

Editorial

# Usefulness of endoscopic papillary balloon dilation for removal of common bile duct stones as compared to endoscopic sphincterotomy

Endoscopic sphincterotomy (EST) is a commonly used technique for retrieval of common bile duct (CBD) stones. The short-term complications of this technique can include bleeding, perforation, pancreatitis, and cholangitis, and were reported to have a 10% occurrence rate in a multicenter study involving 2347 patients.<sup>1</sup> Endoscopic papillary balloon dilation (EPBD) using balloon diameters of 6–10 mm was first reported by Staritz et al<sup>2</sup> as an alternative endoscopic technique for EST. However, the extent to which EPBD is effective and safe for removal of CBD stones remains controversial. In this issue of the *Journal of the Chinese Medical Association*, Tsai et al<sup>3</sup> evaluated the clinical efficacy of EPBD in patients with recurrent CBD stones after previous EST. Accordingly, we have reviewed some of the commonly-discussed issues about EPBD versus EST as they relate to the article.

## 1. EST versus EPBD for removal of CBD stones

Compared with EST, EPBD is a less complicated procedure, and the incidence of complications, such as bleeding and perforation, are decreased, as demonstrated in a meta-analysis including 14 randomized trials and 1975 patients (980 with EPBD and 995 with EST).<sup>4</sup> In addition, the function of the sphincter of Oddi is expected to be better preserved with EPBD than with EST. However, the incidence of pancreatitis was reported to reach 15% in patients undergoing EPBD.<sup>5</sup> A meta-analysis also demonstrated that compared to EST, the incidence of pancreatitis after EPBD significantly increased.<sup>4</sup> Further analysis of the data, as shown in studies involving Western and Asian patients, indicated that EPBD increased the incidence of pancreatitis in Western patients ( $p < 0.0001$ ), but not in Asian patients ( $p = 0.08$ ) as compared to EST. As such, EPBD is not recommended as an alternative to EST for routine use in practice guidelines, although it may be a reasonable option in select circumstances, e.g., coagulopathy, periampullary diverticulum, or surgically altered anatomy that increases the difficulty of EST.<sup>6</sup>

## 2. Is the ballooning time of EPBD associated with pancreatitis risk?

The length of time the balloon is inflated during EPBD is generally around 1 minute (ranging from 10 seconds to 300

seconds) after the intended maximal target diameter of the balloon has been reached.<sup>3,7</sup> Is a high incidence of post-EPBD pancreatitis associated with the ballooning time? A randomized trial comparing 1-minute and 5-minute EPBD (using a 10 mm balloon) for extraction of bile duct stones revealed that successful stone extraction (92.9% vs. 80.2%) was more common and pancreatitis (4.8% vs. 15.1%) was less common in the 5-minute group than in the 1-minute group.<sup>5</sup> The authors postulated that the sphincter of Oddi was loosened to a greater extent from a longer dilation duration/larger balloon or a prior EST, which should allow more volume expansion within the compartment after papillary dilation and thus reduce the risk of pancreatitis. The European Society of Gastrointestinal Endoscopy suggests that EPBD may be advantageous in selected patients and the duration of dilation should be longer than 1 minute.<sup>6</sup> Further studies are warranted to determine the optimal duration of balloon inflation during EPBD.

## 3. Endoscopic papillary large balloon dilation for removal of large CBD stones

In recent years, endoscopic papillary large balloon dilation (EPLBD) using balloon size of 12–20 mm following small EST has been shown to be a useful alternative technique in patients with bile duct stones that were difficult to extract due to large stone size (> 15 mm) or tapering of distal bile duct, while reducing the need for mechanical lithotripsy.<sup>8,9</sup> A meta-analysis including seven randomized controlled trials and 790 patients showed that EPLBD is a safe and effective procedure for retrieval of large CBD stones.<sup>9</sup> First, hemorrhage occurred less frequently with EPLBD than with EST. Additionally, there was no significant difference in post-procedure pancreatitis, perforation, and cholangitis between EPLBD and EST.<sup>10</sup> The rate of pancreatitis after EPLBD generally ranged from 0% to 7%.<sup>3,8,9</sup> The higher pancreatitis rates seen with primary EPBD may be mitigated by the preceding minor EST with EPLBD. Paik et al<sup>8</sup> compared the efficacy and cost-effectiveness of EPLBD and EST for large CBD stone removal. They found that EPLBD is the better treatment because EPLBD requires fewer ERCP sessions and is less expensive. The guideline of the American Society for Gastrointestinal Endoscopy considers EPLBD as a strategy for

managing large bile duct stones. Therefore, EPLBD is recommended in patients with an underlying coagulopathy or need for anticoagulation following ERCP.<sup>9</sup>

#### 4. Is preceding minor EST before EPLBD necessary?

It is presumed that minor EST (up to one-third to one-half the size of the papilla) prior to balloon dilation might decrease the risk of pancreatitis, because preceding EST results in separation of the pancreatic and biliary orifices.<sup>8</sup> EPLBD alone without preceding EST was shown to be simple, safe, and effective in dealing with large CBD stones.<sup>11</sup> A meta-analysis including 2511 procedures of EPLBD with EST from 30 articles and 413 procedures of EPLBD without EST from three studies showed that the initial success rate (84.0% vs. 76.2%,  $p < 0.001$ ) was significantly higher, while the rate of use of mechanical lithotripsy was significantly lower (14.1% vs 21.6%,  $p < 0.001$ ), in EPLBD with EST.<sup>7</sup> There is no difference in the rate of overall adverse events, pancreatitis, bleeding, and perforation between the two groups. They concluded that EPLBD with or even without EST is a safe and effective procedure for the removal of large or difficult CBD stones.

#### 5. Recurrence rate of biliary stones after EPBD/EPLBD or EST

The physiologic and anatomical changes of the sphincter after EPBD are unclear. It is presumed that EPBD could preserve the sphincter function and reduce the occurrence of duodenobiliary reflux and bacteria contamination, thus decreasing the biliary stone recurrence.<sup>10,12</sup> A retrospective study by Kojima et al<sup>12</sup> revealed that the recurrence rate of CBD stones was higher in 233 patients after EST than in 453 patients after EPBD (17.0% vs. 6.8%,  $p < 0.05$ ), and the sphincter of Oddi function was protected in 70% patients after EPBD. A meta-analysis also showed that the stone recurrence rate was significantly reduced in EPBD as compared with that in EST.<sup>4</sup> There were several risk factors for CBD stone recurrence. A dilated CBD results in bile stasis and bacterial infection, which play an essential role in the formation of pigment stones.<sup>13</sup> Three independent risk factors for CBD stone recurrence after EST were identified by Sugiyama et al<sup>14</sup>: (1) interval between initial EST and repeat ERCP  $\leq 5$  years; (2) bile duct diameter  $\geq 15$  mm; and (3) periampullary diverticulum. However, EPLBD was not shown to be superior to EST for the prevention of biliary stone recurrence.<sup>8</sup> It could be thought that mechanical lithotripsy was performed in a high percentage of patients (61%), and the possibility of small remnant stone fragments after mechanical lithotripsy may act as a nidus for recurrent stones. Dilated CBD was the only significant factor associated with recurrent biliary stones after stone removal using EPLBD or EST.<sup>8,11</sup>

#### 6. Efficacy of EPBD or EPLBD without minor EST for the extraction of recurrent CBD stones after previous EST

In this issue of the *Journal of the Chinese Medical Association*, Tsai et al<sup>3</sup> demonstrated that EPBD or EPLBD

without EST is beneficial for patients with recurrent CBD stones after a previously complete EST. They showed that the bile duct clearance rate was 96% and no complications such as pancreatitis, perforation, and bleeding were noted in 23 patients undergoing EPBD or EPLBD. In addition, the rate of second recurrent CBD stones was significantly reduced after EPBD/EPLBD as compared with that without EPBD (17% vs. 60%,  $p < 0.001$ ). In the report of Tsai et al,<sup>3</sup> EST was not used for facilitating stone clearance. The authors presumed that there is no space for another EST in patients with previously complete EST. However, repeated EST for recurrent CBD stones is feasible. Sugiyama et al<sup>14</sup> reported that 49 (58%) of 84 patients with recurrent bile duct stones after EST had no visible evidence of prior sphincterotomy and 69 patients underwent EST. Of the 84 patients, 26 (31%) had bile duct stone recurrence during a follow up period of 2.2–26.0 years (median 10.9 years). Yoon et al<sup>15</sup> reported that EPLBD without repeat EST was effective and safe for the extraction of recurrent difficult bile duct stones after previous EST in 52 patients. The re-recurrence rate of CBD stones after EPLBD was 17.3% during the follow-up period (mean  $27.0 \pm 14.1$  months). However, a large-scale controlled study is warranted to certify the benefit of EPBD or EPLBD without EST for patients with recurrent CBD stones after previous EST or EPBD, especially for those patients with small stones that could be removed without EPBD.

In conclusion, EPBD/EPLBD and EST are options for the removal of CBD stones. The choice should be made utilizing the sound discretion of attending endoscopists and be tailored to factors such as stone size, anatomy of papilla and CBD, and presence of a bleeding diathesis. EPLBD, with or without minor EST, is a safe and effective procedure for the removal of large or difficult CBD stones.

#### Conflicts of interest

The author declares that there are no conflicts of interest related to the subject matter or materials discussed in this article.

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