

Precut sphincterotomy: A reliable salvage for difficult biliary cannulation

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the setting of a failed standard cannulation method. This paper discusses the technical details, timing, efficacy and potential complications of precut sphincterotomy.

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Abstract

Even experienced endoscopists have 90% success in achieving deep biliary cannulation with standard methods. Biliary cannulation may become difficult in 10%-15% of patients with biliary obstruction and pre-cut (access) sphincterotomy is frequently chosen as a rescue treatment in these cases. Generally, precut sphincterotomy ensures a rate of 90%-100% successful deep biliary cannulation. The precut technique has been performed as either a fistulotomy with a needle knife sphincterotome or as a transpapillary septotomy with a standard sphincterotome. Both methods have similar efficacy and complication rates when administered to the proper patient. Although precut sphincterotomy ensures over 90% success of biliary cannulation, it has been characterized as an independent risk factor for pancreatitis. The complications of the precut technique are not limited to pancreatitis. Two more important ones, bleeding and perforation, are also reported in some publications as being observed more commonly than during standard sphincterotomy. It is also reported that precut sphincterotomy increases morbidity when performed in patients without dilatation of their biliary tract. Nevertheless, precut sphincterotomy is a good alternative as a rescue method in

INTRODUCTION

With the development of increasingly sophisticated imaging methods, endoscopic retrograde cholangiopancreatography (ERCP) is currently used more for the treatment than the diagnosis of biliary tract disease. The first choice of treatment for biliary calculus, postoperative bile leak and benign or malignant biliary stenosis is endoscopic, i.e., therapeutic ERCP. A preliminary condition to successful therapeutic ERCP is selective biliary cannulation. Deep biliary cannulation performed by an experienced endoscopist using standard cannulation techniques is successful in approximately 90% of cases^[1]. Biliary cannulation may become particularly difficult in the 10%-15% of patients with an anatomical problem or a disease such as fibrosis, tumor of the sphincter of Oddi, periampullary diverticuli, calculus impaction in the sphincter, or status post Billroth I - II. Such situations are also risk factors for complications of ERCP^[2,3]. In a retrospective review of 502 patients, Fukatsu *et al*^[4] were not successful in cannulating the biliary tract within the first 20 min using standard methods in 80 of these patients (16%) for one of the following reasons: female sex, post-hepatectomy

hypertrophy of the left lobe, status post Billroth I gastric resection with reconstruction, and malignant stenosis. In such patients, deep biliary cannulation fails often enough, notwithstanding the use of various instruments such as a tapered or standard-tip catheter, a sphincterotome, a guide wire, a metal-tip catheter, *etc.* Alternatively, the pancreatic duct ends up being cannulated. Every new attempt to cannulate through the papilla, or repeated cannulation of the pancreatic duct, inevitably increases the risk of post-ERCP pancreatitis (PEP)^[5]. Published reports indicate that ten or more transpapillary cannulation attempts or more than five cannulations of the pancreatic duct are independent risk factors for PEP^[2,3,5].

The most popular method to address a difficult cannulation is needle-knife (NK) precut sphincterotomy, which has been in use since the 1980s. The term precut was first used by Siegel^[6] and later popularized by Huibregtse *et al.*^[7]. A more recent technique for difficult cases is transpancreatic precut sphincterotomy (TPS), which was described after 1990^[8]. Although precut (access) sphincterotomy ensures over 90% success of biliary cannulation^[9], it has been characterized as an independent risk factor for PEP^[10,11]. Patients in whom the precut technique is applied are, however, already at a high risk for PEP; they have, as a rule, already undergone mechanical trauma due to previous attempts at transpapillary cannulation. Both situations are well known as PEP risk factors. Therefore, a timely use of the precut technique could reduce the risk of PEP. The complications of the precut technique are not limited to PEP. Two more important ones, bleeding and perforation, are reported in some publications as being observed more frequently than during standard sphincterotomy. It is also indicated that precut sphincterotomy increases morbidity when performed in patients who have no dilatation of their biliary tract. This paper discusses the technical details, timing, efficacy and complications of precut sphincterotomy.

TECHNICAL DETAILS

Precut sphincterotomy is an endoscopic technique used for deep biliary cannulation, and also for reaching the pancreatic duct in rare cases. It consists of an incision in the papilla in the absence of free biliary cannulation or a guide wire. The incision is performed most frequently with a needle-tip sphincterotome, and the technique is referred to as “NK precutting”. Depending on the point of origin of the incision, the technique is designated as “standard” or “modified”.

Standard technique

The incision starts at the orifice and proceeds upwards, in the direction of 11 h on a clock dial, until it is past the papillary protuberance. The length of the cut is determined by the intraduodenal part of the common bile duct: it stops at the upper limit of the duodenal bulge of the common bile duct.

Modified technique

The incision starts where the lower two thirds of the papillary protuberance meet the upper third, and it proceeds downwards on the left of the median line of the papilla and stops before reaching the papillary orifice. The incision depth is obtained with 2-3 pushes on the NK in a straight plane, while exerting sufficient pressure from the surface of the ampulla towards the catheter.

Transpancreatic precut sphincterotomy or transpancreatic papillary septotomy

This technique provides bile duct cannulation by entering the common duct or pancreatic duct through the papillary orifice and then cutting the septum that separates the pancreatic duct from the bile duct. Transpancreatic papillary septotomy can be either wire-guided after introducing a guide wire in the pancreatic duct, or it can be performed without a guide. The wire-guided method consists of introducing a soft guide in the pancreatic duct, then directing a papillotome, usually of the standard type, towards the bile duct to perform the cut. The catheter is introduced into the bile duct after its ostium has become visible. The unguided technique first introduces the sphincterotome into the common duct; the septum between the pancreatic and the bile ducts is incised, and the biliary and pancreatic orifices are made visible separately. The pancreatic orifice is generally lower than the central position, to the right of the papillary median line, and the bile duct orifice is to its left in the middle. The latter presents a velvety appearance with an off-yellow color. After visualizing the biliary orifice, deep biliary cannulation is performed, and the sphincterotomy operation is completed.

Different sphincterotomes have been developed for precutting and NK^[12] (Table 1). The catheters may possess a single, double or triple lumen Iso-Tome. An isolated-tip papillotome to prevent energy leakage from the needle point has also been developed, as well as a coated-tip NK aimed toward preventing perforation. The Erlangen-type papillotome is one of these. It is similar to the standard traction-type sphincterotome, with a 5 mm monofilament cutting wire and a catheter tip measuring less than 1 mm. Other modifications of the short-tip or noseless sphincterotome are also used for precutting. They are available with insulated or non-insulated cutting wires. Yet another type of device used to perform a papillotomy to permit access is that of a catheter equipped with a small scissor at the tip^[13]. The lower blade of the scissor is introduced into the papillary orifice, and the scissor blades close to obtain a cut.

How effective is a precut sphincterotomy in achieving deep biliary cannulation? Does it increase post-ERCP complications?

Standard cannulation techniques achieve deep biliary cannulation in approximately 90% of cases, while 10%-15% of cases present difficulties. Patients experiencing such difficulties generally have a disease such as

Table 1 Precut sphincterotomy devices

Product	Distal tip OD (F)	Tip length (mm)	Cut-wire length (mm)	Recommended guidewire size (inch)	Comments
Boston Scientific (United States)					
Needle knife RX	5	NA	5	0.035	Triple lumen, shortwire
Micro knife XL	5	NA	5	0.035	Triple lumen, precut
Mediglobe (Tempe, Arizona)					
Precut sphincterotome	5 or 6	NA	20 or 30	0.021-0.035	Double or triple lumen, noseless, erlange n-type sphincterotome
Needle knife	5 or 6	NA	0-15	NA	Single lumen
Olympus (Tokyo, Japan)					
Triple lumen needle with clever coating	5	NA	5	0.035	Precut device
Triple lumen needle knife	5	NA	5	0.035	Precut device
Cook Medical (Winston-Salem, NC)					
Huibregtse triple lumen needle knife	5	NA	4	0.035	Triple lumen, precut
Zimmon needle knife	5	NA	7	0.035	Precut device
Fusion needle knife	6	NA	4	0.035	Short-wire system

OD: Outside diameter; NA : Not available.

a stenosis or a tumor of the sphincter of Oddi, periampullar diverticula, status post-Billroth II, *etc.*, or an anatomic abnormality. Cannulation difficulties lead to multiple attempts. The resulting trauma and edema create a favorable ground for PEP. Precut papillotomy is an invasive procedure to help achieve deep biliary cannulation. Studies and discussion of precut papillotomy have been ongoing since the early 1980s, when this technique was first used. Rabenstein *et al*^[14] reviewed the patients on whom they had performed precut papillotomy and ERCP, dividing them in two groups based on the year of the operation, 1981-1987 and 1988-1993. In both periods, approximately one-third of the patients needed a precut papillotomy to achieve deep biliary cannulation, and precutting was successful in 85% of these cases. The complication rates of primary endoscopic sphincterotomy (6.8%) and precutting (7.3%) were similar. Foutch *et al*^[15] succeeded in the deep cannulation of 414 of 456 patients (91%); endoscopic sphincterotomy was successful in 395 patients (87%), and 40 patients (9.7%) experienced complications, 21 (5.1%) of which were serious. Precutting, which was used in 52 patients because of insufficient deep cannulation or endoscopic sphincterotomy (EST), was successful in 47 patients (90%), 3 (5.8%) of whom experienced complications, and these complications were serious in 2 (3.8%). No mortality related to EST or precutting was observed. Binmoeller *et al*^[16] used precutting with an Erlangen-type instrument in 123 (38%) of 327 patients. Selective biliary cannulation was successful in all patients. Hyperamylasemia, observed in half of the patients who underwent precutting, was present in 27% of the standard sphincterotomy group ($P < 0.001$), while clinical PEP and the bleeding frequency were similar in both groups (2.7% *vs* 2.4% and 1.6% *vs* 3.9%, respectively). Palm *et al*^[17] compared their results in 121 patients on whom they had performed precutting with the same type of papillotome with the result of procedures performed in 481 other patients who had received standard sphincterotomy (a precut ratio of

25%). As in the earlier cited study, hyperamylasemia was more frequent in the patients who underwent precutting than in those with EST (31.3% *vs* 13.3%), while the rates of other complications were similar (7.18% *vs* 8.3%). Precutting resulted in a success rate of 98.2% for deep biliary cannulation. In a study comparing primary and secondary precutting, de Weerth *et al*^[18] reported a 100% success rate of biliary cannulation with a cannulation time of 6.9 ± 1.8 min in the primary precutting. In 146 patients with secondary precutting who had previously undergone attempts at standard cannulation and sphincterotomy, 104 had a successful cannulation within 8.3 ± 2.1 min ($P < 0.001$), and 42 had to repeat the secondary precutting. PEP was observed with the same frequency in both groups (2.1% *vs* 2.9%), and 1 patient in the secondary precut group experienced light bleeding. The authors conclude that primary precutting is safer, more efficient and faster. Kasmin *et al*^[19] achieved a successful biliary cannulation at the first attempt in 50 (67%) of 72 difficult patients, and 17 others were successful at the second attempt, for a total of 67 (93%) successful procedures with NK sphincterotomy. Complications were observed in eight (11%) patients, including guide wire-related perforation, bleeding from precutting and pancreatitis. A narrow common bile duct diameter was determined to be an independent risk factor for complications in patients undergoing precutting. In a study of the correlation of NK precut and PEP, Testoni *et al*^[10] performed NK precutting in 12.8% of their 732 patients with naive papilla, with an 85% success rate. The PEP frequency was 14.9% in the precut group *vs* 6.1% in the non-precut group. Female sex, stenosis of the sphincter of Oddi, partial pancreatic drainage and more than 15 previous cannulation attempts were independent risk factors for PEP, while NK precutting was not. A stent was implanted in the pancreatic duct in 22 patients, and five of these experienced pancreatitis. The authors indicate that the pancreatic stent provides no protection from PEP to patients at risk. Perforation, bleeding or

Table 2 Precut admission, success and complication rates (%)

Ref.	The need for precutting	Deep biliary cannulation	Precut-associated complication	Standard sphincterotomy-associated complication
Bailey <i>et al</i> ^[10]	12.8	85	14.9	6.1
Rabenstein <i>et al</i> ^[14]	30	85	7.3	6.8
Foutch <i>et al</i> ^[15]	9	90	9.8	9.7
Binmoeller <i>et al</i> ^[16]	38	100	5.5	5.1
Palm <i>et al</i> ^[17]	25	98.2	8.3	7.18
Cennamo <i>et al</i> ^[20]	20	92	8	
deWeerth <i>et al</i> ^[18]	30	99	2.9	2.1

severe pancreatitis were not observed. As for Cennamo *et al*^[20], they applied criteria somewhat differently from the previous studies, performing precutting if the standard attempt failed within 5 min or after three repeated cannulations of the pancreatic duct; they compared this group of patients to those who had undergone late precutting after failed cannulation within 20 min. In the early precut group, cannulation was successful in 32 (92%) of 36 patients at the first attempt and 100% at the second. In 78 of the 110 late precut patients, biliary cannulation was achieved within an average of 7.6 min by standard methods, while precutting was performed in the first 20 min in the remaining patients. Deep biliary cannulation was successful at the first attempt in 26 (81%) of these patients and at the second in the remaining four. The complication rate was 8% in the early precut group and 6% in the late precut ($P = 0.7$). Patients with periampullary diverticuli, gastric surgery and papillary neoplasia were excluded from this study. Oddi's sphincter stenosis was not an exclusion criterion, but it was not found in any of the patients during the procedure. The authors concluded that there was no difference between the early and late precut patient groups with regard to biliary cannulation success rates and complication rates. Considering, however, the early decision regarding the failure of standard cannulation in the early precut group, it can be speculated that biliary cannulation could still have been achieved by standard methods with a longer trial in some of these patients. Another question is the exclusion of patients with important PEP risk factors and the absence of cases of stenosis of the sphincter of Oddi, which both may have contributed to the absence of a difference in terms of complications. Additionally, an apparent difference in the first-pass success rates in favor of the early precut patients, 92% *vs* 81%, was not discussed in the conclusion. A review of these studies (Table 2) shows that precutting is successful in achieving deep biliary cannulation in more than 95% of the cases, without causing a substantial increase in the complication rate.

The timing of the precutting intervention is important for reducing the complications. The number of transpapillary cannulation attempts and that of pancreatic duct cannulations are two of the most important factors contributing to PEP. Published reports indicate that

ten or more transpapillary cannulation attempts or more than five cannulations of the pancreatic duct are independent risk factors for PEP. Precutting before reaching such a number of attempts would not constitute an additional PEP risk factor. In a meta-analysis by Cennamo *et al*^[21] of six controlled, randomized studies, pancreatitis was found in 2.5% of patients undergoing early precutting *vs* 5.3% in those in whom the unsuccessful attempts continued (odds ratio 0.47, 95% confidence interval: 0.24-0.91); early precutting was shown to lower the risk of PEP. In another study, Tang *et al*^[22] found fewer cases of PEP in patients subject to precutting before reaching 10 unsuccessful cannulation attempts through the papilla as opposed to those with 10 or more attempts. When comparing the patients who underwent early precutting with those in whom the endoscopists persisted with difficult cannulation, the success rates were, respectively, 75% and 73%, and the complication rates were 4% and 9%; the differences were not significant. Kaffes *et al*^[23] performed early NK precut sphincterotomy in 70 (20%) patients out of a population of 346 undergoing therapeutic ERCP. The operation was performed in patients in whom selective biliary cannulation was not successful within the first ten min or those with more than five cannulations of the pancreatic duct. Successful biliary cannulation was achieved at the first attempt in 58 (83%) patients, and at the second attempt 24-48 h later, it was successful in 7 more patients. Precutting was unsuccessful in 5 patients. Thus the total success rate for biliary cannulation was 95%; six patients had light bleeding, and one had light pancreatitis. It was concluded that early precutting does not add to the PEP risk. Bruins Slot *et al*^[24], reporting a success rate of 99% for precut sphincterotomy in achieving biliary cannulation with a complication rate of 12%, interestingly found a 0.1% PEP rate but observed relatively frequent perforation (3%) compared to other reports, where perforation is rare, and bleeding was reported in 5.5% of patients. The bleeding reported with the NK precutting procedure is characterized as mild, but it is generally more frequent than with standard sphincterotomy. As a result of all these reviewed studies, it may be said that, in addition to not representing a risk factor for developing PEP, early precut sphincterotomy does not cause complications in addition to those of the ERCP or standard sphincterotomy methods, and it is safe.

Should a transpancreatic septotomy and NK precut method be used, and what are their respective advantages and complications? To answer these questions, the results of several studies should be considered. In a paper by Goff^[25], who also first described TPS, on the long-term comparative results of this technique *vs* those obtained with standard sphincterotomy, 51 (25%) patients of a total of 200 were subjected to precutting. Of these, 49 (94%) had a successful biliary cannulation at the first attempt; the complication rate was 2.1% for standard and 1.96% for precut sphincterotomy. Catalano *et al*^[26] performed TPS in 29 patients and NK precutting in 34. The cannulation success rate was 100% in the former and 77% in

Table 3 The comparison of needle knife papillotomy and transpancreatic precut sphincterotomy (%)

Ref.	Transpancreatic precut	Needle knife precut	P value
Catalano <i>et al</i> ^[26]			
Successful biliary cannulation	100	77	0.01
Complications	3.5	17.7	NS
Wang <i>et al</i> ^[27]			
Successful biliary cannulation	90	90.8	NS
Complications	14.9	18.4	NS
Halttunen <i>et al</i> ^[30]			
Successful biliary cannulation	97.3	7.3	< 0.001
Complications	9.3	8.2	NS

NS: Not significant.

the latter group ($P = 0.1$). Complications were observed in one TPS patient (3.5%) and in six (17.7%) who had NK. Wang *et al*^[27] applied TPS in 140 patients and NK in 76, with similar rates of biliary cannulation success, PEP, and other complications (90% *vs* 90.8%, 11.4% *vs* 11.8% and 14.9% *vs* 18.4%, respectively). Akashi *et al*^[28] performed TPS without using a guide wire in 172 patients, with 163 (95%) successful biliary cannulations and a 10% complication rate. They note in their conclusions that the general complication rate of ERCP was low at 0.8%, and that of TPS was relatively elevated ($P < 0.001$). Kahaleh *et al*^[29] obtained a deep biliary cannulation success rate of 85% without guide wire in 116 patients; three patients (2.6%) experienced bleeding, 9 (8%) had pancreatitis, and 2 (1.7%) had a perforation. The authors reported that these frequencies were no different than those of the standard sphincterotomy patients. Halttunen *et al*^[30] used precutting in 588 (9%) of 6209 ERCP patients due to cannulation difficulties and compared TPS to NK. Precutting was successful in 529 of the 588 patients. Of these, 351 had TPS and 178 had NK. The success rate for biliary cannulation was 97.3% in the TPS group and 71.3% with NK ($P < 0.001$); the frequency of PEP was 8.8% in the TPS group and 5.1% in the NK patients ($P = 0.16$). The authors characterized TPS as a substantially efficient and safe technique (Table 3). Weber *et al*^[31] inserted a soft guide wire in the pancreatic duct to perform TPS in 108 patients; 94 (87%) of these were successfully cannulated at the first attempt, and nine others were successful at a second session 1-4 d later, for a total success of 103 (95.4%) patients. PEP was observed in six (5.6%) cases, four of which were mild, and bleeding was similarly observed in six (5.6%) patients, four of whom required transfusion. There was no perforation and no mortality. The bleeding frequency was higher than usual in the last study; this may be related to the reported use of a pure cutting current. As summarized above, the results of TPS with or without the placement of a guide in the pancreatic duct seemed to be similar to each other with regard to the rates of biliary cannulation success and complications. Although there is thus no definite evidence as to the superiority of either method, the macroscopic appearance of the papilla and the presence or absence of

bile duct dilatation may be decisive. Patients in whom there is no stenosis of the sphincter of Oddi and the bile duct, and thus no bulging in the duodenum of the duodenal portion of the bile duct, are not good candidates for fistulotomy or the modified technique of NK precut. The perforation risk due to precutting was elevated in such patients; TPS is more adapted to these cases. Patients with a stenosis of the sphincter of Oddi are at high risk for PEP, and biliary cannulation by TPS following the placement of a stent in the pancreatic duct is the procedure of choice. As for patients with an impacted calculus in the orifice, or those with a papillary orifice displaced downwards due to a tumor of the sphincter of Oddi, fistulotomy or NK precut by the modified technique are appropriate.

Stent placement in the pancreatic duct has also been attempted to prevent PEP. Goldberg *et al*^[32] were successful in the deep cannulation of 38 (97.4%) out of 39 patients who presented cannulation difficulties, using TPS after having implanted a stent in the pancreatic duct. Two (5.1%) of these patients had mild pancreatitis. Performing TPS after pancreatic duct stent implantation seemed to be as successful in cannulation as other methods, while the lower pancreatitis frequency was doubtful. This was a retrospective study with few patients. Madácsy *et al*^[33] implanted a pancreatic duct stent in 22 patients with a dysfunction of the sphincter of Oddi if cannulation had failed within the first ten min or if the pancreatic duct had been entered five times before performing NK precutting. Biliary cannulation was successful in 20 patients, and none developed PEP, which was present in 14 of the 35 control group patients. A reduction of the risk of PEP due to the use of a pancreatic stent in patients at high risk is a possibility; prospective studies with more patients are needed to resolve this issue. The stent mostly falls off spontaneously within 3-5 d from the time of implantation because its distal notch is generally left outside the duct. If the stent is still in place on the follow-up abdominal x-ray at one week, it must be pulled out by esophagogastroduodenoscopy.

In a study comparing the standard technique to the modified technique for NK^[22], three patients in each group had bleeding, and one in the modified technique group had pancreatitis. No difference was detected among the two techniques regarding their complications. It is assumed that the pancreatic duct orifice is protected by the incision in the modified technique, which starts at the summit of the papillary protuberance and ends before reaching the orifice, and PEP will not develop after its use. The only patient who experienced pancreatitis in the cited study was, however, in the group that received the modified technique. It may be that edema due to temperature elevation in the tissues obstructs the pancreatic duct orifice. The emptying of the pancreatic duct is easier with the standard technique or TPS due to the incision of the common duct or even the pancreatic duct starting from the papillary orifice.

Articles on precut sphincterotomy generally start with the following disclaimer: "this method is efficient

and safe if performed by experienced endoscopists". Sphincterotomy and precutting are the most critical therapeutic operations during ERCP, and they necessitate a certain amount of experience. A study regarding this by Rabenstein *et al*^[34] showed a complication frequency of 5.6% with endoscopists who treated 40 or more cases per year *vs* 9.3% for those with fewer cases ($P < 0.05$). In their study addressing the endoscopist's experience in precut fistulotomy, Lee *et al*^[35] used this technique in 23% of cases, achieving 88.7% biliary cannulation success in the first session and 93.7% by the second session. PEP developed in 5.7% of cases. More than 15 cannulation attempts before fistulotomy was defined as being a PEP risk factor. The study determined that the operation duration decreased in an inverse relationship to the number of interventions practiced by the endoscopist, thus reducing the operative complications. Sufficient experience is of crucial importance not only for precutting but also for ERCP, especially for procedures of therapeutic nature. Experience is acquired by treating a large number of cases, following what is being performed, and continuously updating knowledge. The endoscopist will be entirely familiar with papillary anatomy after having observed many cases. The person performing the endoscopy must know what will be observed, what is being sought and what will be found in every millimeter that is being cut.

Is precutting the ultimate solution to difficult biliary cannulation? There is no doubt that it is not. A new technique is that of endoscopic ultrasound (EUS) rendezvous for common bile duct cannulation. Dhir *et al*^[36] have compared precutting to the rendezvous technique with EUS in a non-randomized, retrospective study. Successful common bile duct cannulation was achieved in 90% of patients with precutting and 98% with EUS ($P = 0.03$); the complication rates were 6.9% and 3.4%, respectively ($P = 0.27$). The authors reported that the EUS rendezvous technique is more successful than precutting for difficult biliary cannulation. It would be wrong, however, to accept these results from a retrospective, non-randomized study as unbiased; additionally, conventional cannulation was considered to have failed after five attempts and EUS was initiated, where one may speculate that extending this limit to ten or another number could have allowed it to succeed. Without a doubt, the EUS rendezvous technique represents an important step to be used as a salvage procedure when precutting is insufficient.

CONCLUSION

Precutting is necessary in roughly 10% of patients with biliary obstruction. Precut sphincterotomy ensures a rate of 90%-100% successful deep biliary cannulation in patients in whom such cannulation is difficult. The frequency of side effects, varying between 5% and 10%, is not different from that of a standard sphincterotomy. Even with these efficacy and safety ratios, the method

should remain reserved for patients who need a therapeutic intervention.

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