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Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD012080.

DOI: 10.1002/14651858.CD012080.pub2.

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[Diagnostic Test Accuracy Review]

Non-invasive diagnostic tests for *Helicobacter pylori* infection

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Editorial group: Cochrane Upper GI and Pancreatic Diseases Group.

Publication status and date: New, published in Issue 3, 2018.

Citation: Best LMJ, Takwoingi Y, Siddique S, Selladurai A, Gandhi A, Low B, Yaghoobi M, Gurusamy KS. Non-invasive diagnostic tests for *Helicobacter pylori* infection. *Cochrane Database of Systematic Reviews* 2018, Issue 3. Art. No.: CD012080. DOI: 10.1002/14651858.CD012080.pub2.

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ABSTRACT

Background

Helicobacter pylori (*H pylori*) infection has been implicated in a number of malignancies and non-malignant conditions including peptic ulcers, non-ulcer dyspepsia, recurrent peptic ulcer bleeding, unexplained iron deficiency anaemia, idiopathic thrombocytopenia purpura, and colorectal adenomas. The confirmatory diagnosis of *H pylori* is by endoscopic biopsy, followed by histopathological examination using haematoxylin and eosin (H & E) stain or special stains such as Giemsa stain and Warthin-Starry stain. Special stains are more accurate than H & E stain. There is significant uncertainty about the diagnostic accuracy of non-invasive tests for diagnosis of *H pylori*.

Objectives

To compare the diagnostic accuracy of urea breath test, serology, and stool antigen test, used alone or in combination, for diagnosis of *H pylori* infection in symptomatic and asymptomatic people, so that eradication therapy for *H pylori* can be started.

Search methods

We searched MEDLINE, Embase, the Science Citation Index and the National Institute for Health Research Health Technology Assessment Database on 4 March 2016. We screened references in the included studies to identify additional studies. We also conducted citation searches of relevant studies, most recently on 4 December 2016. We did not restrict studies by language or publication status, or whether data were collected prospectively or retrospectively.

Selection criteria

We included diagnostic accuracy studies that evaluated at least one of the index tests (urea breath test using isotopes such as ¹³C or ¹⁴C, serology and stool antigen test) against the reference standard (histopathological examination using H & E stain, special stains or immunohistochemical stain) in people suspected of having *H pylori* infection.

Data collection and analysis

Two review authors independently screened the references to identify relevant studies and independently extracted data. We assessed the methodological quality of studies using the QUADAS-2 tool. We performed meta-analysis by using the hierarchical summary receiver operating characteristic (HSROC) model to estimate and compare SROC curves. Where appropriate, we used bivariate or univariate logistic regression models to estimate summary sensitivities and specificities.

Non-invasive diagnostic tests for *Helicobacter pylori* infection (Review)

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Main results

We included 101 studies involving 11,003 participants, of which 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection in the studies ranged from 15.2% to 94.7%, with a median prevalence of 53.7% (interquartile range 42.0% to 66.5%). Most of the studies (57%) included participants with dyspepsia and 53 studies excluded participants who recently had proton pump inhibitors or antibiotics. There was at least an unclear risk of bias or unclear applicability concern for each study.

Of the 101 studies, 15 compared the accuracy of two index tests and two studies compared the accuracy of three index tests. Thirty-four studies (4242 participants) evaluated serology; 29 studies (2988 participants) evaluated stool antigen test; 34 studies (3139 participants) evaluated urea breath test-¹³C; 21 studies (1810 participants) evaluated urea breath test-¹⁴C; and two studies (127 participants) evaluated urea breath test but did not report the isotope used. The thresholds used to define test positivity and the staining techniques used for histopathological examination (reference standard) varied between studies. Due to sparse data for each threshold reported, it was not possible to identify the best threshold for each test.

Using data from 99 studies in an indirect test comparison, there was statistical evidence of a difference in diagnostic accuracy between urea breath test-¹³C, urea breath test-¹⁴C, serology and stool antigen test ($P = 0.024$). The diagnostic odds ratios for urea breath test-¹³C, urea breath test-¹⁴C, serology, and stool antigen test were 153 (95% confidence interval (CI) 73.7 to 316), 105 (95% CI 74.0 to 150), 47.4 (95% CI 25.5 to 88.1) and 45.1 (95% CI 24.2 to 84.1). The sensitivity (95% CI) estimated at a fixed specificity of 0.90 (median from studies across the four tests), was 0.94 (95% CI 0.89 to 0.97) for urea breath test-¹³C, 0.92 (95% CI 0.89 to 0.94) for urea breath test-¹⁴C, 0.84 (95% CI 0.74 to 0.91) for serology, and 0.83 (95% CI 0.73 to 0.90) for stool antigen test. This implies that on average, given a specificity of 0.90 and prevalence of 53.7% (median specificity and prevalence in the studies), out of 1000 people tested for *H pylori* infection, there will be 46 false positives (people without *H pylori* infection who will be diagnosed as having *H pylori* infection). In this hypothetical cohort, urea breath test-¹³C, urea breath test-¹⁴C, serology, and stool antigen test will give 30 (95% CI 15 to 58), 42 (95% CI 30 to 58), 86 (95% CI 50 to 140), and 89 (95% CI 52 to 146) false negatives respectively (people with *H pylori* infection for whom the diagnosis of *H pylori* will be missed).

Direct comparisons were based on few head-to-head studies. The ratios of diagnostic odds ratios (DORs) were 0.68 (95% CI 0.12 to 3.70; $P = 0.56$) for urea breath test-¹³C versus serology (seven studies), and 0.88 (95% CI 0.14 to 5.56; $P = 0.84$) for urea breath test-¹³C versus stool antigen test (seven studies). The 95% CIs of these estimates overlap with those of the ratios of DORs from the indirect comparison. Data were limited or unavailable for meta-analysis of other direct comparisons.

Authors' conclusions

In people without a history of gastrectomy and those who have not recently had antibiotics or proton pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests were less accurate for diagnosis of *Helicobacter pylori* infection. This is based on an indirect test comparison (with potential for bias due to confounding), as evidence from direct comparisons was limited or unavailable. The thresholds used for these tests were highly variable and we were unable to identify specific thresholds that might be useful in clinical practice.

We need further comparative studies of high methodological quality to obtain more reliable evidence of relative accuracy between the tests. Such studies should be conducted prospectively in a representative spectrum of participants and clearly reported to ensure low risk of bias. Most importantly, studies should prespecify and clearly report thresholds used, and should avoid inappropriate exclusions.

PLAIN LANGUAGE SUMMARY

Accuracy of different non-invasive methods for identifying *Helicobacter pylori*

Why is it important to know whether someone has *Helicobacter pylori*?

Helicobacter pylori (*H pylori*) is a type of bacteria which may be present in the stomach of some people. *H pylori* is believed to cause a number of cancers, including stomach cancer, pancreatic cancer, and throat cancer. *H pylori* is also linked with other diseases including stomach ulcers, heart burn, and a bloated feeling. If *H pylori* is found in an individual, appropriate treatment can be started.

What is the aim of this review?

To compare the accuracy of three different types of test for *H pylori*. These are: urea breath tests, blood tests (the specific blood test is called serology), and stool tests (in faeces).

What was studied in this review?

There are two types of urea breath test which use two different forms of carbon known as ^{13}C and ^{14}C , as well as multiple versions of serology and stool tests.

What are the main results of the review?

We found 101 studies which included 11,003 people who were tested for *H pylori*. Of these 11,003 participants, 5839 (53.1%) had *H pylori* infection. All the studies used one of the three tests listed above and compared these test results with the diagnosis given by endoscopic biopsy. Endoscopic biopsy involves obtaining tissue from the stomach using a thin flexible tube introduced through the mouth and testing for the presence of *H pylori* under the microscope. It is currently the most accurate available test, however it causes physical discomfort to the patient, with associated risks for harm. This is in contrast to the alternative non-invasive tests in this review which are significantly less uncomfortable and have minimal or no risk of harm, making them desirable alternatives if they can be shown to be as accurate at diagnosing *H pylori* as endoscopic biopsy. Most of the studies included participants with heart burn or similar problems in the stomach and excluded participants who had previously undergone partial removal of the stomach and those having treatment for *H pylori*.

Thirty-four studies (4242 participants) used serology; 29 studies (2988 participants) used stool antigen test; 34 studies (3139 participants) used urea breath test- ^{13}C ; 21 studies (1810 participants) used urea breath test- ^{14}C ; and two studies (127 participants) used urea breath test but did not report the type of carbon used. Studies varied in the limit they used before saying a test was positive for *H pylori* infection and the type of stains used to examine the biopsy material. When we looked at all the data we found that urea breath tests were more accurate than blood and stool tests. The results mean that, on average, if 1000 people are tested, there will be 46 people without *H pylori* who will be misdiagnosed as having *H pylori*. Also, there will be 30, 42, 86, and 89 people with *H pylori* infection for whom the diagnosis of *H pylori* infection will be missed by urea breath test- ^{13}C , urea breath test- ^{14}C , serology, and stool antigen test, respectively. When we looked at the seven studies which compared urea breath test- ^{13}C and serology, or urea breath test- ^{13}C and stool antigen tests in the same participants, the results were uncertain and we cannot tell which test is more accurate.

How reliable are the results of the studies?

Except for one study, all the studies were of poor methodological quality, which makes their results unreliable.

Who do the results of this review apply to?

These results apply to children and adults with suspected *H pylori* infection, but only in those who have not previously undergone stomach operations and those who have not recently had antibiotics or treatment for *H pylori* infection.

What are the implications of this review?

Urea breath tests, blood tests, and stool tests may be suitable for identifying whether someone has *H pylori* infection. However, the level of the result of urea breath test, blood test, or stool test which should be used to make a diagnosis of *H pylori* infection remains unclear.

How up-to-date is the review?

We performed a thorough literature search for studies reporting the accuracy of these different tests until 4 March 2016.

BACKGROUND

Helicobacter pylori (*H pylori*) is a gram negative spiral bacterium (NCBI 2014). Approximately 13% to 81% of people have *H pylori* infection (Peleteiro 2014). Prevalence of the bacterium varies according to age (generally increasing with age, although infection rates tend to fall among older age groups in some Latin Ameri-

can and Northeast Asian countries); region (lower infection rates are seen in Australia and the UK, while higher rates are reported in Chile, China, Japan, Korea, and Latvia); race (more prevalent amongst Afrocarribeans compared to white people); and socio-economic class (more common in poorer settings) (Graham 1991; Laszewicz 2014; Muhsen 2012; Peleteiro 2014).

Based on observational studies, *H pylori* infection has been implicated in a number of malignancies, including gastric cancer, premalignant lesions of the stomach (atrophic gastritis and intestinal metaplasia), gastric lymphoma, pancreatic cancer, colorectal cancer, and laryngeal cancer (Huang 1998; Huang 2003; Wu 2013; Xiao 2013; Xue 2001; Zhuo 2008). However, *H pylori* is associated with a lower incidence of oesophageal adenocarcinomas (Islami 2008). *H pylori* is also associated with a number of non-malignant conditions, including peptic ulcers, non-ulcer dyspepsia, recurrent peptic ulcer bleeding, unexplained iron deficiency anaemia, idiopathic thrombocytopenia purpura, and colorectal adenomas (DuBois 2005; Franchini 2007; Gisbert 2004b; Huang 2002; Jaakkimainen 1999; Wu 2013).

Although a number of pathogenic factors such as cytotoxin-associated gene A (CagA), vacuolating cytotoxin A (VacA), and blood group antigen binding adhesin (BabA) are associated with increased virulence of *H pylori* (Huang 2003; Malfertheiner 2012), detection of these pathogenic factors currently has no role in the management of *H pylori* infection (Malfertheiner 2012). The recommended initial treatment for *H pylori* infection is with a combination of a proton pump inhibitor, clarithromycin, and amoxicillin or metronidazole (triple therapy) in regions with low resistance to clarithromycin (< 20% resistance rate in the area), and the triple therapy along with bismuth (quadruple therapy) in regions with high resistance to clarithromycin (> 20% resistance rate in the area) (Malfertheiner 2012). If this results in failure of eradication, bismuth-quadruple therapy or levofloxacin-triple therapy (replacement of clarithromycin with levofloxacin in the classical triple therapy) when triple therapy was used as the initial treatment and levofloxacin-triple therapy when bismuth quadruple therapy was used as the initial treatment is recommended (Malfertheiner 2012). If even this treatment fails to eradicate *H pylori*, then further treatment should be based on antibiotic susceptibility (Malfertheiner 2012). Eradication of *H pylori* might lead to a decrease in malignant and non-malignant conditions associated with *H pylori* infection. Adverse events related to *H pylori* treatment include taste disturbance, diarrhoea, nausea, headache, skin rash, abdominal pain, dizziness, bloating, myalgias (muscle pain), and constipation (Ye 2014).

A glossary of terms is included in Appendix 1.

Target condition being diagnosed

Helicobacter pylori infection.

Index test(s)

Urea breath test

The urea breath test is based on the presence of urease enzyme in live *H pylori* which breaks down urea into ammonia and carbon dioxide (McNulty 2005; Ricci 2007). After ingestion of urea labelled with either ¹³C or ¹⁴C, breath samples are collected for up to 30 minutes by exhaling into a carbon dioxide-trapping agent (Ricci 2007). The urea breath test is performed by the clinician or the clinician's assistant. The thresholds used include the percentage of carbon recovered during the collection time or counts per minute (Ferwana 2015). Threshold levels above 4% or 5% are commonly used to diagnose *H pylori* infection (Ferwana 2015). A wide range of threshold counts per minute, ranging from more than 25 counts per minute to 1000 counts per minute, have been used for diagnosis of *H pylori* infection (Ferwana 2015).

Serology

These tests are based on circulating antibodies to *H pylori*. There are three main methods for these tests: the enzyme-linked immunosorbent assay (ELISA) test, latex agglutination tests, and Western blotting (Ricci 2007). Of these, ELISA is the most commonly used method. Total immunoglobulin, immunoglobulin subtypes, and antibody response to specific antigens can all be tested. Since they do not require any special equipment, they can be easily performed (Ricci 2007). However, serology may be positive because of the presence of active infection at the time of the test, previous infection, or because of non-specific cross-reacting antibodies (McNulty 2005). Tests that use whole blood (rather than serum) and other bedside tests (using a bedside centrifuge) are also available, although these whole-blood tests and bedside serum tests are generally considered unreliable (Ricci 2007). Routine serum tests are performed by the laboratory technician and interpreted by the clinician. The bedside serum tests and whole-blood tests are performed by the clinician or the clinician's assistant. Different researchers evaluating the prevalence of *H pylori* have used different thresholds to define the positivity of serology, for example Lindsetmo 2008 used a titre ≥ 300 while Granberg 1993 used a titre ≥ 500 .

Stool antigen tests

These tests use monoclonal and polyclonal antibodies to detect the presence of *H pylori* antigen in stools and active *H pylori* infection can be diagnosed (McNulty 2005; Ricci 2007). Serum tests are performed by the laboratory technician and interpreted by the clinician. Several thresholds have been used for other tests, for example, an optical density of ≥ 0.15 , ≥ 0.16 , and ≥ 0.19 have all been used as thresholds for diagnosis of *H pylori* using monoclonal antibodies for stool antigen tests.

Clinical pathway

Evidence from randomised controlled trials (RCTs) showed that screening and eradication programmes for *H pylori* in populations at high risk of gastric cancer (e.g. East Asians) lowered the incidence of gastric cancer (Ford 2014). The Asia-Pacific Gastric Cancer Consensus conference recommended that screening and eradication of *H pylori* was advisable in populations in countries at high risk of gastric cancer (i.e. Japan and Korea) (Talley 2008). The updated European Helicobacter Study Group (EHSG) Fourth Maastricht/Florence Consensus Conference guidelines suggest that people should be tested for *H pylori*, and eradication of *H pylori* (when present) has been recommended for the following conditions (Malfertheiner 2012):

1. People at high risk of gastric cancer.

2. Adults with dyspepsia with a locally-determined age cut-off point (depending on local incidence of gastric cancer in different age groups), and without 'alarm' symptoms or signs associated with an increased risk of gastric cancer such as weight loss, dysphagia, upper gastrointestinal bleeding, abdominal mass, or iron deficient anaemia.

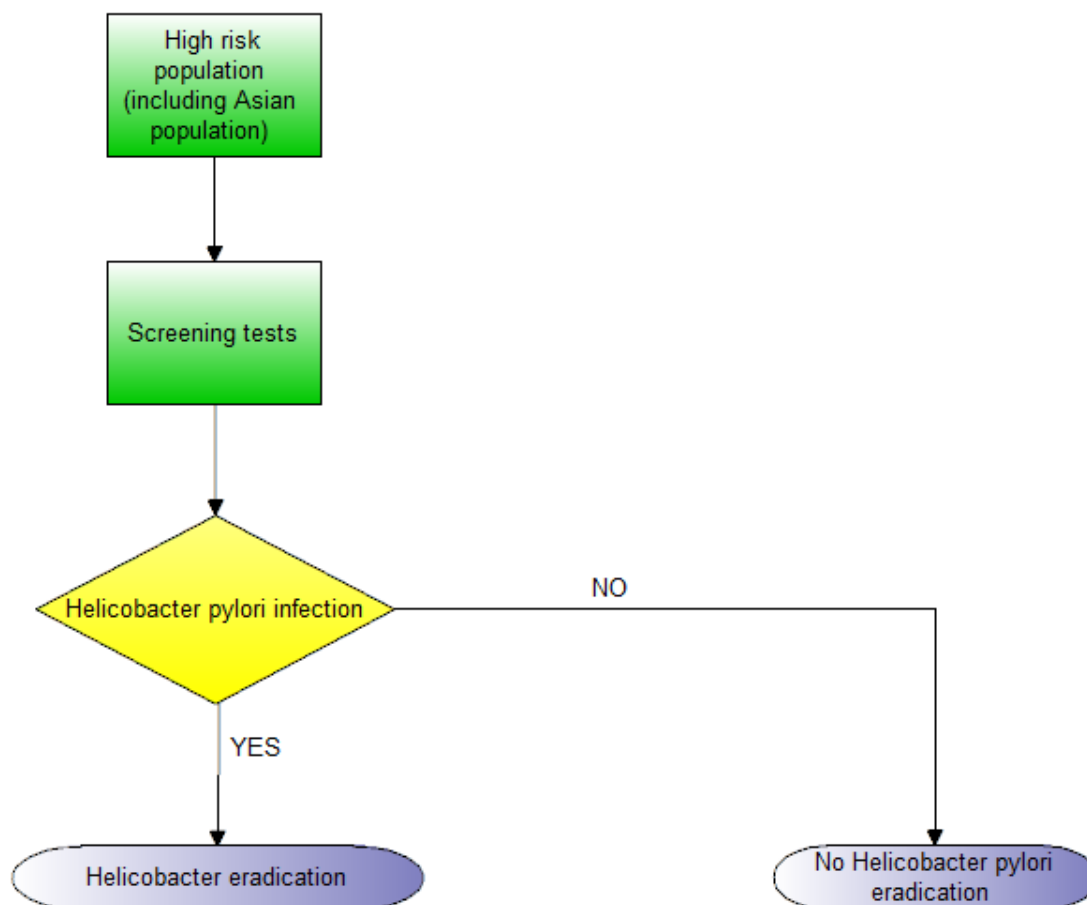
3. Unexplained iron deficiency anaemia.

4. Idiopathic thrombocytopenic purpura.

5. Uninvestigated young patients with dyspepsia should also be considered for testing for *H pylori* when the prevalence of *H pylori* is high ($\geq 20\%$).

The clinical pathway is shown in Figure 1.

Figure 1. Clinical pathway



Prior test(s)

The index tests can be performed without any prior test.

Role of index test(s)

The index tests are used for screening and diagnosis of *H pylori*.

Alternative test(s)

Other tests used in the screening and diagnosis of *H pylori* infection include non-invasive saliva and urine antigen-based tests (Ricci 2007), and invasive gastric biopsy followed by Campylobacter-like organism (CLO) test, culture, histology, and polymerase chain reaction (PCR) (Van Doorn 2000). We do not include non-invasive saliva and urine antigen-based tests in this review because these tests are not commonly used (Ricci 2007).

Rationale

Testing for *H pylori* and eradication of *H pylori* have been recommended for a number of population groups (Clinical pathway). These tests have to be non-invasive so that a large number of people can be tested. People with undetected *H pylori* continue to be at high risk of gastric cancer or continue to have dyspepsia, anaemia, or purpura. Overdiagnosis (false positive test results) of *H pylori* means that patients are subject to unnecessary adverse events related to eradication therapy (approximately 27% of patients receiving eradication therapy develop mild adverse events such as bitter taste, nausea, diarrhoea, etc.). Comparing the diagnostic accuracy of different index tests will highlight the best test for the diagnosis of *H pylori* infection.

OBJECTIVES

To compare the diagnostic accuracy of urea breath test, serology, and stool antigen test, alone or in combination, for diagnosis of *H pylori* infection in symptomatic and asymptomatic people, so that eradication therapy for *H pylori* can be started.

Secondary objectives

To investigate the following potential sources of heterogeneity: type of reference standard, risk of bias, publication status, prospective versus retrospective studies, symptomatic versus asymptomatic participants, recent or current use of proton pump inhibitors or antibiotics, different subtypes of tests, and the interval between the index test and reference standard.

METHODS

Criteria for considering studies for this review

Types of studies

We include studies that evaluate the accuracy of the index tests in the appropriate patient population (see Participants), regardless of language or publication status, or whether data were collected prospectively or retrospectively. However, we exclude reports that describe how the diagnosis of *H pylori* was made in an individual patient or group of patients, and which do not provide sufficient diagnostic test accuracy data (i.e. the number of true positives, false positives, false negatives, and true negatives). We also exclude case-control studies because these are prone to bias (Whiting 2011).

Participants

Symptomatic and asymptomatic people in whom *H pylori* infection status is sought so that eradication therapy for *H pylori* can be started. We exclude studies that included only people with acute upper gastrointestinal bleeding because such patients are likely to undergo endoscopy and invasive testing can be performed, if required.

Index tests

Urea breath test-¹⁴C, urea breath test-¹³C, serology, and stool antigen test, alone or in combination. We included only initial testing and excluded repeat testing (monitoring success of treatment), since diagnostic accuracy may vary depending on the purpose of testing (Ricci 2007).

Target conditions

H pylori infection.

Reference standards

There is no gold standard for diagnosis of *H pylori* infection and the diagnosis is made by a combination of tests following endoscopic biopsy; endoscopic biopsy followed by histology, endoscopic biopsy followed by polymerase chain reaction (PCR), and endoscopic biopsy followed by rapid urease testing all have excellent sensitivity and specificity (Chey 2007). However, PCR methodology is not standardised across laboratories (Chey 2007); it is an unreliable reference standard. Endoscopic biopsy followed by rapid urease testing has poor sensitivity following treatment with proton pump inhibitors (Chey 2007). Endoscopic biopsy with culture has high specificity but poor sensitivity (Chey 2007). We therefore considered only endoscopic biopsy followed by histology (using haematoxylin and eosin (H & E) stain, special histological stains such as Giemsa stain and Warthin-Starry stain, or immunohistochemical stain) as the reference standard in this review.

Immunohistochemical stains are more accurate than special stains, while special stains and immunohistochemical stains are thought to have better specificity than H & E stains for diagnosis of *H pylori* infection (Laine 1997; Lee 2015b). For this reason, we considered endoscopic biopsy with histology using immunohistochemical stain as the best reference standard, and endoscopic biopsy with histology using H & E stain as the worst reference standard.

Search methods for identification of studies

We included all studies, irrespective of the language of publication and publication status. If we found articles in languages other than English, we obtained translations.

Electronic searches

We searched the following databases.

1. MEDLINE via OvidSP (January 1946 to 4 March 2016) (Appendix 2).
2. Embase via OvidSP (January 1947 to 4 March 2016) (Appendix 3).
3. Science Citation Index Expanded via Thomson Reuters Web of Science (January 1980 to 4 March 2016) (Appendix 4).
4. National Institute for Health Research (NIHR HTA) via Centre for Reviews and Dissemination, University of York. (www.crd.york.ac.uk/CRDWeb/) (4 March 2016) (Appendix 5).

Searching other resources

To identify additional studies, we examined references in the included studies to see if any might be relevant. We also searched for articles related to the included studies by using the 'related search' function in MEDLINE (OvidSP) and Embase (OvidSP). We conducted a 'citing reference' search (by searching articles which cited the included articles) (Sampson 2008) in MEDLINE (OvidSP) and Embase (OvidSP) on 4 December 2016.

Data collection and analysis

Selection of studies

Two review authors (KG and LB, SS, or AS) independently searched the references to identify relevant studies. We obtained the full text for references considered relevant by at least one of the two review authors. Two review authors independently screened the full-text papers against the inclusion criteria, resolving any differences in study selection by discussion. We attempted to contact study authors if there were doubts about the eligibility of a study.

Data extraction and management

Two review authors (KG and LB, SS, or AS) independently extracted the following data from each included study, using a pre-piloted data extraction form, and resolving differences by discussion.

1. First author.
2. Year of publication.
3. Study design (prospective or retrospective cohort studies; cross-sectional studies or randomised controlled trials).
4. Inclusion and exclusion criteria for individual studies.
5. Total number of participants.
6. Number of female participants.
7. Average age of the participants.
8. Initial testing versus testing after eradication.
9. Number of people with bleeding ulcers, gastric atrophy, lymphoma, and recent or current use of proton pump inhibitors or antibiotics.
10. Number of symptomatic participants.
11. Tests carried out prior to the index test.
12. Description of the index test.
13. Threshold used for the index test.
14. Reference standard.
15. Number of true positives, false positives, false negatives, and true negatives (i.e. 2 x 2 data) at each threshold reported.

If a study reported multiple index tests, we extracted the 2 x 2 data for each index test at each threshold. For studies that reported test accuracy for different reference standards, we extracted 2 x 2 data for only one of the reference standards. For this purpose, due to the accuracy of the stains, we preferred the immunohistochemical stain over special stains, which in turn we preferred over the H & E stain.

Although the number of uninterpretable index test results may provide information on the applicability of the tests in clinical practice and may affect the cost effectiveness of a test, we had planned to exclude patients with uninterpretable index test results from the meta-analyses. We made this decision because in clinical practice uninterpretable index test results would result in additional testing. Nevertheless, we would have extracted and reported such data if available from the studies.

If we suspected an overlap of participants between multiple reports due to common study authors and centres, we planned to contact the study authors for clarification; however, this was not required, since we could identify multiple reports of the same study using the information provided in the reports. We sought further information from study authors, if necessary.

Assessment of methodological quality

Two review authors independently assessed study quality using the QUADAS-2 tool (Whiting 2006; Whiting 2011), resolving differences by discussion. The criteria used for the assessment are shown in Appendix 6. We considered studies classified as 'low risk

of bias' and 'low concern' in all the domains of the QUADAS-2 tool as studies with high methodological quality. It must be noted here that 'risk of bias' refers to internal validity (i.e. whether there were systematic errors in performing the study with respect to the particular domain), while 'applicability concern' refers to external validity (i.e. whether there were concerns that the population, index test or reference standard used in the studies matched the review question).

Statistical analysis and data synthesis

We plotted study estimates of sensitivity and specificity on forest plots and in receiver operating characteristic (ROC) space to explore between-study variation in the accuracy of each test. We examined the thresholds reported for each test and the reference standards used. Due to between-study variation in thresholds, we performed meta-analyses by using the hierarchical summary receiver operating characteristics (HSROC) model to estimate SROC curves (Rutter 2001). For these analyses, if a study reported test accuracy at multiple thresholds, we selected the threshold used by the study authors for their primary analysis.

Prior to comparative meta-analyses of the tests, we performed meta-analysis of each test separately for preliminary investigation of the shape of the SROC curve of each test and to assess heterogeneity in test performance. We used this approach to understand the data and to guide modelling assumptions we may need to make in the comparative meta-analysis. These preliminary analyses were done noting the availability of comparative studies. To compare the accuracy of the index tests, we added test type as a covariate to the HSROC model (Macaskill 2013). For the indirect comparison where we used all available data (i.e. not restricted to comparative studies), we assessed the effect of test type on the accuracy, threshold, and shape parameters of the HSROC model. We also explored the effect of test type on the variance of the random effects for accuracy and threshold. To determine the final meta-analytic model, we used likelihood ratio tests to assess model fit. Likelihood ratio tests were also used to determine the statistical significance of differences in test accuracy. When SROC curves are symmetric (i.e. HSROC model without the shape parameter), each curve can be described using the diagnostic odds ratio (DOR) to quantify the accuracy of the test. We used the ratio of DORs as a summary of the relative accuracy of two tests.

Summary sensitivities and specificities can be obtained from a HSROC model but they are not clinically interpretable here because we included studies with different thresholds. We therefore estimated sensitivities at points on the SROC curves that correspond to the lower quartile, median and upper quartile of the specificities from the studies included in the meta-analysis. When comparative studies that had evaluated two tests head-to-head were available, we performed direct comparisons of the tests (Takwoingi 2013). For these analyses, we fitted HSROC models with symmetric SROC curves, as the available data were insufficient for

reliable estimation of the shape of the SROC curves (Takwoingi 2017).

If there were at least two studies that reported the accuracy of a test at the same threshold, we considered meta-analysis to obtain summary estimates of sensitivity and specificity. Due to the small number of studies in these analyses, we performed meta-analyses using univariate fixed-effect or random-effects logistic regression models, depending on the extent of heterogeneity observed in forest plots and in ROC space (Takwoingi 2017). When there were only two or three studies at the same threshold, and little or no heterogeneity observed in ROC space, we used univariate fixed-effect logistic regression models to pool sensitivities and specificities separately. When there were two or three studies and we observed heterogeneity, we did not perform meta-analysis, as random-effects models would be more appropriate in such situations. However, random effects cannot be reliably estimated with very few studies.

We performed meta-analyses using the NLMIXED procedure in SAS.

Investigations of heterogeneity

We used forest plots and scatter plots of sensitivity against specificity for preliminary investigation of potential sources of heterogeneity such as:

1. Type of reference standard (different histological stains).
2. Studies at low risk of bias in all the QUADAS-2 domains versus those at unclear or high risk of bias.
3. Full-text publications versus abstracts (may provide insight into publication bias if there is an association between the results of a study and full publication of the study) (Eloubeidi 2001).
4. Prospective versus retrospective studies.
5. Symptomatic versus asymptomatic participants.
6. Recent or current use of proton pump inhibitors or antibiotics, as these patients are at higher risk of false negative results for the urea breath test and stool antigen test, with serology being the only non-invasive test unaffected by the use of proton pump inhibitors or antibiotics (Malfertheiner 2012; Ricci 2007).
7. Different subtypes of tests (ELISA, latex agglutination test, and Western blot methods of serological tests; formal serological tests versus bedside serological tests; and monoclonal versus polyclonal antibodies for stool antigen tests).
8. Interval between index test and reference standard. Resolution of *H pylori* infection in people with *H pylori* infection (usually with treatment) and infection in those without *H pylori* infection may occur if there was a long interval between the index test and reference standard.

We formally investigated heterogeneity for each test by adding a covariate to a HSROC model (meta-regression). We used likelihood ratio tests to assess the statistical significance of differences in test accuracy by comparing models with and without the covariate.

Sensitivity analyses

We planned to examine the impact of data inconsistencies on the meta-analytic findings. For example, if test accuracy data reported in the text of a paper differed from those in the figures, we planned to assess the impact of using different data in sensitivity analyses; however, we did not find such inconsistencies.

Assessment of reporting bias

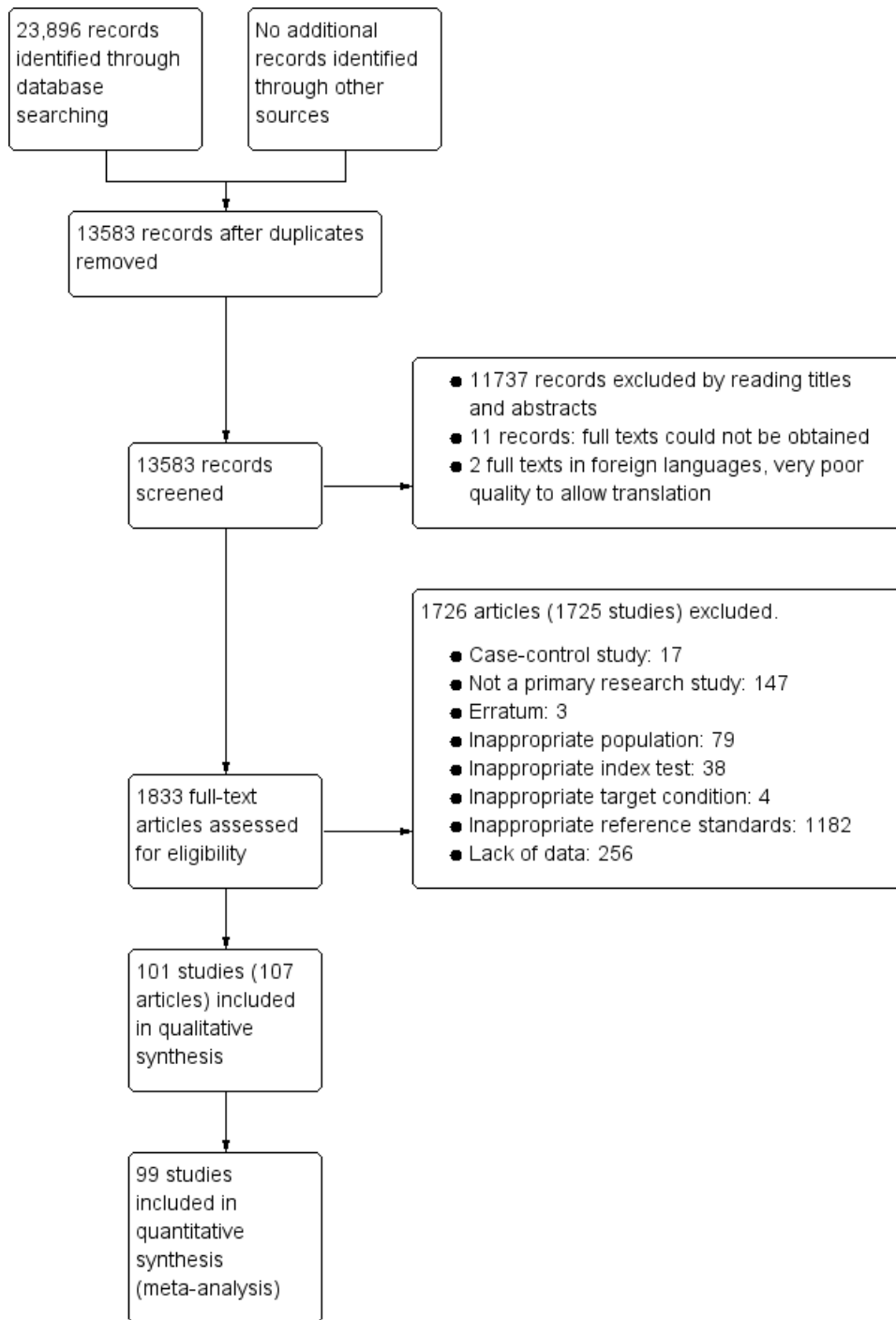
Due to limited data, we were unable to formally investigate whether test accuracy differed between studies that were published as full texts and those available only as abstracts.

RESULTS

Results of the search

We identified 23,896 references through electronic searches of MEDLINE, Embase, Science Citation Index, and NIHR HTA. We did not identify additional references through other searches. The flow of studies through the screening process is shown in [Figure 2](#). After removing 10,313 duplicates, there were 13,583 references. Of these, we dropped 11,737 irrelevant references through reading the titles and abstracts. We could not obtain the full text of 11 references. The quality of copies of two references was too poor to allow translation and we were unable to obtain better copies. We assessed the full text of the remaining 1833 references. We excluded 1728 references (1727 studies) for reasons stated in Appendix 7 (also see Characteristics of excluded studies below). The remaining 107 references (101 studies) met our inclusion criteria. Two references reported diagnostic accuracy data separately for people who underwent gastrectomy and those who did not undergo gastrectomy, and so we considered these subgroups as separate studies ([Adamopoulos 2009a](#); [Adamopoulos 2009b](#); [Sheu 1998a](#); [Sheu 1998b](#)).

Figure 2. Study flow diagram.



Characteristics of included studies

We summarise the characteristics of the 101 included studies in the [Characteristics of included studies](#) table. The studies included 11,003 participants, of which 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection ranged from 15.2% to 94.7% with a median of 53.7% (interquartile range: 42.0% to 66.5%).

Of the 101 studies, 34 evaluated urea breath test-¹³C; 21 evaluated urea breath test-¹⁴C; two evaluated urea breath test but did not report the isotope used; 34 evaluated serology; and 29 evaluated stool antigen test. Seventeen studies evaluated more than one test. Of these, 15 evaluated two tests (Dede 2015; El-Din 2013; Eltumi 1999; Hafeez 2007; Inelmen 2004; Korstanje 2006; Kuloglu 2008; Lahner 2004; Lottspeich 2007; Mansour-Ghanaei 2011; Ogata 2001; Soomro 2012; Vandenplas 1992; Yoshimura 2001; Yu 2001), and two evaluated three tests (Monteiro 2001a; Salles-Montaudon 2002). Studies used different thresholds, with 15 studies reporting test accuracy at more than one threshold (Chey 1998; Dede 2015; Delvin 1999; Formichella 2013; Ladas 2002a; Mana 2001a; Misawa 1998; Monteiro 2001a; Morales 1995; Noguera 1998; Novis 1991; Ozturk 2003; Trevisani 2005; Weiss 1994; Yu 2001).

Eleven studies were prospective (Adamopoulos 2009a; Adamopoulos 2009b; Al-Fadda 2000; Arian 2004; Dede 2015; Eltumi 1999; Fallone 1995; Kalach 1998a; Kuloglu 2008; Ogata 2001; Qadeer 2009); six studies were retrospective (Bosso 2000; Czerwionka-Szaflarska 2007; Graham 1996a; Iqbal 2013; Mion 1994; Wardi 2012), while the remaining 84 studies did not state whether they were prospective or retrospective studies. Six studies were published as abstracts only (Han 2012; Mohammadian 2007; Rathbone 1986; Sheu 1998a; Sheu 1998b; Thobani 1995), and the remaining 95 were full-text publications.

Fourteen studies included only children (Argentieri 2007; Behrens 1999; Czerwionka-Szaflarska 2007; Delvin 1999; Dinler 1999; Eltumi 1999; Hafeez 2007; Kalach 1998a; Kuloglu 2008; Lottspeich 2007; Ogata 2001; Rafeey 2007; Vandenplas 1992; Yoshimura 2001). Five studies clearly included only adults (Atli 2012; Chen 1991; Kamel 2011; Safe 1993; Salles-Montaudon 2002). Although not clearly specified in the remaining 82 studies, it appeared that most or all of the participants were adults. The mean or median age of the participants included in these studies ranged between 31 years and 85 years in the 45 studies that reported this information. One study included only participants without symptoms (Wang 2008). Fifty-eight studies included only participants with symptoms, usually abdominal pain or dyspepsia (Adamopoulos 2009a; Adamopoulos 2009b; Aguilar 2007; Al-Fadda 2000; Allardyce 1997; Behrens 1999; Bosso 2000; Ceken 2011; Chen 1991; Czerwionka-Szaflarska 2007; D'Elis 2000; Delvin 1999; Dinler 1999; Ekesbo 2006; El-Din 2013; El-Mekki

2011; El-Nasr 2003; Eltumi 1999; Fanti 1999; Faruqui 2007; Ferrara 1998; Germana 2001; Guo 2011; Gurbuz 2005; Hafeez 2007; Jordaan 2008; Kamel 2011; Kuloglu 2008; Ladas 2002a; Lahner 2004; Lee 1998; Lottspeich 2007; Mansour-Ghanaei 2011; Mion 1994; Misawa 1998; Mohammadian 2007; Morales 1995; Novis 1991; Ogata 2001; Ozturk 2003; Peitz 2001; Qadeer 2009; Rafeey 2007; Rasool 2007; Rathbone 1986; Safe 1993; Scuderi 2000; Segamwenge 2014; Selcukcan 2011; Sharbatdaran 2013; Sheu 1998a; Soomro 2012; Surveyor 1989; Thobani 1995; Vandenplas 1992; Villalobos 1992; Weiss 1994; Yoshimura 2001). The remaining 42 studies did not report the type of participants included. Five studies included only participants who had previously undergone gastrectomy (Adamopoulos 2009b; Lombardo 2003; Schilling 2001; Sheu 1998b; Wardi 2012). Two studies included only participants with atrophic gastritis (Korstanje 2006; Ogata 2001). It was clear that participants who received recent proton pump inhibitors or antibiotics were excluded from 53 studies (Ceken 2011; Chey 1998; Debongnie 1991; D'Elis 2000; Delvin 1999; Duan 1999; El-Mekki 2011; El-Nasr 2003; Eltumi 1999; Fallone 1996; Fanti 1999; Ferrara 1998; Formichella 2013; Germana 2001; Guo 2011; Gurbuz 2005; Jekarl 2013; Jensen 1998; Jordaan 2008; Kalach 1998a; Kim 2016; Kuloglu 2008; Ladas 2002a; Lahner 2004; Lee 1998; Lombardo 2003; Lottspeich 2007; Mana 2001a; Mansour-Ghanaei 2011; Monteiro 2001a; Ogata 2001; Ozturk 2003; Peitz 2001; Peura 1996; Puspok 1999; Qadeer 2009; Rafeey 2007; Rasool 2007; Schilling 2001; Segamwenge 2014; Selcukcan 2011; Sharbatdaran 2013; Shin 2009; Tiwari 2014; Trevisani 2005; Vandenplas 1992; Villalobos 1992; Wang 2008; Weiss 1994; Yan 2003; Yoshimura 2001; Yu 1999; Yu 2001). It was not clear whether such participants were included or excluded in the remaining 48 studies.

Thirty-two studies used H & E stain as a reference standard (Aguilar 2007; Al-Fadda 2000; Arian 2004; Atli 2012; Behrens 1999; Ceken 2011; Chen 1991; Chey 1998; Czerwionka-Szaflarska 2007; D'Elis 2000; Dinler 1999; Eggers 1990; El-Nasr 2003; Fallone 1996; Faruqui 2007; Graham 1996a; Gramley 1999; Gurbuz 2005; Iqbal 2013; Jordaan 2008; Kalach 1998a; Kamel 2011; Lee 1998; Logan 1991a; Noguera 1998; Puspok 1999; Segamwenge 2014; Selcukcan 2011; Sheu 1998a; Sheu 1998b; Tiwari 2014; Yu 2001); 24 studies used special stains such as Warthin-Starry stain, Giemsa stain, or silver stain (Argentieri 2007; Bosso 2000; El-Din 2013; Fallone 1995; Guo 2011; Hafeez 2007; Han 2012; Ivanova 2010; Kim 2016; Ladas 2002a; Lahner 2004; Mion 1994; Mohammadian 2007; Morales 1995; Novis 1991; Ozturk 2003; Peura 1996; Qadeer 2009; Schilling 2001; Scuderi 2000; Shin 2009; Soomro 2012; Villalobos 1992; Yan 2003); two studies used immunohistochemical staining (Ekesbo 2006; Misawa 1998); and the remaining 43 studies used a combination of different stains.

The interval between the index test and reference standard was reported only in 21 studies. The interval was less than two weeks in 19 of the 21 studies (Adamopoulos 2009a; Adamopoulos 2009b; Bosso 2000; Debongnie 1991; Duan 1999; Fallone 1995; Fallone 1996; Formichella 2013; Gurbuz 2005; Hafeez 2007; Lahner 2004; Lee 1998; Logan 1991a; Lottspeich 2007; Mansour-Ghanaei 2011; Mion 1994; Ozturk 2003; Peura 1996; Safe 1993), and was between 15 days and 23 days in one study (Dede 2015); it was within 30 days in the remaining study (Lombardo 2003).

Characteristics of excluded studies

We excluded 1726 references (1725 studies). The reason for exclusion is stated for each study in Appendix 7 and summarised below.

- Case-control study: 17
- Not a primary research study: 147
- Erratum: 3
- Inappropriate population: 79
 - In monitoring: 33
 - Not in humans: 1
 - Only in *H pylori* negative people: 2
 - Only in *H pylori* positive people: 39

- Only in people with gastrointestinal bleeding: 2
- Selection of participants was based on the results of other *H pylori* tests: 1

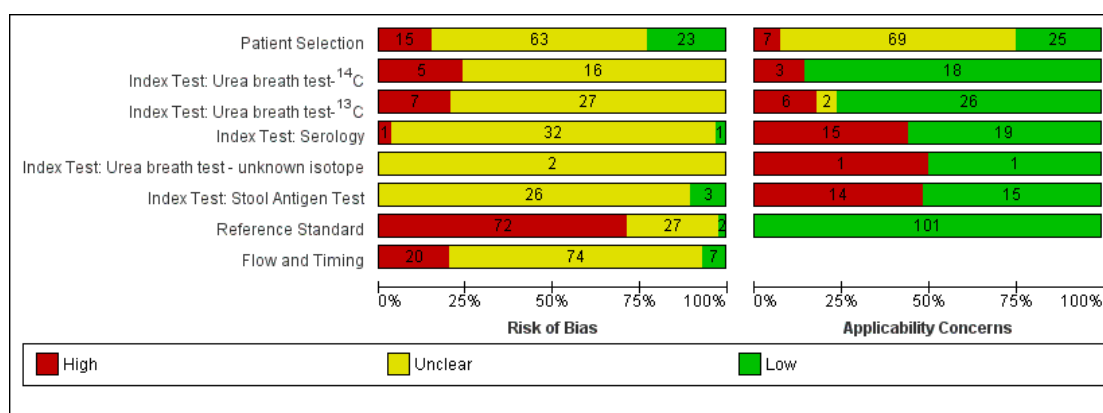
Includes people who were being monitored for *H pylori* status: 1

- Inappropriate index test: 38
- Inappropriate target condition: 4
- Inappropriate reference standards: 1182
- Lack of data: 256
 - Insufficient diagnostic test accuracy data: 25
 - No diagnostic accuracy data: 42
 - Not a diagnostic test accuracy study of non-invasive *H pylori* diagnosis: 188
 - Incorrect data (correct information could not be obtained): 1

Methodological quality of included studies

The methodological quality of the included studies is summarised across all studies in Figure 3. None of the included studies was of high methodological quality (i.e. low risk of bias in all the domains). Appendix 8 shows the results for individual studies for urea breath test-¹³C, urea breath test-¹⁴C, serology and the stool antigen test, respectively.

Figure 3. Risk of bias and applicability concerns graph: review authors' judgements about each domain presented as percentages across included studies. For each domain, the numbers shown on the bar represent the number of studies that were scored as high, unclear or low in terms of risk of bias or applicability concern.



Patient selection domain

In the patient selection domain, 23, 15 and 63 studies were at low, high and unclear risk of bias, respectively. All 15 studies were at high risk of bias because they did not include a consecutive or

random series of participants.

Twenty-five, seven and 69 studies were of low, high and unclear applicability concern. In the 69 studies of unclear applicability concern it was not clear whether participants similar to those seen

in the clinical setting where the test is used were excluded, while the seven studies of high concern clearly excluded such participants. In these seven studies, only people who had undergone gastrectomy or those with atrophic gastritis were included.

Index test domain

In the index test domain, studies generally had an unclear risk of bias because it was unclear whether the index test results were interpreted without the knowledge of the results of the reference standard, and/or it was unclear whether a threshold was prespecified.

Urea breath test

None of the studies that evaluated the urea breath test (^{13}C , ^{14}C , or unknown isotope) were at low risk of bias. The risk of bias was unclear in the two studies that did not report the type of isotope (Han 2012; Lombardo 2003). Of the 34 studies that evaluated urea breath test- ^{13}C , seven (21%) had a high risk of bias while 27 (79%) had unclear risk of bias. There were 21 studies of urea breath test- ^{14}C , 16 (76%) of which had unclear risk of bias while five (24%) had high risk of bias.

For the two studies with unknown isotope, applicability concern was high in one study and low in the other. Of the 34 urea breath test- ^{13}C studies, applicability concerns were unclear for two (6%) studies, high for six (18%) studies and low for 26 (76%) studies. For urea breath test- ^{14}C , applicability concerns were generally low (18/21; 86%) with only three studies having high applicability concerns (Selcukkan 2011; Surveyor 1989; Yu 1999).

Serology

One study (Ladas 2002a), had a low risk of bias, and another study (Rathbone 1986), had a high risk of bias. The risk of bias for the remaining 32 (94%) studies was unclear. Applicability concerns were low in 19 (56%) studies and high in 15 (44%) studies.

Stool antigen test

None of the 29 studies had a high risk of bias. Most of the studies (26/29; 90%) had an unclear risk of bias; three studies (Islam 2005; Kuloglu 2008; Sharbatdaran 2013), had a low risk of bias. All the studies were of low applicability concern.

Reference standard domain

Two studies were at low risk of bias in the reference standard domain (Fallone 1995; Ladas 2002a). For 27 studies, the risk of bias was unclear because it was not clear whether reference standard results were interpreted without knowledge of the results of the index tests. The remaining 72 studies were at high risk of bias because the reference standard was endoscopic biopsy with H & E stain in some or all participants.

All the studies were of low applicability concern.

Flow and timing domain

Seven studies were at low risk of bias in the flow and timing domain. The risk of bias was unclear for 74 studies because the interval between the index test and reference standard was unclear or it was unclear whether all participants were included in the analysis. The remaining 20 studies were at high risk of bias because some participants were clearly excluded from the analysis. These studies did not report the reference standard results for the excluded participants. None of the studies reported indeterminate results (i.e. there were no indeterminate index test results in studies which provided a clear participant flow and none of the exclusions were due to indeterminate index test results).

Findings

Urea breath test- ^{13}C

The 34 studies of urea breath test- ^{13}C included 3139 participants, of whom 1526 had *H pylori* infection (Figure 4). The threshold used in six studies was either unknown (Eggers 1990; Monteiro 2001a), or unclear (Sheu 1998a; Sheu 1998b; Vandenplas 1992; Wardi 2012). At the most commonly reported threshold of delta over baseline > 4% (30 minutes after administration of urea), the summary sensitivity (95% confidence interval (CI)) and specificity (95% CI) from 10 studies (958 participants) were 0.95 (95% CI 0.79 to 0.99) and 0.95 (95% CI 0.87 to 0.98). Other thresholds were used by a limited number of studies (Figure 5; Appendix 9). When possible we performed meta-analysis to estimate summary sensitivities and specificities at these common thresholds. The results are presented in Table 1.

Figure 4. Forest plot of urea breath test-I3C.FN = false negative; FP = false positive; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. For threshold, the number of minutes in brackets is the time after administration of urea.

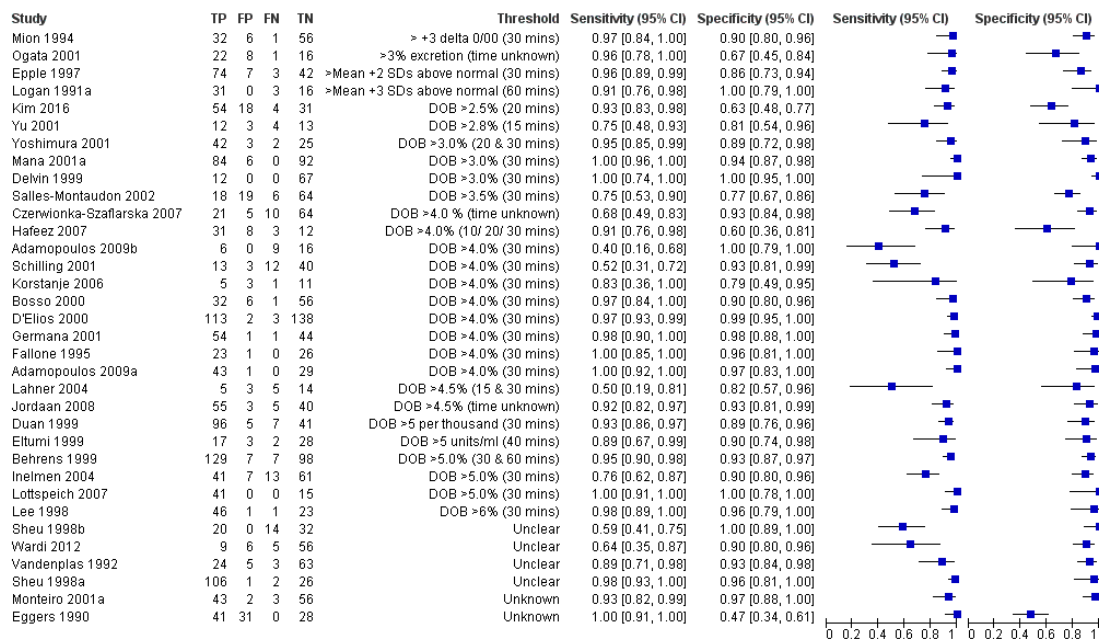
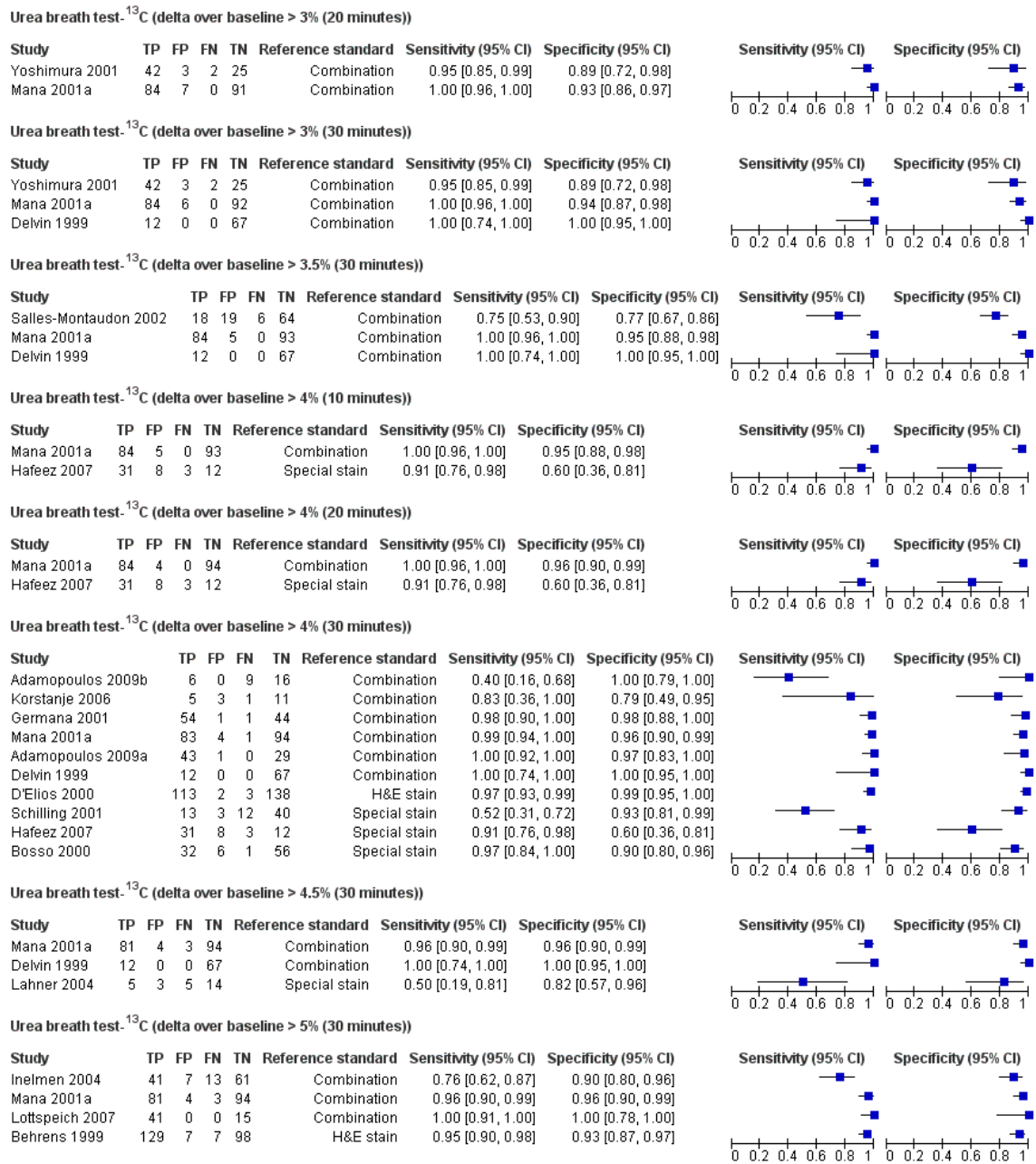


Figure 5. Forest plot of urea breath test-¹³C at commonly reported thresholds. FN = false negative; FP = false positive; TN = true negative; TP = true positive. Thresholds are shown in brackets and the number of minutes in brackets is the time after administration of urea.

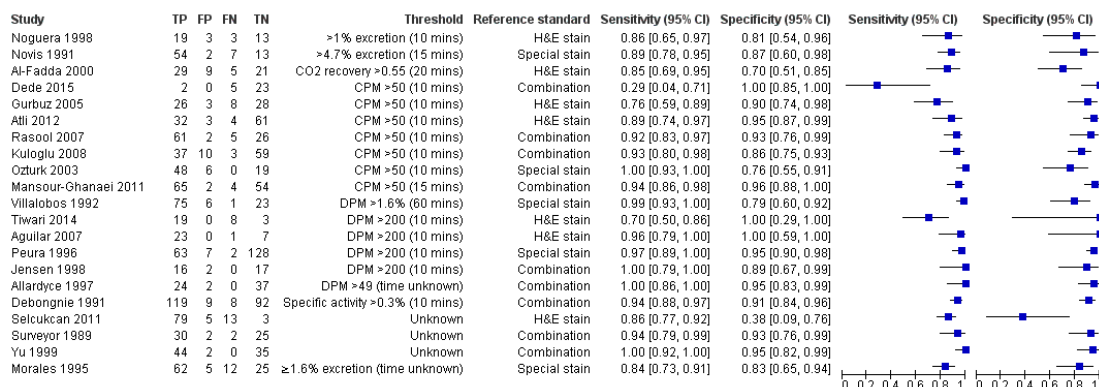


Urea breath test-¹⁴C

Figure 6 shows the 21 studies of urea breath test-¹⁴C. The studies included 1810 participants (involving 1018 *H pylori* cases). Three studies did not state the thresholds used (Selcukcan 2011; Surveyor 1989; Yu 1999). The two most commonly used thresholds were counts per minute > 50 (10 minutes after administration of urea) in six studies (471 participants) and disintegrations per minute

> 200 (10 minutes) in four studies (296 participants) (Table 1). Test accuracy results for other thresholds are shown in Appendix 9. The summary sensitivity (95% CI) and specificity (95% CI) at the counts per minute > 50 threshold were 0.89 (95% CI 0.55 to 0.98) and 0.91 (95% CI 0.79 to 0.96). For the disintegrations per minute > 200 threshold, the summary sensitivity (95% CI) and specificity (95% CI) were 0.95 (95% CI 0.33 to 1.00) and 0.95 (95% CI 0.80 to 0.99).

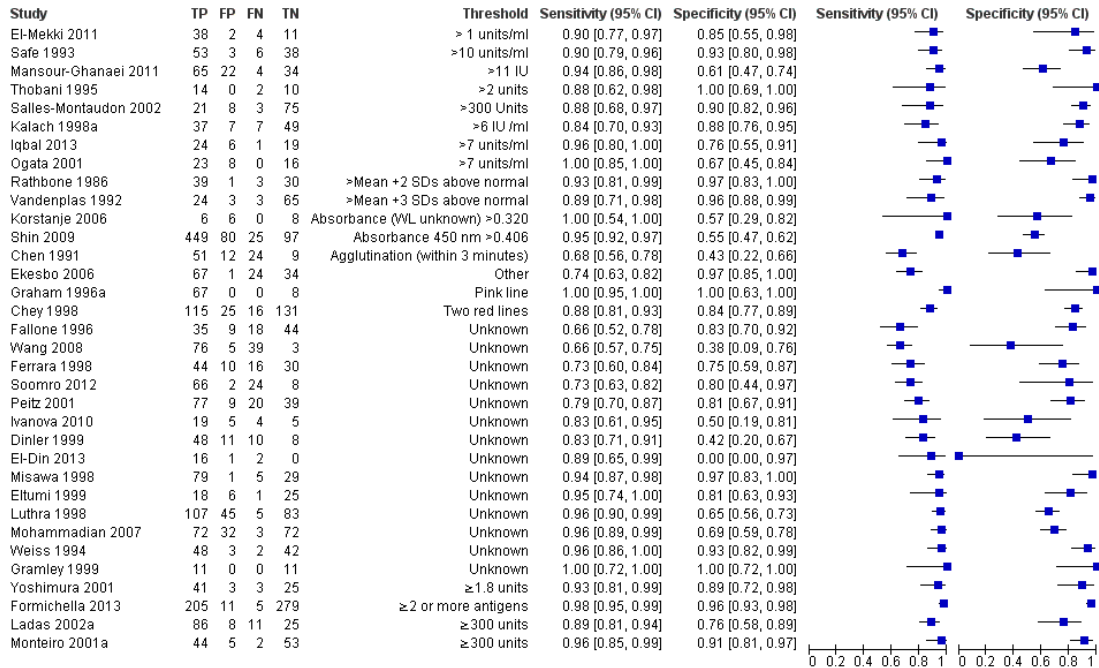
Figure 6. Forest plot of urea breath test-¹⁴C. FN = false negative; FP = false positive; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. For threshold, the number of minutes in brackets is the time after administration of urea.



Serology

Serology was evaluated in 34 studies with a total of 4242 participants, of whom 2477 had *H pylori* infection (Figure 7). There was considerable variation in the thresholds used but 14 (41%) studies did not state the thresholds used. A threshold of > 7 units/ml was used in two studies (Iqbal 2013; Ogata 2001), involving 97 participants, and two studies involving 234 participants (Ladas 2002a; Monteiro 2001a) used a threshold of ≥ 300 units (Table 1). The summary sensitivity (95% CI) and specificity (95% CI) at the > 7 units/mL threshold were 0.98 (95% CI 0.74 to 1.00) and 0.71 (95% CI 0.51 to 0.86), and 0.91 (95% CI 0.82 to 0.96) and 0.86 (95% CI 0.72 to 0.93) for the ≥ 300 units threshold.

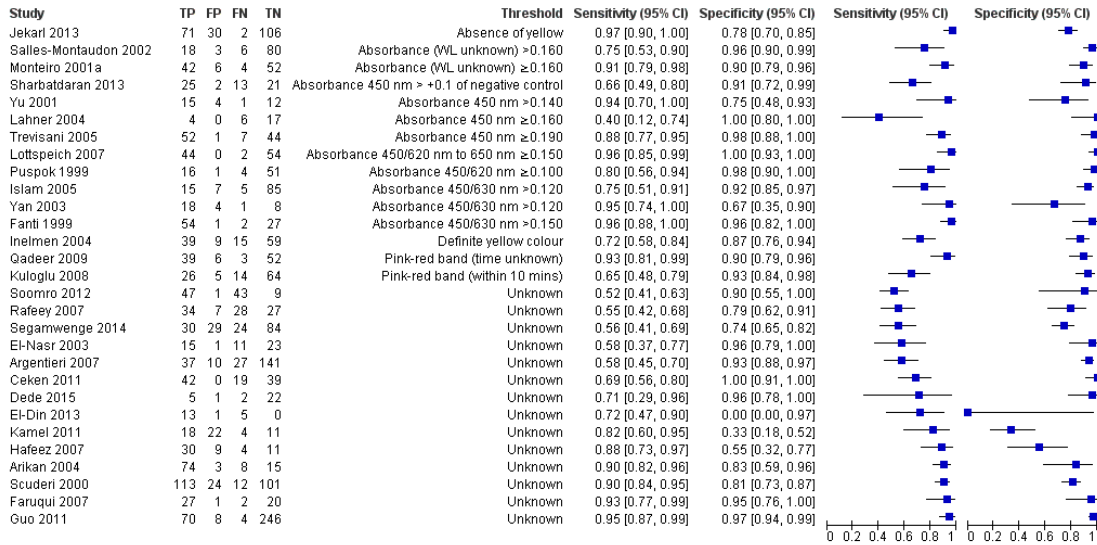
Figure 7. Forest plot of serology. FN = false negative; FP = false positive; SD = standard deviation; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. Other threshold is staining of a 120kDa protein (CagA) gel band and/or at least two of five proteins between 28-33 kDa.



Stool antigen test

Twenty-nine studies assessed the stool antigen test in 2988 participants (including 1311 *H pylori* cases) (Figure 8). The threshold used was unknown in almost half of the studies (14/29, 48%). None of the thresholds reported were used by more than one study. Summary estimates of sensitivity and specificity were therefore not obtained at a common threshold.

Figure 8. Forest plot of stool antigen test. FN = false negative; FP = false positive; TN = true negative; TP = true positive; WL = wavelength. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity.



Comparative accuracy of non-invasive tests for *H pylori* infection

Comparison based on all studies (Indirect test comparison)

Across the four tests (urea breath test-¹³C, urea breath test-¹⁴C, serology and stool antigen test) 99 studies (5694 cases; 10799 participants) were included in this comparative meta-analysis (Figure 9). Preliminary assessment of each test separately indicated there was no significant association between test accuracy and threshold, and so a symmetric SROC curve is plausible for each test. Based on these preliminary assessments, and likelihood ratio tests comparing different HSROC meta-regression models with covariate

terms for test type and examination of the variance parameters in these models, the final model we fitted allowed for differences in accuracy and threshold as random effects (i.e. unequal variances for the random effects) with symmetric SROC curves for the tests. Overall, there was statistical evidence of a difference in accuracy ($P = 0.024$). The DORs (95% CI) for urea breath test-¹³C, urea breath test-¹⁴C, serology and stool antigen test were 153 (95% CI 73.7 to 316), 105 (95% CI 74.0 to 150), 47.4 (95% CI 25.5 to 88.1) and 45.1 (95% CI 24.2 to 84.1) respectively (Table 2). The accuracy of urea breath tests (¹³C and ¹⁴C) was significantly higher than that of serology and stool antigen test. For example, the ratio of DORs (95%) for urea breath test-¹³C compared to serology was 3.22 (95% CI 1.24 to 8.37), $P = 0.017$.

Figure 9. Summary ROC plot of non-invasive tests for H pylori infection. The SROC curves for the four tests are parallel. The curve for each test is drawn within the range of estimates of specificity from the studies included for the test.

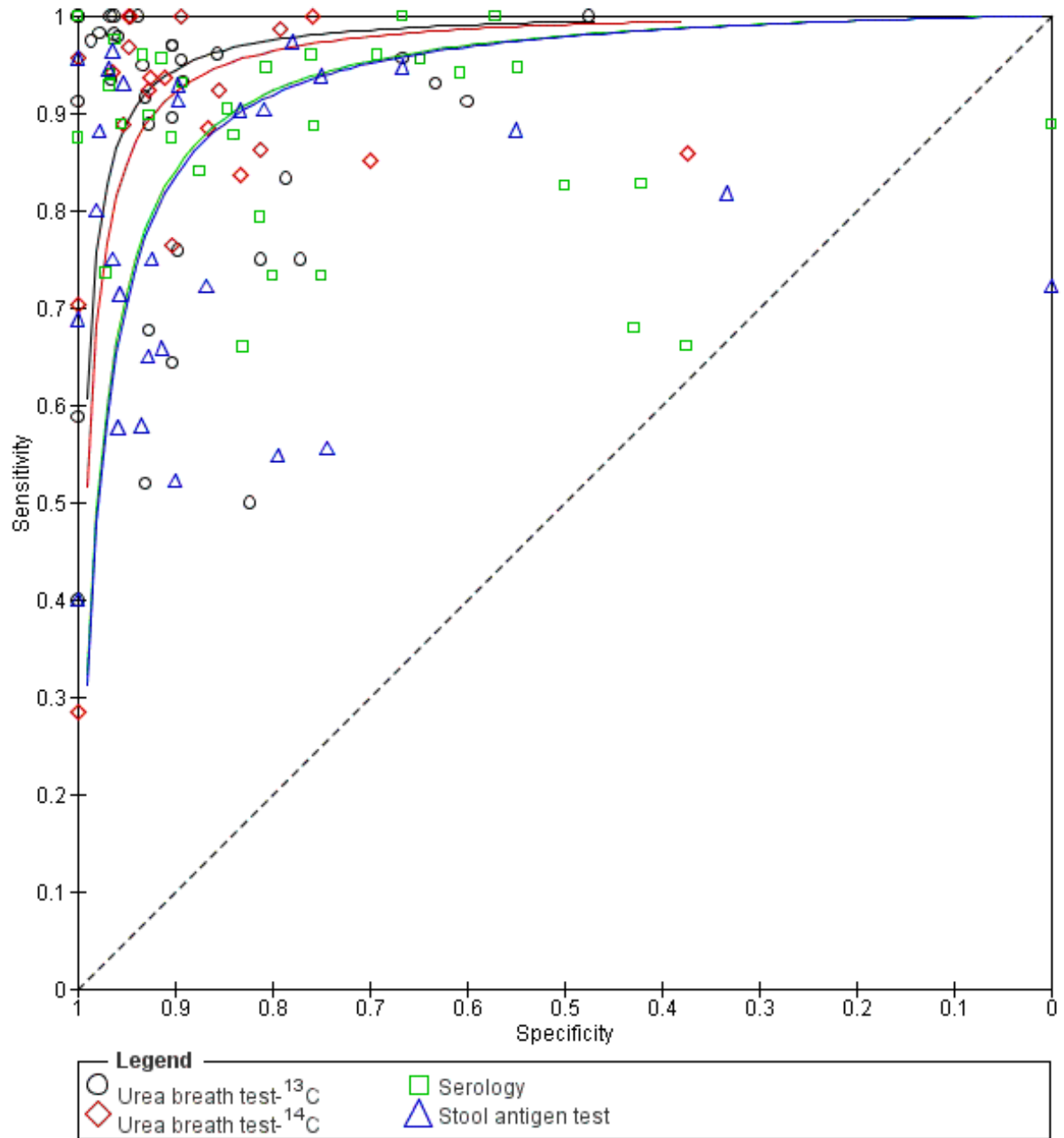


Table 3 shows the clinical implications of using each of the four tests in a hypothetical cohort of 1000 people with different levels of prevalence of *H pylori* infection. For example, given a prevalence of 53.7% and a specificity of 0.90, 46 people who do not have *H pylori* infection will be treated and urea breath test-¹³C, urea breath test-¹⁴C, serology and stool antigen test will miss 30, 42, 86 and 89 people respectively who have *H pylori* infection.

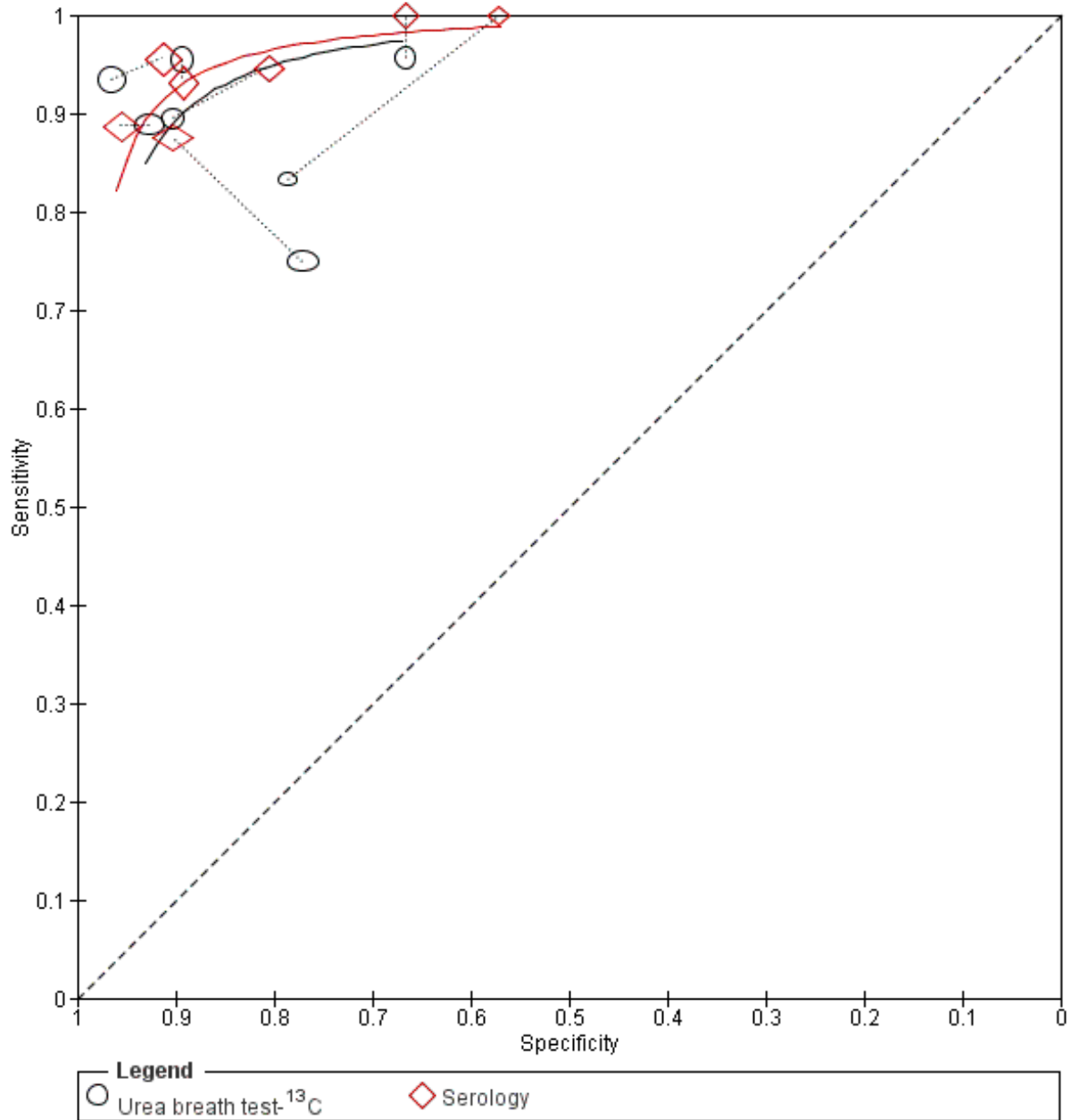
Direct comparisons (restricted to comparative studies)

Direct comparisons were based on few studies. Table 4 shows the

number of studies (*N*) for each pairwise comparison and, where meta-analysis was possible, the ratio of DORs with 95% CIs and P value. There were no comparative studies of urea breath test-¹³C and urea breath test-¹⁴C. All other comparisons were based on seven or fewer studies. Each pair of tests were evaluated as follows:

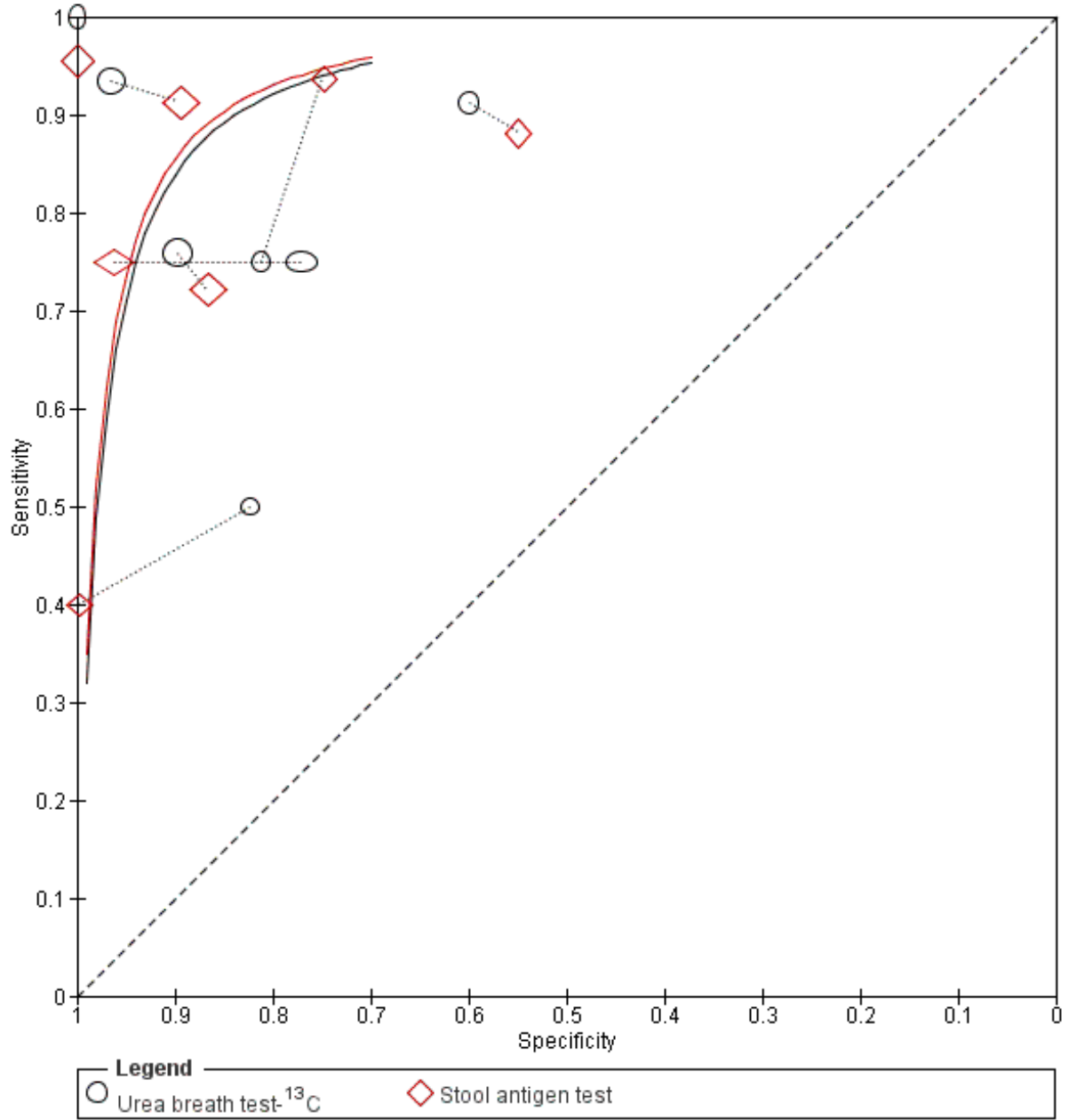
- Urea breath test-¹³C versus serology (Figure 10): seven studies (Eltumi 1999; Korstanje 2006; Monteiro 2001a; Ogata 2001; Salles-Montaudon 2002; Vandenplas 1992; Yoshimura 2001).

Figure 10. Summary ROC plot of direct comparisons of urea breath test-13C and serology. Each summary curve was drawn restricted to the range of specificities for each test. The size of each symbol was scaled according to the precision of sensitivity and specificity in the study. A dotted line joins the pair of points for the two tests from each study.



- Urea breath test-¹³C versus stool antigen test (Figure 11): seven studies (Hafeez 2007; Inelmen 2004; Lahner 2004; Lottspeich 2007; Monteiro 2001a; Salles-Montaudon 2002; Yu 2001).

Figure 11. Summary ROC plot of direct comparisons of urea breath test-¹³C and stool antigen test. Each summary curve was drawn restricted to the range of specificities for each test. The size of each symbol was scaled according to the precision of sensitivity and specificity in the study. A dotted line joins the pair of points for the two tests from each study.



- Urea breath test-¹⁴C versus serology: two studies (Dede 2015; Kuloglu 2008).
- Urea breath test-¹⁴C versus serology: one study (Mansour-Ghanaei 2011).
- Serology versus stool antigen test: four studies (El-Din 2013; Monteiro 2001a; Salles-Montaudon 2002; Soomro 2012).

The ratios of DORs (95% CI; P value) were 0.68 (95% CI 0.12 to 3.70; P = 0.56) for urea breath test-¹³C versus serology, and 0.88 (95% CI 0.14 to 5.56; P = 0.84) for urea breath test-¹³C versus stool antigen test. Due to paucity of data and substantial heterogeneity observed in ROC space which precluded the use of simpler meta-analytic models, meta-analyses were not possible for the other two test comparisons that had more than one study. For the single study of urea breath test-¹⁴C versus serology (Mansour-Ghanaei 2011), both tests had similar sensitivity, but specificity was higher for urea breath test-¹⁴C than for serology.

Investigation of heterogeneity

We were unable to investigate subtype of tests because most of the serological tests were ELISA (17/20 (85%) studies that provided the type of serology test) and most studies (24/29 (83%) studies)

did not report whether monoclonal or polyclonal antibodies were used for stool antigen tests. Studies did not report the precise interval between index test and reference standard (unless they were performed on the same day), i.e. many studies did not report the interval at all, while some reported that the tests were performed within a few days of each other without stating the exact time interval. Of those that reported the interval, only two studies had an interval of more than two weeks (Dede 2015; Lombardo 2003). For each of the four tests, Appendix 10 shows the number of studies in each subgroup of other factors we had planned to investigate. Given the availability of data, we were only able to perform meta-regression to investigate the effect of reference standard on the accuracy of each test. Of the 99 studies, 42 (42%) used a combination of stains and there were few data for Immunohistochemical stains (2/99; 2%). The analyses were therefore limited to comparisons of H & E stain versus special stain for each test (Appendix 11). Although the effect of reference standard was not consistent across tests, there was no statistical evidence of a difference in test accuracy for any of the tests. For urea breath test-¹⁴C, the DOR for special stain was higher than for H & E stain, while for the other tests the DOR of both types of stain were similar or higher for H & E (Appendix 11).

Summary of findings

What is the best non-invasive test for diagnosis of <i>H pylori</i> infection?				
Population	Children and adults with gastrointestinal symptoms			
Setting	Primary care setting			
Index tests	Urea breath test- ¹³ C, Urea breath test- ¹⁴ C, serology, and stool antigen test			
Threshold	Various thresholds were used for each test			
Role and purpose of test	Screening and diagnosis of <i>H pylori</i>			
Reference standard	Endoscopic biopsy with Haematoxylin & Eosin stain, special stains, or combination of Haematoxylin & Eosin and special stains			
Quality of evidence	Risk of bias was generally high or unclear with respect to the selection of participants, and the conduct and interpretation of the index tests and reference standard. Applicability concerns were also generally high or unclear with respect to selection of participants			
Limitations	There was heterogeneity in thresholds and reference standards. Studies did not often prespecify or clearly report thresholds used			
Pre-test probability (prevalence of <i>Helicobacter pylori</i>)	Median (interquartile range) = 53.7% (42.0% to 66.5%)			
Index test	Number of participants (studies)	Diagnostic odds ratio (95% CI)	Sensitivity (95% CI) at fixed specificity of 0.90¹	Missed <i>H pylori</i> cases per 1000 people tested (95% CI)²
Urea breath test- ¹³ C	3139 participants (34 studies)	153 (95% CI 73.7 to 316)	0.94 (0.89 to 0.97)	30 (15 to 58)
Urea breath test- ¹⁴ C	1810 participants (21 studies)	105 (95% CI 74.0 to 150)	0.92 (0.89 to 0.94)	42 (30 to 58)
Serology	4242 participants (34 studies)	47.4 (95% CI 25.5 to 88.1)	0.84 (0.74 to 0.91)	86 (50 to 140)

Stool antigen test	2988 participants (29 studies)	45.1 (95% CI 24.2 to 84.1)	0.83 (0.73 to 0.90)	89 (52 to 146)
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Comparison of non-invasive tests for *H pylori* infection

Based on an indirect comparison of the four tests using all the studies, there was statistical evidence of a difference in diagnostic accuracy ($P = 0.024$). Direct comparisons were based on few head-to-head studies. The ratios of diagnostic odds ratios (95% CI; P value) were 0.68 (95% CI 0.12 to 3.70; $P = 0.56$) for urea breath test- ^{13}C versus serology (seven studies), and 0.88 (95% CI 0.14 to 5.56; $P = 0.84$) for urea breath test- ^{13}C versus stool antigen test (seven studies). The 95% confidence intervals of these estimates overlap with those of the ratios of diagnostic odds ratios from the indirect comparison. Data were limited or unavailable for meta-analysis of other direct comparisons

Conclusions

In people with no history of gastrectomy and those who have not recently had antibiotics or proton pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests had lower accuracy to detect *H pylori* infection. Although susceptible to bias due to confounding, this conclusion is based on evidence from indirect test comparisons as evidence from direct comparisons was based on few studies or was unavailable. It should be noted that studies were generally of poor methodological quality. The thresholds used for the tests were highly variable and there is currently insufficient evidence to recommend specific thresholds for use in clinical practice

¹The sensitivities were estimated along the SROC curves at the median specificity across the studies included for the four tests.

²Based on the sensitivity estimated at the median specificity of 0.90, and the median prevalence of 53.7% from the included studies, the numbers of missed *H pylori* cases were calculated using a hypothetical cohort of 1000 people suspected of having *H pylori* infection. The 95% CI for the number of missed cases is from the 95% CI for sensitivity. For a specificity of 0.90 and prevalence of 53.7%, there will be 46 false positives. See [Table 3](#) for results for other values of specificity and prevalence.

DISCUSSION

Summary of main results

We included 101 studies (11,003 participants) that evaluated the diagnostic accuracy of different non-invasive methods for the diagnosis of *H pylori*. Of these 11,003 participants, 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection ranged from 15.2% to 94.7%. The median prevalence was 53.7% (lower quartile: 42.0% and upper quartile: 66.5%).

The summary of results for urea breath test-¹³C, urea breath test-¹⁴C, serology and stool antigen test is given in [Summary of findings](#). The studies used different thresholds and reference standards. As a result, there were few data for pooling sensitivities and specificities at specific thresholds, and we mainly estimated and compared SROC curves. The test comparison based on all available data (99 studies) for the four tests showed a statistically significant difference in diagnostic accuracy between the test ($P = 0.024$). There was no statistical evidence of a difference in diagnostic accuracy between urea breath test-¹³C and urea breath test-¹⁴C, while serology and stool antigen test were inferior to both urea breath tests. Direct comparisons are more reliable than indirect comparisons, due to the potential for confounding in indirect comparisons ([Takwoingi 2013](#)). However, we found few head-to-head studies and meta-analysis was possible for only two pairwise comparisons (urea breath test-¹³C versus serology, seven studies; and urea breath test-¹³C versus stool antigen test, seven studies). Most of the tests that used visual assessment (for example, appearance of a pink-red line) were stool antigen tests, although some serology tests also used visual assessment. Some serology and stool antigen tests are therefore easy to use (stool antigen test is easier to use as described below), but low diagnostic accuracy is a disadvantage when compared to urea breath tests. Urea breath test is a cumbersome test and involves the use of radioisotopes; however, urea breath test-¹³C may be the most accurate test among the non-invasive tests. This has implications in the screening of individuals for *H pylori* as a decision has to be made regarding the use of a cumbersome and relatively costly test but with good diagnostic accuracy versus cheap tests that can be performed easily but with lower diagnostic accuracy. A further decision to make if one opts for easy-to-use tests is the threshold at which the test should be used. For example, one can use a threshold that provides higher sensitivity (at the cost of lower specificity, necessitating endoscopic biopsy confirmation or treatment) or a threshold that provides higher specificity (at the cost of lower sensitivity, resulting in people with *H pylori* not being treated). Although at first sight it appears that the treatment for *H pylori* is relatively harmless and one would prefer a threshold at which the test has higher sensitivity rather than higher specificity, the decision to give antibiotics is not a straightforward one, because of the association

between unnecessary antibiotic use and development of antimicrobial resistance ([Llor 2014](#)). Serology and stool antigen test have similar diagnostic test accuracy and the choice between the two may be made based on ease of carrying out the tests. Only one study included in this review used whole blood for performing serology ([Chey 1998](#)). Even this test required a laboratory technician to interpret the test result ([Chey 1998](#)). So, there are no bedside tests available for serology testing. On the other hand, bedside kits with easy interpretation by colour changes are available for stool antigen tests, making them easy to administer ([Inelmen 2004](#); [Jekarl 2013](#); [Kuloglu 2008](#); [Qadeer 2009](#); [Trevisani 2005](#)). A cost-effectiveness study may clarify the most cost-effective non-invasive test in people with suspected *H pylori*, but it is difficult to factor in the price of antimicrobial resistance to an individual as the price of antimicrobial resistance is paid by future generations (through increased mortality and decreased productivity), rather than the individual for whom the treatment decision has to be made ([Taylor 2014](#)).

Strengths and weaknesses of the review

We conducted a thorough literature search and included full-text publications and abstracts without any language restrictions. There are currently no reliable search strategies to identify diagnostic test accuracy studies ([Beynon 2013](#)). We did not use any diagnostic filter in our search strategy, thereby ensuring that studies on the topic were identified. Two review authors independently identified and extracted data from the studies, potentially decreasing errors related to single data extraction. PCR methodology is not standardised across laboratories and it is an unreliable reference standard ([Chey 2007](#)). Endoscopic biopsy followed by rapid urease testing has poor sensitivity following treatment with proton pump inhibitors, and endoscopic biopsy with culture has high specificity but poor sensitivity ([Chey 2007](#)). We used a strict reference standard (histology) which is likely to diagnose the target condition with a high degree of accuracy. These are the major strengths of the review.

A major limitation was the diversity of thresholds used in the studies. As a result, data were sparse for each threshold, which limited estimation of summary sensitivities and specificities. Therefore there is insufficient evidence to recommend specific thresholds for each of the tests. Nonetheless, we were able to estimate and compare SROC curves by including studies with different thresholds. There was a high proportion of studies at high risk of bias and with high concern regarding applicability in all the four domains of the QUADAS-2 tool. This makes the validity and applicability of the results questionable. The major concerns were lack of reporting of the threshold used or when the thresholds were reported, there was no information to judge whether the thresholds were prespecified. Despite the lack of statistical evidence of an effect of type of reference standard on test accuracy, as there were few studies for each subgroup and other differences between studies, we cannot

conclude that diagnostic accuracy does not depend on type of reference standard.

Comparison with other systematic reviews

We identified several relevant systematic reviews (Ferwana 2015; Gisbert 2001; Gisbert 2004a; Loy 1996; Zhou 2014; Zhou 2017). The findings from this review support those of Zhou 2017, and Ferwana 2015, that urea breath test has high diagnostic accuracy and that there was significant heterogeneity in the diagnostic accuracy of the urea breath test (Zhou 2017). Our findings agree with those of Zhou 2014 that stool antigen test has only modest diagnostic test accuracy. The review findings are contrary to those of Gisbert 2001, and Gisbert 2004a, which suggested that stool antigen tests are highly accurate. This difference may be due to the strict reference standards that we used in this review and how we handled the issue of heterogeneity in thresholds. In agreement with the findings of Loy 1996, the role of serology in clinical practice is uncertain, as stool antigen tests provide equivalent diagnostic accuracy to serology and are easier to interpret.

Applicability of findings to the review question

This review included adults and children who underwent non-invasive tests for the diagnosis of *H pylori*. Most of the studies included only symptomatic people and so the findings of this review are applicable only to people with symptoms. Most studies excluded people who had previous gastrectomy and those who had recent antibiotics or proton pump inhibitors. Hence, the findings of this review are not applicable in these populations.

AUTHORS' CONCLUSIONS

Implications for practice

In people with no history of gastrectomy and those who have not recently had antibiotics or proton pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests had lower accuracy to detect *H pylori* infection. Although susceptible to bias due to confounding, this conclusion is based on evidence from indirect test comparisons, as evidence from direct comparisons was based on few studies or was unavailable. There was high or unclear risk of bias for many studies with respect to the selection of participants, and the conduct and interpretation of the index tests and reference standard. The thresholds used for these tests were highly variable, thus there is insufficient evidence to identify specific thresholds that might be useful in clinical practice.

Implications for research

Further comparative studies of high methodological quality are necessary to obtain more reliable evidence of accuracy between the tests (urea breath tests, serology, and stool antigen tests) in people with upper gastrointestinal symptoms and people without any symptoms suggestive of *H pylori*. Such studies should be conducted prospectively in a representative spectrum of participants, and be clearly reported to ensure low risk of bias. Most importantly, studies should pre-specify and clearly report the thresholds used, should apply appropriate reference standards such as endoscopic biopsy with special stains, and should avoid inappropriate exclusions.

ACKNOWLEDGEMENTS

We thank the Cochrane Upper Gastrointestinal and Pancreatic Diseases (UGPD) Group, and the DTA editorial team for their advice in the preparation of this review. We thank the copy editors for improving the readability of the review.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Adamopoulos 2009a

Study characteristics			
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 73 Female: 24 (33%) Age: 63 years Presentation: 1. People who had undergone endoscopy (for various indications) Setting: secondary care, Greece		
Index tests	Index test: urea breath test - ¹³ C Further details: Technical specifications: manufacturer - Infai Institut für Biomedizinische; Analytik & NMR-Imaging GmbH, Bochum Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and histopathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		

Adamopoulos 2009a (Continued)

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Adamopoulos 2009b

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 31 Female: 8 (25.8%) Age: 71 years Presentation: 1. People who had undergone Billroth II gastrectomy and endoscopy (for various indications) Setting: secondary, Greece
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: manufacturer - Infai Institut für Biomedizinische; Analytik & NMR-Imaging GmbH, Bochum Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and histopathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High

Adamopoulos 2009b (Continued)

DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Aguilar 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 31 Female: 5 (16.1%)

Aguilar 2007 (Continued)

	Age: not stated Presentation: 1. Dyspepsia Setting: secondary care, Peru		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Aguilar 2007 (Continued)

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Al-Fadda 2000

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 64 Female: not stated Age: not stated Presentation: 1. Patients with upper gastrointestinal symptoms Setting: secondary care, Peru

Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: CO ² recovery > 0.55 (20 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Allardyce 1997

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 63 Female: 26 (41.3%) Age: not stated Presentation: 1. Dyspepsia Setting: secondary care, New Zealand
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: disintegrations per minute > 49 (time not stated)

Allardyce 1997 (Continued)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		

Allardyce 1997 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	No		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Argentieri 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 215 Female: not stated Age: not stated Presentation: 1. Children undergoing upper gastrointestinal endoscopy Exclusion: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA Performed by: Not stated Criteria for positive diagnosis: Not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist

Argentieri 2007 (Continued)

	Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Argentieri 2007 (Continued)

		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Arikan 2004

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion: 1. Malignancy 2. Taken antibiotics or proton pump inhibitors in last 2 weeks Setting: secondary care, Turkey
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA Performed by: Not stated Criteria for positive diagnosis: Not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			

Arikan 2004 (Continued)

Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Atli 2012

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 57 (57%) Age: 71 years Presentation: 1. Patients with dyspepsia and symptoms or signs related to peptic ulcer > 65 years of age Exclusion: 1. Patients who had taken antibiotics or anti-ulcer treatment in the past 2 weeks 2. Advanced dementia 3. Cerebrovascular disease 4. Advanced respiratory problems 5. Alarm symptoms for malignancy Setting: secondary setting, Turkey
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: counts per minute > 50 (10 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			

Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Behrens 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 252 Female: not stated Age: not stated Presentation: 1. Children (3 years to 18 years) with abdominal pain, nausea, or vomiting Exclusion criteria: 1. Previous treatment with antibiotics or proton pump inhibitors 2. WBC < 3500/microlitre or platelets < 100,000/microlitre Setting: secondary setting, Germany
Index tests	Index test: urea breath test - ¹³ C Further details: Technical specifications: Promochem, Wesel Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes and 60 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Behrens 1999 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Bosso 2000

Study characteristics			
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 95 Female: not stated Age: not stated Presentation: 1. Patients with upper abdominal symptoms Exclusion: 1. Patients with previous gastric surgery Setting: secondary care, France		
Index tests	Index test: urea breath test ⁻¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

		Unclear	
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Ceken 2011

Study characteristics

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 67 (67%) Age: 48 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Antibiotics or anti-ulcer treatment within last 4 weeks 2. Gastric surgery Setting: secondary care, France
Index tests	Index test: stool antigen test Further details: Technical specifications: Helicobacter Antigen Quick Caste Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Ceken 2011 (Continued)

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Chen 1991

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 96 Female: not stated Age: not stated Presentation: 1. Adult patients with dyspepsia Setting: secondary care, China		
Index tests	Index test: serology Further details: Technical specifications: Pyloriset Performed by: not stated Criteria for positive diagnosis: presence of agglutination (within 3 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low

Chen 1991 (Continued)

DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Chey 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process

Patient characteristics and setting	<p>Sample size: 287 Female: 140 (48.8%) Age: 53 years Presentation: 1. People undergoing endoscopy Exclusion: 1. Recent treatment for <i>H pylori</i> or anti-ulcer treatment Setting: Variable settings, USA</p>		
Index tests	<p>Index test 1a: serology Further details: Technical specifications: HM-CAP (Enteric Products Inc.) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology (serum) Further details: Technical specifications: Hp Chek (Chem Trak) Performed by: not stated Criteria for positive diagnosis: 2 red lines Index test 1c: serology (whole blood) Further details: same as for index test 2</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		

Chey 1998 (Continued)

Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Study characteristics			
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: 66 (66%) Age: 13 years Presentation: 1. Children with gastrointestinal disorders Setting: secondary care, Poland		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0 % (time not stated)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear

DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

D'Elcios 2000

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 256 Female: not stated

	Age: not stated Presentation: 1. Patients with dyspepsia Exclusion: 1. Gastric surgery 2. Recent treatment for ulcer or <i>H pylori</i> 3. Pulmonary failure Setting: secondary care, Italy		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: AB Analitica Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			

D'Elíos 2000 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Debonnie 1991

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded
Patient characteristics and setting	Sample size: 230 Female: not stated Age: not stated Presentation:

Debongnic 1991 (Continued)

	<p>1. Patients referred for upper gastrointestinal surgery Excluded: 1. Gastric surgery 2. Haematologic disease 3. Immunodeficiency 4. Gastric cancer 5. Recent treatment for ulcer or <i>H pylori</i> 6. Atrophic gastritis Setting: secondary care, Belgium</p>		
Index tests	<p>Index test: urea breath test-¹⁴C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: specific activity > 0.3% (10 minutes)</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Cresyl Violet stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 27 (11.7%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			

Debonnie 1991 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Dede 2015

Study characteristics

Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 30 Female: 8 (26.7%) Age: 55 years Presentation:

	1. Patients who had undergone partial gastrectomy Setting: secondary care, Turkey		
Index tests	<p>Index test 1: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated</p> <p>Index test 2: urea breath test-¹⁴C Further details: Technical specifications: Heliprobe System, Kibion AB Performed by: not stated</p> <p>Different criteria for positive diagnosis:</p> <ul style="list-style-type: none"> • Counts per minute > 23 (10 minutes) • Counts per minute > 29 (30 minutes) • Counts per minute > 35 (20 minutes) • Counts per minute > 50 (10 minutes) • Counts per minute > 50 (20 minutes) • Counts per minute > 50 (30 minutes) 		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and modified Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	No		
Did all patients receive the same reference standard?	Yes		

Were all patients included in the analysis?	Unclear		
		High	

Delvin 1999

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 79 Female: not stated Age: not stated Presentation: 1. Children with gastrointestinal symptoms Exclusion: 1. Children with functional abdominal pain 2. Anti-ulcer or <i>H pylori</i> treatment in last 6 weeks Setting: secondary care, Canada
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: Dia 13-Helico; Dianatec iso Performed by: not stated Different criteria for positive diagnosis: <ul style="list-style-type: none"> ● Delta over baseline > 2.0% (30 minutes) ● Delta over baseline > 2.5% (30 minutes) ● Delta over baseline > 3.0% (30 minutes) ● Delta over baseline > 3.5% (30 minutes) ● Delta over baseline > 4.0% (30 minutes) ● Delta over baseline > 4.5% (30 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Delvin 1999 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Dinler 1999

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 77 Female: 48 (62.3%) Age: 13 years Presentation: 1. Children with recurrent abdominal pain Setting: secondary care, Turkey		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Dinler 1999 (Continued)

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

Dinler 1999 (Continued)

		Unclear	
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Duan 1999

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 149 Female: 35 (23.5%) Age: 44 years Presentation: 1. Patients with gastritis or gastric ulcer Exclusion: 1. Treatment with antibiotics or bismuth in the previous 2 months 2. Previous gastric surgery or gastric cancer Setting: secondary care, China		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: Finniga, MAT-252, USA Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5 per thousand (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Duan 1999 (Continued)

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Eggers 1990

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Setting: secondary care, Germany		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 8 (7.4%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear

DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ekeshbo 2006

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded

Patient characteristics and setting	Sample size: 126 Female: not stated Age: not stated Presentation: 1. Patients undergoing gastroscopy for dyspepsia or gastrointestinal bleeding Setting: primary care, Sweden		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: staining of a 120 kilodalton protein gel band and/or at least 2 of 5 proteins between 28 - 33 kilodaltons		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with immunostaining Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 40 (24.1%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Serology			

Eklesbo 2006 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

El-Din 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients without pathologic data excluded
Patient characteristics and setting	Sample size: 19 Female: 6 (31.6%) Age: 47 years Presentation:

	1. Patients with upper gastrointestinal disorders Setting: secondary care, Egypt		
Index tests	<p>Index test 1: serology Further details: Technical specifications: Ridascreen Performed by: not stated Criteria for positive diagnosis: not stated</p> <p>Index test 2: stool antigen test Further details: Technical specifications: Immunodiagnostik AG Performed by: not stated Criteria for positive diagnosis: not stated</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 33 (63.5%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Stool Antigen Test			

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

El-Mekki 2011

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 55 Female: 35 (63.6%) Age: 37 years Presentation: 1. Patients with dyspepsia Setting: secondary care, Saudi Arabia		
Index tests	Index test: serology Further details: Technical specifications: HeliSAL TM serum Performed by: not stated Criteria for positive diagnosis: > 1 units/ml		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low

DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

El-Nasr 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 16 (32%)

	Age: 36 years Presentation: 1. Patients with dyspepsia Setting: secondary care, Egypt		
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridien Diagnostics Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Eltumi 1999

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 17 (34%) Age: 11 years Presentation: 1. Children referred for endoscopy Exclusion: 1. Recent treatment for <i>H pylori</i> Setting: Tertiary care, UK

Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5 units/ml (40 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Epple 1997

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 126 Female: 70 (55.6%) Age: 48 years Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Gastric cancer 2. Previous gastric surgery Setting: secondary care, Germany		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 2 standard deviations above normal level (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

Epple 1997 (Continued)

		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Fallone 1995

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients

Fallone 1995 (Continued)

Patient characteristics and setting	Sample size: 50 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion 1. Conditions that would make gastric biopsy dangerous 2. Lactating 3. Pregnant or women of child-bearing potential who were not using adequate control Setting: secondary care, Canada		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 1.5% excretion (15 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Silver stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 4 (7.4%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			

Fallone 1995 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Fallone 1996

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 106 Female: 51 (48.1%) Age: 54 years Presentation:

Fallone 1996 (Continued)

	1. Patients undergoing endoscopy Exclusion: 1. Recent treatment for <i>H pylori</i> Setting: secondary care, Canada		
Index tests	Index test: serology Further details: Technical specifications: HeliSAL TM serum Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Fallone 1996 (Continued)

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Fanti 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 84 Female: 45 (53.6%) Age: 50 years Presentation: 1. Patients with dyspepsia 2. Not on current treatment for <i>H pylori</i> or ulcers Setting: secondary care, Italy

Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: Absorbance 450/630 nm > 0.150
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low

Fanti 1999 (Continued)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Faruqui 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 26 (52%) Age: 36 years Presentation: 1. Patients with dyspepsia despite anti-ulcer treatment Exclusion: 1. Myocardial infarction in the last 6 months 2. Cardiac failure 3. Bleeding diathesis Setting: secondary care, Pakistan
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated

Faruqui 2007 (Continued)

	Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			

Faruqui 2007 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ferrara 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 56 (56%) Age: not stated Presentation: 1. Patients with dyspepsia 2. Not on current treatment for <i>H pylori</i> Setting: secondary care, Italy
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated

Ferrara 1998 (Continued)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		

Ferrara 1998 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Formichella 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 500 Female: 263 (52.6%) Age: 50 years Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Undergone <i>H pylori</i> eradication therapy 2. Active immunosuppressive therapy 3. Suffering from malignant diseases Setting: secondary care, Germany
Index tests	Index test 1a: serology Further details: Technical specifications: recomWell ELISA (Mikrogen) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology Further details: Technical specifications: not stated Performed by: not stated

	Criteria for positive diagnosis: 2 or more antigens Index test 1c: serology Further details: Technical specifications: Immunoblot Helicobacter (Mikrogen) Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Germana 2001**Study characteristics**

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 52 (52%) Age: 51 years Presentation: 1. Patients with dyspepsia 2. Not on current treatment for <i>H pylori</i> Setting: secondary care, Italy
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: Wagner Analysen - Tecturik Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)

Germana 2001 (Continued)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and immunohistochemical stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		

Germana 2001 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Graham 1996a

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 75 Female: not stated Age: not stated Presentation: 1. Patients undergoing screening for <i>H pylori</i> and who underwent endoscopy Setting: secondary care, USA
Index tests	Index test: serology Further details: Technical specifications: FlexSure HP Performed by: not stated Criteria for positive diagnosis: pink line
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy

Graham 1996a (Continued)

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 476 (86.4%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low

Graham 1996a (Continued)

DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Gramley 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 22 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Setting: secondary care, USA
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Gramley 1999 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Guo 2011

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 328 Female: 90 (27.4%) Age: 47 years Presentation: 1. Patients with gastrointestinal symptoms 2. No previous treatment or stopped treatment for <i>H pylori</i> Setting: secondary care, China		
Index tests	Index test: stool antigen test Further details: Technical specifications: Kyowa pharmaceutical Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with silver stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Gurbuz 2005

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded		
Patient characteristics and setting	Sample size: 65 Female: 45 (69.2%) Age: not stated Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Undergone <i>H pylori</i> eradication therapy 2. Pregnancy or lactation 3. Prior gastric surgery Setting: secondary care, Turkey		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: Heliprobe system Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 3 (4.4%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		

Gurbuz 2005 (Continued)

Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with inadequate breath samples excluded		
Patient characteristics and setting	Sample size: 60 Female: not stated Age: not stated Presentation: 1. Children with gastrointestinal symptoms Setting: secondary care, Pakistan		
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (10 minutes, 20 minutes, and 30 minutes) Index test 2: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 6 (10%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		

Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		

Hafeez 2007 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Han 2012

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 99 Female: not stated Age: not stated Presentation: 1. Patients who had undergone urea breath tests and endoscopy Setting: secondary care, South Korea		
Index tests	Index test: urea breath test - unknown isotope Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test - unknown isotope			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Inelmen 2004

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 122 Female: 81 (66.4%) Age: 80 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, Italy		
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: BreathQuality-UBT 13C-Urea Kit, Zeta Farmaceutici SpA Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes) Index test 2: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: definite yellow colour		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Inelmen 2004 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Iqbal 2013

Study characteristics			
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 50 Female: 19 (38%) Age: 41 years Presentation: 1. Patients who underwent upper gastrointestinal endoscopy Setting: secondary care, Pakistan		
Index tests	Index test: serology Further details: Technical specifications: HpG screen ELISA kit Performed by: not stated Criteria for positive diagnosis: > 7 units/ml		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Islam 2005

Study characteristics			
Patient sampling	Type of study: prospective study Consecutive or random sample: neither - patients without stool samples excluded		
Patient characteristics and setting	Sample size: 112 Female: not stated Age: not stated Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, New Zealand		
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: pathologists Criteria for positive diagnosis: Absorbance 450/630 nm > 0.120		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Immunoperoxidase stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 15 (11.8%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear

DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ivanova 2010

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process

Patient characteristics and setting	Sample size: 33 Female: 16 (48.5%) Age: 42 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, Bulgaria		
Index tests	Index test: serology Further details: Technical specifications: Rapid HP, US Meds Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference stan-	Unclear		

Ivanova 2010 (Continued)

ard?			
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Jekarl 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with a recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 209 Female: 85 (40.7%) Age: not stated Presentation: 1. Patients undergoing routine health check-up and upper gastrointestinal endoscopy Exclusion: 1. Recent ulcer or <i>H pylori</i> treatment 2. Previous gastric surgery

	3. Previous gastric cancer Setting: secondary care, Korea		
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absence of yellow		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 57 (21.4%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		

Jekarl 2013 (Continued)

		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Jensen 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear
Patient characteristics and setting	Sample size: 35 Female: not stated Age: not stated Presentation: 1. Patients referred for endoscopy Exclusion: Recent <i>H pylori</i> treatment Setting: secondary care, USA
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated

	Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 7 (16.7%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			

Jensen 1998 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Jordaan 2008

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastrointestinal surgery excluded
Patient characteristics and setting	Sample size: 103 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent <i>H pylori</i> therapy 2. Major gastrointestinal surgery Setting: secondary care, South Africa
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.5% (time not stated)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 8 (7.2%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		

Jordaan 2008 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Kalach 1998a

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 35 (35%) Age: 11 years Presentation: 1. Children undergoing upper gastrointestinal endoscopy for recurrent epigastric pain or upper GI tract disorders Exclusion: 1. Recent <i>H pylori</i> treatment Setting: secondary care, France
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 6 IU /ml
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated

Kalach 1998a (Continued)

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		

Kalach 1998a (Continued)

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Kamel 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 55 Female: not stated Age: 67 years Presentation: 1. Older adults with dyspepsia and no gastrointestinal bleeding Setting: secondary care, Egypt
Index tests	Index test: stool antigen test Further details: Technical specifications: CerTest <i>H pylori</i> Card Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	

Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Kamel 2011 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Kim 2016

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 107 Female: 56 (52.3%) Age: 41 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Exclusion: 1. Recent <i>H pylori</i> treatment Setting: secondary care, South Korea		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: UbiT-IR300 apparatus Performed by: not stated Criteria for positive diagnosis: delta over baseline > 2.5% (20 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

		Unclear	
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Korstanje 2006

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 20 Female: 9 (45%) Age: 68 years Presentation: 1. Patients with atrophic gastritis Setting: primary care, Netherlands		
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: INFAL, Bochum, Germany Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not stated) > 0.320		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Korstanje 2006 (Continued)

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			

Korstanje 2006 (Continued)

Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Kuloglu 2008

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: neither - patients without a either a stool sample or a breath sample excluded
Patient characteristics and setting	Sample size: 109 Female: 58 (53.2%) Age: 12 years Presentation: 1. Children with symptoms suggestive of <i>H pylori</i> infection Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Turkey
Index tests	Index test 1: urea breath test- ¹⁴ C Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes) Index test 2: stool antigen test Further details: Technical specifications: Rapid HpSA test (Li NEAR Chemical) Performed by: not stated Criteria for positive diagnosis: pinkish red band (within 10 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy

Kuloglu 2008 (Continued)

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 16 (12.8%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			

Kuloglu 2008 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ladas 2002a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 130 Female: 48 (36.9%) Age: 50 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Recent <i>H pylori</i> therapy 2. Malignancy 3. Pregnancy 4. Gastric surgery Setting: secondary care, Greece
Index tests	Index test 1a: serology Further details: Technical specifications: Pyloriset EIA-G Performed by: not stated

Ladas 2002a (Continued)

	Criteria for positive diagnosis: ≥ 300 Index test 1b: serology Further details: Technical specifications: Milenia H Pylori IgG Performed by: not stated Criteria for positive diagnosis: ≥ 44		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	Low

Ladas 2002a (Continued)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Lahner 2004

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 27 Female: 19 (70.4%) Age: 52 years Presentation: 1. Patients with atrophic gastritis Exclusion criteria: 1. Gastric surgery 2. Gastric malignancy 3. Recent <i>H pylori</i> treatment 4. Diarrhoea 5. Constipation Setting: not stated

Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.5% (15 minutes and 30 minutes) Index test 2: stool antigen test Further details: Technical specifications: HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm ≥ 0.160		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Lee 1998

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 71 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy for duodenitis, gastritis, duodenal ulcer, gastric ulcer Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Singapore		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 6% (30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Logan 1991a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process

Logan 1991a (Continued)

Patient characteristics and setting	Sample size: 50 Female: 24 (48%) Age: 51 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> infection 2. Previous gastric surgery Setting: secondary care, UK
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 3 standard deviations above normal level (60 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			

Logan 1991a (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	No		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Lombardo 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - histology performed in a subset of patients
Patient characteristics and setting	Sample size: 28 Female: not stated Age: not stated Presentation:

Lombardo 2003 (Continued)

	1. Patients who had undergone gastrectomy Setting: secondary care, Italy		
Index tests	Index test: urea breath test - unknown isotope Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4 per ml (at 5-minute intervals up to 30 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 72 (72%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	High
DOMAIN 2: Index Test Urea breath test - unknown isotope			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Lombardo 2003 (Continued)

		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	No		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Lottspeich 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 56 for urea breath test, 100 for stool antigen test Female: not stated Age: 10 years Presentation: 1. Children with abdominal symptoms undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Germany
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated

Lottspeich 2007 (Continued)

	Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes) Index test 2: stool antigen test Further details: Technical specifications: IDEIA HpStAR assay (DakoCytomation) Performed by: not stated Criteria for positive diagnosis: Absorbance 450/620 nm to 650 nm \geq 0.150		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain or Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 44 (44%) for urea breath test; 0 (0%) for stool antigen test		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Lottspeich 2007 (Continued)

		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Luthra 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process

Patient characteristics and setting	Sample size: 240 Female: not stated Age: not stated Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Excluded: 1. People with upper GI bleeding 2. People with coagulation abnormalities Setting: not stated		
Index tests	Index test: serology Further details: Technical specifications: Pyloristat (BioWhittaker) Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain, immunostain, or Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			

Luthra 1998 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Mana 2001a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 182 Female: not stated Age: not stated Presentation:

	<p>1. Patients undergoing upper gastrointestinal endoscopy 2. People not taking <i>H pylori</i> medication Setting: secondary care, Belgium</p>		
Index tests	<p>Index test 1: urea breath test-¹³C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis:</p> <ul style="list-style-type: none"> ● Delta over baseline > 3.0% (10 minutes) ● Delta over baseline > 3.0% (20 minutes) ● Delta over baseline > 3.0% (30 minutes) ● Delta over baseline > 3.5% (10 minutes) ● Delta over baseline > 3.5% (20 minutes) ● Delta over baseline > 3.5% (30 minutes) ● Delta over baseline > 4.0% (10 minutes) ● Delta over baseline > 4.0% (20 minutes) ● Delta over baseline > 4.0% (30 minutes) ● Delta over baseline > 4.5% (10 minutes) ● Delta over baseline > 4.5% (20 minutes) ● Delta over baseline > 4.5% (30 minutes) ● Delta over baseline > 5.0% (10 minutes) ● Delta over baseline > 5.0% (20 minutes) ● Delta over baseline > 5.0% (30 minutes) 		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with immunohistochemistry and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		

Mana 2001a (Continued)

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 125 Female: 65 (52%) Age: 36 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Recent or past <i>H pylori</i> eradication 2. Pregnancy 3. Severe cardiopulmonary disorders or other life-threatening illnesses Setting: secondary care, Iran		
Index tests	Index test 1: urea breath test- ¹⁴ C Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (15 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 11 IU		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			

Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Mion 1994

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 95 Female: not stated Age: not stated Presentation: 1. Patients with upper abdominal symptoms Exclusion: 1. Patients with previous gastric surgery Setting: secondary care, France
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > + 3 delta 0/00 (30 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		

Mion 1994 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Misawa 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 114 Female: 46 (40.4%) Age: not stated Presentation: 1. Patients with gastritis, gastric, or duodenal ulcers Setting: secondary care, Japan
Index tests	Index test 1a: serology (IgA) Further details: Technical specifications: GAP-IgA (BioMerica) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology (IgG) Further details: Technical specifications: GAP-IgG (BioMerica) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with immunostaining (Carnoy's solution) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	
Methodological quality	

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Misawa 1998 (Continued)

Were all patients included in the analysis?	Unclear		
		Unclear	

Mohammadian 2007

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 179 Female: 108 (60.3%) Age: 54 years Presentation: 1. Patients undergoing endoscopy for gastrointestinal problems Setting: secondary care, Iran		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Monteiro 2001a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 104 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> therapy 2. Bleeding disorders or other conditions with contraindication for endoscopy or biopsy Setting: secondary care, France
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: ABCA, Europa Scientific Performed by: not stated Criteria for positive diagnosis: not stated Index test 2a: serology Further details: Technical specifications: Pyloriset EIA Kit (Orion Diagnostica) Performed by: not stated Criteria for positive diagnosis: > = 300 Index test 2b: serology Further details: Technical specifications: Helicoblot Immunoblot kit Performed by: not stated Criteria for positive diagnosis: not stated Index test 3: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not reported) > = 0.160
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Monteiro 2001a (Continued)

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Monteiro 2001a (Continued)

If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Morales 1995

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 104 Female: 52 (50%) Age: 50 years Presentation: 1. Patients with upper abdominal symptoms Setting: Outpatients, Mexico

Morales 1995 (Continued)

Index tests	Index test 1: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: First criterion: $\geq 1.6\%$ excretion (time not stated) Second criterion: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		

Morales 1995 (Continued)

		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Noguera 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear
Patient characteristics and setting	Sample size: 38 Female: not stated Age: not stated Presentation: 1. Patients undergoing urea breath tests and endoscopic biopsy Setting: secondary care, Argentina
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis:

Noguera 1998 (Continued)

	<ul style="list-style-type: none"> • > 1% excretion (10 minutes) • > 1% excretion (20 minutes) • > 1% excretion (30 minutes) 		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 87 (69.6%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			

Noguera 1998 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Novis 1991

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 76 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy for gastrointestinal symptoms Setting: secondary care, Israel
Index tests	Index test 1: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: <ul style="list-style-type: none"> • > 4.7% excretion (5 minutes) • > 4.7% excretion (10 minutes) • > 4.7% excretion (15 minutes) • > 4.7% excretion (20 minutes)

	<ul style="list-style-type: none"> > 4.7% excretion (25 minutes) 		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target	Yes		

Novis 1991 (Continued)

condition?			
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ogata 2001

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 47 Female: 27 (57.4%) Age: 12 years Presentation: 1. Children with dyspepsia undergoing endoscopy Exclusion: 1. Recent <i>H pylori</i> treatment 2. Immunosuppressive treatment or chemotherapy 3. Extradigestive disease Setting: secondary care, Brazil
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: Isomed Performed by: not stated Criteria for positive diagnosis: > 3% excretion (time not stated) Index test 2: serology Further details: Technical specifications: Cobas Core II (Roche)

Ogata 2001 (Continued)

	Performed by: not stated Criteria for positive diagnosis: > 7 U/ml		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Serology			

Ogata 2001 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ozturk 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 73 Female: 56 (74.6%) Age: 41 years Presentation:

	1. Patients with dyspepsia Setting: secondary care, Turkey		
Index tests	Index test 1a: urea breath test- ¹⁴ C Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes) Index test 1b: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 100 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			

Ozturk 2003 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Peitz 2001

Study characteristics

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 145 Female: 87 (60%) Age: 59 years Presentation: 1. Patients with dyspepsia

Peitz 2001 (Continued)

	<p>Exclusion criteria:</p> <ol style="list-style-type: none"> 1. Recent <i>H pylori</i> treatment 2. Recent NSAID treatment 3. Previous gastric surgery 4. Clotting disorders <p>Setting: secondary care, Germany</p>		
Index tests	<p>Index test: serology</p> <p>Further details:</p> <p>Technical specifications: Helisa Rapid Whole Blood Test (Cortecs Diagnostics Ltd)</p> <p>Performed by: not stated</p> <p>Criteria for positive diagnosis: not stated</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection</p> <p>Reference standard: endoscopic biopsy with H & E stain and Giemsa stain</p> <p>Further details:</p> <p>Technical specifications: not stated</p> <p>Performed by: endoscopist and pathologist</p> <p>Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated</p> <p>Number of patients who were excluded from the analysis: 0 (0%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference stan-	Unclear		

Peitz 2001 (Continued)

dard?			
If a threshold was used, was it pre-specified?	Yes		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Peura 1996

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 200 Female: 118 (59%) Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Gastric surgery

	Setting: secondary care, USA		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Peura 1996 (Continued)

		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Puspok 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 72 Female: 42 (58.3%) Age: 55 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Austria
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics)

Puspok 1999 (Continued)

	Performed by: not stated Criteria for positive diagnosis: Absorbance 450/620 nm \geq 0.100		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			

Puspok 1999 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Qadeer 2009

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 50 (50%) Age: 39 years Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent <i>H pylori</i> therapy 2. Not on anti-coagulant therapy 3. Oral anticoagulants or NSAID treatment Setting: secondary care, Pakistan
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: pink-red band

Qadeer 2009 (Continued)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

Qadeer 2009 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Rafeey 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 96 Female: 31 (32.3%) Age: 8 years Presentation: 1. Children with dyspepsia or abdominal pain Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Diarrhoea Setting: secondary care, Iran
Index tests	Index test: stool antigen test Further details: Technical specifications: Equipar HPSA test Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Rafeey 2007 (Continued)

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Rasool 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 94 Female: 34 (36.2%) Age: 41 years Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Pregnancy 3. Gastric surgery Setting: secondary care, Pakistan
Index tests	Index test: urea breath test Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes)
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low

DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Rathbone 1986

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 73 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Setting: secondary care, UK
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 2 standard deviations above normal level
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Rathbone 1986 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Safe 1993

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: 59 (59%) Age: 72 years Presentation: 1. Elderly dyspeptic patients Setting: secondary care, UK		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 10 units/ml		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Salles-Montaudon 2002

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 107 Female: 71 (66.4%) Age: 85 years Presentation: 1. Adults > 75 years Exclusion criteria: 1. Contraindication to biopsy Setting: secondary care, Switzerland		
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: ABCA, Europa Scientific Performed by: not stated Criteria for positive diagnosis: delta over baseline > 3.5% (30 minutes) Index test 2: serology Further details: Technical specifications: Pyloriset EIA Kit (Orion Diagnostica) Performed by: not stated Criteria for positive diagnosis: > 300 Units Index test 3: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not reported) > 0.160		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Salles-Montaudon 2002 (Continued)

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			

Salles-Montaudon 2002 (Continued)

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Schilling 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 68 Female: 20 (29.4%) Age: 62 years Presentation: 1. Patients with partial gastric resection Exclusion criteria: Recent <i>H pylori</i> treatment Setting: secondary care, Germany
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)

Schilling 2001 (Continued)

Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

Schilling 2001 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Scuderi 2000

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 250 Female: 127 (50.8%) Age: 58 years Presentation: 1. Patients with dyspeptic symptoms Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy

Scuderi 2000 (Continued)

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low

DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Segamwenge 2014

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 160 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Exclusion criteria 1. Could not tolerate endoscopy 2. Recent <i>H pylori</i> treatment 3. Pain attributable to pancreas or liver 4. NSAID-related dyspepsia Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Rapid strip HPSA (Meridian Bioscience) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			

Segamwenge 2014 (Continued)

Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Selcukcan 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 47 (47%) Age: not stated Presentation: 1. Infants undergoing endoscopy Exclusion criteria: 1. No recent <i>H pylori</i> treatment Setting: secondary care, Turkey
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Selcukcan 2011 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Sharbatdaran 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 61 Female: 36 (59%) Age: 31 years Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent <i>H pylori</i> infection 2. Gastric cancer 3. Bleeding during endoscopy Setting: secondary care, Iran
Index tests	Index test: stool antigen test Further details: Technical specifications: GA Generic Assay Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm > + 0.1 of negative control
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	
Methodological quality	

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Were all patients included in the analysis?	Yes		
		Unclear	

Sheu 1998a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 135 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Setting: secondary care, Mexico
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Sheu 1998a (Continued)

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Sheu 1998b

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 66 Female: not stated Age: not stated Presentation: 1. Patients with gastrectomy Setting: secondary care, Mexico		
Index tests	Index test: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	High

Sheu 1998b (Continued)

DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Shin 2009

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 651 Female: 254 (39%)

	<p>Age: 58 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Chronic medication 3. Gastric surgery Setting: secondary care, South Korea</p>		
Index tests	<p>Index test: serology Further details: Technical specifications: Genedia <i>H pylori</i> Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm > 0.406</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			

Shin 2009 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Soomro 2012

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 44 (44%) Age: not stated Presentation: 1. Patients undergoing endoscopic biopsy for dyspepsia or gastritis

	Setting: secondary care, Pakistan		
Index tests	<p>Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated</p> <p>Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference stan-	Unclear		

ard?			
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Surveyor 1989

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 63 Female: 30 (47.8%) Age: 59 years Presentation: 1. Patients with symptoms related to upper gastrointestinal tract undergoing endoscopy Setting: secondary care, Australia		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low

Surveyor 1989 (Continued)

DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Thobani 1995

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 26 Female: not stated

Thobani 1995 (Continued)

	Age: not stated Presentation: 1. Patients with upper gastrointestinal symptoms Setting: secondary care, Pakistan		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 2		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Thobani 1995 (Continued)

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Tiwari 2014

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 30 Female: 25 (83.3%) Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, India

Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Trevisani 2005

Study characteristics

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 105 Female: 50 (47.6%) Age: 58 years Presentation: 1. Patients referred to endoscopy centre Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Pregnancy or lactation 3. Steroids or NSAID treatment 4. Prior gastric surgery 5. Bleeding peptic ulcer 6. Severe concomitant diseases Setting: secondary care, Italy

Index tests	Index test 1a: stool antigen test Further details: Technical specifications: Amplified IDEA Hp StAR Performed by: doctor Criteria for positive diagnosis: Absorbance 450 nm \geq 0.190 Index test 1b: stool antigen test Further details: Technical specifications: Immunocard Stat Performed by: doctor Criteria for positive diagnosis: pink red band (5 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		

Trevisani 2005 (Continued)

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Vandenplas 1992

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 95 Female: 50 (52.6%) Age: 9 years Presentation: 1. Children with chronic abdominal pain Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Belgium

Index tests	<p>Index test 1: urea breath test-¹³C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated Index test 2: serology Further details: Technical specifications: Malakit Helicobacter pylori (Biolab) Performed by: not stated Criteria for positive diagnosis: > Mean + 3 standard deviations above normal level</p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Vandenplas 1992 (Continued)

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Villalobos 1992

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 105 Female: 69 (65.7%) Age: not stated Presentation: 1. Patients with dyspepsia Excluded: 1. Recent <i>H pylori</i> treatment 2. Patients taking steroids 3. Patients with coagulopathy 4. Patients allergic to penicillin 5. Pregnancy or lactation Setting: secondary care, Mexico		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 1.6% (60 minutes)		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		

Villalobos 1992 (Continued)

Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Wang 2008

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded		
Patient characteristics and setting	Sample size: 123 Female: 69 (56.1%) Age: 48 years Presentation: 1. Asymptomatic individuals Exclusion criteria: 1. Recent <i>H pylori</i> therapy 2. Gastric surgery Setting: secondary care, Italy		
Index tests	Index test: serology Further details: Technical specifications: Assure <i>H pylori</i> Rapid Test (CIM-test, Genelabs Diagnostics Ltd) Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 214 (63.5%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

		High	Unclear
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Wardi 2012

Study characteristics			
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 76 Female: 15 (19.7%) Age: 70 years Presentation: 1. Patients with partial gastrectomy Setting: secondary care, Israel		
Index tests	Index test: urea breath test - C13 Further details: Technical specifications: BreathID Performed by: not stated Criteria for positive diagnosis: not clearly stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	High

Wardi 2012 (Continued)

DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Weiss 1994

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 95 Female: not stated

	Age: not stated Presentation: 1. Patients with abdominal pain Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, USA		
Index tests	Index test 1a: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology Further details: Technical specifications: Cobas Core anti- <i>H pylori</i> (Roche) Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear

DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Yan 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded

Patient characteristics and setting	Sample size: 31 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, China		
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absorbance 450/630 nm \geq 0.120		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 32 (50.8%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	Unclear
DOMAIN 2: Index Test Stool Antigen Test			

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Yoshimura 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 72 Female: 34 (47.2%) Age: 13 years Presentation:

Yoshimura 2001 (Continued)

	1. Children undergoing endoscopy for symptoms such as anaemia and abdominal pain Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Japan		
Index tests	Index test 1: urea breath test- ¹³ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 3.0% (20 minutes and 30 minutes) Index test 2: serology Further details: Technical specifications: HM-CAP Anti- <i>H pylori</i> -EIA; Kyowa Medics Performed by: not stated Criteria for positive diagnosis: ≥ 1.8		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	Unclear
DOMAIN 2: Index Test Urea breath test-¹³C			

Yoshimura 2001 (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Yu 1999

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded		
Patient characteristics and setting	Sample size: 88 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment Setting: secondary care, Singapore		
Index tests	Index test: urea breath test- ¹⁴ C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 16 (16.5%)		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

Yu 1999 (Continued)

		High	Unclear
DOMAIN 2: Index Test Urea breath test-¹⁴C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Yu 2001

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: consecutive patients

Patient characteristics and setting	<p>Sample size: 32 Female: 14 (43.8%) Age: 51 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent <i>H pylori</i> treatment 2. Gastric surgery Setting: secondary care, Taiwan, China</p>		
Index tests	<p>Index test 1: urea breath test-¹³C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 2.8% (15 minutes) Index test 2: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Multiple criteria for positive diagnosis: <ul style="list-style-type: none"> • Absorbance 450 nm > 0.140 • Visual assessment by gastroenterologists </p>		
Target condition and reference standard(s)	<p>Target condition: <i>H pylori</i> infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of <i>H pylori</i> in biopsy</p>		
Flow and timing	<p>Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)</p>		
Comparative			
Notes			
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Yu 2001 (Continued)

Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test Urea breath test-¹³C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	Low
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Yu 2001 (Continued)

Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

CO₂ - carbon dioxide;

H & E stain - haematoxylin and eosin stain;

HpSA - *H pylori* stool antigen;

IgA - immunoglobulin A;

IgG - immunoglobulin G;

NMR - nuclear magnetic resonance;

NSAID - non-steroidal anti-inflammatory

WBC - white blood cell

All other acronyms and abbreviations are the full title of either products or companies producing products included in the study.

Characteristics of studies awaiting classification [ordered by study ID]

Buhigas-Garcia 2008

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test- ¹³ C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Fazeli 2004

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	salivary test, potential index tests of interest
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Fuke 2009

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Glupczynski 1991

Study characteristics	
Patient sampling	
Patient characteristics and setting	

Glupczynski 1991 (Continued)

Index tests	urea breath test- ¹³ C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Karczewska 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Kushch 2014

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	unclear
Target condition and reference standard(s)	
Flow and timing	

Kushch 2014 (Continued)

Comparative	
Notes	

Lappas 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	salivary test, potential index tests of interest
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Lee 1999a

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test- ¹³ C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Martin-de-Argila 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Mason 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Thong-Ngam 2011

Study characteristics	
Patient sampling	
Patient characteristics and setting	

Thong-Ngam 2011 (Continued)

Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Tokunaga 2005a

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Xu 1995

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test- ¹³ C
Target condition and reference standard(s)	
Flow and timing	

Xu 1995 (Continued)

Comparative	
Notes	

DATA

Presented below are all the data for all of the tests entered into the review.

Tests. Data tables by test

Test	No. of studies	No. of participants
1 Urea breath test- ¹³ C	34	3139
2 Urea breath test- ¹⁴ C	21	1810
3 Urea breath test - Unknown isotope	2	127
4 Serology	34	4242
5 Stool antigen test	29	2988
6 Urea breath test- ¹³ C (delta over baseline > 3% (20 minutes))	2	254
7 Urea breath test- ¹³ C (delta over baseline > 3% (30 minutes))	3	333
8 Urea breath test- ¹³ C (delta over baseline > 3.5% (30 minutes))	3	368
9 Urea breath test- ¹³ C (delta over baseline > 4% (10 minutes))	2	236
10 Urea breath test- ¹³ C (delta over baseline > 4% (20 minutes))	2	236
11 Urea breath test- ¹³ C (delta over baseline > 4% (30 minutes))	10	958
12 Urea breath test- ¹³ C (delta over baseline > 4.5% (30 minutes))	3	288
13 Urea breath test- ¹³ C (delta over baseline > 5% (30 minutes))	4	601
14 Urea breath test- ¹⁴ C (counts per minute > 50)	6	471
15 Urea breath test- ¹⁴ C (disintegrations per minute > 200)	4	296
16 Serology > 7 units/ml	2	97
17 Serology ≥300 units	2	234

ADDITIONAL TABLES

Table 1. Summary of results at thresholds commonly reported for urea breath test-¹³C, urea breath test-¹⁴C and serology

Threshold	Studies	Number of participants (cases)	Sensitivity (95% CI)	Specificity (95% CI)
Urea breath test-¹³C				
Delta over baseline > 3% (20 minutes)	2	254 (128)	0.98 (0.90 to 1.00)	0.92 (0.82 to 0.97)
Delta over baseline > 3% (30 minutes)	3	333 (140)	0.99 (0.92 to 1.00)	0.95 (0.90 to 0.98)
Delta over baseline > 3.5% (30 minutes)	3	368 (120)	0.75 to 1.00	0.77 to 1.00
Delta over baseline > 4% (10 minutes)	2	236 (118)	0.91 to 1.00	0.60 to 0.95
Delta over baseline > 4% (20 minutes)	2	236 (118)	0.91 to 1.00	0.60 to 0.96
Delta over baseline > 4% (30 minutes)	10	958 (423)	0.95 (0.79 to 0.99)	0.95 (0.87 to 0.98)
Delta over baseline > 4.5% (30 minutes)	3	288 (106)	0.50 to 0.96	0.82 to 0.96
Delta over baseline > 5% (30 minutes)	4	601 (315)	0.95 (0.49 to 1.00)	0.94 (0.84 to 0.98)
Urea breath test-¹⁴C				
Counts per minute > 50 (10 minutes)	6	471 (231)	0.89 (0.55 to 0.98)	0.91 (0.79 to 0.96)
Disintegrations per minute > 200 (10 minutes)	4	296 (132)	0.95 (0.33 to 1.00)	0.95 (0.80 to 0.99)
Serology				
> 7 units/ml	2	97 (48)	0.98 (0.74 to 1.00)	0.71 (0.51 to 0.86)
≥ 300 unit	2	234 (143)	0.91 (0.82 to 0.96)	0.86 (0.72 to 0.93)

Tests evaluated at the same threshold by more than one study are presented in the table. When there were two or three studies at the same threshold, and little or no heterogeneity was observed in ROC space, estimates of summary sensitivity and summary specificity were obtained by using univariate fixed-effect logistic regression models to pool sensitivities and specificities separately. When there

were two or three studies and we observed heterogeneity, we did not perform meta-analysis but report the range of the sensitivities and specificities.

Table 2. Indirect comparison of the accuracy of non-invasive tests for *H pylori* infection

Index tests	Studies; participants (<i>H pylori</i> present)	DOR (95% CI)	Ratio of diagnostic odds ratios (95% CI), P value		
			Urea breath test- ¹³ C	Urea breath test- ¹⁴ C	Serology
Urea breath test- ¹³ C	34; 3139 (1526)	153 (73.7 to 316)	-	-	-
Urea breath test- ¹⁴ C	21; 1810 (1018)	105 (74.0 to 150)	1.45 (0.65 to 3.26), P = 0.36	-	-
Serology	34; 4242 (2477)	47.4 (25.5 to 88.1)	3.22 (1.24 to 8.37), P = 0.017	2.22 (1.09 to 4.51), P = 0.028	-
Stool antigen test	29; 2988 (1311)	45.1 (24.2 to 84.1)	3.39 (1.30 to 8.83), P = 0.013	2.33 (1.14 to 4.76), P = 0.020	1.05 (0.44 to 2.53), P = 0.91

The indirect comparison included all studies that evaluated at least one of the four tests, i.e. all available data. The ratio of diagnostic odds ratios is the diagnostic odds ratio (DOR) of the test in the column divided by the DOR of the test in the row. If the ratio is greater than one, then the test in the column is more accurate than the test in the row; if the ratio is less than one, the test in the row is more accurate than the test in the column.

Table 3. Accuracy of non-invasive tests for *H pylori* infection at different levels of prevalence

Prevalence (%)	Specificity	False positives ¹	Test	Sensitivity (95% CI)	Missed cases (95% CI)
42.0	0.79	122	Urea breath test- ¹³ C	0.98 (0.95 to 0.99)	10 (5 to 20)
			Urea breath test- ¹⁴ C	0.97 (0.95 to 0.98)	15 (10 to 20)
			Serology	0.93 (0.87 to 0.96)	31 (17 to 54)
			Stool antigen test	0.92 (0.87 to 0.96)	32 (18 to 57)
53.7	0.79	97	Urea breath test- ¹³ C	0.98 (0.95 to 0.99)	13 (6 to 26)
			Urea breath test- ¹⁴ C	0.97 (0.95 to 0.98)	19 (13 to 26)
			Serology	0.93 (0.87 to 0.96)	39 (22 to 69)
			Stool antigen test	0.92 (0.87 to 0.96)	41 (23 to 72)

Table 3. Accuracy of non-invasive tests for *H. pylori* infection at different levels of prevalence (Continued)

66.5	0.79	70	Urea breath test- ¹³ C	0.98 (0.95 to 0.99)	16 (8 to 32)
			Urea breath test- ¹⁴ C	0.97 (0.95 to 0.98)	23 (16 to 32)
			Serology	0.93 (0.87 to 0.96)	49 (27 to 85)
			Stool antigen test	0.92 (0.87 to 0.96)	51 (28 to 89)
42.0	0.90	58	Urea breath test- ¹³ C	0.94 (0.89 to 0.97)	23 (12 to 46)
			Urea breath test- ¹⁴ C	0.92 (0.89 to 0.94)	33 (24 to 46)
			Serology	0.84 (0.74 to 0.91)	67 (39 to 110)
			Stool antigen test	0.83 (0.73 to 0.90)	70 (41 to 114)
53.7	0.90	46	Urea breath test- ¹³ C	0.94 (0.89 to 0.97)	30 (15 to 58)
			Urea breath test- ¹⁴ C	0.92 (0.89 to 0.94)	42 (30 to 58)
			Serology	0.84 (0.74 to 0.91)	86 (50 to 140)
			Stool antigen test	0.83 (0.73 to 0.90)	89 (52 to 146)
66.5	0.90	34	Urea breath test- ¹³ C	0.94 (0.89 to 0.97)	37 (18 to 72)
			Urea breath test- ¹⁴ C	0.92 (0.89 to 0.94)	53 (38 to 72)
			Serology	0.84 (0.74 to 0.91)	106 (62 to 173)
			Stool antigen test	0.83 (0.73 to 0.90)	111 (64 to 180)
42.0	0.96	23	Urea breath test- ¹³ C	0.86 (0.75 to 0.93)	57 (30 to 103)
			Urea breath test- ¹⁴ C	0.81 (0.76 to 0.86)	78 (58 to 103)
			Serology	0.66 (0.52 to 0.79)	141 (90 to 204)
			Stool antigen test	0.65 (0.50 to 0.78)	146 (93 to 209)
53.7	0.96	19	Urea breath test- ¹³ C	0.86 (0.75 to 0.93)	73 (38 to 132)
			Urea breath test- ¹⁴ C	0.81 (0.76 to 0.86)	100 (74 to 132)
			Serology	0.66 (0.52 to 0.79)	181 (115 to 260)
			Stool antigen test	0.65 (0.50 to 0.78)	187 (119 to 267)

Table 3. Accuracy of non-invasive tests for *H pylori* infection at different levels of prevalence (Continued)

66.5	0.96	13	Urea breath test- ¹³ C	0.86 (0.75 to 0.93)	90 (47 to 163)
			Urea breath test- ¹⁴ C	0.81 (0.76 to 0.86)	124 (92 to 163)
			Serology	0.66 (0.52 to 0.79)	224 (142 to 322)
			Stool antigen test	0.65 (0.50 to 0.78)	231 (148 to 331)

¹Average number of participants who are diagnosed with *H pylori* infection but do not have the infection per 1000 tested.

The sensitivities were estimated from the SROC curves at fixed values (lower quartile, median and upper quartile) of specificity from the included studies across all tests. Based on these sensitivities and specificities, and quartiles of prevalence from the included studies (across all tests), the numbers of missed *H pylori* cases and false positives (i.e. overdiagnosed people) were calculated using a hypothetical cohort of 1000 people suspected of having *H pylori* infection.

Table 4. Direct comparison of the accuracy of non-invasive tests for *H pylori* infection

Test	Urea breath test- ¹³ C	Urea breath test- ¹⁴ C	Serology
Urea breath test- ¹³ C	-	-	-
Urea breath test- ¹⁴ C	N = 0	-	-
Serology	N = 7 DOR (95% CI) of urea breath test- ¹³ C = 74.8 (95% CI 17.8 to 314) DOR (95% CI) of serology = 111 (95% CI 41.2 to 297) RDORs (95% CI) of urea breath test- ¹³ C versus serology, P value = 0.68 (95% CI 0.12 to 3.70), P = 0.56	N = 1	-
Stool antigen test	N = 7 DOR (95% CI) of urea breath test- ¹³ C = 46.6 (95% CI 3.30 to 658) DOR (95% CI) of stool antigen test = 53.0 (95% CI 5.34 to 527) RDORs (95% CI) of urea breath test- ¹³ C versus stool antigen test, P value = 0.88 (95% CI 0.14 to 5.56), P = 0.84	N = 2	N = 4

DOR = diagnostic odds ratio; N = number of studies; RDORs = ratio of diagnostic odds ratios.

Due to paucity of data and substantial heterogeneity observed in ROC space which precluded the use of simpler meta-analytic models, meta-analyses were not possible for two test comparisons that had more than one study. For the single study of urea breath test-¹⁴C versus serology (Mansour-Ghanaei 2011), both tests had similar sensitivity, but specificity was higher for urea breath test-¹⁴C than for serology. The ratio of diagnostic odds ratios is the DOR of the test in the column divided by the DOR of the test in the row. If the

ratio is greater than one, then the test in the column is more accurate than the test in the row; if the ratio is less than one, the test in the row is more accurate than the test in the column.

CONTRIBUTIONS OF AUTHORS

LB, SS, AS, AG, BL, and KG identified studies and extracted data for the review. LB entered the characteristics of included and excluded studies. KG and YT analysed the data and wrote the review. MY provided critical comments for the review.

DECLARATIONS OF INTEREST

This report is independent research funded by the National Institute for Health Research (NIHR Cochrane Programme Grants, 13/89/03 - Evidence-based diagnosis and management of upper digestive, hepato-biliary, and pancreatic disorders). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

LB: none known.

SS: none known.

AS: none known.

AG: none known.

BL: none known.

MY: is an Editor with the Cochrane Upper GI and Pancreatic Diseases (UGPD) Review Group. However, other UGPD Editors were responsible for the editorial processing of this review.

KS: none known.

YT: none known.

SOURCES OF SUPPORT

Internal sources

- University College London, UK.

External sources

- National Institute for Health Research, UK.

This project was supported by the National Institute for Health Research, via Cochrane Programme Grant to the CHBG and UGPD groups. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- We considered urea breath test-¹⁴C and urea breath test-¹³C as different index tests.
- Because of the paucity of data, we did not stratify the analysis by reference standard; however, we investigated reference standard as a potential source of heterogeneity.
- Because studies reported different thresholds and following recommendation from peer reviewers, we used the HSROC model for the primary analyses. For estimation of summary sensitivities and specificities at specific thresholds, we used univariate fixed- and random-effects logistic regression models due to paucity of data.
- We performed direct comparisons whenever possible, rather than deciding this on the basis of the number of studies.