Impact of introduction of endoscopic ultrasound on volume, success, and complexity of endoscopic retrograde cholangiopancreatography in a tertiary referral center

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ABSTRACT

Background and Objectives: Endoscopic ultrasound (EUS) is commonly used to examine pancreaticobiliary disorders. We hypothesize that the introduction of EUS service may change the pattern and the complexity of endoscopic retrograde cholangiopancreatographies (ERCPs) performed. The aim of this study is to assess the impact of introducing EUS on the volume, success, and complexity of ERCP.

Materials and Methods: This is a single-center retrospective data review of ERCP procedures done “before” and “after” the introduction of EUS (before EUS and after EUS). Patients’ demographics, ERCP indications, types of sedation, therapeutic interventions, outcomes, complications, and complexity of ERCP were collected. The categorical and continuous variables were compared using Fisher’s exact test and the unpaired t-test, respectively. Multivariable logistic regression analysis was used to compare ERCP outcomes.

Results: A total of 945 ERCPs performed over a 3-year period between January 2010 and January 2013 (411 and 534 in the “before EUS” and “after EUS” time periods, respectively) were included in this study. There was a 30% relative increase in the volume of ERCPs after the introduction of EUS. ERCP success rate was higher after the introduction of EUS, even after adjusting the complexity grade [odds ratio (OR) = 4.54, P = 0.001]. Significant increase in the complexity of ERCP was observed after the introduction of EUS service. The OR of performing grade 4 ERCP was 4.44 (P = 0.0005) after the introduction of EUS.

Conclusions: The introduction of a new EUS service in our tertiary referral university medical center is associated with an increase in the volume, success, and complexity of ERCP procedures. EUS expertise may be valuable for better ERCP outcomes.

Key words: Complexity, endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS), success, volume

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) remains the “gold standard” for evaluation of the pancreaticobiliary tree.[1,2] It is indicated for both advanced diagnostic and therapeutic interventions of the pancreaticoobiliary ductal system.[3] The major

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The drawback of this invasive procedure is the potential for serious complications, such as pancreatitis and cholangitis. Endoscopic ultrasound (EUS) is a minimally invasive, excellent diagnostic tool for biliary imaging and gastrointestinal malignancies, providing high-quality images of the pancreaticobiliary tree. Given the vast indications of EUS, including accurate diagnosis of common bile duct stones, it was noted that many unnecessary ERCPs were avoided by performing EUS first.\cite{[1,2]}

EUS can aid in biliary duct and pancreatic duct cannulation in settings where conventional ERCP techniques fail, such as in severe biliary strictures, inaccessible ampulla, or ampullary tumor.\cite{[4,5]} EUS may be helpful to select patients for therapeutic ERCP, thereby increasing the safety and efficacy, and reducing the complications. Evidence showing the changes in ERCP pattern with the introduction of EUS is limited. Although this concept is well known, it has never been studied systematically in the past.

The current study aims to assess the change in the volume, success, and complexity of ERCPs performed in our institution after the introduction of EUS expertise that aids in more complex ERCP. Thus, we retrospectively evaluated ERCP procedures before and after the introduction of EUS, analyzing the changes in the clinical practice of ERCP.

**MATERIALS AND METHODS**

**Subjects**

This study was approved by the institutional review board at our hospital. All procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000. The study is a single-center retrospective study reviewing all ERCP procedures performed over a 3-year period between January 2010 and January 2013. The first one and half years from January 2010 to July 2011 before the introduction of EUS in the hospital was considered as the “before EUS” time period. The remaining one and half years from August 2011 to January 2013 after the introduction of EUS in our institution was considered as the “after EUS” time period. All procedures were performed by single 4th-year trained therapeutic endoscopists. This cohort of patients was referred to the division of Gastroenterology at our tertiary medical center for further work-up of suspected pancreaticobiliary disorders.

**Data collection**

The ProVation® (Minneapolis, MN, USA) system is a proprietary electronic database that is used at our institution to enter procedural information in real-time. All data were extracted using the same electronic database. The data include patient demographics (age, gender), indication of the ERCP, type of sedation (general anesthesia, monitored anesthesia care, or moderate sedation), therapeutic interventions, ERCP findings, ERCP success, complications, and complexity of ERCP as per American Society for Gastrointestinal Endoscopy (ASGE) complexity guidelines.\cite{[6]}

**Definitions**

The outcome of an ERCP was classified as a complete success, a partial success, or a failure.

Complete success meant that all intended therapeutic procedures for that patient were performed. Partial success was defined as a procedure in which some components of the intended therapy were performed successfully, regardless of whether the patient required a second ERCP. Failure was defined as inability to perform even a single component of the intended therapeutic goal.\cite{[7]} Bleeding was defined in the range of mild endoscopic and clinical bleeding requiring no blood transfusion, to moderate/severe bleeding requiring blood transfusion or angiographic/surgical intervention.\cite{[8,9]} ERCP-related perforation was defined as a slight leak or definite perforation requiring medical treatment.\cite{[8,9]} Post-ERCP pancreatitis was diagnosed if patients had new or worsening abdominal pain along with threefold hyperamylasemia 24 h following ERCP. Cholangitis is an infection defined as fever, tachycardia, tachypnea, and leukocytosis, which can occur after the procedure.\cite{[8,9]} Complexity of ERCP was defined as per ASGE complexity guidelines described by Cotton et al.,\cite{[6]} summarized in Table 1.

**Data processing and statistical analysis**

Descriptive statistics was used to represent the means, averages, and percentages of data collected. The categorical variables between the two time periods (before EUS and after EUS) were compared using Fisher’s exact test, while continuous variables were compared using the unpaired $t$-test. Logistic regression and multinomial logistic regression were used to obtain the odds ratio (OR) of ERCP success, complexity level, and complications between the two time periods. Multivariable logistic regression was used to compare the ERCP procedure outcome after adjusting the
complexity level, and $P$ value less than 5% was considered as statistically significant. Analysis was performed using Statistical Analysis System (SAS) V9.3 (SAS Institute, Cary, NC, USA).

## RESULTS

### Baseline characteristics

A total of 945 ERCPs were included in the study. Four hundred eleven (411) ERCPs (43.4%) were present in the “before EUS” and 534 (56.5%) in the “after EUS” time period, respectively. One hundred seventy-five (175) patients in the “before EUS” time period were males with a mean age of 51.2 years. Two hundred three (203) patients in the “after EUS” time period were males with a mean age of 51.9 years [Table 2].

The two most common indications of ERCP in both time periods were obstructive jaundice (before EUS, 36.98%; after EUS, 34.08%) and choledocholithiasis (before EUS, 25.54%; after EUS, 26.03%). The most commonly used sedations were moderate sedation (up to 65%) before the introduction of EUS and general anesthesia (up to 76%) after the introduction of EUS.

### Volume and success

There was a 30% relative increase in the volume of ERCPs after the introduction of EUS (411 before EUS, 534 after EUS). There was an increase in the frequency of precut sphincterotomy (0.97% vs 5.43%, $P = 0.0002$), metal stent placement (1.95% vs 5.43%, $P = 0.0062$), pancreatic stent placement (5.6% vs 10.11%, $P = 0.0119$), use of spyglass (3.16% vs 6.37%, $P = 0.0247$), and EUS-guided biliary cannulation “rendezvous” (0% vs 1.5%, $P = 0.0127$) after the introduction of EUS. There was also an increase in the number of ERCPS (levels 1, 2, and 3) after the introduction of EUS, but $P$ values were not significant.

### Complexity

The complexity of ERCP was increased after the introduction of EUS. The OR of complexity level 4 ERCP was 4.44 (CI: 1.92-10.24, $P = 0.0005$) after EUS introduction [Table 3]. On further analysis, there was an increase in the number of ERCPS (levels 1, 2, and 3) after the introduction of EUS, but $P$ values were not significant.

### Complications

The complication rate was 4.6 times higher in the “after EUS period” compared to the “before EUS period” (OR = 4.63, CI: 1.90-11.3, $P = 0.0007$). The most common complications we found in the “after EUS” time period were cholangitis (up to 73.3%) and post-ERCP pancreatitis (up to 20%). It was noted that bleeding and cholangitis were common in the “before EUS” time period, each contributing up to 42.8% [Table 3].

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**Table 1: ERCP proposed complexity levels (Cotton et al., Reference 6)**

| Level of complexity | Description |
|---------------------|-------------|
| **Level 1 of complexity** | Deep cannulation of duct of interest, main papilla, sampling |
| **Level 2 of complexity** | Biliary stent removal/exchange |
| **Level 3 of complexity** | Biliary stone extraction <10 mm, Treat bile duct leaks, Treat intrahepatic benign and malignant strictures, Place prophylactic pancreatic stents |
| **Level 4 of complexity** | Biliary stone extraction > 10mm, Minor papilla cannulation in divisum and therapy, Removal of internally migrated biliary stents, Intraductal imaging, biopsy, fine needle aspiration, Management of acute or recurrent pancreatitis, Treat pancreatic strictures, Removal of pancreatic stones mobile and <5 mm, Treat hilar tumors, Treat benign biliary strictures, hiliar and above, Manage suspected sphincter of Oddi dysfunction, EUS guided biliary cannulation “rendezvous”, ERCP after Whipple or Roux-en-Y bariatric surgery |

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**Table 2: Baseline characteristics of patients who underwent ERCP in “before EUS” and “after EUS” time periods**

|                      | “Before EUS” | “After EUS” | $p$ value |
|----------------------|-------------|-------------|-----------|
| Total number, n      | 411         | 534         |           |
| Males, n (%)         | 175 (42.6)  | 203 (38.01) | 0.20      |
| Females, n (%)       | 236 (57.4)  | 331 (61.99) |           |
| Mean age in years    | 51.2        | 51.9        | 0.13      |
| Common indications   |             |             |           |
| of ERCP, n (%)       |             |             |           |
| Jaundice             | 152 (36.98) | 182 (34.08) | 0.005     |
| Choledocholithiasis  | 105 (25.54) | 139 (26.03) |           |

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DISCUSSION

In the last 20 years we have observed a continuous evolution in EUS, as the quality of images has markedly improved.\textsuperscript{[10]} It has transitioned from a technique purely for diagnostic imaging to an invasive diagnostic procedure with the advent of fine-needle aspiration (FNA). Finally, it has evolved to a therapeutic procedure with an increase in the number of endoscopists performing the procedure.\textsuperscript{[10]} EUS is the most sensitive and specific imaging modality for the diagnosis of pancreaticobiliary disorders and gastrointestinal malignancies.\textsuperscript{[1,2,9]} The ability to perform therapeutic intervention with EUS guidance is potentially advantageous in complex ERCP, and it can improve outcomes and minimize complications.\textsuperscript{[9]}

In the current study, we evaluated the variability of the success rate and complexity of ERCP with the introduction of new EUS in our hospital. We found that the success rate of ERCP significantly improved. Furthermore, we were able to perform more complex ERCP procedures, including level 4 ERCP, after the introduction of EUS. In addition, there was an increase in EUS-guided biliary cannulation “rendezvous” in the “after EUS” time period from the “before EUS” time period. It is worth mentioning that the complication rate was higher after the introduction of EUS. This could be due to referral bias, as sicker and more complex patients were referred to our center after the introduction of the therapeutic EUS service.

Our study also showed an increase in the volume of ERCP after the introduction of EUS. Ideally, the volume of ERCP was expected to be lowered because diagnostic ERCPs were not performed any time after the introduction of EUS. However, introducing the EUS service increased regional referral for both EUS and ERCP.

Many previous studies have compared EUS and ERCP in various dimensions. Scheiman et al. showed that EUS was most useful for confirming a normal biliary tree and should be considered as a low-risk alternative to ERCP.\textsuperscript{[2]} Mesenas considered therapeutic ERCP to have had a vital role in the treatment of pancreatic and biliary disorders, even though EUS-guided FNA was well established.\textsuperscript{[11]} As per Ahmad et al., ERCP and EUS retain equally important roles in the management of both benign and malignant pancreatic and biliary disease in a therapeutic setting.\textsuperscript{[12]} Liu et al. showed that EUS could safely replace diagnostic ERCP in the management for selecting patients with choledocholithiasis for therapeutic ERCP with a higher successful examination rate, a higher sensitivity in the detection of cholelithiasis, and a comparable morbidity rate.\textsuperscript{[13]} As per Lee et al., it has been shown that EUS is a safe and accurate test to select patients of biliary obstructive disease for therapeutic ERCP.\textsuperscript{[14]}

Our study was the first evaluation of the direct impact of EUS service on the success and complexity of ERCP in a tertiary referral center. Because EUS is becoming increasingly popular and is also being used for therapeutic interventions, the introduction of EUS is very beneficial for better ERCP outcomes in addition to increasing the feasibility of performing complex ERCP procedures. This study has a limitation. As it is a retrospective single-center study, there was potential for selection bias.

CONCLUSION

In summary, the introduction of a new EUS service in our tertiary referral medical center is associated with an increase in the volume, success, and complexity of ERCP procedures. EUS expertise may be valuable for better ERCP outcomes.

Table 3. Volume, success, complexity and complications of ERCP between ‘before EUS’ and ‘after EUS’ time periods

|                          | “Before EUS” | “After EUS” | Odds ratio (Confidence Interval) | p-value |
|--------------------------|-------------|-------------|---------------------------------|---------|
| Volume, N                | 411         | 534         |                                 |         |
| Success, N               | 384         | 495         | 4.54 (1.85-11.14)               | 0.001   |
| Complexity level 4 ERCP, N | 7           | 48          | 4.44 (1.92-10.24)               | 0.0005  |
| Complications, N         | 7           | 30          | 4.63 (1.90-11.3)                | 0.0007  |
| Bleeding, N (%)          | 3 (42.8)    | 1 (3.3)     |                                 |         |
| Perforation, N (%)       | 1 (14.3)    | 1 (3.3)     |                                 |         |
| Post-ERCP pancreatitis, N (%) | 0 (0.0) | 6 (20.0)     |                                 |         |
| Infection/Cholangitis, N (%) | 3 (42.8) | 22 (73.3)    |                                 |         |
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CONFLICTS OF INTEREST
There are no conflicts of interest.

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