Bowel management program for pediatric postoperative fecal incontinence in China
A surgeon's experience

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Abstract
The purpose of this article is to report the status of the efficacy of and long-term adherence to the Bowel Management Program (BMP) for fecal incontinence (FI) postoperation in China. Children over 3 years of age with FI postoperation referred to our medical center were included in the study. Evaluations were performed before and 2 years after their clinic visit. The cost of bowel care, improvement in incontinence, health-related quality of life, and family functioning with the BMP were analyzed.

A total of 48 children with FI were included in our study, of whom 38 were boys. The median treatment fee was 660.1 dollars. The complications included abdominal pain (4 patients, 8%), occasional vomiting (2 patients, 4%), and hypoglycemia (1 patient, 2%). The incontinence status and health-related quality of life improved significantly after the BMP. Despite the good outcome of the BMP, half of the patients discontinued the program.

The BMP is an effective approach to manage FI and improve the patients' quality of life. Poor long-term adherence is currently the main challenge affecting the BMP application in China.

Abbreviations: ARM = anorectal malformation, BMP = Bowel Management Program, FI = fecal incontinence, HD = Hirschsprung disease, IQR = interquartile range.

Keywords: bowel management program, efficacy, fecal incontinence, long-term adherence

1. Introduction
Fecal incontinence (FI) is one of the most disturbing and psychologically distressing problems affecting children.[11] Several psychological problems are associated with unsuccessful bowel programs in the pediatric surgery field. It is a problem that affects more children than previously thought, affecting those born with anorectal malformation (ARM), Hirschsprung disease (HD), presacral tumor, or spinal cord problems.

Fecal incontinence depends on 3 main factors: voluntary sphincter muscles, anal canal sensation, and colonic motility.[2] Patients with true FI are those who lack voluntary bowel movement ability, either because they were born with a congenital malformation with a poor functional prognosis or because of hypothyroidism, hypocaleamia, allergy, and other pathogenesis; in this study, we focused on the former cases in the pediatric surgery field. We have learned how to evaluate these patients to recognize the exact pathogenesis of FI. Of the patients with ARM, 25% experience FI due to functional defecation disorder, weak sphincter muscles, iatrogenic injury, and abnormal innervation.[2] Yet, a small significant number of patients with HD (<5%) experience FI owing to their destroyed dentate line and bowel dismotility.[5] Patients with spinal problems, such as tethered cord, presacral tumor, or injuries, can lack voluntary bowel movement ability.[6]

The Bowel Management Program (BMP), developed by Drs Alberto Peña and Marc Levitt for over 30 years, has a low cost, can be implemented at home, and ensures that the patients remain clean for 24 hours.[5,7,8] It is an artificial tailored enema program to keep patients clean on a 24-hour basis. It is very popular in the United States[5,8] and some South American and Asian countries as well.[8] However, there have been no reports related to BMP in China. Since the implementation of the BMP in 2013, we have treated 48 cases to date. The objective of this study was to evaluate the status of BMP implementation in a children’s medical center. We summarized the effectiveness of the BMP in improving the quality of life of children with FI. The patients’ bowel function, satisfaction with the program, treatment cost, and family acceptance were also assessed.
2. Methods

This cross-sectional study was conducted in a children’s medical center in South China. Children above 3 years of age with FI postoperations who underwent the BMP from February 2013 to December 2015 were considered for this study. The children who did not participate in all the interviews pertaining to data collection or who had FI not related to their primary diagnosis of ARM, HD, presacral tumor, or spinal cord problems or who were treated successfully with diet and drug were excluded from the study. This study was approved by the ethics committee of Guangzhou Women and Children’s Medical Center. In total, 48 patients fulfilled the inclusion criteria of the study.

The BMP includes administration of daily enemas with saline solution alone or with glycerin, with the volume and concentration determined via trial and error over a period of 1 week based on the clinical response and the amount and distribution of stool in the colon (as revealed by a plain abdominal X-ray).15,7,8

We collected data related to the FI cases treated with the BMP via a face-to-face interview or phone. The basic data collected from the patients included sex, age, time required for the treatment process, treatment cost, and BMP time. We observed the clinical efficacy of the BMP in terms of the improvement in the defecation symptoms.

The Cleveland score was used to evaluate the efficacy of the program for FI; the score ranges from 0 to 20, and the test evaluates the type (solid, fluid, or gas) and frequency of stools (0=perfect control, 20=severe incontinence). In 2013, all the parents who answered the first questionnaire were asked to complete a second questionnaire in 2015 via a phone call or a face-to-face interview.

The PedsQL 4.0 questionnaire was filled out by the parents and was used to assess the quality of life before and after the program.10,11 The questionnaire had 4 modules with 23 items encompassing the physical (8 items), emotional (5 items), social (5 items), and school (5 items) domains. The items were reverse-scored and linearly transformed to a scale from 0 to 100 (0=0, 100=100, 1=75, 2=50, 3=25, 4=0), with high scores indicating a better quality of life.

2.1. Statistical analysis

Continuous variables were expressed as medians and interquartile ranges (IQR). The paired two-tailed Student t test was used to compare the Cleveland FI and PedsQL scores before and after the program when the data conformed to a normal distribution. Otherwise, the Wilcoxon-signed rank test was used. Correlations between the Cleveland FI score and PedsQL score as well as its dimension scores were assessed using the Spearman correlation analysis. Results with P < .05 were considered statistically significant. All the analyses were performed using the R version 3.3.2.

3. Results

3.1. Characteristics of the patients

The patient characteristics are listed in Table 1. Of the 48 patients who met the inclusion criteria, 26 were born with ARMs, 12 had Hirschsprung disease, and the remaining had meningomyelocele, tethered cord, and sacral teratoma. Thirty-eight of the patients were boys. The median treatment fee was 660.1 (IQR: 471.0–821.8) dollars. The median age and follow-up period were 7 years (IQR: 6–8 years) and 1.75 years (IQR: 1.0–2.0 years), respectively. Only 2 patients agreed to undergo the Malone procedure. Complications included abdominal pain (4 patients, 8%), occasional vomiting (2 patients, 4%), and hypoglycemia (1 patient, 2%).

3.2. Treatment effects before and after the program

Table 2 shows that the Cleveland FI score significantly decreased after the program (from 10.42 to 2.60). Compared with the scores before the program, there were statistically significant increases in the PedsQL (from 59.14 to 73.09), emotional function (from 36.67 to 63.65), social function (from 35.42 to 57.81), and school function (from 40.00 to 54.79) scores at the end of the study,8 other than the physical function score.

3.3. Correlations between the Cleveland FI score and PedsQL score

To assess the correlation between the Cleveland FI score and PedsQL score, the Spearman correlation analysis was used. As shown in Table 3, changes in the Cleveland FI score and PedsQL score as well as its dimension scores were assessed using the Spearman correlation analysis. Results with P < .05 were considered statistically significant. All the analyses were performed using the R version 3.3.2.

3.4. Trends in the program and improvement in the Cleveland FI score and PedsQL score

As shown in Fig. 1, the total PedsQL, emotional function, social function, and school function scores increased with the program.

Table 1

| Characteristics of children with fecal incontinence. | n = 48 |
|-----------------------------------------------|-------|
| Variables |       |
| Sex |     |
| Boys | 38/48 |
| Age, y | 7.0 (5.3–8.0) |
| Diagnosis |     |
| ARM | 26/48 |
| HD | 12/48 |
| M+TT | 8/48 |
| ST | 2/48 |
| Treatment fee, dollar | 660.1 (471.2–821.8) |
| Hospital stay, d | 7 (6–8) |
| BMP time, y | 1.75 (1.0–2.0) |
| Malone procedure | 2/48 |

Table 2

| Comparisons of the Cleveland FI score and PedsQL score before and after treatment. |       |
|-----------------------------------------------|-------|
| Score |       |
| Pre | Post |
| Cleveland FI score | 10.42 ± 4.12 | 2.60 ± 1.83 | <.001* |
| PedsQL total score | 59.14 ± 7.59 | 73.09 ± 7.04 | <.001* |
| Physical function | 100 | 100 | — |
| Emotional function | 36.67 ± 16.89 | 63.65 ± 17.56 | <.001* |
| Social function | 35.42 ± 18.27 | 57.81 ± 16.01 | <.001* |
| School function | 40.00 ± 11.81 | 54.79 ± 10.67 | <.001* |

Pfi=fecal incontinence, PedsQL=Pediatric Quality of Life Inventory.

*P values are shown for comparisons of absolute scores using Wilcoxon signed rank test.

*P values are shown for comparisons of absolute scores using paired Student t test.
Conversely, the Cleveland FI score decreased, indicating that both anorectal function and quality of life improved following the BMP.

### 3.5. Reasons for abandonment of the program

Twenty-four patients discontinued their BMP; the parents of 9 patients believed there should be better methods, such as operations and defecation training, that could allow their children to gain bowel control. About 4 (17%) and 4 (17%) of the parents commented that they are too busy and that the implementation of the program is complicated, respectively. Only 1 patient abandoned the program because of the high treatment fee (Fig. 2).

### 4. Discussion

This is the first study that illustrates the practice and outcomes of bowel care for pediatric FI in China. The most interesting result from our study is that even though the patients showed improvements in the quality of life and bowel care, ~50% discontinued the BMP, and most of them refused to undergo the Malone procedure to follow the program.

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**Table 3**

| Variables                        | PedsQL total score | Emotional function score | Social function score | School function score |
|----------------------------------|--------------------|--------------------------|-----------------------|----------------------|
| Cleveland FI score before treatment | −0.35†            | −0.15                    | −0.38‡                | −0.25                |
| Cleveland FI score after treatment | 0.04               | −0.24                    | 0.25                  | −0.01                |
| Change of Cleveland FI score     | −0.32†             | −0.42‡                   | −0.14                 | −0.09                |

† P < .05.
‡ P < .01.

FI = fecal incontinence; PedsQL = Pediatric Quality of Life Inventory.

*Change of Cleveland FI score = Cleveland FI score before treatment − Cleveland FI score after treatment.*

![Figure 1](image-url)
There are several therapeutic approaches to treat FI in China, including biofeedback, antegrade enema, sphincteroplasty, sphincter replacement, or colostomy, when all other treatment methods fail. Biofeedback is a noninvasive approach; however, its functional results are dubious in children. Surgical interventions, such as rebuilding or replacement of the anal sphincter, showed “good” results in 20% to 60% of the cases; however, the complication rates were high at 50% to 60%. With this, the Malone procedure may be considered one of the options for the treatment of FI. However, antegrade enema should be recommended only after proving that the bowel management has been successful. This enema requires only a different route; the key to its success depends on the enema formula and not the route.

The Cleveland score based on a questionnaire was lower in patients with better social continence. We decided to use the Cleveland score because it is easy to use and complete and can be useful in prospective studies. The adoption of the BMP in our study enabled a dramatic reduction in the FI after the BMP. The incontinence status of some patients who discontinued their BMP for various reasons was better than that of those who continued their BMP, possibly owing to an improvement in the bowel function using enema or bowel control with age. Further, the parents who participated in the program may have started these protocols to complete our diagnosis for appropriate treatments. Considering that it was conducted in a country with a population of more than 1 billion, the sample population of the study does not represent the general population. Besides, in future studies, age-matched healthy samples drawn from local populations would be optimal to allow for a more direct comparison between the population with FI and healthy control children.
5. Conclusions

In conclusion, this study demonstrates that the BMP can be successfully implemented in China, despite its limitations. It can significantly improve the quality of life for children with FI. However, great efforts are required to make the program acceptable to parents in China. As surgeons, we should explain the pathophysiological issues of the BMP patiently and in considerable detail to the families. Furthermore, the government should consider establishing an FI treatment center. Early interventions for FI can greatly improve the patient’s quality of life and reduce the psychological impact on children with FI.

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