

*Original Article*

# Randomized, Double-Blind, Placebo-Controlled Trial of Oral Docusate in the Management of Constipation in Hospice Patients

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## **Abstract**

**Context.** The stool softener docusate is widely used in the management of constipation in hospice patients. There is little experimental evidence to support this practice, and no randomized trials have been conducted in the hospice setting.

**Objectives.** To assess the efficacy of docusate in hospice patients.

**Methods.** This was a 10-day, prospective, randomized, double-blind, placebo-controlled trial of docusate and sennosides vs. placebo and sennosides in hospice patients in Edmonton, Alberta. Patients were included if they were age 18 years or older, able to take oral medications, did not have a gastrointestinal stoma, and had a Palliative Performance Scale score of 20% or more. The primary outcome measures were stool frequency, volume, and consistency. Secondary outcomes were patient perceptions of bowel movements (difficulty and completeness of evacuation) and bowel-related interventions.

**Results.** A total of 74 patients were randomized into the study (35 to the docusate group and 39 to the placebo group). There were neither significant differences between the groups in stool frequency, volume, or consistency, nor in difficulty or completeness of evacuation. On the Bristol Stool Form Scale, more patients in the placebo group had Type 4 (smooth and soft) and Type 5 (soft blobs) stool, whereas in the docusate group, more had Type 3 (sausage like) and Type 6 (mushy) stool ( $P=0.01$ ).

**Conclusion.** There was no significant benefit of docusate plus sennosides compared with placebo plus sennosides in managing constipation in hospice patients. Docusate use should be considered on an individual basis. *J Pain Symptom Manage* 2013;45:2–13. © 2013 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

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**Key Words**

*Docusate sodium, sennosides, constipation, hospice care, palliative care, laxatives*

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**Introduction**

Constipation is one of the most common problems in palliative care, having been cited as a major concern by 32–87% of patients.<sup>1</sup> A significantly higher proportion of cancer patients in the hospice setting experience constipation compared with hospitalized and community cancer patients.<sup>2</sup> The prevalence of constipation is reported to be 83–87% in palliative care patients who are treated with opioids and 61–63% in patients not treated with opioids;<sup>3</sup> however, prevalence varies widely depending on the patient population, consistency of assessment, and definition of constipation used. In the hospice setting, constipation causes discomfort and distress, and demands significant bowel management attention from health care providers.

In many North American facilities for chronically and terminally ill patients, the current practice for the management of constipation involves the use of a stool softener, docusate sodium (docusate), in combination with a stimulating laxative, such as a sennoside.<sup>4</sup> The routine ordering of docusate is very common, but the practice is based on inadequate experimental evidence.<sup>5</sup> Since 1956, five prospective randomized controlled clinical trials (RCTs) in chronically ill patients<sup>6–10</sup> and one sequential cohort study in hospitalized cancer patients<sup>11</sup> evaluating the efficacy of docusate have been published. Two studies published in 1956<sup>6</sup> and 1957<sup>7</sup> showed that patients on docusate produced significantly more bowel movements than the control group; the other four studies<sup>8–11</sup> showed no significant difference between docusate and control groups. A small randomized, single-blind, crossover study also found that docusate had no effect on stool weight and frequency.<sup>12</sup> There is considerable variation in the study design and outcome measurements recorded among these studies, including differences in the symptomatic definition of constipation used. Despite its widespread use, no prospective controlled studies have been published examining the efficacy of docusate for constipation in hospice patients.

To assess the efficacy of docusate in hospice patients, we conducted a RCT of docusate and sennosides vs. placebo and sennosides. The null hypothesis was that there is no difference between the treatments in terms of stool frequency, volume, and consistency.

**Methods***Study Design*

This was a 10-day prospective, randomized, double-blind, placebo-controlled trial. Eligible hospice patients were randomly assigned to one of two groups, the docusate or placebo group. Written consent was obtained from all patients or their proxies before study enrollment. Patients, proxies, attending physicians, nursing staff, and the research assistant collecting the study data were blinded to the study treatment. The study was approved by the Health Research Ethics Board (Biomedical Panel), University of Alberta, Edmonton, Alberta, Canada, and was conducted from December 2005 to November 2010. The trial was registered with [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT00902031).

*Study Setting*

Patients were recruited from three inpatient hospice units in Edmonton, Alberta: St. Joseph's Auxiliary Hospital (14 beds) beginning December 2005; Edmonton General Continuing Care Center (22 beds) beginning April 2006; and CapitalCare Norwood (23 beds) beginning March 2009. The three units were integrated within the Edmonton Zone Palliative Care Program (EZPCP), which sets overall policies and guidelines for care. All patients in the units were admitted to attending family physicians. A palliative care physician consultant and a nurse from the EZPCP provided consultation services to the hospice units at the request of the admitting physician. Although administratively and operationally separate, patient care within each hospice was provided by registered nurses, licensed practical nurses, and nursing attendants. At the time of the study, the standard treatment for constipation at the hospices was

docusate in combination with sennosides.<sup>13</sup> During the 2008/2009 fiscal year, the median length of stay in the units was 16 days and more than 97% of the patients were discharged with death as the reason.<sup>14</sup>

### *Patients*

Patient inclusion criteria were initially defined as: being 18 years of age or older, able to take oral medications, no difficulty in swallowing, currently on or newly started on opioid analgesics, diagnosed with a malignancy, having a Palliative Performance Scale (PPS)<sup>15</sup> score of 20% or more (able to tolerate sips or food, may or may not be bedbound, may or may not be confused), and newly admitted to the hospice. Early in the study, it became clear that the condition of many eligible patients rapidly deteriorated (became unable to tolerate oral intake, including medications) from the time of eligibility assessment to the time of hospice admission, which resulted in few patients being included. Consequently, in April 2006, the inclusion criteria were expanded to include patients with nonmalignant disease and those not on opioids. Excluded from the study were patients with a gastrointestinal stoma, those with a contraindication to docusate, those prescribed docusate "as needed," if docusate was prescribed in liquid or crushed form, or if docusate was discontinued or withheld before the patient was screened.

### *Study Protocol*

The docusate group received two 100 mg docusate (dioctyl sodium sulfosuccinate) tablets twice daily (morning and late afternoon) plus one to three sennoside tablets (8.6 mg/tablet) taken one to three times daily. The placebo group received two cornstarch capsules twice daily, in addition to one to three sennoside tablets (8.6 mg/tablet) taken one to three times daily. All study medication was administered by hospice nursing staff. Patient and nursing staff blinding was achieved by using capsules of the same size, shape, and color and taken with the same daily frequency for both the study and placebo medication. The docusate medication was rolled in cornstarch and placed into nontransparent blue capsules. The placebo contained cornstarch inside the blue capsule. After the 10 study days were completed, patients reverted to their previous

treatment for constipation. Patients were allowed to take additional laxatives and bowel interventions as needed throughout the study.

### *Study Procedures*

At the outset of the study, a palliative nurse consultant from the EZPCP conducted patient recruitment. Staffing issues within the EZPCP resulted in a change to using a trained research assistant for recruitment. Written consent was obtained by the research assistant from eligible patients who had a Folstein Mini-Mental Status Examination (MMSE)<sup>16</sup> score of more than 23 (not cognitively impaired or deemed to have capacity to consent) or from the patient's proxies if the MMSE was 23 or less (cognitively impaired). Once a patient met inclusion criteria and provided written consent, the research assistant telephoned the pharmacist who maintained the randomization code, which was generated using the public domain computer program Epistat (Tracy L. Gustafson, Round Rock, TX) for assigning unpaired subjects to two groups prospectively. The pharmacist assigned patient study numbers and ensured that the appropriate medication (docusate or placebo) was delivered to the unit for each patient. The pharmacist could break the randomization code at the request of the attending physician or patient, if circumstances so warranted. For data analysis purposes, the randomization code was broken after the study outcome measures were collected by chart review.

As per usual practice, nursing staff at the hospices assessed and recorded bowel activities (stool frequency and volume, stool consistency, constipation symptoms, and ease and completeness of defecating). To standardize the recording of stool consistency and volume, educational sessions were provided to the nursing staff several times at each hospice during the course of the study.

### *Outcome Measures*

The primary outcome measures were stool frequency, stool volume, and stool consistency. Secondary outcomes included type and frequency of additional bowel care interventions, patient's perception of difficulty and completeness of evacuation, and symptoms possibly related to constipation (pain, tiredness, nausea, drowsiness, anxiety, depression, appetite loss, well-being, and shortness of breath).

Symptoms scores were based on the Edmonton Symptom Assessment System (ESAS)<sup>17</sup> and were recorded daily by nursing staff as a part of the standard practice in the EZPCP. The ESAS, an 11-point numerical rating scale ranging from zero (no perception of symptoms) to 10 (the most severe possible perception of symptoms), was administered daily. The operational definition of constipation for this study was determined using the Rome II diagnostic criteria for functional bowel disorders.<sup>18</sup>

Patient demographic information and clinical history were collected by the research assistant via medical chart review, using data collection forms designed for the study. Information recorded included patient age, gender, diagnosis, past medical history, bowel habits, current medications, PPS, MMSE, dietary oral intake, and use of hypodermoclysis for hydration. A Bowel Movement Record (Appendix), adapted from a previous form,<sup>19</sup> was used as a standardized recording system for bowel activities. This recording system included information on stool frequency, volume, consistency, additional interventions used, and difficulty (straining) and completeness of evacuation (empty fully). Patients' perception of difficulty and completeness of evacuation was assessed by the questions "Did you need to strain? (yes/no)" and "Did you feel you were able to empty fully? (yes/no)," respectively. Nurses were trained to record bowel consistency using the Bristol Stool Form Scale<sup>20</sup> and to assess stool volume using a standardized plasticine model of three sizes of stool (large = one full cup; medium = ½ cup; and small = ¼ cup). Outcome measures were collected daily during the 10-day study treatment.

### Sample Size

Sample size calculation was based on the formula for comparison of two means (two-sided)  $n = (A + B)^2 \times 2 \times SD^2 / DIFF^2$ , where:  $n$  = the sample size required in each group;  $SD = 0.60^5$  standard deviation of the primary outcome variable, stool frequency;  $DIFF = 0.50$  was assumed as the size of difference in number of bowel movements between the groups to be of clinical importance;  $A = 1.96$  for a two-sided alpha level of 0.05; and  $B = 0.84$  for a power of 80%. As such, the

calculated sample size for each group was 23. In this two-group trial, the intended allocation ratio (number of patients in each group) was 1:1. Allowing for a dropout rate of 50% in the hospice patient population, the sample size was increased to 35 in each group, for a total sample size of 70 patients.

### Data Analysis

The primary outcome variable, stool frequency, was determined for each patient as the number of bowel movements per day. The overall mean number of bowel movements per day per study group was calculated as total number of bowel movements divided by total patients in the study that day. Each stool volume type (smear, small, medium, and large) was analyzed as a percentage of total stool frequency within each study group. Each stool consistency type was calculated as a percent of total stool frequency within each study group.

Types of additional bowel care interventions included bisacodyl suppository, sodium phosphate enema, oil retention enema followed by soapsuds cleansing enema, lactulose, polyethylene glycol, magnesium hydroxide, or mineral oil. Overall, patients were deemed to have received at least one type of bowel care intervention if they received any bowel intervention on any one of the study days.

Descriptive data analyses were performed using SPSS 17 for Windows (SPSS, Inc., Chicago, IL). A  $t$ -test for differences between means,  $\chi^2$  test, and Fisher's exact test were used as appropriate to test for relations between discrete variables; 95% confidence intervals (CIs) were calculated for the mean difference in the number of bowel movements between the groups. In addition, a secondary data analysis approach was used, that of responder analysis,<sup>21</sup> on patients who completed the 10-day trial. Responders were defined in two ways. In the first instance, responders were classified as those who had at least one bowel movement on 50% or more of the study days. Second, responders were defined as those who had at least one bowel movement every three consecutive days (i.e., nonresponders did not have a bowel movement on three consecutive days). An  $\alpha$  level of 0.05 was used to determine statistical significance.

## Results

### Participant Flow

A total of 1426 hospice patients were screened, of whom 305 (21.4%) met the inclusion criteria. Eighty (26.2%) patients agreed to participate and provided written consent, of whom 74 (92.5%) were randomized into the study, 35 to the docusate group, and 39 to the placebo group (Fig. 1). Six patients were not randomized for the following reasons: two died, two were unable to swallow, one was not randomized at the physician's request, and one became significantly nauseated the day of randomization and did not want to take part in the study. Of the 74 randomized patients, 56 (75.7%) completed the full 10-day course of treatment, 25 (71.4%) in the docusate group and 31 (79.5%) in the placebo group. Reasons for noncompletion in the docusate group included: two, unable to swallow

medicine; three, discontinued all oral medications; two, team/family consensus to remove; two, died (unrelated to docusate); and one moved to another province. Reasons for non-completion in the placebo group were: five, unable to swallow; one, medication administration error; one, doctor removed patient from the study for unknown reason; and one, team/family consensus to remove.

### Patient Characteristics

There was no statistically significant difference between patients in the docusate and placebo groups with respect to gender, age, primary diagnosis, PPS, or MMSE (Table 1). The use of hypodermoclysis, sennosides, and metoclopramide, as well as daily oral intake (eating vs. not eating) was comparable between the two groups. In terms of daily opioid use, between 91.7% and 94.1% of docusate

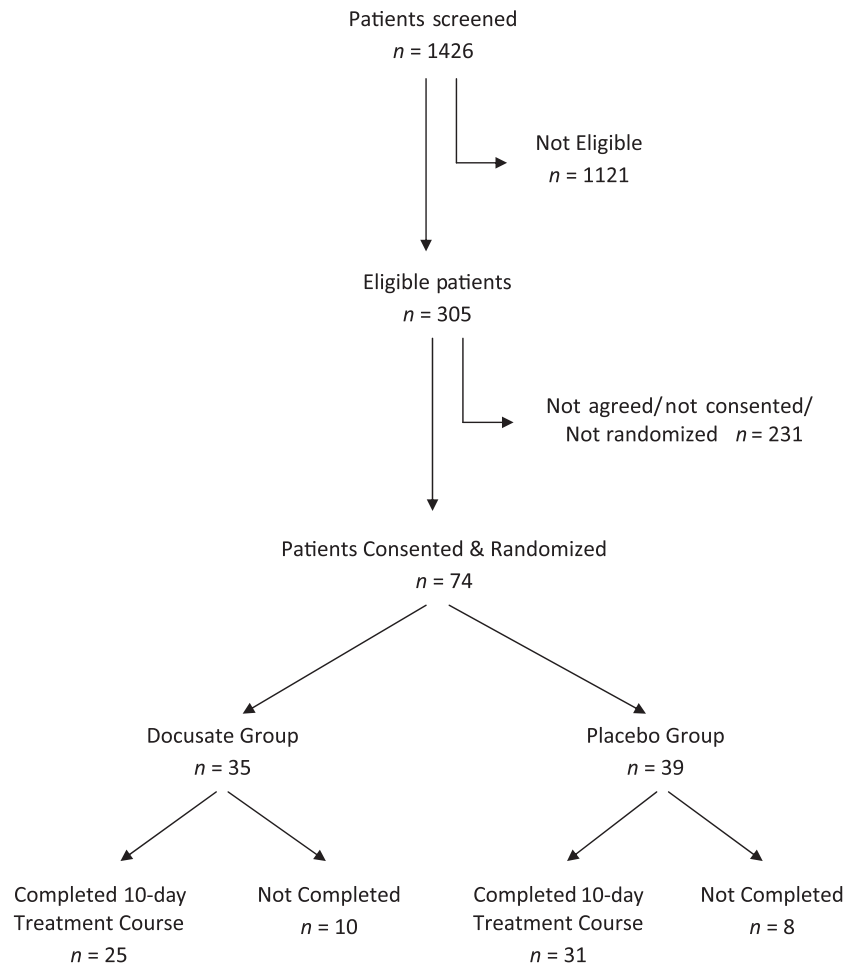


Fig. 1. Participant flow diagram.



Table 1  
Characteristics of Patients by Study Group

Patient Characteristics	Docusate Group <i>n</i> = 35, <i>n</i> (%)	Placebo Group <i>n</i> = 39, <i>n</i> (%)
Gender		
Male	20 (57.1)	21 (53.8)
Female	15 (42.9)	18 (46.2)
Age (years)		
38–59	2 (5.7)	8 (20.5)
60–69	6 (17.1)	4 (10.3)
70–79	15 (42.9)	16 (41.0)
80–89	10 (28.6)	8 (20.5)
90+	2 (5.7)	3 (7.7)
Mean age (y)	75.3	71.9
Primary diagnosis		
Cancer	33 (94.3)	37 (94.9)
Non-cancer	2 (5.7)	2 (5.1)
Palliative Performance Scale score (mean %)	42.0	43.4
Mini-Mental State Examination score (median)	24.0	26.5

patients and 100% of placebo patients received opioids during each of the 10 days of the trial. A relatively higher proportion of patients in the docusate group were on morphine (range 44.0–54.8%), whereas more patients in the placebo group were on hydromorphone (range 54.3–65.6%) during the 10-day trial. There was no difference in the mean morphine equivalent daily dosage (MEDD) between the groups (docusate group = 92.9 mg, placebo group = 154.3 mg,  $P=0.26$ ). Although a strict study protocol was maintained, oversights in medication

administration resulted in six patients in the docusate group and seven in the placebo group missing an average of 3.5 and 2.1 study medication doses, respectively, during the 10-day trial. This difference was not statistically significant.

#### Stool Frequency, Volume, and Consistency

Analysis of stool frequency showed no statistically significant difference in the overall mean number of bowel movements per day between the docusate ( $\bar{X}=0.74$ , standard deviation [SD] = 0.47) and placebo groups ( $\bar{X}=0.69$ , SD = 0.37;  $P=0.58$ ; Fig. 2). The mean difference in the average number of bowel movements was 0.05 (0.74 – 0.69) and the 95% CI around this difference was –0.09, 0.19.

Responder analysis revealed that 56% (14 of 25) of docusate and 71% (22 of 31) of placebo patients had a bowel movement on 50% or more of the study days, and 70.8% (17 of 24) of docusate and 80.6% (25 of 31) of placebo patients had at least one bowel movement every three consecutive days. There was no statistically significant association between being a responder and study group, regardless of which definition of responder was used. Analysis of mean stool frequency by responders also revealed no statistically significant difference ( $P=0.44$ ) between docusate ( $\bar{X}=1.0$ , SD = 0.50) and placebo ( $\bar{X}=0.88$ , SD = 0.30) groups, neither when responders were defined as having at least one bowel movement on 50% or more of study days (CI around mean

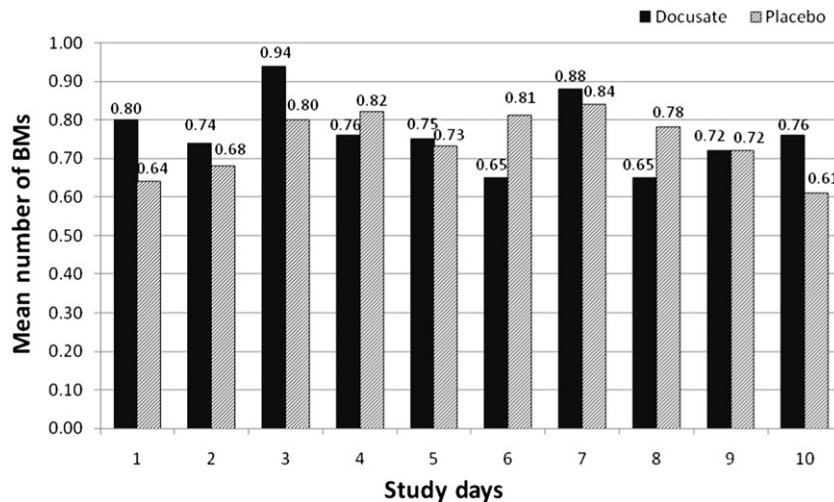


Fig. 2. Mean number of BMs by day by study group. BM = bowel movement.

difference  $-0.19, 0.43$ ) nor when they were classified as having at least one bowel movement every three consecutive days (docusate  $\bar{X} = 0.92$ ,  $SD = 0.49$ ; placebo  $\bar{X} = 0.82$ ,  $SD = 0.33$ ;  $P = 0.45$ ; CI around mean difference  $-0.17, 0.38$ ).

There was no significant association between stool volume and study group ( $P = 0.06$ ; Fig. 3). Although a slightly higher number of patients in the docusate group tended to have large bowel movements, the difference was not statistically significant. Using the Bristol Stool Form Scale to determine stool consistency, more patients in the placebo group tended to have Type 4 (smooth and soft, like a sausage or snake) and Type 5 (soft blobs with clear-cut edges) stool, whereas more patients in the docusate group had Type 3 (sausage, cracks in surface) and Type 6 (mushy stool, fluffy pieces with ragged edges) stool ( $P = 0.01$ ; Fig. 4).

#### Difficulty/Completeness of Defecation

No significant differences were observed between the docusate and placebo groups regarding patients' perceptions of the difficulty (need to strain) or completeness (sense of full evacuation) of defecation. Of the total bowel movements, 32.5% (13 of 40) in the docusate group and 25.0% (14 of 56) in the placebo group were perceived to be difficult ( $P = 0.57$ ); and for 73.5% (25 of 34) and 78.6% (44 of 56) of movements, there was a sense of complete evacuation ( $P = 0.77$ ), respectively.

#### Symptoms of Constipation

For each patient, the mean difference in ESAS scores was calculated as the ESAS score

on the last study day minus the ESAS score at baseline. Negative scores denote an improvement in symptoms. No significant differences were observed in ESAS scores between the groups, with the range of mean differences being  $-0.02$  (shortness of breath) to  $0.69$  (drowsiness). Clinically, values less than one are not considered significant.

#### Bowel Care Interventions

At least one type of additional bowel care intervention was given to 74.4% of those in the placebo group compared with 68.6% in the docusate group (not significant,  $P = 0.77$ ). The interventions primarily included bisacodyl suppository (54.3% vs. 64.1%), sodium phosphate enema (31.4% vs. 38.5%), or lactulose (20.0% vs. 20.5%) in the docusate vs. placebo groups, respectively. Although not significant, a greater proportion of patients in the placebo group (38.5%) than in the docusate group (14.3%) received a bowel intervention on Day 5 of the study ( $P = 0.35$ ).

#### Discussion

This prospective RCT found that docusate plus sennosides was not more efficacious than sennosides alone (placebo plus sennosides) in the management of constipation in hospice patients. Our RCT showed no statistically significant difference in stool frequency, volume, or consistency between docusate and placebo group hospice patients. These findings are consistent with studies that assessed docusate in chronically ill patients.<sup>7-9,11</sup> Moreover, the values within the 95% CI range ( $-0.09, 0.19$ ) around the mean difference of bowel movements between the groups would not be considered to be of clinical significance.

It is possible that the use of cointerventions in both arms of the study may have contributed to the observed lack of difference in study outcomes between the docusate and placebo groups; however, the randomized study design would have reduced/controlled for such an effect. It is also possible that the terminally ill nature of hospice patients and the presence of various superimposed conditions may have resulted in these patients either responding differently or not responding to docusate treatment.

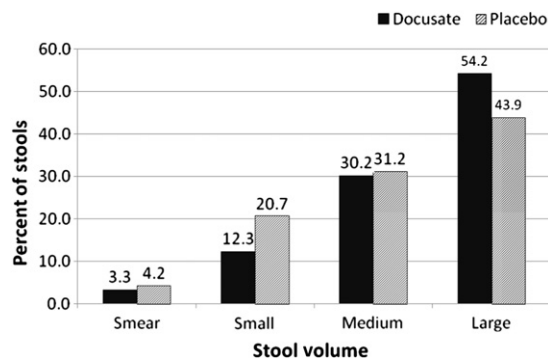


Fig. 3. Stool volume by study group.

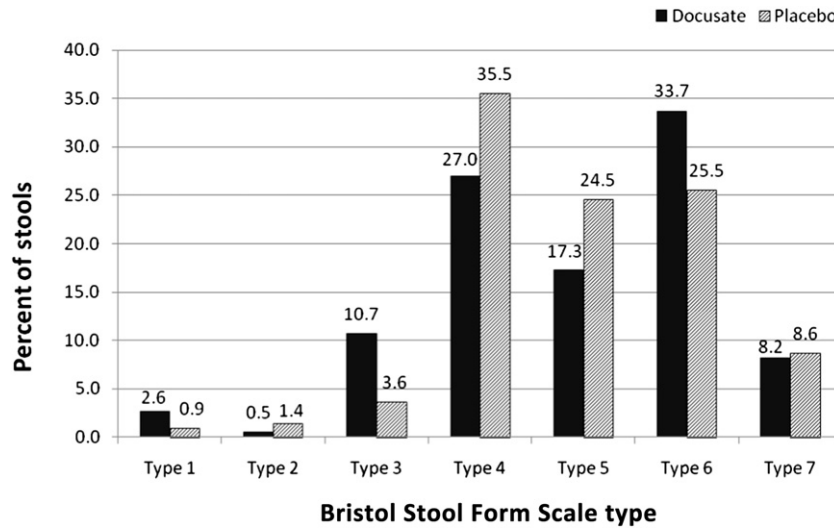


Fig. 4. Stool consistency by study group.

The lack of statistical significance should not be interpreted definitely as lack of efficacy. The study findings only suggest that there may be therapeutic equivalence between placebo and docusate, but do not prove this definitively, particularly in the absence of an internal measure of assay sensitivity and the inability to control for additional bowel care interventions or other medication use. The study findings were not affected by chemotherapy, or hormonal or radiation therapy, as none of the patients were on any of these treatments.

Although the difference in mean MEDD between the docusate (92.9 mg) and placebo (154.3 mg) groups was not statistically significant, it is possible that this difference may have clinical significance. A higher dose of opioid analgesics in the placebo group may have worsened constipation, thereby making the finding of no difference in laxation by the addition of docusate to sennosides more compelling.

The assessment of symptoms related to constipation in this study was made using the ESAS instrument, which measures "pain" in general, rather than abdominal pain in particular. The ESAS is a tool that has been previously validated in the palliative care population. Although it is likely that abdominal pain is included as part of overall pain in the ESAS, having a separate assessment of abdominal pain may have shown a difference in the prevalence

of colic between the docusate and placebo groups.

Despite its high incidence and high impact on burden of care, the regular assessment and screening of constipation is generally not consistent among health care providers, primarily because of the lack of an agreed definition of constipation in the palliative care setting. Constipation is often treated on the basis of a patient's perception that there is a disturbance in bowel function; however, impression may be greatly influenced by the patient's expectation or cognitive function. It is not uncommon for patients and caregivers to attribute the lack of or decreased bowel motion to decreased or no oral intake, or to patients' premonitory habit, yet caregivers still find severe fecal impaction after comprehensive assessment. Some discontinue laxatives because of watery diarrhea, which could in fact be bypassing overflow of colonic fluid. Severe abdominal pain as a result of constipation, with or without severe nausea and vomiting, may be masked by an increased dose of opioid analgesics, which only aggravate constipation. Unless constipation is addressed systematically and routinely, patients and caregivers may underreport the problem as they are often overwhelmed by other major concerns and symptoms related to advanced disease. If not identified by patients and/or caregivers as a concern or discomfort, health care professionals may overlook constipation as merely



one of the symptoms, rather than a significant physiological dysfunction that can negatively affect a patient's general condition and quality of life.

The European Consensus Group on Constipation in Palliative Care (ECGCPC)<sup>1</sup> and the Canadian Consensus Development Group for Constipation in Patients with Advanced Progressive Illness<sup>22</sup> define constipation as the passage of small, hard feces infrequently and with difficulty, while emphasizing that it should be fundamentally defined by the patient in the palliative care setting. The ECGCPC proposed the inclusion of patient strain/discomfort while defecating and completeness of evacuation, following the Rome III diagnostic criteria for functional constipation.<sup>23</sup> In addition, symptoms associated with constipation have been included, such as pain.<sup>11</sup> No previous studies have had a broad inclusion of these components in their operating definitions. Since our study was designed, the Rome II diagnostic criteria have been revised, based on available evidence and expert opinion, to Rome III<sup>23</sup> diagnostic criteria, and the American College of Gastroenterology Chronic Constipation Task Force<sup>24</sup> has published their own definition.

In our study, implementation of the Bowel Movement Record ([Appendix](#)), which facilitates the recording of stool frequency, stool consistency, volume, ease, and completeness of defecation by the nursing staff, enabled comprehensive, standardized bowel recording practices across the participating hospice units. We recommend using the Bowel Movement Record to standardize constipation assessment and bowel recording practices in hospices.

Despite its robust design, the study findings may not be generalizable to all palliative care or hospice patients in other areas, or to patients who receive palliative care services outside of the hospice environment. The study is limited to the very advanced palliative care population that requires hospice admission. It is uncertain if a 10-day course of docusate is the optimum duration to compare outcomes between the two groups; however, given the short life expectancy of hospice patients and relatively short average length of stay in the hospices, a 10-day trial was deemed appropriate.

Over the five-year study period, issues related to nursing staff shortages in hospices and intermittent bed closures contributed to reducing the number of patients in hospices and, thereby, prolonging patient recruitment. Concomitantly, some noticeable changes in the patterns of prescribing laxatives were observed in the hospices; in particular, progressively fewer patients were prescribed docusate. By simply conducting the study and drawing attention to the use of docusate, the study may have had a "Hawthorne effect" on influencing physician prescribing behavior of docusate. Patients who were not prescribed docusate were excluded from the recruitment sampling frame; therefore, otherwise potentially eligible candidates for the study may have been excluded resulting in some patient selection bias. Growing evidence for the use of polyethylene glycol in managing nonpalliative chronic constipation has been progressively adopted recently in hospice settings.<sup>24</sup> Also, methyl naltrexone subcutaneous injection in the management of opioid-induced constipation was introduced in our setting in 2009. This change in the use of laxatives also may have contributed to questioning the efficacy of docusate, thereby leaving fewer clinicians prescribing docusate for their palliative care patients.

Data on patients' perceptions of sense of emptying and difficulty of defecation were obtained on a limited number of patients. This was likely the result of differences in the timing of defecation and nursing assessment of bowel activity, particularly for those patients who did not need assistance with bowel movements. Patients who defecated independently were often unable to reliably recall their sensation afterward, resulting in limited data.

Consistent with previous RCTs in palliative care settings,<sup>25–28</sup> this study experienced a relatively slow rate of patient recruitment, which resulted in the study being conducted over almost a five-year period. Slow patient recruitment in palliative care has been attributed to "attrition owing to early death, opposition to randomization by patients and referral sources, ethical problems raised by randomization of dying patients, the appropriate timing of comparison points, and difficulties of collecting data from sick or exhausted patients and care givers."<sup>25</sup> The wishes of patients' families

at the end of life also confounded and contributed to slow patient recruitment. In addition, the rapid decline of some patients, in particular their inability to swallow medication, restricted patients' ability to continue the study, thereby generating some patient selection bias in favor of less terminally ill patients.

The study findings of no statistically significant difference between the docusate and placebo groups have clinical and operational implications in the management of constipation in terminally ill hospice patients. Given that these patients are usually taxed with taking multiple medications, eliminating nonefficacious medications is a significant consideration. Reducing the number of medications taken and removing a large capsule from this physically vulnerable population has the potential to improve quality of life at the end of life, decrease the time required for medication distribution by nursing staff, and lower the overall cost of care.

We conclude that general standing orders/policies for the use of docusate in the management of constipation on hospice units should be reviewed in light of this study. Future randomized clinical trials assessing the efficacy of docusate in a broader range of palliative care patients, including palliative home care, would be beneficial. Research into finding a more effective bowel management protocol/medication is warranted.

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## Appendix

### Bowel Movement Record

Month: _____												Patient Name: _____												
DATE																								
	N	D	E	N	D	E	N	D	E	N	D	E	N	D	E	N	D	E	N	D	E	N	D	E
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Type																								
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Empty? Y N N/A																								
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<b>Rx</b> D- Dulcolax Supp. G- Glycerin Supp. E- SS Enema FL- Fleet Enema HF- High Fleet OR- Oil Retention R- Relistor	<b>Amount</b> SM- Smearing S- Small (≈1/4 cup) M- Medium (≈1/2 cup) L – Large (>3/4 cup)	<b>Type</b> Use the Bristol Stool Scale Type 1      Type 5 Type 2      Type 6 Type 3      Type 7 Type 4	<b>Questions</b> 1. Did you need to strain? 2. Did you feel you were able to empty fully? Y= Yes    N= No N/A= Not Applicable
N- Night shift    D- Day shift    E- Evening shift			