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ORIGINAL ARTICLE

First-line Versus Second-line ERCP Techniques in Patients with Difficult Biliary Cannulation: A Comparative Cohort Study

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Abstract

Background: **Endoscopic retrograde cholangiopancreatography (ERCP) is recognized as a potential intervention for a range of pancreaticobiliary disorders. However, ERCP is limited by the incidence of failure or difficult cannulation. The current work aims to compare the safety of first-line vs. second-line maneuvers in difficult cannulation and identify the risks of ERCP failure among different patient indications.**

Patient and methods: **The study was a prospective cohort study that included adult patients who received ERCP treatment for different indications. The primary outcome was the rates of failed or difficult cannulation and the time to successful cannulation. Secondary outcomes were the rate of complications associated with the procedure.**

Results: **Out of 231 ERCP patients assessed, 11 (4.76%) failed biliary cannulation. Failed cannulation was higher in patients with previously failed ERCP and malignant patients. Second-line techniques demonstrated a higher incidence of pancreatitis ($P = 0.004$) and cholangitis ($P = 0.025$). The mean cannulation time was comparable among the study groups ($P = 0.2$).**

Conclusion: **Second-line techniques are more frequently implemented in malignant and previously failed ERCP cases. Second-line techniques have more risk of complications. Vigilant monitoring of patients treated with second-line ERCP is strongly warranted.**

Keywords: Biliary, Endoscopic, Endoscopic retrograde cholangiopancreatography

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is both diagnostic and is the treatment option for many pancreaticobiliary disorders. The cornerstone for successful ERCP is biliary cannulation, and even in well-trained endoscopists, cannulation failure can reach up to 5−20% of the cases.[1] When cannulation is difficult initially, different techniques are needed to continue the procedure and achieve bile duct cannulation.[2] The success rate of standard catheters ranges from 54% to 67%.When a guidewire is used with the standard catheter, successful cannulation rise to more than 81%. Using sphincterotome initially is nearly the same as using a catheter with a guidewire. Failure rate for using sphincterotomes ranges between 24% and 16%.[3] The decision to apply second-line techniques depends on the staff, indications, and the patient's situation.[4]

However, sparse evidence does exist about the differences between first-vs. second-line ERCP techniques regarding the indications and post-ERCP complication rates, including pancreatitis,

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cholangitis, and perforation in patients with difficult cannulation.

This study aimed to investigate the rates of failure and difficult cannulation among candidates of ERCP techniques for different indications. In addition, differences in post-ERCP complication rates between first-line and second-line techniques were evaluated in patients identified with difficult cannulation.

2. Patients and methods

This study was a prospective, observational, cohort study carried out at Al-Hussein University Hospital Endoscopy Unit during from May 2020 to April 2022. Adult patients undergoing ERCP for any indication were assessed for eligibility. Excluded patients were pregnant, had a history of ERCP-related pancreatitis, less than 18 years, or known contraindication to ERCP (coagulopathy, anaphylaxis from the contrast dye, or severe cardiopulmonary disorder). Written consent was taken from all patients.

Standard techniques were used for performing ERCP. After the common bile duct was cannulated with a catheter, cholangiography was done. A guidewire was then inserted through the catheter into the bile duct. In case of failure to cannulate the CBD, the double guidewire technique was used, where a wire was inserted into the pancreatic duct, and another wire was used to cannulate the CBD. In some cases with a hidden papilla, the double-catheter technique was used using 5 F catheters. One catheter was used to uncover the papilla and position it for the scope, while the other catheter was used for cannulation. In cases of repeated pancreatic duct cannulation, the transpancreatic sphincterotomy technique was used, where a guidewire was placed in the pancreatic duct and sphincterotomy was performed to expose the bile duct orifice before cannulation. In cases of repeated unintended pancreatic duct cannulation, the precut over the pancreatic stent technique was used, where a stent was placed in the pancreatic duct, followed by a precut sphincterotomy with a needle knife to achieve biliary cannulation. For precut sphincterotomy, the mucosal incision was started from the tip of the orifice of the papilla to the top, and after visualizing the sphincter fibers, they were punctured for bile duct cannulation. Fistulotomy involved puncturing the bulging papilla at the roof to access the duct for cannulation.

Primary outcomes of the study were rate of failed/difficult cannulation of the CBD, and the time needed for cannulation. Difficulty of cannulation was determined according to the number of cannulation trials: easy up to five attempts, moderate up to six to 15 attempt, and difficult more than 15 attempts.[5] Secondary outcomes were the rates of different complications, including pancreatitis, cholangitis, hemorrhage, or perforations. Clinical pancreatitis defined as abdominal pain with elevated serum lipase of more than three-fold.[6] The severity of pancreatitis was classified in line with hospital stay duration.[7]

ERCP was previously reported to be difficult/failed in 14% of candidate cases.[8] According to this data, Cochrane method for infinite population was applied for sample size estimation of proportions, considering prior alpha of 0.05 and 95% confidence level.[9] The sample size was therefore estimated at186 candidate respondents. To account for missing cases, additional 20% of the estimated sample size was added to the study population, making a final sample size of minimum 324 patients.

The statistical analysis was performed with the R statistical package version 4.4.2 (R Foundation for Statistical Computing, Vienna, Austria). Continuous data were summarized using means and standard deviations, while categorical data was summarized using frequency distributions with numbers and percentages. The association between categorical variables was compared using the chi-square test or Fisher's exact test, as appropriate. Continuous variables with normal distribution were compared using a *t*-test. For discrete variables and those that did not follow a normal distribution, a nonparametric Mann–Whitney *U* test was applied. The normality of numeric variables was determined using the Kolmogorov–Smirnov test. All tests were considered two-tailed, and a *P* value of less than 0.05 was considered statistically significant.

3. Results

A total of 231 ERCP cases were evaluated for eligibility, and 78 patients with difficult cannulation were selected for the current study. Out of these, 66.2% (153 patients) experienced successful cannulation, while 4.76% (11 patients) failed. Patients with initial difficult cannulation ($N = 67$ or 29%) were divided into two groups based on the ERCP maneuver used: Group I ($N = 55$): difficult cannulation managed with first-line technique and Group II ($N = 12$): difficult cannulation managed with second-line technique.

The study flow is outlined in Fig. 1, and the details of the cannulation techniques used are presented in Table 1. The baseline clinical and laboratory characteristics of the study groups showed no significant

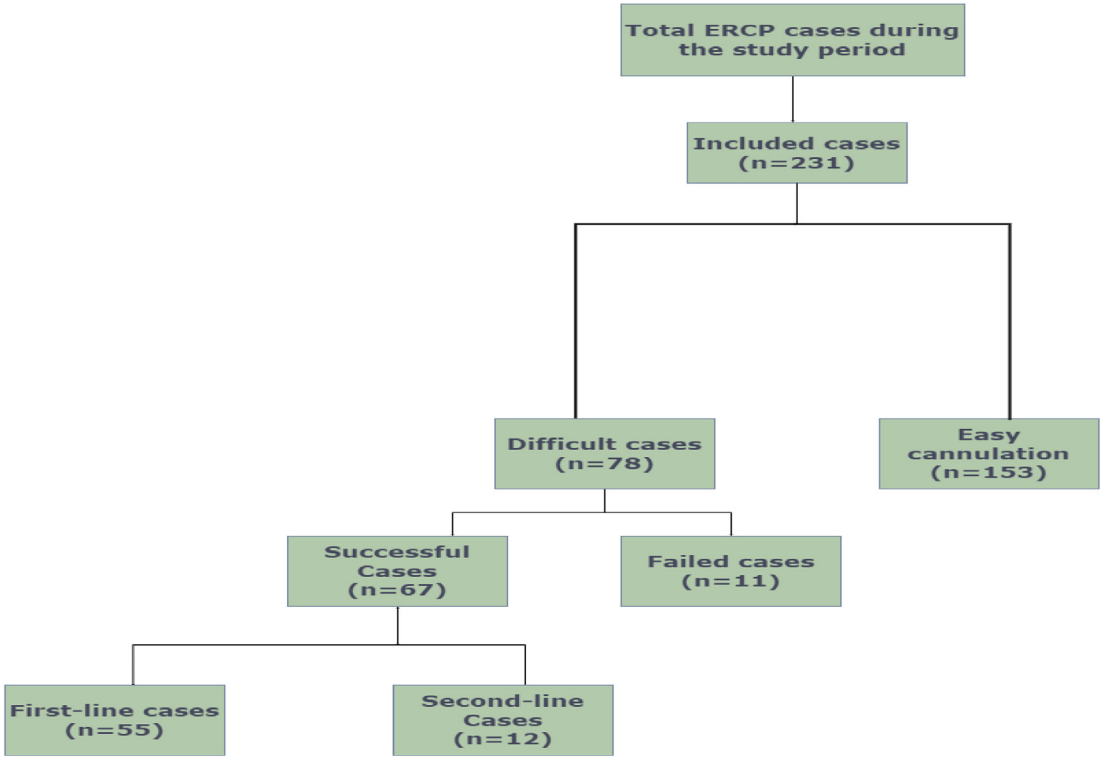

Fig. 1. Study flowchart.

differences (Table 2). The mean cannulation time was comparable between the two groups ($P = 0.2$).

A statistically significant difference ($P < 0.001$) was observed between classic, difficult, and failed cannulation cases based on the patient's indication (Table 3). The majority of the failed cases were neoplastic (45.5%) and the majority of classic ERCP was performed for calcular diseases (56.95%). Difficult cannulation was reported in calcular cases (44.8%), neoplastic cases (31.8%), dilated biliary tree (11.9%), stent removal (2.99%), and previously failed ERCP (8.96%).

The results showed that post-ERCP, pancreatitis was significantly lower in Group I (10.9%) compared with Group II (57.89%, $P = 0.004$). Mild pancreatitis was reported in 7.3% (4/55) of Group I and 25% (3/6) of Group II, while moderate to severe pancreatitis was reported in 3.6% (2/55) of Group I and 25% (3/12) of Group II. Two cases of bleeding occurred in Group I (3.64%) and one case in Group II (8.33%), and were controlled with diluted adrenaline

Table 1. Cannulation techniques implemented in the current study (N = 79).

Procedure	Number (%)
First trial ($N = 67$)	
Double guidewire	34 (50.75)
Double-catheter	16 (23.88)
Guidewire	17 (25.37)
Second trial ($N = 12$)	
Precut over pancreatic stent	4 (33.33)
Transpancreatic sphincterotomy	3 (25.00)
Precut with needle knife sphincterotomy	3 (25.00)
Fistulotomy	2 (16.67)

Table 2. Comparing clinical and laboratory characteristics between the study groups.

Characteristic	First-line group ($N = 55$)	Second-line group ($N = 12$)	P[a]
Age, years	55.2 ± 12.68	58.87 ± 13.53	0.14
Gender, males	25 (45.5%)	6 (50%)	>0.99
ALT, U/l	117.32 ± 87.67	103.33 ± 68.78	0.836
AST, U/l	98.32 ± 70.88	85.45 ± 64.03	0.292
Albumin, g/d	3.48 ± 0.37	3.48 ± 0.35	0.995
PT, second	12.63 ± 2.8	12.88 ± 2.94	0.688
INR	1.37 ± 0.15	1.35 ± 0.12	0.949
T. Bilirubin, mg/d	5.29 ± 5.4	4.52 ± 4.35	0.47
D. Bilirubin, mg/d	1.59 ± 0.81	1.56 ± 0.47	0.458
Hb, g/d	13.8 ± 1.72	14.62 ± 1.17	0.027
ALKP,U/l	175.41 ± 86.56	173.24 ± 83.58	0.935
GGT, U/l	198.15 ± 51.91	198.85 ± 47.59	0.585
Amylase, mg/dl	96.74 ± 18.08	95.58 ± 12.71	0.856
Lipase, mg/dl	80.21 ± 15.67	76.91 ± 10.28	0.725
RBG, mg/dl	86.8 ± 6.67	86.39 ± 6.45	0.851
Creatinine, mg/dl	0.99 ± 0.24	0.96 ± 0.28	0.747
Cannulation time, min	24 ± 7.5	27.17 ± 7.72	0.2

[a] Mann–Whitney *U* test; Pearson's Chi-squared test.

Table 3. Comparing first-versus second-line groups as regarding patient's indication.

Patient's indication	Classic ($N = 153$) N (%)	Difficult cannulation ($n = 67$) N (%)	Failed ($n = 11$) N (%)	P[a]
Calcular	87 (56.9)	30 (44.8)	1 (9.09)	<0.001
Neoplastic	24 (15.7)	21 (31.3)	5 (45.4)	
Dilated biliary tree	3 (1.96)	8 (11.9)	1 (9.09)	
Stent removal	38 (24.8)	2 (2.99)	0 (0)	
Previously failed ERCP	1 (0.65)	6 (8.96)	3 (27.3)	
Post-cholecystectomy	0 (0)	0 (0)	1 (9.09)	

[a] Fisher's exact test.

injection. Acute cholangitis developed in 9.09% (5/55) of Group I and 33.33% (4/12) of Group II. Perforations were not reported in any patient, and similarly, procedure-related bleeding was comparable between the two groups. However, there was a statistically significant difference between the two groups in terms of procedure-related cholangitis ($P = 0.025$). No acute cholecystitis was reported in either group (Table 4, Fig. 2).

4. Discussion

Difficult biliary cannulation was presented in the current analysis with an incidence of 29%, while failure of cannulation was experienced in 11 patients (4.76%). The anticipated rate of cannulation failure contradicts the findings of Tse et al. who reported a failure rate ranging from 10 to 20% in their meta-analysis that included 12 RCTs comprising 3450 participants, who underwent standard ERCP.[10] This discrepancy could be primarily attributed from the variable experience of the endoscopist, and/or variable facilities in the endoscopic centers. For instance, Williams et al. reported that cannulation success rate dropped to 82% of cases when performed in centers with low facilities.[11] Another possible reason is the differences between studies in defining difficult cannulation. Recently difficult cannulation was defined as five contacts or more with the papilla or cannulation time exceeding 5 min or pancreatic duct cannulation more than once.[12,13] However, difficult biliary cannulation definition is variable across different studies significantly and thus comparisons between studies are not practical.[14]

Table 4. Comparing first-vs second-line groups as regards post-ERCP complications.

Characteristic (n, %)	First-line group ($N = 55$)	Second-line group ($N = 12$)	P[a]
Hyperamylasemia	18 (32.7)	4 (33.3)	>0.99
Pancreatitis			
Mild	4 (7.27)	3 (25)	0.004
Moderate to severe	2 (3.64)	3 (25)	
None	49 (89.1)	6 (50)	
Bleeding	2 (3.64)	1 (8.33)	0.45
Cholangitis	5 (9.09)	4 (33.3)	0.025
Cholecystitis	0 (0)	0 (0)	>0.99
Perforation	0 (0)	0 (0)	>0.99

[a] Fisher exact test.

In the current study, we found a significant difference ($P < 0.001$) in the rates of ERCP failure among different indication. ERCP failed cases were neoplastic (45.5%), previously failed ERCP (27.3%), calcular (9.09%), dilated biliary tree (9.09%), or post-cholecystectomy (9.09%). However, difficult cannulation was presented in calcular cases (44.8%), neoplastic cases (31.8%), dilated biliary tree (11.9%), stent removal (2.99), and previously failed ERCP (8.96%). Similarly, the significantly higher rates of failed ERCP in malignant cases was previously reported by Fugazza et al., who conducted a retrospective study of 622 consecutive patients with distal malignant biliary obstruction and demonstrated that 56.4% of patients were matching the definition of difficult cannulation.[15] Moreover, Lee et al. highlighted that duodenal strictures cause difficulty in stent placement in 10–20% of patients with pancreatic cancer, which incurs additional challenge in ERCP procedure in malignant cases.[16] In line with the current findings, Cankurtaran et al. concluded that cannulation was more difficult in patients with cholecystectomy who received ERCP management for choledocholithiasis.[17]

The findings from the current study suggest higher complication rates associated with second-line techniques compared with first-line, including clinical pancreatitis ($P = 0.004$) and cholangitis ($P = 0.025$). In line with the current findings, Fugazza et al. showed that patients with difficult bile duct cannulation showed a higher risk for complications ($P = 0.02$). In addition, they showed that the implementation of more than two techniques for cannulation (OR = 2.88; 95%CI = 1.04–7.97) was associated with the occurrence of adverse events.[15] Since the subjects managed with the second-line techniques in the current study exhibited both factors, it is not surprising to show a significantly higher rates of adverse events.

Another possible cause for the high rates of complications in the second-line ERCP group is related to the intrinsic risks associated with the second-line procedures themselves. For example, Wang et al. demonstrated that precut sphincterotomy was a significant risk factor for overall complications.[18] Pancreatic duct stent was concluded as

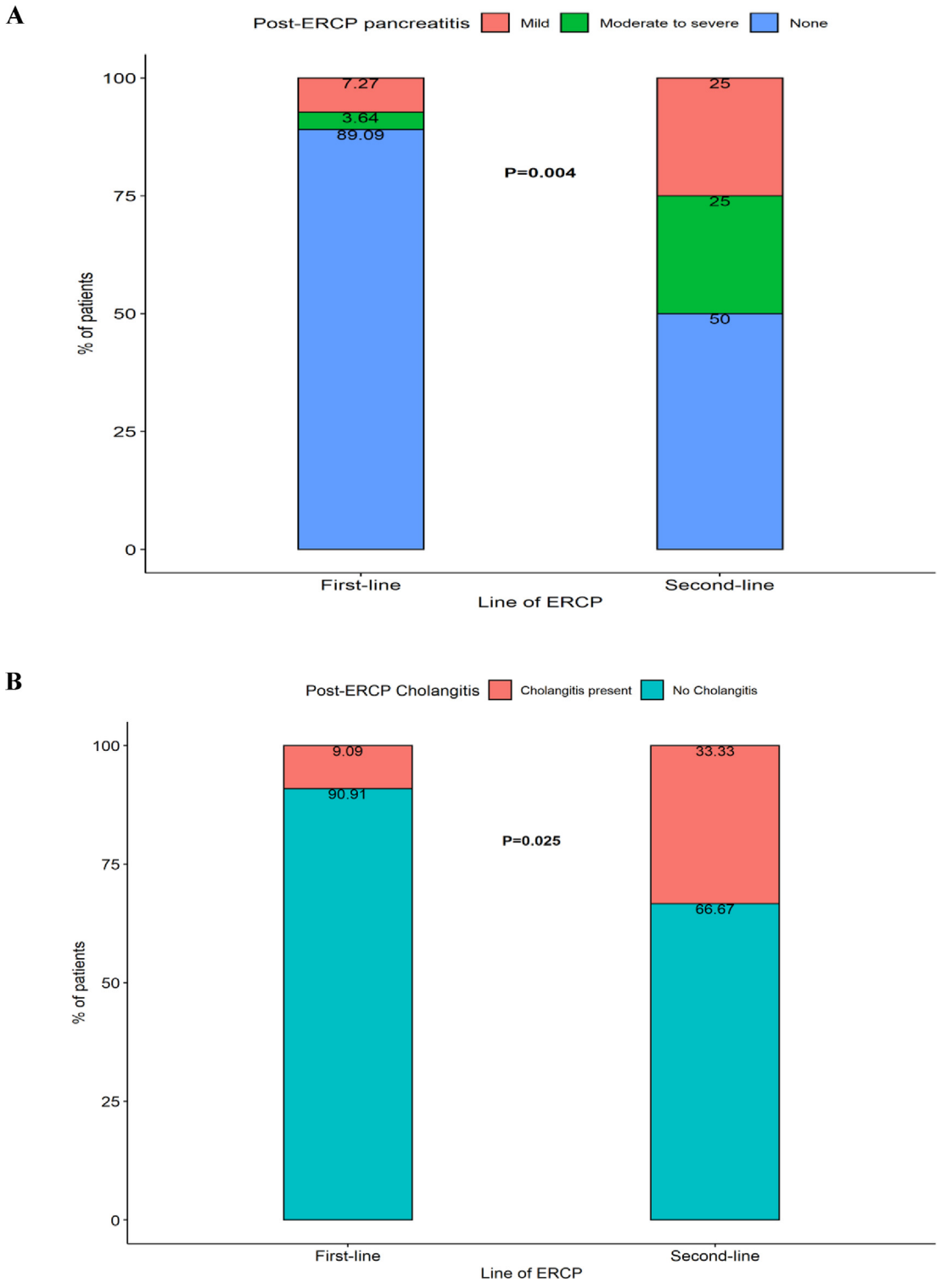

Fig. 2. Comparing the rates of (A) pancreatitis and (B) cholangitis between the study groups.

a risk factor for increasing complications in a recent study,[19] despite previous reports of their neutral effects on post-ERCP pancreatitis, bleeding, or death.[20]

In the current study, the mean time of cannulation was 24 min in the first-line and 27.17 min in the second-line. Despite being nonsignificantly different ($P = 0.2$), there was a trend toward

prolonged cannulation in the second-line group that failed to demonstrate the statistical significance due to the relatively low sample size but contributes partly to the higher incidence of post-ERCP complications. In this context, Lee et al. concluded through a decision tree analysis that biliary cannulation time was associated with a significantly higher rate of post-ERCP pancreatitis ($\chi 2 = 49.857$, $P < 0.001$).[14]

In particular, the incidence of biochemical and clinical pancreatitis was evaluated in the current study. There was no significant difference in post-ERCP hyperamylasemia at 24 h after ERCP was 32.7% (18/55) in the first-line and 33.3% (4/12) in the second-line (There was no significant difference ($P > 0.99$)0.05) between the two groups. However, post-ERCP clinical pancreatitis was demonstrated with significantly higher incidence in the second-line v. first-line group (50% vs 10.9%, $P = 0.004$). The severity of pancreatitis was also significantly lower in the first-line group. Mild pancreatitis was experienced in 7.3% (4/55) of the first-line compared with 25% (3/6) in the second-line. Mododate to rate#-to#severe pancreatitis was experienced in 3.6% (2/55) of the first-line compared with 25% (3/6) in the second-line. The overall rate of post-ERCP clinical pancreatitis was 17.9% (12/67). This contradicts to the relatively low rate of pancreatitis reported by Andriulli et al. in their systematic review that included 21 retrospective studies.[21] They demonstrated that the overall incidence of post-ERCP pancreatitis was 3.47% (95% CI: 3.19−3.75%). Mild-to-moderate post-ERCP pancreatitis occurred in 5.17% (95% CI: 4.83−5.51%), and severe pancreatitis in 1.67% (95% CI: 1.47−1.87%).[21]

The incidence of post-ERCP pancreatitis could be related to many risk factors which could be factors related to the patient like history of previous pancreatitis, dysfunction of sphincter of Oddi, not elevated serum bilirubin, and female sex, or factors related to procedures like pancreatic duct injection, precut sphincterotomy, papillary balloon dilation, and more than five cannulations. Furthermore, in a recent systematic review, history of post-ERCP pancreatitis is considered a risk factor for adverse events. These factors should be kept in mind by the endoscopist before performing ERCP.[22]

The significantly lower rates of clinical pancreatitis in the first-line group vs. the second-line group is related to the prevalent use of the double guidewire technique in the first trial in 34/67 patients (50.75%). Contrast agent injection into the pancreatic duct is a major risk factor for post-ERCP pancreatitis in wire-guided cannulation, while in a double guidewire method a guidewire is cannulated into the bile duct without injection of a contrast agent. So, it became associated with a lower incidence of post-ERCP pancreatitis in comparison with contrast-enhanced methods and increased rate of deep biliary cannulation.[23]

Acute cholangitis was demonstrated with higher incidence in the second-line vs. first-line (33.33% vs. 9.09%, respectively, $P = 0.025$). The rate of cholangitis demonstrated through the current study is much higher than the literature-reported incidence of post-ERCP cholangitis, which ranged between 1 and 2.4%.[24] The higher incidence of cholangitis in the current study is related to the inclusion of significant proportion of patients, who failed ERCP previously (13.4%). Previous history of ERCP was previously demonstrated with increased post-ERCP cholangitis risk during the multivariate analysis of 4234 ERCP cases.[25]

We found no significant difference between the first-line vs. the second-line group as regards the incidence of bleeding ($P = 0.45$). In line with our findings, post-ERCP bleeding was reported to be a rare adverse effect of ERCP.[26] Post-ERCP bleeding was previously found to be related to sphincterotomy, which was adopted in a small proportion of our study group (6/57, 9%). Moreover, none of the patients within our study groups was presented with coagulopathy, or was receiving an anticoagulant therapy, which were previously reported as the most important risk factors for post-ERCP bleeding.[27]

To the best of our knowledge, the current study is the first in our hospitals to evaluate the efficacy and safety outcomes of seven different procedures in the first- and second-line therapeutic ERCP in a wide variety of ERCP patients with difficult cannulation. However, the study is limited by the relatively low sample size and the short period of follow-up following ERCP, which may result in the underestimation of post-ERCP complications. Future research should focus on assessing ECRP outcomes in the populations that are concluded through the current study to have a greater incidence of ERCP complications, including malignant or previously failed ERCP subjects. Studies should be designed to be randomized, controlled, clinical trials with a follow-up period of more than 1 year to minimize the risk of selection bias and to correctly estimate the incidence of long-term complications following ERCP.

4.1. Conclusion

ERCP failure is more frequently experienced in malignant and previously failed ERCP cases.

Second-line ERCP techniques are associated with significantly higher rates of clinical pancreatitis and cholangitis.

Authorship

All authors have a substantial contribution to the article.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

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Declaration of competing interest

The authors declared that there were no conflicts of interest.

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