Antimicrobial resistance testing of H pylori epsilometer test and disk diffusion test
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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
Epsilometer and disk diffusion tests for antimicrobial resistance testing of Helicobacter pylori.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients infected with Helicobacter pylori. The study population was defined in terms of extracted, affected stomach tissue samples.

Setting
A university hospital (Department of Gastroenterology). The economic study was conducted in Japan.

Dates to which data relate
The specific dates to which effectiveness and resource data relate were not given.

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

Link between effectiveness and cost data
The cost data were derived retrospectively from the same sample which formed the clinical study.

Study sample
The sample consisted of 246 H. pylori cases cultured on extracted stomach tissues. No power calculations were used to determine sample size.

Study design
This was a non-randomised trial with concurrent controls at a single centre. 246 H. pylori cases were tested against two antibiotics (metronidazole and clarithromycin) with two different techniques(Epsilometer test and disk diffusion test) concurrently.
Analysis of effectiveness

The analysis of effectiveness was based on intention to treat. The outcomes assessed were the levels of resistance of *H. pylori* to the two antibiotics (metronidazole and clarithromycin) in the Epsilometer test and the disk diffusion test.

Effectiveness results

The resistance of 246 *H. pylori* against metronidazole was categorized into three levels: sensitive (below MIC 8 micro g/ml), medium (between 8 micro g/ml and 32 micro g/ml), and resistant (above 32 micro g/ml). For metronidazole resistance testing the Epsilometer test revealed 205 cases as sensitive, 10 cases as medium and 31 cases as resistant while the disk diffusion test revealed 208 cases as sensitive and 38 cases as resistant. The results of the two tests were correlated at a value of 92.7%. The resistance of 246 *H. pylori* against clarithromycin was categorized into three levels: sensitive (below MIC 2 micro g/ml), medium (between 2 micro g/ml and 8 micro g/ml), resistant (above 8 micro g/ml). For clarithromycin resistance testing the Epsilometer test revealed 213 cases as sensitive, 2 cases as medium and 31 cases as resistant while the disk diffusion test revealed 212 cases as sensitive and 34 cases as resistant. The results of the two tests were correlated at a value of 98%.

Clinical conclusions

The disk diffusion test was well correlated with the Epsilometer test which is highly correlated with the MIC values derived from other agar based reference tests and can therefore be used for antimicrobial resistance testing.

Measure of benefits used in the economic analysis

The measure of benefit can be expressed in terms of the detection correlation between the disk diffusion test and the E-test. As both tests were considered to be equally effective the analysis conducted was cost-minimisation.

Direct costs

The direct costs included were the costs for (blood) agar culture sheets, blank disks, and antibiotics used for both tests. Discounting was not relevant and the price year was not stated. Costs and quantities were reported separately.

Statistical analysis of costs

Not undertaken.

Indirect costs

Not relevant.

Currency

Japanese Yen (Y).

Sensitivity analysis

No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis

The estimated benefits are shown in the effectiveness results above.

Cost results

The costs were calculated for the resistance testing of 100 cases of *H. pylori* against metronidazole and clarithromycin. While the Epsilometer test incurred Y105,300, the disk diffusion test incurred Y19,750 (plus an additional non-
specified cost recorded as ‘alpha’).

**Synthesis of costs and benefits**
Costs and benefits were not combined. As the Epsilometer test and the disk diffusion test were assumed to be equal in effectiveness for antimicrobial resistance testing of H. pylori and the total costs for the disk diffusion were lower than those for the Epsilometer test, the disk diffusion test is assumed to be the dominant strategy.

**Authors’ conclusions**
The authors concluded that the disk diffusion test is a cost-effective and simple method for the screening of antimicrobial resistance of Helicobacter pylori.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of comparator is clear. Compared with other techniques, the Epsilometer test and the disk diffusion test have the advantage of allowing the visualization of resistant subpopulations of bacteria within zones of inhibitions. The cost-effectiveness demonstrated for the disk diffusion test seems to satisfy the authors’ aim of finding a simple, inexpensive and standardized methods for routine antimicrobial susceptibility testing of H. pylori.

**Validity of estimate of measure of benefit**
As the same sample was used for both tests the results are likely to have a high degree of reliability. However, the correlation was slightly lower when considering metronidazole. Other reference tests were also identified but no correlations with these were undertaken although the authors indicate that the E-test is known to be highly correlated with the reference test used.

**Validity of estimate of costs**
Appropriate details were given regarding the costs of test materials and procedures but the price year was not given. No details were given regarding the source of cost data and any potential variability. This may, however, be a feature of the Japanese health care system which regulates and standardises reimbursement levels.

**Other issues**
The generalisability of the results was not specifically addressed by the authors. The authors made appropriate reference to relevant studies which examined the Disk diffusion test.

**Implications of the study**
As the Disk diffusion test was found to be equally effective and less costly it is recommended for routine testing for resistance of Helicobacter pylori to antibiotics.

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