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Emerging Topical Therapies for Pediatric Functional Dyspepsia: A Modern Integrative Approach

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ABSTRACT:

Functional dyspepsia (FD) is a common pediatric gastrointestinal condition characterized by chronic or recurrent upper abdominal symptoms without detectable organic pathology. Despite its prevalence, treatment is still difficult because many therapies have little evidence and symptom profiles vary widely. Recent developments in pharmaceutical and non-pharmacological treatments for pediatric Functional Dyspepsia are highlighted in this review. Prokinetic drugs, proton pump inhibitors, and antidepressants show some advantages, but their regular usage is limited by safety issues and conflicting study results. Although there is a dearth of high-quality pediatric data, complementary and alternative therapies—such as nutraceuticals, probiotics, synbiotics, herbal formulations, dietary changes, cognitive behavioral therapy, yoga, hypnotherapy, acupuncture, and electrical stimulation—show promise in lowering symptoms and enhancing quality of life. Future pediatric applications may be influenced by emerging adult-phase studies of new prokinetics and bile acid modulators. When taken as a whole, these results highlight the significance of integrative, evidence-based approaches that integrate dietary, behavioral, and medicinal therapies to maximize outcomes for children with Functional Dyspepsia.

Keywords: Functional dyspepsia (FD), Pediatric gastrointestinal disorder, Prokinetic drugs, Proton pump inhibitors (PPIs), Complementary and alternative therapies, Integrative treatment.

1.INTRODUCTION:

The word "dyspepsia" (Greek "dys" [bad], "pepsis" [digestion]) refers to a range of symptoms that the patient localizes to the flanks and the epigastric area (between the navel and the xiphoid process).[1] Heartburn, epigastralgia, postprandial discomfort, bloating, and a heavy feeling in the upper abdomen are common symptoms of dyspepsia, one of the most common gastrointestinal disorder are some of these symptoms.[2] Dyspepsia symptoms can be either chronic or acute, as in the case of gastroenteritis. Underlying organic (such as ulcers, reflux, pancreatic diseases, and muscle diseases) or functional variables may be at fault in the latter scenario.[1]

Functional dyspepsia (FD) is a chronic gastrointestinal ailment characterized by symptoms in the upper abdomen that are thought to originate from the gastroduodenal region. Routine investigations, such as upper GI endoscopy, reveal no structural abnormalities.[3]

When regular diagnostic tests, such as endoscopy, fail to find any underlying anatomical or biochemical abnormalities, functional dyspepsia (also known as irritable stomach syndrome) is present. A diagnosis of functional dyspepsia is not refuted by findings such as gallstones, hiatus hernia, stomach erosions, or "gastritis."[1]

After ruling out any organic reasons, patients with non-ulcer dyspepsia, also known as functional dyspepsia, suffer dyspeptic symptoms for at least 12 weeks throughout the past year.[4]

Patients of all ages frequently suffer from functional gastrointestinal diseases, also referred to as disorders of gut–brain connection. Irritable bowel syndrome, functional dyspepsia and its subtypes (epigastric pain syndrome and postprandial distress syndrome), abdominal migraine, and functional abdominal pain-not otherwise specified are all considered functional abdominal pain disorders, a subset of functional gastrointestinal disorders. A number of randomized controlled studies have demonstrated the effectiveness of behavioral therapies like cognitive behavioral therapy and hypnotherapy, with results lasting at least one to five years. However, there is little data supporting the majority of nutritional and pharmaceutical treatments.[5]

In 1990, the Rome Foundation created the first diagnostic standards for functional gastrointestinal disorders. Since then, the Rome Foundation has redefined functional gastrointestinal disorders three times, most recently in 2016 with the creation of the Pediatric Rome IV criteria.[6]

Gastrointestinal tract illnesses that exhibit symptoms without a structural or biochemical pathology are known as functional disorders. These are prevalent issues in pediatrics. A symptom-based classification of functional Gastrointestinal diseases, including recurring abdominal discomfort, was the goal of the Rome II Committee in 1999.[7]

According to Rome III criteria, functional dyspepsia is characterized by symptoms that are believed to originate in the gastroduodenal region without any organic, systemic, or metabolic pathology that could account for the symptoms.[8,9]

Functional dyspepsia, as per the revised Rome IV criteria, is characterized by persistent or recurrent symptoms lasting over 3 months without identifiable organic causes on endoscopy, and excluding relief through defecation or stool irregularities.[1] Rome IV categorized into two subgroup - Epigastric Pain Syndrome, Postprandial Distress Syndrome.[1,6]

For children, the diagnosis requires at least one bothersome symptom, such as postprandial fullness or epigastric pain, occurring for more than four days per month over two consecutive months, without the need for abdominal pain to be the main complaint.[1,6]

Functional dyspepsia has been associated with certain psychological aspects. These include personality features, social support, life events, psychological stress, and life traumas like abuse and grief. In their thorough analysis, Barry et al have skillfully discussed each element and how it relates to Functional dyspepsia. It has been contested that social pressures and psychological morbidity only serve as a catalyst for seeking medical attention.[10]

H pylori should be eliminated if it is present. Prokinetic medications may be taken into consideration if the primary symptom points to dysmotility type Functional dyspepsia. Before cisapride was discontinued due to cardiac side effects, domperidone and cisapride were often used and extremely effective.[10]

It's also crucial to keep in mind that the majority of medications used to treat functional dyspepsia have effects on peripheral receptors that regulate gastrointestinal movement in addition to other areas like the central nervous system or acid secretion.[11]

1.1. Alarm Symptoms and Signs in Children with Functional Dyspepsia:[7]

• Persistent right upper- or right lower-quadrant pain.

• Dysphagia.

• Significant vomiting.

• Gastrointestinal blood loss.

• Family history of inflammatory bowel disease.

• Unexplained fever

• Deceleration of linear growth.

• Delayed puberty.

• Nocturnal diarrhea.

• Perirectal disease.

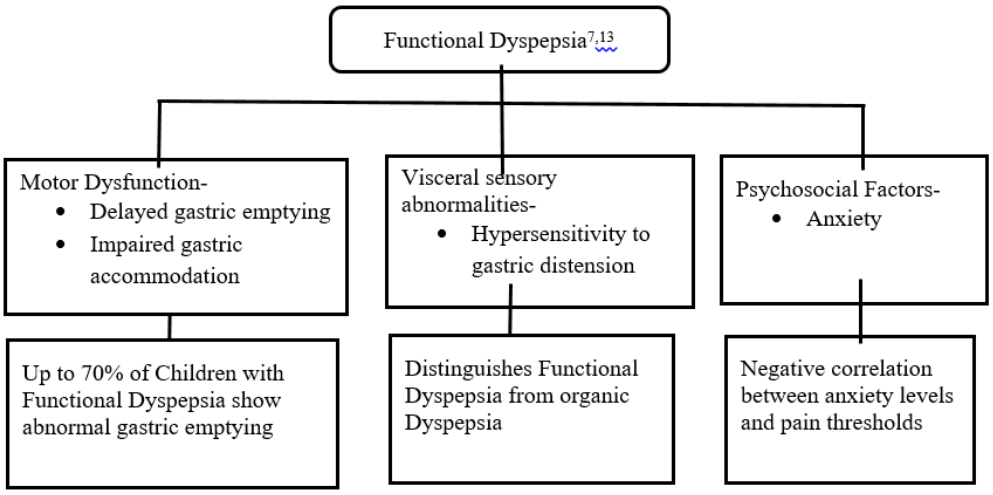
• Involuntary weight loss.

1.2.Epidemiology:

Dyspepsia is frequent in both adults and children, with an annual frequency of 3% to 27% in children and up to 25% in adults in Western countries. 1–30% of children worldwide suffer from functional gastrointestinal disorders, with functional dyspepsia being

particularly common. According to Rome IV criteria, 10% of people may have Functional Dyspepsia, and effective continued therapy requires a substantial shift from childhood to adult care. Research indicates that Functional Dyspepsia and related mental health conditions, like anxiety, are more common in females, especially in children with autism spectrum disorders, obesity, and asthma. A pooled prevalence rate of 21.8% for dyspepsia has been reported globally, notwithstanding the fact that different approaches have an impact on prevalence estimates. Functional Dyspepsia frequently coexists with other illnesses such irritable bowel syndrome and gastro-oesophageal reflux disease, making diagnosis and treatment outcomes more challenging.[6,7,12]

1.3. Pathophysiology-



Because of its complex character and heterogeneous symptoms, the pathogenesis of functional dyspepsia is still unknown despite substantial investigation. Food, stress, and psychosocial comorbidities are some of the variables that affect the complicated interaction between the brain and the gastroduodenal region that results in symptoms. These elements might be consistent with a single etiology, according to published illness models.[12]

2.Pharmacological Treatment:

2.1. Prokinetic Agents:

Prokinetic drugs may enhance stomach motility, according to research on functional dyspepsia. While cisapride and mosapride have demonstrated efficacy in numerous studies, domperidone has demonstrated efficacy in treating children's functional abdominal pain problem. However, cisapride has been removed from the U.S. market due to safety concerns. Acotiamide, a more recent medication, may enhance stomach accommodation and quality of life, especially when combined with proton pump inhibitors (PPIs). Even while prokinetic medications like metoclopramide and itopride show promise, none of them are currently authorized for regular usage, and more study is necessary to ensure their efficacy and safety. Both domperidone and cisapride seem to be beneficial in relieving symptoms, despite the fact that the best outcome measures are yet unknown due to study constraints such small sample sizes and poor design.[1,5,6,8,14,15]

2.2. Antidepressant agent:

There are conflicting findings when using antidepressants, particularly Selective serotonin reuptake inhibitors and tricyclic antidepressants, to treat functional dyspepsia. The low dose Tricyclic antidepressant amitriptyline showed a 53% response rate in a big experiment, while escitalopram and placebo had response rates of 38% and 40%, respectively. Systematic reviews indicate that Tricyclic antidepressant are beneficial for irritable bowel syndrome and chronic pain, but there is little proof of their effectiveness in Functional Dyspepsia due to conflicting findings from different research. Although there is theoretical evidence for in the Tricyclic antidepressant treatment of Functional Dyspepsia, there is not enough data to make firm judgments. To clarify their possible mode of action—whether through pain modulation or effects on anxiety and depression, which are frequently present in Functional Dyspepsia patients.[6,8,15]

2.3. Proton Pump Inhibitors (PPIs):

Although proton pump inhibitors (PPIs) are frequently used to treat functional dyspepsia, their effectiveness is restricted and they are mainly helpful for patients who also have reflux symptoms. While lansoprazole and esomeprazole do not significantly outperform placebo, randomized controlled trials show that omeprazole provides moderate benefits for certain patient populations, such as those who are H. pylori-positive. If patients do not respond, it is recommended that PPIs be stopped after 4–8 weeks. Furthermore, studies have shown that FD patients may have low-grade inflammation and greater exposure to duodenal acid, which can result in more severe symptoms. These days, studies concentrate on mucosal permeability, inflammation, and stomach motility in Functional Dyspepsia patients.[14,16]

2.4 Other Drugs:

Despite safety concerns, the 5-HT3 receptor antagonist alosetron is being studied for functional dyspepsia. Similar effects on duodenal lipid sensitivity are also being investigated using cholecystokinin receptor antagonists. While asimadoline is being studied, the opioid agonist fedotozine demonstrated advantages over a placebo in lowering stomach sensitivity. Because red pepper desensitizes the capsaicin receptor, it may reduce dyspeptic symptoms over time. Furthermore, although its exact mechanism is yet unknown, artichoke leaf extract has considerably enhanced quality of life and decreased symptoms in controlled trials.[17,18]

3.Non pharmacological treatments:

For the treatment of kids with chronic pain, integrative and complementary non-pharmacological therapies are known to be practical and successful. Because these techniques alter the brain circuits that control habits, affection, and cognitive reactions to pain, they may have long-term effects. As a result, therapies like cognitive behavioral therapy (CBT), acupuncture, spinal manipulation, exercise, and others help medical professionals treat children chronic pain.[19]

3.1 Electrical stimulation intervention:

Percutaneous electrical nerve field stimulation (PENFS) significantly reduced the worst pain scores and lowered PFSD composite scores, with an average decrease of 11.48 points, according to Kovacic et al. (2017)'s study of 115 children with functional abdominal pain issues, ages 11 to 18. Patients also reported feeling better overall after three weeks. When compared to the sham (placebo) group, long-term follow-up revealed that PENFS continued to result in higher reductions in pain and PFSD scores.[5]

3.2 Nutraceuticals:

This is a short overview of nutraceuticals and microbiota-targeted treatments for functional dyspepsia (FD) and functional abdominal pain disorders (FAPDs).

In children with functional abdominal pain problems, nutraceuticals such as probiotics, synbiotics, peppermint oil, and different herbal preparations have shown a variety of clinical effect. Probiotics such Lactobacillus rhamnosus GG, Bifidobacterium species, and Lactobacillus reuteri have been shown in a number of studies to reduce recurrent stomach pain in the short term, but many of these studies are small and biased. The effectiveness of L. reuteri and L. rhamnosus is supported by moderate-quality evidence, but there is limited evidence that VSL#3 and specific Bifidobacteria mixes may be beneficial, especially in children with IBS rather than functional dyspepsia. It has been demonstrated that peppermint oil may reduce pain in cases of undifferentiated functional abdominal pain, but not always in cases of IBS.

Combinations of probiotics and prebiotics, or synbiotics, have shown additional therapeutic benefits. According to randomized controlled trials, synbiotic formulations help individuals who suffer from functional constipation and IBS-C with their stool frequency, consistency, bloating, abdominal discomfort, and other gastrointestinal symptoms. Synbiotic-rich infant formulae also lessen colic, constipation, and regurgitation without causing major side effects.

Although there is limited information on FAPDs, herbal remedies including potentilla erecta, carob juice, Matricaria chamomilla combos, and fennel preparations have shown effectiveness in treating diarrhea or infantile colic. Although STW-5 (Iberogast) lacks strong RCT evidence, it offers encouraging retrospective pediatric data.

The potential significance of changed duodenal microbial composition is highlighted by microbiota-targeted treatments for functional dyspepsia. Only a small percentage of infected individuals benefit symptomatically from Helicobacter pylori eradication, with a large number of patients required for treatment and a delayed beginning of relief. According to new research, the probiotic Lactobacillus gasseri OLL2716 reduces the symptoms of FD with greater rates of elimination than a placebo. Additionally promising

is the non-absorbable antibiotic rifaximin, which improved postprandial fullness and belching in H. pylori-negative FD patients in a placebo-controlled trial with a 78% response rate compared to 52% with a placebo. We expect larger multicenter trials.[20]

As a soluble fiber that dissolves in water, PHGG (Partially Hydrolyzed Guar Gum) modifies the gut microbiota in a manner similar to that of a prebiotic which is used as non-pharmacological remedy for AP-FGID (Abdominal pain-related functional gastrointestinal disorder).AP-FGID consists of 4 main disesase conditions: functional dyspepsia, irritable bowel syndrome, abdominal migraine and functional abdominal pain.[21]

3.3 Dietary interventions /Dietary changes:

Diet: There are many diets that can help reduce the symptoms of functional disorders. Eating smaller meals more slowly and avoiding triggers like acidic, spicy, or caffeinated foods are recommended for Functional Disorders.[6]

An elimination diet that briefly eliminates and then reintroduces possible allergens (such as dairy, wheat, eggs, nuts, and seafood) may help people with suspected food sensitivities identify triggers.[22]

Adult studies have demonstrated the effectiveness of ginger root and STW (Iberogast), a herbal treatment that contains iberis, peppermint, and chamomile, in relieving the symptoms of dyspepsia. Reducing consumption of fatty, gaseous, and hot foods is not well supported by research.[7]

"Of 102 people, 16 (15.7%) changed their diet: 4 turned lactose-free, 3 cut back on gluten, 1 avoided apple puree, 1 increased rice and potato consumption, 1 reduced fat intake, 1 reduced nuts, 1 reduced chocolate, 1 reduced sugar, 1 switched to non-carbonated water, 1 avoided tomatoes and oranges, and 1 avoided tomatoes, onions, and garlic."

"These dietary changes were statistically significant ($p = 0.035$), with an average duration of 2.4 (range: 1-4) weeks."
Four (7.7%) of the 52 people in another group altered their diet: One person began consuming one cup of apple tea daily, two people followed a lactose-free diet, and one person switched from cow's milk to oat milk.

The second group had a p-value of 0.05 and an average length of dietary change of 2.6 (range: 0–4) weeks.23

Dietary interventions for treating FGIDs associated with abdominal pain include implementing a low-lactose or low-fructose diet when intolerance is confirmed, and also by using an osmotic laxative along with fiber supplementation in cases of significant constipation.[24]

3.4 Conginitive Behavioural Therapy:

CBT includes teaching methods for coping, distraction strategies, and relaxation techniques; identifying and altering pain-related thinking; and changing how families react to suffering. Cognitive behavioral therapy (CBT) usually consists of a number of components, including education about the pain, boosting self-confidence, cognitive restructuring of maladaptive thinking, practice exercises, relaxation, and parent management strategies.[19]

This therapy aimed to help control symptoms in both children and adults, this type of therapy teaches patients techniques for recognizing and altering thoughts, feelings, and behavioral reactions.[6]

3.5 Yoga:

It has been proved that children can benefit from yoga in a number of ways, including better emotional regulation, less anxiety, and reduced depression.[19]Yoga is another effective mind-body method for treating teenagers with pain-predominant FGIDs. not planned for regular follow-up and randomly assigned to an intervention). Over the course of three months, there was a significant reduction in pain frequency, intensity, and reported problems.[25]

A study by Brands et al. assessed the effects of yoga practice in 20 kids (8–18 years old) who had gastrointestinal pain or inflammatory bowel syndrome. The kids took part in (10) yoga sessions of 1.5hour, and it was noted that the exercises instantly reduced the frequency and intensity of stomach ache.[19]

3.6 Hypnotherapy:

When compared to supportive therapy (34%) and medical treatment (43%), hypnotherapy has also been shown to be beneficial in improving symptoms in adults (73%). Recent studies have demonstrated that children can benefit from this therapy as well. Van Tilburg et al. showed that a self-taught guided imagery program, which kids could use at home with minimal assistance from parents or doctors, was effective in lowering the frequency, intensity, and duration of pain, according to both child and parent reports, in a study of 23 kids aged 7 to 15 who had recurrent abdominal pain. Additionally, Vlieger et al. showed that hypnotherapy was better than standard care for patients with IBS and functional abdominal discomfort at the start of treatment (59% vs. 12%) and at the 1-year follow-up (85% vs. 25%).[25]

3.7 Acupuncture:

China and other East Asian nations have historically utilized acupuncture as a medicinal treatment. In addition to electroacupuncture, acupressure, moxibustion, electric stimulation of acupoints, and non-invasive stimulation of acupoints using a transcutaneous electrical nerve stimulator, the procedure entails inserting tiny needles at different points throughout the body. There is little study on acupuncture's ability to cure pain in pediatric patients, despite the fact that a significant amount of research has demonstrated its efficacy in treating pain in adults . Despite this shortage of research, a comprehensive review of pediatric acupuncture found both common minor side effects and uncommon major harms. The most frequently reported adverse effect is puncture redness, which is followed by needle discomfort and dizziness. Children's phobia of needles presents a challenge while treating the pediatric population.[19]

The effectiveness of acupuncture point P6 stimulation was equivalent for both invasive and noninvasive stimulation techniques.[25]

4.Complementary and alternative medical treatment:

Table No:1[25,26]

Treatment / therapy	Observations from studies (in children with FAPD / AP-FGID / IBS etc.)	Strength / certainty / limitations
Yoga (poses + relaxation/meditation)	At a one-year follow-up, 58% of the children in the yoga + standard care group had a weekly pain reduction of at least 50%, compared to 29% in the standard care only group ($p = 0.01$). At 12 months, there was a substantial decrease in both the frequency and intensity of pain, as well as fewer absences from school in the yoga group ($p = 0.03$). After ten yoga sessions, there was a significant decrease in the frequency and intensity of pain in both younger children (8–11) and older children (11–18) in a smaller pilot trial with 20 participants. Parents reported an improvement in their children's quality of life.	However limited, the evidence is positive. The evidence supporting yoga has been categorized as poor certainty in the largest systematic evaluation of non-pharmacologic therapies. Small sample sizes, bias risk, differences in yoga practices, and unclear long-term benefits are challenges. Frontiers
Acupuncture (and related therapies: moxibustion, non-pharmacologic stimulation etc.)	Acupuncture is being considered as a non-pharmacologic treatment for FAPDs. Acupuncture is listed as one potential non-pharmacological treatment. However, there is a shortage of big, high-quality RCTs and very little data in children—only tiny, irregular trials.	Acupuncture cannot be widely suggested for pediatric FAPDs due to the lack of sufficient data.
Spinal manipulation / manual therapy / physiotherapy / massage / manual-based therapies / osteopathy	Reviews of non-pharmacologic therapies list these therapies among several that are taken into into account for FAPDs. Improvements following physiotherapy or manual therapy have been reported in a few observational/small studies including children with persistent stomach discomfort.	There is limited evidence, mostly from observational or tiny, uncontrolled research. No extensive, controlled RCT data. Consequently, there is not enough data to suggest this as conventional therapy.

Dyspeptic symptoms significantly improved in patients with PDS-type FD, according to a recent Randomized Controlled Trial (RCT) employing rikkunshito and placebo.[14]

4.1 Herbal Medicines:

Dietary supplements and herbal products that may be useful in alleviating the symptoms of FD in both adults and children. Motilitone, cyproheptadine, STW 5 (Iberogast), peppermint oil, modified xiaoyao san, Rikkunshito, Chinese Herbal Medicine, and probiotics are some of these herbal products and dietary supplements.[27]

Among the important herbal medicines studied for functional dyspepsia (FD), **Iberogast (STW5)** is a notable example. It is a combination of nine herbal extracts, and multiple controlled trials as well as meta-analyses have demonstrated its efficacy in improving FD symptoms. However, it remains unclear which specific symptoms respond best and whether there are differences in effect between epigastric pain syndrome (EPS) and postprandial distress syndrome (PDS).[32]

Another promising option is the combination of **peppermint oil and caraway oil**, which has been evaluated in three placebo-controlled randomized trials. These studies consistently showed superiority over placebo in reducing FD symptoms. For instance, May et al. reported a 66% improvement compared to 20.9% with placebo, Rich et al. observed 88% improvement versus 55.4% with placebo, and Chey et al. found improvements in 78% of PDS patients and 72% of EPS patients compared to 50% and 40% in the placebo groups, respectively. Mechanistic studies in healthy volunteers further revealed that peppermint oil decreases intragastric pressure and inhibits gastroduodenal motility.

Finally, **Rikkunshito**, a Japanese multi-herbal preparation, has shown efficacy above placebo in two large studies conducted in Japan. Follow-up analyses indicated that response to Rikkunshito was associated with low baseline des-acyl ghrelin levels, absence of alcohol abuse, and positive *Helicobacter pylori* status. Its mechanism of action is thought to involve increased release and decreased inactivation of ghrelin, a gut hormone that regulates appetite and motility.[26]

Ginger-A few studies have looked into the use of ginger for functional gastrointestinal issues in adults, such as discomfort and bloating, however there is no information on the effectiveness of ginger for children's abdominal pain. More widely, ginger has long been used to treat gastrointestinal issues as an appetizer, stomachic, laxative, gastric emptying enhancer, antiemetic, and antidyspepsic, as well as an antidiarrheal and anticolic drug.[28]

Cannabis-There are no proper studies testing THC (delta-9-tetrahydrocannabinol-TGC is primary psychoactive compound found in Cannabis sativa) or dronabinol for treating stomach problems in children. Very little information exists about using cannabis for stomach pain, especially for functional problems.

Licorice-Because of its anti-inflammatory, antibacterial, and antiviral pharmacologic effects, deglycyrrhizinated licorice (DGL), a processed licorice extract created by eliminating the glycyrrhizin molecule to remove its mineralocorticoid characteristics, has been utilized for a number of gastrointestinal problems. Additionally, functional dyspepsia and stomach hyperacidity are treated with DGL.

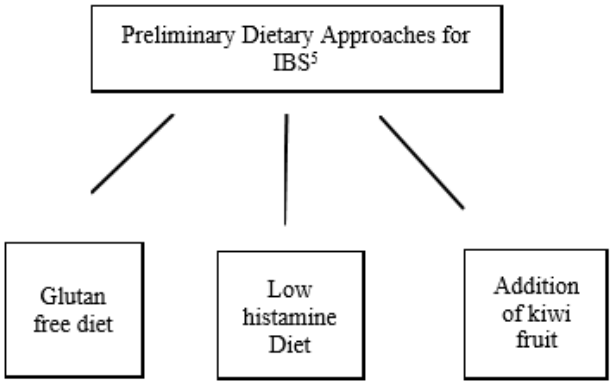
Fennel- Anethole is a component of fennel oil which improves gastric emptying and gastric accommodation in rats which may have positive effects on Functional Dyspepsia. Fennel tea has been investigated for the treatment of newborn colic, however there are no pediatric research evaluating the effectiveness of fennel for FGIDs. About 77% of moms in a descriptive research evaluating the use of herbal remedies in Turkey reported using fennel tea to relieve their kids' constipation and flatulence. Through four randomized controlled trials (RCTs), a systematic review of herbs revealed the effectiveness of fennel in various formulations (seed oil, tea, or in combination with other herbs like Colimil®) to lessen crying episodes in infants with colic (n = 461, age range 2–12 weeks old). These studies did not report any adverse effects.[29]

5.Upcoming treatments for adults:

Several novel treatments are being investigated for adults with FAPDs in comparison to pediatric research. Relamorelin and velusetrag, two more recent prokinetics that are successful in treating diabetic gastroparesis, may also be useful in treating functional dyspepsia.[5]

Table No:2 Prokinetics have showing efficacy for functional dyspepsia in adult phase 1 and 3 trials[5]

Drug/Agent	Mechanism of Action	Target Condition	Key Findings
Plecanatide	Guanylyl cyclase agonist	IBS-C	Efficacy: OR 1.87 (95% CI 1.47–2.38) for 3 mg; OR 1.92 (95% CI 1.48–2.48) for 6 mg. Long-term safety up to 53 weeks.
Tenapanor	Sodium–hydrogen exchanger inhibitor	IBS-C	Improved spontaneous bowel movement frequency, abdominal pain, bloating, cramping, and fullness in phase 2 trials.
Ibodutant	Selective neurokinin-2 receptor antagonist	IBS-D	Improved abdominal pain and discomfort in a large double-blind RCT.
Cholbam (bile acid analogue)	Bile acid analogue	IBS-C	Role still being evaluated.
Elobixibat	Ileal bile acid transporter inhibitor	IBS-C	Role still being evaluated.
Bile acid sequestrants	Bind bile acids to reduce their effects	IBS-D	Emerging as therapeutic options.
Farsenoid receptor antagonists	Block farsenoid receptor signaling	IBS-D	Emerging as therapeutic options.



There are some complementary and alternative therapies which includes acupuncture and moxibustion have gained considerable attention in adults. Moxibustion, which involves placing dried and burned mugwort (moxa) cones to particular acupuncture points, has reduced IBS symptoms, particularly abdominal distension and frequency of feces.[5]

The administration of medicines through oral or parenteral routes—such as subcutaneous, intravenous, or intramuscular delivery—may be less effective for treating dyspepsia in pediatric patients and can also cause pain or discomfort. To overcome these limitations, there is a need for a dosage form that is safe for children, easy to administer, and capable of providing quick relief from dyspepsia and associated discomfort. Considering these requirements, we propose the development of a topical spray dosage form. A topical spray is simple to handle, convenient to store, non-irritating, painless, and can deliver therapeutic effects by alleviating dyspeptic symptoms. Currently, there is limited literature on topical formulations for dyspepsia, and with the growing preference for Ayurvedic and natural remedies—due to concerns about side effects from inappropriate use of synthetic or allopathic medicines—there is a strong rationale for developing a herbal topical spray. Our aim is to formulate a pediatric-friendly herbal spray using natural plant-based ingredients and minimal chemical additives. The proposed formulation is expected to have low side-effect potential while providing symptomatic relief from dyspepsia.[30]

6.Challenges in clinical trials for paediatric FAPDs:

Clinical trials for paediatric functional abdominal pain disorders (FAPDs) face unique challenges, including limited funding, difficulty obtaining approvals, parental reluctance toward placebo groups, high placebo effects, and unreliable symptom reporting. The Rome Paediatric Subcommittee (2016) recommends double-blind, placebo-controlled trials lasting at least four to six weeks, with a minimum age of eight years and patient-reported outcomes prioritized. Abdominal pain reduction of at least 30% from baseline, stool consistency (for IBS), and functional disability are considered key endpoints. Together, these measures aim to improve trial quality and provide more reliable evidence to guide treatment strategies for children with FAPDs.[5] The Rome II

pediatric criteria for functional gastrointestinal disorders (FGIDs) used as diagnostic tools and to enhance empirical research. In this publication, the Rome III Committee attempted to update and amend the pediatric criteria.[31]

7. Conclusion:

Pediatric functional dyspepsia is a complex condition that necessitates a multidisciplinary approach to therapy. While behavioral and complementary therapies are becoming more and more useful in addressing both physiological and mental aspects, current pharmaceutical solutions only offer partial relief. Herbal and microbiota-targeted therapies represent intriguing areas, and new medicines under investigation in adults may increase pediatric possibilities. Large-scale pediatric trials should be given top priority in future research in order to validate treatments and direct comprehensive, long-term care plans.

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