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Upper gastrointestinal endoscopy procedure volume trends, perioperative mortality, and malpractice claims: Population-based analysis

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Authors
Nelli Nurminen[1], Tommi Järvinen[1], Eric Robinson[2], Nanruoyi Zhou[3], Silja Salo[4], Jari Räsänen[1], Ville Kytö[5,6,7], Ilkka Ilonen[1]

Institutions
1 Department of General Thoracic and Esophageal surgery, Heart and Lung Center, HUS Helsingin yliopistollisen sairaala, Helsinki, Finland
2 Department of Thoracic Surgery, Icahn School of Medicine at Mount Sinai, New York, United States
3 Department of Surgery, NewYork-Presbyterian Weill Cornell Medical Center, New York, United States
4 Department of Gastrointestinal Surgery, Abdominal Center, Helsinki University Central Hospital, Helsinki, Finland
5 Heart Center, TYKS Turku University Hospital, Turku, Finland
6 Clinical Research Center, TYKS Turku University Hospital, Turku, Finland
7 Research Center of Applied and Preventive Cardiovascular Medicine, University of Turku, Turku, Finland

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70469 Stuttgart, Germany

Corresponding author
Ilkka Ilonen, HUS Helsingin yliopistollisen sairaala, Department of General Thoracic and Esophageal surgery, Heart and Lung Center, Helsinki, Finland
ilkka.ilonen@hus.fi

ABSTRACT

Background and study aims Upper gastrointestinal endoscopy (EGD) is one of the most common diagnostic procedures done to examine the foregut, but it can also be used for therapeutic interventions. The main objectives of this study were to investigate trends in EGD utilization and mortality related to it in a national low-threshold healthcare system, assess perioperative safety, and identify and describe patient-reported malpractice claims from the national database.

Patients and methods We retrospectively identified patients from the Finnish Patient Care Registry who underwent diagnostic or procedural EGD between 2010 and 2018. In addition, patient-reported claims for malpractice were analyzed from the National Patient Insurance Center (PIC) database. Patient survival data were gathered collectively from the National Death Registry from Statistics Finland.

Results During the study period, 409,153 EGDs were performed in Finland for 298,082 patients, with an annual rate of 9.30 procedures per 1,000 inhabitants, with an annual increase of 2.6%. Thirty-day all-cause mortality was 1.70% and 90-day mortality was 3.84%. For every 1,000 patients treated, 0.23 malpractice claims were filed.

Conclusions The annual rate of EGD increased by 2.6% during the study, while the rate of interventional procedures remained constant. Also, while the 30-day mortality rate declined over the study period, it is an unsuitable quality metric for EGDs in comprehensive centers because a patient's underlying disease plays a larger role than the procedure in perioperative mortality. Finally, there were few malpractice claims, with self-evident causes prevailing.

Introduction

Upper gastrointestinal endoscopy (EGD) with a flexible endoscope is a low-risk diagnostic and therapeutic tool used by a wide range of medical professionals worldwide, including gastroenterologists and surgeons [1, 2, 3, 4, 5, 6, 7].

Although generally considered a low-risk procedure, complications do occur. Cardiopulmonary complications, such as sinus tachycardia and hypoxemia, related to anesthesia (i. e., moderate to heavy sedation) are among the most common adverse events (AEs) [5, 7, 8, 9]. In cases without sedation or low sedation, topical anesthetics are used but are known to bear a small risk of methemoglobinemia [10]. Other complications include bleeding and esophageal perforation, which occurs in only 0.03% of diagnostic EGDs [11]. More invasive procedures, such as esophageal stricture dilatation, endoscopic mucosal resection, endoscopic submucosal dissection, or esophageal stenting, are associated with a greater risk of esophageal perforation [12, 13, 14, 15, 16, 17, 18, 19, 20]. Gastric and duodenal perforations are also possible [21]. EGD is also utilized to place a gastrostomy tube percutaneously (PEG), complications of which include wound infection, bleeding, colon perforation, and tube dislodgement [22, 23]. Aspiration of gastric contents and concomitant pneumonia are other possible complications of EGD, more often in patients with delayed esophageal or gastric emptying or bleeding after EGD [9]. Endogenic and exogenic infections related to EGD have also been described in the literature [24, 25, 26, 27, 28]. Missed pathology is another known possible AE of EGD [29, 30].

Patient- and procedure-related risk factors have been identified and described previously, including comorbidities, American Society of Anesthesiologists (ASA) physical status classification, prolonged procedure, and difficulty intubating the esophagus. Maintaining and monitoring a comprehensive patient-reported malpractice and AE database is one strategy to maintain and improve patient safety during endoscopic procedures. Malpractice claims also offer a source to study complications. However, it is important to recognize that complications are not synonymous with malpractice, which involves negligence, and a certain level of complications is inevitably related to all procedures [31].

There are no comprehensive national-level reports of EGD published, especially concerning patient safety. While prospective national endoscopic databases exist, reports from them are sparse [32]. This study aimed to develop an understanding of the extent of EGDs done at the national level, analyze interventional EGD activity, estimate the perioperative mortality rate, and identify the frequency of malpractice claims after EGDs.

Patients and methods

We identified all malpractice claims for EGDs from the Finnish Patient Injury Center (PIC) registry from January 1, 2010, to December 31, 2020. Only patients aged > 18 years were included. The population of Finland in 2010 was 5.363 million inhabitants, and in 2018, 5.515 million, with a 2.8% increase during the study period. The Nordic Medico-Statistical Committees (NOMESCO) Classification of Surgical Procedures is used nationally as a single classification system. For this patient cohort, EGD cases were identified using NOMESCO codes, as outlined in ▶ **Table 1**.

Finland has a non-fault patient insurance system with a low threshold to file a claim without legal consultation. PIC is a national institution that obtains claims filed from both public and private healthcare, deems if an injury is compensable, and pays the compensation. Companies that engage in patient insurance in Finland constitute and finance PIC. According to the Patient Insurance Act (948/2019), all care providers must have patient insurance. PIC has a national database of filed patient injury claims, with related patient records and the outcome of each claim. The PIC claim process involves expert medical professionals who evaluate the claims and their compensability. The criteria for compensation have been described in more detail in previous studies [33, 34, 35]. All postoperative AEs reported in the claims were collected and classified by Clavien-Dindo Classification. The Comprehensive Complication Index was also calculated for each patient who filed a claim [36, 37].

To estimate the volume of upper endoscopies at a national level, population-based cohort data for all EGDs performed in adults were obtained from the Care Register of the Finnish Institute for Health and Welfare using the previously mentioned NOMESCO codes for the time January 1, 2010 to December 31, 2018. All hospitals in Finland must report the care they provided to the register [38]. The Care Register has a positive predictive value of 75% to 99% for common diagnoses [39]. Charlson Comorbidity Index (CCI) scores were calculated for each patient at the time of their first (index) EGD procedure [40, 41]. Mortality data were obtained from Statistics Finland. Endpoints included 30- and 90-day mortality.

Claims for endoscopic retrograde cholangiopancreatography (ERCP) procedures were excluded because the range of AEs associated with them are unique among other EGD procedures (i. e. hepatobiliary).

Statistical analyses were done by SPSS Statistics version 27.0.1.0 (IBM Corp, Armonk, New York, United States) and SAS version 9.4 (SAS Institute, Cary, North Carolina, United States). The chi-square test was used to compare results with categorical variables and the Mann-Whitney U-test was used to compare results between non-parametric continuous variables. A two-tailed $P < 0.05$ was considered statistically significant.

Approval for this study was obtained from and granted by PIC, Social and Health Data Permit authority (Findata) (permission no: THL/164/14.02.00/2021), Statistics Finland (permission no: TK-53–484–20). Because this was a retrospective registry study, no approval from the ethics committee was required.

Results

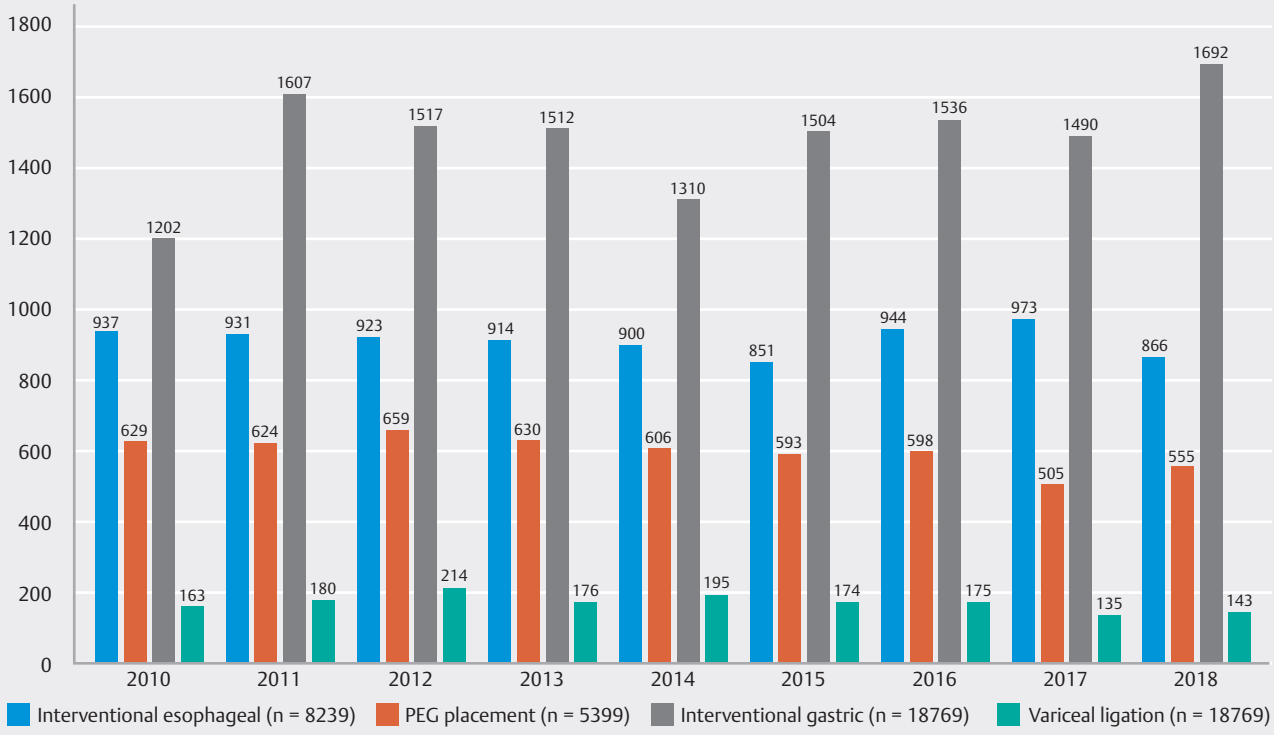
During the study period, 409,153 diagnostic and interventional EGDs were performed in Finland for 298,082 patients. Of the patients, 53.23% (n = 22,361) were women. The mean age of the patients was 61.2 ± 16.6 years. Procedures were most commonly done in non-academic hospitals (n = 156,522, 37.3%),

▶ **Table 1** Nordic Medico-Statistical Committees (NOMESCO) Classification of Surgical Procedure codes used in identifying claims related to upper gastrointestinal endoscopies in 2010–2020 in Finland.

Diagnostic procedure	
UJD10	Esophagoscopy, gastroscopy and duodenoscopy
UJC02	Rigid esophagoscopy
UJC12	Flexible esophagoscopy
UJD02	Gastroscopy
Interventional esophageal	
JCA08	Endoscopic removal of foreign body from esophagus
JCA42	Other endoscopic procedure for hemostasis; esophagus
JCA45	Endoscopic mucosal or submucosal resection in esophagus
JCA52	Other endoscopic procedure using diathermy or heat in esophagus
JCA55	Endoscopic dilatation of esophagus
JCA98	Other local endoscopic operation on esophagus
JCF12	Endoscopic insertion of prosthetic tube into esphagus
Percutaneus gastrostomy	
JDB10	Percutaneous gastrostomy
Interventional gastric	
JDA05	Endoscopic polypectomy in stomach or pylorus
JDA08	Endoscopic removal of foreign body from stomach or pylorus
JDA12	Endoscopic insertion of gastric stent
JDA22	Endoscopic ligature of varices of stomach
JDA32	Endoscopic injection in stomach or pylorus
JDA35	Endoscopic contact coagulation in stomach or pylorus
JDA38	Endoscopic laser therapy in stomach or pylorus
JDA42	Other endoscopic hemostatic procedure in stomach or pylorus
JDA45	Endoscopic mucosal or submucosal resection in stomach or pylorus
JDA52	Other endoscopic procedure using diathermy or heat in stomach or pylorus
JDA55	Endoscopic dilatation of stomach, pylorus or anastomosis of stomach
JDW98	Other transluminal endoscopic operation on stomach or duodenum
Variceal ligation	
JCA20	Ligature of esophageal varices
JCA22	Endoscopic ligature of esophageal varices
JCA32	Endoscopic injection in esophagus for varices
JCA35	Endoscopic contact coagulation in esophagus
JCA38	Endoscopic laser therapy in esophagus for varices

followed by academic hospitals (n = 138,991, 33.1%), and finally primary care settings (n = 124,527, 29.7%). In addition to the primary procedure, an additional procedure was done at the time of the index procedure in 10,932 cases (2.6%). PIC claims were made at a rate of 0.23 per 1000 patients who underwent EGD.

We divided the patients into five subgroups based on the NOMESCO coding: 1) diagnostic; 2) interventional esophageal; 3) PEG placement; 4) interventional gastric; and 5) variceal ligation (▶ **Table 1**). During the study period, 380,590 diagnostic, 8239 interventional esophageal procedures, 5399 PEG placements, 13,370 interventional gastric procedures, and 1555 var-



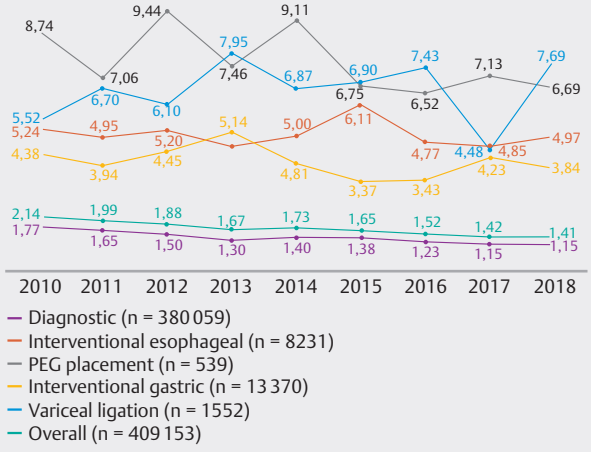
▶ **Fig. 1** Annual case trends of interventional upper gastrointestinal endoscopies between 2010 and 2018, divided by the type of intervention. PEG, percutaneous endoscopic gastrostomy.

iceal ligations were performed. These were done in 287,036 patients for diagnosis, 4878 for interventional esophageal procedures, 4706 for PEG placement, 8076 for interventional gastric procedures, and 1088 for variceal ligations. The annual rate of interventional EGD cases is presented in ▶ **Fig. 1**.

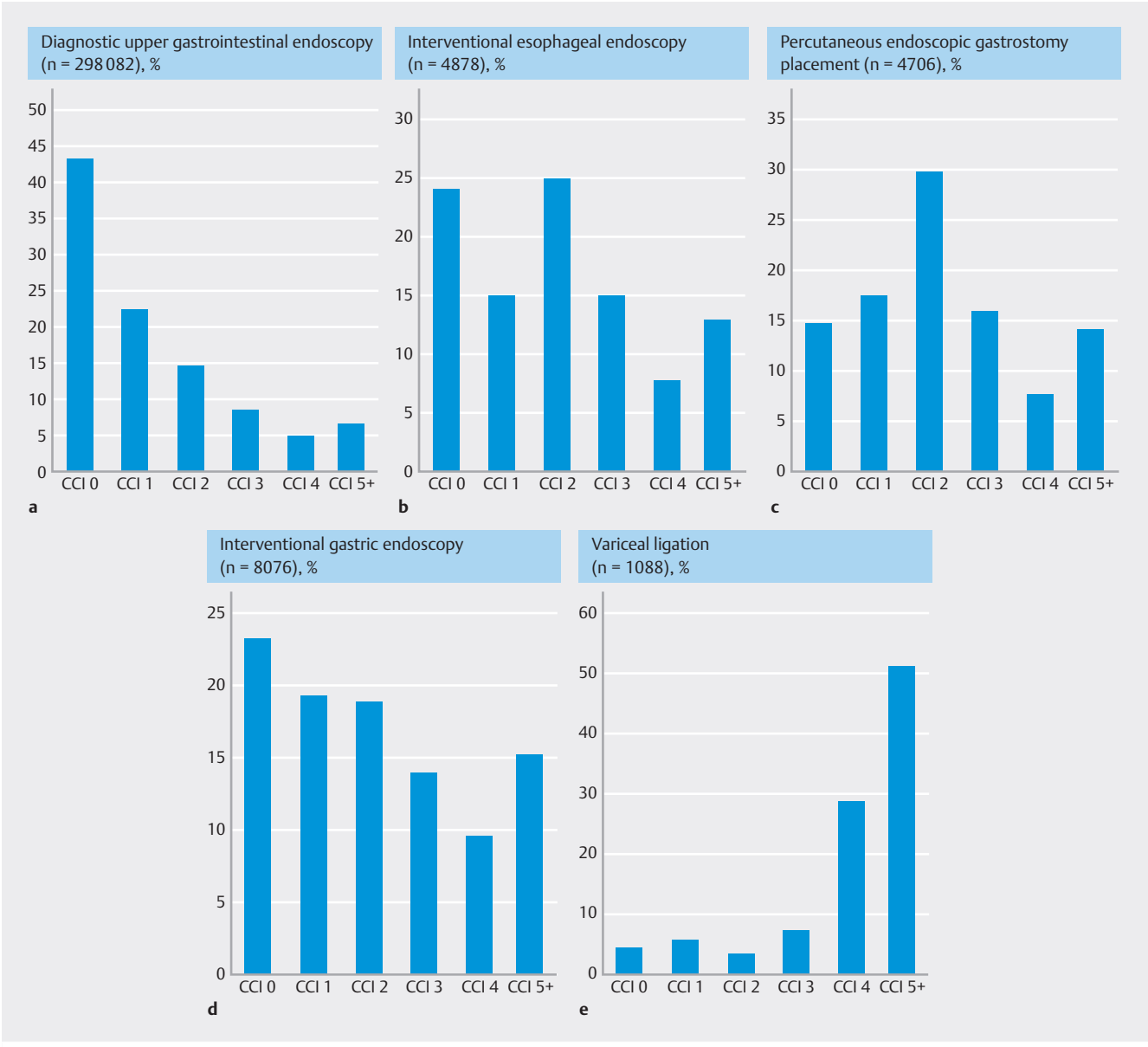
The annual rate of EGDs increased during our study period from 42,108 cases in 2010 to 51,341 cases in 2018 due to an average yearly growth rate of 2.6% among diagnostic endoscopies over the study period, exceeding the overall population growth of 0.354%. Some patients (n = 122,003, 29.0%) underwent multiple EGDs. The distribution of CCI scores for the index operation varied significantly within patient subgroups, and is presented in ▶ **Fig. 2a**, ▶ **Fig. 2b**, ▶ **Fig. 2c**, ▶ **Fig. 2d**, and ▶ **Fig. 2e** by procedure groups.

The rate of overall 30-day mortality was 1.70% (n = 7133) and of 90-day mortality was 3.84% (n = 16.106). Both the 30- and 90-day mortality rates decreased over the study period from 2010 to 2018, with 30-day mortality decreasing from 2.14% (n = 900) to 1.41% (n = 721) and 90-day mortality decreasing from 4.76% (n = 2003) to 3.34% (n = 1714) over the study period. Annual mortality rates divided into subgroups are presented in ▶ **Fig. 3**. A total of 611 patients (0.002%) were lost to follow-up and excluded from the analysis. Thirty- and 90-day mortality was calculated from the time of each endoscopic event in cases of individuals with multiple procedures.

The underlying cause of death for patients who died within 30 days was malignancy in 44.95% (n = 3198), benign gastrointestinal in 21.55% (n = 1533), and cardiovascular in 20.36% (n = 1448). In only two patients (0.03%), the underlying cause of death was due to perforation during an endoscopic procedure. When reviewing all reported ICD-10 codes in the cause of death registry (including underlying, immediate, contributing, and intermediate cause of death), a total of 287 reports for ICD-10



▶ **Fig. 2** Distribution of Charleson Comorbidity Index in percentages within the patient group, divided by the type of procedure. **a** Diagnostic upper gastrointestinal endoscopy. **b** Interventional esophageal endoscopy. **c** Percutaneous endoscopic gastrostomy placement. **d** Interventional gastric endoscopy. **e** Variceal ligation.



▶ **Fig. 3** Annual trends for 30-day mortality in upper gastrointestinal endoscopies between 2010 to 2018, categorized by procedure type. PEG, percutaneous endoscopic gastrostomy.

codes related to procedure complications were documented in a total of 16,225 reports for 7133 patients).

Patient injury claims

A total of 86 PIC claims were identified in the database. Two cases were excluded: one in which the claim concerned a procedure done in 2006 and one in which the claim involved a fundoplication rather than an EGD.

The median age of the claimants at the time of the procedure was 64.1 years (interquartile range [IQR] 19, min-max 30–92). Of the claimants, 62.2% (n = 51) were women. Of the EGDs performed leading to these claims, 56.1% (n = 46) were performed in non-academic hospitals, 26.8% (n = 22) in academic hospitals, and 17.1% (n = 14) by other institutions such as primary healthcare or private sector units. Patient and procedure characteristics are listed in ▶ **Table 2**.

Of these claims, 53.7% (n = 44) involved diagnostic EGD, 19.5% (n = 16) esophageal dilatations, 11.0% (n = 9) PEG placement, 3.7% (n = 3) esophageal stent insertions, and 2.4% (n = 2) foreign body removals. Of the endoscopies, 42.7% (n = 35) were performed under sedation or general anesthesia.

We categorized the claims according to the injury reported in the claim in ▶ **Table 3**. If the claim included several complications, we picked the root complication or the one that was the most severe. The most common complications were perforation (36.9%, n = 31), dental injury (14.3%, n = 12), and bleeding (10.7%, n = 9). Of the perforations, most (n = 25) were esophageal, five were duodenal, and two were gastric perforations.

▶ **Table 2** Patient and procedure characteristics from claims related to upper gastrointestinal endoscopies 2010–2020 in Finland.

	Diagnostic N = 44 Median [IQR] or n (%)		**Interventional N = 38 Median [IQR] or n (%)**		***P* value**
Age	67.0	[18]	62.5	[20]	0.494
Sex					0.280
Male	19	(43.2)	12	(31.6)	
Female	25	(56.8)	26	(68.4)	
Charlson Comorbidity Index					0.383
0	24	(54.5)	18	(47.4)	
1	11	(25.0)	6	(15.8)	
2	5	(11.4)	7	(18.4)	
≤ 3	4	(9.1)	7	(18.4)	
Hospital					0.001
Non-academic	22	(50.0)	24	(63.2)	
Academic	8	(18.2)	14	(36.8)	
Other	14	(31.8)	0	(0.0)	
Procedure sedation	4	(9.1)	31	(81.6)	0.001

IQR, interquartile range.

▶ **Table 3** Adverse events from claims related to upper gastrointestinal endoscopies 2010–2020 in Finland.

	Diagnostic n = 44 Median [IQR] or % (n)		**Interventional n = 42 Median [IQR] or % (n)**		***P* value**
Adverse events					
Perforation	16.7	(7)	57.1	(24)	0.001
Dental	23.8	(10)	4.8	(2)	0.026
Bleeding	11.9	(5)	9.5	(4)	1.00
Neurologic	9.5	(4)	0	(0)	0.116
Infection	0	(0)	4.8	(2)	0.494
Delay in diagnosis	7.1	(3)	0	(0)	0.241
Pancreatitis	2.4	(1)	2.4	(1)	1.00
Missed diagnosis	2.4	(1)	0	(0)	1.00
Cardiopulmonary	0	(0)	2.4	(1)	1.00
Other	14.3	(6)	9.5	(4)	0.738
No	11.9	(5)	9.5	(4)	1.00
Comprehensive complication Index	20.9	[20.1]	33.7	[23.1]	0.001

IQR, interquartile range.

Of the claims concerning PEG insertion, complications included: two PEG site infections, two cases of migration of the internal bumper to the subcutis, one case of intraperitoneal placement of the tube, one case of bleeding, one case of transhepatic placement of the feeding tube, one case of peritonitis, one case of esophageal perforation, and one complication related to procedure sedation.

Three claims (6.1%) involved patient death, two of which were related to diagnostic delay and one death occurred because of severe pancreatitis after duodenal biopsies. One death was unrelated to EGD, during which no AEs occurred. Of the claims, 14.3% (n = 12) did not include any medical complications that could be classified, but the patients were unsatisfied with how they were treated (10.7%, n = 9) or there was a delay in the diagnosis (3.5%, n = 3). Of the claims, 7.3% (n = 6) included a complication with symptoms lasting over 6 months.

The highest Clavien-Dindo scores for these claims was I for 18.3% (n = 15), II for 18.3% (n = 15), IIIa for 7.3% (n = 6), IIIb for 19.5% (n = 16), IVa for 22.0% (n = 18), IVb 1.2% (n = 1), and V for 1.2% (n = 1) of the claims. Several complications were observed in 25.6% (n = 21). Because of the AEs, 24.4% (n = 20) of the patients needed treatment in the intensive care unit. The median Comprehensive Complication Index was 26.2 (IQR 33.7, min-max 0–100). Of all claims, 25.6% (n = 21) resulted in compensation. Compensation was more likely if the EGD was diagnostic than if it included a procedure (29.5%, n = 13 and 21.1% n = 8 respectively), but the difference was not statistically significant ($P = 0.452$).

Discussion

Our study was a comprehensive national review of malpractice claims concerning EGD, which showed that claims remain rare compared with the volume of EGD activity and seldom lead to compensation. From 2010 to 2020, only 82 eligible patient injury claims were made to PIC. Only 71 of these concerned identifiable complications or malpractice, with 35 cases involving diagnostic EGD and 36 cases involving interventional EGD. Over an 8-year study period (2010–2018), 409,153 EGDs were done for both diagnostic and interventional purposes in 298,082 patients. We showed that diagnostic studies are done at a 10-fold higher rate compared with interventional studies

The overall perioperative mortality rate for the unselected study group was 1.7%, which is comparable to the mortality rate of 1.89% reported in a large Swiss tertiary hospital series by Chatelanat et al. [42] We believe that our results are comparable to those of Chatelanat et al., given the similarities in the Swiss and Finnish healthcare systems, namely that both countries offer low-threshold comprehensive regional healthcare access. In this non-selected population, the pathologies for which EGD was performed have independent morbidity and mortality that do not necessarily correlate with the actual procedure performed. As discussed by Chatelanat et al., perioperative mortality in EGD often reflects oncological progression. In more specific settings, EGD bleeding is associated with up to 10% inpatient mortality, even in large prospective series. Our observation was that of the patients who died within 30 days after the procedure, only two had intestinal perforation as the underlying cause of death. While there were significantly more reports of contributing or intermediate causes of death that may relate to EGDs, the number remained low, and EGD was unrelated to the immediate cause of death. Our database, while comprehensive, is not designed to address specific quality concerns on a granular level of each procedure code, which warrants more comprehensive registry-based studies to be done.

While complications from EGD are well known and documented, the profile of these complications is changing due to more complex procedures being done via endoscopy on even more frail patients [43, 44, 45]. There is no recent series that documents the prevalence and types of patient-reported complications for patient injury claims for compensation. Our study demonstrated that compared with diagnostic EGDs, complications arising from interventional EGDs tended to occur at a higher rate in non-academic hospitals (63.2% at non-academic hospitals vs. 38.2% at academic hospitals). Furthermore, the most common complication in interventional EGDs, such as dilation, was perforation, compared with dental complications for diagnostic procedures. Albeit very rare, perforation is still a possible complication of diagnostic EGD and should not be overlooked in that setting. While there are relevant guidelines for managing and reporting iatrogenic endoscopic perforations, the implementation of these guidelines is highly dependent on the endoscopist and they are not currently systematically enforced [46]. Also, there are no prospective studies available, and thus, management is based on case series and case reports. The need for collaborative databases for EGD complication management is apparent but can be difficult to facilitate because the incidence is fairly low even in national centers of expertise.

The low rate of malpractice claims is in line with a recent population-based analysis from Canada, although it is notable that Finnish and Canadian systems to handle medical malpractice differ significantly because Canada uses the court system where the threshold to file a claim is supposedly higher [47]. In a study of Hiyama et al. from Japan, the number of malpractice claims concerning endoscopies has increased over time, which is contradictory to our results [48].

Compared with other endoscopies, EGD with PEG insertion accounted for 13.6% of US endoscopy-related malpractice cases between 1985 and 2008, as reported by Hernandez et al. [49]. In our study, we found that PEG insertion accounted for 11% of claims made, which is comparable to the rate found by Hernandez et al. National compensation policies for malpractice vary significantly. Our national compensation model (PIC) is based on insurance rather than direct negotiations and payments from the provider or hospital. In addition, Hernandez et al. did not consider the clinical scenario or severity of the complications of these procedures for malpractice settlements.

Understandably, patients undergoing endoscopic procedural EGD have a higher CCI score, reflecting the underlying cause of mortality for these procedures (▶ **Table 3**). Thirty-day mortality following EGD procedures remained stable throughout the study period (▶ **Fig. 3**). While the number of diagnostic EGDs increased during the study period, the proportion of procedure cases remained relatively unchanged. This is confirmed by the decreasing trend in overall 30-day mortality among patients, because more diagnostic EGDs were done that did not result in more interventional EGDs. During the study period, there was no active upper or lower intestinal cancer screening ongoing nationally.

Our study has several limitations. A distinction could not be made among emergent, urgent, or elective procedures based on the available data, which resulted in potential reporting bias. However, our results are similar to those of previous reports. Also, we lack data for endpoints that were not reported to the database, such as diagnostic accuracy, indication for the EGD, and possible complications that were not reported to PIC. However, our study endpoints, such as overall survival, repeat endoscopies, and patient-reported malpractice claims, are accurate. Third, endoscopic ultrasound and peroral endoscopic myotomy did not have distinctive NOMESCO codes across the study period, and the impact of these procedures on PIC claims remains unknown. Finally, our study did not account for patient frailty and diagnosis, both of which can have a significant impact on morbidity and mortality related to EGD. Also, we understand that while data from the operative registry encompass 8 years, the PIC claim follow-up time was 10 years. This is warranted, as there is a natural delay between an AE and a PIC claim. Finally, the use of operative sedation remains unknown, especially for diagnostic procedures, because it was not reported systematically in the database. While this is important to acknowledge, PIC reports did not indicate major issues associated with operative sedation during EGD.

Conclusions

Our study showed that diagnostic and operative EGDs were done at an annual rate of 9.30 EGD procedures per 1,000 inhabitants, with an annual increase of 2.6% per year mainly due to diagnostic EGDs. We also noted that 0.23 claims were reported per 1,000 patients who underwent EGD during the study period. Because the rates of procedure-related EGDs remained stable during the study period, the effect of increased diagnostic EGD and the associated low risk of the procedure is the likely explanation for the observation of decreased 30-day mortality over the study period. We noted that the perioperative cause of death was mainly underlying disease rather than the procedure itself, as confirmed by PIC claims and the cause-of-death registry. Thus, 30-day mortality is a poor surrogate for quality or safety in comprehensive centers. Based on this study, it is important to establish a prospective national registry to have deeper insight into national-level data for complications and more granular data for indications for EGDs.

Conflict of Interest

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