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 1⁄4 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.
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Strengths:

Excellent study design: double blinded with allocation concealment, prospective placebo-controlled RCT with predetermined outcomes.

Used objective standardized clinical tools: Bristol Stool Form Scale and Bowel Movement Record. After patients were randomized, the two study groups had comparable demographics and patient characteristics.

Results of study are applicable as study population (Edmonton Hospice patients) is very similar to our patients at Grey Nuns Tertiary Palliative Care Unit, Edmonton.

Weaknesses:

Small sample size of patients completed the trial: 25 patients in treatment arm and 31 in placebo group. This is still enough patients as the authors' predetermined sample sizes were 23.

The majority of patients (74% treatment arm and 69% placebo) had taken additional bowel care interventions including suppositories and enemas.

Correctly conceded by the authors was that the conduction of the study influenced whether or not physicians prescribed docusate (Hawthorne Effect) leading to potential selection bias.

Relevance to palliative care: A well-designed RCT (gold standard) study examining whether docusate has any role in providing palliative care patients any reduction in constipation, and ultimately improvement in quality of life. An excellent example of how health care practioners should scrutinize common practices that may be more habitual then evidence based. This is one of the few studies despite the inclusion of docusate as a common order set in many healthcare facilities in North America - perhaps this may decrease the frequency of this order. For patients and their caregivers, the benefit of not taking an additional medication (docusate, which is twice daily) may outweigh the little constipation improvement they may gain.