Things We Do for No Reason: Prescribing Docusate for Constipation in Hospitalized Adults

Robert J Fakheri, MD1*, Frank M Volpicelli, MD2

1Weill Cornell Medicine, New York, New York; 2NYU Langone Health, New York, New York.

The “Things We Do for No Reason” (TWDFNR) series reviews practices that have become common parts of hospital care but which may provide little value to our patients. Practices reviewed in the TWDFNR series do not represent “black and white” conclusions or clinical practice standards but are meant as a starting place for research and active discussions among hospitalists and patients. We invite you to be part of that discussion.

CASE PRESENTATION
An 80-year-old woman with no significant past medical history presents with a mechanical fall. X-rays are notable for a right hip fracture. She is treated with morphine for analgesia and evaluated by orthopedic surgery for surgical repair. The hospitalist recognizes that this patient is at high risk for constipation and orders docusate for prevention of constipation.

BACKGROUND
Constipation is a highly prevalent problem in all practice settings, especially in the hospital, affecting two out of five hospitalized patients.1 Multiple factors in the inpatient setting contribute to constipation, including decreased mobility, medical comorbidities, postsurgical ileus, anesthetics, and medications such as opioid analgesics. Furthermore, the inpatient population is aging in parallel with the general population and constipation is more common in the elderly, likely owing to a combination of decreased muscle mass and impaired function of autonomic nerves.2 Consequently, inpatient providers frequently treat constipation or try to prevent it using stool softeners or laxatives.

One of the most commonly prescribed agents, regardless of medical specialty, is docusate, also known as dioctyl sulfosuccinate or by its brand name, Colace. A study from McGill University Health Centre in Montreal, Canada reported that docusate was the most frequently prescribed laxative, accounting for 64% of laxative medication doses, with associated costs approaching $60,000 per year.3 Direct drug costs accounted for a quarter of the expenses, and the remaining three quarters were estimated labor costs for administration. Medical and surgical admissions shared similar proportions of usage, with an average of 10 doses of docusate per admission across 17,064 admissions. Furthermore, half of the patients were prescribed docusate upon discharge. The authors extrapolated their data to suggest that total healthcare spending in North America on docusate products likely exceeds $100,000,000 yearly. A second study from Toronto found that 15% of all hospitalized patients are prescribed at least one dose of docusate, and that one-third of all new inpatient prescriptions are continued at discharge.4

WHY YOU THINK DOCUSATE MIGHT BE HELPFUL FOR CONSTIPATION
Docusate is thought to act as a detergent to retain water in the stool, thereby acting as a stool softener to facilitate stool passage. Physicians have prescribed docusate for decades, and attendings have passed down the practice of prescribing docusate for constipation to medical trainees for generations. The initial docusate studies showed promise, as it softened the stool by increasing its water content and made it easier to pass through the intestines.5 One of the earliest human studies compared docusate to an unspecified placebo in 35 elderly patients with chronic atonic constipation and found a decreased need for enemas.6 Some other observational studies also reported a decreased need for manual disimpactions and enemas in elderly populations.7,8 One randomized, controlled trial from 1968 showed an increased frequency of bowel movements compared to placebo, but it excluded half of the enrolled patients because they had a positive placebo response.9 Since those early studies from the 1950s and 1960s, docusate remains widely accepted as an effective stool softener with positive endorsements from hospital formularies and order sets and patient information sheets such as the JAMA Patient Page.10 Furthermore, the World Health Organization lists docusate as an “essential medicine,” reinforcing the notion that it is effective.11

WHY THERE IS NO REASON TO PRESCRIBE DOCUSATE FOR CONSTIPATION
Despite common practice, the efficacy of docusate as a stool softener has not been borne out by rigorous scientific data. On the contrary, multiple randomized controlled trials have failed to show any significant efficacy of this drug over placebo (Table).

The initial trial in 1976 studied 34 elderly patients on a general medical ward for prophylaxis of constipation.12 They random-
ized patients to 100 mg twice daily of docusate sodium versus a control group that did not receive any type of laxative. The number of bowel movements and their character served as the measured outcomes. The study demonstrated no statistically significant differences in the frequency and character of bowel movements between the docusate and placebo groups. Even at that time, the authors questioned whether docusate had any efficacy at all: “[w]hether the drug actually offers anything beyond placebo in each arm for a treatment duration of two weeks and then crossed over to other treatment period with three arms of randomization: docusate sodium 100 mg daily, docusate sodium 100 mg bid, docusate calcium 240 mg daily.

Another trial in 1985 compared docusate sodium 100 mg tid with placebo, no change in quality. An increase in frequency of bowel movements with docusate calcium 240 mg, but no change in quality. Increase in bowel movements in other arms did not meet statistical significance.

A third study in 1985 compared docusate sodium 100 mg three times daily versus placebo in six healthy patients with ileostomies and six healthy volunteers.14 Therapy with docusate “had no effect on stool weight, stool frequency, stool water, or mean transit time.”

Another study in 1991 evaluated 15 elderly nursing home residents with a randomized, double-blind crossover design.15 Subjects received 240 mg twice daily of docusate calcium versus placebo for three weeks and then crossed over to other arm after a two-week wash-out period. The investigators found no difference in the number of bowel movements per week or in the need for additional laxatives, or patient’s subjective experience.

Larger studies were subsequently initiated in more recent years. In 1998, a randomized controlled trial in 170 subjects with chronic idiopathic constipation compared psyllium 5.1 g twice daily and docusate sodium 100 mg twice daily with a corresponding placebo in each arm for a treatment duration of two weeks after a two-week placebo baseline period.16 Psyllium was found to increase stool water content and stool water weight over the baseline period, while docusate essentially had no effect on stool water content or water weight. Furthermore, by treatment week 2, psyllium demonstrated an increase in the frequency of bowel movements, whereas docusate did not. It should be noted that this study was funded by Procter & Gamble, which manufactures Metamucil, a popular brand of psyllium.

Lastly, the most recent randomized controlled trial was published in 2013. It included 74 hospice patients in Canada.

---

**TABLE. Summary of Randomized Controlled Trials Studying Docusate**

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year Published</th>
<th>Sample Size (n)</th>
<th>Patient Population</th>
<th>Intent of Therapy</th>
<th>Site of Care</th>
<th>Docusate Dose</th>
<th>Comparator</th>
<th>Duration</th>
<th>Brief Summary</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyland15</td>
<td>1968</td>
<td>15</td>
<td>Geriatric patients in hospital with chronic constipation</td>
<td>Treatment</td>
<td>Hospital</td>
<td>Docusate sodium 100 mg tid</td>
<td>Placebo with crossover</td>
<td>Four weeks, then four weeks crossover</td>
<td>Increase in bowel movements with treatment</td>
<td>19 patients excluded because of placebo response</td>
</tr>
<tr>
<td>Goodman12</td>
<td>1976</td>
<td>34</td>
<td>Prophylaxis for inpatients on “chronic medical service”</td>
<td>Prophylaxis</td>
<td>Hospital</td>
<td>Docusate sodium 100 mg bid</td>
<td>Control</td>
<td>26 days</td>
<td>No difference in frequency of bowel movements</td>
<td></td>
</tr>
<tr>
<td>Fain13</td>
<td>1978</td>
<td>46</td>
<td>Institutionalized patients with chronic constipation</td>
<td>Treatment</td>
<td>Nursing home</td>
<td>Docusate sodium 100 mg daily, docusate sodium 100 mg bid, docusate calcium 240 mg daily</td>
<td>Placebo period for each arm</td>
<td>Two weeks placebo, three weeks treatment</td>
<td>An increase in frequency of bowel movements with docusate calcium 240 mg, but no change in quality. Increase in bowel movements in other arms did not meet statistical significance</td>
<td></td>
</tr>
<tr>
<td>Chapman14</td>
<td>1985</td>
<td>12</td>
<td>Healthy patients with ileostomies and healthy controls</td>
<td>Prophylaxis</td>
<td>Ambulatory</td>
<td>Docusate sodium 100 mg tid</td>
<td>Control with crossover</td>
<td>Four days</td>
<td>No difference in stool weight, frequency, water content, or transit time</td>
<td></td>
</tr>
<tr>
<td>Castle15</td>
<td>1991</td>
<td>15</td>
<td>Elderly veterans in nursing home on bowel regimen</td>
<td>Treatment</td>
<td>Nursing home</td>
<td>Docusate calcium 240 mg bid</td>
<td>Placebo with crossover</td>
<td>Three weeks then two weeks crossover</td>
<td>No difference in stool frequency, need for additional laxatives, or patient’s subjective experience</td>
<td></td>
</tr>
<tr>
<td>McRorie17</td>
<td>1998</td>
<td>170</td>
<td>Chronic idiopathic constipation</td>
<td>Treatment</td>
<td>Ambulatory</td>
<td>Docusate sodium 100 mg bid</td>
<td>Psyllium 5.1 g bid</td>
<td>Two weeks placebo, two weeks treatment</td>
<td>Psyllium increased stool water content and frequency; docusate had no change</td>
<td>Industry sponsored</td>
</tr>
<tr>
<td>Tarumi18</td>
<td>2013</td>
<td>74</td>
<td>Hospice patients</td>
<td>Prophylaxis and treatment</td>
<td>Inpatient hospice</td>
<td>Docusate sodium 200 mg bid</td>
<td>Placebo</td>
<td>10 days</td>
<td>No difference in stool frequency, volume, or consistency</td>
<td>All patients received sennosides</td>
</tr>
</tbody>
</table>
comparing docusate 200 mg and sennosides twice daily versus placebo and sennosides for 10 days. The study found no difference in stool frequency, volume, or consistency between docusate and placebo.\textsuperscript{17}

A number of systematic reviews have studied the literature on bowel regimens and have noted the paucity of high-quality data supporting the efficacy of docusate, despite its wide-spread use.\textsuperscript{18-22} With these weak data, multiple authors have advocated for removing docusate from hospital formularies and using hospitalizations as an opportunity to de-prescribe this medication to reduce polypharmacy.\textsuperscript{3,4,23}

Although docusate is considered a benign therapy, there is certainly potential for harm to the patient and detrimental effects on the healthcare system. Patients commonly complain about the unpleasant taste and lingering aftertaste, which may lead to decreased oral intake and worsening nutritional status.\textsuperscript{23} Furthermore, docusate may impact the absorption and effectiveness of other proven treatments.\textsuperscript{23} Perhaps the most important harm is that providers needlessly wait for docusate to fail before prescribing effective therapies for constipation. This process negatively impacts patient satisfaction and potentially increases healthcare costs if hospital length of stay is increased. Another important consideration is that patients may refuse truly necessary medications due to the excessive pill burden.

Costs to the healthcare system are increased needlessly when medications that do not improve outcomes are prescribed. Although the individual pill cost is low, the widespread use and the associated pharmacy and nursing resources required for administration create an estimated cost for docusate over $100,000,000 per year for North America alone.\textsuperscript{3} The staff time required for administration may prevent healthcare personnel from engaging in other more valuable tasks. Additionally, every medication order creates an opportunity for medical error. Lastly, bacteria were recently found contaminating the liquid formulation, which carries its own obvious implications if patients develop iatrogenic infections.\textsuperscript{24}

**WHAT YOU SHOULD DO INSTEAD**

Instead of using docusate, prescribe agents with established efficacy. In 2006, a systematic review published in the American Journal of Gastroenterology graded the evidence behind different therapies for chronic constipation.\textsuperscript{21} They found good evidence (Grade A) to support the use of polyethylene glycol (PEG), while psyllium and lactulose had moderate evidence (Grade B) to support their use. All other currently available agents that were reviewed had poor evidence to support their use. A more recent study in people prescribed opioids similarly found evidence to support the use of polyethylene glycol, lactulose, and sennosides.\textsuperscript{25} Lastly, the 2016 guidelines from the American Society of Colon and Rectal Surgeons do not mention docusate, though they comment on the paucity of data on stool softeners. Their recommendations for laxative therapy are similar to those of the previously discussed reviews.\textsuperscript{26} Ultimately, the choice of therapy, pharmacological and nonpharmacological, should be individualized for each patient based on the clinical context and cause of constipation. Non-pharmacologic treatments include dietary modification, mobilization, chewing gum, and biofeedback. If pharmacotherapy is required, use laxatives with the strongest evidence.

**RECOMMENDATIONS**

- In patients with constipation or at risk for constipation, use laxatives with proven efficacy (such as polyethylene glycol, lactulose, psyllium, or sennosides) for treatment or prophylaxis of constipation instead of using docusate.
- Discuss de-prescription for patients using docusate prior to admission.
- Remove docusate from your hospital formulary.

**CONCLUSION**

Docusate is commonly used for the treatment and prevention of constipation in hospitalized patients, with significant associated costs. This common practice continues despite little evidence supporting its efficacy and many trials failing to show benefits over placebo. Decreased utilization of ineffective therapies such as docusate is recommended. Returning to the case presentation, the hospitalist should start the patient on alternative therapies, instead of docusate, such as polyethylene glycol, lactulose, psyllium, or sennosides, which have better evidence supporting their use.

Do you think this is a low-value practice? Is this truly a “Thing We Do for No Reason?” Share what you do in your practice and join in the conversation online by retweeting it on Twitter (#TWDFNR) and liking it on Facebook. We invite you to propose ideas for other “Things We Do for No Reason” topics by emailing TWDFNR@hospitalmedicine.org.

Disclosures: All authors deny any relevant conflict of interest with the attached manuscript.

**References**