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# Treatment Options for Functional Gastrointestinal Disorders: From Empiric to Complementary Approaches

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Functional gastrointestinal disorders (FGIDs) remain a common problem in the pediatric age group.[1,2] These conditions were first recognized by Apley in 19583 when he coined the earlier term 'recurrent abdominal pain' (RAP) for a group of children with recurrent or persistent abdominal pain that interfered with functional daily living and had no evident organic etiology.[2,4] Community-based studies from around the world demonstrate that 10% to 46% of all children meet the criteria for RAP.[5-8] As FGIDs continue to cause emotional and financial burdens on affected families, efforts are being made to better categorize FGIDs as a symptom-based diagnosis, understand their pathophysiology, and investigate effective treatment options.

This review focuses on dietary, pharmacologic, cognitive behavioral, and complementary medical treatment. Because previous literature on treatment used the term RAP, we use that term knowing that it represents a mix of FGIDs. In more recent literature, the specific FGID subtype treated (eg, FAP, FD, IBS) is identified. IBS is most common in adults, and most of the treatments in the adult population have been geared toward treating that disorder. Given similarities in physiological abnormalities such as visceral hypersensitivity among FGIDs, inferences related to treatment findings to other non-IBS FGIDs are made. For treatment of IBS in children refer to article by Sood (page 272). See Table (page 289) for more information on these agents.

## Dietary Intervention

### Low-lactose Diets

Dearlove et al gave 21 children a lactose-free diet for 2 weeks. During the next 2-week period either lactose solution or placebo were administered in a double-blind crossover trial. No differences in pain symptoms were observed in either group.[9] Lebenthal et al found an abnormal oral (2 g/kg) lactose tolerance test in 21 of 69 children with RAP (symptoms of cramps, pain, bloating, gas, diarrhea, or loose stools) documented by a blunted rise in blood glucose of < 20 mg/ml.[10] In three successive 6-week blinded trials (cow-milk formula containing lactose, soy protein-based non-lactose formula, and normal diet and milk consumption), pain frequency was increased in 10/21 after the lactose formula and in 7/21 on the lactose-free soy.[10] In children who underwent small intestinal mucosal biopsy and lactase assay, the prevalence of lactase deficiency was similar in RAP and control children (8/26 compared with 16/61).[10] Despite their limitations, these two studies suggest that lactose intolerance may play a role in symptom production in some but not most children with RAP.[9]

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### Dietary Fiber

Christensen et al studied 40 children between 3 to 15 years randomized to receive either a cracker with a psyllium fiber content of 2% (placebo) or 66% (treatment) and observed no differences between groups in the mean number of episodes of pain.[9] Feldman et al randomized children to eat cookies with or without corn fiber and noted 13 of 26 children in the fiber-supplemented group had a 50% reduction in the frequency of their attacks ($P = 0.04$).[9] However, using an odds ratio analysis, Cochrane reviewers found no significant differences between groups.[9]

Humphreys et al randomized 64 children with RAP to receive fiber supplementation alone, fiber in combination with biofeedback, fiber with biofeedback and cognitive-behavioral interventions, or fiber, biofeedback, cognitive behavioral interventions, and family support.[11] All groups improved their symptoms, although it is uncertain if the response in the fiber-alone group could have resulted from a placebo effect.[11] Paulo et al evaluated dietary macronutrients and fiber intake in a cross-sectional retrospective evaluation of RAP. The patients were divided into three groups: 1) RAP alone; 2) RAP with constipation for 3 or more months; and 3) children without RAP who served as controls. Although there were no significant differences in macronutrient intake, fiber intake was higher in the control group compared with both RAP groups. In the control group compared to the two RAP groups, 51% compared with 78%, respectively, reported an intake less than the minimum recommended value ($P = 0.021$). This study suggests that a low-fiber diet serves as a risk factor for RAP.[1]

Fiber may have beneficial effects on GI tract motility and sensitivity in addition to serving as a stool softening and bulking agent to alleviate some of the hypothesized contributing factors of RAP including constipation.[1] Although studies have shown clear benefits of supplemental fiber in adults with IBS, further studies are needed to delineate its beneficial role, if any, in the treatment of RAP in children. It is unlikely that soluble fiber will exacerbate symptoms, and it may provide symptom relief in some children. A trial of 0.75 g per year of age per day takes into account that children in this age range (7 to 18 years) receive approximately 14 to 16 g/d of fiber in the diet.

### Low-fructose Diet

Fructose, especially in the form of high-fructose corn syrup, has been thought to cause chronic abdominal pain. Fructose is consumed ubiquitously by children as a common sweetener used in sodas, juice, candy, and even fruits. Fructose, like lactose, when malabsorbed by the small intestinal lumen, may cause an osmotic diarrhea and also serve as a substrate for colonic bacterial fermentation, and thus, gas production and subsequent abdominal pain. Gomara et al found 11 of 32 children with FGIDs malabsorbed fructose, 12 33% in the 15-g and 61% in the 45-g challenged groups had positive breath tests ($P < 0.005$). GI symptoms such as nausea, bloating, and abdominal pain also occurred more frequently in the higher dose fructose group ($P < 0.05$). Following dietary fructose restriction, those having positive breath tests reported significantly less abdominal pain at their 2-week and 2-month followups.[12] Although the study design had limitations, a trial of a low or no fructose diet for 2 weeks may prove beneficial in some children.

## Pharmacologic Treatment

### Antidepressants

Although incompletely understood, the mechanism for FGIDs has been suggested to involve dysregulation of the enteric and central nervous system affecting intestinal sensation and motility.[13] Medications used to treat depression, anxiety, and seizures have become increasingly attractive agents for use in FGIDs because they act upon the central and peripheral

nervous system to modulate mood, visceral, and neuropathic pain, as well as autonomic function, in part, through anticholinergic effects.[13]

Antidepressants such as tricyclic antidepressants (TCAs), serotonin reuptake inhibitors (SSRIs), and monoamine uptake inhibitors improve symptoms of IBS in adults.[13-14] Antidepressants act by decreasing pain perception, improving mood and disturbed sleep patterns, and perhaps regulating motility.[14] TCAs (through an anticholinergic effect) and SSRIs improve diarrhea by slowing transit and constipation by hastening transit time, respectively. Meta-analyses evaluating the effects of antidepressants in adults with FGIDs have demonstrated a beneficial analgesic effect independent of improvements in mood.[14]

TCAs have been the most studied psychotropic agents for FGIDs in adults, including IBS and FD. TCAs in comparison to SSRIs have demonstrated more pronounced pain reduction in chronic neuropathic pain in animal models and are thought to be more effective on the central than peripheral nervous systems. Their side effects, more often seen in tertiary TCAs (amitriptyline, imipramine) than in the secondary amines (desipramine, nortriptyline), include sedation, anticholinergic effects (constipation and urinary retention), and central nervous system effects (insomnia and agitation).[14] In a recent double-blind placebo controlled trial evaluating amitriptyline in 33 adolescents with IBS, compared with placebo, amitriptyline-treated subjects had improved quality of life scores, less right lower quadrant and periumbilical pain, and IBS-related diarrhea.[15] However, these results need to be replicated in a larger study.[15] After EKG screening for prolonged QT syndrome, a trial of 10 mg, 20 mg, or 30 mg by mouth at bedtime for children 30 kg to 50 kg, 50 kg to 80 kg, or over 80 kg, respectively, may help some children.

SSRIs block the reuptake of 5-hydroxytryptamine (5-HT), increasing its concentration at presynaptic nerve endings. Although SSRIs have been shown to reduce neuropathic pain associated with back pain and migraines, the effect on GI-related pain in adults is less clear. The benefit of SSRIs has been shown to be related to improving the overall feeling of well-being, reducing anxiety stemming from GI-related symptoms, treating psychiatric comorbidities, and augmenting the analgesic properties of TCAs when used in combination. However, SSRIs' propensity toward causing diarrhea renders it a potential therapy for constipation-related IBS.[14] In an open-label, prospective, non-controlled pediatric trial with citalopram, children with FAP were found to improve on a clinical global impression scale. They received 10 mg per day of citalopram for the first week, 20 mg per day the second week, and if there was no clinical response and the medication well tolerated, 40 mg daily in week four. Patients tolerated the drug well.[16-17]

## Prokinetics

The etiology of FD is unknown, but the following factors may play a role in individual patients: delay in gastric and small bowel transit time, inadequate postprandial gastric volume accommodation, augmented visceral sensitivity (a common theme amongst all FGIDs), and increased eosinophilic infiltration indicating mucosal inflammation.[16] Agents that act to enhance motility (prokinetics) suppress acid production, reduce visceral pain from gastric distention, or increase postprandial gastric accommodation have been effective in adults with FD and used off-label to treat the same symptoms in pediatric patients.

Prokinetic agents are commonly used in adults to treat FD with the goal of improving symptomatology related to delayed gastric emptying. Previously mentioned 5HT agonists and antagonists that accelerate gastric emptying and improve gastric accommodation18 have shown inconsistent efficacy in treating FD. In addition, due to significant side effects, several including cisapride, tegaserod (5HT4 agonist) and alosetron (5HT3 antagonist), have been withdrawn. Dopamine (D2) receptor antagonists such as metoclopramide and domperidone

(Canada) improve gastric motility but are limited by their side effects including extrapyramidal reactions, drowsiness, agitation, irritability, fatigue, and dystonic reactions.[19]

Motilin agonists (eg, erythromycin) have strong prokinetic properties in the stomach but also reduce accommodation (gastric relaxation in response to food).[18] However, at lower but not higher doses (1 to 2 mg/kg/dose), erythromycin enhances gastric motility without loss of accommodation. To our knowledge, there are no controlled data on the use of any prokinetic drugs in children with FD.

### Other Agents

Famotidine, a histamine H2-receptor antagonist, was shown to improve global dyspeptic symptoms (parents perception only) in a double-blind, placebo-controlled, crossover trial in children.[16] Montelukast (a leukotriene receptor antagonist) was found to be effective in alleviating pain in a double blind, placebo-controlled, crossover study in 40 children in whom duodenal eosinophilia was present on biopsies.[16] Pizotifen was compared to placebo in 16 children with abdominal migraines and showed efficacy in reducing the number and severity of the abdominal migraines.[20]

There is a paucity of studies in pediatric patients with FGIDs evaluating pharmacologic treatment. Because the available studies are few and have not been replicated, the true efficacy of these drugs for FGIDs in children remains to be elucidated.[20] However, in the absence of definitive data, pediatric gastroenterologists use some of these medications empirically when children meet the diagnostic criteria for FGIDs, increasingly in lieu of extensive laboratory, radiographic and endoscopic testing. For example, a trial of an H2-receptor antagonist or proton pump inhibitor can be used on an empiric basis for at least 2 weeks with little risk. In children with presumed delayed gastric emptying, a 1-week trial of erythromycin may be helpful (1 to 3 mg/kg three to four times per day).

## Psychological Interventions

Although the etiology of FGIDs has not been elucidated completely, it is widely accepted that this entity is multifactorial with external stress and environmental factors playing some role. Because treatment with diet or pharmacological agents alone has been partially successful, psychological interventions such as cognitive behavioral therapy (CBT), family intervention, distraction, hypnotherapy, and biofeedback have been instituted with promising efficacy.[21]

Family therapy includes training the family and parents to support the patient in functioning independently through self-coping and self management skills, to develop a higher tolerance of symptoms, and to reduce enabling disability and dependence in the child.[21] Psychotherapy for the child, including cognitive behavioral therapy, allows the child to learn better coping and problem solving techniques, identify triggers, and eliminate or ameliorate maladaptive reactions to them.[21] Relaxation and distraction techniques have been shown to decrease pain perception, thereby increasing pain tolerance.[21]

Studies examining the role of CBT have demonstrated its efficacy. Sanders et al compared CBT family interventions to standard care for the treatment of RAP.[2] The authors reported that children in the CBT group, compared with the standard care group, had significantly higher percentages of pain free subjects at all follow up points. Duarte et al also compared CBT versus standard care.[2] This study reported a significantly lower median number of pain episodes per month during the month prior but not at the study's conclusion.[2] Robins et al evaluated children with RAP who had been randomized to CBT and standard medical care versus standard medical care alone.[2] The results indicated a significant improvement in the CBT group when measuring the Abdominal Pain Index at all time periods (immediately post-treatment, 6 months, and 12

months later).[2] Finally, Sanders et al evaluated CBT versus a waiting list control.[2] The odds ratio for being free of pain immediately posttreatment was 9.0 (95% CI 0.94, 86.52) while that at 3 months was 11.67 (95% CI 0.92, 147.56).[2]

Walker et al evaluated distraction techniques.[22] This study included 104 children in the FAP group and 119 in the control group (children without abdominal pain). The children underwent a water load symptom provocation test to induce discomfort and simulate to a lesser degree the pain they felt when they experienced their own abdominal pain. The parents were assigned randomly to provide attention to the patient, distraction to the patient, or their normal responses (control) when the child expressed discomfort. The results indicated that the children in the distraction group had half the complaints as the children in the control group while the children in the parental attention group doubled their number of complaints when compared to controls. Of particular interest, none of the parents of children with FAP perceived attention as having any potential negative impact in contrast to the perception among parents of well children.

Hypnotherapy, an effective treatment for IBS in adults, was recently studied by Vlieger et al in children 8 to 18 years with the diagnosis of FAP or IBS.[23] Although pain intensity and frequency scores decreased significantly in both groups compared to baseline, in the hypnotherapy group both scores decreased significantly when compared to standard medical therapy ($P < 0.002$ for pain intensity and $P < 0.001$ for pain frequency). Psychological interventions form a mainstay of therapy for children with FGIDs. It is important to recognize the primary goal is to help children cope with their pain. These interventions are recommended for their physiologic effects not in the belief that the pain derives from psychosomatic or primary psychological issues.

## Complementary and Alternative Medicine

As defined by the National Center for Complementary and Alternative Medicine, complementary and alternative medicine “is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.” Conventional medicine is defined as that practiced by individuals holding medical degrees, degrees for doctors of osteopathy, and other allied healthcare workers. Complementary medicine is used along with conventional medicine while alternative medicine is used in place of conventional medicine.[24]

Approximately 36% to 41% of children with GI complaints use complementary medicine each year including the following commonly sought methods: herbal medicines, massage therapy, and acupuncture.[25] There are few data to support the use of massage therapy or acupuncture.

A small, randomized control trial was performed to evaluate the effects of peppermint oil, a smooth muscle relaxant, in children with IBS when compared with placebo.[4] The participants took the capsules three times a day for 2 weeks (374 mg three times a day for children greater than 45 kg and 187 mg three times a day for children between 30 kg and 45 kg). At the end of the trial 76% of the peppermint oil group showed improvement in symptom severity while only 19% of the placebo group had decreased severity ($P < 0.001$). Mean severity of symptoms based on the patients' diaries also was less in the peppermint oil group ($P < 0.03$). When evaluating the patients based on the change in symptom scale, 71% compared with 43% of children in the peppermint oil and placebo groups experienced improvement respectively ($P < 0.002$). Larger and longer-term studies are needed to replicate these findings using validated and/or better defined scales. Reflexology is the use of pressure massage on reflex points on the feet. An uncontrolled trial in 50 children with encopresis suggested that 6 reflexology sessions increased stooling frequency and decreased encopresis episodes.[26] In contrast, a single-blind trial in 34 adults with IBS reported no improvement in abdominal pain, constipation/diarrhea, or abdominal distention.[27]

## Probiotics

Probiotics, defined as live microorganisms capable of surviving and inducing a beneficial effect in the host, are another form of therapy with potential efficacy in treating FGIDs, particularly IBS.[28] It is thought that the normal enteric flora, by its immunologic and metabolic attributes, contribute to the homeostasis of the GI tract and regulate mucosal inflammation and immunity. IBS has been documented to occur in individuals after either GI infection or antibiotic therapy, both of which disrupt normal enteric flora homeostasis. Probiotics are thought to act by competing metabolically with pathogens, improving the intestine's mucosal barrier, and/or altering the intestinal inflammatory response.[28] At this point, the efficacy of probiotics in FGIDs remains uncertain. High-quality, controlled trials are lacking in pediatrics and few conclusions can be drawn as different methods, formulations of probiotics, dosages, and different outcome measures have been used thus far.[28]

In a double-blind randomized controlled trial, 50 children with IBS were treated with either Lactobacillus GG (3×1010 colony forming units twice daily) or placebo for 6 weeks.[29] The results did not reveal any significant differences between the treatment and placebo groups on any stated outcome measure with the exception of abdominal distention. A more recent and larger study used Lactobacillus GG in children with abdominal pain disorders.[30] This trial randomized 104 children with either FD, IBS, or FAP to receive either Lactobacillus GG (3×109 colony forming units twice daily) or placebo for 4 weeks. Twenty-five percent of the children in the Lactobacillus GG group compared with 9.6% in the placebo group responded to therapy (Relative benefit 2.6, 95% CI: 1.05-6.6, NNT 7, 95% CI: 4-123). More specifically children with IBS were more likely to respond to Lactobacillus GG treatment when compared to the placebo or FAP groups. IBS patients treated with Lactobacillus GG also reported decreased pain frequency. Although these findings suggest efficacy for IBS and not FAP or FD, the results must be interpreted cautiously as the confidence intervals were wide and the sample sizes in the individual groups were small. Additionally, whether another probiotic organism (or group of organisms) might be effective is unknown.[30]

## Conclusion

Although a search continues for a pharmacologic “magic bullet” for FGIDs, it is becoming clearer that only a better understanding of the interplay of biopsychosocial mechanisms (physiological, psychological, and behavioral components) that contribute to the development of FGIDs will lead to more effective treatment in children. As each disease entity becomes defined better, we recognize the contribution of factors such as dysregulated motility, visceral hypersensitivity, infection, inflammation, psychology, and behavior in the pathogenesis of these disorders.[14] It is likely that in the future, as now, effective treatment must be customized to fit each patient's disease process and specific symptomatology.

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## Table

Potential Treatments for Functional GI Disorders in Children

| Functional Disorder | Medication | Dose | Level of Evidence | Key Points |
|---|---|---|---|---|
| IBS | Amitriptyline | 10 mg (30-50 kg); 20 mg (50-80 kg); 30 mg (>80 kg); Taken at bedtime | RCT in adolescents | Need screening EKG |
| IBS | Peppermint Oil | 374 mg TID (>45 kg); 187 mg TID (30-45 kg) | Small RCT | 2-week trial to determine benefit |
| IBS | Lactobacillus GG | 3×109 Colony Forming Units twice daily | Small RCT | Small sample size and wide confidence intervals in RCT |
| FAP | Citalopram | Initial 10 mg; 2nd week 20 mg; 4th week 40 mg; Daily dosing | Open-labeled, prospective, non-controlled pediatric trial | May stop increasing dose at minimum effective or tolerated dose |
| FD | Famotidine | 0.5 mg/kg/ dose twice daily | Double blind, placebo controlled, crossover trial | Maximum daily dose of 40 mg |
| FD | Montelukast | 10 mg daily | Double blind, placebo-controlled, crossover trial | Effective in patients with eosinophilia on duodenal biopsies |
| FD with delayed gastric emptying | Erythromycin | 3-5 mg/kg three to four times daily | Empiric | 1-week trial to determine symptomatic relief |