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Original Research Article

The rate of endoscopic observation of the major duodenal papilla can be increased by simple guideline

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ABSTRACT

Background: Ampullary lesions are being detected with increased frequency with the growing use of esophagogastroduodenoscopy. However, it is uncertain how frequently endoscopists properly visualize the major papilla in routine clinical practice. This study was undertaken to determine the actual rate of observing the major papilla by endoscopists and if there is a room for improvement in visualizing the duodenal major papilla when performing esophagogastroduodenoscopy.
Methods: This was a single-center, prospective, randomized study involving 3,088 consecutive patients referred for diagnostic esophagogastroduodenoscopy at tertiary-care referral center between September and November 2010. Six fellows-in-training in the study group attempted to visualize the major papilla up to three times, while six fellows-in-training in the control group performed endoscopy in a standard fashion.
Results: The overall observation rate was significantly higher in study group (975 of 1070 [91.1%]) than in control group (624 of 1022 [61%], p<0.001). "Complete observation" was achieved in 68.2% of the cases in study group compared to 45.0% of the cases in control group (p<0.001). The total procedure time was slightly, but significantly longer in the study group (5.82±2.38 min versus 5.52±2.11 min, p=0.003).
Conclusions: The rate of observing the major papilla for endoscopists is not as high as expected in routine clinical practice; however, the rate of observing the major papilla might improve significantly through application of additional effort with but a modest increase in procedural time.

Keywords: Esophagogastroduodenoscopy, Major papilla, Observation rate

INTRODUCTION

Esophagogastroduodenoscopy (EGD) is a primary diagnostic tool used for evaluation of the upper gastrointestinal tract. It is usually expected that a competent endoscopist should intubate the second part of the duodenum during EGD with visualization of the major papilla. The European society of gastrointestinal endoscopy recommends that the end of endoscope be positioned near the papillary area.[1] Although a gastroscope, a forward-viewing instrument, is not considered as a main tool of observing the major papilla, it often serves as a diagnostic tool not only for esophagogastric lesions, but also for duodenal ampullary lesions, such as ampullary adenomas or carcinomas, diverticula, papillitis, and intraductal papillary mucinous neoplasm (IPMN).[2-5] These lesions are recognized with increased frequency as a result of the increased use of routine screening EGD. However, it is uncertain how frequently endoscopists properly visualize the major papilla in routine clinical practice.

The objective of this study was to evaluate the rate of observing the major papilla in routine clinical practice, and to determine if there is a room for improvement vis-a-vis "additional effort" to visualize the duodenal major papilla when performing conventional, forward-viewing EGD.

METHODS

Study design

This was a single-center, prospective, randomized study involving 3,088 consecutive patients referred for diagnostic EGD. The study protocol was carried out in accordance with the declaration of Helsinki and was approved by institutional review board of Samsung Medical Center.

Subjects

This study was conducted at the Samsung Medical Center (Seoul, Korea) in the routine endoscopy units for 8 weeks between September and November 2010. The total of twelve 1-year gastroenterology fellows (each having performed >1,000 EGDs) at the Samsung Medical Center were included and randomly assigned into 2 groups, as follows: 6 in the study group (SG); and 6 in the control group (CG). The prior EGD experiences of the fellows-in-training were evaluated based on the medical statistics program of this institution.

Consecutive patients referred for diagnostic EGD during the study period were candidates for entry into the study. Once informed consent was obtained, patients were randomized according to a computer-generated randomization protocol to the SG or the conventional EGD group (CG). Patients were blinded to the allocation. The exclusion criteria were as follows: planned therapeutic procedures; known or suspected stenosis in the upper gastrointestinal tract; esophageal, gastric, or duodenal resection for any reason; and a history of pancreatobiliary surgery (except simple laparascopic cholecystectomy). Each subject underwent diagnostic EGD with one of the following endoscopes: GIF-Q 240, GIF-Q 260, or GIF-H260 (Olympus Optical Co. Ltd., Tokyo, Japan).

Intervention

Before starting this study, six fellows-in-training allocated to the SG took a course of instruction which included the exact morphology of duodenal major papilla, and the following three steps to achieve correct visualization of the papillary area during EGD. First, the endoscope was passed via the mouth and advanced into the descending portion of the duodenum, thus deflating the stomach. Second, the endoscopist used the angulation up and turned the endoscope right, then pulled back with straightening and shortening of the endoscope. Third, the camera direction was adjusted to achieve proper photo-documentation of the major papilla and orifice. The process was similar to performing ERCP with manipulation of the duodenoscope. If the endoscopist could not visualize the major papilla despite this effort a maximum of three times, or in the event a patient had any signs of serious distress, the attempts to visualize the major papilla were stopped immediately. The other six fellows-in-training who were randomized to the CG performed the procedure in a standard fashion without supplementary information (vide supra).

The success of visualizing the major papilla during EGD was verified by the endoscopists. All fellows-in-training recorded if the major papilla was or was not observed. If the fellows-in-training successfully visualized the major papilla, the positive results were categorized into two groups (subgroups 1 and 2) according to the accuracy of the results. Observing the major papilla was defined as "complete" and categorized into subgroup 1 when the orifice of the papilla in the oval protuberance at the intersection of a covering transverse mucosal fold and the longitudinal folds were all identified. In the case of suboptimal visualization of the major papilla, the major papilla was categorized to subgroup 2.

The reason for failing to visualize the major papilla was also recorded for the fellows-in-training in the SG only, as follows: an inability to visualize the papilla, despite a maximum of 3 attempts (reason A); or due to signs of patient distress (reason B). The fellows-in-training in the SG were fully informed regarding the method required to properly visualize the major papilla during EGD and kept in mind that these sequences should be completed in a timely manner with minimal patient distress.

A biopsy was performed at the major papilla if any enlargement or any space-occupying lesions at the ampulla were noted by the endoscopist. The total duration of the procedure was defined from insertion of the endoscope (passage through the incisor teeth) to complete withdrawal of the endoscope. The duration of the procedure was measured as displayed on the endoscopic monitor and recorded by the assistant.

Patient preparation and procedure under conscious sedation

All patients completed a demographic questionnaire with questions regarding age, gender, history of abdominal surgery before the procedure. Lidocaine (10%) was sprayed into the posterior pharynx before the examination to reduce the gag reflex in all the patients enrolled. If the patient requested conscious sedation, a combination of midazolam (0.5~5 mg) and meperidine (25~50 mg) was used for sedation. All patients were monitored by continuous pulse oximetry and visual clinical assessment of ventilatory status and electrocardiography (ECG) monitoring. Hypoxemia was defined as saturation which decreased to <90%. If the SpO_2 decreased to 85% for 30 seconds, a midazolam antagonist (flumazenil) was injected, and the procedure was interrupted until normalization of the oxygen saturation. Transient interruption of the procedure was defined as procedure interruption because of adverse events for 30 seconds. If there was transient interruption of the procedure because of sedation-related adverse events, that time was subtracted from the total duration of the procedure.

Monitoring of procedure-related complications

The term "negative outcome" was defined as any deviation from the optimal course after endoscopy or any complication that necessitates therapeutic intervention.

Outcome measurements

The primary endpoint of this study was to compare the rates of observing the major papilla between the two groups and to determine if there was any improvement in the rate of observing the major papilla by application of the "observation method" without using a side-viewing duodenoscope. The secondary outcome measures were the total duration of the procedure and identifying pathologic lesions involving the major duodenal papilla.

Statistical analysis

We assumed that a complete EGD examination and anticipated that the expected observation rate of duodenal major papilla would be 80% for fellows-in-training. The sample size required for our study was estimated based on this predicted 20% difference and designed to detect significant differences at α value of .05 with a power of 80%. Categorical data analysis was conducted using a Fisher's exact test. Continuous data were analyzed using a Mann-Whitney test. All p values were two−tailed and p values <0.05 were considered statistically significant. All statistical analyses were performed using statistical package for the social sciences (SPSS) for Windows (version 18.0; Chicago, IL, USA).

RESULTS

Study population and baseline characteristics

The prior experience of the fellows-in-training in EGD procedures did not differ between the two groups (mean, 1219 cases in the SG; and mean, 1223 cases in the CG (Table 1). During the 8-week study period, the total number of EGDs performed by the fellows-in-training was 3088 (1584 cases in the SG; and 1504 cases in the CG). The number of EGDs performed by individual fellows-in-training varied because the fellows-in-training had different EGD rotation assignments during the study period. Of the 3088 patients who underwent EGDs, 2128 patients were eligible for this study and randomly assigned to the SG and the CG. Because 36 of the patients were withdrawn from the study, 1070 patients in the SG and 1022 in the CG were analyzed. A flow diagram of the study is shown in Figure 1.

Table 2 summarizes the demographic data and procedural indications for the subjects included in the analysis. There were no significant differences in age, gender, height and weight between the two groups. Of the EGDs, 1891 (90.4%) were performed on an outpatient basis and 201 (9.6%) were performed on an inpatient basis. The most common indication for EGD was a routine evaluation for cancer screening in both groups (26.8% and 33.5% in the SG and CG, respectively).

Rate of observing the major papilla and total procedure time

The overall rate of observing the major papilla was significantly higher in the SG (975/1070 [91.1%]) than the CG (624/1022 [61%], p<0.001 (Table 3). Of the 975 patients in the SG in whom visualization of the major papilla was successful, complete observation (subgroup 1) was achieved in 68.2% (665/975) compared to 45.0% (281/624) in the CG (p<0.001). Most of the reason for the failure to visualize the major papilla was reason A, an inability to visualize the papilla despite a maximum of 3 attempts, which accounted for 73.7% of the cases. The remaining cases in which the major papilla was not completely visualized was due to patient distress or at the discretion of the endoscopist (reason B). The mean total procedure duration was 5.82±2.38 min in the SG and 5.52±2.11 min in the CG (p=0.003).

Observation rate depending on use of sedatives and analgesics

Among the 2092 patients, 1174 underwent EGD under conscious sedation, with a similar distribution in both groups (54.3% in the SG; and 58.0% in the CG, p=0.09). The overall observation rate was not different between the sedated and non-sedated subjects in the SG (92.1% and 90.0%; p=0.23), whereas the observation rate was significantly higher in the sedated subjects in the CG (66.6% versus 53.4%; p<0.001) (Table 4). Optimal visualization of the major papilla (subgroup 1) was significantly higher in the sedated patients (Table 5).

Biopsy sampling from the major papilla

There were 6 and 7 cases in the SG and CG, respectively who had biopsy-sampling from the major papilla during the procedure; the primary indication for a biopsy was a prominent, bulging appearance of the major papilla. The pathologic results included no specific pathologic alterations (n=2 in the SG; and n=5 in the CG), chronic duodenitis (n=2 in the SG), surface epithelial hyperplasia (n=1 in the SG), and focal active inflammation (n=1 in the SG; and n=2 in the CG) (Table 6). One of the patients in the SG, a 72-year-old male, was shown to have a mass-like lesion on the major papilla during the endoscopic examination, with diffuse intrahepatic duct dilatation on abdominal computed tomography (CT) scan during the routine health check-up. Although the endoscopic biopsy revealed chronic duodenitis only, he was diagnosed to have an adenomyoma of the ampulla of Vater after surgical resection.

Procedure-related complications

Transient hypoxemia was the most frequently reported adverse event among the patients in both groups (2.1%

[12/581] in the study group and 2.5% [15/593] in the CG; p=0.701). Two patients in the SG and three patients in the CG required transient interruption of the procedure because of hypoxemia. All the patients with hypoxemia were successfully managed with brief airway support, including chin lifting and increased oxygen supply, and the procedure was subsequently completed without additional adverse events. None of the procedure-related complications, including mucosal lacerations or perforations, occurred during the study period.

Table 1: Clinical characteristics of gastroenterology fellows-in-training allocated in each group.

Characteristics	Study group fellows-in-training (n=6)	Control group fellows-in-training (n=6)	P value
Prior mean EGD † cases ‡ (mean±SD)	1218.7±97.7	1222.5±75.1	0.94
Gender ratio (M:F)	1:1	1:1	1.00

†EGD: esophagogastroduodenoscopy, ‡: performed by each fellow-in-training before starting the present study.

Table 2: Demographic and clinical characteristics of the patients.

Characteristics	Study group (n=1070)	Control group (n=1022)	P value
Mean age (range)	57.8(22~94)	57.1(21~88)	0.74
Male (% of patients)	57%	56%	0.69
Height (cm)	165.7(±8.43)	165.8(±9.22)	0.767
Weight (kg)	62.9 (±10.32)	63.1(±10.5)	0.056
Indications for EGD † (N)			
Cancer screening	319	331	0.87
Gastrointestinal symptoms	239	263	0.29
Referred for abnormal EGD† results in outside clinic	183	138	0.09
Others	329	290	1.00
Outpatient/inpatient (N)	958/112	921/101	0.67

†EGD: esophagogastroduodenoscopy.

Table 3: Observation of the major papilla.

Observations	Study group (n=1070) %	Control group (n=1022) %	P value
Observation of major papilla (+), N (%)	975 (91.1)	624 (61)	<0.001
Subgroup 1†	665 (68.2)	281 (45.0)	<0.001
Subgroup 2‡	310 (31.8)	343 (55.0)	
Observation of major papilla (-), N (%)	95 (8.9)	398 (39.0)	
Reason for failure, A§	70 (73.7)		
Reason for failure, B‖	25 (26.3)		
Total procedure duration, min (±SD)	5.82 (±2.38)	5.52 (±2.11)	0.003

† Complete observation, including the orifice of the papilla in the oval protuberance at the intersection of a covering transverse mucosal fold and the longitudinal folds were all identified; ‡ suboptimal visualization of the major papilla; § inability to visualize the papilla, despite a maximum of 3 attempts; ‖ inability to attempt to visualize, due to patient's distress sign.

Table 4: Observation rate depending on the use of sedatives and analgesics.

Parameters	Study group (n=1070)			Control group (n=1022)		
	Sedated (n=581)	**Non-sedated (n=489)**	**P value**	**Sedated (n=593)**	**Non-sedated (n=429)**	**P value**
Observation (+) (N)	535	440	0.237	395	229	<0.001
Observation rate, (%)	92.1	90.0		66.6	53.4	

Table 5: Accuracy of observation depending on the use of sedatives and analgesics (subgroup 1 versus 2).

Observations	Subgroup 1† (n=665)	Subgroup 2 ‡ (n=310)	P value
Sedation (+) (N %)	387 (58.2)	148 (47.7)	0.0024
Sedation (-) (N %)	278 (41.8)	162 (52.3)	

† Complete visualization of major papilla, ‡ suboptimal visualization of major papilla.

Table 6: Biopsy sampling from the major papilla.

Endoscopic finding: prominent major papilla, such as a bulging or nodular, enlarged appearance	Pathologic report
Study group (n=6)	No specific pathologic alteration (n=2)
	Chronic duodenitis (n=2)
	Focal active inflammation (n=1)
	Surface epithelial hyperplasia (n=1)
Control group (n=7)	No specific pathologic alteration (n=5)
	Focal active inflammation (n=2)

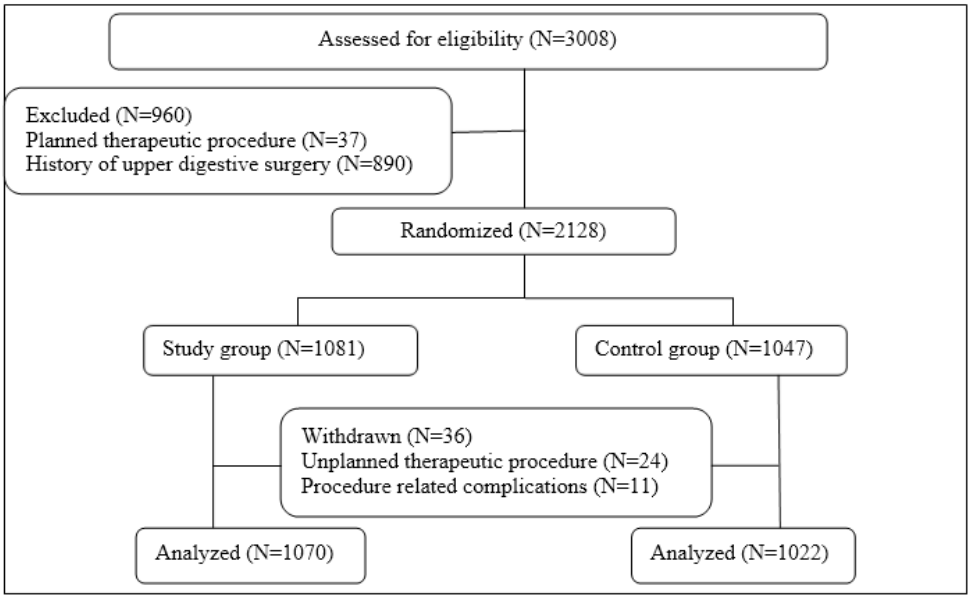

Figure 1: Study flow diagram.

DISCUSSION

Under normal conditions, the duodenal papilla is situated on the posteromedial wall of the second part of the duodenum, 7-10 cm distal to the pylorus.[6,7] The major duodenal papilla has a hemispheric or oval appearance, and is often covered with circular folds on the oral side with a frenulum running vertically on the anal side, which forms a T configuration.[8] The major papilla is known to be located in the middle third of the descending duodenum (75% of cases) or the horizontal portion of the duodenum (25%).[9] Another report demonstrated that the major papilla is mainly located in the descending part of the duodenum (82%), and occasionally in the transition between the descending duodenum and the horizontal (12%) part, or in the horizontal part (6%).[7] It is thought that visualization of the major papilla is often impossible with any effort due to the variation in location, size, and shape of the major papilla.

It has been considered that the major papilla is only partially visualized with a forward-viewing endoscope so that complete evaluation almost always requires the use of a side-viewing duodenoscope.[4,10] In fact, the results of this study demonstrated a 61% observation rate for the major papilla during routine EGD in the CG, which was not that as high as expected. However, the present study also yielded encouraging results of significant improvement in the observation rate, 91.1% in the SG with a concern for major papilla. It is presumed that the leading reason for failure to visualize the major papilla is anatomic, accounting for 74% of cases, not because of signs of patient distress. Moreover, the major papilla was completely observed in up to two-thirds of the cases with application of the methods, even without using a side-viewing duodenoscope. Although partially visualized, it seems unlikely that pathologic lesions were missed because the papilla is generally enlarged in cases of adenoma during endoscopy.[4] It is well-known that inadequate excessive manipulation of the endoscope in the duodenum can cause serious complications, such as bleeding or perforations; however, no serious complications occurred during the study period.[11]

The total procedure time was slightly, but significantly longer (mean, 18 seconds) in the SG than the CG; however, there was a much higher rate of observing the major papilla in comparison with the CG. The value of visualizing the major papilla in everyday practice during EGD is questionable; however, it might have clinical significance not only because ampullary adenomas are more likely to undergo malignant transformation than

adenomas arising elsewhere in the duodenum, but also a much higher percentage of ampullary tumors can be detected at an earlier stage before becoming symptomatic from tumor progression, which in turn is an indication of endoscopic resection, thus avoiding an invasive surgical procedure, such as pylorus preserving pancreatoduodenectomy.[12-14]

A prominent papilla is often encountered when performing EGD and can be seen in healthy individuals as well as patients with various pathologic conditions.[15] In the present study, 13 of 2128 patients showed a prominent papilla, a bulging or enlarged appearances. Although the biopsy results were typically non-specific, only one of the prominent papilla was associated with a suspicious lesion on abdominal CT scan, and in turn was diagnosed as an adenomyoma of the ampulla of Vater after surgery. It is not surprising that none of the lesions were adenomas or carcinomas considering the relatively short study period and low incidence of ampullary tumors.[16,17] Moreover, our study targeted average-risk patients for ampullary tumors including who undergo EGD for routine health checks, not high risk patients such as FAP patients. For duodenal polyposis surveillance in FAP patients, use of a side-viewing endoscope is generally recommended for examination and biopsy of the duodenal papilla.[18] It is well-known that ERCP is the most accurate tool for diagnosing neoplastic and non-neoplastic conditions in or around the ampulla of Vater. However, ERCP is not suitable for use as a primary screening method for averaged-risk patients due to the inherent morbidity and invasiveness of ERCP. Given that EGD is currently provided in the form of annual mass screenings in Korea, where the prevalence of gastric cancer is high, EGD might serve as a screening tool around the ampullary lesion in terms of early detection of ampullary tumors, with a similar concept for gastric cancer.[19]

According to our data, the rate of observing the major papilla for patients who underwent examination under conscious sedation was significantly higher in the CG. Also, the accuracy of the observation was significantly affected. As it is well-known that patient satisfaction with upper endoscopy is highly associated with adequate sedation, which guarantees not only a high level of patient acceptance but is also associated with improved quality of examination from the point of view of the endoscopist.[20-25] Consistent with the results from our study, it is suggested that sedated EGD is a more efficacious strategy for the proper visualization of major papilla.

Our study highlights the importance of simple guideline for fellows to improve observation rate of major papilla in clinical practice, which may have more chances to detect abnormal conditions of ampulla of Vater. But this study had several limitations. First, participants allocated to the CG were not able to be fully blinded with the study protocol. It could be argued that marking observations affected the fellows-in-training in the CG; however, the fellows-in-training in the CG were not aware of the application of the observation method. Second, the data presented in this study were generated from procedures performed by the gastroenterology fellows-in-training with similar endoscopic experience during their training period in a single center. As a result, our findings may not hold true for procedures performed by other endoscopists with varying levels of technical skills. Third, the anatomic variation of the major papilla was not evaluated in both groups. However, we suggest that all patients with surgery that may possibly have affected this region were excluded and given that the duodenal papilla is present in all individuals, there was no reason to presume that the remaining patients did not have normal biliary anatomy.

CONCLUSION

The results of this study suggest that the rate of observing the major papilla for endoscopists is not as high as expected in a routine clinical practice, at least in our institution. However, there is a significant improvement in the overall rate of observing the major papilla through application of additional effort with better identification of the major papilla, and by extrapolation, might improve the sensitivity to detect ampullary lesions. It demonstrates that this simple and safe procedure might be an applicable method for one of the useful tools for screening ampullary lesions in routine clinical practice. However, side-viewing duodenoscopy should always be considered for instances in which significant concern exists for an ampullary lesion. Therefore, a further study is needed to achieve a consensus as well as wide acceptance of this result.

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