Prospective, randomized, single-blind comparison of two preparations for screening flexible sigmoidoscopy


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 bowel-cleansing regimens were compared for patients undergoing screening flexible sigmoidoscopy. The oral preparation consisted of 45 mL oral sodium phosphate and 10 mg bisacodyl. The enema preparation comprised 2 Fleet enemas and 10 mg bisacodyl.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients referred from the primary care clinic to the gastroenterology service for screening flexible sigmoidoscopy. Those patients with congestive heart failure, ascites, or renal insufficiency (creatinine 2 mg/dL or greater) were excluded from the study.

Setting
The setting was secondary care (VA New York Harbor Healthcare System). The study was conducted in the USA.

Dates to which data relate
The dates during which the data were obtained were 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 patient sample as that used in the effectiveness study.

Study sample
Two hundred and fifty consecutive patients undergoing screening flexible sigmoidoscopy were randomised to receive either an oral preparation (n=126) or enema preparation (n=124). The baseline characteristics of the patients were given in terms of their demographics and clinical history. The sample size was determined in the planning phase of the study using power calculations. This ensured that there were sufficient patients in each arm (119) to detect a statistically significant 20% difference in the quality of the preparation (good or excellent), at a power of 90% and a 5% level of significance.
Study design
This was a prospective, randomised single-blind study carried out in a single centre. Randomisation was performed according to which of the two primary care teams referred the patient for screening sigmoidoscopy. The patients were randomly assigned to a team according to the day of the month (odd or even) that the patient was first enrolled in the primary care clinic. The endoscopist was blinded to which preparation the patient received.

Analysis of effectiveness
The clinical study was analysed on an intention to treat basis, as it appeared that all of the patients completed the study and were included in the final analysis. There were no statistically significant differences between the two groups at baseline (minimum p-value, p=0.14). The primary health outcomes assessed were the mean symptom score during administration of the preparation, the detection of polyps, mucosal abnormalities of the colon, complications, and the quality of the preparation. The mean symptom score was measured by asking patients to rate 13 symptoms experienced during the administration of the preparation on a scale of 0 (none) to 3 (severe). The quality of the preparation was assessed according to the presence of faecal material and the ease of removal.

Effectiveness results
The patients in the oral preparation group (96.8%) were more likely to grade the preparation as easy or tolerable than those in the enema group (56.4%), (p<0.001).

The mean symptom score during preparation was significantly lower in the oral preparation group (0.7) than in the enema group (2.3), (p<0.001).

There were no statistically significant differences between the groups in terms of the number of patients who had at least one polyp detected. The detection rate was 19.3% in the oral group and 14.3% in the enema group, (p=0.82).

There were no statistically significant differences between the groups in terms of the number of patients who had mucosal abnormalities of the colon detected. The detection rate was 23.8% in the oral group and 15.7% in the enema group, (p=0.09).

There were also no significant differences between the groups in terms of the incidence of complications. There were no complications in the oral group, and only one incidence in the enema group.

An adenocarcinoma was detected in one patient in the oral group. The mucosal abnormalities were attributed to the preparation "and therefore biopsies were not obtained routinely".

The endoscopist graded the quality of the preparation as good or excellent in 86.5% of the patients in the oral preparation group, compared with 57.3% in the enema group, (p<0.001).

Clinical conclusions
The oral sodium phosphate preparation resulted in a superior quality endoscopic examination. In addition, the oral preparation was better tolerated than enemas in those patients undergoing screening flexible sigmoidoscopy. The results seemed equivocal in terms of the detection of abnormalities.

Measure of benefits used in the economic analysis
The authors did not report a summary measure of benefit and left the clinical outcomes disaggregated. The study should therefore be considered as a cost-consequences analysis.

Direct costs
The total direct costs were calculated by summing the actual cost of the medications and the cost of the nursing time
required to prepare the patient for the procedure. The resource quantities and unit costs were reported separately. The nursing time was calculated as the time elapsed between checking the patient into the endoscopy suite and having the patient on the endoscopy table ready for sigmoidoscopy. The nursing preparation time included the time spent administering enemas to patients unable to take them at home. The nursing cost was calculated by multiplying the amount of time that the nurses spent preparing the patient for endoscopy by their hourly salary ($27.40). Discounting was irrelevant in this study as the costs were incurred over a period of less than one year.

**Statistical analysis of costs**
The continuous variables were compared using either Student's t-test or a non-parametric test.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

**Cost results**
The mean nursing time in the oral preparation group (34.6 +/- 25.4 minutes) was significantly lower than that in the enema group (65.3 +/- 43.5 minutes), (p<0.001). In addition, the costs in the oral preparation group ($16.39 +/- $11.57) were significantly lower than those in the enema group ($31.13 +/- $19.87), (p<0.001).

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
The oral sodium phosphate preparation resulted in a superior quality endoscopic examination. In addition, the oral preparation was better tolerated and more cost-effective than enemas in those patients undergoing screening flexible sigmoidoscopy.

**CRD COMMENTARY - Selection of comparators**
The authors noted that few data exist on the cost-effectiveness of bowel-cleansing regimens in flexible sigmoidoscopy. Certain guidelines recommended enemas over oral preparations, while a randomised controlled trial (using a different oral preparation) found the latter to be more effective and less costly. Thus, the authors used these data to justify the use of oral and enema preparations in patients undergoing flexible sigmoidoscopy.

**Validity of estimate of measure of effectiveness**
The bias of the measure of effectiveness should be low since the patients were randomised and the results were analysed on an intention to treat basis. In addition, the two groups were shown to be comparable at baseline. Blinding would also have reduced confounding. Finally, since power calculations were undertaken at the planning stage, the
sample size was sufficient to detect the differences specified initially by the authors.

There were, however, some problems with the measures of effectiveness. If the testing was designed to reduce colorectal cancer death and sequelae, then the effectiveness measures should inform on this, at least at an intermediate level, such as in terms of sensitivity. It was difficult to make the connection between these measures and the subjective opinion of the presence of faecal material and the ease of its clearance. One would have to assume equivalence in the accuracy or the benefit of increased patient tolerance, in order to outweigh any loss in detection accuracy.

**Validity of estimate of measure of benefit**
No summary measure of benefit was reported.

**Validity of estimate of costs**
The sources of the direct costs and resource utilisation were clearly presented and accounted for. The unit costs were reported separately from the quantities, which should improve the generalisability of the findings. However, there was no explanation of whether or not the patient and/or indirect costs should have been included. In addition, there was no sensitivity analysis, which also limits the generalisability of the findings.

**Other issues**
The findings were compared with those from other relevant studies. Other than this, the authors did not discuss how generalisable their findings might be to other settings. The results do not seem to have been presented selectively. The authors' conclusions were appropriate to the population studied.

**Implications of the study**
The findings from this study suggested that this particular oral preparation might improve the patient's acceptance of flexible sigmoidoscopy as a screening tool for colorectal cancer, by reducing the discomfort associated with the use of enemas. Further research is needed to investigate the consequences of each technology in terms of the accuracy of colorectal cancer detection.

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