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Original Research

Outcomes of transpancreatic sphincterotomy with and without prophylactic pancreatic stent in cases with difficult biliary cannulation

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ABSTRACT:

Background and aim: Alternative techniques of biliary cannulation are often required during endoscopic retrograde cholangiopancreatography (ERCP). Technical difficulty, success rates and complications associated with these techniques may vary. In this study, we aimed to evaluate and compare the efficacy of transpancreatic sphincterotomy (TPS) with or without pancreatic duct (PD) stenting in cases with difficult biliary cannulation. **Methods**: The data of consecutive patients with difficult biliary access (January 2016 to June 2017) during ERCP was analyzed, retrospectively. Cases who underwent biliary cannulation via TPS were included in the study. Clinical success and complications were compared between the PD stent and no PD stent groups. **Results**: A total of 764 patients underwent ERCP during the study period. Of these, TPS was utilized in 59 patients. TPS was technically successful in all the patients. Clinical success was recorded in 57 patients (96.6%). There was no significant difference in clinical success between the two groups(PD stent 96.77% vs No PD stent 96.4%; P=1.000). Minor adverse events were noticed in 5 patients including mild pancreatitis (3) and intraprocedural bleeding (2). Adverse events were similar in cases with and without prophylactic PD stent placement (6.45% vs 7.14%, p=0.661). **Conclusion**: TPS is a safe and effective technique in cases with difficult biliary cannulation. The placement of prophylactic PD stent does not appear to effect the incidence of complications after TPS.

Key words: endoscopy; cholangiopancreatography; complications.

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INTRODUCTION

Conventional techniques of endoscopic retrograde cholangiopancreatography(ERCP) for biliary cannulation are usually successful in about 80-90% of cases. In cases with difficult biliary cannulation, several alternative techniques have been described. These include double guide wire technique, pre-cut sphincterotomy and transpancreatic sphincterotomy (TPS).[1]More recently, TPS is being increasingly utilized in cases with difficult biliary cannulation mainly due to technical ease of the procedure.[2-4] Although, TPS has been shown to be a safe technique post ERCP pancreatitis (PEP) may still occur. Whether placement of prophylactic PD stent reduces the incidence of PEP after TPS is not well known.

In this study, we aimed to evaluate the success rate of TPS and compare the incidence of PEP in cases with and without prophylactic PD stent placement.

MATERIALS AND METHODS

The study was conducted at a tertiary care centre with high volume of ERCP in India. The data of all the

patients who underwent ERCP in the department of gastroenterology between January 2016 to June 2017, were analyzed retrospectively. Consecutive cases with failed biliary access to conventional techniques and who underwent biliary cannulation by TPS were included in the study. The success rate of cannulation with TPS technique and the adverse events (mainly PEP) were analysed and compared between the groups with and without prophylactic PD stenting after the TPS. Exclusion criteria were as follows: age<18 years, uncorrectable coagulopathy, portal hypertension, pregnancy, altered gastrointestinal anatomy and cases whom techniques other than TPS were utilized for biliary cannulation.

The study was approved by the institutional review board committee and informed consent was obtained from all the patients.

OUTCOMES

The main aim of the study was to evaluate the success rate of TPS in cases with difficult biliary cannulation. The secondary aim was to compare the difference in the incidence of PEP in cases with and without prophylactic PD stenting.

TECHNIQUE OF TPS

The technique of TPS has been described by Goff and colleagues previously.[5]In brief, this technique involves the following steps. A side-viewing duodenoscope (TJF150; Olympus, Tokyo, Japan) was used for all the ERCP procedures. A sphincterotome (Clever cut , KD-V411M-0320; Olympus)or UltratomeXL (Boston Scientific) preloaded with guidewire (TERUMO GS32263M Inc, Tokyo, Japan) was used for cannulation. In cases with unintentional cannulation of the PD on more than one occasion, the guidewire was inserted deep into the PD. Subsequently, sphincterotomy was performed in 11'Oclock direction with the aim to divide the septum between the two ducts i.e. bile duct and pancreatic duct. An electrosurgical generator (ICC200 ERBE, Tubingen, Germany) with pure cutting current was used for sphincterotomy. The extent of sphincterotomy was left to the discretion of the endoscopist performing the procedure. Thereafter, the cannulation of the bile duct was reattempted using the guide wire assistance along the top of the incision. After gaining the biliary access, the sphincterotomy was usually extended depending on the indication for ERCP. At the end of the intended therapeutic ERCP procedure, the decision to place a prophylactic PD stent was left to the operator's discretion. All the patients received rectal suppository (equivalent to indomethacin or diclofenac100mg) for PEP prophylaxis.

DEFINITIONS

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.

Adverse Events: adverse events were defined as per the ASGE lexicon for endoscopic adverse events. Mild, moderate and severe adverse events were classified according to the additional length of hospital stay i.e. ≤3 nights (mild), 4-10 nights (moderate) and >10 nights (severe).

Post ERCP Pancreatitis: a rise in serum amylase ≥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.

STATISTICAL ANALYSIS

The Statistical Product and Service Solutions SPSS 15.0 statistical software and x2 test were used to assess success rates of cannulation and complications. P<.05 was considered statistically significant.

RESULTS

A total of 764 ERCPs were performed for various biliary indications during the study period (January 2016 until June 2017). Of these, difficult biliary access was defined in 87 patients (11.39%). TPS was utilized in 59 cases [36 males, mean age 62.7 years, (range 25-92)]. Prophylactic PD stent was placed in 31 cases (52.54%). The demographic characteristics were similar in both the groups i.e. those who received and who did not receive prophylactic PD stenting. (Table 1)

Success rate of bile duct cannulation

Biliary cannulation was successful in 57(96.61%) cases. There was no significant difference in the success rates between both the groups (PD stent 96.77% vs No PD stent 96.4%; P=1.000). (Table 2). Patients with failed ERCP underwent percutaneous transhepatic biliary drainage.

Postoperative complications

Overall, there were 5 (8.47%) complications including mild PEP in 3 and minor bleeding from the sphincterotomy site in 2 patients. The incidence of complications were not significantly different in both the groups (6.45% vs 7.14%, p=0.661). PEP was managed with intravenous fluids, nil per os and analgesics. Post sphincterotomy bleeding was controlled in both the cases using local injection of diluted epinephrine (1:10,000). There were no major complications or fatality in the study cohort.

Table1: Demographic distribution of patients between the 2 groups

Patient Characteristics	Sphincterotomy group	Sphincterotomy and pancreatic duct stenting group
No. patients	28	31
Sex	17 M,11F	19 M,12 F
Age (mean,range) years	63.4 (25-87)	62.7(27-91)
Etiology		
Benign	19	21
Malignant	09	09

Table: 2 The bile duct cannulation success rates and complication rates between the 2 groups

	Sphincterotomy (28) (n %)	**Sphincterotomy and pancreatic duct stenting** (31) (n %)	**P value**
Bile duct cannulation - Success	27/28 (96.4%)	30/31(96.77%)	NS
Bile duct cannulation - Failure	1/28 (3.6%)	1/31(3.23%)	NS
Overall complications	3/28(10.71%)	2/31 (6.45%)	0.66 (NS)
Pancreatitis	2/28(7.14%)	1/31 (3.22%)	NS
Bleeding	1/28 (3.57%)	1/31 (3.22%)	NS

DISCUSSION

In this study we found that TPS is a safe and effective technique for gaining biliary access in cases with difficult biliary cannulation. There, is no difference in the incidence of adverse events whether a prophylactic PD stent is utilized or not.

The success rate of conventional cannulation techniques has largely remained constant over last several decades. Consequently, alternative techniques of cannulation are required in a sizeable proportion of patients. Needle knife sphincterotomy (NKS) and TPS are the two most often utilized techniques in cases with a difficult biliary access.[6]There is ample data regarding the safety and efficacy of NKS. However, TPS is relatively newer and data on its safety and efficacy are limited when compared to NKS.

In this study, we analyzed the efficacy and safety of TPS in cases with difficult biliary cannulation. Overall, convention ERCP techniques were unsuccessful in about 11% of cases. Our failure rate is in agreement with that of the published literature (10-30%). TPS was technically successful in all the patients. Moreover, successful biliary cannulation was achieved in majority of the patients where this technique was utilized. This means that TPS is an effective technique in these cases. In agreement to the results of our study, several recent studies indicate that TPS is a highly successful technique for biliary cannulation in difficult cases. On the contrary, NKS requires a great deal of expertise and therefore difficult to utilize especially early during the learning curve. In a large study, an experience of at least 100 procedures was suggested to achieve a safe precut sphincterotomy.[7]

The second aim of the study was to evaluate the utility of prophylactic PD stent to prevent PEP in cases who undergo biliary cannulation using TPS.PEP is the most common serious adverse event associated with ERCP.[8]Early use of alternative cannulation techniques like NKS have been shown to reduce the incidence of PEP when compared to repeated cannulation attempts with convention techniques.[9, 10]Various preventive measures have been advocated to prevent PEP which include aggressive hydration with ringer lactate, rectal NSAIDs and prophylactic PD stenting.[11, 12]Of these, prophylactic PD stents are widely utilized for the prevention of PEP.[13, 14]However, there is limited data on the role of prophylactic PD stenting after performing TPS. In this study, there was no difference in the incidence of overall complications as well as PEP in either of the groups. We routinely used rectal NSAID suppositories prior to ERCP for the prevention of PEP explaining the low incidence of PEP in our study. Whether the addition of prophylactic PD stent further lowers the incidence of PEP remains to be seen.

Our study has several implications. First, TPS can be successfully used for biliary cannulation in difficult cases. High technical success implies that TPS is relatively easy to perform when compared to NKS. In-fact, TPS may be more successful than NKS and double guide wire technique as evident in some of the recent trials.[2, 15] Consequently, TPS may be preferred to these latter mentioned techniques for biliary cannulation. Second, there is no additional benefit of placing a prophylactic PD stent in those who undergo TPS. Therefore, the use of PD stent placement may be restricted to selected high risk cases. This approach may

be more cost-effective than routine placement of PD stents in all the patients.

There are certain strengths of the study. To our knowledge, this is the first study from India evaluating the role of TPS in cases with a difficult biliary access. In addition, we addressed an important question regarding the role of prophylactic PD stents in these patients which has not been evaluated adequately in the published studies.

However, certain drawbacks are noteworthy. This was a retrospective study with inherent flaws. We did not segregate the patients according to the risk factors predisposing to PEP. Last, the study may not be adequately powered to compare the difference in the incidences of PEP in the two groups. Therefore, randomized trials are required in future before concluding the superiority of any one approach over the other.

CONCLUSION:

TPS is a safe and efficacious technique to gain biliary access in difficult cases. There is no difference in the incidence of complications in cases with or without PD stenting after TPS.

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