Evaluation of Pena Protocol for Bowel Management in Children with Chronic Constipation

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Abstract

Background: Chronic constipation is one of the most common chronic disorders of childhood, affecting 1% to 30% of children worldwide**.**

Aim: To evaluate the efficacy and feasibility of Pena protocol of bowel management in children with chronic constipation

Patients and methods: This prospective cross-sectional study was conducted on 63 children with chronic constipation in the Pediatric Unit of General Surgery Department at Benha University Hospital

Results: Regarding the final outcome of Pena protocol for management of chronic constipation, the majority of cases had good response (93.7%) while 4 cases still had no response and needed surgery. According to the first step of Pena management among studied cases, which is enema, only 3 cases had antegrade enema and the majority had retrograde enema (95.2%) with mean dose of enema of 735, ranged from 200 to 1000 ml. For content of enema, one third used saline solution, also one third used glycerin, then 23.8% used phosphate, while 3 cases only used Castile soap, and another 3 cases used polyethylene glycol. Regarding the management by laxatives, 34.9% needed laxatives either due to increased number of enemas or increased dose with the majority used bulk forming laxative (59.1%), while osmotic and stool softener laxatives were used in 18.25 and 22.7%, respectively, among cases who used laxatives.

Conclusion: Pena protocol is effective and well-tolerated for bowel management in children with chronic constipation. Therefore, rectal enemas and oral laxatives should be equally considered as the first line therapy.

Key words: Chronic constipation, Pena protocol, Rectal enemas, Laxatives

Introduction

One debilitating ailment is constipation [1]. Adult constipation symptoms include hard or lumpy stools, infrequent bowel movements, heavy straining, a feeling of incomplete evacuation or obstruction, and the use of manual techniques to promote evacuation, according to the Rome IV criteria [2,3]. According to a meta-analysis of 45 population-based research conducted worldwide, the prevalence of chronic constipation is around 14%; however, the included studies differed greatly in terms of the description and geographic location of constipation [4]. Additionally, among functional gastrointestinal illnesses, functional constipation has the greatest prevalence rate in the recently published Rome Foundation Global Study [5].

The illness places a significant strain on the healthcare system, accounting for 10–25% of gastrointestinal consultations and 10% of ER visits for stomach discomfort [6]. Ten percent of children with functional defecation abnormalities treated by a gastroenterologist are still constipated at a 10-year follow-up and one-third of children continue to experience constipation

throughout adolescence [1,7]. Additionally, half of the children with these disorders have persisting symptoms five years after referral. By restricting daily activities and resulting in social and physical suffering, the disease has a substantial negative influence on quality of life [8,9].

The symptoms of Functional Constipation (FC) can range from moderate forms that are typically responsive to fiber, laxatives, and behavioral changes to severe cases that are not responding to routine medical and behavioral care and that are referred for surgical examination [10]. Only 10–30% of patients with FC who seek surgical evaluation have fecal incontinence, but 75% of patients struggle with it [11]. This highlights the significance of careful assessment and committed bowel care for these kids. In 87% of adherent patients with FC, an organized approach to bowel management is the key to managing constipated children which results in a significant reduction in hospital admissions, ED visits, and medical expenses [12,13].

This study aimed to evaluate the efficacy and feasibility of Pena protocol [14] of bowel management in children with chronic constipation.

Patients and methods

Study design:

This prospective study included 63 children with chronic constipation in the Pediatric Unit of the General Surgery Department at Benha University Hospital.

Inclusion criteria: Patients aged 3 to 18 years and with chronic constipation.

Exclusion criteria: Organic etiology for constipation and age less than 3 years or more than 18 years. Patients with spastic anal sphincter were also excluded.

Methods:

All patients were subjected to thorough investigations, physical tests, and history taking. In addition to anorectal malformations and spinal abnormalities, endocrine and metabolic disorders (such as hypothyroidism and celiac disease), medications, connective tissue disorders, milk protein intolerance, and other conditions that should be carefully addressed during the initial evaluation are among the potential causes of constipation.

With a thorough medical history and physical examination being adequate for the diagnosis establishment, several gastroenterological studies do not recommend radiography for the diagnosis of FC (2). However, a contrast enema is necessary to rule out other anatomic causes of constipation in patients with persistent constipation who are referred to a pediatric surgeon. While rectosigmoid redundancy may result in a poor response to medicinal treatments, colon dilatation down to the levator muscle complex is a hallmark sign of FC on contrast enema. The degree of rectosigmoid dilatation, however, was found to be unrelated to the amount of laxative needed to attain social continence if the patient responds to treatment (1,2). Patients with FC who are referred for surgical examination were managed by additional diagnostic and therapeutic measures. To check for anal stenosis and visual abnormalities in the anorectal region, an examination under anesthesia (EUA) was necessary. The examination was done in the clinic if operating room time is not available. To rule out anal stenosis, dilated hemorrhoidal veins, and anal fissures—all of which can result in persistent constipation and an uncomfortable defecation experience , a digital rectal examination was essential. Hirschsprung disease was ruled out via anorectal manometry and/or rectal biopsy if a patient's rectosigmoid index on contrast enema was less than 1 (full-thickness rectal biopsy is still the gold standard)(2-5).

In order to determine the best course of action for children who do not respond to medical management with rectal enemas, anorectal manometry (AMAN), which provides information about the dynamics of defecation, sphincter resting pressures, rectal sensation, and the rectoanal inhibitory reflex (RAIR), was necessary. The patient's participation in following instructions is necessary during the about 30-minute process.

Procedure: Contrast enema with hydrosoluble material was important to obtain a picture after evacuation of the contrast material. This study helped to empty the colon and helps the clinician select the type and volume of enema.

Content of enema: (Glycerin, Castile soap, phosphate and others (Dulcolax, polyethylene glycol).

Dosage:

The patient's age and level of colonic dilatation determined the volumes we employed, which range from 200 to 1,500 ml. The parents should make the saline solution by combining tap water and salt from the kitchen (typically, 0.9% saline is equal to 960 cc of water + 1.5 tablespoons). We used roughly 20 milliliters of glycerin for every 500 milliliters of saline solution. Depending on how the patient responded, we changed the glycerin dosage. We used one package (9 cc) of Castile soap for every 500 milliliters of saline solution. However, we adjusted this sum based on the patient's reaction.

A laxative was added after colon evacuation to make sure the colon is empty. Laxatives fell into one of three categories: bulk-forming laxatives, like methylcellulose, which function similarly to dietary fiber and increase the bulk of stools by helping them retain fluid and encouraging your bowels to push the stools out; osmotic laxatives, like lactulose, which soften and make them easier to pass by increasing the amount of water in bowels; and stimulant laxatives, like senna, which speed up the movement of your bowels by stimulating the nerves that control the muscles lining your digestive tract [(2)].

Dosage:

The dosage of the laxative was increased daily until the right amount of laxative was reached that completely emptied the colon every day.

Surgery:

In patients with FC, the primary indication for surgery is the failure of medical management with laxatives and mechanical treatment options (rectal enemas, transanal irrigations, and antegrade continence enemas, which is followed by significant dilatation of the rectosigmoid and persistent fecal incontinence [15,16]. Diverting ostomy, sigmoid resection with or without a simultaneous ACE procedure, Deloyers procedure, pull-through variations, proctocolectomy with an ileoanal anastomosis, and colon resection with an ileorectal anastomosis were just a few of the numerous surgical procedures used to treat refractory FC that have been documented in the literature [17,18]. The present protocol utilized in this patient group is the main topic of this study. We conducted our program for life and informed parents that constipation would recur if the enema or laxative was stopped.

Outcome and follow up

The primary outcome was successful management of FC with minimizing its complications

The 2^{ry} research objective was decrease the overall burden on the health care system. Follow up was planned to be done subjectively through the patient defecation diaries and Constipation Scoring System [19] (Table 1, Minimum Score 0; Maximum Score 30). With just eight questions

and a 96% accuracy rate, it has become well-liked by research institutes and medical professionals all over the world. The following metrics are assessed: the frequency of bowel movements, the difficulty of evacuation, the sensation of incomplete evacuation, abdominal pain, the number of minutes spent in the bathroom per attempt, the type of assistance used to defecate (enema, laxatives, or manual), the number of unsuccessful evacuation attempts per 24 hours, and the length of constipation.
Every statistic has a minimum score of 0 and a maximum value of 4, correspondingly. When the total score for all items is more than 15, out of a possible total of 30, intestinal chronic constipation is diagnosed and its severity is categorized.

Ethical Approval: This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Benha University. Written informed consent was obtained from all the caregivers of the participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis
Sample size: The following presumptions were taken into account when calculating the sample size using Epi Info STATCALC: - 80% power, 95% two-sided confidence level. The computed odds ratio, with a 5% error, was 1.115. 63 was the ultimate maximum sample size derived from the Epi-Info output.
The gathered data were examined using the proper statistical techniques and displayed in tables. The Cochrane Collaboration Tool for Assessing the Risk of Bias was used to gather data for each study. Medcalc version 11.6.1, Open Epi version 3.01, and SPSS statistical software version 20 (Statistical Package for the Social Sciences) were used to conduct the statistical analysis. The mean ± standard deviation (SD) and frequencies were used to characterize the data based on whether they were quantitative or qualitative, respectively. If the data in the current investigation turned out to be regularly distributed, parametric tests were employed. A P value of less than 0.05 was considered to be a significant difference for all statistical tests.

Table 1: Constipation scoring system[19]

	Score
Frequency of bowel movements	
1–2 times per 1–2 days	0
2 times per week	1
Once per week	2
Less than once per week	3
Less than once per month	4
Difficulty: painful evacuation effort	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Completeness: feeling incomplete evacuation	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Pain: abdominal pain	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Time: minutes in lavatory per attempt	
Less than 5	0
5–10	1
10–20	2
20–30	3
More than 30	4
Assistance: type of assistance	
Without assistance	0
Stimulative laxatives	1
Digital assistance or enema	2
Failure: unsuccessful attempts for evacuation per 24 hours	
Never	0
1–3	1
3–6	2
6–9	3
More than 9	4
History: duration of constipation (years)	
0	0
1–5	1
5–10	2
10–20	3
More than 20	4
Total score	

Results

The mean age of the included patients was 8.1±3.7 years. 55.6% were males. Other socio-demographic data were presented in **Table 2**.

Regarding the physical examination and radiological investigation, all cases had intact sphincters on PR examination, 96.8% had dilated bowel in X-ray **(Table 2).**

Table 2: Sociodemographic data, examination and X-ray findings.

Variable		**N=63**
Age	Mean± SD	8.1±3.7
Sex Females **Males**	N (%)	28 (44.4%) 35(55.6%)
BMI	Mean± SD	23.6±4.33
Physical examination		
Normal anal sphincter	N (%)	63 (100%)
Local anal condition; fissures or piles	N (%)	4 (6.4%)
Abdominal examination		
Abdominal distention	N (%)	54 (85.7%)
X-ray findings		
Dilated bowel loops	N (%)	61 (96.8%)

(BMI: Body mass index)

As regards the manometric findings, the resting and squeeze pressure were higher than normal range for age while the sensations were intact. The RAIR was intact in all included patients. The mean constipation score was 19.4±2.7 **(Table 3)**.

Table 3: Manometric findings and constipation Score in the studied group

Variable		**N=63**
Manometric findings		
Resting pressure **(Normal= 69 ± 14 mmHg)** [20]	Mean± SD	77.2± 19.8
Squeeze Pressure **(Normal=191 ± 64 mmHg)** [20]	Mean± SD	224±88.2
First sensation **(Normal= balloon volumes of 24.4 ± 23.98 cm)** [20]	Mean± SD	26.2±22.8
First Urge **(Normal= balloon volumes of 45.9 ± 34.55 cm)** [20]	Mean± SD	47.6±30.7
Intense urge **(Normal= balloon volumes 91.6 ± 50.17 cm)** [20]	Mean± SD	98.3± 48.2
RAIR presence	N (%)	61(96.8%)
Constipation score	Mean± SD	19.4±2.7

According to the first step of Pena management among studied cases, which is enema, only 3 cases had antegrade enema and the majority had retrograde enema (95.2%) with mean dose of enema of 735, ranged from 200 to 1000 ml. For content of enema, one third used saline solution and one

third used glycerin. For number of enemas used per day, less than one half relived through one enema (44.4%), 39.7% needed 2 enemas to relive symptoms while 15.9% needed 3 enemas per day, which necessitated the use of laxatives to reduce the number and dose of enemas. Regarding the management by laxatives, 34.9% needed laxatives with the majority used bulk forming laxative (59.1%) **(Table 4)**.

Table 4: Results of using Pena protocol for management of constipation (enema) among studied cases

Variable		N=63
Enema used		
Antegrade **Retrograde**	N (%)	3 60
Enema content		
Saline solution	N (%)	21(33.3%)
Phosphate	N (%)	15(23.8%)
Glycerin	N (%)	21(33.3%)
Castile soap	N (%)	3(4.8%)
Enema dose (ml)	Mean± SD	735±323
Number of enema/days		
1	N (%)	28(44.4%)
2	N (%)	25(39.7%)
3	N (%)	10(15.9%)
Need for laxatives	N (%)	22(34.9%)
Type of laxative		
Bulk-forming	N (%)	13(59.1%)
Osmotic	N (%)	4(18.2%)
Stool softener	N (%)	5(22.7%)

There was statistically significant improvement of the plain erect and incontinence score after Pena protocol. For final evaluation by X-ray at the end of first week of enema and laxative trial, only 4 cases had still dilated colon and 93.7% had clean colon **(Table 5)**.

Table 5: Follow-up after Pena Protocol

Variable		Before Protocol	After protocol	P value
Plain X-ray (Dilated bowel)	N (%)	61(96.8%)	4 (6.3%)	0.001*
Constipation score	Mean± SD	19.4±2.7	12.4±2.3	0.001*
Clinical response Constipated patients	N (%)	63 (100%)	4 (6.4%)	0.001*

*: Significant

Regarding the final outcome of Pena protocol for management of chronic constipation, the majority of cases had good response (93.7%) while 4 cases still had no response and needed surgery **(Table 6)**.

Regarding the comparison of baseline data, clinical data, past history according to response to Pena protocol, it was found that there was statistically significant difference regarding BMI, duration of constipation, history of blood straked stool, number of hours spent with TV/mobile, abdominal distention, appetite, and urinary incontinence (p value <0.05) as the mean BMI was significantly higher among succeeded cases than among failed cases, while duration of constipation and number of hours spent with TV/mobile were significantly lower among succeeded cases than among failed cases. Also, all failed cases had history of blood straked stool, abdominal distention, poor appetite and urinary incontinence compared to succeeded cases (15.3%, 37.3%, 33.9% and 15.3% respectively) **(Table 6)**.

Table (6): Comparison of different variables according to the response to Pena protocol for management of constipation

Variables	Response to Pena protocol		P value
	Succeeded (n=59)	Failed (n=4)	
Age	8±3.9	9±0	0.63
Onset of constipation	5.9±3.3	4±0.2	0.24
Duration of constipation	24±16.7	60±10	<0.001*
Categorization **Isolated constipation** **Mixed with pseudo incontinence**	 39(66.1%) 20(33.9%)	 3(75%) 1(25%)	0.71
Number of defecation/week (<2 times)	49(83.1%)	4(100%)	0.37
Excessive stool retention	40(67.8%)	4(100%)	0.17
Painful bowel movement	50(84.7%)	4(100%)	0.40
History of large fecal mass in rectum	31(52.5%)	4(100%)	0.06
Large hard stool obstructing toilet	33(55.9%)	3(75%)	0.46
History of blood straked stool	9(15.3%)	4(100%)	<0.001*
Sedentary life style	49(83.1%)	4(100%)	0.37
Number of hours spent with TV/mobile	4.1±1.2	8±1	<0.001*
History of high fat	47(79.7%)	4(100%)	0.32
Decreased fluid intake	40(67.8%)	4(100%)	0.17
Abdominal distention	22(37.3%)	4(100%)	0.01*
Appetite **Good** **Fair** **Poor**	 12(20.3%) 27(45.8%) 20(33.9%)	 0(0%) 0(0%) 4(100%)	0.03*
Urinary incontinence	9(15.3%)	4(100%)	<0.001*

Data are presented as Mean± SD or as frequency and percentage
*: Significant

Discussion

Based on the demographic information of the cases under investigation, the current study found that the cases' mean age was 8.1 years, with a range of 3 to 17 years, and that 55.6% of them were males.
Our results concur with those of **Aslam *et al.*** [21] who sought to ascertain if a bowel management program was beneficial for kids with functional constipation. The average height of 91 children, ages 3 to 12, was 107.27 ± 19.32 cm (95% CI: 103.24-111.29), the average weight was 17.49 ± 3.24 kg (95% CI: 16.82-18.17), and the average age was 5.26 ± 2.20 years (95% CI: 4.80-5.72). (30.8%) were females, and 69.2% were males.

Every case had intact sphincters on PR evaluation based on the physical examination and radiological investigation. This was consistent with the findings of **Miller *et al.*** [22] who discovered that most patients (69.4%) had abdominal radiography, and that the majority (78.6%) had either constipation or moderate to large amounts of feces.
Only three cases had antegrade enema, while the rest (95.2%) had retrograde enema, with a mean enema dose of 735, ranging from 200 to 1000 ml, according to the initial stage of Pena therapy among the cases under study, which is enema.

One third utilized saline solution, another third used glycerin, 23.8% used phosphate, three cases used simply Castile soap, and three more cases used polyethylene glycol for the enema's substance. Less than half (44.4%) of the enemas used daily were relieved by a single enema, 39.7% required two enemas to alleviate symptoms, and 15.9% required three enemas daily, requiring the use of laxatives to lower the frequency and dosage of enemas.
Nine out of twenty-one cases with a history of soiled underwear still had the complaint, and 31.7% of cases on enema that were evaluated by X-ray still showed a dilated colon that had not been fully emptied.

This was consistent with the findings of **Bekkali *et al.*** [23] who found that 39% (n=18) of the participants had already used an enema before enrolling in the trial. Ten patients in all were dropouts. Dropout rates in the enema group were caused by patients not showing up at the outpatient clinic (n=2), obtaining five enemas instead of six (n=1), being hospitalized during the study (n=1), or failing to maintain bowel diaries (n=1).

In terms of laxative management, 34.9% of patients required laxatives because of an increase in enemas or dosage, and the majority of those patients (59.1%) used bulk-forming laxatives, while 18.25 and 22.7% of those who used laxatives used osmotic and stool-softening laxatives, respectively. Only four cases had a dilated colon at the end of the first week of the enema and laxative experiment, according to the final X-ray evaluation, while 93.7% of cases had a clear colon.
This was consistent with the findings of **Wood *et al.*** [24] who showed that oral stimulant laxatives were used to treat 73 (32.9%).
Four instances still showed no response and required surgery, however the majority of cases (93.7%) responded well to the Pena protocol for managing chronic constipation.

Similar findings were made by **Miller *et al.*** [22] who discovered that 28% of patients who received an enema were released without a stool softener or laxative. A laxative, most frequently polyethylene glycol (PEG) (79.8%), was given to the majority of patients (73.6%) upon discharge.

One-third received additional dietary guidance, while the majority received typical constipation instructions (dietary advice, follow-up instructions). Only 6.6% of patients were provided stool softeners, and only 2.5% of patients were advised to change their behavior.

Additionally, our results are consistent with those of **Siddiqui *et al.*** [25] who found that 20 patients (23%) had a successful bowel management program prior to the antegrade enema implantation, while 68 patients (77%) had a failure program ($P < 0.05$). 26 (29%) were unsuccessful and 62 (71%) were successful at the most recent follow-up ($P < 0.05$).

As well, our results are in concordance with **Aslam *et al.*** [21] who revealed that effectiveness of bowel management program was found to be in 85 (93.4%) patients.
MI was significantly higher among successful cases than among unsuccessful cases, while duration of constipation and number of hours spent with TV/mobile were significantly lower among successful cases than those that failed. Moreover, compared to 15.3%, 37.3%, 33.9%, and 15.3%, respectively, all unsuccessful cases had a history of blood-stained stool, abdominal distention, low appetite, and urine incontinence. Our findings are in agreement with **Aslam *et al.*** [21] who revealed that significant difference was reported in age group (p=0.040), body mass index (p=0.031), and duration of functional constipation (p=0.014).

Conclusion

Children with chronic constipation can effectively and comfortably manage their bowel movements with the Pena protocol. Consequently, oral laxatives and rectal enemas ought to be equally regarded as first-line treatments. To evaluate the effectiveness of this program and confirm the findings of the current investigation, more clinical trials are necessary.

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