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ORIGINAL ARTICLE

Prospective Study

# Application of the Prague C and M criteria for endoscopic description of columnar-lined esophagus in South Korea

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Author contributions: Choe JW and Kim YC worked in data interpretation, and writing this manuscript; Bak YT worked in data acquisition, data analysis, data interpretation and in writing of this manuscript; all authors read and approved the final form of the manuscript.

Institutional review board statement: The study was reviewed and approved by the institutional review boards of Korea University Guro Hospital in South Korea.

Clinical trial registration statement: Although this research is a prospective study, there is no need to register clinical trial. This study only analyzed the results of endoscopic features, not evaluated or compare the clinical outcome. So, we are so sorry not to provide the trial's registry.

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Conflict-of-interest statement: The authors of this manuscript having no conflicts of interest to disclose.

Data sharing statement: No additional data are available.



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## Abstract

**AIM:** To ascertain whether the Prague circumferential (C) length and maximal (M) length criteria for grading the extent of Barrett's esophagus can be applied prior to its widespread application in South Korea.

**METHODS:** Two hundred and thirteen consecutive cases with endoscopic columnar-lined esophagus (CLE) were included and classified according to the Prague C and M criteria.

**RESULTS:** Of 213 cases with CLE, the distribution of maximum CLE lengths was: 0.5-0.9 cm in 99 cases (46.5%); 1.0-1.4 cm in 63 cases (29.6%); 1.5-1.9 cm in 15 cases (7.0%); 2.0-2.4 cm in 14 cases (6.6%); 2.5-2.9 cm in 1 case (0.5%); and 7.0 cm in 1 case (0.5%). Twenty cases (9.4%) had columnar islands alone. Two hundred and eight cases (97.7%) lacked the circumferential CLE component (C0Mx). Columnar islands were found in 70 cases (32.9%), of which 20 cases (9.4%) had columnar islands alone.

**CONCLUSION:** In regions where most CLE patients display short or ultrashort tongue-like appearance, more detailed descriptions of CLE's in < 1.0 cm lengths and

columnar islands, as well as avoidance of repeating the prefix "C0" need to be considered in parallel with the widespread application of the Prague system in South Korea.

**Key words:** Barrett's esophagus; Endoscopy; Columnar-lined esophagus; Prague criteria



**Core tip:** This was a prospective study to assess the feasibility of the Prague circumferential length and maximal length criteria for the endoscopic description of columnar-lined esophagus in South Korea. In regions like South Korea where the prevalence and endoscopic features of this condition are quite different from the West, we suggest possible modifications that may fit the characteristics of the South Korean source population more properly.

Choe JW, Kim YC, Joo MK, Kim HJ, Lee BJ, Kim JH, Yeon JE, Park JJ, Kim JS, Byun KS, Bak YT. Application of the Prague C and M criteria for endoscopic description of columnar-lined esophagus in South Korea. *World J Gastrointest Endosc* 2016; 8(8): 357-361 Available from: URL: http://www.wjgnet.com/1948-5190/full/v8/i8/357.htm DOI: http://dx.doi.org/10.4253/wjge.v8.i8.357

## INTRODUCTION

Barrett's esophagus (BE) is defined as a histological change of the distal tubular esophagus, from squamous to columnar epithelium, which displays an intestinal metaplasia containing goblet cells[1,2]. Because BE is characterized by an upward shift of the squamocolumnar junction (SCJ) proximal to the gastroesophageal junction (GEJ), the resulting columnar-lined mucosa of the distal esophagus can be identified by its salmon-pink color during endoscopic examination[3,4]. Moreover, multiple endoscopic biopsies at the extended columnar-lined epithelium are needed to confirm BE diagnosis.

BE is associated with gastroesophageal reflux disease (GERD) and is considered a premalignant lesion for esophageal adenocarcinoma[5,6], the incidence of which is steadily rising in the United States and Europe[7,8]. Increasing GERD incidence in South Korea is considered to result from more consumption of westernized foods[9,10]. As patients with chronic GERD are at a higher risk of developing BE[11,12], the expected increase in BE and esophageal cancer incidence rates in the future is a matter of potential concern in South Korea.

Various studies have examined BE length as a risk factor for esophageal adenocarcinoma[13-15]. Results from a study showed that a doubling in BE length resulted in a 1.7-fold increase in the risk of developing esophageal adenocarcinoma[15], and others revealed that a significantly increased risk of dysplasia or adenocarcinoma was related to greater lengths of BE[13,14]. Therefore, accurate measuring of columnar-lined esophagus (CLE) lengths and describing in well-defined clinical terms are important in appropriate risk assessment and surveillance. Although previous diagnostic criteria for BE were based on the 3-cm length threshold of columnar-lined esophagus (CLE), by which BE was divided into 2 types, long ($\geqslant$ 3 cm) and short (< 3 cm), this simple classification of variable endoscopic findings of CLE was a rather crude approach in describing BE. Furthermore, as considerable inter- and intra-observer variability in detecting and describing the CLE are common, the establishment of an accurate BE diagnosis and surveillance may be tricky[16-18].

Therefore, the Prague classification system that measures the circumferential (C) and maximal (M) extents for endoscopic standardization of BE lengths was developed and finally introduced by the International Working Group for the Classification of Oesophagitis (IWGCO) in 2004[19]. However, the overall reliability and validity of the Prague C and M criteria for BE diagnosis continues to be challenged[20-22]. Moreover, its performance in South Korea where the incidence of BE is low and the short-segment BE is the predominant type remains unclear.

In the present study, we aimed to assess the feasibility of the Prague C and M criteria for the endoscopic description of CLE in South Korea where the prevalence and endoscopic features of this condition are quite different from the West and to suggest possible modifications that may fit the characteristics of the South Korean source population more properly.

## MATERIALS AND METHODS

This prospective study was conducted from the endoscopy data of consecutive CLE patients who underwent esophagogastroduodenoscopy (EGD) at Endoscopy Center of the Korea University Guro Hospital, Seoul, South Korea. Exclusion criteria included the presence of esophageal varices, acute upper gastrointestinal bleeding, malignancy near GEJ, and history of gastric surgery. Before each EGD, written informed consent was obtained. All endoscopic procedures were performed by an experienced endoscopist.

GEJ and SCJ were carefully assessed during the insertion of the endoscope. The distal margin of the palisade blood vessels of the lower esophagus was used as a marker of GEJ[23]. If the palisade vessels could not be seen adequately, the proximal margins of the gastric folds were used to identify GEJ. SCJ was used as a marker for upper border of CLE. The length of CLE, that is the distance from GEJ to SCJ, was measured by the insertion depths with the centimeter markings on the endoscope. CLE's shorter than 0.5 cm in length were ignored to avoid possible observation errors that may lead to overdiagnosis. Careful observation was done to look for any presence of islands of columnar mucosa.

The C and M extents of CLE were recorded accord-

**Table 1 Application of Prague circumferential and maximal criteria in cases with ultrashort, short, and long columnar-lined esophagus (*n* = 213)**

| Lengths of CLE (cm) | *n* (%) | C0Mx cases (%) |
|---|---|---|
| 0 (islands only) | 20 (9.4) | 20 (100) |
| 0.5-0.9 | 99 (46.5) | 99 (100) |
| 1.0-1.5 | 63 (29.6) | 61 (96.8) |
| 1.5-1.9 | 15 (7.0) | 14 (93.3) |
| 2.0-2.4 | 14 (6.6) | 12 (85.7) |
| 2.5-2.9 | 1 (0.5) | 1 (100) |
| ⩾ 3.0 | 1 (0.5) | 1 (100) |
| Total | 213 (100) | 208 (97.7)[1] |

[1]Exceptions: 2 cases with C1M1 and 3 cases with either C1M1.5, C1M2, or C1.5M2. CLE: Columnar-lined esophagus.

**Table 2 Application of Prague circumferential and maximal criteria in cases with short and long columnar-lined esophagus (*n* = 139)**

| Lengths of CLE (cm) | *n* (%) | C0Mx cases (%) |
|---|---|---|
| 0 (islands only) | 45 (32.4) | 45 (100) |
| 1.0-1.4 | 63 (45.3) | 61 (96.8) |
| 1.5-1.9 | 15 (10.8) | 14 (93.3) |
| 2.0-2.4 | 14 (10.1) | 12 (85.7) |
| 2.5-2.9 | 1 (0.7) | 1 (100) |
| ⩾ 3.0 | 1 (0.7) | 1 (100) |
| Total | 139 (100) | 134 (96.4)[1] |

[1]Exceptions: 2 patients with C1M1 and 3 patients with either C1M1.5, C1M2, or C1.5M2. CLE: Columnar-lined esophagus.

ing to the Prague C and M criteria proposed by the IWGCO[19]. M lengths were divided into long (⩾ 3 cm), short (1-2.9 cm), and ultrashort (< 1 cm) segments.

## RESULTS

### *Patient demographic characteristics*

A total of 213 CLE patients consisting of 154 men and 59 women, with 53.8 ± 12.3 years in age (mean ± SD) were enrolled.

### *Distribution of CLE lengths and application of the Prague C and M criteria*

**Analysis of cases with CLE's including ultrashort CLE's:** Distribution of CLE's according to their M values, including those with ultrashort CLE's, is shown in Table 1. Among the total 213 cases, 99 (46.5%), 63 (29.6%), 15 (7.0%), 14 (6.6%), 1 (0.5%), and 1 (0.5%) had CLE's of 0.5-0.9 cm, 1.0-1.4 cm, 1.5-1.9 cm, 2.0-2.4 cm, 2.5-2.9 cm, and ⩾ 3.0 cm in lengths, respectively. The remaining 20 cases (9.4%) had columnar islands alone. Therefore, 99 cases (46.5%) had ultrashort CLE's (CLE < 1.0 cm), 113 (53.1%) had short CLE's (1-2 cm) and only one (0.5%) had a long CLE (⩾ 3 cm), showing a CLE of 7.0 cm in length.

When the cases were classified by the Prague criteria, 208 (97.7%) had no C component (C0Mx). Two cases had C1M1 and the remaining three cases had either, C1M1.5, C1M1, or C1.5M2. Columnar islands were observed in 70 (32.9%) cases, of which 20 (9.4%) had columnar islands alone.

**Analysis of cases with CLE's excluding ultrashort CLE's:** Distribution of CLE's according to their M values among those excluding ultrashort CLE's is shown in Table 2. Among 139 cases, 63 (45.3%), 15 (10.8%), 14 (10.1%), 1 (0.7%), and 1 (0.7%) had CLE's of 1.0-1.4 cm, 1.5-1.9 cm, 2.0-2.4 cm, 2.5-2.9 cm and ⩾ 3.0 cm in lengths, respectively. Therefore, 138 (99.3%) out of all 139 cases had short CLE's, and only one showed an exceptionally long CLE.

When 139 cases were classified by the Prague criteria, 134 (96.4%) had CLE's without C component (C0Mx). Two cases had C1M1 and the remaining three patients had either C1M1.5, C1M1, or C1.5M2. Columnar islands were found in 70 (50.4%) cases, of which 45 (32.4%) showing columnar islands alone.

## DISCUSSION

BE is a very well known risk factor for the development of dysplasia and esophageal adenocarcinoma[24-26]. The risk of dysplasia and adenocarcinoma in metaplastic epithelium reportedly increases in parallel to the lengths of BE[13-15]. A recent multicenter study conducted by Gaddam *et al*[13] revealed that for every 1-cm extension in BE length, the risk of high-grade dysplasia and esophageal adenocarcinoma increased by 21%. The study demonstrated that the increase in BE lengths significantly widens the area of metaplasia, which is associated with the progression to high-grade dysplasia/esophageal adenocarcinoma[13]. Although a novel technique using a computer software program to create a two-dimensional image map of the esophagus has been introduced to accurately and reproducibly measure the extent of CLE[27], such a complicated approach is not suitable for a daily clinical practice. Therefore, assessment of BE extent by simple measurement of the height of metaplastic CLE remains as the most commonly used procedure to distinguish short- from long-segment BE[13-15]. However, the study of the clinical course and therapeutic response of BE has been limited because this classic method only provides gross estimates of the area. This system does not measure the surface areas of metaplastic mucosa, which may be more important than the endoscopic lengths[19]. The presence of an irregular border of columnar tissue or interspersed metaplastic mucosal islands can hamper the precise measurement of the extent of CLE[20].

The Prague C and M criteria, suggested by IWGCO, not only allows a more detailed description of the length of the endoscopically recognized CLE, using "C" and "M" values above the GEJ, but can also assist the objective calculation of the actual surface area, which may be more important in the risk assessment of the neoplastic transformation[19-21]. These advances in CLE description have facilitated the depiction and reporting of various

circumferential and tongue-like longitudinal CLE lengths by using a method that can be understood easily and comprehensively. Importantly, high inter-observer reliability in the grading of endoscopically suspected CLE was demonstrated among gastroenterology experts and trainees[22].

In recent years, accelerated life style changes have increased the prevalence of GERD in Asian populations, including South Koreans[9,10,28,29], and BE incidence is also expected to increase[12]. BE prevalence in South Korea was 0.2%-3.6% in the year 2000[11,12,30], lower than in Western countries. Lengths and shapes of CLE's as well as their prevalence in South Korea are quite different from those of the Western countries. Long-segment BE is more common in Western countries, wherein 14%-31% of BE patients show this type[31,32]. However, most cases of BE are short-segment type in South Korea, where long-segment type BE's are extremely rare[11]. In our study, with the exception of the only one case, 212 (99.5%) out of 213 CLE cases were short-segment type (< 3 cm); and from these, 99 cases (46.5%) had ultrashort CLE (< 1 cm). Lee *et al*[33] reported that the reliability coefficients of the C and M values in the endoscopic recognition of short-segment type CLE were 0.90 (95%CI: 0.80%-1.00%) and 0.92 (95%CI: 0.87%-0.98%), respectively. However, the reliability of such coefficients for the recognition of the ultrashort (< 1 cm) CLE extent type was very low, with C and M coefficients of 0.18 (95%CI: 0.03%-0.32%) and 0.21 (95%CI: 0.00%-0.51%), respectively[33].

Therefore, the routine applicability of the Prague C and M criteria as a standardized validated method for the detailed endoscopic description of ultrashort BE and short-segment BE, the most dominant BE types in South Korea, requires further analysis. As our study showed, all ultrashort CLE and almost all short-segment CLE cases lacked the C component and were classified as C0Mx. Therefore, it appears appropriate for us to propose to omit of the prefix "C0" from all C0Mx cases in order to avoid needless repetitions when describing most cases in regions like South Korea. Because the presence of columnar islands is a frequent finding as we have observed in this study and they also may change to dysplasia[34], we propose to add this to the Prague system, which currently does not include this category. Resultant examples following our proposals are: C2M5, if 2.0 cm of C component with 5.0 cm of M component; M2, if 2.0 cm of M component without C component; C2M5i or M2i, if columnar island(s) is/are found in addition to C2M5 or M2 CLE; and M0i, if only columnar island(s) is/are found.

In summary, the Prague C and M system is simple and useful in daily description of endoscopic feature of CLE's. However, in regions like South Korea where most cases with CLE display only short or ultrashort types without C component, we propose to omit the needless repetition of "C0" prefix from C0Mx and to add i component to describe the presence of columnar islands which also may have a potential to be dysplastic.

## COMMENTS

### Background

The Prague circumferential (C) length and maximal (M) length criteria have been adopted widely for grading the extent of Barrett's esophagus (BE). However, its validity in regions with low prevalence of BE, remains unclear. This study was designed to ascertain whether these criteria can be applied prior to its widespread application in South Korea.

### Research frontiers

The Prague C and M system is simple and useful in daily description of endoscopic feature of BE's. But, the overall reliability and validity of the Prague C and M criteria for BE diagnosis continues to be challenged. In this study, there are some suggestions of possible modifications that may fit the characteristics of the South Korean source population more properly.

### Innovations and breakthroughs

In regions like South Korea where most cases with columnar-lined esophagus display only short or ultrashort types without C component, the authors propose to omit the needless repetition of "C0" prefix from C0Mx and to add "i" component to describe the presence of columnar islands which also may have a potential to be dysplastic.

### Applications

This study serves as additional evidence supporting the investigation in parallel with the widespread application of the Prague system in South Korea.

### Terminology

Barrett's esophagus: A histological change of the distal tubular esophagus, from squamous to columnar epithelium, which displays an intestinal metaplasia containing goblet cells; The Prague classification criteria: A system to measure the C and M extents for endoscopic standardization of BE lengths.

### Peer-review

The study is has clear defined inclusion and exclusion criteria and is well conducted despite the lack of a control group. This study is innovative and would be interesting to see if the findings are reproducible in other countries where BE is not as common as in the West.

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# Impact of endoscopic ultrasound quality assessment on improving endoscopic ultrasound reports and procedures

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## Abstract

**AIM:** To evaluate the impact of endoscopic ultrasonography (EUS) quality assessment on EUS procedures by comparing the most recent 2013-2014 local EUS procedural reports against relevant corresponding data from a 2009 survey of EUS using standardized quality indicators (QIs).

**METHODS:** Per EUS exam, 27 QIs were assessed individually and by grouping pre-, intra-, and post-procedural parameters. The recorded QI frequencies from 200 reports (2013-2014) were compared to corresponding data of 100 reports from the quality control study of EUS in 2009. Data for QIs added after 2009 to professional guidelines (added after 2010) were also tabulated.

**RESULTS:** Significant differences ($P$-value < 0.05) were found for 13 of 20 of the relevant QIs examined. 4 of 5 pre-procedural QIs, 6 of 10 intra-procedural QIs, and 3 of 5 post-procedural QIs all demonstrated significant upgrading with a $P$-value < 0.05.

**CONCLUSION:** Significant improvements were demonstrated in QI adherence and thus EUS reporting and delivery quality when the 2013-2014 reports were compared to 2009 results. QI implementation facilitates effective high-quality EUS exams by ensuring comprehensive documentation while limiting error.

**Key words:** Endoscopic ultrasound; Improvement; Fine needle sspiration; Quality indicators



**Core tip:** Consistent implementation of these endoscopic ultrasonography (EUS) quality indicators by endosonographers facilitates effective high-quality EUS procedures by ensuring comprehensive procedural documentation while also limiting error.

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## INTRODUCTION

Endoscopic ultrasonography (EUS) is an endoscopic procedure that has benefited from quality control (QC) analysis and quality indicator (QI) analysis, a benchmark of widely-used guidelines being those of the American Society of Gastrointestinal Endoscopy (ASGE)[1]. Bluen *et al*[2] 2012 demonstrated how responsible QC, including systemic monitoring and evaluation, is critical to rendering EUS fine needle aspiration (EUS-FNA) protocol more effective. The consistency with which practitioners adhere to or comply with these QIs, whether they are pre-, intra- or post-procedure, goes a long way in optimizing the significance of the endoscopic exam. Coe *et al*[3] 2009 studied physician adherence to EUS QIs over an eight-year span and observed statistically significant findings: Improvement was achieved in the EUS areas previously evaluated to have been weak by quality assessment. Lachter *et al*[4] in 2013, explored adherence to EUS QIs at ten different Israeli medical centers with international comparison to the University of Chicago when measured using a standardized table of relevant QIs and observed that an overall improvement in documented quality of EUS exams was found in centers ensuring comprehensive documentation and stronger guideline adherence.

The ASGE and the American College of Gastroenterology (ACG) formed a task force of expert endoscopists and pioneered a way in which efforts of QC could be efficiently carried out to document the quality of endoscopic services and to promote optimal procedural performance[1]. These QIs were developed by the task force to serve as guidelines for the 4 major endoscopic procedures: Esophagogastroduodenoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography, and EUS. A recent update of QIs common to all GI endoscopic procedures was put forth prioritizing indicators that have wide-ranging clinical application, are associated with variation in practice and outcomes, and were validated in clinical studies[5]. This update to the original version in 2006, framed by the ASGE/ACG task force, promotes performance targets for the QIs to help direct continuous quality improvement and an evidence-based system of benchmarks for each QI[5].

The present study aims to evaluate the impact of the EUS quality assessment on the improvement of these procedures by comparing 2013-14 local EUS procedural reports against relevant corresponding data from a 2009 survey of QIs (Lachter *et al*[4]). That is, whether the EUS operators are improving their adherence/compliance to the QIs, and if the incorporation of and adherence to the QIs enhance the overall quality of EUS exams and patient outcomes.

## MATERIALS AND METHODS

Two hundred EUS exam reports from 2013-2014 in Rambam were reviewed for each of the active echoendoscopists. Each EUS report was assessed by a pre-established standardized table of EUS QIs (Table 1). Per EUS exam, QIs are evaluated individually as well as by the following categories: Pre-procedural, intra-procedural, and post-procedural. The hospital medical statistician was consulted and statistics are in accord with her recommendations using SPSS version 21. The comparison group for this study was from a 2009 survey of QIs for 100 EUS examinations. This was used as a comparative baseline to determine whether measures to increase implementation of these QIs were successful in yielding improvements in EUS procedure documentation and quality.

The methods of collection of data are that each of ten echoendoscopists was asked to submit ten EUS anonymized reports in 2008. The results were shared, at a meeting of the national gastroenterology society, without naming any of the echoendoscopists regarding the scores for their respective EUS reports, but rather only giving the pooled results, and comparison of the per-echoendoscopist results, regardless of their years of experience in performing EUS or their volume of procedures performed yearly. The images from EUS were not used, only the verbal reports. The reports were from multiple institutions. Each echoendoscopist could use either radial or linear or both kinds of endoscope. For the 2014 review, three echoendoscopists were reviewed, with varying experience from 3-18 years of experience, from only one institution. Trainees are not authorized to sign off on final EUS reports.

We also emphasize that we cannot be sure that every one of the many echoendoscopists nationally are always maintaining the highest quality standards, but we believe that continual monitoring and reporting the results publically of quality assessments lead to the long-term knowledge that reviews will be made and will be made public. This method of ensuring quality has been shown by various authors, including most recently by Abdul-Baki *et al*[6], to be of significant value in raising quality of procedural documentation of endoscopies.

Reporting frequencies of each QI in EUS reports were calculated. Comparison between our study results with those of the previous study, regarding 20/27 listed standardized QI parameters (Table 1) plus demographics, were tested by Fisher Exact Test. Frequencies for indications for EUS procedures were calculated and then compared in 6 out of the 10 total indications as that was the number of indications that matched the 2009 study. A $P < 0.05$ was considered as significant. Twenty out of the 27 listed QIs were compared with 2009 data for statistical analysis because only 20/27 QIs

**Table 1 Endoscopic ultrasound quality indicators (American Society of Gastrointestinal Endoscopy 2006)**

| |
|---|
| Pre-EUS indicators |
| Indications for procedure |
| Detailed description of the patient by the referring physician |
| Patient completed procedural preparation of minimum 6 h NPO |
| Antibiotics per protocol were given in the need to perform FNA of pancreatic cysts |
| Listing of sedatives administered prior to and during EUS |
| Patient signed agreement of informed consent for EUS and/or if consented for research |
| Intra-procedural indicators |
| A detailed description of the methods used to visualize routinely evaluated EUS organs. If there is any suspicion of organ pathology, the respective organ parenchyma should be described: |
| Suspected pancreatic lesions should include a parenchymal description including the body, head, tail, and duct |
| Common bile ducts and gallbladder contents should be detailed and a description of the biliary tree for sludge, stones, or other findings |
| If found, prominent lymph nodes should be described in detail as well as the kidneys and left liver lobe for the presence or absence of lesions |
| The celiac axis should be described for general arterial structure along with the aorta and superior mesenteric artery as well as the presence or absence of identifiable lymph nodes |
| Description of abnormal/pathological results: |
| Description of any tumor by the tumor, node, and metastasis system |
| Accurate detailing of the lesions and its surroundings in accordance with layers visualized by EUS degree of tumor penetration into organ mucosa and surrounding structures |
| Detailing the presence of lymph nodes when suspicious for malignancy and when performing FNA |
| Presence or absence of any mechanical problems or difficulties including past abdominal surgeries or ascites |
| Patient awakened/uncooperative during the procedure |
| Details of the number of FNAs performed with respective number of passes into each suspected lesion including: |
| Number of passes |
| Needle size |
| Number of needles |
| Impressions of aspirate (bloody, mucinous, color, *etc*.) |
| Cytology and/or histological examination |
| In-room tentative diagnosis |
| Post-procedural indicators |
| Summary of medical diagnoses |
| Examination findings, even if not relevant to the reason for EUS referral, should be listed |
| Physician recommendations shall be listed with respect to examination findings including instructions for the patient |
| Instructions for how patients will receive the results and for referring physician |
| After EUS, the incidence of adverse events should be listed, including pancreatitis, bleeding, and/or infections and the need for hospitalization |

EUS: Endoscopic ultrasonography; NPO: Nil Per Os; FNA: Fine needle aspiration.

corresponded exactly with the previous study's data.

## RESULTS

Significant differences ($P$-value < 0.05) were found in 13/20 QIs (Table 2). For pre-procedural QIs: Minimum 6 h Nil Per Os (NPO); Antibiotics per protocol prior to FNA of pancreatic cysts; Listing of anesthesia administered prior to and during EUS; Patient signed agreement of informed consent. For intra-procedural QIs ($P$-value < 0.05): Suspected pancreatic lesions should include parenchymal regional descriptions citing pancreatic head, body, tail, and duct; common bile duct (CBD) and gallbladder imaging should be detailed including a description for sludge, stones or other findings; lymph node (LN) description as well as pole of left kidney and left liver lobe for lesions; Celiac axis described for arterial structures along w/aorta, superior mesenteric artery and LNs; Presence or absence of mechanical problems or difficulties including past abdominal surgeries or ascites; Patient awakened or uncooperative during procedure. For post-procedural QIs ($P$-value < 0.05): Exam findings, even if not relevant to reason/indications for EUS referral, instructions for how patient will receive cytology/chemistry results, and incidence or absence of adverse events should also be documented.

The mean patient age was 57 years old with a standard deviation of 16 and a range of 18-92 years of age. Fifty-nine point five percent of patients were females. Although there were specific differences in QI adherence among the three EUS operators, there was no statistical significance in such differences found. The primary indications for referral for EUS included suspected CBD (19%), pathologic findings on imaging (9%), mostly of the pancreas, and need for FNA and/or biopsy, as shown in Table 3.

## DISCUSSION

Pre-procedural 6-h NPO preparation was found in 100% of EUS reports, a statistically significant improvement over the 8% of the 2009 results ($P$ < 0.001). The considerable disparity in this result may or may not be due to simple documentation error as opposed to so many patients not aptly preparing for the procedure. Antibiotics per protocol was documented as being given to every (100%) relevant patient prior to FNA of pancreatic cyst, which is a significant improvement over the 40% coverage of the previous study. Although the efficacy of antibiotics prophylaxis is as yet unproven, it

**Table 2 Endoscopic ultrasonography quality indicator frequencies and comparative statistical analysis**

| EUS QIs | Rambam 2013-2014 EUS reports % documented ($n$ = 200) | *WJGE* Lachter *et al* 2013 (data from 2009), EUS reports % documented ($n$ = 100) | Improvement significance ($P$ value) |
|---|---|---|---|
| Pre-procedural | | | |
| Indications for procedure | 99% | 97% | NS |
| Detailed patient description from referring physician | 100% | 8% | $P < 0.001$ |
| Minimum 6 h NPO | 100% | 40% | $P < 0.001$ |
| Antibiotics per protocol prior to FNA of pancreatic cysts | 99.5% | 94% | $P = 0.0014$ |
| Listing of anesthesia administered prior to and during EUS | 100% | 61% | $P < 0.001$ |
| Patient signed agreement of informed consent | 100% | 61% | $P < 0.001$ |
| Intra-procedural | | | |
| Suspected pancreatic lesions should include parenchymal description of body, head, tail, and duct | 95% | 64% | $P < 0.001$ |
| CBD and GB contents should be detailed and a description for sludge, stones or other findings | 98% | 0% | $P < 0.001$ |
| LN detailed description as well as kidney and left liver lobe for lesions | 50% | 35% | $P = 0.04$ |
| Celiac axis described for arterial structure along w/aorta, SMA and LNs | 13% | 5% | NS |
| Description by TNM system | 100% | 95% | NS |
| Detailing of lesions and surroundings in accordance with layers visualized by EUS | 75% | 65% | NS |
| Degree of tumor penetration into organ mucosa and surrounding structures | 80% | 46% | NS |
| Detailing presence of LN when suspicious for malignancy and when performing FNA | 100% | 6% | $P < 0.001$ |
| Presence or absence of mechanical problems or difficulties including past abdominal surgeries or ascites | 100% | 2% | $P < 0.001$ |
| Patient awakened or uncooperative during procedure | 78% | - | - |
| No. of passes (FNA) | 67% | - | - |
| Needle size | 99% | - | - |
| No. of needles | 40% | - | - |
| Impressions of aspirate (bloody, mucinous, color) | 100% | - | - |
| Cytology/histology | 100% | - | - |
| In-room tentative Dx | 100% | - | - |
| Post-procedural | | | |
| Summary of Dx | 95% | 37% | $P < 0.001$ |
| Exam findings, even if not relevant to reason for EUS referral | 100% | 80% | NS |
| Physician recommendations with respect to exam findings | 99% | 52% | $P < 0.001$ |
| Instructions for how patient will receive results | 100% | 0% | $P < 0.001$ |
| Incidence of adverse events should be listed | | | |

NS: Not Significant; Dx: Diagnosis; LN: Lymph node; TNM: Tumor node metastasis; EUS: Endoscopic ultrasonography; NPO: Nil Per Os; FNA: Fine needle aspiration; CBD: Common bile duct; GB: Gallbladder; SMA: Superior mesenteric artery.

**Table 3 Indications for endoscopic ultrasonography referral**

| | Rambam 2013-2014 EUS reports | 2009 EUS reports |
|---|---|---|
| Suspected CBD stone | 19% | 31% |
| Pancreatic tumor suspicion | 8% | 17% |
| Pathologic findings on imaging | 19% | 16% |
| Suspicion of esophageal or stomach tumor | 6% | 12% |
| Pancreatic cyst | 8% | 8% |
| Pancreatitis | 6% | 3% |
| FNA/biopsy | 11% | - |
| Submucosal lesion clarification | 4% | - |
| Screening/followup | 5% | - |
| Other | 12% | - |

EUS: Endoscopic ultrasonography; FNA: Fine needle aspirations; CBD: Common bile duct.

is considered by professional societies to be warranted and should be documented. Anesthesia administered was listed prior to and during EUS for 99.5% of patients reported, statistically more significant than the 94% of the 2009 data. The specifics of sedation and/or anesthesia for EUS procedures is an important area for research, involving the use of large endoscopes and sometimes prolonged procedures. One hundred percent of patients signed informed consent agreement for procedures compared with the 61% documented by Lachter *et al*[4] (Table 2). While it is likely that every patient also gave consent in the latter study, it is critical

that it all be documented so as to maintain the integrity, quality, and completeness of the reports.

As evidenced by the above results (Table 2), most of the intra-procedural QIs saw significant improvement in operator compliance, making for better-executed and well-reported EUS exams. Adherence to a parenchymal description of suspected pancreatic lesions and detailing of biliary contents and pathology (stones, sludge, *etc.*) was 100% and 95% respectively. These were significant improvements over the 40% and 64%, respectively, of the previous study. Prominent LN and/or kidney and left liver lobe lesions were detailed when relevant and present in 98% of patients, which was a QI not adhered to previously. Also, the celiac axis was described half the time, an apparently significant improvement over the 35% in 2009 ($P$ = 0.04). Description of tumors by the Tumor Node Metastasis system is an area for great improvement as only 13% of patients with tumors were reported accordingly. The detailing of submucosal lesions and surroundings in accordance with layers visualized by EUS was always adhered to (100%), but this was not a significant improvement over the previous study's outcome (95%). This difference highlights the difficulty of demonstrating statistically significant improvement when dealing with high outcomes (the upper limit of adherence can't exceed 100%). The 200 EUS reports detailed level of tumor penetration in 75% of patients and detailed LN presence when suspicious for malignancy and when performing FNA for 80% of patients (Table 2). More intra-procedural issues such as mechanical problems like past abdominal surgeries or ascites and patient awakening or uncooperativeness during procedure were documented for 100% of patients, showing a very significant improvement over the 6% and 2% results, respectively, in the 2009 data (Table 2). Checklisting of these items facilitated documentation without having "mandatory" fields.

While the 2009 results consolidated the FNA performance details (number of passes, needle size, *etc.*) into one QI entity, our study meticulously examined each of the QIs for detailing FNAs individually in the EUS procedural reports. As such these QIs (numbered 17-22 in the table) were not comparable as is for statistical analysis. Frequencies were computed: 78% of reports documented number of passes, 67% for needle size, 99% for number of needles, 40% described impressions of aspirate, and 100% adhered to the cytology/histological examination and in-room tentative diagnosis indicators (Table 2).

Post-procedural QIs were documented for almost all of the patients: 100% of reports included summary of diagnoses, 95% of examination reports contained findings unrelated to the original reason for referral-a significant improvement from the 37% adherence previously. Physician recommendations and instructions for patients including how they receive results were included in 100% and 99% respectively, showing an improvement in the latter QI from 52% ($P$ < 0.001). As per Table 2, the incidence of adverse events was listed 100% of the EUS procedural reports. A caveat, however, must be noted: Incidence of post-EUS adverse events, as pancreatitis, bleeding, and/or infection, were checked and recorded only for immediate (within 48 h) follow-up of patients. Long-term adverse effects (14 d following) of procedures were not documented and this was an area in post-hoc analysis considered to be in need of QC monitoring.

### *Limitations*

This study had limitations. It was a comparative retrospective study, and as such did not garner the intrinsic advantages that it would have if done prospectively, such as better oversight and control over variables, confounders, and study conditions. Second, while most of the QIs evaluated overlapped for proper statistical comparison, not every QI did. Thirdly, there was no patient satisfaction data collected and assessed in this study, an area which should be developed. Notably, in the past, a local survey was of importance in determining the satisfaction of referring physicians from the EUS examinations; this too should be revisited periodically, as such a survey may improve an EUS service, recognizing that the secondary clients of an EUS service include the referring physicians[7].

In conclusion, consistent implementation of these EUS QIs by endosonographers facilitates effective high-quality EUS procedures by ensuring comprehensive procedural documentation while also limiting error. Moreover, results of the present study demonstrated that there have been significant improvements in EUS delivery quality and QI adherence when comparing this study to a previous audit of EUS results. The Hawthorne effect describes how workers do better when knowing that their work is being watched and evaluated. By this token, vigilance regarding QIs in EUS, when recorded and published, seems to enhance the adherence to optimizing EUS reports and examinations, as such is the case for this center.

With increasing demand for EUS and the robust number of physicians performing these procedures, recommendations for QIs will continue to evolve and excellence in quality of care will continually be collaboratively pursued.

## COMMENTS

### *Background*

Endoscopic ultrasonography (EUS) is an endoscopic procedure that has benefited from quality control analysis and quality indicator (QI) analysis, a benchmark of widely-used guidelines being those of the American Society of Gastrointestinal Endoscopy.

### *Innovations and breakthroughs*

The present study aims to evaluate the impact of the EUS quality assessment on the improvement of these procedures by comparing 2013-14 local EUS procedural reports against relevant corresponding data from a 2009 survey of QIs. That is, whether the EUS operators are improving their adherence/compliance to the QIs, and if the incorporation of and adherence to the QIs enhance the overall quality of EUS exams and patient outcomes.

### *Applications*

Vigilance regarding QIs in EUS, when recorded and published, seems to enhance the adherence to optimizing EUS reports and examinations, as such is the case for this center.

### *Peer-review*

This manuscript evaluated the impact of EUS quality assessment on EUS procedures by comparing the most recent 2013-2014 local EUS procedural reports against relevant corresponding data from a 2009 survey of EUS. The authors used standardized QIs for EUS quality assessment.

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CASE REPORT

# Delayed perforation after endoscopic submucosal dissection for early gastric cancer: Clinical features and treatment

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Informed consent statement: Informed consent has been obtained publishing website or posting infomation in our hospital.

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## Abstract

Perforation is an important procedural complication of endoscopic submucosal dissection (ESD) for early gastric cancer. Although the incidence of delayed perforation after ESD is low, extreme caution is necessary because many cases require surgical intervention. Among 1984 lesions of early gastric cancer treated in our hospital by ESD in 1588 patients from September 2002 through March 2015, delayed perforation developed in 4 patients (4 lesions, 0.25%). A diagnosis of delayed perforation requires prompt action, including surgical intervention when required.

**Key words:** Endoscopic submucosal dissection; Early gastric cancer; Delayed perforation



**Core tip:** Delayed perforation is a serious complication of endoscopic submucosal dissection for early gastric cancer. A diagnosis of delayed perforation requires

prompt action, including surgical intervention when required.

Yano T, Tanabe S, Ishido K, Azuma M, Wada T, Suzuki M, Kawanishi N, Yamane S, Sasaki T, Katada C, Mikami T, Katada N, Koizumi W. Delayed perforation after endoscopic submucosal dissection for early gastric cancer: Clinical features and treatment. *World J Gastrointest Endosc* 2016; 8(8): 368-373 Available from: URL: http://www.wjgnet.com/1948-5190/full/v8/i8/368.htm DOI: http://dx.doi.org/10.4253/wjge.v8.i8.368

## INTRODUCTION

The development of endoscopic submucosal dissection (ESD) has facilitated the *en bloc* endoscopic resection of larger lesions, as well as lesions with an ulcer scar. Such lesions are now included in the expanded indications for ESD[1].

Perforation is an important procedural complication of ESD, reported to occur at an incidence of 3.6% to 8.7%. Most cases of intraoperative perforation can be closed by clipping[2-4]. In contrast to intraoperative perforation diagnosed during endoscopic treatment, delayed perforation detected after ESD is often associated with peritonitis at time of diagnosis and frequently requires emergency treatment, including surgical intervention[5]. Few studies have reported on delayed perforation, and its management remains controversial. We describe our experience with 4 patients (4 lesions) who underwent emergency surgery for delayed perforation that developed after ESD in our hospital.

## CASE REPORT

### Patients and methods

A total of 1984 consecutive lesions of early gastric cancer treated by endoscopic resection between September 2002 and March 2015 were studied. Informed consent was obtained from all patients in accordance with our institutional protocol.

We defined delayed perforation as the abrupt onset of abdominal pain and signs and symptoms of peritoneal irritation accompanied by the presence of free air on chest and abdominal radiography or abdominal computed tomography (CT) in a patient who showed no evidence of perforation during ESD or free air immediately after ESD, as proposed by Hanaoka *et al*[5].

### ESD procedures

The circumference of the lesion was marked with a needle knife. After injecting glycerol solution into the submucosa, an initial cut was made with a needle knife outside the marking. An IT Knife (Olympus Medical Systems, Tokyo, Japan) was inserted into this cut and operated to cut around the lesion[6]. The marked lesion was separated from the surrounding normal mucosa. Then, the submucosal layer was dissected using the IT Knife, and the lesion was finally removed. An IT Knife was used to perform ESD until the end of March 2007, and an IT Knife2 (Olympus Medical Systems) was used from April 2007 onward[7].

### Results

We have described our experience with 4 patients (0.25%) who underwent surgery for delayed perforation that developed after ESD. The clinicopathological features and clinical outcomes of the patients with delayed perforation are summarized in cases 1 to 4 of Table 1. Among the 4 patients, 1 lesion was resected in 3 patients, and 2 lesions were resected in the other patient. The lesions were located the lower third of the stomach in 3 patients and the upper third of the remnant stomach in 1 patient. The diameters of resected specimens were large, exceeding 50 mm in 3 of the 4 patients; the longest diameter was 102 mm. In 1 of these patients, the ulcer floor had fused together after two adjacent lesions had been resected, and the resected specimen was 80 mm in diameter. The procedure time was longer than 90 min in all 4 patients, and the longest time was 240 min.

All cases of delayed perforation occurring in our hospital developed within 24 h in all except 1 patient. Because all patients had peritonitis at the time of detection of delayed perforation, emergency surgery was required. However, none of the 4 patients died of delayed perforation.

### Case 1

The patient was an 89-year-old man with a superficial and depressed type (0-Ⅱc) differentiated adenocarcinoma, 84 mm × 50 mm, arising in the posterior wall of the lesser curvature at the gastric angle. The tumor invaded the first layer of the submucosa (SM1). ESD was performed using an IT Knife, and the procedure time was 4.0 h. The resected specimen measured 102 mm × 73 mm (Table 1).

In the early morning 2 d after ESD, the patient had dyspnea and abdominal distension. Abdominal CT showed the presence of free air, and emergency surgery was performed on the same day. A perforation was found at the site resected by ESD. Omental implantation was performed at the site. Delayed perforation was apparently caused by the transfer of heat generated by extensive resection and prolonged local dissection to the muscular layer.

### Case 2

The patient was a 74-year-old man with 2 adjacent 0-Ⅱc lesions (20 mm × 17 mm and 17 mm × 10 mm) arising in the anterior and posterior walls of the greater curvature at the gastric angle (Table 1 case No. 2). ESD was performed with the use of an IT Knife2 (Figure 1A). The time required for ESD was 2.4 h. The ulcers had fused together to form a single ulcer on the resected

**Table 1 Clinicopathological features and clinical outcomes in 16 patients with delayed perforation after endoscopic submucosal dissection**

| Case No. | Age | Sex | Location | Tumor size (mm) | Resected specimen size (mm) | Depth of tumor | Scar in tumor | Histological type | Time required for ESD (h) | Device | Time until peritonitis (h) | Size of perforation (mm) | Treatment of perforation | Hospital stay (d) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 89 | Male | L, Lc | 84 × 50 | 102 × 73 | SM1 | Absent | Diff. | 4 | IT | > 24 | 3 | Surgery | 23 |
| 2 | 74 | Male | L, Gc | 17 × 10, 20 × 17 | 80 × 45 (2 lesions) | M | Absent | Diff. | 2.4 | IT2 | 10 | - | Surgery | 15 |
| 3 | 63 | Male | R, P | 15 × 12 | 28 × 28 | M | Absent | Diff. | 1.5 | IT2 | 15 | - | Surgery | 30 |
| 4 | 83 | Female | L, Lc | 37 × 15 | 53 × 30 | SM2 | Present | Diff. | 2.5 | IT2 | 11 | 2 | Surgery | 23 |
| 5[4] | 50 | Female | U, Lc | 20 | 50 | M | Present | Diff. | 3.5 | IT2 | 24 | 20 | Surgery | 16 |
| 6[4] | 60 | Male | M, A | 18 | 32 | SM | Absent | Diff. | 2 | IT | 19 | - | Surgery | 14 |
| 7[4] | 70 | Male | U, A | 15 | 45 | M | Absent | Diff. | 3 | IT | 21 | - | Conservative | 15 |
| 8[4] | 61 | Male | U, P | 50 | 85 | SM | Absent | Diff. | 9 | IT | 15 | - | Surgery | 33 |
| 9[4] | 64 | Female | U, Lc | 12 | 50 | M | Absent | Diff. | 2.2 | IT | 23 | - | Surgery | 20 |
| 10[4] | 64 | Male | U, P | 15 | 45 | M | Present | Diff. | 1.5 | IT2 | 10 | - | Surgery | 12 |
| 11[13] | 70 | Female | R, Lc | 5 | 30 | M | Absent | Diff. | 2 | TT | > 24 | - | Conservative | 21 |
| 12[14] | 60 | Female | U, P | 4 | 19 | M | Absent | Signet | 1.1 | IT2 | > 24 | 2 | Endo clips | 12 |
| 13[8] | 70 | Female | L, Gc | 26 | 38 | M | Absent | Diff. | 0.5 | IT | - | 3 | Endo clips | 13 |
| 14[15] | 60 | Male | M, Gc | 6 × 4 | 18 × 17 | M | Absent | Diff. | 0.4 | - | 10 | 1 | Surgery | 10 |
| 15[16] | 64 | Male | L, A | 18 × 15 | 40 × 38 | SM2 | Present | Diff. | - | - | > 24 (49 d) | 8 | Surgery | - |
| 16[9] | 59 | Female | L, A | 10 | - | M | Present | Diff. | 0.4 | - | > 24 | 20 | Conservative | 33 |

U: Upper body; M: Middle body; L: Lower body; R: Remnant stomach; Lc: Lesser curvature; P: Posterior; A: Anterior; Gc: Greater curvature; Diff.: Differentiated adenocarcinoma; Signet: Signet ring cell carcinoma; TT: Triangle-tip knife; ESD: Endoscopic submucosal dissection.

surface. The resected specimen measured 80 mm × 45 mm (Figure 1B) (Table 1).

The patient had fever and abdominal pain at night on the day of ESD. Chest radiography and abdominal CT on the day after ESD showed the presence of free air, and emergency surgery was performed on the same day (Figure 2). Although there was no distinct evidence of perforation, the muscular layer had become thin. The site was therefore partially resected. Pathological examination showed no distinct signs of perforation. However, the muscular layer had become necrotic (Figure 3). Delayed perforation was most likely ascribed to the transmission of heat resulting from the extensive hemostatic procedure to the muscular layer.

### *Case 3*

The patient was a 63-year-old man who had previously undergone distal gastrectomy with Billroth I reconstruction for gastric cancer. A superficial and elevated type (0-Ⅱa) lesion, measuring 15 mm × 12 mm, had arisen in the posterior wall of the greater curvature in the remnant stomach. ESD was performed using an IT Knife2. The time required for ESD was 1.5 h. The resected specimen measured 30 mm × 24 mm (Table 1).

The patient vomited during the night of the day of ESD. In the early morning of the next day, fever and abdominal pain developed. Abdominal CT showed free air, and emergency surgery was performed on the same day. A perforation was noted at the treatment site. Omental implantation and antecolic Roux-en-Y reconstruction were performed. Delayed perforation was apparently caused by direct exposure of the muscular layer of the remnant stomach to acid and bile after surgery.

### *Case 4*

The patient was an 83-year-old woman with a tumor, 37 mm × 15 mm, in the lesser curvature of the antrum. ESD was performed with an IT Knife2 for local recurrent lesions with an ulcer scar that had developed after ESD. The ESD procedure time was 2.5 h, and the resected specimen measured 53 mm × 30 mm.

Abdominal pain developed during the night of the day of ESD. On the following day, abdominal CT revealed the presence of free air, and emergency surgery was

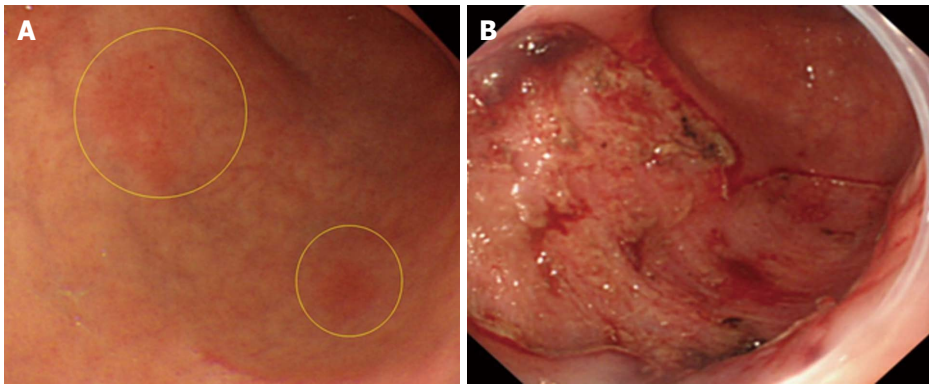


**Figure 1 Endoscopic submucosal dissection.** A: Findings on upper gastrointestinal endoscopy (conventional examination). Patient 2 had delayed perforation after undergoing endoscopic submucosal dissection (ESD) for early gastric cancer (EGC). 0-Ⅱc lesions were found in the anterior and posterior walls of the greater curvature at the gastric angle (circles); B: Findings after ESD. Patient 2 had delayed perforation after ESD for EGC. The 2 lesions were adjacent. The ulcer floor had fused together.

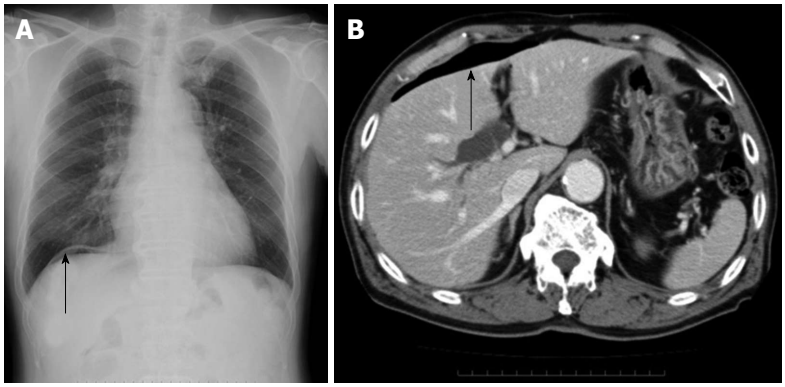


**Figure 2 Radiography and abdominal computed tomography.** A: A chest radiograph, showing free air below the right diaphragm (arrow); B: An abdominal computed tomography scan, showing free air (arrow).

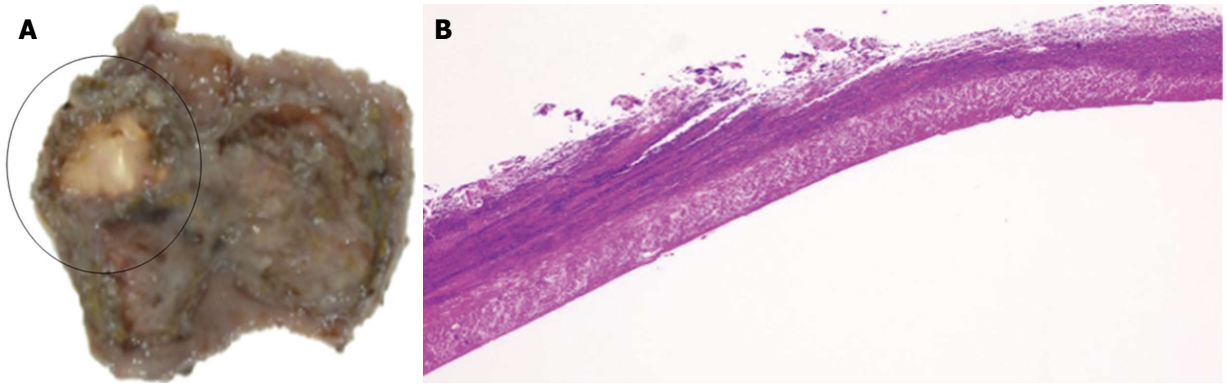


**Figure 3 Muscular layer had become necrotic.** A: The surgically resected specimen. Although no distinct site of perforation was found in the surgically resected specimen, the ulcer floor had become thin after endoscopic submucosal dissection (circled); B: The histopathological specimen stained with hematoxylin and eosin. At the ulcer floor, the muscular layer was exposed, and all layers had become necrotic.

performed on the same day. A perforation was found at the site of treatment. Because the resected lesions were strongly suspected to invade the submucosa, distal gastrectomy with Billroth I reconstruction was performed. Delayed perforation was apparently attributed to the transmission of heat generated by the prolonged local dissection procedure, necessitated by the presence of an ulcer scar, to the muscular layer of the stomach (Table 1).

## DISCUSSION

Perforation can be classified into 2 types according to the time of onset: Intraoperative perforation, which occurs during ESD, and delayed perforation, which is detected after treatment with no evidence of free air during ESD

or on abdominal radiographs obtained immediately after surgery.

There are several possible causes of the delayed perforation that occurred in our hospital: (1) the transmission of heat generated by the prolonged local dissection procedure to the muscular layer of the stomach; (2) direct exposure of the muscular layer to acid and bile in the postoperative remnant stomach; and (3) ischemic changes of the mucosa caused by excessive hemostatic procedures. Patient 1 and patient 2 were treated when we had relatively little experience, shortly after the introduction of ESD. Delayed perforation in these patients was suggested to have been caused by the transmission of excessive heat caused by prolonged dissection to the muscular layer.

It is difficult to predict the risk of delayed perforation occurring after ESD because the incidence is low and unknown risk factors are most likely involved. Hanaoka *et al*[5] proposed that delayed perforation is most likely to occur at sites of lesions involving the lesser curvature of the stomach, which is anatomically susceptible to decreased blood flow. Two of the 4 patients in our study had lesions located in the lesser curvature of the stomach.

As for the treatment of perforations, most intraoperative perforations can be closed by clipping the perforation site and then be followed up conservatively[3]. In contrast, delayed perforations are already associated with peritonitis at the time of detection, and surgical intervention is generally required.

Table 1 summarizes the clinical and histopathological characteristics and the clinical courses of 16 patients (8 men and 8 women) with delayed perforation, including the 4 patients in the present study as well as those reported previously. The median age was 64 years (range, 50-89). Lesions were located in the upper third of the stomach in 6 patients, the middle third in 2 patients, the lower third in 6 patients, and the remnant stomach in 2 patients. Lesions were located along the lesser curvature in 4 patients. The median specimen diameter was 45 mm (range, 18-102). The depth of invasion was intramucosal in 11 patients and submucosal in 5. The median ESD procedure time was 2.0 h (range, 0.4-9.0). Delayed perforation most frequently occurred in patients with a long resected specimen diameter, a deep depth of invasion, and a prolonged ESD procedure time.

Delayed perforation was treated by surgery in 11 patients and conservative therapy including closure with an endoclip and follow-up in 5. The median hospital stay was 16 d (range, 10-33) in the patients who underwent surgery and 21 d (range, 15-33) in the patients who were followed up. The hospital stay thus tended to be longer in the conservatively treated patients. In previous studies, some patients with delayed perforation had minimal abdominal symptoms at the time of diagnosis. In other patients, a small perforation several millimeters in diameter was detected by chance on follow-up endoscopy performed the day after ESD. The perforation was closed by clipping. Patients with localized peritonitis who responded to conservative therapy have also been reported[4]. However, an intraperitoneal abscess developed in some patients who were followed up conservatively, and drainage was required. Long-term hospitalization was also necessary in some patients[8].

Increased intragastric pressure has been reported to reduce mucosal blood flow and cause ischemic changes[9,10]. Therefore, one of the solutions to prevent delayed perforation would be insertion of a nasogastric tube to achieve decompression of the gastric lumen.

Similar to our patients, delayed perforation may extensively involve the ulcer floor, and the muscular layer may already be necrotic. Closure of a perforation by endoscopic clipping may therefore be challenging. Moreover, insufflation at the time of endoscope insertion can increase the size of the perforation and thus have a negative effect. Even if the perforation site can be successfully closed by endoscopic clipping, reperforation accompanied by the intraperitoneal leakage of gastric juice or bile has been reported in postoperative patients with a remnant stomach not surrounded by the greater omentum[3]. Therefore, if delayed perforation is diagnosed on the basis of postoperative abdominal findings and the presence of free air on plain radiographs, surgeons should immediately be consulted about the need for surgical intervention. Performing surgery before the exacerbation of peritonitis will also most likely contribute to a better postoperative course.

Delayed perforation is a serious complication of ESD for early gastric cancer[11,12]. A diagnosis of delayed perforation requires prompt action, including surgical intervention when required.

## COMMENTS

### *Case characteristics*

Among 1984 lesions of early gastric cancer treated in the authors' hospital by endoscopic submucosal dissection (ESD) in 1588 patients from September 2002 through March 2015, delayed perforation developed in 4 patients.

### *Differential diagnosis*

Gastrointestinal perforation.

### *Imaging diagnosis*

Chest radiography and abdominal computed tomography (CT) on the day after ESD showed the presence of free air. They diagnosis delayed perforation.

### *Pathological diagnosis*

At the ulcer floor, the muscular layer was exposed, and all layers had become necrosis.

### *Treatment*

Chest radiography and abdominal CT on the day after ESD showed the presence of free air, and emergency surgery was performed on the same day.

### *Related reports*

Few studies have reported on delayed perforation, and its management remains controversial.

### *Experiences and lessons*

Delayed perforation is a serious complication of ESD for early gastric cancer. A diagnosis of delayed perforation requires prompt action, including surgical intervention when required.

### *Peer-review*

The authors have reported good study for "Delayed perforation after endoscopic submucosal dissection for early gastric cancer" and have submitted a well-written manuscript.

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CASE REPORT

# Diagnosis of a submucosal mass at the staple line after sigmoid colon cancer resection by endoscopic cutting-mucosa biopsy

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Institutional review board statement: The patient was treated with approved diagnostic and therapeutic procedures according to generally accepted standards of care.

Informed consent statement: Informed consent was not required in our facility but obtained from the patient for this case report.

Conflict-of-interest statement: None to report.



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## Abstract

A 48-year-old man underwent laparoscopic sigmoid colon resection for cancer and surveillance colonoscopy was performed annually thereafter. Five years after the resection, a submucosal mass was found at the anastomotic staple line, 15 cm from the anal verge. Computed tomography scan and endoscopic ultrasound were not consistent with tumor recurrence. Endoscopic mucosa biopsy was performed to obtain a definitive diagnosis. Mucosal incision over the lesion with the cutting needle knife technique revealed a creamy white material, which was completely removed. Histologic examination showed fibrotic tissue without caseous necrosis or tumor cells. No bacteria, including mycobacterium, were found on culture. The patient remains free of recurrence at five years since the resection. Endoscopic biopsy with a cutting mucosal incision is an important technique for evaluation of submucosal lesions after rectal resection.

**Key words:** Submucosal tumor; Staple line; Endoscopic cutting-mucosa biopsy



**Core tip:** This case report demonstrates the importance of endoscopic biopsy using a cutting mucosal incision as a diagnostic tool for a submucosal mass that develops next to the staple line after sigmoid colon resection

with a double-stapled anastomosis. We feel that these findings will be of special interest to the readers.

Morimoto M, Koinuma K, Lefor AK, Horie H, Ito H, Sata N, Hayashi Y, Sunada K, Yamamoto H. Diagnosis of a submucosal mass at the staple line after sigmoid colon cancer resection by endoscopic cutting-mucosa biopsy. *World J Gastrointest Endosc* 2016; 8(8): 374-377 Available from: URL: http://www.wjgnet.com/1948-5190/full/v8/i8/374.htm DOI: http://dx.doi.org/10.4253/wjge.v8.i8.374

## INTRODUCTION

Submucosal tumors, such as neuroendocrine tumors (NET) or gastrointestinal stromal tumors (GIST), are occasionally encountered in the rectum, and are categorized based on the tissue of origin as muscular or neural derived. The differential diagnosis of a submucosal mass adjacent to the staple line after colon resection is extensive, and includes NET, GIST, and tumor recurrence. We report a patient with a submucosal mass at the site of a stapled anastomosis that developed five years after initial resection of a tumor.

## CASE REPORT

A 48-year-old male was referred for treatment of sigmoid colon cancer six years previously. He had a past medical history of allergic dermatitis at 26 years of age. Laboratory data showed that both serum levels of carcinoembryonic antigen (CEA) and carbohydrate antigen 19-9 (CA 19-9) were within the normal limits. Enhanced computed tomography (CT) scan showed a sigmoid colon cancer with no evidence of distant metastases. Laparoscopic sigmoid colon resection with a double stapled anastomosis was performed. Macroscopic pathology showed 0-Ip tumor 30 mm in diameter. Microscopic pathology showing a well-differentiated tubular adenocarcinoma invading the muscularis propria with no regional lymph node metastases (UICC category; T2 N0 M0), classified as pathologic stage Ⅰ disease. The patient remained asymptomatic with no signs of recurrence for four years. Five years postoperatively, a submucosal mass measuring 10 mm in size was detected at the staple line located 15 cm from the anal verge during an annual surveillance colonoscopy (Figure 1). Endoscopic ultrasonography (EUS) showed a well-demarcated and circumscribed homogeneous high echoic lesion in the submucosal layer (Figure 2). The surface of the lesion was covered with normal-appearing mucosa. The submucosal tumor showed no deformity with application of air pressure during the colonoscopy and was negative for the "cushion sign". Abdominal CT scan revealed a small, high-density well-demarcated mass without contrast-enhancement in the colonic wall (Figure 3). No metastatic lesions were seen on CT scan. In retrospect, the small high intensity

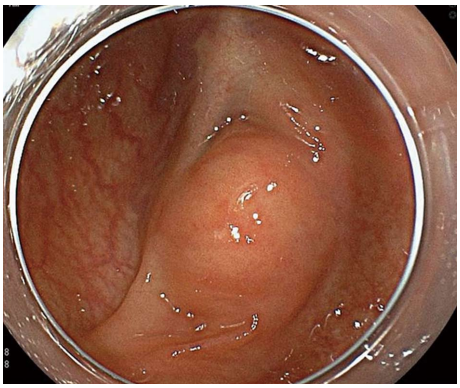

**Figure 1 Endoscopic view of a 10 mm submucosal mass in the lower rectum located 15 cm from the anal verge at the staple line of a previous anastomosis.**

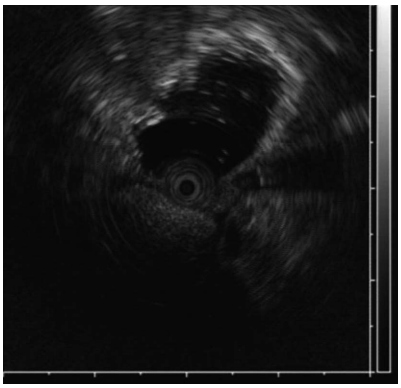

**Figure 2 Endoscopic ultrasonography showed a well-circumscribed submucosal tumor with a hyper-echoic appearance.**

area near the anastomosis had been evident on a CT scan performed four years after resection, and was gradually increasing in size. Tumor markers, including CEA and CA 19-9, remained within normal limits. It was felt unlikely that the mass was malignant based on its appearance and behavior. However, the mass showed slow growth and there was no definitive diagnosis. Routine endoscopic biopsy was thought to be difficult to establish a diagnosis because most of the target lesion was located in the submucosal layer. Endoscopic cutting mucosal biopsy of the lesion was planned. A precutting needle knife (KD-10Q-1, Olympus Corp, Tokyo, Japan) and an electrosurgical generator (VIO 300D; ERBE Elektromedizin Ltd, Tübingen, Germany) in endocut mode (effect, 1; duration, 4; interval, 1) were used. A mucosal incision was made over the lesion with the cutting needle knife technique after submucosal injection of saline containing 0.001% epinephrine and 0.004% indigocarmine. A pale, orange nodule covered by fibrotic material was seen in the submucosal tissue stained with the blue dye of the indigocarmine, compatible with the EUS results. The nodule was easily distinguished from the muscularis propria by its color because the muscularis propria is white. The fibrotic tissue above the lesion was incised using biopsy forceps (Radial Jaw™ 4, Boston Scientific Corp, Marlborough, MA), revealing a

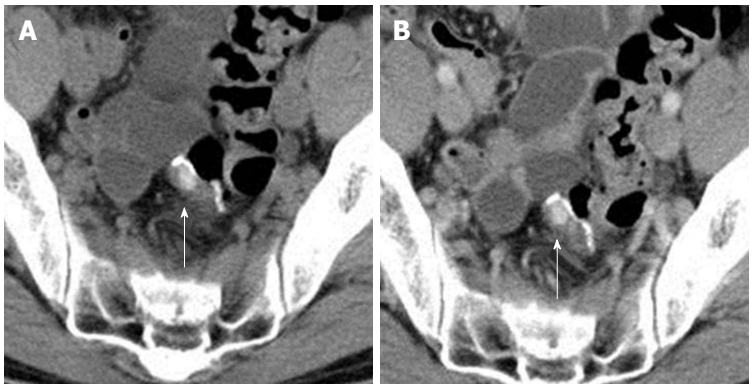


**Figure 3 Un-enhanced and intravenous contrast-enhanced computed tomography scans of the abdomen show a slightly hyperdense mass in the rectal wall without contract enhancement (white arrow).** A: Unenhanced CT; B: Contrast enhanced CT. CT: Computed tomography.

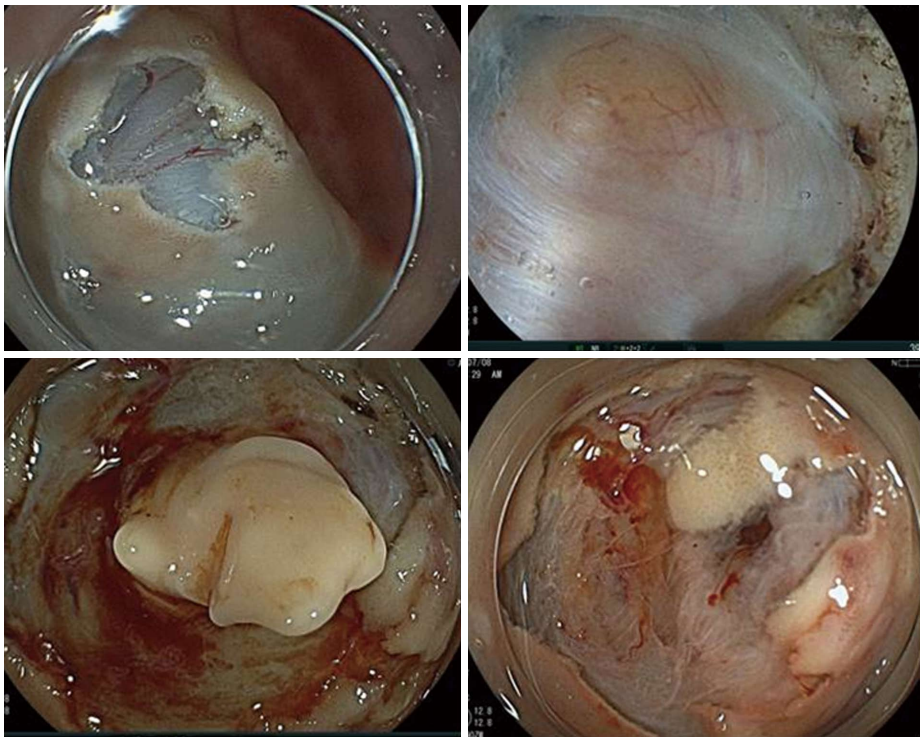

**Figure 4 A cruciate incision over the lesion with the cutting needle knife technique revealed soft, white submucosal tissue.** The wall of the cavity was left intact.

creamy white material, which was completely removed using the forceps. The wall of the remaining cavity was not resected. The specimen was gray-white and soft (Figure 4). The creamy appearance of the material led to the consideration of caseous necrosis associated with tuberculosis. However, pathological examination showed fibrotic tissues with necrotic material and no signs of caseous necrosis associated with tuberculosis, Crohn's disease or malignancy. The patient remains free of recurrence, five years after the initial resection.

## DISCUSSION

The differential diagnosis of submucosal tumors of the colon and rectum includes GIST, NET, inflammatory polyps, desmoid-type fibromatosis, and local recurrence[1]. Submucosal masses due to intestinal tuberculosis are rare[2]. In this patient, a submucosal mass was located next to the anastomotic staple line, with both CT scan and EUS showing no typical signs of GIST, NET or local recurrence. Local recurrence is rare in patients with T1-2 colorectal cancers[3]. However, we could not rule out the possibility of tumor recurrence because the lesion showed slow growth on annual CT scans. Thus, an endoscopic biopsy is a reasonable method to obtain a tissue diagnosis. Endoscopic mucosal cutting biopsy is a safe and effective method to establish the diagnosis of submucosal masses[4]. This technique can be used in institutions where endoscopic submucosal dissection (ESD) is routinely performed for T1 colorectal cancers[5]. ESD of superficial colorectal neoplasms has become well-accepted over the past

decade, with a low complication rate (delayed bleeding 2%, perforation 1.3%, emergency surgical operation 0.2%)[6,7]. In this patient, endoscopic biopsy with mucosal incision avoided the need for a second surgical resection.

The double stapling technique for colorectal anastomoses is commonly used after sigmoid colon resection. Surgical procedures that include partial or total transection of the digestive tract evoke considerable physiological morphological, functional, and metabolic changes in adjacent intestinal tissue[8]. The inflamed area of a fibrotic scar decreases after postoperative day seven with a minimal amount of fibrosis by postoperative day 90[9]. Luijendijk *et al*[10] reported that suture granulomas were seen in 25% of patients with a past history of abdominal surgery. Inflammatory and foreign body reactions to such material can produce lesions mimicking cancer, clinically and radiologically[11]. There are reports of patients who underwent repeat surgical resection to rule out tumor recurrence[10,12]. It is unknown whether the fibrotic lesion was associated with the anastomotic stapler and adjacent tissue inflammation in the present patient. The persistent production of cytokines by inflammatory stimulation associated with the fibrotic process may lead to submucosal fibrosis.

Endoscopic biopsy using a cutting mucosal incision is a useful diagnostic tool for submucosal masses that develop next to a staple line after rectal resection and anastomosis using the double stapling technique.

## COMMENTS

### Clinical diagnosis
Submucosal tumor.

### Differential diagnosis
Gastrointestinal stromal tumors (GIST), neuroendocrine tumors (NEC), local recurrence.

### Laboratory diagnosis
All tumor markers were within normal limits.

### Imaging diagnosis
A malignant tumor was not expected based on computed tomography and endoscopic ultrasonography results.

### Pathological diagnosis
Tissue fibrosis.

### Treatment
Endoscopic repeat biopsy.

### Related reports
References 10 and 12.

### Experience and lessons
There is a possibility of developing a granulomatous mass (fibrotic tissue) at the staple line in future patients. This lesion mimics a submucosal tumor such as a GIST or NEC. Some surgeons may initially plan a second resection, similar to another low anterior resection. This case report reminds surgeons of the possibility of a benign lesion.

### Peer-review
This is an interesting case report.

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