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ORIGINAL ARTICLE

Accuracy of the Ultra-Rapid Urease Test for diagnosis of *Helicobacter pylori* infection

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KEYWORDS
Helicobacter pylori;
Urease;
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Abstract
Background: Rapid Urease Test (RUT) is a simple, cheap and relatively fast method for diagnosing *Helicobacter pylori* infection. It is therefore the preferred method used for patients undergoing gastroscopy. Most kits require 24 h to give results. The new Ultra-Rapid Urease Test (URUT) kit by Biohit® requires less than 1 h.
Objective: To determine URUT's diagnostic accuracy.
Method: Prospective, blind, multi-centre study involving dyspeptic patients. One corpus biopsy and three antral biopsies were obtained during gastroscopy for standard histological analysis,

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RUT and URUT. The URUT result was checked after 1 min, 5 min, 30 min and 60 min and the RUT was checked over the course of 24 h. Histology was used as the gold standard test.
Results: 144 patients were included, 68% female, with a mean age of 49 years old; 50% were *H. pylori* positive. RUT and URUT diagnoses were correct in 85.9% and 90% of the cases, respectively. The mean waiting time for a positive RUT result was 6 h. The sensitivity, specificity, and positive and negative predictive values for RUT were, respectively, 82%, 90%, 89% and 84%. The URUT's results were similar (85%, 94%, 94% and 87%). These figures improved when patients taking PPIs were excluded (RUT: 86%, 91%, 93% and 83%; URUT: 91%, 94%, 96% and 89%). No statistically significant differences were found when comparing RUT and URUT distributions of correct diagnoses (McNemar's Test, $p = 0.3$) but there was a tendency towards better results with the URUT.
Conclusion: The URUT is equivalent to (or slightly better than) the traditional RUT in diagnosing *H. pylori* infection, and provides results in less than an hour.

PALABRAS CLAVE
Helicobacter pylori;
Ureasa;
Gastroscopia;
Diagnóstico

Exactitud del test Ultra-Rapido de la Ureasa para el Diagnóstico de la infección por *Helicobacter pylori*

Resumen
Introducción: El test de la ureasa (TRU) es un método simple, barato y relativamente rápido para el diagnóstico de la infección por *Helicobacter pylori (H. pylori)*. Por tanto, es el método de elección en pacientes sometidos a gastroscopia. La mayoría de los kits requieren 24 h para obtener un resultado. En nuevo test ultrarrápido de la ureasa (TURU) de Biohit requiere menos de una hora.
Objetivo: Determinar la exactitud diagnóstica del TURU.
Método: Estudio multicéntrico, prospectivo y ciego, en el que se incluyó a pacientes dispépticos. Se obtuvieron 3 biopsias de antro y una de corpus durante la gastroscopia para análisis histológico estándar, TRU y TURU. El resultado del TURU se comprobó a los 1, 5, 30 y 60 min, mientras que el TRU se evaluó a lo largo de 24 h. La histología se utilizó como patrón oro.
Resultados: Se incluyó a 144 pacientes, 68% mujeres, edad media 49 años, el 50% fueron positivos para *H. pylori*. TRU y TURU diagnosticaron correctamente el 85,9% y 90,0% de los casos, respectivamente. La duración media de espera para un resultado positivo del TRU fue 6 h. La sensibilidad, la especificidad y los valores predictivos negativo y positivo para el TRU fueron, respectivamente, del 82, el 90, el 89 y el 84%. Los resultados del TURU fueron equivalentes (el 85, el 94, el 94 y el 87%). Estos resultados mejoraron al excluir los pacientes que tomaban IBP (TRU: 86, 91, 93 y 83%; TURU: 91, 94, 96 y 89%). La comparación de distribución de diagnósticos correctos entre TRU y TURU no encontró diferencias estadísticamente significativas (test de McNemar p = 0,3) pero existe una tendencia a mejores resultados con el TURU.
Conclusión: El TURU es equivalente (o algo superior) al TRU tradicional en el diagnóstico de la infección por *H. pylori* y obtiene los resultados en menos de una hora.

Introduction

The management of *Helicobacter pylori* (*H. pylori*) infection requires accurate diagnostic methods. Several diagnostic methods, both direct (histology, culture and urease tests) and indirect (faecal antigen, serology and urea breath test), have been developed.[1–4] Direct or ''invasive'' methods require the biopsy sampling while indirect or ''non-invasive'' methods detect secondary characteristics of the bacteria.[5]

Patients undergoing gastroscopy for dyspeptic symptoms are generally tested for *H. pylori* infection. Rapid Urease Test (RUT) is usually the method of choice as it is simple, cheap, gives an accurate result in 24 h and the result can be observed in the endoscopic units without the involvement of other services.[3–6] Urease kits have a media containing urea and a pH-dependant colour indicator, in which the biopsy is placed. *H. pylori* urease activity alters the pH causing a change of colour of the media.[7]

Common RUTs require up to 24 h to obtain an accurate result, what limits its benefits and utility in clinical practice as the treatment prescription cannot be given in the moment, forcing the patient to come back for the diagnosis to the hospital's outpatient clinic.[1,8] A quicker urease kit would increase efficiency by reducing costs and incommodities to patients.

Recently, new kits have been developed trying to improve the utility and speed of the urease method.[5–7,9] Biohit® commercializes a new urease method that, according to its technical information, is able to give accurate results in 30 min. Previous studies have evaluated the accuracy of different commercial kits obtaining encouraging results.[10–17] It seems that Biohit®'s Ultra-Rapid Urease Test (URUT) is a promising diagnostic method but wider and more diverse evidence is still needed to recommend the systematic use URUT in clinical practice. Therefore, the aim of the present study was to evaluate and compare URUTs diagnostic accuracy for the diagnosis of *H. pylori* in the Spanish population.

Methods

Patients

In this prospective, blind, multicenter study, a total of 144 patients (68% female, mean age 49 years) who attended digestive services for upper gastrointestinal endoscopy were consecutively enrolled. Inclusion criteria were: patients over 18 years of age suffering from dyspepsia. Exclusion criteria were: presence of hepatic, renal, lung, endocrine, metabolic, haematological or malignant diseases; previous *H. pylori* eradication treatment; history of alcohol or drug abuse; and pregnancy or nursing.

Proton pump inhibitor (PPI) treatment was not considered an exclusion criterion as, in clinical practice, most patients undergoing upper gastrointestinal endoscopy are taking these drugs prior to the procedure. However, subanalyses depending on PPI intake were performed for all calculations.

The investigator in charge of each diagnostic test was blinded to the results of the other tests.

Biopsies

Three antrum and one corpus biopsies were obtained. One antrum and the corpus biopsies were used for the standard histological analysis. Biopsies were fixed in 10% formalin and separately embedded in paraffin blocks. The sections, serially cut and stained with haematoxylin & eosin, were examined with light microscopy for the histological assessment of *H. pylori* infection by a pathologist. One antrum biopsy was used for the diagnosis of *H. pylori* infection with the traditional RUT. The other biopsy was used for diagnosis with URUT.

Urease kits

RUT was performed using one out of the three most common kits in Spanish hospitals (CLO test®, Jatrox-test® and Gut plus®). Each hospital used the kit of their own routine clinical practice. The kit was checked out during 24 h. Biohit®'s URUT (Biohit®, Helsinki, Finland) was checked 1 min, 5 min, 30 min and 60 min after the biopsy was included in the kit's media. Flowchart of the patients is present in Fig. 1 (STARD flowchart).

Ethical issues

This study was performed with the approval and follow up by the hospitals' Ethics Committees. The design and development followed the WMA Helsinki Declaration of 1964 and its revisions and all applicable regulations. All patients signed an informed consent.

Statistical analysis

Mean and standard deviation were calculated for quantitative variables, and percentage and 95% confidence interval

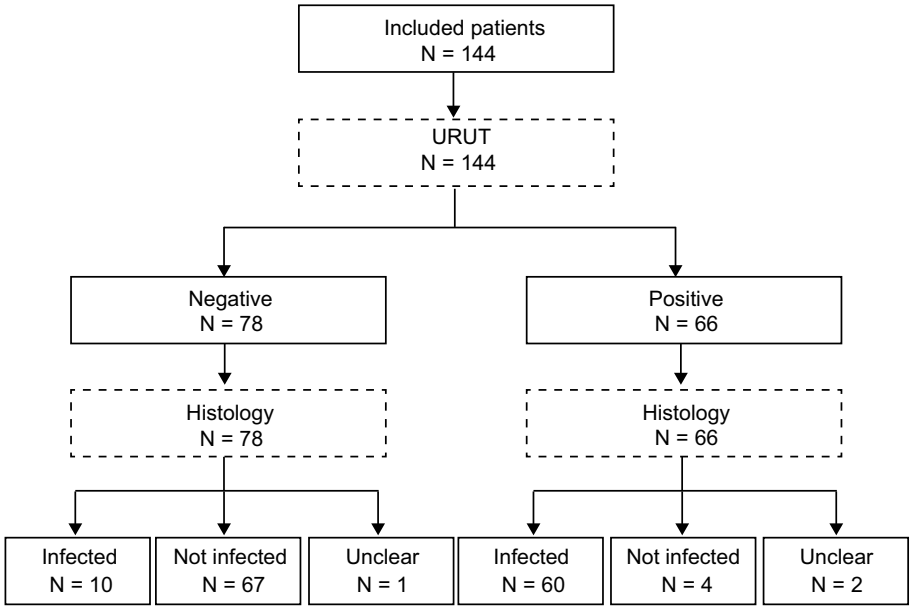

Figure 1 Patient STARD flowchart.

(95%CI) for qualitative variables. Sensitivity, specificity, positive and negative predictive values and positive and negative likelihood ratios were calculated for all urease kits. *Z*-test was used to compare diagnostic success rates. McNemar test was used to compare the distribution of results for both tests. Significance was considered for $p < 0.05$. In order to demonstrate equivalence of RUT and URUT, a sample size of 140 patients was calculated [significance level (alpha) 5%, power (beta) 90% and margin of equivalence (*d*) 5%].

Results

• Study population characteristics

One hundred and forty-four dyspeptic patients were included in 11 hospitals all over Spain in 2009. Average age was 49, and 69% were women. Forty-two percent of patients were taking PPIs. Fifty percent were *H. pylori* positive by histology. Mean waiting time for positive RUT result was 6.2 h.

• Overall diagnostic success of RUT and URUT

RUT and URUT diagnosis were correct in 85.9% (95%CI = 80–92%) (Table 1) and 90.0% (95%CI = 85–95%) (Table 2) of the cases respectively.

• RUT by commercial brand

CLO-test®, Jatrox-test® and Gut-plus® were used for the RUT in 37%, 41% and 22% the patients respectively. Comparing their results with the gold standard, CLO-test® and Jatrox-test® each diagnosed correctly 91% of patients but Gut-plus® only 70% (*Z*-test = 2.55, $p < 0.01$). Therefore subanalyses excluding those patients diagnosed with Gut-plus® were performed (Table 1). Mean time for positive result was 6.2 ± 9.3 h (CLO-test® 9.2 h; Jatrox-test® 3.0 h; Gut-plus® 7.3 h).

• URUT by time checked

One minute after biopsies were placed inside the kit's media, URUT correctly diagnosed *H. pylori* infection in 68% of patients, 78% at 5 min, 86% at 30 min and 90% at 60 min (Table 2).

Table 1 CrossTable of Rapid Urease Tests (by commercial brand) vs. histology in the diagnosis of *H. pylori* infection.

		Histology		Total
		Negative	Positive	
All kits	Negative	62	12	74
	Positive	7	54	61
	Total	69	66	135
CLO-test®	Negative	29	3	32
	Positive	3	22	25
	Total	32	25	57
Jatrox-test®	Negative	21	4	25
	Positive	1	22	23
	Total	22	26	48
Gut-plus®	Negative	11	5	16
	Positive	4	10	14
	Total	15	15	30

• Accuracy depending on PPI intake

All the previous analyses were performed twice, considering all data and excluding those patients under PPI treatment. RUT and URUT (after 60 min) diagnosis was correct in 93% and 97% of patients, including only those patients where the traditional RUT was not Gut-Plus® (Table 3).

• URUT and RUT's accuracy.

Accuracy calculations were performed for RUT and URUT (at checkpoints 30 and 60 min). PPI treatment and RUT brand sub-analyses were also studied and data is shown in Table 4. URUT (at 30 and 60 min) and RUT's diagnostic successes were not significantly different (*Z*-test $p > 0.05$). McNemar tests could not demonstrate statistically significant differences

Table 2 CrossTable of Ultra Rapid Urease Test (URUT) (by time of assessment) vs. histology in the diagnosis of *Helicobacter pylori* infection.

		All Kits			Excluding Gut-Plus®		
		Histology		Total	Histology		Total
		Negative	Positive		Negative	Positive	
URUT 1 min	Negative	68	41	109	54	28	82
	Positive	2	24	26	1	21	22
	Total	70	65	135	55	49	104
URUT 5 min	Negative	67	27	94	54	17	71
	Positive	3	41	44	1	35	36
	Total	70	68	138	55	52	107
URUT 30 min	Negative	67	15	82	54	10	64
	Positive	4	53	57	2	43	45
	Total	71	68	139	56	53	109
URUT 1 h	Negative	67	10	77	54	6	60
	Positive	4	58	62	2	47	49
	Total	171	68	139	56	53	109

Table 3 CrossTable of Rapid and Ultra Rapid Urease Tests (RUT and URUT) vs. histology in the diagnosis of *Helicobacter pylori* infection in patients not taking proton pump inhibitor treatment.

		All kits			Excluding Gut-plus®		
		Histology		Total	Histology		Total
		Negative	Positive		Negative	Positive	
RUT	Negative	30	6	36	27	3	30
	Positive	3	38	41	1	30	31
	Total	33	44	77	28	33	61
URUT	Negative	32	4	36	28	1	29
	Positive	2	42	45	1	34	35
	Total	34	47	81	29	35	64

Table 4 Rapid and Ultra Rapid Urease Test's (RUT and URUT) accuracy for the diagnosis of *Helicobacter pylori* infection in all subanalyses.

		Sensitivity	Specificity	PPV	NPV	PLR	NLR
RUT	All kits	82% (75–88%)	90% (85–95%)	89% (83–94%)	84% (78–90%)	8.6 (4.0–16.4)	0.20 (0.12–0.34)
	No Gut-plus®	86% (80–93%)	94% (90–99%)	94% (89–98%)	88% (82–94%)	16 (5–47)	0.15 (0.07–0.29)
URUT	All kits	85% (79–91%)	94% (91–98%)	94% (89–98%)	87% (81–93%)	15 (6–39)	0.16 (0.09–0.28)
	No Gut-plus®	89% (83–95%)	96% (93–100%)	96% (92–100%)	90% (84–96%)	25 (6–97)	0.12 (0.06–0.25)
RUT No PPI	All kits	86% (79–94%)	91% (84–97%)	93% (87–99%)	83% (75–92%)	10 (3–28)	0.15 (0.07–0.32)
	No Gut-plus®	91% (84–98%)	96% (92–100%)	97% (92–100%)	90% (82–98%)	25 (4–175)	0.09 (0.03–0.28)
URUT 1 h No PPI	All kits	91% (85–97%)	94% (89–99%)	96% (91–100%)	89% (82–96%)	16 (4–60)	0.09 (0.04–0.24)
	No Gut-plus®	97% (93–100%)	97% (92–100%)	97% (93–100%)	97% (92–100%)	28 (4–193)	0.03 (0–0.2)

PPV: positive predictive value; NPV: negative predictive value; PLR: positive likelihood ratio; NLR: negative likelihood ratio.
95% confidence interval is shown in parentheses.

when comparing the distribution of success between RUT and URUT.

Discussion

The present study evaluated the accuracy of RUT and URUT in the diagnosis of *H. pylori* infection and showed equivalent results for RUT kits (24 h result) and Biohit®'s URUT at minutes 30 and 60.

Three RUT kits were studied; Jatrox-test® and CLO-test® offered equivalent results but Gut-plus® had significantly lower accuracy in the studied population. Although this lower accuracy may be due to a low sample size beta error, all the subsequent analyses were calculated both including and excluding patients diagnosed with Gut-plus® kit. Jatrox-test® was able to offer positive results quicker than the other two kits, although the 24 h waiting period was still needed in order to avoid false negative results.

The accuracy of Biohit®'s URUT diagnosis at 30 min was statistically equivalent to the traditionally used RUT kits. Even though the kit's manual clearly establishes the waiting period in 30 min, increasing it to one hour improved sensitivity (better than RUT) in all sub-analyses and did not reduce specificity, thus it may be recommendable to wait 60 min before checking the URUT result.

In accordance to previously published data,[1,7,8] the intake of PPI drugs the two weeks prior to endoscopy reduced the accuracy of all urease kits in our study. Therefore, the withdrawal of PPIs before endoscopy should be recommended to patients. The results of RUT (Jatrox-test® and CLO-test®) and URUT in our study in patients not taking PPI drugs were excellent, especially in the case of URUT's diagnosis after 60 min.

Finally, URUT and RUT kits' incorrect diagnosis mostly occurred in the same patients and no statistically significant differences were found when comparing the distribution of correct and incorrect diagnosis of both methods. This implies that traditional RUTs limitations regarding diagnostic results,[1,4–8] probably due to low bacterial urease activity, are not overcome by URUT.

The main limitation of this study derives from mimicking clinical practice in Spain where there is no systematic implementations of recommendations regarding biopsy collection during endoscopy which did not allow deeper analysis of our patients.

In summary, previous studies comparing diverse ultra rapid urease tests have shown that the accuracy of ultra rapid tests is equivalent to that of traditional ones.[10–15] The present study seems to indicate that the URUT version developed by Biohit® is equivalent to the standard RUT used in Spain, reaching approximately 90% sensitivity and specificity in patients naïve to eradication therapy. In general, the use

of a validated URUT, as it offers equivalent results than 24 h kits, may be recommended in order to start treatment earlier and avoid doubling visits to the outpatient clinic which would reduce overall costs in the management of *H. pylori* infection and minimize inconveniences to patients.

Conflict of interests

Dr. Gisbert has served as speaker, consultant and advisory member for or has received research funding from Almirall, Nycomed, AstraZeneca, Casen Recordati, and Allergan. Dr. McNicholl has received retribution from Allergan for formative actions. Dr. Castro-Fernandez has received retribution from Allergan for formative actions. Dr. Perez-Aísa has received retribution from Allergan and Mylan for formative actions.

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Annex. STARD checklist for reporting of studies of diagnostic accuracy

Section and Topic	Item		On page
TITLE/ABSTRACT/ KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	1
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	2
METHODS			
Participants	3	The study population: The inclusion and exclusion criteria, setting and locations where data were collected.	7
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	7
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	7
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	7
Test methods	7	The reference standard and its rationale.	
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	7
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	7-8
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	7
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	7
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	8
	13	Methods for calculating test reproducibility, if done.	
RESULTS			
Participants	14	When study was performed, including beginning and end dates of recruitment.	9

Annex (*Continued*)

Section and Topic	Item		On page
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	9
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	9 & 15
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	9
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	N/A
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	16-19
	20	Any adverse events from performing the index tests or the reference standard.	N/A
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	16-19
	22	How indeterminate results, missing data and outliers of the index tests were handled.	N/A
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	9
	24	Estimates of test reproducibility, if done.	N/A

Annex (*Continued*)

Section and Topic	Item		On page
DISCUSSION	25	Discuss the clinical applicability of the study findings.	11-12

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