ABSTRACT

Purpose: Recently, great interest has been focused on dietary fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) for the treatment of functional abdominal pain (FAP). Several meta-analyses, including those on the adult population, have been published, potentiating its role. However, pediatric studies are scarce. We aimed to evaluate the effect of a low-FODMAP diet on the severity of FAP in children.

Methods: This clinical trial included 50 patients aged 3–18 years with irritable bowel syndrome and FAP that were not otherwise specified. The patients were instructed to receive a low FODMAP diet guided by a dietitian. The primary outcome was the percentage of responders after 2 months of dietary intervention compared with baseline. Other outcomes included changes in stool consistency and quality of life (QoL) scores using the KIDSCREEN-10 questionnaire, and weight-for-age z-scores.

Results: After the dietary intervention, 74% of patients showed more than 30% lower pain intensity, as examined using the Wong-Baker Faces pain rating scale. Their QoL significantly improved, and patients have gained weight.

Conclusion: A low FODMAP diet can improve pain intensity and QoL among children with functional abdominal pain, with no detrimental effects on body weight.

Keywords: Child; Diet; Oligosaccharides; Disaccharides, Monosaccharides; Abdominal pain; Irritable bowel syndrome

INTRODUCTION

Functional abdominal pain (FAP) is a prevalent disorder affecting children and adolescents. Children with FAP may experience significant school absenteeism, social withdrawal, reduced quality of life, and increased psychological distress [1].

FAP comprises four distinct disorders: irritable bowel syndrome (IBS), functional dyspepsia, abdominal migraine, and FAP-not otherwise specified (FAP-NOS). The latter is a relatively
new entity, which means that the FAP does not fit into the specific diagnostic pattern of any of the first three disorders [2].

The worldwide population studies in children and adolescents (3–16 years of age) reported a pooled global prevalence of 13.8% and 2.3% for IBS and FAP-NOS, respectively [3].

The pathophysiology of IBS is multifactorial and includes disordered communication between the gut and brain, intestinal dysmotility, visceral hypersensitivity, genetic predisposition, stress, and dietary changes [4].

Recently, great interest has been focused on low dietary fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) for the treatment of FAP [5]. They are short-chain carbohydrates that are poorly absorbed in the small intestine, fermentable, and osmotically active. The passage of these short-chain carbohydrates into the colon provides a substrate for colonic bacteria to produce hydrogen and methane [6].

The low FODMAP diet involves three phases: a strict low FODMAP diet that lasts from to 4–8 weeks [7], followed by a reintroduction phase, and an individualized diet phase, which implies the consumption of well-tolerated food for longer periods of time [8].

In adults, medical advisory entities, such as the American College of Gastroenterology and the British Dietetic Association, advise that the Low FODMAP diet is the first- and second-line treatment for IBS respectively [9,10]. However, there is limited evidence of its effectiveness in children [11].

**MATERIALS AND METHODS**

**Aim**
To evaluate the effect of a low-FODMAP diet on the clinical severity of FAP in children. The primary outcome was the percentage of responders after 2 months of dietary intervention compared with their baseline diet. Other outcomes included changes in stool consistency and quality of life (QoL) scores using the KIDSCREEN-10, and weight-for-age z-scores.

**Methodology**
A prospective clinical trial involving a cohort of patients was conducted at the Ain Shams University Pediatrics Hospital. The study protocol was approved by the Ethics Committee at the Faculty of Medicine, Ain Shams University, and complied with the regulations of the Helsinki Declaration, 1964. Informed consent was obtained from the parents or guardians of the children before enrollment in the study.

The study included patients aged 3–18 years who were diagnosed with FAP disorder in the form of IBS and FAP-NOS according to the Rome IV criteria. Exclusion criteria included alarming features for chronic abdominal pain: Family history of inflammatory bowel disease, celiac disease, peptic ulcer disease, persistent upper right or lower right quadrant pain, dysphagia, odynophagia, persistent vomiting, gastrointestinal blood loss, nocturnal diarrhea, arthritis, periarticular disease, involuntary weight loss, deceleration of linear growth, delayed puberty, and unexplained fever [12]. Those who were non-compliant with the diet after initial enrollment were also excluded from the study.
**Sampling method**
Sixty-three patients were randomly included with the intention of treatment; 13 were non-compliant and dropped out early in the course, while 50 completed the study per protocol.

Medical history notes were taken for all patients with a special focus on sociodemographic data, abdominal pain analysis, bowel motion frequency, and stool consistency using the Bristol stool chart for pediatric patients.

- Assessment of pain score: The patient and parents were instructed to describe the pain and correlate it with the Wong-Baker Faces pain rating scale [13]
- QoL was assessed using the KIDSCREEN-10 index to assess children's and adolescents' subjective health and well-being. These instruments were developed as self-report measures that are applicable to healthy and chronically ill children and adolescents [14,15]. The total score is reported out of 50, while there is a subjective overall rating that is graded as poor, accepted, good, very good, and excellent.

**Initial examination**
General examination including anthropometric measurements: Weight, height, and body mass index were measured and plotted against z-scores (weight for age and height for age) as well as abdominal examination.

**Intervention**
After the patient's assessment, patient and family education about the disease was always offered. The weight and height were measured and recorded by the same dietitian. At the initial dietetic consultation, the families provided prerecorded 3-day food and beverage diaries, and the child's dietary intake, nutritional adequacy, food preferences, and the extent to which the patient eats food rich in FODMAPs. These were considered to tailor the diet regimen based on their preferred food, where foods high in FODMAPs were substituted.

Patients were given a list of prohibited and allowed foods in their diet, written in Arabic, and recipes were suggested to increase their compliance with the diet. Nutritional lists were prepared by a pediatric gastroenterology dietitian to provide age appropriate protein, calorie, vitamin, and mineral intakes, and nutrition training was provided. Foods were classified into high- and low-FODMAP diets according to the Monash University classification [16].

**Follow-up**
Children were asked to complete the 8-week restriction phase as strictly as possible and maintain a food and beverage diary throughout to ensure compliance. Telephone calls were held weekly to confirm compliance and adherence to the diet. Patients were followed up with a comparison between their status at baseline and after 2 months of following the low FODMAP diet, with regard to pain score, Bristol stool chart, and QoL questionnaire results. A good response was defined as an improvement in the pain score, better than that found at the baseline for each patient, and it was categorized as poor response (20–30% improvement, moderate response >30–50%), and good response (>50% improvement).

Microsoft Excel was used for data entry, and SPSS statistical package version 27 was used for data analysis. Descriptive analyses were performed in the form of frequency and percentages for qualitative variables and mean±standard deviation and range for quantitative parametric data, whereas median and interquartile range (IQR) were used for non-parametric numerical
data. For the comparison between two groups’ means, independent “t” test was used for parametric data, while the Mann-Whitney test was used for non-parametric data. The chi-square test was used to examine the relationship between two qualitative variables; p-value of <0.05 was considered significant.

RESULTS

Although we initially started with 63 patients, only 50 completed the follow-up period. The data are summarized in Table 1. After 2 months of dietary intervention, 84% of the patients

| Patients’ characteristics                         | Total (n=50) |
|------------------------------------------------|--------------|
| Sex                                             |              |
| Male                                            | 20 (40.0)    |
| Female                                          | 30 (60.0)    |
| Age                                             |              |
| Mean±standard deviation                         | 7.56±3.30    |
| Range                                           | 3–15         |
| Order of birth                                  |              |
| 1                                               | 20 (40.0)    |
| 2                                               | 17 (34.0)    |
| 3                                               | 8 (16.0)     |
| 4                                               | 5 (10.0)     |
| Location of pain                                |              |
| Epigastric and umbilical                        | 4 (8.0)      |
| Epigastric                                      | 7 (14.0)     |
| Peri umbilical                                  | 39 (78.0)    |
| Duration of pain in minutes (min)               |              |
| <30                                             | 39 (72.0)    |
| 30–60                                           | 9 (18.0)     |
| >60                                             | 5 (10.0)     |
| Frequency of pain episode (d)                   |              |
| Median (interquartile range)                    | 3 (2–5)      |
| Range                                           | 1–8          |
| Exacerbating factor                             |              |
| None                                            | 2 (4.0)      |
| Food                                            | 42 (84.0)    |
| Stress                                          | 6 (12.0)     |
| Alleviating factor                              |              |
| Not relieved by defecation                      | 6 (12.0)     |
| Relieved by defecation                          | 44 (88.0)    |
| Family history of GI conditions                 |              |
| None                                            | 19 (38.0)    |
| IBS                                             | 28 (56.0)    |
| Constipation                                    | 3 (6.0)      |
| Drug history                                    |              |
| None                                            | 16 (32.0)    |
| PPI                                             | 4 (8.0)      |
| Antispasmodic drugs                             | 30 (60.0)    |
| Types of functional abdominal pain              |              |
| NOS                                             | 10 (20.0)    |
| IBS                                             | 40 (80.0)    |
| IBS subtypes                                    |              |
| IBS C type                                      | 13 (26.0)    |
| IBS D type                                      | 13 (26.0)    |
| Undifferentiated                                | 14 (28.0)    |

Values are presented as number (%), mean±standard deviation, or median (interquartile range).
GI: gastrointestinal, IBS: irritable bowel syndrome, PPI: proton pump inhibitor, NOS: not otherwise specified.
had a decrease in pain scores, where the median pain score at baseline was 8 (IQR: 6–10), and the range was 4–10, while after 2 months of dietary modification, the median pain score was 4 (IQR: 4–6) and the range was 0–10 (p=0.000). Responders were further categorized according to their percentage of improvement into poor, moderate, and marked, as shown in Table 2.

The comparison of the baseline to post-dietary intervention showed a significantly better QoL among all categories, but with no significant change in stool consistency. The results are presented in Table 3. The weight has also improved from a median and IQR of −0.41 (−0.91–0.26), with the range of −2.47–1.66 at baseline, to −0.11 (−0.65–0.39), with the range of −2.47–1.75, p-value=0.006.

A comparison between responders and non-responders showed no significant difference with regard to sociodemographic data (age/sex/residence) as well as the character of pain before dietary intervention (location, duration, frequency, and initial pain score).

No significant difference was found in stool consistency, which had a median of 3.5 (IQR: 1.5–4.5) among responders and a median of 3 (IQR: 3–5) among non-responders.

Only weight showed a significant improvement among responders compared to non-responders. The non-responders had a median weight of −0.61 (IQR: −1.03–−0.36) with the range of −1.36–−0.25, while the responders had a median weight of 0.07 (IQR: −0.39–0.4) with the range of −2.47–1.75, p-value=0.01.

Comparisons between the percentage of responders in each category of FAP also showed no significant differences, as shown in Table 4.

| Table 2. Percentages of responders to dietary intervention |
|----------------------------------------------------------|
| Response to diet | Value (n=50) |
| Non responders   | 8 (16.0)    |
| Total responders | 42 (84.0)   |
| Poor response (20–30% improvement) | 5 (10.0) |
| Moderate response (30–50% improvement) | 22 (44.0) |
| Good response (>50% improvement) | 15 (30.0) |

Values are presented as number (%).

| Table 3. Comparisons between baseline quality of life and stool consistency with post-dietary intervention |
|----------------------------------------------------------|
| Assessment parameters | Baseline | After 2 months | Test value | p-value |
| Quality of life       |          |               |            |         |
| Poor                  | 16 (32.0)| 4 (8.0)       |            |         |
| Accepted              | 31 (62.0)| 8 (16.0)      |            |         |
| Good                  | 3 (6.0)  | 28 (56.0)     | 50.925*    | <0.001  |
| Very good             | 0 (0.0)  | 6 (12.0)      |            |         |
| Excellent             | 0 (0.0)  | 4 (8.0)       |            |         |
| Quality score         | 16.42±5.24| 27.48±8.62   | −9.014†    | <0.001  |
| Range of quality score| 9–30     | 9–44          |            |         |
| Bristol chart         |          |               |            |         |
| Median (interquartile range) | 3 (1–6) | 3 (3–5)       | −0.665‡   | 0.506   |
| Range                 | 1–7      | 1–7           |            |         |

Values are presented as number (%), mean±standard deviation, or median (interquartile range).

*Chi-square test.
†Paired t-test.
‡Mann-Whitney test.
DISCUSSION

We found that a low FODMAP diet appeared to be effective in reducing pain in children, with subsequent improvement in their quality of life. Many adult studies have investigated the effect of a low-FODMAP diet on FAP; however, pediatric studies are scarce.

The most recently published meta-analysis, which included 22 papers, focused on evaluating the effect of a low-FODMAP diet on IBS symptoms in adults. It was concluded that the low FODMAP diet group showed a moderate reduction in symptom severity and a slight improvement in QoL compared to the control group [17].

Our study showed improvement in 84% of patients. This figure is close to the results of several adult clinical trials that have reported that reducing high-FODMAP foods achieves adequate symptom relief in approximately 70% of IBS patients [18-20]. Most of the adults’ studies used the IBS-SSS score analysis, which is not applied for pediatrics.

The first pediatric study to evaluate the low FODMAP diet in children with IBS was published in 2014. In that small open-label pilot study, the potential benefit of a low-FODMAP diet was compared to baseline in reducing the frequency of abdominal pain. Lowered pain severity and pain-limiting activities in children with IBS were demonstrated in a subset of children [21]. The was followed by another randomized double-blind crossover trial with the use of a low FODMAP diet for only 2 days, followed by a washout period of 5 days. Children on a low FODMAP diet reported a decrease in daily abdominal pain episodes compared with children following the typical American childhood diet [22]. The authors used pain and stool diary to measure the outcome, and defined responders as those who had a decrease of more than 50 percent in pain frequency episodes.

This cohort study was conducted [23] in 2019. It was started in 22 patients with FAP and dyspepsia. The low FODMAP diet was instructed for only two weeks. The outcome was based on the measurement of pain severity (using the visual analog scale), pain frequency, interference with activity, and stool characteristics. All parameters were found to have improved with the low FODMAP diet, except for stool characteristics.

In 2020, Brown et al. [24] conducted a retrospective study of 29 patients who were fed a low-FODMAP diet for 4 weeks. This study included patients with FAP based on the NICE criteria. The physicians assessed the symptoms of bloating, diarrhea, and abdominal pain (using a 7-point Likert scale taken from the IBS Global Improvement scale). In their study, only six

### Table 4. Comparison between the percentage of responders in each category of FAP

| FAP classifications | Non-responders (n=8) | Total responders (n=42) | Test value* | p-value |
|---------------------|----------------------|------------------------|-------------|---------|
| IBS classification  |                      |                        |             |         |
| IBS C type          | 1 (12.5)             | 12 (28.6)              | 1.569       | 0.456   |
| IBS D type          | 1 (12.5)             | 12 (28.6)              |             |         |
| Undifferentiated    | 3 (37.5)             | 11 (26.2)              |             |         |
| FAP type            |                      |                        |             |         |
| NOS                 | 3 (37.5)             | 7 (16.7)               | 1.823       | 0.177   |
| IBS                 | 5 (62.5)             | 35 (83.3)              |             |         |

Values are presented as number (%).

FAP: functional abdominal pain, IBS: irritable bowel syndrome, NOS: not otherwise specified.

*Chi-square test.
patients did not improve on the low FODMAP diet, which was based on reporting <50% reduction in symptoms.

In 2020, Dogan et al. [25] conducted a case control study, with one arm having 30 children advised for a low FODMAP diet for 2 months, and another arm, with the same number of participants, advised of a healthy protective diet devoid of chocolate, caffeine, acidic or spicy food, and high fats. The physicians assessed the patients at 2 months using the clinical global impression improvement score and VAS, which was significantly lower in the low FODMAP diet group at 2 months, but significantly higher at 4 months follow-up (2 months after the cessation of the diet).

On the other hand, Borayden et al. [26], also in 2020, published a randomized controlled trial on 27 children randomized to low FODMAP diet versus a diet based on NICE recommendations for 4 weeks. They measured the severity of abdominal pain using Wong Baker’s faces. Their results showed that the NICE-based diet arm had a significant reduction in abdominal pain severity and frequency and an improvement in stool consistency, but these differences were not significant among children who received the low FODMAP diet.

**IBS subtypes**

In our study, no significant change was observed in stool consistency, and the three subclasses of IBS improved equally. These results are consistent with those of other pediatric studies [21,23], while, in a meta-analysis of the adult population, IBS symptom improvement was also consistent between subgroups stratified according to IBS subtypes. However, three studies regarding stool habit changes in patients with IBS-D showed a significant decrease in stool frequency and a significant improvement in stool consistency in the low FODMAP diet group compared to the control group [17].

**Impact on nutrition**

Since it is a restrictive diet, its nutritional impact might raise great concerns. However, in our study, responders showed positive weight gain. This is similar to the results of the aforementioned pediatric studies, which concluded that these mild gains were, in part, a reflection of GI symptom relief and the subsequent ability of these children to eat more food, especially when a specialized dietitian followed up with the patients [24].

Another meta-analysis that included adult patients described the impact of a low FODMAP diet on nutritional adequacy. It was concluded that substantial nutritional inadequacies do not occur, whether during short-term interventions or through long-term follow-up after initial low FODMAP diet advice [27]. Also, in most of the included studies, subjects received personalized diets and/or nutritional advice, which would have helped to maintain a balanced diet.

**Compliance**

The percentage of dropout was 20%. The adherence to this restrictive diet is difficult, with different dropout rates, mentioned to be of 6–9% in other pediatric studies [23,24].

**Duration of dietary intervention**

Our study chose a relatively longer duration of 2 months restriction phase to ensure maximal benefit; the same duration was used by Dogan et al. [25]. However, most pediatric studies implied four weeks of dietary intervention [23,24], and others were even shorter [21,22].
What is new

Unfortunately, pediatric studies have a small number of patients and are inconsistent regarding the definition of improvement, methods of assessing outcomes, diet compared to the low FODMAP diet, and duration of the low FODMAP diet.

Moreover, there is scarce data on the pediatric population of the Mediterranean region, whose diet is very different from the diet in the United States, as the latter usually includes a much higher amount of FODMAPs than the Mediterranean diet [28].

Almost all published studies investigating the role of diet in the management of FAP disorders involve IBS, with surprisingly little information on FAP-NOS [29]. In our study, the included FAP-NOS patients equally improved in comparison to IBS patients.

To the best of our knowledge, no other pediatric study has measured QoL or included the FAP-NOS category. However, the limitations of this study include the lack of a control group and the relatively short duration of follow-up, where only the restriction phase was included.

In conclusion, a low FODMAP diet improves pain intensity and QoL among children suffering from functional abdominal pain, with no detrimental effects on body weight.

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