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Results of Needle Knife Sphincterotomy at Chris Hani Baragwaneth Academic Hospital

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Abstract: Background: *Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic skill by experts to image the pancreato-biliary tree using a combination of luminal side-viewing endoscopy and fluoroscopy. Needle knife sphincterotomy (NKS) is one of ERCP techniques used to facilitate access to common bile duct when standard cannulation has failed.* ***Aim****: To determine the overall and success rates of NKS, reasons or indications and associated specific procedure related outcomes were analysed.* ***Methods:*** *a retrospective descriptive analysis of CHBAH ERCP database from 2012 – 2016. The study included all adult (≥18 years) patients who underwent ERCP at CHBAH during the study period.* ***Results:*** *2493 ERCPs, standard technique was employed in 86.0% (2142/2493), NKS was used in 14% (351/2493) of the procedures, In the NKS group, successful biliary cannulation 64.2% (225/351) whilst 35.8% (126/351) were unsuccessful. Thus, biliary cannulation was accomplished in 2367 ERCPs performed by standard and NKS techniques. The overall success rate of biliary cannulation was 95% in the entire group. Complications associated with NKS was 14.2% (50/351), Specific NKS related complications were 11.1% in form of bleeding 5.2%, false tract formation 3.10%, duodenal perforation 1.7% (mostly retroperitoneal instrument type and managed non operatively), ampullary oedema 1.10%.* ***Conclusion:*** *The result of NKS in the study compares well with reported large series, However, NKS requires experience and should be performed by senior endoscopist. NKS is quite safe as the complications in comparison with standard technique was not statistically significant, Improved documentation of PEP will provide a better picture in the future.*

Keywords: Needle Knife Sphincterotomy, Successful biliary cannulation, ERCP, needle knife papillotomy, complications.

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique which involves using a combination of luminal endoscopy and fluoroscopic imaging. to facilitate examination and evaluation of the pancreatic and biliary systems [1,2,3].

ERCP is an advanced and complex endoscopic skill that continues to be technically challenging [4]. It is associated with a long learning curve and significant morbidity rate of 5 – 15% and mortality of (0-1%) [5,6]. Selective bile duct cannulation is usually the aim in most instances but pancreatic duct access and imaging may be necessary in certain cases. Therefore, to reduce risks, strict selection criteria are applied in current clinical practice. Risk related problems increase with number of failed attempts to cannulate, anatomy of the ampulla, and/or operator-related factors [5,7]. Failed or difficult cannulations require more advanced techniques such as double guide=wire technique, needle knife sphincterotomy (NKS) or papillotomy [8].

Common complications associated with ERCP include bleeding, perforation, post ERCP pancreatitis and anaesthetic related problems like over-sedation. Reaction to agents and aspiration pneumonia.

Bleeding occurs due to mechanical trauma to the papilla or due to sphincterotomy and varies from 0.76-2.3% [1]. And may require therapy with dilute adrenaline solution injection, use of haemostatic clips and/or deployment of self-expandable metal stents (SEMS). Surgery is rarely required. Correction of coagulopathy with fresh frozen plasma (FFP) infusions in conjunction with already outlined physical therapeutic strategies are necessary for coagulopathy related bleeding.

Perforation less common complication and varies from 0.08-1.1% [2], in the form of false tract in the biliary tree or oesophageal perforation or more likely duodenal [2], and can be managed endoscopically and/or surgery.

Post ERCP pancreatitis acute onset of pancreatic type abdominal pain combined with at least three-fold increase in the pancreatic enzyme in the first 24 - 48 hours after the procedure, with reported incidence of 1.3% -15.1% [2,5,6,8]. Excessive manipulation causes mechanical trauma and oedema of the sphincter, whilst repeated contrast injections into the pancreatic duct accentuates the oedema and development of pressure within the pancreas, resulting in intra-pancreatic activation of the pancreatic pro-enzymes that causes the hallmark inflammation and autodigestive processes of acute pancreatitis.

Unsuccessful biliary cannulation is the most common complication with 10%-15% rate in high volume centre, and with multiple failed attempts there are risks of increases in other procedure related complications. [3,5,7]

A difficult cannulation definition varies in the literature with no established time limit or limits to unsuccessful attempts before the cannulation is determined difficult [8]. Defining limits frequently used in the literature include a time limit of 30 minutes, 3 – 5 pancreatic duct passage or contrast injections and attempts between 5-10 times, [8,9].

Biliary access techniques

The solution to overcome difficult cannulation depend on the choice of how to proceed and various manoeuvres can be used to facilitate access. This includes simple measures such as changing sphincterotome, changing the operator, or repositioning of patient or operator. [8] Advanced or aggressive measures that can be used as reported by include use of pancreatic guide wire, a pre-cut technique Needle knife sphincterotomy (NKS) is an advanced alternative. It is one of the most advanced therapeutic ERCP techniques and should only be used by expert gastrointestinal endoscopist [2,3,9]. The number of NKS performed varies from 0 - 50% of all biliary cannulation attempts [8]**.** However, the efficacy and technical details of NKS remains controversial [14].

Success rate with NKS varies between 90%- 96% while complication rates are between 2%-13% in retrospective studies [8,9]. Furthermore, early decision to use NKS improves the success of biliary access [3,8]. However, the right timing of NKS and actual risk thereof remains unclear in the literature [9] **.**

The literature is grossly sparse of information on NKS and its outcomes. Additionally, there are no published South African data on this topic. The HPB Unit at Chris Hani Baragwanath Academic Hospital (CHBAH) performs about 800 – 1000 ERCPs per annum and it is staffed with highly experienced experts. NKS is frequently employed during ERCPs in the Unit. This study was therefore undertaken to provide some information in respect of NKS within a South African context as well as internationally. Most importantly, the study sought to ascertain the success rates, reasons or indications for the procedure and associated specific procedure related outcomes such as morbidity and mortality. Additionally, a comparison of the CHABH data will be made with that of other studies and where possible, to determine post ERCP pancreatitis rate in patients that had NKS. It is expected that this information will provide reference for further studies in this area.

2. Methodology

This was a retrospective descriptive analysis of CHBAH ERCP database from 2012 – 2016. The study included all adult (≥18 years) patients who underwent ERCP at CHBAH during the study period. Appropriate Institutional ethics clearance (CHBAH Ethics Committee and Witwatersrand University HREC reference M170405). Clinical, laboratory, radiology and ERCP information of patients were retrieved from a. prospectively collected ERCP database as well as electronic copies of ERCP reports generated at time of the procedure and patients' hospital records and/or discharge summary where available and/or accessible. Demographic information, indications for ERCP, use of NKS, reasons for NKS, complications during or after the procedure and mortality data where accessible were analysed. All data were imported into a Microsoft Excel spread sheet for ease of analysis.

Successful cannulation means deep biliary access with standard technique and/or double guide wire or cannulation of bile duct using NKS during the initial procedure and/or within 1 week of the NKS [8]. Failed attempt is failure of bile duct cannulation using standard and/or any of the assisted forms of techniques during the initial procedure and/or within 1 week of NKS[8]. Multiple pancreatic duct cannulation is >3 pancreatic duct cannulation during the initial ERCP procedure[8,9]. An In-experienced endoscopist means medical or surgical specialist undergoing medical or surgical gastroenterology fellowship and/or HPB surgery program as per standardized curricula or endoscopist with less than three years of individual and unsupervised ERCP experience.

Normally distributed data were analysed with descriptive statistics. Comparisons between groups were evaluated using either X^2 for parametric tests or Mann-Whitney U test for non-parametric data. P values <0.05 was considered statistically significant. All Statistical analysis was performed with the statistical package SPSS24.0.

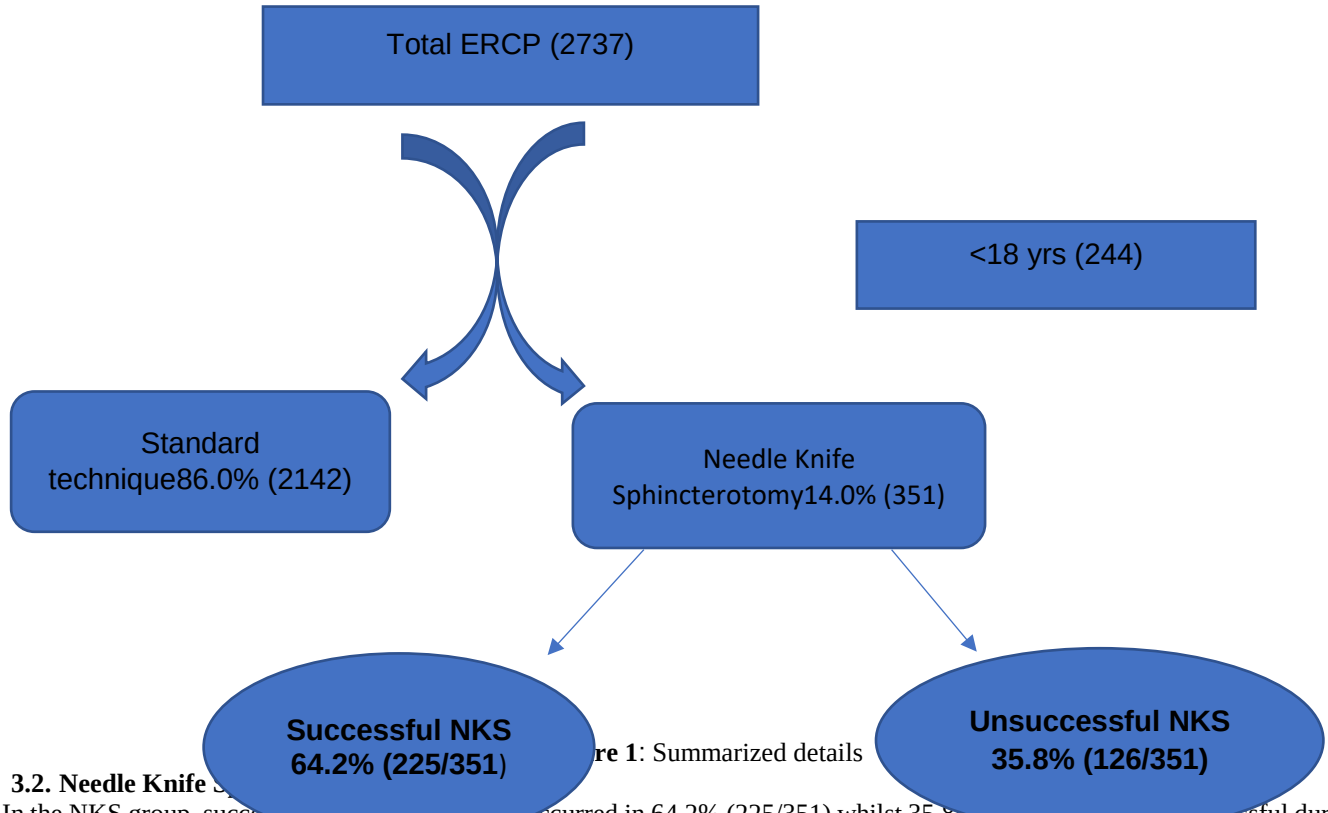
3. Results

3.1 Overall Findings

During the study period, 2493 ERCPs were performed at the CHBAH HPB Unit. The average age of the patients was 53 (range 18 – 89) years. Of this, the standard technique was employed in 86.0% (2142/2493) of procedures. NKS was used in 14% (351/2493) of the procedures. Details are summarized in Figure1. And the pattern of presentation included obstructive jaundice without cholangitis 6.9%, and obstructive jaundice with cholangitis 5.9%. Stent blockage accounted for 1.8% of the cases presenting with obstructive jaundice with cholangitis. Majority of ERCPs were performed for choledocholithiasis (34,8%) followed by pancreatic and ampullary tumours (23,7%). Table 1 summarizes indications for ERCPs in this study**.**

Table 1: Indication for ERCP in general

Malignancy	n	%	Benign	n	%
HOP mass	681	27.3	Choledocholithaisis	867	34.8
Periampullary tumors	206	8.2	prophylatic sphincterotomy for biliary pancreatitis	95	3.9
Cholangiocarcinoma	92	3.7	post cholecystectomy bile leak	87	3.5
Gall bladder Cancer	70	2.8	Pancreatic duct disruption	55	2.2
Metastasis to porta hepatis	42	1.7	Blocked stent	46	1.8
Gastric tumors	21	0.8	Chronic Pancreatitis	41	1.7
Hepatocellular carcinoma	19	0.7	Mirizzi syndrome/ CHD stricture	35	1.4
GIST Duodenum	3	0.1	ARC syndrome	35	1.4
Others	49	1.9	Benign CBD strictures (TB/post op)	37	1.6
			PSC	8	0.3
			Autoimmune pancreatitis	4	0.2
Total	1183	47.2%		1310	52.8%



re 1: Summarized details

3.2. Needle Knife S

In the NKS group, succes… occurred in 64.2% (225/351) whilst 35.8% (…cessful during the initial procedures. Thus, biliary cannulation was accomplished in 2367 ERCPs performed by standard and NKS techniques. The overall success rate of biliary cannulation (standard and NKS techniques) in this study was 95% in the entire group.

Many reasons were noted for low success rate of NKS. Statistically significant (p 0.0003) reasons as depicted on Table 2 included difficult/deformed duodenal and/or ampullary anatomy, Inexperienced endoscopist, failed multiple attempts and other technical difficulties.

Table 2: Reasons noted for low success rate

Reasons			Abnormal anatomy	Experience level	Failed multiple attempts	Others
NKS	Successful	N	95	30	48	52
		%	44.4	9.2	22.3	12.8
	Unsuccessful	N	67	0	37	
		%	53.1	0.0	27.6	

Reasons/indications for NKS:

The main reasons and/or indications for NKS in this study are shown in Table3 and include; abnormal / deformed duodenal and/or ampullary anatomy. failed multiple attempts, level of experience of endoscopist and others (poorly defined or vague).

Table 3: Provides the details of relevant reasons/indications for NKS in this study

Reason	N	%
• Abnormal Anatomy - Ampullary distortion - Duodenal distortion (HOP mass) - Erosion of ampulla/duodenum	162 127 18 17	46.2 78.4 11.1 10.5
• Failed multiple attempts	85	24.2
• Inexperience	30	8.5
• Failed 2-guide wire technique	8	2.3
• Stone lodged at ampulla	4	1.1
• Diverticulum	4	1.1
• Others….. (poorly classified)	58	16.5
Total	351	100

Table 4: Successful cannulation in terms of endoscopist experience

		Successful	Unsuccessful
Experience level	N	25	0
	% within reason	100.0%	0.0%

3.3. Complications:

Complications associated with NKS was 14.2% (50/351) as shown in Figure 2. Specific NKS related complications were 11.1% (Figure 3) in form of bleeding 5.2%, false tract formation 3.10%, duodenal perforation 1.7% (mostly retroperitoneal instrument type and managed non operatively), ampullary oedema 1.10%. Majority of the complications occurred during the procedure, were minor in nature and managed either immediately on-table (e.g., bleeding controlled with 1:10 000 adrenaline-saline solution as well as with balloon tamponade), or conservatively in the hospital.

General complications were mainly related to respiratory arrests at 1.3% from over-sedation and instruments/equipment failure 0.6%. Figure 2 shows complications associated with NKS and Figure 3 shows NKS specific complications

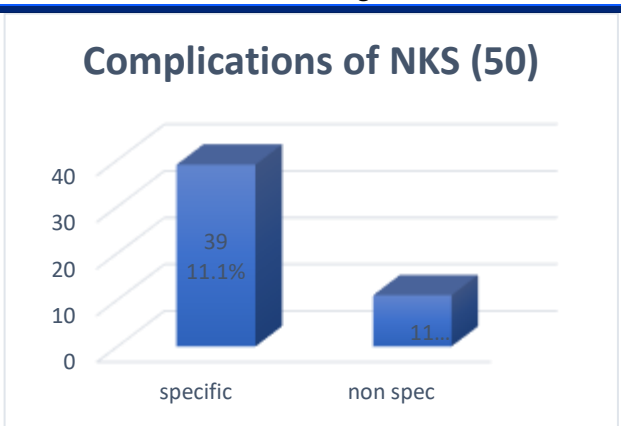


Figure 2: Shows complications associated with NKS

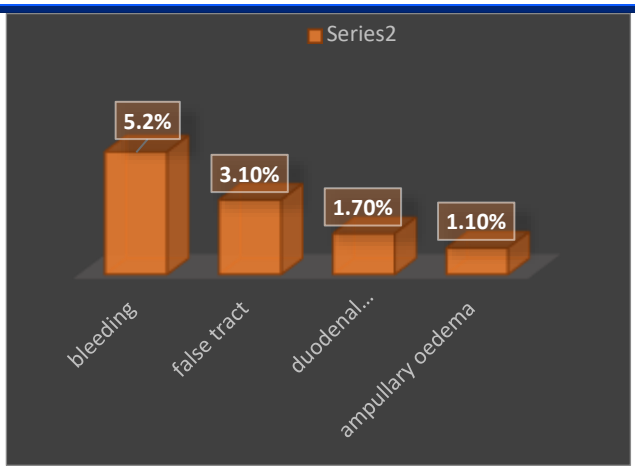


Figure 3: Shows NKS specific complications

3.4. Mortality

There was one on-table death in the NKS group during the study period. This was however unrelated to the performance of NKS. The death occurred in a 91 years old patient with gastric malignancy and obstructive jaundice who arrested on-table following aspiration of inadequately drained gastric content.

3.5. Post ERCP pancreatitis on the whole group.

During the study period, full information of PEP was available in only six (6) patients consisting, five (5) women and one (1) man who all had choledocholithiasis as indication of ERCP. None of these had NKS.

Five patients had mild pancreatitis, whilst one had severe PEP and required 6 days of ICU admission. All patients (100%) had standard sphincterotomy performed and no NKS. The possible reason for this low figure may be due to more than one third of patient being from referral centres, as well as retrospective nature of this

4. Discussion

This study was designed to analyse the results of NKS of ERCPs performed during a period of five years in an urban and regional HPB unit of an academic referral centre, CHBAH, Johannesburg, South Africa. The reported success rates vary from 52% to 97% [8]. However, irrespective of secondary tool selection in difficult cases, the final success rate can be expected to be well over 96% regardless of the primary tool [8].

In total, 2493 ERCPs were undertaken at the CHBAH HPB Unit during the period reviewed. This suggests about 500 ERCPs per annum thus, making this a high-volume centre. Of the total, the NKS rate was 14%. Though somewhat high, this still falls within the 0 – 42% rates reported in the literature [2,12]. In a review of 732 ERCPs, Bailey et al reported NKS rate of 12.8%; which increased to 90% with increasing number of attempts at cannulation [17]. A success rate of 85% and the overall cannulation success rate of 97.7% was reported while PEP was 7.3% and was graded as mild or moderate in severity [17]. In another study, most NKS were for malignancy and choledocholithiasis [7]. Further, Swan et al, demonstrated that choledocholithiasis and pancreatic malignancy accounted for 45% and 18% respectively of a cohort of 51 patients managed with NKS [7]. Anatomic distortions accounted for 46% in this series and were more in patients with malignancy (Table 3). In yet another study, Jamry A et al [14], reported that the standard technique may not be feasible in all ERCP cases due to duodenal lumen stenosis/narrowing in presence of a pancreatic head tumour or obstructed papillary orifice due to the tumour deposit. Of note was the fact that most NKS were performed in patients with a malignancy.

The total success rate of achieving deep biliary cannulation in this study was 95%. This is not far from the 97,7% and 98% reported by Jamery et al and Bailey et al respectively [14,17]. However, the rate is slightly lower than the 100% reported by Swan et al [7]. Successful biliary cannulation following NKS was a bit low, at 64% in comparison to higher rates seen in other reports [2, 9, 14,16]. The low NKS success rate in this study may be a result of the strict definition used. NKS was deemed successful when it resulted in achieving biliary cannulation at the index procedure. Studies reporting higher success rate may have included successful biliary cannulation undertaken at a later trial of ERCP following an index NKS [2, 9, 14,16]. Some reports did not however define success following NKS [17]. Additionally, success rate of NKS correlates well with endoscopists level of experience. Table 4 demonstrated 100% failure with inexperience as defined in this study. Although this fact has not been specifically described in previous reports, Ayoubi et al, suggested that experience of the endoscopist plays some role in achieving successful biliary cannulation following NKS [13], The retrospective nature of this study makes it difficult to make a firm conclusion in this respect. It does stand to reason that the more experienced one is, the better the performance of a procedure. The high success rate coupled with low complication in other high-volume centres has been attributed to firstly, the performance of ERCPs by more senior and experienced endoscopists and secondly to early decision to undertake NKS in order to avoid undue trauma and oedema to the ampulla [9,15]. As a regional academic centre responsible for training of sub-specialists in all aspects of HPB Surgery in a middle-low income country, the need

to capacitate trainees as soon as possible is important. As such, trainees are more likely to perform ERCPs under supervision at an early stage of sub-specialization at the CHBAH HPB Unit. This needs to produce competent ERCPists early in the training may in part account for the reported low success rate and complications in this study.

In line with reported studies, other reasons that could be adduced to the low success rate in this study are summarized on table 2.

This analysis demonstrated specific NKS related complications of 11.1% (Figure 3). The rates of post NKS bleeding and duodenal perforations in this study were comparable to other reports [1,2]. However, there is no literature and/or clarity with respect to the procedure-related complications noted in these studies. As already alluded to however, most of the complications reported herein were minor and easily managed intraoperatively.

The only mortality recorded in this study was as a result of an unrelated complication. The advanced stage of the disease and patient condition may have contributed to the terminal event.

The rate of PEP in this study is difficult to judge as a result of the retrospective nature of the analysis. There was a lot of missing data in respect of this outcome. Additionally, as a referral centre, many patients treated at the CHBAH ERCP Service returned to homebased centres in remote areas limiting data gathering with respect to PEP. Nevertheless, complete information was available for the 6 cases of PEP analysed. Most were mild to moderately severe and resolved with little or no adverse outcome. This compares well with the work by Bailey et al and Swan et al respectively [3, 17]. Swan et al [3] recorded PEP rate of 3.1% in the NKS group whilst Bailey et al [17] showed 7.3% PEP rate in their series.

All in all, the results of this study on NKS compare well with other reports in the literature as shown in Table 5. The NKS rate of 14% in this study is within the 0 – 42% rate in the literature [2,12,21]. Likewise, the specific NKS complication rate of 11.1% compares well with the reported complication rate of 2.6 – 34% **[8,9].** As already noted, the commonest complications were bleeding (5.2%) and retroduodenal perforations (1.7%) respectively. These rates are in keeping with the reported rates of 0.7-2.3%,1 – 48%, 5.5% and 0.0.8 – 1.1%, 0.2-0.6, 3% respectively [1,2,19]. Of note, there is lack of information regarding free duodenal perforations and peritonitis in any study. Currently such duodenal complications appeared to be less than 0.5% [2], likely because of improvement in experience and skill of endoscopists. Other common NKS associated complications in this series were false tract perforation at 3.1% and ampullary oedema at 1.1%. No other study has previously reported these complications.

Table 5: Comparison of CHBAH data with literature

Parameter/s	Literature	CHBAH
Rate	**0 – 42 %**	**14.0%**
Success	**63 – 91%**	**64.1%**
Complications/morbidity (specific)	**2.6 – 34%**	**11.1%**
Mortality	**0 – 2.0%**	**0.1%**

In comparison to the standard technique, NKS seems to be associated with higher complication rate (14% vs11%), however, this did not reach statistical significance (Table 6). Other studies (swan et a, Helsinki trail, China trial) demonstrated similar findings. The Helsinki and the multicentre trials performed in China also reported no differences in the complication rates and efficacy in a direct comparison of NKS and conventional techniques [14,21].

Table 6: Complications Comparison between standard ERCP with NKS

	ERCP		NKS	
Characteristics	**N**	**%**	**N**	**%**
Bleeding	75	3.0%	18	5.6%
Perforation	37	1.5%	9	2.8%
Respiratory arrest	32	1.3%	4	1.2%

P-value 0.507

5. Conclusion:

The result of NKS in the study compares well with reported large series, However, NKS requires experience and should be performed by senior endoscopist., NKS is quite safe as the complications in comparison with standard technique was not statistically significant, Improved documentation of PEP will provide a better picture in the future

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