Case Series

jfms Journal of Feline Medicine and Surgery

Adverse events after fecal microbiota transplantation in nine cats: a case series

Journal of Feline Medicine and Surgery
1–6

DOI: 10.1177/1098612X251337274
journals.sagepub.com/home/jfm

This paper was handled and processed by the American Editorial Office for publication in *JFMS*

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Abstract

Case series summary This case series describes nine cases of fecal microbiota transplantation in cats and associated adverse events (AEs) from two tertiary referral hospitals. AEs were graded according to criteria established by the Veterinary Cooperative Oncology Group's Common Terminology Criteria for Adverse Events (VCOG-CTCAE v2) for clinical trials. Cats received 5–6 g/kg donor feces 2–6 times for chronic enteropathy (n = 4) or therapy-resistant diarrhea (n = 5). AEs included lethargy (n = 7), vomiting (n = 5), diarrhea (n = 5), weight loss (n = 5), inappetence (n = 5), dehydration (n = 5), abdominal pain (n = 2), gastroenterocolitis based on ultrasound (n = 2) and anorexia (n = 1). Temperatures of up to 103.4°F were noted but did not meet the criteria for AEs (>103.5°F). Cats responded to antimicrobials (metronidazole, marbofloxacin), anthelmintics (fenbendazole), supportive care with fluids, ondansetron and mirtazapine (n = 5), gabapentin (n = 2), pradofloxacin (n = 1) or self-resolved (n = 1). Positive response to fecal microbiota transplantation for the presenting complaint was seen in eight cats (seven complete, one partial and transient).

Relevance and novel information Fecal microbiota transplantation is increasing in usage among companion animals. Fecal microbiota transplantations in cats have been rarely described in the literature as have AEs after administration. This case series represents the first description of AEs after fecal microbiota transplantation in cats.

Keywords: Fecal microbiota transplantation; adverse events; chronic enteropathy; chronic diarrhea

Accepted: 6 April 2025

Introduction

Fecal microbiota transplantation (FMT) is performed by administering feces from a healthy donor to a diseased recipient's gastrointestinal system to modulate the host's microbiota.[1] Scarce literature describes FMT in cats with no approved FMT product, indications or systematic studies on administration. A case report, an abstract, a survey-based observational study and a non-randomized clinical trial have described feline FMT.[2–5] A clinical consensus guideline for veterinary FMT includes recommendations for feline FMT without information on adverse events (AEs).[6] Despite this, an observational survey-based study reported that 14/115 (12%) respondents have performed FMT in cats for various gastrointestinal diseases.[5]

The documented benefits after FMT in dogs include parvoviral enteritis, chronic enteropathies, acute diarrhea, acute hemorrhagic diarrhea syndrome and atopic dermatitis.[7–11] Feline gastrointestinal diseases are often associated with concurrent intestinal dysbiosis, and FMT may be of benefit in re-establishing the normal gut microbiome.[12,13] Indications for FMT may include refractory diarrhea, feline chronic enteropathy (CE) including

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inflammatory bowel disease and low-grade intestinal T-cell lymphoma, as well as chronic diarrhea in kittens.[3,14]

Although FMT may harbor potential benefits, the potential for AEs must also be considered. FMT is considered relatively safe in human medicine, with the most commonly reported AEs being abdominal discomfort or pain.[15–17] Scant reports of FMT-related AEs exist in canine literature and none in cats.[5,9,18] The Veterinary Cooperative Oncology Group's revised Common Terminology Criteria for Adverse Events (VCOG-CTCAE v2) provides a systematic way to grade and report AEs in clinical trials.[19] This reports AEs in categories related to the organ system affected and rated on a 5-point scale (grade I = mild, grade II = moderate, grade III = severe, grade IV = life-threatening, grade V = death). This case series describes FMT-related AEs in nine cats at two veterinary teaching hospitals with aims to raise awareness among clinicians about the possible FMT-related AEs in cats.

Case series description

Nine cats with chronic diarrhea received FMTs via a rectal administration of fecal slurries. All donors were deemed disease-free based on a health questionnaire, physical examination and negative results for the following screening tests: fecal flotation and sedimentation, testing for intestinal pathogens ('fecal enteropathogen panel') including PCR testing for *Clostridioides difficile*, *Clostridioides perfringens*, feline panleukopenia virus, *Tritrichomonas (foetus) blagburni* and *Campylobacter jejuni*, enrichment broth PCR for *Salmonella* species, and indirect fluorescent antibody testing for *Cryptosporidium* species and *Giardia* species.

Data collection included signalment, presenting complaint, physical examination findings, treatments before FMT, FMT dosage, types and grades of AEs (summarized in Tables 1 and 2) and response to therapy. Because of the small sample size and the retrospective nature of the study, only descriptive analysis was performed.

Cases 1–5

A litter of five 8-week-old kittens (three males, two females) with a 3-week history of therapy-resistant diarrhea (TRD) were administered FMTs at the Veterinary Medical Teaching Hospital (VMTH) at University of California, Davis. Cats were part of a clinical trial investigating the response of TRD to FMT (IACUC number 22063). TRD was defined as diarrhea with a duration of more than 3 weeks despite treatment and without a known infectious cause (all cats tested negative for fecal enteropathogen panel; see Table 1 for treatments prior). Cats were exclusively indoors for a minimum of 4 weeks and up to date on vaccines with no clinical signs outside of diarrhea. All cats had a fecal score of 1 based on a previously validated cat-specific fecal scoring system (range of 1–6, with 1 representing liquid, watery feces to 6 representing small, very hard fecal pellets).[20] Fecal flotation revealed one (cat 1) to two (cat 3) *Cystoisospora felis* oocysts for two cats, less than 1/40 per high power field *C felis* oocysts for cat 4, and negative for cats 2 and 5.

An adult cat donor's cryopreserved FMT was used. Donor feces were collected immediately after defecation, stored in a refrigerator at −24.8°F for up to 12 h and transported to the VMTH on ice between June and July 2021. Feces were mixed with sterile saline (2.5 ml of 0.9% saline/g of feces), followed by kneading, twice-filtering through mesh sieves and adding sterile glycerol (30%) to a final solution of 10% glycerol.[21] FMT solutions in 60 ml catheter tip syringes were stored at −112°F and thawed at 98.6°F in a water bath. Owners filled out a questionnaire on fecal score, activity level, appetite, vomiting, tenesmus, defecation frequency, mucous or blood on stool, pain on defecation, defecation out of the litter box and any AEs. In July 2021, cats received FMTs at 5 g/kg every 2 days for a total of three treatments via rectal administration of a fecal slurry using a 3 French polyvinyl catheter without sedation. Cats were manually restrained using a towel and handled gently to minimize distress. FMTs were tolerated well by all cats.

After the first two FMTs, the diarrhea reportedly improved (fecal score improved to 2 on day 2 [cats 1–2] or day 6 [cats 3–5] after the initial FMT). Three days after the final FMT, all cats became lethargic (grade I), inappetent (grade I), and had vomiting (grade II) and diarrhea (grade II), with a return of fecal score to 1. Physical examination revealed 7–10% dehydration in all cats (grade II). Cats experienced mild (grade I; cats 2, 4, 5) to moderate (grade II; cats 1, 3) weight loss. Repeat fecal flotation for cats with previous *C felis* oocysts results were negative (cats 1, 5) or 4/40 per high power field *C felis* oocysts (cat 4). Fecal feline enteropathogen panel was negative for cats 1 and 2. An ELISA test for feline panleukopenia virus was negative for cat 2. Abdominal ultrasound for most clinically affected cats (cats 1 and 2) revealed gastroenterocolitis (grade II) for both with variably fluid-filled stomach and small intestines for cat 1 and a small volume of gas and fluid in the stomach and small intestines and moderately fluid filled colon for cat 2.

All cats received supportive care with subcutaneous fluids, metronidazole (15 mg/kg PO q12h × 7 days), fenbendazole (50 mg/kg PO q24h × 7 days) and ponazuril (50 mg/kg PO q24h × 3 days). Because of the persistence of clinical signs, therapy was escalated for all cats 4 days after the final FMT administration with ondansetron (0.5 mg/kg PO q12h × 3 days) and mirtazapine (0.53 mg transdermal, q24h for up to 14 days). As a result of hypersalivation and vomiting associated with metronidazole and lack of clinical response, cat 2's antimicrobial therapy was switched to marbofloxacin (6.6 mg/kg PO q24h × 14 days).

Table 1 Signalment, clinical characteristics and adverse events (AEs) associated with fecal microbiota transplantation (FMT) administration

Parameter	Cats 1–5	Cat 6	Cat 7	Cat 8	Cat 9
Signalment	8-week-old DSH (2 FI, 3 MI)	14-year-old FS DSH	10-year-old MC Siamese	10-year-old FS DLH	7-year-old MC DSH
Clinical signs	Chronic diarrhea >3 weeks	Chronic vomiting >8 months	Chronic diarrhea and weight loss >1.5 years	Chronic vomiting and weight loss	Chronic vomiting, diarrhea, weight loss
Treatments before FMT	Ponazuril 50 mg/kg PO q24h × 5 days, fenbendazole 50 mg/kg PO q24h × 7 days repeated 1 week apart, diet change, probiotics, psyllium husk, Rx Clay	Hydrolyzed diet, metronidazole (unknown dose), prednisolone 2 mg/kg/day PO, chlorambucil unknown dose	Hydrolyzed diet, novel protein diet, metronidazole 10 mg/kg PO q12h, prednisolone 2 mg/kg/day PO, chlorambucil 2 mg PO q2 weeks, cyclosporine 5 mg/kg PO q12h	Hydrolyzed diet, anthelmintics unknown dose	Hydrolyzed diet, prednisolone 2 mg/kg/day PO
Diagnosis	Therapy-resistant diarrhea	Chronic enteropathy	Small intestinal lymphoplasmacytic enteritis	Low-grade intestinal T-cell lymphoma	Inflammatory bowel disease
Diagnostic method	Clinical signs	Clinical signs, abdominal ultrasound	Gastroduodenoscopy, ileoscopy, histopathology	Gastroduodenoscopy, ileoscopy, histopathology	Clinical signs, abdominal ultrasound
Number of FMTs	3	3	6	2	3
FMT dosage	5 g/kg	6 g/kg	6 g/kg	5 g/kg	5 g/kg
FMT days	Days 1, 3, 5	Days 1, 3, 5	Days 1, 14, 21, 28, 35, 42	Days 1, 7	Days 1, 5, 12
Number of AEs	3 grade I in 3 cats 2 grade I in 2 cats 5 grade II in 2 cats 3 grade II in 3 cats	–	1 grade I 1 grade III	1 grade I	1 grade I 1 grade II

Cats 1–5 were clinically diagnosed with therapy-resistant diarrhea and received FMT from University of California, Davis's Veterinary Medical Teaching Hospital. Cats 6–10 were clinically or histopathologically diagnosed with chronic enteropathy and received FMT from North Carolina State University's Veterinary Hospital. AEs are reported according to VCOG-CTCAE. All AEs were gastrointestinal and rated on a 5-point scale (grade I = mild, grade II = moderate, grade III = severe, grade IV = life-threatening, grade V = death). Events in this cohort included appetite altered, anorexia, dehydration, diarrhea, enteritis, nausea/ptyalism, vomiting

DLH = domestic longhair; DSH = domestic shorthair; FI = female intact; FS = female spayed; MC = male castrated; MI = male intact; VCOG-CTCAE = Veterinary Cooperative Oncology Group's Common Terminology Criteria for Adverse Events

Clinical signs resolved completely for all cats by day 6 after the final FMT except for soft stool, which was resolved by the exit examination 17 days after the final FMT (no fecal score available). Cats experienced grade I (n = 5) and II (n = 5) AEs. Types and grades of AEs experienced are further described in Table 2. Feline leukemia virus and feline immunodeficiency virus tests were negative at the time of castration at 3 months old for cats 1–3 (information not available for cats 4 and 5) and all cats were still alive at the time of writing.

Cases 6–9

Four adult cats with CE were administered 2–6 FMTs at the veterinary hospital at North Carolina State University between April 2020 and December 2021. Cats were presented with a history of chronic vomiting, chronic diarrhea and weight loss. Signalment, clinical signs, diagnosis and method of diagnosis, number, dosage administered and dates of the FMTs are listed in Table 1. Cats were trialed with hydrolyzed diet (n = 4), novel protein diet (n = 1), metronidazole (n = 2), prednisolone (n = 3), chlorambucil (n = 2), cyclosporine (n = 1) and anthelmintics (n = 1) before the referral without response (detailed in Table 1). Cats were diagnosed with CE based on clinical signs and abdominal ultrasound (n = 2) or gastroduodenoscopy/ileoscopy with biopsy (n = 2).

Spontaneously passed donor feces were collected immediately after defecation and transported to the veterinary hospital. A total of 6 g of donor feces/kg of the recipient's body weight was mixed with 0.9% saline to a volume of 10 ml/kg and strained to obtain a slurry. All FMTs (5–6 g/kg; approximately 10 ml/kg per cat) were administered the same day via a sedated rectal enema using an appropriately sized polyvinyl catheter as a non-retention enema into the colon.

Cat 6 developed a temperature of 103.4°F 6 h after the first FMT. Pradofloxacin (7.5 mg/kg PO q24h) resolved the pyrexia within 24 h. Repeat FMTs on days 3 and 5

Table 2 Adverse events (AEs) after fecal microbiota transplantation (FMT) in cats according to Veterinary Cooperative Oncology Group's Common Terminology Criteria for Adverse Events (VCOG-CTCAE)

AE/VCOG-CTCAE	Grade I (mild)	Grade II (moderate)	Grade III (severe)	Grade IV (life-threatening)	Grade V (death)
Lethargy	5/5 TRD cats 1/5 CE cats	1/5 CE cats	–	–	–
Vomiting	–	5/5 TRD cats	–	–	–
Diarrhea	–	5/5 TRD cats	–	–	–
Weight loss	3/5 TRD cats	2/5 TRD cats	–	–	–
Inappetence	5/5 TRD cats	–	–	–	–
Anorexia	1/5 CE cats	–	–	–	–
Dehydration	–	5/5 TRD cats	–	–	–
Abdominal pain	1/5 CE cats	–	1/5 CE cats	–	–
Gastroenterocolitis	–	2/5 TRD cats	–	–	–

CE cats are described separately from TRD cats. Grade I consists of asymptomatic or mild clinical signs with no need for intervention, grade II consists of moderate clinical signs that may indicate outpatient or non-invasive intervention, grade III consists of severe or significant but not immediately life-threatening clinical signs where hospitalization may be indicated, grade IV consists of life-threatening consequences and grade V consists of deaths related to the AE, including euthanasia
CE = chronic enteropathy; TRD = therapy-resistant diarrhea

were administered without further AEs. Because of the progression of chronic kidney disease, the cat was euthanized 14 days after the last FMT. Cat 6 experienced no AEs that fitted the VCOG-CTCAE v2 criteria.

Severe abdominal pain (grade III) and anorexia (grade I) developed within 24 h after the second FMT in cat 7 and resolved completely with gabapentin. The cat's presenting clinical signs resolved completely with repeated FMTs with concurrent treatment of a tapering dose of chlorambucil and hydrolyzed diet; the cat is still alive at the time of writing.

Cat 8 developed a temperature of 102.9°F and mild lethargy (grade I) developed immediately after the first FMT, which self-resolved within 48 h. An additional FMT was administered 1 week after the first FMT. A partial and transient response for presenting clinical signs was seen in this cat but the cat was eventually euthanized (reason not reported).

Cat 9 developed moderate lethargy (grade II) and mild abdominal pain (grade I) the day after the third FMT, which responded to gabapentin within 24–48 h. The cat showed complete resolution of presenting clinical signs and was alive at the time of writing.

Discussion

This case series describes nine cats with AEs after FMT administration. AEs were most frequently mild and gastrointestinal in nature and most resolved with supportive care or no intervention. Partial (1/9; 1 CE cat) or complete (7/9; 5 TRD cats and 2 CE cats) response to FMT therapy for the initial presenting complaint was noted.

Previous literature on feline FMTs does not report any AEs, but documentation of AEs was not within their scope.[2–4] Literature on canine FMTs has reported AEs, including decreased activity levels, inappetence, vomiting, diarrhea and increased flatulence.[5,22,23] Recently, FMT has also been described in clinically healthy dogs using CTCAE-VCOG v2, with no serious AEs or deaths after FMT in 28 days;[23] however, published data are still limited.

Human FMT-related AEs are defined by the National Cancer Institute Common Terminology Criteria for Adverse Events as mild to moderate (grades 1–2) and serious (grades 3–5).[24] In a systematic review of 4241 patients, FMT-related AEs were observed in 19%, most commonly diarrhea (10%) and abdominal discomfort, pain or cramping (7%).[16] Serious FMT-related AEs were reported in 1.39% and included aspiration pneumonia (n = 6), bacteremia secondary to transmission from FMT (n = 8) and deaths (n = 5), with four patients receiving their FMTs via an upper gastrointestinal route (oral capsules or a nasogastric tube).[16,25]

In this case series, AEs described after FMT included lethargy, vomiting, diarrhea, weight loss, inappetence, dehydration, abdominal pain, gastroenterocolitis and anorexia. Most commonly, AEs were grade I (n = 16) or grade II (n = 20), and a single grade III AE was experienced. Consistent with AEs in humans and dogs, most AEs were gastrointestinal.[16,23] Cats with TRD experienced a higher number of AEs, possibly due to the difference in population (developing immune system, greater variability in weight due to the small size of kittens), a systematic questionnaire reporting AEs, possible comorbid infections or due to the nature of their disease.

The route of FMT has been suggested to play a role in AEs. Higher rates with upper gastrointestinal administration (43%) compared with lower gastrointestinal FMT (18%) have been reported in humans.[15] This case series only investigated rectal enemas, but lyophilized oral capsule FMT is available (AnimalBiome); a study of 46 cats

that were given these capsules did not report AEs.[4] In addition, TRD cats were given frequent FMT administration and a larger slurry (potentially a larger bacterial load) than previously reported, which may have contributed to AEs.[4] Further studies are required to determine whether administration route (oral, rectal or endoscopic) or the primary disease process may affect the incidence of AEs in cats receiving FMTs.

Tracking the response to therapy was not a primary aim; however, 8/9 cats reported a partial or complete response to FMT for their initial presenting complaint. Whether a safe protocol (dosage, preparation and delivery method, number of FMTs) exists to achieve clinical remission is currently unknown.[6] A previous study of oral capsule FMT in cats with chronic digestive conditions described an improvement in clinical signs of 77%;[4] however, the results were owner-reported, and the inclusion criteria did not specify a diagnosis of gastrointestinal disease by a veterinarian.[4]

This case series has some limitations. Two separate populations of cats were examined, with the TRD cats being from a single litter. Neither the microbiome nor the feline dysbiosis index were assessed. Prior treatments may have impacted the occurrence of AEs or response to therapy. Not all cats with CE were diagnosed with histopathology. FMT administration and donor screening were not standardized. Antimicrobials were administered to six cats (all five kittens and one adult cat) based on the severity of the clinical signs, including progressive severe lethargy or malaise, persistent pyrexia (particularly in young kittens) and concerns about bacterial translocation. However, unless a specific bacterial infection is diagnosed or strongly suspected, antimicrobials should not be considered a first-line treatment for acute or chronic diarrhea as they typically do not hasten recovery, cause antimicrobial resistance and may contribute to long-term dysbiosis.[26–28] Clinicians should carefully weigh the risks and benefits of antimicrobial treatment and prioritize antimicrobial stewardship to mitigate side effects and promote responsible treatment. Pyrexia, observed in a subset of cats in this study, is a commonly reported AE after FMT, though its underlying mechanism remains unclear.[15] Alternatively, pyrexia may have been secondary to pathogenic bacteria (transferred via FMT). CE cats were administered butorphanol for sedation, which cannot be excluded as a cause of pyrexia after FMT.[29] TRD is not a clinically defined term, and a different disease process not recognized by the investigators may have been possible. Three kittens had *C felis* oocysts; however, previous studies imply that *C felis* is not an obligate gastrointestinal pathogen in cats older than 1 month.[30,31] The number of oocysts was low, and given the pathobiology with the timeline of development of AEs, *C felis* is unlikely to be related. Occult infectious organisms that were either a comorbidity or transmitted through the FMT process cannot be ruled out as a possibility. Some cats had limited follow-up information, and it is possible that cats had concurrent diseases that contributed to clinical signs. Lastly, due to the retrospective nature of this case series, reports of AEs may have been inaccurate or lacking.

Conclusions

To the authors' knowledge, there are no published data on feline FMT-related AEs. We intend to raise awareness of AEs after FMT in cats and aid in judicious choices if electing to perform FMT in cats. The correlation between FMT dosage, delivery method, number and frequency of FMTs with the occurrence of AEs warrants further studies.

Author note This paper was presented as an oral abstract at the 2023 ACVIM Forum.

Supplementary material The following files are available as supplementary material:
Supplementary Table 1: Donor characteristics and clinical history for cat stool donors for FMT.
Supplementary Table 2: Complete blood count and serum biochemistry panel results for cat stool donors for FMT.

Conflict of interest Jan Suchodolski and M Katherine Tolbert are part of the Texas A&M Gastrointestinal Laboratory, which provides fee-for-service testing for feline fecal enteropathogen panels on a commercial basis.

Funding The authors received no financial support for the research, authorship, and/or publication of this article.

Ethical approval The work described in this manuscript involved the use of non-experimental (owned or unowned) animals. Established internationally recognized high standards ('best practice') of veterinary clinical care for the individual patient were always followed and/or this work involved the use of cadavers. Ethical approval from a committee was therefore not specifically required for publication in *JFMS*. Although not required, where ethical approval was still obtained, it is stated in the manuscript.

Informed consent Informed consent (verbal or written) was obtained from the owner or legal custodian of all animal(s) described in this work (experimental or non-experimental animals, including cadavers, tissues and samples) for all procedure(s) undertaken (prospective or retrospective studies). No animals or people are identifiable within this publication, and therefore additional informed consent for publication was not required.

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