

A Comparison of the Effectiveness of Therevac SBTM and Bisacodyl Suppositories in SCI Patients' Bowel Programs

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This evaluation was designed to explore the cost-effectiveness of bisacodyl vs. the docusate mini-enema.

The evaluation described in this article compared the Therevac SBTM "mini-enema" with bisacodyl suppositories in the bowel management programs of patients with spinal cord injury (SCI). Of particular interest were (a) determining whether the additional costs of Therevac SB could be justified and (b) identifying the degree of bowel program improvement possible. Fourteen SCI patients were selected from the SCI inpatient unit and the clinic of a Department of Veterans Affairs facility. All patients experienced a delay of at least 45 minutes between insertion of a suppository and the beginning of stool evacuation. Each patient used bisacodyl suppositories for five bowel programs, then Therevac SB for five programs, finally repeating the bisacodyl suppositories for five more programs. Each patient maintained a bowel program log. Ten patients completed the evaluation. Using a MANOVA, the authors found a significant difference between bisacodyl and Therevac SB mean evacuation times for this group. An analysis of direct and indirect costs related to bowel care with the two regimens is also presented.

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Following spinal cord injury (SCI), the most important changes in gastrointestinal functioning are loss of voluntary defecation and changes in autonomic control over bowel activity (Cosman, Stone, & Perikash, 1993; Weingarden, 1992). The level of injury and its completeness are both factors in the degree of any types of changes seen. Bowel transit time is increased by 24 hours to 48 hours in most patients with SCI (Menardo et al., 1984; Nino-Murcia, Stone, Chang, & Perikash, 1990).

Establishing and maintaining a functional bowel program is one of the major challenges faced by people with SCI. The goals of an effective bowel program are to (a) regulate bowel movements to ensure adequate evacuation on a consistent basis; (b) avoid bowel accidents; and (c) prevent constipation, impactions, or diarrhea (Zejdlík, 1992). Finding the right combination of oral medication, diet, suppositories, and techniques (such as digital stimulation) for an individual patient can take weeks or even months. The rehabilitation nurse is the person these clients most commonly trust as a resource regarding bowel management. Most people with SCI are able to manage well with a combination of diet, special techniques, timing, and the use of rectal suppositories.

Many bowel management regimens are based on trial and error, tradition, or an individual nurse's experience. While many journal articles and texts describe appropriate bowel care management (Buchanan & Nawoczinski, 1987; Emerick, 1979; Martin, Holt, & Hicks, 1981; Zedjlik, 1992), the lack of published research literature prevents the use of scientifically validated interventions for these patients. Only one research article about Therevac SB (Brier & Benedict, 1986)—a 4-cc "mini-enema" manufactured by Jones Medical Industries, Inc. (St. Louis, MO)—could be found in the literature.



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Intended audience

This independent study offering is appropriate for all rehabilitation nurses.

Objectives

By reading this article, the learner will achieve the following objectives:

1. Describe study findings comparing the effectiveness of Therevac SBTM and bisacodyl suppositories in bowel management programs for patients with spinal cord injury (SCI).
2. Discuss the study's limitations and related implications.

Table 1. Patient Demographics (N = 14)

Patient	Level/ Frankel Grade	Age	Years Since Injury	Sex
1	T12-L1 B	49	33	M
2	C6 B	27	2	M
3	T10 B	36	2	M
4	C6-7 A	45	24	M
5	T5 A	44	22	M
6	T6 A	50	11	M
7	T6 A	47	25	M
8	T10 D	49	27	M
9	T5 A	36	3	M
10	C5 A	37	15	M
11	T5 A	67	38	M
12	C5 A	50	26	M
13	T10 A	45	11	F
14	C6-7 B	62	27	M
Mean		46	19	

Most of the patients with SCI who receive health care under the aegis of the San Diego Veterans Affairs Medical Center (SDVAMC) use bisacodyl suppositories with good results. However, there remains a subgroup of patients who have ongoing difficulties that have not been resolved with the usual rehabilitation nursing interventions. This group has been described as making up 20% of the SCI population (Stone, Nino-Murcia, Wolfe, & Perlash, 1990). These patients tend to have characteristic problems with bowel management: (a) a delay of at least 45 minutes between the insertion of a suppository and the beginning of bowel evacuation; (b) production of excessive mucus, often hours after the bowel program; (c) frequent bowel accidents; (d) cramping, exhaustion after bowel care, or both; and (e) symptoms of autonomic dysreflexia that are associated with bowel management.

The purpose of the evaluation

We were interested in trying different bowel care products with this subgroup of patients with SCI to give them the further assistance they needed to establish a successful bowel management program. Some of the patients who had received care at other facilities reported that they experienced fewer bowel problems using Therevac SB. They reported shorter evacuation times, better rates of complete emptying, and fewer bowel accidents later in the day.

Therevac SB: Therevac SB is a combination of liquid docusate sodium (283 mg) and glycerine (275 mg) in a liquid soft-soap base (polyethylene glycol). The product is supplied in a

soft plastic ampule with an insertion nipple. The tip of the nipple must be cut off, the nipple inserted into the rectum, and the contents squeezed out. Due to its liquid form, Therevac SB's manufacturers claim, the product works faster and provides more rectal lubrication than suppository products.

After investigating Therevac SB, we had some concern about its expense as compared to that of bisacodyl suppositories. As Therevac SB was not on the SDVAMC-approved formulary, we proposed to the pharmacy and therapeutics committee that Therevac SB be evaluated to provide data on its cost-effectiveness compared with that of generic bisacodyl suppositories in bowel management programs for SCI patients who had problems with bowel management. The clinical comparison was approved by the pharmacy and therapeutics committee, and free samples were obtained from the manufacturer.

Evaluation protocol

Patients: Patients were selected from both the inpatient and the outpatient populations treated at the SDVAMC Spinal Cord Injury Center between December 1992 and July 1993. We screened patients during clinic visits and on rounds and received referrals from other SCI team members. A patient was eligible for the evaluation if he or she (a) experienced a delay of 45 minutes or longer from the time of insertion of the bisacodyl suppository to the beginning of evacuation, (b) had tried all traditional interventions (e.g., timing, diet, techniques, other medications) to improve bowel management without success, (c) was dissatisfied with his or her current bowel care regimen, (d) was able to follow directions for the evaluation and accurately complete the study log, and (e) agreed to make no other changes in his or her bowel management program during the study. If patients met the inclusion criteria, they were invited to participate. No attempt was made to limit patients on the basis of injury level, completeness of injury, or time since injury.

An article informing members about the evaluation was published in the newsletter of the Cal-Diego Chapter of the Paralyzed Veterans of America. In addition, a poster informing patients about the evaluation was placed in the SCI outpatient clinic area of the SDVAMC. Several patients were recruited by word of mouth from patients already using the evaluation protocol. Physicians' orders were obtained for Therevac SB, and the patients were provided with a supply of the donated product through the pharmacy. Fourteen patients participated in the evaluation (see Table 1).

Data collection: A log was designed by the investigators to collect information regarding bowel management for each bowel program. The log included a section for each of the 15 bowel programs in the evaluation as well as for an overall subjective evaluation of the results. Information on the time of insertion of the rectal medication, time of first evacuation, time required to complete the first evacuation, other interventions used, and bowel problems between bowel programs was collected; comments also were collected.

Patients were instructed to continue their usual bowel man-

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agement regimen and techniques during the study. They were also requested to continue the same diet and to refrain from changing any other medications during the study without notifying the investigators. Patients were instructed about accurately recording information in the log. The log was reviewed with the patients before the start of the study by one of the authors; patients also were given a completed sample log to use as a guide. Patients were told to wear a watch or have a clock in view while performing their bowel program so that they could record times accurately. Each patient was asked to continue using bisacodyl suppositories for five bowel programs so that baseline data could be gathered. They then used Therevac SB for five more bowel programs, recording the same type of data in the log. Finally, they recorded five more bowel programs using the bisacodyl suppositories to attempt to eliminate the effect of any change alone or a "drug rest" effect. Patients were asked to notify us immediately if they had an excessive number of bowel accidents, constipation, or other problems during the course of the study. At the completion of the evaluation, patients returned their logs directly to us. Patients were identified on their logs only by code numbers.

Outcomes

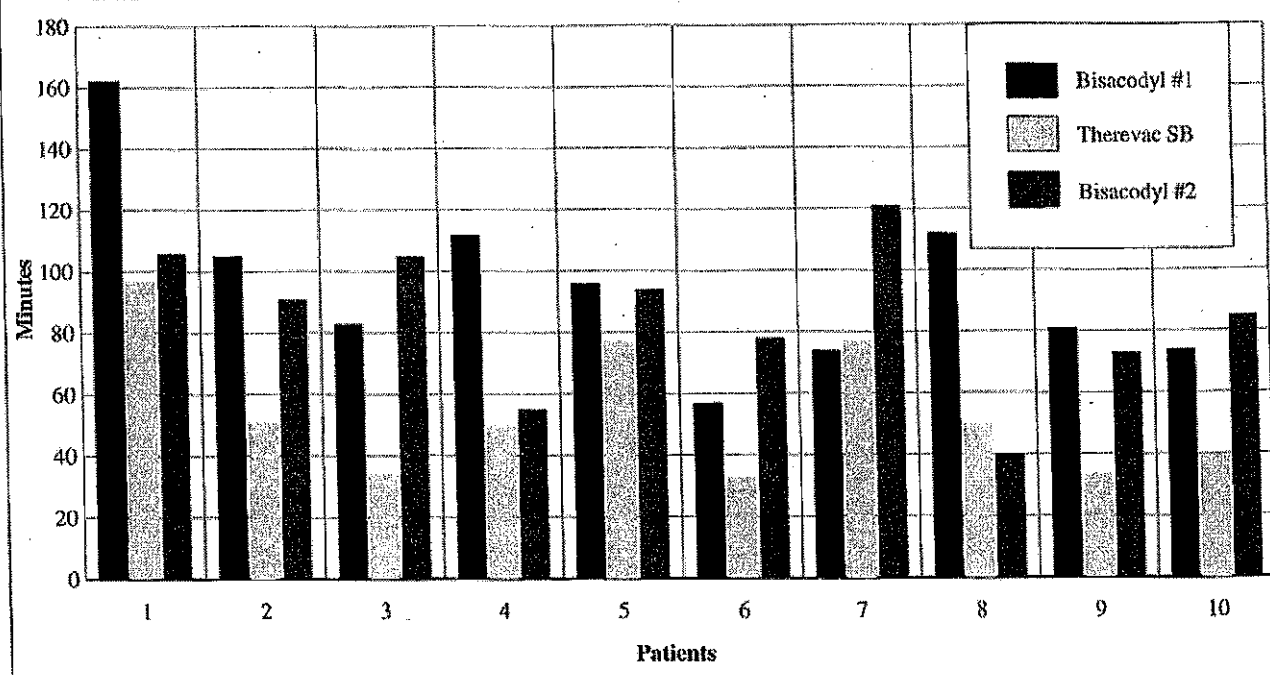
Ten patients (group A) completed all components of the evaluation. Comments were generally positive, and several patients

reported that they experienced less need for extensive digital stimulation while using Therevac SB. Four patients (group B) withdrew during the evaluation due to problems discussed below.

Group A: The mean time in minutes required for complete bowel evacuation for each group A subject was obtained for each of the three phases of the evaluation (see Figure 1). Using a MANOVA test, we found the reduction in mean evacuation times with Therevac SB compared to the mean times with the bisacodyl interventions to be significant ($p < .001$). A Tukey post hoc test was used to analyze the difference between the interventions. There was a significant ($p < .01$) reduction in mean evacuation time with the Therevac SB intervention compared to the mean time with both of the bisacodyl interventions. There was no significant difference in evacuation time between the first and second bisacodyl interventions. The number of patients was insufficient to warrant data analysis on the basis of level of injury, degree of completeness, or time since injury. No females completed the evaluation.

Group B: For the four patients who did not complete the evaluation due to complications (group B), means were obtained for completed data as above (see Figure 2). Patient 11 appeared to have faster results with Therevac SB but chose not to complete the Therevac intervention and dropped out. Patient 12 reported that Therevac SB worked much more slowly than the

Figure 1: Mean Evacuation Times for Group A Subjects



bisacodyl and had two bowel programs with this product with no results at all, which led him to drop out of the evaluation at our suggestion. He also tried the Magic Bullet™ bisacodyl suppository (manufactured by Concepts in Confidence, Commack, NY), which he prefers, but is also considering a colostomy. Patient 13 dropped out after reporting that Therevac SB worked more quickly but was "too strong" and gave her the sensation of bowel cramping for several hours after bowel care. Patient 14 reported that he did not think Therevac SB worked well for him and did not complete the evaluation after using the product. He has since had a colostomy with good results.

Limitations

The small number of patients we evaluated limited the generalizability of the results. In addition, due to the methods we used for patient selection, the patient group was not representative of the total SCI population seen at SDVAMC or in general (as explained earlier). The small number of patients also prevented analysis of outcomes based on other factors such as gender, level and completeness of injury, age, time since injury, or other medications used. There were no newly injured patients in this evaluation, although, in our experience, prolonged bowel care time less often tends to be a problem for the patient who has been injured for only a few months or years. It also

was not possible to control all bowel care interventions by standardizing programs, as subjects already had established a combination of medications and techniques that seemed to work for them. The Therevac SB intervention was used for only five bowel programs, which resulted in the intervention's being applied over a period ranging from only 5 to a maximum of 15 days for each subject. A longer period of using Therevac SB might better indicate if the reduction in bowel care time can be sustained. Due to a very low number of females in the SCI population at SDVAMC, only 1 woman participated in this evaluation. Therefore, no conclusions can be drawn about bowel management in female patients with SCI, but we wanted to make sure that women were represented in the study.

Impact on practice

We presented the results of this evaluation to the SDVAMC Pharmacy and Therapeutics Committee. The committee then added Therevac SB to the hospital formulary for select patients with SCI who (a) experience a delay of at least 45 minutes between insertion of a bisacodyl suppository and a bowel evacuation, (b) have used other appropriate bowel interventions that have resulted in no significant reduction in bowel care time, and (c) have either the ability to manipulate Therevac SB physically or a caregiver's assistance for bowel care.

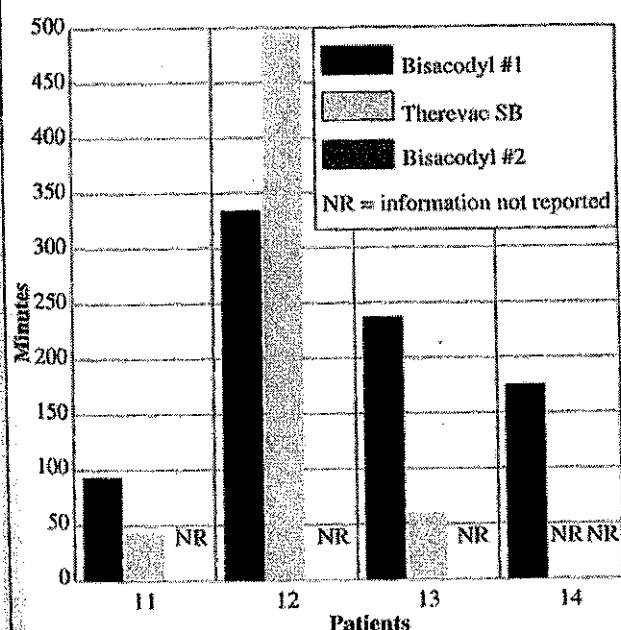
An additional consideration is that initial prescriptions of Therevac SB are good for only 30 days, and no refills are permitted. After this initial trial period, the patient must be evaluated by the SCI clinic nurse coordinator or the SCI clinical nurse specialist. If Therevac SB appears to have significantly reduced bowel care time without untoward complications, the nurse—in collaboration with the pharmacist and physician—then approves the continuation of a Therevac SB prescription thereafter. Patients who do not fit the criteria but prefer Therevac SB must obtain it over the counter at their own expense from a source other than the DVAMC.

Cost analysis

The SDVAMC provides all medications and supplies for SCI inpatients and outpatients. Therefore, we and the members of the pharmacy and therapeutics committee were concerned about the difference between the cost of the two products. Currently, the SDVAMC purchases generic bisacodyl suppositories on contract for \$0.027 each. The annual cost of bisacodyl suppositories for a single patient on an every-other-day program is, thus, only \$4.92. Therevac SB is not purchased on contract; it sells for \$1.18 each. Use of Therevac SB on an every-other-day program would result in an annual cost of \$215.94 per patient—a difference of more than \$200 per year. Currently, an estimated 20 patients actively followed by the SCI center would meet the criteria for using Therevac SB. This would increase the cost to the SDVAMC by \$4,220 annually.

Benefits of using Therevac SB: However, although the direct cost of Therevac SB is significantly higher, the potential indirect cost savings for some patients could also be significant.

Figure 2. Mean Evacuation Times for Group B Subjects



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This evaluation showed that some of these patients reduced the time needed for bowel care by 1 hour or more daily. Using a conservative figure of \$6 per hour for care provided by a private personal care attendant, we estimate that this could result in an annual savings to the patient of approximately \$1,095.

Several subjects reported feeling less fatigued after bowel care when using Therevac SB. This could mean that patients using this evacuation method would have extra time for productive activities such as attending school, participating in family activities, or performing work or volunteer activities.

The reduced time spent sitting on a commode may reduce the risk of pelvic pressure ulcer development. Studies report that the total direct cost of a surgically treated pressure ulcer can exceed \$54,000 (Robinson, Coghlan, & Jackson, 1978).

Finally, SCI clinic and SCI home care nurses spend a significant amount of time in clinic and home visits and phone calls attempting to resolve bowel program problems for this small subgroup of SCI patients. Nursing care time spent on inpatient bowel care for this group is also significantly increased. Often, prolonged bowel care time or fatigue after bowel care interferes with a patient's participation in therapy activities and can increase his or her length of stay.

Summary

This evaluation was designed to explore the cost-effectiveness of only one bowel intervention. There is no single bowel product that will work for all SCI patients; frequently, trial and error with different products is necessary to find one that works for a specific patient. Most of these products or interventions have not been explored scientifically. Research is needed on the systematic evaluation of different medications, techniques, and interventions used in bowel management with the SCI population. Collaborative studies with physicians and pharmacists would be helpful in evaluating and comparing the many prescription and over-the-counter products used by patients with SCI. Collaboration with dietitians would be helpful in evaluating the effects of diet, especially on long-term patients with SCI. An important area needing investigation is the effect that different medications or other interventions may have on bowel function as the spinal cord injured person ages. This general area of study is important for rehabilitation nurses because they must base their practice on research as well as experience to be seen as credible by patients and by other providers.

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