

## Retrospective Study

## Rotational assisted endoscopic retrograde cholangiopancreatography in patients with reconstructive gastrointestinal surgical anatomy

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**Ethics approval:** The study was reviewed and approved by the Duke University Health System (DUHS) Institutional Review Board (IRB).

**Informed consent:** The study is a retrospective review. Only general demographic information in regards to the patients was obtained. No informed consent was obtained from involved persons. A waiver of consent was filled and approved by DUHS IRB.

**Conflict-of-interest:** All authors declare that there is no conflict of interest.

**Data sharing:** No additional data are available.

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### Abstract

**AIM:** To evaluate the success rates of performing therapy utilizing a rotational assisted enteroscopy device in endoscopic retrograde cholangiopancreatography (ERCP) in surgically altered anatomy patients.

**METHODS:** Between June 1, 2009 and November 8, 2012, we performed 42 ERCPs with the use of rotational enteroscopy for patients with altered anatomy (39 with gastric bypass Roux-en-Y, 2 with Billroth II gastrectomy, and 1 with hepaticojejunostomy associated with liver transplant). The indications for ERCP were: choledocholithiasis: 13 of 42 (30.9%), biliary obstruction suggested on imaging: 20 of 42 (47.6%), suspected sphincter of Oddi dysfunction: 4 of 42 (9.5%), abnormal liver enzymes: 1 of 42 (2.4%), ascending cholangitis: 2 of 42 (4.8%), and bile leak: 2 of 42 (4.8%). All procedures were completed with the Olympus SIF-Q180 enteroscope and the Endo-Ease Discovery SB overtube produced by Spirus Medical.

**RESULTS:** Successful visualization of the major ampulla was accomplished in 32 of 42 procedures (76.2%). Cannulation of the bile duct was successful in 26 of 32 procedures reaching the major ampulla (81.3%). Successful therapeutic intervention was completed in 24 of 26 procedures in which the bile

duct was cannulated (92.3%). The overall intention to treat success rate was 64.3%. In terms of cannulation success, the intention to treat success rate was 61.5%. Ten out of forty two patients (23.8%) required admission to the hospital after procedure for abdominal pain and nausea, and 3 of those 10 patients (7.1%) had a diagnosis of post-ERCP pancreatitis. The average hospital stay was 3 d.

**CONCLUSION:** It is reasonable to consider an attempt at rotational assisted ERCP prior to a surgical intervention to alleviate biliary complications in patients with altered surgical anatomy.

**Key words:** Gastric bypass; Gastrostomy; Cholangio-pancreatography; Endoscopic retrograde; Double-Balloon enteroscopy; Ampulla of Vater; Sphincterotomy; Endoscopic; Pancreatitis; Retrospective studies

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**Core tip:** This manuscript shows a single tertiary care center experience in a large number of patients with surgically altered anatomy by evaluating the success rates of reaching the major ampulla, cannulating the bile duct, and subsequently performing therapy utilizing a rotational assisted enteroscopy device in an endoscopic retrograde cholangiopancreatography. This study will also determine the associated morbidity, mortality, and length of hospitalization associated with the procedures. Given our institutions success rates and minimal complication profile, specialized centers could consider this approach in this rapidly growing population. This will be instrumental in the development of new therapeutic options for patients suffering from this condition.

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## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) remains the gold standard in both diagnosis and therapeutic management of pancreato-biliary diseases. However, patients with surgically altered anatomy present a unique endoscopic challenge. In patients with normal anatomy, rate of successful cannulation and sphincterotomy by expert endoscopists is greater than ninety percent<sup>[1]</sup>. In patients who have had reconstructive gastrointestinal surgery, reaching

the ampulla and subsequently performing therapy during ERCP has been reported in a multicenter study to be 63%<sup>[2]</sup>. Additionally, as the obesity epidemic has widened in the United States, patients with altered anatomy due to bariatric surgery are increasingly presenting with the need for evaluation for pancreato-biliary disease<sup>[3]</sup>.

Multiple methods have been described to gain access to the biliary tract in post surgical patients, which is particularly challenging because the standard duodenoscope cannot reach the ampulla due to increased distance of the Roux limb. Methods to gain biliary access with a standard duodenoscope, such as a surgically created gastrostomy have been previously described<sup>[4-6]</sup>. Non-surgical endoscopic methods using different types of enteroscopy techniques have also been described. These endoscopic techniques include double-balloon, single-balloon, and rotational assisted-ERCP (RA-ERCP)<sup>[7-9]</sup>.

The goal of this retrospective study is to review a single tertiary care center experience in RA-ERCP in patients with reconstructive gastrointestinal surgery. Outcomes measured include the success rates of reaching the major ampulla, cannulating the bile duct, and subsequently performing a complete ERCP. Additionally, the associated morbidity, mortality, and length of hospitalization associated with RA-ERCP were measured.

## MATERIALS AND METHODS

### Study and patients

An IRB approved retrospective review of all patients undergoing rotational assisted ERCP was performed.

Between June 1, 2009 and November 8, 2012, a total of 42 RA-ERCPs were attempted for patients with altered anatomy. Thirty-three of these patients underwent Roux-en-Y gastric bypass, 2 underwent Billroth II gastrectomy, and 1 underwent hepaticojejunostomy associated with liver transplant. A total of 6 patients had repeat procedures.

### Procedures

Sedation for the procedures were either moderate sedation (9 patients) or general anesthesia (33 patients) with the positioning of all patients in the prone position. An attending advanced endoscopist performed all procedures with the assistance of the advanced endoscopy fellow. A total of 4 attending physicians with experience in rotational assisted ERCP performed the procedures.

All RA-ERCPs were performed using an Olympus SIF-Q180 enteroscope and the Endo-Ease Discovery SB overtube manufactured by Spirus Medical.

Patients were not randomized, as the procedure was chosen based on availability and physician discretion. Procedural time for RA-ERCP was determined from the onset of the "time-out" patient verification to the time

**Table 1 Patient characteristics**

No. of patients	36
No. of ERCPs	42
Age	49.3
Sex	M = 2, F = 34
BMI	36.3
Roux-en-Y surgery patients	33
Billroth II surgery patients	2
Hepaticojejunostomy associated with liver transplant	1

M: Male; F: Female; ERCP: Endoscopic retrograde cholangiopancreatography.

**Table 2 Indications for endoscopic retrograde cholangiopancreatography**

Suspected gallstones/choledocholithiasis	13
Sphincter of Oddi dysfunction I / II	1/3
Biliary obstruction on imaging	20
Ascending cholangitis	2
Biliary obstruction with negative imaging	1
Bile leak	2

the patient arrived in the recovery bay.

### Statistical analysis

The statistical methods of this study were reviewed by Majed El Zouhairi, MD and Rebecca Burbridge, MD from Duke University Medical Center.

## RESULTS

Rotational enteroscopy was performed in forty-two separate procedures, in thirty-six patients with altered anatomy. Thirty-four patients were women (94.4%) and the mean age was 49.3 (range 29-75) (Table 1). The indications for ERCP were: biliary obstruction suggested on imaging 20 of 42 (47.6%), choledocholithiasis 13 of 42 (30.9%), suspected sphincter of Oddi dysfunction 4 of 42 (9.5%), ascending cholangitis 2 of 42 (4.8%), bile leak 2 of 42 (4.8%), and abnormal liver enzymes 1 of 42 (2.4%) (Table 2). The ability to reach and visualize the major ampulla was successful in 32 of 42 procedures (76.2%) (Figure 1). Attempted cannulation of the bile duct was performed in 29 out of the 32 procedures which successfully reached the major ampulla, with a subsequent bile duct cannulation rate of 89.7% (Figure 2). No attempt was made to cannulate the bile duct in three patients because procedures were only intended to remove previously placed stents. The reason for failed cannulation in the three patients in whom we were not able to cannulate the bile duct despite reaching the ampulla was an ampullary polyp (1 patient) and biliary stricture (2 patients). Successful therapeutic intervention including, but not limited to, sphincterotomy, stone removal, bile duct/pancreatic duct stent placement, balloon sweeping, and brushing was completed in 24 of 26 procedures

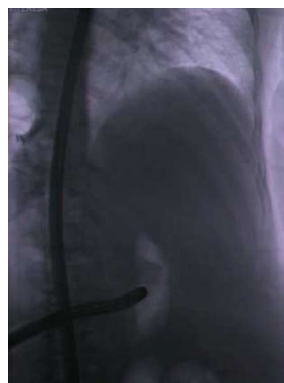


Figure 1 Scout film with the positioning of the scope.



Figure 2 Cholangiogram.

in which the bile duct was cannulated (92.3%) (Figure 3). Of the total 42 cases, there were 15 failed cases, and 27 successful procedures, therefore the overall intention to treat success rate was 64.3%. In terms of cannulation success, 24 of 39 attempts at cannulation were successful, with an intention to treat success rate of 61.5%.

Ten patients out of 42 procedures (23.8%) required hospital admission for abdominal pain and nausea following the procedure. Three of those 10 patients (7.1%) had a diagnosis of post-ERCP pancreatitis. The average hospital stay was 3 d (Table 3). There were no overtube related complications.

## DISCUSSION

Surgically altered anatomy has become increasingly more common in the United States, particularly due to bariatric surgery. Reaching the ampulla in patients with surgically altered anatomy remains challenging even for skilled endoscopists despite advances in deep small bowel enteroscopy. Currently, the standard of care for pancreato-biliary disease in these patients often involves surgical assistance to help access the major ampulla. Success rates with single-balloon<sup>[10-13]</sup> and double-balloon enteroscopy systems<sup>[2,14-19]</sup> have been reported to range from 60% to 88%<sup>[2]</sup>. In limited studies, RA-ERCP has been shown to be a promising

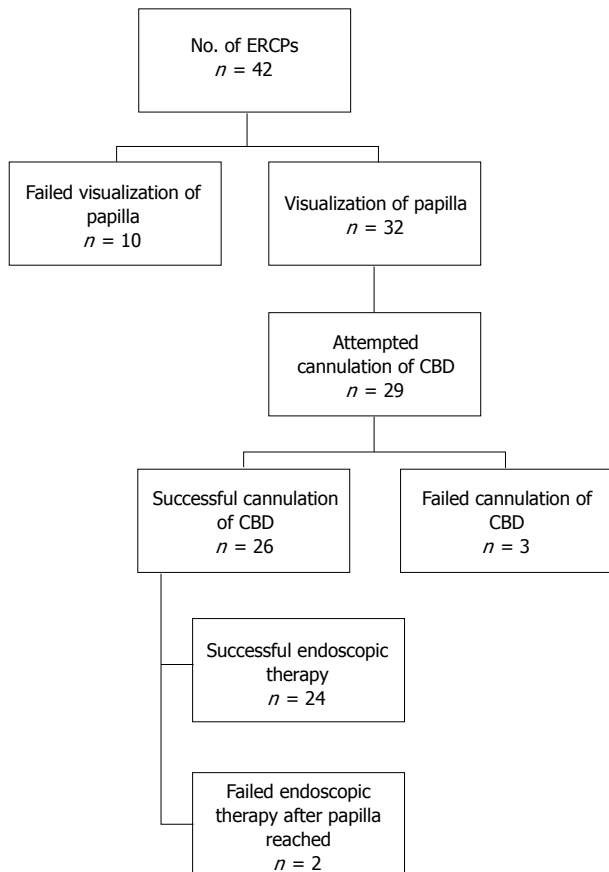


Figure 3 Outcomes. ERCP: Endoscopic retrograde cholangiopancreatography.

technique for pancreato-biliary access in post surgical patients. Hegde *et al*<sup>[7]</sup> reported that RA-ERCP allowed successful cannulation in 2 patients after double-balloon assisted ERCP had failed, but that it was more time-consuming. Al-Lehibi *et al*<sup>[8]</sup>, also noted that RA-ERCP was successful in 5 of 6 cases. A recent prospective study reported in 2012 by Wagh *et al*<sup>[9]</sup> on 13 patients showed that cannulation of the desired duct and endoscopic therapy using RA-ERCP in patients with surgically altered anatomy was successful in 90% of the procedures if the papilla/duct-enterostomy was reached.

A recent multi-center retrospective study published in January 2013 by Shah *et al*<sup>[2]</sup> compared ERCP success in 129 patients with surgically altered anatomy utilizing single-balloon (SBE), double-balloon (DBE), or rotational overtube enteroscopy. Fifty-seven RA-ERCP cases were performed with an intention to treat success rate of 63%, defined as successful planned therapeutic intervention. They concluded that therapeutic success in long-limb surgical bypass was similar regardless of the endoscopic method used.

Our study is the largest single-center experience evaluating RA-ERCP in patients with reconstructed gastrointestinal anatomy. We noted RA-ERCP procedural success rate in visualizing the ampulla of 76.2%, cannulating the bile duct in procedures reaching the major ampulla of 81.3%, and successfully completing

Table 3 Complications

Adverse events	10
No. of admission	10
Length of hospital stay after admission (d)	3

therapeutic interventions after cannulating the major ampulla of 92.3% with an overall intention to treat success rate of 61.5%. This seems consistent with the rate published by Shah *et al*<sup>[2]</sup>, and would suggest that RA-ERCP is on par with other non-surgical endoscopic techniques.

Limitations of this study include the lack of direct comparison with other deep enteroscopy techniques. A second limitation is that all procedures were performed in a tertiary-care center which may not be generalizable to smaller gastroenterology practices which serve a local community. Additionally, the strength of one specific endoscopic technique for non-ERCP enteroscopy has not been consistently demonstrated. The concept that experience may play an important role in success is supported by data from the non-ERCP enteroscopy literature. For example the efficacy of double balloon compared to rotation assisted enteroscopy is still debatable and experience in either modality may be more important than the type of enteroscopy modality chosen<sup>[20-22]</sup>.

Given our institution's success rates and minimal complication profile, we believe it is reasonable to consider an attempt at rotational assisted ERCP prior to a surgical intervention to evaluate pancreato-biliary diseases in patients with altered surgical anatomy. Our data, as well as other smaller studies, have confirmed the safety and relative efficacy of this approach. In determining the method of endoscopic approach to ERCP in post surgical patients, relative experience with other enteroscopy modalities such as DBE or SBE should also be considered.

## COMMENTS

### Background

Endoscopic retrograde cholangiopancreatography (ERCP) has been a mainstay in the diagnosis and management of pancreato-biliary diseases. With the use of a standard duodenoscope, success rates are greater than ninety percent in patients with normal gastrointestinal anatomy. However, reaching the ampulla and subsequently performing therapy during ERCP is difficult in patients with surgically altered anatomy. Utilizing a rotational enteroscopy device to assist in reaching the ampulla in this population may increase the chances of being able to successfully complete the procedure.

### Research frontiers

There have been only a few small number of studies examining the use of RA-ERCP in approaching biliary complications in patients with Roux-en-Y gastric bypass surgery.

### Innovations and breakthroughs

This manuscript shows a single tertiary care center experience in a large number of patients with surgically altered anatomy by evaluating the success rates of reaching the major ampulla, cannulating the bile duct, and subsequently performing therapy utilizing a rotational assisted enteroscopy device in order to complete an ERCP. This study will also determine the associated morbidity, mortality, and length of hospitalization associated with the procedures.



## Applications

Surgically altered anatomy has become increasingly more common in the United States, particularly due to bariatric surgery. Currently, the standard of care for pancreatobiliary complications in these patients often involves surgical assistance to help access the major ampulla. Given our institutions success rates and minimal complication profile, the authors believe it is reasonable to consider an attempt at rotational assisted ERCP prior to a surgical intervention to alleviate biliary complications in patients with altered surgical anatomy.

## Terminology

ERCP; rotational assisted-ERCP (RA-ERCP); single-balloon enteroscopy (SBE); double-balloon enteroscopy (DBE).

## Peer-review

This paper is interesting.

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