

Randomized Controlled Trial of a Natural Food-Based Fiber Solution to Prevent Constipation in Postoperative Spine Fusion Patients

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BACKGROUND: Constipation after orthopaedic surgery occurs frequently, likely due to a combination of high levels of opioid medications for severe pain management and mobility limitations after surgery. It can result in serious complications, increased cost, and patient discomfort.

PURPOSE: This study evaluated a natural food-based fiber solution to prevent constipation in postoperative orthopaedic patients.

METHODS: A posttest control group-randomized study design was used. Dependent variables were presence of postoperative constipation, time to first bowel movement (BM), and total number of postoperative BMs. Descriptive statistics, Student's *t* tests, and Mann-Whitney nonparametric 2-group tests with chi-square analysis were used. Level of significance for all tests was $p < .05$. Forty-six participants were evaluated.

RESULTS: Ages were similar for both the intervention and control groups. Bowel Function Index (BFI) scores were not significantly different ($p = .448$). No significant group differences were present for the individual BFI item scores ($p > .05$). The number of patients with a BM during the first 3 days was not significantly different ($p = .489$). There were no significant differences found between the 2 groups regarding laxative administration ($p > .05$ for all laxatives).

CONCLUSION: Further studies are indicated that address natural fibers and pharmaceutical methods for the prevention of constipation after spinal surgery.

Introduction

Constipation in hospitalized patients is a common problem, particularly in postoperative patients. Multiple factors contribute to the development of constipation in the postoperative patient, including changes in fluid intake, diet, and mobility (Davidson, 2006). Although a number of pharmacological agents can contribute to constipation, opioid medications in postoperative patients often lead to constipation, even in patients with no history of bowel difficulties. Constipation after

orthopaedic surgery occurs frequently, likely due to a combination of high levels of opioid medications for severe pain management and mobility limitations after surgery (Ross-Adjie, Monterosso, & Bulsara, 2015).

Although constipation may be considered mild and self-limiting, it can increase the length of hospital stay and increase financial burdens for both the patient and the institution. Constipation may lead to significant morbidity and, in rare cases, death (Davies et al., 2008). Reported rates of constipation in postoperative orthopaedic patients are between 40% and 60% (Park, Kim, Yun, & Yu, 2016; Ross-Adjie et al., 2015). Because constipation frequently occurs in the postoperative orthopaedic population, prevention and treatment of constipation are essential.

Dietary fiber is thought to improve gastrointestinal (GI) motility and is recommended as the first line of therapy for prevention and treatment of constipation by national gastroenterology groups (American Gastroenterological Association, Bharucha, Dorn, Lembo, & Pressman, 2013; Locke, Pemberton, & Phillips, 2000). Fiber agents are commonly used to bulk the stool, whereas increased fruit and fiber intake helps promote more frequent passage of stools (Dreher, 2018; Liu, 2011).

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The vast majority of studies on dietary fiber for constipation are not randomized controlled trials (RCTs) and have been conducted in nursing home residents and nonhospitalized individuals with chronic constipation (Suares & Ford, 2011). Research on the prevention of constipation in the postoperative orthopaedic patient population is sparse, and most of the studies on constipation are limited in scope or methods.

Systematic reviews of the small number of RCT studies regarding constipation found evidence of benefit from dietary fiber when used as a treatment of constipation (Suares & Ford, 2011; Yang, Wang, Zhou, & Xu, 2012). Specifically, individuals included in the analysis received dietary fiber regimen and had significantly more frequent bowel movements (BMs) than those who did not receive dietary fiber.

Studies have shown that administration of dietary fiber may prevent constipation in postoperative patients with no history of constipation (Kaçmaz & Kaşçı, 2007; Ouellet, Turner, Pond, McLaughlin, & Knorr, 1996; Schmelzer, 1990). In one underpowered study of postoperative orthopaedic patients ($N = 16$), 2.5 g of wheat bran was consumed by the experimental group ($N = 8$) for 4 days after surgery (Schmelzer, 1990). The study concluded that the experimental subjects who ate more wheat bran did have more BMs and requested fewer laxatives than the control group.

Using a quasi-experimental study design ($N = 81$), one study found that the dietary addition of 20 g of wheat bran once a day in postoperative orthopaedic patients significantly increased spontaneous BMs and decreased laxative administration (Ouellet et al., 1996). Because of serious methodological problems (poorly described methods), study findings are not generalizable. In a more recent nonrandomized study of postoperative orthopaedic patients ($N = 60$) conducted in Iran, an unspecified amount of dietary bran wheat was administered on postoperative days (POD) 2–4 (Kaçmaz & Kaşçı, 2007). In addition to the bran, study patients received education about strategies to decrease constipation (increasing fluid intake and activity levels; set time for defecation). Although the time to defecation was significantly less and the number of BMs significantly higher for the experimental group on the fifth POD, the authors failed to address significant differences between groups for those same outcome variables on POD 1 before the study intervention had begun. Constipation outcome variables were found to be similar between the two groups. Anecdotal findings of this study included complaints by the experimental group patients that the foods with the wheat bran were dry and distasteful.

Another source of dietary fiber constitutes plums/prunes. Similar to wheat bran, prunes are thought to increase GI motility because of their fiber content but unlike wheat bran, GI motility may also be aided by chlorogenic acids that are present in dried plums and prune juice and are known to increase peristaltic activity (Stacewicz-Sapuntzakis, 2013). In a recent systematic review of four RCT studies of prunes, all were conducted on nonhospitalized individuals who were given prunes over weeks to months (Lever, Cole, Scott, Emery, & Whelan, 2014). Prunes were found to be better than psyllium (i.e., Metamucil) for increasing stool frequency

and consistency. Meta-analysis was not done because of heterogeneity of study populations and methods. The reviewers concluded that additional trials are needed to further confirm these results.

Because fruit juices contain sorbitol, fructose, and phytochemicals, as well as water and fiber components, fruit juices are generally considered helpful for the prevention of constipation. Apple, prune, and pear juices are often recommended for the prevention and treatment of constipation (American Gastroenterological Association et al., 2013; Bae, 2014). Yet, no studies were found to support apple juice specifically as treatment for the prevention of constipation in the postoperative orthopaedic population.

No RCT studies have been conducted to date on the effects of prune and apple juice ingestion combined to create a palatable dietary fiber solution for the prevention of constipation in postoperative orthopaedic patients. The purpose of this RCT was to evaluate the effectiveness of a prune juice and apple juice fiber solution to prevent constipation in postoperative orthopaedic patients. Results of this study will add to the evidence base for the use of natural oral agents to prevent constipation in postoperative patients.

Materials and Methods

This study was conducted in an academic orthopaedic specialty hospital in the southeastern region of the United States on an inpatient unit. Study approval was obtained from the institutional review board prior to data collection. Data collection was completed over a 12-month period.

STUDY DESIGN

A posttest, control group-randomized study design was used to evaluate the effects of administering a dietary fiber solution orally for 3 days after surgery. The dependent variable for this study was the presence of postoperative constipation, time to first BM, and total number of postoperative BMs. Random assignment to groups was done using a computerized randomization scheme, with investigators blinded to group assignment until after study enrollment.

SAMPLE SELECTION

Subjects for this study were adult patients undergoing posterior spine fusion that required at least a 3-day hospital stay. Inclusion criterion was tolerating oral fluids. Exclusion criterion was a medical history of chronic lower GI disease (i.e., severe constipation; inflammatory bowel disease; colostomy/ileostomy; bowel obstruction). A minimum sample size of 46 patients undergoing spinal fusion was determined by power analysis for statistical testing with Student's t test on the primary outcome variable (constipation scores). Effect size was 0.85, power of 0.8, and α of .05 (Faul, Erdfelder, Lang, & Buchner, 2007). Effect size was calculated and based on a prior study evaluating constipation scores in patients receiving opioid medications (Rentz, Yu, Müller-Lissner, & Leyendecker, 2009) and a desire to achieve a minimum of 20% reduction in constipation scores for the dietary fiber group compared with the control group. A

reduction of 20% in constipation scores between groups would achieve values experts believe represent clinical improvement of symptoms (Rentz et al., 2009).

STUDY INTERVENTION

The dietary fiber solution intervention consisted of 4 ounces (oz) of prune juice mixed with 4 oz of apple juice and warmed in the microwave for 10 seconds. The dietary fiber solution was given twice daily (9 a.m. and 9 p.m.) beginning on POD 1 and followed by 8 oz of room temperature water. The study period was 3 days because many patients at this institution are discharged from the hospital after 3 days.

STUDY OUTCOMES

Constipation was measured by the Bowel Function Index ([BFI]; Izumi, 2014) and the Constipation Assessment Scale ([CAS]; McMillan & Williams, 1989). The BFI and CAS survey are patient self-reports of their symptoms associated with BMs. The BFI score is an average of the scores on three visual analog scales (VASs) asking patients to rate the following: ease of defecation; feelings of incomplete bowel evacuation; and personal judgment of constipation. The end of each VAS is anchored by words that represent absence of the constipation symptom, with the other end anchored by severe constipation symptoms. Ratings are done by having the patient draw a perpendicular line through the 100-mm long VAS line at the level of his or her current symptom presence. Scores are determined by measuring from the bottom of the line to the intersection with the patient's mark. Scores on each VAS range from 0 to 100 mm, with scores less than 28 mm considered to reflect nonconstipation (Ueberall, Müller-Lissner, Buschmann-Kramm, & Bosse, 2011) and scores of more than 50 mm reflecting moderate to severe constipation (Abramowitz, Beziaud, Chuberre, Allaert, & Perrot, 2013). The BFI values were found to average 63 ± 16 in patients with opioid-induced constipation. Validity of the BFI was found to be good, with Cronbach's α values of more than 0.70 (Rentz et al., 2009; Vondrackova et al., 2008).

The CAS measures the presence of constipation symptoms in the last day using eight descriptors for constipation (abdominal distention or bloating, change in the amount of gas passed recently, less frequent BMs, oozing liquid stool, rectal fullness or pressure, rectal pain with BM, small volume of stool, unable to pass stool; McMillan & Williams, 1989). The subject is asked to respond to whether the descriptor is "no problem," "some problem," or a "severe problem." Scoring of the levels is from 0 to 2, with total scores ranging from 0 to 16. Zero represents no problem with constipation, and 16 represents severe constipation. The CAS has been found to have excellent discrimination between patients with and without constipation (construct validity), good internal scale consistency (Cronbach's $\alpha = 0.70$), and high test-retest capability ($r = .98$) (McMillan & Williams, 1989).

The time to first BM was the number of hours from postoperative admission to the study unit until the first notation is made of a BM in the electronic medical record. The number of BMs was the total number of BMs

recorded in the electronic medical record for the first three POD.

STUDY PROCEDURE

Investigators were trained in all study procedures before beginning study enrollment. Nursing staff on the patient care unit were oriented to the study procedures related to administration of the dietary fiber solution intervention.

Consenting participants had demographic data recorded following admission to the postoperative care unit. Postoperative patients were then randomly assigned by a computer-generated number sequencer to one of two groups: twice-daily oral administration of a natural fiber-based solution; and usual care (no administration of a natural fiber-based solution). Beginning on the first POD, intervention group participants received twice-daily administration of a natural fiber-based solution. Administration of the oral solution continued until 9 p.m. on the third POD.

At 9 p.m. on the third POD, participants in both groups completed the constipation scale surveys. The time to first BM and the number of BMs since unit admission were then calculated from the electronic medical record for both groups.

DATA ANALYSIS

Data were summarized using descriptive statistics. Student's *t* tests and Mann-Whitney nonparametric two-group tests were used to determine the differences between the two groups for age, constipation scores, and number of BMs. Chi square analysis was used for categorical variables. The Kaplan-Meier analysis (censored for subjects who either did not have a BM during the first 3 days or left the study before the end of the 3 days) performing a log-rank test was conducted to test for differences between the two groups for time to first BM. The level of significance for all tests was $p < .05$.

Results

A total of 46 patients were studied. Patient ages ranged from 36 to 82 years, with the intervention group averaging 68.2 ± 10.6 years, and ranged from 37 to 82 years, with the usual care group averaging 65.5 ± 11.4 years (see Table 1). Patient ages were similar for both the intervention and control groups ($p = .405$).

The BFI scores were missing for 12 patients (26.1%; six in the intervention group and six in the usual care group, which were not significantly different between the two groups, $p = .861$). The BFI scores for the 34 patients who completed the BFI ranged from 0 to 100, with median scores 54 (IQR [interquartile range] = 13.3, 85.3) and median 35 (IQR = 11.7, 78.1) for the intervention and control groups, respectively (see Table 1). This difference was not significant ($p = .448$). No significant group differences were seen for the individual BFI item scores ($p > .05$); however, the BFI scores for "feelings of incomplete bowel evacuation" were the highest, with overall median scores of 73.5 (IQR = 6.8, 97.3), followed by "ease of defecation" with median scores of 51.5 (IQR = 5.5, 91.5), with "judgment of how constipated you

TABLE 1. CONSTIPATION OUTCOMES IN POSTOPERATIVE ORTHOPAEDIC INPATIENTS GIVEN A NATURAL FIBER-BASED ORAL SOLUTION TWICE DAILY FOR 3 DAYS (INTERVENTION; *N* = 22) AND NO NATURAL FIBER-BASED SOLUTION (USUAL CARE; *N* = 24)

	All Patients (<i>N</i> = 46)	Intervention (<i>N</i> = 22)	Usual Care (<i>N</i> = 24)
Age, mean \pm SD (years)	66.8 \pm 11.0	68.2 \pm 10.6	65.5 \pm 11.4
BFI scores, median [IQR]	44 [11.7, 84.3] <i>N</i> = 34	54 [13.3, 85.3] <i>N</i> = 16	35 [11.7, 78.1] <i>N</i> = 18
BFI ease of defecation, median [IQR]	51.5 [5.5, 91.5] <i>N</i> = 34	53.5 [9.3, 96.8] <i>N</i> = 16	36 [4, 84.8] <i>N</i> = 18
BFI feelings of incomplete bowel evacuation, median [IQR]	73.5 [6.75, 97.3] <i>N</i> = 34	84 [9.8, 97.8] <i>N</i> = 16	45.5 [5.8, 97.8] <i>N</i> = 18
BFI judgment of how constipated you are, median [IQR]	29.0 [2.0, 69.0] <i>N</i> = 34	38.5 [3, 90] <i>N</i> = 16	29 [2, 59.3] <i>N</i> = 18
CAS score eight items total score, median [IQR]	5 [1.5, 7] <i>N</i> = 33	5 [2, 6.8] <i>N</i> = 16	5 [0, 7] <i>N</i> = 17
BM "Yes," <i>n</i> (%)	29 (63.0%)	15 (68.2%)	14 (58.3%)
Number of BMs, median [IQR]	1 [1, 3] <i>N</i> = 29	1 [1, 3] <i>N</i> = 15	1 [1, 2.5] <i>N</i> = 14
Time to first BM, median [IQR] (hours)	54.7 [45.8, 71.3] <i>N</i> = 29	52.4 [44.8, 68.8] <i>N</i> = 15	57.8 [47.1, 72.7] <i>N</i> = 14
Median hours to BM (<i>SE</i>)	65.3 (<i>SE</i> 3.4) <i>N</i> = 45	59.9 (<i>SE</i> 3.6) <i>N</i> = 21	70.2 (<i>SE</i> 5.2) <i>N</i> = 24

Note. BFI = Bowel Function Index; BM = bowel movement; IQR = interquartile range; SD = standard deviation; SE = standard error.

are" being the lowest with median scores of 29.0 (IQR = 2.0, 69.0) (see Table 1). The CAS scores were missing for 13 patients (28.3%; six in the intervention group and seven in the usual care group, which were not significantly different between the two groups, $p = .887$). The scores for the 33 patients who completed the CAS ranged from 0 to 13, with median scores 5 (IQR = 2.0, 6.8) and median 5 (IQR = 0, 7) for the intervention and control groups, respectively (see Table 1). This difference was not significant ($p = .624$).

The number of patients with a BM during the first 3 days was 29 (63.0%), with slightly more in the intervention group (68.2%) compared with only 58.3% in the usual care group, which was not significantly different ($p = .489$). For the 29 patients who had a BM, the number of BMs ranged from zero to nine, with 1 median BM (IQR = 1, 3) and 1 median BM (IQR = 1, 2.5) for the intervention and control groups, respectively (see Table 1), which were not significantly different ($p = .983$). For the 29 patients who had a BM, the time to the first bowel movement ranged from 17.8 to 98.7 hours. The median time to first BM estimated from the Kaplan–Meier censored analysis was 59.9 hours (*SE* [standard error] = 3.6) for the intervention group, which was 10 hours less than the median time of 70.2 hours (*SE* = 5.2) for the usual care group, but this difference was not significantly different (log-rank test $p = .151$) (see Table 1).

Stool softeners administered as requested by the intervention and control groups over the 3-day study period are summarized in Table 2 for 45 patients—this information was unavailable for one patient. The most common two stool softeners administered were Colace (docusate) and Senokot (senna glycoside), with almost half of the patients taking one or both of these on all 3 days. Dulcolax (bisacodyl) suppositories (laxative) were the third most common treatment, with 20% of the patients taking these on 1 or 2 days. There were no significant differences found between the two groups for stool softener or laxative administration ($p > .05$).

Discussion

This study was the first RCT study with well-described methods to evaluate a common natural fiber-based solution to prevent constipation in orthopaedic postoperative patients. This study found that BFI and CAS scores were statistically nonsignificant in the two groups. Time to first BM was not significantly different. Stool softener and laxative use was remarkably similar for those who received the fiber-based solution and those receiving usual care. In patients who had undergone spinal fusion, the administration of a twice-daily dietary fiber solution did not have a significant impact on the prevention of postoperative constipation after spine surgery.

Unlike the Soares and Ford (2011) study, this study was an RCT and it was conducted in an acute care hospital setting rather than a long-term care facility. Because of flaws in describing the methodology, other studies that showed an increase in BMs and decreased constipation could not be replicated or generalized. One systematic review of four studies comparing prunes, another natural fiber, with a particular laxative showed that prunes were better than the laxative for increasing stool frequency and consistency (Lever et al., 2014). Unlike the systematic review that used prunes as a natural fiber, this RCT study did not find the fiber solution to prevent constipation as measured in this study by bowel fullness, ease of defecation, and time to first BM after spine surgery. In this short-term study conducted on a hospital postoperative unit, it showed that the natural fiber solution was not superior to usual treatment. In patients who had undergone spinal fusion, the administration of a twice-daily dietary fiber solution did not have a significant impact on constipation.

Limitations

This study is limited to the use of one type of natural fiber-based solution to prevent constipation coupled with usual care that included stool softeners and

TABLE 2. LAXATIVE USE IN POSTOPERATIVE ORTHOPAEDIC INPATIENTS GIVEN A NATURAL FIBER-BASED ORAL SOLUTION TWICE DAILY FOR 3 DAYS (INTERVENTION; N = 22) AND NO NATURAL FIBER-BASED SOLUTION (USUAL CARE; N = 24)

Laxative Use as Requested (Sum of 3 POD)	All Patients (N = 46)	Intervention (N = 22)	Usual Care (N = 24)
Colace			
1 day	7 (15.2%)	4 (19.0%)	3 (12.5%)
2 days	16 (34.8%)	7 (33.3%)	9 (37.5%)
3 days	22 (47.8%)	10 (47.6%)	12 (50.0%)
Senokot			
1 day	9 (19.6%)	5 (23.8%)	4 (16.7%)
2 days	16 (34.8%)	6 (28.6%)	10 (41.7%)
3 days	20 (43.5%)	10 (47.6%)	10 (41.7%)
Magnesium citrate			
1 day	4 (8.7%)	2 (9.5%)	2 (8.3%)
Milk of magnesia			
1 day	1 (2.2%)	1 (4.8%)	0 (0%)
Dulcolax suppository			
1 day	8 (17.4%)	4 (19.0%)	4 (16.7%)
2 days	1 (2.2%)	0 (0%)	1 (4.2%)
Fleet enema			
1 day	3 (6.5%)	2 (9.5%)	1 (4.2%)
Other			
1 day	5 (10.9%)	2 (9.5%)	3 (12.5%)
2 days	2 (4.3%)	1 (4.8%)	1 (4.2%)
3 days	2 (4.3%)	0 (0%)	2 (8.3%)

Note. POD = postoperative day.

laxatives if requested by the patient. Results from the use of other types of natural fiber-based substances with or without oral stool softeners laxatives may be different. This study only evaluated the impact of the natural fiber-based solution over a short period of time (3 days) and whether the results found in this study persist beyond this time point is unknown. In addition, 12 subjects failed to complete their questionnaires. This could have impacted the outcome. We did not evaluate the presence or absence of constipation prior to surgery; therefore, it limits the strength of our conclusions because the groups may have differed in this regard.

Implications for Nursing Practice

The findings of this study do not support the use of this natural fiber-based solution to prevent constipation that may occur in postoperative orthopaedic patients who have undergone spine surgery. Because constipation occurs frequently and fiber is indicated in the prevention of constipation, additional studies are indicated that evaluate other natural fiber solutions as alternatives to standard laxatives. This study did not evaluate for the presence of constipation prior to surgery; this should be included in future studies. Future studies are indicated that evaluate bowel habits prior to the surgery and extend the study period beyond hospital

discharge to the follow-up postoperative visit. Other studies involving multiple fiber solutions to compare efficiency and tolerability of various fiber-based solutions for prevention of constipation in the population of orthopaedic patients who have undergone spine surgery are indicated.

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