

New Technique of Endoscopic Sphincterotomy with Iso-Tome[®] to Incise the Distal Papillary Roof in Patients with Choledocholiths and Choledochoduodenal Fistula

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Background/Aims: It is sometimes difficult to incise the distal papillary roof (PR) completely in patients with choledocholiths and choledochoduodenal fistula (CDF). The Iso-Tome[®] (MTW-Endoskopie W. Haag KG), which is helpful in preventing electrical leakage, has good orientation capabilities and can be easily placed at the orifice of the CDF or ampulla of Vater (AV). We aimed to evaluate the efficacy of endoscopic sphincterotomy (ES) with the Iso-Tome[®] for cutting the distal PR. **Methods:** Between May 2003 and July 2012, 35 patients were analyzed retrospectively. The distal PR was cut downward and/or upward using the Iso-tome[®] until the pink intrapapillary mucosa was fully exposed. Downward incisions were performed from the opening of the CDF to the orifice of the AV; upward incisions were performed in reverse. **Results:** Spontaneous or artificial CDF occurred in four and 31 patients, respectively. The technical and therapeutic success rates were 94.3% (33/35) and 94.3% (33/35), respectively. There was no case of electrical damage to the pink intrapapillary mucosa. Adverse events occurred in 2.9% (1/35; 1, mild bleeding) of patients. **Conclusions:** The new technique of ES with the Iso-tome[®] is feasible and useful for effectively incising the distal PR in patients with CDF and choledocholiths. (*Gut Liver*, 2015;9:231-238)

Key Words: Endoscopic sphincterotomy; Iso-Tome, Choledochoduodenal fistula; Distal papillary roof; Choledocholiths

INTRODUCTION

Endoscopic sphincterotomy (ES) is a useful technique for diagnosing and treating pancreaticobiliary disease in endoscopic retrograde cholangiopancreatography (ERCP). For ES to be clinically effective in patients with choledocholiths, the papillary roof (PR) of the ampulla of Vater (AV) should be sufficiently and safely opened.¹⁻³

A choledochoduodenal fistula (CDF) on the PR is formed spontaneously or artificially.^{4,5} Spontaneous CDF is generally associated with impacted biliary stone in the AV, and an artificial CDF is created by precut papillotomy (ampullostomy) to enhance the success rate of bile duct cannulation. The PR is divided by the CDF into the proximal and distal parts (Fig. 1). It is usually not difficult to incise the proximal PR, which is de-roofed by using a pull-type papillotome in general. It is, however, relatively difficult to incise the distal PR. The following two types of papillotomes are available for cutting the distal PR; needle-knife (NK) and pull-type papillotome. But the pull-type papillotome requires successful bile duct cannulation through the orifice of the AV in advance, and the NK papillotome may increase the risk of pancreatitis by electrical damage to the AV.

Iso-Tome[®] (MTW-Endoskopie W. Haag KG, Wesel, Germany) is a modified NK papillotome that has a semi-oval or round tip made of epoxide or sapphire in order to block electrical discharge from the incision needle and to prevent unintended electrical damage.⁶ It is as convenient to manipulate the Iso-Tome[®] as it is with the NK papillotome. The semi-oval or round tip of the Iso-Tome[®] works like a hook and is useful to place and re-

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Received on January 16, 2014. Revised on March 11, 2014. Accepted on April 1, 2014. Published online on October 7, 2014

pISSN 1976-2283 eISSN 2005-1212 <http://dx.doi.org/10.5009/gnl14019>

Presented, in part, at the annual meeting of the American Gastroenterological Association (AGA), May 18-21, 2013, Orlando, FL, USA (*Gastroenterology* 2013;144:S257-8).

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tain the papillotome at the orifice of the AV or CDF. The aim of this study was to evaluate the clinical usefulness of a new technique of ES using the Iso-Tome® for incising the distal PR in patients with choledocholiths and with spontaneous or artificial CDF.

MATERIALS AND METHODS

1. Patients

Between May 2003 and July 2012, patients with choledocholiths and with spontaneous or artificial (ampullectomy) CDF were consecutively enrolled. Eighteen patients excluded even though ampullectomy was performed for the treat-

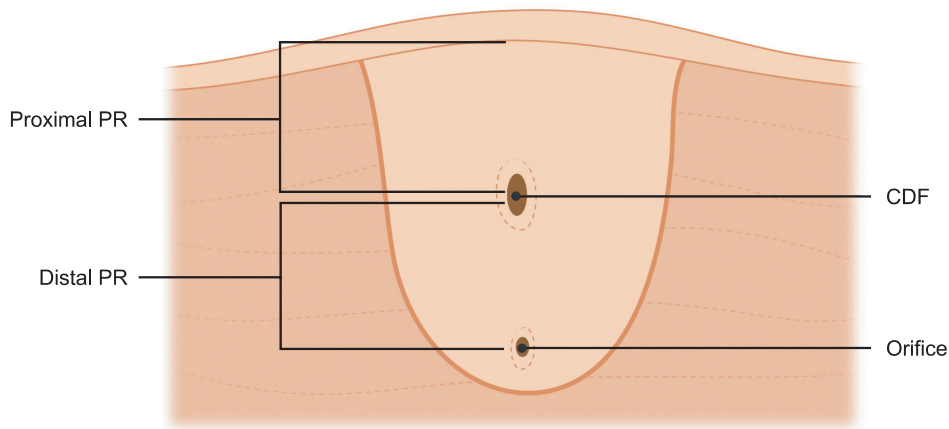


Fig. 1. Ampulla of Vater with choledochoduodenal fistula (CDF). PR, papillary roof.

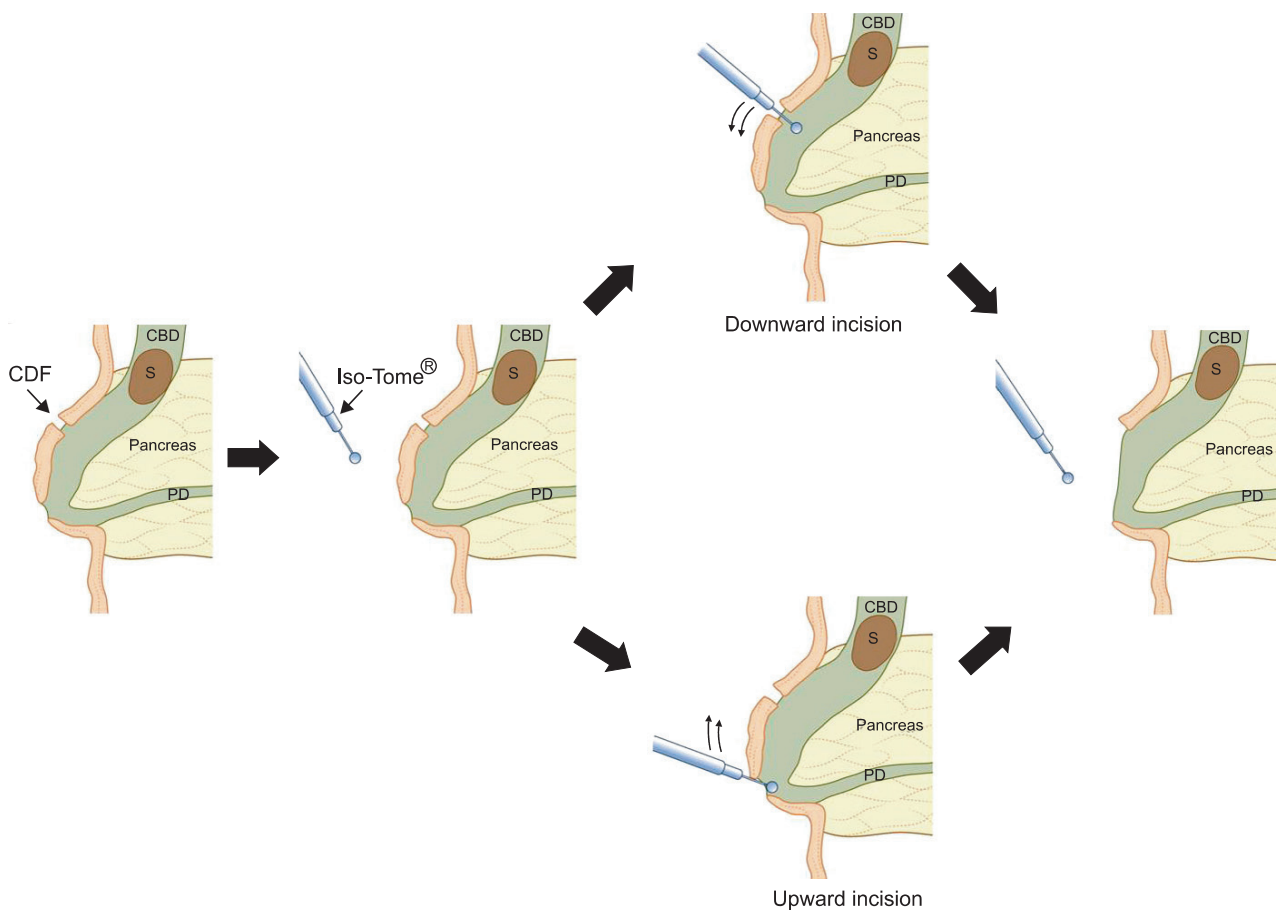


Fig. 2. Illustrations of downward and upward incisions with the Iso-Tome® (MTW-Endoskopie W. Haag KG) in the ampulla of Vater with choledochoduodenal fistula (CDF). CBD, common bile duct; S, stone; PD, pancreatic duct.

ment of choledocholiths. Of these patients, three had coagulopathy, two had benign biliary strictures, one had congenital pancreaticobiliary anomaly, five had pancreaticobiliary malignancies, two had Billroth gastric operation, two had a periampullary diverticulum with intradiverticular papilla (1) or a papilla at the edge of a diverticulum (1), and other three patients were not sure. This study was conducted retrospectively and medical records were reviewed in all patients. This study was approved by the Institutional Review Board of our hospital and written informed consent for this study was obtained from all patients.

2. Incision of the distal PR using the Iso-Tome®

All patients fasted for 1 night. ERCP using a duodenoscopes (TJF-240; Olympus Optical Co., Ltd., Tokyo, Japan) was performed in each patient in a prone or left lateral position after deep sedation with an intravenous injection of a mixture of midazolam (0.05 mg/kg) and propofol (0.5 mg/kg). Propofol was additionally injected for maintaining sedation. Only a pure-cutting current was used until 2003; from 2004, a blended current

with an electrosurgical unit (UES-30 generator; Olympus Optical Co., Ltd., Tokyo, Japan) was used. All ERCPs in this study were performed by one endoscopist (S.H.P.) who had more than 5 years' experience of ERCPs.

Ampullectomy for making an artificial CDF was performed from the very first in patients with an impacted AV stone, which was definitively defined on endoscopy and/or an image studies (i.e., multidetector computed tomography and/or magnetic resonance cholangiopancreatography). Ampullectomy was also performed in patients with a prominent or hook-nosed AV when bile duct cannulation using conventional methods with a standard catheter or a guide-wire failed.⁷ Ampullectomy was performed using the NK papillotome as mentioned in our previous reports.^{7,8}

After confirming successful bile duct cannulation via CDF in all patients with spontaneous and artificial CDF, the distal PR was cut by downward, upward, or combined incision with the Iso-Tome® depending on the relative ease of accessibility (Fig. 2). For downward incision, the semi-oval or round tip of the Iso-Tome® was placed at the CDF (Figs 3 and 4). The positions

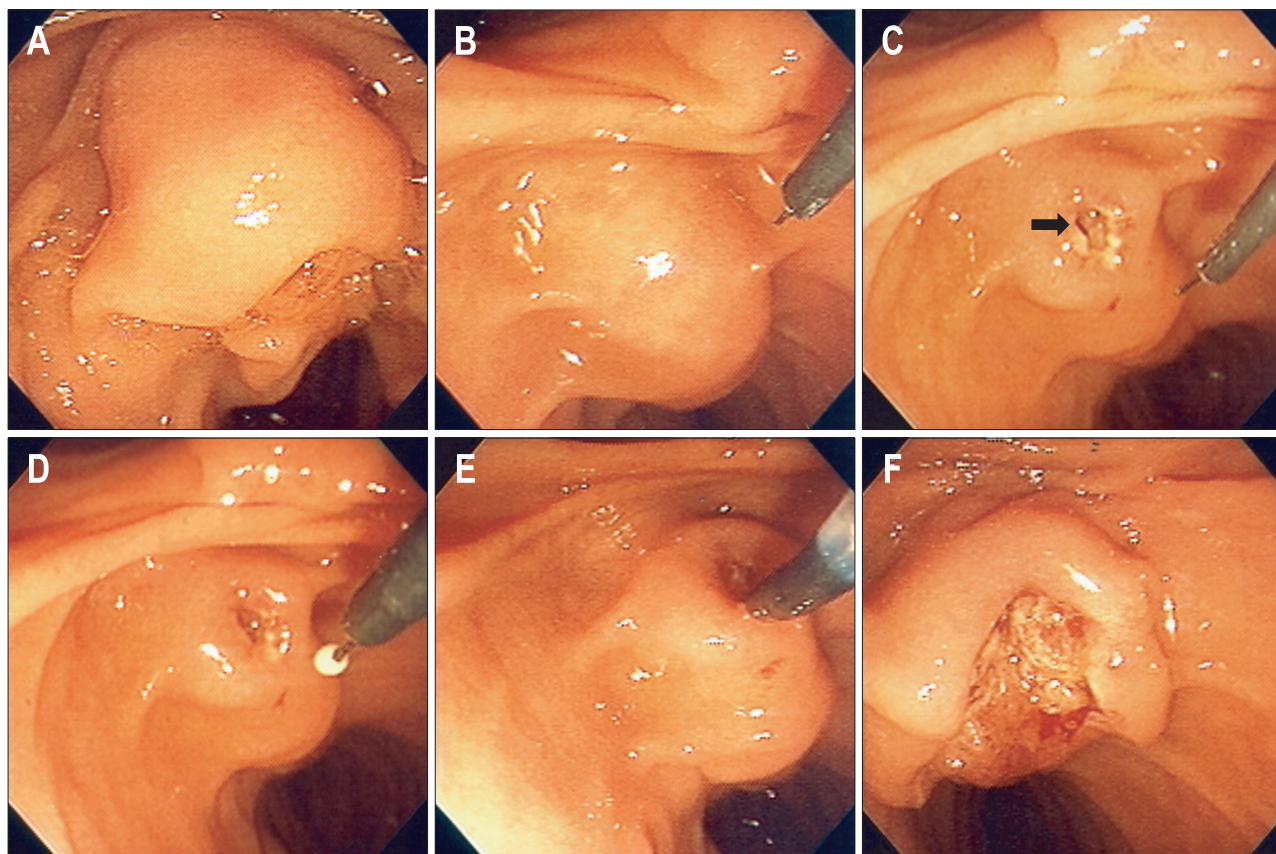


Fig. 3. Case 1 with artificial (needle-knife [NK] ampullectomy) choledochoduodenal fistula and downward incisions using the Iso-Tome® (MTW-Endoskopie W. Haag KG). (A) Duodenoscopy showed a prominent ampulla of Vater (AV) due to an impacted stone. (B) NK papillotome was introduced to perform the ampullectomy. (C) A successful artificial (ampullectomy) choledochoduodenal fistula (CDF, arrow) was created. An impacted stone in a prominent AV was dislodged into the distal common bile duct so that the AV was collapsed during ampullectomy. (D) The Iso-Tome® was advanced to perform the incision on the distal papillary roof (PR). (E) The isolated tip of the Iso-Tome® was placed at the opening of an artificial (ampullectomy) CDF. (F) The distal PR was successfully de-roofed by a downward incision from the opening of the artificial CDF to the orifice of the AV.

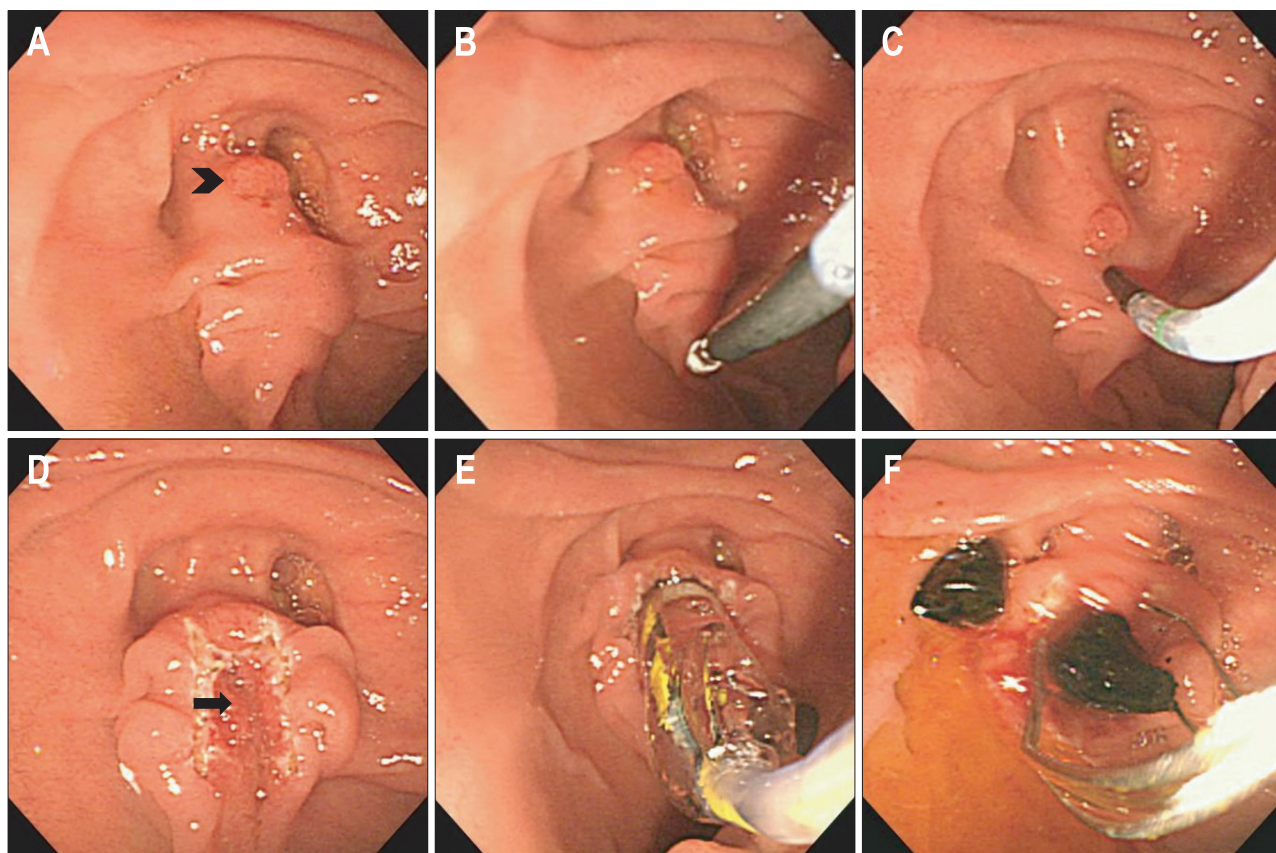


Fig. 4. Case 2 with spontaneous choledochoduodenal fistula (CDF) and downward incision using the Iso-Tome® (MTW-Endoskopie W. Haag KG). (A) Duodenoscopy showed a spontaneous CDF (arrowhead) on a prominent ampulla of Vater (AV) with periampullary diverticulum. (B) The Iso-Tome® was advanced to perform the incision on the distal papillary roof. (C) The isolated tip of the Iso-Tome® was placed at the opening of the spontaneous CDF. (D) After a successful downward incision from the opening of the spontaneous CDF to the orifice of the AV, the pink intrapapillary mucosa (arrow) was exposed without electrical injury. (E) Endoscopic papillary balloon dilation with a Hurricane® (8 mm; Boston Scientific) balloon catheter was performed for 1 minute. (F) Multiple common bile duct stones were removed using a stone basket.

of the Iso-Tome® and the duodenoscope were then adjusted to make the incision correctly. With the application of electric current, an intentional sweep was performed to incise the distal PR downward from the opening of the CDF to the orifice of the AV. An upward incision was made by the same technique as for the downward incision, but the direction of the incision was opposite from the orifice of AV to the opening of CDF (Fig. 5). If the distal PR was not sufficiently opened, the incision was repeated until the pink intrapapillary mucosa (PIPM) was clearly exposed.⁹ If the downward or upward incision alone was not successful in de-roofing the distal PR, incisions were performed in both directions (combined incisions).

3. Management of the proximal PR

The proximal PR was incised using a pull-type papillotome or Iso-Tome® depending on the circumstance. In patients in whom incision with those papillotomes was technically difficult, endoscopic papillary balloon dilatation with an inflated-balloon catheter (CRE®, Hurricane®; Boston Scientific, Natick, MA, USA) was applied. If one method was insufficient or ineffective, mul-

tipple methods were combined. After cutting the proximal PR as fully as possible, choledocholiths were removed by using a biliary stone retrieval basket or an inflated stone-retrieval balloon catheter. Large biliary stones were fragmented by using a mechanical lithotripter (MTW-Endoskopie W. Haag KG, Wiesel, Germany). If choledocholiths was not completely removed on the first session, follow-up ERCP was undertaken 2 to 3 days later.

4. Evaluations

The size and number of choledocholiths were measured and counted on fluoroscopic image, multidetector computed tomography and/or magnetic resonance cholangiopancreatography. The number of incisions to completely cut the distal PR was also counted. After successful incision of the distal PR, the PIPM which is a valuable landmark to guide successful bile duct cannulation⁹⁻¹¹ was carefully evaluated to assess whether there was electrical damage or not. Technical and therapeutic success rates (SR) were evaluated. Technical SR was the rate of successful incision of the distal PR by using the Iso-Tome®, and therapeutic

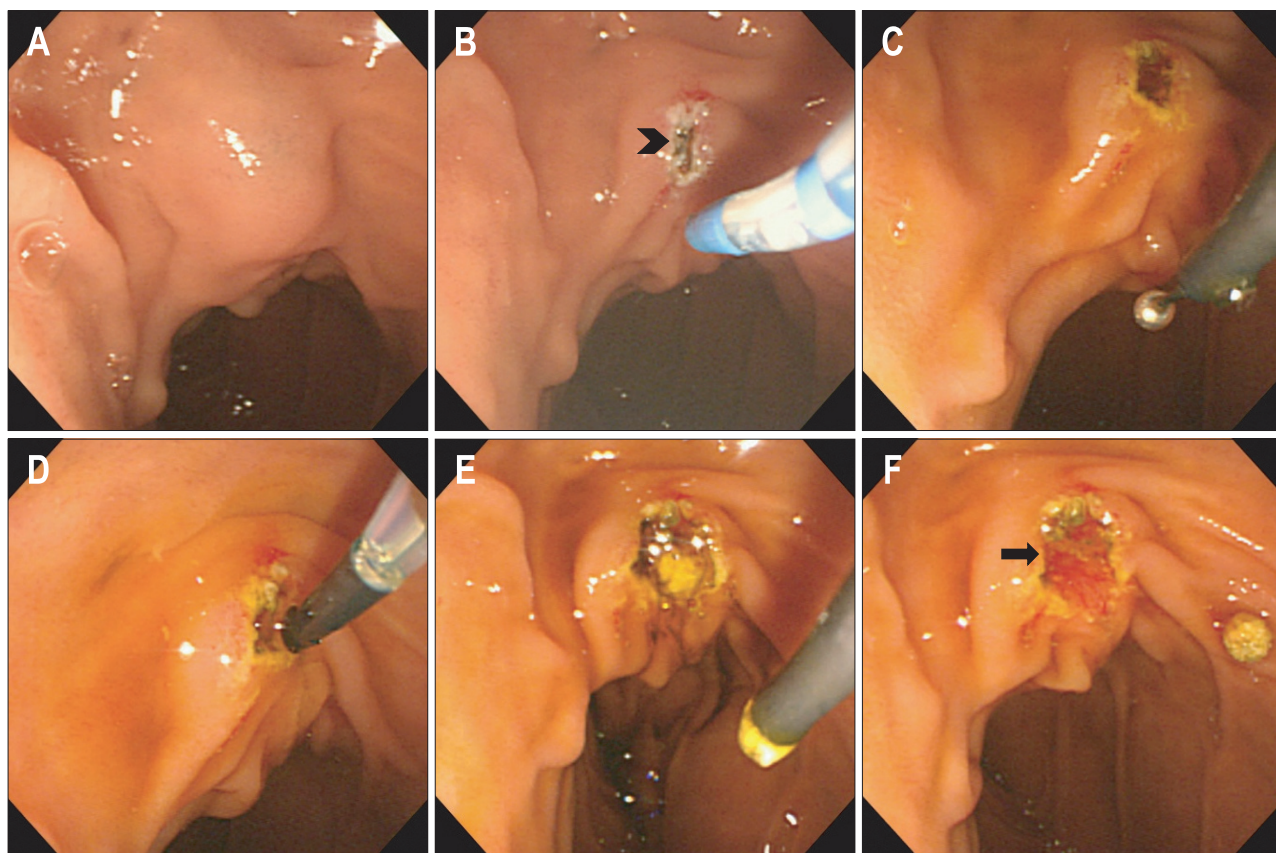


Fig. 5. Case 3 with artificial (ampullofistulotomy) choledochoduodenal fistula (CDF) and an upward incision using the Iso-Tome® (MTW-Endoskopie W. Haag KG). (A) Duodenoscopy showed a prominent ampulla of Vater (AV) suspicious for stone impaction. (B) An artificial (ampullofistulotomy) CDF (arrowhead) was successfully created using the needle-knife papillotome. (C) The Iso-Tome® was introduced to perform the incision of the distal papillary roof (PR). (D) Incision with the Iso-Tome® was made from the orifice of the AV to the opening of the artificial (ampullofistulotomy) CDF. (E) A small and impacted stone was discovered in the AV after the successful de-roofing of the distal PR. (F) After the stone was removed, the pink intrapapillary mucosa (arrow) without electrical damage was revealed.

SR was the rate of successfully removing choledocholiths by using this technique. Post-ES adverse events were assessed according to consensus guidelines.¹²

RESULTS

Thirty-five patients (15 men, 20 women) with a median age of 72 years (range, 27 to 92 years) met the inclusion criteria (Table 1). Indications for ERCP were choledocholiths in 19 and impacted stone in the AV in 16. The median size and number of biliary stones was 1.2 cm (range, 0.6 to 2.6 cm) and 1.0 (range, 1 to 5), respectively. The type of CDF was spontaneous in four and artificial (ampullofistulotomy) in 31.

The directions of incisions were downward in 27, upward in three, and combined in five (Table 2). Proximal PR were managed by using the pull-type papillotome in 22, Iso-Tome® in four, endoscopic papillary balloon dilatation in seven, and combined in two. The technical SR was 94.3% (33/35). The median number of incisions required for complete cutting of the distal PR was 1.2 (range, 1 to 4), and a single incision only was suf-

Table 1. Baseline Characteristics

Characteristic	Value
No. of patients	35
Sex, male/female	15/20
Age, yr	72 (27-92)
Indications for ERCP	
CBD stones	19
Impacted stones in AV	16
Stone size, cm	1.2 (0.6-2.6)
No. of stones	1.0 (1-5)
Type of CDF	
Spontaneous	4
Artificial (needle-knife ampullofistulotomy)	31

Data are presented as median (range) or number. ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct; AV, ampulla of Vater; CDF, choledochoduodenal fistula.

Table 2. Outcomes

Outcome	Value
Direction of incision, no.	
Downward	27
Upward	3
Combined	5
No. of incisions, median (range)	1.2 (1–4)
Only one, % (no./total no.)	74.3 (26/35)
PIPM damage, %	0
SR, % (no./total no.)	
Technical SR*	94.3 (33/35)
Therapeutic SR [†]	94.3 (33/35)
Adverse events, % (no./total no.)	
Bleeding	2.9 (1/35) [‡]
Pancreatitis	0
Perforation	0

PIPM, pink intrapapillary mucosa; SR, success rate.

*Success rate of performing the incision; [†]Success rate of removing choledocholiths; [‡]Mild bleeding.

ficient in 74.3% (26/35) of patients. There was no case of electrical damage to the exposed PIPM in all 33 patients in whom the distal PR was successfully opened by using the Iso-Tome®. In two patients in whom this technique failed, the distal PR was de-roofed by using the NK papillotome.

Choledocholiths were successfully removed in 32 of 33 patients in whom the distal PR incisions were successful at the first session. Stone extraction failed in one patient with multiple and large choledocholiths, which were completely removed at the second session 2 days later. Thus, the overall therapeutic SR was 94.3% (33/35). Mechanical lithotripsy was performed in 2.9% (1/35) of patients.

Of the 35 patients, adverse events occurred in one (2.9%). One case of mild bleeding developed, which was completely cured by conservative treatment. There was no pancreatitis, perforation, or death.

DISCUSSION

The fundamental purpose of ES in managing choledocholiths is to open the PR safely and to widen the orifice of the AV as fully as possible. Following the introduction of ES by Kawai *et al.*¹³ and Classen and Demling¹⁴ in 1974, various techniques for ES have steadily been developed to obtain better results in spite of the diverse difficulties of the situation. Such advancements in the techniques of ES have been based on the invention of new papillotomes and endoscopic accessories (or devices) such as guide-wires or stents.

The isolated-tip NK papillotome, Iso-Tome®, is one of several papillotomes that have been developed.⁶ The advantages of the

Iso-Tome® are in the prevention of electrical damage by the incision needle of the NK papillotome, the good orientation of the incision by the NK papillotome, and the relative simplicity of placing and retaining it at the orifice of the AV. Several new techniques for ES using the Iso-Tome® have been reported.^{6,9,15,16}

CDF, spontaneous or artificial (ampullofistulotomy), is infrequently encountered during ERCP. Spontaneous CDF mostly occurs due to an impacted biliary stone in the AV, leading to inflammation and necrosis of the PR.⁴ Since spontaneous CDF is accompanied by choledocholiths in most cases, effective ES is necessary to remove choledocholiths perfectly. Artificial CDF is usually formed by ampullofistulotomy, which is a very useful technique for precut papillotomy to enable a better success rate for bile duct cannulation.⁵ Post-ERCP pancreatitis occurs less frequently in ampullofistulotomy because electrical damage to the orifice of the AV is avoidable.^{5,17,18}

To extract choledocholiths effectively, it is important to incise the PR as completely as possible.^{1–3} Mavrogiannis *et al.*¹⁹ reported the efficacy of two different NK precutting techniques, NK precut papillotomy and NK ampullofistulotomy, for the treatment of choledocholiths. The distal PR in the NK ampullofistulotomy group was not de-roofed. The success rate of stone extraction with standard accessories (balloon or Dormia basket) in the NK ampullofistulotomy group (83.33%) was lower, compared to that of the NK precut papillotomy group (97.82%) ($p < 0.05$). In patients with CDF, it is not difficult to incise the proximal PR, but it is occasionally difficult to incise the distal PR. Even though the distal PR of the AV with CDF sometimes remains intact in the management of choledocholiths,²⁰ it is usually opened by using the NK or pull-type papillotome. The NK papillotome, however, carries the risk of causing pancreatitis due to thermal damage to the orifice of the AV. An incision using a pull-type papillotome should be preceded by successful bile duct cannulation via the orifice of the AV. Ampullofistulotomy, however, is usually carried out in the case of failed bile duct cannulation via the orifice of the AV as done in the majority of cases in this study.

In this study, the technical and therapeutic SR were 94.3% (33/35) and 94.3% (33/35), respectively. It means that a new technique using the Iso-Tome® is effective in incising the distal PR. Unfortunately it is not available to compare our results with other papillotomes such as the NK or pull-type papillotome because there are no reference data using those papillotomes.

There were two cases of failure with a large and impacted AV stone, even though artificial CDF was created successfully. In these cases, a large stone was so tightly impacted in the AV that it was hard to manipulate the Iso-Tome® properly for performing incisions on the distal PR. In these patients the distal PR was de-roofed by using NK papillotome, and choledocholiths were completely removed.

The median number of incisions made using the Iso-Tome® was as little as 1.2 (range, 1 to 4), and successful incision was

possible with only a single incision in 74.3% (26/35). It is also difficult to compare the number of successful incision needed with other papillotomes, the NK or pull-type papillotome, because of the lack of reference data. Of the 33 patients in whom the distal PR incision was successful, no patient had electrical damage to the PIPM. This means that the isolated-tip of the Iso-Tome® protects the PIPM of the AV from electrical damage.

Impacted stones in the AV were present in 45.7% (16/35) of the patients. The NK papillotome is convenient to incise the distal PR if a stone in the AV is impacted tightly and is not too small, as in some cases in this study. An impacted stone in the AV protects the orifice and the PIPM of the AV from electrical damage. Occasionally, however, an AV stone as in case 1 was not too tightly impacted; therefore, the AV stone was dislodged into the distal CBD during or after ampulofistulotomy using the NK papillotome. The prominent PR of the AV then was suddenly collapsed and the NK incision on the distal PR became difficult and increased the possibility of electrical damage to the orifice or the PIPM of the AV. When the impacted stone in the AV is relatively small, there is only a suspicion of stone impaction in the AV as in case 3. In this case the NK papillotome is more likely to cause electrical injury to the orifice or the PIPM of the AV because there is no protection offered by the impacted stone. In this study, ES with the Iso-Tome® was safe and effective in those patients like case 1 and 3.

Choleliths were completely removed in all 33 patients in whom the distal PR incision with the Iso-Tome® was successful; one session was enough in 32 patients and two sessions were needed in one patient with multiple and large choleliths. Thus the overall therapeutic SR of this technique was 94.3% (33/35), which is comparable to other reports.^{19,21,22}

Adverse events occurred in 2.9% (1/35) of patients, which is also comparable to other reports.² One case had mild bleeding, which was well managed by conservative treatment. There was no case of pancreatitis, perforation, or death. Pancreatitis, which is the most serious adverse event in precut papillotomy,^{5,17,18} did not develop. These results may have occurred for the following reasons. First, ampulofistulotomy was done from the beginning without any trial of bile duct cannulation attempt via the orifice of the AV in 45.7% (16/35) of patients with an impacted AV stone in this study. The early precut implementation reduced post-ERCP pancreatitis.²³ Second, ampulofistulotomy with the NK papillotome was performed at the PR remote from the orifice of the AV so that there was the avoidance of electrical and thermal injury on the orifice of the AV. Third, the exposed PIPM was intact in all patients. Therefore it was presumed that the isolated-tip of the Iso-Tome® prevented electric damage to the orifice and the PIPM of the AV. Finally, the median number of incisions required for completely incising the distal PR was as little as 1.2 (range, 1 to 4), and a single incision was sufficient in 74.3% (26/35) of patients. Physical and electrical trauma to the orifice and the PIPM of the AV was relatively minor.

In conclusion, the new technique of ES, downward or/and upward sphincterotomy with the Iso-Tome®, is feasible and useful for effectively incising the distal PR in patients with choleliths and spontaneous or artificial (ampulofistulotomy) CDF. Further prospective studies with a larger number of cases or comparative studies with other papillotomes, especially the NK papillotome, are needed to clarify the indications for this new technique of ES in detail.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

ACKNOWLEDGEMENTS

We deeply appreciate Ms. Hye-Ok Lee who draws informative illustrations, Figs 1 and 2.

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