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**Endoscopic retrograde cholangiopancreatography by double-balloon enteroscopy in patients with surgically altered gastrointestinal anatomy**

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**ABSTRACT**

**Background:** Endoscopic retrograde cholangiopancreatography (ERCP) allows a diagnostic and therapeutic evaluation of pancreatobiliary diseases. However, the procedure in patients with surgically altered gastrointestinal anatomy represents a technical challenge.

**Objective:** to report the diagnostic and therapeutic outcome of device-assisted enteroscopy (DAE) ERCP in patients with a surgically altered gastrointestinal anatomy.

**Methods:** a prospective cohort of patients with a history of surgically altered gastrointestinal anatomy undergoing DAE-ERCP in a referral center was used. A double-balloon enteroscope was used to reach the papillary area or the bilio-enteric anastomosis. The clinical and endoscopic characteristics, and technical, diagnostic and therapeutic success were described. Clinical and endoscopic differences were evaluated according to diagnostic success, as well as the biochemical response in those patients with therapeutic success.

**Results:** ninety-six procedures were included in the study in 75 patients. Roux-en-Y hepaticojejunostomy (RYHJ) was the main surgical anatomy (82.3%) and cholangitis was the main indication for ERCP (49%). Diagnostic success was obtained in 69.8% of the participants. Of these, therapeutic success was obtained in 83.6% (overall success 58.3%). Cases with a diagnostic success had a higher frequency of cholangiography compared to those without diagnostic success (94% vs 0%,  $p < 0.001$ ), as well as a lower probability of a failed cannulation (1.5% vs 100%,  $p < 0.001$ ). A significant improvement was observed in patients with a therapeutic success in bilirubin, transaminases and alkaline phosphatase levels ( $p < 0.05$ ).

**Conclusions:** ERCP by means of double-balloon enteroscopy is a useful technique in patients with a surgically altered gastrointestinal anatomy, in whom access to the bile duct is required. However, these procedures are very challenging and diagnostic and therapeutic success were achieved in up to 60% of cases.

**Key words:** Double balloon enteroscopy. Surgical altered anatomy. Endoscopic retrograde cholangiopancreatography.

## INTRODUCTION

Modern gastrointestinal surgery has led to various reconstruction techniques, such as Roux-en-Y, to maintain gastrointestinal and pancreatobiliary continuity. The need for

invasive pancreatobiliary interventions is not uncommon in these patients. Endoscopic retrograde cholangiopancreatography (ERCP) is a well-recognized intervention and the standard approach in many scenarios (1). Access to the pancreatobiliary ducts has been possible since the development of device-assisted enteroscopy (DAE) ERCP (2).

There are several challenges when performing DAE-ERCP in patients with surgically altered gastrointestinal anatomy. These include the length of the afferent limb, acute angle at the jejunojunostomy, tortuosity due to adhesions, biliopancreatic cannulation failure and the need for subsequent diagnostic and therapeutic procedures (3). DAE-ERCP in these patients entails greater technical difficulties than in individuals with a normal gastrointestinal anatomy (1). The success of the procedure is difficult to achieve even when the native papilla or hepaticojejunostomy is reached. One of the reasons for DAE-ERCP failure is the design of the enteroscopes, which are not meant for ERCP. The scope is slim with a small working channel diameter, which limits the use of many accessories. In addition, these are forward-viewing devices, representing an added difficulty to cannulate the papilla or hepaticojejunostomy (4). This is particularly true for the latter in unfavorable orientations of the pancreatobiliary anastomosis or significant stenosis, especially when the intact papilla is approached (5-7).

ERCP success rate has improved substantially since McCune et al. reported a 25% cannulation rate in 1968 in patients with a normal gastrointestinal anatomy (8). Skinner et al. reported a systematic review in 2014 of DAE-ERCP in patients with surgically altered gastrointestinal anatomy, which included 945 procedures in 679 patients. The study reported an endoscopic success rate with the use of a double-balloon enteroscope (DBE) of 89% (73-100%), a 93% diagnostic success rate (85-100%) and an ERCP success rate of 82% (63-95%). Single-balloon procedures had a lower success rate, with 82% endoscopic success (75-100%), 86% diagnostic success (76-100%) and 68% for ERCP (60-100%) (9). However, studies that included a greater number of cases with a history of Roux-en-Y hepaticojejunostomies (RYHJ) reported lower overall successes (60-66%) (10,11).

The aim of this study was to report the outcomes of DAE-ERCP in patients with surgically altered gastrointestinal anatomy in a population with a high frequency of RYHJ.

## **METHODS**

This was a prospective observational study of consecutive patients with surgically altered gastrointestinal anatomy undergoing DAE-ERCP from June 2010 to July 2016. The study was performed at a third level academic center in Mexico City (National Institute of Medical Sciences and Nutrition Salvador Zubirán).

The procedure (DBE-ERCP), therapeutic possibilities (injection, sphincterotomy, precut access, dilation, plastic stent placement) and the alternative procedures to endoscopy (interventional radiology, surgery) were explained to each patient. All participants gave their written informed consent prior to the procedure. The study was performed in accordance with the Declaration of Helsinki.

The following outcomes were considered: a) *enteroscopic, technical or intubation success*, defined as access to the blind end of the afferent limb or identification of the papilla; b) bilioenteric or pancreaticoenteric anastomosis; c) *diagnostic success* such as cannulation of papilla or bilioenteric or pancreaticoenteric anastomosis, with/or adequate diagnostic cholangiography/pancreatography; and d) *therapeutic success* such as the ability to treat the underlying cause (dilation, stone removal, insertion or withdrawal of plastic stents, sphincterotomy, precut).

In addition, the biochemical response was evaluated in patients with therapeutic success by comparing the levels of total bilirubin (TB), direct bilirubin (DB), alanine amino transferase (ALT), aspartate amino transferase (AST) and alkaline phosphatase (AF) before and two weeks after the study. ERCP complications were defined according to standard criteria (cholangitis, pancreatitis, bleeding and perforation) (12,13). Patients were followed for two weeks after the procedure in order to collect the data.

### **Description of the procedure**

All procedures were performed by two expert endoscopists (> 200 enteroscopy procedures/year). ERCP studies were performed with the long-length DBE (EN-450T5 with a 2.8-mm diameter working channel and DBE-EN-580T with a 3.2-mm diameter working

channel, Fujinon, Saitama, Japan) and the short-type DBE (EC-450BI5 with a 2.8-mm diameter working channel, Fujinon, Saitama, Japan), attaching a cap to the tip of the scope (Distal Attachment Cap 11.35 mm, US Endoscopy, Ohio, USA). The patients were placed in the prone position and the endoscopy was performed under sedation with midazolam, propofol and fentanyl or orotracheal intubation, according to the anesthesiologist's judgment. Vital signs were continuously monitored. Antibiotics were administered prior to the procedure according to the endoscopist's judgment and hyoscine was administered in cases of vigorous peristalsis to allow cannulation. Endoscopic procedures were performed under fluoroscopic control using a C-arm (Siemens, Germany). In patients with Roux-en-Y, the double balloon was advanced in the small intestine until it reached the jejunojejunal anastomosis. The identification of the afferent limb in cases of Roux-en-Y was performed by anatomic characteristics (position, angulation, presence of bile), intraluminal injection of indigo carmine or enterography with CO<sub>2</sub> insufflation under fluoroscopic guidance if the indigo carmine did not reach the area of the anastomosis (14,15). Cannulation of the hepaticojejunostomy/pancreaticojejunostomy or papilla was performed using the standard sphincterotome or Billroth-II (MTW, Wesel, Germany) and guide wire (MTW, Wesel, Germany). Additional accessories were used to achieve the following interventional procedures: cholangiography and stone extraction using a triple lumen balloon (MTW, Wesel, Germany); wire guided balloon dilatation catheter for diameters of 8-10 mm and 10-12 mm (Boston Scientific CRE™ TTS, Microvasive, Cork, Ireland); sphincterotomy using Billroth-II papillotome or precut access using a HF-needle (MTW, Wesel, Germany). CO<sub>2</sub> was supplied in all patients at a rate of 1.8 l/min (GW-1, Fujifilm).

### **Statistical analysis**

Demographic, clinical and endoscopic characteristics were presented using descriptive statistics. A univariate analysis was performed to identify the differences in clinical and endoscopic variables between procedures, with and without diagnostic success, using the Mann-Whitney U test for independent samples with quantitative variables and the

Fisher's exact test for nominal variables. Differences in biochemical variables, pre and post-intervention, were analyzed using the Wilcoxon test. A p value of < 0.05 was considered as statistically significant. The analysis was performed using the Statistical Package for Social Sciences Version 21 (SPSS IBM, Armonk, New York, USA).

## RESULTS

A total of 96 procedures in 75 patients were analyzed, which included 13 participants with two procedures and four participants with three procedures. The enteroscopes used were DBE-EN-450T5 (n = 55, 57.3%), DBE-EC-450BI5 (n = 20, 20.8%) and DBE-EN-580T (n = 21, 21.9%). Table 1 shows the demographic, clinical and endoscopic characteristics of the participants. The main type of anatomy was RYHJ (82.3%) and the main indication was the presence of cholangitis. Other indications were the presence of a cholestatic pattern in liver function tests, documentation of stenosis of hepaticojejunostomy or lithiasis documented by imaging studies (computed tomography or magnetic resonance cholangiography). The technical success was 77.1% and the diagnostic success was 69.8%; of the latter, therapeutic success was achieved in 84.4% (overall success 58.3%).

In cases where there was technical but not diagnostic success (n = 7), three were due to failures related to the enteroscope. It was not possible to advance the accessory devices through the long-length enteroscope in two cases (DBE-EN-450T5, 2.8 mm diameter working channel) and there was a failure with the lighting source in another case. In the remaining cases, the failure was due to a lack of identification of bilioenteric anastomosis and unfavorable positions for cannulation. It is important to mention that diagnostic success was achieved in one failed cannulation case, although the bilioenteric anastomosis was not found. Once the correct position of the scope at the blind end of the afferent limb was confirmed by fluoroscopic guidance, the scope balloon was inflated and then contrast media was injected, CO<sub>2</sub> insufflation was performed and a cholangiography was obtained. There was no evidence of the stenosis reported by magnetic resonance cholangiography imaging.

Table 2 compares the clinical and endoscopic characteristics between the procedures, with and without diagnostic success. As expected, a higher frequency of cholangiography was observed in cases with a diagnostic success (94% vs 0%,  $p < 0.001$ ), as well as a lower frequency of failed cannulation (1.5% vs 100%,  $p < 0.001$ ). A significant improvement in the biochemical parameters of cholestasis was observed in cases with therapeutic success ( $n = 56$ ), two weeks after the ERCP procedure (Fig. 1).

## DISCUSSION

This study evaluates the role of DBE-ERCP in patients with surgically altered gastrointestinal anatomy and is one of the series with the highest prevalence of patients with HY-RY (82.3%). This type of anatomy comprises around 30-50% in meta-analysis and systematic reviews (9,16). Success in DAE-ERCP can be defined as enteroscopic, diagnostic and therapeutic. There were 30% of failed studies (29/96) in our series, which were entirely due to enteroscopic failure and is similar to that reported by Saleem 2010 (10). The above can be attributed to the type of population evaluated, since the vast majority of our patients needed deep intubations due to the presence of anatomy with Roux-en-Y. In addition, they had more than one surgical intervention and episodes of abdominal sepsis. This resulted in technically difficult procedures due to the presence of adhesions, tortuosity and tight angulations in the small bowel (Fig. 2).

Meta-analyses have reported a greater overall success rate of the DAE-ERCP than that found in our study (63.55-76%) (9,17). However, when the studies included the largest number of cases with RYHJ, their overall therapeutic success rates vary greatly. For example, the overall therapeutic success was 63% in the 2013 Shah multicenter study. However, the number of patients with RYHJ in this series was only 24/129 (18.6%) (11). On the other hand, 41/56 patients (73%) with RYHJ were included in the Saleem 2010 study and the global diagnostic success rate was 70%. However, it is noteworthy that therapeutic procedures were not performed in more than 40% of the 39 patients who had diagnostic success, as they were not required or indicated (10). In our series, this situation only presented in a patient whose study indication was the presence of recurrent



cholangitis. A short afferent limb with the presence of intraluminal indigo carmine was found during the endoscopic examination, with an assumed etiology of ascending cholangitis.

The variability in reported success rates shows the heterogeneity in the type of population studied. This is due to the variability in the surgical technique that determines different lengths of afferent limbs, the type of anastomosis and a lack of standardization of the DAE-ERCP technique. This could be due to the fact that it is a relatively recent endoscopic procedure and to the technical difficulties inherent in each patient.

It is important to emphasize the safety and low rate of major complications related to this procedure. The major complications in the reported studies ranged from 0 to 12% (11,18). In our study, the overall complication rate was 14.5% (14/96), of which 9.4% (9/96) were major complications, mostly related to cholangitis, and all episodes were classified as mild. However, hospitalization was necessary because they were patients with frequent bile duct instrumentation and recurrent episodes of cholangitis. In this regard, it is important to comment that invasive procedures of the bile duct are frequent in this group of patients, which favors their colonization. Thus, increasing the susceptibility to perform bacterial translocation during the endoscopic procedure.

One of the strengths is the evidence of the improvement in biochemical parameters in those patients in whom therapeutic success was achieved (Fig. 1). Previously, Pohl J in 2008 and Raithel M in 2011 reported an improvement in bilirubin levels after ERCP. However, early improvement of the parameters of cholestasis and transaminases has not been documented (18,19). In the study by Shah in 2013, the reduction in liver enzymes and/or normalization in bilirubin levels was considered as a parameter of clinical response (11). However, the follow-up time (mean 6.1 months) was longer than in our study (two weeks), which may explain the greater reduction reported. The presence of clinical and biochemical data of chronic liver disease was reported in our population and it must be considered for future studies. This may influence the lack of normalization of liver enzymes and bilirubin, as well as greater decompensation in case of complications during the procedure.

Although DAE-ERCP has positioned itself as a useful tool in the management of patients with surgically altered gastrointestinal anatomy, there are currently limitations for the generalization. These include the lack of availability of this technique in all the centers and the requirement for trained personnel, equipment and special accessory devices (in the case of long enteroscopes). Therefore, the management of this group of patients must be multidisciplinary, and other therapeutic modalities such as radiology and surgery are fundamental and complementary. In this study, cases of endoscopic failure were referred for management with interventional radiology (55.2%), surgery (34.5%) and endoscopic ultrasound (3.4%).

Enteroscopy has the advantage of direct and fluoroscopic viewing, greater control of the procedure and specific procedures are allowed such as selective cannulation of the bile duct, direct cholangioscopy, biopsy, etc. Furthermore, there is a prompt detection of complications and endoscopic treatment in specific scenarios (hemostasis, closure of perforations and tears, etc.). Among the main limitations of this study are the short follow-up and the small sample size, which did not allow a stratified analysis.

In conclusion, diagnostic and therapeutic procedures by DAE-ERCP in patients with surgically altered gastrointestinal anatomy are possible and the frequency of major complications is acceptable. Therefore, it could be considered as one of the standards in the management of pancreatobiliary complications in this group of patients.

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**Table 1. Clinical, biochemical and endoscopic characteristics of the patients**

	<i>Media</i>	<i>Range</i>
Age (years)	45.3	18-48
	<i>n</i>	<i>%</i>
Female sex	69/96	71.9
Anatomy		
RYHJ	79/96	82.3
Whipple	10/96	10.4
Billroth II	3/96	3.1
Gastric bypass	2/96	2.1
Esophagus jejunum anastomosis (Roux-en-Y)	2/96	2.1
Indication of ERCP		
Cholangitis	47/96	49.0
Other indications	49/96	51.0
Diagnostic success	67/96	69.8
Overall therapeutic success	56/96	58.3
Therapeutic success in diagnostic success	56/67	83.6
Endoscopic treatment		
Dilation	53/56	94.6
Stone extraction	44/56	78.6
Sphincterotomy/precut	6/56	10.7
Stent	4/56	7.1
Lithotripsy	1/56	1.8
Complications	14/96	14.5
Complications required hospital admission	9/96	9.4
Type of complication		
Cholangitis	7/96	7.3
Pancreatitis	2/96	2.1
Perforation	2/96	2.1

Mucosal tear	2/96	2.1
Hemorrhage	1/96	1.0
Failed ERCP	29/96	30.2
Radiology in failed ERCP	16/29	55.2
Surgery in failed ERCP	10/29	34.5
EUS in failed ERCP	1/29	3.4
	<i>Media</i>	<i>Range</i>
TB (mg/dl)	4.9	6.0
DB (mg/dl)	3.0	3.9
ALT (mUI/ml)	106.6	94.2
AST (UI/l)	96.2	73.5
AF (mUI/ml)	541.6	368.7

ERCP: endoscopic retrograde cholangiopancreatography; RYHJ: Roux-en-Y hepaticojejunostomy; EUS: endoscopic ultrasound; TB: total bilirubin; DB: direct bilirubin; ALT: alanine aminotransferase; AST: aspartate aminotransferase; AF: alkaline phosphatase.

**Table 2. Comparison of the clinical, endoscopic and biochemical characteristics between procedures, with and without diagnostic success**

	<i>Diagnostic success</i>		<i>Without diagnostic success</i>		<i>p</i>
	<i>n = 67</i>		<i>n = 29</i>		
<i>Age (years)</i>	<i>Media</i>	<i>DE</i>	<i>Media</i>	<i>DE</i>	
	45.8	13.6	44.1	15.3	0.607
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	
<i>Men</i>	17	25.4	10	34.5	0.459
<i>Anatomy</i>					
<i>RYHJ</i>	53	79.1	26	89.7	0.258
<i>Whipple</i>	9	13.4	1	3.4	0.273
<i>Billroth</i>	2	3.0	1	3.4	1.000
<i>Gastric bypass</i>	2	3.0	0	0.0	1.000
<i>Esophagus jejunum anastomosis (Roux-en-Y)</i>	1	1.5	1	3.4	0.515
<i>Cholangiography</i>	63	94.0	0	0.0	< 0.001
<i>Failed cannulation</i>	1	1.5	29	100.0	< 0.001
<i>Complications</i>	11	16.4	2	6.9	0.332
<i>Complications required hospital admission</i>	7	10.4	2	6.9	0.719

ERCP: endoscopic retrograde cholangiopancreatography; RYHJ: Roux-en-Y hepaticojejunostomy.

Fig. 1. Biochemical parameters before and after ERCP in the therapeutic success cases. ALT: alanine aminotransferase; AST: aspartate aminotransferase.

$p = 0.002$   $p = 0.015$

$p = 0.023$

$p = 0.025$

$p = 0.029$

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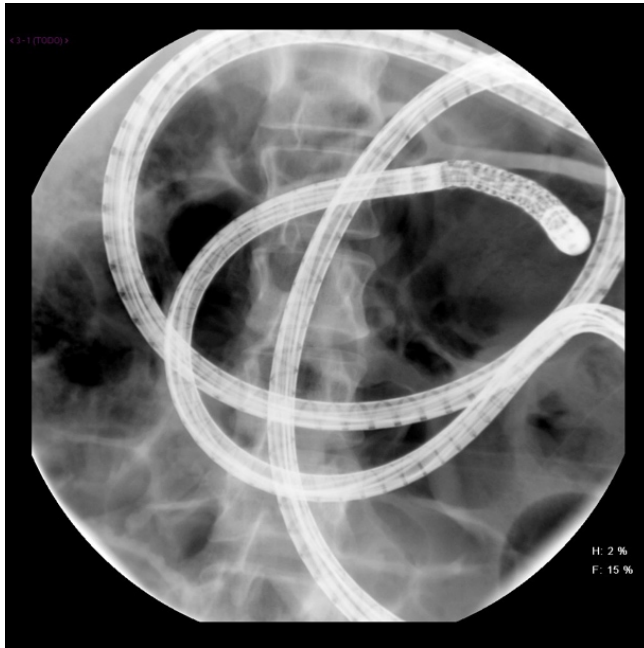


Fig. 2. Failed ERCP due to the presence of adhesions.

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