

## Feasibility of the Mucosa-Tracking Technique in Precut Papillotomy with the Iso-Tome as an Alternative to the Needle-Knife Technique

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**Background/Aims:** The aim of this study was to evaluate whether the mucosa-tracking technique is effective for improving precutting-related pancreatitis and the sustained failure of bile duct cannulation in precut papillotomy (PP) with the Iso-Tome (MTW Endoskopie). **Methods:** From September 2004 to June 2006, PP was performed with the Iso-Tome if biliary cannulation failed by conventional methods for approximately 5 minutes. The pink intrapapillary mucosa (PIPM) exposed by PP was tracked and classified into four groups: fully exposed and oriented to the direction of the bile duct (group A) or the pancreatic duct (group B), partially exposed (group C), or unexposed (group D). The success rate of bile duct cannulation (SRBC), the procedure time required for successful bile duct cannulation (PTBC), and the complications in the first session were compared between the mucosa-exposed groups (MEGs; group A, B, and C) and the mucosa-unexposed group (MUEG; group D). **Results:** A total of 59 patients (25 females, 34 males) with a mean age of 65.2 years were enrolled. The MEGs and MUEG comprised 52 (88.1%) and 7 (11.9%) patients, respectively. SRBC in the first session was 86.4% (51/59) in total and 92.3% (48/52) in the MEGs, compared to only 42.9% (3/7) in the MUEG ( $p=0.005$ ). The mean PTBC in the MEGs and MUEG was 8.7 minutes and 16.3 minutes, respectively ( $p=0.23$ ). Complications occurred in 6.8% of the patients (4/59; all pancreatitis); there were no differences between the MEGs (5.8%, 3/52) and MUEG (14.3%, 1/7;  $p=0.41$ ). All four patients with pancreatitis were managed medically. **Conclusions:** The mucosa-tracking technique in PP with the Iso-Tome is a feasible and

useful method of enhancing SRBC. PIPM is an important endoscopic landmark for successful PP. (*Gut Liver* 2010;4:76-83)

**Key Words:** Precut papillotomy; Iso-Tome; Mucosa-tracking technique; Pink intrapapillary mucosa

### INTRODUCTION

Precut papillotomy (PP) is a useful technique for enhancing bile duct cannulation when conventional methods using a standard catheter or guide-wire failed. PP is also a crucial step for an endoscopist in becoming an expert in performing an ERCP. Although PP is such a valuable technique, there are two primary obstacles to overcome. First is the risk of precutting-related pancreatitis, and second is the sustained failure of bile duct cannulation even after PP.<sup>1-3</sup>

Post-precutting pancreatitis rates vary from 3% to 35%.<sup>1,3,4</sup> It is strongly recommended that PP should only be done under the supervision of experts due to the risk of developing pancreatitis.<sup>5</sup> Post-precutting pancreatitis is related to multiple unsuccessful and unintended attempts at cannulation, as well as electric trauma on the ampulla of Vater (AV). This leads to papillary edema and eventually to pancreatic duct obstruction.<sup>6-9</sup>

Bile duct cannulation is still unsuccessful in 5% to 10% of patients who have undergone PP, even when it was performed by experts.<sup>1,2</sup> An edematous and shaggy AV, which is induced by precutting, may be related to unsuccessful bile duct cannulation because re-attempts at

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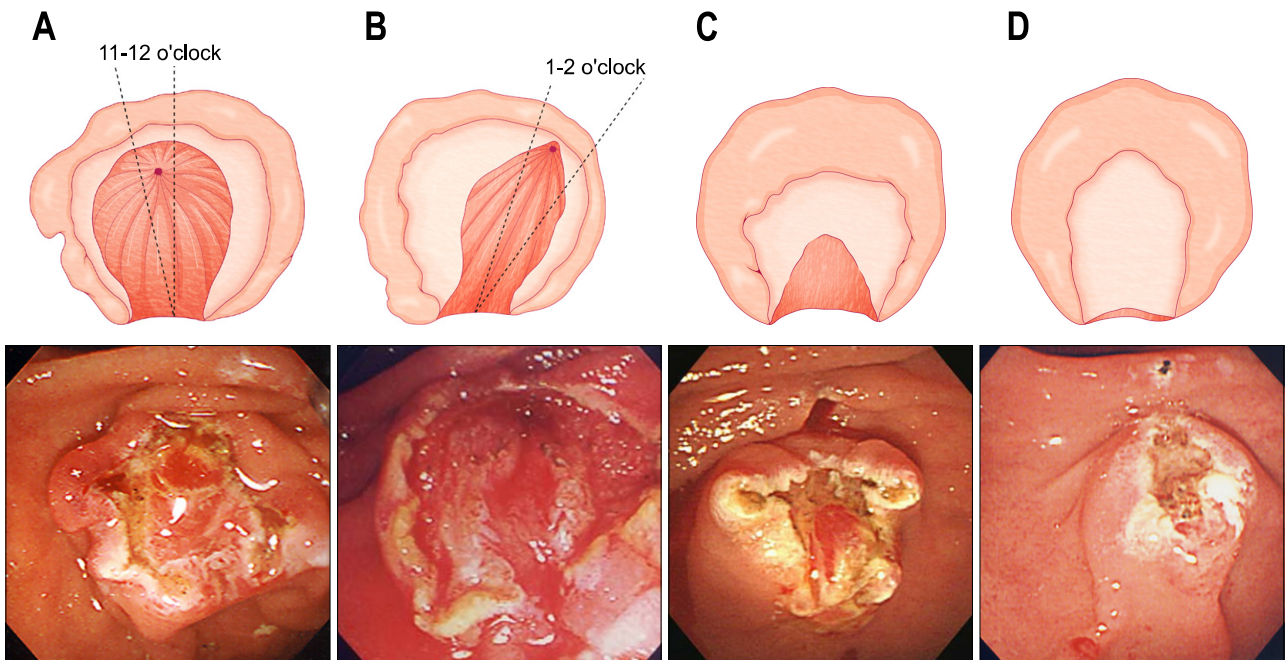
cannulating a bile duct several days later increases the success rate in about 10% to 20% of patients.<sup>1,2,10</sup>

The pink intrapapillary mucosa (PIPM) of the AV, which consists of the mucosa of the common channel, the bile duct, and the pancreatic duct, has been suggested as a guide for successful bile duct cannulation.<sup>1,2,11</sup> We hypothesized that blind cannulation, or unintended manipulation of the AV leading to papillary edema, would decrease if the bile duct cannulation is guided by the PIPM, which is exposed after precutting. Therefore, the PIPM may be a key factor in ensuring a successful bile duct cannulation and in reducing the risk of post-PP pancreatitis.

The mucosa-tracking technique (MTT) is a technical skill applied to cautiously track the PIPM exposed by precutting. PP with Iso-Tome (MTW Endoskopie, Wesel, Germany), an isolated-tip needle-knife papillotome, resulted in a bile duct cannulation rate of 92% (23/25), and a 20% (5/25) rate of post-procedure pancreatitis, which was relatively high based on previous reports.<sup>12</sup> MTT was originally devised as a new technique that could be helpful for improving the previous results of PP with Iso-Tome with regards to bile duct cannulation and the risk of post-precutting pancreatitis. This study was performed to evaluate whether MTT is clinically useful for overcoming these two obstacles in PP with Iso-Tome.

## MATERIALS AND METHODS

From September 2004 to June 2006, ERCPs for this study were performed by a single endoscopist (Park SH) in 375 consecutive patients with pancreatic or biliary tract disease. All patients underwent an ERCP with duodenoscopy (TJF-240; Olympus Optical Co. Ltd., Tokyo, Japan) while in the left lateral decubitus or prone position after sedation with intravenous midazolam (0.05 mg/kg) and/or propofol (0.5 mg/kg). Before precutting, there were less than 5 unsuccessful attempts of selective biliary cannulation with the free and guidewire technique for approximately five minutes. PP, which was performed using the Iso-Tome in a blended current with an electrosurgical unit (UES-30 generator; Olympus Optical Co. Ltd.), was started from the orifice of the AV, as described in a previous report.<sup>12</sup> Patients were excluded if they had an impacted stone in the AV, severe bowel movement, coagulopathy, AV cancer, Billroth II gastrectomy, or a perampullary diverticulum with intra-diverticular papilla or a papilla at the edge of a diverticulum. Medical records and video tapes of the procedures were retrospectively reviewed in all cases. This retrospective study was approved by the ethics committee of our hospital.



**Fig. 1.** The degree of pink intrapapillary mucosa (PIPM) exposure by precut papillotomy with the Iso-Tome was used to divide the patients into four groups. (A) Group A; fully exposed PIPM, oriented toward the bile duct. (B) Group B; fully exposed PIPM, oriented toward the pancreatic duct. (C) Group C; partially exposed PIPM. (D) Group D; unexposed PIPM.

## 1. Mucosa-Tracking Technique (MTT)

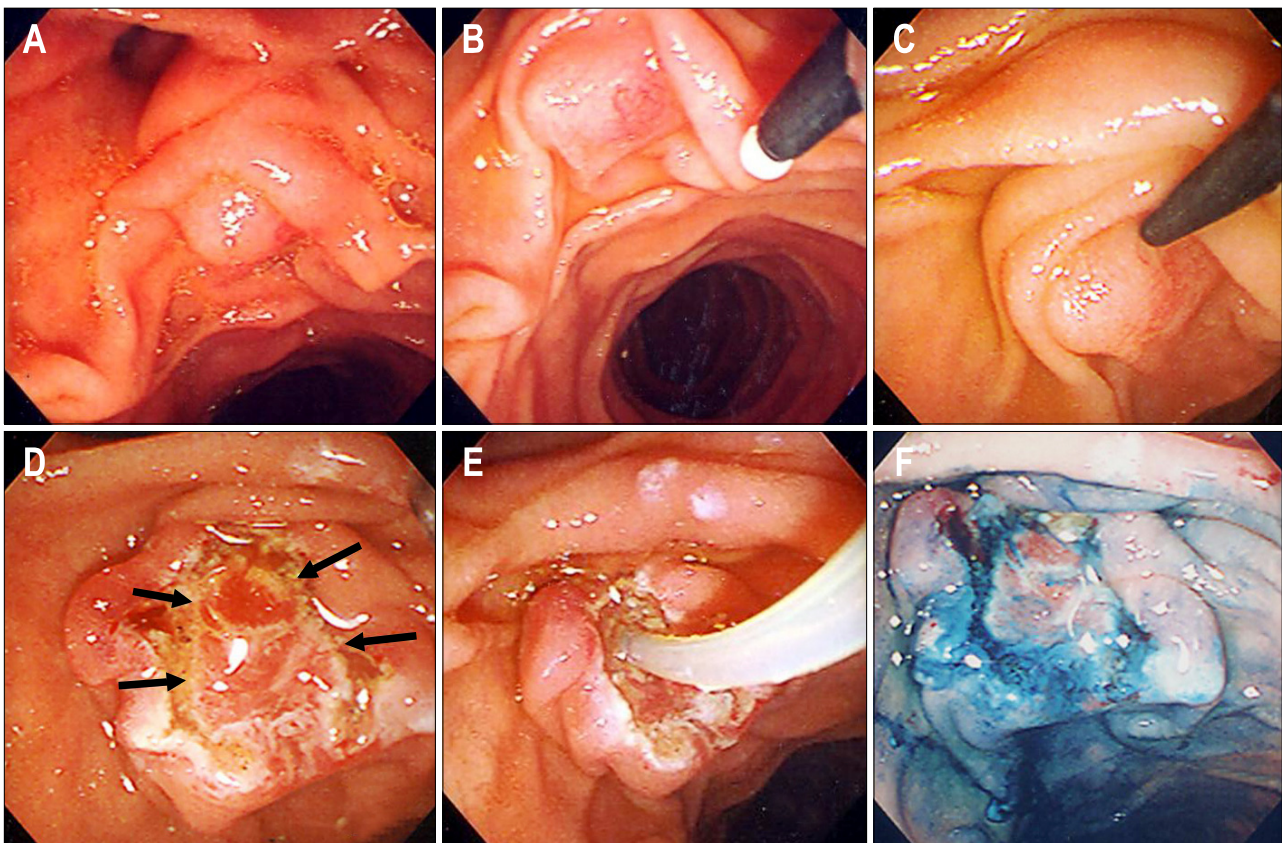
### 1) Theoretical backgrounds of MTT

MTT was designed on the basis of the anatomy of the AV, the advantages of the Iso-Tome, and the technical tips of ERCP. Anatomically, the bile and pancreatic ducts are along the direction of 11-12 and 1-2 o'clock, respectively. In the majority of cases, the bile and pancreatic ducts drain into the duodenum through the same opening of the AV.<sup>13</sup> Therefore, when the initial incision exposes the PIPM, which is orientated toward the bile or pancreatic duct, the orifice of the other duct is usually located on the mid or lower portion of the exposed PIPM. Iso-Tome, which is available in Europe, Russia, and South Korea, has an isolated-tip that prevents electric discharge from the tip of the incising needle. This allows the PIPM in contact with the isolated-tip of Iso-Tome to be well preserved without electric damage during PP, starting

from the orifice of the AV.<sup>12</sup> This PIPM has a good color contrast with the whitish or brown color of the submucosa, which is induced by the electric damage of PP. Therefore, it is easy to clearly demarcate the PIPM from the whitish or brown submucosa using the endoscope. Endoscopic air deflation creates artificial bulging at the AV along the direction of 11-12 o'clock. This indicates the intramural segment of the bile duct.<sup>14,15</sup>

### 2) Technical practice of MTT

The most important step in MTT is to delineate the PIPM. After precutting with the Iso-Tome from the orifice of the AV, it is necessary to wait until the PIPM was sufficiently exposed and distinctly identifiable. The exposed PIPM was then carefully tracked and classified into four groups according to the grade and orientation of exposure. Fully exposed PIPM that was oriented in the direction of the bile duct was categorized as group A (Fig. 1A). Fully exposed PIPM oriented in the direction of the



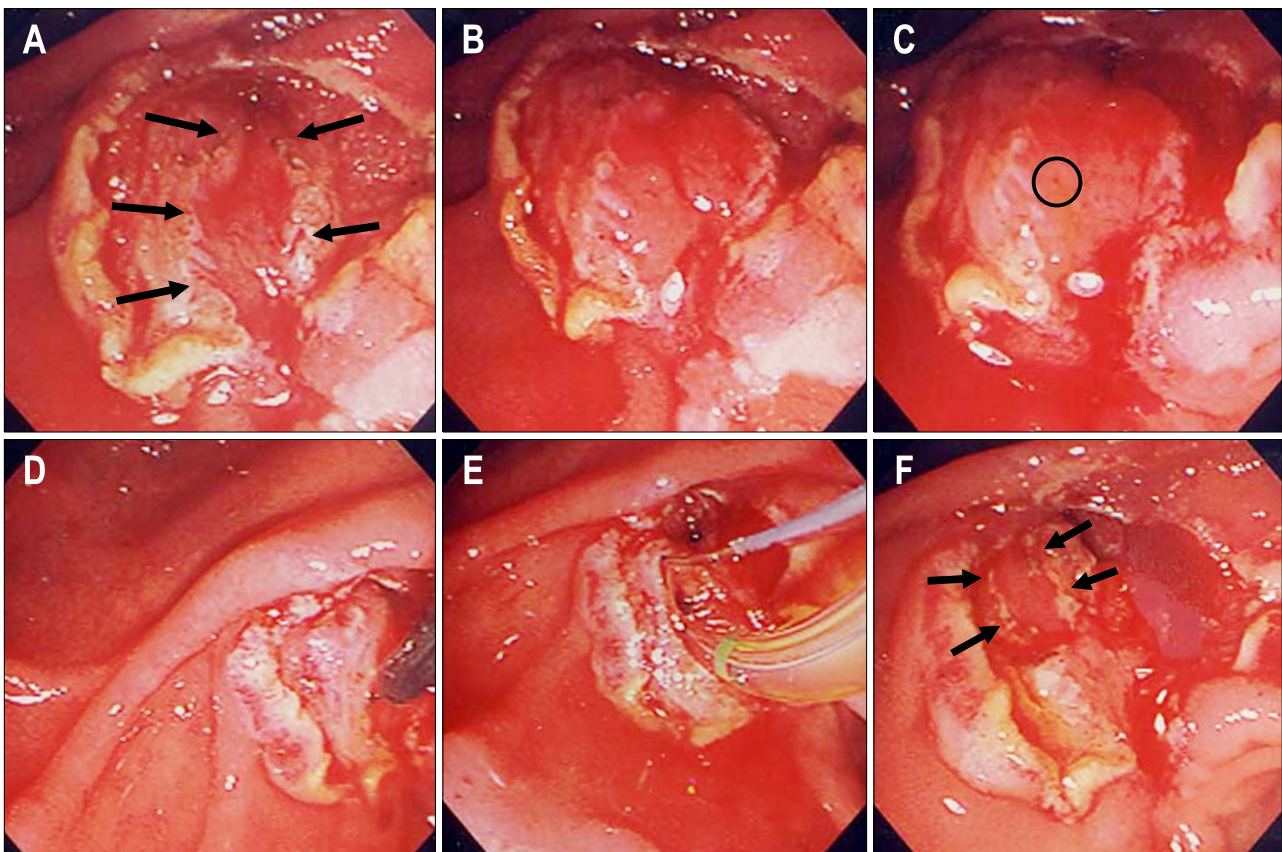
**Fig. 2.** Endoscopic findings of the mucosa-tracking technique in precut papillotomy (PP) with the Iso-Tome in group A. (A) Duodenoscopy showed a prominent ampulla of Vater (AV) with a periampullary diverticulum. (B) The Iso-Tome was introduced to perform PP. (C) The isolated-tip of the Iso-Tome was placed at the orifice of the AV. (D) After precutting with the Iso-Tome, the pink intrapapillary mucosa (PIPM, arrows) was fully exposed and orientated in the direction of the bile duct, at 11-12 o'clock. (E) Bile duct cannulation with the Iso-Tome was achieved successfully. (F) Spraying with methylene blue increased the visibility of the PIPM of the bile duct.

pancreatic duct was put in group B (Fig. 1B). Partially exposed PIPM was put in group C (Fig. 1C). If PIPM was not exposed, it was put in group D (Fig. 1D).

For patients in group A, it was very easy to find the presumed orifice of the bile duct on the fully exposed PIPM. Bile duct cannulation with the Iso-Tome or a standard catheter was intentionally attempted at that orifice (Fig. 2). After successful bile duct cannulation, methylene blue was tentatively sprayed on the AV to identify the PIPM more visibly in 2 or 3 cases in group A in an early stage of this study. When the exposed PIPM was proven to be oriented toward the pancreatic duct in patients in group B, the orifice of the bile duct was located using the following technique (Fig. 3). Duodenal luminal air was deflated by endoscopic suction to create a protrusion on the orientation of 11-12 o'clock. The crossing area between the exposed PIPM of the pancreatic duct

and the mid or lower portion of an artificial bulge produced by endoscopic air deflation was closely inspected for several minutes. It was then found that bile was secreted from a small orifice in that area. This indicated the opening of the bile duct. The isolated-tip of the Iso-Tome was placed at that orifice and a further incision was added toward the 11-12 o'clock direction of the bile duct. As bile duct cannulation with the Iso-Tome or a cannulating catheter was successful, a further incision with a pull-type papillotome was made to fully expose the PIPM of the bile duct.

For patients in groups C and D, a needle knife papillotome was used to make a supplementary incision, if necessary. When bile duct cannulation was successfully achieved, the incision was extended with a pull-type papillotome in the majority of cases. If the first session did not succeed in selectively cannulating the bile duct, a sec-



**Fig. 3.** Endoscopic findings of the mucosa-tracking technique in precut papillotomy with the Iso-Tome in group B. (A) After precutting with the Iso-Tome, the pink intrapapillary mucosa (PIPIM, arrows) was fully exposed and orientated in the direction of the pancreatic duct, at 1 o'clock. (B) An artificial bulge indicating the intramural segment of the bile duct was created by endoscopic air deflation in the orientation of 11-12 o'clock. (C) A small opening (circle) was observed on the crossing area between the lower portion of the exposed PIPIM and the artificial bulge identified by endoscopic air deflation. (D) The isolated-tip of the Iso-Tome was placed at the small opening that was presumed to be the orifice of the bile duct. A further incision was added toward the 11-12 o'clock direction of the bile duct. (E) Successful bile-duct cannulation was followed by an additional incision with a pull-type papillotome. (F) PIPIM of the bile duct (arrows) was clearly identified.

ond session was done two or three days later. All PP were performed without placing a protective pancreatic stent.

Success rates of bile duct cannulation (SRBC), procedure time (in minutes) required for successful bile duct cannulation from placing the Iso-Tome at the orifice of the AV (PTBC), and post-procedure complications in the first session were compared between the mucosa-exposed group (MEG; group A, B, and C) and the mucosa-unexposed group (MUEG; group D). Post-procedure complications were classified according to a consensus guideline.<sup>6</sup>

### 3) Statistical analysis

Statistical analysis was performed using SPSS 12.0 (SPSS Inc., Chicago, IL, USA). A two-tailed p value of less than 0.05 was considered statistically significant. Univariate analyses were performed using Student's t-test or Fisher's exact test.

## RESULTS

Fifty-nine of the 375 patients (15.7%; 25 females, 34 males) with a mean age of 65.2 years (range, 27-93 years) met the inclusion criteria. Characteristics of the patients in the four groups are shown in Table 1. There were 52 (88.1%) patients in the MEG, and 7 (11.9%) in MUEG. There are no statistically significant differences in

gender and age between the MEG and the MUEG. Because of the number of patients, it is difficult to compare the indications of PP between the MEG and the MUEG.

After PP using the Iso-Tome, the SRBC in the first session totaled 86.4% (51/59). The SRBC for the first session in the MEG was 92.3% (48/52), significantly higher than 42.9% (3/7) in the MUEG ( $p=0.005$ ) (Table 2). Interestingly, in the groups of fully exposed PIPM, group A and B, SRBCs were 96.6% (28/29) and 100% (4/4), respectively.

Two or three days later, the second session of bile duct cannulation was done successfully in 7 of the 8 patients (87.5%) in whom it failed in the first session. Bile duct cannulation failed in one case of group A in the MEG due to a severe benign stricture of the distal common bile duct. This was ultimately managed surgically. The final SRBC was 98.3% (58/59) of the patients.

The mean PTBC was 8.7 minutes in the MEG, which was similar to 16.3 minutes in the MUEG ( $p=0.23$ ) (Table 2). The mean PTBC in group A was 4.3 minutes, the shortest among the four groups. Noticeably bile duct cannulation was successful in all cases in group B even though the mean PTBC was 23.9 minutes, the longest among the four groups.

Of the 59 patients, complications occurred in 4 (6.8%; 3 mild pancreatitis, 1 moderate pancreatitis). The compli-

Table 1. Patients' Characteristics

	Mucosa-exposed group (n=52)			Mucosa-unexposed group (n=7)	p-value
	Group A (n=29)	Group B (n=4)	Group C (n=19)	Group D (n=7)	
Female/Male		20/32		5/2	0.12
	8/21	3/1	9/10	5/2	
Age, y (SD)	63.5 (16.2)	65.5	67.8 (12.1)	62.4 (14.8)	0.6
Diseases. (59)					
CBD stone (35)	18	31	12	4	0.776
Malignancy (11)	4	11	4	0	0.328
Pancreatitis (6; 4 acute, 2 chronic)	4	5	1*	1*	0.548
SOD (3)	1	2	1	1	0.320
Pancreas divisum (2)	0	1	1	1	0.225
Benign biliary stricture (1)	0	0	1	1	1.000
Mirizzi's syndrome (1)	1	0	0	0	1.000
	1	0	0	0	

SD, standard deviation; SOD, sphincter of Oddi dysfunction.

\*Chronic pancreatitis.

**Table 2.** Comparisons of Success Rate of Bile Duct Cannulation (SRBC), Procedure Time Required for Successful Bile Duct Cannulation (PTBC), and Complications in the First Session between the Mucosa-exposed Group (Group A, B, and C) and the Mucosa-unexposed Group (Group D)

	Mucosa-exposed group (n=52)			Mucosa-unexposed group (n=7)	p-value
	Group A (n=29)	Group B (n=4)	Group C (n=19)	Group D (n=7)	
SRBC (%)	96.6% (28/29)	92.3% (48/52)	84.2% (16/19)	42.9% (3/7)	0.005
PTBC, min (mean±SD)	4.3±2.8	8.7±10.3	12.4±13.6	16.3±14.4	0.23
Complications (%)	0%	5.8% (3/52)	10.5% (2/19) <sup>†</sup>	14.3% (1/7) <sup>‡</sup>	0.41

SD, standard deviation.

\*1 moderate pancreatitis; <sup>‡</sup>2 mild pancreatitis; <sup>†</sup>1 mild pancreatitis.

cation rate was 5.8% (3/52; 2 mild pancreatitis, 1 moderate pancreatitis) in the MEG, comparable to 14.3% (1/7; 1 mild pancreatitis) in the MEUG (p=0.41) (Table 2). All 4 patients with complications were successfully managed with medical treatments. There were no cases of bleeding, perforation, or death.

Bile duct stones were successfully removed using a stone basket in 35 patients with CBD stones. Mechanical lithotripsy was used in three patients. ERBD with a plastic or self expandable metallic stent was also performed in 1 of 2 (50%) patients with chronic pancreatitis, and in 9 of 11 (81.8%) patients with a pancreaticobiliary malignancy.

## DISCUSSION

Several techniques for PP had been introduced to reduce or prevent the precutting-related pancreatitis and to enhance the SRBC. These techniques include early institution of PP, pancreatic duct stenting, fistulotomy (infundibulotomy), and retrieval one to three days later.<sup>1,2,16-19</sup> The endoscopically visible papillary roof or an artificial bulge created by inflated-balloon-pulling technique are endoscopic landmarks which guarantee safe and effective endoscopic biliary sphincterotomy.<sup>15,20</sup> PP can also be made safer and more effective if endoscopic landmark is suggested. Several reports have noted that bile, or the PIPM which is exposed by PP, can be used as a guide for successful bile duct cannulation.<sup>1,2,11,21</sup>

There are two points to be emphasized for conducting an effective PP. The first is to avoid unintentional and unsuccessful attempts at cannulation which leads to papillary edema and pancreatic duct obstruction, eventually followed by pancreatitis. The second consideration is to precisely delineate the PIPM in order to improve the

SRBC. The more important of these two factors is delineating the PIPM. Failed attempts at cannulation will decrease if bile duct cannulation is selectively guided by, and precisely focused on, the exposed PIPM.

MTT was originally designed on the basis of previous reports in purpose to enhance the SRBC and to reduce the risk of procedure-related pancreatitis.<sup>12</sup> The SRBC for the first and second session were 86.4% (51/59) and 98.3% (58/59), respectively. This is comparable with the rates of 65% and 99% seen in other reports.<sup>1,2,10,11,16</sup> The SRBC for the first session in the MEG was 92.3% (48/52), significantly higher than 42.9% (3/7) in the MUEG (p=0.005). Interestingly in the groups of fully exposed PIPM, group A and B, the SRBC was very successful in nearly all (97%, 32/33) of the cases.

It is significant that bile duct cannulation was successfully achieved in all four cases in group B, although the initial incision was improperly orientated toward the pancreatic duct and the PTBC is the longest among the four groups. This means that the PIPM is very helpful for guiding a successful bile duct cannulation. It is recommended that the PIPM would be exposed as fully as possible in order to maximize the chances of a successful PP. There is an increase in the SRBC for the second session of about 12%. This is comparable to other reports.<sup>1,2,10</sup>

The mean PTBC of MEG was 8.7 minutes, similar to 16.3 minutes of MUEG (p=0.23). This may be because of group B, in which the mean PTBC is the longest among the four groups. Group A had the shortest mean PTBC among the four groups because it is very easy to delineate and to target the fully exposed PIPM of the bile duct.

Complications occurred in 6.8% (4/59; 3 mild pancreatitis, 1 moderate pancreatitis) of patients. Protective pancreatic stents were not used as it was in the previous

report.<sup>12</sup> The rate of pancreatitis is relatively low, 6.8%, even with the blended current, compared with the rate of 20% (5/20) with only the cutting current as seen in a previous report.<sup>12,22</sup> This may be related to the early use of precutting, which was done within five minutes in this study, compared with 20 minutes in the previous report.<sup>2,12</sup> There was less than 5 unsuccessful attempts of bile duct cannulation in this study, compared to over 10 unsuccessful attempts in the previous study.<sup>12</sup> Additionally, there was an intentional effort to reduce blind attempts at cannulation after PP.

There were no statistical differences in the rates of post-procedure pancreatitis between the MEG, 5.8% (3/52), and the MUEG, 14.3% (1/7) ( $p=0.41$ ). However, this result is contrary to what we expected. Further studies are needed to evaluate whether this result is related to the low volume of cases or caused by other factors. It is interesting to note that group A had the shortest mean PTBC, 4.3 minutes, and the lowest complication rate, 0%. This is important because the PIPM was fully exposed and directed toward the bile duct in group A. This result correlates with what Sriram *et al.*<sup>2</sup> asserted: the crucial step in precutting is to achieve a clean cut on the appropriate plane in the least number of attempts.

In this study, the PIPM is presumed to be an important endoscopic landmark that is helpful in guiding a successful bile duct cannulation in PP, as suggested in other reports.<sup>1,2,11</sup> Unsuccessful attempts at cannulation and blind incisions during PP, which are related to complications and failure of bile duct cannulation, could be avoided if the PIPM is fully exposed and the basic concept of MTT is completely understood.<sup>1,6-9</sup> In addition, the PIPM should be preserved as much as possible and protected from a shaggy incision.<sup>2</sup> The Iso-Tome appears to be useful for this. Other devices, such as the Erlangen-type or short-nosed pull-type papillotome, could also be helpful.<sup>2,11</sup>

There were 32.2% (19/59) of group C, the partially exposed PIPM group, and 11.8% (7/59) of group D, the unexposed PIPM group. Several factors contributed to these results. In some of the patients, the AV itself was so redundant and unfixated that it was displaced toward the duodenal wall when an incision with the Iso-Tome was attempted. The transverse duodenal mucosal fold just above the AV was overhanging so much so in some cases that the extent of the incision was restricted to avoid electric contact damage to the transverse duodenal mucosal fold. The semi-oval-shaped tip of Iso-Tome was not adjustable for some patients who had a small orifice of the AV. This tip was recently changed to a round shape, which is more adjustable to various size orifices of the

AV and is now being tested.

In conclusion, MTT is a feasible and useful technique for enhancing bile duct cannulation in PP with the Iso-Tome. The PIPM is a useful endoscopic landmark helpful in guiding a successful bile duct cannulation. When PP with Iso-Tome or other papillotomes is performed, it is suggested that the PIPM would be exposed as fully as possible and then tracked carefully, instead of hastily performing the blind incision and unintentional attempts at bile duct cannulation. Further large prospective studies with Iso-Tome or other papillotomes are warranted.

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