Randomized clinical trial comparing consultant-led or open access investigation for large bowel symptoms


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 use of consultant-led versus open access investigation of patients with large bowel symptoms, referred by their general practitioner (GP), was examined. Patients referred to the consultant-led group were seen at the surgical clinic and investigations were planned as deemed appropriate to the clinical findings. Patients in the open access group were given the next available appointment for flexible sigmoidoscopy if they were less than 55 years old, and colonoscopy if they were aged 55 years or older.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients referred for investigation of large bowel symptoms, with the exception of those who had an obvious mass on rectal examination, or who had a history of adenoma or colorectal cancer. Patients with a family history of colorectal cancer, or those with iron deficiency anaemia, were excluded.

Setting
The setting was secondary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered between August 1999 and April 2001. The costs appear to have been estimated in 2001 prices.

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 a sub-sample of patients included in the effectiveness analysis.

Study sample
Power calculations were carried out. These showed that the study had 90% power at a 5% level of significance to detect a 10% absolute difference in the number of abnormal examinations between the two randomised groups, assuming a 60% incidence of abnormal findings in the consultant-led group. A sample of 1,131 patients was initially identified, but
14 pro forma were not completed. Thus, the final study sample comprised 1,117 patients, 552 in the consultant-led group and 565 in the open access group. The mean age of the patients was 52.9 (+/- 17.5) years in the consultant-led group and 52.5 (+/- 17.5) years in the open access group. There were 265 men in the consultant-led group versus 272 in the open access group.

At baseline, the most common symptom was rectal bleeding (66.3% in the consultant-led group versus 71.9% in the open access group). Clinical findings were normal in 63.6% of the consultant-led group versus 67.1% of the open access group. Abdominal mass was observed in 2.4% of the consultant-led group versus 0.7% of the open access group, while abdominal tenderness was observed in 5.1% and 7.8%, respectively. Other observations in the consultant-led group versus the open access group were hepatomegaly (0.2% versus 0.4%), hernia (0.5% versus 0.2%), haemorrhoids (17.9% versus 12.6%), and other clinical findings (12.7% versus 8.7%). Only the difference in the observed rate of abdominal mass was statistically significant, (p=0.001).

Study design
This was a prospective, pragmatic, randomised clinical trial that was presumably carried at a single centre. Randomisation was by a telephone call to a randomisation operator. The individual performing the diagnostic investigation was blinded to the randomisation group, although this did not preclude taking a brief history from the patient before the procedure was performed. The length of follow-up was 3 months. Data were available for 355 patients (64.3%) in the consultant-led group and 389 patients (68.8%) in the open access group. A total of 107 patients (52 in the consultant-led group and 55 in the open access group) withdrew from the study or did not attend for investigation. To limit the impact of different endoscopists performing the procedure, each endoscopist conducted the same proportion of investigations for both groups. Eighteen months after the last patient had been randomised, a computer check of all subsequent admissions was performed to ensure that no gastrointestinal cancer had been missed.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The outcome measures used were:

- investigations booked and performed;
- the results of the investigations;
- the time to final diagnosis;
- changes in anxiety and depression, which were evaluated using a postal questionnaire; and
- patient satisfaction, based on a questionnaire.

The study groups were comparable in terms of demographics and clinical characteristics.

Effectiveness results
In general, the GP missed three hernias, one rectal cancer, and one case of hepatomegaly.

The rates of investigations booked (99.5% versus 99.1%) and investigations performed (90% versus 89.4%) were comparable.

However, flexible sigmoidoscopy procedures (43.2% versus 57.1%), abdominal ultrasonography (2.9% versus 0.9%), upper gastrointestinal endoscopy (2.2% versus 0.7%), and other procedures (7.1% versus 0.2%) were significantly different between the consultant-led and open access groups.

There was a significant trend for patients in the consultant-led group to have more investigations, (p<0.001), and more patients in this group had no investigation, (p<0.001).

The results of the investigations were comparable. For example, the rate of patients diagnosed with a significant
pathology was 13.9% in the consultant-led group versus 15.4% in the open access group. Similarly, the time to final diagnosis was comparable.

Depression and anxiety score did not differ between the groups. Overall, the patients were less anxious but more depressed.

Patient satisfaction was also comparable (83.8% in the consultant-led group versus 79.5% in the open access group; p=0.678). Around 90% of patients in each group recommended the same investigations to friends or colleagues.

No gastrointestinal cancer was missed in the 18 months after randomisation of the last patient.

**Clinical conclusions**
The effectiveness analysis showed that the clinical outcomes were comparable across the groups. Despite more investigations being carried out on consultant-led patients, the yield of large bowel symptoms of other pathology did not improve in comparison with open access patients. Similar patient satisfaction was observed.

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

**Direct costs**
Discounting was not relevant as the costs were incurred during a short time. The unit costs were not presented separately from the quantities of resources used. The health services included in the economic evaluation were related to GP and clinic services, investigations, and patient travel expenses. The cost/resource boundary of the National health Service (NHS) appears to have been adopted for the direct costs. Resource use was estimated using data derived from a random sample of the trial population. GP and clinic costs were estimated from reference costs derived from the NHS Executive. The source of the other costs was not reported. The price year appears to have been 2001.

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

**Indirect Costs**
The indirect costs (i.e. employment costs) were included in the analysis. This was appropriate as a societal perspective was adopted. The unit costs were not presented separately from the quantities of resources used. Days of missed work were estimated from Scottish Economic Statistics 2002. Discounting was not relevant because of the short timeframe of the analysis.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.
Cost results
The total costs were 169,663 in the consultant-led group and 114,420 in the open access group.

The main categories of costs were clinical attendance and investigations in the consultant-led group, and investigations in the open access group.

The difference in cost between the two groups was mainly due to clinical attendance.

The average cost per patient was 307 in the consultant-led group and 203 in the open access group.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was performed.

Authors' conclusions
Patients with large bowel symptoms, referred by their general practitioner (GP), should be directly managed in an open access large bowel investigation unit rather than by consultant-led clinicians. This led to cost-savings without affecting the diagnostic yield.

CRD COMMENTARY - Selection of comparators
The selection of the comparators appears to have been appropriate, as it reflected the two possible referral strategies for the management of patients requiring further investigation of large bowel symptoms. 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 clinical trial. This was appropriate for the study question as the randomisation procedure limited the impact of bias and confounding factors. Partial blinding was carried out to ensure the validity of the outcome assessment. The methods of randomisation and sample selection were described. Power calculations were performed. The length of follow-up appears to have been appropriate. Many statistical tests were performed to assess the significance of differences between the groups at baseline and in the clinical results. However, the authors acknowledged the substantial loss to follow-up.

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

Validity of estimate of costs
The authors adopted a societal perspective. As such, it appears that all the relevant categories of costs have been examined. There was limited information on the items actually included in the analysis and on the sources used to assess the costs. The direct costs were estimated from 2001 sources, whereas the indirect costs were estimated from a 2002 database. Resource use was estimated from a sub-group of patients included in the effectiveness study. The cost estimates were specific to the study setting and were not varied in the sensitivity analysis. The costs were treated deterministically, although statistical analyses were performed to investigate the comparability of resource use between the groups.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not performed, which limits the external validity of the analysis. The authors noted and discussed some critical points of their study.
Implications of the study
Further studies should investigate the reasons for patients not attending further diagnostic work-up after attending GP visits.

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