Effectiveness of preoperative staging in rectal cancer: digital rectal examination, endoluminal ultrasound or magnetic resonance imaging


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 digital rectal examination (DRE), endoluminal ultrasound (EUS) and T2-weighted magnetic resonance imaging (MRI) for diagnosis in the preoperative staging of rectal cancer. EUS was carried out using a 7.5 or 10 MHz radial scanning transducer with water filled probe cover. DRE, EUS and MRI were undertaken at baseline and were repeated within 2 weeks prior to total mesorectal excision surgery, to provide comparative data with the resection specimen.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with biopsy diagnosed rectal cancer.

Setting
The setting was secondary care. The economic analysis was conducted in the UK.

Dates to which data relate
The dates when the effectiveness and resource data were collected were not reported. The cost estimates were derived from published studies that varied in date from 1999 to 2001. A price year was 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 retrospectively on a different sample of patients to that used in the effectiveness analysis.

Study sample
The study sample comprised 26 females and 72 males (age range: 28 - 89), who consecutively consented to enter the study during a 3-year period. No summary statistics were reported. The authors did not report that power calculations were carried out to assess the impact of chance on the results. This initial sample was appropriate for the clinical question since it included patients with biopsy diagnosed rectal cancer.
Study design
The analysis was based on a diagnostic yield study. The technologies of interest were used to classify cases as favourable, unfavourable, or locally advanced (depending on the T stage and node status) and advanced stage (if the potential circumferential resection margin was at risk). Results from the three technologies of interest (i.e. DRE, EUS and MRI) were compared with the results from the resection specimen. The classifications were used to determine the treatment schedule.

Analysis of effectiveness
The analysis was based on the results of the four diagnostic tests. The primary health outcomes were the classification of the cancer and resultant treatment schedule. There were no comparator groups of patients, which was appropriate.

Effectiveness results
A favourable prognosis (requiring surgery only) was correctly identified in 22 patients by DRE, 14 by EUS and 31 by MRI. This is relative to 31 patients who actually required surgery alone.

An unfavourable prognosis (short-course radiotherapy) was correctly identified in 14 patients by DRE, 32 by EUS and 33 by MRI. This is relative to 39 patients who actually required short-course radiotherapy.

Locally advanced tumours (long-course radiotherapy) were correctly identified in 3 patients by DRE, 1 by EUS and 22 by MRI. This is relative to 28 patients who actually required long-course radiotherapy.

With EUS 47 patients (48%) would have been correctly selected for treatment, while with MRI 86 patients (88%) would have been correctly selected.

Clinical conclusions
The authors did not draw any clinical conclusions independently from the cost conclusions, although it was clear from the results that MRI represented the most accurate diagnostic technique.

Measure of benefits used in the economic analysis
The authors did not estimate a summary measure of benefits. Therefore, the study was considered to be a cost-consequences analysis.

Direct costs
The authors estimated the cost implications for the preoperative radiotherapy budget. Given this cost horizon it appears, although it was not explicit, that a very short period of time was used and, therefore, discounting was not required. The costs of long- and short-course radiotherapy and chemotherapy sessions were derived from actual data obtained from the participating oncology centre. Some cost estimates were derived from published studies that seemed to date from 1999 to 2001. However, the dates when the cost data were collected were not explicitly stated and a price year was not reported.

Statistical analysis of costs
The authors reported that "agreement between EUS, MRI and DRE with pathology assessment of tumour favourability was calculated with the chance-corrected agreement given as the kappa statistic based on marginal homogenised data”.

Indirect Costs
The indirect costs were not estimated and were not relevant given the narrow horizon of costs estimated.
Currency
UK pounds sterling (€).

Sensitivity analysis
A sensitivity analysis was carried out to account for variation in cost between centres. The impact of assuming the resource implications of understaging are zero, increasing the cost of MRI and including only procedural costs, were assessed.

Estimated benefits used in the economic analysis
Not relevant.

Cost results
The total cost per staged patient was 1,017 for DRE, 1,273 for EUS and 332 for MRI.

Synthesis of costs and benefits
The costs and benefits were not combined. From the sensitivity analysis, the total cost of staging was 15,204 when using MRI versus 54,150 with EUS and 27,006 with DRE. The total cost of an MRI procedure would have to rise to 1,079 to equate the cost of MRI with that of EUS.

Authors’ conclusions
Magnetic resonance imaging (MRI) dominated both digital rectal examination (DRE) and endoluminal ultrasound (EUS) in terms of the cost and effectiveness. The authors reasoned “improved accuracy of assessment translates into better patient selection”, thus resulting in improved costs.

CRD COMMENTARY - Selection of comparators
The authors compared DRE, EUS and MRI with resection specimen pathology to establish the clinical and cost-effectiveness of these observational techniques. The authors justified their inclusion of the alternatives with a valuable discussion of each technique.

Validity of estimate of measure of effectiveness
The study was well designed to assess the stated objective, that is, to compare the accuracy of the technologies in identifying rectal carcinomas. Analysis was based on a diagnostic form of study, which assessed the accuracy of the technologies of interest in comparison with a stated ‘gold’ standard. The sample was representative of the study population as it included a consecutive stream of patients with biopsy diagnosed rectal cancer. Appropriate statistical methods were used to assess agreements between the technologies of interest and pathology assessment.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit.

Validity of estimate of costs
The authors did not state a perspective for the costing analysis carried out. Therefore, it is not possible to assess whether all the relevant costs were included. However, the authors stated that they were interested in the impact of preoperative radiotherapy budgets. This suggests that they were interested in a budgetary impact from the perspective of a hospital or health care provider. A short-term horizon was adopted, thus discounting was neither relevant nor conducted. A breakdown of the cost components within the individual techniques was not reported. A complete understanding of the cost implications of these technologies is not possible, owing to the very limited nature of the cost reporting.
Other issues
The authors reported that no studies had assessed the accuracy of EUS in total mesorectal specimens, thus explaining some of the failure to compare results with other studies. Nevertheless, the authors could have compared the accuracy of DRE and MRI to aid the reader in assessing the strengths of the results. Several issues that could have been addressed were not, such as the ability to generalise the results (this was improved by the limited sensitivity analyses that were carried out) and the limitations inherent in the study. The limitations of the study lay in the cost analysis and reporting. These problems could have been rectified with some further work and improved reporting methods. The conclusions were an accurate representation of the results presented and clearly reflected the scope of the analysis.

Implications of the study
The authors did not make any recommendations for policy or practice following their study, although a preference for MRI was clear. Further work, to assess the value of EUS in staging early lesions and selecting patients for local excision, was suggested.

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