ORIGINAL ARTICLE

AG-2021-99
doi.org/10.1590/S0004-2803.202200001-06

Factors associated with difficult biliary cannulation in a training center for endoscopic intervention of the biliary tract

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Received: 7 May 2021
Accepted: 3 August 2021

ABSTRACT – Background – This paper aims to determine factors associated with difficult biliary cannulation (DBC) that are identifiable before procedures. **Methods –** This is a nested case-control study within a historical cohort in adult patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) from 2015–2019 in the Hospital Universitario San Ignacio, Colombia. This study assessed the associations among variables that could be identified before or at the beginning of procedures and the probability of DBC. These associations were evaluated through a bivariate and multivariate analysis. The study used criteria for DBC defined by the European Society of Gastrointestinal Endoscopy. **Results –** A total of 498 ERCP performed in 376 patients were analyzed. Of all procedures, 144 (29%) fulfilled criteria for DBC. The multivariate analysis showed an association between DBC and the acute care hospital setting (OR:2.92; CI95% 1.70–5.01; $P<0.001$), redundant papilla (OR:7.26; CI95% 3.38–15.61; $P<0.001$), or peridiverticular papilla (OR:2.45; CI95% 1.38–4.36; $P=0.002$). No association was found between DBC and endoscopist's experience, bilirubin levels, or dilation of the biliary tract. **Conclusion** –– The DBC is a frequent event. Alterations in the papilla and ERCP performed in the acute care hospital setting are the principal factors associated with DBC. This information might be useful to predict DBC and establish healthcare and administrative strategies to reduce its implications.

Keywords – Difficult biliary cannulation; endoscopic retrograde cholangiopancreatography.

INTRODUCTION

Despite technological advances in endoscopic retrograde cholangiopancreatography (ERCP), the technique continues to be difficult and requires a high level of experience from the endoscopist. In reference centers, as many as 35% of biliary cannulations are unsuccessful. General complications in biliary cannulation patients are about 2% in centers with expertise in this population, compared to 7% in centers with low volume ($P<0.001$)[1,2].

The concept of difficult biliary cannulation (DBC) has changed over time[3-5]. Recently, the European Society of Gastrointestinal Endoscopy (ESGE) redefined DBC as more than five contacts with the papilla, unsuccessful cannulation longer than 5 minutes, or more than one unintentional cannulation/opacification of the pancreatic duct (PD)[6]. Even in patients with normal anatomy and easily visible papilla, multiple cannulation attempts can cause mechanical trauma to the papilla and make subsequent attempts more difficult[7]. The resulting edema may obstruct the PD. Also, chemical injury from the inadvertent injection of contrast media in the PD increases the risk of post-ERCP pancreatitis (PEP)[8].

Several factors have been associated with DBC, including the experience level of the endoscopist and the patient's anatomy (type of papilla, altered anatomy, or anatomical variant)[7,9]. Information on this subject, however, continues to be limited. There has not been an assessment based on ESGE's new definition of how factors identifiable before the procedure would be associated with the probability of a DBC. This information might be very useful in ERCP planning, allowing necessary precautions to improve the probability of success.

The objective of this study is to analyze the associations among factors identifiable before or at the beginning of ERCP procedures and DBC probability at a training center for endoscopic intervention of the biliary tract in Bogotá, Colombia.

METHODS

This observational, analytical, case-control study was nested in a historical cohort. The study included adult patients undergoing ERCP for any indication in the Gastroenterology Unit of the San Ignacio University Hospital, Colombia, between 2015 and 2019. Exclusion criteria were a history of upper digestive tract surgery and any procedures ended before a biliary cannulation attempt. The Ethics Committee of the San Ignacio University Hospital and the Pontificia Universidad Javeriana approved the study.

All patients undergoing ERCP in the study period were identified from a database where all procedures performed in the Gastroenterology Unit are systematically registered. All patients were taken to ERCP after preparation with fasting of at least 8 hours,

Declared conflict of interest of all authors: none
Disclosure of funding: no funding received
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withdrawal of anticoagulant medications within the safety times established by international recommendations. All patients received general anesthesia after pre-anesthetic evaluation. According to the preference of the professional in charge, we proceeded in supine or left lateral decubitus. The equipments used in the study were the Duodenum olympus TJF 160 duodenoscope and Duodenum olympus TJF Q180.

A randomized sample completed the calculated sample size. The demographic characteristics, ERCP indication, laboratory test results, and complications after the procedure until hospital discharge were obtained from the electronic clinical histories. Criteria for DBC, the expertise of the endoscopist, anatomical variants, and complications during the procedure were obtained from reports performed by each endoscopist at the end of ERCP.

Difficult biliary cannulation was defined as one of the following, according to ESGE recommendations: more than five contacts with the papilla, unsuccessful cannulation attempts for longer than 5 minutes, or an unintentional cannulation or opacification of the PD on two or more occasions[6]. The definition of papilla contacts establishes the intentional and continuous contacts of the cannulation accessory. The endoscopist's degree of expertise was defined as senior professional or junior endoscopist. Senior professionals had fulfilled the biliary tract training curve (>200 ERCP and >40 ERCP/year). Junior endoscopists were professionals who had not fulfilled that criterion. The cannulation time and the cannulation space available to endoscopists in training to decide the need for intervention by the expert endoscopist, was counted using the clock displayed on the endoscopy monitor, after marking the start of the procedure. Technical success for cannulation was defined as achieving selective biliary cannulation using any technique. Technical success for ERCP was defined as the fulfillment of the technical purpose of the ERCP given the pathological condition intervened. Clinical success was defined as cessation of signs and symptoms after the endoscopic intervention. Evaluated complications during and/or after the ERCP included bleeding, gastrointestinal perforation, cholangitis, and post endoscopic pancreatitis, defined as abdominal pain and enzymes significant elevation.

For description of patients' sociodemographic and clinical characteristics, central tendency and dispersion measures were used, depending on data distribution. The Shapiro Wilk test was used to evaluate the normal distribution assumption. For categorical variables, absolute numbers and proportions were reported. For group comparison, the X^2 test or the Mann-Whitney U test was used, according to the type of variable. Association between each factor and DBC was assessed first in a bivariate analysis, calculating 95% odds ratio and confidence intervals. A subsequent multivariate analysis aiming to identify independent factors was performed, using a logistic regression model with the backward stepwise method. This included variables showing statistically significant association in the bivariate analysis (P<0.05). All the statistical analysis was performed with the statistical analysis package Stata 15®.

RESULTS

FIGURE 1 shows the process for patient selection. A total of 498 ERCP, performed in 376 patients, were analyzed. Clinical and sociodemographic characteristics of the patients are presented in TABLE 1. Of the sample, 54% were women, median age 69 years (interquartile range 57–79), and 66.5% were hospitalized at the time of the procedure. Choledocholithiasis was the most frequent indication for the ERCP (71%). 32.5 % of patients underwent the procedure more than once.

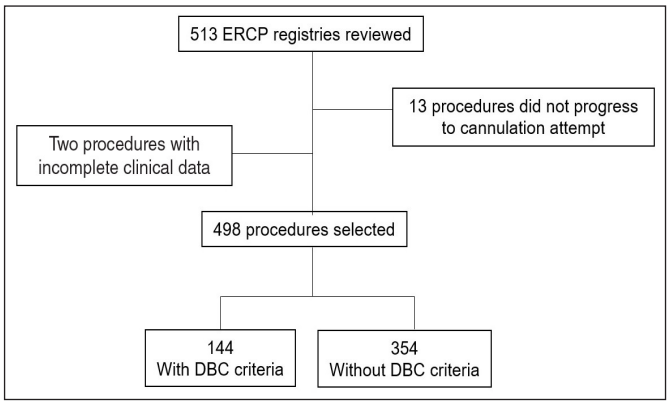

FIGURE 1. Patient selection.

TABLE 1. Clinical and sociodemographic characteristics of patients undergoing ERCP.

Characteristics	n=376
Gender (female), n (%)	203 (54.0)
Age (years), median (IQR)	69 (57–79)
Hospital environment, n (%)	250 (66.5)
ERCP indication, n (%)	
Choledocholithiasis	238 (71.0)
Cholangitis	21 (6.7)
Post-surgical biliary stenosis	21 (6.7)
Pancreatic cancer	14 (4.2)
Biliary pancreatitis	10 (3.0)
Number of ERCP performed, n (%)	
1	254 (67.5)
2	90 (23.9)
3	24 (6.4)
4	4 (1.1)
5	3 (0.8)
6	1 (0.3)

IQR: Interquartile range; ERCP: Endoscopic retrograde cholangiopancreatography.

Technical and clinical outcomes, and complications

Of the 498 ERCP performed, 29% (144) fulfilled DBC criteria, with more than five cannulation attempts the most frequent 1 (52%). TABLE 2 shows the comparison between the procedures with and without this outcome. A higher proportion of DBC was observed in women (49.4 vs 62.5%, P=0.008) and hospitalized patients (64.1 vs 82.6%, P< 0.001). Also, significant differences were found between groups for ERCP indications and for the proportion of redundant/peridiverticular papilla (14.7 vs 34%, P< 0.001), the latter being more frequent in the DBC group. Procedures performed by a senior professional had a similar percentage for both groups (51.7 vs 55.5%; P=0.397). The most frequently used cannulation technique after failure of conventional techniques was double cannulation (42.3%), followed by precut (15.4%).

TABLE 2. Comparison of ERCP with and without DBC criteria.

	Non-difficult cannulation (n=354)	Difficult cannulation (n=144)	*P* value
Gender (female), n (%)	175 (49.4)	89 (62.5)	0.008
Age, median (IQR)	69 (57–78)	69 (58–76)	0.88
Acute care hospital setting, n (%)	227 (64.12)	119 (82.63)	<0.001
Senior professional, n (%)	183 (51.69)	80 (55.5)	0.397
DBC criterion			
>5 attempts		75 (52.08)	
>5 minutes		16 (11.11)	
MPD cannulation/opacification		53 (36.81)	
ERCP indication, n (%)			
Choledocholithiasis	223 (70.54)	79 (62.70)	
Cholangitis	23 (7.28)	11 (8.73)	
Biliary neoplasia	5 (1.58)	0 (0)	
Pancreatic cancer	10 (3.16)	13 (10.32)	
Acute biliary pancreatitis	8 (2.53)	2 (1.59)	0.002
Chronic/recurrent pancreatitis	7 (2.22)	0 (0)	
PO biliary fistula	9 (2.85)	6 (4.76)	
PO biliary stenosis	23 (7.82)	4 (3.17)	
Other	8 (3.17)	11 (8.72)	
Papilla, n (%)			
Usual	293 (82.76)	80 (55.5)	
Redundant	12 (3.38)	25 (17.36)	<0.001
Peri-diverticular	40 (11.29)	24 (16.66)	
Anatomical variation, n (%)	9 (5.54)	7 (4.86)	0.08
Surgically altered anatomy, n (%)			
Hepatic surgery	2 (0.56)	0 (0)	0.14
Total bilirubin >10 g/dL	26 (12)	17 (14.53)	0.507
Dilated biliary tract >6 mm	265 (82.55)	58 (76.32)	0.209
Technical success, ERCP, n (%)	345 (98.3)	82 (56.9)	<0.001
Technical success, cannulation, n (%)	346 (98.9)	83 (57.6)	<0.001
Clinical success, n (%)	348 (98.8)	142 (98.6)	0.704
Complications, n (%)			
Mild bleeding	11 (3.1)	12 (8.3)	0.011

ERCP: endoscopic retrograde cholangiopancreatography; IQR: interquartile range; MPD: main pancreatic duct; PO: post-operative; DBC: difficult biliary cannulation.

Patients with DBC had a lower rate of technically successful ERCP (98.3 vs 56.9%, *P*<0.001) and lower rate of technically successful biliary cannulation (98.9 vs 57.6%, *P*< 0.001). There were not statistically significant differences between groups regarding clinical success of the procedure. Bilirubin level above 10 mg/dL, biliary tract dilation, or the number of previous ERCP were not associated with DBC.

Regarding complications, mild bleeding (without transfusion requirement) was the most frequent in the DBC group (3.1 vs 8.3%, *P*=0.01 (TABLE 2). There were no post endoscopic pancreatitis, gastrointestinal perforations, or cholangitis.

Bivariate and multivariate analysis

Bivariate analysis showed an association between DBC and female gender (OR 1.70; CI95% 1.12–2.49; *P*=0.01), procedures performed in the acute care hospital setting (OR 2.75; CI95% 1.68–4.49, *P*<0.001), pancreatic cancer (OR 3.52; CI95% 1.50–8.25, *P*=0.004), and the presence of redundant or peridiverticular papilla (TABLE 3).

The multivariate analysis evidenced a direct and independent association between DBC and acute care hospital setting (OR 2.92; CI95% 1.70–5.01; *P*<0.001) and the presence of redundant papilla (OR 7.26; CI95% 3.38–15.61; *P*<0.001) or peridiverticular

TABLE 3. Association between difficult cannulation and clinical variables of patients undergoing ERCP. Bivariate and multivariate analysis.

	Bivariate analysis			Multivariate analysis		
	OR	CI 95%	*P* value	OR	CI 95%	*P* value
Gender (female)	1.70	[1.12;2.49]	0.01	1.44	[0.93;2.23]	0.104
Age	1.00	[0.98;1.01]	0.85			
Acute care hospital setting	2.75	[1.68;4.49]	<0.001	2.92	[1.70;5.01]	<0.001
Senior professional	1.20	[0.81;1.78]	0.349			
Papilla						
Usual	Reference					
Redundant	7.63	[3.67;15.85]	<0.001	7.26	[3.38;15.61]	< 0.001
Peri-diverticular	2.35	[1.34; 4.11]	0.002	2.45	[1.38;4.36]	0.002
Anatomical variant	2.4	[0.87;6.6]	0.08			
Total bilirubin >10 g/dL	1.24	[0.64;2.4]	0.508			
ERCP indication						
Pancreatic cancer	3.52	[1.50;8.25]	0.004			
Biliary tract >6 mm	0.68	[0.37;1.24]	0.211			

ERCP: endoscopic retrograde cholangiopancreatography.

papilla (OR 2.45; CI95% 1.38–4.36; *P*=0.002). Analysis of the endoscopist's experience did not show any association with DBC (TABLE 3).

DISCUSSION

The percentage of DBC found in the analysis of this study was 29%, which is consistent with the frequency reported in medical literature of between 10–35% of procedures performed by experienced endoscopists[1].

The definition for DBC has changed in the last decades and varies among studies. For this study, ESGE criteria were selected, considering that they have allowed a more generalized identification of DBC[6]. There is, however, controversy over the best definition. Some authors consider it more appropriate to determine the length of the procedure than the number of cannulation attempts, given the relationship between procedure length and rate of complications[10]. A prospective study evaluating 907 ERGP reported that, in expert hands, 80% of cannulations were possible within the first 2 minutes by conventional technique. After 5 minutes without achieving cannulation, the success rate reduces dramatically to as low as 8%[11]. The analysis in this study showed that, in this Gastroenterology Unit, the criterion number of cannulation attempts was more frequent than the criterion time to achieve successful cannulation. These results address the need for establishing quality parameters adapted in the training of new endoscopists, with strict time measurement for cannulation from the moment of first contact with the papilla and/or cannulation/opacification of the PD.

As lengthier procedures are associated with higher risk of complications, the authors propose a 10-minute limit for a cannulation attempt in endoscopist training[12]. Also, when DBC is anticipated, early strategies should be used to minimize the risk of complications and adjust the role of involved endoscopists.

The findings in this study are consistent with medical literature on the association between papilla alterations and DBC probability[13]. Intra- and peri-diverticular papilla are difficult to identify, and they can relate to common bile duct obstruction, pancreatitis, perforation, hemorrhage, and, rarely, carcinoma. Intra- and peri-diverticular papilla presence predicts that cannulation will need extra time, the use of advanced techniques, and the participation of a more experienced endoscopist[14]. There are several classifications for periampullary diverticula. Recent comparison between classifications has shown that Li-Tanaka classification has a clinical advantage as a tool for the endoscopist in cannulation planning and in the evaluation of potentially difficult cases[15].

This study also identified the acute care hospital setting as a DBC predictor, which might relate to the severity of the ailment being treated. Previous studies have also demonstrated that failed ERCP increase the risk of intra-hospital mortality. It has been proposed that the presence of more severe diseases and the complications from their management, might explain such an increase in mortality[16].

Female gender is acknowledged as a risk factor for post endoscopic pancreatitis, and there is no strong evidence on the underlying mechanisms. The DBC is a possible explanation, although there is no strong evidence that cannulation is more problematic in women than in men[17]. In this study, the bivariate study suggested an association between female gender and DBC, but this association was not statistically significant in the multivariate analysis. A prospective study that analyzed 364 ERCP performed by expert endoscopists in native papilla found a tendency toward prolonged times and a higher requirement of alternative techniques to achieve successful cannulation in women. This difference, however, was not statistically significant (*P*=0.061 y=0.054, respectively)[18]. Further studies with a larger sample are required to clarify this association.

Several studies have researched the number of ERCP required to achieve the necessary skills for selective biliary cannulation in patients with native papilla. An 80% success rate in biliary cannulation has been proposed as the goal for ERCP training[19]. An experience of more than 200 procedures has been considered adequate in the ERCP learning curve of an endoscopist. That number is considered the threshold for a significant increase in cannulation success rate (36% at the start compared to 85% after

200 procedures, $P<0.001$)[20]. Other authors report that successful cannulation rate increases from 43% at the start of training to values above 80% after 350 to 400 supervised procedures[21]. Mandai et al. suggested in 2017 that an experience of 300 procedures or less and malignant biliary stenosis due to pancreatic cancer were associated with prolonged time lengths for biliary cannulation[22].

There have been contradictory data regarding student participation in ERCP having a negative impact on cannulation success. A study in 2017 did not find significant differences in cannulation rates between procedures with a learner compared to those without a learner (91% vs 93%, $P=0.8$). However, the average time for biliary cannulation with the presence of a learner was 7 minutes, compared to 5 minutes without a learner[23]. Given that teaching ERCP is the most difficult task in an endoscopic training program, further study is required to clarify that association and to design standardized, structured, and effective ERCP training programs[24].

It has been proposed that the higher the bilirubin level, the higher the DBC risk, this under the assumption that a very high bilirubin is associated with a more severe obstruction, and so to a higher difficulty in passing the catheter. However, DBC mechanisms are not completely elucidated, and DBC can occur with proximal lesions, malignant etiologies, or in the presence of normal bilirubin levels. This study did not find an association between DBC and a high bilirubin level. The number of patients with levels higher than 15 mg/dL, however, was very limited. Further studies are required to determine if such patients do have a higher risk of DBC.

The number of analyzed procedures and DBC events detected is a strength of the study. The main limitation is retrospective data collection. The amount of lost data in the clinical history registries and procedure reports was low, however, so the authors consider lost data irrelevant to the study's conclusions.

This study found DBC a frequent event. Also, it identified papilla variations and performing ERCP in the acute care hospital setting as the two main factors associated with DBC. This information might be useful to predict DBC and establish healthcare and administrative strategies to reduce DBC's implications. Such strategies would include supply preparation and performance of the procedure by senior endoscopists, among others.

Authors' contribution

Cáceres-Escobar D, Muñoz-Velandia OM and Rubio RV: study conception, design, and analysis; writing, revision and editing. Caceres-Escobar D: data collection.

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Cáceres-Escobar D, Muñoz-Velandia OM, Rubio RV. Fatores associados à difícil canulação biliar em um centro de treinamento para intervenção endoscópica do trato biliar. Arq Gastroenterol. 2022;59(1):29-34.

RESUMO – **Contexto** – Este artigo tem como objetivo determinar fatores associados à dificuldade de canulação biliar que sejam identificáveis antes dos procedimentos. **Métodos –** Trata-se de um estudo de caso-controle dentro de uma coorte histórica em pacientes adultos submetidos a colangiopancreatografia retrógrada endoscópica (CPRE) de 2015 a 2019 no Hospital Universitário San Ignacio, em Bogotá, Colômbia. Avaliou-se as associações entre variáveis que poderiam ser identificadas antes ou no início dos procedimentos e a probabilidade de difícil canulação biliar (DCB). Essas associações foram avaliadas por meio de análise bivariada e multivariada. O estudo utilizou critérios para DCB definidos pela Sociedade Europeia de Endoscopia Gastrointestinal. **Resultados –** Foram analisados 498 CPRE em 376 pacientes. De todos os procedimentos, 144 (29%) preencheram critérios para DCB. A análise multivariada mostrou associação entre a DCB e o ambiente hospitalar de atenção aguda (OR:2,92; CI 95% 1,70–5,01; $P<0,001$), papila redundante (OR:7,26; CI95% 3,38–15,61; $P<0,001$), ou papila peridiverticular (OR:2,45; CI95% 1,38–4,36; $P=0,002$). Não foi encontrada associação entre a DCB e a experiência do endoscopista, dos níveis de bilirrubina ou da dilatação do trato biliar. **Conclusão –** A DCB é um evento frequente. Alterações na papila e CPRE realizadas no ambiente hospitalar de cuidados agudos são os principais fatores associados a DCB. Essas informações podem ser úteis para prever a DCB e estabelecer estratégias de saúde e administrativas para reduzir suas implicações.

Palavras-chave – Canulação biliar difícil; colangiopancreatografia retrógrada endoscópica.

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