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Use of the Anal Plug in the Treatment of Fecal Incontinence in Patients With Meningomyelocele

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Background: Children with meningomyelocele (MMC) commonly present with urinary and fecal incontinence. Despite bowel training and enemas, many still suffer from fecal soiling, which may cause skin irritation and malodor. Fear and embarrassment may cause some of these children to avoid partaking in social activities. The anal plug (AP), an anal tampon, has been developed to prevent fecal soiling. The purpose of this study was to evaluate the use of the AP in children with MMC with regard to reduction of fecal soiling and impact on social functioning. Methods: Twenty children and young adults with MMC, neurological level L_5 or proximal, participated in the study. Main outcome measures: Number of incidents of fecal soiling, degree of comfort of the accessory of choice, and impact of fecal soiling on social functioning were used as the main outcome measures for this study. Intervention: Each participant kept a daily diary reporting on each of the outcome measures over the course of 5 weeks. The first week, prior to intervention with the AP, was used as the base control for each patient. Over three sessions, the use of the AP was explained and demonstrated, after which it was given to the participants to be used. Results: Seventy-five percent of the participants completed the study. There was a significant improvement in all outcome parameters following the intervention. The median number of weekly incidents of soiling dropped from 4 to 0 (p = .002). The median reported effect of fecal soiling on social integration before the use of the AP was found to be *very bothersome,* whereas during the use of the AP, it was *barely bothersome* (p = .004). Conclusion: Use of the AP in children and young adults with MMC can prevent fecal soiling and promote "social continence."

Key words: Meningomyelocele; Fecal incontinence; Anal plug

FAILURE OF CLOSURE of the notochord during embryonic development results in spina bifida. Meningomyelocele (MMC), which involves the meninges and the spinal nerves, is the most severe form of the defect. MMC presents clinically with neurological impairment distal to the involved level, which, in most cases, is in the lumbar spine (Northup & Volick, 2000). The invariable results are paraplegia, loss of sensation, and incontinence (both fecal and urinary). Insertion of a ventriculoperitoneal shunt is necessary to treat the associated hydrocephalus caused by the presence of Arnold–Chiari malformation. Intelligence is normal in most cases, but many children have learning disabilities. The incidence of MMC in Israel is 2.7:10,000 among Jews and 6:10,000 among non-Jews (Ministry of Health, 2004).

More than 75% of patients with MMC have fecal incontinence (FI; Sanchez, Barrientos, Arrojo, & Vazquez, 1999), and achieving fecal continence and subsequent "social continence" is a major goal in the rehabilitation of these people. The continence nurse, a primary figure on the rehabilitation team, traditionally deals with bowel training, including dietary supervision. In many cases, despite all these, fecal soiling still occurs. Soiling may lead to skin irritation, malodor, and, in some instances, anger, depression, and a negative effect on the child's self-esteem. Embarrassment and fear of other peoples' reactions lead to withdrawal from social integration (Van Ginkel et al., 2000).

The anal plug (AP) was developed as a treatment modality for fecal soiling. The AP is a spongy

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tampon, which, when inserted into the rectum, expands, "plugs" the anal outlet, and prevents escape of feces. It can be left in situ for up to 12 hours at a time while the patient continues normal activity, including swimming. The AP cannot be used for more than 12 hours a day.

A limited number of studies on the AP have been published. Mostly, they report on the use of the AP in adults with FI as a result of a variety of pathologies, all with intact rectal sensation. It was found that the AP prevented fecal soiling in 50–64% of the cases. However, 70–80% of the participants complained of discomfort and did not agree to continued use of the AP (Christiansen & Roed-Petersen, 1993; Norton & Kamm, 2001). Sanchez et al. (1999) studied the use of the AP in 19 children with MMC. They found the AP to be useful in preventing fecal soiling, and more than 90% of the participants showed interest in continuing its use. Pain or discomfort was not an issue in this population.

Children and adolescents with MMC are managed in Alyn Hospital's Continence Clinic, which is supervised by a trained continence nurse. The purpose of this study was to evaluate the efficacy of the AP in preventing fecal soiling and thereby the impact of its use on the social functioning of patients with MMC treated in Alyn.

METHODS

Study Design

This study is a self-controlled clinical trial involving a convenience sample.

Population

The study included 20 children, adolescents, and young adults treated in Alyn Hospital's Spina Bifida Clinic. All participants have FI. The participants with rectal prolapse, hemorrhoids, or persistent rectal bleeding were excluded. Informed consent was obtained from each subject or from his or her legal guardian; this study was authorized by the Helsinki Committee.

Data Collection

The weekly number of incidents of fecal soiling and individual coping strategy (use of a sanitary napkin, a diaper, or, eventually, APs) and the degree of comfort of the chosen device were chosen as the main outcome measures for this study.

The first visit began with an explanation of the study's purpose and what will be expected from each participant. Baseline information regarding incidence of fecal soiling, coping strategies, and FI's impact on social functioning was gathered after the participants gave their consent to participate. Participants were then asked to keep a daily record of which device was used, how often it was replaced, the reason for its replacement, and the degree of comfort of their chosen device. Each participant was also asked to describe and rate on a scale of 0 to 4 (0 = *not bothersome*, 1 = *barely bothersome*, 2 = *somewhat bothersome*, 3 = *bothersome*, 4 = *very bothersome*) the effect of FI on general social functioning and on two personally chosen aspects of daily life. Each participant was asked to return after 1 week. At the beginning of the second session, the information collected during the control session was reviewed for accuracy. The AP was then demonstrated and explained, and the participants were taught how to use it. After insertion, they were asked to remain in the vicinity to check for discomfort or expulsion of the device. Reinstruction was given where necessary. Participants were equipped with 10 APs and asked to return after 1 week's use while continuing to maintain a record as in the previous week. The third session consisted of reviewing the events of the past week, reinforcing information regarding the use of the AP, supplying 20 more APs, and asking the participants to return 3 weeks later while continuing to keep a record of events. In the fourth and final session, the participants brought their records of events of the previous 3 weeks. Participants were asked to continue their routine lifestyle throughout the entire study.

Data Analysis

The description of the study sample was performed using mean, median, and range for continuous variables and frequency and percentage for categorical variables. Differences in outcome variables (before and after the program) were tested using the Wilcoxon signed rank test. p values $<.05$ were considered statistically significant. All analyses were carried out with the SPSS-12 program for Windows.

RESULTS

The average age of the participants (8 males and 12 females) of this study was 12 years (range = 4–29 years), with a median neurological level of L_3 (range = T_4–L_5). Before trying the AP, 17 (85%) of the participants used diapers, and the rest used sanitary napkins. At the baseline interview, 50% of the subjects replied that FI "severely impeded" their

daily life. Only one subject replied that FI "only slightly" impeded daily life. Before intervention, the median number of weekly incidents of fecal soiling was 4 (range = 0–28; one child had no incident of fecal soiling during the week prior to the interview but is known to occasionally suffer from fecal soiling). Seventy-five percent of the participants completed the study. After intervention with the AP, all of the participants reported that FI only slightly or "does not" impede daily life. The median number of weekly incidents of fecal soiling was reduced to 0 (range = 0–8), all occurring during hours the AP was not in use (Table 1).

A significant improvement was found in all of the outcome measures. At baseline, only 66% of the participants reported that the accessory they were using was comfortable. After intervention, 98% found their accessory, the AP, comfortable (p = .001), and the median number of weekly soiling incidents dropped from 4 to 0 (p = .002). Nine participants reported that FI does not interfere with their chosen aspect of life (school, swimming, family events, etc.), eight participants reported that FI only slightly interferes (p = .004), and all participants reported that the level of interference with their daily life was significantly reduced (p = .001). There were no complications or adverse side effects reported due to the use of the AP (Table 2).

DISCUSSION

A median of 4 weekly soiling episodes was reported at the beginning of the study, with

Table 1. Study Population: Demographics, Neurological Level, and Outcome Measures Before and After Intervention

			Before Intervention			After Intervention	
Age (years) *	Gender †	Neurological Impairment Level ‡	Number of Weekly Soiling Incidents §	Effect on Chosen Aspect of Daily Life ‖	Use of AP ¶	Number of Weekly Soiling Incidents #	Effect of FI on Chosen Aspect of Daily Life **
29	Male	L_4	0	3	No (due to discomfort)		
28	Female	L_3	0	2	No (due to discomfort)		
26	Female	T_8	0	4	Yes	0	1
24	Female	T_8	13	3	No (due to behavioral problems)		
20	Female	L_3	7	4	Yes	4	0
17	Female	T_8	3	3	Yes	0	0
13	Female	T_{12}	2	1	Yes	0	0
13	Male	T_4	3	4	No (due to device expulsion)		
11	Female	T_3	1	4	Yes	0	1
10	Female	L_1	10	4	Yes	5	1
9	Female	T_6	5	4	Yes	0	1
9	Female	L_4	6	4	Yes	1	0
8	Female	T_{12}	4	4	Yes	0	0
8	Male	L_3	2		Yes	0	1
8	Female	L_2	0	4	Yes	0	0
7	Male	L_2	28	4	Yes	8	1
6	Male	L_3	8	2	Yes	0	1
5	Male	L_1	0	2	Yes	0	1
5	Male	L_5	15	3	No (due to device expulsion)		
4	Male	L_3	11	3	Yes	3	0

* $M \pm SD = 13.5 \pm 8$ years.

** Mode 1 = *barely bothersome.*

† Forty percent were male.

‡ *Mdn* = L_3; range = T_4–L_5.

§ $M \pm SD = 7 \pm 7$.

¶ Seventy-five percent of the patients used an AP.

‖ Mode 4 = *very bothersome.*

\# $M \pm SD = 1.5 \pm 2.7$.

Table 2. Outcome Measures Before and After Intervention

	Before Intervention (Diaper/Pad)	After Intervention (AP)	p *
Weekly soiling incidents	4 (0–28)	0 (0–8)	.002
Effect of FI on chosen aspect of daily life	4 (1–4)	1 (0–1)	.004
General effect of FI on daily life	2 (0–4)	0 (0–2)	.001

Note. Values are expressed as median (range).
* Wilcoxon signed rank test.

more than 50% of the participants reporting that their daily life was severely impeded. Use of the AP significantly lowered the incidence of soiling episodes and the negative impact of soiling on daily life. These findings were similar to those reported in the study by Krogh, Lie, Bilenberg, and Laurberg (2003) of children with MMC and in other studies of patients with FI (Rothbarth et al., 2001; Thornton, Kennedy, Lubowski, & King, 2004).

In an effort to improve social functioning and quality of life of children with MMC and FI, medical caregivers search for innovative solutions while patients are usually willing to try new devices. Compliance and willingness to use the AP were lower in most of the published studies as compared with our study. Norton and Kamm (2001) reported a compliance rate of only 20%; Pfrommer, Holschneider, Loffler, Schauff, and Ure (2000) reported a rate of 60%; and Christiansen and Roed-Petersen (1993) showed a rate of 56%, whereas 71% of the subjects reported discomfort during use. Discomfort or pain was the main reason for not wanting to continue the use of the AP. As anticipated, discomfort or pain during the use of the AP was not an issue in most of our subjects because all subjects were insensate to level L_5 at least. However, two of the five subjects who dropped out of the study cited discomfort as the reason; this occurred in the study performed by Sanchez et al. (1999) as well. Three other subjects dropped out of the study for other reasons: one female has behavioral problems, and the other two were not able to use the AP because they were not compliant with their bowel training regimen and had uncontrolled bowel movements that caused expulsion of the device. The option of future use of the AP encouraged the parents of the latter two children to try to adhere more closely to their prescribed regimen.

Both of the subjects citing discomfort as their reason for leaving the study were older than 18 years, with neurological levels similar to the younger children. We do not know if their discomfort was genuine or just an excuse to avoid trying a new device. We suggest that exposure to the AP at an early age may ensure continued use as an adult.

Rate of soiling incidents was significantly reduced by using the AP. This is similar to the findings in some literature (Kim et al., 2001; Mortensen & Humphreys, 1991; Norton & Kamm, 2001; Pfrommer et al., 2000). It seems that the AP prevents fecal soiling regardless of age or underlying pathology.

The negative impact of FI on daily life was significantly changed by lowering the incidence of soiling episodes. The AP has been described as a useful modality in reducing the worry and fear associated with soiling incidents during social integration. Christiansen and Roed-Petersen (1993) reported that some patients with sensation will use the AP on special occasions but not during their daily routine due to discomfort. The high compliance rate in our population is probably due to the fact that because the patients are insensate, they do not experience discomfort.

SUMMARY

The AP is a useful aid in achieving social continence by reducing or even abolishing fecal soiling throughout most of the day. Although "accidents" may still occur, this modality should be offered to young patients with MMC as part of their continence program.

REFERENCES

Christiansen, J., & Roed-Petersen, K. (1993). Clinical assessment of the anal continence plug. *Diseases of the Colon and Rectum*, *36*, 740−742.

Kim, J., Shim, M. C., Choi, B. Y., Ahn, S. H., Jang, S. H., & Shin, H. J. (2001). Clinical application of continent anal plug in bedridden patients with intractable diarrhea. *Diseases of the Colon and Rectum*, *44*, 1162−1167.

Krogh, K., Lie, H. R., Bilenberg, N., & Laurberg, S. (2003). Bowel function in Danish children with myelomeningocele. *APMIS Supplementum*, *109*, 81−85.

Ministry of Health Israel, the genetic community section (2004). Incidence of Spinal Cord Defects in Israel 2003. Retrieved September 2005 from, http://www.health.gov.il/download/forms/a2749_summary_2004ntd.pdf.

Mortensen, N., & Humphreys, M. S. (1991). The anal continence plug: A disposable device for patients with anorectal incontinence. *Lancet*, *338*, 295−297.

Northup, H., & Volick, K. A. (2000). Spina bifida and other neural tube defects. *Current Problems in Pediatrics*, *30*, 317−332.

Norton, C., & Kamm, M. A. (2001). Anal plug for faecal incontinence. *Colorectal Disease*, *3*, 323−327.

Pfrommer, W., Holschneider, A. M., Loffler, N., Schauff, B., & Ure, B. M. (2000). A new polyurethane anal plug in the treatment of incontinence after anal atresia repair. *European Journal of Pediatric Surgery*, *10*, 186−190.

Rothbarth, J., Bemelman, W. A., Meijerink, W. J., Stiggelbout, A. M., Zwinderman, A. H., Buyze-Westerweel, M. E., et al. (2001). What is the impact of fecal incontinence on quality of life? *Diseases of the Colon and Rectum*, *44*, 67−71.

Sanchez, M. R., Barrientos, F. G., Arrojo, V. F., & Vazquez, E. J. J. (1999). The anal plug in the treatment of fecal incontinence in myelomeningocele patients: Results of the first clinical trial. *Anales Españoles de Pediatría*, *51*, 489−492.

Thornton, M. J., Kennedy, M. L., Lubowski, D. Z., & King, D. W. (2004). Long-term follow-up of dynamic graciloplasty for faecal incontinence. *Colorectal Disease*, *6*, 470−476.

Van Ginkel, R., Benninga, M. A., Blommaart, P. J., Van der Plas, R. N., Boeckxstaens, G. E., & Buller, H. A. (2000). Lack of benefit of laxatives as adjunctive therapy for functional nonretentive fecal soiling in children. *Jornal de Pediatria*, *137*, 808−813.