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Comparison of GastroPanel® and GENEDIA® in Diagnosing *Helicobacter pylori* Infection and Gastric Lesions

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Serological tests for *Helicobacter pylori* needs local validation as the diagnostic accuracy may vary depending on the prevalence of *H. pylori*. This study examined the diagnostic performance of two ELISA, GastroPanel® (GastroPanel ELISA; Biohit Oyj) and GENEDIA® (GENEDIA® *H. pylori* ELISA, Green Cross Co.) in Korean population. One thousand seventy seven patients who visited for esophagogastroduodenoscopy between 2013 and 2023 were prospectively enrolled, and serum samples from the subjects were tested using both GastroPanel® and GENEDIA®. The two tests were compared for their diagnostic accuracy in detecting atrophic gastritis (AG), intestinal metaplasia (IM), gastric adenoma (GA), and gastric cancer (GC), and the positivity rates by age and sex were observed. There was substantial correlation (Pearson coefficient [r] = 0.512, $P < 0.001$) and agreement (Cohen's Kappa coefficient [κ] = 0.723, $P < 0.001$) between the results obtained using GastroPanel® and GENEDIA®. The test results from the two kits did not match perfectly with a discrepancy observed in approximately 16% of cases, that 67 subjects were positive only on GENEDIA® while 75 subjects were positive only on GastroPanel®. The area under receiver operating characteristic curve for AG, IM, GA, and GC using GastroPanel® were 0.666, 0.635, 0.540, and 0.575, while the results tested using GENEDIA® were 0.649, 0.604, 0.553, and 0.555, respectively, without significant difference between the two results. GastroPanel® and GENEDIA® showed similar performance in terms of diagnostic accuracy; but the test results did not match perfectly. A large-scale validation study in Koreans is needed.

Key Words Helicobacter pylori, Serology, Enzyme-linked immunosorbent assay, Diagnosis

INTRODUCTION

Serological tests for diagnosing *Helicobacter pylori* infection measure the immune response to *H. pylori* by detecting antibodies against the bacteria, specifically immunoglobulin (Ig) G. They are relatively inexpensive, fast, and simple, and has the advantage of causing less discomfort to the patient as it does not require endoscopy. Therefore, such non-invasive testinh methods are useful for diagnosing *H. pylori* infection in children or for epidemiological studies involving large populations [1,2]. Additionally, serological tests are less likely to produce false-negative results in cases involving structural changes to the gastric mucosa, proton pump inhibitor use, or ulcers with active bleeding [3,4].

In South Korea, serological tests include bacterial agglutination, complement fixation, indirect immunofluorescence test, and immunoassay, depending on the antibody measurement method [2], and among immunoassay techniques, enzyme immunoassay, ELISA, radioimmunoassay, and chemiluminescent immunoassay are commonly used, with ELISA being the most widely utilized method [2,5,6]. GENEDIA® *H. pylori* ELISA (Green Cross Co.) is a method that detects anti-*H. pylori* IgG antibodies (HpIgG) in serum using two strains isolated from Korean patients with chronic gastritis (MBRIHP 2) and duodenal ulcers (MBRIHP 8), and processed by ultrasound [2]. The diagnostic performance of GENEDIA®

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has been established. In a study comparing GENEDIA® with culture alone or both rapid urease test and culture being positive, it showed a sensitivity of 97.8% and specificity of 92% [7]. In another study comparing GENEDIA® with tissue biopsy (hematoxylin and eosin, Giemsa stain), the results showed sensitivity of 96.2%, specificity of 56.8%, positive predictive value of 78.9%, and negative predictive value of 90.0% [8].

Recently, GastroPanel®, an ELISA-based biomarker assay panel, was introduced in Europe [9]. The test kit is composed of ELISA of pepsinogen I (PG I), PG II and gastrin-17 combined with an ELISA assay of HpIgG, all being measured from the same serum/plasma sample [10]. GastroPanel® has been introduced as a method to quickly and accurately diagnose the condition of the gastric mucosa and the presence of *H. pylori* infection with a single blood test. Its effectiveness in diagnosing high-risk lesions for gastric cancer (GC) and *H. pylori* infection has been partially demonstrated through a number studies [11,12], and a study comparing GastroPanel® HpIgG with tissue biopsy results reported a diagnostic agreement rate of 91% (91/100) [13]. However, most of the studies have been conducted in Europe, and there have not yet been large-scale validation studies using this diagnostic kit in South Korea. Because the accuracy of serological tests depends on the antigen used in commercial kit and the prevalence rate of specific *H. pylori* strains employed as the source of antigen, proper antigens, either local strains or pooling antigens from strains of different groups, and reliable cutoff value of serological test should be validated locally [1].

Considering this, we aimed to compare the diagnostic accuracy of *H. pylori* infection using GastroPanel® and GENEDIA® kits on the same sample. Additionally, we sought to compare the positivity rates of HpIgG by age and sex, as well as the diagnostic accuracy of gastric mucosal lesions such as atrophic gastritis (AG), intestinal metaplasia (IM), gastric adenoma (GA), and GC using each kit.

MATERIALS AND METHODS

Study participants

A total of 1,077 patients who visited for upper endoscopy between June 2013 and May 2023 were prospectively enrolled. The medical histories of the participants were reviewed using electronic medical record, and subjects with postgastrectomy status, those requiring continuous medication due to chronic conditions, or those have taken acid-suppressing drugs such as proton-pump inhibitors within the last six months were excluded.

The study protocol was reviewed and approved by the Institutional Review Board of the Seoul National University Bundang Hospital (B-2403-889-303), and written informed consent was obtained from all the participants (B-0602-030-001, B-0903-071-001, B-1012-117-013, and B-1103-123-004). There were no potential conflicts of interest regarding the use of commercial kits, and the study design, data collection, analysis, and manuscript preparation were conducted entirely at the authors' discretion.

Serologic and endoscopic testing for *H. pylori*

An existing study by our team was referred to for the acquisition of blood and tissue samples and measurement methods [14]. Briefly, fasting serum samples were collected from all the participants at the time of enrollment. The samples were centrifuged immediately at 4°C and stored at –80°C until required. Serum HpIgG was measured using GENEDIA® (GENEDIA *H. pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits.

To diagnose *H. pylori* infection, a rapid urease test (CLO test; Delta West) was also performed. One specimen from the lesser curvature of the antrum and one specimen from the lesser curvature of the mid-body were subjected to the CLOtest. In addition, two biopsy specimens from the antrum (one from the greater curvature and one from the lesser curvature) and two from the body (one from the greater curvature and one from the lesser curvature) were taken during the endoscopy and fixed in formalin, and the degree of inflammatory cell infiltration, AG, and IM (all determined by hematoxylin and eosin staining), and the presence of *H. pylori* (by modified Giemsa staining) were determined. The histological features of the gastric mucosa were recorded using the updated Sydney system scores (0 = none, 1 = slight, 2 = moderate, and 3 = marked). Additionally, history of *H. pylori* eradication was investigated through medical history taking.

Outcome assessment and statistical analysis

As mentioned, the primary outcome of this study was the comparison of diagnostic accuracy for *H. pylori* infection between the GastroPanel® and GENEDIA® kits. The positivity rates of HpIgG by age and sex were observed, and the diagnostic accuracy of gastric mucosal lesions such as AG, IM, GA, and GC using each kit was compared additionally.

All statistical analyses were performed using SPSS software (version 25.0; IBM Corp.). Student's *t*-test or a paired *t*-test was used to compare the two groups, and analysis of variance was used to compare multiple groups. Correlations between the histological and serological features and between the two kits were analyzed using the Spearman correlation test. The sensitivities and specificities of the two kits were calculated and compared using receiver operating characteristic (ROC) curves. The effects of *H. pylori* infection and PG I/II ratio on the risk of GC were calculated using multivariate logistic regression, and expressed as ORs and 95% CI. Statistical significance was set at *P*-values of < 0.05.

RESULTS

Study participation and demographics

Baseline characteristics of the enrolled patients are shown in Table 1. There were 652 (60.5%) males and 425 (39.5%)

females, with an average age of 58.01 years. The study participants included 552 (51.3%) normal controls without dysplastic lesions, and 166 (15.4%) and 359 (33.3%) with histologically confirmed GA or GC, respectively. In the *H. pylori* seropositive group by GENEDIA®, the proportion of males, individuals with a history of alcohol consumption or smoking was higher, and the proportion of dysplastic lesions such as GA or GC was significantly higher compared to the *H. pylori* seronegative group. In the comparison between GENEDIA® and GastroPanel®, 86.8% of the total subjects showed concordant results, while 13.2% showed discordant results. That is, 67 (6.2%) were positive only in GENEDIA®, while 75 (7.0%) were positive only in GastroPanel®.

Comparison of GENEDIA® and GastroPanel® on prediction for specific factors

When analyzing the concordance and correlation between the results of the two kits, the Cohen's Kappa coefficient was 0.723 ($P < 0.001$), and Pearson's r was 0.512, showing substantial correlation and agreement.

HpIgG titer on GENEDIA® and GastroPanel® according to clinicopathological factors was compared (Table 2). As results, the HpIgG levels were statistically significantly higher in individuals with AG, IM, and gastric ulcers compared to those without these conditions on both GENEDIA® and GastroPanel®. In contrast, HpIgG levels were significantly higher in individuals with duodenal ulcers compared to those without in the case of GENEDIA®, whereas no such difference was observed with GastroPanel®. In individuals with gastric dysplastic lesions, HpIgG levels were higher in those with GA or GC compared to the control group, and there was no significant difference between the GA group and the GC group when tested with GENEDIA®. On the other hand, there was a tendency for HpIgG levels to increase in the order of control, GA, and GC group when measured with GastroPanel®. When analyzed by age, both kits showed the highest HpIgG levels in the 40 to 69 age group. When analyzed by sex, GENEDIA® showed a tendency for higher levels in males, but this was not statistically significant, whereas HpIgG levels were significantly higher in males on GastroPanel®.

Comparison of GENEDIA® and GastroPanel® in the diagnosis of gastric lesions

The diagnostic accuracy of GENEDIA® and GastroPanel® in gastric lesions was compared using ROC curve (Fig. 1, Table 3). The areas under the curve (AUCs) for GENEDIA® in diagnosing AG, IM, GA, and GC were 0.649, 0.604, 0.553, and 0.555, respectively, with the optimal cutoff values being

Table 1. Basic characteristics of study subjects

Variable	Total (n = 1,077)	*Helicobacter pylori* seropositive by GENEDIA® (n = 651)	*H. pylori* seronegative by GENEDIA® (n = 426)	*P*-value
Sex				< 0.001
Male	652 (60.5)	428 (65.7)	224 (52.6)	
Female	425 (39.5)	223 (34.3)	202 (47.4)	
Age (yr)	58.01 ± 13.25	58.25 ± 12.38	57.68 ± 14.50	0.500
Smoking				0.022
Never	476 (44.6)	267 (41.5)	209 (49.4)	
Ex-smoker	221 (20.7)	147 (22.8)	74 (17.5)	
Current smoker	370 (34.7)	230 (35.7)	140 (33.1)	
Alcohol drinking				0.009
Never	588 (55.2)	336 (52.3)	252 (59.7)	
Ex-drinker	316 (29.7)	213 (33.1)	103 (24.4)	
Current drinker	161 (15.1)	94 (14.6)	67 (15.9)	
Previous *H. pylori* eradication history				0.106
No	886 (85.2)	550 (86.6)	336 (83.0)	
Yes	154 (14.8)	85 (13.4)	69 (17.0)	
Endoscopic findings				< 0.001
Normal control	327 (30.4)	137 (21.1)	190 (44.6)	
Duodenal ulcer	87 (8.1)	64 (9.8)	23 (5.4)	
Gastric ulcer	138 (12.8)	92 (14.1)	46 (10.8)	
Gastric adenoma	166 (15.4)	119 (18.3)	47 (11.0)	
Gastric cancer	359 (33.3)	239 (36.7)	120 (28.2)	
H. pylori serology by GastroPanel®				< 0.001
Negative	418 (38.8)	67 (10.3)	351 (82.4)	
Positive	659 (61.2)	584 (89.7)	75 (17.6)	

Values are presented as number (%) or mean ± SD. Values are measured using. GENEDIA® (GENEDIA *H. pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits.

Table 2. Comparison of titer of GENEDIA® and GastroPanel® on prediction for specific factors

Variable	HpIgG titer on GENEDIA® (OD)	*P*-value	HpIgG titer on GastroPanel® (EIU)	*P*-value
Atrophic gastritis		< 0.001		< 0.001
Present	1.34 ± 1.01		212.29 ± 405.36	
Absent	0.86 ± 1.00		107.13 ± 302.80	
Intestinal metaplasia		< 0.001		< 0.001
Present	1.26 ± 1.01		201.96 ± 408.76	
Absent	0.96 ± 1.03		113.05 ± 290.91	
Gastric ulcer		0.044		0.033
Present	1.29 ± 1.08		226.27 ± 419.69	
Absent	1.09 ± 1.06		145.64 ± 350.09	
Duodenal ulcer		0.003		0.708
Present	1.43 ± 1.02		145.20 ± 270.02	
Absent	1.08 ± 1.06		156.93 ± 367.55	
Gastric dysplastic lesion		0.005		0.029
Control	1.01 ± 1.07		129.93 ± 313.03	
Adenoma	1.22 ± 1.01		157.72 ± 336.97	
Cancer	1.22 ± 1.06		194.84 ± 429.78	
Age (yr)		0.008		0.093
< 40	0.91 ± 1.05		96.43 ± 249.67	
40-69	1.18 ± 1.06		170.08 ± 389.41	
≥ 70	0.99 ± 1.07		137.04 ± 294.39	
Sex		0.156		< 0.001
Male	1.15 ± 1.02		192.95 ± 413.16	
Female	1.05 ± 1.13		98.93 ± 249.38	

Values are presented as mean ± SD. Values are measured using GENEDIA® (GENEDIA *Helicobacter pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits. HpIgG, anti-*H. pylori* antibody immunoglobulin G; OD, optical density; EIU, enzyme-immunosorbent units.

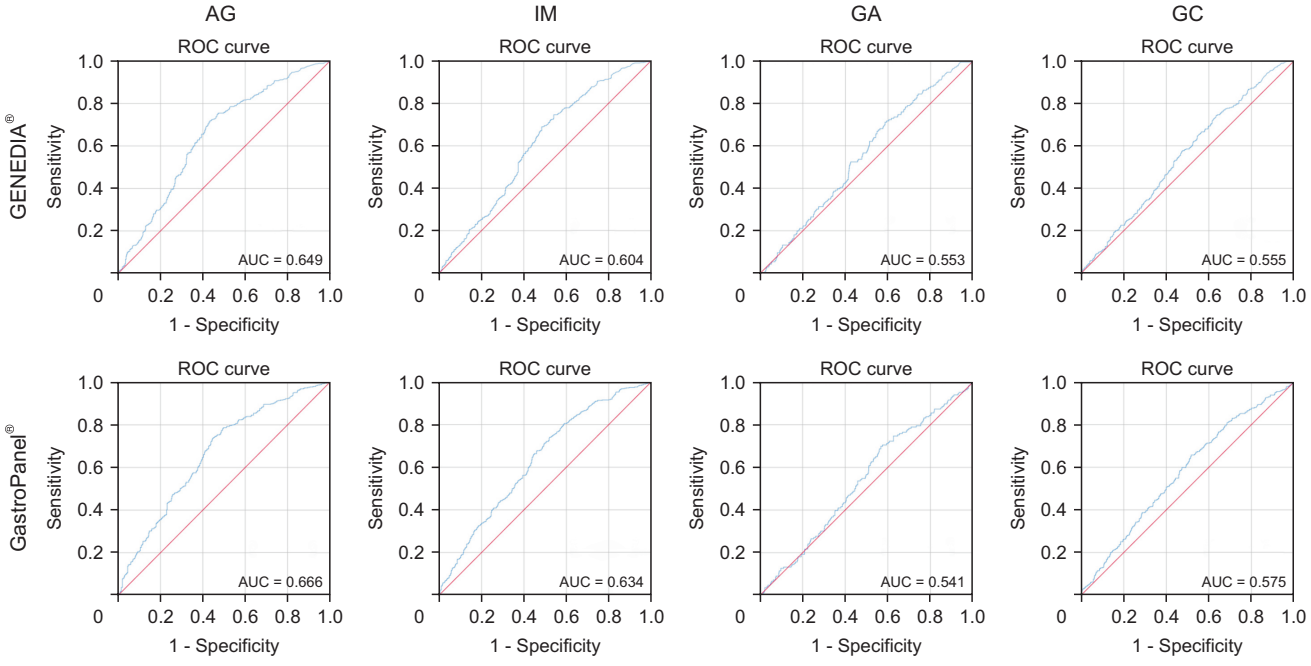

Figure 1. The diagnostic accuracy of GENEDIA® (GENEDIA® *Helicobacter pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) in gastric lesions was compared using ROC curve. AG, atrophic gastritis; IM, intestinal metaplasia; GA, gastric adenoma; GC, gastric cancer; ROC, receiver operating characteristic; AUC, area under the curve.

0.46, 0.30, 0.40, and 0.21. For GastroPanel®, the AUCs for diagnosing AG, IM, GA, and GC were 0.666, 0.634, 0.541, and 0.575, respectively, with the optimal cutoff values being 18.31, 17.53, 18.35, and 19.33. When comparing the two kits, there was no statistically significant difference, but GastroPanel® showed slightly higher sensitivity and specificity than GENEDIA®.

Table 3. Comparison of GENEDIA® and GastroPanel® in the diagnosis of gastric diseases

Variable	GENEDIA®	GastroPanel®
Atrophic gastritis		
AUC	0.649	0.666
P-value	< 0.001	< 0.001
HpIgG cutoff[a]	0.46	18.31
Sensitivity (%)	72	74
Specificity (%)	57	55
Intestinal metaplasia		
AUC	0.604	0.634
P-value	< 0.001	< 0.001
HpIgG cutoff[a]	0.30	17.53
Sensitivity (%)	75	74
Specificity (%)	46	48
Gastric adenoma		
AUC	0.553	0.541
P-value	0.030	0.097
HpIgG cutoff[a]	0.40	18.35
Sensitivity (%)	71	70
Specificity (%)	41	43
Gastric cancer		
AUC	0.555	0.575
P-value	0.003	< 0.001
HpIgG cutoff[a]	0.21	19.33
Sensitivity (%)	74	66
Specificity (%)	36	48

Values are measured using GENEDIA® (GENEDIA *Helicobacter pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits. HpIgG, anti-*H. pylori* antibody immunoglobulin G; AUC, area under curve. [a]Optical density for GENEDIA®; enzyme-immunosorbent units for GastroPanel®.

HpIgG positivity rates by age and sex

The HpIgG positivity rates by age and sex were analyzed (Table 4). The results showed that males had higher HpIgG positivity rates compared to females across all age groups in both kits, and the highest positivity rates were observed in the 40 to 69 age group for both sexes. The results from the two kits were similar for individuals under 40 and those aged 40 to 69, while some differences were observed between the two kits in males aged 70 and above, that the HpIgG positivity rate was higher with GastroPanel® compared to GENEDIA® in the group of males aged 70 and older.

Subgroup analysis of discrepancy cases

As previously mentioned, a total of 142 discrepancy cases were observed: 67 cases were positive only in the GENEDIA® test, while 75 cases were positive only in the GastroPanel® test (Table 5). An analysis of such discrepancy between the two kits revealed that individuals in the discrepant group were more likely to have a history of prior *H. pylori* eradication treatment, had less advanced gastritis such as AG and IM, and had fewer lesions such as GA and GC compared to cases where both kits showed positive results. When comparing HpIgG titers between groups, the discrepant group showed values lower than the positive group but higher than the negative group, that values close to the cutoff thresholds (0.4 optical density for GENEDIA®, and 17.8 enzyme-immunosorbent units [EIU] for GastroPanel®, respectively).

DISCUSSION

In this study, we compared the diagnostic accuracy of *H. pylori* infection and gastric mucosal lesions including AG, IM, GA, and GC using GastroPanel® and GENEDIA® kits, and compared the positivity rates of HpIgG by age and sex additionally. GastroPanel® and GENEDIA® kits showed substantial correlation and agreement, but the test results from

Table 4. Anti-*Helicobacter pylori* antibody immunoglobulin G positivity rates by age and sex

Variable		Total population		Male		Female	
		Positive	Negative	Positive	Negative	Positive	Negative
GENEDIA®	Total	651 (60.4)	426 (39.6)	428 (65.6)	224 (34.4)	223 (52.5)	202 (47.5)
	Age (yr)						
	< 40	50 (45.5)	60 (54.5)	31 (58.5)	22 (41.5)	19 (33.3)	38 (66.7)
	40-69	483 (64.2)	270 (35.8)	318 (69.3)	142 (30.7)	165 (56.3)	128 (43.7)
	≥ 70	118 (55.1)	96 (44.9)	79 (56.8)	60 (43.2)	39 (52.0)	36 (48.0)
GastroPanel®	Total	659 (61.2)	418 (38.8)	442 (67.8)	210 (32.2)	217 (51.1)	208 (48.9)
	Age (yr)						
	< 40	49 (44.5)	61 (55.5)	30 (56.6)	23 (43.4)	19 (33.3)	38 (66.7)
	40-69	479 (63.7)	274 (36.3)	321 (69.9)	139 (30.1)	158 (53.9)	135 (46.1)
	≥ 70	131 (63.7)	83 (38.8)	91 (65.5)	48 (34.5)	40 (53.3)	35 (46.7)

Values are presented as number (%). Values are measured using GENEDIA® (GENEDIA *Helicobacter pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits.

Table 5. Subgroup analysis of discrepancy cases

Variable	*Helicobacter pylori* seropositive by GENEDIA®		*H. pylori* seronegative by GENEDIA®		*P*-value
	H. pylori seropositive by GastroPanel® (n = 584)	*H. pylori* seronegative by GastroPanel® (n = 67)	*H. pylori* seropositive by GastroPanel® (n = 75)	*H. pylori* seronegative by GastroPanel® (n = 350)	
Age (yr)	58.15 ± 12.43	59.01 ± 11.97	62.09 ± 12.63	56.72 ± 14.70	0.012
Sex					< 0.001
Male	389 (66.6)	39 (58.2)	53 (70.7)	171 (48.7)	
Female	195 (33.4)	28 (41.8)	22 (29.3)	179 (51.3)	
Atrophic gastritis					< 0.001
Present	314 (65.4)	25 (52.1)	30 (51.7)	85 (31.5)	
Absent	166 (34.6)	23 (47.9)	28 (48.3)	185 (68.5)	
Intestinal metaplasia					< 0.001
Present	337 (63.8)	26 (48.1)	32 (53.3)	114 (39.2)	
Absent	191 (36.2)	28 (51.9)	28 (46.7)	177 (60.8)	
Gastric adenoma					0.010
Present	107 (18.3)	12 (17.9)	11 (14.7)	36 (10.3)	
Absent	477 (81.7)	55 (82.1)	64 (85.3)	315 (89.7)	
Gastric cancer					0.002
Present	222 (38.0)	17 (25.4)	26 (34.7)	94 (26.8)	
Absent	362 (62.0)	50 (74.6)	49 (65.3)	257 (73.2)	
Previous history of *H. pylori* eradication					< 0.001
Present	68 (11.9)	17 (27.0)	19 (27.1)	50 (14.9)	
Absent	504 (88.1)	46 (73.0)	51 (72.9)	285 (85.1)	
HpIgG titer on GENEDIA® (OD)	1.88 ± 0.84	0.80 ± 0.52	0.19 ± 0.11	0.09 ± 0.09	< 0.001
HpIgG titer on GastroPanel® (EIU)	272.60 ± 458.09	16.41 ± 0.82	27.42 ± 20.17	15.65 ± 0.73	< 0.001

Values are presented as number (%) or mean ± SD. Values are measured using GENEDIA® (GENEDIA *H. pylori* ELISA, Green Cross Co.) and GastroPanel® (GastroPanel ELISA, Biohit Oyj) kits. HpIgG, anti-*H. pylori* immunoglobulin G antibodies; OD, optical density; EIU, enzyme-immunosorbent units.

the two kits did not match perfectly. In the diagnosis of gastric mucosal lesions using HpIgG, GastroPanel® demonstrated noninferior results compared to GENEDIA®. In the analysis of the HpIgG positivity rates by age and sex, males had higher HpIgG positivity rates compared to females across all age groups in both kits, and the highest positivity rates were observed in the 40 to 69 age group for both sexes. However, the HpIgG positivity rate was higher with GastroPanel® compared to GENEDIA® in males aged 70 and older. In those discrepant cases, the prevalence of AG and IM was relatively low, whereas the prevalence of prior *H. pylori* eradication treatment history was relatively high.

As mentioned earlier, HpIgG titer testing can be used to assess the density of colonized *H. pylori* [15,16], the possibility of reinfection and the success of eradication therapy [17-19], and the presence and progression of histological gastritis [20]. Recent reports also suggest that it is associated with the risk of GC [21] and can be useful for early screening of high-risk patients [22]. To the best of our knowledge, this study is the first to validate the seroprevalence of *H. pylori* using the GastroPanel® kit in Korea. In this study, we were able to confirm the established characteristics of HpIgG using the GastroPanel® kit, such as an increased positivity rate in males and the elderly, as well as a higher positivity rate in cases with gastric mucosal lesions like AG or IM [22]. Additionally, the GastroPanel® kit demonstrated substantial correlation and agreement, and it showed comparable diagnostic accuracy in identifying gastric mucosal lesions compared to the GENEDIA® kit, although it did not achieve high diagnostic accuracy enough to be used alone. The GENEDIA® kit, used as a comparator in this study, is widely utilized in Korea and has been validated in a number of studies including nationwide multicenter study on *H. pylori* seroprevalence [23-26].

It should be noted that the test results from the two kits were not entirely consistent. As mentioned, the rate of discrepancies was higher in individuals without AG or IM, and with a prior history of *H. pylori* eradication treatment, and in males aged 70 years or older. Nevertheless, neither kit showed a pronounced tendency for false positives or false negatives, and the number of subjects with GastroPanel® positive and GENEDIA® negative results was similar to those with GastroPanel® negative and GENEDIA® positive results. Although there are no existing studies directly comparing these two kits, a Korean study that compared GENEDIA® with other ELISA HpIgG kits reported a discrepancy rate of 19% (18/96) [27]. The study interpreted these discrepancies as being related to the differences in the cutoff values and interpretation criteria for each kit. To account for the potential

errors of GastroPanel®, we conducted additional analyses using cutoff values identified from the ROC curve for AG, IM, GA, and GC, in addition to the manufacturer's recommended cutoff value (17.8 EIU). Still, no significant differences were observed. Moreover, a study that compared GastroPanel® HpIgG with histology suggested that the uneven distribution of *H. pylori*, specifically the different *H. pylori*-prevalence in the antrum and corpus, could potentially impact the performance of HpIgG ELISA [13].

An analysis of the 142 cases with discrepant results between the two kits revealed that individuals in the discrepant group were more likely to have a history of prior *H. pylori* eradication treatment, had less advanced gastritis such as AG and IM, and had fewer lesions such as GA and GC compared to cases where both kits showed positive results. When comparing HpIgG titers across groups, most individuals in the discrepant group had titers close to the cutoff values. Based on this, it can be inferred that the discrepancy may be due to a decrease in HpIgG titers over time following *H. pylori* eradication treatment, leading to a positive result in only one of the kits. Another consideration is, GastroPanel® is a kit that has not yet been validated in Korea while GENEDIA® is a kit developed using *H. pylori* strains isolated from Korean patients. Therefore, the discrepancies may be related to the strains used rather than the cutoff value. Additional analysis considering factors such as the time elapsed after *H. pylori* eradication and the presence of antibiotic-resistant strains would be necessary to further explore these issues.

In the analysis by age and sex, both kits showed the highest HpIgG positivity rate in the 40 to 69 age group, and the positivity rate was significantly higher in males compared to females across all age ranges. In a recent nationwide multicenter study in Korea, the *H. pylori* seroprevalence decreased from 66.9% in 1998 to 51.0% in 2015, and the seroprevalence was reported as 54.1% in males and 48.8% in females in 2015 [28]. In this study, the HpIgG positivity rates were 60.4% for GENEDIA® and 61.2% for GastroPanel® in total population, 65.6% for GENEDIA® and 67.8% for GastroPanel® for males, and 52.5% for GENEDIA® and 51.1% for GastroPanel® for females. These higher rates, especially in males, are likely due to the inclusion of a significant number of subjects with gastric mucosal lesions such as AG, IM, GA, and GC, which may not be representative of the general population. Nonetheless, the higher HpIgG positivity rates in males and older individuals align with previous studies [29,30], and this finding may be meaningful in confirming the accuracy of the GastroPanel® kit.

Our present study has several limitations. First, in comparing the GastroPanel®, the GENEDIA® kit was used instead of histology, as endoscopic biopsy for *H. pylori* diagnosis was not performed on all patients. However, as mentioned earlier, GENEDIA® is a kit developed using *H. pylori* strains isolated from Korean patients and has been validated in a number of Korean studies [15-18], confirming its reliability. Through this study, we were able to confirm its noninferiority. Second, this study was conducted on patients visiting a tertiary medical institution, rather than a large-scale health screening cohort, so the characteristics of the study participants may differ from those of the general population. The exact incidence of GA is difficult to determine, but the reported incidence of GC in Korea in 2023 was approximately 63 per 100,000 males and 32 per 100,000 females, with an overall rate of about 48 per 100,000 [31]. This shows a significant difference from the characteristics of the study population. That is, the results of this study were analyzed in a group with a very high prevalence of GA and GC. Therefore, to apply these findings to screening, it may be necessary to adjust the cutoff value to achieve higher specificity, and additional research in general health check-up populations is needed. Third, although the possibility of discrepancies due to time elapsed after *H. pylori* eradication was suggested, this study did not analyze changes over time after *H. pylori* eradication treatment. Additionally, the possibility that *H. pylori* strains may have affected diagnostic accuracy cannot be excluded. Therefore, for cases with discrepant results, it may be necessary to identify the *H. pylori* strains of the respective patients. However, our study did not include such analyses.

In conclusion, GastroPanel® and GENEDIA® showed similar performance in terms of diagnostic accuracy though the test results from the two kits did not match perfectly. A large-scale validation study in Koreans is needed.

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CONFLICTS OF INTEREST

No potential conflicts of interest were disclosed.

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