%) and headache (2%, 0%). TR serious AEs and TRAEs leading to death or discontinuation of study drug or chemotherapy were not observed in either arm. **Conclusions:** In this first global phase 3 RCT of ROMI vs PBO for CIT, ROMI was well tolerated and efficacious in the treatment and prevention of CIT in GI cancers. These results are potentially practice-changing for a common serious condition encountered routinely in clinical practice worldwide that prevents delivery of on-time, full-dose anticancer therapy. Final results from long-term follow-up will be presented. Clinical trial information: NCT03362177. Research Sponsor: Amgen Inc.

Carica papaya leaf extract (CPLE) versus placebo to improve chemotherapy induced thrombocytopenia (CIT): Results of a phase III triple blinded, randomized placebo controlled trial (PACT study).

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Background: There is a lack of approved therapeutic options to ameliorate CIT in patients with solid tumors receiving chemotherapy. Carica papaya leaf extract (CPLE) is known to increase platelet counts (PC) in certain infections. **Methods:** The PACT study is a triple blinded randomized phase III study conducted in two academic centres in patients with solid tumors receiving chemotherapy and developing at least grade 2 or grade 3 CIT (platelet counts < 75,000 x 10^9/ liter and > 25,000 x 10^9/liter). Patients were randomized 2:1 to CPLE arm (capsule CPLE per oral 1100mg three times daily) or placebo arm (capsule per oral three times daily), which was continued till PC improved to greater than > 75,000 x 10^9/ liter, requirement for platelet transfusions or D+10 post intervention. Baseline PC were graded as per the Common Terminology Criteria for Adverse Events (CTCAE) grades. The primary endpoint of the study was to evaluate whether CPLE improves PC significantly faster (as assessed on D+4 of intervention) and above 75,000 x 10e9 /L as compared to placebo (spontaneous recovery of platelets). To achieve 80% power to detect a difference between the group proportions of 0.25 (50% to 75%) with an alpha of 0.05, 219 patients were required (146 in CPLE group and 73 in placebo group), assuming 10% loss to follow-up rates. **Results:** Between March 2020 and October 2024, 219 patients were randomized, of whom 198 patients (CPLE arm: 129; placebo arm: 69) were analysed for outcomes. All the baseline parameters were equally distributed in both the arms (2:1) except the proportion of patients in the placebo and the experimental arms had equal number of patients with grade 3 thrombocytopenia (17/129 vs 17/69; p = 0.049). The most common chemotherapeutic regimens were oxaliplatin based (37%) and carboplatin based (27%). The primary outcome of increasing PC > 75,000 x 10^9/ liter at D+4 was significantly improved by CPLE (83/129, 64% vs 33/69, 48%; p = 0.034) as compared to placebo. This improvement was significantly quicker in subgroups including three weekly regimen vs weekly/ biweekly, palliative intent vs. curative, > 2 cycles of chemotherapy (< = 2 cycles vs. > 2 cycles) and body surface area (BSA) < 1.6 vs. more. There were no grade 3 or grade 4 treatment related adverse events associated with CPLE. **Conclusions:** CPLE is the first therapeutic intervention that appears to improve grade 2 and grade 3 chemotherapy induced thrombocytopenia faster and to a greater extent than placebo in this phase III randomized trial. It should be used as a secondary prophylaxis to maintain the chemotherapy intesnity. There were no major safety concerns with the use of CPLE. Clinical trial information: CTRI/2019/08/020987. Research Sponsor: Micro Pharma Pvt Ltd; IASCC; Cadila Healthcare; Lupin Pharma Pvt Ltd.

12009 Rapid Oral Abstract Session

A randomized controlled trial of cognitive behavioral therapy and bright light therapy for insomnia and fatigue during breast cancer treatment: SleepCaRe trial.

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Background: Women on chemotherapy for breast cancer (BC) report high levels of insomnia and fatigue. This trial aimed to test the main effects of Cognitive Behavioral Therapy for Insomnia (CBT-I) and Bright Light Therapy (BLT) on insomnia and fatigue symptoms. **Methods:** This multi-center, randomized, controlled, 2 x 2 factorial, superiority, trial enrolled 219 women receiving cytotoxic chemotherapy for any stage BC. Interventions were: (1) neither CBT-I nor BLT (sleep hygiene education; SHE), (2) BLT, (3) CBT-I, and (4) BLT+CBT-I. The 6-week interventions included one telehealth, 1:1 session followed by emails and a mid-treatment call. Assessments occurred at baseline, 3 and 6 weeks. Dual primary outcomes were the insomnia severity index (ISI) and PROMIS Fatigue. Intention-to-treat analyses were latent growth models. Effect sizes are standardized mean differences (SMDs). **Results:** Mean age was 50.7y and 24% had metastatic cancer. At baseline, average ISI was 13.24 (SD = 5.48; sub-threshold insomnia), and fatigue was 59.57 (SD = 7.91; moderate fatigue). 88% (n = 198) completed the telehealth session. 75% (n = 165) reported post-treatment outcomes. ISI and fatigue decreased in all conditions (see Table). CBT-I improved ISI (mean difference = -2.03; p = .001; SMD = -0.37), but BLT did not (mean difference = -1.09; p = .082; SMD = -0.20). Neither intervention affected fatigue (SMDs -0.06 to -0.07; $p > 0.60$). There was no BLTxCBT-I interaction for ISI nor fatigue ($p > 0.50$). **Conclusions:** In patients receiving chemotherapy for BC, brief CBT-I can improve insomnia but not fatigue symptoms. BLT did not improve insomnia or fatigue. We found no evidence of an interaction between BLT and CBT-I. During chemotherapy, fatigue may not be responsive to brief sleep and circadian-oriented treatments. Clinical trial information: ACTRN12620001133921. Research Sponsor: None.

Between group (main effects) and within group (change).

	ISI *[95% CI] P, SMD*	Fatigue *[95% CI] P, SMD*
Main Effects		
BLT	-1.09 [-2.31, 0.14]	-0.49 [-2.87, 1.88]
	p= .082, *SMD* = -0.20	p= .68, *SMD* = -0.06
CBT-I	-2.03 [-3.25, -0.81]	-0.54 [-2.92, 1.83]
	p= .001, *SMD* = -0.37	p= .65, *SMD* = -0.07
Change: 0–6 weeks		
SHE	-3.41 [-4.65, -2.17]	-3.75 [-6.16, -1.34]
	$p < .001$, *SMD* = -0.62	p= .002, *SMD* = -0.47
BLT	-4.89 [-6.12, -3.66]	-3.75 [-6.13, -1.37]
	$p < .001$, *SMD* = -0.89	p= .002, *SMD* = -0.47
CBT-I	-5.83 [-7.12, -4.54]	-3.80 [-6.30, -1.31]
	$p < .001$, *SMD* = -1.06	p= .003, *SMD* = -0.48
CBT-I+BLT	-6.53 [-7.88, -5.18]	-4.79 [-7.44, -2.14]
	$p < .001$, *SMD* = -1.19	$p < .001$, *SMD* = -0.61

12010 Rapid Oral Abstract Session

Alliance A221805: Duloxetine to prevent oxaliplatin-induced chemotherapy-induced peripheral neuropathy (CIPN)—A randomized, double-blind, placebo-controlled phase II study.

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Background: Standard-of-care chemotherapy treatment regimens for colorectal cancer (CRC) include oxaliplatin, a drug known for causing CIPN. CIPN is characterized by upper and lower extremity numbness and tingling, and pain that can persist for years beyond chemotherapy completion, causing impaired function and poor quality of life. According to the American Society of Clinical Oncology's (ASCO) 2020 Clinical Practice Guidelines, there are no known effective preventative interventions. While the ASCO guidelines recommend duloxetine to treat established painful CIPN, its efficacy to prevent CIPN has not been established. **Methods:** A221805 (NCT04137107) was conducted within the National Cancer Institute-supported Community Oncology Research Program; Alliance for Clinical Trials in Oncology was the coordinating group. The randomized, 3-arm, double-blind, placebo-controlled, noncomparative, multicenter phase II study screened 2 doses of daily duloxetine to prevent sensory CIPN. Enrollment occurred between May 1, 2020, and March 24, 2023. Patients (pts) were randomized 1:1:1 to 30 or 60 mg of daily duloxetine, or daily placebo. Eligible pts had stage II-III CRC and no baseline neuropathy, were $\geq$ 25 years of age and scheduled to receive oxaliplatin via one of the following schedules: 85 mg/m2 every 2 weeks (wks; 6 or 12 doses) or 130 mg/m2 every 3 wks (4 doses). Duloxetine/placebo was taken once daily beginning on day 1 of cycle 1 and continued for 17 wks. Blinding was achieved via drug encapsulation. The primary outcome was measured on wk 19-21 using a validated patient-reported outcome measure: 6 sensory items from the EORTC QLQ-CIPN20. Responders were pts who reported little to no CIPN; their highest score was $\leq$ 2 (i.e., 1 = "Not at all"; 2 = "A little") on any of the 6 items. **Results:** 199 pts were accrued (n = 66, 30 mg duloxetine; n = 66, 60 mg, duloxetine; Placebo, n = 67); based on modified intent-to-treat criteria, 46, 47, and 50 pts (N = 143, 71.8%) respectively, were evaluable for the primary endpoint analysis. The pt mean age was 55.1 years (SD = 10.43). Most were White (n = 113, 80.7%) and male (n = 82, 58.6%).There was no difference in the proportion of responders when comparing those who received either duloxetine 30mg (65.2%), 60mg (66.0%), or placebo (68.0%). Fatigue (51.9%) and nausea (46.5%) were the most common solicited adverse events. Duloxetine adherence rates, measured via pill counts, in the 30mg (44.44%), 60mg (50.92%), and placebo (65.57%) groups were low ($<$ 75%). **Conclusions:** We were unable to show that any dose of duloxetine was more promising than placebo, possibly due to an unexpectedly high placebo response rate. Low duloxetine/placebo adherence may have compromised efficacy. Placebo-response mitigation methods should be considered in future CIPN clinical trials. Clinical trial information: NCT04137107. Research Sponsor: National Cancer Institute; 1UG1CA189823; R01CA235726.

12011 Rapid Oral Abstract Session

Peri-transplant supportive and palliative care and/or comorbidity management for older, medically infirm, and/or frail recipients of allogeneic hematopoietic cell transplantation (Allo-HCT): Phase II and interim phase III trial analyses.

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Background: Patients (pts) with high HCT-Comorbidity Index scores (HCT-CI of ≥3), older age (≥65 years), and/or who are frail per gait speed (<0.8 meters/second) have increased morbidity and mortality after allo-HCT compared to younger and healthier counterparts. We report the phase II analysis (PIIA) and interim phase III primary outcome analysis (PIIIA) of a seamless phase II/III prospective, randomized clinical trial conducted at 11 transplant centers to test new approaches to improve quality of life (QOL) in this population. **Methods:** Phase II compared specialist-administered supportive and palliative care (SPC), patient-administered management of comorbidities (MC, e.g. physical exercise, stress reduction, etc), both (SPC+MC), and usual care (UC) for change in Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) QOL scores from baseline to day 90 (D90). Pts deceased prior to D90 were assigned FACT-BMT score=0. The winning phase II arm moved forward versus UC in phase III. **Results:** PIIA was done after enrolling 35 pts to each of the 4 study arms. Calculating the difference between FACT-BMT scores on D90 minus baseline, excluding missing data, indicated that only SPC resulted in a small improvement in QOL compared to either MC or SPC+MC (Table); hence SPC was the winning phase II arm. The PIIIA was conducted after enrolling 158 SPC pts and 153 UC pts. The SPC and UC arms were well balanced with median age (both 68 years), HCT-CI ≥3 (49% vs 55%), frailty per gait speed (13% vs 12%), female sex (41% vs 34%), non-white race (9.5% vs 11.5%), and Hispanic or unreported ethnicity (7.7% vs 5.7%), respectively. After median follow-up of 362 days, 45 pts had died in each arm. The mean QOL difference between D90 and baseline was 2.83 for SPC and 4.27 for UC (difference of differences, -1.44, 95% CI of difference, -5.03 to 2.14, p=0.43). Fitting a generalized linear model that included baseline, D30, and D90 values and testing the null hypothesis that the slope of scores differs between SPC and UC resulted in p=0.85. Using the Kaplan Meier method, no difference in survival was observed across arms (HR 1.13 [0.75-1.73]). **Conclusions:** Specialist-administered palliative care showed no meaningful improvement in QOL, nor a survival advantage, compared to usual care in frail, older and comorbid allo-HCT recipients, resulting in the cessation of this Phase II/III trial. Analysis of the whole patient population for primary and secondary outcomes is in progress. Clinical trial information: NCT03870750. Research Sponsor: National Cancer Institute.

Change in FACT-BMT (D90 value minus baseline value) comparing the 4 arms of phase II.

Group	Mean difference (sd)	Median difference (range)
SPC (n=28)	-2.93 (28.52)	0.25 (-102 to 38.22)
CM (n=18)	-18.37 (33.80)	-9.50 (-98.33 to 11)
SPC+CM (n=27)	-15.76 (32.69)	-7.67 (-90 to 32)

12012 Rapid Oral Abstract Session

Efficacy of treatment with traditional Chinese medicine (Renshen Yangrong Tang granules) for cancer-related fatigue in patients with platinum-based chemotherapy: A randomized, double- blinded, placebo-controlled, multicenter trial.

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Background: Although there is higher incidence of cancer-related fatigue (CRF) in patients undergoing chemotherapy, effective drugs is still in need. Renshen Yangrong Tang (RSYRT), a Traditional Chinese Medicine, has shown promise in alleviating CRF. This trial aims to investigate whether RSYRT could reduce fatigue and improve quality of life in cancer patients with platinum-based chemotherapy. **Methods:** This prospective, multicenter, double-blinded, placebo-controlled trial was implemented at 4 centers in China, enrolling 192 platinum-treated cancer patients with Visual Analogue Scale for Fatigue ≥4 points on the 10th day of the first cycle of chemotherapy. Participants were randomized to receive RSYRT (10.35g, 2 times per day) or a matching placebo orally simultaneously with chemotherapy from C1D10 to C2D10. The study was conducted between April, 2020 and September,2023, with a final follow-up on October,2023. The primary outcome was the change in total mean score (range: 0[no fatigue] to 10[extreme fatigue] points) on the Brief Fatigue Inventory(BFI-C) from baseline to week 3. Secondary outcomes include quality of life(European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire C30, QLQ-C30), fatigue score (MD Anderson Symptom Inventory for Traditional Chinese Medicine MDASI-TCM) and adverse events. RSYRT were compared with the placebo group using a linear mixed model. **Results:** Among 192 patients randomized, 163 participants completed assessment (RSYRT:81 and Placebo:82). There was no significant differences of "Usual fatigue in last 24 hours" score (RSYRT:5.15±1.41 vs Placebo: 5.40±1.44,*P*= 0.256) in BFI between two groups at baseline. By the end of week 3, the RSYRT group achieved normal fatigue levels compared to the placebo group (RSYRT: 3.35±1.95 vs Placebo: 4.15±2.12, *P*= 0.013). The overall health status of QLQ-C30 also showed statistically significant differences (Pre intervention [RSYRT: 52.78 ± 15.14 vs. placebo: 49.49 ± 17.63, *P*= 0.204] , After intervention [RSYRT: 65.53 ± 15.52 vs. placebo: 57.72 ± 19.98, *P*= 0.006]) . The fatigue score of MDASI-TCM was comparable at baseline (RSYRT: 5.72 ± 1.69 vs placebo: 5.90 ± 1.70, *P*= 0.483) , and a significant decrease was observed in the third week (RSYRT: 3.69 ± 2.05 vs placebo: 4.56 ± 2.30, *P*= 0.012) . There was no difference in adverse events occurrence between RSYRT and the placebo groups. **Conclusions:** In this randomized clinical trial among platinum-treated cancer patients with CRF, RSYRT reduced fatigue severity and improved quality of life compared to placebo. Clinical trial information: NCT05229029. Research Sponsor: Capital's Funds for Health Improvement and Research.

12013 Rapid Oral Abstract Session

Pathways to Advance Targeted and Helpful Serious Illness Conversations (PATH-SIC): A randomized clinical trial.

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Background: Serious illness conversations (SICs) can improve quality of life and decrease intensive care utilization at the end of life for patients with cancer. Yet SIC rates for patients with cancer are low and sustainable strategies are needed to engage patients and oncology clinicians in SICs. **Methods:** This randomized controlled trial was conducted at a tertiary cancer center. Using a cancer treatment guideline program (Pathways), oncology subspecialists identified treatment decision points where patients have an average prognosis <1 year and they would recommend an SIC. We enrolled patients with breast, gastrointestinal, genitourinary, gynecologic, and thoracic cancers who reached these points and did not have SICs documented in the Advance Care Planning tab (ACP-SICs) of the electronic medical record in the previous 6 months. Patients were randomized to receive a patient nudge (a mailed letter encouraging discussion of their values and preferences with their oncologist; arm 1), a clinician nudge (emails sent to oncology clinicians encouraging an SIC the day prior to the clinic visit; arm 2), both nudges (arm 3), or no nudges (arm 4). The primary analysis compared ACP-SIC documentation 60 days post-randomization for the combined vs no-nudge arms (arm 3 vs 4) using a generalized estimating equation model with a logit link adjusted for disease center and prior clinician SIC training, clustered on oncologists. A pre-specified alternative primary outcome used natural language processing (NLP) to identify SICs in free text notes in the 6 months prior to randomization and 60 days after to evaluate the presence of an NLP- or ACP-SIC 60 days after randomization using the same model. Similarly-constructed Cox proportional hazards models were used to estimate time to SIC. **Results:** Among 1051 patients randomized (arm 1: 273, arm 2: 240, arm 3: 277, arm 4: 261), median age was 65 years (range: 25-94), 40% were male, 79% White, 52% had gastrointestinal and 20% breast cancers. The Table displays unadjusted ACP and NLP+SIC rates. In adjusted analyses, compared to patients in the no-nudge arm (arm 4), patients in the combined nudge arm (arm 3) had 79% higher odds of ACP-SIC at 60 days (odds ratio 1.79, 95% CI 1.11-2.88, p=0.02) and 59% higher odds of NLP+ACP-SIC at 60 days (odds ratio 1.59, 95% CI 1.14-2.22, p=0.006). Time to ACP-SIC was 59% faster in clinician nudge-containing arms than the no-nudge arm (adjusted HR 1.59, 95% CI 1.16-2.19, p=0.004). **Conclusions:** Clinician emails increased SICs within 60 days, whereas patient nudges were ineffective. NLP increased detection of SICs by 49.7%, demonstrating the importance of evaluating SICs in free-text notes in SIC interventions.Long-term analyses will evaluate the interventions' impact on care delivery outcomes. Clinical trial information: NCT05629065. Research Sponsor: None.

Unadjusted SIC at 60 days.

Arm	1: Patient	2: Clinician	3: Combined	4: None
ACP, %	10.6	16.7	17.3	10.7
NLP+ACP, %	22.4	27.8	34.0	24.4

12014 Rapid Oral Abstract Session

Trajectories of patient-reported cognitive function and age-related conditions in a longitudinal observational trial of immune checkpoint inhibitor (ICI) treatment: The DiRECT Cohort.

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Background: ICIs have become a mainstay in cancer treatment, but their impact on patient-centered side effects such as decline in cognitive function and age-related conditions (e.g., nutritional status, mobility) has not been fully characterized. Black patients have also been underrepresented in prospective studies of ICIs. Prior research indicates that Black cancer patients have strong pro-inflammatory immune responses, which could affect the impact of ICI treatment on cognitive function and age-related conditions. **Methods:** The longitudinal DiRECT cohort (URCC21038, NCT05364086) was established to examine ICI outcomes and side effects in Black and White patients through the NCI Community Oncology Research Program (NCORP). Patients reported their cognitive function through the PROMIS-Cog and age-related conditions through the Geriatric 8 (G8), with assessments before (A1), after (A2), 6 months after (A3), and annually after (A4+) their first ICI infusion. A longitudinal mixed-effects model (LMEM) with an unstructured covariance matrix and assessment as a nominal factor was used to evaluate trajectories of the two outcome variables. The models were adjusted for cancer type, race, and age (<65, 65+), including interactions with assessment. Multiple comparisons were conducted with a Sidak adjustment to maintain an overall significance level of $p<0.05$. **Results:** A total of 1,677 patients enrolled between 04/01/2022 and 08/31/2024 were included in the analysis: mean age 64; 409 Black; 626 lung, 290 breast, 251 gastrointestinal, 240 genitourinary, 131 gynecologic, 72 head/neck cancers; modal cancer stage IV. In unadjusted models, statistically and clinically significant declines from A1 to A3 were found for both cognitive function (SE=-2.54, $p<0.0001$) and age-related conditions (SE=-0.70, $p<0.0001$), with no change from A3 to A4. Patients with breast cancer experienced the steepest declines in both outcomes (SE=-3.40, $p<0.0001$ and SE=-0.76, $p<0.01$, respectively). Black patients experienced a steeper decline in cognitive function than White patients, particularly from A1 to A2 (SE=-1.28, $p=0.01$). There was no significant difference in trajectory of functional status by race. Patients <65 experienced steeper declines in cognitive function and age-related conditions (SE=1.21, $p=0.02$ and SE=0.84, $p=0.04$, respectively); Black patients <65 had steeper declines in cognitive functioning than White patients <65 (SE=-1.55, $p=0.02$). **Conclusions:** Breast cancer patients on ICIs appear to experience poor trajectories of cognitive function and age-related conditions over the first 6 months of treatment, while Black patients, particularly those <65, experience poor trajectories in cognitive function. These findings can inform tailored and risk-stratified interventions to improve ICI side effects. Research Sponsor: National Cancer Institute; UG3 CA262602; National Cancer Institute; UG1 CA189961.

12015 Rapid Oral Abstract Session

Severe sarcopenia and symptom burden prior to chemotherapy among older adults (70+) with advanced cancer: A URCC NCORP nationwide study.

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Background: Sarcopenia – defined as significant loss of strength, muscle mass and physical function– leads to reduced mobility, increased falls, difficulty performing activities of daily living, loss of independence, worse prognosis, and higher mortality among older cancer patients. Older patients with sarcopenia are at an even greater risk for these negative outcomes when additional co-morbid symptoms are present. Despite this, sarcopenia is not routinely screened for in this population. This study aims to describe the proportion of older patients with advanced cancer prior to chemotherapy who present with severe sarcopenia and the additional co-morbid symptoms they are most likely to be experiencing. **Methods:** In a randomized controlled trial (NCT02054741), 718 older adults (age 70+) with advanced cancer and age-related conditions were recruited prior to starting chemotherapy from community oncology practices across the United States who were affiliated with the University of Rochester NCI Community Oncology Research Program (NCORP) Research Base. We analyzed data from a subset of 159 participants prior to chemotherapy who completed assessments for muscle strength (chair stand; seconds [s]), skeletal muscle index (CT scan; SMI [cm^2/m^2]); physical performance (timed up and go; TUG [s]) at baseline. Severe sarcopenia was diagnosed if participants met all three clinically accepted criteria: 1) chair stand $>$ 16.7s for five rises, 2) SMI $<$ 41 cm^2/m^2 (women) and $<$ 43 cm^2/m^2 (men; BMI $<$ 24.9 kg/m^2) or $<$ 53 cm^2/m^2 (men; BMI $>$25 kg/m^2), and 3) TUG $>$ 13.5s. Symptoms (i.e., fatigue, insomnia, pain, anorexia, dyspnea, cognitive issues, nausea, sensory neuropathy, constipation, and diarrhea) were assessed via the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). **Results:** Fifty-two of the 159 participants (33%; mean age: 76.7 years; 60% male) had severe sarcopenia. Chi-square analyses revealed participants with severe sarcopenia were significantly more likely to report fatigue (94% vs. 81%; p = 0.03), anorexia (73% vs. 55%; p = 0.03), and pain (73% vs. 60%; p = 0.13) compared to those without severe sarcopenia. Logistic regression indicated those with severe sarcopenia were almost 4x more likely to experience fatigue (OR [95%CI]: 3.75 [1.06-13.28]) and twice as likely to experience anorexia (OR [95%CI]: 2.21 [1.07-4.54]) compared to those without severe sarcopenia. **Conclusions:** One-third of older adults with advanced cancer are likely to present with severe sarcopenia, fatigue, anorexia, and pain prior to the initiation of chemotherapy. Clinicians should consider screening older adults for sarcopenia and other comorbid symptoms to inform cancer treatment decisions prior to the initiation of therapy, and supportive care interventions should be prescribed to mitigate these symptoms. Funding: NCI UG1CA189961 T32CA102618. Research Sponsor: None.

12016 Rapid Oral Abstract Session

Effect of incorporating symptom burden with mortality as a composite outcome on accuracy and bias in palliative care identification algorithms in oncology.

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Background: Machine learning (ML) algorithms are increasingly used to identify patients for early palliative care (PC) or advance care planning (ACP). Most PC/ACP algorithms are trained using only mortality as an outcome. However, increasing availability of structured patient-reported outcomes (PROs) in electronic health record (EHR) databases can facilitate more comprehensive identification of palliative care need by training algorithms on composite outcomes of mortality and symptom burden. **Methods:** Our cohort consisted of patients with cancer seen at one of 18 practices in 2019 within a large academic cancer center. We leveraged structured EHR data, consisting of 153 demographic, laboratory, and comorbidity features and 12 symptom scores derived from CTCAE-PRO that were routinely reported at medical oncology encounters (72% response rate). Our Base Model was a random forest model predicting 180-day mortality from the date of an initial medical oncology encounter (index encounter) that was used in practice to prompt earlier ACP conversations. We retrained models using a Composite Label of mortality and/or severe symptoms (≥3 out of 5 in at least 1 symptom) within 180-days of an index encounter. We report performance for Base vs. Retrained models in 1,000 bootstrapped samples predicting the Composite Label using area under the precision-recall curve (AUPRC) and true positive rate (TPR) for All Patients, Black Patients, and White Patients. We hypothesized that Retrained models would improve performance and reduce Black-White disparities. **Results:** Our cohort consisted of 4908 patients (median age 64.1 years [IQR 17.5], 53.0% female, 59.6% solid tumor malignancies). Retrained Models improved TPR over Base Models for All (0.56 [95% CI 0.52-0.59] vs. 0.18 [95% CI 0.15-0.21]), Black (0.60 [95% CI 0.52-0.67] vs. 0.20 [95% CI 0.14-0.26]), and White (0.55 [95% CI 0.50-0.59] vs. 0.17 [95% CI 0.14-0.20]) patients, with similar AUPRC. TPR improvement was marginally greater for Black vs. White patients (0.02 [95% CI -0.01-0.05]). **Conclusions:** In this cohort study, retraining a PC identification algorithm on a Composite outcome of symptom burden + mortality significantly enhanced identification of PC need, with disproportionate improvements for Black patients. Incorporating PROs into PC identification model outcome labels should be strongly encouraged. Research Sponsor: National Cancer Institute; K08CA263541.

Comparison of base vs. retrained model performance.

	All Patients[a]		Black Patients[a]		White Patients[a]		Other[b]
Model	Base	Retrained	Base	Retrained	Base	Retrained	Difference in Black vs. White Improvement
AUPRC	0.71 (0.68, 0.74)	0.71 (0.68, 0.74)	0.80 (0.73, 0.85)	0.79 (0.72, 0.85)	0.68 (0.65, 0.72)	0.68 (0.65, 0.72)	0 (-0.01, 0.08)
TPR	0.18 (0.15, 0.21)	0.56 (0.52, 0.59)	0.20 (0.14, 0.26)	0.60 (0.52, 0.67)	0.17 (0.14, 0.20)	0.55 (0.50, 0.59)	0.02 (-0.01, 0.05)

[a]Mean (95% CI) [b]Mean difference (95% CI).

12017 Rapid Oral Abstract Session

Precision-calibrated LightGBM machine learning model to predict serious adverse events in oncology patients using FAERS.

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Background: The U.S. Food and Drug Administration's Adverse Event Reporting System (FAERS) is a large national repository capturing postmarketing drug safety events. Predicting serious adverse events (SAEs) is especially critical for oncology patients, who often face complex regimens and higher toxicity risks. Currently, there are no well-established predictive tools to identify those at highest risk of SAEs in the cancer population. We aimed to develop a machine learning (ML) model that leverages FAERS data to address this clinical gap. **Methods:** We collated FAERS records from 2012Q4–2024Q3 that listed cancer as an indication, encompassing demographics, outcome codes (SAEs defined as death, life-threatening, disability, hospitalization, or congenital anomaly/birth defect), and drug data. Excluding non-cancer or incomplete entries, we split the dataset into 80% for training and 20% for testing, applying cross-validation to derive 95% confidence intervals. Training data underwent SMOTETomek oversampling to counter class imbalance. We then built a precision-focused LightGBM model using high-depth RandomizedSearchCV to fine tune the hyperparameters and subsequently applied sigmoid calibration to yield stable probability estimates and enhanced interpretability. Additionally, a logistic regression model was built under the same pipeline as a baseline comparator. **Results:** Of the final 2.28 million oncology-related reports, ~44% met SAE criteria. On the ~450,000-report test subset, our calibrated LightGBM model achieved 75% accuracy, with precision = 73.7% and recall = 86.3%, yielding an F1 of 0.795. The AUROC reached ~0.82 (95% CI ~0.80–0.84), underscoring robust discrimination, and the AUPRC approached 0.77. By comparison, logistic regression attained 73% accuracy (precision 72.9%, recall 81.5%, F1 = 0.77). Thus, the LightGBM pipeline offered notable gains in recall and F1 while preserving practical precision. Cross-validation demonstrated stable performance (±~1–2% across folds), and preliminary partial SHAP analysis indicated that older age (≥65 years), multi-agent chemotherapy, and prior adverse event histories were among the strongest predictors of SAE risk. **Conclusions:** In this largest FAERS-based oncology SAE analysis, our LightGBM model markedly outperformed logistic regression, achieving high recall (86%) and balanced precision (74%). These findings represent a significant advance in real-world pharmacovigilance, enabling earlier and more reliable detection and prediction of severe toxicities in cancer patients. Future prospective validations, potentially incorporating external datasets, may further amplify its clinical impact. Research Sponsor: None.

12018 Poster Session

Cardiovascular risks associated with aromatase inhibitors versus tamoxifen in breast cancer: A systematic review and meta-analysis.

Danilo Monteiro Ribeiro, Isabela Junger Meirelles Aguiar, Gustavo Tadeu Freitas Uchôa Matheus, Barbara Antonia Dups Talah, Laura Morales Meirelles, Nayara Rozalem Moretti, Layaly Ayoub Silva, Pedro Henrique De Souza Wagner, Francinny Alves Kelly, Francisco Cezar Aquino de Moraes; Escola de Medicina - Universidade Anhembi Morumbi, Piracicaba, Sao Paulo, Brazil; Federal University of Triangulo Mineiro, Uberaba, MG, Brazil; Catholic University of Parana, Curitiba, Brazil; University of Santo Amaro, Sao Paulo, Brazil; University of Western São Paulo, Sao Paulo, Brazil; Federal University of Santa Catarina, Florianópolis, Brazil; Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil; Federal University of Pará - UFPA, Belém, Pará, Brazil

Background: Aromatase inhibitors (AIs), such as anastrozole, letrozole, and exemestane, are commonly used in the treatment of women with early or advanced-stage breast cancer (BC). However, the potential cardiovascular risks associated with AI treatment, particularly the occurrence of cardiovascular events (CVEs) such as acute myocardial infarction and ischemic stroke, remain a concern. This meta-analysis aims to evaluate the impact of AI and tamoxifen treatment on the risk of CVEs in women with BC. **Methods:** A comprehensive search was performed across PubMed, Embase, and Cochrane databases for randomized controlled trials (RCTs) and cohort studies comparing cardiovascular outcomes in patients with BC receiving AIs (anastrozole, letrozole, or exemestane) versus those receiving tamoxifen. Data were analyzed using a random-effects model, and the odds ratios (OR) with 95% confidence intervals (CI) were calculated. P values $>$ 0.10 and I2 values $>$ 25% were considered to indicate significance for heterogeneity. Statistical analysis was performed using R, version 4.4.2. **Results:** Sixteen studies, involving 188,635 participants, were included in the analysis, of whom 124,473 (65.98%) received AI treatment. A statistically significant difference was observed in heart failure and cardiomyopathy, with the treatment showing an increased risk of these events (OR: 1.48; 95% CI [1.11 to 1.99]; p = 0.0079; I2: 79%). Similarly, myocardial infarction was also significantly more likely to occur in the AI group (OR 1.20; 95% CI [1.01 to 1.42]; p = 0.033; I2: 59%). Thromboembolic events were less frequent in the AI group compared to the Tamoxifen group (OR 0.75; 95% CI [0.56 to 0.99]; p = 0.044; I2: 82%). Arrhythmia was associated with a HR of 1.2306 (95% CI [0.8295 to 1.8255]; p = 0.302; I2: 89%). Cardiovascular death had a HR of 1.09 (95% CI [0.86 to 1.40]; p = 0.451; I2: 55%), and stroke had a HR of 1.0233 (95% CI [0.90 to 1.15]; p = 0.715; I2: 41%). Cardiovascular death in terms of OR was 1.26 (95% CI [0.94 to 1.69]; p = 0.128; I2: 84%), and the risk of cardiovascular events was associated with an OR of 1.38 (95% CI [0.99 to 1.92]; p = 0.054; I2: 64%). Heart failure and cardiomyopathy had a HR of 1.24 (95% CI [0.98 to 1.56]; p = 0.064; I2: 79%), while thromboembolic events had a HR of 1.02 (95% CI [0.88 to 1.17]; p = 0.774; I2: 0%). The HR for myocardial infarction was 1.12 (95% CI [0.93 to 1.36]; p = 0.214; I2: 59%). Hypertension was associated with an OR of 1.07 (95% CI [0.94 to 1.21]; p = 0.2866; I2: 40%), and stroke had an OR of 1.10 (95% CI [0.91 to 1.33]; p = 0.320; I2: 66%). **Conclusions:** This systematic review and meta-analysis indicate that AI treatment in BC patients is associated with an increased risk of heart failure, cardiomyopathy, and myocardial infarction. Notably, AI treatment demonstrated a protective effect against thromboembolic events. Research Sponsor: None.

Effectiveness of the Automated Heart-Health Assessment (AH-HA) tool on cardiovascular health improvements among post-treatment cancer survivors: 12-month results from WF-1804CD.

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Background: Cardiovascular disease causes significant morbidity and mortality among US survivors. To enhance guideline recommended cardiovascular health (CVH) discussions during survivorship care, our team developed the EHR-based AH-HA clinical decision support tool, which displays modifiable CVH factors and cancer treatments with cardiotoxic potential. This tool significantly improved delivery of guideline-concordant CVH discussions, the primary study outcome; here we report AH-HA impacts on 12-month CVH improvements. **Methods:** The Wake Forest NCORP Research Base coordinated this practice-randomized clinical trial (NCT# 03935282) comparing AH-HA and usual care (UC) practices. Participants were survivors ≥ 6 months post-potentially curative treatment for breast, prostate, colorectal, endometrial cancers, or lymphoma, scheduled for routine follow-up. The AH-HA tool, based on the American Heart Association (AHA) Life's Simple 7, aimed to enhance CVH awareness and action by providers and survivors. At AH-HA practices, providers used the tool with survivors during an outpatient oncology visit. CVH data were collected from the EHR and survivors (diet quality & physical activity) at baseline and 12 months. Outcomes included Simple 7 total CVH score (0-100, using AHA algorithm) and meaningful change in individual CVH factors (Table). Generalized estimating equations calculated rates of clinically meaningful improvements in CVH factors at 12 months by group, adjusting for cancer type and clustering within practice. **Results:** 645 survivors (82.3% breast cancer; 96.0% female; 83.9% white non-Hispanic, 7.8% Black, 3.7% Hispanic) enrolled at 9 practices (5 UC and 4 AH-HA). The total CVH score did not significantly change from baseline or between groups (Table 1, $p>.05$). Within the AH-HA arm, 20.3% of survivors achieved 5% weight reduction compared to 12.6% in UC; physical activity also improved more in the AH-HA arm, but not significantly. Rates were similar between arms for diet, blood pressure, and hemoglobin A1c. **Conclusions:** In addition to facilitating guideline concordant CVH discussions, AH-HA shows promise for encouraging weight loss among survivors. It is notable that a brief intervention delivered as part of standard oncology care impacted weight reduction. Clinical trial information: NCT03935282. Research Sponsor: National Cancer Institute; R01CA226078; National Cancer Institute; 5UG1CA189824; National Cancer Institute; P30CA012197.

12 month cardiovascular health outcomes among post-treatment survivors.

CVH Outcomes	AH-HA 4 practices, (n=281)	Usual Care 5 practices, (n=342)	Adj P-value
Improvement, % Yes			
BMI (5% weight ↓)	20.3	12.6	**0.02**
Blood Pressure (5 mm ↓)	53.1	52.0	0.75
Physical Activity (+ 30 mins)	40.9	34.3	0.14
Healthy Diet Score (0-1 to 2-5, or 2-3 to 4-5 components)	21.7	18.9	0.45
Cholesterol (20% ↓)	8.6	9.6	#
A1c (0.5% ↓)	8.9	8.8	0.97
Change in total CVH Score adjusted for baseline (positive=improvement)	0.9	-0.5	0.28

#Model did not converge due to small sample size.

12020 Poster Session

Primary prevention of cardiotoxicity in cancer patients treated with fluoropyrimidines: A randomized controlled trial.

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Background: Fluoropyrimidines (FP) are the third most used chemotherapeutic drugs administered in solid tumors but have cardiotoxic side effects. The aim of this study is to determine whether pre-chemotherapeutic cardiological assessment and management of cardiovascular risk factors could prevent FP-induced cardiotoxicity and if the coronary artery calcium (CAC) score was predictive of chest pain. **Methods:** This was a randomized, controlled, single center trial (ClinicalTrials.gov NCT03486340) of patients with various cancer types who were treated with FP and had no known ischemic heart disease. All patients had CAC score obtained by cardiac CT scan. Patients were randomized to pre-chemotherapeutic cardiological management or standard care. Cardiological management included risk reduction based on electro- and echocardiographic evaluation and blood samples. Primary composite endpoint included hospital admission for chest pain, acute coronary syndrome, coronary angiography intervention, or all-cause mortality. Secondary outcome was chest pain. Follow-up was 6 months. Data were analyzed using Kaplan-Meier survival function with log-rank test and ROC-analyses. **Results:** Of the 192 patients included, the primary endpoint occurred in 9/95 (9.5%) patients in the intervention group and 15/97 (15.5%) patients in the control group (log-rank p = 0.19) with an incidence rate ratio (IRR) of 0.57 (95% CI [0.22 – 1.39]). Chest pain occurred in 6/95 (6.3%) patients in the intervention group and 13/97 (13.4%) in the control group, yielding an IRR of 0.44 (95% CI [0.14 – 1.23]). CAC score did not predict chest pain occurrence. **Conclusions:** Cardiological management of cardiovascular risk factors prior to treatment with fluoropyrimidines resulted in half as many cardiotoxic events but the study did not reach statistical significance. Further studies are needed to investigate the optimal strategies to prevent fluoropyrimidine-induced cardiotoxicity in cancer patients. Clinical trial information: NCT03486340. Research Sponsor: Region of Southern Denmark.

12021 Poster Session

DNA methylation biomarkers of cardiotoxicity risk in breast cancer patients treated with anthracyclines.

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Background: Anthracyclines are effective chemotherapeutic agents for treating breast cancer but are associated with significant risks of chemotherapy-related cardiac dysfunction (CTRCD). Current predictors of CTRCD, including patient demographics and clinical characteristics, are insufficient for accurately assessing cardiotoxicity risk before treatment initiation. Here, we examine CTRCD risk associations with pre-treatment DNA methylation (DNAm)-derived biomarkers of biological age, called "epigenetic clocks," and circulating leukocyte composition. **Methods:** A retrospective cohort of 137 newly diagnosed breast cancer patients who received anthracycline-based therapy was sampled from the Total Cancer Care cohort at Moffitt Cancer Center. DNAm profiles were assayed using MethylationEPIC v2 BeadChips on pretreatment whole blood samples and used to derive six biological age metrics and percentages of twelve circulating leukocyte subsets. CTRCD events occurring within one year of treatment initiation were identified through medical records and defined as either a reduction in left ventricular ejection fraction (≥10%) or symptomatic heart failure. Logistic regression models, adjusted for chronological age and traditional cardiotoxicity risk factors (e.g., hypertension, diabetes, baseline ejection fraction, and cumulative anthracycline dose), estimated odds ratios (ORs) for associations between DNAm biomarkers and CTRCD. **Results:** Among 137 newly diagnosed breast cancer patients (mean age: 54 years; 94% white), 33 (24%) experienced CTRCD. In age-adjusted models, the percentage of circulating naïve CD4+ T cells was inversely associated with CTRCD risk, and Horvath18 AgeAccel was positively associated with CTRCD risk, but these associations did not reach statistical significance after additional adjustment for other cardiotoxicity risk factors. In fully adjusted models, a higher percentage of circulating eosinophils was positively associated with CTRCD risk (OR: 1.49; 95% CI: 1.02, 2.24; P = 0.04). **Conclusions:** A higher percentage of circulating eosinophils appears to be a novel risk factor for CTRCD in breast cancer patients. While eosinophils may contribute to CTRCD susceptibility through mechanisms such as creating a pro-inflammatory environment in cardiac tissue, further studies are needed to clarify the role of eosinophils and confirm these findings. Typically, monocyte/macrophage-mediated pathways, including IL-6 and other cytokines, are thought to play a central role in anthracycline-related cardiac injury, but eosinophil-mediated effects may represent an alternative or complementary pathway. Integrating DNAm biomarker and leukocyte composition assessments into clinical workflows could improve CTRCD risk stratification in newly diagnosed breast cancer patients. Research Sponsor: Florida Breast Cancer Foundation; (1049299).

Association of sodium-glucose co-transporter-2 inhibitors with cardiac outcomes and mortality in cancer patients: A systematic review and meta-analysis.

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Background: Sodium-glucose co-transporter 2 inhibitors (SGLT2is) have proven effective in improving cardiac outcomes, including heart failure (HF) hospitalizations and cardiovascular mortality. However, data on the role of SGLT2is in cancer patients with diabetes remain limited. **Methods:** We conducted a systematic review and meta-analysis of studies on patients with concomitant cancer and diabetes to compare cardiac outcomes and mortality between SGLT2i users and non-users. Data were collected from PubMed, Embase, and Cochrane Central databases. Statistical analysis was performed using R Software v4.4.1. A random-effects model was applied to pool risk ratios (RRs) and 95% confidence intervals, with statistical significance set at $p < 0.05$. **Results:** Ten studies, with a total of 100,004 patients (mean age = 66.4 years, 47% female), were included. The mean follow-up duration was 2 years. The results showed that cancer patients with diabetes on SGLT2is had significantly reduced all-cause mortality (RR: 0.48; 95% CI: 0.34 to 0.68; $p < 0.001$; $I^2 = 98\%$), cancer therapy–related cardiac dysfunction (CTRCD) (RR: 0.68; 95% CI: 0.62 to 0.75; $p < 0.001$; $I^2 = 0\%$), and risk of heart failure exacerbation (RR: 0.78; 95% CI: 0.70 to 0.86; $p < 0.001$; $I^2 = 0\%$) compared to the control group. However, the incidence of heart failure (HF) (RR: 0.66; 95% CI: 0.22 to 1.96; $p = 0.453$; $I^2 = 18\%$) and risk of clinically significant arrhythmias (RR: 0.30; 95% CI: 0.06 to 1.55; $p = 0.151$; $I^2 = 0\%$) were comparable between two groups. **Conclusions:** In cancer patients with diabetes, SGLT2is inhibitors are associated with reduced all-cause mortality, CTRCD, HF incidence, and risk of heart failure exacerbation with a non-significant trend toward HF incidence and clinically significant arrhythmias compared to the control group. Research Sponsor: None.

Outcome	Risk ratios with 95% Confidence Intervals (CI)	p-value
All-cause mortality	0.48 (0.34 to 0.68)	P<0.001
Cancer therapy–related cardiac dysfunction	0.68 (0.62 to 0.75)	P<0.001
Heart failure exacerbation	0.78 (0.70 to 0.86)	P<0.001
Heart failure incidence	0.66 (0.22 to 1.96)	P=0.453
Clinically significant arrhythmias	0.30 (0.06 to 1.55)	P=0.151

12023 Poster Session

Effects of SGLT2i dapagliflozin in primary prevention of cardiotoxicity induced by short-term anthracycline and HER2 blocking agent therapy through inhibition of MyD88 and NLRP-3 pathways.

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Background: Anthracyclines, such as doxorubicin, and HER-2 blocking agents, like trastuzumab, are integral in breast cancer treatment but are associated with significant cardiotoxicity. Sodium-glucose cotransporter 2 (SGLT2) inhibitors have been suggested to provide cardiorenal benefits in the context of anthracycline therapy. However, the cardioprotective effects of SGLT2 inhibitors during combined anthracycline and HER-2 blocking agent therapy remain largely unexplored. The study aimed to investigate the cardioprotective potential of Dapagliflozin in primary prevention of anthracyclines and HER-2 blocking agents-mediated cardiotoxicity in preclinical models. **Methods:** Female C57Bl/6 mice were treated for 10 days with a saline solution or DOXO-Trastuzumab (both at 2.17 mg/kg), DAPA (10 mg/kg), or DOXO-Trastuzumab combined with DAPA. Systemic levels of ferroptosis-related biomarkers, galectin-3, high-sensitivity C-reactive protein (hs-CRP), and pro-inflammatory chemokines (IL-1α, IL-1β, IL-2, IL-4, IL-6, IL-10, IL-12, IL17-α, IL-18, IFN-γ, TNF-α, G-CSF, and GM-CSF) were quantified. After treatments, immunohistochemical staining of myocardial and renal IL-1, IL6, CXCR4, NLRP-3 and Myd88 was performed. **Results:** DAPA prevented the reduction of radial and longitudinal strain and ejection fraction after 10 days of treatment with DOXO-Trastuzumab. A reduced myocardial expression of NLRP-3, MyD-88, IL-6 and IL1 was seen in the DOXO-TRA+ DAPA group compared to DOXO-TRA mice. Systemic levels of IL-1β, IL-6, TNF-α, G-CSF, and GM-CSF were significantly reduced after treatment with DAPA. Serum levels of galectine-3 and hs-CRP were strongly enhanced in the DOXO-Trastuzumab group; on the other hand, their expression was reduced in the DAPA+DOXO-Trastuzuab group. Troponin-T, B-type natriuretic peptide (BNP), and N-Terminal Pro-BNP (NT-pro-BNP) were strongly reduced in the DOXO-Trastuzumab+DAPA group, revealing cardioprotective properties of SGLT2i. Mice treated with DOXO-Trastuzumab and DAPA exhibited reduced myocardial and renal IL-1, IL6, CXCR4, NLRP-3 and Myd88 IHC straining. **Conclusions:** This study presents the first evidence of Dapagliflozin's cardioprotective and anti-inflammatory effects in the context of anthracycline and HER-2 blocking agent-induced cardiotoxicity. These findings support the potential use of Dapagliflozin for primary prevention of cardiovascular events associated with doxorubicin-trastuzumab therapy in breast cancer patients, warranting further clinical investigation. Research Sponsor: Ministero della Salute, Ricerca Corrente.

12024 Poster Session

Long-term trastuzumab safety in tailored dose-dense anthracycline containing adjuvant chemotherapy in the PANTHER phase III trial.

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Background: Cardiotoxicity is a known side effect of trastuzumab and combination with anthracyclines increases the risk for cardiotoxicity. Adjuvant dose-dense (DD) chemotherapy has demonstrated beneficial breast cancer (BC) outcomes in patients with high risk for relapse, but data on long-term cardiac toxicity when combined with trastuzumab is scarce. We have previously reported on the safety of trastuzumab at six years follow-up, in a subset of patients treated with dose-dense chemotherapy in the Pan-European Tailored Chemotherapy (PANTHER) phase III trial. We hereby present long-term safety data from 10-year follow-up from the same subset. **Methods:** This is a protocol-predefined cardiac safety study, among Swedish sites included in the PANTHER trial, including patients with HER2-positive (HER2+) and HER2-negative (HER2-) BC matched for age, treatment group and institution. Enrolled patients were up to 65 years old with node-positive or high-risk, node-negative BC were randomized 1:1 to either dose tailored (according to hematologic nadirs) and biweekly DD epirubicin and cyclophosphamide followed by docetaxel or standard 5-fluorouracil, epirubicin, and cyclophosphamide plus docetaxel every 3 weeks. Patients with HER2-positive disease received 1 year of adjuvant trastuzumab. They underwent echocardiography (ECHO) or multigated acquisition scanning and electrocardiography at baseline, at 4, 6 and 10 years of follow-up. Data on cardiac medication NT-proBNP, lipid profile and ECG were also collected. **Results:** ECHO at 10-years follow-up was available for 94 patients; 48 HER2+ (19 DD, 29 control) and 46 HER2- (21 DD, 25 control). Overall, incidence of cardiotoxicity was low. Mean LVEF was 58 % (range 49-68%) and 60.65% (range 50-76%) in HER2+ and HER2- respectively. Only one patient had LVEF $<$ 50% (DD HER2+) and additional 12 patients had LVEF 50-54%, equally distributed between the treatment groups. In total, 27 patients were treated with cardiac medications at this point; 15 (56%) of which had been treated with trastuzumab and 10 of them (n = 7 HER2+), not reporting cardiac medication at previous timepoints. The majority of the patients did not report any symptoms related to heart disease, per NYHA-classification (41 patients in both groups report NYHA class 0). Overall, no significant changes were seen in the biomarkers. **Conclusions:** Cardiotoxicity of trastuzumab in DD anthracycline chemotherapy, examined in the context of a randomized trial sub-study, was very low. Our results underline the safety of trastuzumab in this context, providing support to offer the patients best treatment options for improving breast cancer survival. Clinical trial information: NCT00798070. Research Sponsor: Swedish Cancer Society (Cancerfonden); Swedish Breast Cancer Association (Bröstcancerförbundet); Radiumhemmet; Amgen; Roche; Sanofi-Aventis; Swedish Society for Medical Research (Svenska Sällskapet för Medicinsk Forskning).

12025 Poster Session

Does early recognition and treatment of immune-related myositis and myasthenia gravis reduce mortality of immune-related myocarditis?

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Background: Immune checkpoint inhibitors (ICIs) have revolutionized cancer treatment. However, some immune-related adverse events (irAEs) can be severe, even fatal. ICI-induced myocarditis (ICI-M) carries the highest mortality rate of 30-50%. Notably, ICI myocarditis frequently co-occurs with ICI-induced myositis (ICI-M^2) or as a triad of ICI-induced myocarditis, myositis and myasthenia gravis (ICI-M^3). Despite this known association, it remains unclear whether these entities represent distinct disease processes or a spectrum of disease severity. Therefore, we sought to compare outcomes among those diagnosed with ICI-M, ICI-M^2 and ICI-M^3. **Methods:** We performed a single-institution retrospective cohort study using the electronic health record to identify patients seen in a solid tumor clinic between 1/21/11 – 1/21/25, who had received ICI therapy. There was a concern for myocarditis in 82 patients, of which 33 were deemed to have > grade 2 ICI-induced myocarditis. Of the 33 cases, 36% had ICI-M, 36% had ICI-M^2 and 27% had ICI-M^3. We then assessed differences in age, sex, cancer type & stage, immunotherapy regimen, number of immune suppressants given, myocarditis grade, and overall survival across these groups. **Results:** The Table shows patients with ICI-M presented at an earlier cancer stage and more commonly after ICI monotherapy than combination therapy. Despite this, these patients typically had more severe grade ≥ 3 myocarditis (75%) compared with ICI-M^2 (42%) and ICI-M^3 (44%) and had a worse overall survival (33%) as compared to ICI-M^2 and ICI-M^3 (67% and 78% respectively). Notably ICI-M patients typically presented with cardiac-specific symptoms and presented after more cycles of ICI therapy (avg. of 4 cycles). In contrast, ICI-M^2 and ICI-M^3 patients presented after fewer ICI cycles (avg. of 2 cycles) with symptoms of myositis or myasthenia. They typically did not present with cardiac-specific symptoms and were then incidentally found to have mildly elevated troponin levels. **Conclusions:** Patients with ICI-M presented after more ICI cycles, had more severe myocarditis and worse overall survival as compared to ICI-M^2 and ICI-M^3 patients. Our findings suggest that patients who developed concurrent symptoms of myositis or myasthenia gravis, prompted earlier recognition of mild myocarditis, leading to earlier initiation of immunosuppressive treatment thereby improving clinical outcomes. Research Sponsor: None.

	ICI-M (n = 12)	ICI-M^2 (n = 12)	ICI-M^3 (n = 9)	Total (n = 33)
Median Age (yrs)	67	64	77	69
Sex (% male)	50	83	56	64
Cancer type (% melanoma)	42	75	44	55
Cancer stage (% stage IV)	67	92	78	82
ICI treatment (% dual ICI)	33	67	56	55
Avg. # of cycles before toxicity (range)	4.2 (1-13)	2.2 (1-4)	2.1 (1-3)	2.8 (1-13)
Severity of myocarditis (% grade ≥ 3)	75	42	44	55
Immunosuppressant agents (% given 2 or more agents)	50	33	78	52
Overall survival (% alive)	33	67	78	58

12026 Poster Session

Temporal trends and disparities in cardiovascular mortality among breast cancer patients: A 25-year population analysis of the CDC WONDER database (1999-2023).

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Background: Breast cancer and cardiovascular disease (CVD) are leading causes of mortality among women in the United States. While advancements in breast cancer treatment have improved survival rates, these therapies may contribute to CVD-related complications, influencing long-term outcomes. This study examines 25-year trends (1999–2023) in CVD mortality among breast cancer patients, with a focus on racial, regional, and urbanization disparities. **Methods:** Data was analyzed from the CDC WONDER (Centers for Disease Control and Prevention for Wide-ranging Online Data for Epidemiologic Research) covering the period from January 1, 1999, to December 31, 2023, to evaluate CVD mortality among breast cancer patients. Analysis was done using Joinpoint regression. Age-adjusted mortality rates (AAMR) per 100,000 person-years were calculated, and trends were assessed using annual percent change (APC) with statistical significance defined at $p < 0.05$. Disparities were evaluated across racial/ethnic groups, U.S. census regions, and urban-rural settings. **Results:** 85,316 CVD-related deaths were recorded among breast cancer patients from 1999 to 2023. AAMR declined significantly overall (APC: -2.73, $p < 0.001$), decreasing from 1.66 in 1999 to a nadir of 0.72 in 2016 (APC: -5.11, $p < 0.001$), followed by a rebound to 0.84 in 2023 (APC: +3.29, $p < 0.001$). Disparities were noted among racial groups: non-Hispanic Black women had the highest mortality rates, followed by non-Hispanic Whites and Hispanics, all showing significant downward trends with APCs of -1.93, -2.63, and -2.431, respectively ($p < 0.001$). The lowest mortality rates were recorded in 2016 for all groups, except for non-Hispanic Blacks, who had their lowest in 2015. Regionally, the Northeast initially had the highest AAMR until 2016, after which rates converged; by 2023, the South reported the highest mortality (0.86). Rural areas consistently exhibited higher AAMR than urban areas, though both declined significantly over the study period. **Conclusions:** Despite an overall decline in CVD mortality among breast cancer patients, persistent racial, regional, and urban-rural disparities highlight systemic inequities in care. The post-2016 resurgence in mortality underscores potential gaps in long-term cardiovascular surveillance for survivors. Targeted interventions addressing racial disparities, regional resource allocation, and rural healthcare access are critical to mitigating CVD risk in this population. Further research is needed to elucidate drivers of these trends and inform equitable policy reforms. Research Sponsor: None.

Major adverse cardiovascular events (MACE) in cancer patients treated with tirzepatide compared to GLP-1 receptor agonists: A target trial emulation using real-world data.

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Background: Cardiovascular disease (CVD) is a leading cause mortality in cancer patients. Obesity and type 2 diabetes are well-known modifiable risk factors for CVD progression and adverse CV related outcomes. We aim to assess the CV benefit of tirzepatide versus GLP-1 receptor agonists (GLP-1RA), a mainstay treatment in management of obesity and cardiometabolic disease, in cancer patients. **Methods:** We conducted a target trial emulation using TriNetX, an aggregated EHR platform. We identified adults (May 2022-Jan 2024) diagnosed with solid neoplasm and cardiometabolic conditions (hypertension, dyslipidemia, obesity, or type 2 diabetes). We excluded patients with in situ neoplasms, hematologic malignancy, metastatic solid neoplasm, medication contraindication (type 1 diabetes, gastroparesis, thyroid cancer), performance status ECOG $>$ 3, or on dialysis. Patients were divided into two exclusive groups: tirzepatide or GLP-1RA. The first prescription of each medication was defined as time zero/index event. Individuals with any MACE within 60 days prior to index event were excluded. Study groups were propensity matched, using a 1:1 nearest neighbor algorithm, for 55 covariates: demographics, Charlson comorbidity index and cardiac conditions, chemotherapy, radiation, BMI, HbA1c, LDL, eGFR, systolic BP, medications, smoking/alcohol, and social determinants. Primary outcome was incidence of MACE (acute myocardial infarction, stroke, or CV death) and overall survival over a 2-year period. Secondary outcomes were changes in HbA1c and BMI. Kaplan Meier analysis and hazard ratios (HRs) were calculated to compare time-to-event outcomes. **Results:** We identified 42,584 patients [mean age 55.4 ($\pm$12.1) years; 62.5% female; 63.1% White; mean HbA1c 6.82 ($\pm$1.81); mean BMI 37.5 ($\pm$7.7)] with solid tumors and cardiometabolic conditions. Tirzepatide was associated with a significant MACE reduction compared to GLP-1RA and improved overall survival (Table 1). At follow-up, mean HbA1c was significantly lower in tirzepatide group (6.21 $\pm$ 1.28) compared to GLP-1RA (6.50 $\pm$ 1.46; $p <$ 0.001). Patients on tirzepatide also experienced greater BMI reduction (34.7 $\pm$ 7.7 kg/m2) compared to GLP-1RA (35.5 $\pm$ 7.7 kg/m2; $p <$ 0.001). **Conclusions:** Tirzepatide was associated with significant reductions in MACE, HbA1c, and BMI compared to GLP-1RA, suggesting a preferential pharmacotherapy option for addressing obesity and cardiovascular disease reduction in cancer patients while improving overall survival outcomes and quality of care in this high-risk population. Research Sponsor: None.

Outcome	Adjusted HR (95% CI)	*p*-value
MACE	0.761 (0.616-0.940)	**0.011**
Myocardial Infarction	0.650 (0.475-0.889)	**0.007**
Stroke	1.103 (0.937-1.300)	0.240
Ischemic Heart Disease	0.785 (0.627-0.983)	**0.035**
Cardiac Death	0.621 (0.365-0.890)	**0.032**
Overall Survival	0.563 (0.415-0.736)	**<0.001**

12028 Poster Session

Effect of a letter of condolence proposing a post-mortem consultation to the relatives of cancer patients on anxiety, depression and grief: Results of a multicenter randomized study.

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Background: The relativesof cancer patients are at risk for developing emotional distress following the death of their loved one. The aim of this study was to analyze whether sending a condolence letter offering a post-mortem consultation with the referent oncologist to the relatives of patients who have died of cancer improve their long term reported outcomes, such as anxiety, depression and complicated grief. **Methods:** In this multicenter, prospective, randomized, academic trial, bereaved relatives, of cancer patients who died in hospital, were randomized between receiving a condolence letter (CL) suggesting post-mortem consultation *versus* no CL. At 3 months and 6 months after enrolment, anxiety (HAD-A), depression (HAD-D) and grief (Texas Revised Inventory of Grief [TRIG]) were assessed using self-administered questionnaires. **Results:** Of the 426 randomized relatives, 118 agreed to take part in the study, of whom 102 (49 CL, 53 no CL) completed the questionnaire 3 months after the relatives' death and 92 (43 CL, 49 no CL) at 6 months. There was no differences in socio-demographic characteristics or history of depression between the two groups. Palliative care was involved for (69% CL, vs 52% non-CL) of patients, with no statistical difference between the two groups. At 3 months post enrolment, both anxiety and depression were significantly lower in the CL group than the non-CL group (mean HADS-A score 7.3 vs 9.4, p=0.026; mean HADS-D score: 5.4 vs 8.1, p=0.009). In addition, receiving a condolence letter was associated with less grief at patient's death (past TRIG subscale: 20.7 vs 25.8, $p<0.001$), and less current grief (present TRIG subscale score: 45.7 vs 52.0, p=0.025). At 6 months, the HADS-D score was significantly lower in the condolence letter arm (mean score 5.7 vs 8.3, p=0.025), as was grief at patient's death (past TRIG subscale: 21.5 vs 25.0, p=0.035). Only 5% of CL had a post mortem consultation. **Conclusions:** Sending a letter of condolence to relatives of cancer patients who have died in hospital may reduce subsequent grief, depression and anxiety in loved ones. Encouraging this widespread post mortem contact such as correspondence may be a non-drug alternative to reduce post-mortem depression and improve the bereavement process for relatives of cancer patients. Clinical trial information: NCT02861625. Research Sponsor: French National Cancer Institute; PHRC-K 14-042.

12029 Poster Session

Disparities in receipt of palliative treatments among disaggregated Hispanic populations with breast, lung, and prostate cancer in the United States.

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Background: Despite palliative interventions' ability to improve the quality of life and possibly improve overall survival, significant inequalities persist in uptake. Disparities in the receipt of palliative-intent interventions are characterized by broad race, socioeconomic, and geographical categories; however, less is known among disaggregated Hispanic populations. We examine disparities among Hispanic subgroups in receipt of palliative-intent interventions among disaggregated Hispanic patients with stage IV lung, breast, and prostate cancer. **Methods:** Using the National Cancer Database (NCDB), we collected data on the receipt of palliative-intent interventions (including radiotherapy, chemotherapy, and/or other pain management therapy) among Hispanic subgroups diagnosed with AJCC analytic stage IV breast, lung, and prostate cancer between 2004 and 2021. Multivariate linear regressions (adjusting for age group, country of origin, year group, sex, insurance status, 2016 median income quartiles, facility type, CDCC Score, and facility location) were conducted for each cancer type to quantify the disparities in uptake of palliative-intent interventions among Hispanic subgroups. **Results:** Among 945,894 total patients, disaggregated analyses revealed reduced receipt of palliative-intent interventions for lung, breast, and prostate cancer patients of Mexican descent (Lung AOR 0.74, [0.67-0.81], P<0.001; Breast AOR 0.69, [0.58-0.82], P<0.001; Prostate AOR 0.82, [0.69-0.99], P=0.03) compared to non-Hispanic white patients. Receipt of palliative-intent interventions for patients of South or Central American descent and Cuban descent were also reduced in comparison to White patients for lung and breast tumors. Reuptake of palliative-intent interventions for breast cancer was significantly reduced for patients of Dominican Republic descent compared with non-Hispanic white patients (AOR 0.65, [0.43-1.00], P=0.05). **Conclusions:** Our findings expose that disparities exist in the receipt of palliative-intent interventions among Hispanic subgroups upon disaggregation. We highlight the need for research to characterize such disparities and discuss community-level and patient-centric solutions to address their drivers. Research Sponsor: None.

Palliative-intent treatment receipt stratified by subgroup and tumor type.

Race	% Lung Tumor	% Breast Tumor	% Prostate Tumor
Non-Hispanic White	26.4	21.7	12.1
Mexican	16.7	12.7	8.8
Puerto Rican	27.8	22.7	17.0
Cuban	19.2	17.0	11.4
South/Central American	21.5	15.0	11.5
Other Specified Spanish/Hispanic origin	28.2	23.0	10.2
NOS	19.5	17.0	10.9
Spanish surname	16.6	910.0	9.9
Dominican Republic	30.0	19.0	12.7
Non-Hispanic other	24.4	19.9	12.1

12030 Poster Session

Disparities in place of death in patients with lung cancer.

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Background: Place of death (PoD) significantly impacts both patient and caregiver experiences at end-of-life in the United States (U.S.), with disparities often reflecting inequities in access to palliative care, hospice services, and caregiver resources. However, there is limited understanding of PoD and associated disparities in patients with lung cancer. This retrospective study examined sociodemographic differences in PoD among U.S. lung cancer decedents from 2003 to 2020. **Methods:** We analyzed de-identified death certificate data from the CDC Wonder database, focusing on lung cancer as the underlying cause of death (identified by ICD codes) from 2003 to 2020. The data were stratified by ethnicity, race, gender, and age (< 65 or ≥ 65 years). PoD was categorized into four groups: (1) medical facility, (2) nursing home, (3) home, and (4) hospice facility. The Annual Percentage Change (APC) in PoD across sociodemographic groups was calculated. **Results:** A total of 2,759,733 decedents were included (44.8% women, 72.4% age ≥ 65 years, 3.3% Hispanic, 10.5% Non-Hispanic Black (NHB), and 83.4% Non-Hispanic White (NHW)). Between 2003 and 2020, deaths in medical facilities declined from 37.2% (58,778) to 24.6% (33,416) (APC -2.55%), while hospice deaths increased from 0.5% (849) to 11.2% (15,290) (APC 25.37%). In 2020, men were more likely to die in a medical facility than women (26.4% vs 22.4%), and women were more likely to die in a nursing home (9.4% vs 8.4%). Younger patients (< 65) had higher rates of medical facility deaths than older patients (31.5% vs 22.4%), with a slower decline in medical facility deaths (APC -2.01% vs -2.75%). Hispanic individuals were more likely to die at home (52.5% in 2003 vs 51.0% in 2020) and less likely to utilize hospice (11.2% in 2020) or die in a nursing facility (8.9% in 2020). NHWs had the lowest rates of medical facility deaths (22.8% in 2020) and the highest rates of hospice deaths (11.6% in 2020). NHBs, despite an increase in hospice utilization (APC 26.73%, 2003-2020), remained more likely to die in medical facilities (33.6% in 2020). **Conclusions:** Over the past two decades, lung cancer PoD patterns have shifted, with reduced medical facility deaths and increased hospice utilization. However, significant disparities in end-of-life care persist across demographic groups, highlighting the need for targeted interventions to ensure equitable access to preferred care settings, including home-based and hospice services. Research Sponsor: None.

12031 Poster Session

Economic impact and mortality outcomes of palliative care integration among cancer patients: Analysis of National Inpatient Sample 2018-2022.

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Background: While palliative care integration into oncology represents a quality metric, its relationship with mortality outcomes and cost implications remains incompletely characterized. This study evaluates the association between palliative care consultation and healthcare utilization across major cancer types. **Methods:** We conducted a retrospective analysis using the National Inpatient Sample (2018-2022). Eligible patients included adults with primary diagnoses of lung, breast, prostate, or colon cancer. Palliative care utilization was identified (ICD-10 code Z51.5). Primary endpoints included in-hospital mortality, length of stay (LOS), and total charges. Propensity score matching (1:1 nearest neighbor, caliper 0.2) was used to account for selection bias. Confounding variables included age, race, insurance status, hospital characteristics, and comorbidity burden. Missing data were handled using complete case analysis. Temporal trends were assessed using Cochran-Armitage test. **Results:** Among 1,104,888 eligible hospitalizations (469,831 lung, 203,857 breast, 204,837 colon, 226,065 prostate), 70,863 in-hospital deaths occurred. Palliative care consultation was associated with reduced LOS (adjusted mean difference: -1.2 days; 95% CI: -1.4 to -1.0; $p<0.001$) and lower total charges (adjusted mean difference: -$31,947; 95% CI: -$34,521 tor o -$29,373; $p<0.001$) among deceased patients. Cancer-specific mortality rates with without were: lung (31.26% vs 4.16%, $p<0.001$), breast (26.72% vs 2.16%, $p<0.001$), colon (25.60% vs 2.27%, $p<0.001$), and prostate (27.07% vs 1.98%, $p<0.001$). Overall palliative care utilization increased from 13.50% to 15.91% (2018-2022; APC: +0.68%; p-trend<0.001). DNR status strongly predicted palliative care utilization (adjusted OR: 4.50; 95% CI: 4.41-4.60; $p<0.001$). **Conclusions:** In this large nationwide analysis, palliative care consultation was associated with significant reductions in healthcare utilization and costs among deceased cancer patients. Universal implementation could potentially save 27,744 hospital days and $996.4 million annually, suggesting substantial opportunities for healthcare system optimization. Research Sponsor: None.

Healthcare utilization outcomes by cancer type and palliative care status.

Cancer Type	Deaths (N)	PC Rate (%)	Adjusted Cost Difference* ($)	Adjusted LOS Difference* (Days)
Lung	41,808	61.45	-32,655 (-35,124, -30,186)	-0.94 (-1.12, -0.76)
Breast	9,981	60.80	-31,382 (-34,276, -28,488)	-0.97 (-1.18, -0.76)
Colon	9,667	56.95	-47,079 (-50,612, -43,546)	-1.32 (-1.56, -1.08)
Prostate	9,407	56.61	-37,099 (-40,388, -33,810)	-0.81 (-1.02, -0.60)

*Values represent adjusted differences (95% CI) between palliative care and non-palliative care groups.
PC = Palliative Care; LOS = Length of Stay.

12032 Poster Session

Improving pain management knowledge among hospice family caregivers: A randomized controlled trial.

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Background: Poor pain management in home hospice settings is often due to family caregivers not adhering to analgesic regimens. Healthcare technology, like digital applications, can improve caregivers' access to education and communication with nurses, though it has been underutilized in home hospice. We developed and tested a digital pain management app called e-PainSupport in an NIH-funded randomized controlled trial with 44 hospice patient and caregiver dyads. The purpose of this study was to examine mediating effects of caregiver pain management knowledge on change in pain intensity, controlling for study condition and patient gender. **Methods:** We developed and tested a digital pain management app called e-PainSupport in an NIH-funded randomized controlled trial with 44 hospice patient and caregiver dyads. Utilizing a two-group, two-week, randomized controlled trial with dyads (N = 44) of Hospice patients (52% female, mean age 74.1 years) and their caregivers (75% female, mean age 55.2 years), dyads were randomly assigned to either the e-PainSupport intervention or usual care control condition. Outcome measures included caregiver knowledge and patient-reported pain intensity. **Results:** In the study, 60.87% of caregivers used the app's educational element at least once, with an average use of 5.43 times. Pain assessments were recorded by 91.30% of caregivers, averaging 3.74 assessments per caregiver. Additionally, 87.00% of caregivers reported pain management activities, averaging 46.05 entries. Patient pain intensity was tracked by 87.00% of caregivers, who completed the end-of-day summaries an average of 4.9 out of 14 days. Patients in the intervention condition were 2.50 times more likely to have a decrease in pain for worst pain than patients in the control condition over the two-week study period. Although we observed a positive effect of the app on caregivers' pain management knowledge, the improvement was limited, likely due to the brevity of the educational modules designed to minimize caregiver burden. To enhance caregiver knowledge without increasing their burden, we propose converting the written educational materials into videos. The enhanced intervention will be tested in a larger, full-scale RCT in the future. **Conclusions:** The use of the e-PainSupport app by caregivers is feasible and may contribute to improved caregiver knowledge and reduced hospice patient pain. Clinical trial information: NCT04869085. Research Sponsor: National Institute of Nursing Research.

A multi-center case-control study on osteoporosis risk in cancer patients receiving chemotherapy.

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Background: Chemotherapy and cancer can worsen osteoporosis, a growing concern with improved cancer survival rates. This study aimed to assess osteoporosis risk in chemotherapy patients versus healthy individuals and identify predictive factors. **Methods:** This multi-center case-control study included 257 chemotherapy-treated cancer patients and 257 age- and gender-matched controls (1:1) using propensity score matching. Exclusions included recent alcohol use, severe organ impairments, endocrine disorders, specific treatments (estrogen, progesterone, glucocorticoids, bisphosphonates, calcium supplements), and cancer-related bone conditions. Bone mineral density (BMD) at the femur and lumbar spine (L1-L4) was measured via dual-energy X-ray absorptiometry (DXA), with T-scores categorized as normal ($T \geq -1.0$), osteopenia ($-2.5 < T < -1.0$), or osteoporosis ($T \leq -2.5$).Statistical analyses were performed using SPSS 24.0, with t-tests, Mann-Whitney U tests, and regression analysis ($p<0.05$). **Results:** The study included 174 females and 83 males (median age 59) in both groups. Of cancer patients, 112 had breast, 54 had colorectal, 39 had upper gastrointestinal, 32 had lung, and 20 had gynecological cancer. Among cancer patients, 35.8% had osteopenia, and 21.0% had osteoporosis in lumbar vertebrae, compared to 15.2% and 2.3% in controls ($p<0.001$). For total femur, 28.0% had osteopenia, and 5.8% had osteoporosis in cancer patients, versus 16.3% and 1.2% in controls ($p<0.001$). Median lumbar BMD was 0.90 g/cm^2 in cancer patients and 1.22 g/cm^2 in controls ($p<0.001$); median femur BMD was 0.89 g/cm^2 and 0.98 g/cm^2, respectively ($p<0.001$). No correlation was found between osteoporosis and cancer stage. Breast cancer had the highest normal BMD (51.2%) but shared the highest osteoporosis rate (31.5%) with colorectal cancer. Gastric cancer showed the highest osteoporosis rate for femur BMD (33.3%, p=0.024). Vitamin D deficiency (<12 ng/mL) was more common in cancer patients (50.6% vs. 18.1%) and linked to reduced bone density (p=0.009). BMI was a significant predictor of osteoporosis (<0.001), with higher BMI protective; obesity (BMI >30) was more frequent in controls (50.2%) than cancer patients (26.9%).Serum creatinine, alkaline phosphatase, calcium, and phosphate levels were similar in groups, with no link to osteoporosis. Logistic regression showed cancer increased osteoporosis risk 6.8-fold ($p<0.001$, 95% CI: 4.024–11.494). BMI was protective, reducing odds by 4.5% per unit increase (p=0.036, 95% CI: 0.915–0.997). **Conclusions:** Lumbar osteoporosis and osteopenia were 9.1 and 2.3 times more common in cancer patients, with lumbar and femur BMD reduced by 26.2%and 9.2%, compared to controls. Cancer type and Vitamin D levels are key predictors of osteoporosis. Addressing bone health in cancer patients is crucial for improving quality of life and reducing osteoporosis burdens. Future research on survival, fracture risks, and outcomes will inform proactive bone health management. Research Sponsor: None.

12034 Poster Session

Effectiveness of alternating magnetic field therapy on quality of life among cancer survivors with chemotherapy-induced peripheral neuropathy: Insights of SMILE study.

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Background: Chemotherapy-induced peripheral neuropathy (CIPN) reduces patients' quality of life (QoL) due to consistent sensory and motor disturbances. SMILE study investigated the safety and efficacy of an alternating magnetic field therapy device (AT-04) for CIPN. **Methods:** This was a multicenter, randomized, sham device-controlled, double-blind study. Patients were eligible if they had CIPN symptoms with a pain Numeric Rating Scale score of 4/10 or more, at least 12 weeks after perioperative chemotherapy, and there was no recurrence. Patients were randomly assigned to use AT-04 or a sham device for 84 days. We showed the primary endpoint, the change in pain NRS at day 85, and notable effect sizes of AT-04 in patients whose last chemotherapy was over a year ago for tingling and numbness NRS. Herein, we report one of the secondary endpoints, EORTC QLQ-CIPN20 (CIPN20), asked at baseline and days 15, 29, 57, 85, and 113. **Results:** Fourteen patients were allocated to each group. At day 85, there were no significant differences in the mean changes of the CIPN20 sensory scale (-5.25 ± 15.4 in AT-04 vs. -5.72 ± 19.5 in sham; p = 0.95, effect size = 0.03), the motor scale (-8.18 ± 16.6 vs. -1.68 ± 10.2; p = 0.28, effect size = 0.47), or the autonomic scale (-1.85 ± 27.5 vs. -1.52 ± 5.0; p = 0.97, effect size = 0.02). However, the CIPN20 motor scales showed a significant decrease in AT-04 at day 29 (-9.82 ± 13.8 vs. -0.74 ± 8.7; p = 0.04, effect size = 0.92) and day 57 (-11.81 ± 10.6 vs. -0.54 ± 6.7; $p < 0.01$, effect size = 1.26). Furthermore, among patients whose last chemotherapy was completed more than one year earlier (n = 8 in each group), CIPN20 motor scale significantly decreased from day 29 (-12.43 ± 10.3 vs. 2.38 ± 8.9; $p < 0.01$, effect size = 1.55) to day 85 (-11.76 ± 10.1 vs. -0.07 ± 11.5; $p < 0.05$, effect size = 1.08), and this effect persisted at day 113 (28 days after the end of the study treatment). Additionally, both sensory and autonomic scales showed improvement (sensory scale, -8.33 ± 13.5 vs. -0 ± 18.4, p = 0.32, effect size = 0.52; autonomic scale, -10.42 ± 23.5 vs. -2.08 ± 5.9, p = 0.35, effect size = 0.49). **Conclusions:** In patients whose last chemotherapy occurred more than one year prior, mean changes in the CIPN20 scores showed improvement across the sensory, motor, and autonomic scales. Clinical trial information: jRCT2032220295. Research Sponsor: Japan Agency for Medical Research and Development; Peace of Mind Co., Ltd.

12035 Poster Session

Autoimmune conditions and 'breast implant illness' in breast cancer patients with implant-based breast reconstructions.

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Background: The safety of silicone breast implants (SBIs) has been challenged in various large observational studies that suggest an association with autoimmune and rheumatic diseases (ARDs). Additionally, an increasing number of women seem to attribute constitutional, rheumatic, mental and cognitive symptoms to their SBIs. This constellation of symptoms is often referred to as 'Breast implant illness (BII). To date, BII is a self-identified diagnosis without an evidence-based definition. The risks of ARDs and BII have not been evaluated in breast cancer survivors with implant-based breast reconstructions. **Methods:** We conducted a retrospective cohort study among patients treated for breast cancer between 2000 and 2015 in six large regional hospitals. Clinical data and diagnoses of ARDs were obtained up to 2023 from prospectively maintained institutional and nationwide registries. Patients who were alive at the time of study were invited to participate in a survey. The occurrence of eighteen symptoms, that have been associated with BII by international experts, was assessed. The SBI-exposed patients were compared with patients who had received other surgical treatment modalities. In the entire cohort (including deceased patients and survey non-responders), Hazard Ratios (HRs) for receiving an ARD diagnosis were estimated through multivariable Cox models. Among responders to the survey, person-centered symptom clusters were determined through a latent class analysis approach. The association between SBI-exposure and the observed symptom clusters was analyzed in multivariable logistic regression models. **Results:** Of 12,262 women in the entire cohort, 3,082 (25%) had received a SBI-based breast reconstruction. Median follow-up time was 12.0 (IQR, 7.0) years. Compared with non-exposed patients, patients with an implant-based breast reconstruction did not have an increased risk of ARDs in general (HR, 1.06, 95% CI [0.89–1.27]) or any specific ARD-category or specific condition. In total, 6,073 patients (64.5% of all invited patients) completed the questionnaire including 1,818 patients with an SBI. In the survey cohort, the median follow-up time was 13.7 (IQR, 6.8) years. Five distinct BII-related symptom clusters were identified, none of which were significantly associated with SBI-exposure in multivariable logistic regression analyses. Additionally, when comparing exposed to non-exposed women, women with SBIs did not have a significantly increased risk for any of the individual BII-associated symptoms. **Conclusions:** Our results indicate that breast cancer patients with SBIs do not have an increased risk of ARDs nor do they experience more BII-associated symptoms compared with breast cancer patients without SBIs. This information can aid healthcare professionals in counseling breast cancer patients who are worried about the alleged long-term harms of SBI(s). Research Sponsor: None.

A hierarchical clustering approach to dissect behavioral symptoms in early-stage breast cancer (BC).

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Background: Fatigue, cognitive impairment, insomnia, anxiety, and depression are cancer-related behavioral symptoms that frequently co-occur and share underlying risk factors. We investigated the clustering of these symptoms at different time points, aiming to identify drivers of symptom segregation. **Methods:** Patients with stage I-III BC from CANTO (NCT01993498) were included. Hierarchical cluster analysis was performed at three time points: baseline (BC diagnosis), year (Y) 1 (3-6 months post-surgery, chemotherapy [CT], and/or radiotherapy), and Y2. Clustering used the Ward method via R^2 and Pseudo T^2 statistics, incorporating dichotomized self-reported symptoms based on clinically meaningful thresholds: fatigue (EORTC QLQ-C30 ≥40/100), cognitive impairment (<75/100), insomnia (>50/100), and anxiety or depression (HADS ≥11/21). **Results:** Among 6,486 patients, the mean age was 56.2 years; 90% had stage I-II BC, 53% received CT, and 83% endocrine therapy (ET). Analysis of dendrograms identified six distinct clusters (CL) consistently across time points. There was substantial difference in symptomatology between baseline/Y1 and baseline/Y2 (Cramer's V 0.23, 0.22), while there was greater symptom overlap post-treatment between Y1 and Y2 (V 0.32). No specific behavioral symptom drove hierarchical segregation at baseline. However, by Y1, depression and fatigue emerged as primary drivers: CL1 (38%) comprised patients with low symptom scores, similarly to other time points; CL2 (14%) was mostly characterized by cognitive dysfunction and anxiety; CL3 (14%) was defined by patients with clinically meaningful insomnia but without fatigue, while CL5 and CL6 included patients with fatigue but no emotional distress, further segregated by the presence (CL5, 12%) or absence (CL6, 10%) of cognitive dysfunction. Patients reporting depression were consistently grouped in CL4. Notably, CL4 (12%) was heterogeneous and characterized by multi-symptomatology (Table). The use of CT and ET was significantly associated with membership in CL4 and CL5 at Y1 ($p < .001$). At Y2, the clustering remained consistent with what observed at Y1, however the prevalence of individual symptoms was higher in the multi-symptom clusters, including CL4 where all patients with depression were exclusively segregated. **Conclusions:** Hierarchical clustering revealed dynamic changes over time, potentially reflecting the impact of the acute treatment phase on interrelationships among symptoms. Depression and fatigue emerged as key drivers of segregation. Accounting for variability in symptom clustering can enable better targeting of therapeutic options. Clinical trial information: NCT01993498. Research Sponsor: Conquer Cancer the ASCO Foundation and Rising Tide Foundation for Clinical Cancer Research; CPG 2020; ARC; ARCPGA2022010004401_4882; ANR; ANR-10-COHO-0004; ANR; ANR-18-IBHU-0002; ANR; ANR-17-RHUS-008.

Proportions of patients with clinically meaningful symptoms by CL at Y1 (may not add up to 100% due to multiple symptoms).

	Fatigue	Cognitive dysfunction	Insomnia	Anxiety	Depression
CL1	0	0	0	0	0
CL2	16	75	0	47	0
CL3	0	34	100	20	0
CL4	91	74	85	82	51
CL5	100	100	57	0	0
CL6	100	0	48	0	0

12037 Poster Session

Systematic review of prognostic models for cardiomyopathy and heart failure applicable to survivors of adolescent and young adult cancer.

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Background: Survivors of adolescent and young adult (AYA) cancer who receive cardiotoxic chemotherapy and/or radiation are at risk of developing cancer therapy-related cardiac dysfunction (CTRCD), including asymptomatic reduction in left ventricular ejection fraction and symptomatic heart failure. Early detection and intervention using risk-adapted surveillance strategies can reduce morbidity and mortality. While numerous risk prediction models (RPM) have been developed and/or validated for CTRCD in pediatric or older adult cancer populations, it is unclear whether they can be applied to survivors of AYA cancer. **Methods:** We undertook a systematic review of cardiovascular RPM (including CTRCD) development/ validation studies in survivors of cancer diagnosed at any age. We searched MEDLINE, EMBASE, and Web of Science with additional hand searching until November 2024. Two reviewers screened abstracts and full texts; we included studies that used real-life patient data to predict asymptomatic or symptomatic CTRCD (per European Society of Cardiology guidelines) $\geq$1 year from diagnosis and after completing therapy. We excluded abstracts, non-English studies, and RPM which used data not routinely accessible in outpatient clinics. We extracted study data and applied the Prediction model Risk of Bias ASsessment Tool for risk of bias (RoB) and applicability to AYA cancer survivors. When not reported, we estimated AYA (age 15-39) proportions using cancer incidence patterns. We used descriptive statistics to evaluate studies, models, included risk factors, and participants overall and by proportion of AYA. Meta-analysis was not possible given limited overlap in the identified models. **Results:** We screened 12740 abstracts and 249 full text articles; of these, 100 studies underwent a second full text screen to identify CTRCD models. We identified 22 studies (7 enrolled $>$ 20% AYA) which developed and/or validated 64 models (32.8% machine learning) to predict CTRCD (54.7% symptomatic) in 129077 cancer survivors (10.7% AYA) using clinically available data. Nine (14.1%) models validated existing RPM (e.g. those developed in non-cancer populations); the remainder were newly developed models, with age at diagnosis, diabetes, hypertension, and anthracycline dose the most common predictors ($>$ 50% of models). Most models (n = 54) were at high RoB, primarily due to concerns with analytical reporting. Only 2 studies/8 models were rated as both low RoB and high applicability to AYA survivors. **Conclusions:** Several RPM for subclinical and overt CHF are available for pediatric and adult cancer survivors, with varying applicability to AYA cancer survivors. Adherence to recommended statistical reporting methods is poor and RoB high, further limiting utility. Additional development and validation of high-quality RPM for heart failure in AYA cancer survivors is warranted. Research Sponsor: CIHR; 186971.

Out of touch: Understanding the frequency and trajectory of chemotherapy-induced neuropathy peripheral (CIPN) in breast cancer survivors.

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Background: CIPN, primarily associated with sensory neuropathy rather than motor or autonomic dysfunction, is a potentially long-term complication of cancer treatment including taxanes and platinums (T/Ps), and can negatively impact quality of life for breast cancer (BC) survivors. This project aims to quantify the severity of neuropathic symptoms at one and three years after diagnosis in BC survivors, comparing recipients of T/P to non-recipients. **Methods:** In the Mayo Clinic Breast Registry (MCBDR), a longitudinal cohort, surveys and medical record data from patients with stage 1-3 BC were used to understand the burden of neuropathic symptoms at 1- and 3-years post-diagnosis (denoted as Y1 and Y3). Y1 and Y3 raw scores from The Quality of Life Questionnaire-Chemotherapy-Induced Peripheral Neuropathy 20 (CIPN20) composite (CIPN20-C) and sensory subscale (CIPN-S) were converted to a 0-100 point scale, with lower scores corresponding to worse symptoms. Patients with BC recurrence prior to Y3 or incomplete surveys were excluded. We used two sample t-tests and multivariable linear regression modeling to compare recipients of T/P to non-recipients of T/P (with threshold for statistical significance $p < 0.05$). **Results:** 786 patients were included, 112 of whom (14.2%) received T/P. T/P recipients were younger ($p<0.001$), more likely to have Stage II/III disease ($p<0.001$), and less likely to have received endocrine therapy ($p<0.001$). Univariate analyses revealed worse CIPN20-C score at Y1 ($p=0.02$) and worse CIPN20-S scores ($p=0.004$) at Y1 and Y3 in T/P recipients compared to non-recipients (Table). However, differences between the groups were no longer statistically significant after adjustment for age, stage and endocrine therapy. **Conclusions:** In this cohort, neuropathic symptom severity at Y1 and Y3 after a breast cancer diagnosis did not differ between recipients of taxane and/or platinum agents and nonrecipients after adjustment for age, stage, and endocrine therapy. These data may reassure patients and clinicians who are concerned about CIPN and considering use of these chemotherapies in this setting. Research Sponsor: None.

Patient demographics and CIPN20 results.

Clinical characteristic	T/P recipients	Non-recipients of T/P
Age at diagnosis, mean (SD)	55.3 (11.6)*	59.8 (11.9)
White race, N (%)	108 (96.4%)	660 (97.9%)
Clinical stage II/III, N (%)	76 (68.5%)*	250 (37.5%)
Endocrine therapy, N (%)	73 (65.2%)*	636 (94.4%)
Diabetes mellitus, N (%)	9 (8.9%)	52 (8.6%)
Y1 CIPN20-C score, mean (SD)	89.6 (10.9)*	92.0 (9.7)
Y3 CIPN-C score, mean (SD)	89.4 (11.4)	91.1 (9.7)
Y1 CIPN20- S score, mean (SD)	87.3 (15.1)*	91.3 (13.0)
Y3 CIPN20-S score, mean (SD)	88.2 (14.1)*	91.1 (11.7)

*Statistically significant ($p < 0.05$) on univariate analysis.

12039 Poster Session

Single-cell RNA sequencing atlas of intestinal injury induced by different clinical treatments in colorectal cancer patients.

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Background: Colorectal cancer (CRC) patients often experience intestinal injury due to various treatment regimens, including chemotherapy (CT), chemoradiotherapy (CRT), and chemoradioimmunotherapy (ICRT). Despite advances in treatment, the underlying mechanisms of treatment-induced intestinal injury remain poorly understood. **Methods:** We performed single-cell RNA sequencing and histological staining on intestinal samples obtained from 18 colorectal cancer patients undergoing different treatment regimens, including untreated (CTRL), CT, CRT, and ICRT groups. We also employed bulk RNA sequencing to compare paired cancer and normal tissues from ICRT patients, identifying similarities and differences in gene expression patterns between the cancer and normal tissues. **Results:** Histological staining showed that there were no morphological changes in CT, while the damage in CRT was obvious, and the damage in ICRT was even more severe. Intestinal epithelial cells exhibit distinct differentiation trajectories into secretory and absorptive lineages. CRT-induced damage triggers reverse differentiation via revival stem cells (revSCs), driven by fetal-like genes like CLU, while ICRT disrupts this process. In CD8+T cells, effector T cells (TEFF) increase significantly in the ICRT group and differentially expressed genes (DEG) revealed unique patterns across different treatments, including upregulation of senescence-related genes in CRT and interferon- and TNF-related genes in ICRT, highlighting potential therapeutic targets for treatment-induced intestinal injury. In B cells, distinct differentiation pathways were observed, with CRT increasing atypical memory (Atm) B and ICRT promoting germinal center (GC) B, the latter correlating with follicular helper T (TFH) cells and potentially indicating tertiary lymphoid structure (TLS) formation, similar to the patterns of tumor response after ICRT. So we conducted bulk RNA sequencing analysis between paired tumor and normal tissues, which revealed a correlated expression of effector markers, suggesting a shared biological pattern between tissue damage and tumor killing. Also, patients in the ICRT group showed a significant correlation between clinical intestinal injury scores (LARS) and tumor regression grade (TRG), which means we can predict the treatment efficacy of ICRT by a more direct and convenient way. We also performed metabolism analysis and found tryptophan metabolism was significantly altered following CRT and ICRT treatments, closely linked to epithelial repair and inflammation, highlighting tryptophan metabolism can be used as treatment of intestinal injury. **Conclusions:** Our study presents a comprehensive single-cell atlas of treatment-induced intestinal injury in CRC patients, offering insights for future strategies to reduce treatment-related intestinal damage. Research Sponsor: None.

Incidence of ocular toxicities in patients with relapsed/refractory multiple myeloma treated with belantamab mafodotin: A systematic review and meta-analysis of phase 3 randomized controlled trials.

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Background: Belantamab mafodotin is a novel antibody-drug conjugate approved by the FDA in August 2020 to treat relapsed/refractory multiple myeloma (RRMM). However, it was withdrawn from the market in March 2023 following the DREAMM-3 randomized controlled trial (RCT) failure to show superior progression-free survival (PFS). Later in 2024, further RCTs published (DREAMM-7 & 8) have shown PFS benefit which opens the door to a possible FDA reapproval in the future. Several concerns about ocular adverse events (AEs) have emerged from those trials. This meta-analysis aims to evaluate the incidence of those events in patients with RRMM receiving belantamab. **Methods:** A systematic literature search was performed across MEDLINE and EMBASE databases up to December 31, 2024. Phase 3 RCTs investigating belantamab regimens in RRMM were included. Pooled risk ratios (RR) with 95% confidence intervals (CI) were calculated using the Mantel-Haenszel method. Heterogeneity was assessed using Cochran's Q-statistic. Fixed effects model was employed. **Results:** A total of 1,102 patients from three phase 3 RCTs (DREAMM-3, DREAMM-7, DREAMM-8) were analyzed. The following ocular AEs were noted more frequently in the belantamab group compared to the control group: any-grade (AG) ocular AEs 76.85% vs 24.95% (RR 3.30; 95% CI: 2.80–3.89; $P < 0.00001$), high-grade (HG) ocular AEs 34.65% vs 2.03% (RR 17.61; 95% CI: 9.40–33.00; $P < 0.00001$), AG dry eyes (DE) 45.16% vs 6.69% (RR 7.47; 95% CI: 5.29–10.54; $P < 0.00001$), HG DE 6.24% vs 0% (RR 21.40; 95% CI: 4.40–104.07; $P = 0.0001$), AG blurred vision (BV) 59.77% vs 10.14% (RR 6.54; 95% CI: 4.97–8.60; $P < 0.00001$), HG BV 14.78% vs 0.41% (RR 27.39; 95% CI: 8.86–84.68; $P < 0.00001$), AG photophobia 36.95% vs 2.64% (RR 15.55; 95% CI: 8.97–26.96; $P < 0.00001$), HG photophobia 1.81% vs 0% (RR 7.08; 95% CI: 1.40–35.70; $P = 0.02$), AG eye irritation (EI) 37.27% vs 5.48% (RR 7.60; 95% CI: 5.17–11.19; $P < 0.00001$), HG EI 3.28% vs 0% (RR 12.23; 95% CI: 2.52–59.33; $P = 0.002$), AG eye pain (EP) 26.27% vs 3.04% (RR 9.40; 95% CI: 5.61–15.76; $P < 0.00001$), AG foreign body eye sensation (FBES) 41.71% vs 4.26% (RR 10.68; 95% CI: 6.94–16.45; $P < 0.00001$), AG cataract 16.58% vs 9.13% (RR 2.06; 95% CI: 1.49–2.85; $P < 0.0001$), and HG cataract 4.76% vs 2.64% (RR 2.08; 95% CI: 1.10–3.94; $P = 0.02$). No statistically significant difference was noted between the two treatment arms in terms of HG EP or FBES. **Conclusions:** This study revealed a significantly increased risk of ocular AEs in patients with RRMM treated with belantamab compared to the other traditional myeloma treatments. Close monitoring and early intervention are crucial for prompt identification and providing the appropriate management for those events in order to optimize the patients' quality of life and compliance. Research Sponsor: None.

12041 Poster Session

Risk of non-breast cancer–related mortality in breast cancer and dependence on disease characteristics, treatment, and survival duration.

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Background: Breast Cancer (BC) has seen significant improvement in survival in both early (eBC) and metastatic (mBC) setting. Prolonged survival increases the risk of acquisition of other comorbidities and result in non-BC related mortality (NBCRM). Purpose of this study is to identify the high-risk disease characteristics and trends for NBCRM. **Methods:** Patients (pts) with BC diagnosed as first primary malignancy between 2010-2019 were identified from 2023 release of SEER 17 database, with follow up till 12/31/2021. Causes of mortality were extracted and categorized as BC related mortality (BCRM) and NBCRM. BC related competing risk adjusted fine and gray regression model was used for survival analysis for NBCRM and subdistribution hazard ratio (SHR) is reported. Restrictive mean survival time (RMST) was calculated for pts with radiation and chemotherapy. Pearson chi-square tests used for comparison of categorical data. **Results:** 457,655 BC pts were identified. Median overall survival (OS) for mBC was 34 months (m) (95% CI 33-35 m) and not reached for eBC. For adjusted NBCRM, risk of mortality was higher for age $\geq$ 65 (eBC SHR 10.2, mBC SHR 2.5, Both $p < 0.01$) and age 51-65 (eBC SHR 2.5, mBC SHR 1.5, both $p < 0.05$) compared to age $\leq$ 50 years. Triple negative (TNBC) (eBC SHR 1.2, $p < 0.05$) had higher risk compared HR+/HER2- but not for mBC. For eBC, higher risk for Stage II (SHR 1.5, $p < 0.05$) and Stage III (SHR 2.0, $p < 0.05$) compared to Stage I. Lobular histology had lower risk of NBCRM for eBC (HR 0.86, $p < 0.05$) and no difference was seen for mBC (SHR 0.93, $p = 0.27$). Pts with radiation (RT) had lower risk of NBCRM (eBC SHR 0.57, mBC SHR 0.86, Both $p < 0.05$). RMST difference for Pts with RT vs no RT increased from 0.08 m at 1 year to 1.7 m at 5 years for eBC and 0.09 m at 1 year to 1.38 m at 5 years for mBC. Similarly, pts with chemotherapy (CT) had lower NBCRM (eBC SHR 0.52 $p < 0.05$, mBC SHR 0.7, $p < 0.01$). RMST difference for pts with CT vs no CT increased from 0.35 m at 1 year to 1.31 m at 5 years for eBC and 0.27 m at 1 year to 3.53 m at 5 years for mBC. Cardiovascular (CVS) (30.76%) and subsequent malignancies (19.96%) were most common causes of NBCRM for eBC. Of all CVS-mortality, 11% occurred $<$ 1 year of diagnosis and 40% after 5 years. Subsequent solid malignancy- mortality was 6.8% in $<$ 1 year and 41% for $>$ 5 years. Subsequent hematological malignancy- mortality was 5.9% in $<$ 1 year and 38% for $>$ 5 years. For mBC, the above trends for NBCRM were inconclusive, given median OS was $<$ 3 years. **Conclusions:** With the rising number of BC survivors, it is imperative to identify high-risk disease characteristics which can lead to NBCRM. Risk of NBCRM was noted to be related to age of diagnosis, stage, histology and treatment. Risk of CVS and subsequent malignancy related mortality was significantly more for pts surviving more than 5 years, especially in the eBC setting, highlighting the importance of adherence to preventive health guidelines and lifestyle modifications. Research Sponsor: None.

12042 Poster Session

Incidence of venous thromboembolism (VTE) events in patients with EGFR-mutant non-small cell lung cancer (NSCLC) treated with amivantamab: A systematic review and combined meta-analysis of phase 3 randomized controlled trials.

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Background: Amivantamab is a bispecific antibody that was granted accelerated approval by the FDA in May 2021 for the treatment of non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) mutations. In addition, it also targets the mesenchymal-epithelial transition (MET) pathway which is involved in cancer cell proliferation. While amivantamab approval is considered a significant advancement in the EGFR-mutant lung cancer management, its introduction has raised concerns about potential new adverse events. This study aims to evaluate the incidence of venous thromboembolism (VTE) events in patients with EGFR-mutant NSCLC receiving amivantamab. **Methods:** We conducted a comprehensive literature search using MEDLINE and EMBASE databases from inception through December 31, 2024. Phase III randomized controlled trials (RCTs) utilizing amivantamab in EGFR-mutant NSCLC and reporting VTE adverse events were included. Mantel-Haenszel method was used to calculate the estimated pooled risk ratio (RR) with 95% confidence interval (CI). Heterogeneity was assessed with Cochran's Q-statistic. Random effects model was employed. **Results:** A total of 1,791 patients from three phase III RCTs (MARIPOSA n = 849, MARIPOSA-2 n = 636, PAPILLON n = 308) were included in the analysis. MARIPOSA tested amivantamab-lazertinib vs osimertinib vs lazertinib, while MARIPOSA-2 involved amivantamab-lazertinib-chemotherapy vs chemotherapy vs amivantamab-chemotherapy, and PAPILLON tested amivantamab-chemotherapy vs chemotherapy. Randomization ratios were 2:2:1, 2:2:1, and 1:1, respectively. The incidence of any-grade VTE was higher in the amivantamab group compared to the control group, with a rate of 25.90% vs 7.26% (RR, 3.69; 95% CI: 2.74-4.98; $P < 0.00001$). VTE as a serious adverse event was reported higher in the amivantamab arm compared to the control arm, 5.69% vs 2.42% (RR, 2.36; 95% CI: 1.31-4.27; P = 0.004). There was no statistically significant difference between the two treatment groups in terms of incidence of high-grade VTE. A subgroup analysis based on the type of VTE was performed. Incidence of both pulmonary embolism (PE) and deep vein thrombosis (DVT) was higher in the amivantamab cohort compared to the control cohort, with a rate of 9.94% vs 3.75% (RR, 2.62; 95% CI: 1.50-4.58; P = 0.0007) and 7.97% vs 1.81% (RR, 5.0; 95% CI: 2.90-8.62; $P < 0.00001$), respectively. **Conclusions:** This study showed increased risk of VTE events in patients with EGFR-mutant NSCLC treated with amivantamab-containing regimens compared to the standard arm. These findings highlight the importance of close monitoring for those events in order to early detect and provide the appropriate management. Further studies are needed to better understand this association between amivantamab and VTE. Research Sponsor: None.

Radioimmunotherapy-associated myeloid neoplasms: Real-world multicenter retrospective study using TriNetX database.

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Background: Radioimmunotherapy (RIT) utilizing monoclonal antibodies conjugated with therapeutic radionuclides, has emerged as a promising treatment option in oncology. While demonstrating significant clinical efficacy, concerns regarding therapy-related myeloid neoplasms (t-MNs) have been raised in other contexts, particularly following RIT for non-Hodgkin lymphoma. This study aims to investigate the risk of t-MNs following treatment with Lutathera (177Lu-DOTATATE) and Pluvicto (177Lu-PSMA-617) in patients with neuroendocrine tumors and metastatic castration-resistant prostate cancer. **Methods:** We conducted a multicenter retrospective study using the TrinetX database network, a federated Electronic Medical Record Network including adult patients with a history of using Lutathera and/or Pluvicto and developed t-MNs. Statistical analysis is performed on the TrinetX research platform. Outcome analysis was performed for 1) Incidence of t-MNs. 2) Mortality rates and Survival analysis. **Results:** A total of 2370 patients who received either Lutathera (n=1368; 57.7%) or Pluvicto (n=1002; 42.3%) were identified in the database. Mean age was 71 years (±11 years), 64.98% (n=1540) were males and 70.08% were whites. Of the 2370 patients, 1.6% (n=39) developed t-MNs (26 MDS (1.09%), 13 AML (0.54%). Among these, 27 were in the Lutathera cohort (1.97% of total patients), and 12 were in the Pluvicto cohort (1.12%). The mean age in the t-MN cohort was 72 years (±9 years) and 50% were males. 16 (41%) patients with t-MN had prior chemo or radiotherapy. The remaining 23 patients (59%) received no anticancer therapy associated with t-MNs. Median survival for patients with t-MNs was 38.1 months, with an overall mortality of 51.2% at median follow-up. **Conclusions:** This is the largest study reporting the incidence of t-MN associated with RIT. Our study demonstrated a significant risk of therapy-related t-MNs following RIT, even in patients who did not receive additional chemoradiotherapy. Given the short follow-up, we hypothesize that the risk may increase with longer-term follow-up. Using this real-world data, our Next step would be to include Next-Generation Sequencing for further characterization of the genomic landscape of these patients. Research Sponsor: None.

Demographic, treatment, and follow-up data of the study population.

Baseline characteristics	RIT	RIT with t-MNs
Total patients	2370	39
Mean age (in years) (SD)	71 (±11)	72 (±9)
Gender*(%)		
Males	64.98	50.0
Females	22.07	46.6
Race*(%)		
Whites	70.08	73.33
African American	7.60	8.6
Radiation therapy (%)	20.2	
Chemotherapy (%)	-	
Cabazitaxel	5.20	41.0
Docetaxel	16.7	
Carboplatin	0.73	
Cisplatin	0.22	
Doxorubicin	0.76	
Olaparib	5.0	
Median follow-up (in months)	11.4	27.3
Median survival (in months) (IQR)	44.5 (41.6-48.3)	38.1 (15-51.6)
Mortality rates (%)	28.9	51.2

*Indicates remaining Unknown/Other; IQR: Interquartile range.

Multisite validation of biomechanical computed tomography for osteoporosis assessment and fracture prediction in patients with high-risk or metastatic prostate cancer.

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Background: Long-term androgen deprivation therapy (ADT) among men with high-risk localized or metastatic prostate cancer (PCa) results in a 10-20% risk of significant bone fracture at 10 years. While guidelines recommend routine bone mineral density (BMD) screening for men with PCa receiving ADT, most do not undergo it. We studied whether Biomechanical Computed Tomography (BCT), a radiomic technique to opportunistically measure femoral and vertebral bone strength and BMD from CT scans performed for routine staging, can predict incident fractures among men with PCa beginning ADT. **Methods:** In this retrospective cohort study among 2 academic cancer centers and 2 Veterans Affairs facilities, we identified 711 men with de novo high-risk localized or metastatic PCa diagnosed between 2010-2018. CT scans at PCa diagnosis were analyzed by BCT. Incident fractures were ascertained by trained radiologists and defined as any new fractures occurring after the initial CT scan. We used Cox proportional hazards models to estimate associations of fragile femur bone strength (≤3500N), fragile vertebral bone strength (≤6500N), or osteoporosis (femoral neck areal BMD T-score ≤-2.5 or trabecular volumetric BMD ≤80 mg/cm3), with incident fracture, adjusted for age, BMI, & race/ethnicity. **Results:** 673 men were eligible (mean age 69.8±9.3, 49.3% white, 35.2% received prior ADT, 42.3% had prior BMD screening). 198 (29.4%) incident fractures were observed. Using BCT, 123 men (18.3%) had fragile femur bone strength or osteoporosis, and 105 men (15.6%) had fragile vertebral bone strength or osteoporosis by volumetric BMD. BCT-derived fragile femur or vertebral bone strength (adjusted HR 1.81, 95% CI 1.27-2.59) and osteoporosis by BMD criteria (aHR 2.20, 95% CI 1.32-3.62) were associated with incident fracture (Table). **Conclusions:** In men with high-risk PCa, opportunistic BCT analysis of routine staging CT scans improves osteoporosis detection and fracture prediction, identifying men who may have not otherwise qualified for antiresorptive treatment. BCT is a novel approach to risk-stratify men with PCa for early fracture risk mitigation. Research Sponsor: U.S. Department of Defense; W81XWH2210151.

Association between BMD and bone strength with incident fracture.

Femur Bone Strength	HR (95% CI)	p-value
Normal ***(≥5000N)***	1 (reference)	
Low ***(3500-5000N)***	1.80 (1.25–2.58)	0.002
Fragile ***(≤3500N)***	2.50 (1.59–3.93)	<0.001
Vertebral Bone Strength		
Normal ***(≥ 8500N)***	1 (reference)	
Low ***(6500–8500N)***	1.09 (0.60–1.99)	0.78
Fragile ***(≤6500N)***	1.71 (0.96–3.25)	0.07
Femoral Neck BMD ***(T-score)***		
Normal ***(≥ −1.0)***	1 (reference)	
Low Bone Density/Osteopenia ***(−1.0 - −2.5)***	1.92 (1.38–2.67)	<0.001
Osteoporosis ***(≥ −2.5)***	2.20 (1.32–3.62)	0.003
Vertebral Trabecular BMD		
Normal ***(≥120 mg/cm^3)***	1 (reference)	
Low Bone Density/Osteopenia ***(80-120 mg/cm^3)***	0.99 (0.53–1.84)	0.98
Osteoporosis ***(≤80 mg/cm^3)***	1.95 (1.04–3.67)	0.04

Impact of pembrolizumab on geriatric syndromes in older patients with NSCLC: A propensity-matched retrospective cohort study.

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Background: Non-small cell lung carcinoma (NSCLC) predominantly affects older adults (≥65 years), where immune checkpoint inhibitors (ICIs) are a key treatment, especially in those without driver mutations. However, the effect of ICIs on age-related health issues (geriatric syndromes), which impact quality of life in this population, is unclear. This study aims to investigate the impact of ICIs on geriatric syndromes in older adults with NSCLC. **Methods:** We utilized data from the Global Collaborative Network-TrinetX to evaluate the impact of pembrolizumab on geriatric syndromes in elderly NSCLC patients, dividing them into two groups based on pembrolizumab treatment status defined by International Classification of Diseases (ICD-10) codes. Propensity score matching (PSM) was used to balance the cohorts based on demographic characteristics, comorbidities, medications, and without driver mutations. Geriatric syndromes were assessed over 30-day and 1-year follow-up periods. Multivariate logistic regression models assessed the association between pembrolizumab treatment and geriatric syndromes, with results expressed as odds ratios and 95% confidence intervals. **Results:** Following PSM, there were two balanced cohorts of 3288 patients each. The pembrolizumab cohort had a mean age of 75.6 ± 6.93 years, while the non-pembrolizumab cohort had a mean age of 78.2 ± 7.9 years. Multivariate analysis revealed that pembrolizumab treatment was significantly associated with increased fatigue risk at 30 days (OR 1.600, 95% CI 1.062-2.411, P=0.023), persisting at 1 year (OR 1.769, 95% CI 1.463-2.140, P<0.001). Additionally, pembrolizumab treatment was linked to increased risks of insomnia (OR 1.331, 95% CI 1.052-1.683, P=0.017) and delirium (OR 1.494, 95% CI 1.105-2.019, P=0.009) at 1 year. Notably, pembrolizumab treatment was not significantly associated with risk of dementia, frailty, urinary incontinence, or falls at 30 days and 1 year. **Conclusions:** Our study shows that pembrolizumab was significantly associated with increased risks of persistent fatigue, delirium, and insomnia in geriatric NSCLC patients at one-year follow-up. This emphasizes the need for monitoring and targeted interventions to mitigate these adverse events and improve quality of life in this population. Research Sponsor: None.

Geriatric syndromes in NSCLC patients on pembrolizumab.

OUTCOME	30 DAYS FOLLOW-UP		1 YEAR FOLLOW-UP	
	OR and 95% CI	P-value	OR and 95% CI	P-value
Falls	1.381 (0.631-3.114)	0.434	1.264 (0.946-1.690)	0.113
Dementia	0.993 (0.413 −2.390)	0.988	0.993 (0.581-1.697)	0.980
Delirium	1.400 (0.621-3.156)	0.416	1.494 (1.105-2.019)	0.009
Insomnia	1.656 (0.998-2.748)	0.049	1.331 (1.052-1.683)	0.017
Urinary incontinence	N/A*		N/A	
Fatigue	1.600 (1.062-2.411)	0.023	1.769 (1.463-2.140)	<0.001
Frailty	1.000 (0.416-2.405)	0.999	1.233 (0.733 −2.073)	0.429

*No outcomes were observed within the follow-up period.

New-onset osteopenia/osteoporosis among long-term survivors of breast cancer: Role of hormone therapies and metabolic risk factors.

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Background: Anti-cancer therapies (including aromatase inhibitors [AIs]) and metabolic risk factors are known to result in bone mineral density (BMD) loss in breast cancer survivors (BCS). There is limited information regarding the very long-term risk of new-onset osteopenia/osteoporosis among BCS and the associated risk factors. **Methods:** Patients who survived ≥1y after BC underwent q2y dual x-ray absorptiometry (DXA) screening at a single center; those exposed to bisphosphonates or with osteopenia/osteoporosis prior to BC were excluded. All DXAs from BC diagnosis to diagnosis of osteopenia/osteoporosis were processed in Python via automated analysis. New-onset osteopenia/osteoporosis was defined as a DXA with a T-Score < -1 at any bone site. Demographics, treatment exposures, and metabolic risk factors were abstracted from medical records. Cumulative incidence described the risk of osteopenia/osteoporosis, and Cox proportional hazards models described the risk factors, treating therapeutic exposures as time-varying variables. Multivariable linear regression models with generalized estimation equations assessed longitudinal trend of BMD prior to onset of osteopenia/osteoporosis. **Results:** We evaluated 4,575 DXAs in 1,267 BCS (median age at BC: 55y; median follow-up: 9.8y; non-Hispanic Black: 28.6%). Overall, 39.2% received AIs, 18.7% received selective estrogen receptor modulators (SERMs), 20.1% received AIs & SERMs, and 21.9% received neither. The cumulative incidence of osteopenia/osteoporosis in the entire cohort was 19% at 2y, increasing to 42% at 5y and 68% at 15y after BC. In those exposed to AIs, the cumulative incidence of osteopenia/osteoporosis was 38%, 75%, and 96% at 2y, 5y, and 15y, respectively. Multivariable analysis revealed the following to be independently associated with osteopenia/osteoporosis: AIs (HR = 1.94, 95%CI = 1.61-2.34), increasing age: (HR = 1.03, 95%CI = 1.02-1.04), pre-BC dyslipidemia (HR = 1.36, 95%CI = 1.06-1.75), and post-BC dyslipidemia (HR = 1.47, 95%CI = 1.19-1.81). Black race (HR = 0.44, 95%CI = 0.36-0.54, ref = white race), pre-cancer obesity (HR = 0.71, 95%CI = 0.56-0.91), and post-cancer obesity (HR = 0.79, 95%CI = 0.65-0.96) were protective. Exposure to SERMS was not a risk factor (HR = 0.97, 95%CI = 0.76-1.23). Among those exposed to AIs, radial wrist BMD declined significantly more steeply among those who eventually developed osteoporosis/osteopenia (0.45%/year), when compared with those who did not (0.11%/year) (p = 0.04). **Conclusions:** These results provide evidence for close surveillance of BC survivors at increased risk of osteopenia/osteoporosis for extended periods, and aggressive management of dyslipidemia before, during and after BC. Research Sponsor: None.

12047 Poster Session

Non-infectious sarcoid-like inflammatory granulomatous conditions (NSIGC) associated with immune checkpoint inhibitors (ICIs) for cancer: Results from the International ICARUS (Immune Checkpoint Associated Rare and Unique Side effects) consortium.

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Background: ICIs can be associated with a broad range of toxicities; however, limited data exists on NSIGC secondary to ICIs. Herein, we assembled the first international cohort of patients (pts) with cancer who received ICIs and subsequently developed NSIGC. **Methods:** We retrospectively collected data from 14 institutions globally on pts with cancer who received ICIs between 2015-2025 and subsequently developed biopsy-confirmed NSIGC. Pts were eligible if they received anti-programmed cell death protein-1/programmed death-ligand 1 (anti-PD-1/PD-L1) alone or in combination with additional anti-cancer therapies such as chemotherapy, targeted agents or anti-CTLA-4, or if they were treated with other immunotherapies. The chi-squared goodness of fit test was used to analyze the distribution of different ICI regimens and their association with NSIGC, assuming a uniform distribution with an expected frequency of 25 for each of the 5 ICI regimens. **Results:** The study included 125 pts with biopsy-confirmed NSIGC post-ICI. Of these, 58.4% (n = 73) were male and 83.2% (n = 104) were Caucasians. Median age at cancer diagnosis was 62 years. The top three cancers in the cohort were melanoma (45.6%; n = 57), non-small cell lung cancer (16.8%; n = 21), and renal cell carcinoma (6.4%; n = 8). Out of 125 pts, 48.8% (n = 61) received anti-PD-1/PD-L1 monotherapy, 20% (n = 25) anti-PD-1/PD-L1 + anti-CTLA-4, 17.6% (n = 22) anti-PD-1/PD-L1 + chemotherapy, 8% (n = 10) anti-PD-1/PD-L1 + targeted agents, and 5.6% (n = 7) received other immunotherapies. Our result showed a significant difference between expected and observed NSIGC frequencies across different ICI regimens ($X2 = 74.2$, $df = 4$, $p < 0.01$), indicating a potential association between anti-PD-1/PD-L1 monotherapy and NSIGC. The median time to the diagnosis of NSIGC after ICI initiation was 7.1 months (range: 3.9-26.7 months). Of 125 pts, 55.2% (n = 69) were diagnosed after treatment completion. Among these 69 pts, 56.5% (n = 39) were diagnosed within 6 months, 14.5% (n = 10) between 6 months and 1 year, 10.1% (n = 7) between 1 and 2 years, and 18.8% (n = 13) were diagnosed after 2 years. The remaining 44.8% (n = 56) were diagnosed during treatment, out of which 48.2% (n = 27) required permanent treatment discontinuation due to NSIGC and 3.6% (n = 2) were re-challenged. 19.2% (n = 24) received steroid treatment for NSIGC. **Conclusions:** To our knowledge, this is the largest dataset to date demonstrating NSIGC as a rare side effect of ICIs. NSIGC frequently occurs after ICI therapy completion but can also result in ICI discontinuation. Biopsy confirmation is critical to prevent misdiagnosis, and further research is required to elucidate the biology, risk factors, and implications for ICI continuation or rechallenge to optimize patient outcomes. Research Sponsor: None.

Identifying genetic susceptibility for severe cardiac events in testicular cancer survivors.

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Background: Testicular cancer (TC) survivors face an increased risk of cardiovascular diseases (CVD) as a late adverse effect of oncological treatment, especially after cisplatin-based chemotherapy. To explore genetic susceptibility, we performed a genome-wide association study using hierarchical clustering and assessed impact of polygenic risk scores (PRS). **Methods:** A subcohort of TC patients treated at expert centers in the Netherlands between 1976 and 2007 was established by hospital stratified random sampling, and enriched with all identified cases of severe CVD (coronary artery disease, myocardial infarction, heart failure) of the entire cohort (Lubberts et al J Clin Oncol 41:3512-3522, 2023). Genotyping was performed using the Global Screening Array. The study population consisted of 396 TC patients: 92 survivors with cardiac disease and 304 survivors without cardiac disease. Seven general population derived PRSs from the CARDIoGRAMplusC4D consortium were applied to assess cardiac risk, followed by hierarchical SNP aggregation based on linkage disequilibrium to identify cardiac risk-associated SNPs. These SNPs were used for co-functionality analysis and decision tree analyses to develop novel PRSs. **Results:** Five of the seven external PRSs were significantly associated with cardiac risk, explaining 8%-12% of the variance, with the CARDIoGRAM GWAS PRS showing the strongest association. Patient's age at diagnosis explained the largest variance in cardiac risk (21%). Hierarchical SNP aggregation identified 67 cardiac risk-associated SNPs, individually explaining 3% - 12% of the variance. Co-functionality analysis revealed biological processes, including cardiovascular development, immune signaling, and DNA damage repair, as potential mediators of these SNPs' effects. Using decision tree analysis, a novel PRS was developed incorporating CVD risk-associated SNPs and clinical risk factors at start of treatment. This PRS+ achieved the highest concordance statistic of 0.783 (standard error 0.022) and explained maximum variance (50%) among all tested models. This PRS+ identified that patients diagnosed at age $>$ 41 years had higher cardiac risk, independent of genotype data. Whereas a subset of patients diagnosed at age $\leq$41 years could be identified as having increased cardiac risk based on the minor allele frequency of five SNPs (rs6830970, rs17666409, rs10782601, rs2446862, rs767707). **Conclusions:** This study introduces a novel PRS to identify TC patients with a higher risk of CVD, enabling the development of personalized cardiovascular risk management strategies at the start of their cancer treatment. It also advances understanding of the biological mechanisms underlying this increased risk. Clinical trial information: NCT02276430. Research Sponsor: Dutch Cancer Society (KWF); NKI 2011-5209.

12049 Poster Session

Prevalence of sexual dysfunction among men with cancer before the initiation of systemic treatment.

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Background: Sexual health significantly impacts the quality of life, yet its relationship with systemic cancer treatments in men remains underexplored, particularly outside prostate cancer-focused studies. In Brazil, the prevalence of moderate to complete sexual dysfunction among men is approximately 14.5%. This prospective cohort study conducted at a Brazilian Cancer Center evaluated the prevalence of sexual dysfunction before the initiation of systemic therapy in men diagnosed with solid tumors using the Male Sexual Quotient (MSQ) tool. **Methods:** Sexually active, treatment-naïve male patients with solid tumors were enrolled, excluding those with prostate cancer, active brain metastases, spinal compression, or prior pelvic irradiation/extensive pelvic surgery for rectal or bladder cancer. Baseline sexual function was assessed using the MSQ, which evaluates five domains: premature ejaculation, erectile dysfunction, hypoactive sexual desire, orgasm frequency, and dissatisfaction with sexual activity. An MSQ global score ≤60 defined moderate to complete sexual dysfunction. Hormonal profiles, including testosterone, FSH, and LH, were measured. The Hospital Anxiety and Depression Scale (HADS) was used to identify risks of anxiety or depression. All participants provided informed consent, and the local ethics committee approved the protocol. **Results:** Between October 2023 and December 2024, 73 male patients were recruited (median age 58 years, IQR 47.5–68.0); 78% were married, and 75% had an ECOG performance status of 0. At diagnosis, 34% presented with metastasis, including 19% with visceral involvement. Primary cancer sites included head and neck (25%), colorectal (19.1%), lung (15%), melanoma (8.2%), and kidney (8.2%). Treatment regimens comprised chemotherapy (76%), immunotherapy (31.5%), and targeted therapy (9.5%). Most patients (83%) had no risk of anxiety or depression per HADS, with one patient showing a high risk. Moderate to complete sexual dysfunction was observed in 22.2% of patients, higher than the general Brazilian male population. The most affected domains were hypoactive sexual desire, premature ejaculation, and erectile dysfunction. Despite these findings, median hormone levels were within the normal range: testosterone (356 ng/dL, IQR 300–468), FSH (64 mIU/mL, IQR 29–93), and LH (39 mIU/mL, IQR 28–52). **Conclusions:** The prevalence of moderate to complete sexual dysfunction was 22.2% in this cohort. This rate is higher than that observed in the general male population in Brazil. The evaluation of sexual quality of life in men with cancer undergoing systemic treatment is often overlooked. This data points to the need to develop new policies and studies to increase awareness about this critical issue. Research Sponsor: None.

A pilot exercise program in breast cancer survivors: Group vs individual training outcomes.

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Background: Exercise interventions have consistently led to improved fitness in breast cancer patients. Best practices to ensure longevity of lifestyle changes have not been well explored. The purpose of this study was to evaluate long-term effectiveness of exercise intervention for patients. We sought to determine if group (Gr) or individual (Ind) exercise sessions would have differing effects in maintaining long term muscular strength, cardiorespiratory endurance, and range of motion (ROM). **Methods:** Thirty female patients underwent 3 months of individual exercise training, and were then randomized to continue with Ind (n=13) or Gr sessions (n=17) for another 3 months. Assessments were performed at baseline, after 3 months, and 1 year from baseline. **Results:** Ind showed significant strength improvements from baseline to 3 months, and 1 year. Gr did not show significant strength improvements at either time point. Cardiorespiratory endurance (VO2peak) improved in Ind from baseline to 3 months, and 1 year. Gr showed significant endurance improvement from baseline to 1 year only. Ind shoulder (ROM) improved from baseline to 3 months and 1 year. No significant improvement in ROM was found in Gr at either time point. **Conclusions:** In our study, we found six months of exercise intervention improved long-term strength, endurance, and ROM significantly in Ind session, and non significantly in Gr. A post-analysis chart review revealed increased exercise limitations in the Gr due to injury and/or non-cancer related medical conditions, which may explain some of the differences in outcomes. Clinical trial information: NCT04013568. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P30.

Endurance, strength, and range of motion measures by exercise session type at baseline (BL), 3 months (3M), and 1 year (1Y).

	Baseline		3 Month P value		Ind P value		1 Year Gr P value		Ind P value	
	Gr N = 17	Ind N = 13		Gr N = 17		Ind N = 13		Gr N = 17		Ind N = 13
Left Lateral Raise (degree)	164.6 ± 9.0	172.1 ± 6.9	0.95	171.8 ± 7.6	0.03	173.1 ± 10.1	0.46	171.9 ± 7.9	0.02	175.6 ± 8.8
Right Lateral Raise (degree)	163.1 ± 12.3	169.5 ± 16.2	0.87	169.8 ± 6.9	0.11	172.0 ± 8.7	0.65	172.1 ± 9.2	0.04	173.9 ± 9.1
Seated Cable Row (kg)	26.5 ± 3.9	27.4 ± 4.2	0.10	31.4 ± 4.1	<0.01	30.7 ± 4.2	0.16	33.1 ± 6.9	<0.01	30.5 ± 4.7
Leg Extension (kg)	36.4 ± 12.0	35.0 ± 10.6	0.25	48.7 ± 12.8	0.01	42.8 ± 14.7	0.13	48.9 ± 12.7	<0.01	44.2 ± 14.4
VO2 Peak (ml/kg/min)	27.9 ± 5.4	29.2 ± 6.1	0.06	32.0 ± 4.3	0.03	35.1 ± 7.2	0.05	33.7 ± 5.8	<0.01	34.2 ± 4.5

Gr=Group, Ind=Individual. Mean ± SD.

Trajectories of multidimensional worry in survivors of early breast cancer (BC).

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Background: Worrisome thoughts are common future-oriented behaviors and may affect quality of life (QoL) years removed from BC diagnosis. We aimed to identify trajectories of worry and their determinants, focusing on age-related specificities. **Methods:** Disease-free stage I-III BC survivors from CANTO (NCT01993498) completed the Impact of Cancer scale v2 at end of treatment (EoT) and years (Y) 1, 3, and 5 post-EoT. Group-based trajectories were identified modeling continuous scores of the worry subscale (range: 1-5, higher = worse), which evaluates uncertainty and worry about the future and health, a sense of time running out, fear of cancer recurrence (FCR), and symptom-triggered FCR. Adjusted multinomial logistic regression incorporating pre-treatment anxiety/depression assessed membership determinants. QoL (EORTC QLQ-C30/BR23) was described by trajectory. Analyses were stratified by age. **Results:** We included7824 survivors, 31% were ≤50 and 69% > 50 years old. Among those aged ≤50, we identified five worry trajectories: most had high (41%) or very high (18%) worry (mean scores [95% CI] at EoT: 3.57 [3.55-3.60] and 4.37 [4.33-4.41], respectively, stable); 21% showed improvement (2.77 [2.73-2.82] at EoT, 2.14 [2.08-2.21] at Y5); and 12% had low worry (1.58 [1.53-1.63] at EoT, stable). Finally, 7% had moderate worry at EoT (2.21 [2.14-2.28]) that worsened sharply, stabilizing at high levels by Y5 (3.40 [3.29-3.52]). These patterns, especially in the worsening group, were primarily driven by persisting FCR and increasing uncertainty about health. Among those aged > 50, similar trajectories emerged, however worry levels in the worsening group (17%) remained low-to-moderate (2.04 [2.01-2.06] at EoT, 2.34 [2.27-2.40] at Y5). Younger age was a significant determinant of very high worry, both in the ≤50 (Odds Ratio v low worry [95% CI] per 10-year decrease: 1.92 [1.33-2.77]) and in the > 50 age group (1.50 [1.20-1.90]). Partnered status was associated with worsening worry in the ≤50 age group (v not: 2.54 [1.24-5.19]), whereas chemotherapy with very high worry in the > 50 age group (v no chemo: 1.77 [1.14-2.73]). BC grade, stage, BRCA status, family history of cancer, and comorbidities were not linked to worry in either age group. Psychological and physical domains of QoL, including fatigue, sleep, cognitive function, appetite, and gastrointestinal symptoms, were significantly worse in trajectories at higher worry ($p < .001$ at all time points). **Conclusions:** More than two-thirds of younger BC survivors report high levels of worry that either remain unchanged or worsen 5 years post-EoT, with a more pronounced decline and different determinants than older counterparts. These patterns appear to be largely driven by the post-traumatic effects of BC on unresolved FCR and by negative projections about health. Early referral to mental health professionals and monitoring strategies focused on reducing anxious arousal are warranted. Clinical trial information: NCT01993498. Research Sponsor: Conquer Cancer, the ASCO Foundation and Rising Tide Foundation for Clinical Cancer Research; ARC; ARCPGA20220100044401_4882; ANR; ANR-10-COHO-0004; ANR; ANR-18-IBHU-0002; ANR; ANR-17-RHUS-008.

12052 Poster Session

Prospective observational study on health resource utilization and patterns of care for skeletal-related events in patients with bone metastases secondary to solid tumors.

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Background: Bone metastases are a common complication of advanced solid tumors, leading to significant morbidity through skeletal-related events (SREs). This study evaluates health resource utilization (HRU), treatment patterns, and clinical outcomes associated with SREs, with a focus on bone-modifying agents (BMAs) such as zoledronic acid and denosumab. **Methods:** This single-center, prospective, observational study included 199 patients with bone metastases secondary to solid tumors who experienced at least one SRE. Eligible patients were adults (≥18 years) with an Eastern Cooperative Oncology Group (ECOG) performance status of 0–3. Data collected included demographics, primary cancer type, comorbidities, treatment patterns, type and timing of SREs, and HRU. The impact of BMAs on SRE-free survival and overall survival (OS) was assessed using Kaplan-Meier analysis and multivariate Cox regression models. **Results:** The median age at the first SRE was 56 years, with 51.8% of patients being female. Breast cancer was the most common primary tumor site (30.2%), followed by genitourinary (22.1%) and gastrointestinal (18.6%) cancers. Visceral metastases were present in 56.3% of patients. Radiation therapy accounted for 80.9% of first SREs, followed by cord compression (8.5%), pathological fractures (7%), and surgical fixation (3.5%). Only 16.5% of patients received BMAs before their first SRE, increasing to 38.2% after the first SRE. Patients who received BMAs before the first SRE had significantly prolonged SRE-free survival (median 9.9 vs. 2.03 months, $p = 0.001$) and OS (median 45.6 vs. 29.8 months, $p = 0.05$). Similarly, BMA use after the first SRE improved SRE-free survival (median 18.9 vs. 10.3 months, $p < 0.001$) and OS (median 25.9 vs. 13.6 months, $p = 0.001$). The most common BMA-related adverse event was hypocalcemia (44.7%). **Conclusions:** This study highlights the underutilization of BMAs before the first SRE despite their significant impact on SRE-free survival and OS. Post-SRE BMA use was associated with improved outcomes, underscoring the need for earlier initiation of BMA therapy. Future research should focus on identifying barriers to early BMA utilization, optimizing management of therapy-related complications, and assessing the cost-effectiveness of BMAs in real-world settings. Research Sponsor: Amgen.

12053 Poster Session

Hot flashes and night sweats in women with breast cancer: Prevalence and severity of symptoms.

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Background: Hot flashes(HF) and night sweats(NS) are common endocrine-related symptoms experienced by breast cancer patients, which potentially arise from the tumor or treatment-related pharmacologic effects. They can significantly diminish patients' quality of life. However, there is a paucity of studies in China investigating the incidence and characteristics of HF and NS among patients with breast cancer. **Methods:** This study was a multi-center, cross-sectional survey that included women diagnosed with breast cancer from seven hospitals' oncology departments in China. Information was collected about demographic characteristics, psychological status (the Hospital Anxiety and Depression Scale and the Distress Thermometer), the frequency and severity of HF and NS(modified Hot Flash and Night Sweat scale), and patients' perceptions of these symptoms. Group differences based on the presence or absence of HF and NS were analyzed using t-tests or chi-square tests. Finally, univariate analyses was conducted to explore factors associated with the frequency of HF and NS. **Results:** Between October and November 2024, 960 questionnaires were distributed, and 767 Chinese female breast cancer patients(aged 25 to 79) replied and completed fully. Over 56% (n = 430) patients reported experiencing HF or NS.The average weekly frequency was 8.6 times for HF and 7.3 times for NS. Patients attributed HF and NS primarily to treatment (HF:36.8%;NS:32.7%) or uncertain causes (HF:15.8%;NS:17.4%). Compared to patients without HF and NS, those experiencing the symptoms had significantly higher levels of anxiety ($p < 0.001$), depression ($p = 0.019$), and psychological distress ($p < 0.001$). Notably, Patients reported severity, distress, and impact on life scores above 4, with HF at 47.90%, 37.46%, and 35.89%, and NS at 49.67%, 43.46%, and 40.85%, respectively. Among those affected, 59.24% of patients with HF and 63.7% of patients with NS adopted coping strategies, primarily resting/lying down (HF:27.7%; NS:36.3%). Regarding coping ability, HF group had a significant higher score than NS group (HF: 5.90; NS: 5.30, $p = 0.012$). Furthermore, univariate analysis revealed that HF and NS were associated with distress(HF:$p = 0.032$; NS:$p = 0.030$) and sleep quality(HF:$p = 0.031$; NS: $p = 0.043$). Additionally, for HF, single marital status ($p = 0.017$) was identified as a relevant factor, while stage IV tumor status ($p = 0.044$) was associated with NS. **Conclusions:** HF and NS affect over half of Chinese breast cancer patients, impacting their mental well-being and life quality, while low coping ability and limited coping strategies further underscore the need for healthcare professionals to pay closer attention to patients experiencing these symptoms, particularly single individuals and those with advanced-stage breast cancer. Research Sponsor: None.

Cardiovascular risk factor severity and adverse cardiovascular events: A report from the Childhood Cancer Survivor Study (CCSS).

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Background: Among survivors of childhood cancer, more severe grades of CVRFs are associated with increased risk for adverse cardiovascular events (ACE). The impact of low severity CVRFs has not been defined. **Methods:** Among 25,723 long-term survivors of childhood cancer, CVRF severity was graded using longitudinal self-report: Grade 1 conditions are reported but not on medications; Grade 2 are prescribed medications. Cumulative incidence of CVRFs were estimated into the 6th decade of life with death and Grade 2 CVRFs a competing risk event for Grade 1 CVRFs. Starting at 1st report of a CVRF, multivariable piecewise-exponential models were used to estimate relative rates (RR) of heart failure (HF), myocardial infarction (MI), valvular disease (VD), arrhythmia, and cardiac death relative to survivors without hypertension (HTN), diabetes (DM), and hyperlipidemia (HLD), all as time-dependent covariates. **Results:** The median age of survivors was 35y (range 9-70) and 26y (range 7-52) from cancer diagnosis. Cumulative incidence by age 55 of Grade 1 HTN, DM, and HLD were 7.8% (CI 7.1-8.5%), 4.3% (CI 3.8-4.9%), and 10.8% (CI 9.9-11.6%), respectively. The cumulative incidences of Grade 2 HTN, DM, and HLD were 37.9% (CI 36.4-39.3%), 14.0% (13.0-15.0%), 31.3% (29.9-32.7%), respectively. Grade 2 CVRFs were significantly associated with an increased RR for nearly all ACE (table). Grade 1 CVRFs were also significantly associated for most ACE; often with a similar magnitude as Grade 2 CVRFs. Grade 1 vs no HTN was associated with a 2 to 5-fold significantly increased RR of HF, MI, VD, arrhythmia, and cardiac death. Grade 1 vs no DM was associated with an increased RR of HF (1.9, CI 1.1-3.4). Grade 1 vs no HLD was associated with an increased RR of MI (2.9, 1.9-4.2) and arrhythmia 2.1 (1.2-3.5). **Conclusions:** Grade 1 CVRFs are associated with increased risk for ACE. These data suggest a role for more aggressive treatment of Grade 1 CVRFs among survivors. Research Sponsor: National Cancer Institute.

Relative rates of ACE among survivors by CVRF severity.

Individual models for each CVRF vs no respective CVRF (ref)	HF RR (95% CI)	MI RR (95% CI)	VD RR (95% CI)	Arrhythmia RR (95% CI)	Cardiac death RR (95% CI)
HTN Grade 1	2.9 (1.9-4.4)	3.6 (2.4-5.3)	4.7 (3.0-7.5)	2.8 (1.6-4.8)	1.9 (1.1-3.3)
HTN Grade 2	7.2 (6.1-8.6)*	7.1 (5.9-8.5)*	4.7 (3.7-6.1)	5.3 (4.2-6.7)	1.5 (1.1-2.0)
DM Grade 1	1.9 (1.1-3.4)	1.5 (0.7-3.0)	0.8 (0.3-2.5)	1.5 (0.6-3.7)	0.6 (0.1-2.2)
DM Grade 2	2.5 (1.9-3.2)	2.7 (2.2-3.5)	2.2 (1.6-3.1)	2.3 (1.6-3.2)	1.8 (1.3-2.6)
HLD Grade 1	1.5 (0.95-2.4)	2.9 (1.9-4.2)	1.5 (0.8-2.8)	2.1 (1.2-3.5)	1.2 (0.6-2.2)
HLD Grade 2	3.8 (3.2-4.7)*	6.5 (5.4-7.8)*	3.8 (2.9-4.8)*	3.1 (2.4-4.0)	1.1 (0.8-1.4)

Models adjusted for sex, race, current age, age at diagnosis, current smoking, obesity, sedentary lifestyle, anthracycline and heart radiation dose. Models fitted separately for each ACE. No respective CVRF as referent group. *Grade 2 vs Grade 1 condition above, $p<0.05$.

Impact of neighborhood disadvantage and residential isolation on cognitive outcomes in cancer survivors.

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Background: The Social Vulnerability Index (SVI), a composite measure of socioeconomic deprivation, household composition, minority status, and housing type and transportation, is a reliable marker of neighborhood disadvantage. Residential Segregation measures the degree to which a minority group is distributed differently than the majority group across census tracts. The isolation index is a measure of segragation that captures the extent to which minority members are exposed only to one another. These measures have been associated with poor survival in patients with cancer, yet studies on adverse outcomes in surviors are limited. Cognitive impairment is an adverse outcome highly prevalent in up to 40% and persists up to 5y in hematologic cancer survivors treated with blood or marrow transplantation (BMT). We postulate that neighbohood disadvantage and residential isolation may have a negative effect on cognitive outcomes in BMT survivors. **Methods:** We included 71 patients treated with allogeneic BMT, enrolled in the the Cognitive Training and Genetics Attitudes (cTAG) study. Objective cognitive function was measured using a comprehensive in-person battery of standardized neuropsychological tests. Standardized T-scores were categorized as deficit scores (range 0 to 5), and averaged across all tests to estimate a global deficit score(GDS), which was used as a measure of cognitive impairment. Residential addresses, geocoded and joined to corresponding Census block group and tract, were used to match patients with their corresponding SVI and residential segregation scores. Multivariable logistic regression models adjusted for age, sex, race, and clustering at the tract level were used to estimate associations with GDS. **Results:** Median age at study participation was 58y (IQR: 46, 63), 57.8% were male, and 16.9% were non-Hispanic Black. Primary diagnosis was 66.2% acute leukemia and 22.5 myelodysplastic/myeloproliferative neoplasms. Average time since BMT was 1.5y (SD = 1.2). Prevalence of global cognitive impairment was 19.7% (95%CI: 11.2-30.9). A high overall SVI score was associated with GDS (aOR = 4.7, 95%CI: 1.1, 20.2, p = 0.035). Vulnerability related to socioeconomic status (aOR = 4.9, 95%CI: 1.2, 20.2, p = 0.03) and housing type and transportation (aOR = 4.0, 95%CI: 1.1, 15.2, p = 0.04) were significantly associated with GDS. Higher residential isolation index ($>$ 0.6) was significantly associated with increase in GDS (aOR = 5.4, 95%CI: 1.3, 22.5, p = 0.02) adjusting for age, sex, race, and clustering at the tract level. **Conclusions:** Cancer survivors residing in areas with higher indicators of social vulnerability and isolation are at increased risk of cognitive decline post-BMT. These findings highlight the overall need for dedicating appropriate resources and care planning especially for individuals surrounded by others from their same group within their residential areas. Research Sponsor: Leukemia Lymphoma Society; 3386-19; Be The Match.

12057 Poster Session

Pilot study of a muscadine grape extract supplement to decrease fatigue among older cancer survivors.

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Background: Fatigue is a prevalent symptom among older cancer survivors and is associated with declines in physical function and quality of life (QOL). A proprietary muscadine grape extract supplement (MGES) may decrease fatigue based on pre-clinical data showing effects on oxidative stress, inflammation, and mitochondrial function and clinical observations from a Phase 1 trial suggesting a relationship between higher dose of MGES and decreased fatigue. The objective of this pilot study was to evaluate whether MGES may decrease fatigue and improve function and QOL among older cancer survivors. **Methods:** We conducted a randomized placebo-controlled pilot study (NCT04495751) of MGE supplementation (4 tablets twice daily, approximately 1280 mg total phenolics) for 12 weeks (wks) among older adult cancer survivors who reported baseline fatigue. Additional eligibility included age ≥65 years, history of solid tumor or lymphoma with no evidence of disease, at least 1 year post completion of active treatment. Fatigue was assessed with the PROMIS Fatigue 7a at baseline, and 2, 4, 8, 12 (primary outcome) and 16 wks. Physical function [Pepper Assessment Tool for Disability (PAT-D, activities of daily living and self-reported mobility subscales, higher scores indicate more limitations), Short Physical Performance Battery (SPPB, higher scores indicate better performance), 6-minute walk] and QOL (PROMIS Global Health) were measured at baseline and 12 wks. Toxicity was assessed using the CTCAE v5. Intention to treat (IIT) analyses utilized t-tests with a one-sided alpha = 0.10 to compare outcomes at 12 wks. **Results:** Sixty-four adults (mean age 76 years, 78% female, 91% white, 6% black) were randomized. Most common malignancies were breast (50%), lymphoma (12.5%), and prostate (12.5%). Fifty-one participants (80%) completed 12 wks of MGES or placebo with N = 62 evaluable for IIT analysis. There were no ≥grade 3 toxicities; 26 grade 2 toxicities (gastrointestinal) were attributable to study intervention. In IIT analyses, there was no difference in fatigue by randomization at 12 wks (MGE 50.1 vs placebo 51.4, p = 0.22). However, participants randomized to MGES reported improved physical function (PAT-D total score 1.4 vs 1.6, p = 0.07, ADL score 1.2 vs 1.4 p = 0.08, mobility score 1.7 vs 2.2, p = 0.05) and had improved gait speed scores on the SPPB, 3.7 vs 3.3, p = 0.1).There were no differences in total SPPB score (9.8 vs 9.2, p = 0.37), six-minute walk distance (369 vs 349 feet, p = 0.43) and QOL at 12 wks. **Conclusions:** In this pilot study, MGE supplementation for 12 wks among older cancer survivors did not improve fatigue or QOL compared to placebo but self-reported physical function and gait speed score were improved, suggesting a potential benefit on physical function. Ancillary studies investigating effects on oxidative stress, inflammation, mitochondrial function, and microbiome are on-going. Clinical trial information: NCT04495751. Research Sponsor: National Cancer Institute; P30 CA012197; National Center for Advancing Translational Sciences; UL1TR001420.

12058 Poster Session

Trends and disparities in palliative care utilization in advanced head and neck cancer hospitalizations.

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Background: Greater than 60% of Head and neck cancer (HNC) patients have advanced cancer at the time of presentation. They have unique physical and psychological symptoms due to the cancer's anatomical location and multimodal treatment-related toxicities. Early integration of palliative care (PC) in their management can improve health-related quality of life. We examined the trends and predictors of PC utilization among hospitalized advanced HNC patients in the US. **Methods:** A retrospective longitudinal study was conducted using the NIS database (2008-2021). Using joinpoint regression and multivariable logistic regression, trends and factors associated with PC receipt were assessed. **Results:** The overall prevalence of palliative care utilization among 326,265 hospitalizations with advanced HNC was 11%. Over the period, palliative care utilizations increased from 3,651 to 16,982 per 100,000 advanced HNC admissions (p-trend <0.001) with an average annual percentage increase of 9.7%. Females with metastatic HNC had higher odds (Adjusted odds ratio (AOR): 1.11; 95% CI: 1.04-1.19) of receiving palliative care compared to males. There was similar likelihood of utilizing palliative care across racial groups. Patients in teaching hospitals had 46% higher likelihood (AOR: 1.46; 95% CI: 1.33-1.60) of palliative care use in comparison to patients in non-teaching hospitals. Large hospitals had higher palliative care use compared to small hospitals (AOR: 1.12; 95% CI: 1.01-1.25). Admissions in the south and west had higher likelihood of palliative care use relative to those in the North-east region. Patients covered by Medicaid had higher odds of palliative care receipt compared to those covered by Medicare. Relative to patients who had a routine discharge home or with self-care, those discharged to facilities or with home health care were four-fold more likely (AOR: 4.35; 95% CI: 3.98-4.75) to receive palliative care. Those who died during hospitalization were also more likely to use palliative care (AOR: 21.4; 95% CI: 19.1-24.0). Non-elective admissions had higher likelihood of palliative care receipt relative to elective visits. **Conclusions:** Although palliative care utilization has improved over the years, it remains suboptimal. Tailored interventions addressing sociodemographic and hospital-level disparities will promote equitable access and meet the unique needs of this patient population. Research Sponsor: None.

Predictors of PC use.

Variables		AOR (95% CI)
Age	*"60 years and above" vs "Less than 60"*	1.0 (0.93-1.07)
Gender	*Female vs Male*	1.11 (1.04-1.19)
Race	*Non-Hispanic Black vs Non-Hispanic White*	1.02 (0.93-1.13)
	Hispanic vs Non-Hispanic White	1.10 (0.97-1.25)
	Non-Hispanic Others vs Non-Hispanic White	0.92 (0.82-1.03)
Hospital region	*Midwest vs Northeast*	1.09 (0.97-1.23)
	South vs Northeast	1.23 (1.10-1.37)
	West vs Northeast	1.37 (1.22-1.55)
Hospital Teaching Status	*Teaching vs Nonteaching*	1.46 (1.33-1.60)

12059 Poster Session

A phase 1b study of SHR-2017, a RANKL/NGF targeted antibody, in patients (pts) with breast cancer bone metastasis.

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Background: Bone metastasis is a common site of metastasis in malignant tumors. For patients (pts) with bone metastasis, pain is the predominant symptom, significantly impairing the quality of life. SHR-2017, a first-in-class fully human monoclonal antibody targeting RANKL/NGF, is designed to prevent skeletal-related events and alleviate pain in pts with bone metastasis. Here, we present the preliminary pharmacokinetics, pharmacodynamics, efficacy and safety results from a multicenter, open-label, single-arm phase 1b study in pts with bone metastasis from breast cancer. **Methods:** Breast cancer pts with at least one bone metastasis and an average Numeric Rating Scale (NRS) score of ≥ 4 at the index bone metastasis cancer pain site at baseline were eligible. Pts could be undergoing stable anti-tumor treatment or have no plan to change their anti-tumor treatment within 2 weeks after drug administration in this study. Pts received subcutaneous injection of SHR-2017 at 180 mg every 4 weeks for 6 cycles. To assess pain, pts maintained a diary (daily through week 8 and then weekly to week 48) to record the average and worst pain over the previous 24 h (on a numeric rating scale from 0 = no pain to 10 = worst possible pain) at the index bone metastasis cancer pain site. **Results:** As of Dec 31, 2024, 22 pts were enrolled and treated (prior bone targeted agents [BTA] use, 36%; mean NRS of average pain, 4.17 [SD: 0.76]). Following a single dose, the median time to peak concentration of SHR-2017 was 7 days, with a mean half-life ($t_{1/2}$) of 11.4 days and a mean clearance (CL/F) of 0.88 L/day. Among 12 pts without prior BTA use, a reduction in urine N-telopeptide of type I collagen adjusted for urine creatinine (uNTX/Cr), a biomarker for bone resorption, was evident by cycle 1 and sustained over time; the median reduction from baseline was -83.0% (range -96.9% to -60.6%) at week 5 (C2D1). By week 13 (C4D1), among 8 pts without prior BTA use, the median reduction in uNTX/Cr was -78.7% (range -93.1% to -64.6%). Daily NRS score showed a continuous decrease during cycle 1 in all pts, the mean reductions from baseline in average and worst pain were -1.95 (SD: 1.21) and -1.90 (SD: 1.46) at week 2, respectively. By week 4, the reductions were -2.46 (SD: 1.03) and -2.45 (SD: 1.45), respectively. Treatment-related AEs (TRAEs) occurred in 7 (32%) pts (grade 1, n = 6; grade 2, n = 1), with the most common being increased parathyroid hormone (PTH), the one grade 2 TRAE being rash. There were no TRAEs leading to dose discontinuation. **Conclusions:** Preliminary data indicated promising anti-bone resorption and analgesic effects, with a favorable safety profile for SHR-2017 in pts with bone metastasis from breast cancer. The trial is ongoing to further evaluate SHR-2017 following multiple dosing. Clinical trial information: NCT06380881. Research Sponsor: Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Baseline circulating growth differentiation factor-15 and the cancer phenotype in the PROACC-1 phase 2 study of the efficacy and safety of ponsegromab in patients with cancer cachexia.

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Background: Growth differentiation factor-15 (GDF-15) is an emerging therapeutic target in cancer cachexia. However, the association of circulating GDF-15 with the cancer cachexia phenotype remains poorly characterized. **Methods:** Serum GDF-15 was measured using the Roche Elecsys GDF-15 assay at screening in a phase 2, randomized trial of ponsegromab (an investigational anti-GDF-15 monoclonal antibody) in patients with cancer cachexia, and an elevated serum GDF-15 ($\geq$ 1500 pg/mL) (NCT05546476). Cachexia was defined by international consensus criteria and sarcopenia by standardized sex-specific cut-off values for lumbar skeletal muscle index. Cross-sectional associations of GDF-15 with various demographic and clinical parameters were explored post-hoc using summary statistics and Pearson's correlation (with GDF-15 on the $\log_{10}$ scale). **Results:** A total of 187 patients were enrolled in this study with a median (IQR) age of 67 (60-74) years and 37% were female. Baseline median GDF-15 values were higher among patients with cachexia and colorectal and pancreatic cancers, compared to NSCLC. GDF-15 elevation was higher in patients with stage IV disease, sarcopenia, and worse performance status (Table). Higher GDF-15 levels were associated with lower serum albumin (r = -0.31 [95% CI: -0.44, -0.177]) and pre-albumin (r = -0.17 [95% CI: -0.31, -0.03]). No significant associations were observed between GDF-15 levels and appetite or fatigue assessments. **Conclusions:** Among patients with cancer cachexia, GDF-15 elevation was more pronounced in those with more advanced cancer, sarcopenia, and worse performance status. In addition, GDF-15 levels were negatively correlated with markers of nutritional status. Clinical trial information: NCT05546476. Research Sponsor: Pfizer, Inc.

Demographic or Clinical Characteristic	n	Median (IQR) serum GDF-15, pg/ml
Age, years		
- 18-44	6	2718 (2461, 8117)
- 45-64	70	4197 (2366, 9425)
- ≥65	111	3849 (2310, 7125)
Type of cancer		
- NSCLC	74	2701 (2114, 4094)
- Pancreatic	59	4714 (2408, 9561)
- Colorectal	54	6468 (4106, 10052)
Interval from cancer diagnosis		
- <1 year	96	4259 (2447, 8919)
- ≥1 year	91	3781 (2259, 6997)
Stage of cancer		
- I/II	16	3551 (2264, 6320)
- III	34	3232 (2461, 5704)
- IV	137	4365 (2387, 8117)
Body mass index (BMI), kg/m2		
- <20	99	3254 (2220, 6801)
- ≥20	88	5052 (2712, 8749)
% weight loss in 6 months prior to screening		
- < 10%	99	3849 (2290, 7677)
- ≥ 10%	88	4118 (2381, 7595)
Sarcopenia status		
- Yes	144	4259 (2402, 7672)
- No	40	2928 (2136, 8052)
ECOG Performance Status		
- 0	33	2842 (2408, 5673)
- 1	123	4094 (2366, 8623)
- 2/3	31	5119 (2272, 7667)
Systemic anticancer therapy		
- Platinum-based therapy	68	5760 (3053, 10008)
- Antimetabolite agents	100	5914 (2847, 10768)
- Biological agents	40	5744 (3317, 9644)
- Antimicrotubule agents	73	4891 (2762, 9425)
- PD-1 or PD-L1 inhibitors	30	2744 (2149, 4787)

12061 Poster Session

IPElife: Phase III, double-blind trial of *cannabis sativa* extract in pain management and quality of life in patients with metastatic lung cancer.

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Background: Pain and deterioration in quality of life (QoL) are among the most common and problematic symptoms reported by patients with late-stage lung cancer. Thus, *cannabis sativa* extract has been identified as a potencial adjuctive therapy for enhancing QoL and managing symptoms, including oncology pain. Objective: The aim is to assess pain management and quality of life in patients with locally advanced or metastatic lung cancer using *cannabis sativa* extract. **Methods:** A randomized, prospective, double-blind, placebo-controlled, phase III trial was conducted, which included patients, which included patients with locally advanced or metastatic lung confirmed by histopathology. The participants were subdivided into two groups of 20 patients each, with 1:1 allocation ratio. The primary outcome was pain control, measured using the Visual Analog Scale (VAS) for pain. The secondary outcomes included quality of life, assessed using the EORTC QLQ-C30 and its specific module for lung cancer (QLQ-LC13). The *cannabis sativa* extract administration protocol involved dose escalation, starting at 10mg/day, with titration every 5 days until the patients reached their goals or the maximum dose of 100mg/day. The questionnaires and the VAS scale were applied every 21 days from T1 to T5. Continuous variables were analyzed using the paired t-test or signed-rank test, depending on the date distribution. **Results:** The difference in mean pain scores (measured using the EVA tool) was greater in the CBD group compared to the placebo group between periods T1 and T5 (5.0 vs 3.7) (Table1). Similarly, the difference in mean pain scores, as measured using the EORTC-QLQ-C30 scale (47.2 vs 35.7), favored the CBD group. Regarding the quality of life analysis, in the overall assessment date were not statistically significant, however difference was observed in the levels of insomnia (p-value 0.01) and dyspnea (p-value 0.02) between patients in the CBD and placebo groups, with results favoring the CBD group. **Conclusion:** The *cannabis sativa* extract may be considered an adjuvant in the management of pain and quality of life in patients with metastatic lung cancer and locally advanced. Clinical trial information: 6.036.463. Research Sponsor: GreenCare Pharma.

Pain control analysis by the EVA scale between times.

	T1	T3	T5
	Mean (SD)	Mean (SD)	Mean (SD)
CBD group	7.2 (2.1)	3.3 (2.6)	2.2 (2.4)
Placebo group	7.4 (1.8)	3.7 (3.1)	3.7 (3.3)

Average EVA scale scores by group and time.

12062 Poster Session

eHealth disease educational intervention vs. outpatient palliative care as usual among incurable cancer patients cared by family caregivers at home.

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Background: To determine whether ehealth disease educational interventions (eDEI) with fast-delivering interfaces and concise key messages can enhance capability of family caregivers and improve physical and psychological aspects of health-related quality of life (HRQoL) of incurable cancer patients at home. **Methods:** A randomized, open-label controlled trial was conducted in cancer center in Shanghai, China. Eligible participants (age≥18 years) with incurable cancer receiving palliative care and Karnofsky performance ≤ 70, along with a family caregiver (age ≥18 years), were randomly assigned 1:1 to either intervention (eDEI plus palliative care as usual (CAU)) or control group (CAU only). eDEI as a mobile application provides family caregivers with texts, audios and videos of symptom/side effect management and nursing skills. The intervention lasted for two months.The primary outcomes were physical aspects of HRQoL on the European Organization for Research and Treatment of Cancer Core Quality of Life Scale (EORTC QLQ-C30) and psychological aspects of HRQoL on the Hamilton Anxiety Rating Scale (HAM-A) from baseline to the end of 2nd month. The secondary outcome was caregiver satisfaction on a questionnaire focusing on skill enhancement using Mann-Whitney tests at the end of 2nd month. The exploratory outcome was survival benefit using Kaplan-Meier method with log rank hazard model from the enrollment to the death. The primary analyses were based on intention-to-treat principles, covering all patients who completed baseline assessment. False discovery rate (FDR) was used for multiple testing correction. **Results:** From Jul 28 to Nov 3, 2023, 154 eligible patients with family caregivers were randomly and evenly assigned to the intervention group and control group. 74 and 73 patients with their caregivers, in the intervention and control group respectively, completed baseline assessment. Among the 147 patients (mean age 59.9 years, 42.9% female) from baseline to the end of 2nd month, Linear Mixed Model analyses showed that the intervention group had significant improvement of HRQoL compared with the control group, evidenced by EORTC QLQ-C30 score (FDR-adjusted $p < 0.0001$, Cohen's d 0.42) and HAM-A score (FDR-adjusted $p < 0.0001$, Cohen's d -0.43). There was a significant difference of caregiver satisfaction at the end of 2nd month (mean difference score 0.57, $p < 0.0001$, Cohen's d 1.19). Besides, a post-trial exploratory survival analysis showed that the intervention group had longer survival compared to the control group (median 220 days vs. 141 days, $p = 0.012$, hazard ratio 1.83, 95%CI 1.14 to 2.92) after adjustment of baseline characteristics. **Conclusions:** The fast-delivering and concise eDEI can enhance caring capability of family caregivers, improve physical and psychological aspects of HRQoL, and prolong survival among incurable cancer patients. Clinical trial information: 2300077346. Research Sponsor: None.

12063 Poster Session

Impact of elinzanetant on sleep disturbances and quality of life in women undergoing adjuvant endocrine therapy for breast cancer: Phase 3 OASIS 4 trial.

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Background: Vasomotor symptoms (VMS) and sleep disturbances are common in women taking adjuvant endocrine therapy (AET) for hormone receptor-positive (HR+) breast cancer and can impact quality of life and treatment adherence, potentially affecting breast cancer outcomes. There are few efficacious treatments and none approved in this indication. Elinzanetant (EZN) is a dual neurokinin-1 and -3 receptor antagonist in development for the treatment of VMS. **Methods:** OASIS 4 (NCT05587296) is a 52-week randomized, placebo-controlled phase 3 trial evaluating the safety and efficacy of EZN for the treatment of VMS in women taking AET for HR+ breast cancer. Women aged 18–70 years being treated for, or at high risk of developing, HR+ breast cancer and experiencing ≥35 moderate-to-severe VMS/week associated with tamoxifen/aromatase inhibitors were randomized 2:1 to receive EZN 120 mg for 52 weeks or placebo for 12 weeks followed by EZN for 40 weeks. Impact of EZN on sleep disturbances and menopause-related quality of life were evaluated as key secondary endpoints, measured by mean changes from baseline to week 12 in Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form (PROMIS SD SF) 8b total T-score and Menopause-specific Quality-Of-Life questionnaire (MENQOL) total score, respectively. These endpoints were analyzed using a mixed model with repeated measures (one-sided p-values). **Results:** At baseline, mean (standard deviation [SD]) PROMIS SD SF 8b total T-scores were 60.6 (6.3) in the EZN group and 60.7 (6.8) in the placebo group, corresponding to moderate sleep disturbances based on established thresholds in a reference population. At week 12, reductions from baseline in PROMIS SD SF 8b total T-score were -10.6 (8.2) and -4.1 (7.4) in respective groups, suggesting an improvement in sleep disturbance. Reductions between EZN and placebo showed a statistically significant difference (least squares [LS] mean difference [95% confidence interval (CI)]: -6.1 [-7.5, -4.8]; $p<0.0001$). Mean (SD) MENQOL total scores at baseline were 4.8 (1.2) in the EZN group and 4.8 (1.3) in the placebo group. At week 12, reductions from baseline in MENQOL total score were -1.3 (1.1) and -0.5 (1.2), respectively, corresponding to an improvement in menopause-related quality of life. Reductions between EZN and placebo showed a statistically significant difference (LS mean difference [95% CI]: -0.7 [-0.9, -0.5]; $p<0.0001$). Reductions in PROMIS SD SF 8b total T-scores and MENQOL total scores were maintained in both treatment groups throughout the 52-week treatment period. **Conclusions:** EZN demonstrated efficacy in reducing sleep disturbance and improving quality of life in women undergoing AET for breast cancer. Concomitant intake of EZN and AET may improve tolerability and adherence to AET, with a potentially favorable impact on breast cancer outcomes. Clinical trial information: NCT05587296. Research Sponsor: Bayer.

12064 Poster Session

Nationwide trends and disparities in end-of-life care for acute myeloid leukemia: A 2019–2021 NIS analysis of palliative care utilization and hospitalization costs.

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Background: Acute myeloid leukemia (AML) is a life-threatening hematologic malignancy with high morbidity and mortality, particularly among older adults. Early integration of palliative care (PC) has been shown to improve symptom management, quality of life, and healthcare outcomes in AML patients. However, significant disparities in PC utilization persist, driven by socioeconomic factors such as race, income, and insurance status. This study examines trends in PC use among AML inpatients, focusing on its impact on mortality, hospitalization costs, and complications, while highlighting barriers to equitable care access. **Methods:** We conducted a retrospective cohort study utilizing the National Inpatient Sample (NIS) database from 2019 to 2021, identifying AML patients via ICD-10 codes, and were classified based on their PC utilization. The Institutional Review Board (IRB) approval was not mandatory since the NIS contains deidentified data. The primary outcome was inpatient mortality, with secondary outcomes including length of stay (LOS), total hospital costs, and key complications. Statistical analysis included t-tests, chi-square tests, and multivariable logistic regression adjusting for demographic, socioeconomic, and hospital factors. **Results:** A total of 220,790 AML hospitalizations were identified, with 27,540 (12.4%) utilizing PC. PC patients were older (67.41 vs. 58.65 years, $p < 0.01$) and predominantly White (75.27% vs. 70.70%, $p < 0.01$). Odds of PC utilization were lower for Black (OR 0.9, $p = 0.05$), Hispanic (OR 0.7, $p < 0.01$), and Asian (OR 0.77, $p < 0.01$) patients. Utilization was highest in urban teaching hospitals (89.2%, $p < 0.01$) and Medicare patients (OR 1.87, $p < 0.01$), followed by private insurance (22.99%), Medicaid (8.91%), and self-pay patients (1.38%). Mortality was significantly higher in the PC group (37.4% vs. 4.42%, OR 11.74, $p < 0.01$). Secondary outcomes included longer stays (12.94 vs. 12.25 days, $p < 0.01$), higher costs ($214,915 vs. $174,193, $p < 0.01$), and more complications (tumor lysis syndrome, stroke, thrombocytopenia, sepsis, anemia; all $p < 0.01$). **Conclusions:** Palliative care in AML patients was associated with higher mortality, longer hospital stays, increased costs, and complications, likely reflecting its introduction at more advanced stages of the disease. These findings underscore the urgent need for earlier integration of palliative care into treatment protocols. Addressing barriers such as healthcare inequities and improving access to timely interventions could enhance patient quality of life, reduce complications, and optimize resource utilization, ultimately fostering more equitable, efficient, and cost-effective care for AML patients. Research Sponsor: None.

12065 Poster Session

Early palliative care, intensity of end-of-life care, and their impact on overall survival in cancer patients: A real-world study.

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Background: Early palliative care (EPC) and reduced aggressive end-of-life (EOL) interventions improve quality of life in advanced cancer. While trials suggest a potential survival benefit, the real-world impact on overall survival (OS) remains underexplored. This study examines the association between palliative care (PC) timing, EOL care intensity, and OS in a large real-world cohort. **Methods:** We conducted a population-based study using the French health claims database (SNDS) for patients with metastatic solid tumors diagnosed within 2 years who died in 2022. Patients with hematologic malignancies or PC initiated before metastasis were excluded. Patients were stratified by PC referral timing: no PC, EPC ($\leq$2 months post-diagnosis), and late PC (LPC) ($>$ 2 months post-diagnosis). EOL care intensity was assessed using Earle criteria (care structure/processes) and MIEOL criteria (physically invasive interventions). The primary endpoint was OS (time from diagnosis to death). **Results:** Among 159,288 decedents, 85,192 met inclusion criteria (no PC = 27,325; EPC = 29,016; LPC = 28,851). Digestive (n = 29,668) and pulmonary (n = 17,065) cancers predominated. Patients with EPC/no PC had higher poor-prognosis adapted Charlson scores than LPC (23.6% and 23.4% vs. 18%, $p < 0.001$). EOL aggressiveness was greater in no PC compared to EPC/LPC (Earle $\geq$1: 51.4% vs. 23.4% vs. 21.6%; MIEOL $\geq$1: 25.7% vs. 16.9% vs. 17.6%; $p < 0.001$). Mean OS differed significantly (no PC: 167 $\pm$ 190 ; EPC: 74 $\pm$ 100 days days; LPC: 344 $\pm$ 182 days; $p < 0.001$). LPC was associated with the longest OS. Patients meeting Earle and MIEOL criteria were significantly associated with shorter survival ($p < 0.001$). **Conclusions:** This real-world analysis revealed no survival advantage with early PC initiation, likely reflecting clinical fragility in these patients. Early referral often signifies advanced disease rather than a direct survival benefit of PC itself. LPC was linked to the longest survival, emphasizing the need for graduated PC from metastatic diagnosis. No PC was associated with higher EOL care intensity, which did not improve survival, highlighting possible unreasonable overtreatment. Research Sponsor: None.

Socioeconomic disparities in palliative care utilization among children with late-stage bone and soft tissue sarcomas: A National Cancer Database analysis.

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Background: Palliative care seeks to improve the quality of life for many children living with cancer, but it remains underused. Racial and socioeconomic disparities have been identified in the receipt of palliative care among adult patients with advanced soft-tissue sarcomas and metastatic renal cell carcinoma. Our study seeks to determine if similar barriers exist in palliative care receipt among pediatric patients with late-stage bone and soft tissue sarcomas. **Methods:** We used the National Cancer Database (NCDB) to perform a retrospective review of children aged 0-25 with Stages III and IV bone and soft tissue sarcomas from 2004 to 2022. We used a 1:1 propensity score matching algorithm to compare the utilization of palliative treatment by race and ethnicity and to balance potential confounding covariates. Kaplan-Meier estimation was utilized for survival analysis. **Results:** A total of 8,030 patients were included in this analysis. Of these patients, 375 (4.7%) received at least one form of palliative treatment, including surgery (n=31), radiation (n=99), chemotherapy (n=55), pain management (n=98), multiple modalities (n=77), and others (n=15). The median age was 16 years (IQR: 12-20). Osteosarcoma (29.2%) was most common, followed by Ewing's sarcoma (28.1%), non-rhabdomyosarcoma soft tissue sarcoma (21.6%), and rhabdomyosarcoma (21.0%). The 5-year overall survival rate was 14.7% (95% CI 11.2%-19.3%) for patients receiving palliative care versus 44.7% (95% CI 43.6%-45.9%) for those who did not. After propensity score matching, non-Hispanic Black children were found to be less likely to receive palliative care than non-Hispanic White children (3.4% vs. 5.9%, p = 0.047). Hispanic children were also less likely to receive palliative treatment than non-Hispanic White children (2.5% vs. 5.5%, p = 0.007). **Conclusions:** Hispanic and Black children with sarcomas were less likely to receive palliative care compared to White children. Further research is warranted to understand the impact of other factors contributing to palliative care receipt and how they may be addressed to optimize the quality of life in sarcoma treatment in children. Research Sponsor: None.

Post-propensity score matching univariate analysis for palliative care use by race and ethnicity.

Palliative Care Utilization*	RACE Total (n=1286)	Non-Hispanic White (n=643)	Non-Hispanic Black (n=643)	p-value	ETHNICITY Total (n=1418)	Non-Hispanic White (n=709)	Hispanic (n=709)	p-value
No	1226 (95.3%)	605 (94.1%)	621 (96.6%)	0.047	1361 (96.0%)	670 (94.5%)	691 (97.5%)	0.007
Yes	60 (4.7%)	38 (5.9%)	22 (3.4%)		57 (4.0%)	39 (5.5%)	18 (2.5%)	

*Patients were matched based on age at diagnosis, sex, insurance status, median income of county of residence, high school graduation percentages of county of residence, mean tumor size, primary tumor sjte, AJCC stage, and presence of metastases at diagnosis.

Androgen deprivation therapy and quality of life: A concept map analysis.

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Background: Androgen deprivation therapy (ADT) is the backbone of systemic treatments for prostate cancer (PC), but is associated with side effects that decrease quality of life (QOL). There lacks a robust qualitative exploration of the nuanced entirety of physical, mental, and social changes men experience during ADT. While interventions typically focus on metabolic and cardiovascular effects, it is unclear if these are the most impactful contributors to QOL as experienced by men themselves. **Methods:** We conducted concept mapping, a participatory mixed-methods research approach, involving item generation, pile sorting, and rating to identify and categorize side effects of ADT. Thirty men who started ADT for PC in the past 3-12 months and reported undesirable changes from ADT participated. Men on oral androgen axis inhibitors were included, but those receiving other systemic therapies or with comorbidities that could confound results were excluded. Men who had surgery or radiation for PC were enrolled after ≥3 months post-treatment. We conducted semi-structured brainstorming interviews to generate lists of undesirable changes participants experienced. Study team members reviewed each list for completeness, then combined all 676 items into 79 unique items. Fifteen participants sorted these items into named groups and rated each item on a 1-5 Likert scale for the following questions (5 representing maximal response): "After starting ADT, how much did this change negatively affect your life?" and "After starting ADT, how much additional support would you have liked to receive for the following change?" GroupWisdom Concept Mapping software generated a cluster map and calculated mean Likert scale ratings for each cluster. **Results:** Based on participant sorting, items were grouped into four main clusters: Physical Manifestations; Sexual Changes; Mental Health Changes & Concerns of Stigma; and Motivational Changes (13 iterations, stress value 0.29). The Table presents sample items and mean Likert scale cluster ratings. **Conclusions:** While men on ADT reported expected physical and sexual changes, qualitative interviews uncovered changes in motivation, mental health, and concerns of stigma. Men reported sexual changes as having the largest negative impact on QOL. The concept mapping can be utilized to provide anticipatory guidance to men starting ADT, as well as guide the development of supportive interventions. Research Sponsor: None.

Cluster	Example Items	Negative Affect on Life Rating (1-5; 5=Most Negative)	Additional Support Wanted Rating (1-5; 5=Most Support Wanted)
Physical Manifestations	- Physical Strength Decreased	2.6	2.1
Sexual Changes	- Sex Drive/Libido Diminished	2.9	2.0
Motivational Changes	- Wanting to Sit and Do Nothing/ Watch TV; Being Less Active; Feeling "Lazy"	2.2	1.7
Mental Health Changes & Concerns of Stigma	- Not Wanting to Share Information About Diagnosis/ Treatment with Others -More Pessimistic/Less Optimistic	1.8	1.5

12068 Poster Session

Care needs and considerations for implementing a community-based palliative care program for women with breast or cervical cancer in three Nigerian states.

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Background: Breast and cervical cancer pose a significant public health burden in most sub-Saharan African countries including Nigeria. With ~70% of cases presenting at late stages (III & IV), high mortality is often a characteristic feature. This underscores the critical need for comprehensive palliative care services to improve the quality of life for Nigerian women with breast and cervical cancers. Despite the growing recognition of this need, there is limited evidence for integrating community resources into cancer-directed palliative care services in Nigeria, hence this study explored the needs of Nigerian women with breast or cervical cancer, and their caregivers, and sort to identify resources necessary for developing a robust palliative care initiative across the community and healthcare facility settings. **Methods:** We conducted a qualitative study including 45 purposively sampled adult female caregivers of women with breast or cervix cancers, from 3 states in Nigeria: Abuja-Federal Capital Territory, Nasarawa, and Rivers states respectively. Focus Group Discussions using semi-structured interview guide were carried out and included questions about cancer care needs of both caregivers and the patients, including considerations for implementing a community-based palliative care program. Data were analysed using thematic analysis for deductive identification of key themes, while allowing for new themes to emerge inductively, and then we phenomenologically investigated respondents' palliative care needs perceptions and their meaning. **Results:** Four overarching themes were identified namely, i) needs of women with breast or cervical cancer, ii) needs of caregivers, iii) human resources for community-based palliative care, and iv) feasibility of a community-based palliative care program. Respondents revealed that to attain wholistic wellbeing for women with breast or cervical cancer, their peculiar needs and those of their caregivers which were largely unrecognised deserve attention. Adequate human resources, including trained healthcare workers and support staff, and clearly defined feasibility criteria for palliative care, were identified as crucial for the successful implementation of a community-based palliative care program. **Conclusions:** A community-based palliative care program for Nigerian women with breast or cervical cancer will be acceptable and feasible if it is designed to address the peculiar medical and non-medical needs of both the cancer patients and their caregivers. Research Sponsor: German government.

12069 Poster Session

Granisetron transdermal delivery system for nausea and vomiting prophylaxis in HER2-positive metastatic breast cancer patients receiving pyrotinib and capecitabine: A single-arm phase II study.

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Background: The efficacy of granisetron transdermal delivery system (GTDS) in managing nausea and vomiting caused by intravenous chemotherapy is well-established; however, its effectiveness for emesis induced by oral antineoplastic agents remains unclear. This study aimed to evaluate the efficacy and safety of GTDS for the prophylaxis of nausea and vomiting in patients receiving daily oral anticancer agents with moderate emetic risk, specifically pyrotinib combined with capecitabine for HER2-positive metastatic breast cancer (mBC). **Methods:** A single-arm, single-center phase II trial was conducted, enrolling 77 patients with HER2-positive mBC. Patients received 2 consecutive doses of GTDS (with a 7-day interval between the doses) during the first treatment cycle (21 days) of pyrotinib (400 mg daily, days 1–21) and capecitabine (1000 mg/m^2 twice daily, days 1–14). The dual primary endpoints were the complete response (CR) rate of nausea and vomiting (no emesis and no rescue medication) and the incidence of ≥grade 3 diarrhea. Secondary endpoints included complete control (CC) rate, daily emesis/nausea frequency and adverse events (AEs). **Results:** During the first treatment cycle, 62.3% of patients achieved CR, and the CC rate was 54.5%. Weekly CR rates were 79.2%, 70.1%, and 79.2% in weeks 1, 2, and 3, respectively, while CC rates were 72.7%, 61.0%, and 70.1%, respectively. The mean daily number of emetic episodes ranged from 0.1 to 0.6, peaking in week 2. The mean daily nausea scores ranged from 0.6 to 1.1, with a slight increase starting from day 4. Grade 3 diarrhea occurred in 28.6% of patients, peaking on day 7. AEs were reported in 53.25% of patients, with the most common being gastrointestinal symptoms, fatigue, and rash. No QT prolongation was observed. **Conclusions:** Prolonged administration of GTDS demonstrated efficacy and safety in preventing nausea and vomiting in HER2-positive mBC patients receiving daily oral pyrotinib and capecitabine; however, it did not reduce the incidence of ≥ grade 3 diarrhea. Clinical trial information: NCT04472143. Research Sponsor: None.

Efficacy of Chinese medicine compound Fufang E'jiao Syrup for symptom burden of cancer-related fatigue in patients with advanced cancer: A randomized clinical trial.

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Background: *Cancer-related fatigue* (CRF) is often accompanied by a high symptom burden, significantly impacting the quality of life in patients with advanced cancer. Traditional Chinese medicine compound *Fufang E'jiao Syrup* (FFEJS) has shown promising potential in alleviating fatigue and reducing the overall burden of cancer-related symptoms. This study aims to investigate the efficacy and safety of FFEJS in reducing symptom burden in patients with advanced cancer. **Methods:** This multicenter, double-blinded, placebo-controlled trial was conducted across 29 hospitals in China and included 611 patients with advanced non-small cell lung cancer, colorectal cancer, or gastric cancer experiencing moderate-to-severe fatigue (Visual Analogue Fatigue Scale score ≥ 4). Participants were randomized to receive FFEJS (20 mL, 3 times daily) or placebo for six weeks. The primary outcome was the change in symptom burden, assessed via the Edmonton Symptom Assessment Scale (ESAS; score range 0-110, higher scores indicate greater burden). Secondary outcomes included changes in 11 individual symptoms (e.g., tiredness, depression, pain) and the incidence of adverse events. Linear mixed models were used for statistical analysis. **Results:** Among 611 patients randomized (303 received FFEJS and 308 received placebo; 210 [34.4%] had non-small cell lung cancer, 201 [32.9%] had colorectal cancer, and 200 [32.7%] had gastric cancer; mean [SD] age 62.8 [9.3] years; 413 [68.6%] male; mean [SD] baseline mean total symptom burden 38.96 [15.68] points, 503 (82.3%) completed the primary end point analysis. At week 6, FFEJS demonstrated a significantly greater reduction in total symptom burden compared to placebo (6.67 vs 3.16; adjusted mean difference: 3.51[95% CI 1.21−5.8]; $P = .004$). Patients in the FFEJS arm showed significant improvements in tiredness (1.68 vs 0.79; adjusted mean difference, 0.89 [95% CI, 0.62-1.18]; $P < .001$), drowsiness (1.13 vs 0.50; adjusted mean difference, 0.63 [95% CI, 0.32-0.95]; $P < .001$), pain (0.34 vs 0.01; adjusted mean difference, 0.33 [95% CI, 0.08-0.62]; $P = .049$), depression (0.41 vs -0.15; adjusted mean difference, 0.56 [95% CI, 0.28-0.86]; $P = .003$) compared with the placebo arm. Subgroup analysis revealed greater symptom reduction in geriatric patients (≥ 60 years; $P < .001$) and in non-small cell lung ($P = .044$) and colorectal cancer ($P = .047$), compared to gastric cancer ($P = .123$). **Conclusions:** FFEJS significantly reduced total symptom burden and improved fatigue-related symptoms in patients with advanced cancer. Subgroup analysis highlighted enhanced efficacy in geriatric populations and certain cancer types. These results highlight the potential of FFEJS as a valuable integrative therapy for improving symptom management and quality of life in advanced cancer care. Clinical trial information: NCT04147312. Research Sponsor: National Key Research and Development Program of China.

12072 Poster Session

Single low-dose 5-mg versus 8-mg dexamethasone with NEPA for the 168-h prevention of highly or moderately emetogenic (high-risk patients) chemotherapy-induced nausea/vomiting: An open-label, randomised, controlled, phase 3 trial.

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Background: Tailoring Dexamethasone (DEX) dosing to reduce corticosteroid exposure is a challenging issue in the chemotherapy induced nausea /vomiting(CINV) management. This study aims to identify the efficacy of single low-dose 5mg versus 8mg dex with nepa for the 168h prevention of highly or moderately emetogenic (high-risk patients) CINV. **Methods:** This open-label, randomized trial compared the efficacy and safety of 5 mg versus 8 mg DEX regimens, both with NEPA, in patients receiving MEC or HEC chemotherapy. Patients were 1:1 randomized to 5 mg or 8 mg groups. The primary endpoint was complete response (no emesis, no rescue medication) from 0 to 168 hours. Secondary endpoints included total control, complete control, and daily CINV incidence. This study was registered with ChiCTR2400089311. **Results:** From June 20, 2024 to June 20, 2025, a total of 164 eligible individuals were assigned at random to the 5 mg or 8 mg DEX treatment arms.Primary efficacy endpoints:The overall CR rates for the prevention of CINV, observed throughout the study period, were 91.7% in the 5 mg group and 92.5% in the 8 mg group (P=0.400) . In the acute phase, the CR rates were 97.9% for the 5 mg group and 97.5% for the 8 mg group (P=1.000). During the delayed phase, the CR rates were 91.7% for the 5 mg group and 92.5% for the 8 mg group (P=1.000). In the long-delayed phase, the CR rates were 93.8% for the 5 mg group and 97.5% for the 8 mg group (P=0.744). Secondary efficacy endpoints: During the whole observation period, the total control rates were 77.1% for the 5 mg group and 62.5% for the 8 mg group (P=0.208); the complete control rates were 85.4% for the 5 mg group and 87.5% for the 8 mg group(P=1.000). Secondary safety endpoints: The safety profiles of both dosages were similar and majority of treatment-related adverse events (TRAEs) were mild to moderate (grades 1 or 2), with no significant differences in the occurrence or severity of TRAEs (hyperglycemia, indigestion/heartburn or reflux and constipation, prevalence of QTcB interval prolongation or increase ect) would warrant particular concern. **Conclusions:** This study identify single low-dose 5mg DEX is equally effective as 8mg DEX with NEPA for the 168h Prevention of HEC or MEC (high-risk patients) CINV. Moreover, the 5mg DEX group has better therapeutic safety. It offers evidence-based recommendations for using a lower dose of DEX in combination with NEPA for the prevention and treatment of CINV. These promising results pave the way for reduction of DEX in antiemetic care. Clinical trial information: ChiCTR2400089311. Research Sponsor: None.

A novel staging system for cancer cachexia.

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Background: Cancer cachexia affects a large percentage of advanced cancer patients. It's defined by a consensus definition of unintentional >5% body weight loss over six months. There is no standard way of assessing severity of cancer cachexia. We developed a novel cancer cachexia staging system based on routine clinical parameters. **Methods:** In a prospective case control study of newly diagnosed cancer patients to identify biomarkers of cancer cachexia, cases were patients with stage III/IV cancer and >5% body weight loss and serum albumin of <3.5g/dl. Controls were patients with stage I-III without weight loss and serum albumin of ≥3.5g/dl. Patients were prospectively followed up between April 2020 and August 2024 with blood biomarkers, anthropometric measurements and radiological parameters. Utilizing data from cases only a novel cancer cachexia staging system was developed called (University of Texas) UT Cancer Cachexia Staging System using 4 clinical parameters namely body mass index (BMI), serum albumin (Alb), neutrophil to lymphocyte ration (NLR) and resting heart rate (RHR). Using quartiles as cut off for each of these four variables, patients were divided into three groups and given a score of 0.5, 1.5 or 2.5 (Table). The cumulative score of each patient was calculated based on individual values of these 4 variables at the time of diagnosis and then categorized into stage I (≤5), Stage II (5-7) or Stage III (>7) cancer cachexia. Kaplan-Meier survival curves were generated for patients in each stage. The univariable Cox regression model was used to compare hazard ratios across the 3 stages. The multivariable Cox regression model was employed to compare hazard ratios between the stages, adjusting for other key demographic and clinical covariates. **Results:** A total of 109 patients were enrolled in the cachexia group (Male=69, Females=40, Median age = 69 years). The cancer types included Lung cancer (n=50), GI cancers (n=41) and other cancers (n= 18). There were 49 patients (45%) patients with stage I cachexia, 40 (36%) with stage II and 20 (18%) with stage III cachexia. Median overall survival (OS) for patients with stage I cancer cachexia was 11.4 months, for stage II 6.5 months and for stage III 3.5 months. In univariate cox-regression model the difference in hazard ratio between stage I and stage II patients was statistically significant (p=0.004) as was between stage I and stage III (P =0.007). In multi-variable Cox-regression model controlling for age, gender and cancer type, patients with stage II and III cancer cachexia had significantly worse outcome as compared to patients with stage I cancer cachexia. **Conclusions:** UT cancer cachexia staging system represents a novel staging system which should be validated on a larger data set. Once validated this can help guide clinical management as well as clinical research in patients with cancer cachexia. Research Sponsor: U.S. National Institutes of Health; R01 AR063786-06A1; National Center for Advancing Translational Sciences (NCATS); 1UM1TR004906-01.

Development of cancer cachexia staging system based on BMI, albumin, NLR and RHR by using quartiles as cutoff points in the case group (n=109).

	Score=0.5		Score=1.5		Score=2.5	
Variable	**Cutoff**	**Number of patients**	**Cutoff**	**Number of patients**	**Cutoff**	**Number of patients**
BMI	≥29	26	21-29	56	<21	26
Albumin	≥3.2	30	2.3-3.2	60	<2.3	18
NLR	<3	30	3-8	50	>8	28
RHR*	<73	25	73-95	57	>95	26

UT cancer cachexia stage groups defined by using cutoff points for total cancer cachexia score.

Stage I	<5
Stage II	5-7
Stage III	>7

12074 Poster Session

Machine learning models to predict skeletal-related events in bone metastasis from advanced cancer.

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Background: Skeletal-related events (SREs) are detrimental clinical events in bone metastasis from advanced cancer, defined by pathologic fracture, spinal cord compression, and inevitable surgical or radiational intervention to the bone. Given their negative impact on quality of life and prognosis and interpatient heterogeneity in the SRE risk, accurate identification of patients with high SRE risk is critical. **Methods:** The patient-level data from three randomized clinical trials that administered zoledronic acid (ZA) to patients with bone-metastatic breast cancer, castration-resistant prostate cancer (CRPC), and other types of cancer were analyzed. (N = 460, 452, and 315, respectively) Machine learning (ML) models to predict SREs within 18 months (breast cancer), 12 months (CRPC), and 9 months (other cancers) were developed based on more than 40 baseline clinical and laboratory data. Seven ML algorithms and five feature selection methods were utilized to develop multiple models. The ML model with the best performance was identified based on the F1 score and the area under the receiver operating characteristic curve (AUC-ROC) for each cancer type and interrogated for important features with Shapley additive explanations. Lastly, the ML models' ability to stratify patients by the cumulative SRE risk was evaluated by calculating hazard ratio (HR) with Cox-proportional hazards models. **Results:** Among the multiple ML models developed with different algorithms and feature selection methods, the model developed utilizing the random forests algorithm and the Boruta method for selecting features demonstrated the best performance in all types of cancer (F1 0.70, 0.67, and 0.67, and AUC-ROC 0.72, 0.68, and 0.73 for breast cancer, CRPC, and other cancers, respectively). In the ML model for breast cancer, performance status (PS), history of SRE, serum alkaline phosphatase (ALP), history of anti-neoplastic surgery, radiation therapy, and pathologic fracture were included as important features. Serum ALP, albumin, sodium, Gleason scores, and geographic regions were shown to be relevant in the CRPC model. For other cancers, serum ALP, albumin, total protein, phosphorus, red blood cell count, white blood cell count, visceral metastases, and history of arthritis were incorporated in the ML model. The ML model prediction successfully stratified the patients for cumulative SRE risk in all three cohorts. (HR with 95% confidence interval: 2.43 [1.86 – 3.18], 1.92 [1.51 – 2.45], and 3.06 [2.29 – 4.09] for breast cancer, CRPC, and other types of cancer, respectively). **Conclusions:** ML models incorporating baseline clinical and laboratory data can identify patients with bone metastasis on ZA harboring a high SRE risk. Research Sponsor: None.

Virtual reality for pain and anxiety management during bone marrow biopsy: A systematic review.

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Background: Bone marrow biopsy (BMB) procedures often cause significant pain and anxiety. Virtual reality (VR) has emerged as a promising non-pharmacological intervention, but its effectiveness needs systematic evaluation. **Methods:** A systematic review following PRISMA guidelines examined studies from 2014-2024 that evaluated VR interventions during BMB procedures through literature searches in PubMed, Scopus, and EMBASE. Studies were included if they evaluated VR as a non-pharmacological intervention and reported pain or anxiety outcomes. **Results:** Five studies (n=481) met inclusion criteria, including three randomized controlled trials and two prospective studies. Patient ages ranged from 6-87 years. VR interventions showed high retention rates (66.7-93.3%) with low discontinuation (5%). Pain and anxiety reduction was significant in two studies ($p<0.05$ and $p<0.001$ respectively), while three showed no significant difference versus standard care. Patient satisfaction exceeded 90%, with minimal adverse events, mainly discomfort leading to discontinuation in 5% of participants. **Conclusions:** VR represents a safe, well-tolerated intervention during BMB procedures with high patient satisfaction. While pain and anxiety reduction results were mixed, the consistent safety profile and positive patient experience suggest VR may be a valuable adjunct to standard care, particularly for anxiety management. Future research should focus on standardizing protocols and defining patient selection criteria to optimize outcomes. Research Sponsor: None.

Study characteristics and clinical outcomes of virtual reality use during bone marrow procedures.

Study	Sample Size	Patient Population	VR Type	Control Group	Pain Outcomes	Significant Pain Reduction?	Anxiety Outcomes	Significant Anxiety Reduction?	Patient Satisfaction	Adverse Events
Glennon 2018	97	Adults	ezVision X4 VR goggles with nature scenes + lidocaine	Standard TV viewing + lidocaine	VR: 3.9 vs Control: 4.0 (NPRS)	No ($p > 0.05$)	State anxiety decrease: VR: 2.3 pts vs Control: 1.3 pts (5 item Likerty-type scale)	No ($p = 0.42$)	98.3% satisfied	None reported
Le Du 2023	126	Adults	Meta Quest VR headset	None specified	VR: 3.0 vs Control: 3.5 (VAS)	No ($p = 0.26$)	No difference on STAI scores	No ($p = 0.83$)	Not reported	Not reported
Korkmaz 2023	126	Adults	Bliss VR with 4 environments	MEOPA (nitrous oxide/ oxygen)	VR: 3.8 vs Control: 6.28 (VAS)	Yes ($p < 0.001$)	VR: 32.06 $\pm$ 8.69 vs Control: 40.88 $\pm$ 11.36 (STAI)	Yes ($p = 0.022$)	95% satisfied	5% discontinued
Reitze 2024	75	Adults	Support V5 VR headset	Standard care (No distraction)	Mean difference -1.0 with VR (VNRS)	Yes ($p < 0.05$)	VR: 28.6 vs Control: 33.5 (BAADS)	Yes ($p < 0.001$)	$>$ 90% satisfied	5% mild effects
Soret 2022	57	Children (6-18y)	Not specified	Standard care (No distraction)	VR: 3.8 (IQR 2.0-6.3) vs Control: 3.0 (IQR 1.9-3.0) (FPS-r)	No ($p = 0.09$)	No difference between groups (mYPAS-SF)	No ($p = 0.71$, 0.42)	71% more relaxed	5% discontinued

12076 Poster Session

Multidisciplinary and multi-institutional cancer symptom management strategies in the Veterans Affairs: A mixed methods study.

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Background: Effective symptom management in patients undergoing cancer treatment improves quality of life and overall survival. Yet, variability persists in how symptoms are assessed and managed across oncology settings. This mixed-methods study, conducted across 14 Veterans Affairs (VA) facilities in two regional Veterans Integrated Service Networks (VISN) 21 and 22, aimed to: 1) identify current symptom assessment strategies in use and 2) explore opportunities for standardizing, implementing, and scaling strategies to optimize care for Veterans undergoing cancer treatment. **Methods:** We conducted a comprehensive survey and semi-structured interviews to evaluate current symptom assessment and management practices, perspectives on standardized proactive strategies, and barriers and facilitators to implementation. The 10-question survey was distributed to 65 clinicians, nurses, social workers, navigators, pharmacists, behavioral medicine specialists, and ancillary care providers across 14 facilities in VISN 21 and 22, using an online staff directory. In addition, 25 facility-level oncology leaders and 10 Veterans receiving cancer care at these facilities were invited to participate in 30-minute semi-structured interviews. The interviews focused on attitudes, knowledge, and preferences regarding proactive symptom assessment, as well as interest in piloting potential interventions. Survey data were analyzed using descriptive statistics, and interview data were analyzed through thematic analysis. **Results:** A total of 40 participants (61.5% response rate) completed the survey, including 24 physicians (60%), 12 nurses/nurse practitioners (30%), 2 social workers (5%), and 2 pharmacists (5%). Of the 40 respondents, 36 (90%) reported assessing symptoms during clinical visits, with 12 (30%) utilizing only standardized psychological distress screening tools, such as the National Comprehensive Cancer Network Distress Thermometer. Infrastructure and resources varied widely across facilities with some facilities noting no palliative care providers, nurse practitioners, nurse navigators, or oncology nurses. Only 2 facilities integrated volunteers or lay peer support into cancer care. Among interviewees, 25 oncology leaders and 10 Veterans with cancer participated (100% response rate). Two key themes emerged: 1) urgent need for standardized, proactive symptom assessment and management; 2) importance of adaptable solutions, such as peer-led initiatives, tailored to facility and patient preferences rather than a one-size-fits-all approach. **Conclusions:** Proactive symptom assessment is underutilized across VISN 21 and 22 facilities. Standardized, adaptable strategies that combine high-touch and low-tech approaches, such as peer-led initiatives, are preferred and may provide a scalable solution to enhance cancer care for Veterans. Research Sponsor: None.

Comparison of outcomes for patients diagnosed with small cell lung cancer between a university and safety net hospital.

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Background: With immunotherapy, the five year overall survival (OS) for small cell lung cancer (SCLC) is 12%. However, real world factors such as social determinants of health (SDH) and enrollment to clinical trials may vary. Here, we compare treatment patterns and outcomes for SCLC between two affiliated hospital settings. **Methods:** A retrospective analysis was conducted on patients with SCLC seen at university hospital (UH, Indiana University Melvin and Bren Simon Comprehensive Cancer Center) or its affiliate safety net hospital (SNH, Sidney and Lois Eskenazi Hospital) from 1/1/2018 to 8/31/2024. SDH was defined as housing, food, financial, or transportation instability. Chi-square, Fisher's exact test, t-test, Wilcoxon two-sample test, and Kaplan-Meier were applied accordingly. *P* value $< .05$ was considered significant. **Results:** A total of 189 patients were identified; 50 (26%) at SNH and 139 (74%) at UH. Stage, age, sex, and tobacco use were similar. Variations in race and SDH were noted (Table). Receipt of chemo-immunotherapy was comparable. Chemotherapy-free interval (CTFI) was shorter at UH (3.3 months; 95% CI, 2.7–4.3) vs at SNH (7.8 months; 95% CI, 3.7–11.5; $P = .015$). Patients at UH were enrolled in more SCLC-related trials, received more second line therapies, GCSF or CDK4/6 inhibitor (Table), and had increased adverse events (UH, 64% vs SNH, 40%, $P = .003$). At data cut-off, no difference was found between UH and SNH for use of lurbinectedin (15.8% vs 8%, $P = .16$) or tarlatamab (3.6% vs 2%, $P = 1$). OS was analogous between UH (16 months; 95% CI, 11.3–18.7) and SNH (12.8 months; 95% CI, 7.6–NE; $P = .21$). **Conclusions:** Patient at UH were found to have shorter CTFI with first line chemoimmunotherapy. This difference may reflect the referral patterns for patients with complex SCLC presentations to an academic cancer center. More SDH was identified at UH. Patients at UH were more likely to enroll in SCLC trials and receive supportive care medications. Patients at SNH received more PC referrals. Further studies are needed to evaluate the effect of socioeconomic factors on SCLC outcomes. Research Sponsor: None.

Outcomes stratified by hospital setting.

	Stratified by Hospital Setting			
Variable	**Overall N=189**	**Safety Net Hospital N=50**	**University Hospital N=139**	***P* Value**
Black race	22 (11.6%)	**16 (32%)**	6 (4.3%)	**<.001***
White race	160 (84.7%)	33 (66%)	**127 (91.4%)**	**<.001***
Positive SDH	87 (46%)	15 (30%)	**72 (51.8%)**	**.008**
Consented to a SCLC clinical trial	47 (24.9%)	1 (2%)	**46 (33.1%)**	**<.001**
Received second line treatment	87 (46%)	16 (32%)	**71 (51.1%)**	**.020**
Received supportive care with GCSF or CDK4/6 inhibitor	85 (45%)	8 (16%)	**77 (55.4%)**	**<.001**
Referred to palliative care (PC)	86 (45.5%)	**45 (90%)**	41 (29.5%)	**<.001**

Note: Values expressed as n (%). *Indicates Fisher's exact test.

12078 Poster Session

Disparities in receipt of palliative interventions across disaggregated Hispanic subgroups with late-stage colon cancer in the United States.

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Background: Palliative interventions, defined as cancer-directed therapies with palliative intent, improve the quality of life and alleviate suffering for patients with advanced cancer. Limited research examines disparities in their receipt across disaggregated Hispanic subgroups. We analyzed palliative intervention receipt among Hispanic patients with stage IV colon cancer. **Methods:** Using the National Cancer Database, we retrospectively analyzed adults diagnosed with stage IV colon cancer (2004–2021) with known palliative intervention receipt status (defined binarily). We performed logistic regressions to characterize palliative intervention receipt rates across a) broad racial groups and b) country of origin, relative to Non-Hispanic White patients (alpha<0.05). Regressions included a race*year interaction term to examine changes in palliative intervention receipt over time (alpha<0.1). **Results:** We analyzed 1,021,293 patients;3.24% (n=33,132) received palliative interventions. Hispanic Black patients were 0.55x as likely (P=0.030) to receive palliative interventions as non-Hispanic White patients. The year*race interaction term was significant for Hispanic-Black patients, suggesting that invention rate improvements were distributed unequally over time. Specifically, the rate of intervention receipt among Hispanic Black patients decreased from 5.4% in the 2004–2012 cohort to 4.6% in the 2013–2021 cohort (95% CI: 0.32–0.94, P interaction = 0.030), compared to greater decreases observed in the reference group. When disaggregated, Mexican patients were 31% less likely (P=0.006), Cuban patients 35% less likely (P=0.043), NOS patients were 33% less likely (P<0.001), and Dominican Republic patients nearly twice as likely (P=0.009) to receive interventions compared to non-Spanish, non-Hispanic patients. **Conclusions:** Hispanic Black, Mexican, Cuban, and NOS patients experienced lower receipt of palliative interventions, revealing disparities in access to equitable cancer-directed end-of-life care. Efforts should be made to expand palliative intervention access for diverse racial/ethnic groups. Research Sponsor: None.

Receipt of palliative care by country of origin.

Racial/Ethnic Group	% Patients receiving palliative care (All Years)	% Patients receiving palliative care (2004-12)	% Patients receiving palliative care (2013-21)
Non-Spanish, Non-Hispanic White	3.35	2.31	4.30
Mexican	2.74	1.86	3.33
Puerto Rican	3.66	2.49	4.53
Cuban	2.40	1.60	3.48
South/Central American (ex. Brazil)	3.26	1.74	4.28
Other Specified Spanish/ Hispanic	3.26	2.55	4.09
NOS	3.16	2.03	3.84
Spanish Surname only	2.80	1.49	4.16
Dominican Republic	4.18	4.96	3.80

12079 Poster Session

A patient advocacy-focused rehabilitation pilot program: Real-life experience in enhancing quality of life for metastatic lung cancer patients.

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Background: Living with lung cancer (LC) is a prolonged and challenging journey, where the disease's consequences and treatment-related adverse events significantly affect the quality of life (QOL) of patients. Recognizing these challenges, healthcare professionals (HCPs) in collaboration with a patient advocacy organization designed and implemented a personalized rehabilitation pilot program tailored specifically for patients with unresectable metastatic LC. **Methods:** 50 Stage IV unresectable metastatic lung cancer patients were recruited via a patient advocacy group on Facebook. Participants underwent a personalized rehabilitation program with four one-on-one physiotherapy sessions, during which a tailored regimen was developed. Each participant received a customized booklet and equipment to support their rehabilitation. The program incorporated two key components: aerobic exercises and strength-training activities. Additionally, patients and their caregivers participated in three online mental health support sessions, providing holistic care. EORTC QLQ-C30 questionnaire was used at the beginning, end of the program and two months after. The physiotherapists measured the patients' 5 repetitions sit to stand time and 10-meter walk time at the beginning and the end of the program. Significance of results was calculated with repeated measure\within subjects T test with one way hypothesis and a confident interval of 0.95%. **Results:** Significant improvement was observed from the beginning of the program to the end in the Sit-to-stand test, from 19.3s to 15.1s, p = 0.0001 and the 10-meter-walk test, from 12.5 to 10.5 p = 0.017. In addition, a significant improvement from beginning to end of the program was observed based on the EORTC QLQ-30 in the global health status, physical functioning, role functioning as well as in the symptoms of fatigue, nausea, vomiting and appetite loss. In social functioning and constipation, significant improvement was maintained even two months after completion of the program. No significant change was observed in emotional and cognitive functioning, pain symptoms, dyspnea, insomnia, diarrhea and financial difficulties. **Conclusions:** The real-life survivorship journey of metastatic lung cancer patients involves numerous challenges including sequela of side effects and symptoms that impact QOL of the patient that impacts the caregiver as well. Our duty to support "beyond the pill" led us to this real-life pilot program that shows the feasibility and efficacy of home-based rehabilitation. Even among patients who experienced disease progression during the program, notable benefits were observed. These findings underscore the importance of further research and the need for sustained support after program completion to ensure long-term maintenance and improvements in patients' well-being. Research Sponsor: The Lung Ambition Alliance.

12080 Poster Session

Muscle mass evaluation among ambulatory cancer patients in China: Comparison of different methods and association with survival.

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Background: Cancer patients are at high risk of malnutrition and cachexia. Muscle mass reduction (MMR) is one of the three phenotypic criteria to diagnose malnutrition in the Global Leadership Initiative on Malnutrition (GLIM) framework, but there are no consensus about what method should be used to evaluate MMR in clinical practice. Among multiple methods to evaluate MMR, muscle mass index (MMI) in computed tomography (CT) image was considered to be accurate but not convenient in clinical practice. This study aimed to compare the correlations between different methods of measuring MMR and to assess their relevance to survival. **Methods:** A single-center cohort study was conducted among ambulatory cancer patients who were receiving intravenous anti-cancer therapy. All participants underwent CT, calf circumference (CC) measurement, bioelectrical impedance analysis (BIA) and hand grip strength measurement. MRR was identified by MMI in CT image at the level of lumbar vertebra 3 (L3), CC, fat-free mass index (FFMI) and appendicular skeletal muscle index (ASMI) in BIA respectively. Low MMI was defined as MMI $<$ 43 in men with body mass index (BMI) $<$ 25kg/^{2}, $<$ 53 in men with BMI$\geq$25kg/^{2} or $<$ 43 in women. Low CC was defined as CC$<$ 34cm in men or $<$ 33cm in women. Low FFMI was defined as FFMI $<$ 17kg/m^2 in men or $<$ 15kg/m^2 in women. Low ASMI was set as ASMI $<$ 7.0kg/m^2 in men or $<$ 5.7kg/m^2 in women. Low muscle strength was defined by hand grip strength $<$ 28kg in men or $<$ 18kg in women. The correlation between low MMI and MMR diagnosed by other methods were calculated. The correlation between MMR, low muscle strength and one-year mortality was also evaluated. **Results:** A total of 312 consecutive patients were included. Of the 312 patients 62.8% (196/312) were male and 37.2% (116/312) were female. The median age of the patients was 59.0 years (range, 21-80y; interquartile range 52.0-65.0y). FFMI and SMI diagnosed by BIA correlated with MMI diagnosed by CT (Pearson Correlation 0.798 and 0.738 respectively). Except for low hand grip strength (p = 0.005, HR 2.482, 95%CI 1.324-4.655), no single indicators for MMR indicated higher one-year mortality. However, in combination of MMI, CC, FFMI and ASMI, MMR indicated higher one-year mortality (p = 0.004, HR 2.549, 95%CI 1.342-4.843). **Conclusions:** FFMI and SMI diagnosed by BIA correlated with MMI diagnosed by CT, indicating that BIA can be a good choice in evaluating MMR. Low hand grip strength and MMR diagnosed using multiple methods indicated higher one-year mortality, underscoring the importance of measuring muscle strength as well as evaluating muscle mass. Research Sponsor: Beijing Xisike Clinical Oncology Research Foundation; Y-NESTLE2022MS-0228,Y-Young2023-0070; the Clinical Research Fund For Distinguished Young Scholars of Peking University Cancer Hospital; QNJJ2023032; the Leading Talents of Science and Technology Innovation in the National "Ten thousand Talents Program".

12081 Poster Session

The impact of cannabis use on patient outcomes post immune checkpoint inhibitor (ICI) therapy in a longitudinal observational trial: The DiRECT Cohort.

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Background: Prior small retrospective studies suggest that cannabis might compromise the efficacy of ICIs for cancer therapy due to its immunosuppressive properties. Evidence from large prospective studies is lacking. **Methods:** We addressed this research gap in the DiRECT Cohort (URCC21038, NCT05364086), an ongoing, observational trial enrolling self-identified Black and White cancer patients (melanoma excluded) who are about to start ICI-containing therapy through the URCC NCORP Research Base nationwide clinical trial network. Longitudinal data on cannabis use are collected through self-administered surveys at baseline (A1), 6 months (A3), and annually (A4+), along with clinical data and patient-reported outcomes on physical and psychological symptoms. This interim analysis on cannabis use includes 1,666 patients enrolled between 04/01/2022 and 08/31/2024, with outcome data updated to 11/30/2024. **Results:** The mean age was 63.7 (±12.4) years; 408 (24.5%) patients were Black; 905 (54.3%) were women; the most common diagnosis was lung cancer (621 or 37.3%); and a majority had stage IV disease (906 or 54.4%). At A1, 284 (17.1%) patients reported cannabis use in any form, mostly orally (58.1%) or via inhalation (32.3%). Use rates remained stable at A3 (15.6%) and A4 (15.4%) ($P = 0.47$); yet patients reported fewer days of use in a month ($P < 0.0001$) but more times in a day ($P = 0.07$) than at A1. Cannabis users were younger and more likely to be Black, from states with permissive cannabis laws, and current or former cigarette smokers (P's < 0.05), with no differences observed by gender, cancer type, or stage. After a median follow-up of 10.4 months (range: 0.03-31.0), 381 patients died, and 174 patients had progressed disease or entered hospice care. Median overall survival (OS) and event-free survival (EFS) were slightly higher in cannabis users than non-users at A1 (6.1 vs. 5.3 months, $P = 0.07$ and 6.0 vs. 5.4 months, $P = 0.15$, respectively). Cox hazards models adjusted for age, gender, cancer type, and stage revealed no significant association between cannabis use and OS (adjusted hazards ratio [aHR] = 0.82, 95% CI 0.61-1.10) or EFS (aHR = 0.92, 95% CI 0.72-1.17). Subgroup univariate analysis showed cannabis use was associated with longer OS and EFS within men (n = 743) and former smokers (n = 765) (P's < 0.05), which became non-significant after adjusting for covariates in Cox models, except for OS within former smokers (aHR = 0.52, 95% CI 0.33-0.83). A significant interaction was noted between cannabis use and smoking status ($P = 0.02$). **Conclusions:** In this nationwide, diverse community-based oncology cohort, 17% of patients reported cannabis use concurrent with ICI therapy. Unlike previous retrospective studies, our prospective analysis finds no detrimental effect of cannabis on OS or EFS. Further analyses are ongoing to elucidate its impact on symptom management. Clinical trial information: NCT05364086. Research Sponsor: National Cancer Institute; UG1CA189961.

12082 Poster Session

Outpatient palliative care consultation and end-of-life outcomes among a retrospective cohort of patients treated with immunotherapy for non-small cell lung cancer.

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Background: Immune checkpoint inhibitors (ICIs) have been shown to be effective against a wide range of cancers and are available to most patients due to their favorable side effect profile. Studies have shown that palliative care consultation prolongs overall survival (OS) in patients with advanced cancer, but most of these studies assessed cytotoxic chemotherapy and not ICIs. Other studies have shown that outpatient palliative care consultation (OPCC) has a greater effect on a variety of end-of-life outcomes than in the inpatient setting. Our study aims to analyze the association between OPCC and survival in patients with lung cancer treated with an ICI. **Methods:** We designed a retrospective registry of all patients at a comprehensive cancer center and its outreach clinics who received one or more doses of an ICI. The investigators created a secure, cloud-based registry (REDCap), validated it with data quality rules, resolved all discrepancies, and obtained data on palliative care encounters; clinical research specialists at Vasta Global (New York, NY) captured most of the data. Comparisons were made using chi-square or Fisher's exact for categorical variables. Cox proportional hazards model was built controlling for confounders. Survival time for patients with palliative visits was only considered after initial OPCC. Statistical significance was defined as $p < 0.05$. The study had institutional IRB approval. **Results:** Our cohort consisted of 1,114 patients with non-small cell lung cancer, 55% of whom were metastatic at diagnosis. 6% (n = 70) of the patients had an OPCC at some point after their diagnosis. When controlling for stage at diagnosis and age, OPCC was associated with an adjusted hazard ratio of 0.57 (95% CI 0.34–0.98). None of the patients with OPCC received ICI within 14 days of death compared to 6.5% of those without OPCC ($p = 0.018$). Similarly, only 2.9% of those with OPCC received ICI within 30 days of death, compared to 16.4% of those without OPCC ($p = 0.003$). **Conclusions:** In patients with lung cancer treated with ICI, OPCC was associated with improved OS regardless of age or stage at diagnosis. Our analysis also showed that patients who received OPCC were less likely to receive ICI near the end of life. It is possible that OPCC may prolong survival by decreasing the ineffective use of aggressive care at the end of life. Further research is needed to clarify the relationship between OPCC and cancer outcomes. Research Sponsor: None.

12083 Poster Session

Demographic and clinical factors associated with sleep disturbance in breast cancer survivors.

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Background: Fatigue and sleep disturbance are prevalent during and after cancer treatment; sleep-related symptoms affect 30-50% of patients with cancer, and sleep-wake disruptions persist beyond the immediate post-surgical period in breast cancer (BC) survivors. Identifying demographic- and treatment-related factors associated with sleep-related symptoms during survivorship is critical to inform interventions for those at highest risk of sleep disturbance. **Methods:** Patients who were seen at least once at Mayo Clinic Rochester following an initial diagnosis of BC at age 18 or older and provided informed consent were prospectively enrolled in the Mayo Clinic Breast Disease Registry. Surveys mailed to this cohort included two 11-point numeric rating scale questions regarding difficulty falling asleep and staying asleep in the past week, with values for each ranging from 0 (no problem) to 10 (as severe as you can imagine). Participants who provided sleep-related information on the Year 1 survey (answered approximately one year after cancer diagnosis) were included. Participants were excluded if they had clinical or pathologic metastatic disease and/or recurrence prior to the Year 1 survey. Associations of sleep-related symptoms with demographic and clinical characteristics were assessed using multivariate linear regression models, fitting the sleep difficulty rating scale as the outcome and clinical and demographic factors as exposures. **Results:** In total, 3,354 participants met inclusion criteria. The average age at BC diagnosis was 59, and most participants were female (99.3%), White (95.4%), non-Hispanic (96.2%), married (78.1%), had at least some college education (80.4%), did not report financial insecurity (76.2%), did not consume alcohol (60.6%) or smoke tobacco (93.2%), and reported at least some weekly exercise (76,6%). Sixty-two percent of participants had clinical stage 0 or I disease; 50.3% underwent lumpectomy (not mastectomy), 59.2% received radiotherapy, 34.1% received chemotherapy, and 67.2% received endocrine therapy. Overall, sleep-related symptoms were relatively low (mean rating for falling asleep = 2.1, mean rating for staying asleep = 3.1). In multivariate analyses, more difficulty falling asleep was associated with higher clinical stage ($p < 0.001$), more cigarettes smoked per day ($p = 0.012$), less moderate and/or strenuous exercise ($p = 0.001$), and more financial hardship ($p < 0.001$). More difficulty staying asleep was associated with higher clinical stage (0.003), older age ($p < 0.001$), more education ($p = 0.011$), and more financial hardship ($p < 0.001$). **Conclusions:** In our cohort of BC survivors, factors associated with both increased difficulty with falling and staying asleep at one year after diagnosis are higher clinical stage and more financial hardship. Future research should explore the course of these symptoms over time and across varied treatment trajectories. Research Sponsor: This research was supported by the Mayo Clinic Breast Registry. Funding provided through the Breast Cancer Research Foundation.

12084 Poster Session

Trends in inpatient palliative care utilization among adolescents and young adults with metastatic cancer.

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Background: Adolescents and young adults (AYA) with advanced cancer, including metastatic cancer, have a unique set of medical, social and psychological needs and often experience several disparities in cancer care when compared with children and older adults. Despite recommendations for early integration of palliative care for patients with serious illnesses, age-appropriate interventions and teams specifically designed for this age group are limited. Objective: To determine the trends in inpatient palliative care utilization as well as associated factors and clinical outcomes among AYA with metastatic cancers in the United States between 2008-2021. **Methods:** A retrospective longitudinal study using the National Inpatient Sample database (2008-2021) was conducted. We examined trends in the prevalence of palliative care utilization in the cohort, as well as sociodemographic and hospital-level factors associated with palliative care utilization. Using Joinpoint regression and multivariable logistic regression, we examined trends and factors associated with palliative care utilization, as well as specific clinical outcomes including inpatient mortality, length of stay, and total hospital costs. **Results:** In this period, 604,856 hospitalizations were recorded for AYA with metastatic cancer. Overall, palliative care utilization was recorded in 10.6% of these encounters and increased over time from 3,036 to 16,568 per 100,000 admissions (p-trend $<$0.001). The adjusted prevalence rate of palliative care utilization increased by an annual percentage change (APC) of 15.9% from 2010 to 2015. However, from 2015 to 2021, no significant changes were observed. Females with metastatic cancer had 18% higher odds (Adjusted odds ratio (AOR):1.18; 95% CI: 1.12-1.24) of receiving palliative care compared to male patients after we adjustments had been made for potential confounders. Non-elective admissions were associated with four times higher odds (AOR: 3.99, 95% CI: 3.68-4.32) of receiving palliative care compared to elective admissions. Palliative care utilisation was associated with higher odds of longer hospital stay (9.3 vs 6 days, β: 3.29, 95% CI: 3.07-3.50) and increased hospital expenditure ($107,758 vs $78,255, β: -29,747, 95% CI: 26,190 - 33,304). A significantly increased odds of palliative care utilization was observed in those who died during the hospital admission (AOR: 16.16; 95% CI: 14.8-17.6). **Conclusions:** Palliative care utilization has been increasing over the earlier part of the decade but has stalled since 2015 among AYA with metastatic cancer. In the AYA group with metastatic cancer, palliative care appears to be utilized majorly in the sickest patients closer to the end of life. This represents an area of future research and interventions on earlier integration of palliative care and its impact on quality of life and hospital outcomes in this patient population.
Research Sponsor: None.

12085 Poster Session

Effectiveness and safety of multimodal analgesic management based on the ERAS concept in the perioperative period of TACE for patients with Intermediate and advanced hepatocellular carcinoma.

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Background: To evaluate the effectiveness and safety of multimodal analgesic management based on the enhanced recovery after surgery (ERAS) concept in the perioperative period of transarterial chemoembolization (TACE) for patients with advanced hepatocellular carcinoma. **Methods:** A retrospective analysis was conducted on 90 patients who underwent TACE at the First Affiliated Hospital of Sun Yat-sen University from January 2022 to October 2023. Patients were divided into two groups: Group A received a multimodal analgesic regimen based on the ERAS concept, which included preoperative administration of 6 mg hydromorphone hydrochloride and 50 mg flurbiprofen axetil, diluted in normal saline to a total of 100 ml and infused via a patient-controlled intravenous analgesia (PCIA) pump. Group B received conventional perioperative management combined with traditional analgesic methods, using intravenous flurbiprofen axetil 50 mg or intramuscular tramadol 100 mg for postoperative pain. Pain levels were recorded using the Numeric Rating Scale (NRS) at various time points: intraoperatively, immediately postoperatively, and at 1, 6, 12, and 24 hours post-surgery, along with the incidence of adverse reactions within 24 hours. Inflammatory indicators were compared before and after TACE, and patient satisfaction and cost-effectiveness analyses were conducted. **Results:** The NRS scores for Group A at the five time points were 3.0 (3.0–2.0), 3.0 (4.0–2.0), 4.0 (5.0–3.0), 3.0 (3.5–2.0), and 1.0 (1.0–0.5), respectively. For Group B, the scores were 4.0 (5.0–3.0), 4.0 (5.0–3.0), 5.0 (6.0–3.5), 3.0 (4.0–2.0), and 1.0 (2.0–1.0) , respectively. Except for the NRS score at 12 hours post-surgery, all other time points showed statistically significant differences. There was no statistically significant difference in the levels of PCT and IL-6 before and after surgery between the two groups, but a trend of lower postoperative PCT and IL-6 levels in Group A compared to Group B was observed. The incidence of various adverse reactions 24 hours post-surgery did not differ significantly between the two groups ($P > 0.05$). Patient satisfaction with analgesia at 48 hours post-surgery was significantly higher in Group A than in Group B, with a statistically significant difference ($P = 0.001$). Group A demonstrated better economic benefits. **Conclusions:** The results of this study indicate that multimodal analgesic management based on the ERAS concept has better analgesic effects during the perioperative period of TACE treatment, with comparable safety and improved economic benefits. This provides strong support for the clinical application of multimodal analgesic management based on the ERAS concept in TACE for liver cancer. Research Sponsor: None.

12086 Poster Session

Evaluating palliative care needs of early-phase clinical trial patients.

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Background: Specialty palliative care (PC) is increasingly recognized as essential for patients (pts) in early phase clinical trials (EPT), as highlighted by ASCO's 2024 PC guideline. However, concerns persist regarding trigger referrals' impact on resource-constrained PC services. In a pilot, we employed a trigger PC referral system for patients referred to EPT to increase access in this population. **Methods:** We conducted a retrospective cohort study comparing EPT and non-EPT pts seen by outpatient PC between January 1, 2021 and June 30, 2023. We evaluated demographic characteristics, clinical variables, symptom severity at the initial PC visit and end-of-life (EOL) outcomes. Mann-Whitney U tests were used for continuous variables; chi-square or Fisher's exact tests for categorical variables. Multiple comparisons were adjusted using the Benjamini-Hochberg method. **Results:** A total of 1068 pts were included, 136 (12.7%) EPT pts with 67 (6.3%) started on trial. 86 (63.2%) were seen by EPT before outpatient PC and 54 (39%) were referred to PC by EPT team through trigger referral system. EPT pts were younger (median age 61 vs 64 years; p=0.001), had better PS (ECOG 0-1: 57.4% vs 46.5%; p=0.020), and referred after more lines of therapy (median 3 vs. 1; $p<0.001$). Cancer type distribution differed significantly between groups (p=0.005), with EPT pts having higher proportions of GI (41.9% vs 26.5%) and GYN cancers (16.2% vs 9.2%). Physical discomfort was the most prevalent symptom in both EPT and non-EPT groups (86.9% vs 84.9%), followed by inactivity (74.2% vs 76.3%). While most symptoms showed similar prevalence between groups, EPT pts had higher rates of constipation (65.4% vs 50.7%, adjusted p=0.025) and nausea (48.1% vs 38.0% (adjusted p=0.193). After adjustment for multiple comparisons, there were no significant differences in symptom severity between groups. Of those on trial(n=67), 46 (69%) came off trial due to progression and 16 (24%) due to toxicity or worsening PS. After trial discontinuation, 35 (56.5%) received further treatment, and 37 (59.7%) had PC follow-up. Among deceased pts (EPT n=70 (18%), non-EPT n=320 (82%)), there were no differences in EOL outcomes: hospice enrollment (37.1% vs 29.1%, p=0.198), hospital death (58.6% vs 58.4%, p=1.000), chemotherapy in the last 30 days (22.9% vs 18.8%, p=0.411), and median hospital length of stay in the last 30 days (7 vs 5 days, p=0.825). **Conclusions:** EPT pts accounted for 12.7% of new pts to specialty PC over 30 months. Despite demographic and clinical differences between EPT and non-EPT patients, EOL outcomes and symptom severity were largely comparable between groups. These results highlight the feasibility of a trigger-based PC referral system for EPT patients without overburdening resource-constrained PC services, supporting its continued use and potential refinement to address specific symptom management needs.
Research Sponsor: None.

12087 Poster Session

Impact of palliative care on mortality, length of stay, and hospital charges in common cancers.

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Background: Palliative care is a vital component of advanced cancer management, offering symptom relief, improved quality of life, and comprehensive care for patients with complex health needs. While its clinical benefits are well-documented, its impact on hospital outcomes—such as in-hospital mortality, length of stay (LOS), and total hospitalization charges (TOTCHG)—remains underexplored across major cancers. Using the 2021 National Inpatient Sample (NIS), this study evaluates the influence of palliative care utilization on these outcomes among hospitalized patients with breast, lung, colon, bladder, and prostate cancers. **Methods:** This retrospective analysis examined 966,753 weighted hospitalizations, representing breast (163,594), lung (383,215), colon (168,750), bladder (86,555), and prostate (182,280) cancers. Palliative care utilization was the primary exposure. Outcomes assessed included in-hospital mortality, LOS, and TOTCHG. Survey-weighted logistic and linear regression models were used to adjust for patient demographics (age, sex, race, income quartile), comorbidities (Charlson Comorbidity Index, CCI), and hospital characteristics (location, teaching status, region, bed size). **Results:** The overall mortality rate was 6.6%, highest in lung (9.3%) and lowest in prostate (4.7%) and colon cancers (4.8%). Palliative care patients had higher mortality (28.5%; $p < 0.001$). Adjusted analyses showed increased mortality with higher CCI (OR = 0.71, $p < 0.001$) and urban hospitals (OR = 1.40, $p < 0.001$), while female patients had reduced risk (OR = 0.86, $p < 0.001$).LOS averaged 5.98 days, longer for palliative care patients (7.68 days; $p < 0.001$). TOTCHG averaged $83,430, higher for palliative care ($90,488; $p < 0.001$). Black patients incurred higher charges (+$10,475, $p = 0.001$), and urban hospitals had lower costs (-$35,094, $p < 0.001$).Palliative care was concentrated in urban (93.7%) and teaching hospitals (80%), with significant underrepresentation of Black and Hispanic patients in the utilisation of palliative care. (19.2% and 8.8%). **Conclusions:** Palliative care in hospitalized cancer patients addresses the needs of patients with advanced disease and significant comorbidities. However, the study highlights stark disparities in healthcare access, resource utilization, and demographic representation based on race, socioeconomic status, and hospital characteristics. Research Sponsor: None.

Palliative care outcomes cancer comparison table.

Cancer Type	Total Hospitalizations	Mortality Rate (%)	Mean LOS	Mean Hospital Charges	Palliative Care Mortality Rate (%)	Palliative Care LOS	Palliative Care Charges
Breast	163594	6.6	7.34	85727	26.4	7.34	85727
Lung	383215	9.3	6.19	82776	30.55	7.53	89760
Colon	168750	4.8	6.62	96148	24.99	8.09	95202
Bladder	86555	4.7	8.33	92731	25.9	8.33	92731
Prostate	182280	4.7	5.41	79410	27.12	7.81	91883

Early supportive and palliative care referral at a comprehensive cancer center: A seven year study.

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Background: Despite ASCO supporting the benefits of early supportive/palliative care (SPC) integration, many patients with advanced cancer were referred < 6 months before death or not at all. Our comprehensive cancer center has an active SPC program to promote early access. This study evaluated how the timing of SPC referral changed over the past seven years and identified predictors of early SPC referral. **Methods:** This study included a random sample of 100 patients seen for consultation at the SPC clinic per year from 2017 to 2023. Data included demographics, cancer type, disease stage, symptom burden, performance status, date of SPC referral, and date of death or last follow-up. The primary outcome was overall survival (OS) from SPC consultation. Timing of referral and number of visits were examined using time-to-event analysis. Early SPC referral was defined as occurring ≥ 6 months before death among decedents. Univariable and multivariable logistic regression models were used to identify predictors of early SPC referral. **Results:** Among 700 patients (median age 62, 54% female, 92% with advanced cancer), OS from SPC referral increased significantly over the years (Median OS: 9.3 months in 2017, 31.7 months in 2021, and not reached in 2023) (Table). The median follow-up for alive individuals was 19.1 months. The median number of follow-up SPC visits increased from 3 in 2017 to 7 in 2023 (P < 0.001). Early SPC referral occurred in 72% (n = 449) of decedents. In multivariable analysis, male sex (OR: 1.85, P = 0.014), head and neck cancer (OR: 4.64, P < 0.001), hematologic malignancies (OR: 3.31, P = 0.013), less pain (OR: 0.9, P = 0.008) and less anorexia (OR: 0.88, P = 0.001) were associated with early SPC referral. **Conclusions:** Patients at our center were referred to SPC earlier and earlier over the past 7 years, achieving a median OS of 32 months. This trend highlights that early SPC is not only possible but potentially self-reinforcing, facilitating timely, longitudinal care along the cancer journey, particularly as patients are living longer with advanced cancer. Research Sponsor: None.

Outpatient supportive/palliative care referral between 2017 and 2023.

Year	2017	2018	2019	2020	2021	2022	2023	P-Value
Number of SPC Consults*	1,844	1,766	1,863	1,804	2,055	2,221	2,178	0.011
All Patients								
Median OS, Months	9.3(6.9 – 14.2)	9.1(6.4 – 19.5)	18.9(10.7 – 30.7)	31.8(14 – NR)	31.7(13.3 – NR)	NR	NR	0.0001
6-months OS %	63	61	70	75	75	83	79	
Advanced Cancer Only								
Median OS, Months	9.3(6.9 – 14.2)	7.1(5.7 – 18.9)	15.9(9.5 – 25.8)	24.2(13.4 – NR)	25.8(12.7 – NR)	24.7(16.4 – NR)	NR	0.0014
6-month OS %	63	59	68	73	73	79	78	
Total SPC Visits, Median	3(3 – 4)	4 (3– 5)	3 (2– 4)	5 (3 – 7)	4 (4 – 9)	7(5 – 15	7 (6 – NR)	< 0.001

Abbreviations: SPC, Supportive/Palliative Care; NR, not reached; OS, overall survival.
*100 patients were randomly selected per year for analysis.
Ranges in parentheses represent 95% CI (confidence interval).

12089 Poster Session

Current patterns of care: Referral to palliative care for patients with metastatic gynecologic cancer.

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Background: Multiple professional cancer organizations have clinical guidelines that recommend that patients with advanced cancers be referred to palliative care early in the disease course, typically within eight weeks of diagnosis (1). The extent to which these guidelines are adhered to, however, remains uncertain, particularly for patients with metastatic gynecologic cancers (MGC). We sought to characterize our current institutional patterns of referral to palliative care for these MGC patients. **Methods:** We conducted a retrospective chart review of gynecologic oncology patients treated at our institution between January 2022 and January 2024. We included adult, female patients with a diagnosis of FIGO stage IVB MGC, or cancer that has spread distantly. Patients with primary endometrial, cervical, ovarian, vaginal, or vulvar cancer were included. We excluded patients with less advanced disease or metastatic cancer from a non-gynecologic primary site. Data from the electronic health records of these patients were analyzed to determine key dates, including the diagnosis of stage IVB MGC, referral to palliative care, the first palliative care visit, and subsequent follow-up visits. Descriptive statistics were used to summarize the results. **Results:** Of the 549 patients included in the analysis, 152 (27.7%) had MGC. Within this subgroup, 76 patients (50%) were referred to palliative care. Of those referred, 65.8% (N = 50) were referred to palliative care either before or within 8 weeks of metastatic diagnosis. Referrals were made in both inpatient (47.4%, N = 36) and outpatient (52.6%, N = 40) settings. Following referral, 84.2% of patients (N = 64) had a consultation with a palliative care provider. However, less than half of these patients (48.4%, N = 31) continued outpatient follow-up with palliative care. When stratified by referral setting, 57.5% of patients (N = 23) referred in the outpatient setting continued follow-up care, compared to only 27.8% of those (N = 10) referred in the inpatient setting. **Conclusions:** Despite guidelines recommending early initiation of palliative care for all patients with advanced cancer, many patients with MGC either never receive a referral or experience considerable delays between metastatic diagnosis and palliative care consultation. In many cases, referrals are made only when patients are already hospitalized due to their cancer. Furthermore, we found that a substantial number of patients do not continue outpatient palliative care follow-up after their initial referral, with a more notable decline in continuity of care when the referral is made during an inpatient hospitalization. References: 1. Justin J. Sanders et al., Palliative Care for Patients With Cancer: ASCO Guideline Update. JCO 42, 2336-2357(2024). DOI: 10.1200/JCO.24.00542. Research Sponsor: None.

12090 Poster Session

Depression in patients with advanced prostate cancer in SWOG advanced cancer clinical trials.

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Background: Depression is common in patients with advanced cancer, but its prevalence has not been well documented. Moreover, depression is likely associated with other patient factors, including sociodemographic and clinical variables. We examined depression at enrollment in clinical trials for patients with advanced prostate cancer. **Methods:** We pooled clinical trial data from the SWOG Cancer Research Network. We identified phase III treatment trials of advanced prostate cancer patients with baseline mental health symptom measurements. Baseline depression was derived from emotional functioning items from the FACT-G, the SF-36, and the EORTC QLQ-C30 instruments. Using Likert scale distributions, depression was categorized as none, mild or moderate, and severe. We evaluated the prevalence of depression and its association with other baseline variables including age, race, ethnicity, insurance, rural/urban locale, the Area Deprivation Index, measurable disease, and prognostic risk. Generalized estimating equations with binomial logistic regression were used to assess the association of baseline variables with the odds of any depression and severe depression, with study as the clustering variable. A composite risk model was developed by summing the number of baseline risk factors adversely associated with depression. **Results:** Overall, N = 4,103 patients from four phase III trials were examined, including 69.8% aged 65 or older, 17.5% Black, 3.4% Hispanic, 18.4% rural, and nearly half (46.4%) from socioeconomically deprived areas (ADI score above the national median). At baseline, 50.4% of patients had depression (mild/moderate, 38.3%; severe, 12.1%). Depression was associated with age < 65 years, non-Black race, Hispanic ethnicity, having Medicaid or no insurance, and worse disease clinical characteristics. Patients with >3 risk factors (high risk) vs. 0-2 risk factors (low risk) were more likely to experience depression (54.3% vs. 43.2%, $p < .0001$) and severe depression (21.0% vs. 9.7%, $p < .0001$), corresponding to a 50% (OR = 1.50; 95% CI: 1.34-1.67; $P < .0001$) and 135% (OR = 2.35; 95% CI: 1.84-3.02; $P < .0001$) increase in risk, respectively. Quartile (Q) level proportions of any depression were 32.8% (Q1), 44.4% (Q2), 53.1% (Q3), and 72.0% (Q4), respectively, with a fivefold higher risk for those in the highest vs. lowest quartiles (Q4 vs. Q1, OR = 4.97; 95% CI, 2.86-8.64, $p < .0001$). Similar findings were seen with severe depression. **Conclusions:** Evidence of depression at baseline was reported by one-half of patients with advanced prostate cancer in clinical trials. Moreover, we showed that the number of adverse socioeconomic and clinical variables could strongly predict the prevalence of depression. Screening for depression in patients with cancer could help guide patients to appropriate mitigation resources. Interventions to help screen and treat patients with advanced cancer are warranted. Research Sponsor: NIH/NCI/NCTN/NCORP grants U10CA180888, U10CA180819, UG1CA189974; The Hope Foundation.

12091 Poster Session

Intravenous selenium to prevent oral mucositis in patients with lymphoma or myeloma undergoing high-dose therapy followed by autologous hematopoietic cell transplantation: A double-blind randomized trial.

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Background: Oral mucositis (OM) is a frequent complication in patients with lymphoma and myeloma receiving high-dose therapy (HDT) and autologous hematopoietic cell transplantation (HCT) that can lead to severe pain, malnutrition due to difficulties in drinking and eating, and local and systemic infections. In severe cases, patients require opioid analgesics, supplemental nutrition, and additional antimicrobial therapy while very few preventive interventions have proven useful. Because of its anti-oxydant activity, some studies have suggested that selenium could be useful in this context. We therefore led a double-blind randomized trial to evaluate the use of selenium in preventing OM in patient with lymphoma or myeloma receiving HDT (NCT04080622). **Methods:** Patients ≥18 years with lymphoma or myeloma undergoing HDT (carmustine, etoposide, cytarabine, and melphalan [BEAM] for patients with lymphoma and high-dose melphalan for patients with myeloma) followed by autologous HCT were randomized beween intravenous selenium 300 μg/day or placebo from the first day of chemotherapy to hospital discharge. The primary endpoint was the incidence of severe (grade 3-4) OM by intention to treat as defined by the World Health Organization (WHO). Secondary endpoints included any grade oral mucositis (WHO), auto and hetero-évalaution (NCI-CTCAE) of OM, opioid, nutrition, and antimicrobial therapy used, duration of hospitalization, and adverse events (AE). **Results:** From October 2019 to October 2023, we included 100 patients with lymphoma (n = 29) and myeloma (n = 71) who received HDT and autologous HCT that were randomized between selenium (n = 50) and placebo (n = 50). Baseline characterstics (age, gender, and tobacco use, type of hematologic disease, disease status at HDT, and baseline albumin and selenium levels) were balanced between the two treatment arms. The rate of severe OM was strictyl identical in both arms (60%, *P*= 1) with a mean maximum grade of mucositis of 3.26 in the selenium arm and 2.82 in the placebo arm (*P*= 0.71). Other methods to evaluate OM showed similar results. Opioid use (mean 6.92 *versus* 6.12 days in the placebo group, *P*= 0.53), parenteral nutrition (mean 10.88 *versus* 9.27 days, *P*= 0.19), antibiotic use (9.12 *versus* 7.02 days, *P*= 0.05), antifungal use (1.02 *versus* 0.39 days, *P*= 0.33), and duration of hospitalization (24.94 *versus* 19.58 days, *P*= 0.24) were not statistically different between the two groups. The rate of grade 3-4 AE was higher in the selenium arm (100% *versus* 90%, *P*= 0.03) with similar rates of grade 3-4 diarrhea (10% *versus* 16%, *P*= 0.55). **Conclusions:** Intravenous selenium did not improve oral mucositis in patients with lymphoma or myeloma undergoing HDT followed by autologous HCT. Clinical trial information: NCT04080622. Research Sponsor: None.

12092 Poster Session

The impact of early versus late palliative care referral (PCR) on healthcare utilization in pancreatic cancer patients: A single-center retrospective study.

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Background: Pancreatic cancer is one of the most aggressive malignancies, imposing substantial physical, psychosocial, and financial stress that significantly compromises patients' quality of life (QOL). Despite its importance, only limited data exists on the optimal timing of a palliative care referral (PCR) in the course of pancreatic cancer. We propose that early PCR offers a proactive approach that not only alleviates symptom burden and improves QOL but also reduces healthcare utilization (HCU) and associated costs. **Methods:** We performed a retrospective analysis for patients diagnosed with pancreatic cancer at Allegheny Health Network from January 2015 to January 2024. Based on the timing of PCR from the diagnosis of pancreatic cancer, patients were categorized into early PCR (< 3 months), and late PCR (> 3 months) cohorts. HCU metrics were compared between the two cohorts including the number of emergency department (ED) visits, hospital admissions and intensive care unit (ICU) admissions, using Mann Whitney U test. Statistical analysis was performed using SAS 9.4, with an alpha level of 0.05. **Results:** From 2015- 2024, 2020 patients were diagnosed with pancreatic cancer and only 309 patients received a PCR. The patients who got a PCR had a median age of 66 years, 56% of them were males and 97% were non-Hispanic. Among these, 172 patients had an early PCR, and 137 patients had a late PCR. The patients in the early PCR group were generally non-Hispanic males with a mean age of 68 years, while those in the late PCR group being non-Hispanic males with a mean age of 64 years. The median number of ED visits was significantly higher in the late PCR cohort compared to the early PCR cohort, {3 [Interquartile range (INR)2-5] versus 2 [INR1-3] respectively, $p < 0.0001$}. 52.55% patients in the late PCR cohort had an ED visit due to pain, compared to only 37.79% patients in the early PCR cohort ($p < 0.009$). 36.63% patients in the early PCR group had an ICU admission as compared to 62.04% patients in the late PCR group ($p < 0.0001$). Similarly, early PCR group had a significantly lesser number of hospital admissions, 2 (INR 1-3), than the late PCR group, 4 (INR 1-10), $p < 0.0001$.While Chemotherapy use in the last 2 months from death was observed in 30.66% patients with late PCR and 29.07% of patients with early PCR, the difference was not statistically significant. **Conclusions:** Our study shows the use of early PCR in reducing aggressive care towards the end of life including ED visits and hospital and ICU admissions. Due to the advanced nature of pancreatic cancer at presentation, early integration of palliative medicine into comprehensive cancer care would be beneficial for improving the QOL of patients and would also reduce the HCU, enhancing economic sustainability of care. Further research is needed to show the effect of early PCR on the psychological stress experienced by pancreatic cancer patients. Research Sponsor: None.

12093 Poster Session

Differences in supportive care service utilization among long term metastatic breast cancer survivors by rurality.

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Background: Patients living with metastatic breast cancer (MBC) have unique psychosocial and medical needs, which often go unrecognized. Many patients living in rural areas travel farther for care. We examined differences in supportive care service referrals and utilization by sociodemographic, psychosocial, and clinical predictors among long term MBC survivors living in rural versus urban areas. **Methods:** 233 patients from the Ohio State University Stefanie Spielman Comprehensive Breast Center, who had been diagnosed with MBC for ≥1 year, were asked to complete a one-time, online survey to assess their demographic characteristics, quality of life, self-rated health, symptoms, and supportive care needs. Chi-square and fisher exact tests were used for categorical variables and two sample t-tests were used for continuous variables to determine sociodemographic (age, race, education, income, rural/urban residency), psychosocial/quality of life (PROMIS physical component score, PROMIS mental component score, MOS social support), and clinical factors (time since diagnosis, current treatment, metastasis site, fatigue, pain, and sleep) associated with utilization of supportive care services. **Results:** 66 patients residing in rural areas (RURAL) and 167 patients residing in urban areas (URBAN) were recruited. There was a higher rate of supportive care service utilization among URBAN (n=82, 49.1%) versus RURAL (n=22, 33.3%) patients. For URBAN, service utilization was associated with lower (worse) PROMIS physical scores, PROMIS mental scores, MOS social support total scores, and greater fatigue and pain scores. However, no significant associations were seen for RURAL. Higher education and income levels were associated with increased service utilization for RURAL, but not URBAN participants. The Table details referral and utilization rates for the top 5 supportive care services. **Conclusions:** Patients living in rural areas had lower supportive care utilization compared to patients living in urban areas. However, urban patients reported worse PROMIS and social support scores. While a no cost service (dietitian) had similar utilization rates between URBAN and RURAL, another (James Care for Life programs) did not. Services amenable to same day coordination had no statistical differences in utilization rates between URBAN and RURAL. More research is needed to evaluate the impact of distance, financial, and time barriers on equitable access to supportive care services. Research Sponsor: None.

Top 5 supportive care referrals and utilization.

	Rural		Urban	
	Referred	Utilized	Referred	Utilized
Counseling	8 (12.1%)	4 (50%)	34 (20.4%)	20 (58.8%)
Dietitian	11 (16.7%)	8 (72.7%)	35 (21%)	27 (77.1%)
James Care for Life Programs	8 (12.1%)	3 (37.5%)	27 (16.2%)	15 (75%)
Living Well with Advanced Breast Cancer Clinic	14 (21.2%)	2 (14.3%)	20 (12%)	15 (75%)
Physical Therapy	7 (10.6%)	6 (85.7%)	36 (21.6%)	29 (75%)

12094 Poster Session

Race and correlates of cancer cachexia in the Detroit Research on Cancer Survivors cohort.

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Background: Cancer cachexia is a multifunctional syndrome characterized by the ongoing loss of skeletal muscle mass that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment limiting quality of life. It is also associated with poor response to therapies which impact long-term survival. The current investigation examines the prevalence and determinants of cachexia in a racially diverse cancer cohort. **Methods:** We used data gathered on a subset of participants in the Detroit Research on Cancer Survivors (ROCS) study, one of the largest cohorts conducted exclusively among Black cancer survivors to understand the complex nature of poorer outcomes in this population. At baseline, participants diagnosed and/or treated at the Karmanos Cancer Institute with breast, colorectal and lung cancer were asked to provide their weight one year prior to diagnosis and current weight, height, medical history, health behaviors and health-related quality of life (HRQOL). Responses were compared with a frequency-matched set of White cancer survivors. Cachexia was defined as an unintentional weight loss of 5% or more for patients with a BMI 20 or higher and 2% or more for patients with a BMI < 20 over 6 months. **Results:** Among 899 cancer survivors (509 Black and 390 White), 35.3% reported weight loss consistent with cachexia. A significantly higher proportion of Black survivors were cachectic (40.3%) compared with White survivors (28.7%; $p < 0.001$). Racial differences were equally pronounced regardless of tumor type, but overall the highest proportion of cachexia was observed among lung cancer survivors (54.2%). Examination of the electronic medical records of these patients found that older age at diagnosis (p-trend < 0.005) and a medical history of diabetes (OR = 2.18; 95%CI 1.31, 3.63) were both significantly associated with the presence of cachexia. **Conclusions:** We found that Black patients are more likely to have cachexia at the time of cancer diagnosis than white patients. Since cachexia is an important predictor of poor outcomes in cancer patients, developing strategies to prevent or reverse the loss in the skeletal muscle mass is critical in improving outcomes and reducing disparities in related outcomes. Research Sponsor: U.S. National Institutes of Health; U01 CA199240.

12095 Poster Session

Barriers to palliative care access in patients with brain metastases: A comprehensive national study.

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Background: Palliative care (PC) improves the quality of life for patients with advanced cancer, including those with brain metastases (BM). Despite nearly 170,000–200,000 cases of BM annually in the United States, evidence supporting utilization of early PC in malignant brain tumors remains limited. This study aimed to identify factors influencing access to PC for patients with BM from lung, breast, and colorectal cancer to delineate patient uptake of PC. **Methods:** This retrospective cohort study analyzed the National Cancer Database (NCDB) data (2010-2021) for patients with BM from lung, breast, and colorectal cancer. Variables analyzed included age, sex, race, ethnicity, facility type, insurance status, socioeconomic factors, and primary cancer site. The primary outcome was receipt of PC. Descriptive statistics summarized patient characteristics, and logistic regression identified predictors of access to PC, reporting odds ratios (OR) with 95% confidence intervals (CIs). **Results:** Of 214,940 patients with BM, 94% had lung cancer, 4.2% had breast cancer, and 1.7% had colorectal cancer. The cohort was 50.9% female, 82.6% White, 12.2% Black, 3.8% Asian, 96.4% non-Hispanic, and 3.6% Hispanic. In the multivariate analysis, older patients had lower odds of receiving PC compared to patients aged 18-59 (60-69: OR 0.95, 95% CI 0.93-0.98; 70+: OR 0.88, 95% CI 0.86-0.91; $P < 0.001$), while sex was not associated with PC (OR 0.99, 95% CI 0.97-1.01; $P = 0.333$). Compared to White patients, Black (OR 0.96, 95% CI 0.93-0.99; $P = 0.014$), and Asian (OR 0.95, 95% CI 0.91-1.00; $P = 0.066$) patients had lower likelihood of PC. Hispanics were also less likely to receive PC (OR 0.85, 95% CI 0.80-0.90; $P < 0.001$). Integrated facilities (i.e., part of a larger network with centralized cancer care) had a lower probability of providing PC than community hospitals (OR 0.97, 95% CI 0.95-0.99; $P = 0.002$), whereas academic facilities showed no differences ($P = 0.105$). Medicaid patients had slightly higher odds of receiving PC than those with private insurance (OR 1.04, 95% CI 1.00-1.07; $P = 0.026$), while Medicare and other government insurance showed no significant differences. Medicaid expansion improved access (January 2014: OR 1.55, 95% CI 1.50-1.60; late expansion: OR 1.55, 95% CI 1.50-1.61; $P < 0.001$). Patients living >10 miles from a facility had lower odds of access (OR 0.97, 95% CI 0.94-0.99; $P = 0.002$). Compared to patients with breast cancer, those with lung cancer had lower odds (OR 0.92, 95% CI 0.87-0.96; $P < 0.001$), and colorectal cancer patients had the lowest odds (OR 0.73, 95% CI 0.67-0.80; $P < 0.001$) of accessing PC. **Conclusions:** Significant disparities in PC access among patients with BM exists. Age, racial and ethnic subgroups, geographic barriers, and primary cancer type impact uptake of PC. Targeted interventions, including strategies to improve access for underserved populations, are needed to increase health equity among BM patients. Research Sponsor: None.

12096 Poster Session

Age-specific unmet needs among older patients with cancer enrolled in an outpatient palliative care program: A retrospective analysis.

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Background: Older adults with cancer often experience diverse unmet needs. Understanding these needs is crucial for tailoring palliative care interventions. This study analyzed unmet needs among older patients enrolled in an outpatient palliative care program (OPCP), stratified by age (65–75, 76–86, and 87–97 years). **Methods:** This retrospective study included 474 patients enrolled in an OPCP from November 2022 to April 2024. Patients completed the Integrated Palliative Outcome Scale (IPOS), a validated measure assessing physical, psychological, social, and spiritual needs, as well as overall quality of life (QoL). Multinomial logistic regression was performed to evaluate associations between age groups and specific unmet needs, with adjustments for sociodemographic and clinical factors. **Results:** From the total sample, median age was 77 years (range 65–97); 51% were female, 36% had high school, and 32% were college-educated. Cancer types included gastrointestinal (25%), genitourinary (20%), lung (14%), and breast (12%). QoL scores did not differ across age groups. However, unmet needs varied by age group: 65–75 years: Greater likelihood of reporting pain (OR 0.118, 95% CI 0.01–0.42, p=0.04), fatigue (OR 8.27, 95% CI 6.76–9.96, p=0.04), drowsiness (OR 2.15, 95% CI 2.11–3.46, p=0.04), depressive symptoms (OR 2.28, 95% CI 1.23–3.35, p=0.04), and lower anxiety with treatment (OR 0.11, 95% CI 0.02–0.52, p=0.005). 76–86 years: Greater prevalence of drowsiness (OR 20.77, 95% CI 12.14–26.31, p=0.02) and reduced anxiety about the disease (OR 0.13, 95% CI 0.03–0.62, p=0.01). Feeling at peace was less common (OR 0.38, 95% CI 0.002–0.64, p=0.02). 87–97 years: More likely to report pain (OR 11.38, 95% CI 8.11–16.63, p=0.02), anxiety about the disease (OR 9.39, 95% CI 4.11–11.47, p=0.005), and satisfaction with receiving requested information (OR 6.19, 95% CI 3.71–8.42, p=0.04). **Conclusions:** Distinct unmet needs were identified across age groups in older cancer patients receiving outpatient palliative care. Younger older adults (65–75) had higher physical and psychological unmet needs, while the oldest patients (87–97) were more likely to report pain and anxiety about their disease but experienced better communication. Tailored interventions addressing these specific needs are essential to improving patient-centered care. Research Sponsor: None.

Disparities in cachexia and anorexia in hospitalized female patients with breast cancer: A national population-based study.

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Background: Breast cancer is the most common cancer in females in the US. Cachexia and anorexia are common complications from either the disease itself or the treatment regimen. Specific disparities in the prevalence of anorexia and cachexia in female breast cancer patients is not known. This study seeks to address this gap in knowledge by comparing the prevalence of this issue among different demographic factors. **Methods:** The National Inpatient Sample (NIS) databases (2016–2021) of the Healthcare Cost and Utilization Project (HCUP) was used. We applied discharge weight (DISCWT) provided in the database to generate the national estimates. Pearson Chi-square test for categorical variables and Student's t-tests/one-way ANOVA for continuous variables were applied to compare the baseline demographics and hospital characteristics between the groups. The objective of the study was to determine demographic factors associated with increased cachexia, specifically race (African American vs all races), income (lowest quarterlies vs highest), Insurance type (private vs all types) and age (older than 65 years old vs younger). Multivariate linear and logistic regression models were used to adjust for confounders such as demographics, tobacco use, hypertension, COPD, Ischemic heart disease, prior CVA, and prior diagnosis of anorexia nervosa. **Results:** Anorexia, cachexia or malnutrition were documented in 12% of 1,037,185 hospitalizations of females with breast cancer. After adjusting for confounders, there were higher odds of anorexia and cachexia in patients of the African American race (aOR:1.28; CI 1.11 - 1.52; p-value < 0.001) and patients who are 65 years old or older (aOR:1.18; CI 1.06 - 1.35; p-value 0.015). Having a private insurance was associated with lower odds of anorexia and cachexia (aOR:0.69; CI 0.62 - 0.78; p-value < 0.001). There were no significant differences between patients of different levels of income. **Conclusions:** Female breast cancer patients of certain demographics have higher odds of developing cachexia or anorexia, a very common complication of breast cancer. Further considerations for these vulnerable populations should be studied and focused efforts should be made to ensure adequate healthcare access for all demographics. Research Sponsor: None.

Demographic studied	Prevalence of anorexia/cachexia (aOR, P-value, CI)
African American race vs all races	1.28, <0.001*, 1.11 - 1.52
Age ≥ 65 vs <65	1.18, 0.015*, 1.06 - 1. 35
Private insurance vs all insurance types	0.69, <0.001*, 0.62 - 0.78
Income (lowest quarterile vs highest)	1.05, 0.45, 0.81 - 1.23

*Statistically significant.

12098 Poster Session

Economic outcomes of palliative care in colorectal cancer hospitalizations: A propensity-matched retrospective cohort study on resource utilization.

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Background: The economic burden of colorectal cancer (CRC), a major cause of cancer-related death worldwide, is significant and is fueled by extended hospital stays, intensive treatments, and expensive end-of-life care, with costs expected to rise as the population ages. While clinical research has established the benefits of palliative care (PC) in improving patient outcomes, its economic impact within CRC care pathways remains underexplored. This study employs a large-scale, propensity-matched cohort analysis to evaluate the economic burden of PC integration during CRC hospitalization, addressing knowledge regarding the impact of early palliative interventions on healthcare expenditures and resource utilization. **Methods:** Utilizing data from the Global Collaborative Network-TriNetX, this retrospective cohort analysis evaluated the economic ramifications of early palliative care integration in adults (≥18 years) hospitalized with colorectal cancer. Using ICD-10 codes, we identified patients with malignant colorectal neoplasms, stratifying them into two cohorts: Cohort 1 (n=14,430) comprised individuals receiving palliative care within one month of diagnosis, while Cohort 2 (n=752,405) included those without palliative care exposure. Cohorts were balanced across sociodemographic and clinical variables via propensity score matching. Outcomes using surrogates for healthcare resource utilization and economic burden (inpatient, emergency department, and outpatient visits) were assessed over a 10-year follow-up period (beginning one day post-diagnosis). Results are reported as odds ratios (ORs) with 95% confidence intervals (CIs). **Results:** Following propensity score matching, two balanced cohorts (n=13,991 each) were established, with comparable baseline characteristics. The palliative care cohort had a mean age of 75.8 years, predominantly white—58.7%—and 54.3% males and 45.7% females—while the non-palliative care cohort averaged 76.3 years, predominantly white—59.8%—53.8% males and 46.2% females. Compared to the non-palliative care cohort, the palliative care cohort demonstrated significantly lower risks of inpatient admissions (OR 0.371; 95% CI 0.333–0.413; $p < 0.001$), emergency department visits (OR 0.342; 95% CI 0.311–0.377; $p < 0.001$), and outpatient visits (OR 0.397; 95% CI 0.357–0.441; $p < 0.001$). **Conclusions:** Our study found that early integration of palliative care (PC) in colorectal cancer (CRC) hospitalizations is associated with significant cost savings, achieved through reduced utilization of resource-intensive services, including inpatient, outpatient, and emergency department admissions. These findings suggest that PC could have a positive impact on financial sustainability and end-of-life quality while alleviating the economic burden on healthcare systems and individuals. Research Sponsor: None.

12099 Poster Session

"The telehealth means I get distance from the hospital so I don't feel so much like a patient": A qualitative sub-study examining the acceptability of nurse-led follow-up for ovarian cancer via telehealth using the MOST-S26 to structure consultations.

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Background: The MOST-S26 is a patient-reported outcome measure that complements follow-up after first-line treatment for ovarian cancer (OC). MOST-S26 enables assessment of physical and psychological symptoms, and well-being. A randomized trial was conducted to evaluate nurse-led follow-up for OC via telehealth using the MOST-S26 to structure consultations vs routine hospital follow-up (ACTRN12620000332921). A qualitative sub-study assessed acceptability of the intervention from patient and nurse perspectives. **Methods:** Semi-structured interviews via video or telephone explored experiences of receiving or delivering nurse-led follow-up. Patients that participated in at least two nurse-led follow-up appointments were eligible. Study nurses delivering the intervention were interviewed at the end of the trial. Interviews were recorded, transcribed and coded using a Framework Approach following five stages: familiarisation, developing a thematic framework, indexing, charting, mapping and interpretation. **Results:** From June 2021, 38 patients were enrolled at 6 Australian sites. The trial closed to acrual in April 2024. Twenty-one participants were interviewed (15 women with OC and 6 study nurses). Analysis identified 3 overarching themes: (1) *key patient-centred benefits* (convenience and flexibility; providing a sense of connection and feeling cared for; enabling personalised, holistic care and prompt management of symptoms; providing dedicated space for patients' to freely express experiences and emotions); (2) *challenges to delivery from nurses' perspectives* (emotional impact of patients' cancers recurring; lack of referral pathways; inability to observe physical cues; difficulties establishing rapport; and, lack of suitability for all patients e.g. non-English speaking or patients with low literacy); and, (3) *Nurse views on usefulness of MOST-S26 to support consultations* (provides a useful tool to guide consultations/referrals, detect recurrence, track symptoms over time, flag symptoms for discussion, and, helps patients' reflect on their symptoms). **Conclusions:** Results confirmed acceptability of this type of follow-up for both OC patients and nurses. Both reported several benefits compared with standard hospital-based follow-up. Challenges that should be considered prior to routine implementation of this follow-up model included: the need to provide support to nurses to cope with the emotional impact of patients' cancers recurring; developing clear referral pathways for symptom management; and considering the characteristics of patients most and least suitable for this type of follow-up. Clinical trial information: ACTRN12620000332921. Research Sponsor: Western Australia Health Translation Network; Australian Government's Medical Research Future Fund; Australia and New Zealand Gynaecological Oncology Group; Jakovich Family; The Ladybird Foundation.

12100 Poster Session

Telemedicine-enabled synchronous medical oncology and home hospice visits.

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Background: Hospice is underutilized at end-of-life by patients with cancer. Among the barriers to earlier acceptance of hospice may be the perceived loss of the therapeutic alliance and emotional support provided by the oncology team once the hospice team starts care. With the growing utilization of telemedicine, we sought to understand patient, caregiver, hospice nurse, and oncologist perceptions of synchronizing home hospice visits by the hospice nurse with remote telemedicine visits performed by the oncologist in their clinic. **Methods:** Thirty-four newly enrolled hospice patients (age 57-90+; 20 female & 14 male; 28 white non-Hispanic,1 white Hispanic, 3 black/African American, 2 other; 19 married, 3 single, 3 divorced, 1 significant other, 7 widowed, 1 other) and 34 caregivers were consented to an IRB-approved study between 5/14/21-9/9/24. Home hospice nurse visits were coordinated with the oncologist's clinic schedule and telemedicine visits were securely conducted through Epic MyChart functionality. Mixed methodology was utilized with patients, caregivers, hospice nurses and oncologists completing five-point Likert-scale surveys at baseline and subsequent serial surveys for patients and caregivers. **Results:** All groups rated improvement in overall communication. Likert scores for ease and quality of communication improved for oncologists (3.0 to 1.5) and nurses (2.0 to 1.0). Therapeutic alliance scores for patients and caregivers were stable and improved for oncologists (2.5 to 1.5) and nurses (2.0 to 1.5). **Conclusions:** Patients and caregivers expressed highly favorable ratings of hospice experience at baseline and improvement with telemedicine visits. There was no degradation in patient and caregiver therapeutic alliance scores, suggesting preservation of patient experience. Improvement among oncologists and hospice nurses was seen for both communication and therapeutic alliance scores once synchronous telemedicine hospice visits were instituted. These findings suggest that all four groups found value in oncologist-hospice patient telemedicine visits. Qualitative interviews and thematic analysis of caregivers' impressions of the program continue to identify how better to support patients and caregivers during home hospice care. Research Sponsor: None.

Quantitative results.

			Baseline Score Median (IQR)	Improvement in Score Median (IQR)
Patient	Communication	Overall	2.0 (1.25-2.75)	1.0 (0.5-1.0)
	Therapeutic Alliance	Support received from oncologist	2.0 (1-3)	0.0 (-0.5-2.5)
Caregiver	Communication	Overall	2.0 (1.75-3)	1.0 (0.0-1.0)
	Therapeutic Alliance	Support received from oncologist	1.0 (1-3)	0.0 (0.0-0.0)
Oncologist	Communication	Overall	3.0 (2-4.75)	2.0 (0.0-3.0)
	Therapeutic Alliance	Connection	2.5 (2.0-3.0)	1.0 (0.0-2.0)
Hospice Nurse	Communication	Overall	2.0 (2-2.75)	1.0 (0.0-1.0)
	Therapeutic Alliance	Connection with patient & family	2.0 (1-2)	0.5 (0.0-1.0)

IQR – interquartile range.

12101 Poster Session

Evaluating the feasibility of a peer-support group for patients with cancer (presently).

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Background: Many patients with cancer experience significant mental health challenges (commonly depression, anxiety, and adjustment disorders) which can impair quality of life and treatment adherence. Despite this, few seek mental health care due to barriers such as stigma, limited resources, and lack of suitable programs. We sought to determine the feasibility of "Presently", a novel, trauma-informed, virtual, peer-support program for patients regardless of cancer type or treatment, facilitated by trained cancer survivors. **Methods:** An 8-week pilot was implemented at Kaiser Permanente San Francisco, allowing self-enrollment. Demographic and clinical utilization data were collected from one year prior to the program through its completion (9/1/23–11/1/24). Post-program evaluation included surveys and participant feedback sessions. **Results:** Of 42 self-enrolled patients, 31 (74%) attended at least one session, averaging 4 sessions per participant. Most attendees were female (87%) and white (68%). Mental health comorbidities were prevalent, with 59% having an active diagnosis and 34% prescribed psychotropic medications. Participants represented diverse cancer types: breast (32%), lymphoma (24%), genitourinary (21%), gastrointestinal (10%), leukemia (7%), lung (3%), and pre-cancerous (3%). Disease stages varied: 38% local, 24% locally advanced, and 38% metastatic. Nearly half (48%) were undergoing active treatment. In the year prior, attendees utilized more healthcare services, including 157% more oncology and 10% more primary care visits than non-attendees. Participant feedback was positive: 65% found Presently very effective in providing emotional support and 64% were highly likely to recommend it to others. Most participants (82%) found support from peers meaningful, with 71% appreciating staff facilitation and 59% valuing opportunities to help others. All non-attendees expressed interest in future participation. **Conclusions:** The Presently program demonstrated feasibility in supporting patients with diverse cancer diagnoses, stages, and mental health histories. Positive participant feedback underscores the potential for novel peer-led models to address the increasing mental health needs of patients with cancer. Future research will investigate clinical outcomes and potential reductions in healthcare utilization through larger-scale implementation. Research Sponsor: None.

Quality of life among oncology patients with distinct spiritual well-being profiles.

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Background: Individuals undergoing treatment for cancer experience multiple symptoms moderated by stress/resilience that impact quality of life (QOL). Spiritual well-being (SWB) is an understudied QOL component that may influence outcomes. Purpose: Identify SWB profiles and associations with symptoms, stress, resilience, and QOL. **Methods:** Patients with breast, gastrointestinal, gynecologic and lung cancer undergoing chemotherapy were enrolled in a symptom clusters study. Assessments included: SWB subscale of theMultidimensional Quality of Life Scale-Patient Version (MQOLS); Lee Fatigue Scale (LFS), Attentional Function Index (AFI), Spielberger State-Trait Anxiety Inventory (STAI), Center for Epidemiological Studies-Depression scale (CESD), General Sleep Disturbance Scale (GSDS); Perceived Stress Scale (PSS), Connor-Davidson Resilience Scale (CDRS) and MQOLS. Latent profile analysis (LPA) was used to identify the distinct SWB profiles. Differences among latent classes were evaluated using analysis of variance, Kruskal-Wallis, or Chi Square tests with a Bonferroni corrected p-value of <0.008. **Results:** Among 1324 patients, four distinct SWB profiles were identified (Table). Patients in the Low SWB class were older, better educated, and more likely to be male and White compared to other groups (all $p<0.008$). Low SWB patients reported greater fatigue, anxiety, and depression, poorer general health and mental health, and greater stress. Compared to High and Very High classes, patients in the Low and Moderate classes had lower resilience scores. Low SWB patients reported poorer QOL. **Conclusions:** Four distinct SWB profiles were identified. Patients with lower SWB reported higher symptom burden, higher levels of stress and poorer QOL. An evaluation of patients' SWB may assist clinicians to identify a modifiable condition that warrants targeted interventions. Research Sponsor: National Cancer Institute; CA134900.

Differences in symptoms, stress, resilience, and QOL scores among SWB classes.

Characteristics	Low (1) n=188 (14.2%)	Moderate (2) n=450 (34.0%)	High (3) n=421 (31.8%)	Very High (4) n=265 (20.0%)	Statistics
Evening fatigue (>5.6)	5.5 (2.1)	5.4 (2.1)	5.6 (2.0)	4.8 (2.3)	F = 8.61, p <.001 1, 2, and 3 > 4
AFI (<5.0 = Low, 5 to 7.5 = Moderate, >7.5 = High)	6.2 (1.7)	6.3 (1.8)	6.4 (1.8)	6.8 (1.8)	F = 6.40, p <.001 1, 2, and 3 < 4
STAI (>32.2)	38.2 (13.5)	34.4 (12.0)	33.4 (12.4)	30.6 (11.1)	F = 14.51, p <.001 1 > 2, 3, and 4 2 and 3 > 4
CESD (>16.0)	15.4 (10.9)	13.2 (9.8)	12.4 (9.4)	11.0 (8.6)	F = 7.95, p <.001 1 > 3 and 4 2 > 4
GSDS (>43.0)	55.5 (18.6)	54.1 (19.6)	51.0 (20.5)	50.0 (21.4)	F = 4.47, p = .004 1 and 2 > 4
PSS total (0 to 56)	20.8 (8.7)	19.2 (8.3)	18.1 (8.1)	16.3 (7.2)	F = 12.89, p <.001 1, 2, and 3 > 4 1 > 3
CDRS total (0 to 40)	28.1 (6.4)	29.2 (6.4)	30.7 (6.1)	32.0 (6.0)	F = 18.06, p <.001 1 and 2 < 3 and 4
MQOLS: Psychological well-being	4.8 (1.8)	5.4 (1.8)	5.6 (1.9)	6.0 (1.9)	F = 15.50, p <.001 1, 2, and 3 < 4 2 and 3 < 4
MQOLS: Social well-being	5.6 (2.0)	5.9 (2.0)	5.5 (2.0)	5.9 (2.0)	F = 2.60, p = .051

12103 Poster Session

Awareness of gestational surrogacy among female patients treated for cancer: A national survey.

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Background: ASCO and other international guidelines recommend fertility counseling at diagnosis for all reproductive-aged cancer patients. Yet, how commonly gestational surrogacy (GS) is presented as an option remains unclear. To date, there is very little data to inform the question. Our primary objective was to determine the proportion of cancer survivors aware of GS as an option for parenthood. For the purposes of this study, we defined a gestational surrogate as one who carries a pregnancy using an embryo from the intended parents or a donor embryo, and as such, has no genetic link to the fetus. **Methods:** We developed a national survey that covered fertility preservation options, with specific questions regarding GS. Survey validation and usability testing were conducted with 17 cancer survivors, providing input on the final instrument. Following IRB approval, the survey was disseminated online via REDCap in partnership with multiple cancer advocacy organizations between April and November 2024. All respondents had the ability to select multiple responses as appropriate. Frequencies, proportions, and 95% confidence intervals (CI) were calculated using SAS 9.4 (SAS Institute, Cary, NC). **Results:** 519 female participants completed the survey. By cancer type: 60.7% breast, 14.3% hematologic, 8.1% cervical/uterine, 4.4% ovarian, 3.7% GI, and 8.9% other. Mean age (SD) was 31.1 (6.6) at diagnosis and 36.8 (7.4) at survey response; 30% had children at diagnosis. Overall, 75.9% expressed a desire for children post-cancer at the time of their diagnosis. Among respondents, 302 (58.2%; 95% CI 54.0-62.4) reported that they were aware of GS at diagnosis. Among those aware of GS, a similar proportion learned about it through oncologists (32.1%; 95% CI 26.9-37.4) or REI specialists (31.1%; 95% CI 25.9-36.4). However, the majority learned about GS through non-clinical resources (73.2%; 95% CI 68.2-78.2), including internet/social media (46.0%; 95% CI 40.5-51.7). Of those aware, GS was actively considered by 134 (44.5%) participants, of which 20 (14.9%) pursued GS and 16 (11.9%) have had a child using GS. Of those who did not actively consider GS but who were aware, common barriers included cost (45.3%), not ready to build a family (41.4%), preference to carry the pregnancy (29.9%), and using/planning other methods (20.5%). **Conclusions:** GS is a common route to parenthood in the US and internationally. While almost 60% of participants were aware of GS as an option, the primary source of information was through non-clinical resources. These data indicate GS should be routinely included in fertility counseling at diagnosis, especially in cases where cancer treatment compromises the patient's ability to carry a pregnancy. Education is needed to ensure oncologists are equipped to provide access to accurate, patient-centered oncofertility care, including REI referral. Research Sponsor: None.

12104 Poster Session

Inclusion of gestational surrogacy in oncologist-led fertility counseling at cancer diagnosis: A national survey.

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Background: ASCO guidelines recommend that oncologists discuss infertility risks and fertility preservation early with reproductive-aged cancer patients. However, little is known about how often gestational surrogacy (GS) is presented as a parenthood option, or the factors influencing these conversations. GS is defined as someone who carries a pregnancy using an embryo from the intended parents or donor, with no genetic link to the fetus. We sought to assess the frequency and predictors of oncologist-provided GS counseling among a national cohort of female cancer survivors diagnosed at a reproductive age. **Methods:** We developed a REDCap survey on GS counseling experiences and demographic/cancer-related information, incorporating feedback from 17 survivors. The final survey was distributed nationally via multiple cancer advocacy organizations (April–November 2024). Fisher's exact tests, T-tests, and multiple logistic regression identified predictors of GS counseling, with $p < 0.05$ considered significant. **Results:** 519 female cancer survivors completed the survey. By cancer type: 60.7% breast, 14.3% hematologic, 8.1% cervical/uterine, 4.4% ovarian, 3.7% GI, and 8.9% other. Mean age at diagnosis was 31.1 (SD 6.6). 82.1% of patients recalled their doctor discussing the impact of cancer treatment on fertility. Only 18.7% received GS counseling from their oncologist. Patients with cervical/uterine (35.7%) and ovarian (30.4%) cancer were significantly more likely to receive GS counseling from their oncologist compared to breast (19.1%), hematologic (13.5%), GI (5.3%), and other cancers (8.7%) ($p = 0.007$). Patients who were younger age at diagnosis (mean 30.0 vs. 31.4 years, $p = 0.05$), had a younger current age (mean 34.2 vs. 37.4, $p < 0.001$), fewer years since diagnosis (21.3% < 5 years vs. 20.6% 6-10 years vs. 6.0% > 10 years since diagnosis, $p = 0.003$), and were childless at diagnosis (21.3% vs. 12.9% with children, $p = 0.03$) were significantly more likely to receive counseling. GS counseling did not vary by patient race, sexual orientation, relationship status, geographic location, income, or education. Logistic regression showed older current age (aOR 0.90; 95% CI 0.95-0.95) and having children at diagnosis (aOR = 0.56; 95% CI 0.31-0.98) predicted lower odds, while gynecologic cancer increased odds of GS counseling (aOR = 2.21; 95% CI 1.06-4.49). **Conclusions:** Fewer than 1 in 5 survivors received GS counseling from their oncologist, with younger, childless patients with gynecologic cancers more likely to be counseled. These findings highlight potential biases in counseling practices and underscore the need for systematic, equitable fertility discussions at diagnosis, before gonadotoxic treatment. Research Sponsor: None.

12105 Poster Session

Using large language models to assess adherence to ASCO patient-oncologist communication standards.

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Background: The American Society of Clinical Oncology (ASCO) convened a multidisciplinary panel resulting in patient-oncologist communication guidelines published in 2017. These guidelines contain recommendations across topics including goals of care, treatment selection, end-of-life care, facilitating family involvement, and clinician training in communication. Ideally, these conversations should be documented in the electronic health record (EHR), so that they can be referred to at future visits as a patient's clinical course evolves. Tracking adherence to these communication guidelines may be beneficial for quality improvement efforts. However, manual chart review of unstructured free text notes is tedious and burdensome. The recent development of Large Language Models (LLMs) may represent a new computational approach that can capture such documentation more efficiently than chart review. To our knowledge, no prior study has used LLMs to capture such documentation in free text notes, validated against gold-standard manual chart review. **Methods:** As part of a larger study on development of LLMs for tracking palliative care quality measures, we randomly selected 30 patients with advanced cancer and clinical notes in the month following navigation to a poor prognosis treatment node. We used *GPT-4o-2024-05-13*, our HIPAA-secure tool, to develop an LLM prompt for identifying 14 ASCO communication domains in clinical text. The LLM prompt required output to generate source text to support identification of a communication domain. A "hallucination score" was calculated for source text, which is a measure of evidence produced by LLMs not found in source text. We then compared to gold standard manual chart review using standard performance metrics. **Results:** Across communication domains, note-level LLM analysis achieved sensitivity ranging from 0.43-1.0, specificity ranging 0.32-0.99, and accuracy ranging 0.51-0.99. Examples of documentation identified by both the LLM and chart review include goals of care and prognosis ("recently informed that her disease had progressed with treatment. Currently on 'last line' of chemotherapy"), treatment options and clinical trials ("her oncologist recommended a potential trial treatment, and she is contemplating involvement in this"), end-of-life care ("if her cancer continues to progress with her current treatment, they will transition her care to home hospice for comfort measures only"), and cost of care ("financial insecurity - referred to resource specialist"). Average hallucination index for documentation identified by the LLM was low. LLM frequently identified information missed by annotators. The LLM extracted information relevant to communication domains in a fraction of the time required by manual chart review. **Conclusions:** LLMs can identify communication domains in EHRs, potentially contributing to quality improvement efforts. Research Sponsor: National Institute on Aging; National Cancer Institute.

12106 Poster Session

The association between emotional distress prior to receiving immune checkpoint inhibitors and overall survival among patients with cancer: A population-based study.

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Background: Immune checkpoint inhibitors (ICIs) are widely used across cancer care. Emerging evidence from smaller studies links pretreatment emotional distress (ED) to poorer outcomes in patients with melanoma and non-small cell lung cancer undergoing ICIs due to changes in inflammatory states but large-scale studies are lacking. We conducted a population-level retrospective cohort study to assess the impact of pre-treatment ED on overall survival (OS) across solid tumor patients treated with ICIs. **Methods:** Using population-level administrative data, a cohort of patients with cancer, age 18 years or older, who received at least one dose of an ICI between June 2012 to October 2018 in Ontario, Canada, were identified using systemic therapy databases. Databases were deterministically linked to obtain socio-demographic, clinical co-variates, pre-treatment ED levels, and overall survival. ED was defined as having the sum of the Edmonton Symptom Assessment Scale (ESAS) anxiety and depression score ≥ 4. Multivariable Cox proportional hazard models assessed the association between ED and OS, adjusted for age, sex, body mass index, history of autoimmune conditions, cancer centre facility level, comorbidity score, and hospitalization within 60 days prior to starting ICI. **Results:** Among the 3237 patients who received ICIs and completed the ESAS prior to ICI treatment, most were male (58%), median age 67 years (IQR 59-74), the median combined ESAS anxiety and depression score was 3 (IQR 0-7); 45% had pre-treatment ED. The majority had lung cancer (49%), melanoma (37%) or renal cancer (9%), and were either treated with nivolumab (42%), pembrolizumab (36%) or ipilimumab (19%). Median OS was 330 days. Pre-ICI treatment ED was associated with poorer OS (aHR = 1.23, 95% CI [1.12–1.34] $P < 0.0001$) and when analyzed as a continuous variable, a higher combined ESAS anxiety and depression score was associated with poorer OS (aHR = 1.02 per 1 unit increase, 95% CI [1.01-1.03] $P < 0.0001$). Pre-treatment ED was associated with poorer OS for both males (aHR_{males}= 1.27, 95% CI [1.12–1.43] P = 0.0001) and females ($aHR_{females}$= 1.18, 95% CI [1.03–1.36] P = 0.02). Among disease sites, ED was associated with reduced OS among patients with lung cancer (aHR = 1.33, 95% CI [1.17–1.51] $P <$ 0.0001) and showed a similar but non-significant trend among patients with melanoma (aHR = 1.14, 95% CI [0.98–1.32] P = 0.09); while ED not significantly associated OS for patients with renal cancer (aHR = 0.98, P = 0.89). Similar results were observed across sexes and disease sites when evaluating the combined ESAS anxiety and depression score and OS. **Conclusions:** Among patients receiving ICIs, pretreatment ED is associated with poorer OS. These findings suggest the importance of screening for and addressing ED as a part of routine cancer care, which may potentially influence ICI treatment outcomes. Research Sponsor: University of Toronto; Conquer Cancer, the ASCO Foundation.

12107 Poster Session

Effect of a single home visit on distress in cancer patients undergoing chemotherapy: A comparative study.

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Background: This study aimed to investigate whether a home visit after the first chemotherapy can significantly reduce cancer patients' psychological distress levels. **Methods:** The National Comprehensive Cancer Network Distress Thermometer and problem list was used to assess patients' level of distress on a scale from 0 to 10, with scores of 4 or higher considered a high level of distress. Between 01 Mar and 01 Nov 2024 chemotherapy naïve cancer patients were divided into two groups – the study group had a home visit by a medical oncologist within 10 days after the start of their 1st chemotherapy, and the patients in the control group were only seen at the clinic before the start of their 1st and 2nd chemotherapy course. During the home visits, a patient-led discussion was held, in which the oncologist answered various questions about the patient's staging, prognosis, therapy and its anticipated effects. Home visits were offered to all patients, but only those who opted in received them. All patients in both groups had their distress levels assessed at two time points – before the start of 1st chemotherapy course and before the start of the 2nd chemotherapy course. Responses were analysed and compared between the two groups. **Results:** The level of psychological distress was assessed in 126 patients with solid tumours; of them, 88 (69.8%) opted in for a home visit and formed the study group, while 38 refused and were only seen at the clinic and served as the control group. Mean age in the study group was 60.6±12.4 and 56.9±14.4 for the controls. In both groups, breast, lung, and colon cancer prevailed. High baseline levels of distress (before the start of chemotherapy) were similarly prevalent in both groups: 72.7% of the home visit group and 65.8% of the control group scored 4 or higher. McNemar's test showed that the number of patients with high levels of distress at the second interview was significantly reduced in the home visit group, from 72.7% to 53.4% ($p < 0.001$), in contrast to the controls, where it remained almost unchanged from 65.8% to 68.4%. In addition, the Wilcoxon test showed that one home visit significantly decreased the level of distress in the study group, from 4.9±2.6 to 3.4±2.5 ($p < 0.001$). In contrast, distress levels in the control group, comprising patients who declined home visits, showed no significant improvement, barely dropping from 4.6±2.8 to 4.2±2.7 ($p = 0.263$) between the first and second interviews. **Conclusions:** This study demonstrates that a single home visit by an oncologist after the start of chemotherapy can significantly reduce distress levels in cancer patients and thus enhance overall patient well-being.
Research Sponsor: None.

12109 Poster Session

Promoting resilience in stress management within patients with early stage breast cancer.

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Background: Women with breast cancer often experience persistent psychological distress, including fear of recurrence, which can be exacerbated in marginalized populations. Promoting Resilience In Stress Management (PRISM) is an intervention initially developed for adolescents and young adults with serious illness that builds resilience utilizing skills-based coaching, which may be able to be adapted and deployed to address psychological needs of women with breast cancer. **Methods:** This pilot study examined PRISM's feasibility and preliminary effects in women with early-stage breast cancer undergoing chemotherapy. Six PRISM sessions were delivered individually by trained coaches, targeted getting to know participants, stress-management, goal setting, cognitive-reframing, meaning making, and family integration. Feasibility, the primary outcome, was defined as 70% of participants completing the PRISM intervention, baseline, and follow-up surveys. Secondary outcomes were measured using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, Feasibility of Intervention Measure, PROMIS-Global Quality of Life, Post-Traumatic Growth Inventory, Connor-Davidson Resilience scale, Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being, Fear of Cancer Recurrence Inventory, Patient Health Questionnaire Depression Scale, General Anxiety Disorder–Anxiety Scale, and Patient Activation Measure. Pre- and post- results were analyzed using paired t-tests for continuous measures and McNemar's test for categorical measures. Effect sizes were calculated using Cohen's d and Cramer's V. **Results:** From February to September 2024, 30 patients participated in the PRISM intervention pilot. The study population had a median age of 51 years (IQR 47-59), were predominantly Black (57%) and unemployed at the start of the study (37%). Two patients died, two withdrew, and one patient was lost to follow-up, resulting in a completion rate of 83%, meeting the primary feasibility endpoint. Patients reported that the sessions were acceptable (mean 4.6 [SD 0.7]), appropriate (mean 4.5 [SD 0.9]), and feasible (mean 4.6 [SD 0.4]).The largest effect was observed in participants' resilience (mean 4-point increase; d = 0.6). There was also a mean 14-point increase of patient growth and self-improvement (d = 0.5). Modest effect sizes were observed for improvements in overall spiritual well-being and reductions in fear of cancer recurrence (both d = 0.4). Small effects were observed for depression, anxiety symptoms, patient activation, global health, physical health, and mental health (d = range 0.1 to 0.2). **Conclusions:** The PRISM intervention was feasible amongst a diverse group of women with early-stage breast cancer and effect sizes suggest potential benefit, warranting further investigation in a future randomized control trial. Clinical trial information: NCT06133348. Research Sponsor: American Cancer Society.

Systematic screening of perception of curability among patients with advanced cancer: A longitudinal analysis.

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Background: Clinicians do not routinely assess patients' illness understanding despite its importance in decision making. Systematic screening of illness understanding is a novel approach that normalizes discussion of this sensitive topic, helps identify patients with information needs and allows clinicians to monitor and support their patients' understanding over time. In this study, we examined the changes in perception of curability over time in patients who completed systematic screening at our supportive care clinic (SCC). **Methods:** We implemented universal electronic systematic screening of illness understanding in our SCC using two questions from the Prognosis and Treatment Perception Questionnaire at consultation and every 2 months. We included all advanced cancer patients who completed screening at their consultation and at least one follow-up visit within one year. The primary outcome was patients' perception of curability, which was categorized as accurate if they reported the likelihood of cure as $< 25\%$. Patients were grouped into one of four categories based on responses at their first and last SCC visits: accurate-accurate, accurate-inaccurate, inaccurate-accurate and inaccurate-inaccurate. We examined patient characteristics associated with the inaccurate-inaccurate group versus all others using univariate and multivariate logistic regression analysis. **Results:** 432 patients (mean age 58 [SD 13], female n=248 [57.4%], white n=331 [76.6%]) were included. The mean number of SCC visits was 2.69 [SD 0.9] and the median duration between the first and last SCC visits was 157 days [IQR 129-194]. At visits 1, 2, 3, 4 and 5+, 34% [147/432], 37% [159/432], 36% [71/197], 38% [30/78] and 46% [11/24] of patients had an accurate understanding of their curability (p=0.24), respectively. Comparing the first and last visit, 233 [54%] were inaccurate-inaccurate, 119 [28%] were accurate-accurate, 52 [12%] were inaccurate-accurate and 28 [6%] were accurate-inaccurate. Asian race and greater well-being at baseline were associated with being inaccurate-inaccurate (Table). **Conclusions:** Systematic screening identified that only ~1 in 3 advanced cancer patients had an accurate understanding of their curability at SCC consultation and this did not improve significantly over time. Certain subgroups were more likely to remain inaccurate at last follow-up. Our findings highlight the need to systematically screen for illness understanding and to work towards bridging information gaps with better communication and coping support. Research Sponsor: None.

Multivariate analysis of patient characteristics associated with being in the inaccurate-inaccurate group.

Patient Characteristic	Odds Ratio	95% CI	p-value
Race (versus White)			
Asian	3.92	1.52-12.2	0.009
Black or African American	1.91	0.90-4.26	0.1
Edmonton Symptom Assessment System Well-Being	0.82	0.73-0.93	0.003

12111 Poster Session

A longitudinal analysis of social networks and patient-reported outcomes among young adult cancer survivors.

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Background: Nearly 80,000 young adults (YAs; aged 18-39) are diagnosed with cancer each year in the United States with > 80% expected to survive beyond 5 years. Social connectedness (connections/relations with others) is one of the most documented psychosocial factors cited as influencing health and well-being among YA survivors. However, given cancer diagnosis, treatment, and the challenging late effects, the social networks of YA survivors invariably change, including the quantity, quality, and types of relationships. Limited work has focused on identifying the extent of changes within YA survivors' social networks, such as the social network structure (network size) and social network composition (sociodemographic characteristics) that may confer risk. To understand this, we present preliminary data mapping the social networks of YA survivors, analyzing network changes over a 3-month period and associations with depression and anxiety. **Methods:** YAs (N= 25) completed a baseline social network questionnaire capturing social network structure (number of network members), composition (network member characteristics), and types of support each network member provides. YA survivors also completed measures of depression and anxiety at 3 months post baseline. Wilcoxon signed-rank tests assessed changes in social network metrics; correlations examined associations between baseline social network metrics and depression and anxiety at 3 months. **Results:** YA survivors (M_{age}= 27.0, SD= 5.4, range = 18-37) were majority female (56%) and white (56%). YA survivors reported a wide range of cancer diagnoses (leukemia, lymphoma, testicular, thyroid, breast) and were on average 2 years since diagnosis (M= 22 months). On average YA survivors' networks over 3 months contracted by 0.96 people (Z= -2.09, p= 0.036). Social networks changed compositionally over time, with a decrease in second degree relatives (Z= -2.066, p= 0.039) and male network members (Z= -2.17, p= 0.03), but no change in the mean age or in the number of female network members. The types of support that YA survivors received over time also changed, with a decrease in the amount of emotional support (Z= -2.03, p= 0.04). Only the number of parental network members at baseline was positively associated with depression (r= 0.53, p= 0.007) and anxiety (r= 0.51, p= 0.009) at 3 months. There were no other significant associations between baseline social network metrics on depression and anxiety scores at 3 months. **Conclusions:** Despite networks getting smaller and less heterogeneous over time, this was not associated with later depression or anxiety in our preliminary sample. More work is needed to inform the development and delivery of targeted social network interventions focused on intervening upon social network indicators to improve the long-term health and well-being of this vulnerable YA survivor population. Research Sponsor: Pediatric Hematology and Oncology Research Center of Excellence.

12112 Poster Session

Is metastatic cancer curable? A survey of medical oncologists.

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Background: More patients with metastatic cancer are living longer due to treatment advances like immune checkpoint inhibitors and targeted therapies. We aimed to determine oncologists' attitudes about the possibility of cure in metastatic cancer and to understand how they discuss cure with their patients. **Methods:** We invited medical oncologists and medical oncology trainees via a national mailing list and social media to complete a digital 21-question purpose-built survey. Descriptive statistical analyses were conducted. **Results:** Between September and October 2024, 127 respondents completed the survey. Median age was 39 years (IQR 36-45). Most participants worked in an Australian (64%) metropolitan (88%) public practice (56%), and 51% were women. Clinical experience ranged from <5 years (36%), 5 to 10 years (24%) and >10 years (34%) since oncology qualification; 6% were trainees. The most frequently treated cancer types were breast (55% of participants), lung (52%), and colorectal (50%). 82% reported thinking patients with metastatic cancer can be cured. The types of metastatic cancer that participants thought had the highest chance of cure were testicular (81%), melanoma (32%) and colorectal (16%) (Table). At the time of diagnosis, 51% of participants reported they would tell a patient with metastatic cancer that cure is possible. After delivering treatment for metastatic cancer, 29% reported telling some patients that they *have been* cured, while 74% reported telling some patients that they *may have* been cured. During treatment, 1%, 4% and 17% of participants thought a patient had been cured if the cancer had not progressed 1, 2, and 5 years after starting treatment. A greater proportion *thought* cure was a realistic possibility when discussing the benefits of immunotherapy (83%) compared to chemotherapy (40%), but only 44% and 27% respectively reported they would *tell* patients this. When discussing prognosis, most reported using multiple ranges of time with probabilities e.g. best-case, typical-case and worst-case scenarios (68%). **Conclusions:** Although most oncologists in this survey believed metastatic cancer is curable, only a minority would tell a patient with metastatic cancer they have been cured. Research Sponsor: None.

Median cure rates by disease as reported by participants.

Cancer type	Median cure rate (%)	IQR (%)
Testicular	81	71-88
Melanoma	32	20-50
Colorectal	16	9-25
Lung	13	6-21
Genitourinary	8	1-17
Breast	7	4-14
Gynaecological	6	1-12
Head and Neck	5	0-11
Gastroesophageal	2	0-7
Mesothelioma	2	0-7

12113 Poster Session

Sexual health communication and young-onset cancer (YOC): Healthcare practitioners' attitudes and practices.

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Background: Sexual health-related discussions are often challenging for Healthcare Practitioners (HCPs) and patients, making sexual health communication a frequently neglected aspect of cancer care. HCPs' lack of knowledge regarding LGBTQ+ cancer care contributes to greater unmet survivorship needs.We explored HCPs' attitudes and practices regarding sexual health-related discussions with YOC patients (25yrs–50yrs) to identify barriers and training needs for improving effective communication. **Methods:** A cross-sectional, mixed-methods design was employed. 160 HCPs working with patients with gastrointestinal and head & neck cancers at the Trinity St James Cancer Institute, Dublin, Ireland were invited to complete an anonymised 23-item online questionnaire. Data was analysed using descriptive statistics for quantitative responses, and thematic analysis for qualitative insights. **Results:** 52 respondents included; Medical Oncology (46.2%), Surgical Oncology (36.5%), Radiation Oncology (11.5%), Psych-Oncology (5.8%), and Palliative Care (5.8%). 34.6% (18/52) and 25.0% (13/52) reported 'rarely' and 'never' enquiring about sexual health-related issues during routine consultations. 34.6% (18/52) reported feeling 'somewhat' or 'very' unconfident initiating a sexual health-related discussion, while 5.7% (3/52) reported feeling adequately trained to enquire about sexual health-related issues. 43.1% (22/51) reported feeling 'somewhat' knowledgeable regarding the impact of cancer on sexual health, while 52.9% (27/51) reported they do not have sufficient knowledge regarding LGBTQ+ cancer care needs. Whilst 63.5% (33/52) agreed knowing a patient's sexual orientation and/or gender identity is relevant to their healthcare, 19.2% (10/52) reported asking about sexual orientation in routine practice. Notably, 98.1% (51/52) reported 'rarely' or 'never' enquiring about gender identity. Common identified barriers included: lack of training or knowledge (76.9% (40/52)), inappropriate time/setting (59.6% (31/52)), HCP discomfort (46.2% (24/52)), and patient discomfort (48.1% (25/52)). There was strong interest in receiving formal sexual health-related education and training, and 75.0% (39/52) believed access to a specialist for advice and/or to whom patients could be referred would increase HCPs confidence. **Conclusions:** HCPs acknowledged the importance of sexual health-related communication with YOC patients, yet significant gaps exist in knowledge, confidence, and training, particularly regarding the LGBTQ+ population.These findings underscore the need for targeted training and education to empower HCPs to engage in meaningful sexual health communication. Research Sponsor: None.

12114 Poster Session

Shared decision-making in follow-up care for lung cancer screening.

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Background: Shared decision-making (SDM) is a critical component of lung cancer screening (LCS) decisions to ensure patients understand the benefits, risks, and follow-up processes. Follow-up discussions on adherence to LCS present unique challenges, including managing patient expectations, addressing concerns about outcomes, and integrating smoking cessation efforts. This study uses The Centers for Disease Control and Prevention (CDC) SHARE model to examine SDM dynamics to identify areas for improvement in patient-provider communication. **Methods:** A thematic content analysis using ATLAS.ti was conducted by four trained coders on transcripts from primary care provider (PCP) visits between September 2022 and May 2024 with 24 patients referred for LCS. Guided by the CDC SHARE model for SDM—Seek, Help, Assess, Reach, and Evaluate—consultations were analyzed to examine how PCP revisited prior screening attempts and results, engaged patients in follow-up screening decisions, and addressed barriers to continued screening and smoking cessation. Inter-rater agreement ranged from 83.8% to 92.3%. Code prevalence was assessed using frequency counts (i.e., groundedness). **Results:** Five themes from the SHARE model were identified: (1) Evaluating prior LCS decisions made in the past (15), (2) Seeking patient participation in the SDM process by explicitly communicating that a choice about LCS adherence still exists (n = 7); (3) Helping patients explore the risks and benefits of LCS, including clarifying potential risks and outcomes (n = 13); (4) Assessing patient values and concerns regarding LCS, such as fears about false positives or financial burden (n = 8); and (5) Reaching a decision about a new LCS, where PCP guided patients through the decision-making process and confirmed next steps (n = 21). In addition to the themes derived from the SHARE model, two new emergent themes were identified: (a) providing supportive talk and reassurance (n = 7) to address patient uncertainty and encourage engagement in LCS; and (b) addressing smoking cessation if patients indicated that they still smoke (n = 6), with discussions initiated primarily by PCP and narrowly focused on pharmacological treatments. Notably, LCS decision aids were not used or discussed in any consultation. **Conclusions:** This study identifies strengths and gaps in PCP communication during LCS discussions. While PCP assessed patient risk factors and facilitated screening decisions, significant gaps in SDM emerged. Smoking cessation discussions were limited, and decision aids were absent, highlighting missed opportunities for patient-centered care. Follow-up consultations for LCS require addressing barriers to adherence to LCS and integration of smoking cessation as a standard component of care. Incorporating decision aids could improve patient engagement and adherence to long-term screening recommendations.
Research Sponsor: None.

12115 Poster Session

Temporal trends of suicide among cancer patients: A SEER database analysis from 2000 to 2021.

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Background: Cancer is a known cause of morbidity and mortality, with over 2 million new diagnoses and 600,000 deaths projected in 2024. Some of the most common cancers have shown an increased incidence, including breast and prostate cancer. There is an increasing mortality trend towards younger populations, with colorectal cancer becoming the leading and second most common cause of cancer death in men and women younger than 50 years respectively. An estimated 20-25% of cancer patients suffer from depression, which alongside specific cancer diagnoses and demographic factors translates to increased suicidality. Here we attempt to elucidate the relationship between specific cancer diagnoses and suicide. **Methods:** We conducted a population-based cohort study of suicide/self-inflicted injury deaths among cancer patients using the National Cancer Institute Surveillance, Epidemiology and End Results Program (SEER) over the period 2000 through 2021. The SEER data is comprised of 22 different registries across the United States (US) which captures approximately 47.9% of the US population. We applied simple linear regression with total suicides as response variable and year as predictor variable to estimate the rate of change of the annual number of suicides among cancer patients. Subgroup analysis included sex, age group, household income, and the primary site of cancer. Results are reported as counts and percentage and the rates of change are reported as regression slope and 95% confidence interval (β, 95% CI). **Results:** A total of 16,156 suicide mortalities were identified of which 13,520 (83.7%) were male and 2,636 (16.3%) were female. The total number of suicides rose approximately ten-fold from 123 in 2000 to 1,211 in 2021 corresponding to β = 54.6 / year (95% CI 50.6 – 58.7). Male suicides rose from 107 in 2000 to 1,017 in 2021 (β = 44.6 / year (95% CI 41.7 – 47.5)) while Female suicides rose from 16 in 2000 to 194 in 2021 (β = 10.0 / year (95% CI 8.6 – 11.5)). The most common primary cancer sites were prostate 3,624 (22.4%), lung and bronchus 1,699 (10.5%), urinary bladder 1,108 (6.9%), and breast 977 (6.0%). Prostate cancer suicides increased from 16 in 2000 to 283 in 2021 (β = 14.0 / year (95% CI 12.9 - 15.1)). Lung cancer suicides rose from 36 in 2000 to 122 in 2021 (β = 2.6 / year (95% CI 12.9 - 15.1)). Breast cancer suicides rose from 4 in 2000 to 80 in 2021 (β = 4.0 / year (95% CI 3.3 – 4.7)). The distribution of ages among suicides was 14.0% for under 50 years old, 19.3% between 50 and 59, 27.8% between 60 and 69, 26.5% between 70 and 79 and 12.5% for 80 years old or greater, with each age group demonstrating significant increase in annual suicides over the period analyzed. **Conclusions:** A significant and increasing trend of suicide is observed across various cancers. Almost half (47.1%) of suicide attempts were among patients between 50 and 69 years. Males committed suicide more often than females, an exacerbation of the trend seen in the general population. Research Sponsor: None.

12116 Poster Session

Adequacy of immune checkpoint inhibitor-associated thyroid function monitoring following therapy.

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Background: Immune checkpoint inhibitor (ICI)-induced thyroid dysfunction is the most common endocrine immune-related adverse event. While ICI-induced thyroid dysfunction rates during therapy are well documented, data on post-treatment dysfunction is limited. Describing these rates is important as ICIs are increasingly used in the curative treatment setting. This study aimed to evaluate the rates of post-ICI thyroid dysfunction, evaluate for predictors of post-ICI thyroid dysfunction and assess adequacy of post-ICI thyroid function surveillance. **Methods:** A retrospective analysis of 3626 patients treated with ICIs for various malignancies and cancer stages within a single health system from March 2013 to December 2022 was conducted. Rates of clinically acted upon thyroid dysfunction (diagnosis or thyroid-directed medication) were evaluated before, during, and after ICI therapy, alongside rates of thyroid laboratory surveillance in the post treatment setting. A multivariate analysis evaluated the odds of developing clinically acted upon post-ICI thyroid dysfunction based on patient/treatment characteristics. Rates of clinically acted upon thyroid dysfunction were evaluated based on therapy duration. Statistical analyses were carried out using R V4.1.0. **Results:** Clinically acted upon thyroid dysfunction occurred in 8.1% of patients (294/3626) during treatment and 4.4% (159/3626) after treatment. However, in patients alive two months after ICI cessation, 53.9% (989/1834) had no post-ICI thyroid function tests performed. Among the 1170 patients with post-ICI thyroid labs and no prior dysfunction, 11.6% (136/1170) developed post-ICI thyroid dysfunction. Thirty percent of patients with abnormal TSH values and no clinically acted upon thyroid dysfunction prior to therapy discontinuation subsequently developed clinically acted upon thyroid dysfunction. The rate of post treatment thyroid dysfunction in patients who underwent thyroid test surveillance and received <9 months of therapy was 13.3% compared to 6.5% in those who received therapy >9 months. The odds ratio for developing post-ICI dysfunction were 1.76 (95% CI, 1.03 to 2.95) for patients with urologic malignancies compared to patients with respiratory malignancies as the reference group. **Conclusions:** Post-ICI thyroid dysfunction is frequent, with 11.6% of patients who undergo thyroid function surveillance being affected. Patients with abnormal TSH before ICI discontinuation and those who received treatment for <9 months as well as those with urologic malignancies may benefit from more stringent post-ICI surveillance. Research Sponsor: None.

12117 Poster Session

Equivalence of Ina, an AI-based nutrition platform, to human dietitians for counseling patients with cancer.

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Background: Addressing nutritional issues in patients with cancer can reduce symptoms, shorten hospitalizations, enhance treatment adherence, and improve quality of life. However, most patients never receive nutrition counseling due to dietitian workforce shortages and healthcare access disparities. Advances in artificial intelligence (AI) and high rates of mobile device utilization among all demographics provide opportunities to expand reach. This study assessed if guidance from an expert-designed AI nutrition platform, "Ina", is equivalent to that of human Oncology-Credentialed Registered Dietitians (RD-CSO). **Methods:** RD-CSOs were recruited from a professional message board and grouped by quartiles of RD experience (yrs). We randomly selected 1 from each quartile as "Responders" (n = 4) and 3 with >10 yrs experience as expert "Reviewers" (n = 3). To compare Ina to RD Responders, a list of 20 top oncology nutrition queries was developed and assigned to 10 hypothetical patient profiles representing common cancer types, comorbidities, side effects, food allergies and preferences. Both Ina and RD Responders answered the queries. The Reviewers then blindly rated each answer (n = 100) using a modified version of the validated Quality Assessment of Medical AI (mQAMAI) instrument, which individually scores domains of accuracy, clarity, relevance, completeness, and usefulness yielding a total score between 5-25. Within-query differences between Ina and Responders were expressed as mean differences (SD) and tested for significance using a Signed Rank or two-tailed paired T-test. Equivalence was defined a priori as a mean within-query difference < 5. **Results:** The criteria for equivalence was met and no statistically significant differences were found between the total scores of Ina and each RD Responder. Ina's average total score was superior to the combined RD Responders (19.3 vs 18.3, 95% CI [0.1,1.8]; p = 0.02). A descriptive analysis of individual mQAMAI domains demonstrated higher scores for Ina compared to averaged RD Responder scores (Table). Ina had a 54% faster response time (8.5 vs 18.5 min per 2 queries; CI [-0.21,-0.13]; $p < 0.001$) and 27% easier readability (Flesch-Kincaid grade level 7.2 vs 9.9; CI [-3.3,-1.9]; $p < 0.001$). **Conclusions:** Ina provides equivalent nutritional guidance to that of human dietitians for patients with cancer, with greater speed and readability. This technology offers a solution to meet the needs of patients with cancer in settings where access to dietitians is limited. Research Sponsor: Savor Health LLC.

Mean mQAMAI score.

	Total Quality Score	Accuracy	Clarity	Relevance	Completeness	Usefulness
AI-Platform Mean (SD)	19.3 (2.7)	3.9 (0.7)	4.2 (0.5)	4.1 (0.6)	3.3 (0.8)	3.8 (0.7)
RD Responders Mean (SD)	18.3 (3.0)	3.8 (0.7)	3.9 (0.6)	3.9 (0.6)	3.2 (0.8)	3.5 (0.7)
Mean Difference [95% CI]	0.9 [0.1,1.8]	0.1 [-0.1, 0.3]	0.3 [0.1, 0.5]	0.2 [0.0, 0.4]	0.1 [-0.1, 0.3]	0.2 [0.0, 0.4]
P val	0.02	0.06	0.001	0.04	0.36	0.02

Immune profiling to identify predictive biomarkers and highlights the potential efficacy of IL-6R blockade in checkpoint inhibitor–related myocarditis.

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Background: Immune checkpoint inhibitor–associated myocarditis (ICI-My) is a rare but potentially life-threatening complication. Advancing our understanding of its underlying immunological mechanisms is essential for the development of improved diagnostic tools and treatment strategies, with the aim of minimizing morbidity and mortality. **Methods:** This retrospective single-center study (July 2019–June 2024) identified 33 patients who developed ICI-My. A Comprehensive immuno-profiling was conducted using 49 cytokines, 7 traditional cardiac biomarkers, and 46 mass cytometry markers. These profiles were compared to the baseline levels of a cohort of 97 cancer patients prior to ICI treatment. The analysis assessed the identification of biomarkers for differentiating low and high-grade myocarditis and corticosteroids (CS)-refractory ICI-My. The therapeutic efficacy of tocilizumab was assessed in eight cases of CS-refractory myocarditis. **Results:** ICI-My patients showed marked elevations in IL-6, CXCL9, CXCL10, CXCL13, VEGF-A, and sCD25 compared with baseline cancer patients prior to ICI initiation. High-grade myocarditis was characterized by lower levels of CCL4 and CXCL12, with predictive accuracies of 78.6% and 82.1%, respectively. In contrast, conventional biomarkers (cTnT, cTnI, CK, CK-MB, NT-ProBNP, and d-dimers) failed to differentiate disease severity. Mass cytometry revealed a distinct immune profile in ICI-My, including increased immature neutrophils, reduced switched and unswitched memory B cells, elevated double-positive ($CD38^+$/$HLA\text{-}DR^+$) T cells across $CD4^+$ and $CD8^+$ subsets, decreased $CXCR5^+$ leukocytes, and diminished CXCR3 expression within all memory T-cell subsets. Notably, no complement activation was detected. HGF, CXCL10, and BDNF successfully discriminated patients requiring immunosuppression from those untreated (accuracies of 89%, 79%, and 79%, respectively), while IL-18 and CCL4 predicted the need for tocilizumab (TCZ) therapy (accuracies of 79% and 82%, respectively). This underscores the dual benefit of CCL4. In addition, all cases of corticosteroid (CS)-refractory myocarditis (n = 8), including those unresponsive to mycophenolate mofetil or infliximab, responded effectively to TCZ. **Conclusions:** This study provides the first comprehensive immuno-profile of ICI-My. CCL4 and CXCL12 outperformed some traditional cardiac biomarkers as prognostic tools, while IL-18 and CCL4 emerged as key predictors for tocilizumab therapy, which could offer a personalized therapeutic approach. The absence of complement activation indicates that cytokine-mediated and cellular pathways are central to ICI-My pathogenesis. Notably, the success of anti-IL-6 therapy in CS-refractory cases highlights new therapeutic opportunities, enhancing patient care and guiding future interventions.
Research Sponsor: CHUV pôle prioritaire.

12119 Poster Session

Comparison of two electroacupuncture regimens on symptoms and brain structures in breast cancer survivors: A randomized, controlled trial.

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Background: Although electroacupuncture (EA) has shown usefulness in managing neuropsychiatric symptoms in cancer survivors, a specific acupoint regimen has not been established. We conducted a randomized, controlled, patient- and assessor-blinded pilot trial to compare two EA regimens on neuropsychiatric symptoms and associated brain structural changes in breast cancer survivors. (Clinicaltrials.gov: NCT05283577). **Methods:** Breast cancer survivors who self-reported cognitive impairment, fatigue, insomnia, or psychological distress were randomized (1:1) to receive ten weekly therapeutic EA to target either neuropsychiatric-specific (nEA) or non-neuropsychiatric-specific (sham EA, sEA) acupoints. Outcomes were assessed using patient-reported outcomes (EORTC QLQ-C30, FACT-Cog, MFSI-SF), neurocognitive tests (CANTAB), and neuroimaging (measuring gray matter, white matter, cerebrospinal fluid, diffusion tensor metrics, and volume and mean intensity of the hippocampus) before and after treatment. We computed group-specific treatment effect sizes (Glass's Δ) adjusted for baseline variability using linear mixed models. A Pearson's correlation analysis was performed between the neurocognitive scores and the imaging metrics. Multiple testing was controlled via the Benjamini-Hochberg method, with statistical significance set at P-adjusted < 0.05. Adverse events (AEs) were graded with CTCAE v5. **Results:** Thirty-five participants were recruited, of which five dropped out, leaving 30 (86%) completing all treatment sessions. The average ($\pm$SD) age was 58.2 $\pm$12.2 years, with 66% non-Hispanic White, 77% holding a Bachelor's degree or higher, 94% received systemic treatment and/or radiotherapy for cancer, 86% reporting $\geq$2 neuropsychiatric symptoms. Both groups showed statistically significant pre-post medium-to-large effect sizes in perceived cognitive function, fatigue, and quality of life. nEA group observed significant improvement in cognitive domains of attention (ES=0.708, P-adjusted=0.004), memory (ES=0.488, P-adjusted=0.026), and emotional functioning (ES=0.664, P-adjusted=0.004). Neuroimages showed greater gray matter volume change (P=0.0327) and post-treatment hippocampus mean intensity (P=0.0468) in nEA versus sEA. In the nEA group, correlations were observed between attention and gray matter volume (P=0.0198) and between executive function and hippocampus volume (P=0.0204). All AEs were grade 2 or lower: nEA participants reported pain (n=1) and bleeding (n=1), while sEA participants reported numbness (n=2), bruising (n=1), nausea (n=1), and redness (n=1). **Conclusions:** Ten weeks of electroacupuncture targeting neuropsychiatric-related acupoints, compared to sham acupoints, improves neuropsychiatric symptoms in breast cancer survivors, supported by clinically relevant structural brain changes. Clinical trial information: NCT05283577. Research Sponsor: California Breast Cancer Research Program; UCI Anticancer Challenge.

12120 Poster Session

MOLGEN: Detecting new DPYD variants for the safer delivery of 5FU and capecitabine.

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Background: Adverse drug reactions (ADRs) pose a significant challenge to healthcare systems, leading to 6.5-15% of NHS hospital admissions costing over £2.2 billion annually. Genetic factors play a crucial role in predisposing patients to ADRs. One notable example is dihydropyrimidine dehydrogenase (DPD) enzyme deficiency, which affects the metabolism of anti-cancer drugs like 5-fluorouracil (5FU), capecitabine and tegafur. Current genetic testing in the NHS focuses on four DPYD gene variants associated with European populations, potentially leaving non-European populations at greater risk of drug toxicity. This study aims to expand the genetic evidence base by identifying additional DPYD variants. **Methods:** This observational study recruited patients who experienced grade 3 or 4 toxicities after receiving 5FU and capecitabine, despite undergoing standard DPYD genetic testing. Participants include both European and non-European patients meeting specified inclusion criteria. Blood samples were collected for genetic testing using either Sanger or next generation sequencing of exons and intron-exon boundaries. Clinical data, including administered dose and toxicity grade, were recorded. Clinicians received genetic results to inform discussions with patients about future treatment. **Results:** Fifteen patients experienced grade 3-4 toxicity despite standard testing. Of these patients, one patient was heterozygous for c.2846A > T, and therefore predicted to have decreased DPD activity. This patient was wild-type based on NHS standard testing, and was therefore treated with full dose capecitabine, resulting in Grade 3 diarrhoea and vomiting. However, the Clinical Pharmacogenetics Implementation Consortium (CPIC) dosing guideline suggests a 50% dose reduction in the presence of this variant. Three patients were found to be heterozygous for other DPYD variants, including c.771C > A, c.2786T > C, c.2766+1G > A, and c.1757T > C. for which there are no current dosing guidelines. The functional impact of these variants requires further study, currently ongoing. All three patients had severe reactions after 1-2 cycles of capecitabine, including one patient requiring a seven-week ICU admission for Grade 4 neutropenic sepsis. Seven patients have found to be heterozygous for DPYD variants that result in normal predicted DPD enzyme activity according to current knowledge, but again further work is needed. Four patients had no DPYD variants. **Conclusions:** By broadening the genetic analysis of DPD deficiency and identifying new variants, opportunities exist for enhanced patient safety and treatment efficacy. Expanding the variants in DPYD testing in the future, including those found in diverse ancestral populations could lead to improved dosing strategies and reduced the risk of severe ADRs. The findings have the potential to inform future NHS genetic testing protocols and promote equitable healthcare outcomes. Clinical trial information: iras 7086. Research Sponsor: None.

12121 Poster Session

NG11-2 phase-Ib trial to prevent/reduce severe oral mucositis induced by radiotherapy.

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Background: Radiation-induced oral mucositis (RIOM) affects up to 80% of people undergoing treatment for head and neck cancer (HNC), reaching nearly 100% in altered or accelerated fractional radiation. Current approaches necessitate multiple supportive care pharmacotherapies with no approved preventative pharmaceutical products available for the reduction of RIOM in patients with HNC. To address this unmet medical need an innovative oral topical vasoconstrictor solution (NG11-2) has been developed and a phase-Ib dose escalation study carried out to assess the safety and preliminary efficacy of NG11-2 in preventing/reducing RIOM in patients undergoing treatment for HNC. **Methods:** In this single arm, multi-centre, phase-1b "2+4" dose escalation study (NCT06669390) using NG11-2, 15 participants, with a diagnosis of HNC and scheduled to receive radiotherapy with at least 30Gy exposure to the oral cavity and/or buccal mucosa (with or without chemotherapy) were enrolled, with 2 each into the 0.92mg/mL, 1.83mg/mL, 3.66mg/mL and 5.5mg/mL dose cohorts. An additional 7 patients were enrolled in the 5.5mg/mL cohort as an expansion phase. Safety was the primary endpoint, with secondary endpoints including duration, incidence and time to onset of severe RIOM using World Health Organization [WHO], Radiation Therapy Oncology Group [RTOG], and National Cancer Institute-Common Terminology Criteria for Adverse Events [NCI-CTCAE] V5 grading criteria, with severe levels being Grade 3 or above. Patient Reported Outcome Measurements were also performed. The Kaplan-Meier method was applied to the expanded dose cohort to estimate the median duration, incidence and time to onset of severe RIOM. **Results:** No Dose Limiting Toxicities or Serious Adverse Reactions were observed during the study. The duration and incidence of severe RIOM were reduced in the 5.5mg/mL cohort (15.5 days and 44.4% using WHO criteria respectively, 14 days and 33.3% using RTOG respectively, 17days and 33.3% using NCI-CTCAE respectively), relative to the 0.92mg/mL cohort (18-46 days and 100% respectively using the WHO, RTOG and NCI-CTCAE criteria). **Conclusions:** NG11-2 is well tolerated in the patient population included in this study. NG11-2 shows encouraging preliminary efficacy results which support proceeding to larger scale confirmation studies. Clinical trial information: NCT06669390. Research Sponsor: None.

12122 Poster Session

Examining the link between p16, an aging biomarker, and a clinically meaningful functional outcome in older adults with early breast cancer.

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Background: Chemotherapy is thought to accelerate aging by disrupting fundamental processes of aging such as cellular senescence. Senescence is a state of terminal cell cycle arrest that is linked to increased inflammation, tissue damage, and impaired regeneration. In older adults with early breast cancer, treatment with neo/adjuvant chemotherapy is associated with persistent increases in circulating $p16^{INK4a}$ (p16) expression, an established biomarker of senescence. However, it remains unknown whether higher levels of p16 correlate with clinically meaningful aging outcomes, such as physical function, in older adults with early breast cancer. **Methods:** We analyzed a prospective cohort of 501 adults age >65 with stage I-III breast cancer receiving neo/adjuvant chemotherapy. We assessed physical function using the timed up and go test (TUG), at two time points: pre-chemotherapy (T1) and post-chemotherapy (T2). The TUG score was measured as the time (in seconds) a participant takes to stand up from a standard armchair, walk 3 meters, turn around, walk back to the chair, and sit down. We collected blood at T1 and quantified p16 expression levels in circulating CD3+ T lymphocytes. Expression of p16 was determined using TaqMan quantitative reverse-transcription polymerase chain reaction. We calculated the Spearman correlations to examine the relationship between blood p16 levels at T1 with TUG score at T1, at T2, and change in individual TUG score from T1 to T2. **Results:** The median age of participants was 70 years (range 65-86). The majority (64.4%) had stage II/III disease and 58.1% received an anthracycline. Baseline TUG scores were available for 467 participants and baseline p16 data were available for 317 participants. The mean baseline p16 level was 10.2 $\log_2$ p16 units (SD = 0.9). Mean TUG scores were 11.4 sec (SD = 4.6) at T1 and 11.5 sec (SD = 5.3) at T2. The mean change in TUG score from T1 to T2 was 0.3 (SD = 4.2). There was no significant correlation observed between p16 and TUG score at T1 ($r = 0.11$, $p = 0.05$), T2 ($r = 0.06$, $p = 0.36$), or the change in TUG score from T1 to T2 ($r = 0$, $p = 0.99$). **Conclusions:** In this cohort of older adults with early breast cancer treated with neo/adjuvant chemotherapy, we did not find a correlation between pretreatment p16 and physical function as measured by TUG. Future studies are needed to understand the role of biological aging markers in improving precision risk assessment of treatment toxicity in older adults with cancer. Clinical trial information: NCT01472094. Research Sponsor: U.S. National Institutes of Health; R01 AG037037.

Effect of IV magnesium supplementation in reducing adverse cisplatin associated kidney outcomes.

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Background: Cisplatin is a commonly used chemotherapy agent that is associated with significant nephrotoxicity due to renal tubular cell injury. IV magnesium (mg) has emerged as a potential agent for preventing cisplatin-induced kidney injury. This study aims to explore the efficacy of IV mg in reducing cisplatin induced major adverse kidney events (MAKE). **Methods:** This is a retrospective observation cohort study of the TriNetX research network (with NLP) which included 105 Health care organizations (HCOs). Patients who received first dose of IV Cisplatin between 09/30/2004 to 09/30/2024 were included. Cohort further divided into two groups based on IV Mg supplementation during chemotherapy: IV Mg and Control groups. To mitigate potential confounding variables, we conducted 1:1 propensity score matching (PSM) that involved 42 variables covering demographics, comorbidities, medications, and laboratory results. The primary outcome of interest was MAKE, defined as stage 3 AKI, Dialysis or eGFR $<$ 15 ml/min/1.73m2, Death at 30 days. Secondary outcomes were mortality and dialysis needing AKIs at 30 days. Adjusted hazard ratios (AHRs) with 95% CIs and P values were calculated using Cox proportional hazards regression models for all outcomes. The Kaplan-Meier method was used to estimate survival probabilities after PSM, considering 2-sided $p < .05$ as statistically significant. Sensitivity analyses with different observations and study window and subgroup analysis were done. **Results:** Our analysis consisted of 106,141 adults who received their first dose of IV Cisplatin. After excluding 519 patients with previous ESRD, 23,761(age 60.1+12.6, Male-51.8%, White-75.1%) were in IV Mg group(22.5%) and 81,861 (age 56.2+14.5, Male-58.5%, White-40.9%) in control group(77.5%). After PSM, each group had 20,647 participants. MAKE incidence was 586/20647(2.84%) in IV Mg group vs. 1934/20647(9.37%) in the control (aHR 0.28; 95% CI, 0.26-0.31). The mortality incidence was 274/20,647(1.33%) in the IV Mg group compared to 515/20,647 (2.49%) in the control group (aHR 0.53; 95% CI, 0.45-0.61). Dialysis needing AKIs were 27/20,647(0.13%) in IV Mg group vs. 102/20,647(0.49%) in control group (aHR 0.26; 95% CI, 0.17-0.40). Sensitivity analysis with 90 days observation window and last 5 years of study period (09/30/2019 to 09/30/2024) and different subgroup analysis showed consistent results. **Conclusions:** IV mg supplementation is associated with reduced MAKE and mortality in patients receiving cisplatin. Research Sponsor: None.

Baseline characteristics of patients after propensity score matching.

Characteristic	IV Mg group	Control	Std Diff
Demographic			
Age, mean	59.5(12.9)	59.1 (13.7)	0.035
Male, n (%)	10810 (52.36%)	10724 (51.94%)	0.008
White, n (%)	14834 (71.85%)	15095 (73.11%)	0.028
Hispanic, n (%)	1248 (6.04%)	1478 (7.16%)	0.045
Comorbidities, n (%)			
Malignant neoplasms of ill-defined, other secondary and unspecified sites	10789 (52.26%)	10700 (51.82%)	0.009
Hypertension	8408 (40.72%)	8402 (40.69%)	0.001
Malignant neoplasms of Head and Neck	4844 (23.46%)	4427 (21.44%)	0.0482
Hyperlipidemia	4801 (23.25%)	4670 (22.62%)	0.015
Nicotine dependence	4478 (21.69%)	4445 (21.53%)	0.004
Type 2 diabetes mellitus	3048 (14.76%)	3035 (14.7%)	0.002
Ischemic heart diseases	2554 (12.37%)	2534 (12.27%)	0.003
Chronic obstructive pulmonary disease	2403 (11.64%)	2292 (11.1%)	0.017
Cerebrovascular diseases	1038 (5.03%)	1043 (5.05%)	0.001
Chronic kidney disease	933 (4.52%)	893 (4.33%)	0.009
Heart failure	698 (3.38%)	726 (3.52%)	0.007
Medications, n (%)			
Beta-Blockers	6594 (31.94%)	6655 (32.23%)	0.006
Proton pump inhibitors	6018 (29.15%)	6111 (29.6%)	0.01
Statin	4911 (23.79%)	4949 (23.97%)	0.004
RAS Blockers	4739 (22.95%)	4664 (22.59%)	0.009
Diuretics	4475 (21.67%)	4666 (22.6%)	0.022
NSAIDS	4155 (20.12%)	4348 (21.06%)	0.023
Allopurinol	662 (3.21%)	776 (3.76%)	0.03
Gemcitabine	522 (2.53%)	465 (2.25%)	0.018
Methotrexate	448 (2.17%)	391 (1.89%)	0.02
PD-1/PDL-1 inhibitors	325 (1.57%)	314 (1.52%)	0.004
Doxorubicin	288 (1.4%)	304 (1.47%)	0.007
VEGF/VEGFR inhibitors	226 (1.1%)	208 (1.01%)	0.009
Zoledronic acid	203 (0.98%)	207 (1%)	0.002
Cyclophosphamide	159 (0.77%)	165 (0.8%)	0.003
Pemetrexed	111 (0.54%)	113 (0.55%)	0.001
Ifosfamide	21 (0.1%)	46 (0.22%)	0.03
Laboratory			
Blood Pressure, Systolic	125.8 (20.5)	125.3 (20.5)	0.025
BMI, mean (SD), kg/m2	27.6 (6.5)	27.2 (6.5)	0.059
>= 30 kg/m2, n (%)	5930 (28.72%)	5993 (29.03%)	0.007
Sodium, mean (SD), mmol/L	138.2 (3.2)	137.9 (3.5)	0.075
Potassium, mean (SD), mmol/L	4.2 (0.4)	4.1 (0.5)	0.09
Creatinine, mean (SD), mg/dL	0.87(1.42)	0.85 (0.35)	0.018
Hemoglobin A1c, mean (SD), %	6.5 (2.0)	6.4 (1.5)	0.102
Hemoglobin, mean (SD), g/dL	12.7(2.1)	12.4 (2.1)	0.163
< 10 g/dL, n (%)	4444 (21.52%)	4671 (22.62%)	0.027
Albumin, mean (SD), g/dL	3.9(0.6)	3.8 (0.6)	0.187
< 3 g/dL, n (%)	3175 (15.38%)	3413 (16.53%)	0.031
Magnesium, mean (SD), mg/dL	1.96 (0.25)	1.97 (0.29)	0.039
< 1.7 mg/dL, n (%)	3853 (18.66%)	4065 (19.69%)	0.026

Exploring unmet needs in radiation-induced nausea and vomiting after moderately emetogenic treatment.

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Background: Despite their prevalence and clinical significance, interventions to improve radiation-induced nausea and vomiting (RINV) are insufficiently researched and prioritized. The 2020 ASCO Antiemetic guidelines categorize craniospinal radiation therapy (RT) as a moderate risk for RINV requiring 5HT3-RA prophylaxis +/- dexamethasone. Yet, RINV guideline implementation and associated clinical outcomes remain poorly characterized. **Methods:** We performed a retrospective analysis at an NCI-designated comprehensive cancer center. Our primary aim was to determine the proportion of adult patients with guideline-concordant antiemetics prescribed prior to craniospinal RT between 06/2020-10/2023. Patients were excluded if they received concurrent chemotherapy. We selected the first eligible RT regimen. Secondary aims included determining the proportion of consult notes documenting RINV risk, patient report of RINV, and correlating RINV with clinical variables using logistic regression. **Results:** A total of 212 patients met inclusion criteria, with a median age of 67 and 37% were female. The most common malignancies were prostate (27%), breast (14%), and lung (11%). At the start of RT, 44% had a prescription for a 5HT3-RA and 42% had dexamethasone prescribed for pain and/or edema. 41% of radiation oncology consult notes documented RINV as a risk of RT. Overall, 39% of patients reported RINV during or up to 10 days after RT. An increased risk of RINV was associated with a documented history of prior chemotherapy-induced nausea and vomiting (CINV; OR 2.50, p=0.017), younger age (OR 2.28, p=0.018), and a 5HT3-RA prescription prior to the start of RT (OR 1.76, p=0.047). There was no association between RINV and sex, prior chemotherapy, dexamethasone, or 5HT3-RA/dexamethasone combination at the start of RT. **Conclusions:** Despite the prevalence of RINV, standardized prophylaxis remains suboptimal for patients receiving craniospinal RT. A key opportunity exists to enhance patient outcomes by conducting prospective interventional studies to address this unmet clinical need.
Research Sponsor: None.

			Outcome: RINV (yes vs. no)	
Patient Characteristics	**Categories**	**N (%)**	**Odds Ratio (95% CI)**	**p-value**
Sex	Male^	133 (62.7)		
	Female	79 (37.3)	1.46 (0.82-2.57)	0.196
Age	≥55 yo^	170 (80.2)42 (19.8)	2.28 (1.15-4.56)	
	<55 yo			**0.018**
Prior exposure to chemotherapy	No^	124 (58.5)		
	Yes	88 (41.5)	1.08 (0.62-1.89)	0.783
Documented history of CINV	No^	179 (84.4)		
	Yes	33 (15.6)	2.50 (1.18-5.41)	**0.017**
5HT3-RA at RT start	No^	119 (56.1)93 (43.9)		
	Yes		1.76 (1.01-3.10)	**0.047**
Dexamethasone (pain, edema) at RT start	No^	123 (58.0)		
	Yes	89 (42.0)	0.75 (0.43-1.32)	0.328
5HT3-RA + dexamethasone at RT start	No^	169 (79.7)		
	Yes	43 (20.3)	0.92 (0.46-1.83)	0.825

^Reference level for logistic regression odds ratio (odds of RINV).

12125 Poster Session

Germline determinants of pneumonitis in patients with cancer treated with antibody drug conjugates.

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Background: Antibody-drug conjugates (ADCs) are now essential in the treatment of solid and hematologic cancers. While effective, ADCs can cause adverse events (AEs) requiring careful management. Pneumonitis, a potentially severe AE, may result in treatment discontinuation or mortality. However, its risk factors and underlying mechanisms remain poorly understood. **Methods:** Patients (pts) with solid or hematologic malignancies treated with ADCs at Dana-Farber Cancer Institute up to August 1, 2024, were screened. Only those with available genomic data were included. Pneumonitis was evaluated based on the Common Terminology Criteria for AEs v4.03. A total of 18 candidate single nucleotide polymorphisms (SNPs) linked to drug-related AEs and implicated in ADC metabolism pathways were identified using PharmGKB. SNPs were inferred from targeted panel sequencing using the STITCH pipeline, with 3 SNPs that could not be successfully imputed. The association between the SNPs, as probabilistic dosages, and occurrence of pneumonitis was tested using a multivariable Cox regression model, adjusting for age, sex, race, cancer type, and sequencing panel version. Pts were censored at the end of treatment or death. P-values were adjusted using the Bonferroni correction. **Results:** The study included 1,184 pts with cancer treated with ADCs, encompassing a total of 1,465 ADC treatments, as some pts received multiple lines of ADCs. The median age at treatment initiation was 60 years (interquartile range: 20). Most pts were female (80.7%). Breast cancer was the most common cancer (54.6%), followed by urothelial (13.3%), and ovarian (11.6%) cancers. The most frequently administered ADCs included trastuzumab deruxtecan (33.1%), sacituzumab govitecan (25.1%), and enfortumab vedotin (11.3%). A total of 92 pneumonitis events were observed in 89 pts (Table), among which 54 (58.6%) were grade 2 or higher. The prevalence of pts carrying the minor alleles (intermediate or poor metabolizers) of rs4646437 (CYP3A4) and rs776746 (CYP3A5) was 16.8% and 15.6%, respectively. Multivariable analysis revealed that carriers of the minor allele of rs4646437 (Hazard Ratio [HR]: 3.03, 95% Confidence Interval [CI]: 1.73–5.29, P= 0.001) or rs776746 (HR: 2.43, 95% CI: 1.56–3.81, P= 0.001) had a significantly higher risk of developing pneumonitis, after adjusting for age, sex, race, cancer type, and sequencing panel version. **Conclusions:** Our findings highlight the potential role of inherited genetic factors in modulating treatment-related toxicities of ADCs. Understanding these associations can provide valuable insights into personalized treatment strategies and inform risk assessment to optimize the safety and efficacy of ADCs. Research Sponsor: None.

Rates of pneumonitis.

	% per Group	N
Trastuzumab Deruxtecan	13.1	64
Mirvetuximab Soravtansine	8.4	10
Tisotumab Vedotin	5.0	1
Enfortumab Vedotin	3.6	6
Trastuzumab Emtansine	3.3	6
Sacituzumab Govitecan	1.3	5

12126 Poster Session

CDK4/6 inhibitor toxicity in geriatric subgroups: Evidence from the FAERS database.

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Background: Despite their widespread use, the safety of cyclin-dependent kinase 4/6 inhibitors (CDK4/6i) in geriatric patients remains underexplored. **Methods:** We conducted a retrospective analysis of cases reported in the FAERS database regarding CDK4/6i in female breast cancer patients from January 1, 2015, to September 30, 2024, focusing on hematological, gastrointestinal (GI), and liver toxicities. The cases were categorized into different age subgroups. **Results:** We identified 46,871 female patients with breast cancer treated with CDK4/6i (abemaciclib, n = 3,987 [8.5%]; palbociclib, n = 37,020 [79.0%]; ribociclib, n = 5,864 [12.5%]). According to multivariate analysis considering age subgroups, CDK4/6i type, and concomitant treatments, 75-84 age group had a lower risk of hematologic toxicity (OR = 0.93 [95% CI 0.86–1.00]; *P*= 0.040), with a similar trend identified in patients aged ≥85 years (OR = 0.88 [0.76–1.01)]; *P*= 0.077). Ribociclib was associated with a higher risk of hematologic toxicity (OR = 1.31 [1.17–1.47]; *P*< 0.0001), whereas palbociclib was associated with a reduced risk (OR = 0.90 [0.82–1.00]; *P*= 0.041). However, only 75-84 age group treated with abemaciclib (OR = 0.57 [0.41–0.77]) and ≥85 years group treated with palbociclib (OR = 0.85 [0.73–0.99]) showed a reduced risk compared to patients younger than 65, while no significant differences were found among age subgroups treated with ribociclib. Despite the overall higher risk of GI toxicity associated with abemaciclib (OR = 7.53 [6.65–8.56]; *P*< 0.0001), ≥85 years group showed a lower risk compared to patients younger than 65 (OR = 0.59 [0.38–0.88]). The overall risk of GI toxicity was also higher in patients treated with palbociclib compared to ribociclib (OR = 1.17 [1.04–1.31]), with no significant differences observed among the age subgroups. Among patients treated with ribociclib, 65–74 (OR = 1.33 [1.03–1.71]) and 75–84 (OR = 1.45 [1.06–1.96]) age groups showed a higher risk of GI toxicity, while no significant difference was observed in ≥85 years group (OR = 1.64 [0.79–3.04]). Ribociclib was associated with a higher risk of liver toxicity (OR = 1.37 [1.20–1.55]; P < 0.0001), whereas palbociclib was associated with a reduced risk (OR = 0.30 [0.27–0.34]; *P*< 0.0001). In both palbociclib- and ribociclib-treated patients, all geriatric age subgroups showed a reduced risk of liver toxicity (Palbociclib; 65-74 y, OR = 0.80 [0.70–0.91]; 75-84 y, OR = 0.49 [0.41–0.58]; ≥85 y, OR = 0.35 [0.23–0.51]; Ribociclib; 65-74 y, OR = 0.80 [0.67–0.96]; 75-84 y, OR = 0.51 [0.38–0.65]; ≥85 y, OR = 0.52 [0.25–0.95]). However, only 75-84 age group treated with abemaciclib (OR = 0.70 [0.49–0.97]) showed a reduced risk of liver toxicity. **Conclusions:** Our findings demonstrated that liver toxicity was lower across all geriatric age subgroups, and hematological toxicity was reduced only in 75-84 age group. There were no significant differences in GI toxicities among the age subgroups. Research Sponsor: None.

12127 Poster Session

Impact of health literacy in cancer outpatients receiving oral anticancer drugs and followed by the ONCORAL multidisciplinary city-hospital educational follow-up: The LITTORAL study.

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Background: Multidisciplinary follow-up is crucial to manage drug-related problems (DRP) associated with oral anticancer therapies (OAT). However, these approaches might fail to address social vulnerability determinants, such as a low level of health literacy (HL), which can be a barrier to patient education and contributes to inappropriate self-management of medications. This study aims to assess the impact of HL on relative dose intensity (RDI) of OAT and health-related quality of life (HRQoL) in cancer patients followed by Oncoral, a multidisciplinary program consisting in personalized face-to-face consultations with a pharmacist and nurse after each subsequent oncologist consultation, to prevent and correct DRPs. **Methods:** This prospective cohort study enrolled adult cancer patients who initiated OAT (baseline) from 11/03/2019 to 24/08/2022 and were followed by Oncoral for ≥6 months. HL was assessed at baseline using the HLS-EU16 questionnaire. The primary endpoint was RDI at 6 months, defined as the ratio between the prescribed dose of OAT and the optimal dose to be administered according to Summary of Product Characteristics. A RDI ≥80% was considered satisfactory, based on the literature. The secondary endpoint was the variation in HRQoL from baseline to 6 months of OAT, measured by the EORTC QLQ C30 questionnaire. **Results:** This study included 182 patients (58.2% male, median [range] age 69 [29-101] years), mostly with hematological malignancies (60.4%, including multiple myeloma 29.7% and chronic lymphocytic leukemia 11.0%) and breast cancer (12.1%). At baseline, the majority (71.8%) lived with a partner, 20.0% had children living at home. Most were retired (67.1%) but 18.2% worked full-time. Household incomes were inferior to French minimum wage for 20.6% of patients, and 20.6% only received elementary education. Mean HL score was 12.1 ± 3.12, 52.7% of patients having a HL score considered sufficient (13-16), 32.4% problematic (9-12) and 14.8% insufficient (0-8). RDI at 6 months was evaluable for 135 patients (74.2%), 68.9% of which maintained a RDI ≥ 80%. Mean RDI was 83.9 ± 20.4%. HL had no influence on 6-month RDI. Variation of HRQoL was evaluable for 114 patients (62.6%). Patients with inadequate HL showed lower emotional ($p = 0.02$) and cognitive scores ($p = 0.03$) at baseline. A significant improvement was shown at 6 months for global health status (+9.83 out of 100, $p = 0.001$), emotional functioning (+10.73, $p < 0.001$), insomnia (-14.03, $p < 0.001$), pain (-11.76, $p = 0.02$) and fatigue (-11.76, $p = 0.005$), with no difference in other scales. **Conclusions:** Cancer patients followed by Oncoral globally maintain a 6-month RDI ≥ 80% regardless of HL, with a HRQoL maintained or improving in all dimensions, suggesting that this personalized follow-up benefits to all patients and may limit the impact of social vulnerability. Research Sponsor: None.

12128 Poster Session

Impact of proton pump inhibitor (PPI) pharmacogenomics (PGx) on toxicities associated with immune checkpoint inhibitor (ICI) therapy.

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Background: There is evidence for the impact of PPIs on clinical outcomes when given concurrently with ICI therapies. Moreover, CYP2C19 genotype impacts PPI metabolism; poor and intermediate metabolizers having higher PPI effectiveness. Cancer patients routinely receive PPIs for acid suppression; we therefore undertook a PGx analysis to evaluate the impact of PPIs on adverse events (AEs) in patients receiving curative-intent ICI therapy. **Methods:** We performed a retrospective analysis on data from four Roche studies with atezolizumab (A) (NCT03197935, NCT02486718, NCT02450331, NCT03038100) and included patients who had available germline whole-genome sequencing information. PGx variants of the CYP2C19 gene were assessed using PharmCAT which predicted metabolizer phenotypes- normal, rapid/ultra-rapid, and poor/intermediate. Exposure to PPIs was categorized using the ConMedClassify R package. The primary outcome was time to the first Grade $\geq$ 3 AE. We used an extended multivariate Cox proportional hazards model that accounted for delayed entry into the PPI exposure class and stratified by study ID. An interaction term was included between PPI exposure, primary cancer treatment (A containing: yes/no), and CYP2C19 metabolizer phenotype. We adjusted for baseline covariates: race, sex, age, BMI, ECOG status, plasma albumin level, and neutrophil-to-lymphocyte ratio. Missing data were imputed with missRanger. Marginal effect estimates were pooled across the completed datasets using the mice R package. **Results:** This analysis included 816 patients who received A as adjuvant/neoadjuvant therapy in triple negative breast cancer, non-small cell lung cancer, and urothelial cancer, or for stage III/IV ovarian cancer indications; and 775 patients who received non-A based treatment as standard of care across corresponding tumor types. Patients receiving A-containing regimen and having a predicted intermediate/poor metabolizer phenotype [(N = 241 (30%)] were more likely to experience Grade $\geq$ 3 AEs if they were exposed to a PPI versus if they were exposed to H2 blocker (HR = 3.117, 1.319 - 7.368 95% CI, p-value = 0.01, FDR = 0.172, Ns in contrast groups: 46 vs 89). The analysis to evaluate the impact of PPI PGx on ICI efficacy outcomes is ongoing. **Conclusions:** Given the widespread use of PPIs in cancer patients receiving ICI therapies, consideration may be needed regarding CYP2C19 genotype data to guide acid suppression therapy. Where possible, prescribing a lower dose of PPI, considering PPIs with less CYP2C19 metabolism, or substituting with H2 blockers in patients receiving curative ICI therapy may minimize the risk of toxicity in patients with intermediate/poor metabolizer status (30% in our cohort from four A trials). This would be especially important in early disease settings where there may be less risk tolerance for toxicity compared with advanced disease. Research Sponsor: None.

12129 Poster Session

Association of *IL7* germline variants with immune-related adverse events (irAEs) in cancer patients (pts) treated with immune checkpoint inhibitors (ICIs).

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Background: Despite the transformative impact of ICIs on cancer treatment, their efficacy remains limited by adverse events (AEs), underscoring the need for reliable biomarkers. Here, we aimed to investigate the effect of a previously identified *IL7* SNP in predicting irAEs across two clinical trials and an East Asian pan-cancer cohort. **Methods:** In this pooled analysis, we included 1,205 pts from the CheckMate-025 trial (CM025, NCT01668784) with renal cell carcinoma (RCC) who received either nivolumab (NIVO) or everolimus (EVE), from the BinTA-0037 (BTA-037, NCT03631706) in non-small cell lung cancer (NSCLC) treated with pembrolizumab (PEMBRO), and from the Asan ICI-treated pan-cancer cohort. The rs7816685 SNP dosages were inferred from blood and/or tumor whole exome sequencing (WES) using STITCH for CM025, and Minimac4 for Asan. For BTA-037, a surrogate SNP (rs16906062, R^2=1.0) was extracted from tumor WES. The association between the SNP carrier status and the time to incident AEs was investigated via multivariable cause-specific Cox regression models. RNA-sequencing (RNA-seq) was performed on blood samples from the Asan cohort collected pre- and post-initiation of ICI. Blood immune cell fractions were estimated from RNA-seq data using ImmucellAI. **Results:** The frequency of the risk allele was 15% in CM025, 17% in BTA-037, and 24% in Asan. *IL7* SNP carriers demonstrated a significantly higher risk of AEs when treated with ICI therapies in all 3 cohorts, but not with EVE (non-ICI control) (SNP´treatment $P_{interaction}$=0.0012 in CM025) (Table). The SNP showed a consistent effect across different tumor types and irAE profiles, with no apparent impact on survival outcomes. RNA-seq data revealed the expression of a novel *IL7* cryptic exon in carriers, and a significant increase in peripheral cytotoxic T-cell post-ICI (q=0.002). Both features were significantly correlated (R=0.29, P=1x10-11), suggesting a potential mechanistic link. **Conclusions:** The *IL7* SNP (rs7816685) is associated with a higher risk of immune toxicity in pts treated with ICI. Overall, our findings support the use of this germline biomarker for irAE risk stratification, and pave the way for future functional studies. Research Sponsor: None.

Adjusted hazard ratios (HRs) from multivariable Cox models adjusting for baseline covariates in each cohort.

Cohort	Cancer type	Treatment	N	SNP	adjusted HR for irAEs
CM025	RCC	NIVO	189	rs7816685	3.01 [1.59-5.68], *P*=0.0007
CM025	RCC	EVE	193	rs7816685	0.65 [0.33-1.28], *P*=0.22
BTA-037	NSCLC	PEMBRO	152	rs16906062	2.3 [1.16-4.6], *P*=0.017
Asan	Pan-cancer	Any ICI	671	rs7816685	1.12 [1.02-1.2], *P*=0.015

12130 Poster Session

Impact of cancer related fatigue on quality of life of 1,262 patients with breast cancer receiving chemotherapy: A URCC NCORP nationwide phase III RCT.

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Background: Cancer-related fatigue (CRF) is one of the most common and debilitating symptoms reported by cancer patients, significantly impairing quality of life (QoL) across physical, functional, emotional, and social domains. Despite its prevalence, limited data exist quantifying how rapid changes in CRF after a single chemotherapy cycle influence QoL. We aim to evaluate if rapid clinically meaningful changes in CRF post chemotherapy impact QoL in breast cancer patients. **Methods:** This Phase III RCT (NCT03367572) enrolled chemotherapy-naïve breast cancer patients across 21 NCORP practices receiving high/moderate emetogenic chemotherapy. CRF was assessed at baseline and post chemotherapy cycle 1 (n = 1,262) using a four-day home diary, with maximum fatigue change as the primary outcome. For analysis, the CRF variable was dichotomized into two categories: a clinically significant increase (≥3 points) and less than a 3-point increase. QOL was measured with FACT-G and its subscales: emotional (EWB), functional (FWB), physical (PWB), and social (SWB). ANCOVA and Cohen's d effect size (ES) evaluated whether clinically meaningful CRF changes predicted QOL changes across cycles. **Results:** Among 1,262 patients with valid fatigue scores, 74.8% experienced increased CRF after cycle 1, with 53.2% reporting a ≥3-point increase and a mean increase of 2.9 points for the group. Clinically significant increases in CRF strongly impacted quality of life (QOL), as reflected in FACT-G Total Score changes post-cycle 1 (≥3: −12.4 vs < 3: −4.7; mean difference: 7.7, $p < 0.001$, ES: 0.74), exceeding the clinically meaningful threshold of > 5 points. Analysis of the subscales revealed PWB with the largest changes of 4.8 (≥3: −X vs < 3: −X; $p < 0.001$, ES: 1.00). FWB changes were 2.1 (≥3: −X vs < 3: −X; p≤0.0001, ES: 0.48) and EWB changes were 0.7 (≥3: −X vs < 3: −X; $p < 0.001$, ES: 0.26). CRF did not significantly impact SWB. Notably, many of these subscale changes surpassed the clinically meaningful threshold of > 2 points. **Conclusions:** This study underscores the rapid onset and significant impact of CRF on QoL in breast cancer patients receiving chemotherapy. Clinically meaningful increases in CRF, even after a single chemotherapy cycle, were predictive of substantial declines in QoL, particularly in physical and functional well-being. These results emphasize the urgent need for targeted fatigue management strategies, such as tailored interventions addressing physical and functional domains, to improve patient outcomes. Clinical trial information: NCT03367572. Research Sponsor: National Institutes of Health (NIH) Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant; T32CA102618; RO1; R01CA200579; University of Rochester-NCORP Research Base; NCI UG1CA189961.

Virtual yoga (vYOCAS) intervention for psychological distress: A decentralized digital randomized controlled trial with cancer survivors.

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Background: Psychological distress is highly prevalent among cancer survivors, and it interferes with their ability to recover after treatment and resume normal life activities. Yoga is a promising therapy that may reduce psychological distress and facilitate optimal recovery for survivors. However, accessibility can be limited for survivors who have higher risks of infection due to immunosuppression or high travel burden. Virtual delivery of yoga may increase accessibility for survivors. **Methods:** We conducted a decentralized, digital, phase II randomized controlled trial (RCT) examining the efficacy of virtual yoga compared to usual care for improving psychological distress among survivors. Participants were cancer survivors who completed primary treatment (e.g., surgery, chemotherapy, radiation therapy) within the last 2-60 months. Participants were randomized to receive virtual yoga or usual care. The Zoom platform was used to virtually deliver the Yoga for Cancer Survivors (vYOCAS) intervention. vYOCAS is a 4-week intervention based on gentle Hatha and restorative yoga. Each yoga session was delivered by a certified yoga instructor in small groups (2-4 survivors/group) for 75 minutes, twice a week. Psychological distress was assessed via the Profile of Mood States (POMS) at baseline and post-intervention. POMS evaluated tension-anxiety, depression, anger-hostility, fatigue, confusion, and overall mood. T-tests and ANCOVAs with baseline as a covariate were used to evaluate within- and between-group changes, respectively. **Results:** 42 survivors (93% female; mean age 58.5±11.6 years; 60% breast cancer; 17% residing in small town/underserved areas) were randomized and completed the study. On average, participants attended 6.2 of 8 prescribed yoga sessions. 44% of vYOCAS participants reported additional home practice of 62.8 minutes over 4 weeks. vYOCAS participants reported significant decreases in psychological distress (tension-anxiety: -1.5±0.6; depression: -1.2±0.4; fatigue: -2.4±0.7; overall mood: -7.3±2.4; all $p < 0.05$) at post-intervention. Usual care participants did not demonstrate similar improvements. ANCOVA results also revealed that vYOCAS participants experienced significantly greater improvements in fatigue (-2.1±0.8, $p = 0.02$) and overall mood (-6.4±3.1, $p = 0.04$) compared to usual care participants. No intervention-related adverse events were reported and the majority of survivors would recommend virtual yoga to others. **Conclusions:** vYOCAS is safe, feasible, and amenable for cancer survivors. vYOCAS may also significantly improve psychological distress.Clinicians should consider recommending virtual yoga therapy for survivors with psychological distress to overcome barriers related to accessibility. Future phase III decentralized digital RCTs are needed to confirm these findings. Clinical trial information: NCT04458194. Research Sponsor: National Cancer Institute; UG1CA189961, T32CA102618.

12132 Poster Session

Immune-related endocrinopathy in cancer patients receiving immune checkpoint inhibitor therapy in the nationwide prospective DIRECT cohort.

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Background: Immune checkpoint inhibitors (ICIs) have transformed cancer treatment, extending patient survival. However, side effects such as endocrinopathies are common and have severe, sometimes irreversible outcomes if not managed promptly. Predictive factors for endocrinopathies are poorly understood. We examined whether demographic and clinical characteristics are linked with the development of ICI-induced endocrinopathies. **Methods:** The DiRECT Cohort (URCC21038, NCT05364086) is an ongoing observational trial of cancer patients scheduled to receive anti-PD-(L)1 ICI therapy and enrolled through the URCC NCORP Research Base nationwide network. This analysis was based on 1,525 patients with toxicity data assessed 12/31/2024. Endocrinopathies were graded using the Common Terminology Criteria for Adverse Events (CTCAE) criteria version 5.0. Toxicity data was collected after each infusion of ICI. Demographics (age, sex, BMI, race) and clinical factors (cancer type, cancer stage, treatment agent, autoimmune disease, and significant comorbidities) were collected at baseline. We tested bivariate associations with chi-square tests and multivariable associations with logistic regression; statistical significance was set at a p-value of 0.05. **Results:** Of the 1.525 participants, 533 (35%) had lung cancer, 263 (17.3%) had breast cancer, 812 (53.3%) were aged $\geq$ 65, 1142 (75.4%) White, 828 (54.4%) women, 1009 (66.3%) had BMI $<$ 30, 802 (52.7%) had at least one comorbidity, and 128 (8.4%) had an autoimmune disease, 831 (55.2%) had stage IV cancer, and 930 (61.1%) were on pembrolizumab. 252 (16.5%) developed endocrinopathies of any grade: Hyperthyroidism, 61 (24.2%); Hypothyroidism, 156 (61.9%); Thyrotoxicosis, 7 (2.75%); and Adrenal insufficiency, 11 (4.37%). The most common of these were hypo/hyperthyroidism, of which 9% were grade $\geq$2. In bivariate analyses, grade $>$2 endocrinopathies were associated with younger age (11% age $<$ 65 vs. 7% age $\geq$65, p = 0.012), female sex (10% in women vs. 4% in men, p = 0.001), and obesity (12% of those with BMI $>$30 vs 7% with BMI $<$ 30, p = 0.001). We found no significant associations with other factors evaluated. In multivariable logistic regression analyses, younger age, female sex, and obesity were significant predictors, with higher odds of endocrinopathy for those of age $<$ 65 (OR: 1.58, 95% CI: 1.35-1.85), female sex (OR: 1.75, 95% CI: 1.48-2.08), with BMI $\geq$30 (OR: 1.97, 95% CI: 1.68-2.31). **Conclusions:** In this nationwide observational trial, younger age, female sex, and obesity were associated with a higher likelihood of developing grade $\geq$2 ICI-induced endocrinopathies. Future work will focus on identifying biomarkers predictive of endocrinopathy and developing predictive models for risk stratification. Research Sponsor: National institute of Health (NIH)/ National cancer Institute (NCI); NCI UG1CA189961; UH3CA260602.

12133 Poster Session

Glucagon-like peptide-1 receptor agonists and the risk of chemotherapy-induced peripheral neuropathy in patients with diabetes: A real-world study.

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Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a prevalent condition that significantly affects quality of life in patients with cancer. Diabetes and the use of taxane or platinum-based chemotherapy are major risk factors for CIPN. Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RA) have emerged as promising agents for preventing CIPN due to their potent antihyperglycemic and weight-loss effects. However, the effects of GLP-1RA on CIPN are unknown. **Methods:** We conducted a retrospective, propensity score-matched cohort study utilizing the TriNetX Analytics Network database. Adult patients with concurrent diagnoses of cancer and diabetes who were treated with taxane and/or platinum-based chemotherapy and either GLP-1RA or non-GLP-1RA (including Insulin, Dipeptidyl peptidase-4 inhibitors, Sodium-glucose Cotransporter-2 Inhibitors, Metformin, Thiazolidinediones) anti-diabetes agents were included. Patients with a prior history of neuropathy were excluded. The index date was defined as the initiation of chemotherapy. The primary outcome was the occurrence of CIPN, identified using International Classification of Diseases codes, within one year following the index date. Secondary outcomes included the use of neuropathic pain medications, such as gabapentinoids, serotonin and norepinephrine reuptake inhibitors (SNRI), tricyclic antidepressants (TCA), and tramadol. Cohorts were matched on variables such as age, race, sex, hemoglobin A1c, BMI, cancer type, metastatic disease, and underlying comorbidities. **Results:** We identified 39,772 patients eligible for inclusion, among which 1813 received GLP-1RA and 37,959 received non-GLP-1RA. After propensity score matching, cohorts were all well-balanced across variables. We included 1,763 patients in each cohort for the final analysis. The mean BMI for the GLP-1RA and non-GLP-1RA groups are 32.5 $\pm$ 7.5 and 32.2 $\pm$7.7, and the mean HbA1c are 7.7 $\pm$ 1.8 and 7.6 $\pm$ 1.8, respectively. When compared with patients who received non-GLP-1RA, patients who received GLP-1RA had a higher risk of CIPN (13.9 vs 10.9%, HR 1.34 [95% CI: 1.11 - 1.62]) and significantly increased use of gabapentinoids, SNRI, and tramadol (Table). **Conclusions:** GLP-1RAs are associated with a higher risk of CIPN and greater use of neuropathic pain medications than non-GLP-1RA in patients with cancer and diabetes receiving taxane/platinum-based chemotherapy. Further studies are required to elucidate the possible mechanism underlying the increased risk of CIPN associated with GLP-1RAs. Research Sponsor: None.

	GLP-1RA vs. non GLP-1RA HR (95% CI)	P-value
Chemotherapy-induced neuropathy	1.34 (1.11 - 1.62)	0.002
Gabapentinoids (gabapentin/ pregabalin)	1.26 (1.13 - 1.41)	<0.001
duloxetine	1.66 (1.30 - 2.12)	<0.001
Venlafaxine	1.56 (1.09 - 2.22)	0.010
TCA	1.05 (0.69 - 1.61)	0.70
Tramadol	1.30 (1.16 - 1.54)	<0.001

12134 Poster Session

Interrogating the interleukin-6 (IL-6)/IL-23/T-helper (Th)17 axis in immunotherapy toxicity: Mechanistic insights and therapeutic implications.

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Background: Immune checkpoint inhibitors (ICIs) have transformed cancer therapy, but grade ≥ 3 immune-related adverse events (irAEs) affect 60% of patients. The mechanisms driving irAEs remain poorly understood, hindering the development of strategies to mitigate toxicity without compromising efficacy. **Methods:** We analyzed biomarkers from an ongoing phase I/II trial (NCT04940299) evaluating tocilizumab (IL-6R blockade) in two regimens; 162 mg subcutaneously weekly (regular dose, RD) or bi-weekly (dose-dense, DD), combined with ipilimumab (3 mg/kg) and nivolumab (1 mg/kg) up to 12 weeks as front-line therapy for advanced melanoma. Longitudinal analyses of blood, tumor, and inflamed tissue biopsies were performed to identify biomarkers for risk stratification and to elucidate the immunobiology of irAEs and antitumor responses across four patient subgroups, categorized by tumor response and the presence or absence of grade ≥ 3 irAEs. **Results:** A total of 35 patients were treated with the triplet and followed for up to 15 months. By week 12 after treatment initiation, grade ≥ 3 irAEs occurred in 15 patients (43%), with similar frequencies in the RD (44%) and the DD (40%) cohorts. Within 90 days after last tocilizumab dose, the incidence of grade ≥ 3 irAEs increased to 56% in the RD cohort but remained unchanged in the DD cohort, resulting in an overall incidence of 51%. The best overall response rate (ORR) was 66%, with 64% in the RD cohort and 70% in the DD cohort. NanoString analysis of tumor biopsies identified 31 upregulated genes in patients with grade ≥ 3 irAEs compared to those without, including RORC, a key regulator of Th17 differentiation, which was significantly elevated in longitudinal biopsies (pre: n = 8; post: n = 6) of patients with high-grade irAEs. IL-17, IL-1, and TNF signaling pathways were significantly decreased after tocilizumab treatment in the subgroup of patients without the grade ≥ 3 irAEs (pre: n = 14, post: n = 9). LunaPhore-COMET analysis showed elevated Th17 and γδ T-cell subsets (CD4+ and CD8+) in inflamed tissues compared to matched healthy or tumor tissues. CyTOF profiling of blood showed higher γδ T-cell levels at baseline in patients with grade ≥ 3 irAEs (n = 6), which remained elevated following tocilizumab treatment. **Conclusions:** These findings underscore the pivotal role of Th17 cells in the development of irAEs and suggest that current tocilizumab regimens may provide insufficient IL-6 blockade or require combination strategies, such as concurrent IL-23 inhibition, to more effectively target Th17 cells expansion and maintenance. Notably, this study is the first to identify γδ T-cells as potential predictive biomarkers for irAEs, yet their utility requires further validation. A randomized phase II trial exploring these mechanisms is underway. Clinical trial information: NCT04940299. Research Sponsor: National Institute of Allergy and Infectious Diseases (NIAID); K01AI163412.

Association between epigenetic clocks and chemotoxicity in older adults with early breast cancer.

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Background: Epigenetic clocks are blood-based biomarkers developed to predict biological age and mortality risk from DNA methylation data. Here, we investigated the association between epigenetic clocks and grade 2+ chemotoxicities, given that low grade toxicity has significant clinical impact in older adults with breast cancer. **Methods:** This was a secondary analysis of a prospective cohort of 394 adults age ≥65 with stage I-III breast cancer who completed treatment with neo/adjuvant chemo. We analyzed peripheral blood DNA methylation to estimate epigenetic age acceleration (EAA) prior to chemo. We estimated EAA using three generations of epigenetic clocks (1st gen: Horvath and Hannum; 2nd gen: PhenoAge and GrimAge; 3rd gen: DunedinPACE). Our outcomes of interest were the five most frequently reported grade 2+ chemotoxicities. Using multivariable logistic regression, we examined the association between EAA (as continuous variables) and the chemotoxicities of interest, adjusting for age, stage, race/ethnicity, education, regimen, organ function, cell composition, and geriatric assessment variables. **Results:** The median (range) chronological age of the participants was 70 (65-85). Most (65%) had stage II/III disease, 38% received anthracycline, and 75% received G-CSF prophylaxis. A total of 334 (84.8%) participants experienced a grade 2+ toxicity. The five most common grade 2+ toxicities were fatigue (34%), anemia (31%), infection (30%), neuropathy (20%), and diarrhea (13%). On multivariable analysis, we observed an association between pretreatment GrimAge and infection (OR=1.35, 95% CI 1.03-1.77, p=0.03) as well as DunedinPACE and diarrhea (OR=1.43, 95% CI 1.01-2.03, p=0.04). **Conclusions:** In this study of older adults with early breast cancer, we saw an association between some measures of EAA and select grade 2+ toxicities. Further research is needed to examine how measures of biological age can guide the care of older adults with early breast cancer. Clinical trial information: NCT01472094. Research Sponsor: U.S. National Institutes of Health; R01 AG037037.

Grade 2+ chemotoxicity in older adults with early breast cancer, odds ratio (95% CI).

Measures of EAA*	Fatigue (n=134)	Anemia (n=121)	Infection (n=120)	Neuropathy (n=77)	Diarrhea (n=53)
First gen					
Horvath	0.86 (0.67-1.10)	0.97 (0.75-1.26)	0.95 (0.75-1.22)	1.22 (0.91-1.65)	1.02 (0.74 -1.41)
Hannum	0.90 (0.69-1.16)	1.14 (0.86-1.50)	1.03 (0.79-1.33)	1.15 (0.84-1.56)	0.81 (0.56-1.17)
Second gen					
PhenoAge	1.13 (0.86-1.48)	1.10 (0.81-1.48)	1.02 (0.77-1.35)	1.22 (0.88-1.69)	1.10 (0.76-1.60)
GrimAge	1.11 (0.86-1.44)	1.17 (0.88-1.56)	**1.35 (1.03-1.77)**	1.04 (0.76-1.43)	1.39 (0.98-1.96)
Third gen					
DunedinPACE	1.24 (0.96-1.61)	1.09 (0.82-1.44)	1.06 (0.81-1.38)	1.14 (0.83-1.56)	**1.43 (1.01-2.03)**

*The first and second gen clocks are in chronologic years and DunedinPACE is in biological year per chronologic year. OR adjusted for age, stage, race/ethnicity, education, regimen, organ function, cell composition, and geriatric assessment variables.

TPS12136 Poster Session

In-bedroom renewed air as anti-inflammatory adjuvant therapy in cancer survivors: BREATHS trial.

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Background: Inflammation plays a pivotal role in both cancer progression and adverse cardiovascular (CV) effects of anticancer treatments. Cardio-oncology rehabilitation with inflammatory pathways-targeting therapies is emerging as a promising approach for cancer survivors at high risk of CV toxicity. In-home air filtration interventions effectively lower interleukin-6 levels in high-risk populations for CV and respiratory events and significantly impact C-reactive protein (CRP) levels in patients with atherosclerosis. Evidence indicates that CRP can serve as a reliable clinical indicator of residual inflammatory risk and cardiotoxicity after cancer therapy. Concurrent administration of purified air therapy along with conventional pharmacological agents—including statins, cyclooxygenase inhibitors, and beta-blockers—may potentiate the desired therapeutic effect, yet the underlying interactions are not fully understood. We investigate whether overnight in-bedroom air filtration effectively reduces inflammation and cardiac markers in survivors of adult-onset cancer at high risk of CV toxicity.
Methods: This is a series of N-of-1 randomized, adaptive, blinded, and placebo-controlled trials conducted in the homes of adult survivors residing in densely populated urban areas of Valencia, Spain, with the poorest air quality levels, as evidenced by particulate matter concentrations exceeding the WHO and EU Directive limits. Inclusion criteria are age $\geq$ 18 years, prior history of breast, colorectal, prostate, lung, or hematologic cancer, exposure to cardiotoxic cancer therapy, and CRP level $\geq$ 3 mg/L. Participants will be randomly assigned to three treatment sets, each comprising a 14-day period of active therapy (portable air purifier at 275 m^3/h) and a 14-day period of placebo (sham purification). In-bedroom air filtration treatment and placebo will be administered nightly for a minimum of 7 consecutive hours. The blinded sequence will last between 4 and 12 weeks per participant, depending on the clinical efficacy evidenced after each treatment set (CRP $<$ 2 mg/L or CRP reductions $\geq$ 35%). Participants who fail to achieve the clinically meaningful change in the last treatment set will undergo an open-label phase: 14 days of no treatment and 14 days of active therapy administered nightly and daily (air purifier operating continuously at 275 m^3/h). Participants will be asked to keep a daily in-bedroom time log. The primary endpoint is defined as the change in blood CRP levels after each cycle. Secondary outcomes include changes in D-dimer, serum amyloid A and glycated hemoglobin A1c concentrations, and blood pressure. Exploratory endpoints include the feasibility of at-home point-of-care testing to monitor residual inflammatory toxicity. Ten participants will be enrolled in the trial. No enrolled participants at the time of abstract submission. Clinical trial information: NCT06778122. Research Sponsor: None.

TPS12137 **Poster Session**

Social genomic mechanisms of health disparities among adolescent/young adult survivors of Hodgkin and non-Hodgkin lymphoma: ECOG-ACRIN EAQ211.

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Background: Research in human genomics maps molecular pathways through which social and psychological factors regulate gene expression in immune cells and tumor tissue, thus affecting chronic disease progression, symptom development, antiviral resistance, morbidity, and mortality. In many cases, psychosocial factors trigger neural and endocrine responses that regulate expression of genes involved in cancer progression (inflammation, metastasis, treatment resistance) and immune function (stimulating inflammatory genes and suppressing antiviral gene transcription, as observed in the "Conserved Transcriptional Response to Adversity" / CTRA transcriptome signature). However, nothing is known about how such effects impact AYA cancer survivors. This study aims to identify functional genomic pathways through which psychosocial factors influence gene regulation and alter health outcomes in AYA cancer patients; and define the role of such effects in structuring health disparities in post-treatment survivorship. **Methods:** This longitudinal single cohort study is administered through the ECOG-ACRIN Cancer Research Group. Subjects are accrued through the NCI Community Oncology Research Program (NCORP) or self-refer through a broad network of cancer support organizations and clinical programs that serve the AYA population. Accrual goal is 2,000 survivors of Hodgkin or Non-Hodgkin Lymphoma who have achieved complete response to therapy at time of study registration, aged 15-39 years at time of diagnosis, and recruited within three years following completion of treatment. Current accrual is n=117. Upon enrollment, participants complete an online survey of patient-reported outcome measures of social and psychological risk and resilience factors, including quality of life (QOL), social isolation, socioeconomic status, and exposures to childhood trauma. Clinical records are reviewed for medically reported comorbidities and vital status. Data are collected at baseline and repeated every 6 months for two years. Blood specimens also are collected at each time point. The CTRA transcriptome profile will be assayed using an established 53-gene index comprised of a block of 19 pro-inflammatory genes (e.g., *IL1B, IL6, IL8/CXCL8, TNF*) and 34 genes involved in innate antiviral response (e.g., *IFNA/B, IFI-, OAS-,* and *MX*-family genes), with CTRA representing the difference in average expression of those 2 blocks (inflammatory – interferon). CTRA is a biological intermediate state, which is hypothesized to mediate relationships between proposed psychosocial risk and resilience factors and outcomes (morbidity, mortality, QOL). Defining effects of psychosocial conditions on gene expression and their role in structuring disparities for AYA survivors will fill a critical gap in knowledge that informs risk-based models for cancer survivorship care. Research Sponsor: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute; R01CA261752; ECOG-ACRIN Cancer Research Group (Peter J. O'Dwyer, MD and Mitchell D. Schnall, MD, PhD, Group Co-Chairs); UG1CA189828.

TPS12138 Poster Session

Testosterone replacement therapy for fatigue, sexual dysfunction, and quality of life in older men with cancer (TEMEC).

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Background: Fatigue is prevalent in men with cancer, affecting 70-100% of survivors. Fatigue impairs quality of life (QOL), increases caregiver burden, and is associated with reduced lean body mass and sexual dysfunction. Muscle loss, fatigue, sexual dysfunction and depressed mood are common in older males with testosterone deficiency, with or without cancer. Testosterone replacement therapy (TRT) in non–cancer patients improves fatigue, body composition and sexual function. However, despite high prevalence of testosterone deficiency in men with cancer (50-90%), no TRT practice guidelines are available. Older age, chronic inflammation, opioids, megestrol acetate, corticosteroids and some anti-neoplastic therapies are implicated in lowering testosterone. A preliminary (n=29) double blind trial comparing 4 weeks of intramuscular (n=13) TRT to placebo (n=16) in men with advanced cancer reported improvement in fatigue and sexual desire scores. Based on these findings, TRT may mitigate fatigue and related symptoms but requires a large, adequately powered trial. **Methods:** Randomized, double-blind, placebo-controlled trial of daily transdermal testosterone or placebo gel for 6-months in men ≥55 years, with solid or hematological cancer. Participants with no evidence of disease or receiving anti-neoplastic therapy are eligible if they report fatigue, have low serum testosterone by mass spectrometry <348 ng/dl or free testosterone <70 pg/ml and the interval from last treatment (chemotherapy, radiation therapy, immunotherapy), is ≤60 months. Ineligibility includes prostate cancer, elevated PSA, hematocrit >48% or recent thromboembolism. Sample size is predicated on 1:1 randomization to two arms, stratified by 3 sites and 90% power to detect relevant effects. Assignment of participants to either testosterone or placebo via permuted block design is known to statistician, study pharmacists, and unblinded study physician responsible for dose-adjustment. By December 2024, 150 of planned 230 participants are enrolled. NCT04301765. Primary outcome is change in fatigue by Functional Assessment of Chronic Illness Therapy fatigue scale (FACIT-Fatigue). Secondary outcomes include Harbor-UCLA 7-day Sexual Function Questionnaire including sexual activity and desire. Additional outcomes include questionnaires of erectile function, positive and negative affect scale (PANAS), Brief Assessment Scale determining Caregiver Burden (BASC) and body composition by dual energy X-ray absorptiometry. Physical performance evaluations include maximal leg press strength, 6-minute walk test and actigraphy. Additionally, lived experiences of 60 participants at baseline and 24 weeks are assessed by semi-structured, qualitative phone interviews with men from testosterone and placebo arms. Clinical trial information: NCT04301765. Research Sponsor: National Institute on Aging; AG061558.

TPS12139 Poster Session

Randomized trial of a clinical nurse specialist–led enhanced survivorship and early palliative care intervention for patients with metastatic cancer.

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Background: While the benefits of early palliative care and clinician empathy for patients with metastatic cancer are well established, cancer survivorship remains inadequately integrated into the care of patients with distant metastases (Langbaum, N Engl J Med 380: 1300, 2019). Moreover, the optimal model of care delivery is poorly defined. Based on these data, we developed a novel multidisciplinary care model in which the radiation oncology Clinical Nurse Specialist develops therapeutic relationships with survivors with metastatic cancer and identifies and coordinates interventions to address their unmet physical and emotional issues. The goal of this intervention is to improve quality of life and overall survival. **Methods:** Eligible patients are adult patients with metastatic solid tumor malignancy with a predicted median survival of ≥1 year using the validated NEAT model. Using block randomization with varying block sizes of 4, 6 and 8, we plan to randomize 100 patients to either usual care or a supplemental Clinical Nurse Specialist led survivorship and palliative care intervention. Patients randomized to the Clinical Nurse Specialist have personalized coordination of services, patient education and referral to supportive care services resulting from additional in-person and phone-based touchpoints. These supplemental interactions address individual needs, such as medication side effects, physical therapy, end-of-life planning and access to community and spiritual resources. The primary endpoint of this trial is patient reported symptom burden using the Edmonton Symptom Assessment System score. Secondary endpoints are patient reported quality of life using the NCCN survivorship assessment and long-term overall survival. To date, 45 patients have been enrolled. Clinical trial information: NCT05947695. Research Sponsor: Good Samaritan Hospital Foundation.

TPS12140 **Poster Session**

Fecal microbiota transplantation (FMT) for opioid-induced constipation (OIC): A prospective, multicenter, single-arm, phase II clinical study.

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Background: Opioids are the cornerstone of cancer pain management. Opioid-Induced Constipation (OIC) is the most common adverse effect of opioid therapy. OIC significantly impairs patients' quality of life and reduces compliance, making it a major factor in inadequate pain control. Recent studies indicate that opioids cause gut microbiota dysbiosis, with gut microbes playing a role in modulating opioid-mediated analgesia and tolerance, including constipation. Currently, fecal microbiota transplantation (FMT) has been shown to be an effective method for adjusting gut flora by introducing various metabolically active bacteria. Therefore, we initiated this study to evaluate the efficacy of FMT in treating OIC. **Methods:** In this multicenter, single-arm exploratory study, 30 cancer patients aged 18-80 years who receive opioid treatment for manageable pain but suffer from persistent constipation are planned for enrollment. Other inclusion criteria include ECOG status 0-2, expected survival $\geq$3 months, having received opioid therapy for at least two weeks, currently stable opioid dosage, manageable pain with NRS $\leq$4, and ability to undergo standard laxative treatment and anticancer therapy. Patients unable to ingest enteric capsules or requiring antibiotics for infections are excluded. Enrolled patients will receive weekly FMT. The treatment will be administered continuously for 4 weeks, with follow-up until constipation reoccurs or one month after the last dose, whichever comes first. The primary endpoint is the improvement of constipation (assessed by BFI scale), while secondary endpoints include cancer pain before and after treatment (evaluated by NRS scale), quality of life (measured by QLQ-C30 scale), nutritional status improvement, and safety. Blood and fecal samples will be collected during the study for efficacy evaluation. The study is currently in the open recruitment phase, with the first patient enrolled in January 2025. Clinical trial information: ChiCTR2500096421. Research Sponsor: None.

TPS12141 **Poster Session**

A randomized phase III study comparing stereotactic body radiotherapy (SBRT) versus conventional palliative radiotherapy (CRT) for participants with painful non-spine bone metastases (NCT06391242).

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Background: Stereotactic body radiotherapy (SBRT) is efficacious in the treatment of painful spinal metastases [1]. Data are required regarding the efficacy feasibility, toxicity and clinical outcomes associated with SBRT in patients with painful non-spine bone metastases prior to widespread adoption of this technique. **Methods:** This is a Canadian Cancer Trials Group led multi-centre, phase III randomized controlled trial comparing SBRT to conventional palliative external beam radiotherapy (CRT) in patients with solid tumours and a dominant painful non-spine bone metastasis (worst pain score >2). *Treatment arms:* EBRT 20Gy/5fr (control) versus SBRT 35 Gy/5fr or 30Gy/5fr (experimental). *Primary objective*: To compare 3-month complete pain response (CPR) rate and analgesic intake assessed using the International Consensus on Palliative Radiotherapy Endpoints [2]. Secondary objectives evaluate pain response pattern at 1, 3 and 6 months and assess re-irradiation rates, fracture incidence within RT target site, incidence of Grade > 2 adverse events, image-based local control, and patient reported outcomes (EORTC QLQ-C30 and QLQ-BM22). *Statistical design:* The target accrual is 230 patients, randomized 1:1. The trial is powered at 80% with a two-sided alpha of 0.05 to detect an improvement in the CPR rate from 17% (CRT) to 34% (SBRT), accounting for a 15% missing data rate. *Conduct to Date*: Study was activated on June 26, 2024. Supported by CCS grant # 707213. [1] Sahgal, Arjun, et al. "Stereotactic body radiotherapy versus conventional external beam radiotherapy in patients with painful spinal metastases: an open-label, multicentre, randomised, controlled, phase 2/3 trial." *The Lancet Oncology* 22.7 (2021): 1023-1033. [2] Chow E, Hoskin P, Mitera G, Zeng L, Lutz S, Roos D, Hahn C, van der Linden Y, Hartsell W, Kumar E; International Bone Metastases Consensus Working Party. Update of the international consensus on palliative radiotherapy endpoints for future clinical trials in bone metastases. Int J Radiat Oncol Biol Phys. 2012 Apr 1;82(5):1730-7. doi: 10.1016/j.ijrobp.2011.02.008. Epub 2011 Apr 12. PMID: 21489705. Clinical trial information: NCT06391242. Research Sponsor: Canadian Cancer Society (CCS); 707213.

TPS12142 Poster Session

A phase 1b dose escalation study of AV-380 (anti-GDF15 monoclonal antibody) in combination with standard-of-care therapy in cancer patients with cachexia.

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Background: Cachexia is a complex and common cancer comorbidity associated with a high risk of death. Despite its significant impact, no FDA-approved therapies exist to treat cancer cachexia, and current off-label treatments are limited and increase the risk of side effects. Circulating GDF-15, an inflammatory cytokine involved in the stress response and body weight regulation, has emerged as a main modulator implicated in the pathogenesis of cachexia. Further, preclinical models have shown that elevated levels of circulating GDF-15 elicit cachexia, and GDF-15 expression increases in proportion to disease severity. AV-380 is a high-affinity anti-GDF-15 IgG1 monoclonal antibody resulting in circulating GDF-15 elimination. AV-380 has been shown to reverse weight loss and increase muscle recovery in animal cancer models. In a phase 1 healthy volunteer study (in-house data), AV-380 was well-tolerated without serious AEs. **Methods:** This is an open-label, dose-escalation, multicenter phase 1b study to assess the safety, tolerability, PK, and PD of AV-380. Eligible patients must be ≥18 years of age, have cancer with cachexia (per international consensus criteria), receive standard-of-care antineoplastic therapy, have a prognosis of ≥3 months, and have an ECOG PS ≤2. Patients with known brain metastases (unless treated and stable for ≥2 weeks), myocardial infarction or grade 3/4 heart failure (≤3 months), uncontrolled third-spacing of fluids (pleural effusion, pericardial effusion, and/or ascites), or non-cancer-related cachexia, are excluded. Primary endpoints will evaluate the safety and tolerability per dose-limiting toxicities, adverse events (NCI CTCAE v5), and laboratory test results. Secondary endpoints include PK analysis, and exploratory endpoints include anti-drug antibodies, weight changes, patient-reported outcomes (Functional Assessment of Anorexia Cachexia Therapy, Patient Global Impression of Severity, Patient's Global Impression of Change, Patient-Reported Outcomes Measurement Information System) physical function (by digital measures), and body composition (Lumbar 3 Skeletal Muscle Index). Escalating dose cohorts of AV-380 consist of 3-6 patients each, following a standard 3+3 design. The treatment is structured into 28-day courses for each cohort. AV-380 will be administered by IV infusion. Patients will remain on AV-380 until they have unacceptable toxicity, complete 4 courses, withdraw consent, or the sponsor terminates the study. Statistical analyses will be completed by cohort and summarized descriptively. Clinical trial information: NCT05865535. Research Sponsor: AVEO Oncology.

TPS12143 Poster Session

Supervised home-based exercise in patients with advanced non-small cell lung cancer (NSCLC) on maintenance immune checkpoint inhibitors (ICI).

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Background: Lung cancer is the leading cause of cancer-related mortality in the US and results in significant morbidities, including fatigue, depression, and decreased quality of life. Exercise has been shown to reduce severity of fatigue and depression while improving cardiorespiratory fitness (CRF) in patients with lung cancer. Past trials have primarily investigated exercise interventions in patients who received surgery and/or chemotherapy; data on the impact of exercise in patients with lung cancer on immune checkpoint inhibitors (ICI) has been sparse. Following the advent of ICI as maintenance therapy in advanced lung cancer, patients have experienced improved survival and more favorable toxicity profile that better positions them to both participate in and derive benefit from an exercise program. In addition, exercise is expected to promote a patient's response to ICI by promoting mobilization of natural killer-cells and T-cells. Already observed in animal and patient derived xenograft models, the combination of exercise and ICI reduced tumor growth by influencing the tumor microenvironment, increasing tumor infiltrating lymphocytes. In this trial, we are investigating the impact of a supervised home-based exercise program on fatigue, depression, CRF, physical function, muscle mass and biomarkers of immune activation in patients with advanced lung cancer on maintenance ICI. **Methods:** This prospective, randomized phase II trial (NCT06513663) aims to enroll 86 patients with advanced NSCLC receiving maintenance ICI. Patients are randomized 1:1 to an exercise intervention or usual care, stratified by baseline frailty as determined by short physical performance battery (SPPB). Eligible patients have locally advanced (stage III) or metastatic (stage IV) NSCLC and are currently receiving maintenance ICI for at least 1 month with plans for at least an additional 3 months of therapy. The trial is targeting an enrollment of 3-4 patients per month over a period of 2 years, and began in June 2024. Patients randomized to exercise participate in 60-minute sessions including aerobic, resistance, and balance exercises, delivered virtually three days per week for 12 weeks by a professional trainer. The primary endpoint is the change in patient-reported fatigue using the Functional Assessment of Cancer Therapy: Fatigue (FACT-F) questionnaire from baseline to post-intervention, compared between the intervention and usual care. Secondary endpoints include changes in patient-reported depression using Hospital Anxiety and Depression Scale (HADS), muscle mass on CT scan, CRF by VO_{2peak} on a ramp treadmill test, objective and subjective physical function, and adherence to exercise intervention. Exploratory analysis will include changes in circulating tumor cells and T-cell subsets. Patients will be followed post-intervention for up to 2 years. Clinical trial information: NCT06513663. Research Sponsor: None.

TPS12144 **Poster Session**

Virtual personalized exercise program for subjects with lung cancer: A feasibility study.

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Background: With improved outcomes, cancer is increasingly viewed as a chronic disease, highlighting the need for exercise programs to enhance the quality of life for survivors. Unlike heart disease, diabetes, and pulmonary disease, where exercise has been recommended for decades, exercise recommendations for cancer patients have been slow to evolve. Exercise and rehabilitation interventions have shown to clearly benefit cancer survivors by improving outcomes, response and tolerability to treatments, delaying progression, and preventing development of new primary cancer. Despite these benefits and strong endorsements from societies such as ASCO, exercise programs are not typically included in lung cancer treatment plans. **Methods:** This is a single-arm, investigator-initiated feasibility study of a virtual exercise platform targeted to patients with non-small cell lung cancer (NSCLC) who receive surgery (+/-) neoadjuvant/adjuvant chemo (+/-) immunotherapy (cohort A); radiation +/- chemo (cohort B); or systemic treatment only (cohort C) at our Cancer Center. This study will assess the feasibility and usability of this program. Potentially eligible subjects are referred to physiatry for evaluation, enrollment, and personalized virtual exercise prescription, which can be accessed by patients using their personal electronic device. Enrollees complete a baseline quality of life FACT-L questionnaire. Pulmonary Function Test (PFT), Six Minute Walk Test (6MWT), and Sit to Stand Test (STS) are also obtained at the start and end of the 12-month program. FACT-L, Patient and Physician Platform Satisfaction questionnaires are collected every three months. We hypothesize that the virtual exercise program is feasible for patients with lung cancer to participate in and will have beneficial outcomes across all cohorts. The primary objective is feasibility, aiming for 50% of those who qualify and enroll to complete the program at 12 months. The secondary objective is satisfaction, as assessed by patient and provider satisfaction questionnaires. Exploratory objectives include improvement in pulmonary function tests and physical endurance as assessed by the PFTs, 6MWT, and STS, as well as improvement or maintenance of quality of life. **Results:** 20 patients are consented and 10 are active. Of the 10 patients who are no longer part of the study, four were screen-fails, and six patients withdrew consent/did not comply with appointments within the study timeline. Patient compliance increased exponentially after the patient navigator was recruited, who started at the end of November. Since this time, six consents were signed and four remain compliant with the study. **Conclusions:** If feasible and acceptable to patients and providers, this program can be practice-changing, leading to the implementation of virtual exercise prescriptions for patients with all cancer types within Northwell and potentially beyond. Clinical trial information: NCT06540495. Research Sponsor: The Northwell Health Cancer Institute; AstraZeneca; Global Initiatives Group at Northwell.

TPS12145 Poster Session

An open-label randomized trial of exercise ± creatine supplementation to augment the adaptations of exercise training in cancer survivors.

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Background: Breast cancer survivors face a heightened risk of skeletal muscle wasting, which can be worsened by cancer treatments, adversely affecting their ability to perform daily activities. Additionally, lower extremity muscle weakness has been linked to persistent fatigue in survivors. Research on resistance exercise interventions has demonstrated significant improvements in strength, endurance, and body composition among breast cancer survivors. Nonetheless, developing effective strategies to optimize exercise adaptations for this population remains a critical area of focus. Creatine phosphate (CP) supplementation has gained attention in the medical field because of the numerous health and quality of life benefits. CP is crucial to maintaining muscle energetics because of its role in rephosphorylating adenosine diphosphate to adenosine triphosphate (ATP). To date, few studies have examined the use of CP supplementation to augment exercise adaptations in breast cancer survivors. As such, we propose the THRIVE clinical trial to assess the effects of 12-weeks of CP supplementation in combination with home-based resistance exercise on outcomes of strength, body composition, physical function and mechanistic biomarkers. **Methods:** The THRIVE clinical trial is a prospective, open-label, randomized trial aiming to recruit thirty breast cancer survivors that have completed infusion chemotherapy less than 6 months prior to study enrollment. Patients will be randomized (1:1) to either the CP plus exercise group or exercise only group. Participants who are randomized to receive CP will be initially dosed at 20 g per day for 7 days to boost the availability of CP systemically. Thereafter, the dose will be reduced to 5 g per day for maintenance throughout the duration of the 12-week protocol. All participants will engage in 3 virtually supervised, home-based exercise session each week. Each session will last roughly 1 hour and include a 10-minute warm-up and a 50-minute stimulus phase consisting of upper body and lower body resistance exercises. Primary outcomes will be strength, body composition (DXA scan), physical function (6 min walk test) and mechanistic biomarkers (growth factor and inflammatory biomarkers). Secondary objective will be muscle cross-sectional area and intramuscular creatine, phosphocreatine and ATP as measured by magnetic resonance imaging and spectroscopy, respectively. Tertiary outcomes will be patient reported outcomes on quality of life. To date, 11 of the planned 30 patients have been enrolled. This study is registered with clinicaltrials.gov (NCT06395506). Clinical trial information: NCT06395506. Research Sponsor: Thrivewell Cancer Foundation.

TPS12146 Poster Session

A pilot study of the ApricityCare program for early detection and management of treatment-related adverse events in patients with metastatic cancer.

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Background: Immune checkpoint therapies (ICTs) induce T cell-mediated anti-tumor immunity and can provide long-term survival benefits for cancer patients. However, ICTs may also cause life-threatening immune-related adverse events (irAEs), often requiring treatment discontinuation and high-dose steroids, leading to significant comorbidities. Early detection and intervention in irAEs can reduce steroid use, enable continuation of ICTs, and improve clinical outcomes. To address the need for earlier detection of severe irAEs, we are implementing ApricityCare, a digital health service that integrates remote symptom reporting via smartphone application, telephone, or text message, with telehealth feedback for patients on ICTs. The platform analyzes patient-reported symptoms and alerts triage nurses to intervene based on pre-specified algorithms. Hypothesis: We hypothesize that early detection and intervention in severe irAEs will improve outcomes and enable ICT continuation. **Methods:** This phase IV clinical trial evaluates ApricityCare's impact on treatment outcomes for patients receiving systemic therapies for metastatic cancer. The study includes a 50-patient run-in phase (Part I) focusing on genitourinary metastatic cancers (prostate, kidney, bladder) to assess feasibility, followed by an expansion of up to 1,000 patients (Part II) across three cohorts: investigational immunotherapies (IO), standard-of-care IO, and standard-of-care non-IO. In Part I, the primary objective is to assess patient symptom reporting via ApricityCare, defined as 80% of patients reporting symptoms for at least 80% of the study duration. Part II aims to determine the rate of therapy discontinuation due to toxicity. Exploratory objectives include associations between alerts and diagnoses, corticosteroid use (>2 weeks), and emergency visits/hospitalizations. Futility for each cohort will be evaluated using a Bayesian optimal phase 2 design, monitoring patients without therapy discontinuation over 3 months. The study is open for enrollment. ApricityCare usage will be analyzed by study phase and cohort. Symptom reporting frequency, Net Promoter Score (NPS), corticosteroid dose, and emergency visit/hospitalization rates will be summarized using frequencies, medians, and interquartile ranges. Time from symptom onset to active management will be assessed with Kaplan-Meier methods. Associations between alerts and confirmed diagnoses will be evaluated for sensitivity and specificity, with clinical diagnoses as the gold standard. The modified intention-to-treat (mITT) population includes all patients receiving at least one anticancer regimen dose. Longitudinal data will be used to identify symptom profiles associated with and preceding irAEs, informing future clinical trials. Clinical trial information: NCI-2024-09566 and MDACC 2024-0229. Research Sponsor: None.

TPS12147 Poster Session

ACTIVATE: A pilot randomized activity coaching trial to increase vitality and energy during post-operative pelvic radiation therapy for endometrial cancer.

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Background: The ASCO-Society for Integrative Oncology guidelines strongly recommend exercise as a therapeutic strategy for cancer-related fatigue (CRF), advising that exercise regimens be tailored to each patient's capabilities. Despite this broad endorsement, at least two-thirds of cancer patients are unable to adhere to the recommendation of exercise due to symptoms and barriers, with women being more likely than men to report barriers to adherence to exercise. There is a lack of data on how to effectively integrate exercise into the treatment regimens of pelvic radiation therapy (RT). Most studies focus on other cancer types or male patients, leaving a significant gap in the literature regarding female patients with gynecological malignancies. Given the high prevalence of CRF and its impact on QoL, interventions reducing fatigue are vital. The primary objective of the ACTIVATE pilot trial(NCT06746428)is to evaluate the feasibility and acceptability of conducting a randomized trial with an exercise coaching program as the intervention in this patient population. Secondary objectives include estimating preliminary efficacy of exercise coaching on fatigue and health-related quality of life, quantifying baseline fatigue levels in our patient population, assessing eligibility criteria suitability, and exploring behavioral mechanisms and variables influencing intervention strength. **Methods:** The study methods include randomization of immediate versus delayed intervention with attention-control of 16 women treated with total or modified radical hysterectomy and surgical staging for Stage I-IVA endometrial cancer and are planned to complete pelvic RT as part of their adjuvant treatment. The intervention is an exercise coaching program which will consist of weekly check-ins for 10 weeks with a certified oncology exercise coach with a goal to address readiness for exercise, identify barriers, and develop an individualized plan for exercise for each week with a goal of increasing activity to 150 minutes of moderate activity per week. The immediate-start group begins with the start of RT; the delayed-start group starts at 6-8 weeks post-RT. Participants will be asked to wear an activity monitor to track steps and moderate activity minutes, complete assessments of patient-reported fatigue (FACIT-Fatigue), bowel/urinary toxicity (EPIC), sexual function and satisfaction (PROMIS), and quality of life (PROMIS-29+2 Profile v2.1), and participate in a six-minute walk test (6MWT) at predefined time points throughout the study. Feasibility will be evaluated on a prior goal of 50% provider acceptability, 50% patient acceptability, 50% appropriateness of screening criteria, and 70% adherence to the coaching session and physical activity monitor. Enrollment began in January 2025 and accrual is expected to be complete within 6 months. Clinical trial information: NCT06746428. Research Sponsor: None.

TPS12148 **Poster Session**

A phase II randomized placebo-controlled study of fisetin and exercise to mitigate chemotherapy-related functional decline in postmenopausal women with early breast cancer (PROFFi).

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Background: Despite substantial improvements in survival, postmenopausal survivors of breast cancer remain at high risk of functional decline after cancer treatment. One potentially targetable mechanism of chemotherapy-related functional decline is cellular senescence, a state of cell cycle arrest. Senescent cells (Sncs) develop a senescence-associated secretory phenotype (SASP), where they secrete a milieu of inflammatory cytokines that drive functional decline over time. In patients with stage I-III breast cancer treated with chemotherapy, markers of Sncs and SASP sharply increase after treatment and persist over time. Emerging data suggest that senolytics and exercise can decrease Snc burden. Senolytics are novel agents that eliminate Sncs and improve physical function in non-cancer populations. Among the existing senolytics, fisetin is a natural compound that is safe and tolerable in humans. Exercise also reduces Sncs in individuals without cancer and is well-established to improve physical function in survivors of cancer. More recent pre-clinical data shows that senolytics combined with exercise led to a greater reduction in Sncs than either intervention alone. However, no studies have tested whether senolytics and exercise, either alone or in combination, can reduce Sncs and improve physical function in cancer survivors. Therefore, we hypothesize that targeting Sncs with a combination of fisetin and exercise will lead to both independent and synergistic effects to prevent physical function decline in postmenopausal breast cancer survivors. **Methods:** This multicenter phase II randomized, placebo-controlled study will enroll 200 postmenopausal women with stage I-III breast cancer. Key eligibility criteria include completing neo/adjuvant chemotherapy within 12 months with diminished physical function as measured by the 6-minute walk distance (6MWD). Using a 2x2 factorial design, participants will be randomized 1:1:1:1 to exercise with fisetin, exercise alone, fisetin alone, or a control group for a total 16-week course. Fisetin will be dosed at 20mg/kg on days 1-3 every 14 days. Those randomized to the exercise arms will undergo a tailored, supervised remote exercise program led by a qualified exercise physiologist. The primary objective is to determine the effect of fisetin and/or exercise on physical function, as measured by the change in 6MWD from baseline to end of treatment. Secondary objectives include evaluating the effect of exercise and/or fisetin on other measures of physical, cognitive, psychosocial, and cardiometabolic function as well as digital biomarkers. We will also examine the effect of exercise and/or fisetin on markers of Sncs and SASP. Enrollment on this study began July 2024 and is currently ongoing (NCT06113016). Clinical trial information: NCT06113016. Research Sponsor: U.S. National Institutes of Health; R01 CA280088.

TPS12149 Poster Session

Epidermal growth factor receptor (EGFR) inhibitor-induced dermal toxicity treated with topical application of a novel Staphylococcus epidermidis compound.

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Background: Agents targeting the EGFR-mediated signaling pathway are used for the treatment of advanced lung, pancreatic, colorectal, and head and neck cancers. Significant dermal toxicities, occurring in up to 90% of patients treated with EGFR inhibitors (EGFRIs) and other medications inhibiting downstream signaling pathways, may be disruptive to a patient's quality of life and adherence to therapy. Inhibition of the EGFR pathway may suppress host defenses and lead to opportunistic pathogenic colonization or infection. Dermal toxicity is associated with elevated levels of Staphylococcus aureus and IL-36γ. ATR04-484 is an S. epidermidis strain isolated from a healthy human volunteer, selected for its ability to reduce S. aureus colonization and inhibit IL-36γ when applied topically. Reconstructed human epidermis (RHE) and ex vivo pig skin were utilized to measure the effect of ATR04-484 on S. aureus in therapeutic and prophylactic settings with S. aureus added prior to or after ATR04-484, respectively. ATR04-484 inhibited growth of both methicillin-resistant (MRSA) and methicillin-sensitive (MSSA) S. aureus in both therapeutic and prophylactic settings. IL-36γ levels were measured on RHE treated with erlotinib alone or in combination with ATR04-484. Application of ATR04-484 reduced erlotinib-induced IL-36γ to a level comparable to non-erlotinib treated RHE. The effect was dose-dependent; application of 10^9CFU/cm^2 of ATR04-484 showed more potent IL-36γ reduction compared to 10^8 CFU/cm^2. ATR04-484 has a promising profile of activities for the treatment of EGFRI-induced dermal toxicity by significantly reducing *S. aureus* growth and completely ameliorating IL-36γ levels. **Methods:** This multicenter, randomized, double-blind, vehicle-controlled Phase 1/2 clinical study is designed to evaluate the safety and tolerability of topical ATR04-484 (10^9 CFU/g) for the treatment of EGFRI associated dermal toxicity affecting the face of adult patients. ATR04-484 or its vehicle (3:1 randomization) will be applied in a stable volume to all patients and may include application to prioritize affected areas of the neck, chest, back, and paronychial areas (using remaining product on unaffected skin in the same areas, as needed). The key objectives of the study are to assess the safety and tolerability of topical ATR04-484 and to evaluate efficacy signals including severity of disease, pruritus, and pain. The bioavailability of ATR04-484 and pharmacodynamic parameters (including IL-36γ) are also studied. This clinical study will establish the basis for continued clinical development of ATR04-484. Clinical trial information: not yet assigned. Research Sponsor: Azitra Inc.