Management of constipation in residents with dementia: sorbitol effectiveness and cost

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study compared the therapeutic substitution of sorbitol for lactulose in the treatment of chronic constipation among nursing home residents with dementia. The doses ranged from 30 mL every other day to 6 mL twice daily.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised the residents of a dementia special care unit (DSCU) in a Veterans Administration hospital. All residents who experienced chronic constipation and were receiving an osmotic laxative were included.

Setting
The study was conducted at a DSCU in a Veterans Administration hospital in Massachusetts, USA.

Dates to which data relate
The dates to which the effectiveness evidence and resources use data related were not reported. The price year was also not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
No power calculations were reported. In addition, the method used to select the sample was not given. All residents who experienced chronic constipation were included. Chronic constipation was defined as a condition that required regular administration of a laxative to assure bowel evacuation at least every 3 days. Forty-one male residents (47%) from the 88 treated on the unit experienced chronic constipation. Their mean age was 76.4 (+/- 7.0) years (range: 51 - 86) and they were moderately or severely demented. The mean cognitive performance scale score was 4.85 (+/- 0.94).

Study design
This was a within group comparison (before-and-after) study that was conducted in a single centre. The outcomes were compared before and after the therapeutic substitution of sorbitol for lactulose. The patients were cared for by two attending physicians who used the same strategy to treat constipation. After collecting baseline information for a week, sorbitol was substituted for lactulose on an equal volume basis at the same time in all patients. Three more weeks of data were then collected. Blinding of the outcome assessment or treatment administration was not reported.

**Analysis of effectiveness**
The primary health outcomes in the analysis were the use of oral or rectally administered laxatives, and the classes and quantities of drugs in each strategy. No statistics tests to analyse differences in demographic characteristics, conditions, drug classes, or intervention effectiveness were reported.

**Effectiveness results**
There was no difference in the efficacy of lactulose and sorbitol.

No obvious changes in the use of laxatives were observed, although there was a trend toward less use of Milk of Magnesia with sorbitol on approximately 10% of days/patient.

Fleet enemas were used on three occasions (two residents) during 2 weeks on sorbitol.

The use of bisacodyl suppositories decreased to 2% to 4% of days/patient.

Both of the residents who received a Fleet enema also had an order for a bisacodyl suppository and the suppositories were used in the previous weeks.

These results were stated without reporting whether the differences were significant.

**Clinical conclusions**
The authors stated that the results of this study indicated that sorbitol could be substituted for lactulose with no loss of efficacy in the treatment of constipation.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was reported in the economic evaluation. As the clinical effectiveness results were left disaggregated and no primary outcome measure was reported, the study was therefore classified as a cost-consequences analysis.

**Direct costs**
The cost categories included in the analysis were the acquisition, supply and labour costs related to medication, both oral and rectally administered laxatives. Information on labour costs was obtained from two articles published in 2002. The sources for the other cost categories were not reported. Discounting of the costs was unnecessary because of the relatively short duration of the study period (i.e. 4 weeks). The quantities and the costs were not reported separately. The quantities and costs were estimated from actual data and published literature. The price year was not reported.

**Statistical analysis of costs**
No statistical analysis of the costs was reported.

**Indirect Costs**
The indirect costs were not reported.
Currency
US dollars ($).

Sensitivity analysis
As the two sources of labour costs differed, the authors reported two scenarios for the labour costs and total costs connected with the treatment of constipation within their facility.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost was slightly lower with sorbitol ($892.61 or $547.78/patient per year, depending on the labour cost used) than with lactulose ($976.51 or $621.52/patient per year) as a result of the lower acquisition cost of sorbitol.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors’ conclusions
The results of this study indicated that sorbitol could be substituted for lactulose with no loss of efficacy in the treatment of constipation, thus resulting in a lower cost. In addition, the routine use of sorbitol was more cost-effective than the routine use of docusate sodium or a Fleet enema.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was explicitly justified on the basis that it is a usual and current practice in the authors’ setting. You should judge whether these treatment strategies are relevant in your setting, or whether other comparators from other treatment or drug classes could also have been relevant.

Validity of estimate of measure of effectiveness
The analysis was based on a non-blinded within-group comparison study, with before and after analysis on the same sample of patients. However, such a study is associated with some disadvantages, such as time-related bias. This may limit the validity of the comparison, and should be borne in mind when considering the results. As the authors reported equal efficacy, it would have been important to report power calculations in order to be confident that it was a negative study. Blinding of the outcome assessment, which could reduce potential bias, was not reported. In addition, authors did not report that statistical analyses were undertaken to analyse the results. Furthermore, the follow-up of lactulose treatment lasted for one week, whereas that for sorbitol treatment was 3 weeks. This might have led to an under-estimation of the benefits of the lactulose treatment. Although limited details of the study population were provided, it would appear that the study sample was representative of the study population since the authors did not report stringent eligibility criteria for entry into the study.

Validity of estimate of measure of benefit
Since the authors did not derive a measure of health benefits and no primary outcome was reported, the study was therefore classified as a cost-consequences analysis.

Validity of estimate of costs
Although the perspective adopted in the economic analysis was not explicitly stated, it appears that appropriate costs relating to a health service perspective have been included in the analysis. The costs and the quantities were not reported.
separately, which will limit the generalisability of the authors' results. However, a breakdown of the direct cost components was given (e.g. acquisition, staff and materials). Further, there was limited information on the sources of the costs and no statistical analysis was performed. These factors limit the validity and generalisability of the cost analysis. Discounting was not necessary since all the costs were incurred during a 4-week period. The price year was not reported, which will hamper any future reflation exercises.

Other issues
The findings were compared with the results of other relevant studies. The generalisability of the results to other settings was addressed by the authors stating that, even when all residents in the study were males and had dementia, there was no reason to expect that the effectiveness of sorbitol would be different according to gender or according to cognitive conditions of individuals in a more usual nursing home population. The authors highlighted an additional limitation in that they did not collect data on the frequency of bowel movements in the resident population. However, less frequent bowel movements would be reflected in increased use of p.r.n. (as needed) laxatives because of their policy in that regard. The authors do not appear to have presented their results selectively and the scope of the analysis was clearly reflected in the authors' conclusions.

Implications of the study
The use of oral laxatives, primarily sorbitol, combined with close monitoring of bowel movements and subsequent changes in dose or frequency as necessary, might minimise the need to use rectally administered laxatives. All efforts combined to maintain a normal toileting regime might contribute to decreasing staff time, both in medication administration and incontinence care. According to the authors, the treatment strategy described in this study would also be effective in a more usual nursing home population. More controlled studies are needed to develop the best cost-effective strategy for the treatment of chronic constipation.

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