

Pharmacologically Initiated Defecation for Persons With Spinal Cord Injury: Effectiveness of Three Agents

J. Glen House, MD, Steven A. Stiens, MD

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Objective: To compare the effectiveness of hydrogenated vegetable oil-based bisacodyl (HVB) suppositories, polyethylene glycol-based bisacodyl (PGB) suppositories, and polyethylene glycol-based, glycerine, docusate sodium mini-enemas (TVC) in subjects with upper motor neuron spinal cord lesions.

Study Design: Prospective randomized double blind. Fifteen subjects received one of 3 HVB and 3 PGB suppositories in randomized sequence for each of six scheduled bowel care sessions. Additionally, 10 subjects received 3 TVC. The analysis used timed events that divided the bowel care sessions into discrete intervals. The analysis also compared digital simulations, incontinence, and quantity of stool. Wilcoxon rank sum tests and paired *t* tests were used to compare the means of intervals during bowel care initiated by HVB, PGB, and TVC.

Results: (means in minutes and *p* values): *Time to Flatus*—HVB, 32; PGB, 15; TVC, 15; *p* < .026, HVB-PGB; *p* < .983, PGB-TVC; *Flatus to Stool Flow*—HVB, 6.7; PGB, 5.5; TVC, 3.9; *p* < .672, HVB-PGB; *p* < .068, PGB-TVC; *Defecation Period*—HVB, 36; PGB, 20; TVC, 17; *p* < .037, HVB-PGB; *p* < .479, PGB-TVC; *Wait Until Transfer*—HVB, 10.9; PGB, 10.7; TVC, 7.4; *p* < .932, HVB-PGB; *p* < .043, PGB-TVC; *Total Time for the bowel program*—HVB, 74.5; PGB, 43; TVC, 37; *p* < .010, HVB-PGB; *p* < .458, PGB-TVC; percent incidence of incontinence between bowel care sessions—HVB, .067; PGB, .067; TVC, .033; *p* < 1.0, HVB-PGB; *p* < .678, PGB-TVC; *amount of stool produced*—HVB, 3.30; PGB, 3.49; TVC, 3.38; *p* < .276, HVB-PGB; *p* < .630, PGB-TVC; average number of digital stimulations per bowel care procedure—HVB, 4.4; PGB, 4.1; TVC, 3.8; *p* < .411, HVB-PGB; *p* < .293, PGB-TVC; time per digital stimulation in seconds—HVB, 107; PGB, 40; TVC, 83; *p* < .149, HVB-PGB; *p* < .352, PGB-TVC; and the total time, in minutes, spent performing digital stimulations during bowel care—HVB, 10.0; PGB, 2.7; TVC, 5.9; *p* < .151, HVB-PGB; *p* < .325, PGB-TVC.

Conclusion: Bowel care took less time when initiated with the PGB bisacodyl suppository or TVC mini-enema as compared with the HVB bisacodyl suppository (*p* < .01).

This is a US government work. There are no restrictions on its use.

From the Department of Physical Medicine and Rehabilitation, Baylor College of Medicine, Houston, TX, and University of Washington School of Medicine, Seattle (Dr. House); and the Spinal Cord Injury Unit, Veterans Administration Puget Sound Health Care System, Seattle Division, and Department of Rehabilitation Medicine, University of Washington, Seattle (Dr. Stiens).

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Reprint requests to Steven A. Stiens MD, MS, Mail Location 356490, Health Sciences Building BB938, 1959 NE Pacific, Seattle, WA 98195.

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SPINAL CORD INJURY (SCI) results in many impairments that profoundly affect a person's life. Neurogenic bowel dysfunction is one of the most significant complications that affects the quality of life.¹ Furthermore, bowel care often occupies a relatively large portion of the day for a person with SCI.^{2,3}

More than 20% of persons with SCI report difficulty with evacuation of their bowels. Bowel care procedures can require up to 3 hours for completion, and still yield insufficient results.^{2,4} Complications related to bowel dysfunction can lead to patient morbidity and require surgical intervention.⁴ Fecal impaction is the most common colonic complication after SCI, but complications also include intractable constipation and overflow incontinence.⁵ Bowel dysfunction continues to be a major cause of autonomic dysreflexia after SCI. Chronic complications, such as diverticuli, develop more rapidly after SCI but rarely occur before 5 years after injury and are assumed to be acquired.^{2,5,6} It has been suggested that appropriate bowel program management to prevent chronic rectal overdistention may postpone or prevent these complications.⁷

After SCI, volitional defecation is disrupted, and a bowel program that includes scheduled bowel care sessions is often required to achieve predictable defecation, continence of stool, and prevention of complications.^{7,8} Several techniques are used to initiate defecation,⁹ such as rectal insertion of suppositories, mini-enemas, enemas, and digital stimulation.

Individuals with SCI occasionally attempt to augment their bowel programs with laxatives. Oral laxatives have been categorized into four groups: dietary fiber and bulking agents, osmotic laxatives, stimulant laxatives, and stool softeners. Bulking agents (bran, wheat husk, etc) cause fluid retention within the colon and increase bulk and stool softness, leading to facilitated intestinal transit. Osmotic laxatives (mannitol, sorbitol, lactulose, magnesium citrate) retain water in the feces to produce a consistency that facilitates transit. Stimulant laxatives (bisacodyl, phenolphthalein, glycerol) act at the intestinal mucosa and stimulate intestinal motility, which decreases the time available for salt and water absorption, further decreasing transit time. Stool softeners (docusate sodium, etc) directly decrease stool firmness, reducing constipation.¹⁰

Suppositories frequently contain a contact stimulant laxative and are administered to enhance colonic peristalsis.¹¹ Currently, bisacodyl is the active ingredient most commonly used in bowel evacuation suppositories. Bisacodyl (bis (p-acetoxyphenyl)-2-pyridyl-methane), is a compound that is practically insoluble in water and alkaline solutions. This agent is very poorly absorbed by the colon and acts directly at the mucosa to stimulate the sensory nerves, producing a parasympathetic reflex response of increased peristaltic contractions throughout the large intestine.¹² A rectally-administered water suspension of bisacodyl produces increased peristaltic activity within 3 minutes.¹³ Bisacodyl also stimulates fluid and electrolyte accumulation within the colon, adding to the laxative effects.¹⁴

The most commonly used laxative suppositories contain 10mg bisacodyl powder distributed within a hydrogenated vegetable-oil base (HVB).¹⁴ A considerably long waiting period has been observed after rectal insertion of the HVB suppository until initial results of flatus and first stool flow.¹¹ Studies have

found that up to 20% of patients require at least 45 minutes from HVB suppository insertion to first stool flow and may experience excessive mucus production after the completion of the bowel care, as well as stool incontinence.¹⁵ A water-miscible, bisacodyl-containing suppository compounded with a polyethylene glycol base (PGB) that has recently become available has been anecdotally reported to decrease overall bowel care time.¹⁶ Previously, a single subject study completed at this institution¹¹ and an unblinded trial at the Tampa (FL) Veteran's Medical Center¹⁷ suggested a clinically significant decrease in bowel care time using the PGB suppository.

Mini-enemas are an increasingly popular method of administration of stimulant laxatives for the initiation of bowel care. The Theravac SB mini-enema (TVC) is a small soft plastic ampule with a 3cm extended tip that is inserted into the rectum after its distal end is cut off or punctured; the bulb is squeezed and the contents enter the rectum, acting on the mucosa as a surface stimulant within minutes. TVC contains a 4mL liquid combination of glycerine (275mg) and docusate sodium (283mg) in a polyethylene glycol base.

This randomized, prospective, double-blind study was designed to compare the effectiveness of bowel care using bisacodyl suppositories compounded with HVB and PGB. Additionally, the PGB suppository and the TVC mini-enema were compared independently.

METHOD

The study design and objectives were approved by the Intra-departmental Scientific Merit Review and University Human Subjects Committees. Subjects were recruited from an inpatient SCI unit at a VA Health Care System Division, and participated after signed consent. Inclusion criteria included: 3 months or longer since the SCI, spinal cord lesions above the 12th thoracic neurological level, lack of anal sensation, lack of voluntary anal sphincter contraction, a stable bowel program with pharmacologically-triggered bowel care, and the absence of known gastrointestinal disease. Subject history was reviewed for consistency in bowel care. Chart review identified lesion level, sensory and motor performance, anal cutaneous reflex, bulbocavernosus reflex, and lower extremity phasic stretch reflexes.

The two types of bisacodyl suppositories used in the study differed only in the base used for dispersion of the active ingredient. The HVB suppositories¹⁸ contained 10mg bisacodyl USP in a hydrogenated vegetable-oil base. The PGB suppositories⁹ contained 10mg bisacodyl dissolved in a mixed polyethylene glycol polymer base of two molecular weights: E1450 and E400.

A randomized, prospective, double-blind study was implemented. Each subject was designated a previously determined randomized sequence of six suppositories to study three HVB and three PGB suppositories known only to the pharmacy. Time events and data were collected for three bowel care sessions in 10 subjects, who normally use Theravac SB mini-enema,¹⁹ after completing the suppository study.

The investigators, nurses, and subjects were unaware of each individual's randomized sequence. Pharmacy personnel possessed the only suppository randomization sequence and dispensed the subject's predetermined suppository blindly to the nursing staff. The nurses then administered the suppository to the subject and recorded timed bowel care events (table 1).¹¹

Bowel care was performed using a consistent protocol. Subjects were either seated upright or lying on their side (left or right specified) during the bowel program. This position remained unchanged for each subject throughout the study and was consistent with their usual bowel care position. At the time of each regularly scheduled bowel care session, either a 10mg

Table 1: Time Intervals and Events of Bowel Care

Events	Intervals
Suppository Insertion	Time to Flatus
First Flatus	Flatus to Stool Flow
Begin Stool Flow	Defecation Period
End Stool Flow	Wait Until Transfer
Transfer Off Toilet	

HVB or 10mg PGB suppository was inserted half a finger's length through the anal sphincter and placed against the mucosal surface of the rectal wall. Theravac SB mini-enema tips were cut off or punctured and the 3cm extension was inserted into the rectum with the bulb remaining outside. The bulb was then squeezed by the patient or the nurse if the patient did not have the required dexterity. The time of insertion of the suppository or squeeze of the Theravac SB contents into the rectum was considered time 0 and the progress of bowel care was documented with time parameters (table 1). Digital stimulation and/or manual evacuation was not performed during suppository insertion, but was allowed only after either first flatus or first stool flow.

The total bowel care period was divided into intervals by discrete events¹¹ (table 1): *First Flatus* marks the end of the interval from insertion of the suppository until the first gas is passed, *Begin Stool Flow* marks the beginning of the defecation interval, *End Stool Flow* marks the end of the defecation interval, *Time Off Toilet* marks the interval from the last stool flow to transfer off toilet or completion of clean-up if in bed, *Total Time* marks the time from insertion of the suppository to the last stool flow. Both duration and frequency of digital stimulation and manual evacuation were recorded. Stool results were recorded as: 0, none; 1, minimal; 2, small; 3, moderate; 4, large; and 5, very large. All episodes of incontinence were recorded and defined as any passage of substance through the anus (include stool, mucus, liquid, etc) at any time outside the designated bowel care procedure.

Statistical analysis. Continuous mean interval data were compared using paired *t* tests.¹⁸ Ordinal data were compared with Wilcoxon rank sum tests. Probability (*p*) values were derived taking .05 as the level of significance.

RESULTS

The subject demographics include nine cervical and six thoracic level injuries. Of the 15 subjects, 11 were complete and 4 were incomplete spinal cord lesions. All patients had a positive anal cutaneous reflex and bulbocavernosus reflex and normal to hyperreflexic lower extremity phasic stretch reflexes to tendon percussion.

The 15 subjects had a mean age of 45 years (range, 26 to 61), were between 3 months and 45 years postinjury, and had been admitted to a VA Medical Center SCI unit for reasons unrelated to gastrointestinal pathology.

One hundred fourteen bowel care sessions were studied from the 15 subjects: 43 using PGB suppositories, 43 using HVB suppositories, and 28 using TVC. No subjects reported gastrointestinal symptoms or autonomic dysreflexia during or around the time of the bowel care. There were 10 incontinence episodes reported. Ten occurred within 1 hour of the end of the bowel care, 3 after PGB, 5 after HVB, and 2 after TVC. Two of the 5 HVB incontinence episodes occurred on the same day in one subject, separated by a 2-hour period.

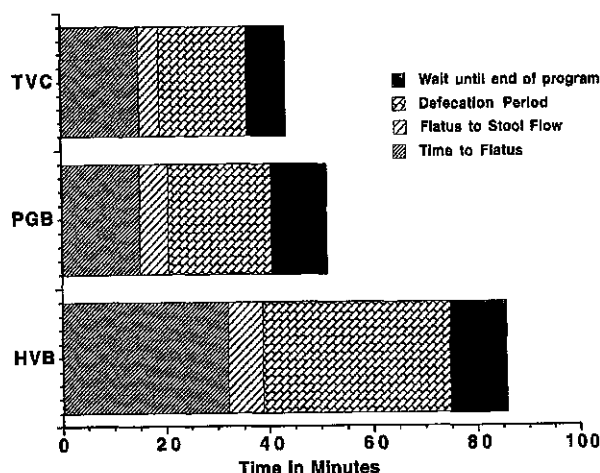


Fig 1. The time intervals of the experimental bowel care sessions were averaged and are presented in minutes for HVB and PGB bisacodyl suppositories and TVC mini-enema. The Time to Flatus was comparable for PGB and TVC, although HVB was significantly longer than PGB. Flatus to Stool Flow was not significantly different between the agents. HVB Defecation Period was significantly longer than PGB. PGB and TVC Defecation Periods were comparable. Wait Until Transfer was significantly longer for PGB compared with TVC, whereas PGB and HVB showed no difference.

Intervals were calculated to compare the mean times in minutes between the HVB, PGB, and TVC groups using the Wilcoxon rank sum tests (fig 1). The p values and means of the intervals are listed in sequence of recorded occurrence and are as follows: Time to Flatus—HVB, 32 minutes; PGB, 15 minutes; TVC, 15 minutes ($p < .026$, HVB-PGB; $p < .983$, PGB-TVC); Flatus to Stool Flow—HVB, 6.7 minutes; PGB, 5.5 minutes; TVC, 3.9 minutes ($p < .672$, HVB-PGB; $p < .068$, PGB-TVC); Defecation Period—HVB, 36 minutes; PGB, 20 minutes; TVC, 17 minutes ($p < .037$, HVB-PGB; $p < .479$, PGB-TVC); Wait Until Transfer—HVB, 10.9 minutes; PGB, 10.7 minutes; TVC, 7.4 minutes ($p < .932$, HVB-PGB; $p < .043$, PGB-TVC); Total Time for bowel care—HVB, 74.5 minutes; PGB, 43 minutes; TVC, 37 minutes ($p < .010$, HVB-PGB; $p < .458$, PGB-TVC); percent of bowel care sessions followed by an incontinence episode—HVB, .067; PGB, .067; TVC, .033 ($p < 1.0$, HVB-PGB; $p < .678$, PGB-TVC); amount of stool produced—HVB, 3.30; PGB, 3.49; TVC, 3.38 ($p < .276$, HVB-PGB; $p < .630$, PGB-TVC); average number of digital stimulations per bowel care session—HVB, 4.4; PGB, 4.1; TVC, 3.8 ($p < .411$, HVB-PGB; $p < .293$, PGB-TVC); time per digital stimulation in seconds—HVB, 107; PGB, 40; TVC, 83 ($p < .149$, HVB-PGB; $p < .352$, PGB-TVC); and total time spent performing digital stimulations during bowel care—HVB, 10.0 minutes; PGB, 2.7 minutes; TVC, 5.9 minutes ($p < .151$, HVB-PGB; $p < .325$, PGB-TVC).

DISCUSSION

This randomized, double-blind, prospective study examined the statistical and clinical significance of the use of polyethylene glycol-based (PGB) bisacodyl suppositories versus the use of vegetable-oil-based (HVB) bisacodyl suppositories and found that use of the PGB suppository significantly decreased bowel care time. Stool volume and number of bowel incontinence episodes were similar with the use of either PGB or HVB. The PGB suppository was independently compared with the TVC mini-enema, and results for all time intervals, stool production,

incontinence events, and number of digital stimulations were similar. The only significant difference was in *Wait Until Transfer*, with the TVC producing reduced times. This may be due to familiarity with TVC or previous experience with HVB suppositories and a need to prolong this wait interval to prevent incontinence.

The mean bowel care interval that was most reduced when comparing the suppositories was *Time to Flatus* (PGB, 15 minutes; HVB, 36 minutes). This suggests that the rate of dissolution of the base and dispersion onto the rectal mucosa is directly related to the bioavailability of the bisacodyl and the subsequent peristaltic response of the colon. The colonic environment includes mucus in a polar water-based solution. The polyethylene glycol base is a water-soluble compound that rapidly dissolves within 3 minutes delivering the active ingredient, bisacodyl, to the rectal mucosa, causing an increase in the spasmodic peristaltic activity.¹³ In contrast, HVB is a hydrophobic lipid-soluble compound and relies on body heat to dissolve the suppository. Complete dispersion of the HVB suppository is prolonged significantly, slowing the delivery of bisacodyl to the rectal mucosa. Bisacodyl may be more bioavailable as a gut stimulant when dispersed as a solute in the water-miscible PGB.¹¹ This bioavailability might explain the difference in *Time to First Flatus* and *Total Time* for bowel care between the two suppositories. In time, both PGB and HVB dissolved and equal amounts of the bisacodyl may have been exposed to the bowel wall, resulting in the lack of significance in the amount of stool produced. The possibility that polyethylene glycol may act independently or synergistically with bisacodyl is currently under investigation.

The PGB suppository and the TVC mini-enema produced consistently similar results in all timed intervals, stool production, number of incontinence episodes, and the number and total time of digital stimulations. The only significant difference was in the *Wait Until Transfer* time interval, possibly because of subjects' awareness of the wait duration required for the familiar HVB suppository. TVC mini-enemas contain a mixture of docusate sodium, glycerin, and polyethylene glycol. Only glycerin has been shown to cause peristalsis,¹⁴ although polyethylene glycol may contribute to peristalsis in both PGB and TVC. TVC contents are immediately bioavailable to the rectal mucosa, while PGB bioavailability requires only minutes. This increased bioavailability may account for TVC having slightly reduced, although not statistically significant, flatus to stool flow and defecation intervals in comparison to PGB.

Several studies have demonstrated that bisacodyl is an effective bowel evacuant.^{11,13,19} The exact mechanism is currently unknown. It does act directly on the intestinal mucosa, likely stimulating enteric afferents producing a conal mediated reflex defecation. Therefore, to prevent gastrointestinal complications that can occur due to fecal distention of the colon, a bisacodyl suppository on a scheduled routine would facilitate bowel evacuation and prevent impaction.

The findings in this randomized, double-blind, prospective comparison of the two suppositories (PGB, HVB) are consistent with those in the single subject study that was previously performed at this institution¹¹ and those in an unblinded trial.¹⁷ All three studies found the greatest reduction in time to first flatus and total time of bowel care. The difference in number of digital stimulations per bowel care session was not statistically significant. These findings demonstrate a clinically significant decrease in the amount of nursing time for persons requiring attendant assistance with bowel care, and less time spent performing bowel care for independent individuals.

A cost comparison analysis of the three agents was derived using the price of each single agent as charged to a university

hospital and the nursing time required for bowel care. The per-dose cost of the agents are: HVB, \$0.06; PGB, \$0.38; and TVC, \$1.00. Nursing wages throughout the country comparing bed size, geographic location, type of hospital, age, education, and years experience were averaged resulting in an hourly rate of \$18.15.²⁰ Our average total times for the bowel care sessions were: HVB, 74.5 minutes; PGB, 43 minutes; and TVC, 37 minutes. The sum of the price of each agent and the nursing cost associated with the average time required for the bowel care procedure was calculated. The calculated average total cost per bowel care session was: HVB, \$22.60; PGB, \$13.39; and TVC, \$12.19. This calculation does not account for the frequent occurrence of nurses caring for multiple patients intermittently during one individual's bowel care procedure or the lower per-hour cost of nurse's aids, who often assist or perform bowel care.

The consideration of the effects of various defecation-triggering agents on the bowel care of each person with SCI should be made by the treating interdisciplinary team. Hospital pharmacies should provide formularies that offer a sufficient variety of agents for pharmacologic initiation of defecation. This allows alternatives for individual patient trials.

There were several limitations to this study. We did not routinely record whether the patient had stool in the rectal vault at the start of bowel care. Normal defecation is preceded by rectal distention by stool advanced into the vault dilating the internal sphincter.^{21,22} The presence of stool near the anal verge may reduce the threshold for colon stimulation and facilitate rapid stool flow in response to the chemical stimulus. If no stool had yet advanced to the rectal vault by the time of suppository insertion, the time to stool flow may be prolonged. This information might partly explain why one PGB suppository took 60 minutes to produce stool flow. In contrast, a finding such as an overfilled rectal vault might explain why one HVB suppository took only 10 minutes to trigger defecation. Finally, the variety of nursing staff who did the bowel care procedures or collected data may have introduced some variation in technique and subjective judgment in the recording of data.

The PGB suppository and the TVC mini-enema demonstrated a significant reduction in bowel care time in comparison to the HVB suppository. PGB and TVC have similar clinical effectiveness based on the measures of this study. TVC mini-enema does not contain bisacodyl but does have a polyethylene glycol base. Further studies are in progress to compare the PGB suppository to polyethylene glycol without dissolved bisacodyl to determine if polyethylene glycol acts alone as a gut stimulant. PGB suppositories have a functional advantage over the mini-enemas for individuals with limited dexterity who have difficulty squeezing the container. Also, the potential to perforate the anal mucosa with the serrated edge tip is eliminated with the PGB suppository. Finally, a preparation of bisacodyl in a solution containing polyethylene glycol may achieve an even greater reduction in bowel care time when compared with the PGB suppository.

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Suppliers

- Laxative suppositories vegetable oil based bisacodyl 10mg USP NDC 0536-1355-01, Product No 603-1357; Rugby Laboratories, 900 Orlando Avenue, West Hempstead, NY 11725.
- Laxative suppositories polyethylene glycol based bisacodyl 10mg NDC 57648-002-01; Concepts in Confidence, 1797-32 Veterans Highway, Islandia, NY 11722.
- Theravac SB Mini Enemas; Jones Medical Industries, 1945 Craig Road, St. Louis, MO 63146.