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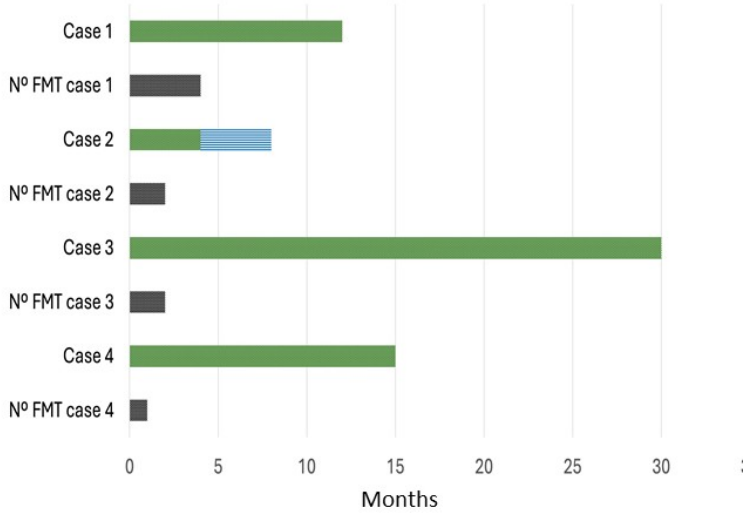
Fecal microbiota transplantation for prevention of recurrent acute cholangitis. Review of four published cases

Follow-up of patients with recurrent acute cholangitis (RAC) after fecal microbiota transplantation (FMT) and number of FMT procedures carried out in each patient (No. FMT)

A significant reduction in the number of episodes of RAC was observed

In case 2, another FMT was performed 4 months after the initial procedure due to recurrence



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Fecal microbiota transplantation for prevention of recurrent acute cholangitis. Review of four published cases

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Lay Summary

Recurrent acute cholangitis (RAC) is a serious infection of the bile ducts that often comes back in some patients. These repeated infections can lower a person's quality of life and may even be life-threatening. Standard treatments usually involve antibiotics, but over time, these can stop working and may lead to antibiotic-resistant bacteria.

This article explores a new and promising approach: fecal microbiota transplantation (FMT). FMT involves transferring healthy gut bacteria from a donor into the patient's digestive system. It has already been proven effective in treating another type of infection caused by Clostridioides difficile.

The authors reviewed four published cases where FMT was used to prevent RAC. These patients had different medical backgrounds but shared one thing in common: traditional treatments had failed to stop their infections. After receiving FMT, all four patients experienced fewer or no new episodes of cholangitis for several months. In some cases, the treatment also helped reduce harmful bacteria in the gut and improved liver function.

Here is a quick look at the four cases:

- One patient with a rare liver disease had no new infections for a year after FMT.
- An elderly patient stopped having RAC for several months without evidence of resistant bacteria
- A woman with a complex surgical history remained infection-free for over two years.
- A 93-year-old man avoided new infections for 15 months after taking FMT capsules.

While these results are encouraging, the authors caution that more research is needed. The number of patients is small, and the methods used (such as how FMT was given) varied. Still, these cases suggest that restoring healthy gut bacteria might help prevent bile duct infections in some people.

In conclusion, FMT could be a valuable tool for patients with RAC who don't respond to standard treatments. However, it should only be used in clinical trials or under medical supervision until more evidence is available.

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Abstract

Introduction. Recurrent acute cholangitis (RAC) constitutes a relevant clinical problem that may condition the prognosis of the patient. Chronic suppressive antibiotic therapy can be used for preventive purposes, but it is associated with adverse effects and can select resistant bacterial strains. Fecal microbiota transfer (FMT) has been shown to be effective in preventing recurrent *Clostridioides difficile* infection and could be a useful strategy in patients with RAC.

Objective. To review the experience of the use of FMT in the prevention of episodes of RAC by reviewing published cases. This article is based on previously published cases without presenting new original clinical data.

Result. Four cases were identified in which FMT significantly reduced RAC episodes. The patients were characterized by lack of efficacy of conventional treatments, had different predisposing factors for RAC and frequent colonization and infection by multidrug-resistant bacteria.

Conclusions. The four cases presented provide limited but encouraging evidence of the preventive effect of FMT on successive episodes in patients without biliary tract obstruction. Larger and more adequately designed studies will be necessary to deepen the knowledge of this possible preventive strategy.

Keywords: Fecal microbiota transplantation. Cholangitis. *Escherichia coli.* Reinfection. Biliary tract.

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Introduction

Acute cholangitis is usually caused by the invasion of bacteria of intestinal origin into the biliary tract (1). In some, the fundamental triggering factor is obstruction of the biliary tract and in others, an anatomical or functional alteration that favors bacterial reflux from the intestine to the biliary tract. There are, therefore, obstructive and non-obstructive causes (1) (2). The treatment of these episodes requires administration of antibiotics and, when necessary, resolution of the obstruction by surgery or endoscopic procedures.

Unfortunately, a quarter of these patients with acute cholangitis usually present recurrences of this infection which is a very relevant challenge from the clinical point of view with a negative influence on the patient's quality of life and survival (3). Recurrent acute cholangitis (RAC) can be caused by biliodigestive anastomosis, frequent in patients with chronic biliary pathology or liver transplant recipients, or by obstruction of a neoplastic or lithiasic nature without technical solution or inoperability of the patient (3). To reduce the tendency to suffer from these episodes, chronic suppressive antibiotic therapy (CSAT) can be used, which can be associated with side effects and the selection of resistant bacteria (3-5).

An imbalance of the intestinal flora consisting of a reduction in the number of bacteria, or their diversity could contribute to bacterial translocation between intestine, portal circulation and the biliary tree that could facilitate episodes of RAC (6,7). Fecal microbiota transfer (FMT) is considered a safe procedure and consists of the infusion of fecal bacteria from a healthy donor into the gastrointestinal tract. This technique has established itself as an effective treatment in the prevention of recurrent *Clostridioides difficile* infection (8). In recent years, FMT has also been used in the prevention of recurrent urinary tract infections and in the elimination of the intestinal carrier state of resistant bacteria (9-11).

The objective of this article is to present the clinical features of four previously published patients who illustrate the beneficial effects of FMT in patients with non-obstructive RAC refractory to standard treatments. This is, therefore, a narrative description of the cases of RAC identified in the literature. For the selection of these cases, the possible combinations of the following terms were used in PubMed:

"repeat*", "recurrent", "acute cholangitis", "bacterial cholangitis", "pyogenic cholangitis", "acute cholangitis". These cases may form the basis for future research such as large case series or randomized clinical trials that could provide support for this preventive strategy in patients with RAC.

Results

In the review of the literature, 4 cases were identified in which the effect of FMT on episodes of RAC could be analyzed. The main clinical features of these cases are shown in Table 1 and Visual abstract.

Case 1: RAC in a patient with primary sclerosing cholangitis.

38-year-old male diagnosed with primary sclerosing cholangitis, without associated inflammatory bowel disease, who developed three episodes of RAC during six months, the last episode requiring admission to the intensive care unit for septic shock. Magnetic resonance imaging (MRI) of biliary ducts revealed mucosal irregularities in the right and left hepatic ducts with no evidence of dominant stenosis. At that time, the possibility of using FMT from a healthy donor to study the possible change of enteric flora in the course of his recurrent infections was proposed. The patient underwent 4 sessions of FMT for one month (one a week), using 200 mL of filtered and homogenized feces that were instilled in the second portion of the duodenum. During this period antibiotics were suspended, maintaining only ursodeoxycholic acid. The patient did not present new episodes of RAC for one year. Improvement was also observed in liver function tests and circulating bile acid levels. Significant changes in the intestinal bacterial community were also evident, with a decrease in Proteobacteria and an increase in Bacteroidetes and Firmicutes. One year later, a new episode of RAC was observed. The patient denied a new FMT and was referred to the liver transplant consult (12).

Case 2: Patient with RAC and multiresistant bacteria

87-year-old male with a history of chronic renal failure and cholelithiasis for which he had undergone cholecystectomy. Subsequently, he presented multiple episodes of

calculous cholangitis that were treated with papillary sphincterotomy and extraction of stones in the common bile duct. To reduce the number of episodes of RAC, a choledochoduodenostomy was additionally performed, but the patient continued to suffer repeated episodes of RAC requiring hospital admission, despite the absence of stones or biliary sludge. A biliary scan demonstrated slowing of bile flow but complete emptying at the end of the procedure. The patient continued with this type of infection despite probiotics, systemic CSAT, rifaximin, prokinetics and ursodeoxycholic acid. Positive cultures for multidrug-resistant *Escherichia coli*, *Enterobacter aerogenes* and *Klebsiella pneumoniae* were obtained in the various episodes. The patient agreed to receive FMT using colonoscopy. Although he continued to have episodes of RAC, no multidrug-resistant bacteria were identified thereafter. Repeat upper endoscopic FMT was associated with a 4-month period of no new episodes of RAC. A repeat upper endoscopic FMT was performed without the appearance of new episodes in the follow-up time until the publication of the article (four additional months) (13).

Case 3: Patient with RAC after total pancreatectomy and pancreatic islet transplantation

51-year-old woman with post-surgical insulin-dependent diabetes mellitus and lateral pancreato-jejunal bypass (Puestow procedure) together with cholecystectomy, partial gastrectomy and splenectomy. Three years later she underwent total pancreatectomy with pancreatic islet transplantation to treat episodes of recurrent pancreatitis associated with *pancreas divisum*. After this surgery, she began to experience episodes of RAC occurring at increasingly shorter intervals, some of which were associated with *C. difficile* infection. Over a two-year period, she experienced five hospitalizations for sepsis characterized by high fever, chills, abdominal pain, increased inflammatory markers and mildly elevated liver function tests attributed to RAC. A MRI of the biliary tract consistently excluded obstruction. She was treated with various antibiotic regimens whose composition was rotated. The clinical course was further complicated due to bacteremia by extended-spectrum beta-lactamase (ESBL) producing *E. coli* . She was offered FMT in an attempt to modify the course of recurrent *C. difficile* infection, but also with the expectation that microbiota transplantation would produce some

positive effect on episodes of RAC. FMT was administered simultaneously by upper endoscopy (in the jejunum) and colonoscopy, respectively. The patient was followed for 30 months with no further episodes of cholangitis or *C. difficile* infection (14).

Case 4: Elderly patient with RAC

93-year-old male with a history of type II diabetes mellitus, hypertension and urothelial carcinoma in remission. He presented on first admission with chills without fever, shivering, epigastric pain and moderate jaundice. Ultrasonography and abdominal computed tomography showed dilatation of the intrahepatic and extrahepatic ducts up to the papilla without evidence of mass. Endoscopic retrograde cholangiopancreatography was performed with removal of abundant biliary sludge. Despite the placement of several plastic and metallic biliary prostheses over several months, the patient presented multiple episodes of RAC, some of them produced by ESBL-producing *E. coli*. The patient subsequently underwent a biliodigestive bypass (hepaticojejunostomy). The appearance of new episodes of RAC led to CSAT with several antibiotics such as cotrimoxazole, amoxicillin/clavulanic acid and quinolones in reduced doses (half or quarter of the conventional dose). Because the patient continued with RAC, it was decided to perform FMT from a healthy donor and suspend chronic suppressive treatment. FMT was applied on compassionate use based on previously published positive results. From a 50 g fresh stool sample, the same local protocol used for *C. difficile* treatment was followed; after processing and lyophilization, five gastroresistant capsules were obtained and administered. Despite the persistence of ESBL-producing *E. coli* colonization in the stool, no new clinical episodes of RAC were observed in the following 15 months (15).

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Discussion

The clinical course of the cases presented evidences an association of FMT with a significant reduction in the number of episodes of RAC. These cases, previously refractory to conventional treatment, experienced sustained clinical remissions, which could represent a relevant improvement in their evolution.

The heterogeneity observed in administration methods and clinical response underscores the need for more standardized techniques. These differences suggest the need for additional studies to identify the best possible method. In the case published by Phillips et al, there was a concomitant benefit in the biochemical parameters associated with the underlying disease (primary sclerosing cholangitis), which shows that FMT can be associated with positive effects of various kinds, confirming the multiple functions that the intestinal microbiota can exert (12).

The positive response of FMT in patients with RAC contrasts with the reduced efficacy of standard treatment, which in these cases consists of individual treatment of each episode with or without secondary prophylaxis with CSAT, usually at low doses (2,4,16). CSAT produces a reduction of enteric bacterial load, but it distorts its physiological composition. Moreover, the success of CSAT is not usually long-lasting (8), and the continued use of antibiotics presents the risk of adverse effects, selection of resistant bacterial strains and *C. difficile* infections (17). FMT is aimed at a more physiological restoration of the intestinal flora and a more lasting effect (12-15).

The beneficial effect observed in the cases presented could be due to the recovery of the intestinal flora with reduction of colonization by virulent bacteria (7). FMT promotes the restoration of a healthy microbiome that displaces pathogenic bacteria through ecological competition and production of antimicrobial metabolites (18). It may also have improved the integrity of the intestinal barrier, reducing bacterial translocation and the production of substances such as lipopolysaccharide that would reach the portal circulation and biliary tree, triggering inflammation (7,19). FMT, by restoring a healthy microbiome, can improve the barrier function through the production of butyrate, which helps to maintain the intestinal epithelium, contributing to the prevention of translocation and inflammation of the biliary tract. Modulation of bile acid metabolism with antimicrobial and immunomodulatory signaling properties

could be another mechanism to reduce episodes of RAC (19). Additionally, FMT could also enhance the gut-associated immune system and modulate the systemic immune response by reducing cytokine production (20). Although FMT has been shown to reduce colonization of the gastrointestinal tract by resistant bacteria, eradication of colonization by resistant intestinal bacteria was achieved in only one of the two cases presented where this was an issue (13,15 (22,23).

The case analysis suggests that changes in the gut microbial ecosystem with FMT could positively influence RAC prevention. These cases serve as proof of concept, supporting the gut-liver-biliary axis hypothesis in the pathogenesis of RAC. It would also represent a new avenue of research for a pathology with limited options (2,7,21). With the available evidence it is difficult to draw conclusions about the modality of FMT, which may be more successful in these patients. No information was provided on donor characteristics such as age. Analyzing the 4 cases, it could be deduced that simultaneous administration through the upper and lower digestive tract and a younger age of the recipient could be associated with a longer period of recurrence-free times.

Considering the small number of patients included in this article, it is imperative that experience be gathered in other centers, implementing larger case series and prospective cohort studies to confirm or discard initial results. Ideally, placebo- or standard treatment-controlled clinical trials should be promoted to establish, in a more robust manner, their potential efficacy and safety. Pathophysiological studies analyzing changes in the microbiota of the small intestine and biliary tract and possible changes in inflammatory markers after FMT should also be promoted to better understand this possible positive effect (12-15).

The main limitation of the study is the small number of patients in whom this preventive strategy has been used. The heterogeneity with respect to doses, routes of administration and number of procedures used in each case make it difficult to draw firm conclusions. We cannot rule out a publication bias that could have prevented the dissemination of similar experiences, but with worse results. On the other hand, and considering that this treatment has only been used in cases of non-obstructive RAC, these results should not be generalized to patients with RAC due to bile duct

obstruction.

Conclusions

This limited case series provides preliminary evidence suggesting a benefit of FMT in reducing episodes of RAC in patients with non-obstructive biliary pathology. The observed results suggest that restoration of the gut microbiota could improve the pathophysiology of the gut-liver-biliary axis and reduce colonization by virulent bacteria. The use of FMT as a preventive strategy should only be considered in the context of clinical trials or structured research studies. There were also differences in the duration of the preventive effect. One patient with primary sclerosing cholangitis also showed improvement in cholestasis enzymes. Successful decolonization of resistant bacteria occurred in only one of the two affected patients.

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Writing – review & editing:, ARM, AGV, MGH, IFY, ANF, AMR, AFC, JCP

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Conflicts of Interest

No author has any conflict of interest with what is published in this article.

Statement of Generative AI and AI-assisted technologies in the writing process

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Inclusion and diversity statement

We support inclusive, diverse, and equitable research.

Declaration of data availability

Data supporting the study findings are available from the corresponding author upon request

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Table 1. Characteristics of patients with recurrent acute cholangitis episodes treated with fecal microbiota transplantation

Ref	**Age (years) /Gender**	Baseline pathology	Route of TMF administration	Number of TMF infusions	Bile duct obstruction	R re fr
12	38 / M	Primary sclerosing cholangitis without predominant stenosis	Via upper endoscopy (weekly infusion x 4 weeks)	4	No	1
13	87 / M	Biliodigestive bypass (choledochoduodenostomy)	Upper (jejunum) x 2 and lower (colon) x 1	2	No	2 m
14	51 / F	Biliodigestive bypass (hepaticojejunostomy)	Upper (jejunum) and lower (colon) endoscopy simultaneously	2	No	3
15	93 / M	Biliodigestive bypass (hepaticojejunostomy)	5 lyophilized gastroresistant capsules for oral administration	1	No	1

Ref: bibliographic reference. FMT: fecal microbiota transplantation. M: male. F: female. In case 2, FMT was repeated by upper endoscopy at 4-month follow-up