Gastric ulcers at endoscopy: brush, biopsy, or both

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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
Three diagnostic strategies were investigated in the diagnosis of malignant gastric ulcers: (a) cytological brushing alone, (b) histological biopsy alone and, (c) both cytological brushing and histological biopsy.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with gastric ulcer found at endoscopy.

Setting
Hospital. The economic study was carried out in Canada.

Dates to which data relate
The effectiveness data were obtained from studies published between 1977 and 1993. The resource use data were based on the protocols assumed by the authors, which were partly based on studies published in 1992. The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a synthesis of previously completed studies and assumptions made by the authors.

Modelling
A decision tree model was used to estimate costs and benefits. The model included a time span of 16 weeks from the time of the initial endoscopic diagnostic test to the time the last endoscopy procedure was performed with or without laparotomy (for non-healing ulcers). Within this time frame, both the true- and false-negative cases from the initial test undergo medical treatment for an 8-week period after which another endoscopy is performed, with non-healing cases undergoing the same diagnostic strategy as initially used. The medical treatment follows for another 8 weeks. At the end of this period, endoscopy is repeated and non-healing cases undergo laparotomy independent of the diagnostic results. The model assumed that this procedure was performed for all cases found positive at initial diagnosis, while healing of the ulcer is associated with benign cases and no further follow-up or therapy is considered.

Outcomes assessed in the review
The true- and false-positive rates associated with each diagnostic strategy were the main outcomes assessed in the
review by generating summary receiver operator curves (SROCs). Clinical probabilities, including the probability of ulcer in H. pylori-infected patients, ulcer healed with histamine-2-blocker therapy, ulcer healed with omeprazole therapy, prevalence of cancer, H. pylori eradication with triple therapy, H. pylori eradication with MOC therapy, and indefinite cytology, were also obtained from the literature.

**Study designs and other criteria for inclusion in the review**
The study designs of the primary studies included in the review were not systematically reported. Only English language studies published from 1966 to July 1995 were included. The studies had to meet the following criteria: a) the study had to provide new data, b) had to focus on the detection of gastric adenocarcinoma or lymphoma, c) cytology had to use the brush method (salvage studies were not included), d) the biopsy had to include at least four gastric biopsies taken from the margin or base of the ulcer, and e) enough information had to be available to allow the calculation of true and false-positive rates (TPR and FPR) from the data in the study.

**Sources searched to identify primary studies**
MEDLINE was searched along with references from the articles retrieved.

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

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
A total of 20 publications (out of 288 reports identified in the literature search) was included in the analysis to estimate TPR and FPR by generating SROCs. 17 further publications were used to extract values for the other clinical probabilities required in the model.

**Methods of combining primary studies**
The studies were combined using meta-analysis. The data obtained from the literature search was used to construct summary receiver operator curves (SROCs).

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

**Results of the review**
The true-positive rates (TPR) (ranges found in the literature in brackets) were: Cytology, 0.89 (0.84-0.91); biopsy, 0.88 (0.87-0.88); cytology and biopsy, 0.91 (0.90-0.92). The corresponding figures for the false-positive rates (FPR) were 0.03 (0.01-0.05), 0.03 (0.01-0.05), and 0.06 (0.02-0.10). The values assigned to the clinical probabilities were: probability of ulcer in H. pylori-infected patient, 0.7 (0.7-0.96); ulcer healed with histamine-2-blocker therapy, 0.89 (0.875 - 0.913); ulcer healed with omeprazole therapy, 0.95 (0.5-1.0); prevalence of cancer, 0.04 (0.01-0.06); H. pylori eradication with triple therapy, 0.85 (0.81-0.87); H. pylori eradication with MOC therapy, 0.90 (0.86-0.95); indefinite cytology, 0.034 (0.032-0.059).

**Methods used to derive estimates of effectiveness**
Assumptions about effectiveness were also made by the authors.
Estimates of effectiveness and key assumptions
The model assumed that all gastric ulcers were ‘equally amenable’ to either the brushing or biopsy strategy and that malignant ulcers do not achieve endoscopic healing. The model assumed that no patient was lost to follow-up.

Measure of benefits used in the economic analysis
Diagnostic days saved was the benefit measure used in the effectiveness analysis. The corresponding expected outcome was calculated by means of a decision tree Markov model, which covered a maximum time span of 112 diagnostic days (16 weeks).

Direct costs
Costs were not discounted due to the short time span of the study. The costs measured were those associated with the procedural costs (diagnostic devices, the materials, personnel), medical follow-up treatment, and costs of operation (laparotomy). The perspective adopted in the cost analysis was that of a hospital. The source of quantities of resource use was primarily the authors' assumptions as expressed in the different clinical courses in the branches of the decision model. The source of unit costs was published information from Canada. The price year was 1995.

Indirect Costs
Not considered.

Currency
Canadian dollars (Can$).

Sensitivity analysis
One-way simple sensitivity analyses were performed using the probabilities and costs of each branch in the decision model, by using the ranges found in the literature. A threshold analysis was reported in terms of the unit costs of the diagnostic procedures.

Estimated benefits used in the economic analysis
The number of diagnostic days saved in terms of baseline values with the cytology, the biopsy and the combined strategies were 51.9, 50.6, and 52.8, respectively.

Cost results
The (per case) costs associated with the cytology, the biopsy and the combined strategies, were Can$1,167, Can$1,165, and Can$1,464, respectively.

Synthesis of costs and benefits
The cost per diagnostic day saved was the outcome measure used in the synthesis of costs and benefits. In terms of 1995 prices, the respective figures for the cytology, the biopsy and the combined diagnostic strategies were Can$22.5, Can$23.0, and Can$27.7, respectively. The results were sensitive to the true- and false-positive rates investigated, which nonetheless, did not alter the main results of the study. In the worst case presented, the difference in per case cost between cytology and biopsy increased from Can$2.00 to Can$6.00 in favour of the biopsy strategy. The threshold cost of cytology was reported as Can$78, for a fixed cost of biopsy of Can$75.00.

Authors' conclusions
For gastric ulcers discovered at endoscopy, the diagnostic strategy of choice is to perform either cytological brushing or histological biopsy. The previously recommended strategy of performing both cytological brushing and histological
biopsy should be reconsidered.

**CRD COMMENTARY - Selection of comparators**

reason for the choice of the comparator is clear.

**Validity of estimate of measure of benefit**

validity of the study results cannot be objectively assessed given the lack of information regarding the specific designs of the primary studies included in the review and the possible differences amongst them. The authors noted that the assumption of equal amenability of all gastric ulcers to either of the cytological or biopsy strategies was not accurate since ulcers in the cardia of the stomach are best sampled with cytological brushing.

**Validity of estimate of costs**

quate details of methods of cost estimation were provided, with quantities of resource use being reported and the main cost items being included in the model. However, no account was taken of the risk of complications arising in laparotomy or indirect costs generated by the false-positive patients who undergo laparotomy with each strategy (the authors considered that, if included, the indirect costs would only widen the cost gap between that strategy and the single diagnostic strategies).

**Other issues**

conclusions reached by the authors cannot be properly judged on the basis of the information provided. However, the results of sensitivity analyses lend some support to the conclusions and the generalisability of the findings.

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