ANNALS OF GASTROENTEROLOGY 2010, 23(1):48-52

Original article

Needle knife papillotomy with discarded sphincterotomes: Cost effective and safe

(see editorial page 15)

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SUMMARY

Background: Efficacy of therapeutic biliary endoscopy depends on the success rate of selective cannulation of common bile duct. Precut papillotomy using a needle knife is a technique used to improve access to common bile duct. The cost of the procedure increases exponentially with the use of special accessories like a needle knife. We evaluated the safety and efficacy of a needle knife made out of discarded sphincterotomes at our institute. Methods: Prospectively collected non-randomized data was analysed at an academic tertiary referral center. The study included all patients in a two-year period that underwent endoscopic retrograde cholangiopancreatography. The main outcome measures of the study were success and complications of precut papillotomy done using a needle knife shaped out of discarded sphincterotomes. Observations: 438 ERCPs were performed during the study period and 78 patients (17.81%) needed a precut papillotomy. Selective biliary cannulation after precut papillotomy with the newly prepared needle knife was successful in 100 % of cases. Complications seen in 7 % of cases, were similar to those observed in other studies and none of them were life threatening. Conclusion: Precut papillotomy using needle knife made out of discarded sphincterotomes is effective and safe when performed by an experienced endoscopist. In a developing economy where cost of medical treatment is a major obstacle in providing health care, small innovations like the above will help in decreasing the cost of endoscopic retrograde cholangiopancreatography.

Key words: needle knife papillotome, papillotomy, discarded sphincterotomes cost effectiveness.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) first performed by McCune forty years ago, is now predominantly used as a therapeutic procedure.[1] Selective cannulation of biliary or pancreatic systems is necessary for therapeutic success. Since the first endoscopic sphincterotomy performed in 1974 by Kawai and Classen, it has become the primary means of accessing the pancreaticobiliary system for treatment.[2,3,4]

Standard cannulation techniques fail between 5% and 20% of the time.[4,5,6] Precut papillotomy is a technique employed to gain access to the common bile duct (CBD) when standard methods using catheters, sphincterotomes, and guidewires have failed. In this technique, the papilla is cut with a needle knife for a certain distance from the orifice so as to facilitate selective deep cannulation of the CBD. It significantly improves the overall success rate of CBD access. Studies in the past reported a cumulative success rate of gaining access to CBD ranging from 77% - 97%. Complication rates were also reported to range from 2.6 % to 20% and precut papillotomy has been generally recommended for experienced operators.[5]

The cost of accessories used in ERCP is the major obstacle in providing treatment in a developing country like India. We evaluated the safety and success rate of cannulation of CBD using needle knives made from discarded sphincterotomes at our centre.

PATIENTS & METHODS

This prospective study evaluated the success and complication rates of precut papillotomy using needle knife shaped out of discarded sphincterotomes by a single experienced endoscopist from March 2006 to March 2008. Ours is a tertiary referral centre for gastroenterology and hepatobiliary diseases and is a high volume centre for ERCP[7]. Majority of the procedures are done for therapeutic purposes.

Access to CBD was obtained initially using a diagnostic cannula or sphincterotome and a guide wire. If selective cannulation was unsuccessful even by the experienced endoscopist, then precut papillotomy was attempted using a needle-knife shaped out of discarded sphincterotomes only by a single experienced[8] endoscopist (RPM).

Preparing the needle knife: These were made from discarded enlargen type sphincterotomes (ultratomes of Boston scientific and sphincterotomes of Wilson cook). The most common reason for discarding the sphincterotomes was a broken wire (Fig 1). Sphincterotomes were properly cleaned to get rid of any clots or debris and the ability to pass the guidewire freely was also checked. Such sphincterotomes were selected and with the use of a sharp cutting instrument, distal 5 of the discarded sphincterotomes is cut away (Fig 2).

This leaves us with a cut end from which the wire, which then functions as a needle, can be brought out by opening the handle of the sphincterotome.(Fig 3). The rough end of the sheath and the needle are smoothened. The maximum length of the needle was 5-8 mm. (Fig 4). A direct segmental incision starting from the papillary orifice was used. In this method, the prepared needle knife

Figure 1.

Figure 2.

was introduced in the papillary opening and needle tip extended for 3-5mm and incision was made in the direction of 1 o'clock using blended current (Erbe cautery). Thereafter cannulation of CBD was obtained and the incision was extended for the desired length using standard sphincterotome. All the accessories were sterlised in ethylene oxide sterliser or were kept in 2% gluteraldehyde for 20 min. These needles could be used for 8-15 procedures (average 9 times). Success of precut papillotomy was defined as the ability to deeply cannulate the CBD. Complications were classified using the criteria previously published by Cotton et al.[6] All patients gave writ-

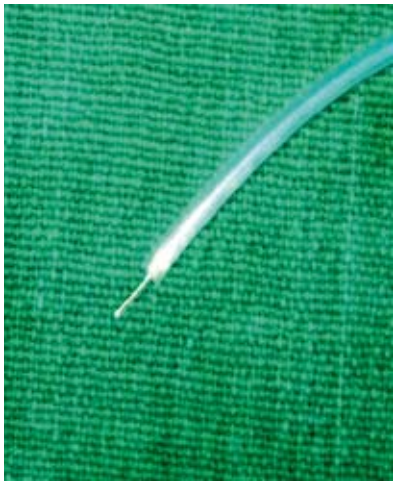

Figure 3.

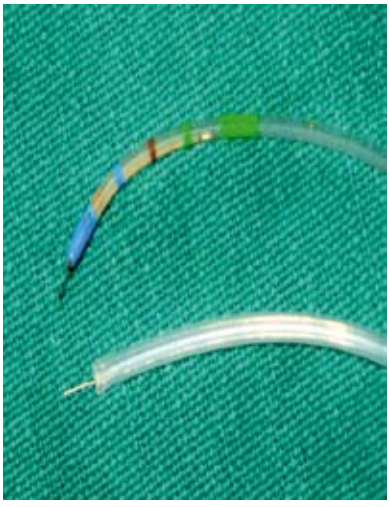

Figure 4.

ten informed consent for the procedure. Permission of the institute's ethics committee was also obtained.

RESULTS

The Indications for ERCP and precut papillotomy are shown in tables 1-3.

Selective cannulation of CBD was obtained by standard method in 360 cases (82.19%). In 78 cases (17.81%) selective cannulation was achieved only after precut papillotomy was done by the needle knife made as described above. Among the 78 patients who required precut papillotomy, 40 were females and 38 were males. The median age was 45 years. Conditions requiring needle knife papillotomy are shown in tables 2 and 3. 46 (16.4%) of the 322 cases with benign etiology required precut papillotomy and 32 (27.5%) of the 116 cases with malignant etiology required needle knife papillotomy to gain access into CBD. In all cases except 2 i.e. in 97% of times CBD cannulation after needle knife papillotomy was obtained in the first sitting. In these 2, access to CBD was obtained in the second session after a period of 3-5 days.

Table 2. Benign conditions requiring precut papillotomy

CBD stones	25/230 (10.86%)
CBD stricture	11/33 (33.33%)
Bile duct Injury	4/15 (26.66%)
Choledochal cysts	3/6 (50.00%)
Others	3/38 (15.78%)
Total	46/322 (7.89%)

Table 3. Malignant conditions requiring precut papillotomy

Cholangiocarcinoma	13/45 (28.8%)
Pancreas Head Carcinoma	13/29 (44.8%)
Periampullary Carcinoma	3/21 (14.28%)
Carcinoma Gall bladder	3/21 (14.28%)
Total	32/116 (27. 5 %)

Complications were encountered in 6 (7.6%) of the 78 cases. Bleeding in 4 cases and pancreatitis in 2 cases. Bleeding was easily controlled with injection adrenaline 1:10,000 in 3 cases and or balloon tamponade in 1 case. None of the cases required blood transfusion or surgical intervention. Pancreatitis was mild and both the patients responded to conservative management. As the bleeding was mild patients were not followed for bleeding after discharge from the hospital.

Among cases with standard cannulation, complications occurred in 28 patients i.e. in 7.77% cases. Fourteen cases were bleeding, 2 cases required blood transfusion and surgical exploration, and rest were managed with adrenalin injection or balloon tamponade. Three cases of perforation were noted and all were managed conservatively. Pancreatitis was seen in 11 cases, all responded to conservative treatment.

Table 1. Indications for ERCP (standard + precut papillotomy) in 438 cases

BENIGN CONDITIONS	N=322 (73.52%)	MALIGNANT CONDITIONS	N =116 (26.48%)
Gallstone disease	230 (71.4%)	Carcinoma Head of pancreas	29 (25%)
Biliary Strictures	33 (10.2%)	Cholangiocarcinoma	21 (18.1%)
Bile duct /cystic duct injury	15 (4.7%)	Periampullary Carcinoma	45 (38.8%)
Choledochal cysts	6 (1.9%)	Carcinoma gallbladder	21 (18.1%)
Others (worms, portal biliopathy, PSC, SOD, hepatic abscesses, HIV cholangiopathy)	38 (11.80%)		
TOTAL	322 (100%)		116 (100%)

(PSC=Primary sclerosing cholangitis, SOD=sphincter of Oddi dysfunction)

322 ERCP's are for benign conditions and 116 for malignant conditions. 10.86% of benign cases (Table 2) and 27.5% of malignant conditions(Table 3) required precut papillotomy. P value < 0.003.

Table 4. Success rate and complications of precut papillotomy by various authors

Study Group	Success rate (%)	Complication (%)
Dhir et al 10	65%	6%
Pai et al 11	93.6%	20%
Zhang et al 9	90%	2.94%
Lindsay et al	87%	7%
Rathi et al 2008 (present study)	100%	7.6%

DISCUSSION

Our findings re-enforce that precut papillotomy using needle knife if performed by an experienced endoscopist is a safe and effective alternative to access the CBD. Complication rates are similar to cannulation with standard techniques. Precut papillotomy was performed in 78 (16%) of 438 cases undergoing ECRP. The success rate of standard cannulation is approximately 85% in this study. This may be due to previous attempts at cannulation by inexperienced endoscopist leading to edema of the surrounding tissues and secondly the confidence of the experienced endoscopist in needle knife papillotomy which led to more frequent use of needle. In 97 % of cases after precut papillotomy, cannulation was achieved in the first sitting. This high success rate in obtaining CBD cannulation may be due to the proper selection of cases. It also reflects on the efficacy of the newly prepared needle knife.

Cases with malignant etiology required needle knife papillotomy more frequently (25% of 116 cases) than benign causes (less than 15% of 322 cases) which was statistically significant ($p< 0.003$).This may be because of distorted anatomy and edema of the periampullary area resulting in difficult cannulation by standard methods. Among the benign causes, congenital CBD dilatation and choledochal cysts and cases with injury during previous surgery required needle knife papillotomy more frequently. Difficult cannulation is expected in a collapsed CBD secondary to biliary leak. Complication rates (6.7%) in our study are similar to other larger series[4,9] (Table 4).

C G Pai[11] in a similar study, using discarded sphincterotomes, has reported a similar success rate with more complications. He cut the sphincterotomes about 2 cm from the distal tip, and could use the needle for 15–20 procedures. Proper selection of cases by an experienced endoscopist usually reduces the morbidity of this procedure.

India is a developing country with a rapidly growing population that puts additional burden on the already stretched health care facilities. The per capita income of India is 32,140 INR (Indian Rupees) approximately 650 $ (US dollars)[12] compared to that of United States with a per capita income of 44040 $.[13] The annual per capita expenditure on health in India is $ 91 compared to $ 6096 in United States of America (USA) and $ 277 in China.[13] Moreover in India, more than 60% of the health cost is borne by the households of which more than 90% is in the form of out of pocket payments. This is in sharp contrast to 23 % out of pocket payments in USA[(13)]. So the cost of any additional accessory required for the procedure will put additional burden on the patient who pays for most of the procedural cost. The cost of hospitalization per day using the standard commercially available single use equipment is approximately 550 USD. (includes the cost of the commercially available single use needle knife, approximately 200 USD). The hospitalization cost is similar in patients undergoing procedure with homemade catheters, except for the cost of the needle knife, which in this case was made from the discarded sphincterotome. This alone resulted in reducing the cost of the procedure by one third. The cost of the standard sphincterotome is 175 USD approximately, from which home made needle knives were made and were used in average of nine times. (Each patient has to pay less than 20 USD instead of 200USD. Total cost now is 350 +20= 370 USD instead of 550USD) which according to us is of immense benefit to patients without increasing the complications. Moreover the hospitalization time was similar in the two groups, except in patients with complications, where they were kept under observation for a few extra days. But this number was very low and similar to patients undergoing procedures with standard sphincterotome. By using a needle knife made from a discarded sphincterotome, papillotomy can be done without any additional cost to the patient. It should also be noted that the amount of biomedical waste generated while disposing of all the discarded sphincterotomes was also reduced. This study highlights the fact that without adding to the cost of the procedure, with proper and simple modification of a sphincterotome which instead of being discarded can be put to good use without compromising the safety of the patient.

Previous studies have shown that even the ‘single use sphincterotome’ can be reused safely without compromising the safety and efficacy of the procedure. Moreover, reusing the sphincterotome was able to cut costs significantly.[14] The reasons cited for discarding were broken sphincterotomy wire in 42 %, improper bowing of the wire in 27 %, inability to pass guidewires in 7 % and inability to clean in 4 %. The patients were not followed up for complications once they were discharged. We did not compare the success rate and complications of precut papillotomy

using a standard needle knife and our needle knife (from discarded sphincterotomes) since the standard needle knife was not available to us most of the time.

Franklin et al[14] have shown very high success and comparable complication rates with standard cannulation techniques and cannulation after precut papillotomy. Our data suggests that when used by an experienced endoscopist needle knives made from discarded sphincterotomes are a safe and effective alternative to standard needle knives.

CONCLUSION

Precut papillotomy performed with needle knives prepared from discarded broken sphincterotomes is an effective alternative when standard techniques of cannulation fail. If done by an experienced endoscopist it is safe and has a very high success rate. This simple modification can reduce the cost of ERCP in a developing country like India. Further studies may be done to compare the safety and efficacy of standard needle knives and needle knife made from discarded sphincterotomes to confirm our findings.

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