A quality improvement project comparing two regimens of medication for colonoscopy preparation

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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
Two regimens of medication for colonoscopy preparation were examined. The bowel preparations considered were Fleet Phospho-soda and Colyte with Dulcolax. Phospho-soda was administered in 2 doses of 45 mL. The first dose was taken the evening before colonoscopy at 7 pm, while the second dose was taken the next morning 3 hours before leaving for the examination. The Colyte-Dulcolax regimen consisted of Dulcolax at 10 am the day before colonoscopy, followed by 4 litres of Colyte starting at 4 pm in the evening, with one glass taken every 15 minutes until completed.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing colonoscopy for the detection of pre-cancerous polyps.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from January 2000 to April 2001. The price year was not explicitly reported.

Source of effectiveness data
The effectiveness evidence was 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 study.

Study sample
Power calculations were not reported. The study consisted of three phases during which the patients were enrolled. In Phase I (started in January 2000 and continued for 9 weeks), there were 197 patients in the Colyte-Dulcolax group and 70 patients in the Phospho-soda group. In Phase II, (October 2000), there were 23 patients in the Colyte-Dulcolax group and 70 patients in the Phospho-soda group. In Phase III (March to April 2001), there were 66 patients in the Colyte-Dulcolax group and 201 patients in the Phospho-soda group. Therefore, a total sample of 627 patients was enrolled (286
in the Colyte-Dulcolax group and 341 in the Phospho-soda group). The demographics of the patients were not reported. Phase I reflected current practice, but there was a prescribing preference for Colyte-Dulcolax. Therefore, in Phase II preference was given to Phospho-soda, unless there was a specific contraindication. Phase III was a confirmatory period that was carried out to determine patient preferences for the two medications.

**Study design**
This was a prospective cohort study that was carried out in a single centre, the Gastroenterology Clinic at the US National Naval Medical Center, Bethesda (MD). No follow-up was performed and there was no explicit blinding of the outcome assessment.

**Analysis of effectiveness**
All of the patients included in the initial study sample were accounted for in the analysis of effectiveness. The outcome measures used were:

- clinical effectiveness, based on the evaluations of 12 examining endoscopists who ranked the effectiveness of the study medication on colon preparation using seven criteria ranging from "excellent" to "poor";
- patient tolerability (i.e. incidence of nausea and/or vomiting);
- patient compliance (i.e. amount of medication consumed by the patients); and
- patient preference toward the study medication, which was assessed in a sub-group of 71 respondents of 84 patients in the Phospho-soda group who had previously received Colyte-Dulcolax.

The outcomes were assessed using a questionnaire. The baseline comparability of the study groups was not discussed.

**Effectiveness results**
The participating endoscopists rated colon preparation as excellent-to-good in 88% of the Phospho-soda group and in 76% of the Colyte-Dulcolax group, (p<0.01). The rate of adequate-to-fair assessment was 10% (Phospho-soda) versus 21% (Colyte-Dulcolax). The rate of poor assessment was 2% (Phospho-soda) versus 3% (Colyte-Dulcolax).

There was no statistically significant difference in patient tolerability. Nausea and/or vomiting were reported in 5% of Phospho-soda patients and in 7% of Colyte-Dulcolax patients. Nausea without vomiting was observed in 18% of Phospho-soda patients and in 21% of Colyte-Dulcolax patients.

Significantly more Phosphate-soda patients than Colyte-Dulcolax patients were able to drink all of the preparation. The difference was statistically significant.

Of the 71 patients who had received both medications (Phospho-soda in the current evaluation and Colyte-Dulcolax for previous colonoscopies), 68 patients (96%) preferred Phospho-soda.

**Clinical conclusions**
The effectiveness analysis showed that Phospho-soda was well tolerated and was more effective than Colyte-Dulcolax. Patients preferred Phospho-soda to Colyte-Dulcolax and the compliance rate was higher.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were presented separately from the quantities of resources used. The economic analysis considered only the unit costs of Phospho-soda and Colyte-Dulcolax. The cost/resource boundary of the study appears to have been that of the hospital. The costs were derived from the hospital pharmacy. The fixed costs of operating the pharmacy were not considered. Resource use was based on patient-level data that were derived from the sample of patients included in the clinical trial. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

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

**Cost results**
The cost to the pharmacy was $0.98 for Phospho-soda and $6.39 for Colyte-Dulcolax.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant since, in effect, a cost-consequences analysis was carried out.

**Authors’ conclusions**
The adoption of Phospho-soda, in place of Colyte-Dulcolax, as medication for colonoscopy preparation reduced the costs, increased patient satisfaction and convenience, and improved the quality of the colonoscopy.

**CRD COMMENTARY - Selection of comparators**
The authors stated that Colyte-Dulcolax and Phospho-soda were two medications for colonoscopy preparation that are currently used at their institution. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a prospective cohort study, which was appropriate for the study question. Treatment allocation was based on prescribing patterns at the authors’ institution, and was changed over the three phases of the study in order to achieve a similar number of patients in each study group. The use of randomised allocation would have helped reduce the potential impact of confounding and selection bias. The baseline comparability of the study groups was not shown and the outcome assessment was not blinded. This could have introduced some assessment bias. In general, all of the patients were included in the analysis of the main outcome measures. The exception was patient preferences, which were examined in a small group of patients who had received Phospho-soda in the current evaluation. However, these patients based their preferences for Colyte-Dulcolax on prior experience. Therefore, the
outcome of interest was not evaluated concurrently. The study sample came from a single institution and it was unclear whether it was representative of the patient population. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because, in effect, a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The authors did not state which perspective was adopted in the study, but it appears that the cost/resource boundary of the hospital has been applied since the costs were derived from the hospital pharmacy. Only the costs of the two tracers were considered in the analysis. The impact of the interventions on other resources was not investigated. The unit costs were presented separately from the quantities of resources used, which enhances the possibility of replicating the analysis. The price year was not reported, which limits the possibility of reflating the results of the study in other settings. The costs were treated deterministically and were specific to the study setting.

**Other issues**
The authors undertook a review of the literature to identify other studies that had compared the two preparations under investigation. Fourteen of 19 published studies found Phospho-soda to be the preferred medication. Similar rates of clinical effectiveness were observed. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed. This limits the external validity of the analysis.

**Implications of the study**
The authors stated that after the conclusions of the study, Phospho-soda was used at their institution as the medication of choice for colonoscopy preparation, unless contraindicated. Therefore, the results of the analysis led to an actual change in patient treatment.

**Source of funding**
None stated.

**Bibliographic details**

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Attitude to Health; Bisacodyl /adverse effects /economics /therapeutic use; Cathartics /adverse effects /economics /therapeutic use; Comparative Study; Drug Combinations; Drug Costs; Electrolytes /adverse effects /economics /therapeutic use; Hospitals, Military; Humans; Maryland; Patient Compliance; Phosphates /adverse effects /economics /therapeutic use; Polyethylene Glycols /adverse effects /economics /therapeutic use; Quality of Health Care