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• *BRIEF REPORTS* •

Evaluation of urine ELISA test for detecting *Helicobacter pylori* infection in Taiwan: A prospective study

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Abstract

AIM: To evaluate the diagnostic accuracy and clinical utility of a new ELISA (URINELISA) test for detecting *Helicobacter pylori* (*H pylori*) antibody in the urine of Taiwanese population.

METHODS: In this prospective study, 317 consecutive dyspeptic patients (171 men, 146 women; mean age, 51.0 years) were included. They underwent gastroendoscopy for evaluation. Invasive tests, including culture, histology, and rapid urease test (RUT), and non-invasive ^{13}C-urea breath test were preformed. At the same time, urine specimens were collected for URINELISA. The status of *H pylori* infection was considered as positive when either culture was positive, or when two of the other, RUT, histology or 13C-UBT, were positive.

RESULTS: The sensitivity, specificity, positive predictive value, and negative predictive value of URINELISA are 91.7% (211/230), 90.8% (79/87), 96.3% (211/219), and 80.6% (79/98) respectively.

CONCLUSION: This URINELISA test is reliable, inexpensive and easy-to-use. The high diagnostic accuracy warrants the use of URINELISA as a first-line screening tool for diagnosis of *H pylori* infection in untreated patients.

Key words: *H pylori*; URINELISA

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INTRODUCTION

Since the discovery of *Helicobacter pylori* (*H pylori*) by Marshall and Warren in 1983[1], overwhelming evidence has confirmed that *H pylori* infection plays a significant role in the development of chronic active gastritis, peptic ulcer, and gastric adenocarcinoma[2]. *H pylori* infection is very common throughout the world, occurring in 40-50% of the population in developed countries, 80-90% of the population in developing regions[3], and about 54.4% of the population in Taiwan[4].

A large number of methods have been developed to diagnose *H pylori* infection, including invasive and non-invasive tests. The former requires endoscopy exam for gastric mucosal biopsy. Because of the patchy nature of the infection, biopsy-based tests may suffer sampling errors[5]. There is an increasing interest in non-invasive tests, as they are not influenced by sampling error and can profitably replace endoscopy making the diagnosis and determining the management of some types of patients[6]. The urea breath test (UBT) is based on the carbon dioxide labeled with carbon-13 or carbon-14 in expired air to detect *H pylori* urease activity[7]. Serological tests are based on the detection of a specific anti-*H pylori* immunological response, mostly by IgG antibodies in patient's serum. Same as serum antibody testing, an enzyme immunoassay method (URINELISA test, Otsuka Pharmaceutical Co., Ltd, Japan) for detecting *H pylori* antibody in the urine has been marketed in Japan, but at present, data on its clinical utility are limited[8,9]. It is possible that different genetic background of patients and *H pylori* strains could induce different antigen-antibody responses that would affect the results of URINELISA[10-14]. The aim of this study is to evaluate the usefulness of this new test in detecting *H pylori* antibody in the urine as a predictor of *H pylori* status in pretreatment settings in Taiwan.

MATERIALS AND METHODS

Patient selection and exclusion criteria

Three hundred and seventeen dyspeptic patients (171 men and 146 women; mean age, 51.0 years; range, 16-81 years) were recruited for this study. Exclusion criteria were as follows: antibiotic, bismuth salts, proton pump inhibitor therapy 2 mo before recruitment, previous anti-*H pylori*

treatment, chronic use of corticosteroids or immunosuppressant drugs, prior gastric surgery, presence of a bleeding peptic ulcer, severe concomitant disease, pregnancy, and lactation. Informed consent was obtained from each patient, and the study was performed in accordance with the Declaration of Helsinki.

Study design

All patients underwent gastroendoscopic examination, and gastric mucosal biopsies were performed. Non-invasive tests including URINELISA and ^{13}C-urea breath test (^{13}C-UBT) were also carried out. *H pylori* infection status was considered positive, when either culture was positive or when two of the following three tests, histology, rapid urease test (RUT), and ^{13}C-UBT, were positive. Urine samples were collected on the same day after endoscopic examination. The endoscopic biopsy protocol is shown in detail as follows: two specimens from the antrum and body for culture, five specimens from the angle and both greater and lesser curvatures of the antrum and body for histology and four specimens, excluding angle, for RUT.

Diagnostic tests for H pylori infection

Histology One set of specimens was fixed with formalin and embedded in paraffin. Sections were then stained with hematoxylin and eosin (H&E).

Rapid urease test CLO-test (Delta West, Bentley, Australia) was selected for determination of the presence of urease in the biopsied gastric mucosa. The results of the CLO-test were interpreted as positive if the color of the gel changed from yellow to pink or red within 6 h at room temperature.

Culture Culture of *H pylori* was made by rubbing the specimen on the surface of a Campy-BAP agar plate [Brucella agar (Difco)+IsoVitalex (Gibco)+10% whole sheep blood], and then incubating it at 35 ℃ under microaerobic conditions (5% O_2, 100 mL/L CO_2, and 85% N_2) for 4-5 d. The *H pylori* culture was considered positive if one or more colonies of gram-negative, oxidase (+), catalase (+), and urease (+) spiral or curved rods were present.

^{13}C-urea breath test (^{13}C-UBT) The ^{13}C-urea was 100 mg 99% ^{13}C-labeled urea produced by the Institute of Nuclear Energy Research (INER), Taiwan, and 100 mL of fresh milk was used as the test meal. This procedure has been modified since our previous study[15]. Patients were asked to fast at least 6 h beforehand, then a baseline sample was collected in duplicate by exhaling through a straw into a vacuum container tube 5 min after consuming the test meal. Five minutes later, the patients drank the urea solution prepared by dissolving 100 mg ^{13}C-urea in 50 mL of sterile water. Immediately after ^{13}C-urea consumption, subjects were asked to gargle rinsing the mouth to avoid detecting oral urease activity. The patient then rested on their sides for 15 min, changing sides every 5 min. Fifteen minutes after ^{13}C-urea was ingested, a breathing sample was collected in duplicate as the method of collecting baseline samples. All samples were sent to INER, where a continuous-flow isotope ratio mass spectrometer (CF-IRMS, Europa Scientific Ltd, Crewe, UK) was used for analysis. Based on findings from our previous study, the cut-off value was 4.2/mL at 15 min after ingesting ^{13}C -urea.

URINELISA *H pylori* antibody test All patients were asked to deliver a fresh urine specimen on the day of endoscopy. Urine samples were stored at 4 ℃ before analysis. Urinary antibodies to *H pylori* were determined by URINELISA *H pylori* antibody test (Otsuka Pharmaceutical Co., Ltd, Japan). This kit is an enzyme-linked immunosorbent assay (ELISA) kit using a 96-well microplate, and, as a solid phase of an antigen, a protein extracted from an *H pylori* strain isolated from a Japanese patient with gastritis is used. The assay procedure was performed according to the manufacturer's recommendations. To each well of the solid-phase microplate, 25 μL each of a buffer solution and 100 μL each of the urine specimen, the negative controls or positive controls were added in turn. After a reaction at 37 ℃ for 1 h, the plate was washed. One hundred microliters of an enzyme-labeled antibody solution was added to each of the wells subjected to the reaction at 37 ℃ for 1 h, and then washed. One hundred microliters of a substrate solution was then added. After the reaction was conducted for 15 min, 100 μL of a reaction stopping solution was added to each well. Absorbance was determined at a wavelength of 450 nm by an ELISA reader. Two positive controls and three negative controls were measured simultaneously. The cut-off value for urine-based ELISA was determined as the value calculated by the following formula: (mean absorbance of two positive controls)/8.5+ (mean absorbance of three negative controls). The equation employed was based on the results of numerous clinical studies[16]. Absorbance below the cut-off value was assessed as negative, and absorbance greater than the cut-off value was assessed as positive.

RESULTS

Of 317 patients, 230 (72.6%) were *H pylori*-infected and 87 (27.4%) were uninfected. Of the infected patients, 75 (23.7%) had non-ulcer dyspepsia, 224 (70.7%) had duodenal and gastric ulcers, and 18 (5.7%) had gastric adenocarcinoma. URINELISA was positive in 219 cases (8 of which were false positives) and negative in 98 (19 of which were false negatives). A summary of the diagnostic efficacy of individual tests is shown in Table 1. The urine test showed

Table 1 Summary of diagnostic efficacy of all tests used in this study

	URINELISA(%)	^{13}C-UBT (%)	RUT (%)	Culture (%)	Histology (%)
Sensitivity	91.7 (88.7–94.8)	96.7 (94.7–98.7)	94.4 (91.9–96.9)	55.6 (50.1–61.1)	86.7 (83–90.4)
Specificity	90.8 (87.6–94.0)	95.2 (92.8–97.6)	95.2 (92.8–97.6)	100 (100)	79.7 (75.3–84.1)
PPV	96.4 (94.3–98.5)	96.7 (94.7–98.7)	96.6 (94.6–98.6)	100 (100)	85.6 (81.7–89.5)
NPV	80.6 (76.2–85.0)	95.2 (92.8–97.6)	92.3 (89.4–95.2)	61.2 (55.8–66.6)	80.6 (76.2–85)

Results are expressed by percentages, with a 95%CI.

sensitivity of 91.7%, specificity of 80.8%, positive predictive value of 96.4% and negative predictive value of 80.6%. That is, the diagnostic efficacy of URINELISA was similar to ^{13}C-UBT and RUT.

DISCUSSION

Since the early 1980s, when *H pylori* was first discovered, significant progress has been made in identifying this infection, especially with respect to non-invasive techniques. The UBT, first described by Graham *et al*., in 1987[17], is presently considered as the most effective non-invasive test for *H pylori*[18]. Based on the direct identification of a bacterial enzyme activity (urease), the UBT detects an active, ongoing infection and is highly accurate even shortly after therapy[19]. However, the availability of ^{14}C-UBT is limited by the strict regulations governing the use, handling, and storage of radioactive isotopes, which in practice precludes use outside hospitals and the testing of children and women of childbearing age. ^{13}C on the other hand is a safe isotope that can be used for breath testing, but it is expensive ($ 250-350) when compared with other non-invasive tests ($ 20-100)[20], and does require the use of a CF-IRMS, thereby limiting widespread applicability. Furthermore, UBT for detection of *H pylori* is less effective in patients who have had a prior gastrectomy[21] and in those with severe atrophic gastritis[22]. In addition, equivocal or false-negative UBT results often occur in patients taking acid-suppression therapy[23-26]. Moreover, in most of the approved UBT protocols, demands are made on patients' time and cooperation (i.e., fasting before the test, the necessity of an office/laboratory visit, consumption of a test meal, and collection of a second breath sample after a time lag). Therefore, it is not easy to perform a UBT test on patients who cannot cooperate, such as children, psychological patients and unconscious patients.

Serology has clear advantages over breath tests, both in terms of cost and in being a non-invasive screening strategy, and it is the most important tool for epidemiological studies[27]. However, old-fashioned serological tests have suffered from cross-reactivity with *Campylobacter* species[28], resulting in a high rate of false positives. The reported sensitivity of serological tests is approximately 98-100%, but specificity varies from 26% to 96.4%[29]. Results of these assays may be due to the reference method used to confirm *H pylori* status, the source of the antigen on which the assay is based, and the reference population studies[29]. Furthermore, the specificity of most serologic tests decreases by approximately 10%, when sera from subjects more than 45 years are examined[30].

Recently, urine-based antibody tests have been developed for the screening of infectious diseases, including *H pylori*[31]. The benefits of using urine as the specimen are as follows: (1) Urine can be obtained easily, and its collection requires little skill. (2) Urine does not require centrifugation. (3) The cost of using urine as a sample is much lower than that of serum. (4) Urine tests can be simply formatted for use in doctors' offices or even for home testing. (5) Using urine provides a simpler alternative sample for epidemiological and screening studies. Laboratory-based urine testing using ELISA technology to detect IgG antibody is inexpensive (under $ 20), non-invasive, and well suited to primary care practice. Urine-based testing also combines the advantages of simplicity, cost-effectiveness and applicability under circumstances in which serological testing is largely impracticable. It has been reported that antibodies in urine are stable for 55 days at room temperature, and for one year at 2-8 ℃[32]. Katsuragi *et al*.[8], also confirmed that *H pylori* antibodies in urine were viable for at least 60 d at 4 ℃ and 25 ℃, and for at least 3 d at 37 ℃ and 45 ℃. In contrast, stool samples must be kept at 4 ℃ within 12 h after defecation, or diagnostic efficacy decreases.

Two studies have been performed in different populations with similar diagnostic efficacy with our results reported[33,34]. These studies show that URINELISA has a high degree of consistency in detecting *H pylori* infection in both Asian and European populations. Therefore, URINELISA is suitable for mass screening of *H pylori* infection. Such consistency has not been observed in stool antigen tests. In our own experience[35], and based on other reports made of an Asian population[34,36], the diagnostic efficacy of Premier Platinum HpSA® has been less consistent in an Asian population. However, there is a new stool antigen test, ImmunoCard HpSA STAT®, which seems to have higher diagnostic accuracy in Asian population[38]. In conclusion, URINELISA test is reliable, inexpensive and easy-to-use, and its high degree of diagnostic accuracy warrants its use as a first-line screening tool for the diagnosis of *H pylori* infection in untreated patients.

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