

Title:	Carbon-labelled urea breath tests for diagnosis of <i>Helicobacter pylori</i> infection February/March 2006 (printed July 2006)
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Aim

To assess the safety, effectiveness and cost-effectiveness of carbon-labelled urea breath tests (C-UBTs) for diagnosis of *Helicobacter pylori* infection and under what circumstances public funding should be supported for the procedure.

Conclusions and results

Safety The potential risk for patients undergoing C-UBTs for diagnosis of *H. pylori* infection are minimal due to the non-invasive nature of the procedure. Data from four case series indicated that the procedure was well tolerated by patients and that systemic, gastrointestinal and allergic-type events are extremely rare.

Effectiveness Twelve cross-sectional studies reporting the diagnostic characteristics of UBTs against the reference of endoscopy and testing of biopsy samples as a first line diagnostic test were included. Across studies, sensitivity ranged from 90-100%, specificity from 86-100%, and positive and negative likelihood ratios from 6.8-66.7 and 0.0-0.1, respectively. These diagnostic characteristics indicate that UBTs are the most accurate non-invasive tests for diagnosing *H. pylori* infection.

Four prospective RCTs comparing health outcomes of dyspeptic patients undergoing UBTs as a first line diagnostic test for *H. pylori* infection and subsequent management with those of patients receiving endoscopy and subsequent management or empirical treatment were included. Results suggest improved outcomes for people undergoing the UBT followed by management compared to empirical treatment, and similar outcomes compared to endoscopy and subsequent management.

Cost-effectiveness Results of a cost-effectiveness analysis of UBT as a first line diagnostic test in the management of uncomplicated dyspepsia compared to serology, empirical antisecretory treatment and endoscopy suggested that, under baseline assumptions, serology and UBT were similar with respect to total cost, total QALYs and time living without dyspepsia over a one-year timeframe. The results of an analysis of the financial implications of substituting UBT into current clinical practice suggest that there may be financial cost savings of more than \$15 million per annum.

Recommendations

Public funding should be supported for the use of carbon-labelled urea breath testing as a first line procedure for the diagnosis of *Helicobacter pylori* infection.

Method

MSAC conducted a systematic review of literature via Medline, Embase, the Cochrane Library, CINAHL, Biological Abstracts and the Australasian Medical Index from 1966 to May 2005.