







# A Comparative Study of Transpancreatic Sphincterotomy, Double Guidewire Technique, and Precut Sphincterotomy in Difficult Naive Biliary Cannulations in a Tertiary Care Center in Western India

Shivani Chopra<sup>1</sup>  Vikramaditya Rawat<sup>1</sup> Meghraj Ingle<sup>1</sup> Saiprasad Lad<sup>1</sup> Deepak Sasikumar<sup>1</sup>   
Vinay D. Borkar<sup>1</sup>  Yatin Lunagariya<sup>1</sup> Kiran B.<sup>1</sup> Mit Shah<sup>1</sup> Chintan Tailor<sup>1</sup>  Somraj Patil<sup>1</sup>

<sup>1</sup> Department of Gastroenterology, Lokmanya Tilak Municipal Medical College, Mumbai, Maharashtra, India

Address for correspondence Meghraj Ingle, MD DNB, Department of Gastroenterology, Room no 2, College building first floor, Lokmanya Tilak Municipal Medical College and General Hospital, Sion, Mumbai 400022, Maharashtra, India (e-mail: gastroSION@gmail.com).

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## Abstract

**Introduction** Difficult biliary cannulation leads to prolonged papillary manipulation and repeated attempts at cannulation are known to increase the risk of postendoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. This study aims to compare the efficacy and complications of three rescue methods, transpancreatic biliary sphincterotomy (TP), double guidewire technique (DGW), and precut sphincterotomy (precut) in difficult common bile duct (CBD) cannulations.

**Methods** Seventy-six patients (>12 years of age) with a native papilla undergoing ERCP for biliary cannulation were recruited. Those who had inadvertent pancreatic duct cannulations (>1) were included. A pancreatic stent was inserted in all cases. They underwent either DGW ( $n = 25$ ), precut ( $n = 25$ ), or TP ( $n = 26$ ) as rescue methods and were compared in terms of the success of cannulation and post-ERCP complications.

**Results** Of the total 76 cases, 82% were for benign indications, the most common being choledocholithiasis (69.7%). Jaundice was noted in 52% ( $n = 13/25$ ), 60% ( $n = 15/25$ ), and 38.5% ( $n = 10/26$ ) of the DGW, precut, and TP cases, while 40% ( $n = 10/25$ ), 12% ( $n = 3/25$ ), and 30.8% ( $n = 8/26$ ), respectively, were in cholangitis at presentation. The most common type of papilla was type 1 overall and each subgroup. While successful cannulation was achieved in 88.5% ( $n = 23/26$ ) of TP and 84% ( $n = 21/25$ ) of the DGW group, only 64% ( $n = 16/25$ ) of the precut cases were cannulated. Three ( $n = 3/25$ ) cases had mild bleeding and two mild pancreatitis, one severe pancreatitis, and one perforation were recorded in the precut group. One patient each had severe and mild pancreatitis in the DGW group, while one had mild pancreatitis and two had moderate pancreatitis in the TP group. All the patients were managed conservatively.

**Conclusion** There was no significant difference in the technical success rate ( $p = 0.075$ ) as well as complications ( $p = 0.117$ ) between the three salvage methods for difficult naive CBD cannulations.

## Keywords

- ▶ difficult biliary cannulation
- ▶ ERCP
- ▶ double guidewire
- ▶ precut
- ▶ transpancreatic sphincterotomy

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## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was first done in 1968. Therapeutic pancreaticobiliary endoscopy subsequently was developed with the introduction of endoscopic sphincterotomy in 1974.<sup>1</sup> In a naive papilla, cannulation may become difficult due to small size of the papilla, peripapillary diverticulum, or surgically changed anatomy (e.g., Billroth II anastomosis). As per the European Society of Gastrointestinal Endoscopy (ESGE), difficult biliary cannulation is defined by the presence of one or more of the following: more than 5 contacts with the papilla while attempting to cannulate; more than 5 minutes spent attempting to cannulate following visualization of the papilla; or more than one unintended pancreatic duct (PD) cannulation or opacification.<sup>2</sup> Difficult biliary cannulation leads to multiple attempts, causing trauma and edema to the papilla, further leading to post-ERCP pancreatitis.

This study compares the outcomes of three salvage methods in cases of difficult biliary cannulation—precut sphincterotomy, double guidewire technique, and transpancreatic sphincterotomy, in patients with naive papillae undergoing ERCP in a tertiary health care center.

## Materials and Methods

### Study Design and Inclusion Criteria

We conducted retrospective analysis of data collected prospectively in a single center from October 2022 to December 2023. The patients were >12 years of age undergoing ERCP with native papillae. The patients with difficult biliary cannulation along with inadvertent PD cannulation (>1) only, were included. The three rescue methods applied were transpancreatic biliary sphincterotomy (TP), double guidewire technique (DGW), and precut sphincterotomy (precut). An essential criterion was occurrence of inadvertent PD cannulation (>1).

### Exclusion Criteria

Patients less than 12 years of age and those who had undergone successful ERCP cannulations in the past were not included. Direct precut sphincterotomy, without attempting conventional biliary cannulation were excluded. Patients with altered anatomy and deranged coagulation profiles were excluded from the study.

### Protocol

All the patients who were >12 years of age undergoing ERCP biliary cannulation for the first time, presenting/referred to our center were included. The demographics, nature and etiology of the pathology, clinical history suggestive of jaundice, cholangitis, and pancreatitis were recorded. Guidewire-assisted biliary cannulation was attempted in all cases. All etiologies requiring ERCP were included. After institutional ethics approval (approval no.: IEC/92/22), informed consent explaining the procedure, possible complications, and consequences was obtained from all the cases. The procedure was performed by six endoscopists with experi-

ence of at least 200 ERCP procedures<sup>3</sup> using a side-viewing duodenoscope (Olympus TJF-150). Procedure was performed in left lateral position under intravenous sedation or general anesthesia as per general condition of the patient. Those experiencing difficult biliary cannulation defined as per the ESGE guidelines and undergoing at least one inadvertent PD cannulation were further selected and consecutively subjected to one of the rescue methods for biliary cannulation. Data regarding the type of papilla was noted.

The method of transpancreatic biliary sphincterotomy involves cannulating the PD through the papillary orifice, cutting the septum that separates the PD from the bile duct at the 11 to 12 o'clock position in the direction of the bile duct, till the biliary duct orifice is exposed thus facilitating cannulation of the common bile duct (CBD).<sup>2,4</sup> Double guidewire technique involves using a guidewire to physically occupy the PD to prevent repeated PD cannulation and guide the direction of the wire into the bile duct. The sphincterotome is placed above the PD wire and pushes it out of the way, so CBD cannulation with the second guidewire is facilitated, without cut of the septum.<sup>5</sup> Precut sphincterotomy consists of an incision in the papilla starting at the upper margin of the papillary orifice in the direction of the bile duct until the underlying biliary sphincter is visualized.<sup>2</sup>

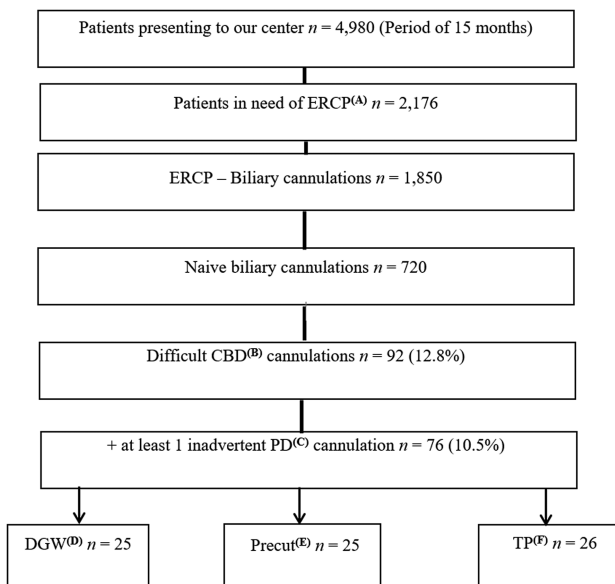
A PD stent (5 Fr × 5 cm) was left in place in the PD in all cases,<sup>6</sup> prior to sphincterotomy in the precut group<sup>7</sup> and after the cannulation and completion of procedure in the transpancreatic sphincterotomy and DGW groups. Intravenous fluids (1.5 mL/kg/h) and rectal indomethacin was given to all patients. Standard care for respective underlying etiology and antibiotics for cholangitis were given. The success or failure of the technique was recorded. Intraprocedural complication like bleeding was managed by standard practices. In cases of failure, the second approach used included use of another technique, percutaneous transhepatic biliary drainage (PTBD), or abandoning the procedure and reattempting at a later date. This choice was made at the discretion of the endoscopist. All the patients were followed up during ward stay or telephonically regarding the development of complications, pancreatitis, and perforation. The complications were graded using Cotton's grades for post-sphincterotomy bleed and post-ERCP pancreatitis.

### Outcome Measures

The three salvage methods for difficult biliary cannulation were compared in terms of the success of the technique, in terms of successful biliary cannulation, and the complication rate.

### Statistical Analysis

Data was entered into Microsoft Excel (Windows 7; Version 2007) and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 22.0; SPSS Inc., Chicago, Illinois, United states). Descriptive statistics such as mean and standard deviation for continuous variables were calculated, while frequencies and percentages were calculated for categorical variables. Association between variables was analyzed by using the chi-square test



**Fig. 1** Study design. (A) Endoscopic retrograde cholangiopancreatography. (B) Common bile duct. (C) Pancreatic duct. (D) Double guidewire. (E) Precut sphincterotomy. (F) Transpancreatic sphincterotomy.

for categorical variables. We took proportion of difficult cannulation among total naive cannulations, as 12%,<sup>8</sup> with 95% confidence limit. Level of significance was set at 0.05, beta error of 20%, and power of the study was 80%. Sample size was calculated using the formula,  $\text{Sample size} = \frac{[Z_{(1-\alpha)}]^2 * p * q}{(d)^2}$ , where  $\alpha$  is the level of significance (5%),  $Z$  is the standard normal variate for 95% of confidence interval = 1.96,  $q$  is  $100-p$ ,  $p$  is 12%, and  $d$  is absolute precision = 8%. Accordingly, the sample size calculated was 63.36, rounded off to 66. Hence, minimum 22 study subjects had to be taken for the study in each group.

## Results

Of the total patients presenting to our center ( $n = 4,980$ ) over 15 months (October 2022–December 2023), 2,176 required ERCP. Biliary stenting was done in 1,850, out of which 720 were naive CBD cannulations. Ninety-two patients (12.8%) had difficult biliary cannulation, out of which 76 (10.5%) had an essential inadvertent PD cannulation (► Fig. 1). Therefore, 76 patients (mean age = 50.82 years; males = 43 [56.6%]) were included in our study; 82.9% of the cases were benign in nature, and the most common cause being choledocholithiasis ( $n = 53$ , 69.7%). The most frequent malignant etiology was pancreatic cancer (9.2%). Half of the cases had jaundice at presentation, while 27.6% had cholangitis and 7.9% had pancreatitis. The 76 cases were grouped into double guidewire ( $n = 25$ ), precut sphincterotomy ( $n = 25$ ), and transpancreatic sphincterotomy ( $n = 26$ ). There was no significant difference between the demographic and clinical characteristics of the three groups ( $p > 0.05$ ) (► Table 1).

The most frequent papilla encountered was type 1 ( $n = 36$ , 48%), followed by type 2 ( $n = 17$ , 22.7%), type 4 ( $n = 15$ , 20%), and type 3 ( $n = 7$ , 9.3%). This frequency was similar in the

DGW and TP subsets, while the precut group had type 1 ( $n = 13$ , 52%), type 4 ( $n = 8$ , 32%), type 3 ( $n = 3$ , 12%), and type 2 ( $n = 1$ , 4%), with a  $p$ -value of 0.047.

Of the total cases, 78.9% ( $n = 60$ ) achieved successful cannulation and 21.1% ( $n = 16$ ) were unsuccessful. Among them, the success rates of DGW, precut, and TP are 84% ( $n = 21$ ), 64% ( $n = 16$ ), and 88.5% ( $n = 23$ ). However, there was no statistical difference among them ( $p = 0.075$ ). The presence of jaundice, cholangitis, or pancreatitis did not influence the outcome of the procedure (► Table 2).

The 16 cases (21.1%) which could not be cannulated were subjected to a second method. In the four cases of the DGW group (16%), half underwent cannulation with a precut and the other half with a TP approach. Among the nine precut failures (36%), one each succeeded with the DGW and TP approach, while three patients were referred to interventional radiology for PTBD and four were abandoned and reattempted at a later date with successful cannulation. The TP group had three failed cannulations (11.5%), which were salvaged by a precut, PTBD, and repeat attempt.

Twelve patients (15.8%) of the total developed complications. The most common complication was pancreatitis ( $n = 8$ , 10.52%), albeit half of them were mild ( $n = 4$ , 5.3%) in severity and two had moderately severe pancreatitis (2.6%). The two (2.6%) patients with severe acute pancreatitis did not require any intervention and recovered with conservative management. A perforation was seen in one case (1.3%) and three patients (3.9%) experienced mild bleeding, all of which belonged to the precut group (► Table 3).

Note that 27.6% ( $n = 21$ ) of the patients required admission or prolongation of hospital stay—DGW ( $n = 4$ , 16%), precut ( $n = 10$ , 40%), and TP ( $n = 7$ , 26.9%) each, albeit the  $p$ -value was 0.164.

## Discussion

Difficult biliary cannulation is seen in 10 to 15% of patients of biliary obstruction.<sup>9</sup> In such cases, the application of a rescue method facilitates the completion of the procedure. It also avoids trauma and edema to the papilla, which commonly occur due to persistent failed attempts at conventional cannulation. The three methods used in our study include double guide technique (DGW), needle knife precut sphincterotomy (precut), and transpancreatic sphincterotomy (TP). The DGW technique involves placement of a guidewire in the PD, and cannulation of the CBD using another guidewire. In the TP method, after PD cannulation, a sphincterotomy is performed to cut the septum between the PD and CBD, exposing the biliary orifice for aiding cannulation. In the precut group, a sphincterotomy is performed along the direction of the biliary duct to expose the biliary epithelium. Usually, a precut sphincterotomy does not require PD cannulation.<sup>2</sup> Our study includes patients of difficult biliary cannulation in native papillae with inadvertent PD cannulation. A PD stent was placed in all the cases.

A study by Dalal et al in 2022, showed a difficult biliary cannulation rate of 12.8%,<sup>10</sup> similar to our study. Morphology of duodenal papilla influencing choice of advanced

**Table 1** Epidemiology, clinical, and endoscopic characteristics of the cases

|                                    |                         | Method of cannulation |                         |                     | Total     |
|------------------------------------|-------------------------|-----------------------|-------------------------|---------------------|-----------|
|                                    |                         | DGW ( <i>n</i> = 25)  | Precut ( <i>n</i> = 25) | TP ( <i>n</i> = 26) |           |
| Gender                             | Female                  | 12 (48.0)             | 10 (40.0)               | 11 (42.3)           | 33 (43.4) |
|                                    | Male                    | 13 (52.0)             | 15 (60.0)               | 15 (57.7)           | 43 (56.6) |
| Mean age (y)                       |                         | 49.92                 | 51.72                   | 50.81               | 50.82     |
| Nature of disease                  | Benign                  | 19 (76.0)             | 23 (92.0)               | 21 (80.8)           | 63 (82.9) |
|                                    | Malignant               | 6 (24.0)              | 2 (8.0)                 | 5 (19.2)            | 13 (17.1) |
| Etiology                           | Choledocholithiasis     | 13 (52.0)             | 21 (84.0)               | 16 (61.5)           | 50        |
|                                    | CBD stricture           | 3 (12.0)              | 1 (4.0)                 | 3 (11.5)            | 7 (9.2)   |
|                                    | Carcinoma GB            | 3 (12.0)              | –                       | 2 (7.7)             | 4 (5.3)   |
|                                    | Carcinoma pancreas      | 2 (8.0)               | 2 (8.0)                 | 3 (11.5)            | 7 (9.2)   |
|                                    | Bile leak               | 5 (20.0)              | 1 (4.0)                 | 2 (30.8)            | 8 (10.5)  |
|                                    | PCC                     | 1 (4.0)               | –                       | –                   | 1 (1.3)   |
|                                    | Biliary ascariasis      | –                     | –                       | 1 (3.8)             | 1 (1.3)   |
| Clinical history                   | Jaundice                | 13 (52.0)             | 15 (60.0)               | 10 (38.5)           | 38 (50.0) |
|                                    | Cholangitis             | 10 (40.0)             | 3 (12.0)                | 8 (30.8)            | 21 (27.6) |
|                                    | History of pancreatitis | 3 (12.0)              | 1 (4.0)                 | 2 (7.7)             | 6 (7.9)   |
| Difficulty grade of ERCP (by ASGE) | 1                       | 1 (4.0)               | 2 (8.0)                 | 1 (3.8)             | 4 (5.3)   |
|                                    | 2                       | 15 (60.0)             | 20 (80.0)               | 18 (69.2)           | 53 (69.7) |
|                                    | 3                       | 9 (36.0)              | 3 (12.0)                | 7 (26.9)            | 7 (26.9)  |
| Type of papilla                    | 1                       | 12 (50.0)             | 13 (52.0)               | 11 (42.3)           | 36 (48.0) |
|                                    | 2                       | 5 (20.8)              | 1 (4.0)                 | 11 (42.3)           | 17 (22.7) |
|                                    | 3                       | 3 (12.5)              | 3 (12.0)                | 1 (3.8)             | 7 (9.3)   |
|                                    | 4                       | 4 (16.7)              | 8 (32.0)                | 3 (11.5)            | 15 (20.0) |

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CBD, common bile duct; DGW, double guidewire; ERCP, endoscopic retrograde cholangiopancreatography; GB, gallbladder; Precut, precut sphincterotomy; TP, transpancreatic sphincterotomy.

cannulation techniques was studied in 805 naive papillae by Angsuwatcharakon et al. Note that 23.2% required advanced cannulation techniques, types 2 and 4 more than type 1. Type 3 required precut sphincterotomy at a higher rate.<sup>11</sup> Our study had type 1 papilla as the most common papilla; however, the method of cannulation in our study was independent of the type of papilla.

A retrospective analysis by Wang et al of transpancreatic sphincterotomy (*n* = 140) and needle knife precut sphincterotomy (*n* = 76), showed no significant difference between the success rates of cannulation (90.0 vs. 90.8%) and post-ERCP complications (14.3 vs. 18.4%). Pancreatic stenting was done only in 18.6 and 2.6% of the transpancreatic and needle knife sphincterotomy cases.<sup>8</sup>

A comparative study between needle knife (*n* = 34) and transpancreatic sphincterotomy (*n* = 29) of 63 consecutive patients by Catalano et al,<sup>12</sup> showed a 100% success of cannulation in the transpancreatic group, against a 77% success rate in the needle knife group. The complications were less frequent in the transpancreatic sphincterotomy group (1/29, 3.5%) compared with the needle knife sphincterotomy group (6/34, 17.7%). Another study by Halttunen

et al, comparing transpancreatic sphincterotomy with needle knife sphincterotomy showed a difficult cannulation rate of 9%. Needle knife sphincterotomy was performed in those cases where PD cannulation was unsuccessful. The success of cannulation was 97.3% in the transpancreatic group versus 71.3% in the needle knife group (*p* < 0.001). There was no difference in the post-ERCP pancreatitis between the two groups.<sup>13</sup> Our study included only those cases with inadvertent PD cannulation and a pancreatic stent was placed in every case, which could explain the lack of difference between the methods.

In a multicenter randomized control trial by Herreros de Tejada et al, of 188 patients comparing DGW technique to standard cannulation, showed DGW to be noninferior to standard cannulation and with a higher rate of pancreatitis.<sup>14</sup> This could be a result of the PD being cannulated selectively in the DGW group, as the criteria for difficult cannulation was 5 failed attempts of biliary cannulation only. A Korean randomized controlled study over 5 years compared the double guidewire technique (*n* = 34) and transpancreatic sphincterotomy (*n* = 37). While the success rate was similar for both the groups (91.2 vs. 91.9%), the

**Table 2** Influence of preprocedure characteristics on outcome of technique

| Preprocedure    | Technique      | Method of cannulation |                 |             | Total     |
|-----------------|----------------|-----------------------|-----------------|-------------|-----------|
|                 |                | DGW (n = 25)          | Precut (n = 25) | TP (n = 26) |           |
| Cholangitis     | Successful     | 8 (80.0)              | 2 (66.7)        | 7 (87.5)    | 17 (81.0) |
|                 | Not successful | 2 (20.0)              | 1 (33.3)        | 1 (12.5)    | 4 (19.0)  |
| No cholangitis  | Successful     | 13 (86.7)             | 14 (63.6)       | 16 (88.9)   | 43 (78.2) |
|                 | Not successful | 2 (13.3)              | 8 (36.4)        | 2 (11.1)    | 12 (21.8) |
| p-Value         |                | 0.656                 | 0.918           | 0.918       | 0.229     |
| Jaundice        | Successful     | 10 (83.3)             | 6 (60.0)        | 14 (87.5)   | 30 (78.9) |
|                 | Not successful | 2 (16.7)              | 4 (40.0)        | 2 (12.5)    | 8 (21.1)  |
| No jaundice     | Successful     | 11 (84.6)             | 10 (66.7)       | 9 (90.0)    | 30 (78.9) |
|                 | Not successful | 2 (15.4)              | 5 (33.3)        | 1 (10.0)    | 8 (21.1)  |
| p-Value         |                | 0.930                 | 0.733           | 0.846       | 1.000     |
| Pancreatitis    | Successful     | 2 (66.7)              | 1 (100.0)       | 2 (100.0)   | 5 (83.3)  |
|                 | Not successful | 1 (33.3)              | 0               | 0           | 1 (16.7)  |
| No pancreatitis | Successful     | 19 (86.4)             | 15 (62.5)       | 21 (87.5)   | 55 (78.6) |
|                 | Not successful | 3 (13.6)              | 9 (37.5)        | 3 (12.5)    | 15 (21.4) |
| p-Value         |                | 0.382                 | 0.444           | 0.595       | 0.783     |

Abbreviations: DGW, double guidewire; Precut, precut sphincterotomy; TP, transpancreatic sphincterotomy.

complication of post-ERCP pancreatitis were higher in the DGW group (38.2 vs. 10.8%;  $p < 0.011$ ).<sup>5</sup> An Italian single-center data of 202 patients with unintended PD cannulation, the rate of success of biliary cannulation was higher in the DGW group (94.8%) compared to TP (79.2%) at the first attempt ( $p = 0.001$ ).<sup>15</sup> The trial of 68 patients by Sugiyama et al, revealed a success rate of 94% in the TP against 58.8% in the DGW group.<sup>16</sup>

Facciorusso et al in 2022 published a systematic review and network meta-analysis of 2,015 patients in 17 randomized controlled trials of 2 arm studies of adjunctive methods (needle knife techniques, pancreatic guidewire-assisted technique, pancreatic-assisted technique, and transpancreatic sphincterotomy) with each other or persistence with standard techniques. In the pairwise analysis, the transpancreatic sphincterotomy was superior to early needle knife sphincterotomy and noninferior to guidewire-assisted

techniques with respect to the success of cannulation. The network meta-analysis showed significantly higher success rates of transpancreatic sphincterotomy over the other methods. The post-ERCP pancreatitis was significantly lower in the early needle knife and transpancreatic sphincterotomy cases compared with persistence of standard techniques and other adjunct methods.<sup>17</sup>

Our study is a first of a three-armed comparison of rescue methods (DGW, precut, TP) for difficult native CBD cannulations. Only the cases where inadvertent PD cannulation has occurred have been included. Direct precut sphincterotomy cases were not included and there was placement of pancreatic stents in all the cases, unlike the previously described studies. The success rates of DGW, precut, and TP were 84% ( $n = 21$ ), 64% ( $n = 16$ ), and 88.5% ( $n = 23$ ) with a  $p$ -value of 0.075. Second rescue procedures were successful in all cases and were selected at the discretion of the endoscopist.

**Table 3** Complications of rescue techniques of biliary cannulation

| Complications  | Method of cannulation |                 |             | Total     |
|--|-----------------------|-----------------|-------------|-----------|
|  | DGW (n = 25)          | Precut (n = 25) | TP (n = 26) |           |
| Yes  | 2 (8.0)               | 7 (28.0)        | 3 (11.5)    | 12 (15.8) |
| No   | 23 (92.0)             | 18 (72.0)       | 23 (88.5)   | 64 (84.2) |
| Chi-square test, $p$ -value = 0.117, not significant |                       |                 |             |           |
| Pancreatitis (mild)                                  | 1 (4.0)               | 2 (8.0)         | 1 (3.8)     | 4 (5.3)   |
| Pancreatitis (moderate)                              | –                     | –               | 2 (7.7)     | 2 (2.6)   |
| Pancreatitis (severe)                                | 1 (4.0)               | 1 (4.0)         | –           | 2 (2.6)   |
| Perforation  | –                     | 1 (4.0)         | –           | 1 (1.3)   |

Abbreviations: DGW, double guidewire; Precut, precut sphincterotomy; TP, transpancreatic sphincterotomy.



Complications developed in 15.8% ( $n = 12/76$ ) of the cases. All the cases were managed conservatively and did not require any surgery or intervention. There was no significant difference in the complication rates of the three methods ( $p = 0.117$ ).

**Limitations:** It is a single-center prospective study. Time to completion of procedure was not compared between the methods. The methods of cannulation attempted were independent of the type of papilla, which may influence the success of procedure. In addition, a larger sample size may lead to a statistical difference in the outcomes among the techniques.

## Conclusion

In cases of difficult biliary cannulation, with an inadvertent pancreatic cannulation, one of the rescue methods of cannulation must be applied in order to facilitate success of procedure, considering precut sphincterotomy as one of the options in spite of PD cannulation. This will not only prevent an additional procedure at a later date, but also reduce hospital stay, and optimize utilization of health care resources. Though there is no significant difference between the success rates and complications among the three techniques in our study, larger, randomized, multicenter studies must be done, along with a comparator arm of persistence of standard cannulation.

### Ethical Approval

This study was approved by the institutional review board (approval no.: IEC/92/22).

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None declared.

### Conflict of Interest

None declared.

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