Gut power for better health: microbial therapeutics

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Purpose of review
To critically evaluate the literature over the past year on microbial therapeutics in the management of disorders of the large intestine. The primary focus is on disorders where the microbiome has been implicated in pathophysiology, and its modulation has been a therapeutic target.

Recent findings
Though widely consumed, data on the impact of probiotics and prebiotics in gastrointestinal disorders continue to pose challenges in interpretation due to shortcomings in study design; postbiotics, meanwhile, because of some logistical and regulatory advantages, are attracting attention. Though time-honored for its role in infections due to *Clostridioides difficile* (CDI), FMT has encountered challenges in relation to regulation leading to the appearance of highly standardized, extensively screened and rigorously prepared microbial products [defined as live biotherapeutic products (LBP)], which show great promise; two have been approved by the FDA for prevention of recurrent CDI. Outside of CDI, efforts to define a role for FMT in the management of various diseases have met with mixed results.

Summary
The translation of findings in studies of microbiome composition to successful therapies has proven disappointing to date, though attempts to develop selective and targeted microbial consortia show promise and may lead the way to personalized bacteriotherapy.

Keywords
colon, fecal microbiota transplantation, microbiome, postbiotic, probiotic

INTRODUCTION

As home to by far the largest number and greatest diversity of microbes in the human gastrointestinal tract, the colon and its microbiome have been of great interest to clinicians and scientists alike, and a disrupted (or dysbiotic) microbial population in the large intestine has been implicated in a host of intestinal and extra-intestinal disorders [1–3]. Most of these studies, while demonstrating associations between a certain microbial signature and a given disease process, fall well short of establishing causation, and their interpretation is hampered by shortcomings common to many microbiome studies in humans, absence of longitudinal data, small sample sizes, and a failure to account for confounding factors such as disease activity, diet, and therapies [4▪▪]. While convenient and, therefore, widely practiced, fecal sampling may not provide a complete picture of the colonic microbiome by, for example, failing to account for the very special juxta-mucosal microbes [5]. Just defining what is there may no longer be acceptable as providing a pathophysiologically meaningful representation of the role of the microbiome in any given disease and is often now superseded by either predictions of genetic potential function, as provided by metagenomics, or actual measures of metabolic activity or function, as provided by metabolomics or metatranscriptomics, respectively [6]. Although microbial therapeutics hold much promise [7], the aforementioned shortcomings in relation to our understanding of diseases processes, must be borne in mind when reviewing studies that, in one way or another, modulate the microbiome.

Although acknowledging that many other factors from diet to various medications and, of course, antibiotics impact on the colonic microbiome, for the purposes of this review, the focus will be on biotics and fecal microbiota transplantation.

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KEY POINTS

- Data accumulate to support alterations in the gut microbiome in a variety of gastrointestinal disorders but, in many instances, these describe association and do not prove causation.
- Among biotics, studies on prebiotics and probiotics often frustrate because of limitations in study design.
- Postbiotics and live biotherapeutic products (LBPs) are relatively new categories, the former referring to inanimate bacteria or their components, the latter to microbial products being evaluated for the treatment of human disease.
- *Clostridioides difficile* infection (CDI is still the best target for FMT; the recent approval of selected bacterial consortia for recurrent CDI may pave the way for a new era in microbial therapeutics – personalized bacteriotherapy.

BIOTICS

For many years, this field was limited to the study of live bacteria (probiotics) and substrates in food (usually carbohydrates) that promote the growth of beneficial microbes (prebiotics). Inevitably, these were combined in a single product – a synbiotic. As studies appeared demonstrating biological activity of dead bacteria or bacterial components, the concept of the postbiotic emerged and was recently defined by the International Scientific Association for Probiotics and Prebiotics (ISAPP) as 'a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host' [8]. While details of this definition have been challenged by others [9], the regulatory and logistical attractiveness of an inanimate but bioactive organism has generated much interest in the postbiotic concept. Meanwhile, another term has emerged, the live biotherapeutic product (LBP). This term developed by the Food and Drug Administration in the United States defines LBPs as 'products containing live microorganisms that were applicable to the prevention, treatment, or cure of a disease or condition in human beings' [10]. This is, in essence, a regulatory nuance but, of critical importance, moves a probiotic or other live biotherapeutic into a realm where they are assessed as a drug and not as a food supplement – a much higher bar to surmount [11▪▪,12].

Irritable bowel syndrome

Irritable bowel syndrome (IBS), a common gastrointestinal disorder, continues to pose a considerable challenge for the clinician and generate controversy among investigators [13]. Originally anecdote but, more recently, a series of studies demonstrating various influences of microbiome on the pathophysiology of IBS [14▪] prompted trials of various biotic interventions in this disorder. When combined in a meta-analysis, there is good evidence for benefits for probiotics as a class in IBS but when one attempts to dissect out which strains or combinations thereof are most effective the data shrink and conclusions become less certain [15], leaving the consumer and the prescriber in limbo. Studies over the past year on probiotics, prebiotics, and postbiotics in IBS have revealed variable effects on symptoms, gut barrier function, microbiome composition, and metabolome [16–21], but it is fair to say that results were, overall, far from game-changing with many of the usual shortcomings of probiotic clinical trial design again being evident [11▪▪]. Others looked towards bacterial metabolites, such as short-chain fatty acids (SCFAs), as mediators of probiotic benefits in IBS [22].

Chronic idiopathic constipation

Chronic idiopathic constipation (CIC) is common worldwide, but its impact on wellbeing and quality of life are generally under appreciated. Though the role of the microbiome in the pathophysiology of CIC has not been extensively explored, several studies have explored physiological and clinical responses to biotics. Although a number of smaller studies demonstrated positive effects on various bowel functions and constipation-related symptoms [23–29], the largest study in the past year showed no benefit for a probiotic over placebo [30].

Clostridioides difficile-associated disease

Of the many diseases and disorders that have been linked to a disrupted microbiome, none have been as irrefutably established as that resulting from infection with *Clostridioides difficile*. *C. difficile*-associated disease (CDAD) or *C. difficile* infection (CDI) continues to cause significant morbidity and an appreciable mortality among high-risk hospitalized individuals and is now recognized as a significant cause of diarrhea in the community [31]. Although antibiotics and fecal microbiota transplantation have been the primary therapeutic approaches in CDAD/CDI [32▪▪], there has been some interest in probiotics as adjunctive therapy in acute infections and in prevention of recurrence. Chitapanarux and colleagues demonstrated that the addition of *Saccharomyces boulardii* to vancomycin reduced recurrence rates but had little impact on the outcome of the acute infection [33].

FECAL MICROBIOTA TRANSPLANTATION AND OTHER MICROBIAL THERAPIES

The idea that the transfer of fecal material from a healthy individual to one suffering from a gastrointestinal ailment has been extant for millennia but did not gain significant scientific attention until applied to the treatment of resistant or recurrent CDI. Since then, fecal microbiota transplantation has been used to treat a myriad of diseases and disorders usually in an uncontrolled fashion and, at times, in the absence of any medical supervision.

Fecal microbiota transplantation in *Clostridioides difficile*-associated disease/ *Clostridioides difficile* infection

FMT has become an established therapy for the treatment of an episode of *C. difficile* infection that fails to respond to antibiotics. For those who respond to antibiotics, recurrence remains a problem, as recurrent infections are accompanied by higher rates of morbidity and mortality than a primary infection [34▪]. However, in one trial in Veterans Administration hospitals across the United States, FMT was not superior to placebo in preventing recurrent infection [35], while three meta-analyses supported the efficacy of FMT in preventing recurrent CDI [36], in general, as well as among patients with inflammatory bowel disease [37,38]. Although an earlier meta-analysis failed to demonstrate a benefit for FMT over medical therapy [36], a recent trial from Norway, compared FMT on its own to vancomycin 125 mg four times daily for 10 days and reported clinical cure without recurrence within 60 days in 67% of those who received FMT vs. 61% of those who received the antibiotic [39▪▪]. Though this difference was not statistically different, the authors concluded that as noninferiority had been demonstrated, FMT should be considered as a first-line option [39▪▪]. In support of this proposal, others found that FMT was more cost-effective than vancomycin monotherapy in the management of a first or second episode of CDI [40].

The widespread use of FMT in the treatment of CDAD has been limited by issues of standardization, screening of donors, and regulatory approval, leading to efforts to develop standardized preparations. Several have been studied and two have received FDA approval under the category of LBP. Fecal microbiota, live-jslm, marketed under the name REBIOTA, is a consortium of fecal anaerobes augmented with Bacteroidetes strains and fecal microbiota spores, live-brpk, is a mixture of 50 species of purified Firmicutes spores from fecal microbiota and marketed under the name VOWST [34▪,41,42]. The former is administered once as an enema, the latter taken orally as four capsules once daily for 3 days. Both have demonstrated efficacy in reducing the incidence of recurrent infection [34▪,41,43], and their success and engraftment in the short-term and long-term linked to shifts in microbiome composition towards normality and from primary to secondary bile acids [34▪,44,45]. Other LBPs, involving various microbiome consortia, are in various stages of development. VE303 is a defined consortium of eight purified, clonal bacterial strains, which reduced recurrence rate by more than 80% compared to placebo and was again linked to favorable changes in the microbiome and metabolome [46▪▪], while CP101, described as a complete microbiome therapeutic when administered orally also demonstrated a significant impact on recurrence (likelihood of not recurring 75 vs. 62% for placebo) [47▪]. Attempts to develop a vaccine against *C. difficile* toxins continue [48,49].

Fecal microbiota transplantation in other diseases and disorders

Inflammatory bowel disease

The role of FMT in the management of *C. difficile* infection occurring in the context of ulcerative colitis has already been alluded to; how about efficacy in IBD, *per se*? Studies in ulcerative colitis, while, in aggregate, suggesting some benefits are difficult to interpret due to variability in study design and FMT protocol; for now, FMT is not recommended as a first-line therapy for ulcerative colitis [50]. Some factors that may contribute to FMT success (or failure) in ulcerative colitis have been identified and include donor selection [51], the relative distribution of various taxa in the fecal microbiome post-FMT [52] and the influence of donor phageome [53]. Data in Crohn's disease are sparse. One small study in adults was negative [54], while another open label study in children produced some positive findings [55]. A single study in pouchitis found that FMT was no more effective and was less well tolerated than placebo [56].

Irritable bowel syndrome and chronic idiopathic constipation

In a manner akin to IBD, outcomes from FMT studies in IBS have been very variable. There is one remarkable outlier; the group from Bergen, Norway have produced a series of studies demonstrating remarkable responses in the short-term and long-term with FMT. In their latest analysis of their results, they attributed success to small intestinal instillation, repeated instillation, the engraftment of certain

bacteria [57▪] and the production of butyrate [58]. It is also important to note that all of their studies involved FMT from a single 'super-donor'. Others failed to correlate post-FMT changes in the microbiome to clinical response [59]. In a small study in children with intractable constipation, FMT augmented the beneficial effects of retrograde colonic enemas on the frequency of spontaneous bowel movements [60].

Liver disease

In a phase II study in patients with cirrhosis and hepatic encephalopathy, FMT was well tolerated and reduced the recurrence rate for hepatic encephalopathy to 9% in comparison to 40% for placebo over 6 months [61▪]. On the other hand, serial administration of FMT had no impact on hepatic steatosis or related metabolic parameters in patients with metabolic-associated fatty liver disease (MAFLD) [62].

Other intestinal disorders

Though well tolerated, FMT did not improve lower gastrointestinal symptoms in patients with scleroderma (progressive systemic sclerosis) [63].

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Conflicts of interest

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