ORIGINAL ARTICLE

Comparative diagnostic performance of rapid urease test with the sweeping method versus tissue sampling method after *Helicobacter pylori* eradication (with video)

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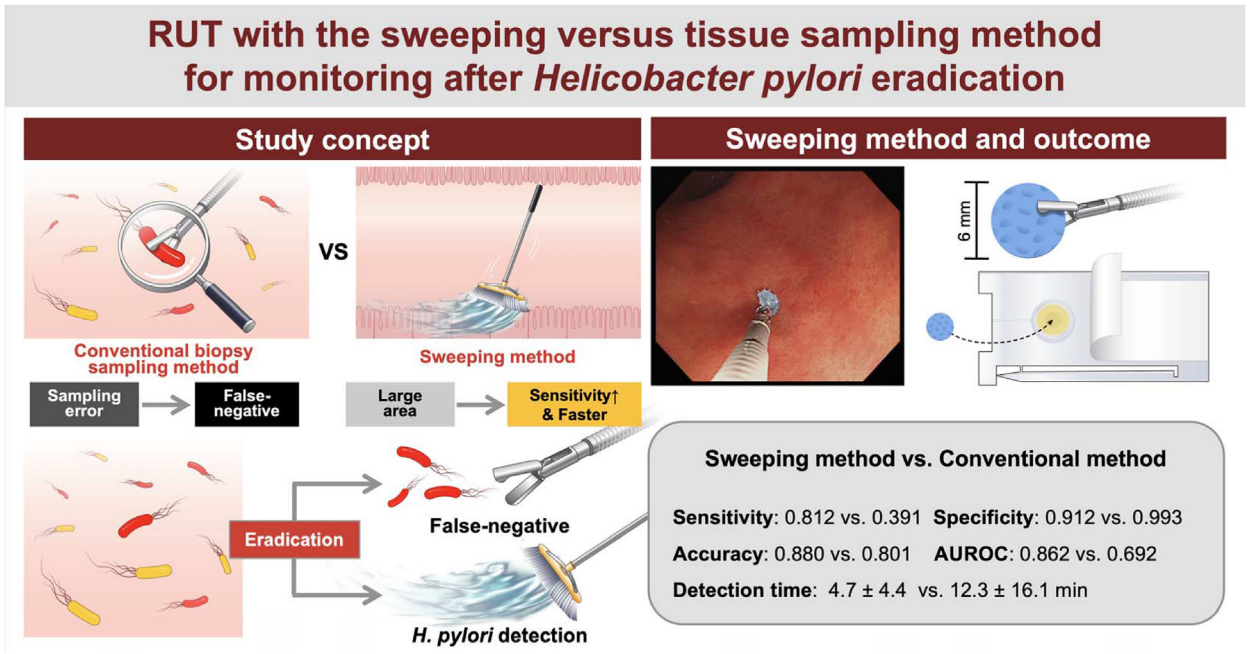
GRAPHICAL ABSTRACT



Background and Aims: The rapid urease test (RUT) is widely used to detect *Helicobacter pylori* infection; however, it is not preferred as a monitoring strategy after eradication owing to its low sensitivity. In this study, we evaluated the diagnostic performance of RUT using the sweeping method, which overcomes the limitations of conventional tissue sampling methods after eradication.

Methods: Patients who received *H pylori* eradication treatment were enrolled. Each of the sweeping and conventional methods was performed on the same patients to compare diagnostic performance. Urea breath test (UBT), histology, and polymerase chain reaction were performed to determine true infection. Logistic regression analysis was conducted to investigate reasons for discrepancies between the results of the 2 methods.

Results: In 216 patients, the eradication success rate was 68.1%, and the sensitivity and specificity of the sweeping method were 0.812 and 0.912, respectively, whereas those of the conventional method were 0.391 and 0.993, respectively ($P < .05$ for all). The area under the receiver operating characteristic curve for the sweeping method was higher than that for the conventional method (0.862 vs 0.692, $P < .001$). The mean time to *H pylori* detection for the sweeping method was 4.7 ± 4.4 minutes and 12.3 ± 16.1 minutes for the conventional method ($P < .001$). The risk for inconsistent results between the 2 methods was the highest for UBT values of 1.4‰ to 2.4‰ (odds ratio, 3.8; $P = .016$).

Conclusions: The RUT with the sweeping method could potentially replace the tissue sampling method as a test to confirm *H pylori* eradication and be an alternative option to UBT for patients requiring endoscopy. (Gastrointest Endosc 2024;■:1-10.)

(footnotes appear on last page of article)

Helicobacter pylori infection is one of the most common bacterial infections affecting more than 50% of the world's population and is associated with the development of various gastric diseases.[1-4] To eradicate *H pylori* infection, treatment with proton pump inhibitors combined with at least 2 antibiotics is recommended.[5] A 100% eradication success rate has never been attained[6]; the absence of *H pylori* infection should be confirmed via monitoring tests after eradication, such as the urea breath test (UBT), stool antigen tests, and histologic examination (if endoscopic assessment is required), which can aid in the assessment of active infection.[7] Among the invasive methods, unlike histologic examination, which requires Giemsa staining or immunohistochemical (IHC) analysis, the rapid urease test (RUT) is a simple method that provides results within 1 hour and can be conducted by examining tissues obtained during a bedside test using a commercial kit.[8] However, eradication treatment hinders the clustering of *H pylori* in the mucosa, and sampling errors caused by the heterogeneous distribution remain a major challenge, which significantly reduces the sensitivity of RUT after eradication.[9] Therefore, RUT is not a recommended monitoring test after eradication because of the high probability of false-negative results.[10]

RUT with the sweeping method performed using swab materials, which we first introduced, showed good *H pylori* detection performance by overcoming the limitations of the biopsy sampling method (ie, the conventional method).[11] The rationale for the sweeping method is as follows: first, *H pylori* is a noninvasive bacterium dwelling in the mucus layer, and tissue sampling is not required because only a mucus sample is needed for the urease test.[12,13] Second, RUT indirectly tests for the presence of urease secreted by *H pylori* instead of capturing *H pylori* to confirm the presence of bacteria.[14] Soh et al[15] demonstrated the superiority of the sweeping method, and the bacterial load observed using the swab material was 22 to 31 times higher than that observed using a tissue biopsy sample.

Based on previous results, we hypothesize that the sweeping method can overcome the limitations of the conventional method in cases where endoscopy is required after *H pylori* eradication. Therefore, to test this hypothesis, we compared the monitoring performance of our sweeping method with that of the conventional biopsy tissue sampling method in patients who received standard first-line *H pylori* eradication treatment.

METHODS

Study design and patients

In this prospective, crossover, single-center study, we included patients with *H pylori* infection who received eradication treatment and were scheduled for EGD and eradication confirmation tests at Ajou University Hospital (Suwon, Republic of Korea) between March 2019 and May 2022. The exclusion criteria were as follows: (1) age of <20 years, (2) history of *H pylori* eradication treatment, (3) history of antibiotic use within the last 6 months, and (4) severe coagulopathy. The study protocol was approved by the Institutional Review Board of Ajou University Hospital (approval no. AJOUIRB-OBS-2018-527), and all patients provided written informed consent. This study followed the Standards for Reporting of Diagnostic Accuracy.[16]

H pylori eradication treatment and confirmation test

All patients received eradication treatment consisting of a standard first-line triple regimen (standard dose of a proton pump inhibitor, amoxicillin [1 g], and clarithromycin [500 mg] twice daily) for 7 days.[17] Six tests to confirm *H pylori* eradication were performed 4 weeks after treatment completion.[17] For this study, RUT was performed using sweeping and conventional methods. The order of the 2 methods was determined using 1:1 randomization to exclude the possibility that the order of using the 2 methods could affect the outcomes (crossover setting; sweeping followed by conventional method or conventional followed by sweeping method). To confirm *H pylori* infection, UBT was performed on all patients (UbiT-IR 300, Otsuka Pharmaceutical Co Ltd, Tokyo, Japan), along with histopathology and formalin-fixed, paraffin-embedded tissue polymerase chain reaction (PCR). When there were discrepancies between the results of experiments performed using the sweeping and conventional methods, swab materials and tissue samples were retrieved from the RUT kit for additional PCR. (This protocol is referred to herein as rescue PCR.) The cutoff value of UBT was 2.5‰, as recommended by the manufacturer, and a $^{13}CO_2$ content of ≥2.5‰ was considered positive for *H pylori* detection. For histopathology (hematoxylin and eosin, Giemsa, and IHC staining), 2 tissue samples were collected from the antrum and corpus (4 cm proximal to the angulus and the middle portion of the greater curvature, respectively), and 1 tissue sample was obtained from

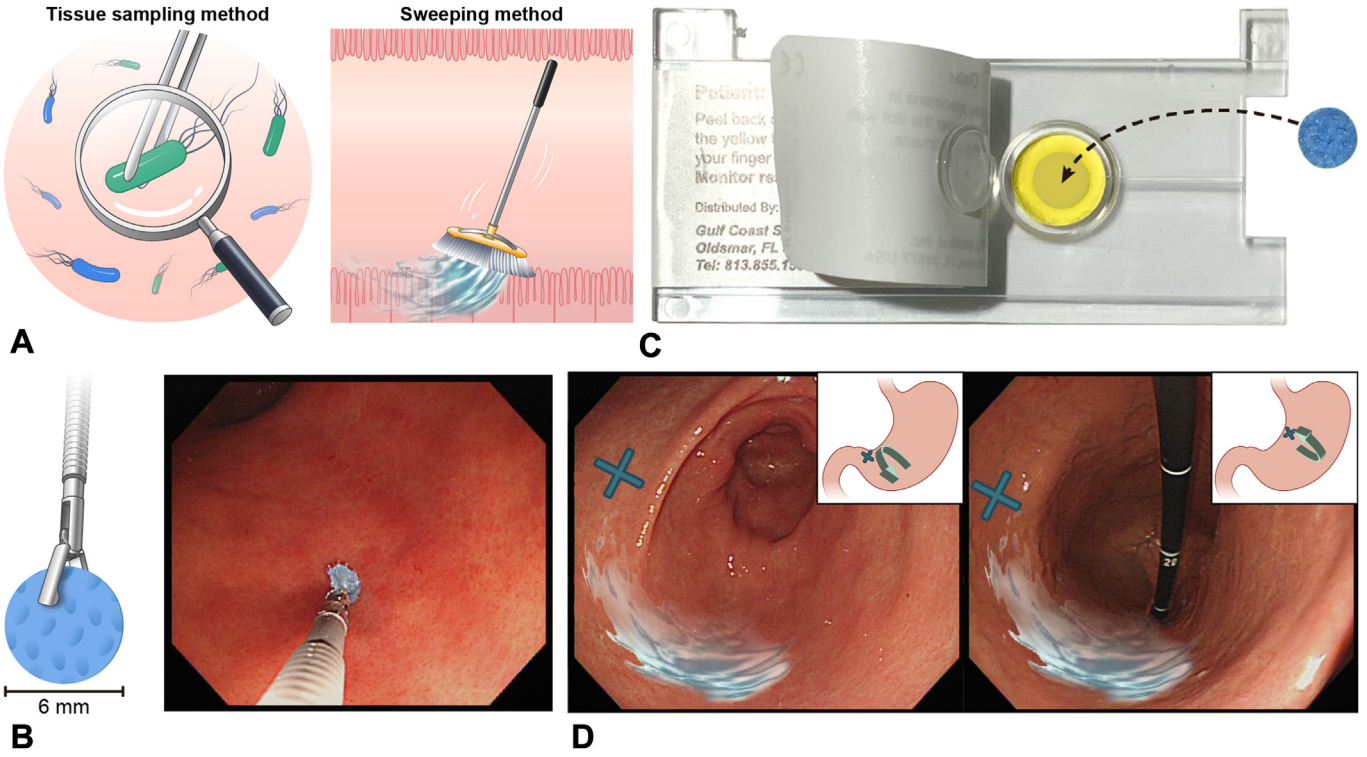


Figure 1. Study concept and process of the sweeping and conventional methods. **A,** Illustration of the study concept. **B,** Endoscopic image of the sweeping method and mimetic image of swab material. **C,** Illustration and actual image showing placement of the swab material in the rapid urease test kit. **D,** Sampling area of the sweeping and conventional tissue sampling methods in the antrum (left) and corpus (right).

the incisura angularis based on the updated Sydney system.[18] Biopsy sampling was performed at locations where there was no atrophy or metaplasia identified through endoscopy. Real-time PCR was performed using formalin-fixed, paraffin-embedded tissue blocks to analyze additional tissues for diagnosing lesions. In patients without lesions (n = 49), tissue was sampled from the normal mucosa. All tests were performed on the same day.

Rapid urease test

Sweeping method. The sweeping method we developed involves collecting the gastric mucosa using a sweeping motion where the swab material is held using forceps (Fig. 1A).[11] For the swab material (wafer), a nonwoven fabric used as a surgical or procedural drape (LIVSEN SMMS BU3, Toray Advanced Materials Korea Inc, Guri, Korea) was cut into pieces of 6 mm in diameter using a hole puncher and subsequently sterilized (Fig. 1B); these pieces fit perfectly in the grooves provided to place samples in most commercial RUT kits (Fig. 1C). Sweeping was continuously performed 10 times in the antrum and corpus (Fig. 1D and Video 1, available online at www.giejournal.org), and swab materials were placed into the grooves provided in the RUT kits (Pylo-Plus, Gulf Coast Scientific, Oldsmar, Fla). A positive RUT was determined by a change in color from yellow to red within 60 minutes of sample placement in the kit, as recommended by the manufacturer. The test kits were kept in a tray, and, while being blinded to the other test results, 2 experienced nurses determined the color change. Detection time was defined as the duration taken for an *H pylori*–positive result to be determined based on the color change observed in the RUT kit. We established this method in a previous study.[11]

Conventional tissue sampling method (conventional method). Tissue samples were collected from the antrum (anterior wall of the mid antrum) and corpus (middle portion of the greater curvature) and placed into the RUT kit. The locations from which the tissue samples were collected did not overlap with those used for the sweeping method (Fig. 1D). To maintain blindness of the results, blue-colored swab material, which was the same as the one used for the sweeping method, was placed in the kit, along with the tissue samples.

Gold standard definition for *H pylori* infection

To compare the 2 methods, we used the results of 4 tests with high sensitivity[19,20] and defined eradication failure as at least 1 positive result from the following 4 tests:

- UBT (≥2.5‰);
- Histopathologic analysis, including IHC analysis;
- formalin-fixed, paraffin-embedded tissue PCR; and
- PCR using swab materials and tissue samples in case of a discrepancy in the results (rescue PCR).

Statistical analysis

Based on our previous study,[11] the sample size was calculated to detect a difference of 0.256 between the 2 diagnostic tests, with sensitivities of 0.941 and 0.685, respectively, and a power of 80%. We used a 2-sided McNemar test with the level of significance set at 0.05. Based on the calculated sample size, 213 participants were required (including a 10% dropout rate). Continuous and categorical variables are expressed as mean (standard deviation) and number (frequency), respectively.

The times to *H pylori* detection for the sweeping and the conventional methods were compared using a *t* test. Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value were calculated, including 95% confidence intervals (CIs). The receiver operating characteristic curve was calculated with the corresponding 95% CI, and the statistical difference in the values for the area under the receiver operating characteristic curve for the 2 methods was evaluated.[21] Logistic regression models were used to examine the risk factors associated with the discrepancies between the 2 methods. Statistical analyses were conducted using SAS statistical software (SAS Institute, Cary, NC, USA), and a 2-tailed $P < .05$ was considered significant.

RESULTS

Baseline characteristics of the enrolled patients

Of the 216 patients included in this study, 67.6% (n = 146) were male; the mean age was 58.8 (standard deviation, 11.0) years; 108 (50.0%) underwent *H pylori* eradication for health care purposes (including gastric adenoma); and 48 (22.2%), 46 (21.3%), and 15 (6.9%) patients underwent *H pylori* eradication for peptic ulcers, early gastric cancer, and mucosa-associated lymphoid tissue lymphoma, respectively. In total, 119 (55.1%) patients had chronic atrophic gastritis with metaplasia, and 63 (29.2%) showed only atrophic changes (Table 1).

TABLE 1. Baseline characteristics of enrolled patients (n = 216)

Characteristics	Value
Age, y	58.8 ± 11.0
Male sex	146 (67.6)
BMI, kg/m^2	24.7 ± 3.2
Medical history	
Hypertension	87 (40.3)
Diabetes	45 (20.8)
Cerebrovascular accident	7 (3.2)
Cardiovascular disease	6 (2.8)
Reason for the eradication	
Health care for cancer prevention*	107 (49.5)
Peptic ulcer	48 (22.2)
Gastric cancer	46 (21.3)
MALT lymphoma	15 (6.9)
Diagnosis	
Gastric ulcer	37 (17.1)
Duodenal ulcer	11 (5.1)
Gastric adenoma	58 (26.9)
Early gastric cancer	46 (21.3)
MALT lymphoma	15 (6.9)
Normal	49 (22.7)
Helicobacter pylori eradication success	147 (68.1)
Atrophy	63 (29.2)
Atrophy with metaplasia	119 (55.1)

Values are n (%) or mean ± standard deviation.
BMI, Body mass index; *MALT*, mucosa-associated lymphoid tissue.
*Including gastric adenoma.

H pylori eradication success rates

The eradication success rate was 68.1% (n = 147) (Fig. 2). Of the patients with eradication failure (n = 69), *H pylori* was detected in 56 (81.2%) and 27 (39.1%) patients who underwent RUT using sweeping and conventional methods, respectively. Among those with negative test results using the conventional method (n = 42), *H pylori* was detected in 34 (81.0%) using the sweeping method. Notably, UBT, the most preferred noninvasive monitoring test, detected *H pylori* in only 13 (31.0%) patients. Therefore, the sweeping method showed a much higher *H pylori* positivity rate than UBT.

Diagnostic performance of the 2 methods

The sensitivity of the sweeping method was superior to that of the conventional method (0.812 [95% CI, 0.699-0.896] vs 0.391 [95% CI, 0.276–0.516], $P < .001$). In contrast, the specificity of the sweeping method was slightly lower than that of the conventional method (0.912 [95% CI, 0.854-0.952] vs 0.993 [95% CI, 0.963-1.000], $P = .001$). This result is attributed to the low detection capability of the conventional method owing to its low sensitivity. However, the overall accuracy of the sweeping method was higher than that of the conventional method (0.880 [95% CI 0.829-0.920] vs 0.801 [95% CI, 0.741-0.852], $P < .001$), and the area under the receiver operating characteristic curve of the sweeping method showed a better diagnostic performance than that of the conventional method (0.862 [95% CI, 0.810-0.913] vs 0.692 [95% CI, 0.634-0.751], $P < .001$) (Fig. 3 and Supplementary Table 1, available online at www.giejournal.org).

The mean detection time using the sweeping method was shorter than that using the conventional method (4.7 ± 4.4 minutes vs 12.3 ± 16.1 minutes, $P < .001$). Diagnostic performance of the sweeping method was consistent at all time points (5, 15, 30, and 60 minutes) (Table 2), and the results were determined within 10 minutes in 211 (97.7%) cases and within 5 minutes in 143 (74.5%) cases (Fig. 4).

Diagnostic performance under various conditions

RUT can show false-negative results because of sampling errors depending on the conditions.[22,23] We compared the

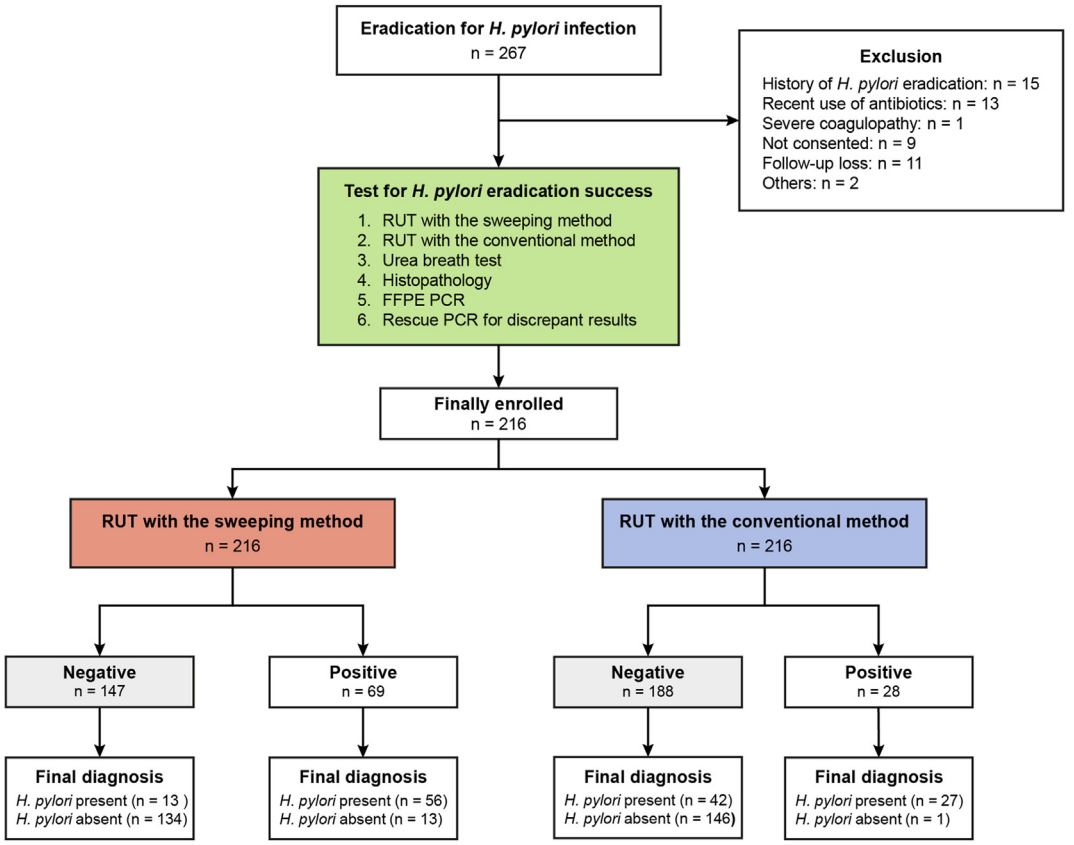


Figure 2. Flow chart prepared according to Standards for Reporting Diagnostic Accuracy (STARD) guidelines. *FFPE PCR*, Formalin-fixed, paraffin-embedded tissue polymerase chain reaction; *H.*, *Helicobacter*; *RUT*, rapid urease test.

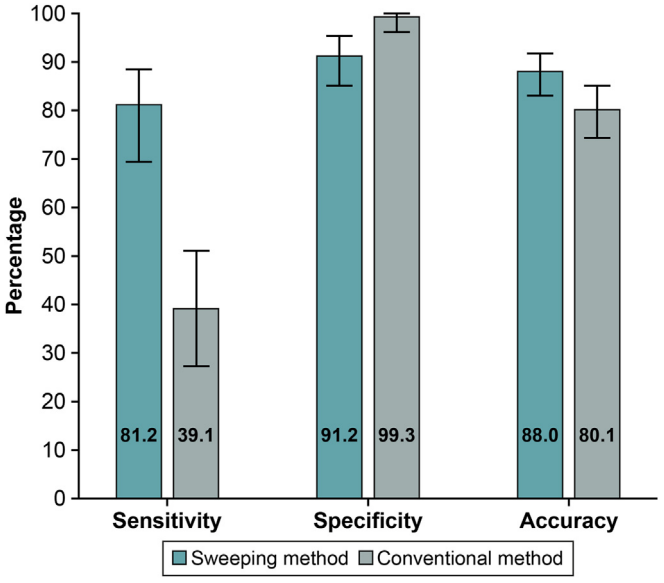


Figure 3. Sensitivity, specificity, and accuracy of the rapid urease test with the sweeping and conventional tissue sampling methods for the diagnosis of *Helicobacter pylori* after eradication treatment. All bars are represented with corresponding 95% confidence intervals.

diagnostic performance of the 2 methods for atrophy only, atrophy with metaplasia, ulcer, cancer, and health care conditions (Table 3). Under every condition, the sweeping method showed a better sensitivity than the conventional method. Especially in cases of atrophy with metaplasia (0.842 [95% CI, 0.688-0.940] vs 0.316 [95% CI, 0.175-0.487], P <.001) and cancer (0.818 [95% CI, 0.482-0.977] vs 0.273 [95% CI, 0.060-0.610], P = .014), the sensitivity of the conventional method was lower than the overall sensitivity (0.391), whereas the sensitivity of the sweeping method was significantly better than that of the conventional method under both conditions. In particular, the sweeping method showed the highest sensitivity in patients without disease among all the conditions, and this sensitivity was superior to that of the conventional method (0.878 [95% CI, 0.738-0.959] vs 0.415 [95% CI, 0.263-0.579], P < .001).

Discrepancy between results of the sweeping and conventional methods

In 51 (23.6%) cases, different results were obtained using the sweeping and conventional methods: although 46 patients showed positive results using the sweeping method, no *H pylori* was detected using the conventional method. Of these 46 patients, 30 (65. 2%) and 34 (73.9%) showed positive results for the rescue PCR (positive in swab material) and gold standard definition, respectively, demonstrating the significantly high sensitivity of the sweeping method. Logistic regression analysis was performed to understand the decrease in the sensitivity of the conventional method after

TABLE 2. Diagnostic performance of the sweeping and the conventional tissue sampling methods based on detection time

Time, min	Sensitivity	Specificity	Accuracy
Sweeping method			
≤5 (n = 203)	0.780	0.931	0.887
≤15 (n = 211)	0.800	0.918	0.882
≤30 (n = 215)	0.809	0.912	0.879
≤60 (n = 216)	0.812	0.912	0.880
Conventional method			
≤5 (n = 202)	0.250	1.000	0.792
≤15 (n = 211)	0.354	1.000	0.801
≤30 (n = 213)	0.373	1.000	0.803
≤60 (n = 216)	0.391	0.993	0.801

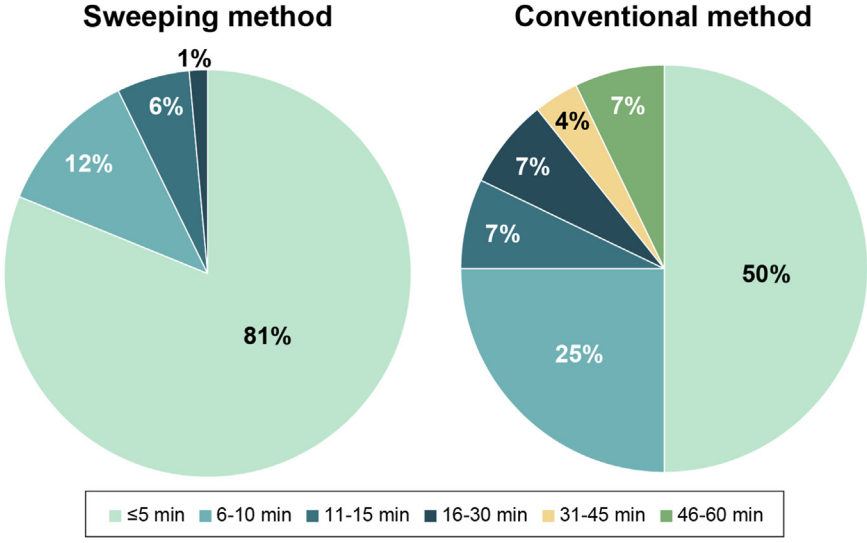


Figure 4. Comparison of the distribution of detection times of the sweeping and the conventional methods.

eradication treatment. Results showed that the UBT value was the only significant factor (Table 4). The highest odds ratio was obtained at UBT values of 1.4‰ to 2.4‰ (3.8 [95% CI, 1.286-11.355], $P = .016$), and at the value of 2.5‰ to 20‰, a 2.8-fold higher risk than that at <1.4‰ (95% CI, 1.111-7.091; $P = .029$) was observed. In other words, the discrepancy between the results obtained using the 2 methods was likely to occur around the UBT cutoff value (2.5‰). The rescue PCR results are shown in Supplementary Table 2 (available online at www.giejournal.org).

DISCUSSION

The RUT diagnostic method can detect *H pylori* by determining the presence of urease in tissues obtained from biopsy samples. Various attempts have been made to increase the accuracy of RUT, such as by refining detection kits[24-27]; increasing the number of tissue samples, thereby decreasing sampling errors[28-30]; and selecting the appropriate sampling location.[29,31,32] However, the reduction in sampling errors is limited. To overcome these issues, we attempted to obtain a high amount of urease and developed and introduced a sweeping method using swab material.[11] In that study, the sweeping method showed better diagnostic performance than the conventional method as a monitoring test after eradication. Importantly, a discrepancy between the results obtained using the 2 methods was most likely to occur near the UBT cutoff value. Overall, the sweeping method showed high sensitivity because *H pylori* could be detected even at low UBT values when using the sweeping method, unlike the conventional method.

The sensitivity of the sweeping method was superior to that of the conventional method; however, its specificity was low because cases where true infection (defined by the gold standard) were not detected earlier could now be

TABLE 3. Comparison of the diagnostic performance of the sweeping and conventional tissue sampling methods under various conditions

Performance characteristics	Sweeping, value (95% CI)	Conventional, value (95% CI)	*P* value
Atrophy only (n = 63)			
Sensitivity	0.773 (0.546-0.922)	0.591 (0.364-0.739)	.206
Specificity	0.902 (0.769-0.973)	1.000 (0.914-1.000)	.046
Accuracy	0.857 (0.764-0.933)	1.000 (0.753-1.000)	.572
PPV	0.810 (0.581-0.946)	0.820 (0.686-0.914)	.081
NPV	0.881 (0.744-0.960)	0.857 (0.746-0.933)	.301
Atrophy with metaplasia (n = 119)			
Sensitivity	0.842 (0.688-0.940)	0.316 (0.175-0.487)	<.001
Specificity	0.889 (0.800-0.945)	0.988 (0.933-1.000)	.005
Accuracy	0.874 (0.801-0.923)	0.773 (0.687-0.845)	<.001
PPV	0.781 (0.624-0.894)	0.923 (0.640-0.998)	.181
NPV	0.923 (0.840-0.971)	0.755 (0.662-0.833)	<.001
Ulcer (n = 48)			
Sensitivity	0.600 (0.262-0.878)	0.500 (0.187-0.813)	.705
Specificity	0.947 (0.823-0.994)	1.000 (0.908-1.000)	.157
Accuracy	0.875 (0.748-0.953)	0.896 (0.773-0.965)	.865
PPV	0.750 (0.349-0.968)	1.000 (0.478-1.000)	.211
NPV	0.900 (0.763-0.972)	0.884 (0.749-0.961)	.775
Cancer (n = 46)			
Sensitivity	0.818 (0.482-0.977)	0.273 (0.060-0.610)	.014
Specificity	0.914 (0.769-0.982)	1.000 (0.900-1.000)	.083
Accuracy	0.891 (0.764-0.964)	0.826 (0.686-0.922)	.005
PPV	0.750 (0.428-0.945)	1.000 (0.292-1.000)	.307
NPV	0.941 (0.803-0.993)	0.814 (0.666-0.916)	.023
Health care (n = 107)*			
Sensitivity	0.878 (0.738-0.959)	0.415 (0.263-0.579)	<.001
Specificity	0.866 (0.760-0.937)	0.985 (0.920-1.000)	.005
Accuracy	0.870 (0.792-0.927)	0.769 (0.678-0.844)	<.001
PPV	0.800 (0.654-0.904)	0.944 (0.727-0.999)	.099
NPV	0.921 (0.824-0.974)	0.733 (0.630-0.821)	<.001

CI, Confidence interval; *NPV*, negative predictive value; *PPV*, positive predictive value.
*Including gastric adenoma.

detected owing to the high sensitivity of the sweeping method (false positives). We performed PCR using all 46 swab samples that showed discrepancies in results (positive by sweeping but negative by the conventional method). The presence of *H pylori* was confirmed in 65.2% of the patients (n = 30); however, we could not detect *H pylori* using PCR in 16 cases because of the following reasons: (1) Other urease-producing bacteria, such as *Proteus mirabilis*, could cause false positives. However, because the urease activity of these bacteria involved in urease hydrolysis is weak, color changes in the RUT kit are attributed to the activity of *H pylori*.[33,34] (2) The swab material was first used in the kit to assess color change and then used for PCR; thus, the amount of mucus obtained by sweeping might have decreased. Among the 16 cases in which *H pylori* was not detected by PCR using swab materials, 10 showed negative results in the sweeping method after second-line eradication treatment, and 5 cases had negative results after third-line eradication treatment. Interestingly, 1 case still had positive test results with the sweeping method even after the third eradication therapy, but the UBT of this sample showed negative results. However, this patient tested positive in a UBT conducted 1 year later. Even though the result is a false positive because of the significantly high sensitivity of the sweeping method, patients can achieve remission using only antibiotics for eradication therapy; thus, a second eradication treatment should

TABLE 4. Logistic regression analysis for risk of discrepancy between 2 rapid urease test methods after *Helicobacter pylori* eradication: sweeping versus conventional methods

Variables	Odds ratio (95% CI)	*P* value
Age, y		
<40	Reference	
41-60	0.6 (0.135-2.471)	.459
>60	0.7 (0.156-2.926)	.601
Male sex	0.8 (0.406-0.159)	.529
BMI, kg/m^2	1.0 (0.888-1.084)	.708
Atrophy only	1.0 (0.492-1.949)	.954
Atrophy with metaplasia	1.1 (0.612-2.158)	.666
Reason of eradication		
Health care	Reference	
Disease treatment*	0.7 (0.394-1.380)	.341
Presence of gastric disease*		
Normal	Reference	
Disease	1.0 (0.463-2.039)	.938
UBT value, ‰		
<1.4	Reference	
1.4-2.4	3.8 (1.286-11.355)	.016
2.5-20	2.8 (1.111-7.091)	.029
>20	2.4 (0.816-6.950)	.112
Presence of clarithromycin resistance	2.4 (0.649-8.608)	.192
Fluid amount in the stomach		
Scanty	Reference	
Other†	0.6 (0.281-1.177)	.130
Failure at the second-line eradication treatment	0.6 (0.209-1.863)	.398

BMI, Body mass index; *CI*, confidence interval; *UBT*, urea breath test.
*Gastric disease included peptic ulcer, early gastric cancer, and mucosa-associated lymphoid tissue lymphoma.
†"Other" included minimal to moderate amounts of gastric fluid.

be administered for these patients instead of considering the possibility of the presence of other strains.

In this study, the UBT positivity rate was 18.1%, similar to the 10-year rate for the same region (17.5%).[35] The results of UBT can be assessed based on the cutoff values; however, establishing a precise cutoff point is still controversial.[36] Values of ^{13}C-UBT between 2.5‰ and 5.0‰ are considered in the "gray zone," and some researchers have suggested that the cutoff value should be decreased to 1.3‰.[37] In our study, in cases where *H pylori* was detected using UBT, using the conventional method to detect *H pylori* would be difficult if the values were low. However, if the UBT result was negative because the UBT value was slightly lower than the cutoff point, *H pylori* could be detected using the sweeping method. In 15 cases, UBT values were 1.4‰ to 2.4‰; using the conventional method, the results of these cases proved negative, whereas in 7 of these cases, the sweeping method yielded positive test results. However, we could not evaluate the possibility of false positive results caused by urease-containing organisms other than *H pylori* in the low acid conditions in this study; therefore, interpretation of the results requires caution.

The sweeping method is easily applied in clinical settings. Preparing the swab material is the only additional process to the existing RUT. Nurses can simply pass the sterilized swab material to endoscopists using forceps. Endoscopists would have almost no difficulty with sweeping motion (see Video 1). Therefore, no training is required for the sweeping method. Additionally, the sweeping method is cost-effective because, like conventional RUT, it uses the same RUT kit and biopsy forceps; only the swab material is added. We used commercially available surgical drapes, and because a large number of swabs can be made from a single drape, the additional cost per swab material is less than 1 cent. The sweeping method can achieve remarkable diagnostic performance simply by changing the method of obtaining *H pylori*.

This study has some limitations. First, this was not a randomized study. Second, this study was a single-center study in an eradication therapy setting; hence, the results may not apply to the general population. However, previous studies have confirmed the superiority of the sweeping method in the general population, including in patients with atrophy.[11,15] Third, we did not culture the samples to analyze the cause of the false-positive results of the sweeping method, especially sweeping-positive but PCR-negative results. Fourth, we did not calculate the bacterial load in the swab and tissue samples. Fifth, because the 2 methods were not compared using samples of patients with confirmed *H pylori* infection, the false positives of each method were not completely evaluated. Sixth, an appropriate material for the swabs remains to be determined. Finally, because we used UBT as a test for defining the gold standard, we did not determine the UBT cutoff value and used the manufacturer's recommended cutoff value. Any variation in the cutoff point could affect the results.

In conclusion, RUT with the sweeping method using swab materials showed high sensitivity and accuracy and rapid detection of *H pylori* after eradication. This method is cost-effective and not associated with adverse events, such as bleeding caused by biopsy sampling. Therefore, RUT with the sweeping method can replace the existing conventional method as a confirmatory test after *H pylori* eradication and is a potential alternative to UBT in patients who require endoscopic evaluation.

DISCLOSURE

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Abbreviations: CI, confidence interval; IHC, immunohistochemical; PCR, polymerase chain reaction; RUT, rapid urease test; UBT, urea breath test.

DIVERSITY, EQUITY, AND INCLUSION: We worked to ensure gender balance in the recruitment of human subjects. We worked to ensure ethnic or other types of diversity in the recruitment of human subjects. We worked to ensure that the language of the study questionnaires reflected inclusion.

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SUPPLEMENTARY TABLE 1. Diagnostic performance of the sweeping method compared with the conventional tissue sampling method for detection of *Helicobacter pylori* infection after eradication treatment

Performance characteristics	Rapid urease test (95% CI)		*P* value
	Sweeping method	Conventional method	
Sensitivity	0.812 (0.699-0.896)	0.391 (0.276-0.516)	<.001
Specificity	0.912 (0.854-0.952)	0.993 (0.963-1.000)	.001
Accuracy	0.880 (0.829-0.920)	0.801 (0.741-0.852)	<.001
PPV	0.812 (0.699-0.896)	0.964 (0.817-0.999)	.030
NPV	0.912 (0.854-0.952)	0.777 (0.710-0.834)	<.001

CI, Confidence interval; *NPV*, negative predictive value; *PPV*, positive predictive value.

SUPPLEMENTARY TABLE 2. Rescue PCR results in discrepancy between results of the sweeping and conventional methods

	Rapid urease test		Rescue PCR					
			Swab material			Tissue sample		
Number	Sweeping	Conventional	Results	A2142G mutation	A2143G mutation	Results	A2142G mutation	A2143G mutation
1	Positive	Negative	Negative	–	–	Negative	–	–
2	Positive	Negative	Negative	–	–	Negative	–	–
3	Negative	Positive	Positive	Negative	Negative	Positive	Negative	Negative
4	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
5	Positive	Negative	Negative	–	–	Negative	–	–
6	Positive	Negative	Negative	–	–	Negative	–	–
7	Positive	Negative	Negative	–	–	Negative	–	–
8	Positive	Negative	Positive	Negative	Negative	Negative	–	–
9	Positive	Negative	Negative	–	–	Negative	–	–
10	Positive	Negative	Negative	–	–	Negative	–	–
11	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
12	Positive	Negative	Negative	–	–	Negative	–	–
13	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
14	Positive	Negative	Positive	Negative	Negative	Negative	–	–
15	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
16	Positive	Negative	Positive	Negative	Positive	Positive	Negative	Positive
17	Positive	Negative	Positive	Negative	Negative	Negative	–	–
18	Negative	Positive	Negative	–	–	Positive	Negative	Negative
19	Negative	Positive	Positive	Negative	Negative	Positive	Negative	Negative
20	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
21	Positive	Negative	Positive	Negative	Negative	Negative	–	–
22	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
23	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
24	Positive	Negative	Positive	Negative	Negative	Negative	–	–
25	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
26	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
27	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
28	Positive	Negative	Negative	–	–	Negative	–	–
29	Positive	Negative	Positive	Negative	Positive	Positive	Negative	Positive
30	Positive	Negative	Negative	–	–	Negative	–	–
31	Positive	Negative	Negative	–	–	Negative	–	–
32	Positive	Negative	Positive	Negative	Positive	Positive	Negative	Positive
33	Negative	Positive	Positive	Negative	Positive	Positive	Negative	Positive
34	Positive	Negative	Negative	–	–	Negative	–	–
35	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
36	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
37	Negative	Positive	Negative	–	–	Positive	Negative	Negative
38	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
39	Positive	Negative	Negative	–	–	Negative	–	–
40	Positive	Negative	Positive	Negative	Negative	Negative	–	–
41	Positive	Negative	Positive	Negative	Positive	Positive	Negative	Positive
42	Positive	Negative	Negative	–	–	Negative	–	–
43	Positive	Negative	Negative	–	–	Negative	–	–

(*continued on the next page*)

SUPPLEMENTARY TABLE 2. Continued

	Rapid urease test		Rescue PCR					
			Swab material			Tissue sample		
Number	Sweeping	Conventional	Results	A2142G mutation	A2143G mutation	Results	A2142G mutation	A2143G mutation
44	Positive	Negative	Positive	Negative	Negative	Negative	–	–
45	Positive	Negative	Positive	Positive	Negative	Positive	Positive	Negative
46	Positive	Negative	Positive	Negative	Positive	Positive	Negative	Positive
47	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
48	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
49	Positive	Negative	Negative	–	–	Negative	–	–
50	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative
51	Positive	Negative	Positive	Negative	Negative	Negative	–	–

–, not applicable; *PCR*, Polymerase chain reaction.