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• BRIEF REPORTS •

Reliability of urinary tests for antibody to *Helicobacter pylori* in patients with pulmonary tuberculosis

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Abstract

AIM: Although the quality of currently available urinary tests for detecting antibody to *Helicobacter pylori* (*H pylori*) have been proved in some populations, the accuracy has not been studied regarding patients who suffer from pulmonary tuberculosis with multi-drug treatments. The present study was conducted to evaluate the accuracy of these urinary tests for antibody to *H pylori* in these patients.

METHODS: Serum samples from 61 inpatients with pulmonary tuberculosis were tested using enzyme immunoassay, and urine samples were assayed by enzyme-linked immunosorbent assay method (URINELISA) and immunochromatography method (RAPIRAN). Medicines prescribed to the patients were recorded for medical charts, to evaluate the influences on the results of urinary tests.

RESULTS: The sensitivity, specificity, and consistency of URINELISA against the serum test were 93.1%, 65.6%, and 78.6% respectively, and those of RAPIRAN were 86.2%, 93.7%, and 90.1% respectively, which were almost equal to the data previously reported. Prescribed medicines had little influence on the results.

CONCLUSION: The two urinary tests for detecting *H pylori* antibody have a diagnostic accuracy in patients with pulmonary tuberculosis given multiple anti-tuberculosis drugs.

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Key words: *Helicobacter pylori*; Pulmonary Tuberculosis; *Helicobacter pylori* antibody; Urinary tests

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INTRODUCTION

As the clinical importance of *Helicobacter pylori* (*H pylori*) infection in gastroduodenal disorders has increased since its discovery, the accurate diagnosis is a subject of great concern for clinicians. Currently available urinary tests for antibody to *H pylori* have proved their high diagnostic quality in certain population, but their accuracy becomes lower in patients with proteinuria or other urinary abnormalities[1-13]. On the other hand, recent reports have indicated that pulmonary tuberculosis (TB) infection has been globally re-emerging[14]. To make the diagnosis of *H pylori* is somewhat troublesome methodologically in patients with active TB, since technicians have a risk for secondary infection with TB when endoscopic methods or breath test is selected. Detection of antibody to *H pylori*, especially that in urine, seems an ideal method for screening in such cases because of not only its non-invasiveness but its safety. However, although patients treated with anti-tuberculosis drugs sometimes develop urinary abnormalities such as coloration induced by rifampicin, little information is available about the accuracy of urinary tests for *H pylori* antibody in those patients.

This study was conducted to evaluate the reliability of two commercialized tests for detecting anti-*H pylori* antibody in urine in cases where anti-tuberculosis treatments were performed for active TB.

MATERIALS AND METHODS

The study subjects were 61 inpatients (42 male, 19 female, age: 54±23 years) of the hospital attached to the Institute of Chemotherapy (Chiba, Japan) in February 2003, who had been treated with anti-tuberculosis medicines for TB for more than one month. Fasting blood and urine samples were collected as a part of the routine physical examination and discarded urine specimens were used for the purposes of this study. The serum samples were stored in freezer and the urine samples were stored in refrigerator until measurement. All the urine samples were assayed both by enzyme-linked immunosorbent assay (URINELISA, Otsuka Pharmaceutical, Tokushima, Japan) and by immunochromatography (RAPIRAN, Otsuka Pharmaceutical, Tokushima, Japan), according to the manufacturer's instructions, in a blinded fashion with reference to clinical information. Judgement of results of RAPIRAN was made by two well-trained technicians. Serum anti-*H pylori* antibody was measured using enzyme immunoassay (E-plate, Eiken, Tokyo, Japan). From medical charts, laboratory data including serum creatinine, blood urea nitrogen and urinarysis, age, gender, and medications were recorded.

The sensitivity, specificity and consistency of the urinary tests were expressed in %. Influences of prescribed medicines and urinarysis (proteinuria and occult blood) on the inconsistent results between three tests were statistically tested using Fisher's exact probability test. Differences in serum creatinine, blood urea nitrogen and age between subjects with consistent results and those without were evaluated by Mann-Whitney's U-test. The level of significance used was 0.05 in these tests.

Informed consents were obtained from the participants prior to the study.

RESULTS

All the subjects received at least two medicines against pulmonary

Table1 Cases with inconsistent results in three commercialized methods for detecting *H pylori* antibody

		Result			Urinarysis				Treatment
		U (R)	U (U)	Serum	OB	Protein	Sugar	WBC	
1	69 M	-	+	- 7.4[1]	±	±	-	+	IREP
2	79 M	-	-	+ 10.6	-	-	-	-	IRE
3	75 F	-	+	- <3	±	±	-	+++	IREP
4	55 M	-	+	- 3.3	++	+	-	+	IRE
5	68 M	-	+	- <3	+	-	-	-	IREP
6	87 M	-	+	- 4.4	-	±	-	±	IRKE
7	52 F	-	-	+ 11.3	-	-	-	-	IRE
8	64 M	-	+	- 9.8	-	-	-	-	IRK
9	59 M	-	+	+ 12.5	±	±	-	-	IRE
10	70 F	+	+	- 3.3	±	-	-	-	IREP
11	58 M	-	+	+ 12.1	-	±	-	-	IREP
12	59 M	-	+	- 4.6	±	-	-	-	IREP
13	84 M	-	+	- 5.2	±	-	-	-	THP
14	39 M	+	+	- 7.5	±	-	-	-	IRSP
15	93 F	-	+	- 7.7	++	±	-	++	IRE

[1]Values are titer of the serum antibody to *H pylori* (cutoff value: 10). U (R):RAPIRAN, U (U): URINELISA, OB: occult blood, WBC: white blood cell, I: isoniazid, R: rifampicin, E: ethambutol, P: pyrazinamide, K: kanamycin, S: streptomycin, TH: ethionamide.

TB. Fifty-seven patients received isoniazid, 48 rifampicin, 44 ethambutol, 35 streptomycin, 21 pyrazinamide, 5 kanamycin, and 2 ethionamide.

Twenty-nine of the subjects (47.5%) were positive for *H pylori* antibody in the serum test. Considering the serum test as standard, the sensitivity, specificity, and consistency of URINELISA were 93.1%, 65.6%, and 78.6%, respectively, and those of RAPIRAN were 86.2%, 93.7%, and 90.1%, respectively. Of the 61 cases, 46 showed consistent results in three methods. Differences of laboratory data between subjects with consistent results and those without were not found statistically. In addition, no influences of medications were seen between the two patient groups. Clinical characteristics of the cases with inconsistent results between serum and urine tests are shown in Table 1, which might mean that anti-tuberculosis medications had little influence on the results.

DISCUSSION

Because of the widespread prevalence of *H pylori*, simple, convenient, and non-invasive techniques are required as a tool for screening the infection. Since urinary anti-*H pylori* antibody was first detected in 1993, urine has been regarded as one of the candidates satisfactory for clinical use[1]. The urine-based enzyme-linked immunosorbent assay kit, URINELISA, and the immunochromatography method, RAPIRAN, have been proved to have a satisfactory accuracy enough to be used clinically[2-13]. For mass screening techniques, these urinary tests are apparently superior to serum tests because of the convenience and non-invasiveness. However, little information is available concerning the accuracy of these noninvasive techniques in patients with TB, and the present data seems precious.

The association of *H pylori* and TB infection remains controversial regardless of the epidemiologic similarities. Some have claimed that *H pylori* infection can be found more frequently in TB patients than in those without, and others have reported no relation between TB and *H pylori*[15-19]. Otherwise, it is clear that not a small population in the world would suffer from TB and *H pylori* infection concomitantly.

The present results indicate that both URINELISA and RAPIRAN have a good accuracy for screening the presence of anti-*H pylori* antibody also in patients treated with multiple anti-tuberculosis medicines. The specificity, sensitivity, and consistency were almost same as those already reported[1-13]. Anti-tuberculosis medications seem to have little influence on the results. Reasons of the inconsistent results remain unclear, but the results of URINELISA have a tendency to be different from the others with low serum antibody titer.

In conclusion, the commercialized two tests are reliable for detecting antibody to *H pylori* in urine and in cases with TB. Considering a risk for secondary infection, we think non-invasive, convenient and safe tests should be preferred for screening *H pylori* infection in patients with TB.

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