

Double Guidewire Technique versus Transpancreatic Sphincterotomy for Difficult Biliary Cannulation

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Abstract

Background: The standard biliary cannulation technique has been reported to fail in approximately 5–20% of cases so, several supplementary techniques have been recommended to facilitate access to the common bile duct (CBD); Double-guidewire technique (DGT) and transpancreatic sphincterotomy (TPS) are effective method in cases of standard biliary cannulation failure.

Objective: To compare the outcomes between DGT and TPS in patients with difficult biliary cannulation regarding the procedure duration, success rate and complications.

Patients and Methods: This was a randomized study conducted in Al-Hussein University Hospital, Endoscopy Unit in the period between May, 2016 to October, 2017. A total of 40 patients, who bile duct cannulation was not possible and selective pancreatic duct cannulation was achieved were randomized into DGT (n = 19) and TPS (n = 21) groups. DGT or TPS was done for selective biliary cannulation. We measured the technical success rates of biliary cannulation, median cannulation time, and procedure related complications.

Results: The distribution of patients after randomization was balanced, and both groups were comparable in baseline characteristics. There was no significant difference between both groups regarding age and sex distribution, clinical presentation, laboratory findings and sonographic findings. Successful cannulation rate and mean cannulation times in DGT and TPS groups were 94.7% vs 95.2% and 20.1 ± 8.7 min vs 21.5 ± 7.8 min, $P = 0.602$, respectively. There was no significant difference between the two groups.

Conclusion: When free bile duct cannulation was difficult and selective pancreatic duct cannulation was achieved, DGT and TPS facilitated biliary cannulation and showed similar success rates. However, post-procedure pancreatitis and Cholangitis were significantly higher in the DGT group.

Keyword: ERCP, Endoscopic Retrograde Cholangiopancreatography, DGT, TPS; Transpancreatic sphincterotomy.

Introduction

Selective biliary cannulation is a crucial step for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) ⁽¹⁾. In the hands of experienced endoscopists, successful biliary cannulation rates are higher than 90% ⁽²⁾.

However, in some cases, bile duct (BD) cannulation can be difficult because of special anatomical features, inflammatory processes, and adenomas of the papilla or periampullary diverticulum ⁽³⁾.

In the past few years, various efforts

have been made to develop alternative endoscopic techniques, with the goal of increasing the rate of successful biliary cannulation ⁽⁴⁾.

The use of a guidewire to physically occupy the pancreatic duct (PD), also known as the double-guidewire technique (DGT). Since its first description, this method has been used with promising results in cases of complex biliary cannulation, especially in patients with a distorted BD anatomy caused by neoplasia or atypical morphology of the

ampulla⁽⁵⁾.

Transpancreatic sphincterotomy (TPS) using a guidewire, another technique for difficult biliary cannulation. A sphincterotomy over the guidewire in the PD helps to cannulate the biliary orifice because the cut either opens the BD or runs along the side of the duct, thus exposing the duct's anatomy⁽⁶⁾.

Double-guidewire technique and TPS might facilitate biliary cannulation and achieving a success rate of 47–93% in patients who fail standard BCH. However, post-ERCP pancreatitis has been reported to occur with DGT and TPS in 0% to 25% of patients⁽³⁾.

Aim of the work:

It is to compare the outcomes of DGT and TPS in patients with difficult biliary cannulation.

Patients and Methods

This randomized study was carried out at Al-Hussein University Hospital, ERCP endoscopy unit, during the period between May 2016 to October 2017, when 504 cases of ERCPs were performed and 40 patients were enrolled in this study. Consecutive patients were considered for inclusion if they underwent ERCP with clear indication of biliary access.

Among these patients, those in whom free cannulation of the BD was not possible and selective PD cannulation was achieved without difficulty were enrolled in this study.

Enrolled patients were randomly assigned to either the DGT group or the TPS group. Patients were excluded for any of the following reasons: (1) Age of less than 18 years; (2) Subjects who underwent prior biliary or pancreatic sphincterotomy or dilatation or stenting of either duct; (3) Acute pancreatitis at the time of the procedure; (4) History of pancreatico-biliary surgery except cholecystectomy; and (4) Intrauterine pregnancy.

We compared both techniques for a

maximum of 10 extra attempts after randomization which is common BD (CBD) cannulation by each method. Thus, we did not impose a time limit for CBD cannulation.

For all patients clear written consent, full clinical and routine laboratory assessment and abdominal sonography were done.

ERCP was performed in the standard manner using a side-view endoscope (*Fujinon ED-250XT Duodenoscope*). After selective cannulation of the common bile duct by the catheter, cholangiography was performed to confirm the diagnosis. A 0.035-inch guidewire (*Boston Scientific, Corp, MA, USA*) was inserted into the bile duct through the catheter.

ERCP standard maneuver: After cannulation of the CBD, an initial cholangiogram was taken and the diameter of the CBD at its most dilated part was assessed, in comparison with the diameter of the shaft of the endoscope.

Double-guidewire technique (DGT): in cases of failed CBD cannulation and the guidewire selectively entered the pancreatic duct on each attempt, guidewire was placed into the pancreatic duct to facilitate wire-guided cannulation of the common bile. The technique basically consisted of leaving the initial guidewire placed in the main pancreatic duct then sphincterotomy was reloaded with another guide wire and advanced through the operating channel of the duodenoscope beside the original guidewire and the second guidewire.

Transpancreatic sphincterotomy (TPS): After inserting the guidewire deeply into the PD without difficulty, the tip of a standard traction sphincterotomy was wedged into the pancreatic orifice, and a sphincterotomy was performed with a cutting wire along the biliary direction at 11 o'clock, aiming to expose the BD orifice. The BD orifice was exposed to the left and either below or above the pancreatic orifice. Then biliary cannulation was attempted.

All patients were monitored at least for 24 hours after the procedure to detect symptoms and signs of complications (e.g. tachycardia, hypotension, fever, vomiting and/or abdominal pain). Serum amylase was done four hours post-ERCP. Patients were then either hospitalized or followed up by phone contact.

Calculations of the mean (M), standard deviation (SD) were used for statistical evaluation. The categorical outcomes were compared using χ^2 test or Fisher's exact test, where appropriate. The mean ages were compared by using Student's *t* test. All *P*-values reported were two-sided, with the significant value of < 0.05 . SPSS software (version 16.0; SPSS, Chicago, IL, USA) was used to analyze the outcome. In that regard, there was no correction made to the *P* value for the comparison of post-ERCP pancreatitis rates because that comparison was considered to be the focal point when making sample size calculations. All other statistical tests of outcome results should be considered to be secondary, and their results should be taken as descriptive only.

Results

Characteristics of patients

During the study period, 504 ERCPs were performed at Al-Hussin University Hospital, Endoscopy Unit. We excluded 32 patients for the following reasons: age of < 18 years (Two patients); previous endoscopic sphincterotomy or endoscopic papillary balloon dilation (19 patients); acute pancreatitis before ERCP (10 patients); and pregnancy (One patient).

After this exclusion, ERCP was attempted in the remaining 472 patients with the native papilla of Vater with standard cannulation technique. In 425 patients (90.04%), selective BD cannulation was achieved within 10 attempts and 10 min; difficult biliary cannulation occurred in 47 (9.95%) patients. Of these, PD cannulation was also not achieved in 7 patients and needle-knife precut was done.

Finally, 40 patients in whom deep PD guidewire cannulation was achieved were enrolled in this study and randomly assigned to the DGT group (19 patients) or the TPS group (21 patients) (Figure 1).

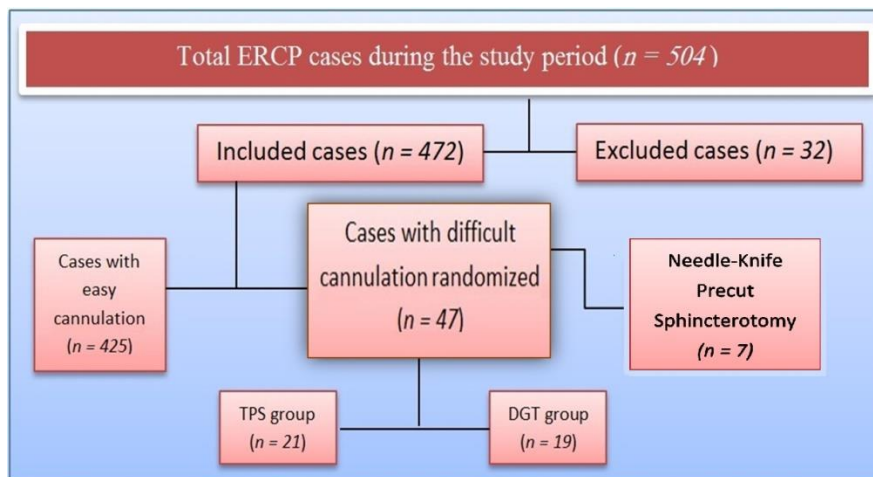


Figure (1): Flow diagram of endoscopic retrograde cholangiopancreatography (ERCP) procedures. DWT, double-guidewire technique; TPS, transpancreatic sphincterotomy.

The distribution of patients after randomization was balanced, and both groups were comparable in baseline characteristics such as ERCP indication, devices used, ERCP findings, and maneuvers. There was no significant difference between both groups regarding age and sex distribution, clinical presentation, laboratory findings and sonographic findings (**Table 1**).

Table 1/ Baseline characteristics, procedures, successful cannulation rate, median cannulation time, and procedure-related complications of the double-guidewire technique and transpancreatic sphincterotomy groups:

Table 1/ Baseline characteristics, procedures, , successful cannulation rate, median cannulation time, and procedure-related complications of the double-guidewire technique and transpancreatic sphincterotomy groups		DGT group	TPS group	P value
		n=19	n=21	
Age (year)		56.16±13.171	58.48±17.792	0.645
Sex	Male	9(47.40)	9(42.90)	0.775
	Female	10(52.60)	12(57.10)	
Indication of ERCP	CBD stone	9(47.40)	10(47.60)	0.882
	Pancreatic cancer	5(26.30)	4(19.00)	
	Cholangiocarcinoma	3(15.80)	5(23.80)	
	Other bile duct disease	2(10.50)	1(4.80)	
	Other pancreatic disease	0(0.00)	1(4.80)	
PADD		4(21.05)	3(14.28)	0.646
Type I		1(5.30)	0(0.00)	
Type II		3(15.80)	2(9.50)	
Type III		0(0.00)	1(4.80)	
ERCP maneuver	Contrast injection in PD	19(100)	20(95.24)	0.335
	EST	14(37.0)	18(76.20)	0.855
	CBD stone extraction	7(36.80)	6(28.60)	0.577
	EPBD	4(21.10)	1(4.80)	0.120
Successful cannulation	First trial	15(78.90)	18(85.70)	0.821
	Including second trial	18(94.73)	20(95.23)	0.821
	Failure of cannulation	1(5.30)	1(4.80)	0.821
Median cannulation Time min (IQR)		20.16±8.751	21.52±7.679	0.602
Post-ERCP hyperamylasemia		6(31.60)	5(23.80)	0.583
Post-ERCP pancreatitis (PEP)		9(47.36)	2(9.52)	0.013*
Mild PEP		7(36.80)	1(4.80)	0.017
Moderate to severe PEP		2(10.50)	1(4.80)	0.596
Bleeding		0(0.00)	1(4.80)	1.000
Cholangitis		8(42.10)	1(4.80)	0.007*
Cholecystitis		0	0	
Perforation		0	0	

*significant; ERCP: Endoscopic retrograde cholangiopancreatography; DGT: Double guidewire technique; PD: Pancreatic duct; EST: Endoscopic sphincterotomy; CBD: Common bile duct; GB: Gallbladder; PADD: Periampullary duodenal diverticulum; EPBD: Endoscopic papillary balloon dilatation; IQR: Inter-quartile range; PEP: Post endoscopic retrograde cholangiopancreatography pancreatitis; TPS: Transpancreatic sphincterotomy.

Successful BD cannulation rates and median cannulation time

Within the limit of 10 extra attempts, initial successful biliary cannulation was achieved in 15 of the 19 (78.9% %) patients in the DGT group and 18 of the 21 (85.7%) patients in the TPS group. Additional successful biliary cannulation was achieved in three and two patients using the initial technique in the second ERCP trial. Thus, the overall successful biliary cannulation rates, including the repeat ERCPs, were 94.7% (18/19) in the DGT group and 95.2% (20/21) in the TPS group. There was no significant difference in the initial and final cannulation rates of BD between the two groups (Table 1). In patients who underwent successful biliary cannulation, the mean time of cannulation was 14.4 min in the DGT group and 14.6 min in the TPS group; the difference between the two groups was not statistically significant (Table 1).

Post-ERCP hyperamylasemia and pancreatitis

The overall incidence of post-ERCP hyperamylasemia was 31.6% (6/19) in the DGT group and 23.8% (5/21) in the TPS group. There was no significant difference between the two groups. Post-ERCP pancreatitis developed in 38.2% (13/34) of the DGT group and 10.8% (4/37) of the TPS group. Post-ERCP pancreatitis was significantly higher in the DGT group than in the TPS group ($P = 0.013$). However, most cases of pancreatitis were mild. Moderate or severe pancreatitis developed rarely in both groups (Table 1).

Other complications

One episode of bleeding occurred in the TPS group (4.8%), and nobleeding was detected in the DGT group. Acute cholangitis developed in 42.1% (8/19) of the DGT group and 4.8% (1/21) of the TPS group. There was no statistically significant difference between the groups in the rates of procedure-related bleeding. However, the incidence of cholangitis was significantly higher in the DGT group than in the TPS group ($P = 0.007^*$). Acute cholecystitis and perforation were not detected in any group (Table 1).

Discussion

In the 1990s, new techniques for overcoming difficult biliary cannulation, such as DGT, TPS, and wire-guided biliary cannulation over the PD stent were introduced⁽⁷⁾. The superior rate of biliary cannulation when using DGT has been attributed to the capability of the pancreatic guidewire to straighten both the PD and BD while at the same time occupying the PD, thus facilitating biliary cannulation and preventing repeated pancreatic cannulation⁽⁸⁾.

One prospective randomized study reported by **Maeda et al.**⁽⁹⁾, compared DGT with standard methods, and indicated a higher cannulation success rate (93%) with DGT with no apparent added risk of post-ERCP pancreatitis. However, in the most recent prospective randomized multicenter study by **Herreros de Tejada et al.**⁽¹⁰⁾, DGT was not superior to standard cannulation techniques (success rates of 47% and 56%, respectively) and may have been associated with a higher risk of post-ERCP pancreatitis (17% and 8%, respectively).

TPS technique is a relatively new precut technique among the various precut techniques, which was first described in 1995. Previous studies have found that TPS is a safe and effective procedure in patients with difficult bile duct access⁽¹¹⁾. However, the use of the precut technique for achieving deep cannulation of the bile duct is not recommended for inexperienced endoscopists as it is claimed to increase post-ERCP complications⁽¹²⁾.

TPS can facilitate cannulation of the biliary orifice because the cut either opens the BD or runs along the side of the duct, thus exposing the orifice **Akashi et al.**⁽¹³⁾, published a prospective series in which TPS was successful in approximately 60% of the patients immediately and in 95% with repeated ERCP. However, the complication rates of TPS were significantly higher than those of standard biliary sphincterotomy (9.9% vs 0.8%, $P < 0.001$).

In another prospective study by **Kahaleh et al.**⁽¹⁴⁾, the primary success rate of pancreatic sphincterotomy was 85%, which, when combined with the needle-knife

technique, rose to 95%. The rate of post-ERCP pancreatitis was 8%, which was not different from that of conventional biliary sphincterotomy.

Our results show that the two techniques facilitate selective biliary cannulation with a similar success rate. The initial success rate of DGT in our study was 78.9%, and the final success rate, including the repeat ERCP, was 94.7%. This result is similar to that reported by **Maeda**⁽⁹⁾ 92.6%, but higher than that reported by **Herrerros de Tejada**⁽¹⁰⁾ 47%.

In the latter study, the difficult cannulation rates were as high as 49.5% and 22%. In comparison, the difficult biliary cannulation rate in our study was lower and more comparable with the experience in high-volume centers. Our difficult biliary cannulation rate was only 9.95%, which represented a truly difficult biliary cannulation group⁽¹³⁾.

In our study, the initial success rate of TPS was 85.7%, and the final success rate was 95.2%. These results are similar to those reported elsewhere⁽¹⁴⁾.

The incidence of post-ERCP pancreatitis after DGT was significantly higher than that after TPS (47.3 % vs 9.6%, $P = 0.013$).

The overall post-ERCP pancreatitis rate in this study was 27.5% (11/40). This is similar to those of previous studies, and most cases of pancreatitis were mild. However, in contrast to the other studies, we did not perform prophylactic PD stenting in any of the cases. The PD stent facilitates biliary cannulation and prevents post-ERCP pancreatitis, but is not usually used in Egypt because the costs of PD stents for prevention of post-ERCP pancreatitis and the financial burden of patients are substantially increased by their use.

Another difference is that we did not use any pharmacologic agents for post-ERCP pancreatitis, such as protease inhibitors, which are widely used by Japanese endoscopists. This might have lowered the frequency of post-ERCP pancreatitis in previous studies. Problems with using a pancreatic guide wire include the potential for

injuring branch ducts and the failure to place the guide wire deeply enough into a tortuous mainduct. In our study, guide wire insertion into the PD was performed under the guidance of contrast and fluoroscopy to minimize branch duct injury. However, repeated PD injection of contrast is one of the risk factors of Post-ERCP pancreatitis.

The incidence of cholangitis after DGT was almost eight times higher than that after TPS (42.1% vs 4.8%, $P = 0.007$); and this difference was statistically significant. Patients with cholangitis had CBD stones or CBD stricture. Therefore, we believe that the difference in cholangitis incidence was due to a difference not in methods, but in patients' characteristics.

One patient from TPS group developed post-sphincterotomy bleeding, and was controlled by diluted epinephrine injection. No blood transfusion was needed. According to the standard definition, this patient was classified as mild bleeding.

Our study has some limitations. First, the number of enrolled patients was relatively small, and the study was conducted in a single endoscopy unit. We enrolled only 40 patients with difficult cannulation from among a total of 504 patients (7.9%) who presented for ERCP during the study period. This may have influenced the interpretation of the difference in success and post-ERCP pancreatitis rates. Therefore, a larger study is necessary to overcome this limitation. However, this also demonstrates that our study included truly difficult cases of BC. Second, information regarding the number of PD injections and patients with sphincter of Oddi dysfunction were not collected. This is one of the main limiting factors in drawing a firm conclusion regarding the role of guide wire insertion in the PD in post-ERCP pancreatitis.

We could conclude that the DGT and TPS facilitated biliary cannulation and showed similar success rates. However, the incidence of post procedure pancreatitis and cholangitis was significantly higher in the DGT group. Therefore, we suggest that the use of TPS when the standard biliary cannulation technique fails and PD

cannulation is achieved is effective and has an acceptable complication profile. Further large-scale multicenter studies are needed.

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