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***Retrospective Cohort Study***

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

Aloysius M *et al.* ERCP-related early Perf

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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 outcome research initiative national endoscopic database 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 Perfs (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 ± 14.8 *vs* 58.1 ± 18.8 (Perf *vs*. NoPerf, *P* = 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 4th quartile, and 11/20 (55%) of Perf occurred in centers with the highest volumes (4th quartile). Total procedure duration in minutes was 60.1 ± 29.9 *vs.* 40.33 ± 23.5 (Perf *vs*. NoPerf, *P* < 0.001). Fluoroscopy duration in minutes was 3.3 ± 2.3 *vs.* 3.3 ± 2.6 (Perf *vs.* NoPerf *P* = 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 (4th 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.

**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 ± 14.8 *vs* 58.1 ± 18.8 years (Perf *vs.* NoPerf, *P* = 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 (4th quartile), while 13/20 (65%) of endoscopists were high-volume achievers.

Total procedure duration was 60.1 ± 29.9 *vs.* 40.33 ± 23.5 min (Perf *vs.* NoPerf, *P* < 0.001, Figure 1B). Fluoroscopy duration was 3.3 ± 2.3 *vs.* 3.3 ± 2.6 min (Perf *vs.* NoPerf *P* = 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 H0 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 ≥ 90% cannulation of the desired duct is a parameter to measure competency in performing ERCP[19].

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 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 (4th 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 (4th 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.

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**Footnotes**

**Institutional review board statement:** The Institutional review board approval was not needed for this study originating from a publicly available database.

**Informed consent statement:** As the study used anonymous and pre-existing data, the requirement for the informed consent from patients was waived.

**Conflict-of-interest statement:** All the Authors have no conflict of interest related to the manuscript.

**Data sharing statement:** The original anonymous dataset is available on request from the corresponding author at doc.hemant@yahoo.com.

**STROBE statement: The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.**

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**Figure Legends**





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

**Table 1 Details of the endoscopic retrograde cholangiopancreatographys 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 | 1 | 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 | 1 | No | No |
| 8 | 3 | 4 | CBD stone | 1 | No | No | No | 1 | 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 | 1 | 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 | 1 | 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 |

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

Table 2 Multivariate regression analysis of age category, endoscopist endoscopic retrograde cholangiopancreatography volume quartile, fluoroscopy time, and total procedure time

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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.