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Safety of Gastrointestinal Endoscopy in Korea: A Nationwide Survey and Population-Based Study

Yunho Jung ,^{1*} Jung-Wook Kim ,^{2*} Jong Pil Im ,³ Yu Kyung Cho ,⁴ Tae Hee Lee ,⁵ and Jae-Young Jang ²

¹Division of Gastroenterology, Department of Internal Medicine, Soonchunhyang University College of Medicine, Cheonan, Korea

²Division of Gastroenterology, Department of Internal Medicine, Kyung Hee University School of Medicine, Seoul, Korea

³Department of Internal Medicine and Liver Research Institute, Seoul National University Hospital, Seoul, Korea

⁴Department of Internal Medicine, College of Medicine, The Catholic University of Korea, Seoul, Korea

⁵Institute for Digestive Research, Soonchunhyang University Seoul Hospital, Soonchunhyang University College of Medicine, Seoul, Korea

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Address for Correspondence:

Jae-Young Jang, MD, PhD

Division of Gastroenterology, Department of Internal Medicine, Kyung Hee University School of Medicine, 26, Kyungheedaero, Dongdaemun-gu, Seoul 02447, Korea.
Email: jyjang@khu.ac.kr

*Yunho Jung and Jung-Wook Kim contributed equally to this work.

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ORCID iDs

Yunho Jung

<https://orcid.org/0000-0002-7760-0050>

Jung-Wook Kim

<https://orcid.org/0000-0002-5383-7934>

Jong Pil Im

<https://orcid.org/0000-0003-1584-0160>

Yu Kyung Cho

<https://orcid.org/0000-0002-7297-6577>

Tae Hee Lee

<https://orcid.org/0000-0003-3049-8252>

Jae-Young Jang

<https://orcid.org/0000-0002-7930-1468>

ABSTRACT

Background: Attention should be paid to endoscopy-related complications and safety-related accidents that may occur in the endoscopy unit. This study investigated the current status of complications associated with diagnostic and therapeutic endoscopy in Korea.

Methods: A questionnaire survey on endoscopy-related complications was conducted in a total of 50 tertiary or general hospitals in Korea. The results were compared to the population-level claims data from the Health Insurance Review & Assessment Service (HIRA), which analyzed endoscopy procedures conducted in 2017 in Korea.

Results: The incidences of bleeding associated with diagnostic and therapeutic esophagogastroduodenoscopy (EGD) and with diagnostic and therapeutic colonoscopy were 0.224% and 3.155% and 0.198% and 0.356%, respectively, in the 2017 HIRA claims data, compared to 0.012% and 1.857%, and 0.024% and 0.717%, in the 50 hospitals surveyed. The incidences of perforation associated with diagnostic and therapeutic EGD and with diagnostic and therapeutic colonoscopy were 0.023% and 0.613%, and 0.007% and 0.013%, respectively, in the 2017 HIRA claims data compared to 0.001% and 0.325%, and 0.017% and 0.206%, in the 50 hospitals surveyed. In the HIRA claims data, the incidence of bleeding/perforation after diagnostic colonoscopy in clinics, community hospitals, general hospitals, and tertiary hospitals was 0.129%/0.000%, 0.088%/0.004%, 0.262%/0.009%, and 0.479%/0.030% respectively, and the corresponding incidence of bleeding/perforation after therapeutic colonoscopy was 0.258%/0.004%, 0.401%/0.007%, 0.408%/0.024%, and 0.731%/0.055%.

Conclusion: The incidences of complications associated with diagnostic and therapeutic EGD or colonoscopy tended to increase with the hospital volume in Korea.

Trial Registration: Clinical Research Information Service Identifier: [KCT0001728](https://clinicaltrials.gov/ct2/show/study/NCT0001728)

Keywords: Endoscopy; Colonoscopy; Bleeding; Perforation

Trial Registration

Clinical Research Information Service
Identifier: KCT0001728

Disclosure

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Jung Y, Kim JW, Im JP, Cho YK, Lee TH, Jang JY. Data curation: Jung Y, Kim JW, Im JP, Cho YK, Lee TH, Jang JY. Formal analysis: Jung Y, Kim JW, Im JP, Cho YK, Lee TH, Jang JY. Investigation: Jung Y, Jang JY. Methodology: Kim JW, Cho YK, Lee TH, Jang JY. Supervision: Jang JY. Visualization: Jung Y. Writing - original draft: Jung Y. Writing - review & editing: Kim JW, Jang JY.

INTRODUCTION

Esophagogastroduodenoscopy (EGD) and colonoscopy are relatively safe procedures, but can sometimes lead to serious, life-threatening complications. As the indications for therapeutic endoscopic procedures continue to expand, the risk for complications is expected to increase. Based on the Korean National Health Insurance Service database from 2002 to 2013, the overall colonoscopy volume increased eightfold over 12 years, and the colon polypectomy rate is also continuously increasing every year.¹ Based on the claims data of endoscopic submucosal dissection (ESD) for early gastric cancer in Korea between November 2011 and December 2014, although the number of gastric ESD trials increased every year, most of them were carried out in tertiary care hospitals in Korea.²

As safety-related issues of endoscopy are closely related to the quality of endoscopists and endoscopy units,³ many countries have emphasized and enhanced endoscopy quality management and have made efforts to improve quality at the national level. In the USA, the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force has been working to improve endoscopic quality with the establishment of the first set of quality indicators for gastrointestinal (GI) tract endoscopic procedures in 2006.⁴⁻⁶ In Korea, the National Cancer Screening Program has included nationwide screening for gastric and colorectal cancer since 1999. The Korean Society of Gastrointestinal Endoscopy (KSGE) has established the National Endoscopy Quality Improvement Program to improve and manage the quality of endoscopic procedures. This program consists of qualification of endoscopists, quality improvement for instruments available at the endoscopy unit and endoscopic procedures, and measurement of outcomes of endoscopy screening.⁷⁻⁹ Furthermore, KSGE implemented the Accredited Endoscopy Unit Program in 2012 to certify and encourage high-quality endoscopy practices.¹⁰ Specifically, the Accredited Endoscopy Unit Program is obligated to document the incidence and types of complications, such as bleeding and perforation. Despite these efforts, quality control assessment programs still assess the documentation of endoscopic complications, but do not assess the actual incidence and management of complications.

Recently, ASGE/ACG has established a performance target associated with colonoscopy related to post-process quality indicators, which recommends that the perforation rate should be < 1/500 overall and < 1/1,000 in screening. It also recommends a bleeding rate < 1% after polypectomy.¹¹ However, there have been few studies on complications related to diagnostic and therapeutic EGD and colonoscopy in Korea, with neither a uniform definition nor standardized reporting system, so there seems to be discrepancies between real clinical practice and research results. Nonetheless, the accredited Endoscopic Unit Program's assessment of high-quality endoscopic practices has a mandatory requirement for documentation of complication rates, which is expected to better reflect data from real practices.

This study assessed the current status of complications associated with diagnostic and therapeutic endoscopy in Korea, to utilize this information to develop safety management indicators and improve quality of care in the endoscopy unit in Korea.

METHODS

Survey of the safety of endoscopy

A PubMed literature search between June 1 and July 15, 2018, was performed to identify the international standard guidelines and quality indicators for the safety of endoscopy. Based on the literature review, items were organized in accordance with the recommended guidelines, and a questionnaire survey produced by members of the Endoscopy Quality Assurance Committee under KSGE was designed to investigate the actual and current safety status of endoscopy units in Korea. In addition, a questionnaire survey was conducted in a total of 50 KSGE member tertiary or general hospitals using the Survey Monkey questionnaire survey site (<https://ko.surveymonkey.com/>). Participating institutions consisted of two community hospitals (4%), 17 general hospitals (34%), and 31 tertiary hospitals (62%), and no clinics. These hospitals have certified the Accredited Endoscopy Unit Program reviewed by KSGE for high-quality endoscopy practices that have passed the evaluation of strict standards for overall quality assessment items, including the qualification of endoscopists, the status of endoscopy procedures, and the records of the occurrence of complications.^{10,12,13} In addition, as these hospitals include most of the institutions that perform very high quality and advanced therapeutic endoscopy procedures in Korea, these data reflect the status of leading groups related to endoscopy in Korea.

The items included in the questionnaire survey were as follows (survey data): 1) Current status of working for medical personnel, 2) Number of diagnostic and therapeutic EGD and colonoscopy procedures performed between 2013 and 2017, and 3) Number and incidence of serious procedure-related complications, such as bleeding, perforation, and death, which occurred during the same period; sedation-related complications (respiratory depression, hypotension, anaphylaxis, shock, and so forth); periprocedural complications (falls, and so forth); and progress of each event (death, surgery, inpatient care, cardiopulmonary resuscitation, intubation, defibrillation).

To increase accuracy, complication data were collected by contacting the endoscopist in charge of the endoscopic unit or endoscopists participating in endoscopic quality management in each hospital. In addition, we asked them to investigate records of disputes related to complications in hospitals. During this collection process, the name of the institution was deleted because safety-related accident reports represent sensitive information for the institutions, and only the type of institution (general hospital, tertiary hospital, and so forth) was recorded. To prevent data leaks to outside parties, the researchers were trained, and written confidentiality agreements were obtained. Each file was assigned a password and handled securely. All files were destroyed upon completion of the study.

Population-based analyses of safety of endoscopy

Data sources and study population

Endoscopic procedures performed in Korea in 2017 were analyzed based on the claims data from the Health Insurance Review & Assessment Service (HIRA). The HIRA dataset contains demographic information on the beneficiaries, along with the adjusted medical and pharmacy claims data for almost 98% of the total Korean population¹⁴; it also contains extensive administrative data of all insurance claims, provider information, care setting, and diagnostic codes defined by the International Classification of Diseases 10th revision (ICD-10). Similar to other claims databases, no information is available about the indications for treatments or procedures received or the results of medical investigations.

The study population included beneficiaries aged 20 years and older who underwent EGD or colonoscopy between January 1, 2017, and December 31, 2017. Endoscopy consisted of EGD and colonoscopy was classified as diagnostic or therapeutic endoscopy using procedure codes. Diagnostic endoscopy was defined as no additional procedures other than biopsy. Therapeutic endoscopy included polypectomy, endoscopic mucosal resection (EMR), and ESD in EGD, and polypectomy and EMR in colonoscopy. Colorectal ESD was excluded from the 2017 claims data because it was not covered by Korean National Health Insurance in 2017. Healthcare settings were categorized as primary clinics (< 30 beds), community hospitals (\geq 30 beds), general hospitals (\geq 100 beds), or tertiary hospitals (a general hospital designated by the Ministry of Health and Welfare specializing in treating severe and difficult diseases) according to the level of patient's capacity in accordance with Korean medical law.

Ascertainment of adverse events from the HIRA dataset

We identified two major adverse events, i.e., perforation and bleeding, within 30 days after endoscopy using ICD-10 diagnosis codes and procedure or surgery claim codes. Patients with claim codes related to adverse events within 1 month prior to endoscopy were excluded. In EGD, claim codes related to each adverse event were defined as follows: perforation included “endoscopic treatment of upper GI perforation” (Q7660) and “simple closure of perforated stomach and duodenum” (Q2540), while bleeding included “surgical clipping” (Q2510), “endoscopic hemostasis of upper GI tract” (Q7620), and “embolization” (M6644). In colonoscopy, perforation included “segmental resection of colorectum” (Q2673), “colectomy” (Q2679), and “repair of bowel and/or mesenteric injury” (Q2771–2773), while bleeding included “sigmoidoscopic hemostasis” (Q7730), “colonoscopic hemostasis” (Q7680) and “embolization” (M6644). During the study period, endoscopic closure for colonic perforation was noted as covered by the HIRA. All emergency department visits within 30 days after EGD and colonoscopy were ascertained. To exclude cases who underwent therapeutic endoscopy due to bleeding rather than as an endoscopy-related complication, we excluded patients with claim codes related to GI bleeding within 1 month prior to endoscopy. In addition, we selected only patients who had bleeding after therapeutic endoscopy and both the procedure-related codes (polypectomy, EMR, or ESD) and the hemostasis-related codes.

Ethical problems and statistical analysis

Descriptive statistics were used to summarize the number of endoscopic procedures performed and the incidence of endoscopy-related complications. Categorical data are expressed as number (percentage), whereas continuous data are expressed as the mean \pm SD. Statistical analyses were performed using R software version 3.5.1 (<http://cran.r-project.org>).

Ethics statement

This study was approved by the Institutional Ethics Committee and is registered at the Clinical Research Information Service (<https://cris.nih.go.kr/cris/en/index.jsp>) (KCT0001728). This study was approved by the Institutional Review Board of Kyung Hee University Hospital (KHUH 2019-01-015). Informed consent was waived by the board.

RESULTS

Incidence of endoscopy-related complications in surveyed hospitals in 2013–2017

The results were from analyses of approximately 3 million endoscopic procedures performed in 50 institutions in 2013–2017. The incidences of bleeding and perforations associated with diagnostic EGD were 0.012% and 0.001%, respectively. The incidences of bleeding and perforations associated with therapeutic EGD, which included polypectomy, EMR, and ESD, were 1.857% and 0.325%, respectively. The incidences of bleeding and perforations related to diagnostic colonoscopy were 0.024% and 0.017%, respectively. The incidences of bleeding and perforations related to therapeutic colonoscopy, which included polypectomy, EMR, and ESD, were 0.717% and 0.206%, respectively (Tables 1 and 2). Sedation-related complications, such as hypersensitivity, drug cross-reactions, respiratory depression, and hypotension, occurred 169 times annually on average. Fall accidents also occurred 18.8 times per year on average.

Table 1. Total number of endoscopic procedures performed in 50 hospitals during 2013–2017

Endoscopic procedures	Year					Total
	2013	2014	2015	2016	2017	
Diagnostic EGD						
Sedation	248,993	262,154	253,164	278,882	286,073	1,329,266
Non-sedation	162,365	163,294	155,426	162,436	155,420	798,941
Diagnostic colonoscopy						
Sedation	115,341	116,994	117,012	124,741	124,457	598,545
Non-sedation	38,492	37,845	39,156	39,442	41,324	196,259
Therapeutic EGD						
ESD	9,225	10,149	5,118	5,548	5,356	35,396
EMR	4,964	5,268	1,318	1,155	1,078	13,783
Polypectomy	1,240	1,286	24,283	22,410	22,433	71,652
Therapeutic colonoscopy						
Polypectomy	27,304	25,738	24,611	28,455	31,898	138,006
EMR	21,251	21,893	6,229	7,320	7,367	64,060
ESD	6,716	6,853	5,118	5,548	5,356	29,591

EGD = esophagogastroduodenoscopy, ESD = endoscopic submucosal dissection, EMR = endoscopic mucosal resection.

Table 2. Numbers of endoscopy-related complications in surveyed institutions during 2013–2017 by year

Complications	Year					Total	Mean
	2013	2014	2015	2016	2017		
Bleeding							
Stomach							
Diagnostic	58	55	40	59	45	257	51.4
Therapeutic	438	436	431	449	490	2,244	448.8
Colon							
Diagnostic	43	42	35	34	33	187	37.4
Therapeutic	301	327	328	346	360	1,662	332.4
Perforation							
Stomach							
Diagnostic	8	7	8	2	5	30	6.0
Therapeutic	64	89	89	75	76	393	78.6
Colon							
Diagnostic	25	34	27	18	30	134	26.8
Therapeutic	106	107	85	83	97	478	95.6
Sedation-related accidents (hypotension, respiratory depression, etc.)	174	162	164	178	167	845	169
Falls	13	15	15	27	24	94	18.8
Deaths	3	3	4	2	4	16	3.2
Other safety-related accidents	3	8	3	6	6	26	5.2
Total	1,236	1,285	1,229	1,279	1,337	6,366	1,273.2

Table 3. Rates of endoscopic procedures according to hospital classification based on 2017 claims data

Medical institutions	Diagnostic EGD			Therapeutic EGD			Diagnostic colonoscopy			Therapeutic colonoscopy		
	No. of endoscopic procedures	Bleeding ^a	Perforation ^a	No. of endoscopic procedures	Bleeding ^a	Perforation ^a	No. of endoscopic procedures	Bleeding ^a	Perforation ^a	No. of endoscopic procedures	Bleeding ^a	Perforation ^a
Clinics	1,064,738	0.170	0.034	5,104	4.898	0.588	635,164	1.294	0	398,581	2.579	0.038
Hospitals	276,591	0.662	0.051	1,840	22.283	6.522	253,392	0.884	0.036	135,395	4.010	0.074
General hospitals	628,347	3.983	0.331	15,179	41.636	8.696	344,106	2.624	0.087	163,243	4.080	0.239
Tertiary hospitals	444,968	5.715	0.649	20,440	31.556	5.577	175,928	4.746	2.296	65,145	7.307	0.553
Outpatient	2,077,760	0.275	0.033	8,283	2.294	0.483	1,278,621	1.074	0.018	647,949	1.463	0.022
Inpatient	336,884	14.367	1.419	34,280	38.623	7.497	129,960	10.856	0.523	114,415	15.426	0.752
Total	2,414,644	2.241	0.227	42,563	31.553	6.132	1,408,509	1.976	0.065	762,364	3.559	0.131

EGD = esophagogastroduodenoscopy.

^aRate per 1,000 cases.

Performance status of endoscopic procedures based on 2017 HIRA claims data

Excluding duplicate claims and cases of endoscopy for health screening, the numbers of EGD and colonoscopy procedures performed were 2,457,207 and 2,170,954, respectively. Diagnostic EGD was performed most often in clinics (44.1%), while therapeutic EGD (EMR or ESD) was performed most often in tertiary hospitals (48.0%). Diagnostic colonoscopy was also performed most often in clinics (45.1%), while therapeutic colonoscopy (polypectomy or EMR) was performed most often in clinics (52.3%), and only 8.5% of these procedures were performed in tertiary hospitals (Table 3).

When divided into age groups, diagnostic EGD was performed most often in patients aged 50–59 years, while therapeutic EGD was performed most often in patients aged 60–69 years. Both diagnostic and therapeutic colonoscopy procedures were performed most often in patients aged 50–59 years. Diagnostic EGD was performed mostly on an outpatient basis (86.0%), while therapeutic EGD was performed mostly on an inpatient basis upon diagnosis (80.5%). Both diagnostic and therapeutic colonoscopy procedures were performed primarily on an outpatient basis (90.8% and 85.0%, respectively) (Table 4).

Incidence of endoscopy-related complications based on 2017 HIRA claims data

The incidences of bleeding/perforation after therapeutic EGD occurring in clinics, community hospitals, general hospitals, and tertiary hospitals were 0.490%/0.059%, 2.228%/0.652%, 4.164%/0.870%, and 3.156%/0.558%. Both bleeding and perforation

Table 4. Number of endoscopic procedures according to age and type of care based on 2017 claims data

Age	EGD		Colonoscopy	
	Diagnostic	Therapeutic	Diagnostic	Therapeutic
< 20	35,241	56	7,977	404
20–29	210,642	586	50,897	6,340
30–39	421,498	1,790	143,979	42,520
40–49	309,269	3,765	275,429	120,120
50–59	508,122	9,782	429,003	240,814
60–69	481,340	13,734	331,425	224,888
70–79	343,702	10,599	147,844	111,315
> 80	104,830	2,251	22,036	15,963
Outpatient	2,077,760	8,283	1,278,621	647,949
Inpatient	336,884	34,280	129,969	114,415
Total	2,414,644	42,563	1,408,590	762,364

EGD = esophagogastroduodenoscopy.

associated with therapeutic EGD showed the highest incidence rates in general hospitals. The incidences of bleeding/perforation after diagnostic colonoscopy occurring in clinics, community hospitals, general hospitals, and tertiary hospitals were 0.129%/0.000%, 0.088%/0.004%, 0.262%/0.009%, and 0.479%/0.030%. Both bleeding and perforation associated with diagnostic colonoscopy showed the highest incidence rates in tertiary hospitals. The incidences of bleeding/perforation after therapeutic colonoscopy occurring in clinics, community hospitals, general hospitals, and tertiary hospitals were 0.258%/0.004%, 0.401%/0.007%, 0.408%/0.024%, and 0.731%/0.055%. Unlike therapeutic EGD, the incidences of bleeding and perforation associated with therapeutic colonoscopy were highest in tertiary hospitals (Table 3).

DISCUSSION

Safety is one of the most important issues in quality management of endoscopy. However, the status of complications related to endoscopy is not well known. This is the first study in Korea to simultaneously analyze population-based data through insurance claims accounting for about 98% of the population and real-world data from 50 institutions certified by KSGE for high-quality endoscopic practices. The HIRA claims data were intended to be used to analyze the overall incidence of complications that occurred over a certain period for all volumes of hospitals in Korea and to analyze the incidence of complications according to the volume of the hospitals. The 50-hospital survey data were collected by tertiary or general hospitals that had performed certain procedures, such as gastric or colonic ESD, and had been certified by the Accredited Endoscopy Unit Program reviewed by KSGE for high-quality endoscopy practices.

Bleeding is a complication that occurs rarely in diagnostic EGD and is primarily associated with mechanical irritation generated by the tip of the endoscope during passage. The incidence of bleeding is approximately 0.15%.¹⁵ The risk for bleeding is higher in patients who have previously undergone gastrectomy and after multiple cold biopsies (8–15 biopsies) of the anastomotic site in Billroth I and Billroth II patients.¹⁶ A Mallory-Weiss tear may also occur due to excessive belching or retching during EGD.¹⁷ The incidences of bleeding associated with therapeutic EGD are 4% after EMR and 4.5% after ESD.¹⁸ In this study, the incidences of bleeding associated with diagnostic and therapeutic EGD were 0.224% and 3.155% in the 2017 HIRA claims data, and 0.012% and 1.857% in the 50 hospitals surveyed, respectively. Diagnostic and therapeutic EGD procedures were performed most frequently in clinics and tertiary hospitals, and the rates of bleeding associated with both procedures were relatively low compared to previous studies. The complications associated with EGD tended to increase as the hospital volume increased, probably due to the larger number of high-risk patients or higher rate of difficult procedures in general or tertiary hospitals.

Bleeding after polypectomy is one of the most common complications associated with colonoscopy. A recent meta-analysis showed that the incidence of bleeding in diagnostic colonoscopy without polypectomy was 0.06%, with rates of 0.98% after polypectomy,¹⁹ 0.82% for immediate bleeding after colorectal ESD, and 1.7% for delayed bleeding.¹⁹ Another meta-analysis of the risk factors for bleeding associated with polypectomy showed that factors such as old age, high blood pressure, cardiovascular disease, right colon position, and polyp size > 1 cm were significantly associated with the occurrence of bleeding after polypectomy.²⁰ In this study, the incidences of bleeding associated with diagnostic and therapeutic colonoscopy

were 0.198% and 0.356% in the 2017 HIRA claims data, and 0.024% and 0.717% in the 50 hospitals surveyed, respectively. Both diagnostic and therapeutic colonoscopy procedures were most frequently performed in clinics. Similar to EGD-related bleeding, the diagnostic and therapeutic bleeding rates related to colonoscopy were relatively low compared to previous studies and tended to increase as the hospital volume increased, which was also probably due to the larger numbers of high-risk patients, such as those taking anticoagulant or antiplatelet drugs and with comorbidities, and the higher rate of difficult procedures, such as polypectomy for difficult location and large polyps, in general or tertiary hospitals.

Perforation during diagnostic EGD is extremely rare. A large prospective study reported that the incidence of perforation in diagnostic EGD was 0.05% and the associated mortality rate was 0.008%.²¹ The risk for perforation during diagnostic EGD was reported to be associated with Zenker's diverticulum, esophageal stenosis, malignant tumors, duodenal diverticulitis, and the experience level of the endoscopist.^{21,22} Esophageal perforation can also occur during therapeutic procedures, such as balloon dilation with esophageal stenosis or achalasia and removal of sharp foreign bodies.²² In a meta-analysis, the incidences of esophageal perforation were 1.3% and 4.0% for EMR and ESD, respectively,²³ and those for stomach perforation were 1.2% and 3.2%.²³ In this study, the incidence rates of perforation associated with diagnostic and therapeutic EGD were 0.023% and 0.613% in the 2017 HIRA claims data, and 0.001% and 0.325% in the 50 hospitals surveyed. The incidences of diagnostic and therapeutic perforation associated with EGD were relatively low compared to previous studies, and the incidence of perforation in therapeutic EGD was lower in tertiary hospitals than in general hospitals.

The incidence of perforation associated with diagnostic colonoscopy was reported to be 0.05% with a mortality rate of 0.0029%, and that of perforation after colorectal polypectomy was 0.08% in a previous meta-analysis.¹⁹ The incidences of perforation related to colorectal ESD were reported to be 4.2% for immediate perforation and 0.22% for delayed perforation.²⁴ During therapeutic colonoscopy, polyp location in the right colon or cecum, lateral spreading or nonpolypoid morphology, non-lifting polyp after submucosal injection due to submucosal fibrosis or deep layer involvement, polyps > 1 cm in size, and multiple polyps are risk factors for perforation.²⁵⁻²⁸ Diagnostic colonoscopy-associated perforations are relatively large and have a greater likelihood of requiring surgery than therapeutic colonoscopy-associated perforations.²⁹ In this study, the incidences of perforation associated with diagnostic and therapeutic colonoscopy were 0.007% and 0.013% in the 2017 HIRA claims data, and 0.017% and 0.206% in the 50 hospitals surveyed, respectively. The incidences of diagnostic and therapeutic perforation associated with colonoscopy were also relatively low compared to previous studies and increased as the hospital volume increased, probably because most cases where perforation occurred in the clinic were transferred to tertiary hospitals for endoscopic management or surgery, and therefore the number of perforations in tertiary hospitals might be overestimated in analyses of HIRA data. The complication rates were higher in hospital survey data than HIRA claim data. This was because the hospital survey data were collected by general or tertiary hospitals that performed more in the way of high-level or high-risk procedures, hospital survey data included complications related to colorectal ESD, and a significant number of procedures might have been performed by GI fellows undergoing training. Also, because the occurrence of complications must be recorded to be certified by the Accredited Endoscopy Unit Program, it was likely that the hospital survey data reflected the occurrence of complications more accurately than the HIRA claim data.

This study had some limitations. We could not completely exclude cases who underwent therapeutic endoscopy due to bleeding rather than as an endoscopy-related complication due to limitations of use of claim data.

It might be impossible to define perforation accurately as a claim code because the clinical course of perforation differs among individuals, from conservative healing to endoscopic treatment to surgery, and coding for complications differs depending on the endoscopist or hospital. The amount of data was very large; therefore, we could not accurately evaluate the causal relationships, because we could not analyze the individual circumstances of each case. In the case of 2017 HIRA claims data, there were limitations with regard to the possible occurrence of complication code entry errors and unclaimed items after a complication had occurred. In the case of survey data, there were limitations with regard to the possible occurrence of missing records or varying definitions of a complication between institutions. Moreover, the investigation and recording of endoscopy-related complications may have been avoided in many cases because of the fear of legal issues arising with the reporting of complications. Thus, many cases of endoscopy-related complications may have been missing from the records.

Analyzing the results of this study, the largest numbers of diagnostic and therapeutic endoscopy procedures were performed in clinics, and the rate of complications was almost negligible. These results may be mistakenly taken to indicate the high degree of safety of endoscopy in clinics. The statistics in this study were not interpreted as absolute numbers because large numbers of complications in clinics were counted as occurring in general or tertiary hospitals because the patients were transferred to these hospitals for treatment and claims were made there. In addition, most procedures performed in clinics were simple, while tertiary hospitals had higher rates of more technically difficult procedures, which could lead to higher rates of complications. These factors may diminish the reliability of statistical analyses, and we cannot exclude the possible occurrence of large statistical errors in this study.

However, despite these limitations, the present study makes a significant contribution, as it is one of very few large-scale studies in Korea to investigate the incidence of endoscopy-related complications using data from HIRA claims and surveys over 5 years in 50 hospitals. Future research should consider various factors, such as diagnostic and therapeutic endoscopy indications, comorbidities, antithrombotic drug use, and experience of endoscopists related to complications according to the type of endoscopic procedure.

In conclusion, the incidences of diagnostic and therapeutic complications associated with EGD or colonoscopy tended to increase with the hospital volume in Korea. To obtain more reliable statistics, a system is needed to effectively report and manage complications at all types of hospital, from clinics to tertiary hospitals, in Korea.

Key message: 1) Diagnostic EGD was performed most often in clinics, while therapeutic EGD (EMR or ESD) was performed most often in tertiary hospitals in Korea. 2) Diagnostic colonoscopy and therapeutic colonoscopy (polypectomy, EMR, or ESD) were performed most often in clinics. 3) The incidences of complications associated with diagnostic and therapeutic EGD, or colonoscopy tended to increase with the hospital volume.

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