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Safety and Utility of Single-Session Endoscopic Ultrasonography and Endoscopic Retrograde Cholangiopancreatography for the Evaluation of Pancreatobiliary Diseases

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Endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) are essential for diagnosing and treating pancreatobiliary diseases. Single-session EUS and ERCP are considered to be essential in reducing the duration of hospital stays; however, complications are a primary concern. The aim of this study was to evaluate the safety and efficacy of single-session EUS and ERCP. Sixty-eight patients underwent single-session EUS and ERCP at a tertiary referral center between June 2008 and December 2012. We retrospectively reviewed patient data from a prospectively maintained EUS-ERCP database and evaluated the procedural characteristics and complications. Thirty-eight patients (56%) underwent diagnostic EUS, and 30 patients (44%) underwent EUS fine-needle aspiration, which had an overall accuracy of 100%. Sixty patients (89%) underwent therapeutic ERCP, whereas the remaining eight procedures were diagnostic. Thirteen patients underwent biliary stone extraction, and 48 underwent biliary drainage. The median total procedural time was 75 minutes. Complications were observed in seven patients (10%). Six complications were post-ERCP pancreatitis, which were resolved using conservative management. One patient developed Mallory-Weiss syndrome, which required endoscopic hemostasis. No sedation-related cardiopulmonary complications were observed. Single-session EUS and ERCP provided accurate diagnosis and effective management with a minimal complication rate. (*Gut Liver* 2014;8:329-332)

Key Words: Endoscopic retrograde cholangiopancreatography; Endoscopic ultrasound; Single-session procedure

INTRODUCTION

Both endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) are required to evaluate and treat patients with pancreatobiliary diseases. ERCP is a well-established technique to evaluate and manage biliary obstructions, but it carries a risk of complications, such as post-ERCP pancreatitis, bleeding, and perforation.¹ Therefore, ERCP is reserved mainly for therapeutic indications. EUS is a less-invasive modality and has high accuracy for diagnosing pancreatobiliary diseases such as biliary stones and pancreatic tumors.^{2,3} These two procedures can be performed during a single session under same anesthesia, but concern regarding their safety has been raised due to complications.^{4,5} However, a single session results in a reduction in hospital stay and avoidance of repeated sedation as compared to multiple sessions.⁶⁻¹¹ Previous studies only evaluate the utility of single-session EUS and ERCP in a single setting. Therefore, we performed a retrospective analysis of patients with pancreatobiliary diseases who underwent single-session EUS and ERCP to evaluate their safety and efficacy in a variable setting.

CASE REPORT

We retrospectively reviewed data from a prospectively maintained database of patients who underwent single-session EUS with/without fine-needle aspiration (FNA) and ERCP at Hokkaido University Hospital between July 2008 and December 2012. The collected data included age, sex, indications for the procedure, primary diseases, endoscopic and clinical outcomes, procedural complications, and pathological findings if observed. This study was approved by the Institutional Review Board

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of Hokkaido University Hospital and was registered with the University Hospital Medical Information Network-Clinical Trial Registry (UMIN-CTR; number, UMIN000008409).

Written informed consent was obtained from all patients before the procedures. Combined EUS and ERCP were performed under conscious sedation using intravenous midazolam with fentanyl. Before 2009, EUS was performed with a radial echoendoscope (GF-UM2000 or GF-UE260; Olympus Medical Systems Co., Tokyo, Japan). After introduction of the linear echoendoscope (GF-UCT240-AL5; Olympus Medical Systems Co.) to our institution, we used either type of echoendoscope at the discretion of the endoscopist. Patients also underwent EUS-guided FNA (EchoTip Ultra, Cook-Japan, Tokyo, Japan; or Expect, Boston Scientific Japan, Tokyo, Japan) with rapid on-site cytology evaluation if necessary. Subsequent ERCP-related procedures were performed following EUS during the same session using a duodenoscope (JF-240, TJF-240, or TJF-260V; Olympus Medical Systems Co.). In patients who were using antithrombotic or antiplatelet agents, each procedure was performed according to the Japanese guidelines.¹² After the procedure, patients were monitored at an inpatient unit in the same way as those who

underwent ERCP alone. Procedural-related complications were classified and graded according to consensus criteria.¹³

A total of 1,519 ERCP and 1,559 EUS procedures were performed respectively at our institution. Among them, 68 patients (mean age, 69 years; 38 males and 30 females) underwent EUS and ERCP in a single session and were included in this study (Table 1). Diagnostic EUS was performed in 38 patients (linear EUS in 14 and radial EUS in 24) with a median procedure time of 32 minutes. EUS-FNA was performed in 30 patients (44%) (Table 2). The sensitivity and specificity of EUS-FNA for malignancy were 100% and 100%. Choledocholithiasis was confirmed in all patients with acute cholangitis. Bile duct cannulation following EUS was successful in all but one patient. Sixty patients underwent therapeutic ERCP, whereas the remaining eight were diagnostic procedures. Thirteen patients underwent endoscopic

Table 1. Patient Characteristics

Characteristic	Value
No. of patients	68
Age, yr	69 (62–76)
Sex, male/female	38/30
Indications for EUS	
Indeterminate biliary stricture	46
Acute cholangitis	20
Other	2
Laboratory data	
WBC, /m ³	5,200 (3,925–7,200)
CRP, mg/dL	0.5 (0.08–2.9)
Total bilirubin, mg/dL	1.6 (1.0–5.9)
Amylase, IU/mL	59 (42–86)
Final diagnosis	
Pancreatic cancer	17
Bile duct cancer	11
Gallbladder cancer	9
Ampullary cancer	2
Lymph node metastasis	3
Pancreatic neuroendocrine tumor	1
Intraductal papillary mucinous neoplasm	1
Autoimmune pancreatitis	3
Choledocholithiasis	19
Benign biliary stricture	2

Data are presented as number or median (interquartile range). EUS, endoscopic ultrasonography; WBC, white blood cells; CRP, C-reactive protein.

Table 2. Characteristics of the Procedures

Characteristic	Value
Total procedure time, min	75 (53–88)
Diagnostic EUS	38 (56)
Linear/radial	14/24
Procedure time, min	32 (18–41)
EUS-FNA	30 (44)
Procedure time, min	40 (26–49)
Puncture site (pancreas/lymph node/bile duct)	13/2/1
Needle (19/22/25 gauge)	3/23/4
Sensitivity, %	100
Specificity, %	100
Accuracy, %	100
ERCP	
Diagnostic/therapeutic	8/60
Biliary cannulation failure	1
Biliary stenting	48 (71)
Plastic stent/ENBD/SEMS	11/25/12
Stone extraction	13 (19)
Sphincterotomy	25 (37)
Procedure time, min	34 (24–44)
Sedative/analgesic agents	
Midazolam, mg	10 (8–13)
Fentanyl, µg	150 (100–200)
Complications	7 (10)
Post-ERCP pancreatitis (mild/moderate/severe)	6 (3/2/1)
Pneumonia	0
Perforation	0
Mallory-Weiss syndrome	1

Data are presented as number (%) or median (interquartile range). EUS, endoscopic ultrasonography; EUS-FNA, EUS-guided fine-needle aspiration; ERCP, endoscopic retrograde cholangiopancreatography; ENBD, endoscopic nasobiliary drainage; SEMS, self-expandable metallic stent.

sphincterotomy followed by stone extraction, whereas six patients underwent plastic stent placement due to severe cholangitis or were taking antithrombotic agents. Biliary drainage was performed using self-expandable metallic stents in 12 patients, plastic stents in 11, and nasobiliary drainage in 25.

Seven complications (10.3%; 95% confidence interval, 3.1 to 17.5) were observed. Six were post-ERCP pancreatitis. One patient with bile duct carcinoma who underwent EUS-FNA for lymph node and endoscopic nasobiliary drainage placement for obstructive jaundice developed severe pancreatitis. Three patients were mild, and two patients were moderate, according to the consensus criteria.¹³ All patients resolved with conservative management. One patient developed Mallory-Weiss syndrome 1 day after the single-session procedure, which required endoscopic hemostasis. No severe cardiopulmonary complications or deaths related to the combined procedure were observed.¹⁴

DISCUSSION

We revealed that single-session EUS and ERCP were both safe and effective for managing pancreatobiliary disorder in a variable setting. The combined procedure facilitated appropriate patient management without severe complications and could be considered a standard treatment that reduces hospital stay and avoids unnecessary sedation.

It was necessary but sometimes difficult to distinguish between malignant and benign originating lesions in patients with biliary obstructions. EUS has greater sensitivity for detecting small pancreatic tumors or preoperative staging than computed tomography,² and improves the diagnosis of indeterminate bile duct strictures without EUS-FNA.¹⁵ Therefore, identifying unresectable malignant tumors by EUS in patients with a biliary obstruction may require a metallic stent rather than a plastic stent due to the longer patency.¹⁶ Furthermore, if the presence of a biliary stent interferes with preoperative staging of a pancreatic head tumor by EUS, EUS should be performed before ERCP to avoid unnecessary laparotomies.¹⁷ In this study, three patients who did not have tumors following the EUS examination were diagnosed with a benign biliary stricture, and were managed successfully. Ascunecce *et al.*⁹ also reported that benign biliary strictures can be diagnosed and managed successfully by single-session EUS-ERCP without FNA.

EUS-FNA has great sensitivity for detecting malignancy in not only pancreatic tumors,¹⁸ but also biliary strictures.¹⁹ Identifying a malignancy by EUS-FNA eliminates the need for biliary brushing, the sensitivity of which is inferior to that of EUS-FNA.²⁰ Furthermore, because preoperative biliary drainage is not necessary in patients with obstructive jaundice who undergo a Whipple resection, positive cytology could avoid unnecessary biliary stenting.²¹ Ross *et al.*⁷ reported that the combination of EUS-FNA with ERCP for evaluation of patients with obstructive jaundice from presumed pancreatic malignancy provides ac-

curate tissue diagnosis and biliary drainage. In this study, EUS-FNA was performed in 30 patients; malignancy was detected in all malignant diseases. Three patients without malignancy were diagnosed with autoimmune pancreatitis and successfully managed with steroid therapy. Furthermore, EUS-FNA immediately after biliary stent placement was associated with a high rate of inconclusive cytology; thus, EUS-FNA should be performed before ERCP for a correct diagnosis.²² In patients with indeterminate biliary stricture, single-session EUS and ERCP would be the most reasonable.

EUS is superior to other modalities for detecting biliary stones and can avoid unnecessary ERCP in patients with suspected biliary stone or biliary pancreatitis.^{3,23,24} Fabbri *et al.*⁸ reported that single-session EUS and ERCP in patients at low risk of biliary stones is safe and effective with reduced procedural time and costs compared to performance in separate sessions. In our study, 13 patients underwent EUS and ERCP with sphincterotomy and stone extraction without complications, whereas the remaining patients with severe cholangitis and/or those who were taking antithrombotic agents underwent placement of a biliary stent without sphincterotomy. One of the concerns regarding a single-session procedure is total procedural time. However, Benjaminov *et al.*⁶ reported that separate EUS and ERCP sessions for symptomatic choledocholithiasis expose the patient to a higher risk of cholangitis as compared to a single-session procedure. Stone extraction in a single session is reasonable considering its safety and decreased hospital stay. Therefore, single-session EUS and ERCP would be the most useful for patients with cholangitis in whom choledocholithiasis could not be confirmed by other imaging modalities.

The advantage of single-session EUS and ERCP as compared to a separate session is expedited patient management, shortening of the hospital stay, reduced cost and avoidance of repeated sedation.^{8,10} The major disadvantages of these procedures are the long procedural time and the increase in intestinal gas volume.^{4,5} However, previous studies of single-session EUS and ERCP reported no severe complications.⁷⁻¹⁰ We observed six cases of post-ERCP pancreatitis, all of which resolved with conservative management. However, post-ERCP pancreatitis is an inherent complication of ERCP and was not attributed to the single-session procedure. We had experienced one Mallory-Weiss syndrome, which was also one of the complications of upper endoscopy. Iles-Shih *et al.*¹¹ reported the safety of single-session EUS and ERCP in elderly patients, with no more adverse events than in nonelderly patients. Therefore, this disadvantage does not preclude performance of both procedures in a single session, considering their efficacy.

Our study had some limitations. First, it was of a retrospective design conducted at a single center. Second, a single-session procedure can be performed only by endoscopists experienced in both EUS and ERCP. A single-session procedure is not the standard. Third, we did not compare hospital stay duration and

the cost of a single-session procedure with those of separate sessions. Fourth, we could not evaluate the patients who could avoid unnecessary ERCP.

Our results show that single-session EUS and ERCP were safe and useful for management of pancreatobiliary diseases. However, development of a new therapeutic endoscope, using which both EUS and ERCP can be performed in a single-session without scope exchange, is necessary for the widespread acceptance of this combined procedure.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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