The Pyloritek test and the CLO test: accuracy and incremental cost analysis

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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
Two rapid urease tests: (1) Pyloritek; (2) CLO.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing upper endoscopy for clinical symptoms (e.g. GI bleeding, dyspepsia, and persistent heartburn). There were 18 males and 53 females in the study, and the mean age was 53 (+

Setting
Clinical microbiology laboratory, Wisconsin (USA).

Dates to which data relate
Data regarding effectiveness and resource use were collected during 1995. The price year was not clearly stated.

Source of effectiveness data
The evidence for final outcomes was derived from a single study.

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

Study sample
There were 71 patients in the study, receiving both the Pyloritek and CLO tests. Three doctors were involved in the study. It was not specified whether a power calculation was used to determine the sample size.

Study design
Single centred, case series. The Pyloritek assay was read at 1 hour by one of two doctors, whilst the CLO test was read at 24 hours by a different trained observer blinded to the results of the Pyloritek assay.

Analysis of effectiveness
It was not stated whether the analysis of the clinical study was based on intention to treat or treatment completers only. The primary outcome was diagnostic accuracy (sensitivity, with discordant cases verified by culture of biopsy specimens).

Effectiveness results
Thirty-two patients had a positive CLO test result and 39 had a negative test result. Of the 32 patients with a positive CLO test result at 24 hours, 31 were positive by the Pyloritek test at 1 hour (97%). All 39 patients with a negative CLO test result also had a negative Pyloritek test result. There was one discordant result in the 71 samples (1.4%), a negative Pyloritek test result and a positive CLO test result. Culture demonstrated growth of H. pylori. This patient was not taking proton pump inhibitors and had not recently received antibiotics. In 13 of 32 (41%) cases with a positive result, the Pyloritek assay turned positive in less than five minutes. The degree of agreement between the two tests was calculated using the K statistic. When K = 0, agreement is only at the level expected by chance; an acceptable level of reliability is represented by K > 0.8. The K statistic was 0.969, thus showing a high degree of interest reliability (SE, 0.0284; 95% CI: 0.925 - 1).

Clinical conclusions
Results of the Pyloritek test at 1 hour and the CLO test at 24 hours were comparable in terms of detection of urease activity.

Measure of benefits used in the economic analysis
The measure of benefits was the additional cases of H. pylori detected.

Direct costs
Some quantities of resource use were reported separately from the costs. The costs measured in the study were:

1. CLO and Pyloritek tests were $290 each for fifty tests;
2. Follow-up office visits ranged from $26 to $57 (according to the insurance plan), with a mean of $38 (+/- $5) and a median of $38
3. Office telephone calls were $12.

The estimation of the costs and quantities was based on actual data collected during March to December 1995. The price year was not clearly stated.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis, in the form of a best-worst case scenario, was performed.

Estimated benefits used in the economic analysis
An additional 3% of patients were detected by CLO over the pyloritek test. There were three possible strategies with the CLO test:

Strategy 1 - all patients who have a CLO test were asked to return to the office one week later to discuss the results and to receive further therapy;

Strategy 2 - all patients with a positive test result at discharge (1 hour) were prescribed antibiotics, and patients who had
a negative or equivocal result returned to the office one week later;

Strategy 3 - patients with a positive CLO test result at 1 hour were prescribed antibiotics. The remainder were called with the results of the test the following day by the physician and treatment was prescribed over the telephone. With the Pyloritek test, the postendoscopy office visit becomes unnecessary.

Cost results
Although total costs were not explicitly reported, the following cost components were included in the analysis:

(1) CLO and Pyloritek tests were $290 each for fifty tests;

(2) Follow-up office visits ranged from $26 to $57 (according to the insurance plan), with a mean of $38 (+/- $5) and a median of $38;

(3) Office telephone calls were $12.

Synthesis of costs and benefits
The incremental cost of performing the CLO test, for every positive patient found by the CLO test and not detected by the Pyloritek test, was $528 for strategy 3, $1,672 for strategy 2, and $2,968 for strategy 1.

Authors' conclusions
The Pyloritek test at 1 hour is a reliable rapid urease test and may offer some advantages over the CLO test.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of comparators was obvious and clear.

Validity of estimate of measure of benefit
The internal validity of the results is questionable due to the lack of any proper power calculations relevant to clinically significant hypothesised differences between tests in the study.

Validity of estimate of costs
Cost data were collected from the patients within the study. The only caveat is that there may be cost variances by region and by country. Also the price year was not clearly reported and neither were quantities of resource use and costs.

Other issues
The conclusions were justified in terms of statistical tests for the effectiveness results and the sensitivity analysis. The issue of generalisability was not adequately addressed. The report of costs was not clear.

Implications of the study
The study is important in so far as a new method, the Pyloritek test, for the diagnosis of Helicobacter pylori can replace the CLO test, which was the standard reference for rapid urease tests. (Provided the study size is adequate to detect clinically significant differences between tests).

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