

Drugs and Therapeutics Backgrounder

Stool Softeners: WHY are they still used?

BOTTOM LINE: Docusate is no more effective than placebo for the prevention and treatment of constipation.

Background:

Docusate salts (sodium and calcium) are widely available, over-the-counter medications classified as stool softeners. Their surfactant action, in theory, keeps stool pliable and prevents straining during defecation. The utility of stool softeners have been questioned for a number of years¹, and objective evidence for their effectiveness in treating and preventing constipation shows no benefit.^{2,3} Despite this, stool softeners are frequently dispensed in Alberta Health Services (AHS) - there were over 2.1 million 100mg doses dispensed in 2013. Although not expensive medications (approximately \$108,000 in acquisition costs), this does represent significant use of pharmacy and nursing resources, and adds to the medication burden borne by our patients for a therapy that has no efficacy.

Efficacy:

A recent review of the evidence and a Canadian consensus statement conclude that that docusate is no more effective than placebo in the prevention or management of constipation in geriatric patients, irritable bowel syndrome patients, and otherwise healthy patients.^{3,4} Using docusate for constipation in palliative or terminally ill patients does not improve stool frequency, consistency or the patient's perceptions of bowel movements.^{6,7} In a study with palliative care patients, adding docusate to sennosides did not improve the frequency or consistency of bowel movements, and it was observed that the patients receiving docusate had an increased need for rescue laxatives.⁸ In patients with opioid induced bowel dysfunction, stool softeners are not effective when administered alone.¹⁰ There is no data for the use of docusate in children.⁵

Safety of stopping docusate:

Docusate is not absorbed systemically and does not interact with receptors in the gastrointestinal tract, withdrawal or rebound effects are not a concern.¹¹ Docusate may be stopped without tapering or additional monitoring.

Sustainability:

As comparative trials between docusate and other laxatives do not indicate any benefit^{2,12}, *patients already using docusate could have it withdrawn without the need to replace it with another laxative.* For patients requiring treatment or prevention of constipation, there are several other effective formulary options available to choose from, such as magnesium hydroxide, polyethylene glycol 3350, psyllium, and lactulose.⁹ Selection of laxative agent(s) depends on several factors and must be individualized to the patient.

References

1. Castle, SC et al. "Constipation prevention: empiric use of stool softeners questioned." *Geriatrics* 46.11 (1991): 84-86.
2. Jones, Michael P et al. "Lack of objective evidence of efficacy of laxatives in chronic constipation." *Digestive diseases and sciences* 47.10 (2002): 2222-2230.
3. Dioctyl Sulfosuccinate or Docusate (Calcium or Sodium) for the Prevention or Management of Constipation: A Review of the Clinical Effectiveness. CADTH Rapid Response Report. Published June 26, 2014.
4. Paré, Pierre et al. "Recommendations on chronic constipation (including constipation associated with irritable bowel syndrome) treatment." *Canadian Journal of Gastroenterology* 21.Suppl B (2007): 3B.
5. van Wering HM Tabbers MM, Benninga MA. "Are constipation drugs effective and safe to be used in children?: a review of the literature" *Expert Opin. Drug Saf.* 2012 11(1): 71-82
6. Tarumi, Yoko et al. "Randomized, double-blind, placebo-controlled trial of oral docusate in the management of constipation in hospice patients." *Journal of pain and symptom management* 45.1 (2013): 2-13.
7. Hurdon, Virginia, Raymond Viola, and Cori Schroder. "How useful is docusate in patients at risk for constipation? A systematic review of the evidence in the chronically ill." *Journal of pain and symptom management* 19.2 (2000): 130-136.
8. Hawley, Philippa Helen, and Jai Jun Byeon. "A comparison of sennosides-based bowel protocols with and without docusate in hospitalized patients with cancer." *Journal of palliative medicine* 11.4 (2008): 575-581.
9. Ramkumar, Davendra, and Satish SC Rao. "Efficacy and safety of traditional medical therapies for chronic constipation: systematic review." *The American journal of gastroenterology* 100.4 (2005): 936-971.
10. Pappagallo, Marco. "Incidence, prevalence, and management of opioid bowel dysfunction." *The American journal of surgery* 182.5 (2001): S11-S18.
11. MedFacts. Meta-analysis covering adverse side effect reports of colace capsules (docusate sodium) patients who developed drug withdrawal syndrome. [http://medsfacts.com/study-colace%20capsules%20%20\(docusate%20sodium\)-causing-drug%20withdrawal%20syndrome.php](http://medsfacts.com/study-colace%20capsules%20%20(docusate%20sodium)-causing-drug%20withdrawal%20syndrome.php) (accessed online April 11, 2014)
12. Gartlehner G, Jonas DE, Morgan LC, Ringel Y, Hansen RA, Bryant CM, Carey T. Drug Class Review on Constipation Drugs. 2007. <http://www.ohsu.edu/drugeffectiveness/reports/final.c>

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