Reduction in Bowel Program Duration With Polyethylene Glycol Based Bisacodyl Suppositories

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- The neurogenic bowel caused by spinal cord injury frequently requires a bowel program (BP) with stimulant suppositories for effective defecation. Objective: The effectiveness of bowel programs initiated by hydrogenated vegetable oil based bisacodyl (HVB) suppositories was compared with that of polyethylene glycol based bisacodyl suppositories (PGB). Design: Single subject, randomized treatment. Setting: Outpatient. Subject: Chronic T2 complete spinal cord injury (SCI). Intervention: The suppository for the every third-day BP was randomized to PGB or HVB. The times in minutes of the following BP events were recorded: suppository insertion, first flatus, begin stool flow, end stool flow, and transfer off toilet. Outcome Measures: BP event times were used to derive BP intervals: suppository insertion to first flatus = Time to Flatus, first flatus until begin stool flow = Flatus to Stool Flow, begin stool flow until end stool flow = Defecation Period, end stool flow until the transfer off the toilet = Total BP Time. The number of digital stimulations required and the amount of stool results were recorded. Results: The data included two groups of BPs: HVB (N = 13) and PGB (N = 13). Wilcoxon's rank sum tests were used to compare mean times for each of the BP intervals: Time to Flatus (HVB 37 minutes, PGB 10 minutes, p < .0001), Flatus to Stool Flow (HVB 6.0 minutes, PGB 5.9 minutes, p = .9578), and the Defecation Period (HVB 31, PGB 21, p = .0043). The average Total BP Time was HVB = 85 minutes and PGB = 46 minutes showing a statistically (p < .0001) and clinically relevant difference.

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Injuries to the spinal cord (SCI) that result in upper motor neuron damage frequently produce neurogenic bowel dysfunction. The upper motor neuron bowel is characterized by fecal retention and uniformly requires a scheduled evacuation plan to avoid impaction and incontinence. These bowel programs (BPs) remain time-consuming processes that may be detrimental to quality of life.1 Bowel regimens may last longer than 3 hours and still produce insufficient results.2 Consequently, despite tedious and exacting BP regimens, serious problems with bowel evacuation are still reported from as many as 20% of people with SCI.3

Suppositories consisting of active laxative ingredients dispersed in a base substance are commonly used in a BP. Bisacodyl is the most commonly used active ingredient in rectal chemical stimulant preparations for defecation. This compound, a diphenylmethane derivative (bis (p-acetox-phenyl)-2-pyridylmethylene) was first introduced for use as a laxative in 1953 because of its structural similarity to phenolphthalein. Acting as a contact laxative, bisacodyl is practically insoluble in water and sparingly soluble in alcohol. Administered rectally in a water suspension, bisacodyl acts within 3 minutes to produce suppression of rhythmic stationary spike wave activity and increases spasmodic propulsive peristaltic spike activity.4

Bisacodyl is available in many rectal preparations including suppositories, enemas, mini-enemas, and solutions.5 Typically, 10-mg suppositories are used because of the ease of insertion and retention. The most common suppository preparation includes bisacodyl powder distributed within a hydrogenated vegetable oil base (HVB).6 Bisacodyl suppositories with a vegetable oil base often require a prolonged period to produce defecation and can cause continued mucosal irritation with resultant mucus accidents hours after the BP. Water-miscible suppositories have recently been used. Bisacodyl suppositories made with the polyethylene glycol polymer bases have been anecdotally reported to produce quicker elimination.6

This study was performed to compare BP times using HVB and polyethylene glycol–based bisacodyl (PGB) suppositories. The primary question in clinical practice relates to the effectiveness of a new treatment regimen in a particular patient. The idiographic, single case study method is used here to show a method of monitoring patient progress with changes in response to a pharmacological bowel elimination regimen.7

METHOD

The subject is a 35-year-old white man with a 10-year history of T2 complete stable paraplegia that resulted from a spinal cord arteriovenous malformation. Physical examination showed moderate scoliosis and decreased abdominal...
Time Intervals and Events of the Bowel Program

**INTERVALS**

- Time to Flatus
- Flatus to Stool Flow
- Defecation Period
- Wait Until Transfer

**EVENTS**

- Suppository Insertion
- First Flatus
- Stool Flow
- Stool Flow to Period Transfer
- Off Toilet

Fig 1—BP events separate the total period into discrete intervals. The BP begins with suppository insertion. First Flatus ends the interval Time to Flatus (suppository insertion until first gas is passed). Begin Stool Flow ends the second interval termed Flatus to Stool Flow and begins the Defecation Period. End Stool Flow represents the time when Defecation Period has immediately ceased. The time of Transfer off the Toilet ends the Wait Until Transfer period that represents the time spent to insure that the BP is over. The time of Transfer Off the Toilet ends the BP.

Muscle tone without voluntary contraction. Rectal examination showed increased sphincter tone without sensation, voluntary contraction, or relaxation. The seated upright bowel program had been the same for the last 8 years on a once every third day schedule with two (HVB) bisacodyl suppositories. There was no change in diet or medication during the study period.

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

Each bowel program was performed by the subject on a once every third day schedule with the same technique. During a 4-month period, typical BPs were selected for randomization to two HVB or two PGB 10mg bisacodyl suppositories. At the time of each bowel program, either two PGB or two HVB bisacodyl suppositories were inserted and positioned against the mucosal surface of the distal rectum. The presence or absence of stool in the rectal vault was recorded. The time of insertion was considered time zero and the progress of the bowel program was documented with time parameters (Fig 1). A single subject design was used to compare parameters of the BP.

Bowel program events were used to separate the total BP period into discrete intervals: First Flatus (ends the interval from suppository insertion until the first gas is passed), Begin Stool Flow (marks the beginning of the defecation interval), End Stool Flow (marks the end of defecation), and Time Off Toilet (marks the end of the period of waiting after stool flow has ended, the subjective end of the BP).

Digital stimulations were performed in a circular motion with a gloved lubricated index finger in attempt to dilate the external and internal anal sphincters and the distal rectum stimulating reflex peristalsis. Digital stimulations were performed if stool flow stopped or slowed in the evacuation process (approximately every 10 minutes). The number of digital stimulations required for each BP was recorded. Digital examination of the rectal vault followed the end of stool flow to assure complete evacuation. The amount of stool produced with each BP was recorded using the following ordinal scale: (0) none, no stool expelled; (1) small, covers less than the bottom of the toilet; (2) moderate, covers the bottom of the toilet; or (3) large, breaks the toilet water surface. Mucus and stool incontinences were recorded if they occurred between bowel programs.

**Statistical Analysis.** Continuous mean interval data were compared using Wilcoxon’s rank sum test. Ordinal data were compared with Fisher’s exact test. Probability (p) values were derived taking .05 as the level of significance.

**RESULTS**

Twenty-six discrete BPs were studied: 13 using HVB and 13 using PGB. On each suppository insertion, stool was consistently palpated in the rectal vault. At the time of the beginning of stool flow the PGB suppositories were frequently observed as only slightly reduced in size suggesting incomplete dissolution. The HVB suppositories were consistently melted by the time of stool flow. There were no bowel or mucus incontinences between BPs. There were no complaints of abdominal cramping or variation in stool consistency.

All the intervals compared between the HVB and the PGB groups showed significant differences, with the exception of Flatus to Stool Flow (Fig 2). Wilcoxon’s rank sum tests were calculated to compare mean times in minutes for each interval of the BPs performed with HVB and PGB. The means and p values obtained were as follows: Time to Flatus (suppository insertion time until first gas expulsion) HVB 37 minutes, PGB 10 minutes, p < .0001, Flatus to Stool Flow HVB 6.0 minutes, PGB 5.9 minutes, p = .9578, and the Defecation Period HVB 31 minutes, PGB 21 minutes, p = .0043. The Total Time for the BPs (from insertion of suppository until transferring off the toilet) averaged 85 minutes for HVB, and 46 minutes for PGB, a statistically significant (p < .0001) difference.

The numbers of digital stimulations required for the BPs were averaged (HVB 5.3, PGB 4.6) and compared using the Wilcoxon scores (rank sums) test. The observed difference did not reach significance (p = .1840). Each BP produced some stool results. The amount of stool produced by the BPs with HVB and PGB, treated as discrete variables with a two-tailed Fisher’s exact test, did not show a significant difference (p = .861).

**DISCUSSION**

This single-subject study investigated the statistical and clinical significance of the use of PGB bisacodyl suppositories versus the use of HVB bisacodyl suppositories using idiographic technique and found comparable bowel program effectiveness with a reduction in BP time by approximately half using the PGB. These time differences were observed with similar volumes of stool results and without stool incontinences. These improvements show a clinically significant result for this subject.
When delivered to the colonic mucosal surface and observed potency of the bisacodyl on moist mucosal membranes. A polar base may allow for quicker dispersion and greater time of stool flow. Bisacodyl, as a compound of three benzene rings with hydroxyl groups, most likely acts more effectively as a solute in an ethylene glycol polymer base. This polar base may allow for quicker dispersion and greater potency of the bisacodyl on moist mucosal membranes.

Although, a specific mechanism of action for bisacodyl on the gut has not been fully defined, this agent has been noted to be an effective gut evacuant in studies that have delivered bisacodyl to the intestinal mucosal surface. When delivered to the colonic mucosal surface and observed with intraluminal electromyography, bisacodyl produces a complete suppression of rhythmic stationary activity and an increase in propagating sporadic spike bursts. This is consistent with the increase in mass peristaltic waves observed in humans under fluoroscopy while adding a diphenylmethane-derived laxative or barium enemas. Persons with SCI have been noted to have significantly more colonic spike wave activity in the basal unstimulated control state as compared with able-bodied controls. Despite the increased spike wave activity fecal retention usually occurs until reflex defecation is triggered mechanically or chemically. This increased spike wave activity could represent excess segmental mixing of colonic contents. Bisacodyl therefore may suppress this activity and trigger a coordinated mass action for effective stool propulsion during defecation.

The findings of this study show a small reduction in mean stool flow time (HVB 31 minutes versus PGB 21 minutes) without a significant difference in the number of digital stimulations required between the two groups. This time reduction is consistent with other investigators' observations. Oral bisacodyl tablets given before a nasogastrically presented lavage have significantly reduced the mean duration required for colonic cleansing. Ewe has noted an inverse linear relationship between the amount of bisacodyl delivered to the upper jejunum and gut transit time. It is possible that the shorter duration of stool flow time observed in this study is caused by properties of the PGB base that offer greater bisacodyl dispersion or better bioavailability. The unlikely possibility that the polyethylene glycol base itself acts as a gut stimulant was not explored.

The decrease in the bowel program time noted by this study represents a clinically significant improvement over HVB suppositories for this subject. The single subject design is particularly useful in showing differing efficiency between regimens for individual patients. Multiple single subject studies under similar conditions are required to establish generalizability of conclusions derived with individual subjects. Expanded studies of the effects of PGB bisacodyl suppositories on BPs after spinal cord injury are currently in progress.

**References**


**Suppliers**
a. Laxative Suppositories Bisacodyl 10mg USP NDC 0536-1355-01, Product No 603-1357, Rugby Laboratories, 900 Orlando Avenue, West Hempstead, NY 11557.
b. Laxative Suppositories Bisacodyl 10mg NDC 57648-002-01, Concepts in Confidence Commack, NY 11725.