

The effectiveness of transcutaneous nerve stimulation in treating children with functional constipation

F. Vander Vennet^{1,*}, J. Desmytter^{1,*}, S. Van Biervliet¹, B. De Muynck², B. Samijn^{3,4}, S. Vande Velde¹

(1) Department of Pediatric Gastroenterology, Ghent University Hospital, Ghent, Belgium; (2) Department of Pediatrics, AZ Groeninge Hospital, Kortrijk, Belgium; (3) Department of Rehabilitation Sciences, Ghent University, Ghent, Belgium; (4) Department of Urology, Ghent University Hospital, Ghent, Belgium.

* Shared first author.

Abstract

Background and study aims: Functional constipation (FC) is a prevalent condition in paediatric populations and while standard therapies, including laxatives and toilet training are commonly used, a substantial proportion of children exhibit an inadequate response. This study aimed to evaluate the effectiveness of transcutaneous nerve stimulation (TENS) as a non-invasive treatment for FC in children.

Patients and methods: Children diagnosed with FC according to the Rome IV criteria and treated with TENS were included in this retrospective cohort study. Data were collected in two Belgian hospitals between 2018 and 2024. Primary outcome measures included stool frequency, stool retention behaviour, faecal incontinence, and stool size. Statistical analyses incorporated post hoc comparison with Bonferroni correction.

Results: A total of 36 children were included (median age 7.5 years, range 3–15 years; 61% male) of whom approximately one-third had a concomitant diagnosis of a neurodevelopmental disorder (NDD). Improvements were observed in faecal incontinence ($p = 0.016$), retentive behaviour ($p = 0.001$), stool frequency (<2 bowel movements/week) ($p = 0.035$), and abdominal pain ($p = 0.006$). After applying a Bonferroni correction, only the effect on retentive behaviour remained statistically significant. Side effects were limited to mild erythema in two patients, which did not necessitate discontinuation.

Conclusion: TENS appears to be a promising and well-tolerated treatment for children with FC and it may be considered as an early intervention within the therapeutic management pathway as the beneficial effects seem particularly evident in children with more severe forms (*Acta gastroenterol belg.*, 2026, 89, 475-481).

Keywords: Functional constipation; TENS; neuromodulation; Rome IV criteria.

Introduction

Functional constipation (FC) is a prevalent paediatric condition, affecting approximately 3% of children worldwide (1). It accounts for 10-25% of consultations with paediatric gastroenterologists and 3-5% of general paediatric visits (2). FC is characterised by infrequent, difficult, and/or painful defecation, often accompanied by faecal incontinence and abdominal pain (1, 2). Despite its high prevalence, FC typically lacks an identifiable organic aetiology (1), and is therefore classified as a functional disorder under the Rome IV criteria (3) (Fig. 1).

Standard first-line treatments for FC include osmotic laxatives (e.g., polyethylene glycol) and behavioural interventions, such as toilet training. However, these interventions are not always effective, with a significant

proportion of patients remaining symptomatic despite adequate therapy. For example, approximately 40% of patients remain symptomatic after treatment with laxatives (1). In Belgium, a single sachet of macrogol costs approximately €0.45 and is not subject to reimbursement. Since effective treatment often necessitates multiple daily doses, the cumulative costs for families can become substantial. This financial burden has driven a growing interest in alternative and adjunctive therapies, such as neuromodulation. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive method of modulating sacral nerve activity, which plays a key role in regulating bowel function. Previous studies suggest that TENS can improve bowel motility by activating sacral reflexes (2), making it a promising alternative to more invasive treatments.

This study aimed to evaluate the clinical effectiveness of daily, home-administered sacral TENS in treating children with FC who were refractory to first-line treatment. Specifically, the study investigated whether TENS could lead to improvement in key constipation-related symptoms defined by the Rome IV criteria, including stool frequency, retentive behaviour, stool diameter, and faecal incontinence.

Methods

Study design

Data were retrospectively collected from children diagnosed with FC according to the Rome IV criteria who demonstrated an inadequate response to conventional therapeutic approaches. Prior to TENS treatment, all patients had received a combination of pharmacological and non-pharmacological interventions. Pharmacological management primarily

Correspondence to: Fleur Vander Vennet and Justine Desmytter, Department of Pediatric Gastroenterology, Ghent University Hospital, C. Heymanslaan 10, 9000 Ghent, Belgium. Telephone number: +3293326468 - Fax number: +3293322170

Email: Fleurvandervennet@hotmail.com - justine.desmytter@hotmail.com
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Diagnostic Criteria for Functional Constipation

Must include *two or more of the following* occurring at least once per week for a minimum of one month with insufficient criteria for a diagnosis of irritable bowel syndrome:

1. Two or fewer defecations in the toilet per week in a child of a development age of at least four years
2. At least one episode of fecal incontinence per week
3. History of retentive posturing or excessive volitional stool retention
4. History of painful or hard bowel movements
5. Presence of a large fecal mass in the rectum

After appropriate evaluation, the symptoms cannot be fully explained by another medical condition.

Figure 1. — Diagnostic criteria for functional constipation (3).

involved the use of osmotic laxatives (macrogol). Non-pharmacological strategies included dietary modifications to increase fibre and liquid intake, structured toilet training routines, and comprehensive education for patients and their caregivers regarding bowel habits and behavioural reinforcement techniques. Throughout the study period, the established therapeutic regimen remained unchanged. Patients continued their pre-existing bowel management protocols, including macrogol intake, toilet training routines, and/or biofeedback therapy. No fleet enemas were administered.

Participants

Data were extracted from the hospital's electronic health records between March 2018 and January 2024, including patients from the paediatric gastroenterology departments of Ghent University Hospital (UZ Gent) and AZ Groeningen Hospital in Kortrijk. Patients with underlying organic conditions or non-retentive faecal incontinence (NRFI) were excluded from the study. Eligibility was restricted to children aged ≥ 3 years meeting the Rome IV criteria for FC. As these criteria represent the most robust and objective diagnostic framework, no further subclassification—such as pelvic floor dysfunction, megarectum, or slow-transit constipation—was performed, given the lack of standardized and universally accepted definitions for these subtypes. Furthermore, in accordance with the clinical nature of the diagnosis, supplementary radiological or specialized diagnostic investigations were not required. (1) Ethical approval was obtained from the UZ Ghent Medical Ethics Committee, and informed consent was obtained from all participants and their guardians.

Intervention

Participants received daily sacral TENS therapy using the Impulse® 3000T TENS unit (Fig. 2A). Two adhesive electrodes were placed bilaterally over the sacral dermatomes (S2-S3) (Fig. 2B). The device

delivered electrical pulses at a frequency of 2 Hz and a pulse width of 60 μ s for two hours per day. The intensity was adjusted according to each child's tolerance, ensuring that the stimulation remained below the motor threshold. Initially, the parents of the children were trained by students or the hospital's urotherapist in the correct placement of the electrodes and the use of TENS with the aim to enable parents to administer the therapy correctly at home over time.

To prevent interpretative bias, a single researcher consistently recorded the same set of data.

Outcome measures

The primary outcomes were assessed according to the Rome IV criteria. These included the categorical variables: 'stool frequency' (≤ 2 times per week / ≥ 3 times per week), 'stool-retentive behaviour' (present / absent), 'faecal incontinence' (present / absent), and 'stool diameter' (large diameter / normal diameter). In addition the continuous variables 'stool frequency per week' and 'number of faecal incontinence episodes per week' were also included.

The secondary outcomes included abdominal pain, pain during defecation (stool pain), and treatment related adverse events. Pain was assessed both as a continuous variable, using the 'Visual Analogue Scale (VAS)', and as a categorical variable with three levels: none, mild and severe.

An attempt was made to stratify participants according to constipation severity, determined by the number of Rome IV criteria met. Five specific Rome IV criteria were recorded as patient data: pain during defecation or abdominal pain (considered present with a VAS score ≥ 1), stool frequency, faecal incontinence, stool diameter, and stool withholding behaviours. The presence of a faecal mass in the rectum was not documented in the database, although it may have been part of the initial diagnostic criteria for FC required for inclusion. Consequently, the number of recorded ROME IV criteria within the study could range between 1 and 5, allowing classification into severe FC ($\geq 3/5$ criteria) and less severe FC ($< 3/5$ criteria).



Figure 2. — Impulse® 3000T TENS Unit (A) and the placement of the electrodes (B).

Data collection and statistical analysis

Data were collected at baseline (week 0) and subsequently at weeks 6, 12, 18, and 24. Symptom progression was assessed using stool diaries and medical records. Data concerning neurodevelopmental issues as well as eventually measured colon transit time were collected from the medical file. Colon transit time was measured if the treating physician deemed it useful by a 6-day pellet study followed by a single abdominal X-ray on day 7 (4). The total colonic transit time (CTT), expressed in radiopaque pellets, was calculated by dividing the CTT in hours by 2.4. Continuation of TENS treatment beyond week 18 was determined by the treating physician, some patients continued until week 24. Exact data on the number of participants using TENS through week 18 or week 24 are not available. Furthermore, those who continued TENS until week 24 did not necessarily use it daily, and there were numerous missing data points.

Continuous variables were analysed using the Wilcoxon Signed Rank test and reported as medians with interquartile ranges (IQRs). Categorical variables were analysed using the McNemar test. Statistical significance was set at $p < 0.05$. To correct for multiple testing when comparing baseline (week 0) with subsequent time points (weeks 6, 12, 18, and 24), a Bonferroni adjustment was applied ($\alpha = 0.05/4 = 0.0125$). Analyses were performed using SPSS (Statistical Package for the Social Sciences), version 29 (IBM Corp.Armonk, NY, USA).

Results

Demographics

The study included 36 children (median age: 7.5 years, range: 3-15 years), 61% of whom were male

($n=22$). Colon transit time (CTT) was measured in 28 (78%) children, 18 of whom ($n=18/28$, 64%) had a prolonged CTT (ranging from 79.2 to 204 hours). Neurodevelopmental status was explicitly mentioned in the medical record of 29 patients (80%) of whom 31% ($n=9/29$) was previously diagnosed with an associated neurodevelopmental disorder (NDD), such as autism spectrum disorder (ASD) or attention deficit disorder (ADHD).

Among the 36 children included, 7 (19.4%) met one Rome IV criterion, 9 (25.0%) met two criteria, 7 (19.4%) met three criteria, 7 (19.4%) met four criteria, and 6 (16.7%) exhibited all five recorded characteristics.

TENS effectiveness

The results on the effectiveness of TENS are summarised in Table I, which highlights the evolution of the key Rome IV criteria across different time points for one patient.

The number of patients with a normal stool frequency ($\geq 3/\text{week}$) increased from 50% at start to 86% after 24 weeks ($p = 0.035$). The absolute number of defaecations was not significantly different between start (median: 2.5, IQR: 1.25-6.5) and end of the study (median: 4, IQR: 3-7) ($p = 0.093$).

Retentive behaviour showed a significant improvement ($p = 0.001$). At baseline 53% of the children exhibited retentive behaviour which decreased to 19% by week 24.

Furthermore, the proportion of patients experiencing faecal incontinence decreased from 75% at baseline to 52% at week 24 ($p = 0.016$). In addition, also the absolute number of faecal incontinence episodes decreased significantly at week 24 (median: 4, IQR: 0.25-7 vs median: 1, IQR: 0-4 respectively) ($p < 0.001$).

No significant changes were observed in the stool diameter throughout the study period.

Table 1. — Results evolution in one child, based on the Rome IV criteria.

	Week 0 (N: 36/36)		Week 6 (N: 17/36)			Week 12 (N: 30/36)			Week 18 (N: 22/36)			Week 24 (N: 29/36)		
	N	N%	N	N%	p value*	N	N%	p-value*	N	N%	p-value*	N	N%	p-value*
Stool frequency	36	100%	1	100%	0,687	30	100%	<u>0,006</u>	20	100%	0,065	28	100%	0,035
- ≤ 2 times per week	18	50%	6	35%		5	17%		2	10%		4	14%	
Stool diameter	36	100%	17	100%	1,000	30	100%	0,227	21	100%	0,180	27	100%	0,424
- Large diameter	17	47%	8	47%		8	26%		6	29%		8	30%	
Faecal incontinence	36	100%	17	100%	0,500	30	100%	0,219	21	100%	1,000	27	100%	0,016
- Present	27	75%	11	64%		17	57%		17	81%		14	52%	
Retentive behaviour	36	100%	16	100%	0,031	30	100%	0,625	21	100%	0,065	27	100%	<u>0,001</u>
- Present	19	53%	4	25%		13	43%		6	29%		5	19%	
Abdominal pain	25	100%	6	100%	1,000	0			12	100%	0,023	21	100%	<u>0,006</u>
- No pain	11	44%	4	67%					11	92%		17	81%	
- Mild pain	8	32%	1	17%		/			1	8%		4	19%	
- Severe pain	6	24%	1	17%					0	0%		0	0%	
Stooling pain	25	100%	6	100%	1,000	19	100%	0,023	11	100%	0,102	21	100%	0,107
- No pain	16	64%	5	83%		16	84%		11	100%		18	86%	
- Mild pain	5	20%	1	17%		2	11%		/	/		3	14%	
- Severe pain	4	16%	0	0%		1	5%		/	/		0	0%	

*P-value for given time point compared to baseline. The underlined p-values are those that remain significant after Bonferroni correction.

Although there was no statistically significant improvement in abdominal pain - as measured by the VAS scale -, ($p = 0.141$) there was a pain reduction if categorised as none/mild/severe ($p = 0.006$). Pain during defecation did not show improvement in week 24 ($p = 0.107$).

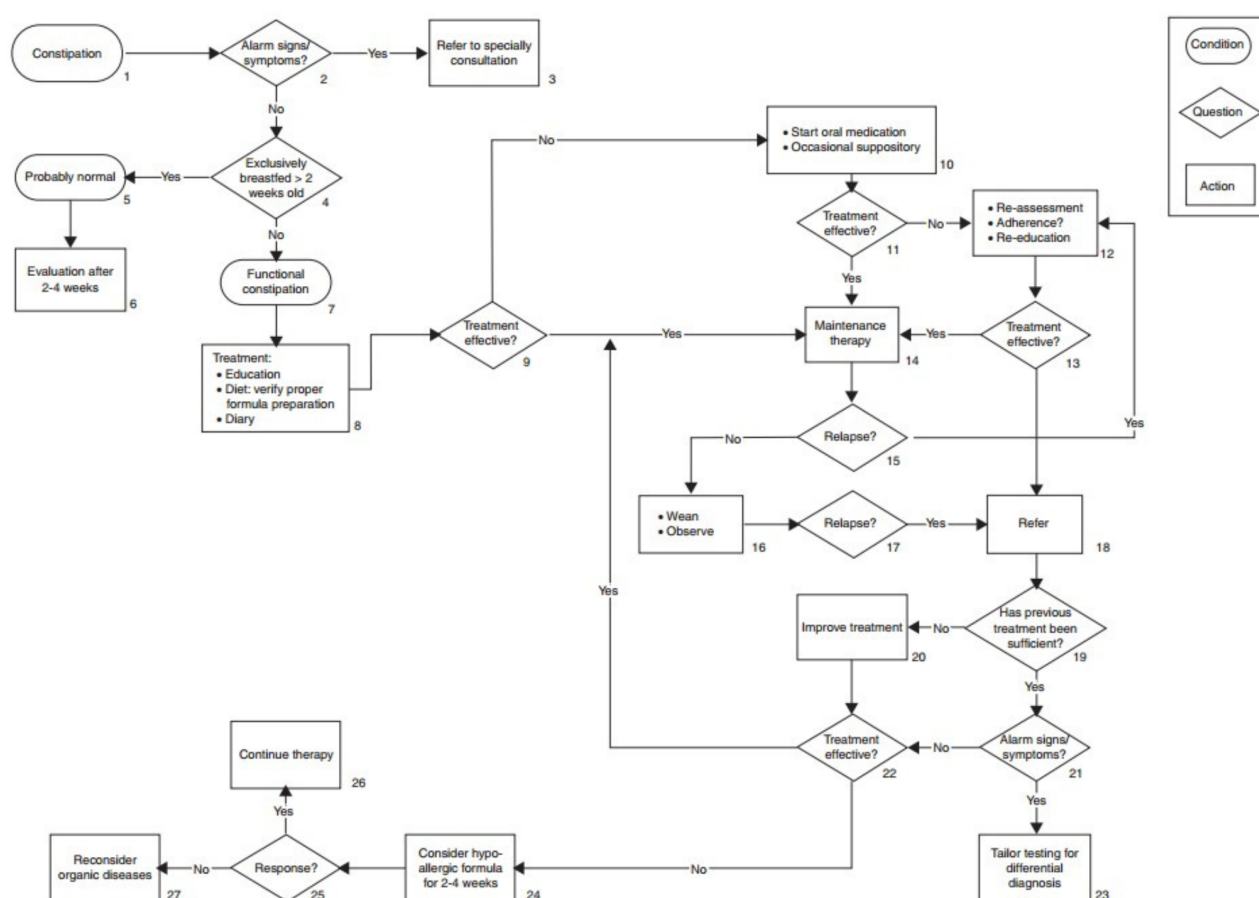
Given the limited sample size of the subgroup with NDD ($n = 9$), analysis was restricted to descriptive statistics. At baseline (week 0), five patients (5/9) presented with reduced defaecation frequency (≤ 2 bowel movements per week); by week 24, all five had achieved normalisation (≥ 3 bowel movements per week). Retentive behaviour, initially observed in four patients, resolved in three cases by the end of the 24-week period. Furthermore, faecal incontinence was reported in seven patients (7/9) at baseline, with resolution achieved in two patients at week 24. Regarding stool consistency, five patients (5/9) reported large-diameter stools at week 0; following 24 weeks of TENS therapy, this symptom had resolved in three of these five patients.

Furthermore, side effects were limited to mild erythema in two patients, which did not necessitate discontinuation.

Discussion

Neuromodulation is an expanding treatment. It has been used to treat both bladder and bowel dysfunction (5). However, it is difficult to compare studies as both direct and transcutaneous methods of neurostimulation as well as tibial and sacral nerve stimulation have been described (5-8). Furthermore, each study differs in terms of patient selection and treatment protocol including the frequency of application, stimulation duration and device settings. This study investigated the effectiveness of an at home sacral TENS treatment in children with FC unresponsive to standard therapy. The treatment aim was a two hour, daily application for 24 weeks. This is to our knowledge the first published cohort in Belgian children.

By week 24 a significant improvement was observed using TENS in children with FC failing the first line treatment in key constipation outcomes, such as faecal incontinence, stool frequency, and retentive behaviour. However, after applying a Bonferroni correction, only the effect on retentive behaviour remained statistically significant. The 'retentive behaviour' criterion showed already an improvement after six weeks, with the most pronounced effect at six months. The other Rome IV

Figure 3. — Algorithm for the evaluation and treatment of infants ≥ 6 months of age (1).

criteria took more than six weeks to be influenced. This is in accordance with the absence of a treatment effect after four weeks in the study of Besendörfer et al.(9). Therefore, it might be important to adjust expectations of patients and caregivers when starting TENS therapy in case of paediatric FC.

Furthermore, the study sought to explore the potential clinical relevance of TENS by identifying which subgroups of children may benefit most from the treatment (i.e., a stratified response), and to assess whether TENS could be considered earlier in the therapeutic plan or algorithm for FC as currently recommended by ESPGHAN and NASPGHAN (Fig. 3) (1).

Neuromodulation appears to have the most pronounced impact on the presence or absence of stool retentive behaviours. Notably, the strong effect on retentive behaviour is significant, as addressing withholding behaviours is crucial in managing constipation in children. Children often lack awareness of the importance of regular bathroom habits, which can lead a constipated child to ignore the need for a bowel movement, rush the process, or avoid it altogether, sometimes due to pain. This avoidance behaviour causes rectal distension, allowing stool to accumulate, harden, and ultimately intensify the pain, trapping the child in a vicious cycle (10).

By potentially enhancing rectal sensations and modulating anal sphincter tone, it may help decrease

withholding behaviours and interrupt the cycle of pain and constipation. This could be particularly relevant for children with NDD's, such as ASS or ADHD, in whom behavioural interventions are often more challenging to implement effectively. In children with NDD's, establishing regular toilet habits and overcoming avoidance behaviours may be complicated by factors such as reduced attention, sensory sensitivities en rigid routines. These challenges may contribute to increased stool retention, worsening constipation, and reduced adherence to standard first-line therapies such as toilet training and laxatives, which are sometimes limited by issues like taste or texture aversion (11-13). In the present study, 31% of participants were identified as having a NDD. This proportion is consistent with that reported by Seidler et al. in their retrospective study, which compared two subcohorts: children with FC only (69%) and children with both FC and a NDD (31%). From a clinical perspective, this represents a substantial proportion, underscoring the potential relevance of TENS for this population. As such, TENS may represent a feasible adjunct or alternative approach for this population. Preliminary descriptive data suggest substantial gains in this cohort, particularly concerning stool frequency. Improvements were also noted in secondary outcomes, including stool withholding patterns and the passage of large-caliber stools.

A considerable proportion of the study population met multiple Rome IV criteria, underscoring the substantial symptom burden within this cohort. Notably, nearly 17% of participants presented with a combination of large stool diameter, withholding behaviours, defecation frequency of less than twice per week, pain during defecation or abdominal pain and faecal incontinence. Overall, more than half of the children (55.5%) met three or more of the primary outcomes assessed, highlighting a level of constipation severity likely to have a significant impact on quality of life and justifying classification as severe functional constipation. The results suggest that the therapeutic benefit of TENS extends to children with severe FC, indicating that even those with a high symptom burden may respond favourably.

In light of the positive results seen in the present cohort, which includes a considerable number of children with severe constipation and NDD, it may be justified to explore the earlier integration of sacral TENS within the treatment algorithm.

Additionally, at the end of the observation period (24 weeks) in this study, a clinical improvement remained evident on faecal incontinence, retentive behaviour and stool frequency even though some children discontinued TENS application at 18 weeks. These results confirm the study by Veiga et al. in children with lower urinary tract dysfunction. They described a significant improvement in faecal incontinence and retentive behaviour, but also in the presence of a large faecal mass in the rectum (14). Furthermore, Ismail et al. as well as Clarke et al., described an increased stool frequency in children using TENS with an interferential current at a frequency of 4 kHz in constipated children (15, 16).

Pain, inherently subjective and especially challenging to assess in children, improved only as a categorical variable. Categorised as none/mild/severe, abdominal pain showed a significant improvement at week 24. This could be the results of missing values in the continuous evaluation but also a non-standardised evaluation of the VAS scale. The fact of asking the score during a hospital visit may already influence the result due to the stress associated to a medical appointment. On the other hand, the categories 'no pain,' 'mild pain,' or 'severe pain' provide a more concrete and less subjective measurement. Significant improvements were observed in abdominal pain. Assessing pain is an added value as a 'history of painful or hard stools' is a Rome IV criterion and it is crucial for assessing the impact of constipation on the child's quality of life.

While this study demonstrated that TENS is effective for children with FC, there remains no consensus on the optimal duration of therapy, the number of sessions required, or the frequency of treatment. In this study, participants were treated with TENS for two hours daily over a period of 18 weeks, with follow-ups extending to 24 weeks. However, the effectiveness of TENS beyond this period is unclear, as some children discontinued the

use after week 18, and there were no long-term follow-ups to assess the persistence of benefits after stopping treatment. The variation in study protocols across the literature reflects the ongoing uncertainty in defining an ideal treatment regimen. Studies like those by Veiga et al. used shorter, more frequent sessions (14), while others, such as Yik et al., employed long-term neuromodulation protocols with sustained follow-up (17). Additionally, some studies in the literature include follow-up periods extending beyond six weeks after therapy cessation, such as the study by Leanne C.Y. Leong et al., which had a follow-up period of three and a half years (18). Without clear guidelines on the appropriate number of sessions, duration, and follow-up, it remains challenging for clinicians to standardise TENS therapy for paediatric FC. Future research is needed to establish a more uniform approach that optimises treatment outcomes and ensures long-term benefits.

Some limitations should be noted, including the lack of a control group, the relatively small sample size, and the presence of missing data. Another important limitation of this study was the lack of consistency regarding the duration of TENS treatment, as some children continued treatment until week 18 while others until week 24. In addition, the current study lacked the statistical power necessary for meaningful age-stratified subgroup analyses. Similarly, the small number of participants with NDD precluded formal hypothesis testing, limiting the analysis of this subgroup to descriptive statistics. Moreover, quality-of-life related data were not processed, in contrast to certain other studies where such analyses are included.

However, when compared to other studies in the literature, this study population represents one of the larger cohorts. A further strength is that the TENS treatment can be administered at home. In contrast, some other studies require children to attend hospital-based sessions, which considerably reduces the accessibility of the therapy. In addition to its non-invasive nature and low side-effect profile, TENS presents a low financial burden. Despite the lack of reimbursement in Belgium, the estimated expenditure of €94 for 24 weeks of therapy is considered economically viable for the majority of families. Another strength is that the study used the Rome IV criteria and attempted to stratify patients who may benefit most from TENS treatment. Only two patients experienced mild erythema, which did not lead to discontinuation of therapy.

Further research is needed to confirm the efficacy of TENS, both in general and in children with NDD's, and to better define its role within treatment pathways. Studies should use ROME IV criteria and be designed as randomised controlled trials with larger populations to further validate these findings. The absence of long-term follow-up data also limits the ability to assess the durability of the improvements seen with TENS therapy.

Conclusion

This study, which we believe to be the first Belgian cohort study on this subject, confirms that sacral TENS is an effective and safe treatment option for children with FC. TENS significantly reduced stool retentive behaviour in children who had not responded to traditional therapies. The beneficial effects seemed to be present in both children with less severe (<3/5 criteria) and severe constipation FC ($\geq 3/5$ criteria). However, after applying a Bonferroni correction, only the effect on retentive behaviour remained statistically significant. In addition, TENS may also offer a feasible alternative for children with NDD. These findings support the consideration of integrating TENS earlier in the therapeutic pathway for FC, rather than limiting its use to refractory cases.

Declarations

Conflict of interest statement: For a period of two years, three TENS devices were borrowed on loan from the company 'Medi-Rent'. The company had no role in the study design, data collection, analysis, interpretation of data, or writing of the manuscript. The authors declare no other conflicts of interest.

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