
Endoscopic biopsy pathology of *Helicobacter pylori* gastritis: comparison of bacterial detection by immunohistochemistry and Genta stain

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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

Immunohistochemistry (IHC) or Genta stain in the detection of *H. pylori* gastritis.

Type of intervention

Diagnosis.

Economic study type

Cost-effectiveness analysis.

Study population

Gastric biopsies from the antrum (81% of *H. pylori* positive group, 74% of *H. pylori* negative group) or from the gastric bodies of patients with gastritis classified as positive or negative for *H. pylori* by Genta stain test.

Setting

The setting was secondary care. The economic study was conducted in the Department of Pathology, Baystate Medical Center, Springfield, Mass, USA.

Dates to which data relate

Data for the effectiveness study were collected over the period 1992 to 1995. No dates for resource use data or prices were specified.

Source of effectiveness data

The estimates for the final outcomes were derived from a single study.

Link between effectiveness and cost data

The retrospective costing was based on average resource use and corresponding prices at the research setting. The costs were not estimated for the same patient samples as those used in the effectiveness analysis.

Study sample

The study sample consisted of 100 consecutive cases of gastritis considered positive for *H. pylori* by Genta stain, and 100 consecutive cases of gastritis considered negative for *H. pylori* by Genta stain. No power calculations were reported in the determination of the sample size.

Study design

This was a non-randomised study based on a case series with concurrent controls, undertaken at a single medical centre.

Analysis of effectiveness

The main outcomes were the sensitivity and specificity of IHC compared to Genta stain test for detection of *H. pylori*. Two observers had independently evaluated the presence of gastritis (defined as the presence of a uniform infiltration of the superficial and/or deep lamina propria by lymphocytes and plasma cells) or activity (defined as additional presence of neutrophils). The 200 cases were stained with anti-*H. pylori* rabbit antiserum (1:160 dilution; Dako Corporation, Carpinteria, Calif; lot III, Ca 93013), using an autoimmunostainer according to the manufacturer's recommendations. Antigen retrieval was performed by microwave heating in a sodium citrate buffer. An avidin-biotin detection method was used with 3,3'-diaminobenzidine tetrahydrochloride visualisation. IHC slides for detection of *H. pylori* were reviewed and graded by 2 observers who were blinded to the results of the Genta stain. Density of organisms was graded for both Genta stain and IHC as focal when found in 1 to 2 gastric pits, multifocal when 3 to 6 gastric pits were involved, and diffuse when the gastric surface and pit epithelium of most of the biopsy showed bacteria.

Effectiveness results

The sensitivity of IHC was 97% for the 100 cases with *H. pylori* detected by Genta stain. The specificity of IHC was 98% for the 100 cases negative for *H. pylori* by Genta stain. The density of bacterial infection was concordant by both techniques in 83 cases (high agreement between the two methods for grading density of organisms $K=0.85$, $p < 0.001$). In 14 discordant cases, bacterial density was diffuse by Genta and multifocal by IHC.

Measure of benefits used in the economic analysis

No summary measure of benefits was used in the economic analysis. The benefits are therefore associated with the effectiveness results reported above. The costs were analysed separately for the two screening methods and thus the cost-effectiveness analysis is of cost-consequences design.

Direct costs

The costs of reagents as well as the technical time costs for IHC and Genta stain tests were reported. Per-hour labour costs for the laboratory were also provided. The costs were based on the average costs at the laboratory. No date for the price data was specified and the costs were not reflatd. Discounting was not relevant due to the short term of analysis (less than one year).

Statistical analysis of costs

A Chi-square test was used to compare positive and negative cases as determined by Genta stain for pathologic features. A significance level of $p=0.01$ was used for multiple comparison of cases. The grading of density of organisms on Genta and IHC stains was compared using the k measure of reliability.

Indirect Costs

No indirect costs were evaluated.

Currency

US dollars (\$).

Sensitivity analysis

No sensitivity analysis was performed.

Estimated benefits used in the economic analysis

Not applicable, the reader is referred to the effectiveness results above.

Cost results

Costs of reagents for IHC and Genta stain tests were the same (\$5 per slide). The technical time for IHC was 1 hour, and 2 hours for Genta stain. The labour costs were \$20 per hour, which resulted in lower costs per case with IHC.

Synthesis of costs and benefits

No synthesis of costs and benefits was performed.

Authors' conclusions

For gastric biopsies submitted to detect *H. pylori* infection, especially after triple therapy, IHC with a specific antibody constitutes an accurate and cost-effective technique.

CRD COMMENTARY - Selection of comparators

As Genta stain was the "gold standard" for testing for *H. pylori*, its selection as a comparator was appropriate.

Validity of estimate of measure of benefit

The estimates of the sensitivity and specificity of IHC and Genta stain for detection of *H. pylori* provide appropriate evidence to show that the two tests are not equivalent.

Validity of estimate of costs

Only some of the directly employed resources were considered. The fact that the average cost estimates of the labour time were not based on the study samples could hinder important cost differences. The lack of a price year limits the generalisability of the cost data.

Other issues

Appropriate comparisons were made with other studies in relation to the association between chronic active gastritis and *H. pylori* infection found in this study. In the case of non-equivalent tests an incremental cost-effectiveness analysis would, perhaps, have been more appropriate, and would permit the estimation of the incremental benefit of providing the most effective test.

Implications of the study

The study was found to support the application of IHC test as a cost-effective method for *H. pylori* detection in gastric biopsies. This conclusion would benefit from additional evidence for the effectiveness and costs of IHC compared to Genta stain tests for detecting *H. pylori*.

Source of funding

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