Validation Of Kyoto Classification Of Gastritis On Magnetic Controlled Capsule Endoscope

Sun Xi

Chinese PLA General Hospital

Jing Liu

Chinese PLA General Hospital

Wu Lili

Chinese PLA General Hospital

Wang Ming

Chinese PLA General Hospital

Wang Zhiqiang (✉ wzq301@263.net)

Chinese PLA General Hospital

Jin Peng

Chinese PLA General Hospital

Tingting Li

Chinese PLA General Hospital

Jun Li

Chinese PLA General Hospital

Research Article

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Abstract

Backgrounds: Previous studies showed that Kyoto classification of gastritis could accurately predict *H. pylori* infection status on conventional gastroscope. The aim of this study was to testify whether Kyoto classification of gastritis applies well on magnetic controlled capsule endoscopy (MCCE).

Methods: This study included two phases, both of which were basically a group of diagnostic tests. In phase one which included 35 participants who had undergone both conventional gastroscope and MCCE, we testified whether major findings documented in Kyoto classification of gastritis could be well recognized on MCCE. Then, in phase two, we consecutively recruited 227 participants who had undergone both MCCE and urea breath test (UBT). The diagnosis of *H. pylori* infection status was independently made by 2 physicians who were blinded to UBT results and well versed in Kyoto classification of gastritis after reviewing MCCE images.

Results: In phase one, all of the 10 findings selected from Kyoto classification of gastritis could be well recognized on MCCE, when findings on conventional gastroscope were used as the gold standard, the overall diagnostic accuracy, sensitivity and specificity were 96.6%, 84.7% and 100.0% respectively. In phase two, MCCE's overall diagnostic accuracy on *H. pylori* infection status was 80.2%. The sensitivity, specificity and diagnostic odds ratio (DOR) for current-infection were 89.4%, 90.1% and 77.1 respectively. Major specific findings were mucosal swelling and spotty redness for current infection, regular arrangement of collecting venules (RAC), streak redness, fundic gland polyp (FGP) for non-infection, and map redness for past-infection.

Conclusions: Kyoto classification of gastritis applied well on MCCE. *H. pylori* infection status could be accurately assessed on MCCE.

Introduction

Gastric cancer (GC) now ranks as the world's third leading cause of cancer related death[1, 2].As estimated by the Global Cancer Observatory (GCO), approximately 950,000 GCs are newly diagnosed every year, and the majority of these newly diagnosed GCs are reported from east Asian countries like Japan, Korea and China [1, 3].Early detection by esophagogastroduodenoscopy (EGD) can effectively reduce GC's mortality rate. However, EGD is an invasive procedure which may raise concerns for patient discomfort and procedure related adverse events (AEs), thus lowering patients' compliance[3, 4].

Technological advances had led to the development of magnetic controlled capsule endoscope (MCCE), a novel noninvasive device which is able to inspect the gastric mucosa without the need for an invasive procedure[5]. In addition, MCCE does not require sedation, making it both a safer and a more comfortable screening modality in contrast to EGD. Moreover, recently published studies show that MCCE's diagnostic accuracy was comparable with that of conventional EGD[5]. In recent years, MCCE has been developing rapidly and continues to gain popularity in China, where prevalence of GC is the highest in the world[2, 6].

Despite these advantages, whether MCCE is sufficient to replace conventional EGD as a screening tool for GC has not been fully evaluated. One important issue remains to be solved is the diagnosis of the *Helicobacter pylori* (*H. pylori*) infection status, as the risk of GC development is largely determined by one's exposure to *H. pylori* [3, 6]. EGD's diagnostic accuracy on *H. pylori* infection status had been significantly improved with the application of image enhanced-endoscopy (IEE), such as narrow band imaging (NBI) and blue laser imaging (BLI) [6]. However, only a few expert endoscopists are trained in using these IEE modalities.

In 2014, Kyoto classification of gastritis was developed to facilitate the diagnosis of *H. pylori* infection status and better stratify the risk of GC using EGD ⁷. Most recent publications demonstrated that the Kyoto classification of gastritis was convenient and reliable in the diagnosis of *H. pylori* infection status [7, 8]. To date, however, whether Kyoto classification of gastritis could be applied well on MCCE remains unknown. Therefore, we conducted this study to validate whether the Kyoto classification of gastritis can be applied to MCCE and if *H. pylori* infection status could be accurately assessed on MCCE.

Methods

Study Design

This study included two phases. In phase one, a pilot trial was carried out to test the accuracy of MCCE in detecting the conventional EGD findings that meet the Kyoto classification of gastritis. From November 1, 2018 to April 30, 2019, we recruited 35 participants who had undergone UBT and EGD before being referred for MCCE. Endoscopic findings of Kyoto classification were recorded on EGD and were later validated on MCCE.

In phase two, the diagnostic performance of MCCE in determining *H. pylori* infection status based on Kyoto classification was evaluated. We recruited individuals who came to our institute on purpose of a health check, these individuals either had mild epigastric symptoms or were totally asymptomatic. Participants were consecutively recruited from May 1 to December 31, 2019. Inclusion criteria were: >18 years old; scheduled for MCCE screening; had an urea breath test (UBT) results. Exclusion criteria were: a history of gastric surgery; prior or current diagnosis of advanced GC; recently on a proton pump inhibitor (PPI), histamine blocker, antibiotics, or bismuth; suboptimal image quality.

In our previous pilot study we estimated that the sensitivity/specificity was around (80%/80%), the required sample size was 62 in case 10% error allowance. The prevalence of *H. pylori* infection in our institution was approximately 30%, in that case, the total sample size required was 205. The estimated sample size was finally set at 220, considering that the drop rate of study participants was 10%. Urea [¹³C] breath test (UBT) diagnostic kit (Beijing Huabo Medical Technology Co., Ltd.) was used for UBT, and all included participants in phase 2 were asked to fast overnight the day before UBT. The UBT was performed within 2 days before or after MCCE, and results were regarded as the gold standard for *H. pylori* infection status. Current-infection was considered if the UBT result was > 4 μmol/L, irrespective of

H. pylori eradication history. Non-infection was considered if the UBT result was < 4umol/L. Past-infection was considered when participants had a negative UBT result and clearly stated a history of successful *H. pylori* eradication more than 6 months before undergoing MCCE and UBT.

This study was conducted in accordance with Helsinki Declaration and had been approved by the ethics committee of PLA (People's liberation army) General Hospital. All participants provided written informed consents.

MCCE Procedure

MCCE used in this hospital was developed by Ankon Technologies Co. Ltd (Shanghai, Wuhan, China). The participants were asked to fast overnight. Before swallowing the capsule, 2 liters of water and simethicone were ingested to ensure a clear vision of the gastric mucosa. The examinations were conducted by an experienced technician (WM) according to the protocol described previously[9, 10].

The Diagnostic Algorithm.

In phase one, 35 EGD procedures were performed by 3 senior endoscopists. According to relevant studies, we selected the following 10 findings listed in Kyoto classification of gastritis which were closely related to *H. pylori* infection status: regular arrangement of collecting venules (RAC), fundic gland polyp (FGP), streak-like redness, xanthoma, map-like redness, spotty redness, diffuse redness, enlarged fold, mucosal swelling and nodularity[7, 8, 12]. EGD findings were used as the gold standard, 2 × 2 diagnostic tables for each finding were constructed, sensitivity and specificity were later calculated. MCCE images were reviewed by an experienced endoscopist who was an expert in CE and blinded to the EGD results.

In phase 2, after reviewing MCCE's real-time videos and still images, the diagnosis of *H. pylori* infection was made independently by an expert physician who had over 1,000 cases of capsule endoscope experience, and a non-expert physician who had less than 200 cases in experience. Both of the 2 reviewers were blinded to the UBT results and *H. pylori* eradication history, and inter-observer disagreements were resolved by a referee who was a veteran endoscopist with over 1000 capsule endoscope experience.

The diagnostic criteria for *H. pylori* infection status in the phase 2 was established in a group session in which both of the 2 reviewers who were well-versed in the Kyoto classification of gastritis [7, 8, 11, 12].

When at least two of the following findings such as spotty redness, diffuse redness, enlarged fold, mucosal swelling and nodularity were observed, the diagnosis of current-infection was made. When RAC, fundic gland polyp (FGP) or streak-like redness were observed, and findings indicate current infection were not found, the diagnosis of non-infection was made (Fig. 1). When map-like like redness was observed alone or in combination with RAC or FGP, the diagnosis of past-infection was made, additionally, if no significant findings for current infection or non-infection were observed, the diagnosis of past-infection could also be considered [7, 8]. (Fig. 1).

Two prediction models were developed to assess *H.pylori* infection status by combining 10 findings. In model 1, non-infection participants were selected out of all the included participants and in model 2, current infection participants were selected from those who were unselected in model 1. Therefore, in model 1, non-infection participants were identified while ,in model 2, current infection participants were identified.

Statistical Analysis.

R-software (<https://www.r-project.org>) was used for statistical analysis. Continuous data were expressed as mean value plus range. Diagnostic accuracy was calculated to evaluate MCCE's overall diagnostic performance for *H. pylori* infection. Sensitivity, specificity, positive predict value (PPV), negative predict value (NPV) and diagnostic odds ratio (DOR) were calculated. Diagnostic parameters were expressed as value plus 95% confidential interval (CI). For each of the two prediction models, multivariate logistic regression analysis and Receiver operating characteristic (ROC) curves for 10 findings were performed. In ROC analysis, area under curve(AUC)s were calculated to demonstrate the overall diagnostic performance. Inter-observer variability was assessed by calculating the kappa value. When kappa values were < 0.20, 0.21–0.40, 0.41–0.60, 0.61–0.80 and > 0.80, poor, fair, moderate, good and excellent agreement were rated respectively.

Results

Phase One

Baseline characteristics.

Thirty-five participants were recruited. The average age was 52.1 years old, with a range of 34-67 years old. There were 23 males and 12 females, the male/female ratio was 1.92. The diagnosis of *H. pylori* infection evaluated by UBT was 16 current infections, 13 non infection and 6 past infections.

Validation of Kyoto classification of gastritis' findings on MCCE.

Despite the relatively lower sensitivities for mucosal swelling, diffusive redness and nodularity, MCCE well recognized most of the 10 findings that we selected out of Kyoto classification of gastritis, with overall diagnostic accuracy, sensitivity and specificity at 96.6% (95%CI: 93.2-100%), 84,7% (95%CI: 74.1-99.3%) and 100.0% (95%CI: 98.0-100%), respectively. Table 2 shows the diagnostic performance of MCCE on Kyoto classification of gastritis.

Phase Two

Baseline characteristics.

There were 239 participants initially enrolled in phase 2. However, 12 participants were excluded from the study because 3 participants had gastric surgery, 5 GERD patients were on PPI and 4 participants had

poor gastric preparation. Finally, 227 participants were enrolled in the phase 2. Their average age was 50.9 years old, with a range of 18 to 82 years old. There were 124 males and 103 females, the male/female ratio was 1.20.

Among the 227 participants in phase 2, the final diagnosis of *H. pylori* infection was current infection in 85 (85/227, 37.4%) participants, non-infection in 99 (99/227, 43.6%) participants and past-infection (eradicated) in 43 (43/227, 18.9%) participants. Other diagnoses made on MCCE were gastro-esophageal reflux disease (GERD) in 18 (18/227, 7.9%) participants, submucosal tumor (SMT) in 15 (15/227, 6.6%) participants, telangiectasia in 13 (13/227, 5.7%) participants and bile reflux in 25 (25/227, 11.0%) participants. Erosions, either elevated or flat type, were found in 95 (95/227, 41.9%) participants (Table 1).

MCCE's diagnostic performance on *H. pylori* infection evaluated by Kyoto classification of gastritis.

In phase 2, among the 227 participants who had undergone MCCE, 90 were diagnosed with current infection, 101 were diagnosed with non-infection and 36 were diagnosed with past infection. The overall diagnostic accuracy on *H. pylori* infection was 80.2% (182/227). The sensitivity, specificity, and PLR for current infection were 89.4%, 90.1%, and 9.07; for non-infection they were 83.8%, 85.9%, and 82.2%; and for past-infection they were 63.9%, 92.3%, and 53.5%, respectively (Table 3). The AUC for ROC1 which predicts non-infection individuals, was 84.7, and that of ROC2 which predicts current-infection individuals was 84.9 (Figure 2).

MCCE findings with high diagnostic value for a particular *H. pylori* infection status.

A number of endoscopic findings were found to have high diagnostic values for indicating *H. pylori* infection status. Findings such as mucosal swelling (PPV 80.2%, DOR 25.6), diffusive redness (PPV 75.9%, DOR 9.2), spotty redness (PPV 79.2%, DOR 10.7), enlarged fold (PPV 85.7%, DOR 11.5) and nodularity (PPV 83.3%, DOR 8.3) were highly indicative of current infection. RAC (PPV 65.5%, DOR 7.7), streak-like redness (PPV 88.9%, DOR 12.1) and FGP (PPV 80.0%, DOR 6.2) were highly indicative of non-infection. For past-infection, only map like redness (PPV 66.7%, DOR 14.0) had high diagnostic value. (Supplementary Table 1, 2, and 3)

Mucosal swelling and spotty redness were simultaneously observed in 40 individuals, when this combination of findings was used as a diagnostic predictor for current infection, the PPV and DOR were 85.0% and 15.1 respectively. Among non-infected individuals, 19 were found to have both FGP and RAC; the PPV and DOR of this combination for non-infection status were 89.5% and 13.1 respectively. And for past-infection, the combination of map like redness plus RAC were observed in 15 individuals, and this combination of findings yielded a PPV and DOR of 86.7% and 39.4 respectively. (Supplementary Table 1, 2, and 3)

Regression analysis

In predict model 1, RAC, FGP and streak-like redness were associated with non-infection. In predict model 2, mucosal swelling, spotty redness, diffusive redness, xanthoma and nodularity were associated with

current-infection, and these findings were inversely associated with non-infection in model 1 (Table.4). Map-like redness had a negative regression coefficient in both model 1 and model 2 (Table.4.)

Inter-observer variability.

Regarding the diagnosis of *H. pylori* infection status, the overall agreement was excellent with Kappa value at 0.86. The kappa values for current-infection and non-infection were 0.91 and 0.82 respectively, whereas the kappa value for past-infection was relatively lower at 0.73.

Most of 10 findings observed on MCCE had high kappa values and were rated as excellent or good agreement, except diffusive redness (Kappa value: 0.54) which was rated as moderate agreement respectively. (Supplementary table.4)

Discussion

One recently published Chinese study concluded that MCCE was able to detect GCs in a large population, but its role as a first line screening tool for GC remains to be further validated [9]. Since the risk of GC is closely related to *H. pylori* infection status, MCCE's diagnostic accuracy on *H. pylori* infection status is of critical importance in risk stratification. Moreover, the morphological features of early GC or high-grade precancerous lesions also differ according to different *H. pylori* infection status, which further established the rationale for our study.

Yoshii et al demonstrated that overall diagnostic accuracy of three *H. pylori* infection status was 82.9% on white light endoscopy by the Kyoto classification of gastritis[8]. In this study, we found that most of the key findings documented in Kyoto classification of gastritis were well recognizable on MCCE, and *H. pylori* infection status could be accurately diagnosed via MCCE, and the overall diagnostic accuracy was 80.2% comparable with EGD.

Previous studies demonstrated that MCCE was capable of detecting various kinds of gastric lesions, including erosions, polyps, ulcers, and even superficial early gastric cancers [5, 6, 9, 13]. In our study, based on the results of phase one, we found that the Kyoto classification of gastritis generally applied well on MCCE in the diagnosis of the *H. pylori* infection status.

In the diagnosis of current infection status, the most reliable finding was mucosal swelling (sensitivity 76.5%, specificity 88.7%, PPV 80.2%), whereas in other recently published EGD studies, that diagnosis was established mainly based on observation of diffusive redness. This difference, we speculate, might have been the reason why MCCE had a much higher DOR for current infection compared with conventional EGD (77.2 vs 21.7) [7, 13, 14]. Additionally, when spotty redness and mucosal swelling were simultaneously observed, the specificity, PPV and DOR were 95.8%, 85.0% and 15.1, respectively; this combination of findings strongly indicates a diagnosis of current infection.

At the moment, in the midst of the COVID-19 pandemic, telemedicine has recently started to gain popularity[15, 16]. With high diagnostic accuracy for current *H. pylori* infection, besides inspecting the

gastric mucosa, MCCE could also occasionally offers an ideal alternative for detecting active *H. pylori* infection in a safe and contactless fashion.

MCCE can reliably diagnose non-infection status, with sensitivity, specificity and PPV of 83.8%, 85.0% and 82.2%, respectively. This diagnosis is mainly based on observation of RAC; although FGP and streak redness were also of high specificity and PPV, these two findings were relatively uncommon. However, MCCE's DOR for non-infection status in our study was much lower compared with that of Yoshii's EGD study (30.7 vs 98.6) in which the authors made the diagnosis based on the same findings. Kyoto gastritis classification defines RAC as micro-vascular networks observed in lower part of the gastric corpus, mainly the lesser curve side[7, 12]. For MCCE, however, due to its steering pattern, sometimes it is difficult to confirm the location of micro-vascular network observed during real-time procedure or on still images. A number of current-infection individuals in this study might have been misdiagnosed as non-infection because RAC were thought to be observed in the gastric fundus or upper gastric corpus.

MCCE's diagnostic performance on past-infection status was suboptimal in our study, largely due to the lack of specific findings. Besides, inter-observer variability might also have played role in its low diagnostic performance. Occasionally, intestinal metaplasia and map-like redness may resemble each other on MCCE, although these two findings could be differentiated at ease by a veteran on EGD, but it might have been difficult for a non-experienced physician to tell them apart on MCCE. That might have been the major cause of inter-observer variability. When map -like redness was used as the main predictor for past-infection, the sensitivity and PPV were 41.9% and 53.5% respectively. A new discovery in our study was that the combination of RAC and map like redness could be used as a highly specific predictor for past-infection, with specificity, PPV and DOR of 98.9%,86.7% and 39.4, respectively. This combination of findings is especially helpful for determining past-infection status when there is diagnostic ambiguity.

Our study had several strengths. First, in phase one, we made a direct comparison between EGD and MCCE using EGD findings as gold standard to validate Kyoto classification of gastritis' applicability on MCCE. Second, this was a prospective study in which the reviewers were blinded to the final results and we used UBT results as the gold standard for the diagnosis of *H. pylori* infection, making the results reliable and robust. Third, we have found several combinations of findings to have high diagnostic value; this is of utility when the diagnosis was uncertain based on observation of a single finding. Further, we performed regression analyses in which the diagnostic performance of MCCE was assessed by combining 10 findings in Kyoto classification of gastritis. Fourth, in phase two, we had an expert and a non-expert reviewed MCCE images, and resolved inter-observer disagreement by a referee, thus making our results reproducible in future studies.

Our study had several limitations too. First, despite the fact that all participants in phase two were prospectively recruited, approximately half of the included participants were *H. pylori* non-infected (44.5%), while the proportion of past-infection participants was particularly low (15.9%), thus according to STARD (Standards for reporting of diagnostic accuracy studies), selective bias was inevitable[17]. Second, according to Kyoto classification of gastritis, sticky mucus and hyperplastic polyps are also key

findings for *H. pylori* infection, but these findings were not found in phase one, nor could we rate the degrees of atrophy and intestinal metaplasia on MCCE, so the scoring system of Kyoto classification of gastritis described in previous studies [22, 23, 24] was not available in this study. Therefore the Kyoto classification of gastritis used in phase two was actually a modified version[7, 8, 9, 12, 18]. Third, spontaneous eradication of *H. pylori* might have been occurred in a tiny portion of the study participants, and that could have had an impact on the evaluation of the diagnostic accuracy, and this issue might have been underestimated in our study [7, 19]. Last but not least, we didn't directly compare the diagnostic performances between EGD and MCCE due to the relatively small sample size in phase one.

In future studies, more specific findings for past-infection are warranted, because using map-like redness as the predictor doesn't appear to have sufficient diagnostic power²². Additionally, in recent years, the introduction of artificial intelligence (AI) has improved the diagnostic accuracy of GI neoplasms as well as EGD's diagnostic accuracy on *H. pylori* infection status[18, 20]. Hopefully, our results could help establishing MCCE's AI diagnosis on *H. pylori* infection status, thus improving GC's early detection in a more comfortable way[20, 21]. Moreover, efforts to establish scoring models for atrophy and intestinal metaplasia on MCCE are required, and that may help us better stratifying GC risks via MCCE[22, 23, 24].

Conclusions

Kyoto classification of gastritis applied well on MCCE. *H. pylori* infection status could be accurately assessed on MCCE.

Abbreviations

AI:artificial intelligence;

BLI,blue laser image;

CI:confidential interval;

COVID-19:corona virus disease 2019;

DOR:diagnostic odds ratio;

EGD:esophagogastroduodenoscopy;

FGP: fundic gland polyp;

GC:gastric cancer;

GERD:gastro-esophageal reflux disease;

GCO:Global Cancer Observatory,

H.pylori:*Helicobacter pylori*;

IEE:image enhanced endoscopy;

MCCE:magnetic controlled capsule endoscopy;

NPV:negative predict value ;

NBI:narrow band image;

PPI: proton pump inhibitor;

PPV:positive predict value;

RAC:regular arrangement of collecting venules

STARD:standards for reporting of diagnostic accuracy studies;

SMT:submucosal tumor;

UBT:;urea breath test.

Declarations

Ethnic approval and consent to participate

This study was conducted in accordance with Helsinki Declaration and had been approved by the ethics committee of PLA (People's liberation army) General Hospital(IRB No.S2018-109-01). All participants provided written informed consents.

Consent for publication

Not applicable

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing interests

All authors of this study declared no conflict of interests.

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Author contributions

SX ,LJ: writing of the manuscript,image review

LT,WL, data collection and statistical analysis

WM , conducting all the MCCE procedures

LJ, ethical approval affairs

WZQ,JP, design of the study,language editing

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Tables

Table 1. Baseline characteristics

Number of participants(n)	All	Phase 1	Phase 2
	262	35	227
Male(n,%)	148,56.5%	23,65.7%	124,54.6%
Female(n,%)	114,43.5%	12,34.3%	103,45.4%
M/F ratio	1.29	1.92	1.20
Age (Years)	51.2(SD:12.5)	52.1(SD:11.7)	50.9(SD:12.4)
Final diagnosis of <i>H. pylori</i> infection evaluated by UBT (n, %)			
current-infection		16,45.7%	85,37.4%
non-infection		13,37.1%	99,43.6%
past-infection		6,17.1%	43,18.9%
Symptoms (n, %)			
upper gastric pain		11,31.4%	45,19.8%
regurgitation		4,11.4%	36,15.9%
dyspepsia		16,45.7%	63,27.8%
abdominal distention		5,14.3%	24,10.6%
Other diagnoses (n, %)			
Telangiectasia		0,0%	13,5.7%
GERD		8,22.9%	18,7.9%
SMT		4,11.4%	15,6.6%
Erosive gastritis		17,48.9%	95,41.9%
Bile reflux gastritis		6,17.1%	25,11.0%

SD:standard deviation

Table 2. MCCE's diagnostic performance on Kyoto classification of gastritis. Validation of Kyoto classification of gastritis on MCCE, 2x2 diagnostic tables of 10 findings related to *H. pylori* infection status.

			sensitivity (95%CI)	specificity (95%CI)
RAC	MCCE+	MCCE-		
EGD+	15	1	93.8%	100.0%
EGD-	0	19	(91.3%-96.6%)	(99.5%-100%)
streak redness	MCCE+	MCCE-		
EGD+	4	0	100.0%	100.0%
EGD-	0	31	(98.1%-100%)	(99.5%-100%)
FGP	MCCE+	MCCE-		
EGD+	7	0	100.0%	100.0%
EGD-	0	28	(99.3%-100%)	(99.5%-100%)
mucosal swelling	MCCE+	MCCE-		
EGD+	10	2	83.3%	100.0%
EGD-	0	23	(78.6%-86.2%)	(99.5%-100%)
spotty redness	MCCE+	MCCE-		
EGD+	10	0	100.0%	100.0%
EGD-	0	25	(99.5%-100%)	(99.5%-100%)
diffusive redness	MCCE+	MCCE-		
EGD+	5	4	55.6%	100.0%
EGD-	0	26	(40.6%-62.2%)	(99.5%-100%)
xanthoma	MCCE+	MCCE-		
EGD+	4	0	100.0%	100.0%
EGD-	0	31	(99.5%-100%)	(99.5%-100%)
enlarged fold	MCCE+	MCCE-		
EGD+	4	2	66.7%	100.0%
EGD-	0	29	(57.2%-72.7%)	(99.5%-100%)
nodularity	MCCE+	MCCE-		
EGD+	2	1	66.7%	100.0%
EGD-	0	32	(44.5%-80.4%)	(99.5%-100%)
map-like redness	MCCE+	MCCE-		

			sensitivity (95%CI)	specificity (95%CI)
EGD+	3	1	75.0%	100.0%
EGD-	0	31	(68.5%-82.2%)	(99.5%-100%)
overall			86.7%	100.0%
			(78.8%-90.2%)	(99.5%-100%)

"+" positive; "-" negative

Table 3. MCCE's diagnostic performance on *H.pylori* infection status

	sensitivity (95%CI)	specificity (95%CI)	PPV (95%CI)	NPV (95%CI)	DOR (95%CI)
current infection n=90	89.4% (81.2%-95.3%)	90.1% (84.0%-95.4)	84.4% (75.0%-91.1%)	93.4% (87.6%-96.9%)	77.2 (65.5-84.2)
non-infection n=101	83.8% (75.3%-89.8%)	85.9% (78.6%-91.0%)	82.2% (72.6%-88.5%)	87.3% (79.8%-93.2%)	30.7 (25.4-33.1)
past- infection n=36	53.5% (38.3%-68.9%)	92.3% (87.7%-95.5%)	63.9% (46.6%-79.0%)	89.5% (83.7%-92.7%)	15.1 (8.9-18.5)

Table 4. Regression coefficients for model 1(non-infection) and model 2 (current infection)

Model1 (non-infection)	Regression coefficient	Model2 (current infection)	Regression coefficient
(Intercept)	0.59295	(Intercept)	0.72204
RAC	0.08841	RAC	-0.32053
Map-like.redness	-0.34265	Map-like.redness	-0.43628
FGP	0.17032	FGP	-0.43844
Mucosal swelling	-0.38814	Mucosal swelling	0.13965
Spotty redness	-0.20445	Spotty redness	0.22071
Diffuse redness	0.01439	Diffuse redness	0.11449
Xanthoma	-0.04811	Xanthoma	0.0956
Streak-like redness	0.17907	Streak-like redness	-0.03524
Enlarged fold	-0.09648	Enlarged fold	0.35527
Nodularity	-0.20485	Nodularity	0.25348

Figures

Figure 1

Comparisons of major Kyoto classification's findings between EGD and MCCE.(A~H, EGD images; a~h MCCE images). **A and a.** mucosal swelling; **B and b.** enlarged folds with spotty redness; **C and c.** nodularity; **D and d.** diffusive redness; **E and e.** map-like redness; **F and f.** xanthoma; **G and g.** RAC; **H and h.**FGP.

Figure 2

Receiver's operative characteristic(ROC) curves for predicting non-infection(A) and current infection(B) based on 10 findings in Kyoto classification of gastritis.

AUC,area under curve

Supplementary Files

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- [supplementarytable1.docx](#)
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