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Unplanned Hospital Encounters Following Endoscopic Retrograde Cholangiopancreatography in 3 Large American States

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Abstract

Background & Aims: We have few population-level data on the performance of endoscopic retrograde cholangiopancreatography (ERCP) in the United States. We investigated the numbers of unplanned hospital encounters (UHEs), patient and facility factors associated with UHEs, and variation in quality and outcomes in the performance of ERCP in 3 large American states.

Methods: We collected data on 68,642 ERCPs, performed at 635 facilities in California, Florida, and New York from 2009 through 2014. The primary endpoint was number of UHEs with an ERCP-related event within 7 days of ERCP; secondary endpoints included numbers of UHE within 30 days and mortality within 30 days. Each facility was assigned a risk-standardized cohort, and variations in numbers of UHE were analyzed using multivariable analysis.

Results: Among all ERCPs, 5.8% resulted in an UHE within 7 days, and 10.2% by 30 days. Performance of sphincterotomy was significantly associated with a higher risk of UHE at 7 and 30 days ($P < .001$). Younger age, female sex, and more advanced comorbidity associated with UHE. There was substantial heterogeneity in rates of UHE among facilities: 4.2% at facilities in the lower 5th percentile and 25.2% at facilities in the 95th percentile. Increasing facility volume and ability to perform endoscopic ultrasound associated inversely with risk. The median number of ERCPs performed each year was 68.7, but 69% of facilities performed 100 or fewer ERCPs per year. Risk for UHE following sphincterotomy decreased with increasing facility volume until an inflection point of 157 ERCPs per year was reached.

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Conclusions: In an analysis of outcomes of 68,642 ERCPs performed in three states, we found a higher than expected number of UHEs. There is substantial unexplained variation in risk for adverse event following ERCPs among facilities—volume is the strongest predictor of risk. Annual facility volumes above approximately 150 ERCPs per year may protect against UHE.

Keywords

complications; quality improvement; bile duct disease treatment

INTRODUCTION

Compared to other advanced industrial nations the United States (U.S.) has a decentralized healthcare system characterized by individual or small group practices delivering the majority of patient care in many communities. While decentralization has certain merits, it also makes the adoption of standards and quality initiatives difficult, non-uniform, and reliant on gradual diffusion. One area that has received increasing attention is the ongoing inability to concentrate high-risk procedures and operations in experienced centers, with potentially deleterious consequences for patients.^{1–5}

Endoscopic retrograde cholangiopancreatography (ERCP) is the main therapeutic modality for bile duct disease in modern practice, with an estimated 600,000 of these procedures performed in the U.S. annually.⁶ ERCP is a complex procedure associated with the potential for significant adverse events including pancreatitis, perforation, hemorrhage, and infection;⁷ despite these risks, ERCP is widely practiced in both tertiary-care as well as in smaller community settings. The quoted rates of adverse events following ERCP are derived mainly from academic centers, and reflect the outcomes of high-volume academic endoscopists practicing in well-equipped endoscopy units, supported by experienced nurses and technicians.^{8–11} As the vast majority of patients in the U.S. do not receive care at academic centers, these data may not accurately reflect the risk patients face when undergoing ERCP in community settings.

Previous studies have examined the association between volume and adverse events.^{12–16} While many European nations have published aggregated statistics on ERCP performance and outcomes,^{13, 17–23} such population-level studies are lacking for the U.S. Moreover, there are currently no guidelines from any of the major gastroenterological societies or accreditation bodies in the U.S. defining a minimum annual recommended volume in order to maintain optimum proficiency at ERCP.

For these reasons, there is a need for population-level data to comprehensively explore and analyze variability in quality of this complex endoscopic procedure. In this study, we aim to define the rate of significant adverse events following ERCP on a general American population, explore patient-level risk factors for adverse events following ERCP, and analyze the degree of and predictors for variability in outcomes at the facility-level across the diverse healthcare landscape of 3 large American states.

METHODS

Data Sources

This study was designed as a retrospective cohort study utilizing the state ambulatory surgery (SASD), inpatient (SID), and emergency department (SEDD) databases of the U.S. Healthcare Cost and Utilization Project (HCUP).²⁴ These databases are compiled from legally mandated encounter records provided by each licensed facility to state health departments. The states of California (CA), Florida (FL), and New York (NY) are the 3 largest states which provide longitudinal patient identifiers by which to track subsequent hospital encounters. The years 2009–2011 for CA, 2012–2014 for FL, and 2011–2013 for NY were chosen, as these were the 3 most recent years of available data at the time of this study.

ERCP Cohort

All elective ERCPs were identified from the SASDs of CA, FL, and NY for the years of the study based on Current Procedural Terminology (CPT®, American Medical Association, Chicago, IL, USA) codes. Both diagnostic and therapeutic ERCPs were included in the cohort (CPT® codes 43260–43265, 43267–43269, 43271, 43272, 43274–43278). Additional patient-level data at time of ERCP were extracted, including age, gender, primary insurance provider, and medical comorbidity using an enhancement²⁵ of the Charlson Comorbidity Index (CCI) score.²⁶ Specific comorbidities of interest were separately captured using a coding scheme based upon the CCI (Supplementary Table 1). A retrospective observation period of 6 months was used to assign comorbidity. To determine procedural indication, a classification scheme based upon International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes was employed (Supplementary Table 2).
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Procedural characteristics were recorded, including the performance of a sphincterotomy (CPT® 43262), insertion of a biliary stent (CPT® 43268, 43274 [year 2014]), exchange of biliary stent (CPT® 43269, 43275–43276 [year 2014]), and lithotripsy (CPT® 43265). For subsequent analysis, ERCPs were analyzed both in aggregate and stratified by performance of sphincterotomy. Sphincterotomy increases the risks of bleeding, pancreatitis and perforation, and is typically performed during therapeutic ERCPs. It may therefore serve as a surrogate for more technically challenging procedures with a higher degree of procedural risk.

Facility characteristics were recorded at time of ERCP. Annual procedural volume incorporated both inpatient and outpatient procedures performed at a facility. Location was classified as urban, suburban/smaller metro area, or rural based upon the classification system developed by the National Center for Health Statistics.²⁴ Facilities were classified as EUScapable facilities if they performed at least 5 endoscopic ultrasounds per annum during the time period of the study. The percentage of patients with Medicaid insurance or non-insurance, as well as the percentage of minority patients seen at each facility was calculated. Minority patients were defined as non-white patients or white patients who ethnically identify as Hispanics.²⁴

Facilities were classified into *a priori* strata based upon pre-determined cutoffs (<50, 50–99, 100–199, 200–299, 300), and crude rates as well as adjusted rates of UHE (adjusting for patient, procedural, and facility characteristics) were calculated. As a sensitivity analysis, facilities were classified by tertile, and crude rates as well as adjusted rates were calculated.

Supplemental analysis was performed to assess the impact of annual endoscopist ERCP volume. We captured the annual ERCP volume per endoscopist from the state of FL only (as of the 3 states studied, only FL provides unique physician identifiers by which volume can be determined). FL endoscopists were then categorized into *a priori* strata based upon predetermined volume cutoffs (<25, 25–49, 50–99, 100 ERCPs per annum), and crude rates as well as adjusted rates of UHE (adjusting for patient, procedural, and facility characteristics) were calculated.

Outcome Measures

A UHE is defined as an unplanned hospital admission or an emergency department visit, and has been used as a surrogate for adverse events following endoscopic procedures.²⁷ Planned admissions included admissions that were coded as scheduled or elective, or whose primary indication was for labor and delivery, maintenance radiation or chemotherapy, or rehabilitation services (Supplementary Table 3).²⁷ The main outcome measure was the rate of UHE with an adverse event related to ERCP within 7 days of ambulatory ERCP. Adverse events related to ERCP included pancreatitis, bleeding, perforation, infection, and cardiovascular events; these were recorded based upon ICD-9-CM coding (Supplementary Table 4). Secondary endpoints included the rate of UHE with an ERCP-attributable event within 15 days, within 22 days, and within 30 days; the 7 day timeframe was chosen as the primary endpoint as this would decrease capture of hospitalizations unrelated to ERCP.^{14, 27} Additional secondary endpoints analyzed in the study included rates of specific adverse events (pancreatitis, bleeding, perforation, infection, and cardiovascular events), as well as all-cause in-hospital mortality within 30 days.

Statistical Analysis

The mean and standard deviation (SD), or the number and percentage of each clinical, demographic, procedural, and facility characteristic were calculated for the cohort. Rates of UHE were calculated and stratified based upon sphincterotomy status. Patient-level, facility-level, and endoscopist-level (FL only) characteristics were analyzed as predictors of UHEs utilizing both univariate and multivariable logistic regression models.

To determine variability in rates of UHE by facility, each facility was assigned a risk-standardized cohort adjusting for case mix. A regression model which was controlled for demographic, clinical, and procedural characteristics incorporating every facility was created; each facility therefore is represented by a unique risk-adjusted coefficient in the logit function. These unique coefficients for each facility were then used to calculate the expected number of UHEs assuming a standardized risk cohort. The risk-standardized rate of UHE was then compared between facilities.

To further assess the relationship between volume and risk for UHE, the risk-standardized rate of UHE was plotted against annual ERCP volume, and a non-parametric local

regression (LOESS) curve was then fitted on the data with smoothing parameter chosen based upon the corrected Akaike Information Criteria. LOESS neither requires parametric modeling assumptions nor the *a priori* assignment of strata, and can offer insight into the relationship between volume and outcomes which traditional modeling may not capture. Discrete points at which the slope of the LOESS curve demonstrated a statistically significant change (“changepoints”) were identified utilizing a random walk Metropolis algorithm, a Markov chain Monte Carlo scheme. This methodology incorporates estimated variation at each point, and may be linear on the log of the response. The LOESS curves were then utilized to calculate an estimated reduction in number of ERCP-associated UHes if volume-based thresholds were adopted.

All models estimated the odds ratio (OR) and 95% confidence intervals (CI), with twosided *P* value <0.05 considered as statistically significant. Adjustments for multiple comparisons was performed using Bonferroni’s method. All analyses were conducted using SAS Enterprise Guide version 7.11 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Cohort Profile

A total of 68,642 ERCPs were captured from CA, FL, and NY. The demographic, clinical, and procedural characteristics of the cohort are depicted in Table 1. State representation in the study was approximately proportional to state population. The mean age was 62.3 years, and females represented 56% of the cohort. The most common indications for ERCP were gallstone disease (31.8%), followed by biliary stricture (23.7%), and known hepatopancreatobiliary malignancy (8.9%). Sphincterotomy was performed in 38.8%, biliary stent insertion in 22.6%, biliary stent exchange in 38.2%, and lithotripsy in 2.9% of ERCPs, respectively.

Facility Profile

Data from 635 facilities performing ERCP in CA, FL, and NY were captured (Table 2). The median number of annual ERCPs performed was 68.7, with the 25th percentile performing 32.3 and the 75th percentile performing 129 ERCPs per annum, respectively. The majority of facilities were located in either urban (45.7%) or suburban/smaller metro (42.4%) areas, with a minority located in rural areas (12.0%). Approximately a quarter of ERCP-performing facilities also offered EUS services. The median percentage of Medicaid or uninsured patients was 13.5%, and the median number of minority patients was 38.2%.

When classified into tertiles by annual volume, facilities in the lowest volume tertile were significantly more likely to be located in rural areas (16.4%) compared to facilities in the highest tertile (6.7%, *P*=0.01). Facilities in the lowest tertile were also much less likely to have EUS capability (4.2%) compared to facilities in the highest tertile (52.4%, *P*<0.001). There were no significant differences in the proportion of minority patients or marginally-insured patients between the tertiles.

Incidence of UHE, Specific Adverse Events, and Death within 30 days

The 7-day rate of UHE was 5.8% (CI 5.6–6.0%), and the 30-day rate of UHE was 10.2% (CI 11.7–12.3%, Table 3). The incidence of UHE was significantly higher in the cohort with sphincterotomy compared to the cohort without sphincterotomy ($P<0.001$). The majority of this increased risk following sphincterotomy occurs within 7 days ($P<0.001$), as there was no significant difference between rates of UHE at 8–15 days, 15–22 days, or 22–30 days (Table 3). The cohort with sphincterotomy demonstrated higher rates of pancreatitis ($P<0.001$), gastrointestinal bleeding ($P<0.001$), perforation ($P=0.002$), and cardiac or vascular event ($P<0.001$). There was no difference in risk of non-biliary infection ($P=0.9$) and rates of cholangitis or obstruction ($P=0.7$) between the two cohorts. There was no difference in 30-day mortality between the two cohorts ($P=0.9$).

Patient-Level Risk Factors for UHE

The association between demographic, clinical, and procedural covariates and the rate of UHE is depicted in Table 3. Older age (OR 0.89, CI 0.87–0.91 per 10 years) associated inversely with UHE, whereas female gender associated with UHE (OR 1.16, CI 1.09–1.22). Lack of insurance associated with UHE (OR 1.18, CI 1.06–1.32) in multivariable analysis. Advancing overall co-morbidity (Charlson score point OR=1.05, CI 1.04–1.06), serious cardiac disease (OR=1.33, CI 1.20–1.47), pulmonary disease (OR 1.17, CI 1.09–1.26), a diagnosis of malignancy (OR 1.31, CI 1.22–1.41), and vascular disease (OR 1.26, CI 1.12–1.43) associated with UHE. UHE frequencies as stratified by comorbidity score and age groups are shown in Supplementary Table 5.

Procedures performed for the indication of pancreatitis (OR 1.45, CI 1.20–1.77), for the management of a pancreaticobiliary malignancy (OR 2.14, CI 1.78–2.57), and for evaluation of Sphincter of Oddi dysfunction (OR 1.98, CI 1.39–2.81) associated with UHE. Performance of a sphincterotomy (OR 1.41, CI 1.34–1.50) associated with UHE, whereas procedures for follow-up stent exchange (OR 0.59, CI 0.56–0.64) associated against UHE.

Facility-Level Risk Factors for UHE

The risk-standardized rate of UHE for each of 635 facilities was determined. The distribution of risk-standardized rates of UHE at 30 days is shown in Figure 1. There was significant heterogeneity in rates between facilities, ranging from a minimum of 0.1% to a maximum of 48.7%. The median rate was 10.0%, and the interquartile range was 6.9%.

Based upon *a priori* strata, increasing facility volume demonstrated a robust and inverse association with risk for UHE in both univariate and multivariable models (P -value for trend <0.001 , Table 5). In the fully-adjusted model, facilities performing >300 ERCPs per annum demonstrated a 25% reduction in odds of an adverse event compared to facilities performing <50 ERCPs per annum. On sensitivity analysis utilizing facility volume tertiles, increasing volume tertile associated inversely with risk for UHE (P -value for trend <0.001 , Table 5). In univariate analysis, performance of ERCP by a facility located in a Suburban/Small metro (OR 1.16, CI 1.05–1.28) or a Rural (OR 1.10, CI 1.05–1.17) area associated with UHE; however, this association attenuated to non-significance in the fully-adjusted model incorporating facility volume. This suggests that the protective effects of ERCP performance

in urban locations was explained mostly by differences in procedure volume between urban and rural areas. Facilities with the technological capability to perform EUS demonstrated a 9% reduced odds of adverse event compared to non-EUS capable facilities. The proportion of marginally-insured patients and minority patients did not associate with risk for UHE.

Association Between Facility Volume and Risk of UHE in Non-Parametric Regression

The risk-standardized rate of UHE for each unique facility was plotted against facility volume and a non-parametric LOESS curve was fitted to ascertain the volume-outcomes relationship for all ERCPs (Figure 2A), ERCPs with sphincterotomy (Figure 2B), and ERCPs without sphincterotomy (Figure 2C). For all ERCPs in aggregate, the risk of UHE approached 12.3% (CI 10.3–14.5%) at low facility volumes; this risk decreased to 10.3% (CI 9.0–11.6%), 9.5% (CI 7.5–11.5%), and 9.2% (CI 7.2–11.2%) at facility volumes of 100, 200, and 300 ERCPs per annum, respectively. The decrease in risk for all ERCPs was continuous, and there did not appear to be a single ‘threshold’ volume above which there was no additional decline in risk with volume; correspondingly, no discrete change-point in the slope was identified. ERCPs with sphincterotomy demonstrated a higher degree of risk; at low volumes, this risk approached 21.0% (CI 16.5–25.4%). The risk declined rapidly and sharply until a change-point in the slope was identified at 157 (CI 152–163) ERCPs per annum; at this point of 157 ERCPs per annum, the risk for UHE was 10.2% (CI 8.0–12.4%). Beyond this change-point, the risk continued to decrease, but with a less marked slope and a more modest decline in risk; at 400 ERCPs per annum the risk was 10.0% (CI 6.1–13.9%) and at 600 ERCPs per annum the risk was 9.5% (CI 3.9–14.0%). ERCPs without sphincterotomy demonstrated much lower risk compared to ERCPs with sphincterotomy. At low volumes, this risk approached 10.0% (CI 7.8–12.0%). This risk decreased to 9.0% (CI 7.8–10.2%), 8.0% (CI 6.0–10.0%), and 7.5% (CI 5.5–9.8%) at annual facility volumes of 100, 200, and 300 ERCPs per annum, respectively. The decrease in risk was continuous, and no change-point in the slope was identified.

Association Between Florida Endoscopist Volume and UHE

The association between FL endoscopist volumes and risk for UHE were analyzed by categorizing endoscopists into volume-based strata (<25, 25–49, 50–99, and 100 ERCPs per annum), and stratified based upon sphincterotomy performance during ERCP (Supplementary Table 6). Among all ERCPs in aggregate, increasing endoscopist volume associated inversely with risk for UHE following adjustment for patient and procedural characteristics (*P* value for trend 0.004), and following adjustment for facility characteristics (*P* value for trend 0.004). In the sub-group of ERCPs with sphincterotomy, this inverse association remained significant following adjustment for patient and procedural characteristics (*P* value for trend 0.02), and following adjustment for facility characteristics (*P* value for trend 0.005). In the sub-group of ERCPs without sphincterotomy, no significant association was seen between increasing endoscopist volume and risk for UHE in univariate analysis (*P* value for trend 0.9), or following adjustment for patient and procedural (*P* value for trend 0.3) or facility (*P* value for trend 0.6) characteristics. While limited to only the state of FL, these data suggest that increasing endoscopist volume may confer a protective benefit.

Estimate of Preventable UHEs

Utilizing the non-parametric models described above, reductions in the number of ERCP-attributable UHEs were estimated based upon volume-based performance thresholds. If all facilities performed at least 50 ERCPs per annum (including both with and without sphincterotomy), an estimated one UHE per 111 ERCPs could be prevented. If this threshold were increased to 100 ERCPs per annum, one UHE would be prevented for every 48 ERCPs performed. If this threshold were further increased to 200 ERCPs per annum, then one UHE would be prevented for every 34 ERCPs performed.

For ERCPs requiring sphincterotomy, if a volume threshold of 50 per annum were adopted by all facilities then one UHE would be prevented for every 12 ERCPs performed. If thresholds were increased to 100 and 200 ERCPs per annum, then one UHE would be prevented for every 9.8 and 9.1 ERCPs performed, respectively.

DISCUSSION

This population-level study provides one of the first comprehensive descriptions of the practice of ERCP across the diverse healthcare landscape of the U.S. In this study, we find that there is substantial inter-facility variability in rates of adverse events following this complex procedure. This study analyzed patient-level and facility-level risk factors, and finds that facility procedural volume is an important predictor of risk. This study further demonstrates that a significant number of facilities in the U.S. perform a low number of ERCPs, and defines a clear volume-outcomes relationship for ERCP performance.

This study indicates that the risk of significant adverse events following ERCP in the general American population may be higher than previously estimated. A meta-analysis of prior studies totaling approximately 17,000 patients estimated a pooled ERCP-attributable adverse event rate of 6.9% (CI 6.5–7.2%).⁹ In contrast, this study captured data from over 68,000 patients and found an adverse event rate at 30 days of 10.2% (CI 10.0–10.5%) following all ERCPs, and 11.4% (CI 11.0–11.8%) following ERCPs with sphincterotomy. The higher adverse event rates noted in this study may in part be explained by the capture of data from community facilities, sources from which ERCP outcomes have rarely been previously reported. Another finding was the high degree of variability in post-ERCP outcomes between facilities, which tended to be magnified at low facility volumes. Previous population-based studies have shown variation in quality among facilities for colonoscopy;^{27, 28} the substantial and otherwise unexplained variability in outcomes demonstrated in this study may hold even more serious consequences for patients, given the higher degree of risk associated with ERCP compared to colonoscopy.

The study suggests that the benefit of additional facility and endoscopist procedural volume is most pronounced for ERCPs associated with sphincterotomy. As sphincterotomy is usually performed during an index therapeutic ERCP (and much less commonly during repeat procedures), part of the increased risk may also reflect the increased procedural complexity of an index ERCP. These data suggest that subsequent ERCPs carry reduced risk with a reduced importance of procedural experience. The increased importance of facility

and endoscopist experience in index ERCPs may be of great relevance to patients and to referring physicians.

The low ERCP volumes performed at many American facilities may relate to the size of their catchment populations, particularly for rural and suburban/smaller metro facilities. Additionally, the nature of training the endoscopists employed by these facilities receive may be a factor. Unlike other endoscopic procedures (such as colonoscopy or upper endoscopy), ERCP training has never been considered a core competency required for successful completion of gastroenterology training in the U.S. An early study suggested that competency could not be evaluated prior to the performance of 180 ERCPs;²⁹ however, a survey of third-year gastroenterology fellows in the U.S. revealed that only 36% of fellows who planned to perform ERCPs in practice achieved this volume and competency standard upon graduation.³⁰ Such endoscopists who have not undergone advanced endoscopy fellowship training and are incompletely trained in ERCP may be more likely to gravitate to lower volume facilities, where they may be encouraged to perform ERCP for a variety of reasons, including personal reputational enhancement and economic gain, catering to patient preference to get the procedure performed locally, and facility preference to manage patients' endoscopic care in order to secure capture of downstream surgical/oncological care. This pressure for sub-optimally-trained endoscopists to perform ERCPs at lower volume facilities may reflect the economic and social realities of a decentralized healthcare delivery system.

Volume plays an important role in outcomes, resulting from a combination of not only endoscopist experience, but also nursing and ancillary staff experience, a likely higher level of investment in ERCP-related equipment, and patient selection. Beyond volume, we also found that the ability to perform additional advanced endoscopic procedures such as EUS protected against adverse event; centers with the expertise and the staffing to offer EUS may have a higher level of investment in endoscopic equipment, more recently-trained endoscopists, or may serve as regional referral centers of excellence. ERCP is also not unique among technically challenging procedures which have demonstrated a robust volume-outcomes relationship, as prior literature has suggested that surgical facility volume, operator volume, and operator specialty all have impact upon outcomes.^{31–33}

There have been increasingly vociferous calls to limit patient exposure to unnecessary morbidity and mortality associated with variability in surgical and procedural quality.³⁴ One avenue by which to achieve this may be the concentration of high-risk procedures to high-volume centers staffed with experienced physicians. In the diverse, multi-payer healthcare landscape of the U.S., centralization may be more challenging than in single-payer systems; however, the avoidance of unnecessary, costly hospitalizations may serve as a powerful market-driven impetus for commercial payers to incent payment for quality healthcare delivery. The growth of dedicated advanced endoscopic training programs,^{35, 36} which incorporate a year of endoscopic training following standard gastroenterology fellowship, is producing a cohort of well-trained endoscopists who over the coming years may gradually supplant the current generation of endoscopists, many of whom learned ERCP through informal training pathways. This trend may aid in the effort to concentrate high-risk endoscopic procedures in the hands of experienced operators and centers.

The results of this study should be interpreted in light of notable limitations. The states chosen for analysis (CA, FL, NY) may contain ethnic, racial, socioeconomic, and local health insurance market characteristics different from other regions of the U.S. The data regarding endoscopist volumes are derived from only the state of FL, therefore limiting generalizability of these results. Misclassification of both exposure and outcome are possible, as data is reliant on accurate procedural and diagnostic coding of claims. HCUP databases are state-specific such that physicians who practice on state borders or who practice itinerantly (*e.g.* practicing on a *locum tenens* basis) would not have all of their procedures captured, leading to underestimation of their volume. Misclassification of outcome is possible, as patients that live close to a state border and who are admitted to a hospital in a neighboring state would not be included for analysis. There could be confounding bias introduced by the choice of a prevalent analysis, as patients who require multiple ERCPs may have greater complexity and comorbidity than patients who require only a single ERCP. If certain facilities are performing higher numbers of repeated procedures on medically complex patients, some of the observed difference in rates of UHE may be due to pre-existing comorbidity rather than procedural skill.

The findings from this retrospective, population-level study of ERCP performance and outcomes reinforce the variability in quality of healthcare delivery across the broad landscape of the U.S. It is hoped that these results will stimulate additional prospective research to confirm the volume-outcomes relationship inferred from this study, and to evaluate the impact of interventions at both facility- and endoscopist-levels to reduce variability in quality.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

(ERCP)	endoscopic retrograde cholangiopancreatography
(U.S.)	United States
(CA)	California
(NY)	New York
(FL)	Florida
(HCUP)	Healthcare Cost and Utilization Project
(CPT)	Current Procedural Terminology
(CCI)	Charlson Comorbidity Index

(ICD-9-CM)	International Classification of Disease, 9th Revision, Clinical Modification
(UHE)	unplanned hospital encounter
(EUS)	endoscopic ultrasound

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Figure 1: Heterogeneity in rates of unplanned hospital encounters

Risk-standardized rate of unplanned hospital encounter (UHE) at 30 days is plotted against number of facilities, with quantiles displayed in insert.

Figure 2: Relationship between facility volume and outcomes

The risk-standardized rate of unplanned hospital encounter (y-axis) is plotted against annual ERCP volume (x-axis) for each unique facility (gray asterisk), and a local regression curve (with 95% CI) is fitted. Data is shown for all ERCPs (Panel A), ERCPs with sphincterotomy (Panel B), and ERCPs without sphincterotomy (Panel C). Dashed line (Panel B) represents inflection point in the nonparametric regression curve at 157 ERCPs per annum per facility.

Table 1:**Baseline Characteristics of Patients and Procedures**

Covariate	Mean (SD) or Frequency (%)
State of Residence, No. (%)	
California	28,046 (40.9)
Florida	20,396 (29.7)
New York	20,200 (29.4)
Age, mean (SD), years	62.3 (17.0)
Gender, No. (%)	
Male	28,002 (40.8)
Female	38,338 (55.9)
Missing	2,302 (3.4)
Payer, No. (%)	
Medicare	34,147 (49.8)
Private insurance	24,968 (36.4)
Medicaid	5,775 (8.4)
Other/No insurance	3,520 (5.2)
Missing	232 (0.3)
CCI Score, mean (SD), points	1.4 (2.2)
History of malignancy, No. (%)	9,142 (13.3)
Procedural indication, No. (%)	
Gallstone disease	21,812 (31.8)
Biliary stricture	16,074 (23.7)
Hepatopancreatobiliary cancer	6,138 (8.9)
Abdominal symptoms	3,892 (5.7)
Pancreatitis	3,318 (4.8)
Other pancreas pathology	2,520 (3.7)
Cholangitis	1,555 (2.3)
Laboratory abnormalities	1,032 (1.5)
Sphincter of Oddi dysfunction	216 (0.3)
Other	12,085 (17.6)
Procedural characteristics, No. (%)	
Sphincterotomy	26,616 (38.8)
Stent insertion	15,487 (22.6)
Stent exchange	26,219 (38.2)
Lithotripsy	1,963 (2.9%)

Table 2:

Characteristics of ERCP Facilities (N=635)

Characteristic	Number or Percentage				
	All Facilities (N=635)	By Tertile of Volume			
		Lowest (N=213)	Middle (N=212)	Highest (N=210)	P value
Annual ERCP Volume					<0.001
Min.	2.0	2.0	41.3	107.7	
Median	68.7	20.7	68.8	159.8	
Max.	903.7	41.0	107.3	903.7	
Location [†]					0.01
Urban	45.7%	40.9%	42.9%	53.3%	
Suburban/Smaller Metro	42.4%	42.7%	44.3%	40.0%	
Rural	12.0%	16.4%	12.7%	6.7%	
Has EUS capability	23.3%	4.2%	13.6%	52.4%	<0.001
Percentage Medicaid/Uninsured patients					0.3
Min.	0.0%	0.0%	0.2%	0.4%	
25 th percentile	8.6%	9.5%	9.3%	8.1%	
50 th percentile	13.5%	15.8%	13.9%	12.2%	
75 th percentile	18.9%	23.6%	19.2%	16.4%	
Max.	82.1%	82.1%	49.6%	39.5%	
Percentage Minority					0.6
Min.	1.6%	1.6%	2.7%	2.2%	
25 th percentile	18.4%	16.8%	18.0%	22.7%	
50 th percentile	38.2%	34.4%	39.4%	39.0%	
75 th percentile	60.8%	67.3%	59.9%	56.9%	
Max.	100.0%	100.0%	99.6%	98.3%	

[†] classified as urban, suburban/smaller metro area, or rural based upon the classification system developed by the National Center for Health Statistics²⁴

Table 3:

Rate of Unplanned Hospital Encounters and Specific Adverse Events

Diagnosis	Rate of Unplanned Hospital Encounters (95% CI), %			
	Stratified by Sphincterotomy Performance			
	All ERCPs (N=68,642)	With sphincterotomy (N=26,616)	Without sphincterotomy (N=42,026)	<i>P</i> value*
Rate of UHE / Death by Time Period				
UHE within 7 days	5.8 (5.6–6.0)	7.3 (7.0–7.6)	4.9 (4.7–5.1)	<0.001
UHE at 8–15 days	1.9 (1.8–2.0)	1.9 (1.7–2.0)	1.9 (1.8–2.1)	0.6
UHE at 15–22 days	1.3 (1.2–1.4)	1.2 (1.0–1.3)	1.4 (1.3–1.5)	0.1
UHE at 22–30 days	1.1 (1.0–1.1)	1.0 (0.9–1.1)	1.1 (1.0–1.2)	0.3
UHE within 30 days	10.2 (10.0–10.5)	11.4 (11.0–11.8)	9.5 (9.2–9.8)	<0.001
Death within 30 days	0.4 (0.4–0.5)	0.4 (0.3–0.5)	0.4 (0.3–0.5)	0.9
Rate of Adverse Event within seven days of ERCP				
Acute pancreatitis	2.7 (2.6–2.8)	3.8 (3.6–4.1)	2.0 (1.9–2.1)	<0.001
Gastrointestinal bleeding	2.4 (2.3–2.5)	3.0 (2.8–3.2)	2.0 (1.9–2.2)	<0.001
Recurrent biliary obstruction	3.1 (3.0–3.2)	3.0 (2.8–3.2)	3.2 (3.0–3.3)	0.7
Perforation	0.2 (0.1–0.2)	0.2 (0.2–0.3)	0.1 (0.1–0.1)	0.002
Non-biliary infection	3.0 (2.8–3.1)	3.0 (2.8–3.2)	2.9 (2.8–3.1)	0.9
Cardiac or vascular event	1.4 (1.3–1.5)	1.7 (1.5–1.8)	1.3 (1.1–1.4)	<0.001

* Denotes *P*value for comparison between procedures with and without sphincterotomy, after adjustment for multiple comparisons. UHE, unplanned hospital encounter. CI, confidence estimates.

Table 4:**Patient-Level Predictors of Unplanned Hospital Encounters**

Covariate	Univariate Analysis	Multivariable Analysis
	OR (95% CI)	OR (95% CI) [†]
Demographic		
Age (per 10 years)	0.87 (0.86–0.88) [*]	0.89 (0.87–0.91) [*]
Female gender (vs male)	1.20 (1.14–1.26) [*]	1.16 (1.09–1.22) [*]
Payer		
Private insurance	Ref.	Ref.
Medicare	0.72 (0.68–0.76) [*]	0.93 (0.86–1.00)
Medicaid	1.18 (1.08–1.28) [*]	1.10 (1.00–1.20)
Other/No insurance	1.16 (1.04–1.29) [*]	1.18 (1.06–1.32) [*]
Clinical		
Charlson score (per point)	1.03 (1.01–1.04) [*]	1.05 (1.04–1.06) [*]
Cardiac disease	1.08 (0.98–1.18)	1.33 (1.20–1.47) [*]
Chronic pulmonary disease	1.13 (1.05–1.22) [*]	1.17 (1.09–1.26) [*]
Cirrhosis	0.89 (0.78–1.03)	0.89 (0.77–1.02)
Dementia	0.90 (0.63–1.28)	1.19 (0.83–1.71)
Diabetes	0.98 (0.91–1.04)	1.10 (1.03–1.17)
Prior or current malignancy	1.15 (1.07–1.24) [*]	1.31 (1.22–1.41) [*]
Renal disease	0.98 (0.88–1.09)	1.15 (1.03–1.28)
Vascular disease	1.03 (0.92–1.17)	1.26 (1.12–1.43) [*]
Procedural		
Indication of pancreatitis	1.43 (1.18–1.73) [*]	1.45 (1.20–1.77) [*]
Indication of pancreaticobiliary malignancy	1.86 (1.56–2.23) [*]	2.14 (1.78–2.57) [*]
Indication of Sphincter of Oddi dysfunction	2.18 (1.54–3.08) [*]	1.98 (1.39–2.81) [*]
Sphincterotomy	1.67 (1.59–1.76) [*]	1.41 (1.34–1.50) [*]
Stent exchange	0.49 (0.46–0.52) [*]	0.59 (0.56–0.64) [*]
Lithotripsy / Stone Removal	0.77 (0.65–0.91)	0.95 (0.79–1.13)

[†] Adjusting for age, gender and insurance provider.

^{††} Adjusting for age, gender, insurance provider, comorbidity, and procedural characteristics.

^{*} Denotes statistical significance after adjustment for multiple comparisons.

Table 5:

Facility-Level Predictors of Unplanned Hospital Encounters

Covariate	Number of ERCPs	Frequency of UHE (% of total)	OR (95% CI)	OR [†] (95% CI)	OR ^{††} (95% CI)
Annual ERCP Volume					
<50	3,279	275 (7.7%)	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
50 – 99	9,085	581 (6.4%)	0.87 (0.77–0.98)	0.90 (0.80–1.02)	0.90 (0.79–1.01)
100 – 199	19,860	1,145 (5.8%)	0.74 (0.66–0.82)	0.77 (0.69–0.87)	0.79 (0.70–0.88)
200 – 299	6,530	366 (5.6%)	0.73 (0.65–0.84)	0.76 (0.67–0.86)	0.79 (0.69–0.91)
300	29,613	1,617 (5.5%)	0.67 (0.60–0.75)	0.69 (0.62–0.78)	0.75 (0.66–0.85)
<i>P</i> -value for trend			<0.001*	<0.001*	<0.001*
ERCP Volume Tertile					
Lowest (<41 ERCPs)	2,548	181 (7.1)	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
Middle (41 – 108 ERCPs)	11,357	755 (6.7%)	0.93 (0.79–1.10)	0.95 (0.80–1.13)	0.95 (0.80–1.13)
Highest (>108 ERCPs)	54,700	3,045 (5.6%)	0.77 (0.66–0.90)	0.79 (0.67–0.92)	0.79 (0.67–0.92)
<i>P</i> -value for trend			<0.001*	<0.001*	<0.001*
Location					
City	38,038	2,180 (5.7%)	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
Suburban/Small metro	24,912	1,520 (6.1%)	1.16 (1.05–1.28)*	1.11 (1.05–1.17)*	1.06 (1.00–1.13)
Rural	5,655	337 (6.0%)	1.10 (1.05–1.17)*	1.14 (1.04–1.25)*	1.07 (0.97–1.17)
EUS-capable facility	-	-	0.85 (0.81–0.90)*	0.82 (0.78–0.87)*	0.91 (0.85–0.98)*
Medicaid/uninsured (per 10%)	-	-	0.97 (0.94–1.01)	0.95 (0.91–0.99)	-
Minority population (per 10%)	-	-	0.97 (0.96–0.98)	0.97 (0.96–0.98)	-

UHE, unplanned hospital encounter; *Ref.*, reference.

[†]Adjusted for patient (age, gender, payer, comorbidity) and procedural (indication, sphincterotomy performance) characteristics

^{††}Adjusted for patient, procedural, facility (annual ERCP volume, location, and EUS capability) characteristics