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Is ERCP still the elective primary biliary drainage technique in patients with malignant distal biliary obstruction?

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Endoscopic retrograde cholangiopancreatography (ERCP) has been established as the first-line therapy for the resolution of biliary and pancreatic diseases. The main disadvantage of the procedure is its rate of adverse events, around 10 % (1). Thus, despite being a minimally invasive procedure, ERCP has a non-negligible rate of adverse effects (AEs) and secondary mortality (1,2).

On the other hand, endoscopic ultrasonography (EUS) has undergone outstanding therapeutic developments. At the biliopancreatic level, EUS-guided transmural biliary drainage (EUS-TBD) procedures, namely choledochoduodenostomy and hepaticogastrostomy, have caused the relationship between ERCP and EUS to become complementary (3).

Outcomes of EUS-TBD have been progressively improved. In a meta-analysis published in 2016, the overall rate of technical success, clinical success, and AEs were 95.68 %, 90.32 % and 24.41 %, respectively (4). Following the technical advances and greater experience of endoscopists developed in recent years, in a meta-analysis including 7,887 patients, the pooled incidences of clinical success, AEs, serious AEs, and mortality with EUS-TBD were 95 %, 13.7 %, 0.6 % and 0,1 %, respectively (5). Clinical success was significantly lower for hepaticogastrostomy compared with choledochoduodenostomy (92.3 % vs 97.2 %; $p < 0.0001$), while AEs were higher (15.5 % vs 11.9 %, $p < 0.05$) (5).

Despite the initial relatively poor results, the comparison with percutaneous biliary drainage (PTBD) ended up favoring EUS-TBD. In a landmark meta-analysis, EUS-TBD was associated with greater clinical success (OR, 0.45; 95 % CI, 0.23-0.89; I^2 = 0 %), fewer AEs (OR, 0.23; 95 % CI, 0.12-0.47; I^2 = 57 %), and a lower reoperation rate (OR, 0.13; 95 % CI, 0.07-0.24; I^2 = 0 %) (6). In addition, there were no differences in terms of technical success or hospital stay, but EUS-TBD was more cost-effective. Afterwards, EUS-TBD has been accepted as the first-choice technique for biliary drainage when ERCP is not feasible, ahead of PTBD (7-9). However, EUS-TBD is not yet considered the technique of choice for primary biliary drainage, replacing ERCP (10).

In recent years specific EUS-guided therapeutic devices have been developed. A significant milestone in this regard is the introduction of lumen-apposing metallic stents (LAMS) (11). These stents allow firm anastomoses to be performed in a single step and without the need for device exchange, which leads to a faster, and safer procedure (12). LAMS have expanded greatly the therapeutic scope of EUS and numerous applications have been developed for the creation of anastomoses with these stents (13).

If we focus on EUS-guided choledochoduodenostomy, several studies have shown improved outcomes using LAMS (14,15). Thus, in a meta-analysis evaluating the results of EUS-guided choledochoduodenostomy using LAMS, a technical success rate of 93.8 %, clinical success rate of 95.9 %, and 5.6 % of AEs were described (16).

Therefore, EUS-TBD by means of choledochoduodenostomy with LAMS is an effective technique with high rates of technical and clinical success, and an adverse effects rate comparable to or lower than that described for ERCP (14-16). Interestingly, the diameter of the common bile duct is probably a key factor for technical success (14,15).

With these outcomes the procedure could be considered a real alternative to primary biliary drainage with ERCP (Fig. 1). This new approach has several advantages: similar outcomes to ERCP, avoids post-procedure acute pancreatitis, and offers greater efficiency when performing different diagnostic and therapeutic maneuvers with a single endoscope.

As disadvantages, EUS-TBD associates a high percentage of AEs in many studies, with a possibility of fatal evolution (4). In addition, it requires a single endoscope, but one that is much more expensive than a duodenoscope. Finally, the technical difficulty of EUS-TBD requires a long and steep learning curve until adequate experience is achieved (17,18).

In this situation several studies have been conducted to evaluate the results of primary EUS-TBD without previous ERCP. In an initial randomized, controlled trial including 15 patients per arm no differences were found in both technical success (93 % vs 100 %) and clinical success (100 % vs 93 %) with EUS-TBD vs ERCP, respectively (19).

In a multicenter, prospective study the results of primary choledochoduodenostomy with a covered self-expandable metallic stent in patients with distal malignant biliary obstruction were described (20). A technical success rate of 97 %, clinical success rate of 100 % and an AEs rate of 15 % were obtained. In addition, the recurrence rate of biliary obstruction was compared to that from a historical series of biliary drainage by ERCP with the same type of stent, and no significant differences were found (29 % vs 36 %).

A prospective, randomized study compared primary biliary drainage by means of choledochoduodenostomy without LAMS versus ERCP in patients with distal obstructive jaundice secondary to pancreatic cancer (21). There were no differences in terms of technical success (90.9 % vs 94.1 %, $p = 0.67$), clinical success (97 % vs 91.2 %, $p = 0.61$) or reinterventions (3.0 % vs 2.9 %, $p = 0.99$). No significant differences were found either in terms of AEs [21.2 % (6.1 % moderate and the rest mild) vs 14.7 % (5.9 % moderate and the rest mild); $p = 0.49$], respectively.

In another prospective, randomized multicenter study primary EUS-TBD was compared to primary biliary drainage by ERCP (22). The rate of early AEs (6.3 % vs 19.7 %, $p = 0.03$); late AEs (4.7 % vs 19.4 %, $p = 0.01$); post-procedure pancreatitis (0 % vs 14.8 %, $p = 0.001$); need for reintervention (15.6 % vs 42.6 %, $p = 0.001$), and median hospital stay (4 vs 5 days, $p = 0.03$) significantly favoured primary EUS-TBD. Technical success (93.8 % vs 90.2 %) and clinical success (90 % vs 94.5 %) rates did not differ significantly between EUS-TBD and ERCP ($p > 0.05$). Quality of life was better preserved in the EUS-TBD group after 12 weeks of follow-up in terms of global quality of life (4.17 vs -9.03, $p = 0.001$) and parts of functional quality of life: emotional, cognitive, and symptom scale (22).

An international multicenter, randomized study comparing primary biliary drainage with choledochoduodenostomy with LAMS vs ERCP in patients with unresectable malignant distal biliary obstruction showed no significant differences in 1-year stent patency rates (91.1 % vs 88.1 %, $p = 0.52$) (23). The EUS-TBD group had a significantly higher technical success rate (96.2 % vs 76.3 %, $p < 0.001$), whereas clinical success was similar (93.7 % vs 90.8 %, $p = 0.559$). Median procedural time was significantly shorter in the EUS-TBD group (10 vs 25 minutes, $p < 0.001$). The adverse events rate at 30 days and mortality rate at 30 days were both similar (23).

Finally, another multicenter, randomized, controlled trial including patients with malignant distal biliary obstruction secondary to borderline resectable, locally advanced, or unresectable peri-ampullary cancer compared primary biliary drainage with choledochoduodenostomy with LAMS vs ERCP. No differences in technical success, clinical success, AEs, quality of life, and surgical or oncologic outcomes were found ($p > 0.05$). Mean procedure duration was 14 minutes vs 23.1 ($p < 0.01$),

respectively (24).

In a meta-analysis including only patients without duodenal obstruction no differences were found in terms of technical success (96.29 % vs 96.65 %), clinical success (96.25 % vs 93.18 %) or AEs (13.77 % vs 16.31 %) between EUS-TBD and ERCP. The need for reintervention rate was significantly lower in the EUS-TBD group (5.73 % vs 17.51 %, $p = 0.02$) (25).

Therefore, the currently available data suggest that primary EUS-TBD in a specific setting is not inferior to ERCP drainage (19-25). In fact, it is probably associated with a lower rate of AEs and other more favourable secondary data, such as a lower duration of the procedure, shorter hospital stay, and less need for reintervention.

Specifically, it seems that choledochoduodenostomy with LAMS may be the most appropriate option for primary biliary drainage in the context of patients with malignant distal biliary obstruction and significant common bile duct dilation (5,14,15). Some studies consider that the appropriate caliber of the common bile duct offering the best safety profile should be over 15 mm (14).

However, primary EUS-TBD somewhat goes beyond the concept of a complementary relationship with ERCP, and leads to a situation in which the final objective, namely biliary drainage, rather than the endoscopic technique itself is what really matters.

Therefore the instruments with which an examination is performed should not matter so much as long as the outcomes are similar or even improved. Focusing on biliary drainage, if in a subgroup of patients with well-defined characteristics we may achieve better outcomes with EUS-TBD, a change in the paradigm of endoscopic biliary drainage should be considered.

In our opinion, we can draw three clear conclusions. Firstly, from our point of view it is already feasible for an experienced endoscopist to perform a primary EUS-TBD in a tertiary hospital in the context of distal malignant jaundice with significant dilation of the bile duct, especially if ERCP is expected to be complex or high-risk, such as in patients with intradiverticular papilla or with a history of acute pancreatitis. Patients with malignant distal jaundice not amenable to surgical treatment, with a common bile duct diameter greater than 15 mm constitute the ideal setting for EUS-guided primary biliary drainage.

Secondly, it is clear that ERCPists must also master therapeutic EUS, and all those who carry out their training in ERCP should also complete their training in EUS (17) with high-quality standards.

Thirdly, as a consequence of the foregoing, a near future is in sight in which the therapeutic biliary endoscopist will decide, depending on his/her experience and individual patient characteristics, whether to perform an ERCP or an EUS-TBD. In essence, as long as both procedures yield comparable outcomes, an ERCP or EUS-TBD should no longer be requested. Instead, a generic *endoscopic biliary drainage procedure* should be ordered, thus placing the focus on the desired clinical outcome, which is biliary drainage, rather than the specific technique used to achieve said outcome.

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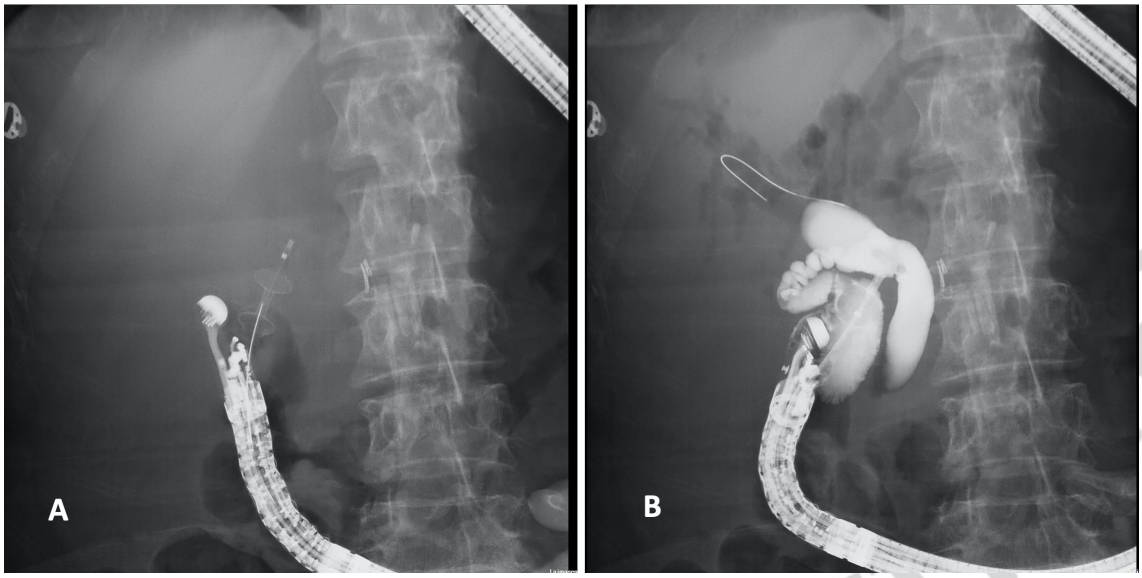

Fig. 1. A. This X-ray image displays the lumen-apposing metallic stent (LAMS) immediately after deployment in an EUS-guided choledochoduodenostomy procedure. B. Subsequent cholangiography through the LAMS confirmed the patency of the bile duct, demonstrating absence of leakage.