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CASE REPORT

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Molnupiravir treatment of 18 cats with feline infectious peritonitis: A case series

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Abstract

Background: Feline infectious peritonitis (FIP) is a viral disease in cats, caused by certain strains of coronavirus and has a high case fatality rate.

Objective: This case series reports the outcomes of treatment of cats with FIP using molnupiravir.

Animals: Eighteen cats diagnosed with FIP at the You-Me Animal Clinic, Sakura-shi, Japan between January and August 2022, and whose owners gave informed consent to this experimental treatment.

Methods: For this prospective observational study, molnupiravir tablets were compounded in-house at the You-Me Animal Clinic. Owners administered 10-20 mg/kg PO twice daily. Standard treatment duration was 84 days.

Results: Among 18 cats, 13 cats had effusive FIP and 5 had noneffusive FIP. Three cats had neurological or ocular signs of FIP before treatment. Four cats, all with effusive FIP, died or were euthanized within 7 days of starting treatment. The remaining 14 cats completed treatment and remained in remission at the time of writing (139-206 days after starting treatment). Elevated serum alanine transaminase (ALT) activity was found in 3 cats, all at Days 7-9, and all recovered without management. Two cats with jaundice were hospitalized, 1 during treatment (Day 37) and 1 with severe anemia at the start of treatment.

Conclusions and Clinical Importance: This case series suggests that molnupiravir might be an effective and safe treatment for domestic cats with FIP at a dose of 10-20 mg/kg twice daily.

KEYWORDS
antiviral, FIP, outcomes, treatment

1 | INTRODUCTION

Feline infectious peritonitis (FIP) is a viral infectious disease mainly occurring in domesticated cats.[1,2] FIP is an aberrant immune response to infection by feline coronavirus (FCoV), which is ubiquitous, especially in breeding and rescue catteries, usually with no to mild

Abbreviations: A/G ratio, albumin-to-globulin ratio; ALT, alanine transaminase; BUN, blood urea nitrogen; COVID-19, coronavirus disease 2019; FcoV, feline coronavirus; FIP, feline infectious peritonitis; FNA, fine needle aspiration; HCT, hematocrit; RT-PCR, reverse transcriptase polymerase chain reaction; SARS-CoV2, severe acute respiratory syndrome coronavirus 2; US, ultrasound; α1AG, α1-acid glycoprotein.

clinical signs. Fecal-oral transmission of FCoV frequently occurs especially in multi-cat environments,[3] and the incidence of FIP in cats exposed to FCoV is up to 14%.[4,5]

Feline infectious peritonitis is typically categorized, based on its clinical presentation, as either an effusive or a noneffusive form.[1,6,7] Until the development of specific antiviral therapy, case fatality associated with FIP was high and the majority of affected cats die within weeks to months after clinical signs appear.

Some nucleoside analogues, including remdesivir (GS-5734) and its active metabolite, GS-441524,[8] inhibit the synthesis of viral RNA and have high antiviral activity against FCoV causing FIP in cats.[9,10] Despite expectations from veterinarians and cat owners, the developer decided not to seek marketing approval for GS-441524 for the treatment of FIP. As a result, many cats with FIP are treated with nonapproved GS-441524 and concerns have been raised regarding the quality, purity, and potency of nonapproved products that are available on the global market. Mutian has excellent efficacy and safety.[11-14] Although the chemical structure of the active ingredient and its accurate concentration have not been disclosed by the manufacturer, its active ingredient is GS-441524.[12]

Molnupiravir is a nucleoside antiviral prodrug suitable for oral administration, with activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease (COVID-19), and has been approved in Japan since 2021 for the treatment of people with COVID-19. Reports on the efficacy and safety of molnupiravir in cats are published,[15] but there is a lack of sufficient data for the use of molnupiravir in cats with FIP. Given the lack of treatment options for FIP, we began offering clients at our clinic molnupiravir, using small tablets compounded in-house to allow easy administration in small cats. Reported here are the results from the first 18 cats to receive this treatment for FIP at our clinic.

2 | MATERIALS AND METHODS

2.1 | Cats

All cats attending the You-Me Animal Clinic, Sakura-shi in Japan from January 2022, that were diagnosed with FIP and whose owners gave informed consent, were included in this case series. Feline infectious peritonitis was diagnosed by a combination of clinical signs (decreased appetite, enlarged abdominal lymph nodes, weight loss, fever, effusions, or uveitis) and laboratory test results for anemia and hyperglobulinemia, including albumin-to-globulin (A/G) ratio and α1-acid glycoprotein (α1AG) values. A presumptive diagnosis of FIP was based on identification of FCoV RNA in samples from an abdominal or pleural effusion (effusive) or whole blood (noneffusive), or from fine needle aspiration (FNA) of pyogranulomatous lesions. Viral detection was undertaken using reverse transcription polymerase chain reaction (RT-PCR) at the following test laboratories: abdominal effusion and FNA samples at the IDEXX Laboratory, Japan (using LightCycler 480 System II, Roche Diagnostics K.K., Basel, Switzerland) and whole blood at the Canine Lab., Japan (using CFX Connect, Bio-Rad Laboratories, Inc, Irvine, CA, USA). Abdominal or pleural effusion samples (1 mL each) were collected by ultrasound-guided abdominocentesis or thoracentesis, respectively, and assessed for total nucleated cell count, protein content, A/G ratio, and cytology. Whole blood samples (1 mL) were collected and shipped in ethylenediaminetetraacetic acid (EDTA) tubes.

2.2 | Drug preparation

Tablets containing molnupiravir 20 mg were compounded in-house at the You-Me Animal Clinic. In brief, molnupiravir powder was removed from 20 commercially sourced molnupiravir 200 mg capsules (MOVFOR, Batch No. HH2201001 [HETERO HEALTHCARE, Hyderabad, India]) and mixed with cellulose powder (Microcrystalline Cellulose powder, NICHIGA, Takasaki, Japan) using a mortar and pestle (Matsuyoshi Medical Instruments Co, Ltd, Tokyo, Japan) to make a total of 12 g of powder mix [Correction added after first online publication on 1 September 2023. The word MOVFORE changed to MOVFOR.]. The powder was shaped into approximately 200 6-mm wide tablets with a secant line, using a generic tablet press made in China.

2.3 | Treatment

Treatment with molnupiravir was initiated when FIP was highly suspected based on clinical presentation or when FCoV RNA was detected with PCR; this date was designated as the first visit. The following doses were chosen: 20 mg/kg/d (as 10 mg/kg twice daily) for cats with the effusive type, 30 mg/kg/d (15 mg/kg twice daily) for cats with the noneffusive type and cats with pyogranulomatous lesions, and 40 mg/kg/d (20 mg/kg twice daily) for cats with neurological or ocular signs of FIP. The dose could be increased or decreased in animals that showed evidence of clinical worsening or adverse events, respectively. The dose was chosen based on the estimated animal dosages reported online,[16,17] and on the adult human dose of molnupiravir for COVID-19, which is 800 mg every 12 hours.[18] This would equate to a per kilogram dose of between 10 and 13.3 mg/kg twice daily for adults weighing 60 to 80 kg. As there is no pharmacokinetic information with cats, we chose the dose for cats under the assumption that feline drug metabolism is equivalent to that of humans.

Owners were instructed to administer the tablets twice daily with 12 hours between doses. The predetermined standard treatment duration was 84 days, as per the GS-441524 study.[10]

2.4 | Measurements

Owners were instructed to record body weight, body temperature, physical activity, appetite, and defecation/urination each day, and were asked to visit the clinic at Weeks 1, 2, 6, and 10. At each visit, the following laboratory tests were required: red and white blood cell counts, hemoglobin, hematocrit (HCT), α1AG, total protein, albumin,

aspartate transaminase (AST), alanine transaminase (ALT), total bilirubin, creatinine, blood urea nitrogen (BUN), and A/G ratio. Samples were analyzed at the clinic using a Catalyst One Chemistry Analyzer and ProCyte One Hematology Analyzer (both IDEXX Laboratories, Westbrook, Maine). The A/G ratio was determined from either a whole blood plasma or fractionated protein sample. We conducted ultrasound assessments of the abdomen and chest of each cat at the start of treatment and after 2, 6, and 10 weeks of treatment, using a Prosound α7 device (Aloka, Japan), including assessment of cardiac function (fractional shortening, ratio of left atrial to aortic diameter, and valve regurgitation).

2.5 | Adverse events

Any unusual laboratory test values or health events that occurred during treatment were considered adverse events and a determination regarding treatment continuation/discontinuation was made.

2.6 | Statistical analysis

As this is a case series, no statistical calculations were performed other than descriptive statistics.

2.7 | Ethics

All owners provided written informed consent before initiation of treatment. Experimental use of molnupiravir was approved by our institutional animal study review board.

3 | RESULTS

3.1 | Disease and treatment characteristics

Eighteen cats had completed treatment by August 4, 2022, and are included in this report.

The presentation of the 18 cats is summarized in Table 1 and Table S1. Median age was 6.5 (range: 3-93) months. All 18 cats had a low serum A/G ratio, 16 had appetite loss, and 14 had mild to severe anemia according to hemoglobin and HCT levels. Thirteen cats had effusive FIP and 5 cats had noneffusive FIP. Neurological or ocular signs indicative of FIP were present in 3 cats before treatment, including epileptic seizure/neurologic signs (#8), blunting of postural reflexes (#10), and slow pupillary reflex (#18) (Table S1). All but 2 cats (#8 and #15) were treated entirely on an outpatient basis. Cat #8 was hospitalized from Day 37 for 3 days because of jaundice. Cat #15 required hospitalization for 5 days upon treatment initiation, because of anemia and jaundice, accompanied by elevated bilirubin concentration and ALT activity. During hospitalization, the cat received molnupiravir as planned, and was hydrated with Ringer's solution and

TABLE 1 Baseline characteristics of the cats in this case series.

	Cats with FIP (n = 18)
Age at disease onset, months, median (range)	6.5 (3-93)
Breed, n (%)	
Domestic mixed-breed	9 (50.0)
Exotic shorthair	2 (11.1)
British shorthair	2 (11.1)
Other	5 (27.8)
Sex, n (%)	
Male entire/male neutered	4 (22.2)/7 (38.9)
Female entire/female neutered	2 (11.1)/2 (11.1)
Weight, kg, mean (SD)	2.72 (0.77)
Duration from disease onset to treatment,[a] days, median (range)	16.5 (2-49)
Effusive type, n (%)	13 (72.2)
Pyogranulomatous lesion in abdomen, n (%)	5 (27.8)
Neurological signs of FIP, n (%)	2 (11.1)
Ocular signs of FIP, n (%)	1 (5.6)
Temperature, °C, mean (SD)	39.3 (0.9)
Hematocrit, %, mean (SD)	27.3 (8.1)
Albumin/globulin ratio, mean (SD)	0.35 (0.10)
Sample type, n (%)	
Abdominal effusion	11 (61.1)
Pleural effusion	1 (5.6)
FNA of pyogranulomatous lesion	2 (11.1)
Whole blood	3 (16.7)
None	1 (5.6)

Abbreviations: FIP, feline infectious peritonitis; FNA, fine needle aspiration.
[a]Based on owner's report of when signs of illness first appeared.

treated with oral ursodeoxycholic acid (Towa, Japan) 10-15 mg twice daily to reduce bilirubin levels. There was no evidence of intravascular hemolysis (HCT remained stable) and microscopic examination of blood smears was negative for hemotropic mycoplasma infection.

The clinician in charge decided to extend treatment to 99 days for Cat #1. This cat developed disturbed consciousness on Day 8 and the dose was subsequently increased to 40 mg/kg. This sign disappeared on Day 15; however, the A/G ratio with a fractionated protein sample did not return to normal. At Day 99, although the A/G ratio was still below the reference range (0.6), the clinician decided to discontinue treatment, as the cat was showing no clinical progression or deterioration.

3.2 | Outcomes

The clinical response in 14 cats was rapid. Doses, findings during the treatment, and outcomes in these animals are summarized in Tables S2 and S3. Fever resolved and appetite recovered within

2-3 days after the first treatment. Remissions were achieved, even in the cats with severe clinical signs. These included Cat #8, #17, and #18 who each had ≥2 cm pyogranulomatous lesions, Cat #4 who had severe anemia and a low A/G ratio, Cat #14 who had pleural effusion and labored breathing, and Cat #15 who had an enlarged kidney. Pyogranulomatous lesions reduced in size or became undetectable on ultrasound in all 5 cases and laboratory values in all cats returned to normal. Three cats presented with neurological signs of FIP before treatment. Cat #12 had no neurological signs of FIP before treatment but had an epileptic seizure on Day 7. The dosage was subsequently increased to 40 mg/kg. Anisocoria was detected by slit lamp in Cat #7 on Day 2, likely related to uveitis. The molnupiravir dosage was increased to 40 mg/kg from Day 15, and all neurological or ocular signs of FIP resolved within 15 days.

Of the 14 cats that achieved remission, no relapses had occurred by August 3, 2022, during 55 to 107 days of follow-up after treatment discontinuation. Three cats died (#2, #11, and #16) and 1 (#13) was euthanized; these cats all had the effusive form of FIP, but did not have any neurological or ocular signs of the disease. All died within 1 week of treatment initiation.

3.3 | Safety

Alanine transaminase activity above the reference value was found in 4 cats; the value of each was 286 U/L (Cat #8 on Day 37), 283 U/L (Cat #9 on Day 9), 154 U/L (Cat #10 on Day 7), and 117 U/L (Cat #17 on Day 9). The 3 cats that developed an early ALT increase on Days 7-9 recovered without management. Cat #8 developed jaundice on Day 37 and was treated as an inpatient for 3 days.

No abnormalities in BUN or creatinine concentrations were noted during molnupiravir treatment.

4 | DISCUSSION

In our series of cats with presumptive FIP treated with an off-label compounded formulation of molnupiravir, 14 out of 18 cats achieved remission and remained in remission at the time of writing, during up to 107 days of follow-up. Four cats showed signs of potential hepatic adverse events; 3 cats developed ALT activity above the reference range during the first 7 to 9 days of treatment, all of which resolved without management, and 1 developed jaundice on Day 37, which required inpatient treatment.

The approved human molnupiravir formulation is 200 mg in capsule form, but must be divided into smaller dosage components for animals to facilitate an appropriate dose by body weight. We chose to compound molnupiravir as small tablets to simplify administration. We speculated that cats might refuse to swallow the drug as a powder or in a water solution and owners might find it difficult to administer the entire dose in powder form every time.

The minimum effective dose of molnupiravir for FIP is recommended to be 4.5 mg/kg PO every 12 hours for cats without neurological/ocular signs of the disease, with the dose increased to 12 mg/kg PO every 12 hours for cats that develop ocular or neurological signs of FIP.[17] Others recommend the dose as 25 mg/kg every 24 hours for dry/wet FIP, 37.5 mg/kg every 24 hours for ocular FIP, and 50 mg/kg every 24 hours for neurological FIP.[16] Because none of these dose recommendations were determined in prospective controlled studies, the dose in this case series was determined by the author according to these estimates, the adult human dose and his experience. Nevertheless, the dosage used in our case series (10 mg/kg twice daily for cats with effusive FIP, 15 mg/kg twice daily for cats with noneffusive FIP or pyogranulomatous lesions, and 20 mg/kg twice daily for cats with neurological or ocular signs of FIP) appears to be effective and safe, and might help to inform the dosages used in future clinical studies.

Four cats died during this study. Each of these cats had the effusive FIP type; however, when considering that some surviving cats had signs that were as severe, or even more severe, than the cats that died, no signs were found that were predictive of an early death. Unfortunately, the treating veterinarian received little information regarding the deaths of the 3 cats that died at home, and no postmortem examinations were performed. One cat (#2) died after vomiting the drug on Day 6, so it is possible that this animal had difficulty swallowing.

Use of GS-441524 in 31 cats with FIP, of which 26 cats completed at least 12 weeks of treatment, resulted in 25 achieving remission.[10] Eight out of 26 cats relapsed or were reinfected within 3 to 84 days after this period. The duration of follow-up in our case series is shorter than in the GS-441524 study[10]; however, follow-up of the cats in our series is currently ongoing and more cats with FIP are being treated with molnupiravir. Further observation will provide longer term efficacy data. Major adverse events reported for injection of GS-441524 study were injection site reactions, in 16 of 26 cats.[10] As the treatment in our study was orally administered, no cats in our series experienced injection site reactions. In our series, the most common adverse event during treatment was an increase in ALT activity. However, longer term follow-up is essential to more adequately assess liver-related reactions, and a larger sample size is needed to more fully assess adverse events with molnupiravir.

Molnupiravir is active against SARS-CoV-2 and other RNA viruses[19] and generates only low-level resistance in a cell culture.[20-22] The efficacy of oral administration of molnupiravir was evaluated in a phase 3, randomized control trial in 1433 people with COVID-19, with a lower percentage of hospitalizations or deaths by Day 29 in the molnupiravir group compared with placebo.[18] Another important clinical question is whether molnupiravir-resistant viruses might be generated, and how many cats experience relapse or reinfection after treatment.

All owners who provided informed consent to this study were included in the order of participation, so there should be little risk of any bias. Nevertheless, selection bias should be considered as this case series was enrolled at a single center in Chiba prefecture, Japan. Another potential limitation of our case series is that the diagnosis of FIP was presumptive in all cases. Cats might have FCoV viremia without FIP, so RT-PCR detection of FCoV RNA is not specific for FIP,[7] although this technique has high sensitivity (90%) and specificity (96%) for FIP when applied to FNA samples.[23] In our series, the

combination of RT-PCR with clinical signs, and other serum biochemistry including low A/G ratio were highly suggestive of FIP.[7] This case series suggests that molnupiravir might be an effective and well-tolerated treatment for FIP.

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DATA AVAILABILITY STATEMENT

The data presented in this study have not been published elsewhere but are available on request from the corresponding author.

CONFLICT OF INTEREST DECLARATION

The author declares no conflict of interest.

OFF-LABEL ANTIMICROBIAL DECLARATION

Experimental use of molnupiravir was approved by the Institutional Review Board of the You-Me Clinic.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) OR OTHER APPROVAL DECLARATION

Informed Consent was obtained from all cat owners included in this study.

HUMAN ETHICS APPROVAL DECLARATION

The author declares human ethics approval was not needed for this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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