A novel Alcian yellow-toluidine blue (Leung) stain for Helicobacter species: comparison with standard stains, a cost-effectiveness analysis, and supplemental utilities

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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
A novel Alcian yellow-toluidine blue (Leung) stain for the detection of helicobacter pylori (Hp).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with Hp gastritis.

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

Dates to which data relate
No dates were reported.

Source of effectiveness data
The evidence for the 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
60 patients with Hp gastritis.

Study design
Randomized controlled trial. The subset of 17 specimens was chosen randomly from a sample of 60 specimens. The method of random allocation was not reported.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. Two different health outcomes were measured in the
study: the pathologist's detection time of the Hp gastritis in the gastric biopsy specimens and respective scores.

**Effectiveness results**
In the 60 specimen group, when the Leung stain was used, mean detection times and HP scores were:

- pathologist 1, 18.4 seconds (range: 2 - 132) and 3.1;
- pathologist 2, 24.2 seconds (range: 4 - 128) and 4.1.

In the 17 specimen group:

- pathologist 1, 17.5 seconds (range: 3 - 63) and 3.8;
- pathologist 2, 20.4 seconds (range: 3 - 81) and 3.7.

In the 17 specimen group, when the MS was used:

- pathologist 1, 9.7 seconds (range: 1 - 50) and 3.7;
- pathologist 2, 6.1 seconds (range: 2 - 32) and 4.5.

In the 17 specimen group, when the Giemsa stain was used:

- pathologist 1, 20 seconds (range: 4 - 56) and 3.6;
- pathologist 2, 21.1 seconds (range: 3 - 65) and 3.8.

In the 60 specimen group, when the Hematoxylin and eosin were used:

- pathologist 1, 36.3 seconds (range: 8 - 300) and 3.3;
- pathologist 2, 61.1 seconds (range: 8 - 300) and 2.6.

In the 17 specimen group:

- pathologist 1, 52.2 seconds (range: 10 - 300) and 3.8;
- pathologist 2, 58.6 seconds (range: 8 - 300) and 3.2.

**Clinical conclusions**
According to the clinical outcomes measured in the study (time to detection and Hp score) the MS stain was superior to the Leung and Giemsa stain in detection of Hp gastritis. However, the differences were relatively small. The Leung stain was more effective when many slides were stained in sequence and provided better contrast compared to the Hematoxylin and eosin stain. The latter, also according to the outcomes measured in the study, had relatively poor performance compared to the other three technologies.

**Measure of benefits used in the economic analysis**
Since the clinical outcomes were shown to be similar for the technologies compared, the analysis was based on comparison of costs only.

**Direct costs**
Costs were not discounted given the short time frame of the study. Quantities and costs were not reported separately. Only costs of slides were included in the analysis. The estimation of quantities and costs was based on actual data.
date to which the prices refer was not specified.

**Statistical analysis of costs**
Not carried out.

**Currency**
Both Canadian (Can$) and US dollars ($).

**Sensitivity analysis**
Not carried out

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
Average material cost for the Leung stain was estimated at Can$0.051 (US$0.36) and the total technologist time for preparation of 20 slides was around 45 minutes. Average material cost for the Giemsa method was Can$0.024 (US$0.17) and time for preparation was around 18 hours. Average material cost using the MS technique was estimated at Can$0.058 (US$0.41) and the total technologist time for preparation of 20 slides was around 1 hour 45 minutes.

**Synthesis of costs and benefits**
Not applicable.

**Authors' conclusions**
According to their clinical outcome, the Leung stain, Giemsa and MS method showed a similar performance, although the MS method was shown to be slightly superior. In the larger group of 60 samples the hematoxyclin and eosin and Leung stain showed similar clinical outcomes. However, when material cost and the technologist's time were considered, the superiority was shifted towards the Leung stain, since the material costs and technologist's time were greater than the Giemsa method, and the technologist's time for MS is almost four times that for the Leung stain. Also, the Leung stain method has the additional merit of staining the mucus from all gastrointestinal sites and metaplastic lesions in yellow, and providing contrast and morphologic definition in gastritis and cryptosporidiosis.

**CRD COMMENTARY - Selection of comparators**
The Leung stain method, as a new method, was compared to some commonly used methods.

**Validity of estimate of measure of benefit**
The sample size might not have been sufficient to detect differences in the diagnostic methods under investigation.

**Validity of estimate of costs**
Costs and quantities were not reported separately. It is not clear whether important costs have been omitted. The time and resources devoted to preparation were not evaluated in monetary terms which makes cost comparisons very difficult.

**Other issues**
The clinical outcomes measured were not analysed statistically and were difficult to compare. No analysis was provided as to whether the differences in the clinical outcomes measured were statistically significant, which may weaken the conclusions drawn.
Source of funding
None stated

Bibliographic details

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9556427

Other publications of related interest
The study is connected with other studies comparing the efficacy of the different stain methods for Hp gastritis:


Indexing Status
Subject indexing assigned by NLM

MeSH
Coloring Agents; Cost-Benefit Analysis; Gastric Mucosa /microbiology; Helicobacter /isolation & purification; Helicobacter pylori /isolation & purification; Histocytochemistry /economics /methods; Humans; Sensitivity and Specificity; Staining and Labeling /methods; Tetrapyrroles; Tolonium Chloride

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