High accuracy and cost-effectiveness of a biopsy-avoiding endoscopic approach in diagnosing coeliac disease

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 a modified immersion technique (MIT) for the diagnosis of coeliac disease (CD). The MIT enables duodenal villi to be directly visualised during an upper endoscopy. Two endoscopic techniques, standard video endoscopy and high-resolution magnifying video endoscopy, were evaluated. The ‘gold’ standard of CD diagnosis is histological confirmation of the characteristic small bowel changes. To enhance histological diagnostic accuracy, at least four biopsy specimens from the duodenal mucosa are needed during an endoscopy.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with positive EMA and/or TTG antibodies who were on an unrestricted diet, and who were undergoing an upper endoscopy for the first time to collect duodenal biopsy specimens.

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

Dates to which data relate
Charges for the 1-year study related to 2004. Patients were recruited for the diagnostic accuracy study during 2004/05.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning stages of the study. Consecutive patients at the authors’ institution were included in the study. The authors did not fully justify the choice of the patient sample with respect to the characteristics of the disease under investigation. In addition, they did not report whether any patients refused to participate in the study. The number of control patients who refused to participate was not reported. Patients were excluded if there were any macroscopic abnormalities of the duodenal mucosa that required biopsy. Seventy-nine
patients with suspected CD were enrolled in the study. Of these, 39 were randomly allocated to receive standard video endoscopy and 40 to receive magnifying video endoscopy.

**Study design**
This was a diagnostic test accuracy study. First of all, patients were randomly assigned to receive either standard or magnifying video endoscopy. The method of randomisation was not stated. Every patient had biopsies taken during the endoscopic procedure. The pathologists who evaluated the biopsies were blinded to the endoscopic results and the clinical characteristics of the patients. Follow-up was performed at 3 months.

**Analysis of effectiveness**
All patients were included in the analysis. The authors reported the test results in tabular form for the histology and the endoscopic tests combined. The sensitivity, specificity positive predictive value and the negative predictive value of each test were determined. The authors did not report the clinical characteristics for the two groups of patients.

**Effectiveness results**
All 79 patients who had positive EMA and or TTG antibodies were identified, by the histology analysis, as having CD. The histology analysis assessed increased intraepithelial lymphocyte infiltration and crypt hyperplasia in all enrolled patients. The CD diagnosis was confirmed at follow-up.

The sensitivity, specificity, positive and negative predictive values of positive (when detecting TVA) endoscopy without biopsy (SEWB or MEWB) in achieving CD diagnosis were always 100%. These values were also 100% for the histological test.

**Clinical conclusions**
The histology did not improve the detection of CD. The standard and magnetic video endoscopies were equally accurate.

**Measure of benefits used in the economic analysis**
The measures of benefit of the different diagnostic strategies were the sensitivity, specificity, positive predictive value and negative predictive value. These were derived directly from the diagnostic accuracy study.

**Direct costs**
The direct costs of the National Health Service were included in the analysis. The costs of antibody testing, endoscopy with or without biopsy, and histology were included in the analysis. Charges were obtained from reimbursement to the authors' institution in 2004. The resource quantities and the unit costs were not reported separately. The study was carried out over one year and, as such, discounting was not relevant.

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

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

**Currency**
euros (EUR).
Sensitivity analysis
A sensitivity analysis was not carried out.

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

Cost results
The total charge per patient was EUR 154 for SEB, EUR 69.8 for SEWB and EUR 69.8 for MEWB.

The total charge for all patients with TVA was EUR 4,931 for SEB (32 patients), EUR 2,234 for SEWB (32 patients) and EUR 2,443 for MEWB (35 patients).

The total charge for all patients with TVA if EMA testing was also performed was EUR 5,347 for SEB (32 patients), EUR 2,650 for SEWB (32 patients) and EUR 2,898 for MEWB (32 patients).

If only one of the EMA and TTG tests was performed, both SEWB and MEWB represented a charge saving of EUR 84.3 per patient with respect to the SEB approach.

Synthesis of costs and benefits
The costs and benefits were not synthesised.

Authors' conclusions
For the diagnosis of celiac disease (CD), a biopsy-avoiding endoscopic approach, whether standard or magnetic, results in a good economic outcome with no detriment to the clinical goal.

CRD COMMENTARY - Selection of comparators
The authors compared two types of endoscopy with endoscopy plus histology. There was no explanation for the choice of different endoscopy approaches. The authors justified their comparison of endoscopy and biopsy. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a diagnostic test accuracy study. The study was well conducted. Positive features of the analysis were that every patient received both an endoscopy test and a biopsy, and that the pathologist was blind to the endoscopy results. However, the method of randomisation to the two endoscopy approaches was not reported and it was unclear whether the sample size was large enough. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The measures of benefit were the test accuracy measures. These are not measures of health benefit, although they do have health implications.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. The costs and the quantities were not reported separately. The price year and the source of the cost data were given. A sensitivity analysis of resources and prices was not undertaken.
Other issues
The authors did not make appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The detailed results of the diagnostic tests were not reported separately for the two endoscopic tests. However, the authors did report that they had the same accuracy results. The authors did not report any further limitations of their study.

Implications of the study
The authors recommended that other biopsy saving strategies, such as a single MIT-guided biopsy, should be investigated in order to encourage clinicians to change their practice.

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