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The use of polyethylene glycol as a maintenance treatment of functional constipation in children living in Egypt

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Abstract

Background Constipation is an underestimated but common health problem worldwide, decreasing the quality of life. Functional constipation (FC) is a common pediatric problem, with reported prevalence ranging from 0.7 to 29.6%. In Egypt, there are no established guidelines for the treatment of constipation in children.

Objectives The aim of this study was to investigate the efficacy of polyethylene glycol (PEG) as a maintenance treatment for functional constipation (FC) in comparison with the classic treatment using (lactulose and senna) in children living in Egypt.

Patients and method This is a randomized single-blinded clinical trial study on pediatric patients who presented with functional constipation at the outpatient clinic of Cairo University Specialized Pediatric Hospital. The study was conducted on 80 children with functional constipation, who were divided into 2 groups: group 1 (40 children), who received polyethylene glycol as maintenance treatment; group 2 (40 children), who received classic treatment in the form of osmotic laxative (lactulose) with or without stimulant (senna-sennosides or senna-glycoside) according to the stool consistency.

Results Our data showed significant improvement in the fecal masses and the number of defecation, fecal pseudo incontinence, painful or hard bowel movement, history of retentive posturing or excessive violation, and large fecal masses in the rectum between group 1 and group 2 after treatment. In group 1, there was a significant improvement in anthropometric measures, CBC parameters, abdominal circumference, and anal fissures and piles after treatment; also, there was a significant decrease in the number of patients that need to continue treatment in group 1 in comparison with group 2 and number of patients that had impaction during treatment. However, there was a statistically significant increase in the number of patients who complained of palatability in group 1.

Conclusion PEG has long-term efficacy in the management of pediatric functional constipation. Significant improvement of results in comparison with the classic treatment (lactulose or senna-lax).

Keywords Functional constipation, Polyethylene glycol

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Background

Constipation is a common health problem worldwide but it is underestimated, it decreases the quality of life [18].

Organic causes of constipation are not common, but most of them can be ruled out clinically. They include Hirschsprung disease, hypothyroidism, hypercalcemia, spina bifida, spina bifida occulta, and drugs that slow

down intestinal motility. Red flags for referral to a pediatrician are delayed passage of meconium beyond 48 h of life and vomiting with abdominal distension, young age of < 6 months, developmental delay or behavioral problems, failure to thrive, and frequent soiling [14].

Functional constipation (FC) is a common pediatric problem, with reported prevalence ranging from 0.7 to 29.6% [24].

The guidelines recommend the use of the ROME IV Criteria to diagnose functional constipation when organic pathology is ruled out [28].

This condition accounts for 3 to 5% of pediatric primary care visits and up to 25% of gastroenterology consultations, and the usual presentation to the emergency department is abdominal pain [27].

In many countries, polyethylene glycol (PEG) is the first choice of laxatives in the treatment of functional constipation in children, it can be used for disimpaction and for maintenance treatment [16].

PEGs are high-molecular-weight, water-soluble polymers that can form hydrogen bonds, in a ratio of 100 water molecules per one PEG molecule. It can be used in two different preparations: PEG 3350 and PEG 4000. Likewise, PEG 3350 can be presented in two forms, pure PEG 3350 and PEG 3350 with electrolytes added (PEG + E), such as sodium bicarbonate, sodium chloride, potassium chloride, and sodium sulfate, in variable concentrations. This is intended to avoid possible dehydration that may happen due to severe diarrhea [23].

In Egypt, there are no established guidelines for the treatment of constipation in children.

Aim of the work

The aim of this study was to investigate the efficacy of polyethylene glycol (PEG) as a maintenance treatment for functional constipation (FC) in comparison with the classic treatment using (lactulose and senna) in children living in Egypt.

Methods

This is a randomized single-blinded clinical trial study on pediatric patients who presented to the Pediatric Gastroenterology Department of Cairo University Specialized Pediatric Hospital suffering functional constipation. The study enrolled 80 children with functional constipation and divided them into 2 groups: group 1 (40 children), those who received polyethylene glycol as maintenance treatment, and group 2 (40 children), those who received classic treatment in the form of osmotic laxative (lactulose) with or without stimulant laxative (senna-sennosides or senna-glycoside) according to the stool consistency. No iron therapy or multivitamins were given during our study.

Inclusion criteria

The following are the inclusion criteria:

- Age from 1 to 16 years of both genders
- All patients with functional constipation according to the ROME IV Criteria
- Patients taken were either de novo or non-compliant

Exclusion criteria

The following are the exclusion criteria:

- Patients who were treated outside the hospital with different regimens
- Patient with organic constipation

Methodology

All included patients were subjected to the following:

1. *History*: With special attention to age, sex, age of presentation, type of treatment, duration of treatment, complications from treatment, and family history of similar condition.
2. *Clinical examination*: Anthropometric measures including weight, height, mid-arm circumference, and measuring *z*-score of weight for age, height for age, and mid-arm circumference for age according to WHO growth charts. Abdominal circumference: measured around the line of greatest volume in the abdominal region, usually coinciding with the level of the umbilical scar. The measurement should be performed at the end of expiration. Abdominal examination is done to detect fecal masses. A perineal examination is done to exclude fissures and piles.
3. *Investigation*: labs: CBC, serum iron.
   - Radiology: plain X-ray abdomen erect to detect the size of fecal mass and amount of retained stool and to confirm fecal disimpaction before starting maintenance therapy; contrast water-soluble enema

Intervention

Patients were randomized into 2 groups as odds number in group 1 and even number in group 2

Group 1 Patients with functional constipation who received polyethylene glycol (PEG) in a dose of (1–1.5 g/kg for 3–6 days) for fecal disimpaction and (0.2–0.8 g/kg) for maintenance therapies for 16 weeks with regular follow-up these patients. PEG sachet was dissolved in water or juice and stirred well until the powder dissolved. PEG with electrolytes is the only product available in the Egyptian markets.

Group 2 Those patients received rectal enema for 2 days before starting treatment for stool disimpaction. Patients then received classic treatment in the form of osmotic laxative as lactulose in a dose of 1–2 g/kg/day divided into 1–2 doses or stimulant as senna, sennosides, or senna-glycosides in a dose according to age: 2–6 years, 2.5–5 mg/day in 1–2 doses; 6–12 years, 7.5–10 mg/day in 1–2 doses; and > 12 years, 15–20 mg/day in 1–2 doses according to stool consistency.

Both groups were followed up in the outpatient clinic for 6 to 12 months after starting the maintenance therapy, and data were collected and analyzed for all of them.

Statistical analysis

Data was entered and statistically analyzed on the Statistical Package of Social Science Software program, version 25 (IBM SPSS Statistics for Windows, version 25.0. Armonk, NY: IBM Corp.). Data was presented using mean, standard deviation, or median with interquartile range for quantitative variables and frequency and percentage for qualitative ones. Comparison between the groups for qualitative variables was performed using the chi-square or Fisher's exact tests (if expected counts < 5) while for quantitative variables, the comparison was conducted using the Mann–Whitney test. Pre- and post-measures were compared through the Wilcoxon test (if quantitative) or McNemar test (if qualitative). *p*-values less than or equal to 0.05 were considered statistically significant (Tables 1, 2, 3 and 4).

Results

Eighty patients with functional constipation were enrolled in the study. Patients were classified into 2 groups (Figs. 1, 2, 3, 4 and 5):

Table 1 Comparison between group 1 and group 2 regarding abdominal and anal examinations before and after treatment

		Group 1 ($n=40$)		Group 2 ($n=40$)		*p*-value
Abdominal circumference in cm	**Before treatment**					
	Range	40–84		44–83		0.164
	Mean ± SD	57.4 ± 9.1		54.8 ± 7		
	Median (IQR)	55.5 (52–60.5)		54 (49.5–58.5)		
	After treatment					
	Range	34–80		40–73		0.476
	Mean ± SD	50.2 ± 9.6		48.3 ± 6.2		
	Median (IQR)	48 (44–54)		47.5 (45–51)		
Abdominal fecal masses	**Before treatment**	40	100%	40	100%	1.000
	After treatment	7	17.5%	18	45%	**0.008**
Anal fissures or piles	**Before treatment**	11	27.5%	5	12.5%	0.094
	After treatment	2	5%	4	10%	0.675

A significant improvement in fecal masses occurred after starting the treatment in group 1 with *p*-value = 0.008 shown in Table 1

Table 2 Comparison between group 1 and group 2 regarding the Rome IV Criteria in children ≤ 4 years old before and after treatment

Rome IV Criteria ≤ 4 years ($n=8$ in each group)		Group 1 ($n=8$)		Group 2 ($n=8$)		*p*-value
Two or fewer defecations per week	**Before treatment**	8	100%	8	100%	1.000
	After treatment	0	0%	5	62.5%	**0.026**
History of excessive stool retention	**Before treatment**	2	25%	1	12.5%	1.000
	After treatment	0	0%	1	12.5%	1.000
History of painful or hard bowel movement	**Before treatment**	8	100%	8	100%	1.000
	After treatment	0	0%	4	50%	0.077
History of large diameters stools	**Before treatment**	1	12.5%	0	0%	1.000
	After treatment	0	0%	0	0%	1.000
Presence of a large fecal mass in the rectum	**Before treatment**	6	75%	7	87.5%	1.000
	After treatment	1	12.5%	4	50%	0.282

Table 2 shows that there was a significant improvement in the number of daily defecation in group 1 after treatment regarding *p*-value = 0.026 due to the effect of polyethylene glycol

Table 3 Comparison between group 1 and group 2 regarding the Rome IV Criteria in children ≥ 4 years old before and after treatment

Rome IV Criteria ≥ 4 years (*n* = 32 in each group)		Group 1 (*n* = 32)		Group 2 (*n* = 32)		*p*-value
Two or fewer defecations in toilet per week	**Before treatment**	29	90.6%	28	87.5%	1.000
	After treatment	5	15.6%	23	71.9%	**0.000**
At least one episode of fecal incontinence per week before starting the treatment	**Before treatment**	15	46.9%	18	56.3%	0.453
	After treatment	1	3.1%	14	43.8%	**0.000**
History of retentive posturing or excessive volition stool retention	**Before treatment**	14	43.8%	17	53.1%	0.453
	After treatment	1	3.1%	13	40.6%	**0.000**
History of painful or hard bowel movements	**Before treatment**	26	81.3%	27	84.4%	0.740
	After treatment	7	21.9%	18	56.3%	**0.005**
Presence of large fecal mass in the rectum	**Before treatment**	10	31.3%	20	62.5%	**0.012**
	After treatment	4	12.5%	17	53.1%	**0.001**
History of large-diameter stools that may obstruct the toilet	**Before treatment**	7	21.9%	2	6.3%	0.148
	After treatment	2	6.3%	2	6.3%	1.000
The symptoms cannot be fully explained by another medical condition	**Before treatment**	0	0%	0	0%	1.000
	After treatment	0	0%	0	0%	1.000

Table 3 Shows that there was a statistically significant improvement in the number of defecation, number of stool incontinence, retentive posturing or excessive volition, and large fecal masses in the rectum and pain or hard bowel movement in group 1 after treatment with *p*-value ≤ 0.001

Table 4 Comparison regarding drug effectiveness, tolerance, availability, dosing, and palatability between group 1 and group 2

	Group 1		Group 2		*p*-value
Number of patient who continued treatment after 16 weeks	7	17.5%	18	45%	**0.015**
Frequency of drug intake after 16 weeks					
Daily	2	5%	8	20%	0.087
Twice weekly	2	5%	6	15%	0.263
Weekly	3	7.5%	4	10%	1.000
Number of patients that had impaction during treatment intake	0	0%	6	15%	**0.025**
Number of patients that decreased the dose of treatment after 16 weeks	5	12.5%	2	5%	0.432
Number of patients complained of palatability	30	75%	10	25%	**0.000**

Table 4 shows that there was a statistically significant decrease in the number of patients that needed to continue treatment in group 1 in comparison with group 2 with *p*-value = 0.015 and the number of patients that had impaction during treatment intake in group 1 with *p*-value = 0.025. However, there was a statistically significant increase in the number of patients who complained of palatability in group 1 with a *p*-value ≤ 0.001

Group 1 included 40 patients who received polyethylene glycol.

Group 2 included 40 who received the classic treatment in the form of osmotic laxative (lactulose) with or without stimulant laxative (senna) according to stool consistency.

Discussion

Constipation is one of the most common chronic health problems reported in the pediatric population worldwide. By far, the most common etiology is functional constipation (FC), which affects more than 10% of children worldwide [17].

The Rome IV Criteria define FC in children (developmental age ≥ 4 years) in the presence of two or more of the following criteria, for at least 1 month: (1) two or fewer defecations per week in the toilet, (2) at least one episode of fecal incontinence per week, (3) retentive behavior, (4) painful or hard bowel movements, (5) detection of large fecal mass in the rectum, and (6) stools of large diameter that may obstruct the toilet. There are also well-defined and overall similar criteria for FC diagnosis in children (toilet-trained and non-toilet-trained) younger than 4 years of age [6].

FC implies a high pharmaceutical cost. Likewise, fecal impaction can lead to a situation that seriously compromises patient health, especially at extreme ages, causing sometimes a vital risk. In order to treat these

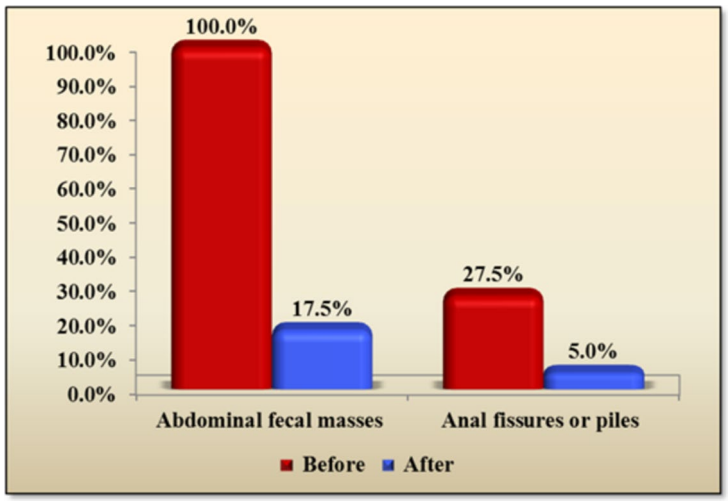

Fig. 1 Comparison regarding abdominal and anal examination before and after treatment in group 1

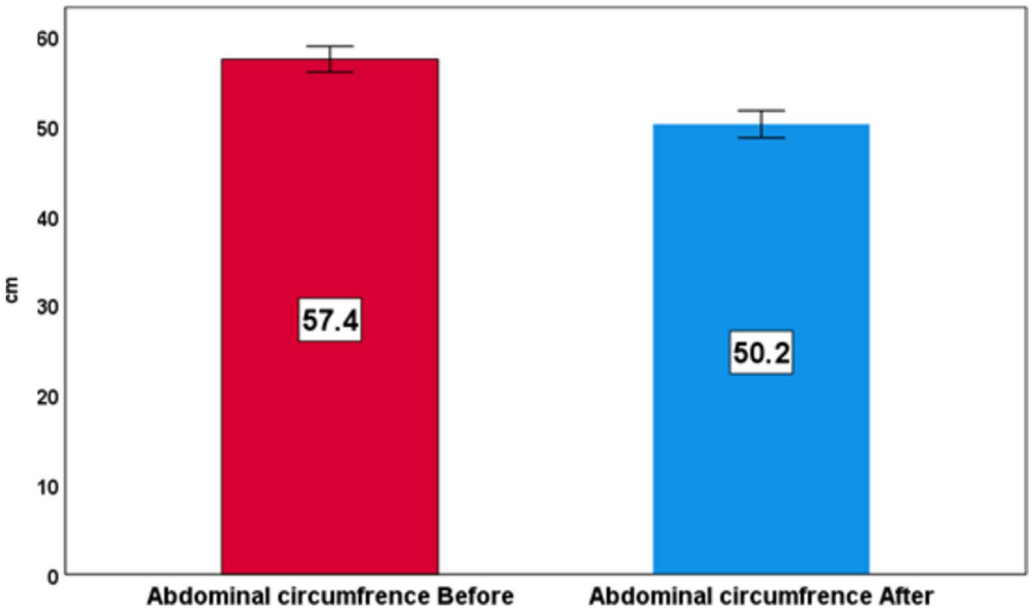

Fig. 2 Comparison regarding abdominal circumference before and after treatment in group 1

pathologies, a variety of resources has been employed, including pharmaceutical resources and others that directly impinge upon patient life habits [20].

The most outstanding and frequently utilized resource is the use of laxatives. Laxatives are substances utilized since ancient times for different applications. Their main function is to provoke feces evacuation and/or bowel cleansing. Today, their use is indicated in different situations: including FC treatment non-responding to dietary hygienic measures [23].

PEG is a polymer that is not metabolized in the gastrointestinal tract and creates an osmotic gradient in the lumen of the colon, subsequently leading to fluid retention and hence softening and loosening of stools [1].

In the current study, we aimed to investigate the long-term efficacy of polyethylene glycol (PEG) as a maintenance treatment for functional constipation (FC) in children living in Egypt.

It is worthy to mention that both groups had received a disimpaction treatment before starting maintenance therapy, which was polyethylene glycol (PEG) in a dose of (1–1.5 g/kg for 3–6 days) in group 1 and one daily phosphate enema for 2 to 3 days for those in group 2.

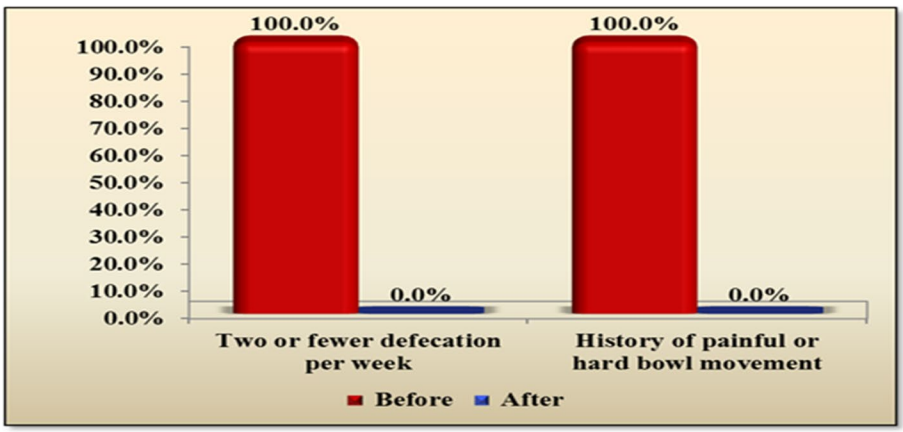

Fig. 3 Comparison regarding the numbers of defecation per week and history of painful or hard bowel movement before and after treatment in group 1

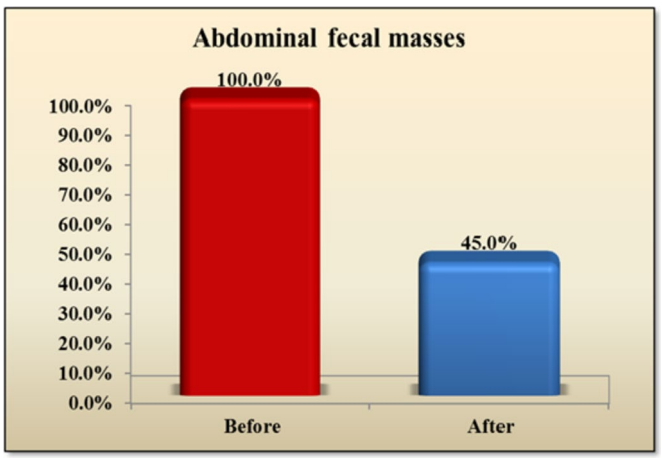

Fig. 4 Comparison regarding abdominal examination before and after treatment in group 2

Disimpaction is confirmed by abdominal examination and a plain X-ray abdomen before starting maintenance therapy.

No statistically significant difference was found between both groups according to age, sex, duration of start complaining, and family history. However, females represented more than half of patients in group 1 and group 2 (55% and 67%, respectively).

These results were different from those in the study of Olaru and colleagues [25] where a higher prevalence was observed in males. Moreover, other studies reported a similar prevalence in boys and girls [21].

Many patients with FC have a positive family history of FC, suggesting that genetic factors may play a role. In our study, we found that family history was reported among (40–27%) for group 1 and group 2. This was consistent with the study of Olaru and colleagues [25] who reported a positive family history of functional constipation among 38.49%.

We found a statistically significant improvement after the treatment in both groups; regarding weight, *z*-score weight for age, height, *z*-score height for age, mid-arm circumference, and *z*-score mid-arm circumference for age as these variables were low before treatment.

This was in accordance with the study of Yousefi and colleague [34] as their study demonstrated that children with symptoms of functional constipation had much less average weight and height than children without constipation. *z*-scores of height and weight for age were considerably different in both groups. In other words, this study showed that functional constipation leads to significant impairment of growth, including children's height and weight which is totally independent of the gender of the child.

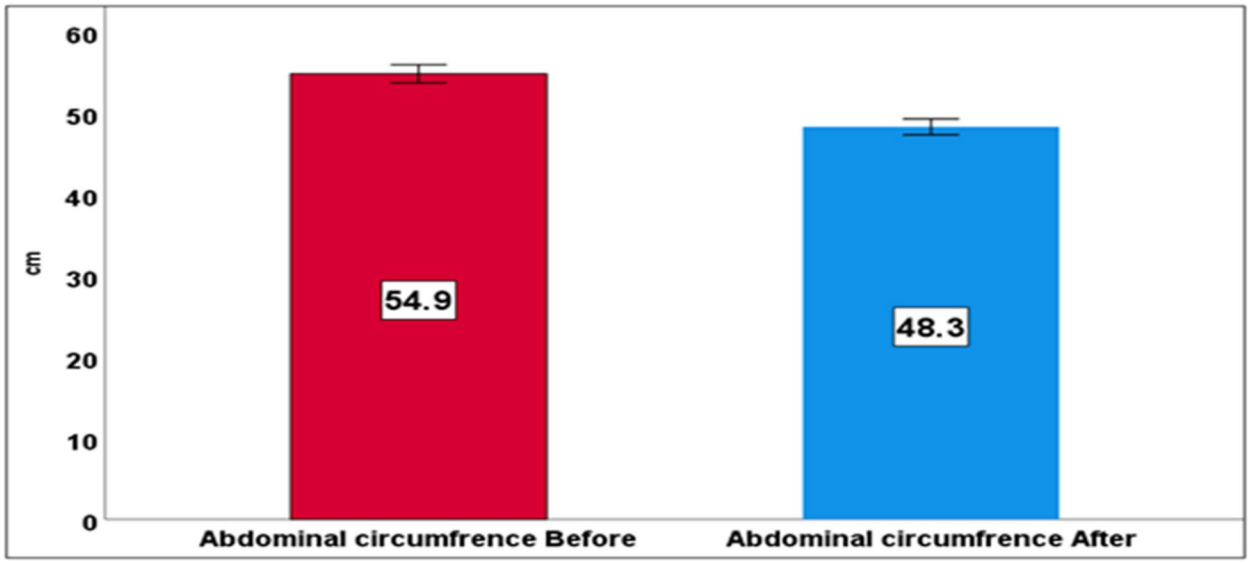

Fig. 5 Comparison regarding abdominal circumference before and after in group 2

The study of Chao and colleagues [5] showed the functional constipation of children as the cause of their growth retardation. In their study, a significant increase in *z*-scores of height and weight for age and body mass index for age was observed after 12 and 24 weeks of constipation treatment in children aged 1 to 15 years with constipation. These results were different from other studies that have shown a high prevalence of obesity in children with functional constipation.

This does not coincide with the study of Koppen and colleagues [15] that showed most of the children with constipation were obese or overweight. A similar study conducted on 100 Iranian children younger than 18 years old with functional constipation found a higher obesity rate and higher BMI and weight *z*-scores in constipated patients compared to the healthy control group [7].

This was in agreement with the study of Pawłowska and colleagues [26] which illustrated that pediatric patients with functional gastrointestinal disorders present with various growth abnormalities. They found that underweight was more frequent in children with functional constipation; also, short stature and stunting were common in patients with functional constipation.

There are various causes for delayed growth in children with constipation. Fecal impaction in these children may cause abdominal fullness and discomfort and nausea leading to decreased appetite and food aversion [34]. On the other hand, the psychological effects of functional constipation on children and their parents impact the child's nutrition and growth, too. Many recent studies have emphasized the significant effects of constipation on children's alimentary habits and on their developmental parameters, which can return to normal growth by treatment of anorexia or the elimination of organic causes associated with constipation [13].

After treatment, both groups showed a significant improvement regarding different parameters as in abdominal circumference, presence of fecal masses, and decrease in anal fissures or piles after treatment in group 1; however, in group 2, there was a significant improvement in abdominal circumference and abdominal fecal masses with a p-value < 0.05. There was a significant improvement in hemoglobin, hematocrit value, and serum iron after treatment in both groups which contributed to improving the appetite of those patients.

Regarding the Rome IV Criteria, there was a significant improvement in the number of defecation, number of fecal incontinence, history of retentive posturing or excessive volition stool retention, and history of pain or hard bowel movement after treatment in children more than 4 years old with a p-value < 0.001 in group 1, but in group 2, there was a statistically significant improvement in pain and hard bowel movement after treatment with a p-value 0.004.

By comparing both groups, a significant improvement was observed in fecal masses after treatment in group 1 with a p-value < 0.05; also, there was a significant improvement in the number of defecations regarding the Rome IV Criteria in children less than 4 years old with a p-value < 0.05 due to the effect of polyethylene glycol.

We found a statistically significant decrease in number of the patients who needed to continue treatment and patients who had impaction during treatment intake in group 1 than in group 2 with a p-value < 0.05. However,

there is a statistically significant increase in the number of patients who complained of palatability in group 1 with a *p*-value of 0.000.

This was in accordance with our findings and the study of Voskuijl and colleagues [31] which analyzed PEG 3350 ($n=46$) versus lactulose ($n=45$) for an 8-week period in a double-blind, randomized clinical trial of parallel groups, constituted by children from 6 months to 15 years of age. Children younger than 6 years took 2.95 g/sachet/day of PEG or 6 g/sachet/day of lactulose and children older than 6 years took 5.9 g/day versus 12 g/day (2 sachets). The dose was increased by another 2.95 g of PEG or 6 g of lactulose if the effect was considered as insufficient, or it was reduced by 50% if diarrhea appeared. The percentage of success (number of patients presenting ≥ three stools per week and ≤ one episode of encopresis every 2 weeks) was higher in the group with PEG (56% versus 29%, $p<0.02$) than in the group with lactulose, in both PEG doses. Moreover, in this group, an improvement in abdominal pain, effort, and pain during bowel movement regarding lactulose intake was also observed.

This was also in accordance with the study of Candy and colleagues [3] which analyzed the long-term (3 months) efficacy to avoid new impaction episodes and to increase the number of defecations/week after a fecal disimpaction treatment in 27 children (2–11 years old). In the lactulose group, 23% of patients suffered impaction, compared to 0% in the PEG-treated group (PGE + E) ($p<0.01$), and the number of weekly stools was significantly higher in the PEG-treated group (9.4 versus 5.9, $p=0.007$, 95% CI 1.0–6.0).

This was also in agreement with the study of Wang and colleagues [33] which evaluated the efficacy and safety of PEG 4000 in children ($n=105$) (20 g/day, during 14 days) versus lactulose ($n=111$) (10 g/day during three days and 6.7 g/day during 11 days) in a blind, randomized, and multi-center study. Clinical remission was considered when patients presented more than three stools per week, and their consistency had a 4–6 value on the Bristol Stool Scale. Moreover, 72.38% of patients treated with PEG achieved remission, compared to 41.44% of patients treated with lactulose; the average frequency of stools in the PEG-treated group increased from 2 to 7, with respect to a 2 to 6 increase in the lactulose-treated group, and stool consistency during the second week was better in the PEG-treated group.

Treepongkaruna et al. [29] compared PEG 4000 versus lactulose in 88 children of 1–3 years of age affected by FC during a period of 1 month in a randomized, double-blind study (8 g per day of PEG 4000 and 3.3 g of lactulose). The average change in the stool frequency/day in both groups was 0.51 stools/day in the PEG group, compared to 0.15 stools/day in the lactulose group. Furthermore, stool consistency and ease of stool passage were significantly better in the PEG-treated group.

In a recent randomized, multicenter study, Mathew and Bhatnagar [19] covered 12 weeks of treatment and 4 weeks of follow-up of patients with functional constipation. Patients were randomized (central randomization) to receive either PEG or lactulose. The primary end points were the number of defecations per week after 12 weeks of treatment and improvement in stool consistency of at least 2 points on the Bristol Scale. The secondary end point was the presence of adverse events. Bowel movements ≥ 3 per week and stool consistency ≥ 2 (Bristol Scale) were considered as successful treatment; at week 12, good clinical outcome was achieved in 98% (PEG) and 90% (lactulose). The PEG group had more defecations per week compared with the lactulose group (7.9 ± 0.6 vs 5.7 ± 0.5, $p=0.008$), and both groups had similar frequency of defecation with pain (5% vs 5%, $p=0.9$), stool retention (7% vs 10%, $p=057$), large volume of stools (30% vs 31%, $p=0.9$), and hard stools (7% vs 13%, $p=0.58$). There were more patients with side effects in the lactulose group (15 vs 23, $p=0.02$), mostly bloating and abdominal pain. The authors concluded that PEG 3350 is more effective and causes fewer side effects compared to lactulose in the treatment of constipation in infants and children [19].

In harmony with our findings, Gordon et al. [11] in the intervention review evaluated the efficacy and safety of osmotic and stimulant laxatives used to treat functional childhood constipation. The authors included in the analysis 6 studies comparing PEG and lactulose. The number of patients included ranged from 50 to 100 in different ages, between 6 months of age and 16 years old. A statistically significant difference in frequency of defecation in favor of PEG over lactulose was seen, with a mean difference of 0.70 stools per week (95% CI 0.10 to 1.31). Thirty-seven percent (46/123) of PEG patients experienced at least one adverse event compared to 45% (54/119) of lactulose patients (95% CI 0.68 to 1.11).

These results were different from the findings of Gremse and colleagues [12] which analyzed in an open, randomized, and crossover study the efficacy of PEG 3350 (10 g/m^2/day) versus lactulose (1.3 g/kg/day in two intakes) in 37 children (2–16 years old) for 2 weeks, and subsequently, treatments were crossed over for another 2 weeks. In addition, the number and features of the stools, colonic transit time, and grade of satisfaction perceived by health care providers and physicians were evaluated. They did not observe significant differences between the treatment groups in any parameter analyzed.

The strength of the current study contributed to the type of study "randomized clinical trial," and according to our knowledge, this study is the first one in Egypt

to compare PEG and our classic treatment (lactulose or senna).

Conclusion

Proper treatment of functional constipation had led to improvement in the anthropometric measures after treatment in both groups which was more pronounced in those who received PEG; significant CBC parameters and serum iron improvement were observed after treatment in both groups due to improvement in appetite. PEG had a good efficacy in the management of pediatric functional constipation. A significant improvement results in the comparison to classic treatment (lactulose or senna) regarding the ROME IV Criteria especially in children ≥ than 4 years old.

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Authors' contributions
All authors read and approved the final manuscript. OK: main investigator, patient follow-up, and data collection. MAG: data collection, follow-up of patients, review of the paper work, and publication. AEE: supervision of the study, idea of the study, and review of the results. MAR: supervision of the investigators and review of the statistics and results. AMH: data collection, statistical analysis, review of the paperwork.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author, but data cannot be shared openly to protect study participant privacy. We can send it on a reasonable request.

Declarations

Ethics approval and consent to participate
It was approved by the Cairo University, Faculty of Medicine, research ethics committee.
Code: MD-346–2020.

Consent for publication
We have a verbal consent for data collection and publication from all parents of children included in this study.

Competing interests
The authors declare that they have no competing interests.

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