Dairy product-induced diarrhea after bowel surgery: a performance improvement opportunity

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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 health technology evaluated was the advance from a clear liquid diet to a soft-solids diet (SSD) as the postoperative diet regimen following bowel surgery. The SSD is described in detail in the paper.

Type of intervention
Rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had undergone bowel surgery. Patients were excluded in the following cases: Crohn's disease, irritable bowel disease, radiation enteritis, short gut syndrome, colitis, bowel obstruction of longer than five postoperative days, a history of lactose intolerance, or having followed a lactose-restricted diet before admission to hospital.

Setting
The setting was secondary care. The study was carried out in York, Pennsylvania, USA.

Dates to which data relate
The dates of the effectiveness date, cost data and price year were not reported.

Source of effectiveness data
The source of the effectiveness data was a single study.

Link between effectiveness and cost data
The costing may have been directly related to the study sample considered in the effectiveness analysis, although this was not clearly stated. The cost data were collected retrospectively.

Study sample
No power calculations were performed in the planning phase of the study in order to assure a certain power. Among 257 patients who underwent bowel surgery over a 15-month period, 193 met the inclusion criteria (98 males) and were considered for the effectiveness analysis. 114 (59.1%) went from clear liquids to LDBD postoperatively, while 79 went from clear liquids to SSD (overall mean age: 67.4 years; standard deviation 14.2 years). 51 patients had their ileocecal valve (ICV) removed during surgery: 28 in the LDBD and 23 in the SSD groups. The authors did not show evidence
that the study sample was representative of the study population.

**Study design**
This was a retrospective cohort study, performed at a single centre. Patients were followed-up during the postoperative period, until they were discharged from the hospital (overall median length of hospital stay was 7 days; range: 2 - 34).

**Analysis of effectiveness**
The primary health outcomes considered in the effectiveness analysis were the number (and percentage) of patients in each diet group who developed diarrhoea, and the number (and percentage) of patients with and without their ICV removed who developed diarrhoea in each of the diet groups. The study groups did not appear to be comparable at baseline in terms of the surgical procedure undergone, and no other baseline characteristics were considered in order to show the comparability of the study groups at baseline. No adjustments were performed to take account of confounding factors.

**Effectiveness results**
36 LDBD patients (31.6%) compared to 4 (5.1%) SSD patients developed diarrhoea (p<0.001). The authors stated that, after switching to SSD, there was a significant reduction in the frequency of diarrhoea among patients who were initially in the LDBD group.

Among patients who had had their ICV removed, there was a significantly greater occurrence of diarrhoea for LDBD patients when compared to SSD patients (16/28 (57.1%), versus 2/23 (8.7%); p<0.001).

Among patients with ICV, the occurrence of diarrhoea was also significantly higher for LDBD patients than for SSD patients (20/86 (23.3%) versus 2/56 (3.6%); p<0.001).

**Clinical conclusions**
The occurrence of diarrhoea was significantly greater for patients who changed from clear liquids to LDBD than for those who changed to SSD, independently of whether they had, or had not, had their ICV removed.

**Modelling**
An algorithm was developed to project the effectiveness and cost results obtained from the single study to the population of the USA. Using data from the National Centre of Health Statistics, the authors assumed there would be approximately 500,000 patients per year who would undergo partial excision of the large intestine or lysis of peritoneal adhesion in their setting.

**Measure of benefits used in the economic analysis**
The summary measure of benefit was the number of patients with diarrhoea associated with each type of diet. This measure of benefit was obtained directly from the single study.

**Direct costs**
The direct costs considered in the economic analysis appeared to be those of the hospital, and included the costs associated with post-surgical hospital stay, although the authors did not report further details of the categories of costs included. The cost data were taken from the financial databases of the hospital where the study was performed. Additionally, the authors made some assumptions. They appeared to consider that the costs per patient depended on whether they experienced diarrhoea, but not on the study group to which they belonged. Resource quantities were not reported separately from the costs. Discounting, correctly, does not seem to be performed, and was not required, since the period of analysis was shorter than 2 years. The dates of the cost data and the prices were not reported. The following direct costs were estimated: the cost per patient, according to whether they had or did not have diarrhoea; the
potential annualised savings for the hospital (considering 200 patients, and assuming 100% compliance with avoiding LDBD, and an incidence of diarrhoea of 5% for SSD patients); and the potential cost savings extrapolated at the national level.

Statistical analysis of costs
The estimated costs were treated in a stochastic manner. The KS Lilliefors test was used to determine whether the data was normally distributed. The t-test and the Mann-Whitney U tests were applied for normal and non-normal data, respectively.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were carried out to assess the robustness of the results when different rates of compliance with SSD were considered (from 100% to 0%). A hypothetical sample size of 1,000 patients was taken into account to run the algorithm used to perform the sensitivity analyses. The area of uncertainty investigated was, therefore, variability in data.

Estimated benefits used in the economic analysis
The reader is referred to the effectiveness results section reported above.

Cost results
The median cost per patient with diarrhoea was $10,337, and without diarrhoea was $6,751 (p<0.001).

This produced a potential annualised saving of $119,000 per 200 patients in the case where all patients were given SSD following a clear liquid diet after bowel surgery, when compared to LDBD.

At the national level, and considering that patients were given SSD or LDBD at a ratio of 3:2, the estimated potential saving was $250 million.

Synthesis of costs and benefits
The estimated benefits and costs were not combined. SSD was reported to be dominant because of fewer occurrences of diarrhoea and lower associated costs.

The results of the sensitivity analyses showed that when a compliance rate of 100% for SSD was considered (i.e. compliance rate of 0% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 0, and the incremental costs associated would be $0.

With an 80% compliance rate for SSD (i.e. compliance rate of 20% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 24, and the incremental costs associated would be $84,000.

With a 60% compliance rate for SSD (i.e. compliance rate of 40% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 98, and the incremental costs associated would be $343,000.

With a 50% compliance rate for SSD (i.e. compliance rate of 50% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 135, and the incremental costs associated would be $472,500.
With a 40% compliance rate for SSD (i.e. compliance rate of 60% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 172, and the incremental costs associated would be $602,000.

With a 20% compliance rate for SSD (i.e. compliance rate of 80% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 246, and the incremental costs associated would be $861,000.

With a 0% compliance rate for SSD (i.e. compliance rate of 100% for LDBD), the additional number of patients with diarrhoea per 1,000 patients would be 320, and the incremental costs would be $1,120,000.

Authors' conclusions
The authors concluded that diarrhoea was less frequent when patients were given SSD, and diarrhoea was relieved when LDBD was switched to SSD. There were cost savings associated with the use of SSD compared to LDBD.

CRD COMMENTARY - Selection of comparators
LDBD appeared to be chosen as the comparator because it was a diet currently used in the authors' setting after bowel surgery. They commented that there are lactose-free liquid diets that may be preferred to LDBD since temporary lactose intolerance following gastrointestinal tract surgery is directly related to diarrhoea. However, the authors did not consider these lactose-free diets as an additional alternative in this study. You must decide which type of diet is most widely prescribed in your own setting after bowel surgery.

Validity of estimate of measure of effectiveness
The study design was retrospective and, therefore, it was more subject to bias because the time lag limited the possibility of controlling confounding factors. A randomised controlled trial would have been more appropriate to analyse the study question. The authors did not show evidence that the study sample was representative of the study population, although they stated that the effectiveness results could be extrapolated to US patients. Neither did they show that the study groups were comparable at analysis. Further limitations reported by the authors were that the evaluation of stool appearance is subjective, oral intake during the study was not accurately recorded and the authors had to rely on the prescribed regimen. Also pectin intake was not measured and they did not control for potential confounding factors such as motility agents, use of antibiotics, and the surgical manipulation of bowel itself. All these factors introduced uncertainty into the reliability of the effectiveness results, limiting both its internal and external validity.

Validity of estimate of measure of benefit
The summary measure of benefit was obtained directly from the single study, in the case of the baseline analysis, and from modelling in the case of the one-way sensitivity analyses performed by the authors. The number of cases of diarrhoea was an appropriate measure of benefit, given the aim of the study. However, alternative measures of benefits, such as the number of quality-adjusted life-years (QALYs) gained, could have been used, which would have allowed the comparison of the results with those from other interventions.

Validity of estimate of costs
The perspective adopted appeared to be that of the hospital. The categories of costs included were not clearly described; therefore it cannot be clearly known whether all the relevant costs associated with this perspective were included in the economic evaluation. A more detailed costing estimation and reporting would have been required. As the authors reported, costs instead of charges were used for the cost estimation, which may have reflected the true opportunity cost of the interventions. However, the dates of the cost data and the price year were not reported. Resource utilisation and costs were not reported separately. These facts would hinder reflation exercises to other settings. Although statistical and sensitivity analyses were performed, and the results were robust, there is uncertainty around the cost results because of the lack of reporting.
Other issues
Appropriate comparisons of the study findings with those from other studies were not reported. The authors commented that their results are applicable to the great majority of patients undergoing this type of bowel surgery in the USA, although the potential savings will vary according to the clinical practice and the proportion of patients who could be transferred to SSD.

Implications of the study
The authors recommended the avoidance of dairy products after bowel surgery, especially in elderly postoperative patients. They also recommended that a prospective study be carried out in order to better address the aims of this study.

Source of funding
None stated.

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cost-Benefit Analysis; Diarrhea; Diet /economics; Eating; Intestines /surgery; Patient Care Management /methods; Postoperative Care /economics /methods; Postoperative Complications /prevention & control; Recovery of Function

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