Cost-effectiveness of endoscopic ultrasonography in the evaluation of proximal rectal cancer

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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 technologies studied were three staging strategies for evaluating nonmetastatic proximal rectal cancer: abdominal and pelvic CT; abdominal CT plus transrectal endoscopic ultrasound (EUS); and abdominal CT plus pelvic magnetic resonance imaging (MRI).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients with nonmetastatic proximal rectal cancer (greater than 4 cm from the anal verge) as determined by abdominal CT. Patients were excluded if they had distal rectal tumours requiring an abdominal perineal resection (generally tumours less than 4 cm from anal verge). It was also assumed that patients referred for each staging strategy were clinically similar.

Setting
The setting was secondary care. The economic study was carried out in Rochester, USA.

Dates to which data relate
Probabilities used as inputs into the model were derived from large prospective studies in the peer-reviewed medical literature from 1977-2001 (the 27 primary studies actually referred to by the authors were published between 1977 and 2000). Data for costs were derived from national sources for 2001.

Source of effectiveness data
Effectiveness data were derived from a review/synthesis of the literature, plus a number of assumptions made by the authors.

Modelling
A decision tree model was used to estimate benefits and costs. The model was designed using the DATA 3.5 software package.

Outcomes assessed in the review
The outcomes assessed in the review included the sensitivity and specificity of EUS, pelvic MRI and pelvic CT for T3,4 tumours. Also included were the prevalence of T3,4 tumours, the recurrence-free rates of T1,2 Nx tumours, T3,4
Nx tumours with preoperative radiotherapy (XRT), T3,4 tumours with postoperative XRT, and the postoperative complication rates for anterior resection without preoperative XRT, and for anterior resection with preoperative XRT.

**Study designs and other criteria for inclusion in the review**
The review consisted of large prospective studies taken from peer-reviewed medical literature between 1977 and 2001. Studies included in the review were based on similar patients i.e. those determined by CT to have nonmetastatic disease.

**Sources searched to identify primary studies**
Peer-reviewed medical literature was searched to identify primary studies. Specific sources are not reported.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
Nothing was reported regarding the methods employed except that the literature derived was peer-reviewed.

**Number of primary studies included**
The authors referred to 27 studies.

**Methods of combining primary studies**
Not reported.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
Recurrence-free rates were 87% (CT plus EUS), 85% (CT alone), and 86% (CT plus MRI).

**Methods used to derive estimates of effectiveness**
In addition, the authors made a number of assumptions regarding key parameters for the model, some of which were based on the medical literature, while for others, no explanation was provided as to how the authors derive the assumptions.

**Estimates of effectiveness and key assumptions**
The following assumptions were made:

patients referred for pelvic CT, EUS and MRI are clinically similar;

no specific indications for any of the three approaches exist;

the effect of surgical mortality (approx 1%) was excluded as this was found to have a negligible effect on model results;

abdominal CT was modelled rather than abdominal MRI as it has been shown to have equivalent sensitivity but is also
less costly;

slight differences in reported postoperative complication rates for surgery in patients with preoperative XRT versus those without preoperative XRT (taken from two references); and,

the authors presented two reasons for not including the performance characteristics of the various staging modalities in N staging (both reasons backed up by findings from studies).

**Measure of benefits used in the economic analysis**
The outcome measure used in the economic analysis was tumour recurrence-free rate.

**Direct costs**
Direct medical costs were estimated from Medicare ambulatory patient classification plus professional fee for hospital-based outpatient procedures. Inpatient hospital costs were calculated as the amount Medicare pays on the basis of assignment to a diagnosis-related group (DRG). Professional fees associated with outpatient visits and hospitalisations were assigned current procedural terminology codes. Costs and quantities were not analysed separately.

**Statistical analysis of costs**
Deterministic costs were presented with sensitivity analyses being utilised to identify areas of uncertainty associated with the estimates.

**Indirect Costs**
Indirect costs were not included and no rationale was provided for their exclusion.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-, two- and three-way sensitivity analyses were carried out to test for variability in data i.e. probabilities, baseline costs.

**Estimated benefits used in the economic analysis**
Recurrence-free rates were 87% (CT plus EUS), 85% (CT alone), and 86% (CT plus MRI).

**Cost results**
The relative costs of the three strategies were: abdominal CT plus EUS ($21,248); abdominal CT plus pelvic MRI ($21,507); and abdominal plus pelvic CT ($22,200).

**Synthesis of costs and benefits**
Benefits and costs were combined in terms of the cost per prevention of local recurrence of rectal cancer per patient.

Abdominal CT plus EUS was the most cost-effective strategy ($24,468) compared with abdominal plus pelvic CT ($26,076) and abdominal CT plus pelvic MRI ($24,870). Thus, the incremental cost-effectiveness analysis showed that both the CT-alone and the CT plus MRI approaches were dominated by EUS.

One-way sensitivity analysis showed the final outcome to be sensitive to variation in sensitivity of EUS (required to be
greater than 66%), sensitivity of pelvic MRI (required to be less than 90%), specificity of EUS (required to be greater than 78%), and specificity of pelvic MRI (required to be less than 90%).

The results of the model were robust to changes in other parameters throughout the suggested ranges. With a two-way sensitivity analysis, abdominal CT plus EUS again remained the optimum choice within plausible ranges of all variables.

**Authors' conclusions**

Abdominal CT plus EUS was the most cost-effective strategy for nonmetastatic proximal rectal cancer. Staging strategies incorporating EUS improved treatment allocation by achieving more accurate T staging, therefore optimising the benefit of preoperative XRT to more advanced tumours.

**CRD COMMENTARY - Selection of comparators**

The therapeutic approach was modelled on clinical practice in the authors' institution and reflects what they perceived to be currently accepted standards of care for these patients. EUS was chosen as the comparator because its clinical accuracy has been illustrated in the literature, but not its cost-effectiveness in relation to other staging strategies commonly used in clinical practice.

**Validity of estimate of measure of effectiveness**

The quality of the literature review was unclear, as the authors did not report it in great detail, except to say that it was a collection of peer-reviewed medical literature. It was not stated whether the review was systematic or not, nor how the primary studies were combined and how the relevance and validity of primary studies were assessed by the authors. The authors appropriately augmented the model's input parameters through assumptions, which were either based on the literature or on their own judgements. Sensitivity analyses were also appropriately conducted to test for variables used in the model.

**Validity of estimate of measure of benefit**

Tumour recurrence-free rate was an appropriate benefit measure, which was derived through the modelling process.

**Validity of estimate of costs**

Sources of direct costs were clearly presented and sensitivity analyses were used to test for robustness of the economic findings. Only direct costs were included in the analysis despite the fact that indirect and patient costs were likely to be very relevant. Under the section entitled "Baseline Costs", the authors stated that the base-case analysis was conducted from a societal perspective. However, in the discussion section, they talk about the impact on their results of adopting a third-party payer perspective. Costs and quantities were not analysed separately.

**Other issues**

The issue of generalisability to other settings was partially addressed by performing sensitivity analyses on the cost items.

**Implications of the study**

The cost-effectiveness of EUS would benefit from being tested in other settings using actual data, rather than modelling techniques, in order to validate its use in 'real-life' settings.

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