Frequency and Causes of Failed Endoscopic Retrograde Cholangiopancreatography in AL-Rajhi Endoscopy Unit

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Background and study aim: Endoscopic retrograde cholangiopancreatography (ERCP) is a well-known procedure with both diagnostic and therapeutic utilities in managing pancreaticobiliary conditions. Both technical- and patient-related aspects of cannulation and cannulation difficulties have previously been investigated. The current study aimed to assess the frequency and predictors for papillary cannulation.

Patients and Methods: The current study was conducted at Al-Rajhi University Hospital between January 2020 and January 2021. 200 cases who underwent ERCP for different indications were eligible for the study. Reviewing the medical records of those patients with data collection related to the procedure of ERCP.

Results: Out of those patients, successful papillary cannulation was achieved in 172 (86%) patients, while in the other 28 (14%) patients, cannulation failed. Both groups of the studied patients based on the outcome of cannulation had insignificant differences as regards baseline, clinical, and laboratory data. The most frequently reported causes of failure were abnormal variation in papilla (53.6%) and infiltrated papilla (28.6%) followed by altered anatomy with previous surgery in 4 (14.3%) patients and large juxa-papillary diverticulum in one patient. Based on the current study, predictors of failed cannulation of major papilla were endoscopists experience < 5 years and malignant obstruction.

Conclusion: ERCP still has some sort of difficulty during canulation. Early prediction of those patients who are vulnerable to failure of cannulation would have a great effect on their outcome with a reduction in the frequency of expected complications. Frequent multicenter studies are warranted to confirm such results.

INTRODUCTION

Although it has fewer complication rate than surgery, endoscopic retrograde-cholangio-pancreatography (ERCP) still representing a challenge to learn how to perform it and avoid high rate of failure or complications. ERCP complications include post-ERCP pancreatitis (1.3: 15.9%), perforation (0.08:1.1%), bleeding (0.76:2.3%), cholangitis (0.57:5.01%) and cholecystitis (0.11:0.68%) **[1-3]**.

This made the total morbidity reaches as high as 15.9% leading to mortality rate of 1%. This is considered superior to open surgery or percutaneous transhepatic duct insertion hence it is the initial modality of management in all cases of jaundice **[4, 5]**.

Newly developed accessories such as catheters, guidewires, and stents lowered the failure, but the endoscopists' experience is critical to perform this step **[6, 7]**. The American Society for Gastrointestinal Endoscopy (ASGE) guidelines define difficult cannulation when more than five minutes' trial failed, or five times in contact with papilla or more than one episode of faulty pancreatic duct cannulation **[8]**.

When ERCP fails, it is recommended to perform another trial days or weeks later to delay the more invasive options such as percutaneous transhepatic biliary drainage. The failure can be traced back to operator causes, technical causes, and patient causes. Establishing this knowledge would aid in failure reduction and elevate the success rate with fewer morbidity and post-operative complications **[8, 9]**. The study was conducted to re-evaluate the ERCP practice in AL-Rajhi endoscopy center by focusing on the main causes of ERCP failure.

PATIENTS/MATERIALS AND METHODS

Study setting& design

A single-center cross-sectional study was conducted at Al-Rajhi University Hospital between January 2020 and January 2021.

Inclusion criteria

All cases who underwent ERCP for different indications were eligible for the study.

Exclusion criteria

Patients with medical records that had any missing or incomplete data were excluded.

Sample size calculation

Based on previously published studies that reported failed cannulation of major papilla during ERCP that was 15% (110), a minimum required number of patients was 196 patients with the following assumptions; 95% power, 0.05 alpha error and 95% confidence interval and p value was significant if <0.05.

Participants and study tools

The current study enrolled 200 patients who underwent ERCP for different reasons. Out of those patients, successful papillary cannulation was achieved in 172 (86%) patients, while in the other 28 (14%) patients, cannulation failed. Failed (difficult) canulation was defined as a combination of a minimum number of cannulation attempts, typically 5 to 15, and a minimum time spent on standard cannulation techniques, typically greater than 5 to 20 min **[8]**.

The medical and ERCP records of those patients were reviewed, and the following data were gathered;

- Demographic data and different characteristics: age, sex, residence, body mass index, and comorbidities (diabetes mellitus, hypertension, ischaemic heart disease, and chronic kidney disease).
- Laboratory data: liver function tests (bilirubin, albumin, alkaline phosphatase, alanine transaminase and aspartate transaminase), kidney function test (urea and creatinine), coagulation profile, serum electrolytes (sodium and potassium), complete blood count and tumors markers if available.
- Radiological data and indications for ERCP as malignant obstructive jaundice, biliary stricture, biliary stones and/or stent exchange.
- The Outcome of ERCP (either successful or failed). Reporting the cause of failure included altered anatomy, abnormal variation of the papilla, distal biliary stricture, duodenal infiltration, and/or juxta-papillary diverticulum.
- Complications of ERCP as PEP, perforation, haemorrhage and/or cholangitis
- Other interventions that were done to the cases with failed cannulation either another trial, surgery or PTD.

Statistical analysis

Data was collected and analyzed by using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). Quantitative data were expressed as mean ± standard deviation (SD) and compared with Student t test. Numerical data are given as numbers (n) and percentages (%). Chi^2 test was implemented on such data. Multivariate regression analysis was used to determine possible risk factors for failed cannulation during ERCP. The level of confidence was kept at 95%, and hence, the P value was considered significant if < 0.05.

RESULTS

Baseline data of the studied patients based on outcome of cannulation (table 1):

Both groups of the studied patients based on the outcome of cannulation had insignificant differences as regards baseline data with except

for significantly higher mean body mass index among those patients with failed papillary cannulation (27.54 ± 4.01 vs. 25.17 ± 2.84 (kg/m^2); $p< 0.001$).

Laboratory data among the studied groups based on the outcome of cannulation (table 2):

There were no significant differences between both groups as regards different laboratory data ($p> 0.05$).

Final diagnosis (indications of ERCP) based on radiological evaluation in the studied patients (table 3):

There was a significant difference between both groups of patients based on different indications of ERCP ($p< 0.001$) where most patients with failed cannulation had malignant obstruction (89.3%). Meanwhile, most patients with successful cannulation had choledocholithiasis (61%) 18 (10.5%) and 15 (8.7%) patients had malignant obstruction and biliary stricture. Thirty-four (19.8%) patients of such group underwent ERCP for stent removal.

Frequency of complications and endoscopist experience in the patients (table 4):

A total of 16 (9.3%) and 13 (46.4%) patients with successfula and failed canulation, respectively developed complications. Duodenal perforation occurred in two cases with cannulation. Experience of endoscopist greatly affected the outcome of cannulation ($p< 0.001$), where in the majority (72.1%) of patients with successful cannulation, the experience of the endoscopist was five years or more. In contrast, in those with failed cannulation, the majority (67.9%) of endoscopists had experienced less than five years.

Causes of failed cannulation and its management (table 5):

The most frequently reported causes of failure were abnormal variation in papilla (53.6%) and infiltrated papilla (28.6%) followed by altered anatomy with previous surgery in 4 (14.3%) patients and large juxa-papillary diverticulum in one patient. Management of those patients was percutaneous transhepatic drainage (35.6%), second trail of ERCP (32.2%), surgical intervention (17.9%) and rendezvous technique (14.3%).

Predictors for failed cannulation in the current study (table 6):

Based on the current study, predictors of failed cannulation of major papilla were endoscopists experience < 5 years (odd's ratio= 2.50) and malignant obstruction (odd's ratio= 4.55).

Table 1. Baseline data of the studied patients based on outcome of cannulation.

	Papillary cannulation		P value
	Successful (n=172)	Failed (n=28)	
Age (years)	**51.20 ± 9.35**	**50.36 ± 8.26**	**0.65**
Sex **Male** **Female**	 **127 (73.8%)** **45 (26.2%)**	 **25 (89.3%)** **3 (10.7%)**	**0.06**
Body mass index (kg/m2)	**25.17 ± 2.84**	**27.54 ± 4.01**	**< 0.001**
Residence **Rural** **Urban**	 **124 (72.1%)** **48 (27.9%)**	 **22 (78.6%)** **6 (21.4%)**	**0.32**
Occupation **Farmer** **Employee** **None**	 **103 (59.9%)** **38 (22.1%)** **31 (18%)**	 **19 (67.9%)** **6 (21.4%)** **3 (10.7%)**	**0.60**
Smoking	**88 (51.2%)**	**18 (64.3%)**	**0.13**
Diabetes mellitus	**58 (33.7%)**	**6 (21.4%)**	**0.14**
Hypertension	**56 (32.6%)**	**6 (21.4%)**	**0.16**
Ischemic heart disease	**24 (14%)**	**4 (14.3%)**	**0.57**
CKD	**20 (11.6%)**	**3 (10.7%)**	**0.27**
Clinical presentation			
Jaundice	**172 (100%)**	**28 (100%)**	**---**

Dark colored urine	**172 (100%)**	**28 (100%)**	**---**
Clay stool	**58 (33.7%)**	**8 (28.6%)**	**0.38**
Biliary colic	**130 (75.6%)**	**22 (78.6%)**	**0.47**
Itching	**31 (18%)**	**3 (10.7%)**	**0.25**
Fever	**48 (27.9%)**	**6 (21.4%)**	**0.32**

Table 2. Laboratory data in the studied groups based on the outcome of cannulation

	Papillary cannulation		**P value**
	Successful (n=172)	**Failed (n=28)**	
Liver function tests			
AST (U/l)	**44.26 ± 24.89**	**44.64 ± 23.55**	**0.19**
ALT (U/L)	**37.77 ± 11.27**	**35.61 ± 11.78**	**0.22**
ALP (U/l)	**174.26 ± 76.56**	**168.94 ± 93.22**	**0.09**
Bilirubin (mg/dl)	**9.87 ± 2.22**	**10.89 ± 3.45**	**0.19**
D.bilirubin (mg/dl)	**6.09 ± 1.10**	**7.77 ± 2.10**	**0.34**
Albumin (g/dl)	**4.42 ± 0.47**	**4.57 ± 0.56**	**0.30**
Complete blood count			
Haemoglobin (g/dl)	**13.53 ± 1.27**	**13.79 ± 1.19**	**0.13**
Leucocytes (103/ul)	**8.03 ± 4.46**	**7.55 ± 3.44**	**0.20**
Platelets (103/ul)	**217.43 ± 40.64**	**201.11 ± 67.88**	**0.53**
Coagulation profile			
INR	**1.03 ± 0.08**	**1.03 ± 0.05**	**0.09**
PC (%)	**89.98 ± 5.55**	**90.09 ± 3.28**	**0.08**
PT (%)	**12.2 ± 1.01**	**11.09 ± 0.90**	**0.81**
Kidney function tests			
Creatinine (mg/dl)	**0.96 ± 0.22**	**0.86 ± 0.17**	**0.90**
Urea (mg/dl)	**8.85 ± 3.02**	**9.23 ± 3.52**	**0.35**
Serum electrolytes			
Sodium (mmol/l)	**137.89 ± 5.21**	**136.87 ± 7.54**	**0.16**
Potassium (mg/dl)	**4.14 ± 0.73**	**4.17 ± 0.87**	**0.25**
Tumor markers*			
CEA (U/l)	**569.09 ± 123.45**	**579.11 ± 156.89**	**0.06**
CA19-9 (U/l)	**234.56 ± 56.98**	**255.89 ± 64.50**	**0.48**

Data expressed as mean (SD). P value was significant if < 0.05**. D.bilirubin**: direct bilirubin; **AST**: aspartate transaminase; **ALT:** alanine transaminase; ALP: alkaline phosphatase; **INR**: international randomized ratio; **PC**: prothrombin concentration; **PT**: prothrombin time; **CEA**: carcino-embryonic antigen; **CA19-9**: carbohydrate antigen19-9

*tumor markers were done in only 23 patients with failed cannulation and 89 patients with successful cannulation

Table 3. Final diagnosis (indications of ERCP) based on radiological evaluation

	Papillary cannulation		P value
	Successful (n=172)	Failed (n=28)	
Diagnosis (indication of ERCP)			**< 0.001**
Choledocholithiasis	**105 (61%)**	**2 (7.1%)**	
Malignant obstruction*	**18 (10.5%)**	**25 (89.3%)**	
Biliary stricture	**15 (8.7%)**	**1 (3.6%)**	
Stent removal	**34 (19.8%)**	**0**	
Data expressed as frequency (percentage). P value was significant if < 0.05. **ECRP**: endoscopic retrograde-pancreatography. *this included both pancreatic and Klatskin tumor			

Table 4. Frequency of complications and endoscopist experience in the patients

	Papillary cannulation		P value
	Successful (n=172)	Failed (n=28)	
Experience **< 5 years** **≥ 5 years**	 **48 (27.9%)** **124 (72.1%)**	 **19 (67.9%)** **9 (32.1%)**	**< 0.001**
Complications			**< 0.001**
None	**156 (90.7%)**	**15 (53.6%)**	
Pancreatitis	**13 (7.6%)**	**10 (35.7%)**	
Bleeding	**3 (1.7%)**	**1 (3.6%)**	
Duodenal perforation	**0**	**2 (7.1%)**	
Data expressed as frequency (percentage). P value was significant if < 0.05. ECRP: endoscopic retrograde-pancreatography *this included both pancreatic and Klatskin tumor			

Table 5. Causes of failed cannulation and its management in the current study

	N= 28
Causes of failure	
Abnormal variation in papilla	**15 (53.6%)**
Infiltrated papilla	**8 (28.6%)**
Altered anatomy with previous surgery	**4 (14.3%)**
Juxta-papillary diverticulum	**1 (3.6%)**
Management	
Percutaneous transhepatic drainage	**10 (35.6%)**
Second trail of ERCP	**9 (32.2%)**
Surgical intervention	**5 (17.9%)**
Rendezvous technique	**4 (14.3%)**

Table 6. Predictors for failed cannulation in the current study

	Odd's ratio	95% confidence interval	P value
Obesity	1.10	**0.34-1.24**	**0.12**
Experience (< 5 years)	2.50	**2.11-4.46**	**< 0.001**
Malignant obstruction	4.55	**2.90-7.87**	**< 0.001**
P value was significant if < 0.05			

DISCUSSION

Despite advances and new developments in endoscopic accessories, selective biliary access fails in 5%-15% of cases, even in expert high volume centers. Various techniques, such as double-guidewire induced cannulation, pre-cut papillotomy, or transpancreatic sphincterotomy with or without placement of a pancreatic stent — have been used to improve cannulation success rates **[10]**.

In the current study aimed to assess the frequency of failure of biliary cannulation during the procedure of ERCP and determine its possible risk factors. A total of 200 patients underwent ERCP were enrolled in the study at Al-Rajhi University Hospital between January 2020 and January 2021.

Out of those patients, successful papillary cannulation was achieved in 172 (86%) patients while in the other 28 (14%) patients, cannulation failed. This was consistent with previous reports about selective biliary access failure that may reach up to 5%—15% of cases, even in expert high volume centers **[10]**.

In the current study, predictors of failed cannulation of major the papilla were endoscopists' experience < 5 years (odd's ratio= 2.50) and malignant obstruction (odd's ratio= 4.55). **Cotton et al.** stated that the likelihood of successful cannulation is influenced by operator factors (experience) and patient factors (anatomy). Expert endoscopists are expected to be successful at biliary access in 95% to 100% of attempts, a goal that is supported by literature. Community success rates should exceed 90% **[11]**.

In agreement with this study, two studies reported that a direct association between the case volume, local expertise, endoscopic training, and practice setting **[12, 13]**. Also, **Cotton et al.** and **Lehman et al.** reported that trainees are deemed competent to perform endoscopic procedures independently when a success rate of 80% to 90% is achieved **[11, 14]**.

The current study stated that failed cannulation had a significantly higher frequency of complications. Thirteen patients (7.6%) and 3 (1.7%) patients with successful cannulation reported pancreatitis and bleeding, while pancreatitis, bleeding and duodenal perforation were reported in 10 (35.7%), 1 (3.6%) and 2 (7.1%) patients with failed cannulation, respectively

The increase in risk related to these technical aspects very likely depends on the fact that pre-cutting generally follows a number of failed cannulations attempts in a lengthy procedure. The risk of post-ERCP pancreatitis further increases with difficult cannulation in patients at high risk for this complication because risk factors have been shown to be independent in multivariate analysis so they might have a cumulative effect **[15-17]**.

Also, the most frequently reported causes of failure were abnormal variation in papilla (53.6%) and infiltrated papilla (28.6%) followed by altered anatomy with previous surgery in 4 (14.3%) patients and large juxa-papillary diverticulum in one patient. Management of those patients was percutaneous transhepatic drainage (35.6%), second trail of ERCP (32.2%), surgical intervention (17.9%) and rendezvous technique (14.3%).

It's known that when selective biliary access is difficult, despite frequent meaningful contact with the papilla or prolonged cannulation times without unintentional pancreatic duct cannulation, an early pre-cut fistulotomy may be preferable. In cases of frequent unintentional PD cannulation, double guidewire induced cannulation, transpancreatic pre-cut with the guidance of a guidewire as well as a pancreatic stent may be useful **[18]**.

Haraldsson et al. studied a total of 1401 patients underwent ERCP with overall frequency of failed cannulation was 2.8%. The authors stated that although the frequency of difficult cannulation among the different types in papilla variations was based on skill level, but the overall frequency of difficult cannulation regardless of papilla type was 42% in their study **[19]**.

The study by **Haraldsson et al** serves as a reminder that anatomic differences in the shape and appearance of the major papilla can affect outcomes during ERCP. This information can potentially help with decision making during the procedure, but regardless of the type of papilla encountered, deep biliary cannulation is still the criterion standard for success **[19]**.

When biliary cannulation fails, other classical techniques, such as radiologic and surgical approaches, may be used to access the bile duct.

One recently proposed approach after a failed cannulation is to transform ERCP to an endosonography-guided cholangiopancreatography during the same session. These alternative techniques are more invasive than ERCP and may entail greater morbidity rates **[7]**.

Here, in this study, we noticed that a second trial of ERCP was done in 9 (32.2%) patients with failed first trial of cannulation. The second trial was done within 4-7 days from the first trial, and all of them were successful. **Kim et al.** state that repeating ERCP a few days after the initial precut failure often reveals an open and easily accessible papilla, allowing cannulation in up to 85% of cases. Furthermore, this second ERCP within days also seems safe **[20]**.

In spite of the efficacy and safety of a second ERCP, however, risk factors associated with this strategy have not been specifically assessed. Additionally, the precut technique used differs widely among endoscopists and institutions, and data assessing the success of a second ERCP are limited to single-center studies **[20-22]**.

Based on the currently available data in the literature, the application of a stepwise algorithm rather than a single technique is needed to facilitate biliary access during ERCP without increasing complications. Several studies have demonstrated that repeating the ERCP within a few days after initial failed pre-cut is a successful strategy and should be tried before contemplating more invasive, alternative interventions **[7, 21]**.

Percutaneous transhepatic biliary drainage is the conventional alternative method in patients who fail ERCP. However, percutaneous transhepatic biliary drainage is associated with high morbidity and can lower patients' quality of life. It may also be difficult to carry out when the intrahepatic bile ducts are not dilated. ERCP occasionally fails because of surgically altered anatomy, gastric outlet obstruction, periampullary diverticulum, indwelling duodenal stent and large tumors **[20]**.

In cases of failed cannulation in surgically altered anatomies, balloon enteroscopy-assisted ERCP is an alternative that has shown high technical and clinical success in specialized centers. Other procedures can be used as endoscopic ultrasound and percutaneous endoscopic rendezvous (PE-RV) may be preferred **[23, 24]**.

The main limitations of the current study are being conducted in single center, relatively small sample size, no long term follow up of cases with failed trail of papillary cannulation. Yet, this study was the first study to discuss such an issue in our locality.

CONCLUSION

Frequency of difficult biliary cannulation is highly variable among different studies. Based on the current study, the most frequent risk factors for such issues were decreased endoscopist experience and malignant biliary obstruction leading to distorted anatomy. Efforts should be directed toward a standard simple documented definition for the selective biliary cannulation and clear reporting of failure or complications.

The Authors declare no conflict of interest or obtained any funding for this study.

Ethical considerations: This study was performed in line with the principles of the Declaration of Helsinki.

Research highlights:

- This analysis included 200 patients who underwent ERCP for different indications. Failure occurred in 28 patient (14%).
- Most cannulation failure was noted in patients with malignant obstruction, abnormal papillary variation; followed by altered anatomy with previous surgery .
- Additional predictors of failure were endoscopists' experience < 5 years and higher body mass index.
- When ERCP failed to achieve drainage a second trail of ERCP within 3-7 days can be usueful, however definite management was percutaneous transhepatic drainage, surgical intervention and rendezvous technique .
- To overcome difficulties in Papillary cannulation early pre-cut fistulotomy may be preferable. In cases of frequent unintentional PD cannulation, double guidewire induced cannulation, trans-pancreatic pre-cut with the guidance of a

guidewire as well as a pancreatic stent may be useful.

- Further clinical trials, training unification and clinical guidelines are needed to minimize procedure failure.

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