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**MINIREVIEWS**

- 634 Endoscopic ultrasound guided gastroenterostomy: Technical details updates, clinical outcomes, and adverse events  
*Wang J, Hu JL, Sun SY*

**ORIGINAL ARTICLE****Retrospective Cohort Study**

- 641 Endoscopic retrograde cholangiopancreatography-related early perforations: A study of effects of procedure duration, complexity, and endoscopist experience  
*Aloysius M, Goyal H, Nikumbh T, Shah NJ, Hammoud GM, Mutha P, Joseph-Talreja M, John S, Aswath G, Wadhwa V, Thosani N*

- 649 Nomogram to predict gas-related complications during transoral endoscopic resection of upper gastrointestinal submucosal lesions  
*Yang J, Chen ZG, Yi XL, Chen J, Chen L*

**Basic Study**

- 658 Animal experimental study on magnetic anchor technique-assisted endoscopic submucosal dissection of early gastric cancer  
*Pan M, Zhang MM, Zhao L, Lyu Y, Yan XP*

**CASE REPORT**

- 666 Hybrid laparo-endoscopic access: New approach to surgical treatment for giant fibrovascular polyp of esophagus: A case report and review of literature  
*Dzhantukhanova S, Avetisyan LG, Badakhova A, Starkov Y, Glotov A*
- 676 General anesthesia with endotracheal intubation ensures the quick removal of magnetic foreign bodies: A case report  
*Tian QF, Zhao AX, Du N, Wang ZJ, Ma LL, Men FL*

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## Retrospective Cohort Study

# Endoscopic retrograde cholangiopancreatography-related early perforations: A study of effects of procedure duration, complexity, and endoscopist experience

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## Abstract

### BACKGROUND

Perforations (Perf) during endoscopic retrograde cholangiopancreatography (ERCP) are rare (< 1%) but potentially fatal events (up to 20% mortality). Given its rarity, most data is through case series studies from centers or analysis of large databases. Although a meta-analysis has shown fewer adverse events as a composite (bleeding, pancreatitis, Perf) during ERCP performed at high-volume centers, there is very little real-world data on endoscopist and center procedural volumes, ERCP duration and complexity on the occurrence of Perf.

### AIM

To study the profile of Perf related to ERCP by center and endoscopist procedure volume, ERCP time, and complexity from a national endoscopic repository.

### METHODS

Patients from clinical outcomes research initiative-national endoscopic database (2000-2012) who underwent ERCP were stratified based on the endoscopist and center volume (quartiles), and total procedure duration and complexity grade of

the ERCP based on procedure details. The effects of these variables on the Perf that occurred were studied. Continuous variables were compared between Perf and no perforations (NoPerf) using the Mann-Whitney U test as the data demonstrated significant skewness and kurtosis.

## RESULTS

A total of 14153 ERCPs were performed by 258 endoscopists, with 20 reported Perf (0.14%) among 16 endoscopists. Mean patient age in years  $61.6 \pm 14.8$  vs  $58.1 \pm 18.8$  (Perf vs. NoPerf,  $P = \text{NS}$ ). The cannulation rate was 100% and 91.5% for Perf and NoPerf groups, respectively. 13/20 (65%) of endoscopists were high-volume performers in the 4<sup>th</sup> quartile, and 11/20 (55%) of Perf occurred in centers with the highest volumes (4<sup>th</sup> quartile). Total procedure duration in minutes was  $60.1 \pm 29.9$  vs  $40.33 \pm 23.5$  (Perf vs NoPerf,  $P < 0.001$ ). Fluoroscopy duration in minutes was  $3.3 \pm 2.3$  vs  $3.3 \pm 2.6$  (Perf vs NoPerf  $P = \text{NS}$ ). 50% of the procedures were complex and greater than grade 1 difficulty. 3/20 (15%) patients had prior biliary surgery. 13/20 (65%) had sphincterotomies performed with stent insertion. Peritonitis occurred in only 1/20 (0.5%).

## CONCLUSION

Overall adverse events as a composite during ERCP are known to occur at a lower rate with higher volume endoscopists and centers. However, Perf studied from the national database show prolonged and more complex procedures performed by high-volume endoscopists at high-volume centers contribute to Perf.

**Key Words:** Endoscopic retrograde cholangiopancreatography; Endoscopy complications; Perforations

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**Core Tip:** We analyzed the profile of perforations (Perf) related to endoscopic retrograde cholangiopancreatography (ERCP) from the clinical outcomes research initiative-national endoscopic database over 12 years. The retrospective analysis of 14153 ERCPs done by 258 endoscopists reported a Perf rate of 0.14% (20 Perf) among 16 endoscopists. The cannulation rate was 100% for Perf and 91.5% for no Perf groups. 65% of endoscopists were high-volume performers, and 55% of Perf occurred in centers with the highest volumes (4<sup>th</sup> quartile). Higher volume endoscopists and centres are known to have less ERCP-related adverse events. However, this national database study on Perf has shown prolonged and complex procedures performed by high-volume endoscopists at high-volume centers contributed to Perf.

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## INTRODUCTION

The indications for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) have increased exponentially over the last decade[1]. Consequently, the complexity of procedures has also increased along with the training required to achieve competencies to perform such high-risk procedures. As a result, the completion success and complication rates vary widely and appear related to the endoscopist volume[2,3].

Although perforation (Perf) during ERCP is uncommon (1%), it can be fatal with up to 20% mortality[4,5]. Most data about ERCP-related Perfs is from case series or analysis of large databases. While a meta-analysis revealed lesser adverse overall events (bleeding, Perf, pancreatitis) during ERCP performed at high-volume centres[6], there is a lack of real-world data regarding endoscopist and centre procedural volumes, ERCP duration, and complexity on the occurrence of early Perf[5,7,8].

We analyzed a national endoscopic repository national institute of health (NIH)-clinical outcomes research initiative-national endoscopic database (CORI-NED) to study the profile of Perf related to ERCP by center and endoscopist procedure volume, ERCP time, and complexity.

## MATERIALS AND METHODS

### Database

CORI-NED is a large prospectively accrued population-based database maintained by NIH. CORI was established in 1995 to study the use and outcomes of endoscopy in diverse gastroenterology practice settings in the United States[9]. Participating physicians are provided with an electronic health record completed at the endoscopy time and generate

procedure reports. Once submitted, the report cannot be altered. Users are required to document at least 95% of the procedures in CORI. A limited dataset from every report is sent to NIH, where it is quality tested and compiled into CORI-NED. Anonymized data is collected and stored per strict health insurance portability and accountability act standards, and users must obtain data user agreements and Institutional Review Board (IRB) approval. This study was IRB-approved. As CORI-NED contains information generated at the time of ERCP, we examined early Perf discovered before the procedure report was generated, signed off, and submitted to the repository.

### Study cohort, design and statistical analysis

Our study is a retrospective population-based analysis of early Perf related to ERCP. Patients over 18 years of age who underwent ERCP from 2000-2012 were studied. Data collected included age, sex, center volume, endoscopist volume, ERCP and fluoroscopy duration, indication, ERCP difficulty, prior biliary surgery dilation of strictures, sphincterotomy, sphincterotomy device used, stent placement, peritonitis. Patients were stratified based on the endoscopist's and center's volume (quartiles), total procedure duration, and complexity grade of the ERCP based on procedure details. We aim to identify age factor, ERCP fluoroscopy time, and total procedure time between patients who suffered Perf *vs* those who did not in the immediate post-procedural period (before the procedure note is uploaded as per CORI-NED).

The effects of these variables on the Perf that occurred were studied. In addition, continuous variables were compared between Perf and no Perfs (NoPerf) using the Mann-Whitney U test, as the data demonstrated significant skewness and kurtosis. All analysis was performed using SPSS (v28.0). The statistical review of the study was performed by a biomedical statistician. The grades of ERCP difficulty were defined by the grading system (Supplementary Table 1) proposed by Raju[10], Schutz and Abbott[11] and were widely used during data collection.

## RESULTS

14153 ERCPs performed by 258 endoscopists at 48 facilities were analyzed. 20 Perf (0.14%) were reported among 16 endoscopists. The mean patient age was  $61.6 \pm 14.8$  *vs*  $58.1 \pm 18.8$  years (Perf *vs* NoPerf,  $P = \text{NS}$ , Figure 1A). The cannulation rate for Perf *vs* no Perf was 100% and 91.5%, respectively. 11/20 (55%) of Perf happened in the centres with the greatest volumes (4<sup>th</sup> quartile), while 13/20 (65%) of endoscopists were high-volume achievers.

Total procedure duration was  $60.1 \pm 29.9$  *vs*  $40.33 \pm 23.5$  min (Perf *vs* NoPerf,  $P < 0.001$ , Figure 1B). Fluoroscopy duration was  $3.3 \pm 2.3$  *vs*  $3.3 \pm 2.6$  min (Perf *vs* NoPerf  $P = \text{NS}$ , Figure 1C). To evaluate the differences between patients who perforated *vs* those who did not Mann-Whitney U test was utilized. The test revealed a significant difference in total procedural time between those who suffered Perf *vs* those who did not (Median 51 *vs* 32 min,  $n = 20$  *vs*  $n = 14133$ ),  $U = 8467$  *vs* 5816,  $Z = 3.536$ ,  $P < 0.001$ ,  $r = 118$  (large effect size). Hence  $H_0$  was rejected. However, age and fluoroscopy time did not differ between the groups.

Half of the procedures were complex and more than grade 1 difficulty (Table 1). 3 out of 20 (15%) patients had prior biliary surgery. 13 out of 20 cases (65%) had sphincterotomies with stent insertion. 1 case (0.5%) had peritonitis (Table 1).

We also performed a multivariate regression analysis of age category, endoscopist ERCP volume quartile, fluoroscopy time, and total procedure time (Table 2). The regression analysis results demonstrate that only prolonged total procedural time among the parameters studied is associated with Perf (hazard ratios 1.022, 95% confidence interval 1.001-1.043,  $P < 0.036$ ).

## DISCUSSION

Our nationwide population-based study about ERCP identified several factors related to procedure complexity, center, and endoscopist performance as significant risk factors for ERCP-related Perf. The risk factors for ERCP-related Perf were a higher grade of complexity requiring a longer duration of the procedure, a high-volume center, and a high-volume endoscopist.

Overall, greater volume endoscopists and centres are reported to have a reduced rate of adverse events during ERCP [6]. Currently, there is a lack of consensus on the minimum required volume to maintain ERCP competency. The minimum standards and mandatory curriculum required for an endoscopist and center to maintain ERCP skills have been recently defined in a multicenter clinical trial but have not been widely adopted[12]. Short-term ERCP complications occur in about 10% of patients, including cholangitis, pancreatitis, bleeding, and Perf[13]. It has also been suggested that ERCP-related complications, especially Perf, tend to occur more frequently in lower-volume centers by and with lower endoscopist volume by quartiles[5,6]. An analysis of the Swedish National Register for Gallstone Surgery and ERCP[14] has also shown that higher endoscopist and center case volumes are associated with safer ERCP, similar to our results. However, this study analyzed only ERCP for stones and malignancy as an indication of ERCP. They found that higher case and center volume correlated with lower complication rates and shorter procedure time in ERCP for Cannabidiol stones. Conversely, factors associated with Perf in our study were the prolonged duration of the procedure, as shown previously by other studies [5,15,16]. A large review of 142847 ERCPs found a 0.39% Perf rate, where sphincterotomy was responsible for 41% of Perf[17]. Interestingly, in our study, ERCP with Perf had a 100% cannulation rate compared to 91.5% in ERCP with no Perf. Also, 50% of the Perf occurred in complex ERCPs (> grade 1 as per the classification proposed by Schultz and Abbott[11] and colleagues)[18]. The success rate of approximately  $\geq 90\%$  cannulation of the desired duct is a parameter to measure competency in performing ERCP[19].

**Table 1** Details of the endoscopic retrograde cholangiopancreatography associated with perforation for clinical outcomes research initiative-national endoscopic database

Physician	Physician volume quartile	Center volume quartile	Indication	ERCP difficulty grade	Dilation of strictures	Sphincterotomy performed	Stent placement	Sphincterotomy device	Peritonitis	Prior biliary surgery
1	4	4	LHD tumor biopsy	3	No	No	No	NA	No	No
2	4	4	Pancreatic tumor	3	No	Yes	Yes	<sup>1</sup>	No	Yes
2	4	4	CBD stone	3	Yes	Yes	Yes	Cotton cannulotome	No	No
2	4	4	CBD stricture	3	Yes	Yes	Yes	Cotton cannulotome	No	No
3	3	3	RHD tumor biopsy	3	No	Yes	Yes	Cotton cannulotome	No	No
4	3	2	CBD stone	1	No	Yes	Yes	Cotton cannulotome	No	No
5	4	4	CBD stone	1	No	Yes	Yes	Papillotome	Yes	No
6	4	3	Stent placement	1	No	Yes	Yes	Autotome	No	No
7	4	3	CBD stone	1	No	No	No	<sup>1</sup>	No	No
8	3	4	CBD stone	1	No	No	No	<sup>1</sup>	No	No
9	4	3	Pancreatic tumor	3	No	Yes	Yes	Cotton cannulotome	No	No
10	3	3	Sphincter of oddi dysfunction	3	No	Yes	Yes	<sup>1</sup>	No	No
11	4	4	CBD stone	2	No	Yes	Yes	Cannulating sphincterotome	No	Yes
11	4	4	Stent replacement	1	No	No	No	NA	No	No
11	4	4	Pancreatic pseudocyst drainage	4	No	Yes	Yes	Needle knife precut	No	Yes
12	4	4	CBD stone	1	No	Yes	Yes	<sup>1</sup>	No	No
13	4	4	CBD stone	1	No	No	No	NA	No	No
14	3	3	Stent placement	1	No	Yes	Yes	Cotton cannulotome	No	No
15	3	3	CBD stone	1	No	No	No	NA	No	No
16	3	3	CBD stone	3	No	No	No	NA	No	Yes

<sup>1</sup>Unavailable. LHD: Left hepatic duct; CBD: Common bile duct; ERCP: Endoscopic retrograde cholangiopancreatography.

The Perf rate following ERCP in our study was lower (0.14%) than in the three previous, where the rates were 0.45%, 0.72%, and 0.39%, respectively[4,5,17]. Participating physicians in CORI-NED database are provided with an electronic health record completed at the endoscopy time and generate procedure reports. Once submitted, the report cannot be altered. Hence only the Perf detected during the peri-operative period are reported in the database. Thus, only early Perf following ERCP are reported and studied. This may explain the low Perf rate reported in our study. However, research on Perf from the CORI-NED has revealed that extended, more complicated procedures carried out in high-volume centres by high-volume endoscopists are a factor in Perf. This is likely due to high-risk procedures with complex pathology been undertaken at tertiary and quaternary centers.

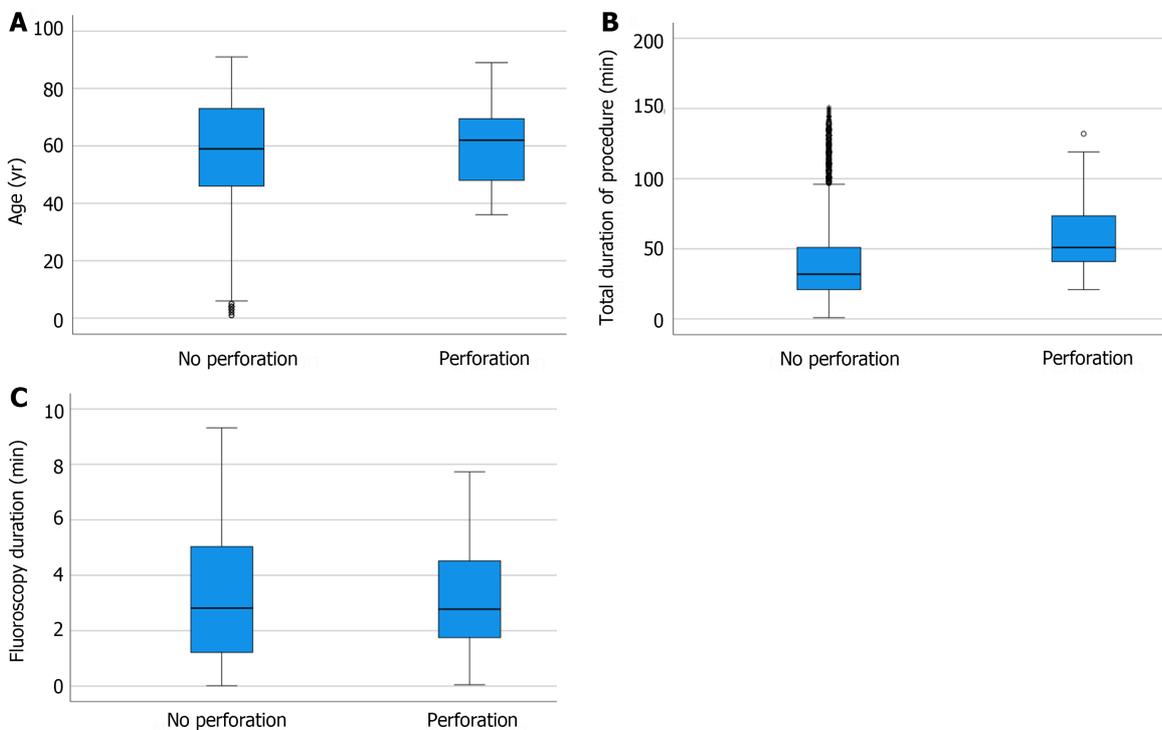
Early diagnosis is most important to reduce associated significant morbidity and mortality rates; thus, prompt management should be initiated as soon as possible. The late recognition of ERCP-related Perf, failure to adequately treat a Perf, and delayed surgery following failed non-operative management worsen outcomes[4,19-22].

The strength of the study is that the CORI-NED was utilized as the primary data source. CORI has strict quality-control measures for all its data. The data repository is checked for anomalies on a daily basis, and unusual activity prompts

**Table 2** Details of the endoscopic retrograde cholangiopancreatography associated with perforation for clinical outcomes research initiative-national endoscopic database

Parameter studied	B	SE	Wald	df	P value	HR	95%CI
Age category in yr (< 40, 40-60, 60-75, > 75). Endoscopist ERCP volume (n) quartiles (< 50, 50-100, 100-150, > 150) fluoroscopy time (minutes). Total duration of the procedure (minutes)	0.086	0.271	0.101	1	0.75	1.09	0.64
							1.856
	-0.094	0.241	0.152	1	0.697	0.91	0.568
							1.46
	-0.104	0.133	0.611	1	0.435	0.901	0.694
							1.17
	0.022	0.01	4.403	1	0.036	1.022	1.001
							1.043

ERCP: Endoscopic retrograde cholangiopancreatography; HR: Hazard ratios; CI: Confidence interval.



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**Figure 1** Comparison of age and time between perforation and no perforation group. A: Mean patient age was  $61.6 \pm 14.8$  vs  $58.1 \pm 18.8$  years [Perforation (Perf) vs no Perfs (NoPerf),  $P = NS$ ]; B: Total procedure duration was  $60.1 \pm 29.9$  vs  $40.33 \pm 23.5$  min (Perf vs NoPerf,  $P < 0.001$ ); C: Fluoroscopy duration was  $3.3 \pm 2.3$  vs  $3.3 \pm 2.6$  min (Perf vs NoPerf  $P = NS$ ).

contact by CORI staff[9]. Moreover, the data is derived from a variety of gastroenterology practice settings, with the majority of sites covered being community-based, followed by veterans’ administration and academic hospitals. This provides an evaluation of real-world representation of the practice of endoscopy.

**Limits of the study**

Our study results should be considered in light of its limitations, most of which are inherent to large database studies. First, this study is prone to site-selection bias. The sites unwilling to share data with CORI-NED may differ in their clinical practice from the participating sites. Generally, smaller practices with higher administrative burdens do not participate in additional data sharing on databases. These practices also refer complex procedures to high-volume centers and endoscopists. It is also likely that less experienced practitioners rarely publish their data[16,23]. Second, CORI-NED database does not give the specific type of Perf encountered during the ERCP procedure. Thus we could not differentiate into duodenal Perf, peri-ampullary or bile duct Perf. Third, the endoscopic report was the source of data in this study.

The CORI-NED database only records the clinical information and events during and immediately after the ERCP in the endoscopic report. Additionally, follow-up data analysis in CORI is limited. Hence delayed Perf would not have been picked up in the study. However, a review of 18 retrospective studies showed that most (73%) Perf are identified during the periprocedural period[17].

## CONCLUSION

Our study shows that the increase in procedure complexity raises the requisite expertise to deal with complex pathology successfully. ERCP will continue its exponential growth to deal with more complex hepatobiliary pathologies. In order to raise the expertise of future endoscopists, higher volume centers with adequate training procedure numbers for aspiring endoscopists are the need of the hour.

## ARTICLE HIGHLIGHTS

### Research background

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely performed procedure in gastroenterology. ERCP perforations (Perf) are rare complication however they lead to severe morbidity and can be fatal.

### Research motivation

Clinical outcomes research initiative-national endoscopic database (CORI-NED) is a large prospectively accrued population-based database maintained by national institute of health (NIH). NIH established CORI in 1995 to study the use and outcomes of endoscopy in diverse gastroenterology practice settings in the United States. Our motivation was to study this large database and look into the complications associated with ERCP.

### Research objectives

ERCP were stratified based on the endoscopist and center volume (quartiles), complexity of the ERCP and total procedure duration based on procedure details. The effects of these variables on the Perf were studied.

### Research methods

ERCP related data from CORI NED database from 2000-2012 was analyzed. Continuous variables were compared between Perf and no Perf (NoPerf) groups using Mann-Whitney U test as the data demonstrated significant skewness and Kurtosis.

### Research results

14153 ERCPs performed by 258 endoscopists at 48 facilities were analyzed. 20 Perfs (0.14%) were reported among 16 endoscopists. The cannulation rate for Perfs *vs* no Perfs was 100% and 91.5%, respectively. 11/20 (55%) of Perfs happened in the centres with the greatest volumes (4<sup>th</sup> quartile), while 13/20 (65%) of endoscopists were high-volume achievers. Total procedure duration in minutes was 60.1 ± 29.9 *vs.* 40.33 ± 23.5 (Perf *vs.* NoPerf, *P* < 0.001). Half of the procedures were complex and more than grade 1 difficulty (Table 1). 3 out of 20 (15%) patients had prior biliary surgery. 13 out of 20 cases (65%) had sphincterotomies with stent insertion. 1 case (0.5%) had peritonitis.

### Research conclusions

Overall adverse events as a composite during ERCP are known to occur at a lower rate with higher volume endoscopists and centers.

### Research perspectives

We analyzed the profile of Perfs related to ERCP from the CORI-NED database over 12 years. The retrospective analysis of 14153 ERCPs performed by 258 endoscopists reported 20 Perfs (0.14%) among 16 endoscopists. The cannulation rate was 100% for Perf and 91.5% for no Perf groups. 65% of endoscopists were high-volume performers, and 55% of Perfs occurred in centers with the highest volumes (4<sup>th</sup> quartile). Higher volume endoscopists and centres are known to have less ERCP-related adverse events. However, this national database study on Perfs has shown prolonged and complex procedures performed by high-volume endoscopists at high-volume centers contributed to Perfs.

## FOOTNOTES

**Author contributions:** Aloysius M and Goyal H designed the study, performed the statistical analysis, generated the figures, and edited the manuscript; Nikumbh T performed the literature review and drafted the initial version of the manuscript and revised manuscript; Shah NJ, Hammoud GM, Mutha P, and Joseph-Talreja M edited the manuscript; John S, Aswath G, Wadhwa V and Thosani N critically reviewed manuscript.

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