

ORIGINAL PAPER

# Does primary care physicians use macrogols as the first-line treatment for functional constipation in pediatric population in central European country?

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## ABSTRACT

**Introduction:** There is little data on the treatment of functional constipation (FC) among pediatric population in Europe. We aimed to evaluate how often Polish primary care physicians (i.e., pediatricians, general practitioners [GPs], and pediatric gastroenterologists) prescribe polyethylene glycol as a treatment of FC. Also, we assessed the impact of educational materials received by parents on the compliance management of FC.

**Material and methods:** This was a prospective, multicenter study. A self-developed questionnaire was distributed among Polish doctors, who treat children with FC; they were asked to complete it twice with patients and their caregivers. Questions were on the treatment of constipation, which the parents used before visiting the doctor and treatment used by the doctor as well as their impression on received educational materials. The study was approved by the Ethics Committee of Warsaw Medical University (AKBE/269/2024).

**Results:** In total, 1,358 children, aged 6 months – 12 years (median: 5 years; boys: 56.1%), were included in the study. We received 688 questionnaires from pediatricians, 270 from GPs, and 400 from pediatric gastroenterologists. Polyethylene glycol was the most prescribed medication by the doctors (84.4% of children). Pediatric gastroenterologists used macrogols less often than pediatricians and GPs (78.5%, 85.3%, and 90.7%, respectively;  $p = 0.000$ ). In the second survey, nine out of ten patients declared complying with recommendations from previous visit. Educational materials were most frequently rated as useful (66.2%), understandable (53.2%), and helpful (49.5%).

**Conclusions:** Pediatric gastroenterologists use macrogols less often than pediatricians and GPs. Education materials help majority of patients to understand the pathophysiology of FC, which can be the key factor helping maintaining appropriate therapy between visits.

## KEY WORDS:

treatment, constipation, functional constipation, practice patterns, pediatric gastrology.

## INTRODUCTION

Functional defecation disorders (FDD) include a combination of chronic, recurrent, and age-dependent gastrointestinal symptoms, which cannot be confirmed by biochemical or structural abnormalities. Diagnosis of FDD is made primarily on presented symptoms. The Rome

IV criteria [1] currently describes all the diagnostic standards of FDD. FDD consist of functional constipation (FC) and non-retentive fecal incontinence (NRFI). Together, FC and NRFI are among the most common reasons for healthcare consultations and expenditure. The pooled worldwide prevalence of FC reaches 9.5% [2]. In 95% of cases, FC is caused by functional gastrointestinal

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disorders, while the remaining 5% have an organic origin (including Hirschsprung's disease, anal malformations, and neurological, metabolic, or endocrine disorders).

FC usually appears in the first year of life, reaching peak incidence at 2–4 years of age, particularly during potty training [3]. The most common mechanism of constipation is the withholding of stool, occurring frequently after previous painful defecation. Stool remaining in the rectum becomes harder and increasingly difficult to expel, leading to a vicious circle and impairing the retention posture. The result is stool retention, leakage of feces from rectal overflow, loss of rectal sensation, and disruption of the normal defecation rhythm [3].

Pharmacological treatment of FC consists of a bowel cleansing phase, maintenance treatment, and further follow-up. It is extremely important to effectively educate patients and parents about the causes of constipation and its symptoms. The child should be provided with appropriate conditions for defecation and above all, allowing the child to maintain the correct body position (hip flexion, supported legs) without being rushed. A reward system is recommended. The effect of treatment should be assessed after about two weeks [4].

Despite national and international recommendations, there is little data on how doctors treat children with FC. Therefore, the aim of this study was to evaluate the patterns of pharmacological and behavioral treatment of FC in pediatric patients treated by primary care physicians, such as pediatricians, general practitioners (GPs), and pediatric gastroenterologists, and pharmacists in Poland. Moreover, the impact of educational materials received by patients and their parents on the compliance management of FC was assessed.

## MATERIAL AND METHODS

This was a prospective, multicenter, anonymous questionnaire study. Participants were recruited nationwide since January 2023 until November 2023, among primary care doctors (i.e., pediatricians, pediatric gastroenterologists and GPs), who treat FC children in hospitals, GPs' offices, and private clinics. A self-developed questionnaire consisted of both multiple-choice and open questions on the symptoms, causes of constipation, diet, physical activity, and defecatory patterns as well as treatment methods used by parents before current medical visit and the treatment prescribed on the first visit. Also, the consistency of stool according to Bristol stool scale [5] was evaluated. Time between the onset of FC and the first doctor's consultation was considered. The surveys with patient and/or their caregivers were conducted twice with at least two-week time interval between the visits. After completing the questionnaire on the first visit, parents received educational materials about constipation (description of pathophysiology, diagnostics, symptoms, and treatment of FC). At the second visit, they were asked if they con-

tinued prescribed therapy as well as if they found the received materials helpful in the management of the FC diagnosis.

Inclusion criteria were children aged between 6 months and 12 years, FC diagnosed with the Rome IV criteria, and consent of the guardian. Patients with new FC diagnosis and those who had been under the care of a specialist for a longer time were included, while patients who did not answer all the questions in the survey were excluded.

The study was approved by the Ethics Committee of Warsaw Medical University (approval number: AKBE/269/2024). Informed consent was obtained from all participants and/or their legal guardians. This study adhered to the ethical principles of the Declaration of Helsinki.

## STATISTICAL ANALYSIS

Data were analyzed with Statistica version 13.0 (Tulsa, Oklahoma, USA). Chi-squared test was used to compare categorical variables between groups, with Bonferroni correction for post-hoc analysis if necessary. McNemar test was employed to examine differences between categorical variables obtained on the first and control visits. A *p*-value of less than 0.05 was considered significant.

## RESULTS

### DEMOGRAPHICS

In total, 1,358 questionnaires were analyzed, out of which 688 were obtained from pediatricians, 270 from GPs, and 400 from pediatric gastroenterologists' offices. The median age of constipated children was 5 years (IQR: 3.7 years; range, 6 months – 12 years; boys: 51.6%). Nearly half of the participants resided in cities with over 100,000 citizens. For 789 (58.1%) patients, the current episode of constipation was the first in their lives. The demographic details are summarized in Table 1.

### PATHOPHYSIOLOGY

During the first visit, 57.3% of the patients had symptoms indicating avoidance or withholding of defecation (gluteal tightening, leg crossing, squatting), whereas 47.8% declared fecal incontinence. Moreover, 72.5% of all patients suffered from painful defecation, with nearly 62% of the patients having large diameter stools. Fulfilling the questionnaire for the first time, 81.1% of the participants reported type 1 and 2 on the Bristol stool scale. The symptoms appeared mostly between 13 and 48 months of age. One-third of the children did not use the correct body position for defecation, and 13% did not have enough time for the passage of stool.

The most popular factors triggering defecatory disorders in the study population were stressful situations

TABLE 1. Clinical characteristics of participants

| Factor                                             | n (%)      |
|----------------------------------------------------|------------|
| Gender                                             |            |
| Male                                               | 701 (51.6) |
| Female                                             | 657 (48.4) |
| Age (years)                                        |            |
| 0–2                                                | 252 (18.6) |
| 3–5                                                | 547 (40.3) |
| 6–8                                                | 302 (22.2) |
| 9–12                                               | 257 (18.9) |
| Attending medical professional                     |            |
| GP                                                 | 270 (19.9) |
| Pediatrician                                       | 688 (50.7) |
| Pediatric gastroenterologist                       | 400 (29.0) |
| Child's place of residence (number of inhabitants) |            |
| < 25,000                                           | 392 (28.9) |
| 25,000–50,000                                      | 180 (13.3) |
| 51,000–100,000                                     | 171 (12.6) |
| > 100,000                                          | 615 (45.3) |

(43.6%) and going to kindergarten (16.3%). The data summarizing pathophysiology factors, signs, and symptoms are shown in Table 2.

## DIAGNOSIS

Most patients included in the study consulted a specialist within more than seven days of the onset of symptoms: the median time to consult a pediatrician was 22 days, a pediatric gastroenterologist 23 days, and a GP 20 days. Nearly half of the participants underwent blood tests, rectal examinations, and radiological tests (45.4%, 40.1%, and 39.6%, respectively). One out of four patients reported the presence of blood in stool on the first visit. Other alarm signs, such as fever and vomiting, were reported occasionally (1.7% and 4.6%, respectively).

## TREATMENT

Before visiting a doctor, 802 patients had implemented other available treatment, with 382 respondents (47.6%) having first consulted a pharmacist. The drug most frequently recommended by pharmacists was lactulose (50.3%). Figure 1 illustrates the combined data of the most frequently recommended drugs by pharmacist. Figure 2 summarizes the effectiveness of this treatment, and Figure 3 provides information about the method of discontinuing treatment prescribed by a pharmacist. The average length of treatment was more than seven days, while around 25% of the patients stopped the treatment after 3 days.

TABLE 2. First visit data on signs, symptoms, and pathophysiology

| Factor                                           | n (%)        |
|--------------------------------------------------|--------------|
| Withholding behaviors                            |              |
| Gluteal tightening                               | 529 (68.0)   |
| Leg crossing                                     | 303 (38.9)   |
| Squatting                                        | 304 (39.1)   |
| Fecal incontinence (age of onset, months)        |              |
| 6–12                                             | 175 (27.0)   |
| 13–24                                            | 147 (22.7)   |
| 25–36                                            | 133 (20.5)   |
| 37–48                                            | 68 (10.5)    |
| > 49                                             | 126 (19.4)   |
| Stool consistency as per the Bristol stool scale |              |
| Type 1                                           | 352 (25.9)   |
| Type 2                                           | 749 (55.2)   |
| Type 3                                           | 185 (13.6)   |
| Type 4                                           | 34 (2.5)     |
| Type 5                                           | 15 (1.1)     |
| Type 6                                           | 15 (1.1)     |
| Type 7                                           | 8 (0.6)      |
| Failure to thrive – Yes                          | 1,190 (87.6) |
| Correct body position during defecation – Yes    | 940 (69.2)   |
| Adequate time for defecation – Yes               | 1,181 (87.0) |
| Other triggering factors                         |              |
| Potty training                                   | 96 (7.1)     |
| Infection                                        | 163 (12.0)   |
| Travelling                                       | 165 (12.2)   |
| Other                                            | 299 (22.0)   |

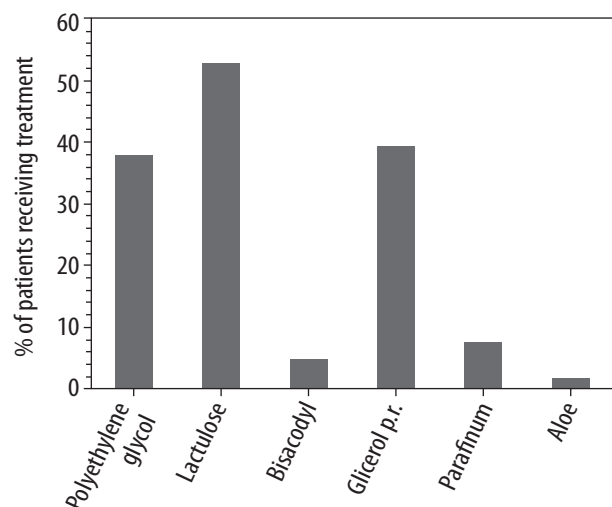


FIGURE 1. The combined data about treatment recommended by pharmacists

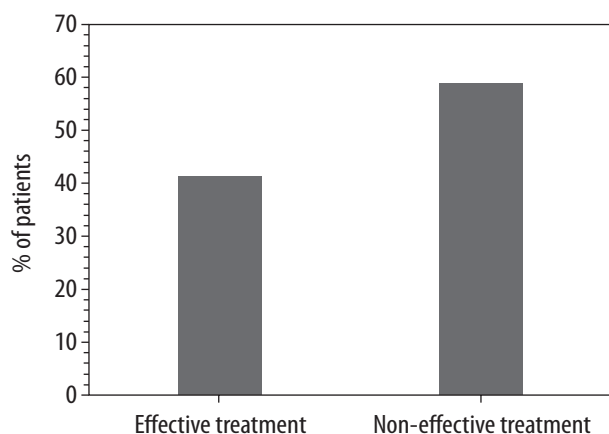


FIGURE 2. Effectiveness of treatment prescribed by pharmacists

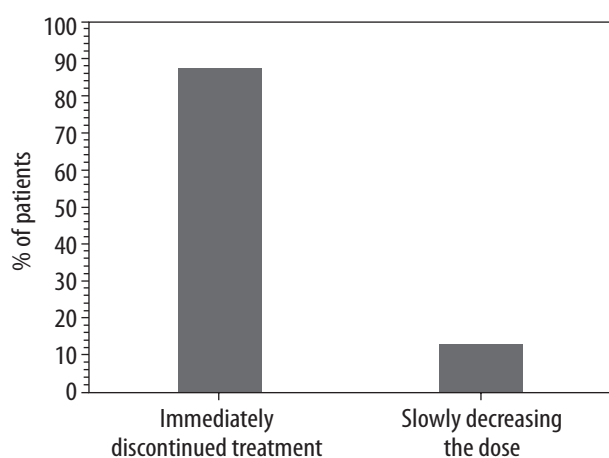


FIGURE 3. Discontinuation of treatment prescribed by pharmacists

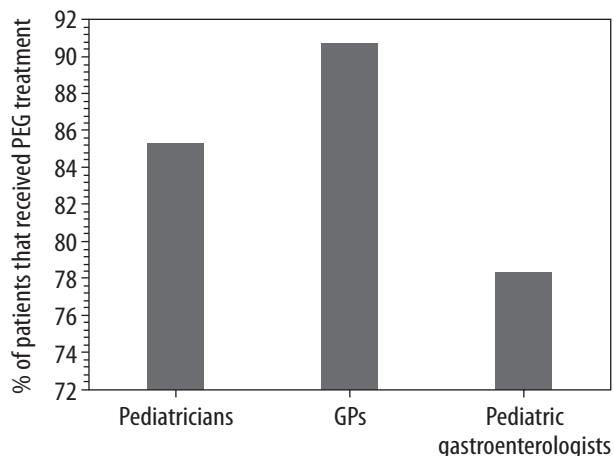


FIGURE 4. Polyethylene glycol (PEG) treatment frequency due to doctors' specialization

On the first visit, 96.7% of the patients received non-pharmacological treatment. Apart from lifestyle changes, they were asked to follow defecation training. GPs most frequently recommended changes in diet (48%), while slightly less pediatricians (41%), and only one in five pediatric gastroenterologists prescribed dietary changes.

Polyethylene glycol (PEG) was prescribed by 84.4% of the doctors on the first visit. Pediatric gastroenterolo-

gists used macrogols less often than pediatricians and GPs. The frequency of prescribing PEGs by each group of the doctors is summarized in Figure 4. Usually, bowel cleansing and maintenance doses were 2–3 sachets per day (39.6% and 42.6%, respectively).

#### SIGNS AND SYMPTOMS ASSESSED ON THE SECOND VISIT

On the second visit, there was a statistically significant decrease in the incidence of withholding behaviors, fecal incontinence, painful defecation, and presence of alarm signs (57.3% vs. 13%, 47.8% vs. 9.2%, 72.5% vs. 8.2%, and 32.1% vs. 4%, respectively). The frequency of large diameter stools was decreased by almost 5-times after treatment prescribed by the doctors, showing improvement in stool consistency. The detailed data about signs and symptoms evaluated before (first visit) and after (second visit) receiving treatment are summarized in Table 3.

Furthermore, patients were asked whether they follow the recommendations from the previous visit: nine out of ten patients declared fulfilling doctors' orders. However, 11.2% of the children participating in the survey were no longer pursuing the pharmacological therapy. Discontinuation of treatment usually occurred immediately after obtaining proper stool consistency (75.7%) and, as a result of an independent decision (88.2%), only 11.8% of patients consulted a doctor before deciding to discontinue treatment.

Educational materials were provided to 91.8% of the respondents, and they rated the leaflet most frequently as useful (66.2%), understandable (53.2%), and helpful (49.5%).

#### DIET

The percentage of patients consuming fruits and vegetables increased significantly during the second visit (83.9% vs. 95.3%;  $p = 0.000$ ). The total fluid intake also increased between the visits (1.2 l/day vs. 1.5 l/day;  $p = 0.000$ ).

#### DISCUSSION

This study analyzed 1,358 questionnaires distributed among a population of Polish doctors, who treat children aged 6 months to 12 years diagnosed with FC. We took a special interest in pathophysiological aspects and treatment strategies advised by specialists, to which patients were primarily referred. The initial visit proved that the majority of patients exhibited avoidance behaviors and suffered from painful defecation. Regardless of the type of intervention, there was a notable reduction in their symptoms. Most patients consulted a specialist within a week of symptom onset, with significant findings observed in alarm symptoms over time. Before first doctor's visit, many parents used over-the-counter treat-

ments, typically lactulose, with only a minority finding it effective. On the first visit, nearly all patients received non-pharmacological treatment focusing on dietary and lifestyle modifications. The most frequently prescribed medication (regardless of the doctor's specialization) was PEG.

Little data is available on constipation treatment and diagnostic strategies used by pediatricians, GPs, and pediatric gastroenterologists as well as how closely guidelines are followed. The European Society of Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), and North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) guidelines, highlight the importance of taking a medical history for each patient in diagnostic process [6, 7]. It should contain information on factors, including age of onset, passage of first meconium, frequency and consistency of stools, abdominal pain, fecal incontinence, withholding behavior, dietary history, vomiting, and weight loss. Moreover, data about stressful life events, neurodevelopmental delays or problems, and family history of gastrointestinal diseases, should be assessed. The Bristol stool scale has become the preferred and standardized method to describe stool consistency [8]. On the first visit, almost three-quarters of patients in our study reported having a history of painful defecation, and more than half of children had symptoms indicating avoidance or withholding of defecation, which are believed to be major causes of FC development. Our results on the pathophysiology of FC are in line with the ESPGHAN/NASPGHAN recommendations [6, 7]. Apart from taking medical history, there are other diagnostic tools that can be considered for patients with FC. A rectal digital examination (DRE) is not always recommended [4, 6, 7]. However, the presence of large fecal masses in the rectum is one of the signs of FC according to the Rome III and IV criteria. Laboratory screening for hypothyroidism, celiac disease, vitamin D status, and hypercalcemia, should be considered only with the occurrence of alarm signs, or when FC does not improve after standard treatment. In our study, doctors were more likely to perform blood tests than DREs or radiological tests. The rates of DRE are similar to those reported by Yang *et al.* [9] and Koppen *et al.* [10]. Having children cooperate during DRE is much more challenging comparing with adults, which could explain the low-rate of performed examinations; both parents and children may be uncomfortable with perianal inspection. If a patient fulfils sufficient criteria for FC diagnosis based on medical history, performing a DRE would not provide useful information and can be omitted. In a study by Burges *et al.* [11], questionnaires were sent to GPs and/or family physicians in Italy, the Netherlands, and the USA. The most frequent diagnostic method was a bowel diary (63%), followed by abdominal X-rays (49%) and laboratory tests (27%). DRE was used by only 31% of primary care physicians;

**TABLE 3.** Effectiveness of treatment evaluated during first vs. second questionnaire

| Second visit, <i>n</i> (%)                     |              | Difference between visits ( <i>p</i> -value) |
|------------------------------------------------|--------------|----------------------------------------------|
| Withholding behaviors                          |              |                                              |
| Gluteal tightening w                           | 106 (59.9)   | 0.000                                        |
| Leg crossing                                   | 44 (24.9)    |                                              |
| Squatting                                      | 50 (28.2)    |                                              |
| Fecal incontinence (total incidence)           | 125 (9.2)    | 0.000                                        |
| Stool consistency (on the Bristol stool scale) |              |                                              |
| Type 1                                         | 11 (0.8)     | 0.000                                        |
| Type 2                                         | 54 (4.0)     |                                              |
| Type 3                                         | 285 (21.0)   |                                              |
| Type 4                                         | 638 (47.0)   |                                              |
| Type 5                                         | 271 (20.0)   |                                              |
| Type 6                                         | 85 (6.3)     |                                              |
| Type 7                                         | 14 (1.0)     |                                              |
| Large diameter stools (yes)                    | 176 (13.0)   | 0.000                                        |
| Painful defecation (yes)                       | 111 (8.2)    | 0.000                                        |
| Presence of alarm signs and symptoms           |              |                                              |
| Blood in stools                                | 25 (1.8)     | 0.000                                        |
| Vomiting                                       | 22 (1.6)     | 0.000                                        |
| Fever                                          | 8 (0.6)      | 0.011                                        |
| Failure to thrive (yes)                        | 1,166 (85.9) | 0.090                                        |
| Correct body position during defecation (yes)  | 1,216 (89.5) | 0.000                                        |
| Adequate time for defecation (yes)             | 1,292 (95.1) | 0.000                                        |

the lowest rate was in the Netherlands (11%), with up to 54% in the USA. Bowel diaries and radiological investigations are less invasive and traumatic for children, explaining their preference for the first-line of diagnosis.

The most common triggering factors for defecatory disorders in our population were going to kindergarten and stressful situations; this is consistent with a latest systematic review by Koppen *et al.* in 2018 [2].

Before visiting a doctor, the majority of patients applied an available non-prescription treatment, and almost half did so after consulting a pharmacist. The most frequently recommended drug by pharmacists in our study was lactulose. Eberlin *et al.* [12] reported that prior to being presented with guideline information, the most frequently recommended treatments for German patients with chronic FC were macrogol (96%), fiber (71%), lactulose (66%), and bisacodyl (21%), while other options were recommended by fewer than 20% of healthcare professionals. Such a discrepancy between the recommenda-



tions of Polish and German pharmacists may be partially explained by the lower cost of lactulose.

The ESPGHAN recommendations emphasize the importance of counseling families to recognize withholding behaviors and to use behavioral interventions as well as proper pharmacological treatment. However, the same guidelines highlight that non-pharmacological treatment plays a secondary role in dealing with FC [7]. Dietary intervention includes normal intake of fibers and adequate fluid intake. Additionally, the ESPGHAN recommendations highlight the importance of parental education as a form of intervention. This should include counselling families to recognize withholding behaviors and educating them on the use of behavioral interventions, such as regular toilet visits, use of diaries to track stool, and reward systems for successful evacuations [4, 7]. As far as pharmacological treatment is concerned, macrogols are recommended as the first-line treatment in both the disimpaction and maintenance phases of therapy. In the absence of macrogols, lactulose is recommended.

As part of the first visit, nearly all our patients received non-pharmacological treatment. Apart from lifestyle changes, patients were asked to follow defecation training consistent with the ESPGHAN/NASPGHAN guidelines [7]. GPs mostly recommended changes in diet, with slightly fewer pediatricians and only one in five pediatric gastrologists prescribing such changes. Our results are similar with those reported in the USA and the Netherlands [10]. Pediatricians were more likely to recommend dietary changes and encouraged patients to keep a bowel movement diary. However, pediatric gastroenterologists more often recommended a reward system or toilet training than pediatricians. The differences between pediatricians and pediatric gastroenterologists were statistically significant.

PEG was the most prescribed medication by all doctors on the first visit. By dividing doctors according to specialization, pediatric gastroenterologists prescribed macrogols less often than pediatricians and GPs. Perhaps pediatric gastroenterologists more frequently encounter complicated cases (probability that patients already used macrogols before visiting a doctor). These children may indeed have initially been treated by GPs or pediatricians, who prescribed PEG.

Our results are in line with data obtained from the USA and the Netherlands in 2018 [10], where PEG was also the most prescribed medication for disimpaction (68%), followed by enemas (25%). The preference of 6% of responders was unclear as they utilized both forms of treatment (PEG and enemas). The primary reasons for choosing PEG over enemas for disimpaction were patient comfort (69%), drug being well-tolerated by patients (53%), and its ease of application (47%). The primary reasons for choosing enemas over PEGs were a more rapid effect (63%) and higher effectiveness perceived (56%). For infants, PEG was the preferred medication for main-

tenance treatment in 57%, while for children aged 1 year or older, 97% of responders preferred PEG as a laxative for maintenance treatment. Similar results were reported by Yang *et al.* [9].

We are aware of the methodological limitations of the present study, as may have been influenced by an unavoidable potential bias related to the Hawthorne effect. The Hawthorne effect refers to a phenomenon, in which a study subject's behavior is altered due to the subject's awareness of being under observation. According to this effect, patients may be more likely to follow their doctor's instructions regarding lifestyle changes and taking prescribed medication. Moreover, they might falsely report better treatment achievements if they knew they would be assessed. Another disadvantage of our study is that there was only one control visit after two weeks of treatment. Therefore, we could not assess the long-term effectiveness of the prescribed treatments. Also, we did not assess the knowledge of diagnostic criteria of FC and NRFI in each specialty of doctors. As our survey focused mostly on oral treatment for disimpaction and maintenance phases of treatment, there are limited data about any other than PEG medication. There were no direct questions about the effectiveness of the prescribed treatment; we only inquired if the patients were still following the course of medication. Additionally, children older than 12 years old were excluded, therefore, the evaluation of demographics and treatment methods of teenagers was not possible.

Prior to our study, this type of survey had never been carried out in Poland; the current study was conducted on a large cohort of 1,358 children. Another strong point of our inquiry is that among the typical questions about the number and consistency of stools, there were also questions about body position during defecation, the use of any equipment during defecation, and whether enough time was allowed to pass the stool. Parents not only responded to the survey, but also received educational material. The majority of parents rated the educational material as valuable and helpful, which can explain great compliance with the prescribed treatment on the second visit (93.8% of patients declared fulfilling doctors' orders, and only 11.2% discontinued taking medications).

## CONCLUSIONS

Despite published guidelines, there is still room for improvement in the treatment provided by pharmacists and primary care physicians for FC children in Poland. Pediatric gastroenterologists use macrogols less often than pediatricians and GPs, with nearly all doctors advising patients lifestyle changes. Non-pharmacological treatment must be followed by adequate pharmacological intervention. Education materials help majority of patients to understand the pathophysiology of FC, which

might be the key factor helping maintain appropriate therapy between doctor's visits.

## DISCLOSURES

1. Institutional review board statement: The study was approved by the Ethics Committee of the Warsaw Medical University (approval number: AKBE/269/2024).
2. Assistance with the article: None.
3. Financial support and sponsorship: USP Zdrowie Sp. z o.o.
4. Conflicts of interest: All authors received fees from USP Zdrowie Sp. z o.o.

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