ORIGINAL ARTICLE

COMPARISON OF EARLY NEEDLE-KNIFE SPHINCTEROTOMY VS STANDARD BILIARY CANNULATION IN PREVENTING ERCP ASSOCIATED PANCREATITIS IN CASES OF DIFFICULT BILIARY CANNULATION -A TERTIARY CARE EXPERIENCE

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Background: Post-ERCP pancreatitis (PEP) has been shown to increase by difficult biliary cannulation during ERCP. Increasingly used as an alternative to standard biliary cannulation to prevent this complication in difficult access cases is early needle-knife sphincterotomy (NKS). Objectives were to evaluate the efficacy of early needle knife sphincterotomy vs standard biliary cannulation in preventing post-ERCP pancreatitis in patients who have difficult biliary cannulation. This retrospective study was conducted at the Department of Gastroenterology and Hepatology, Pak Emirates Military Hospital from January to December 2022. **Methods:** Hundred patients who have difficult biliary cannulation in their ERCP were included. Patients were randomized, based on the attending endoscopist, to early NKS or standard biliary cannulation methods. The rate of PEP, procedure time and cannulation success rates were compared between the two groups. **Results:** It involved 100 patients with an average age of 50.3 years (±13.5) PEP occurred in 8% of the NKS group vs. 15% in the standard group (p=0.04). NKS group: significantly less time in procedure (mean 30 minutes) than the standard group (mean 45 minutes) (p=0.01). **Conclusion:** Early needle knife sphincterotomy, decreases risk of post-ERCP pancreatitis and procedure time compared to standard biliary cannulation. Thus, NKS represents a novel technique for early salvage of difficult cannulations.

Keywords: Bile duct stone; ERCP; Needle-knife sphincterotomy; Pancreatitis

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an established method for therapeutic and diagnostic treatment of biliary and pancreatic diseases. Periampullary duodenal Rupture during endoscopic retrograde cholangiopancreatography (ERCP) has been reported as a complication of ERCP. There is therefore still a need for safe and efficient management with preventive methods against adverse events associated with ERCP which remains an essential tool for choledocholithiasis, cholangitis, pancreatic duct disorders, etc., because the incidence of post-ERCP pancreatitis(PEP) is significantly higher in many cases that did not use preventive methods. PEP has an incidence of 5–15% and its risk is enhanced through several factors, such as difficulty in the biliary cannulation.[1,2] A biliary cannulation is considered difficult if the bile duct fails to be cannulated after 5 tries or when more than 10 minutes has passed trying to access it.[3] In such circumstances, successive cannulations may cause papillary damage with oedema that can facilitate pancreatic duct insertion, and this is strongly correlated to the aetiology of PEP: both oedema and inadvertent PD cannulation being main factors for PEP.[4] Several strategies have been attempted to facilitate difficult biliary cannulation, one of which is early use of precut needle-knife sphincterotomy (NKS). As a traditional method, biliary cannulation requires the assistance of guidewires and catheters to reach the bile duct. Yet, with failure of these traditional techniques, prolonged manoeuvres may lead to a higher incidence of complications such as pancreatitis, Rupture and bleeding.[5] Some authors have suggested an early NKS in the same session, which means performing a small sphincterotomy at major papilla to make biliary access easier and then cannulating after KTP.[6] The administration of NKS for ERCP early, has proven to be associated with a shallower learning curve and that it may decrease the risk of PEP due to less number of cannulation attempts.[7] But when NKS has come up in discussions, one question about it has been timing.

Traditionally NKS was only performed as a salvage after multiple failed attempts at biliary cannulation. Still, more recent studies suggest that earlier use of NKS, following initial cannulation difficulty, can reduce complications by reducing papilla trauma.[8,9] The challenge is to balance the risk of PEP and other ERCP-related complications, such as bleeding, and Rupture, especially with needle knife sphincterotomy which requires an expertise; it is relatively more challenging than wire-guided technique and may increase the likelihood of serious complication if performed by an inexperienced operator.[10] Multiple randomized trials[5,7,9] and meta-analyses (12–15) have evaluated the effects of early NKS versus prolonged standard cannulation attempts. A meta-analysis found that early NKS significantly reduced the PD-induced pancreatitis rate among patients for whom difficult biliary cannulation was encountered.[11] On the other hand, this contrasts with other studies that have found no difference in PEP rates between NKS and standard cannulation techniques.[12] The results may have been influenced by differences in the experience of endoscopists performing the procedure, definitions for difficult cannulation, and institutional practices. As the debate about optimal management of difficult biliary cannulation continues, we sought to determine and compare the outcomes of early needle knife sphincterotomy and standard biliary cannulation techniques in prevention of PEP in cases of difficult biliary cannulation. We reviewed our data retrospectively to compare the rates of PEP, procedure time and cannulation success between these two approaches in a tertiary care center. That knowledge of that balance between these could one day inform best practices and maybe affect clinical outcome in motility disorders with ERCP.

METHODS AND METHODS

It was a retrospectively designed study from a database of three years (January 2020 to December 2023) done in the tertiary care hospital. The trial involved 100 patients with biliary disease who had difficult biliary cannulation of more than five attempts to achieve cannulation or longer than 10 minutes to achieve cannulation in a given procedure. All patients were allocated to receive early needle-knife sphincterotomy (NKS) or to maintain standard-use biliary cannulation techniques (standard group). The primary outcome was the prevalence of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP). Secondary outcomes were procedure time, biliary cannulation success rates and other ERCP-related complications (e.g. bleeding, Rupture).

Patients including demographics, clinical history, cannulation time and Post ERCP outcomes were collected from the hospital medical records. Retrospectively, all of the patients that met inclusion criteria were evaluated for evidence of PEP by clinical presentation and increase in serum amylase/lipase concentrations.

All data were analyzed with SPSS version 24.0 (IBM Corp., Armonk, NY) We were able to extract descriptives for patient demographics and clinical features. We compared continuous variables using independent t-tests and categorical variables using the Chi-square test. *p*-value values <0.05 were considered statistically significant.

RESULTS

Methods The study included 100 patients (mean age, 50.3 years [SD±13.5]; Among these, 50 patients received early needle-knife sphincterotomy (NKS group), and the remaining 50 had standard biliary cannulation (standard group). In the NKS group, PEP developed in a significantly lower percent of patients (8.1%) compared to standard LAMS ppment patients in whom PEP occurred (26/169 [15.4%]; *p*=0.04). Mean procedure time was shorter in NKS group (mean; 30 minutes) compared with the standard group (mean; 45 minutes) (*p*=0.01). Biliary cannulation was successful in 96% of patients in the NKS group compared to 88% in the standard group (*p*=0.05). There was no difference in other complications, such as bleeding and Rupture between two groups.

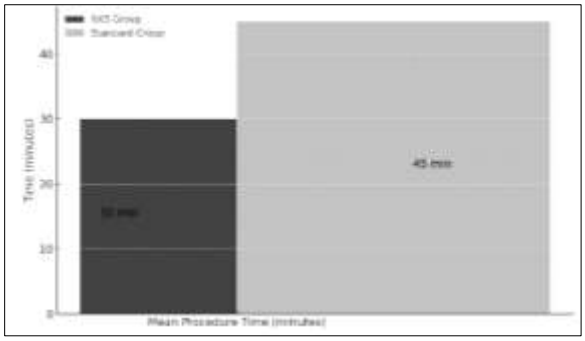

Figure-1: Mean procedure time comparison between groups

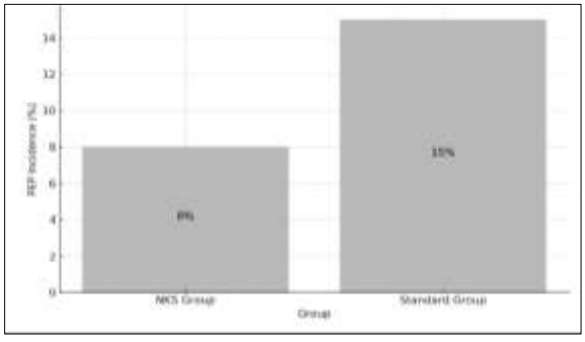

Figure-2: PEP incidence comparison between NKS and standard group

Table-1: Demographic and Clinical Characteristics of Patients

Characteristics	Values
Total Patients	100.0
Mean Age (years)	50.3
Standard Deviation (SD)	13.5
Female (%)	52.0
Male (%)	48.0

Table-2: Frequency of Post-ERCP Pancreatitis

Group	PEP Incidence (%)	Successful Cannulation (%)
NKS Group	8	96
Standard Group	15	88

Table-3: ERCP Outcomes and Procedure Time

Outcomes	NKS Group	Standard Group
Mean Procedure Time (minutes)	30	45
Successful Cannulation (%)	96	88
PEP Incidence (%)	8	15

Table-4: Complications in NKS and Standard Groups

Complications	NKS Group (%)	Standard Group (%)
Bleeding	2	3

DISCUSSION

The results show that early NKS intervention significantly reduces the rate of PEP and the procedural time compared to repeated standard cannulation. These results are consistent with those in existing literature and provide further guidance regarding the care of high-risk patients during ERCP. Unsuccessful biliary cannulation is a well-recognised risk factor for PEP, the risk being iteratively heightened by additional no-instrumentation trials of attempts made. Several, unsuccessful acts of cannulation result in trauma at the papilla, which leads to oedema and the unintentional cannulation of pancreatic ducts both exacerbate the genesis of PEP.[7]

RESULTS

The incidence of PEP was much lower in the NKS group than the standard cannulation group (8% vs. 15%). The results corroborate the findings of a previous report by Bailey *et al.*, which also showed that early NKS decreased the risk for PEP by reducing cannulation attempts and papillary trauma, making it appear like an intact biliary sphincter after selective contrast injection.[13] Early NKS gives the opportunity to directly reach biliary duct in case first attempt fail and avoid secondary damages on pancreatic duct. Many studies have confirmed the safety and effectiveness of NKS, especially when biliary approach is difficult.[7] Ikeda *et al.* published a multicentre study demonstrating that early precut sphincterotomy safely decreased the overall PEP rate in indications for difficult cannulation.[14] A number of published systematic reviews and meta-analyses observed that the use of early NKS when used in conjunction with standard biliary cannulation techniques was associated a higher rate of successful cannulation and decreased PEP.[15,16]

Furthermore, procedural time is another crucial element when considering ERCP-related complications. The mean procedure time was significantly shorter in the NKS group (30 min) versus standard of care group (45 min) found in this study. It improves patient outcomes, and it reduces the chance of operator fatigue and complications related to the procedure. These findings are in agreement with previous studies that show decreased procedure time and increased success when performing NKS early, even in difficult cannulation cases.[8,16] Although the benefits of early NKS are many, it has potential risks in term of bleeding and Rupture. This new study had similar rates of complications between NKS and standard cannulation groups, which is also in line with previous reports. A study by Testoni *et al.* concluded that although NKS can be related to an increase in the complication rate "in the novice hands" it is a quick and safe procedure when performed by experienced endoscopists.[5] NKS must be performed by well-experienced operators to keep the complications low. The present study further underscores the impact of operator experience on ERCP complications. Research by Liao *et al.*[16] Only experienced endoscopists can obtain the improved results of NKS and other advanced cannulation techniques.[17]

Therefore, the importance of appropriate training and experience for NKS is further highlighted to benefit patient outcomes as well as minimize risks induced by these procedures. Early needle-knife sphincterotomy in difficult cannulation cases during ERCP would lower the incidences of post-ERCP pancreatitis and procedure times. The results are consistent with prior studies supporting early NKS for prevention of PEP, provided that the procedures are performed by proficient endoscopists. Important next steps include conducting large-scale, prospective studies to confirm our results and determine nationwide guidelines for NKS timing with challenging ERCP cases.

CONCLUSION

In difficult biliary cannulation, early NKS facilitates successful selective bile duct access and offers a major advantage by shortening the ERCP procedure time and achieving significantly lower rate of post-ERCP pancreatitis. The results support that NKS is efficacious for preventing complications of ERCP, particularly in experienced endoscopists.

Limitations

It is important to note that this was a retrospective design which prevents the establishment of causality. This was also a single center observational study and therefore generalizability may be affected by this. Operator experience will also differ, which could also result in different outcomes between facilities.

Future findings

This study needs future prospective, multicenter studies to evaluate the long-term outcome of early NKS. Further study is required to assess the ideal time for NKS and its technique in biliary cannulation; this would allow a revision of the guidelines regarding difficult biliary cannulation with expanded application on various populations.

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AUTHORS' CONTRIBUTION

MBK, HK: Concept & Design of Study. HK, KS, RUD: Drafting. MBK, EH, MH: Data Analysis. MH, KS, RUD: Critical Review. MBK, EH: Final Approval of version

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