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Medical disputes related to advanced endoscopic procedures with endoscopic retrograde cholangiopancreatography or endoscopic ultrasonography for the management of pancreas and biliary tract diseases

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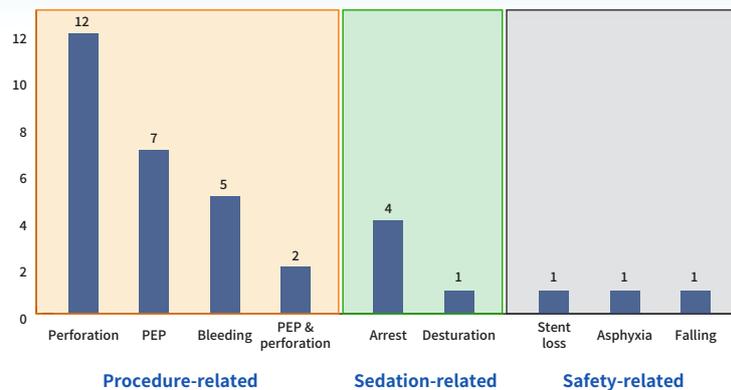
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Medical disputes for ERCP/EUS-related adverse events (AEs) in Korea Medical Dispute Mediation & Arbitration Agency (2012. 4 – 2020. 8)



The ERCP/EUS-related AEs filed in Korea Medical Dispute Mediation and Arbitration Agency showed distinct features: duodenal perforation was the most frequent AE, and clinical outcomes were fatal, resulting in at least more than permanent physical impairment.

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Background/Aims: This study aimed to evaluate the characteristics of endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasonography (EUS)-related adverse events (AEs) that eventually lead to medical disputes or claims on medical professional liability.

Methods: Medical disputes for ERCP/EUS-related AEs filed in the Korea Medical Dispute Mediation and Arbitration Agency between April 2012 and August 2020 were evaluated using corresponding medical records. AEs were categorized into three sections: procedure-related, sedation-related, and safety-related AEs.

Results: Among a total of 34 cases, procedure-related AEs were 26 (76.5%; 12 duodenal perforations, 7 post-ERCP pancreatitis, 5 bleedings, 2 perforations combined with post-ERCP pancreatitis); sedation-related AEs were 5 (14.7%; 4 cardiac arrests, 1 desaturation), and safety-related AEs were 3 (8.8%; 1 follow-up loss for stent removal, 1 asphyxia, 1 fall). Regarding clinical outcomes, 20 (58.8%) were fatal and eventually succumbed to AEs. For the types of medical institutions, 21 cases (61.8%) occurred at tertiary or academic hospitals, and 13 (38.2%) occurred at community hospitals.

Conclusions: The ERCP/EUS-related AEs filed in Korea Medical Dispute Mediation and Arbitration Agency showed distinct features: duodenal perforation was the most frequent AE, and clinical outcomes were fatal, resulting in at least more than permanent physical impairment.

Keywords: Endoscopic retrograde cholangiopancreatography; Endosonography; Legal liabilities; Medical errors; Patient safety

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) are important methods for the diagnosis and treatment of pancreatic and biliary tract diseases. Since the national medical insurance system has been expanding the coverage for endoscopic procedures in Korea, pancreatobiliary (PB) endoscopy has been widely used to treat pancreatic and biliary tract diseases.^{1,2} However, PB endoscopy has a potential risk of complications due to its demanding high-level skill to perform the procedures.³⁻⁵ Therefore, to minimize adverse events (AEs) and secure patient safety during the procedures, certified endoscopists with sufficient training are essential for PB endoscopy.^{6,7} In addition, nurses and technicians who have a full understanding of operating processes and instruments also have an important role in effective endoscopic assistance.^{8,9}

Patient safety and clinical quality have been emphasized, especially in the endoscopic field.¹⁰ In Korea, the Korea Medical Dispute Mediation and Arbitration Agency (K-Medi) was established in April 2012 to obtain a fair medical environment by resolving medical disputes or claims on medical professional liability (MPL) and providing a qualified and unbiased appraisal of medical accidents and has been operated to achieve equitable relief for both plaintiff and dependent through medical mediation.¹¹ Therefore, this study aimed to evaluate the characteristics of medical disputes using actual cases filed in the K-Medi, and identify their causative factors compared to general procedure-related risk factors.

METHODS

Medical disputes filed in K-Medi from April 2012 to August 2020 were retrospectively evaluated using the corresponding medical records. Claims on MPL in civil and criminal justice systems, referred to K-Medi for the appraisal of medical accidents, were also included. In general, the K-Medi database is not available for assessment because each case contains sensitive information about the MPL. However, in this study, the assessment of the database was approved for only accredited researchers by mutual agreement between K-Medi and the Korean Society of Gastrointestinal Endoscopy to perform the project commissioned by the K-Medi titled "analysis of the types and causes of gastrointestinal endoscopy-related medical accidents to make effective preventive measures." Thus, this study was outside the realm of research that required deliberation by the institutional review board of each author's affiliated hospital.

The process of two types of medical appraisal by K-Medi are: (1) medical disputes are filed by the person directly involved in the affair of medical negligence, and (2) claim cases for MPL are commissioned by the police or prosecutors for qualified and unbiased medical appraisal of medical accidents to prepare for medical litigation (both types from here onwards are referred to as medical disputes).¹¹

PB endoscopy encompasses advanced endoscopic procedures performed via ERCP or EUS. The AEs related to PB endoscopy were categorized into three sections: (1) procedure-related, (2) sedation-related, and (3) safety-related AEs. Patient-related factors, such as age, sex, underlying disease, and surgical history,

were evaluated, and body mass index (BMI) was calculated by measuring height and weight. Laboratory findings were also evaluated. Moreover, the locations and types of medical institutions and workplace characteristics were investigated. The severity of endoscopic AEs was graded based on the lexicon proposed by the American Society of Gastrointestinal Endoscopy.¹²

For statistical analysis, variables satisfying the normality test were expressed as the mean±standard deviation, and an independent-sample *t*-test and chi-square test were used. Statistics related to population were obtained from the Korean Statistical Information Service,¹³ and the annual number and average frequencies of ERCP in Korea were obtained from the nationwide database study organized by the Korean Society of Gastrointestinal Endoscopy.¹⁴ For comparison of three or more groups, a one-way analysis of variance (one-way ANOVA) was performed. Variables that did not satisfy the normality test were expressed as median±quartile distributions, and the Mann-Whitney test was performed. To compare three or more groups, the Kruskal-Wallis test was performed. All statistical tests were performed using the statistical program IBM SPSS ver. 20.0 (IBM Corp.), and statistical significance was determined at $p < 0.05$.

Ethical statements

The deliberation by an institutional review board was waived for this study because it used the database compiled by the

Medical Dispute Mediation and Arbitration Agency in Korea.

RESULTS

Among a total of 34 cases, 26 (76.5%) procedure-related AEs, 5 (14.7%) sedation-related AEs, and 3 (8.8%) safety-related AEs were identified. Among the sedation-related AEs, there were four cases of cardiac arrest and one case of oxygen desaturation requiring tracheal intubation. Among the safety-related AEs, there was one case of accidental long-term placement of a biliary plastic stent after endoscopic bile duct stone clearance, one case of asphyxia in the general ward after finishing the procedure, and one case of fall from a hospital bed (Fig. 1).

Regarding the severity of PB endoscopy-related AEs, there were 20 (58.8%) fatal cases, 12 (35.3%) severe cases, and two (5.9%) moderate cases. In addition, for the patients' clinical outcomes at the time of the medical dispute, 20 (58.8%) cases of deaths, three (8.8%) cases of permanent physical impairment, three (8.8%) cases of temporary physical dysfunction, and eight (23.5%) cases of recovered state from AEs were identified, revealing that the patient's clinical outcomes were very poor despite proper management of the PB endoscopic-related AEs.

Regional distribution and types of medical institutions

Regarding the regional distribution of the 34 disputes, most occurred in metropolitan areas, including Seoul (13 cases) and Gyeonggi-do (9 cases); the rest occurred in the following or-

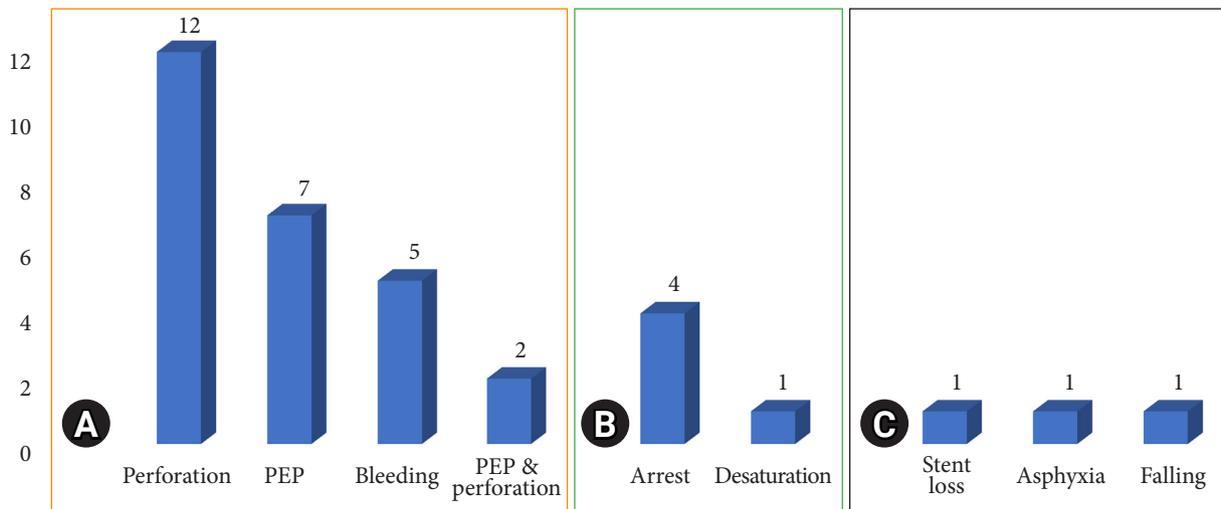


Fig. 1. Three types of medical disputes and specific types of pancreatobiliary endoscopy-related adverse events (AEs). (A) Procedure-related AEs. (B) Sedation-related AEs. (C) Safety-related AEs. (C) safety-related AEs. PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis.

der: Gyeongsang-do (8 cases), Chungcheong-do (3 cases), and Jeolla-do (1 case) (Table 1). The actual number of medical disputes was relatively high in the metropolitan area of Seoul after adjusting for the registered population and Gyeonggi-do after adjusting for the average frequencies of ERCP. Regarding the types of medical institutions, 21 cases occurred in tertiary or academic hospitals, and 13 occurred in community hospitals. However, there were no cases in primary care centers (Table 2).

Baseline characteristics and procedural factors

The baseline characteristics were summarized and compared among the three sections (Table 3). The number of female subjects was 12 (46.2%), 2 (40%), and 1 (33.3%), and the mean age was 66.8 years, 65.4 years, and 76.7 years, respectively. The BMI was 24.41±2.48 kg/m², 21.81±6.67 kg/m², and 22.79±4.27 kg/m², respectively. The history of abdominal surgery was 8 (30.8%), 2 (40%), and 1 (33.3%), respectively, showing no significant differences among the three groups. Regarding drug history, antiplatelet agents were used in 5 (19.2%), 0, and 1

(33.3%) patients; anticoagulation agents were used in 1 (3.8%), 0, and 0 patient. There were 2 (7.7%), 0, and 0 non-steroidal anti-inflammatory drugs and 4 (15.4%), 1 (20%), and 0 steroidal agents. The comorbidities included diabetes mellitus in 9 (34.6%), 1 (20%), and 0 patients, hypertension in 12 (46.2%), 3 (60%), and 1 (33.3%) patients, cardiovascular disease in 4 (15.4%), 1 (20%), and 1 (33.3%) patients, cerebrovascular diseases in 3 (11.5%), 0, and 1 (33.3%) patients, and chronic renal failure in 1 (3.8%), 2 (40%), and 0 patients. There were no patients with liver cirrhosis, and chronic obstructive pulmonary disease was found in one patient (20%) in the sedation-related AEs. In addition, when analyzing procedural factors, the total procedure time was 52.5 minutes in the procedure-related AEs group, which was significantly longer than that in the other AEs groups. However, there was no significant difference in the performance of the procedure in emergency or overtime settings.

1) Procedure-related AEs

A total of 26 cases were identified as procedure-related AEs:

Table 1. Regional distribution of the medical institutions in which ERCP/EUS-related AEs occurred

Region	Procedure-related AEs (n=26)	Sedation-related AEs (n=5)	Safety-related AEs (n=3)	Total AEs (n=34)	
				Crude number	Adjusted with average ERCP
Seoul	11 (42.3)	2 (40)	0	13 (38.2)	0.095
Gyeonggi-do	7 (26.9)	1 (20)	1 (33.3)	9 (26.5)	0.176
Chungcheong-do	3 (11.5)	0	0	3 (8.8)	0.039
Gyeongsang-do	4 (15.4)	2 (40)	2 (66.6)	8 (23.5)	0.084
Jeolla-do	1 (3.8)	0	0	1 (2.9)	0.013

Values are presented as number (%).

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; AE, adverse event.

Table 2. Type of the medical institutions in which ERCP/EUS-related AEs occurred

Variable	Procedure-related AEs (n=26)	Sedation-related AEs (n=5)	Safety-related AEs (n=3)
Indications			
CBD stones	19 (73.1)	4 (80)	3 (100)
CBD cancer	2 (7.7)	0	0
Pancreas head cancer	2 (7.7)	0	0
Gallbladder cancer	1 (3.8)	0	0
Biliary benign stricture	1 (3.8) ^{a)}	1 (20)	0
Chronic pancreatitis	1 (3.8)	0	0
Types of the medical institution			
Tertiary or academic hospital	14 (53.8)	5 (100)	2 (66.7)
Community hospital	12 (46.2)	0	1 (33.3)

Values are presented as number (%).

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; AE, adverse event; CBD, common bile duct stone.

^{a)}Biliary intraepithelial neoplasia.

Table 3. Baseline characteristics of the case patients of ERCP/EUS-related AEs

Variable	Procedure-related AEs (n=26)	Sedation-related AEs (n=5)	Safety-related AEs (n=3)	p-value
Patient characteristics				
Female	12 (46.2)	2 (40)	1 (33.3)	>0.999
Age (yr)	66.8±14.0	65.4±18.5	76.7±14.2	0.523
BMI (kg/m ²)	24.41±2.48	21.81±6.67	22.79±4.27	0.737
History of previous abdominal surgery	8 (30.8)	2 (40)	1 (33.3)	>0.999
Drug history				
Anti-platelets	5 (19.2)	0	1 (33.3)	0.418
Anti-coagulants	1 (3.8)	0	0	>0.999
NSAIDs	2 (7.7)	0	0	>0.999
Steroids	4 (15.4)	1 (20)	0	>0.999
Comorbidities				
Diabetes mellitus	9 (34.6)	1 (20)	0	0.671
Hypertension	12 (46.2)	3 (60)	1 (33.3)	0.858
Cardiovascular diseases	4 (15.4)	1 (20)	1 (33.3)	0.584
Cerebrovascular diseases	3 (11.5)	0	1 (33.3)	0.397
Chronic renal failure	1 (3.8)	2 (40)	0	0.066
Chronic obstructive pulmonary disease	0	1 (20)	0	0.235
Liver cirrhosis	0	0	0	
Procedural factors				
Emergency procedures	5 (19.2)	1 (20)	0	0.541
Total procedural duration (min)	52.5 (12–130)	30 (10–35)	39 (15–63)	0.026

Values are presented as number (%), mean±standard deviation, or median (range).

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; AE, adverse event; BMI, body mass index; NSAID, non-steroidal anti-inflammatory drug.

12 cases of perforation, seven cases of post-ERCP pancreatitis, five cases of bleeding, and two cases of perforation concurrent with severe post-ERCP pancreatitis. The incidence of post-ERCP pancreatitis was higher in females than in males, although the difference was not significant. Furthermore, there were no significant differences in age, BMI, or history of abdominal surgery (Table 4). However, the liver function test (LFT) was within the normal range (65.4%), and the non-dilated state of the common bile duct (CBD) was observed in 46.1% of the patients who developed procedure-related AEs. In particular, the two patients with perforation concurrent with severe pancreatitis showed normal LFT and CBD diameters. Non-dilated CBD was found in 71.4% of the patients with perforation. In addition, inadvertent cannulation into the pancreatic duct occurred in 57.1% of patients with post-ERCP pancreatitis, which was statistically significant (Table 5).

(1) Perforation

Among the procedure-related AEs, perforation occurred in 14 cases, of which two occurred during EUS-guided fine needle aspiration and the others occurred during ERCP. There were

12 cases of duodenal perforation (9 cases of retroperitoneal perforation, three cases of duodenal free wall perforation), 1 case of small bowel perforation, and one case of gallbladder (GB) perforation (Supplementary Table 1). The most common indication for PB endoscopy was the endoscopic clearance of CBD stones (9 cases), followed by cholangiocarcinoma (2 cases), pancreatic cancer (1 case), chronic pancreatitis (1 case), and GB cancer (1 case). The initial response to perforation was six cases of surgery, three cases of endoscopic clipping, three cases of medical treatment using fasting and antibiotics, one case of cardiopulmonary resuscitation, and one case of endoscopic naso-GB drainage. The three patients initially treated with endoscopic clipping eventually succumbed to the complications, and one of six patients (16.7%) who underwent surgical treatment also eventually succumbed to the complications and died (Fig. 2A). Meanwhile, among the six patients who underwent surgery, there was no significant difference in clinical outcomes according to the timing of surgical operation (Fig. 2B).

(2) Post-ERCP pancreatitis

Among the procedure-related AEs, seven cases had post-ER-

Table 4. Patient characteristics between the types of ERCP/EUS-related adverse events

Variable	Perforation (n=12)	PEP (n=7)	Bleeding (n=5)	Perforation combined with PEP (n=2)	p-value
Patient characteristics					
Female	5 (41.7)	4 (57.1)	2 (40)	1 (50)	0.933
Age (yr)	71.1±10.5	60.3±15.1	70.0±14.2	56.0±26.8	0.262
BMI (kg/m ²)	24.8±2.7	24.2±2.0	23.2±2.7	24.8±1.2	0.684
History of previous abdominal surgery	3 (25)	3 (42.9)	2 (40)	0	0.699
Drug history					
Anti-platelets	3 (25)	1 (14.3)	1 (20)	0	>0.999
Anti-coagulants	0	0	1 (20)	0	0.269
NSAIDs	2 (16.7)	0	0	0	0.742
Steroids	3 (25)	0	1 (20)	0	0.565
Comorbidities					
Diabetes mellites	4 (33.3)	1 (14.3)	4 (80)	0	0.112
Hypertension	5 (41.7)	3 (42.9)	3 (60)	1 (50)	0.933
Cardiovascular diseases	1 (8.3)	2 (28.6)	1 (20)	0	0.650
Cerebrovascular diseases	1 (8.3)	1 (14.3)	1 (20)	0	0.822
Chronic renal failure	0	0	1 (20)	0	0.269
Chronic obstructive pulmonary disease	0	0	0	0	.
Liver cirrhosis	0	0	0	0	.

Values are presented as number (%) or mean±standard deviation.

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; PEP, post-ERCP pancreatitis; BMI, body mass index; NSAID, non-steroidal anti-inflammatory drug.

Table 5. Patient-related and procedure-related factors between the types of ERCP/EUS-related adverse events

Factor	Perforation (n=12)	PEP (n=7)	Bleeding (n=5)	Perforation combined with PEP (n=2)	Total (n=26)	p-value
Patient-related factors						
Normal LFT	8 (66.7)	5 (71.4)	2 (40)	2 (100)	17 (65.4)	0.587
Non-dilated CBD	6 (50)	2 (28.6)	2 (40)	2 (100)	12 (46.1)	0.469
Periampullary diverticulum	1 (8.3)	2 (28.6)	1 (20)	1 (50)	5 (19.2)	0.572
Small papilla	1 (8.3)	1 (16.7)	0	0	2 (7.7)	>0.999
Procedure-related factors						
Inadvertent PD cannulation	1 (8.3)	4 (57.1)	0	1 (50)	6 (23.1)	0.032
EPBD	1 (8.3)	1 (14.3)	1 (20)	1 (50)	4 (15.4)	0.430
Precut-EST	3 (25)	3 (42.9)	0 (0)	1 (50)	7 (26.9)	0.485

Values are presented as number (%).

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; PEP, post-ERCP pancreatitis; LFT, liver function test; CBD, common bile duct; PD, pancreatic duct; EPBD, endoscopic papillary balloon dilation; EST, endoscopic sphincterotomy.

CP pancreatitis, all of which occurred during ERCP. Normal LFT was observed in five cases (71.4%), non-dilated CBD in two cases (28.6%), and a periampullary diverticulum in two cases (28.6%). Inadvertent cannulation of the pancreatic duct occurred in four cases (57.1%), and precut sphincterotomy was performed in three cases (42.9%) (Table 5). The incidence of inadvertent cannulation of the pancreatic duct was statistically significant in this study.

(3) Hemorrhage

Among the procedure-related AEs, there were five hemorrhage cases, of which four occurred during ERCP and one during EUS-guided biliary drainage. Two cases had massive hemorrhages leading to death within 24 hours after the complication. One case occurred during endoscopic papillary large-balloon dilation with an 18 mm balloon catheter for the endoscopic removal of large CBD stones in an 87-year-old patient taking

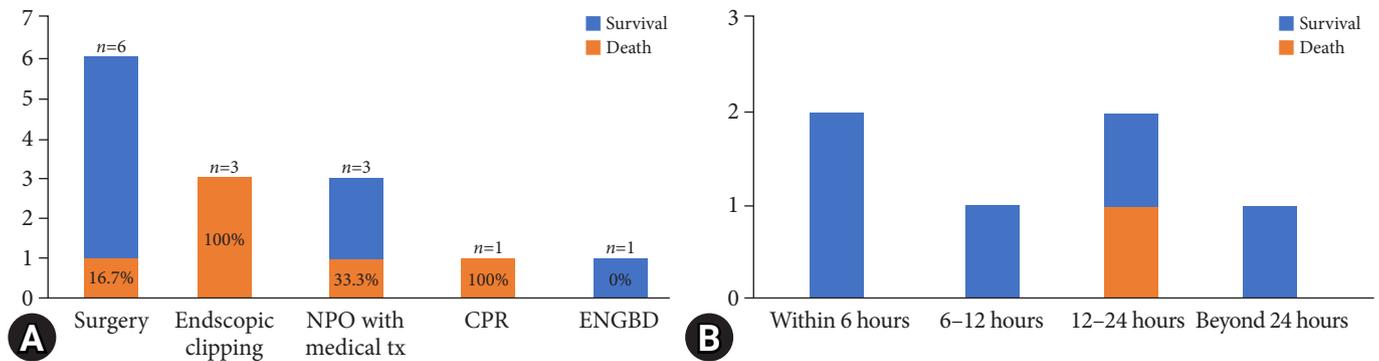


Fig. 2. Clinical outcomes for procedure-related perforation. (A) Based on management types. (B) Based on surgical timing. NPO, nol per os; tx, treatment; CPR, cardiopulmonary resuscitation; ENGBD, endoscopic nasogastric gallbladder drainage.

steroids. The other case occurred during EUS-guided biliary drainage for biliary decompression of malignant obstruction in a patient with pancreatic head cancer since selective bile duct cannulation failed during ERCP.

Risk factors for procedure-related AEs were identified as hemodialysis for end-stage renal failure, use of steroidal agents, large CBD stones of 15 mm or more, abnormal blood coagulation test (prolonged prothrombin time or activated partial thromboplastin time), anticoagulant use due to cardiovascular diseases or arrhythmia, and endoscopic papillary large-balloon dilation (EPLBD) of 15 mm or more.

2) Sedation-related AEs

Five cases were identified as sedation-related AEs; three occurred during the procedures, and two occurred in the recovery room after the procedures. There were three cases of patient death and two cases of permanent physical impairment, all of which resulted in fatal clinical outcomes. For the two cases in the recovery room, cardiac arrest requiring cardiopulmonary resuscitation occurred in a patient with chronic renal failure, in which an inappropriate dose of sedative agents was administered given the glomerular infiltration rate, and in an obese patient with a BMI of 27.9 kg/m² with a short neck and sleep apnea. The sedative agents for PB procedures were identified as midazolam, pethidine, and propofol, with various combinations of each drug.

3) Safety-related AEs

Three cases were identified as safety-related AEs: one case of fall from a hospital bed, one case of cardiac arrest in the general ward due to aspiration after the uneventful procedure, and one

case of accidental long-term placement of a biliary plastic stent after endoscopic bile duct stone removal. The case involving a fall occurred at dawn in a 93-year-old patient with hearing impairment who eventually succumbed to complications despite intensive care with neurosurgical management of stereotaxic aspiration. Cardiac arrest due to aspiration occurred after endoscopic bile duct stone removal for acute calculous cholangitis in a patient with a history of subtotal gastrectomy and Billroth II anastomosis for gastric cancer. Although the procedure took a long time (63 minutes) due to the technical difficulty of the altered anatomy, the patient was transferred to the general ward uneventfully after the procedure. However, cardiopulmonary arrest developed in the general ward, leading to hypoxic brain damage despite immediate tracheal intubation. Eventually, the patient died after eight months, although intensive care was provided to the hypoxic brain. The case of accidental long-term placement of a biliary stent occurred in a patient who had been treated with endoscopic bile duct stone removal and biliary stent placement and then transferred to the surgery department for laparoscopic cholecystectomy of GB stones. However, removal of the previously inserted stent was neglected because follow-up was not performed in the gastroenterology department.

DISCUSSION

Among the 34 medical disputes related to PB endoscopy-related AEs from April 2012 to August 2020, 14 (about 40%) were related to duodenal perforation, and 23 (about 67%) had fatal clinical outcomes, including permanent physical impairment or death. The actual number was relatively high in metropol-

itan areas, including Seoul and Gyeonggi-do. This might be explained by the fact that K-Medi is located in Seoul and, thus, is easier to access in metropolitan areas than in other regions. Regarding the types of medical institutions, more than 60% of cases occurred in academic hospitals. Therefore, considering the rare incidence of duodenal perforation or mortality that is reported to be about 1% in general,¹⁵ the fatality of patients' outcomes might be an inciting factor for medical disputes or claims on MPL about PB endoscopy-related AEs even in tertiary academic hospitals.

The risk factors for PB endoscopy-related AEs were evaluated according to three categories: procedure-related, sedation-related, and safety-related AEs. First, the procedure-related AEs comprised post-ERCP pancreatitis, hemorrhage, and perforation, thus demonstrating that the types are similar to those of the commonly known PB procedure-related AEs.^{3,4} However, perforation was the most common cause of medical disputes among the three AEs, although perforation is reported to be as low as 0.4% to 1% in general cases. This discrepancy can be explained by the fact that the perforation caused by PB endoscopy can lead to rapid clinical deterioration and grave prognosis compared to other types of endoscopic AEs. Duodenal perforation usually contributes to mechanical injuries by endoscopy in the duodenum, which eventually causes emergent surgical management.¹⁶⁻¹⁸ Therefore, when performing endoscopic procedures of ERCP/EUS, special attention should be paid to the prevention of duodenal perforation with gentle endoscopic manipulations. In addition, once duodenal perforation occurs, multidisciplinary approaches are required to prevent fatal outcomes, and sufficient explanations for patients and their families are needed for the best patient care.¹⁶⁻¹⁹

Regarding the risk factors for perforation, the following features were identified as patient factors, although they were not statistically significant in this study: old age, corticosteroid use, normal LFT, non-dilated CBD, small major papilla, peripapillary diverticulum, and small CBD stones of less than 5 mm in size. Technical factors included prolonged procedure time, long biliary stent length, and difficult bile duct cannulation. Therefore, when any of the factors mentioned above are identified, endoscopic operators should be cautious about the increased risk of AEs so that more meticulous approaches are considered during periprocedural management. When biliary stent placement is performed to decompress a malignant biliary ob-

struction, endoscopists should remember that the biliary stent can spontaneously migrate to the downside of the duodenum, causing retroperitoneal perforation, which may not be detected on simple X-rays. Thus, if a patient's symptoms persist, further assessment using abdominal CT should be considered. In addition, when performing EUS examinations, it is important to remember that there is a risk of perforation because an ultrasonic transducer at the tip of EUS is sufficiently rigid to cause perforation when abnormal pressure is applied to the duodenum while the operator is intensely focused on delineation to obtain fine ultrasound images.

For post-ERCP pancreatitis, the following factors were identified as the patient's aspect but were not statistically significant in this study: female sex, normal LFT, non-dilated CBD, and peripapillary diverticulum. Technical factors were inadvertent cannulation into the pancreatic duct and precut sphincterotomy to deal with difficult bile duct cannulation. Therefore, features generally known as risk factors for post-ERCP pancreatitis were also identified in this study. If the factors mentioned above are identified, endoscopic operators should be cautious about the risk of post-ERCP pancreatitis.^{20,21} Recently, sufficient periprocedural hydration has been demonstrated to be helpful for the prevention of post-ERCP pancreatitis.²² Furthermore, rectal non-steroidal anti-inflammatory drugs should be considered because they are well demonstrated to have a preventive effect on post-ERCP pancreatitis, although they are not commercially available in Korea. Thus, it is necessary to administer appropriate hydration to avoid unnecessarily prolonged fasting before the PB procedure.

For bleeding, the following factors were identified as the patient's aspect, although they were not statistically significant in this study: hemodialysis for end-stage renal failure, use of steroids, large CBD stones greater than 15 mm, abnormal blood coagulation test results, cardiovascular diseases or arrhythmia, and EPLBD.²³⁻²⁵ Therefore, if any of the factors mentioned above are identified, endoscopic operators should be cautious about the risk of bleeding, especially when performing EPLBD. Furthermore, for dealing with large CBD stones, mechanical lithotripsy using a specialized basket capable of lithotripsy or secondary procedures after prophylactic biliary stent placement can be considered rescue measures depending on the clinical situation.

Regarding sedation, it should be recognized that the dosage of sedative agents should be adjusted, especially in elderly

patients over 60 years of age or patients with chronic renal failure, because the renal clearance rate or central compartment volume would be reduced. In the case of obese patients, careful observation in the recovery room is required because the anesthetics that have accumulated in adipose tissue redistributed into the circulatory system can cause nausea and vomiting, delayed recovery, and respiratory depression.²⁶ In particular, patients with short necks and medical history of sleep apnea should be carefully monitored for respiratory depression even in the recovery room after endoscopic procedures are finished.²⁷

Effective strategies for patient safety management should be implemented, especially for elderly patients aged >90 years or those with cognitive dysfunction because they are more likely to develop fall accidents, leading to various diseases, including cerebral hemorrhage or bone fractures. Carbon dioxide can be used as a substitute for oxygen gas to prevent AEs caused by excessive oxygen inflation. Furthermore, if the patient is transferred to a department unfamiliar with PB endoscopic procedures for managing other diseases before hospital discharge, outpatient follow-up in the gastroenterology department should be provided to the patient and other medical staff.

Considering that the data of this study were derived from only cases of medical disputes filed with K-Medi, these results have some limitations in representing general aspects of PB endoscopy-related AEs, unlike other studies using claim databases for reimbursement in Korea. In particular, cases that showed a good clinical course even when severe grade AEs developed would not be included in this study as they would not have led to medical disputes. However, the features of PB endoscopy-related AEs can be better understood from these highly selected cases, and the critical points for patient safety and prevention of severe AEs can also be demonstrated. Thus, considering the clinical factors derived from these study cases, advanced endoscopists who perform ERCP/EUS must prepare for possible unfavorable situations, thereby preventing AEs in advance. Furthermore, the K-Medi database is not accessible in general situations because each case has sensitive information on the MPL. Therefore, the results of this study using the K-Medi database would provide valuable information, especially for advanced endoscopists who perform ERCP/EUS procedures requiring a high level of technical skills.

In conclusion, advanced endoscopists who perform ERCP/

EUS procedures always remember that PB endoscopy carries a risk of AEs that can cause fatal complications. Thus, risk assessment for AEs should be performed when performing these procedures. Furthermore, as AEs can occur even in the recovery room or general ward after uneventful completion of the procedure, patient safety measures should be taken during the entire hospitalization period, especially for elderly or obese patients. Finally, whatever type of AE occurs must be responded to as soon as possible to achieve the best patient outcomes through multidisciplinary approaches with sufficient explanations to patients.

Supplementary Material

Supplementary Table 1. The detailed features for procedure-related perforation.

Supplementary materials related to this article can be found online at <https://doi.org/10.5946/ce.2022.208>.

Conflicts of Interest

The authors have no potential conflicts of interest.

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Author Contributions

Conceptualization: YSL, CNP; Data curation: YSL, JYB, EHO, YP, YHK; Formal analysis: YSL, JYJ, JES, JKL, THL, CNP; Funding acquisition: JYJ, THL; Supervision: THL, CNP; Writing—original draft: YSL, CNP; Writing—review & editing: THL, CNP.

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