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Endoscopic retrograde cholangiopancreatography-related adverse events in Korea: A nationwide assessment

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Abstract

Background: Although endoscopic retrograde cholangiopancreatography (ERCP) is a pivotal procedure for the diagnosis and treatment of a variety of pancreatobiliary diseases, it has been known that the risk of procedure-related adverse events (AEs) is significant.

Objective: We conducted this nationwide cohort study since there have been few reports on the real-world data regarding ERCP-related AEs.

Methods: Patients who underwent ERCP were identified between 2012 and 2015 using Health Insurance Review and Assessment database generated by the Korea government. Incidence, annual trends, demographics, characteristics according to the types of procedures, and the risk factors of AEs were assessed.

Results: A total of 114,757 patients with male gender of 54.2% and the mean age of 65.0 ± 15.2 years were included. The most common indication was choledocholithiasis (49.4%) and the second malignant biliary obstruction (22.8%). Biliary drainage (33.9%) was the most commonly performed procedure, followed by endoscopic sphincterotomy (27.4%), and stone removal (22.0%). The overall incidence of ERCP-related AEs was 4.7% consisting of post-ERCP pancreatitis (PEP; 4.6%), perforation (0.06%), and hemorrhage (0.02%), which gradually increased from 2012 to 2015. According to the type of procedures, ERCP-related AEs developed the most commonly after pancreatic stent insertion (11.4%), followed by diagnostic ERCP (5.9%) and endoscopic sphincterotomy (5.7%). Younger age and diagnostic ERCP turned out to be independent risk factors of PEP.

Conclusions: ERCP-related AEs developed the most commonly after pancreatic stent insertion, diagnostic ERCP and endoscopic sphincterotomy. Special caution should be used for young patients receiving diagnostic ERCP due to increased risk of PEP.

KEYWORDS

complication, endoscopic retrograde cholangiopancreatography, hemorrhage, Korea, pancreatitis, perforation

Dong Kee Jang and Jungmee Kim contributed equally as the first authors to this work.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a pivotal procedure for the diagnosis and treatment of pancreaticobiliary diseases.[1–3] As the patients can benefit from less invasiveness, ERCP has replaced surgery in a variety of fields. However, it cannot be free from the procedure-related adverse events (AEs), such as perforation, bleeding, or post-ERCP pancreatitis (PEP), occurring in 5%–10% of the recipients, 20% of whom suffer from severe diseases.[4]

Health Insurance Review and Assessment (HIRA) data, also called National Health Insurance Service (NHIS) data in South Korea is a claims database constructed in the process of reimbursement.[5] Korea established a universal nationwide NHIS system since 2000. The NHIS covers about 97% of the total population, the remaining composed of those covered by the medical aid program or those who are temporary residents. The HIRA, a government organization independent of the NHIS, reviews and evaluates the nationwide claim data of the NHIS. The claims-based HIRA data includes records of diagnoses, prescriptions, hospitalizations, and level of institutions related to medical costs under the insurance coverage. Also it contains patient information such as age, sex, residence, disability. Therefore, a very large scaled data became available for the nationwide real-world practice regarding ERCP including procedure-related AEs. In this study, incidences, annual trends, demographics, characteristics according to the types of procedures, and the risk factors of ERCP-related AEs were assessed with so-called "the Big Data," which was not possible in previous studies.[6]

Key summary

Summarize the established knowledge on this subject

- Although endoscopic retrograde cholangiopancreatography (ERCP) is a pivotal procedure for the diagnosis and treatment of a variety of pancreatobiliary diseases, the risk of procedure-related adverse events (AEs) is significant.
- There have been few reports on the real-world data regarding ERCP-related AEs.

What are the significant and/or new findings of this study?

- This nationwide cohort study encompassing 114,757 patients showed that the most frequent ERCP-related AE was post-ERCP pancreatitis (PEP) (4.6%), followed by perforation (0.06%) and hemorrhage (0.02%) with increasing annual incidences.
- According to the type of procedures, ERCP-related AEs developed the most commonly after pancreatic stent insertion (11.4%) followed by diagnostic ERCP (5.9%) and endoscopic sphincterotomy (5.7%).

METHODS

Dataset

The HIRA database includes all information regarding diagnoses using the International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10) codes, procedures or operations, drug prescriptions, health insurance status, types of medical facility visited, and medical costs. The HIRA database has been used widely in many epidemiological studies, including pancreatobiliary studies.[7,8] The strengths and limitations of this nationwide claims data source and its application in many medical areas or healthcare utilization have been discussed previously.[5]

The data used in the study was generated by the HIRA database between January 2012 and December 2015. During the study period, patients who underwent all of the ERCP procedures were identified with the HIRA prescription code for ERCP (E7621, Q7761-Q7767). If ERCP was performed more than once during the study period, only the first ERCP was included. Information about patient demographics, the indication for ERCP, length of hospital stay, types of medical institutions, and ERCP-related AEs were reviewed for the eligible patients.

Operational definition

Each therapeutic procedure was identified with the HIRA prescription code from Q7761 to 7765, representing endoscopic sphincterotomy, endoscopic removal of biliary or pancreatic stone with balloon or basket, biliary or pancreatic drainage by stent or nasobiliary catheter, biliary dilatation for stricture, and papillary balloon dilatation, respectively. If multiple therapeutic procedures were performed at once, only one most important procedure was recorded. For example, if common bile duct (CBD) stone removal was performed after sphincterotomy, it was recorded as CBD stone removal in the database. The cases with no combined therapeutic procedures including sphincterotomy were considered as diagnostic ERCP. Therefore, diagnostic ERCP includes cases where pure cholangiopancreatography was performed and cases where cholangiography plus intraductal biopsy were performed for indeterminate biliary stricture.

Diagnosis related with indications and AEs of ERCP were determined by the ICD-10 code of each patient's record as the following: Cholelithiasis (K80), pancreatitis (K85, K86.0, and K86.1), and malignant biliary obstruction (any patients with C codes regarding malignant neoplasms). The indications were registered according to the disorders of gallbladder, biliary tract and pancreas (K80 to K87) and benign or malignant neoplasm of biliary tract or pancreas (D01.5, D01.7, D13.5–13.7, and C24 to 25). The ERCP-related AEs were classified into perforation, hemorrhage, and pancreatitis (Table 1). A blood transfusion immediately following ERCP was also considered

TABLE 1 Operational definition of endoscopic retrograde cholangiopancreatography (ERCP)-related adverse events (AEs) according to the International Classification of Diseases (ICD)-10 code

Perforation	K22.3	Perforation of esophagus
	K63.1	Perforation of intestine (ontraumatic)
	K65.0	Acute peritonitis
	S10.0	Contusion of throat
	S10.1	Other and unspecified superficial injuries of throat
	S10.7	Multiple superficial injuries of neck
	S10.8	Superficial injury of other parts of neck
	S10.9	Superficial injury of neck, part unspecified
	S11.0	Open wound involving larynx and trachea
	S11.2	Open wound involving pharynx and cervical esophagus
	S11.7	Multiple open wounds of neck
	S11.8	Open wound of other parts of neck
	S11.9	Open wound of neck, part unspecified
	S36.4	Injury of small intestine
	S36.9	Injury of unspecified intra-abdominal organ
	T81.0	Hemorrhage and hematoma complicating a procedure
	T81.2	Accidental puncture and laceration during a procedure, not elsewhere classified
	Y60.4	Unintentional cut, puncture, perforation or hemorrhage during endoscopic examination
Hemorrhage	K22.6	Gastro-esophageal laceration-hemorrhage syndrome
	K92.2	Gastrointestinal hemorrhage, unspecified
	R04.1	Hemorrhage from throat
	T81.0	Hemorrhage and hematoma complicating a procedure
	Y60.4	Unintentional cut, puncture, perforation or hemorrhage during endoscopic examination
Pancreatitis	K85	Acute pancreatitis, the diagnosis of which was coded within a week from the day on which ERCP was performed

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; ICD, International Classification of Diseases.

as a development of post-ERCP hemorrhage. In case of pancreatitis, those only with hospital days of two or more days were included. The severity of PEP was graded according to the length of hospital stay.[9]

Statistical analysis

The baseline and clinical characteristics were described as number (%) for categorical variables. A mean with standard deviation (SD) was used for continuous variables. Cochran-Armitage test for trend was performed for the *P* for trend of annual incidence of the ERCP-related AEs. In case of ERCP-related AEs, one person with a certain AE may have received more than one ERCP procedure. The risk factors for ERCP-related AEs were analyzed using logistic regression with odds ratios and 95% confidence intervals. The final logistic regression model was verified as adequate with the concordance statistic estimate (c) of 0.62 and SAS Enterprise Guide, version 6.1 (SAS Institute, Inc.) was used for all analyses.

RESULTS

A total of 114,757 patients underwent diagnostic or therapeutic ERCP during the study period receiving a total of 158,038 procedures. Baseline and clinical characteristics were shown in Table 2. Mean age of the study patients were 65 ± 15.2 years. There was 53.2% of male gender. Mean length of hospital stay was 11 ± 9.2 days. Approximately 60% of ERCP was performed in the tertiary referral institutions. The most frequent indication for ERCP was cholelithiasis (49.4%), followed by malignant biliary obstruction (22.8%). Others (27.8%) included presumed gallstone pancreatitis (5.8%), biliary/pancreatic duct stricture, pancreatic duct stone, and so on. Diagnostic ERCP was performed in 9.8% of all the ERCP patients. Among the therapeutic procedures, biliary or pancreatic drainage was the most common (33.9%), followed by endoscopic sphincterotomy (27.4%).

The most frequent ERCP-related AE was PEP (4.6%), followed by perforation (0.06%) and hemorrhage (0.02%; Table 3). The

TABLE 2 Baseline characteristics

ERCP cases, *n* (%)	114,757 (100)
2012	30,641 (26.7)
2013	28,250 (24.6)
2014	27,999 (24.4)
2015	27,867 (24.3)
Age (year), mean ± SD	65 ± 15.2
Male, *n* (%)	62,197 (53.2)
Indication of ERCP, *n* (%)	
Cholelithiasis	56,660 (49.4)
Malignant biliary obstruction	26,189 (22.8)
Others (pancreatitis, biliary/pancreatic duct stricture, pancreatic duct stone, etc.)	31,908 (27.8)
Types of procedures, *n* (%)	
Diagnostic	11,211 (9.8)
Endoscopic sphincterotomy	31,439 (27.4)
Stone removal	25,205 (22.0)
Balloon	20,638 (18.0)
Basket	17,496 (15.3)
Biliary/pancreatic drainage	38,868 (33.9)
Plastic stent(s)	16,144 (14.1)
Metal stent(s)	2694 (2.4)
Nasobiliary catheter	21,641 (18.9)
Pancreatic stent(s)	4875 (4.3)
Biliary dilatation	7147 (6.2)
Others	887 (0.8)
Hospital stay (day), mean ± SD	11 ± 9.2
Level of institution, *n* (%)	
Tertiary care hospital	69,248 (60.3)
General hospital	45,011 (39.2)
Hospital	408 (0.4)
Clinic	90 (0.1)

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.

overall incidence of ERCP-related AEs gradually increased from 2012 to 2015 (*P* for trend <0.001), especially pancreatitis from 4.3% to 4.8%. When classified according to the type of procedures, ERCP-related AEs developed the most commonly after pancreatic stent insertion (11.4%), followed by diagnostic ERCP (5.9%) and endoscopic sphincterotomy (5.8%; Table 4). Perforation occurred the most frequently during diagnostic ERCP, plastic stenting, pancreatic stenting and biliary dilatation with all the same incidence of 0.08%. There were 0.02% cases of perforation during stone removal and, remarkably, no case during 2694 cases of metal stenting. Hemorrhage developed in 28 (0.02%) cases, which developed the most commonly after biliary drainage with plastic stent and pancreatic stenting (0.04% each) and no case was reported after biliary dilatation. There were a total of 5255 (4.6%) cases of PEP. Among them, 3497 (66.6%) were graded as mild to moderate disease and 1758 (33.4%) as severe based on the length of hospital stay.

Table 5 shows the logistic regressions of risk factors for PEP. The risk increased with younger age; the ORs were 2.5, 2.1, and 1.5 for those under 40, 40 and 50 s, respectively, when 80 years of age or older was the reference group ($P < 0.001$). Diagnostic ERCP had a statistically significant increased risk of pancreatitis (aOR = 1.13, confidence interval: 1.01 to 1.26, $P < 0.03$), while biliary drainage with metal stent showed the lowest risk (aOR = 0.13, confidence interval: 0.08 to 0.21, $P < 0.001$).

DISCUSSION

This study assessed the AEs from a total of 114,757 ERCP cases for 4 years using a database which registered the entire Korean population of about 51 million people and the results were compared according to each procedure.

The overall incidence of ERCP-related AEs gradually increased from 2012 to 2015. The increase in PEP is thought to be the main cause of this trend. Rectal non-steroidal anti-inflammatory drugs have not been available in Korea until now. A recent cohort study from the US also showed a rising admission rate and mortality associated with PEP.[10] This trend of increasing PEP is probably due to the recent attempts to more complex cases. In the present study,

TABLE 3 Endoscopic retrograde cholangiopancreatography (ERCP)-related adverse events (AEs)

	2012 (*N* = 30,641)	2013 (*N* = 28,250)	2014 (*N* = 27,999)	2015 (*N* = 27,867)	Total (*N* = 114,757)	*P* value for trend
Perforation	26 (0.08)	16 (0.06)	15 (0.05)	16 (0.06)	73 (0.06%)	0.09
Hemorrhage	5 (0.02)	4 (0.01)	10 (0.04)	9 (0.03)	28 (0.02%)	0.05
Pancreatitis	1313 (4.29)	1260 (4.46)	1342 (4.79)	1340 (4.81)	5255 (4.58%)	0.0002
Mild–moderate (HD < 10 days)	849 (64.66)	846 (67.14)	886 (66.02)	916 (68.36)	3497 (66.55%)	0.04
Severe (HD > 10 days)	464 (35.34)	414 (32.86)	456 (33.98)	434 (31.64)	1758 (33.45%)	
Total	1344 (4.39)	1280 (4.53)	1367 (4.88)	1365 (4.90)	5356 (4.67%)	0.0006

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.

TABLE 4 Endoscopic retrograde cholangiopancreatography (ERCP)-related adverse events (AEs) according to the type of procedures

	Case no.	Perforation (*N* = 73)	Hemorrhage (*N* = 23)	Pancreatitis (*N* = 5255)	Total (*N* = 5356)
Diagnostic	11,211	9 (0.08%)	2 (0.02%)	652 (5.82%)	663 (5.91%)
Endoscopic sphincterotomy	31,439	21 (0.06%)	10 (0.03%)	1787 (5.68%)	1818 (5.78%)
Stone removal	25,205	6 (0.02%)	3 (0.01%)	881 (3.50%)	890 (3.53%)
Balloon	20,638	3 (0.01%)	2 (0.009%)	709 (3.43%)	714 (3.46%)
Basket	17,496	4 (0.02%)	3 (0.01%)	529 (3.02%)	536 (3.06%)
Biliary/pancreatic drainage	38,868	29 (0.07%)	13 (0.03%)	1676 (4.31%)	1718 (4.42%)
Plastic stent(s)	16,144	14 (0.08%)	7 (0.04%)	598 (3.70%)	619 (3.83%)
Metal stent(s)	2694	0 (0%)	1 (0.03%)	15 (0.55%)	16 (0.59%)
Nasobiliary catheter	21,641	12 (0.05%)	5 (0.02%)	845 (3.90%)	862 (3.98%)
Pancreatic stent(s)	4875	4 (0.08%)	2 (0.04%)	548 (11.24%)	554 (11.36%)
Biliary dilatation	7147	6 (0.08%)	0 (0%)	247 (3.45%)	253 (3.53)

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.

TABLE 5 Risk factors of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP)

	N = 114,757	Cases of PEP	cOR[b] (95% CI)	aOR[c] (95% CI)	*P* value
Male, *n* (%)	62,197 (54.2)	2803 (4.5)	0.96 (0.91–1.02)	0.96 (0.91–1.02)	0.15
Age group, *n* (%)					
<40	8504 (7.4)	740 (8.7)	2.64 (2.36–2.94)	2.46 (2.20–2.75)	<0.0001
40–49	9818 (8.6)	741 (7.6)	2.26 (2.03–2.52)	2.13 (1.91–2.38)	<0.0001
50–59	19,424 (16.9)	1028 (5.3)	1.55 (1.40–1.71)	1.47 (1.33–1.63)	<0.0001
60–69	25,687 (22.4)	993 (3.9)	1.11 (1.01–1.23)	1.08 (0.97–1.20)	0.15
70–79	33,379 (29.1)	1127 (3.4)	0.97 (0.88–1.07)	0.95 (0.86–1.05)	0.33
≥80	17,945 (15.6)	626 (3.5)	Ref	Ref	
ERCP procedures, *n* (%)					
Diagnostic	11,211 (9.8)	652 (5.8)	1.33 (1.22–1.45)	1.13 (1.01–1.26)	0.03
Endoscopic sphincterotomy	31,439 (27.4)	1787 (5.7)	1.39 (1.31–1.47)	1.05 (0.96–1.15)	0.008
Stone removal, balloon	20,638 (18.0)	709 (3.4)	0.70 (0.65–0.76)	0.86 (0.76–0.96)	
Stone removal, basket	17,496 (15.3)	529 (3.0)	0.61 (0.56–0.67)	0.65 (0.58–0.73)	<0.0001
Biliary drainage, plastic stent(s)	16,144 (14.1)	598 (3.7)	0.78 (0.71–0.85)	0.78 (0.71–0.87)	<0.0001
Biliary drainage, metal stent(s)	2694 (2.4)	15 (0.6)	0.11 (0.07–0.19)	0.13 (0.08–0.21)	<0.0001
Biliary drainage, nasobiliary catheter	21,641 (18.9)	845 (3.9)	0.82 (0.76–0.88)	0.80 (0.72–0.88)	<0.0001
Biliary dilatation for biliary stricture	829 (0.7)	52 (6.3)	1.40 (1.06–1.86)	1.21 (0.91–1.62)	0.20
Papillary balloon dilatation	211 (0.2)	6 (2.8)	0.61 (0.27–1.38)	0.53 (0.23–1.20)	0.13

Abbreviations: aOR, adjusted odds ratio; cOR, crude odds ratio; ERCP, endoscopic retrograde cholangiopancreatography.

ERCP-related AE developed most commonly after pancreatic stent insertion (11.4%) followed by diagnostic ERCP (5.9%). This result is also because PEP occurred most often in these two procedures. Since pancreatic stent insertion is a procedure for the pancreatic duct, it can naturally increase the risk of developing PEP. Due to the nature of the HIRA database in which only the most major procedures are recorded, it is presumed that the cases recorded as "pancreatic stent insertion" were rarely performed for the purpose of preventing PEP or facilitating biliary cannulation. On the other hand, the fact that the incidence of PEP increases in diagnostic ERCP suggests that, as most practitioners agree, diagnostic ERCP is an undesirable procedure.[11] Therefore, endoscopic ultrasonography or magnetic resonance cholangiopancreatography would be better option in diagnosing choledocholithiasis.[12]

Langerth et al. published a study regarding ERCP-related perforation with the largest number of patients by a Swedish population-based registry so far.[13] They reported 376 (0.72%) cases of perforation out of 52,140 ERCP procedures and malignancy, age over 80 years, and sphincterotomy in the pancreatic duct increased the risk to die after a perforation. Our study included the double number of patients and the incidence of perforation was less than a tenth. It was thought that there was a difference in the definition. The previous study included even the cases of extravasation of contrast dye. However, the case number may have been restricted in our study since we included only the patients who met the operational definition of the ICD-10 codes of K63.1 or K83.2, and T81.2, which meant the perforation of intestine or bile duct and complications of procedures. It was remarkable in our study that perforation occurred the most frequently during diagnostic ERCP, plastic stenting, biliary dilatation, and pancreatic stenting with all the same incidence of 0.08%. On the contrary, there were just 0.02% cases of perforation during stone removal and, remarkably, no case during 2694 cases of metal stenting.

Hemorrhage developed in 28 (0.02%) cases in our data. This value is very low compared to the result of previous Austrian studies (3.6%–3.7%),[14,15] because only diagnosis codes regarding hemorrhage were included in our study. Although the numbers were similar between the procedures, hemorrhage developed the most commonly after biliary drainage with plastic stent and pancreatic stenting. Since only one procedure was selected for reimbursement in the HIRA system, it is highly likely that endoscopic sphincterotomy was performed together in most cases of drainage procedures. Anyhow, it is an interesting finding that hemorrhage was more prone to develop in the cases of drainage procedures that in the cases of stone removal or endoscopic sphincterotomy alone.

There are some differences between our study and the previous large-scale nation-wide studies in other countries. In particular, many research results on ERCP have been published through the famous gallstone surgery and endoscopic retrograde cholangiopancreatography (GallRiks) registry in Sweden,[13,16,17] which is a database using an internet-based platform. However, it does not contain all information on ERCP in Sweden, and there may be input errors. The same is true for databases in the US[10] or Australia.[14,15] In the case of the US database,[10] it is difficult to say that it is representative of the situation of the whole country because it was sample data. However, in the case of our HIRA database, there may also be input errors such as diagnosis codes, but it has the advantage of showing all the ERCP procedures in the country. Considering this aspect, our data can represent the entire situation in Korea.

There was a total of 5255 (4.6%) cases of PEP. Among them, 3497 (66.6%) were graded as mild to moderate disease and 1758 (33.4%) as severe. Since we determined the severity of PEP based on the length of hospital stay, some cases with a prolonged hospital stay for reasons other than ERCP might be included in the category of severe PEP. According to our data, in addition to younger age, diagnostic ERCP turned out to be independent risk factors for the development of PEP, which was thought to be reflection of the classic risk factors of suspected sphincter of Oddi dysfunction and non-dilated bile ducts.[11,18] The lowest risk of biliary drainage with metal stent (OR = 0.13, confidence interval: 0.08 to 0.21) seems a remarkable finding.

There were limitations in our study. First, the final consequences of AEs were not evaluated, especially the mortality rate which was not included in the HIRA data. Second, the severity of AEs could not be available. Third, the laboratory values or the use of contrast medium, which is considered to be established risk factors, information on ERCP volume, and the effect of preventive measures for PEP were not be evaluated.[19] Fourth, due to the nature of the database, even if various procedures were performed in an ERCP session, only one major procedure was recorded. Therefore, procedures such as multiple stenting and prophylactic pancreatic duct stenting were not properly analyzed. In addition, discrepancies can occur between diagnoses entered in the data and diseases that a patient has in reality. Nevertheless, the major strength of our study is that the results represent the data of all ERCP recipients from an entire population of Korea as the study target, which could minimize the selection or recruitment biases which are inevitable in a cohort study.

In conclusion, ERCP-related AEs developed the most commonly after pancreatic stent insertion, diagnostic ERCP and endoscopic sphincterotomy. Special caution should be used for young patients receiving diagnostic ERCP due to increased risk of PEP. The results of this nationwide study can serve as a basis for useful policy standards for quality control and guidance of ERCP practice in the future.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

ETHICS APPROVAL

The study protocol was based on the Declaration of Helsinki and approved by the Institutional Review Board (IRB) of Dongguk University Ilsan Hospital (IRB Approval Number/Date: DUIH-IRB 2019–01–003/Jan-25-2019).

INFORMED CONSENT

The requirement for informed consent for this study was waived.

DATA AVAILABILITY STATEMENT

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

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