

## Original Research

### Outcome of trans-pancreatic sphincterotomy (TPS) in patients with difficult biliary cannulation: A tertiary care center study from India

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#### ABSTRACT:

**Background and aim:** Gaining access to the biliary duct is the most important step for a successful therapeutic biliary endoscopy. In the current study, we evaluated success and complication rates of a wire-guided trans-pancreatic sphincterotomy (TPS) for cannulating inaccessible common bile ducts at our institution. **Methods:** The study was conducted at a tertiary care referral center between January 2016 and December 2018. Consecutive patients with difficult biliary cannulation who underwent transpancreatic sphincterotomy to gain biliary access were included in the study and analyzed, retrospectively. Success rate for selective biliary cannulation (SBC) and adverse events associated with TPS were recorded. 1567 patients were referred to our department for ERCP. **Results:** A total of 1567 patients underwent ERCP for biliary indications during the study period. The success rate for primary cannulation techniques was 89%. TPS was utilized for SBC in 64 patients. Common bile duct cannulation was successfully achieved in 63 (98.4%) patients. One patient (1.56%) required a percutaneous transhepatic biliary drainage. There was no major adverse event. Minor adverse events were noticed in three patients (4.68%) including mild pancreatitis in 2 (3.12%) and mild intra-procedural bleeding in 1 (1.56%) patient. **Conclusion:** Trans-pancreatic sphincterotomy (TPS) is a safe and effective technique in patients with difficult biliary cannulation. Randomized trials are required comparing TPS with other techniques in future.

**Key words:** Endoscopic retrograde cholangiopancreatography; Trans-pancreatic sphincterotomy (TPS); Needle-knifeprecut; Complications, Selective biliary cannulation (SBC).

Received: 12 May, 2019

Revised: 20 May, 2019

Accepted: 21 May, 2019

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**This article may be cited as:** Hussain S, Ram S, Bhargava N, Dadhich SK, Kumar N. Outcome of trans-pancreatic sphincterotomy (TPS) in patients with difficult biliary cannulation: A tertiary care center study from India. J Adv Med Dent Scie Res 2019;7(6): 137-141.

#### INTRODUCTION

Selective bile duct cannulation is often required in therapeutic endoscopic retrograde cholangiopancreatography (ERCP). However, bile duct cannulation may not be successful in upto 10-20% using the conventional techniques of cannulation during ERCP. Various alternative cannulation techniques have been described in these cases including double-guidewire cannulation, biliary cannulation after placement of pancreatic duct stent, needle-knife precut

sphincterotomy (NKS) or fistulotomy (NKF) with or without prior pancreatic duct stenting and transpancreatic septotomy (TPS).<sup>1</sup> Early use of alternative cannulation techniques has been shown to reduce complications (especially pancreatitis) associated with ERCP.<sup>2,3</sup>

In this study, we aimed to evaluate the safety and efficacy of TPS for selective biliary cannulation (SBC).

## MATERIALS AND METHODS

The data of all the patients who underwent biliary cannulation (January 2016 to December 2018) using TPS were analyzed, retrospectively. Exclusion criteria were: age < 18 years, pregnancy, uncorrectable coagulopathy, portal hypertension with collaterals, alternative cannulation techniques other than TPS, altered anatomy, failure to gain deep pancreatic ductal access, a prior history of sphincterotomy and refusal to provide informed consent. The study was approved by institutional review board committee and informed consent was obtained from all the patients.

## DEVICES AND ACCESSORIES

The following devices and accessories were used for the ERCP procedure: side-viewing duodenoscope (TJF150; Olympus, Tokyo, Japan), double-lumen sphincterotome (Claver cut, KD-V411M-0320; Olympus) or Ultratome XL (Boston Scientific), electrosurgical generator (ICC200; ERBE, Tübingen, Germany), hydrophilic guide wires (TERUMO GS32263M Inc, Tokyo, Japan).

## TECHNIQUE OF TRANSPANCREATIC SPHINCTEROTOMY

All the ERCP procedures were performed under deep (Propofol) sedation with the patient in prone position. Rectal NSAIDs (Equivalent to 100 mg Diclofenac or Indomethacin) were routinely administered within half hour prior to the procedure unless contraindication existed. CBD cannulation was initially attempted using the standard wire guided technique. A double-lumen sphincterotome preloaded with a 0.032-inch hydrophilic guidewire was used. In cases with inadvertent pancreatic ductal cannulation on more than one occasion, the guidewire was inserted deep into the pancreatic duct. Subsequently, transpancreatic sphincterotomy was performed using a purecut current. The incision was directed towards 11-o'clock and extended till just below the upper limit of the papillary fold. CBD cannulation was attempted at the apex of the incision. After CBD cannulation, the sphincterotomy was extended if required as per the indication. A prophylactic pancreatic duct stent (5 Fr x 5 or 7 cm) was placed in all the subjects.

## CLINICAL OUTCOMES

The primary outcome of the study was successful biliary cannulation using TPS in cases with difficult biliary cannulation as defined below. In addition, the procedure related adverse events including post-ERCP pancreatitis, bleeding (immediate or delayed) and perforation were recorded.

## DEFINITIONS

- A. **Difficult Biliary Access:** More than five contacts with the papilla while attempting to

cannulate, more than 5 minutes spent attempting to cannulate after visualization of the papilla, or more than one unintended pancreatic duct cannulation or opacification.<sup>4</sup>

- B. **Adverse Events:** Adverse events were defined as per the ASGE lexicon for endoscopic adverse events.<sup>5</sup> Mild, moderate and severe adverse events were classified according to the additional length of hospital stay i.e.  $\leq 3$  nights (mild), 4-10 nights (moderate) and  $>10$  nights (severe).
- C. **Post ERCP Pancreatitis:** A rise in serum amylase  $\geq 3$  fold above the upper limit of normal along with abdominal pain 24 hours after ERCP requiring more than 1 additional night of hospital stay.<sup>6</sup>

## STATISTICS

The data were presented as median (range) or mean ( $\pm$ SD). The data were analyzed using MedCalc for Windows, version 12.2.1.0 (MedCalc Software, Ostend, Belgium).

## RESULTS

### PATIENTS' DEMOGRAPHICS

A total of 1567 patients underwent ERCP for various biliary indications during the study period (January 2016 to December 2018). Of these, alternative cannulation techniques were utilized in 173 (11.04%) patients after failure of conventional methods for CBD cannulation. A total of 64 (36.9%) patients (median age 53.1 years, 34 males) underwent CBD cannulation using TPS and were included in the study. (Figure 1) The indications for ERCP included biliary stones (n = 27, 42.19%), malignant biliary strictures (n = 19, 29.69%), post cholecystectomy complications, (n=09, 14.06%) and chronic pancreatitis (n=04, 6.25%) and others (n=05, 7.81%) (Table 1)

### CLINICAL SUCCESS

Successful cannulation of the bile duct was achieved in 63 (98.4%) patients. In one patient, cannulation was not successful and procedure was abandoned in view of creation of a false tract. This patient underwent percutaneous transhepatic biliary drainage, subsequently.

### ADVERSE EVENTS

There were no major adverse events. Minor adverse events were noticed in 3 (4.69%) patients including mild post ERCP pancreatitis in 2 (3.12%) and intraprocedural bleeding in 1 (1.56%) patients. Sphincterotomy site bleeding was controlled using injection of diluted epinephrine (1:10,000) locally. There was no perforation in any of the study patients.

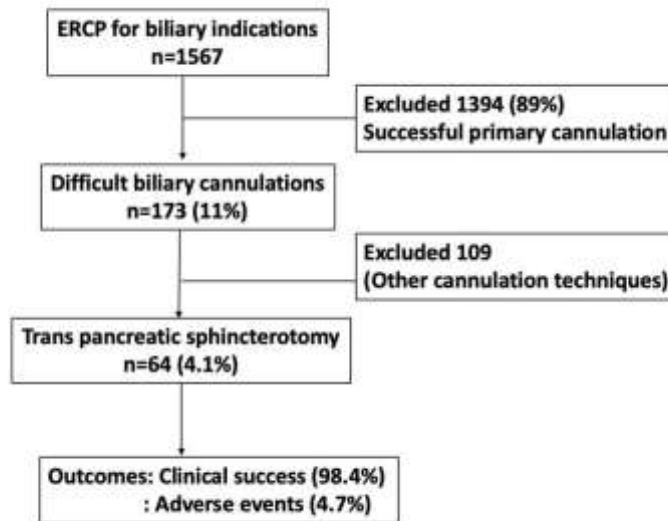
TABLE 1: Baseline characteristics of study patients

	N (%)
Age (median, range) years	53.1 (27-89)
Sex (M/F)	34/30
Benign etiology	45 (70.3%)
- Common bile duct stones	27
- Post cholecystectomy complications	09
- Chronic pancreatitis related biliary strictures	04
- Others (Hydatid, Liver abscess with biliary Communication)	05
Malignant etiology	19 (29.7%)
- Cholangiocarcinoma	04
- Pancreatic cancer	06
- Carcinoma Gallbladder	08
- Periampullary Carcinoma	1

TABLE 2: Outcomes of transpancreatic sphincterotomy in patients with difficult biliary cannulation

Outcome	N (%)
Success rate, n (%)	63 (98.4%)
Complications, n (%)	3 (4.68%)
Pancreatitis, n (%)	2 (3.12%)
Hemorrhage, n (%)	1 (1.56%)
Perforation, n (%)	0 (0%)

Figure 1: Flow diagram depicting study outcomes



**DISCUSSION**

In this study, we found that TPS is a safe and effective technique to gain biliary access in cases with difficult biliary cannulation.

The success of ERCP depends on selective cannulation of the desired ducts which is required to for accomplishing the intended therapeutic procedure. While the conventional techniques of CBD cannulation are successful in the vast majority, alternative cannulation methods may be required in upto 10-20% of patients.<sup>7,8</sup> The modern approach to ERCP aims at

improving the success rate while maintaining low complication rates.<sup>9</sup> Consequently, recent studies support the early use of alternative techniques to minimize the risk of complications especially post ERCP pancreatitis.<sup>2,3</sup>

In this study, we evaluated the outcomes of TPS in 64 cases with difficult biliary cannulation. The failure rate of conventional cannulation techniques was 11% in the current study which is in concordance with the published literature.<sup>7,8</sup> Overall, TPS was utilized in 4.1% patients who underwent SBC.

SBC was achieved in majority (98%) of the patients in whom TPS was utilized. Among the various techniques described for difficult biliary cannulation, NKS or NKF is the most commonly utilized to gain biliary access.<sup>1</sup> Early NKS or NKF has been shown to substantially improve SBC and reduce the incidence of post ERCP pancreatitis. In contrast to NKS which is a free hand technique, the transpancreatic approach to biliary cannulation is more controlled since the sphincterotomy is engaged within the papilla. Therefore, the learning curve appears to be smaller for TPS as compared to NKS which requires considerable expertise. Recent data indicate that TPS is equally or more effective than NKS for biliary cannulation with similar safety profile.<sup>10-13</sup> In addition, TPS has been shown to be more effective than double guide wire technique in a recent randomized trial.<sup>14</sup>

The other major finding of the study was excellent safety profile while using this technique. There were no major adverse events and mild pancreatitis was noticed in only two patients in the current study. Routine use of rectal NSAIDs as well as pancreatic stents could explain the low incidence of post ERCP pancreatitis in the present study.<sup>15</sup> Similar to the results of the current study, the overall rate of adverse events associated with TPS was only 4.1% in a large, recent study. Of note, a higher rate of adverse events has been reported with needle knife sphincterotomy as compared to TPS group in a recent meta-analysis.<sup>11</sup> Likewise, the incidence of post ERCP pancreatitis with double guidewire technique appears to be higher than perceived in the initial studies.<sup>16,17</sup> Therefore, based on the results of our study and the published literature it can be argued that TPS should be utilized early in the course of difficult biliary cannulation and may be preferred over NKS and double guidewire techniques.

The strengths of our study are several folds. This is the first study from India depicting the outcome of TPS in patients with difficult biliary cannulation. The sample size was relatively large and the reporting of adverse events was standardized. However, certain drawbacks are noteworthy. We did not compare TPS with other techniques like NKS and double guidewire method with regards to clinical success and complications. Therefore, the superiority of TPS over other techniques cannot be ascertained from the present study. The use of dual prophylaxis including rectal NSAIDs and prophylactic pancreatic stents may have contributed to a low incidence of post ERCP pancreatitis in the current study.<sup>18,19</sup> Whether prophylactic pancreatic stents should be routinely placed after TPS is debatable and randomized trials are warranted in this regard.

## CONCLUSION

TPS is a safe and effective technique for SBC in cases with difficult biliary cannulation. Randomized

comparison studies are required with other cannulation techniques in future.

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