Optimal dilation time for combined small endoscopic sphincterotomy and balloon dilation for common bile duct stones: A multicentre, single-blinded, randomised controlled trial

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A critical step to successfully perform common biliary duct (CBD) stone extraction is provision of a suitable exit for stone removal by endoscopic sphincterotomy (EST) alone, endoscopic papillary balloon dilation (EPBD) alone, or a combination of both (1,2). EPBD, first introduced in 1982 by Staritz et al., is an alternative to EST that reduces complications such as bleeding and perforation following endoscopic retrograde cholangiopancreatography (ERCP) (3,4). However, use of EPBD alone (using medium-sized balloons; diameter, 6-10 mm) remains unpopular and is not advocated for routine use as it is associated with a lower technical success for stone clearance and a presumed increased risk for post-ERCP pancreatitis, which is the most common complication of this procedure (1,5-6). Combined small EST and balloon dilation (ESBD) has been reported to have similar efficacy in stone extraction as EST while preserving partial function of the sphincter of Oddi. There is a lack of consensus regarding the duration of balloon dilatation (DBD) and success or complications of procedure in all GIS dilatation therapies as in EPBD. The DBD during EPBD may affect the incidence of post-ERCP pancreatitis. However, the optimal dilation time for EPBD to achieve common bile duct stone removal and avoid post-ERCP pancreatitis remains unclear.

A newly published article in Lancet Gastroenterology & Hepatology entitled "Optimal dilation time for combined small endoscopic sphincterotomy and balloon dilation for common bile duct stones: a multicentre, single-blinded, randomised controlled trial" assessed the optimal duration of dilation for combined EST and EPBD for the removal of common bile duct stones (7).

This single-blinded, multicenter randomised controlled trial was performed at 15 tertiary surgical centers in China. Patients who were aged ≥18 years with a native papilla whose CBDs were ≤1, 5 cm in size and who had been scheduled for ERCP were eligible for enrollment. All eligible patients were randomly assigned (1:1:1:1:1) to receive balloon dilation for 0, 30, 60, 180, or 300 s after deep bile duct cannulation. Randomization was performed by an independent statistician using a computer-generated randomization list, stratified by center. Patients and outcome assessors were masked to the treatment allocation. In accordance with this trial procedure, all endoscopists were experienced (>1000 ERCP procedures) and all patients received intravenous conscious sedation and local pharyngeal anesthesia during ERCP. All patients underwent an initial EST (3-5 mm) after successful deep cannulation. A controlled radial expansion dilation balloon of a suitable size was chosen (diameter range, 6-8, 8-10, 10-12, 12-15, or 15-18 mm). The preferred balloon was placed on the partially cut sphincter and then inflated. It was kept inflated for 15 s to enable full expansion and then deflated for the recommended duration (0, 30, 60, 180, or 300 s). Subsequent stones were removed using stone retrieval balloons or baskets. Most adverse events associated with ERCP are detected within 24 h of the procedure. The authors routinely assessed adverse events, including post-ERCP pancreatitis, acute cholangitis, cholecystitis, perforation, and bleeding at 24 and 48 h after the procedure by evaluating symptoms, signs, laboratory test results and performing imaging examinations if necessary. The frequency of post-ERCP pancreatitis was the primary endpoint of this trial. Secondary outcomes included duration of ERCP procedure, length of hospital

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stay, clearance rate of CBDs, success rate of CBD removal on first attempt, proportion of patients who required mechanical lithotripsy, x-ray exposure time, and number of pancreatic duct cannulations. Safety outcomes were post-procedural gastrointestinal bleeding, cholangitis, cholecystitis, perforation, and pain. Patients were contacted at 30 days to assess delayed complications.

From 2015 to 2017, 3721 consecutive patients with CBDs scheduled for EPBD were assessed for eligibility. After screening, 1718 patients were excluded. Following a small (3-5 mm) EST, the remaining 2003 patients were randomly assigned to four groups to receive balloon dilation. However, 83 patients withdrew consent after the ERCP procedure. The remaining 1920 patients were included in the modified ITT analysis (0 s [n=371], 30 s [n=384], 60 s [n=388], 180 s [n=390], and 300 s [n=387]). Baseline characteristics were similar between the five groups.

Of the 1920 patients, 469 (24%) had difficult cannulation (i.e., more than five attempts or >10 min in duration). Stone extraction was successful in >90% of patients with no significant differences between the groups (p=0.43). Overall, post-ERCP pancreatitis occurred in 199 (10%) of 1920 patients (44 [12%] of 371 patients in the 0-s group, 28 [7%] of 384 patients in the 30-s group, 32 [8%] of 388 patients in the 60-s group, 36 [9%] of 390 patients in the 180-s group, and 59 [15%] of 387 patients in the 300-s group). The frequency of post-ERCP pancreatitis in the 30-s, 60-s, and 180-s groups was significantly lower than that in the 300 s group (RR 0.48, 95% CI 0.31-0.73; p=0.0005 in the 30-s group; 0.54, 0.36-0.81; p=0.003 in the 60-s group; 0.61, 0.41-0.89; p=0.01 in the 180-s group). It was found that prolonged dilation (300 s) significantly increased the incidence of post-ERCP pancreatitis compared with shorter durations (p=0.002).

No difference in the success of stone extraction (all ≥90%) was observed between the groups. Following ERCP, 90 (5%) of 1920 patients had acute cholangitis, 14 (<1%) had acute cholecystitis, and 5 (<1%) had gastrointestinal bleeding, with no significant differences between the groups. One (<1%) patient had Stapfer type II perforation, which resolved spontaneously with conservative treatment. There were no significant differences in the median duration of ERCP procedure, X-ray exposure time, and post-ERCP hospital stay. No deaths occurred.

This randomized large patient volume trial showed that a balloon dilation time of 30 s combined with a small EST significantly improved the clinical outcome of ESBD for CBDs. The success rate of common bile duct clearance with dilations of 30 s was high and minimized the risk of post-ERCP pancreatitis. The effect of EPBD alone on post-ERCP pancreatitis may differ from that of ESBD. The use of a small sphincterotomy changes the effect of balloon dilation on the biliary sphincter. The partially cut sphincter is more responsive to balloon stretching, and destruction of the remaining sphincter muscle takes less time. As a result, prolonged compression on the pancreatic orifice by the inflated balloon could cause more edema and impaired drainage from the pancreas. Therefore, prolonged dilation is not necessary after small endoscopic sphincterotomy. This effect may be more pronounced even among non-high-risk patients, which may account for the increased frequency of post- ERCP pancreatitis.

In my opinion, when EPBD is performed without EST, DBD may be associated with a high risk of post-ERCP pancreatitis and unsuccessful stone extraction along with other complications. I believe that if the integrity of the papillary muscles is partially destroyed with a small EST and then EPBD is performed, the risk of post-ERCP pancreatitis and development of other complications will be independent of the dilatation time. The DBD of 30 s seems to be sufficient for this purpose.

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