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Transanal Irrigation in Children: Treatment Success, Quality of Life, Adherence, Patient Experience, and Independence

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ABSTRACT

Objectives: To investigate the clinical effectiveness and patient experience of transanal irrigation (TAI) in children with constipation or fecal incontinence.

Methods: Combined retrospective and cross-sectional study including pediatric patients who used a Navina TAI system. We retrospectively collected baseline characteristics and data on treatment success at 1- and 6-month follow-up (FU). Treatment success was defined as defecating at least 3 times per week and having less than 1 episode of fecal incontinence per week. We cross-sectionally assessed health-related quality of life (HRQoL), treatment adherence, treatment satisfaction (Treatment Satisfaction Questionnaire for Medication [TSQM]), illness perceptions, medication beliefs, and patient empowerment with validated questionnaires.

Results: Thirty-four patients were included (median age at start TAI: 11 years old [range, 6–18]), 32 in the retrospective review, and 26 in the cross-sectional survey (median of 3 years after initiation). Most patients were diagnosed with functional constipation (n = 26; 76%) or a neurogenic bowel disorder (n = 6; 18%). Treatment success rates significantly improved at each FU compared with baseline (baseline: 4/25 [16%]; 1-month FU: 12/16 [75%], $P = 0.008$; 6-month FU: 11/18 [61%], $P = 0.016$; cross-sectional FU: 13/26 [50%], $P = 0.008$). HRQoL scores were high (PedsQL median, 73 [IQR, 54–85]). Adherence (defined as Medication Adherence Report Scale [MARS] ≥ 23) was low (36%), whereas TSQM effectiveness scores were high (median, 69 [IQR, 47–86]). The majority of children (61%) reported an increase in independence since TAI treatment. Patient empowerment (GYPES) levels were similar to those reported in children with other chronic conditions.

Conclusions: TAI with a Navina system is an effective bowel management system for children with intractable constipation or fecal incontinence.

Key Words: child, constipation, fecal incontinence, transanal irrigation

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What Is Known

- Several systems are available for transanal irrigation (TAI) in children with intractable constipation or fecal incontinence. However, no data have been published on TAI with Navina systems in children.

What Is New

- TAI with a Navina system is an effective treatment for children with functional and organic causes of defecation disorders.
- Patients using TAI report relatively high levels of health-related quality of life.
- While patients often use TAI differently than prescribed, satisfaction concerning treatment effectiveness is high.
- TAI treatment may increase patient independence. Patient empowerment levels were similar to those reported in children with other chronic conditions.

Constipation is a common disorder in children and adolescents worldwide (1). It is characterized by infrequent, painful, hard stools and may be accompanied by fecal incontinence and abdominal pain (2). In approximately 95% of children, no organic cause is found, and these children are diagnosed with functional constipation (FC) according to the Rome IV criteria (3,4). Organic causes of constipation include Hirschsprung disease or neurogenic/neuropathic bowel dysfunction (NBD) (5). Initial management consists of demystification, education, toilet training, and laxative treatment (6,7).

study design, the collection, analysis and interpretation of data, the writing of the report, nor the decision to submit the article.

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If conventional treatment fails, healthcare providers turn to more invasive treatment, such as transanal irrigation (TAI).

TAI entails large-volume water irrigation of the rectum and colon via the anus to prevent accumulation of large quantities of stools (8). To facilitate TAI, several devices have been developed. To date, all published pediatric studies on TAI have investigated the use of systems (Peristeen or Alterna) of one specific manufacturer (Coloplast A/S, Humlebaek, Denmark). These studies show high rates of success, both in clinical outcomes and in improvement of health-related quality of life (HRQoL) (9–15). These promising findings prompted us to investigate if similar effects are achieved with a Navina TAI system (Wellspect Healthcare, Mölndal, Sweden).

In addition to the evaluation of clinical effectiveness, HRQoL, and treatment adherence, we wanted to investigate patient experience, patient independence, and patient empowerment (16). These aspects have not been previously studied in children using TAI. We hypothesized that these aspects may affect treatment adherence and quality of life, and may facilitate the parent-to-child transfer of self-management of chronic disease in adolescence.

METHODS

This was a single-center study, which combined a retrospective study and a cross-sectional survey study including children using TAI with a Navina system at our institution, a tertiary hospital for pediatric gastroenterology in the Netherlands. An overview of the questionnaires administered during this cross-sectional survey and the target audience per questionnaire is provided in Supplemental Digital Content 1 (<http://links.lww.com/MPG/C848>). Additional details on our methods and a detailed description of the questionnaires and the statistical analyses are available in Supplemental Digital Content 2 (<http://links.lww.com/MPG/C848>).

Clinical Effectiveness

We collected data on patient's medical history, treatment, symptoms, and treatment success retrospectively. Treatment success was defined in accordance with the Rome IV criteria: defecating at least 3 times per week and having less than 1 episode of fecal incontinence per week (17). Data were retrospectively collected at baseline (before starting Navina), after 1 month of treatment (range 1–3 months), and after 6 months of treatment (range 3–9 months). In the cross-sectional part of the study, we evaluated current symptoms and treatment success.

Cross-Sectional Survey

During the cross-sectional survey, several validated questionnaires were completed electronically via Castor EDC (18). Data are presented separately for children with functional and organic causes of constipation. HRQoL was measured by the PedsQL and PedsQL-GI symptom scales (19–21). These data were compared with HRQoL data of other studies including Dutch healthy children, Dutch children with FC, American children with FC, and children with functional and organic causes of constipation using TAI from Sweden and Norway (22–26).

The Medication Adherence Report Scale (MARS) was used to assess treatment adherence (27,28). The “Beliefs about Medicines Questionnaire (BMQ)—Specific” was used to assess beliefs about the necessity of TAI and concerns about TAI (29). The Brief illness perceptions questionnaire (BIPQ) was used to assess cognitive and emotional perceptions of illness (30). A self-developed questionnaire was used to measure treatment independence, and the Gothenburg Young Persons Empowerment Scale (GYPES) was used to assess patient empowerment (31). The Treatment Satisfaction Questionnaire for Medication (TSQM) was used to assess

treatment satisfaction (28,32). A self-developed questionnaire was used to evaluate patient experience with the TAI system and adverse effects.

RESULTS

For the retrospective study, 37 children were invited, and none opted out for the use of their data. Five children were excluded because, after they received information about TAI with Navina, they never initiated TAI treatment. Therefore, 32 children were included in our retrospective data analysis (see Supplemental Digital Content 3, <http://links.lww.com/MPG/C848>). Of these 32 children, 29 children were eligible for the cross-sectional part of our study. Two additional patients who could not be included in the retrospective part of the study because they were already using Navina were invited for the cross-sectional survey only. Of all patients invited for the cross-sectional survey, 26 of 31 patients (84%) completed all questionnaires (median age, 12.6 years; range, 7–22; 73% male).

Baseline Characteristics

Baseline characteristics of all patients are shown in Table 1. The majority of patients were diagnosed with FC (n = 26; 76%) and NBD (n = 6; 18%). The majority of patients with FC were using Navina Classic (16/24; 67%), whereas the majority of children with an NBD were using Navina Smart (5/6; 83%). The age at which patients started using Navina systems (median age, 11 years old [range, 6–18]) did not significantly differ between patients using Navina Classic and Navina Smart (median age, 10.4 [IQR, 8.3–12.7] and 11.3 [IQR, 8.1–12.5] years, respectively).

Clinical Effectiveness

Data on clinical effectiveness were available for the majority of patients and are provided in Table 2. At baseline, 4 of 25 children (16%) fulfilled the criteria for treatment success (functional: 3/21 [14%], organic: 1/4 [25%]). At 1-month follow-up, 12 of 16 children (75%) fulfilled the criteria for treatment success (functional: 10/12 [83%], organic: 2/4 [50%]); this was a statistically significant change compared with baseline ($P = 0.008$). At 6-month follow-up, 11 of 18 children (61%) fulfilled criteria for treatment success (functional, 9/15 [60%]; organic, 2/3 [67%]), this was a statistically significant change compared with baseline ($P = 0.016$).

At latest follow-up, during the cross-sectional survey, at a median of 3 years after initiation of TAI with Navina systems, 19 of 26 of children (73%) were still using Navina systems (Navina Smart n = 12, Navina Classic n = 7). Most patients were using a regular catheter (n = 9), followed by a small catheter (n = 8), or a cone (n = 1), one patient did not answer this question. At this time, 13 of 26 (50%) fulfilled criteria for treatment success (functional: 11/20 [55%], organic: 2/6 [33%]); this was a statistically significant change compared with baseline ($P = 0.008$). Most children who were not using Navina anymore fulfilled criteria for treatment success (6/7 [86%]), but this was not significantly different compared with children who were still using Navina (7/19 [37%], $P = 0.073$). Treatment success rates at each follow-up did not differ between system types.

Of the 17 children with fecal incontinence at baseline, 11 completed our cross-sectional questionnaire, of whom 4 (36%) were experiencing fecal incontinence on a weekly basis. Of the children using TAI, 14 of 18 (78%) had spontaneous bowel movements in between irrigations. The 7 patients who were no longer using Navina provided the following reasons for cessation: resolution of symptoms (n = 4); worsening of symptoms (n = 2); or dissatisfaction with the TAI treatment/system (n = 1).

TABLE 1. Baseline characteristics at start with Navina

	All patients (n = 34)
Age at start symptoms in years, median (IQR)*	3.8 (0.0–4.0)
Age at start TAI with Navina, median (IQR)	11.0 (8.3–12.8)
Duration of symptoms in years, median (IQR)*	7.7 (5.3–9.5)
Sex (male), n (%)	26 (77)
Constipation-related diagnosis and comorbidities	
Functional constipation, n (%)	26 (76)
Urinary incontinence, n/N (%)	3/26 (12)
ADHD/ADD, n/N (%)	2/26 (8)
Autism, n/N (%)	1/26 (4)
History of perianal abscesses, n (%)	1/26 (4)
Neurogenic bowel dysfunction, n (%)	6 (18)
Spina bifida, n/N (%)	5/6 (83)
Traumatic spinal cord injury, n (%)	1/6 (17)
Hirschsprung disease, n (%)	1 (3)
Functional nonretentive fecal incontinence, n (%)	1 (3)
Previous treatment before initiation of TAI (Navina), n/N (%)	
Polyethylene glycol	17/29 (59)
Transanal irrigation with other system	7/29 (24)
Bisacodyl	3/29 (10)
Pharmacological enemas†	5/29 (17)
Lactulose	1/29 (3.4)
Lubiprostone	1/29 (3.4)
None	6/29 (21)
Reason for initiating TAI (Navina), n/N (%)	
Refractory symptoms	25/31 (81)
Dissatisfied with other irrigation system	5/31 (16)
Dissatisfied with enema use	1/31 (3)

ADHD/ADD = attention deficit disorder/attention deficit hyperactivity disorder; IQR = interquartile range; TAI = transanal irrigation. *Missing: n = 1.

Quality of Life

Overall, children with FC in our population report similar PedsQL scores and even slightly higher PedsQL-GI scores compared with other studies in children with FC (23,24) (see Figure 1 and Supplemental Digital Content 4, <http://links.lww.com/MPG/C848>).

Treatment Adherence, Beliefs, and Illness Perceptions

Data on treatment adherence, beliefs about medication, and illness perceptions are provided in Table 3. Fourteen of the 19 patients who were using TAI at time of data collection completed the MARS questionnaire on treatment adherence, median score was 20 (IQR, 19–23), and 5 children (36%, FC: n = 4; HD: n = 1) had a score ≥ 23 and were considered adherent. Five children (36%) had a score ≥ 22 , and 6 children (43%) had a score ≥ 21 . Low scores were often based on the question about skipping irrigation, where 7 children (50%) reported to sometimes or often skip an irrigation. Perceived TAI necessity was high, with a median BMQ necessity score of 17.5 (IQR, 16–20). TAI concern scores did not exceed necessity scores in any of the children. Results of the illness perception questionnaire showed a wide range in illness perceptions, with relative high scores on the expected duration of constipation, the feeling of control on constipation, and the understanding of constipation.

Patient Independence and Empowerment

Children reported that since TAI use, their independence greatly increased (n = 6; 33%), slightly increased (n = 5; 28%), stayed the same (n = 5; 28%), slightly decreased (n = 1; 6%), or greatly decreased (n = 1; 6%). Most children (n = 14; 78%) performed TAI with the help of someone else, 4 of whom needed support during the whole procedure (age range, 9–13 years old, FC: n = 2, NBD: n = 2). Nine children needed support for parts of the procedure including: assembling the system (n = 2), filling the water container (n = 3), inserting catheter or cone (n = 7), removing catheter or cone (n = 4), controlling the system (n = 3), demounting the system (n = 2), cleaning the system (n = 5), and using the smart app (n = 1). The required amount of time of support ranged between 1–45 minutes (median, 3.5 minutes). Four children (age range, 10–20 years old, FC: n = 2, NBD: n = 1, HD: n = 1) reported to perform TAI independently. One child reported to be able to perform TAI independently while needing help from a parent with the use of enemas. Patient empowerment was measured using the GYPES (FC: n = 11, NBD n = 2). The median total empowerment score was 55 (IQR, 52–59). The highest empowerment score was reported on the knowledge and understanding domain (median, 13 [IQR, 12–13]), and the lowest score was reported on the identity domain (median, 10 [IQR, 8–11]).

Treatment Satisfaction and Patient Experience

Sixteen of the 19 patients who were using TAI at time of data collection completed the TSQM (see Table 3). Since only 1 child reported to have side effects (fatigue), descriptive data of the side effects domain are not included in the table. When combining data of all children, treatment satisfaction effectiveness scores were high (TSQM median, 69 [IQR, 47–86]). On a 5-point Likert scale ranging from very dissatisfied to very satisfied, patients were very satisfied (n = 13; 72%) or somewhat satisfied (n = 5; 28%) with the Navina TAI system.

Overall, children found the use of TAI very bothersome (n = 4; 22%), somewhat bothersome (n = 8; 44%), neutral (n = 2; 11%), not really bothersome (n = 2; 11%), or not bothersome at all (n = 2; 11%). When asked what they found most bothersome responses included: the amount of time it takes (n = 12), abdominal pain (n = 2), inconvenience (n = 1), hassle (n = 1), and one parent reported that her child only lets her perform the procedure.

Adverse Events

From the participants of the cross-sectional survey, 18 of 19 children who were using Navina at time of questionnaire completion and reported data on side effects and adverse events. Data are provided per catheter type in Supplemental Digital Content 5 (<http://links.lww.com/MPG/C848>). The most common adverse reaction was abdominal pain, which 6 children (33%) reported to experience during the TAI procedure.

DISCUSSION

This is the first study to assess the clinical application of TAI with Navina systems in the pediatric population, consisting mainly of patients with FC and NBD. Treatment success rates significantly improved compared to baseline at 1-month and 6-month follow-up and improvement persisted at cross-sectional follow-up. Weekly fecal incontinence rates also significantly improved compared with baseline at 1-month follow-up, and improvement persisted at cross-sectional follow-up. HRQoL scores were high compared with other studies in similar patient populations. Treatment adherence (defined as MARS ≥ 23) was low (36%), whereas TSQM effectiveness scores were high. The majority of children (61%) reported an increase in independence since TAI treatment. Patient empowerment levels

TABLE 2. Clinical effectiveness

	At start Navina (n = 32)	1-month follow-up (n = 25)	6-month follow-up (n = 20)	Latest follow-up (cross-sectional) (n = 26)
Follow-up time in months, median (IQR)	-	1.2 (0.9–1.6)	5.6 (4.5–6.6)	37.8 (27.7–40.4)
Navina use, n (%)	-	25 (100)	17 (85)	19 (73)
Irrigations per week, median (IQR)		7 (7–7)	6 (5–7)	7 (1.5–7)
Symptoms				
Treatment success, n/N (%)	4/25 (16)	12/16 (75)*	11/18 (61)*	13/26 (50)*
<3 bowel movements per week, n/N (%)	11/24 (46)	0/18 (0)	0/19 (0)*	5/26 (19)*
Bowel movements per week, † median (IQR)	3.0 (2.0–4.5)	7.0 (7–7)	7.0 (7–7)	5.0 (3–7)*
Weekly fecal incontinence, n/N (%)	17/25 (68)	4/20 (20)*	7/18 (39)	9/26 (35)*
Fecal incontinence freq/week, ‡ median (IQR)	14 (6–28)	6 (4–6)	6.5 (2–7)	No data
Fecal incontinence freq/week, § median (IQR)	3 (0–15)	0 (0–0)*	0 (0–2)*	No data
Large stools, n/N (%)	6/10 (60)	1/1 (100)	1/2 (50)	6/26 (23)
Painful/hard stools, n/N (%)	11/21 (53)	0/4 (0)	0/4 (0)	7/26 (27)
Withholding behavior, n/N (%)	8/18 (44)	0/1 (0)	No data	8/26 (31)
Abdominal pain, n/N (%)	16/30 (53)	5/19 (26)	7/16 (44)	No data
Additional treatment, n (%)				
Oral laxatives	18 (62)	13 (52)	9 (47)	13 (72)
Pharmacological enemas	5 (17)	2 (8)	2 (11)	2 (11)
Loperamide	0 (0)	2 (8)	2 (11)	0 (0)
None	6 (21)	9 (36)	7 (37)	5 (28)

IQR = interquartile range. *P value <0.05 compared to baseline. †Data of 24 children, 18 children, 18 children, and 26 children, respectively. ‡Only data of children with weekly fecal incontinence episodes: 13 children, 4 children, and 6 children, respectively §All available data on fecal incontinence episodes: 21 children, 20 children, and 17 children, respectively. ||Data of 29 children, 25 children, and 19 children, and 18 children (active Navina users), respectively.

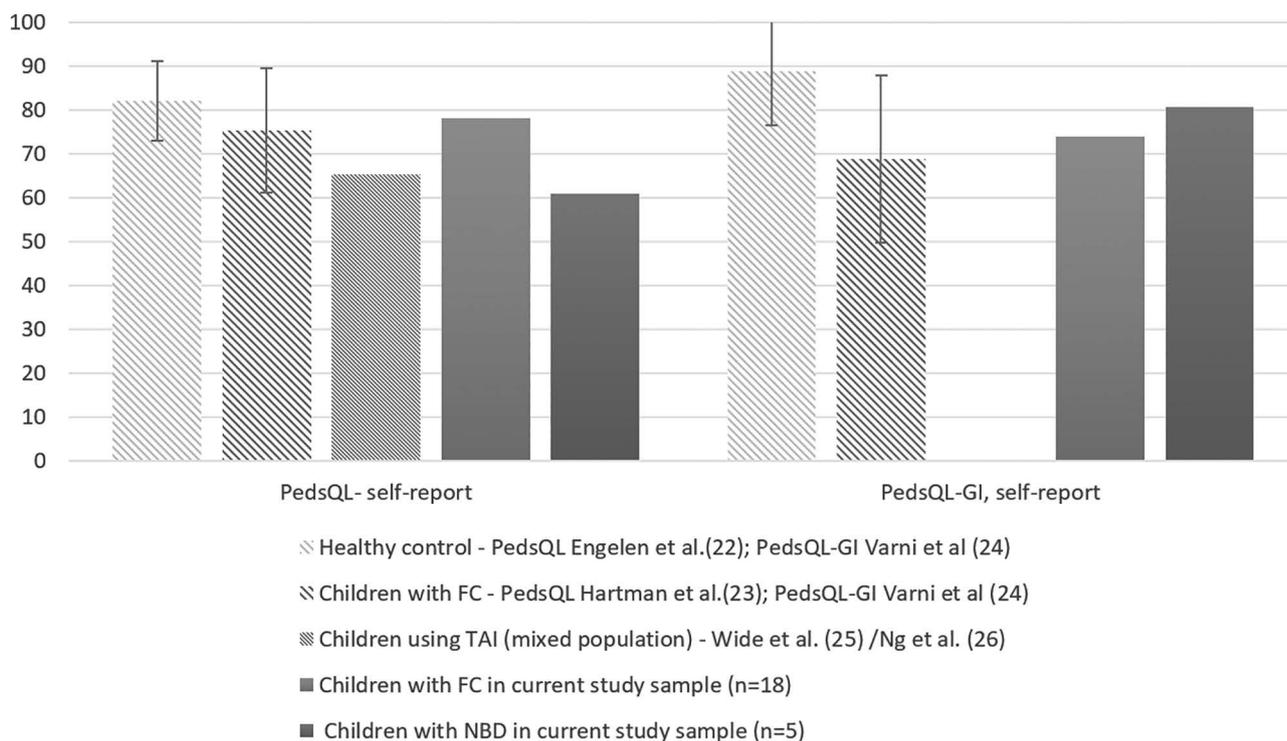


Figure 1. Health-related quality of life by diagnoses and compared with data of healthy children and children with functional constipation. FC = functional constipation; GI = gastrointestinal; NBD = neuropathic bowel dysfunction; PedsQL = Pediatric Quality of Life Inventory; TAI = transanal irrigation.

TABLE 3. Patient experience by cause of constipation of patients who completed the cross-sectional survey

	Functional causes (n = 20)	Organic causes (n = 6)
Age in years, median (IQR)	13.4 (11.1–15.8)	11.7 (10.1–14.9)
Sex (male), n (%)	15 (75)	4 (67)
Currently using Navina system, n (%)	13 (65%)	6 (100%)
Treatment adherence—MARS, total n	11	3
Median score (IQR)	20 (19–23)	20 (19–22)
Adherent patients (MARS ≥ 23), n (%)	4 (36%)	1 (33%)
Medication beliefs—BMQ, total n	9	5
Necessity score, median (IQR)	17 (16–19)	18 (17–21)
Concerns score, median (IQR)	14 (12–15)	11 (8–16)
Differential score, median (IQR)	4 (3–5)	7 (3–12)
Illness perception—BIPQ, total n	20	6
Q1 Consequences, median (IQR)	6.5 (2.3–8.0)	5.5 (4.5–8.5)
Q2 Timeline, median (IQR)	7.0 (2.5–9.8)	9.5 (6.0–10)
Q3 Personal control, median (IQR)	4.5 (2.0–6.8)	3.0 (0.0–8.0)
Q4 Treatment control, median (IQR)	7.0 (5.0–8.0)	6.0 (3.0–7.3)
Q5 Identity, median (IQR)	4.5 (2.0–8.0)	3.0 (1.8–8.5)
Q6 Concern, median (IQR)	4.0 (2.3–7.8)	1.5 (0.0–6.3)
Q7 Understanding, median (IQR)	7.0 (5.0–8.0)	6.0 (2.5–8.5)
Q8 Emotional response, median (IQR)	6.5 (2.0–8.8)	4.5 (0.8–10)
Treatment satisfaction—TSQM, total n	10	6
Effectiveness, median (IQR)	75 (46–85)	58 (43–89)
Convenience, median (IQR)	58 (43–89)	72 (35–79)
Global satisfaction, median (IQR)	53 (43–83)	61 (56–79)

BIPQ = Brief Illness Perceptions Questionnaire; BMQ = Beliefs about Medicines Questionnaire; IQR = interquartile range; MARS = Medication Adherence Report Scale; TSQM = treatment adherence, treatment satisfaction.

were similar to those reported in children with other chronic conditions. Based on these results, TAI with Navina systems can be considered to be an effective bowel management treatment for children. Thus far, most studies in children with FC using TAI (with Peristeen) have used a retrospective study design and various definitions of effectivity, including partial or complete remission of fecal incontinence episodes or resolution of constipation/incontinence symptoms (9,10,15). These studies show effectivity rates ranging between 41% and 73% (9,10,15). In a cross-sectional study in children with FC, fecal incontinence had resolved completely in 41% of all children who still used Peristeen at the time of survey (n = 49) (9). Studies in children with NBD have also used various study designs and outcome measures, including partial or complete remission of fecal incontinence episodes, or improvement in neurogenic bowel dysfunction scores. These studies have shown TAI with Peristeen to be effective in this population in 86%–91% (12,15,33–35). Treatment success rates in our study are potentially lower due to the prospective setup and more strict definition of treatment success. Therefore, it is difficult to compare our data with data of these other studies.

In our sample, HRQoL scores (PedsQL) were comparable to those of Dutch children with FC and similar compared with data of a population of European children with FC and organic causes of constipation using TAI with Peristeen (25,26).

Although the perceived necessity of TAI was high, treatment adherence was low. One study including 78 children with NBD

using Peristeen investigated treatment adherence to TAI by asking if patients were still using TAI after a median duration of 14 months (14). With this method, the authors reported high levels of adherence (80%–92%). When using the same method to measure adherence, the adherence rate in our study sample would also have been high (73%). However, adherence comprises more than confirmation of use. Besides, discontinuation of treatment may be an indication of the treatment being ineffective, or the result of resolution of symptoms. For this reason, we used the validated MARS questionnaire to measure adherence. Another study in children with FC also used the MARS questionnaire to measure adherence to polyethylene glycol (28). This study reported similar adherence rates compared to our study: a median MARS score of 22 (IQR, 20–24) with an adherence rate (MARS ≥ 23) of 37% (28). However, the MARS questionnaire may have a limited validity in patients with defecation disorders since deviation of treatment as measured by the MARS (skipping an irrigation, or changing the amount of TAI fluid) may be inherent to the treatment and the underlying disorder. If children defecate spontaneously without the use of TAI, health care providers may even promote to try to skip an irrigation. In our study sample, low MARS scores were often related to the question concerning skipping an irrigation; therefore, the adherence rate based on the MARS may not be indicative of issues with treatment adherence. In clinical practice, we do not experience issues with treatment adherence on a regular basis in these patients. We think that this might be the consequence of the severity of symptoms in children using TAI and the effectivity of the TAI procedure. Children often experience direct effect of the TAI procedure, which is reflected in the high rates of treatment satisfaction concerning effectiveness in this study cohort, which in turn likely positively affects adherence.

Most children reported to need help with the TAI procedure. Still, the majority of patients reported an increase in independence since starting TAI treatment. Current rates of independent use of TAI range from 16% to 79% in the literature (12,25,36,37). These results are influenced by the definition of independent use and rely on the age and underlying pathology of children. A previous study in 172 children with NBD showed no difference in the independence of children using TAI or antegrade continence enemas (25). In addition, they reported that children who always went to the toilet by themselves reported significantly higher HRQoL scores than those who never went alone. Independence, therefore, could play a role in the HRQoL of children. The reported increase in independence after initiation of TAI may explain the high treatment satisfaction rates and relatively high levels of HRQoL in our study sample. Perceived effectiveness (based on the TSQM) was high compared with data from a study in children with FC using polyethylene glycol (median of 69 [IQR, 47–86] versus median of 48 [IQR, 37–62], respectively) (28). Teens in our study report similar patient empowerment levels as teens with congenital heart disease (mean, 54.5 [SD, 10.5]) (38) and a slightly lower level of empowerment compared with teens with diabetes (mean, 58.9 [SD, 7.9]) (31). However, the clinical consequences of these differences are unclear, as to date, healthy reference values for the GYPES are unavailable.

Adverse events were uncommon in our study, and the most commonly reported adverse event was abdominal pain during the TAI procedure. Patients reported that the most bothersome aspect of TAI is the amount of time it takes. However, we did not collect data on the amount of time they spent on their bowel management before initiation of TAI with Navina. Another study, which investigated the effect of TAI on the time spent on bowel management, reported a significant decrease since initiation of TAI with Peristeen (12). In addition, another study comparing the time spent on bowel management between children using antegrade continence

enemas and TAI reported that children using TAI spent significantly less time at the toilet for defecation (25). Thus, although the TAI procedure is time-consuming, it may turn out to be the most time-efficient for children with intractable constipation unresponsive to conventional medical treatment.

Strengths of our study include the use of multiple questionnaires including self-report and parent-report questionnaires in order to gain a clear view of child and parent perspectives on TAI use. We had a high response rate (84%) and also included participants who were not using TAI anymore.

This study has several limitations inherent to its partial design as a retrospective review. Since part of our study was based on retrospective data, our baseline, 1-month, and 6-month follow-up data rely on data documented in the medical charts. Therefore, the paired measures statistics have a limited reliability due to missing data, as this analysis only takes into account patients with data on both baseline and follow-up time points. In addition, our population originates from a population of only one specialized referral center and may have been at risk of selection bias. Since we had no information on why these children chose to start TAI treatment with Navina, instead of other treatments, or TAI treatment with another system, this could have affected our outcomes and limits the generalizability of our findings. Moreover, we were not able to compare our outcomes with a control group. To further assess the usefulness of TAI with Navina in the management of children with specific indications, prospective studies should be conducted, preferably with validated measurements and standardized symptom-based outcome measures. A randomized controlled trial comparing the efficacy, side effects, and patient/parental satisfaction of different TAI systems or TAI compared with antegrade continence enemas would be of great interest.

CONCLUSIONS

To conclude, TAI with Navina systems is an effective bowel management system for children with constipation or fecal incontinence associated with relatively high levels of HRQoL. An increase in independence was reported since TAI use, and perceived effectiveness was high. Although the TAI procedure may be time-consuming and inconvenient, it should be considered as treatment option for children with constipation unresponsive to conventional medical treatment before more invasive surgical treatment is initiated.

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