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IN THE EXPERT'S FOCUS

Endoscopic partial sphincterotomy coupled with large balloon papilla dilation - Single stage approach for management of extra-hepatic bile ducts macro-lithiasis ☆, ☆ ☆



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Received 29 May 2013; accepted 16 June 2013

KEYWORDS

Biliary stone;
Endoscopic sphincterotomy;
Papilla dilation;
Giant stone;
Sphincteroplasty;
Cholelithiasis;
Video

Abstract

Endoscopic papillary balloon dilation (EPBD) was introduced in the 80s as an alternative for treatment of biliary lithiasis in order to minimize complications related to biliary endoscopic sphincterotomy (ES) and to preserve sphincter mechanism. However it could not gain wide acceptance because of high incidence of post procedural pancreatitis compared to ES alone. In 2003, endoscopic large balloon papillary dilation (ELPBD) coupled with ES, has been proposed as an alternative to lithotripsy for treatment of giant or difficult calculi of the common bile duct. Since then, several studies have evaluated the efficacy of such approach, however in the absence of clear instructions about indications, technique's standardization, morbidity rate and long-term results this procedure has not yet gained wide use. In this report we describe our technique of partial endoscopic sphincterotomy plus large papillary balloon dilation in the

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treatment of common bile duct and cystic duct macro-lithiasis. According to our clinical experience, we would like to focus on the technical points that have to be respected in order to reduce procedure's complications and to achieve successful clinical results. We conclude that endoscopic partial sphincterotomy plus large papillary balloon dilation seems a promising, effective and safe approach to treat giant extrahepatic biliary calculi, if performed after correct patient selection and under established guidelines.

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Video related to this article

Video related to this article can be found online at <http://dx.doi.org/10.1016/j.vjgien.2013.06.003>.

1. Background

- Extraction of giant or multiple calculi from extra-hepatic duct by standard ERCP achieves limited success, mainly due to technical difficulties. Alternative techniques for removal of bile duct stones not amenable to standard endoscopic procedure are: mechanical lithotripsy, electro-hydraulic lithotripsy, extra-corporeal shock wave lithotripsy or laser cholangioscopy-guided lithotripsy. Unfortunately these techniques often require multiple sessions.
- These redo procedures are usually successful if carried out by an expert endoscopist in high volume center.
- Biliary stenting is considered a useful alternative in very old patients and those with serious co-morbidities. Biliary stenting is mandatory if common bile duct clearance cannot be achieved.
- Sometimes surgery is necessary to definitively achieve bile duct clearance.

2. Materials

- Duodenoscope Olympus[®] TJF 160 VR
- Guide Wired Sphincterotome Autotome[®] (Rx Boston Scientific[®])
- Guide wire Hydraxagwire[®] 450 cm, 0.0035
- CRE WG[®] balloon dilation (three different size: 12-15 mm, 15-18 mm; 18-20 mm)
- Manometer Encore26[®]
- Extraction Balloon Extractor Pro Rx[®] (Boston Scientific[®])

3. Endoscopic procedure

- Retrograde Endoscopic Cholangiography confirms a dilated common bile duct (bile duct diameter ≥ 12 mm) and presence of macrolithiasis (stones ≥ 15 mm).
- Cannulation of the intra-hepatic bile ducts with a guide wire.
- Partial sphincterotomy over the guide wire, defined as mid-incision compared to complete sphincterotomy that is extended until the superior margin of intra-duodenal papillary portion.

- Withdrawal of the sphincterotome leaving behind the guide wire inserted in the intra-hepatic ducts.
- Insertion of large balloon over the guide wire choosing the size in accordance with the size of the bile duct and of the stones.
- Positioning of the balloon in the papilla and low part of bile duct, taking care not to incarcerate the stone between balloon and bile duct wall in order to reduce the risk of perforation of the bile duct by stone impaction during dilation. In order to avoid stone incarceration before inflating the balloon is important to push the stone above the balloon under fluoroscopy control.
- Starting dilation by inflating the balloon gradually, under endoscopy and radiological control, using diluted contrast media. Observe the gradual disappearance of the waist of the balloon and then keep it in place for 30 s (1-1.5 min overall dilation time)
- It is fundamental to maintain a stable position throughout the procedure and to guarantee a proper alignment between the biliary axis and the axis of the balloon in order to avoid the risk of bile duct rupture. Sometimes the right axis is achieved gently pushing forward the scope (few centimeters) as to obtain the long position.
- Avoid this procedure (large papillary dilation) in case of suspected neoplastic stenosis.
- Deflating the balloon without moving it and to withdraw it after it is completely deflated keeping the guide wire in place to facilitate access in case of any complication.
- Check with fluoroscopy if any free air is present in abdomen. Perform the extraction of stone with extraction catheter balloon or dormia basket.

4. Discussion

In 1982 papillary dilation with a small diameter balloon was proposed as an alternative to endoscopic sphincterotomy (ES) for stone extraction with the aim to preserve the sphincter function and avoid bleeding [1]. This technique was not widely put into practice because of the high level of pancreatitis related to the procedure compared to the ES alone [2] and for the routinely need of mechanical lithotripsy to achieve complete stone extraction [3]. Current guidelines demonstrated a significant higher incidence of post ERCP pancreatitis (PEP) for EPBD alone compared to ES not recommending this method as an alternative to sphincterotomy in routine ERCP but considering it useful in patients with coagulopathy and altered anatomy [4].

Ersoz et al. [5] in 2003 reported successful endoscopic clearance of biliary stones in tapered shape distal bile ducts or in case of large biliary stone, with ES plus papilla dilation with a large diameter balloon. However this technique struggled for acceptance due to the lack of biliary dedicated large dilation balloon.

In this report we describe, according to our clinical experience, the technique of this procedure standardizing the different steps necessary to avoid complications and evaluating the correct indications [6,7].

This combined approach performed for dilated bile duct and for retrieval of giant stones can reduce complications of the following single procedures: complete sphincterotomy (such as: bleeding, perforation and pancreatitis) and EPBD alone (perforation, duct rupture and pancreatitis). Moreover it amplifies the success rate by achieving a large diameter of sphincterotomy comparable to choledoco-duodenal anastomosis.

Interestingly a Japanese multicentric trial with a mean follow-up of 6.7 years demonstrated a lower risk of stone recurrence following EPBD when compared to ES [8]. Possible factors responsible for an higher recurrence rate of bile duct stones after ES are: bile stasis, bacterial infection and duodenocholedochal reflux [9].

The risk of bleeding is reduced by exploiting a shorter cut of the sphincter and by dilation for mechanical hemostasis. Nevertheless, in literature severe bleeding after EPLBD has been described [10]. However, in our clinical experience no bleeding has been reported [11].

Perforation is avoided because the sphincter is not cut until upper part of infundibulum and its partial dilation preserves the sphincter just by stretching the muscle fibers without risk of disconnection of the bile duct. However, it is mandatory to maintain the correct orientation of the balloon catheter within the papilla throughout the dilation procedure

Post-EPLBD pancreatitis seems to be related to different mechanisms: (a) direct compression of the balloon on the papilla, the pancreatic duct orifice and nearby pancreatic parenchyma resulting in peripapillary edema and spasm (b) repeated bile duct cannulation or transpapillary manipulation due to technical amenities. However it is not clear if the main role in the induction of pancreatitis is played by the dilation itself or by repeated papillary manipulation. Young et al. [12], in their retrospective review, reported as independent risk factors predictive of pancreatitis after EPLBD: smaller dilation of the Common Bile Duct, longer cannulation time and longer stone removal time

Performing selective dilation of bile duct after partial sphincterotomy seems to reduce the incidence of PEP because the pancreatic orifice is separated from the biliary tree and therefore balloon dilation forces do not affect the pancreas [13]. In our experience we had 3 cases out of 36 patients, of mild pancreatitis requiring hospital stay prolongation (≤ 5 days)[11]. For preventing PEP it is also fundamental to keep a guidewire inside the biliary tree in order to avoid unnecessary papillary manipulation during the different steps of the procedure.

Lastly, for such pathology, usually the median age population is advanced, which is a known preventive factor for post procedural pancreatitis.

In case of macro lithiasis with concomitant bile ducts dilation, partial sphincterotomy coupled with large balloon dilation achieves a concomitant dilation of distal part of bile

duct that facilitates smooth en-bloc removal of giant stone avoiding the need of mechanical lithotripsy and potentially abolishing the possibility of recurrence due to the tiny stone fragments missed in the bile duct that may act as a nidus for stone formation [14].

This technique appears to be safe for the removal of large common bile duct stones even in patients with difficult anatomy, such as those with periampullary diverticula and Billroth II surgery [15,16].

In conclusion, partial ES+EPLBD is a safe, simple and effective one stage technique for stone clearance. It requires instruments used in everyday clinical activity by most interventional endoscopists to perform one of the most challenging endoscopic interventions: extraction of macro biliary stones. A pathology that until now has needed multiple endoscopic sessions or surgical intervention such as choledochotomy or choledochoduodenal anastomosis can thus be effectively treated using this technique.

5. Tips and tricks

- Partial sphincterotomy plus large balloon dilation allows to achieve maximal diameter of papilla orifice even in case of small papilla or papilla at the edge of duodenal diverticula.
- Large balloon dilation achieves a concomitant dilation of distal part of bile duct that facilitates smooth stone retrieval.
- Large balloon dilation can provide compressive hemostasis to prevent bleeding especially in patients with coagulopathy or under anticoagulant therapy.
- Partial sphincterotomy plus large balloon dilation has a lower incidence of procedure related pancreatitis compared to dilation alone and has the same incidence of procedure related pancreatitis compared to ES alone. It can be explained by patient's characteristics such as older age (patients with giant biliary calculi are usually older than 60 years) and dilated bile duct (usually larger than 10 mm). These two features are considered a low risk factors for post-procedure hyperamylasemia.
- Partial sphincterotomy separate the pancreatic orifice from the biliary one preserving it from injuries related to biliary dilation.

6. Scripted voiceover

Voiceover Text

Extraction of large or multiple stones during ERCP is usually challenging. Mechanical lithotripsy, electrohydraulic lithotripsy, extra-corporeal shock wave lithotripsy or laser cholangioscopy-guided lithotripsy are alternative techniques proposed to manage this pathology. However these techniques often require multiple treatment sessions and with the exception of mechanical lithotripsy they also require purchase of expensive equipm : first partial sphincterotomy is performed , then large balloon papilla dilation with subsequent extraction of bile duct stones are performed.

Voiceover Text

This MRCP shows large bile duct stones
 Here you see the normal major papilla. We selectively cannulate the common bile duct with a guide wire using a 3 lumen RX sphincterotome
 Injection of contrast shows a dilated common bile duct with macro lithiasis
 Leaving the guide wire in the intrahepatic ducts, a partial sphincterotomy towards 1 o' clock is performed. You see that the cut is carried out until half length of the papillary roof is cut
 The sphincterotome is withdrawn but the guidewire left in place
 A dilation balloon is inserted in the distal part of the common bile duct. Inflation is started under fluoroscopy control in order to verify that the stone is not between the wall of bile duct and the balloon. This is of utmost importance to prevent perforation during dilation.
 Gradually the balloon is inflated up to 6, 7, and 8 atm, at least for 30 seconds at every step, in order to achieve the maximal size of 18mm. Keep the balloon in a stable position throughout the dilation to avoid complications. In the present case we choose a balloon with a maximum width of 18 mm. It is crucial to choose the balloon size in accordance with the size of the bile duct and of the stones.
 The balloon is deflated and removed and the wall of the common bile duct can be seen
 Now we employ a standard extraction catheter balloon to extract the giant stone under fluoroscopic control.
 Occlusion cholangiography with the inflated balloon catheter confirms complete removal of the stones
 With a Roth Net® retriever the stone is grasped and retrieved. This was done on the patient's previous demand. The stone had a width of 12 mm and a length of 25 mm
 Partial sphincterotomy plus large balloon dilation is a safe and effective single stage technique for extraction of giant or difficult lithiasis of the extra-hepatic bile duct

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