Cost-effectiveness of the carbon-13 urea breath test for the detection of Helicobacter pylori: an economic analysis

Masucci L, Blackhouse G, Goeree R

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.

CRD summary
The study evaluated the cost-effectiveness of testing strategies for detecting Helicobacter pylori in patients with uninvestigated dyspepsia. The authors concluded that $^{13}$C UBT testing was dominated by a two-step strategy of ELISA followed by $^{13}$C UBT strategy. Cost per misdiagnoses avoided was $210 for the two-step strategy when compared to ELISA alone. The analysis was generally well reported and methodologically appropriate. Limitations included a short time horizon, use of intermediate outcomes and limited analysis of uncertainty.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The study evaluated the cost-effectiveness of testing strategies for detecting Helicobacter pylori in patients with uninvestigated dyspepsia.

Interventions
Three testing strategies for $H.\ pylori$ were investigated: enzyme-linked immunosorbent assay (ELISA); carbon-13 urea breath test ($^{13}$C UBT); and a two-step testing procedure of ELISA followed by confirmatory $^{13}$C UBT.

In $^{13}$C UBT testing, patients were asked to ingest $^{13}$C in water and then blow into a tube analysed by a mass spectrometer.

Location/setting
Canada/outpatient

Methods
Analytical approach:
Cost-effectiveness was evaluated using a decision tree model which combined published data. The stated perspective was that of the Ministry of Health and long-term care. The time horizon of the model was one month.

Effectiveness data:
Key effectiveness data were sensitivity and specificity of the tests. Effectiveness data were derived from a review of the literature. Accordingly, effectiveness outcomes reported were numbers of false-positive test results, false-negative test results and misdiagnoses. Prevalence of the disease was identified from the literature and used in the model.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
Three measures of benefit were used to generate incremental cost-effectiveness ratios (ICERs): false positive tests avoided; false negative tests avoided; and misdiagnoses avoided (false positives and false negatives). The primary measure of benefit was misdiagnoses avoided.

Cost data:
To reflect the perspective adopted, costs in the model included those for ELISA and $^{13}$C UBT tests and physician visits.
ELISA test costs were derived from the Ontario Schedule of Benefits. Cost of $^{13}$C UBT tests was derived from the Alberta province. Cost per physician visit was assumed to be zero as most GPs (general practitioners) in Ontario worked under a capitation reimbursement model. Costs were reported in Canadian dollars ($). 

Analysis of uncertainty:
One-way sensitivity analyses were conducted varying test costs, test sensitivity and specificity, and the prevalence of *H. pylori*.

**Results**
The ELISA serology test was the least costly at $13.96 and least effective at 0.2023 false positives per test.

$^{13}$C UBT testing cost $74.96 per test and had 0.0588 false positives per test.

The two-step testing strategy was the most effective strategy at a cost of $50.02 and 0.0170 false positives per test; this result was dominant (more effective and less costly) over $^{13}$C UBT testing with an ICER of $195 per false positive test prevented compared to ELISA alone.

Where the measure of benefit was false negative tests avoided, the two-step method was dominated by $^{13}$C UBT and the ICER per false negative avoided was $9,683 compared to ELISA alone.

In the misdiagnoses analysis, the two-step strategy dominated $^{13}$C UBT and had an ICER of $210 per misdiagnoses avoided compared to ELISA alone.

One-way sensitivity analyses had similar results to the base-case with ICERs that ranged between $102 and $250 per misdiagnosis avoided.

In all analyses, the $^{13}$C UBT strategy was dominated by the two-test method.

**Authors' conclusions**
The authors concluded that $^{13}$C UBT testing was dominated by the two-step ELISA then $^{13}$C UBT strategy. The ICER compared to ELISA alone was $210 per misdiagnosis avoided.

**CRD commentary**
**Interventions:**
The interventions were clearly described and included standard care in Ontario, which was the study setting. Additional tests not routinely used in Ontario were discussed and their exclusion was justified. These included $^{14}$C UBT testing and a faecal antigen test.

**Effectiveness/benefits:**
Full details of the economic literature review strategy were provided with sufficient detail. But it was unclear whether clinical data used to populate the model (sensitivity, specificity and prevalence) were derived from this evidence. There were no details of a clinical review.

The authors acknowledged that false positives and false negatives were intermediate outcomes and that a better outcome would be related to patient quality of life. Again, it was not clear that any attempt was made to review the appropriate literature to identify relevant quality of life outcomes. The authors also indicated that dyspepsia was a risk factor for a number of cancers so long-term outcomes may also be important. The time horizon of the model was not sufficient to capture more than the intermediate test outcomes.

**Costs:**
Costs were reported clearly using appropriate sources and methodology. The price year was not reported and this limited both comparisons with other study results and transferability of the results to other settings. The costing was limited to test costs due to the GP payment method in Ontario and the perspective adopted; these issues should be considered when translating the results to other settings. GP costs were assumed to be zero but the number of GP visits required differed between tests.
Analysis and results:
The model structure and inputs were presented clearly. The study results were clearly reported and explained in context. The authors acknowledged limitations related to outcome measures and the model time horizon.

The one-way sensitivity analyses conducted were reported clearly but a full probabilistic analysis that allowed all parameters to vary simultaneously would give a better idea of the effect of uncertainty on model results.

Concluding remarks:
The analysis was generally well reported and methodologically appropriate. There were some limitations: lack of detail for clinical input parameters, an insufficient time horizon for capturing long-term outcomes, use of intermediate outcomes and limited analysis of uncertainty.

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