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Multicenter Study on the Success Rates of Common Bile Duct Cannulation Using Various Techniques

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ABSTRACT

Background

Common bile duct (CBD) cannulation is a critical step in endoscopic retrograde cholangiopancreatography (ERCP), essential for diagnosing and treating biliary and pancreatic disorders.

Objective

The objective of this study is to compare the success rates of common bile duct (CBD) cannulation performed using various techniques.

Methods

A prospective study was conducted in which patients were randomly assigned to receive cannulation with either a standard catheter or a sphincterotome (standard or wire-guided). Multivariate models were used to identify key factors influencing the success rates of both initial and selective cannulation, along with the number of attempts and the time required to achieve selective cannulation.

Results

A total of 83 patients were initially evaluated, 47 were included in the study, with most undergoing ERCP for suspected bile duct stones. Patients were randomized to receive either a standard catheter or a standard/wire-guided sphincterotome for selective common bile duct cannulation. The sphincterotome group had a significantly higher initial cannulation success rate (97% vs. 67%, p = 0.009) and required fewer attempts and less time to achieve cannulation (p = 0.0001). Multivariate analysis identified the initial choice of the catheter as the key independent predictor of both the time and number of attempts needed for successful cannulation.

Conclusion

The standard/wire-guided sphincterotome outperformed the standard catheter in the initial attempt at common bile duct cannulation. The number of attempts required could have clinical implications for the risk of post-ERCP pancreatitis, highlighting the need for further research.

Keywords

Cannulation time, Fluoroscopic time, Selective bile duct cannulation; post-ERCP pancreatitis; Randomized controlled trial, Radiation exposure, Wire-guided cannulation

Introduction

Deep bile duct cannulation is the initial step in performing ERCP biliary interventions. While numerous specialized techniques have been documented, there is a notable absence of

comprehensive reports that cover all cannulation methods within a single series. This prospective study aims to examine the various techniques used for cannulation in the context of routine ERCP procedures (1,2). Biliary cannulation is a crucial step in biliary interventions, yet no universally accepted technique exists. The procedure's success relies on factors such as the type of catheter, the cannulation technique used, and the proficiency of the endoscopist. Complication rates are influenced by patient conditions, procedural details, and the operator's skill (3). Recently, techniques like using a sphincterotome with wire-guided cannulation (WGC) have become more common, demonstrating improved success rates and reduced incidence of post-ERCP pancreatitis (PEP) compared to traditional methods with contrast medium (4). Nonetheless, these improvements are based on studies involving a small number of experienced endoscopists at single institutions, which may limit the generalizability of the results.

Various instruments and techniques are available for selective common bile duct (CBD) cannulation, including standard or tapered catheters, sphincterotomes, pre-cut papillotomy, and guidewires (5). If purely endoscopic methods fail, a combined endoscopic and trans-hepatic approach may be used, though this method has significant risks of complications (6). Endoscopic papillectomy is another option. However, there is no published objective evidence showing a difference in success rates between standard catheters and sphincterotomes for selective CBD cannulation (7). However, the success of CBD cannulation varies widely depending on the skill and experience of the endoscopist. In Pakistan, where ERCP is increasingly utilized, the variability in cannulation success among different endoscopists across multiple centers remains underexplored. This multicenter, randomized study aims to evaluate the success rates of CBD cannulation by various endoscopists in other healthcare settings across the country, providing insights into the procedural challenges and potential areas for improvement in training and technique."

Material and Methods

During 3 months, patients undergoing ERCP with the goal of selective common bile duct (CBD) cannulation were enrolled, excluding those with prior therapeutic ERCP, gastroduodenal abnormalities, or if selective cannulation was not the primary intent. Patients were randomly assigned to use either a standard catheter or a sphincterotome (standard or wire-guided) for selective CBD cannulation. Key metrics recorded included the success rates, number of attempts, and time required for initial and selective cannulation. If the initial attempt failed, patients could crossover to a different catheter type. Procedures were performed by a third-year fellow or junior staff, with a senior staff member involved if multiple attempts were unsuccessful. Informed consent was obtained and the study was IRB-approved. Outcomes were assessed using intention-to-treat analysis, with complications monitored and statistical analyses performed to evaluate the efficacy of the cannulation methods. The study, designed to detect a 30% difference in success rates, was halted early after an interim analysis.

Results

Eighty-three patients were initially evaluated, but 36 were excluded due to previous therapeutic ERCP or anatomical issues, leaving 47 patients (19 men, 28 women, mean age 60.6 years) in the study. Indications for ERCP included suspected CBD stones, pancreaticobiliary malignancies, and bile leaks. Patients were randomized to undergo selective CBD cannulation with either a standard catheter (SC) or a sphincterotome (SS/WS). Initial cannulation success rates were 67% for SC and 97% for SS/WS ($p = 0.009$). Using intention-to-treat analysis, selective cannulation success rates were 94% for SC and 97% for SS/WS (p = NS). The SC group required more

attempts (12.4 ± 6.0) and time (13.5 ± 6.14 minutes) compared to the SS/WS group (2.8 ± 3.1 attempts, 3.1 ± 5.1 minutes; p = 0.0002. Crossover to a different catheter type occurred in 6 cases, all from SC to SS. Pancreatic duct opacification was more common in the SC group (61%) compared to the SS/WS group (21%; p = 0.011). Pancreatitis occurred in 8.5% of patients, with a higher rate in the SS/WS group (10.3%) compared to the SC group (5.6%). Statistical differences in complication rates were not specifically analyzed.

Table 1- Analysis of the time required to achieve successful cannulation

Variables	Estimation of Parameters	Standard Error	Chi-square	Risk Ratio
Catheter	2.244319	0.41115	0.0001	9.433
Age	0.012001	0.01171	0.3052	1.011
Gender	0.367332	0.33919	0.2789	1.443

Table 2- Analysis of the number of attempts required to achieve successful cannulation

Variables	Estimation of Parameters	Standard Error	Chi-square	Risk Ratio
Catheter	2.518631	0.47803	0.0001	12.411

Discussion

In this prospective randomized trial comparing standard catheters with sphincterotomes for selective CBD cannulation, it was observed that sphincterotomes (both standard and wire-guided) significantly reduced both the number of attempts and the time required for successful cannulation. Although previous studies suggested potential advantages of sphincterotomes, this trial was the first to provide comparative evidence through randomized patient assignment (8). In the study, it was hypothesized that the upward tip deflection of sphincterotomes enhances access to the CBD.

Various techniques exist for CBD cannulation, including pre-cut papillotomy, which is often used in emergencies or after prolonged cannulation attempts (9). However, this technique carries a notable risk of complications, including severe pancreatitis (10). Other methods, such as the combined endoscopic and transhepatic approach, and the use of guidewires, have also been described but come with significant risks or drawbacks. Endoscopic papillectomy is experimental and has limited application (11,12,13).

The results of the current study support the hypothesis that upward tip deflection from sphincterotomes facilitates more efficient cannulation compared to standard catheters. Despite this, the final rates of CBD cannulation were similar between the two groups. Approximately a fixed outcome threshold of 15 attempts was set to minimize operator bias and found that operator experience did not significantly impact the results. A study conducted by García-Cano & González-Martín reported a 75.4% success rate with standard cannulation, utilizing alternative methods to achieve a final 98% success rate (14). In a multicenter study, Kawakami et al. found no significant difference in success rates between wire-guided and conventional methods, though

wire-guided cannulation tended to shorten procedure times (15). Hence in another study, Bassi et al. demonstrated that the touch technique was superior to the no-touch technique, with higher primary cannulation rates (88% vs 54%, $p<0.001$) and fewer attempts required (16).
However, Herreros de Tejada et al. found that the double-guidewire technique was not superior to standard cannulation in difficult cases, with success rates of 47% and 56% respectively (17). Post-ERCP pancreatitis rates varied across studies, ranging from 2-17% (18). The limitation of the study was the smaller sample size and imbalance in patient distribution between endoscopists which further suggest that investigations are required where a larger cohort is essential. The higher incidence of pancreatitis in the sphincterotome group (10.3% vs. 5.6% with standard catheters) was not statistically significant due to overlapping confidence intervals, indicating the need for larger studies to confirm these findings. Potential confounders, such as the depth of pancreatic duct cannulation, were not assessed in the study but may contribute to the observed differences. Additionally, while sphincterotomes are more expensive than standard catheters, the cost may be offset by easier cannulation and reduced procedural time (19). A comprehensive cost analysis should consider these factors, including potential savings from reduced procedural time and catheter reuse (20).

Conclusion

This randomized controlled trial demonstrates that sphincterotomes outperform regular catheters for initial selective CBD cannulation. Using a sphincterotome reduces both procedural time and the number of attempts needed, and results in higher initial CBD cannulation rates.

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