

What is the Interest of Sphincteroplasty in the Treatment of Large Bile Duct Stones?

Samir Mrabti*, Ahlame Benhamdane, Asmae Sair, Tarik Addajou, Réda Berrida, Sara Sentissi, Ilham Koti, Fedoua Rouibaa, Ahmed Benkirane and Hassan Seddik

Hepato-gastroenterology Department II Mohammed V Military Instruction Hospital/Mohammed V University/Rabat/Morocco

*Corresponding Author: Samir Mrabti, Hepato-gastroenterology Department II Mohammed V Military Instruction Hospital/Mohammed V University/Rabat/Morocco.

Received: April 12, 2023

Published: May 29, 2023

© All rights are reserved by Samir Mrabti, et al.

Abstract

The aim of our study is to evaluate the efficacy and safety of sphincteroplasty and to study the factors influencing the success or failure of this technique.

Patients and Methods: This is a descriptive and analytical retrospective study conducted in our department between APRIL 2002 and DECEMBER 2022, including 52 patients who underwent sphincteroplasty for the extraction of a large bile duct stone. The success of the endoscopic treatment was defined by the complete emptiness of the common bile duct (CBD) at the end of the procedure. Statistical analysis was performed using SPSS version 24.0 software. The study of the factors associated with the success of endoscopic treatment was carried out using a logistic regression model.

Results: The average age of our patients was 65.37+/-17.46 years with a female predominance of 56.9%. The mean CBD diameter was 16 mm+/-2.97 [8-24 mm]. 16.51% of patients were cholecystectomized, 2% of patients had acute pancreatitis, on the other hand acute cholangitis was objectified in 9.8% of patients. 7.8% of patients had biliary stenosis and only one patient had periampullary diverticulum. The success rate of sphincteroplasty was 96.1% with no notable complications. None of the factors studied seemed to be associated with the success or failure of sphincteroplasty.

Conclusion: Macro-dilation of the sphincter of oddi is a safe and effective technique in the treatment of large bile duct stones. In our study, the success rate was 96.1%, however none of the factors studied was associated with the success or failure of sphincteroplasty.

Keywords: Large Stones; Common Bile Duct; Macro-dilation of the Sphincter of Oddi

Introduction

Common bile duct lithiasis is a very common disease that can occur at any age with a predominance in patients with gallbladder lithiasis, it can be complicated by obstructive jaundice, acute cholangitis or even acute pancreatitis, which requires early diagnostic and therapeutic management [1].

Endoscopic treatment has become the treatment of choice for lithiasis of the common bile duct (CBD), thanks to the development of interventional endoscopy [2].

Endoscopic retrograde cholangiopancreatography followed by endoscopic sphincterotomy was introduced for the first time in 1974 [3,4], and is considered the reference treatment for a cholelithiasis.

The extraction of stones is generally done using an extraction balloon or Dormia basket, with an estimated success rate of 90% [2,5]. This success rate can, however, be reduced by 10% in the presence of a large stone (> 15 mm) [5]. Several techniques have been used, in particular mechanical lithotripsy (ML) to facilitate the extraction. However, these methods can be difficult, expensive and time-consuming [6].

The macrodilation of the sphincter of Oddi (MDSO) was developed in order to face this problem [6], it consists of a hydrostatic dilation of the sphincter of Oddi, after a small sphincterotomy, by a balloon of 12 to 20 mm [7].

The objective of our work was to study the interest of macrodilation of the sphincter of Oddi in the treatment of large stones in CBD, and to study the factors associated with the success of this technique.

Materials and Methods

This is a retrospective analytical and descriptive study carried out within the Hepato-Gastro-Enterology II department of the Military Hospital of Rabat over a period of 20 years between April 2002 and December 2022.

All patients aged over 18 who underwent MDSO for the extraction of a large cholidocian stone (>15 mm) were included.

Patients not included in the study were those with non-lithiasic biliary pathology such as a tumor or malignant stenosis and those with a contraindication to macrodilation (haemostasis disorder).

The data used was collected from medical records and the department's endoscopic activity register.

The cholangiography was performed after the injection of the contrast product, and it allowed us to specify the diameter of the CBD as well as the size of the stone and its seat and the total number of these stones. The size (long transverse axis) of the stones and the caliber of the CBD were measured using the diameter of the duodenoscope as a benchmark. It also made it possible to identify the presence or not of a stenosis or disparity in the caliber of the CBD. The cholangiography data formed the basis for the subsequent endoscopic procedure.

Endoscopic retrograde cholangiopancreatography (ERCP) was performed under general anesthesia in an operating room equipped with an image intensified.

A large stone was defined by an obstructive stone measuring more than 15 mm on cholangiography.

MDSO was performed either immediately after sphincterotomy when this seemed insufficient for the extraction of the stone or after failure of standard techniques.

Sphincteroplasty consisted of placing a hydrostatic dilation balloon (12 to 20 mm in diameter) on a guide wire downstream of the stone and straddling the cut sphincter. Its proximal end could be checked endoscopically. The balloon was then gradually inflated until the notch printed by the sphincter was completely erased.

The maximum diameter of the dilatation balloon was chosen based on the size of the stone and the diameter of the common bile duct. As soon as the papillary orifice was dilated, a Dormia basket or a biliary extraction balloon was introduced into the bile duct for extraction of the stone.

A control cholangiography, by opacification of the CBD, was performed to verify its emptiness and the absence of complications. Incomplete removal of CBD stones or the occurrence of a complication (such as papillary bleeding) leads to the placement of a plastic prosthesis or a naso-biliary drain. A new extraction was done within 7 to 15 days.

Surgical treatment was performed after the failure of any attempt at extraction. A placement of plastic prostheses was performed in patients presenting a contraindication to surgical treatment.

The success of the endoscopic treatment was defined by the complete emptiness of the CBD at the end of the procedure.

Hospital monitoring for at least 24 hours was recommended in all patients, in order to detect any early complications.

Statistical analysis was performed using SPSS version 24.0 software. A descriptive analysis of our population including the various demographic, clinical, endoscopic and radiological variables was carried out.

Qualitative variables were expressed as a percentage and number, while quantitative variables were expressed as a mean plus or minus standard deviation.

The study of the factors associated with the success of endoscopic treatment was carried out using a binary logistic regression model. A p value of <0.05 was considered statistically significant.

Results

Epidemiological data

- 52 patients who underwent MDSO were included in our study, the average age is : 65.37+/-17 years [26 - 95 years].
- In our study: 22 patients were male (43.1%) and 30 patients were female (56.9) with a sex ratio M/F of 0.73.

Clinical data

Background

- 4 patients had a history of cholecystectomy (16.51%), only 1 patient had a history of CBD surgery (2%), 29% of patients had undergone a previous endoscopic biliary sphincterotomy.

Clinical manifestations

In our series, acute pancreatitis was noted in only one patient (2%) on admission, and acute cholangitis in 5 patients (9.8%).

Endoscopic and morphological aspect

- According to the endoscopy data, at the time of the ERCP only one patient presented with a periampullary diverticulum.
- The mean CBD diameter on cholangiography was 16 mm +/- 2.97, with extremes of 8 mm and 24 mm, 4 patients presented CBD stenosis (7.8%).
- 5 patients had a caliber disparity between the distal portion of the CBD downstream of the stone and its proximal portion upstream of it.

The success rate

After the realization of the MDSO the success rate of the elimination of large calculations of the CBD was 96.1%.

Complication rate

None of our patients presented early complications, namely hemorrhage, acute pancreatitis, acute cholangitis, or perforation.

Studies of risk factors

In univariate and multivariate analysis and by adjusting for the factors studied (age, sex, surgical background, acute pancreatitis, acute cholangitis, CBD diameter and stenosis, and periampullary diverticulum) none of these factors did not appear to be associated with the success or failure of macrodilation in the endoscopic treatment of large bile duct stones.

Discussion

Endoscopic biliary sphincterotomy (EBS) is the most commonly used endoscopic technique for the extraction of CBD stones. More than 2/3 of bile duct stones can be removed using an extraction balloon or a Dormia basket.

The presence of large bile duct stones is a known obstacle to endoscopic treatment [8]. Several techniques have been used to overcome this difficulty either by enlarging the endoscopic sphincterotomy or by fragmenting the stones using mechanical lithotripsy (ML) or intra or extracorporeal lithotripsy.

The success rate of ML can reach 90%, but it remains a time-consuming technique with the possibility of technical complications (impaction of Dormia's basket or rupture of its cables), or type of trauma to main bile duct or perforations [5,8].

Intracorporeal lithotripsy breaks up stones using either shock waves (electrohydraulic lithotripsy) or laser (laser lithotripsy). The success rate of the two techniques is estimated at 96% and 92% respectively, but they require specialized and expensive equipment [2,5].

Extracorporeal lithotripsy uses shock waves to split stones, its success rate varies from 73% to 93% but requires the installation of a naso-biliary drain, and the patient's recovery for evacuation of the lithiasic fragments [2,8].

MDSO is an endoscopic technique introduced by ERZOS, *et al.* in 2003 [9]. It consists in carrying out, after performing an EBS, an enlargement of the sphincter of Oddi.

The combination of this technique with the sphincterotomy makes it possible to obtain a hole with a large diameter which facilitates the elimination of large stones that exceed 12mm in diameter. It makes it possible to avoid having recourse to the ML

and reduces the duration of the procedure and the rate of associated complications [8,10,11]. It is a procedure combining both the advantages of papillary dilation and endoscopic sphincterotomy (ES).

It increases the chances of extracting large stones while minimizing the complications of both techniques. ES preceding macrodilation reduces the risk of acute post-ERCP pancreatitis observed in cases of sphincteroclasia (sphincter dilatation without sphincterotomy).

Indeed, the incision made during the SBE makes it possible to separate the pancreatic orifice from the bile duct, which reduces the pressure of the dilatation balloon and the papilledema on the pancreatic duct. Sphincteroplasty also reduces the risk of perforation that would be caused by a very large sphincterotomy to extract a large stone [10].

The operative time of the procedure remains shorter than that of an ES for the removal of a large stone, as shown by TSUCHIDA and al in a Japanese retrospective study: 42.3 min vs 66.6 min respectively [12].

The size of the ES chosen by the endoscopists is variable, but a small ES is used more in order to reduce the rate of complications, in particular bleeding.

Several studies have shown that a large SE is associated with a higher rate of bleeding than with a small SE [13,14]. In our study, despite performing a sphincterotomy adapted to the size of the stone and not a small SE, we did not find an increased risk of bleeding.

A retrospective study by KARSENTI and al showed that wide SE was not associated with a high complication rate [15].

The maximum diameter of the dilatation balloon used in several studies depends on the size of the stone and the size of the CBD, these balloons have a length of 3 to 5.5 cm and a diameter of 12 to 20 mm [16]. In our study the size of the balloons was 14 to 20 mm in diameter. This should not exceed the size of the CBD to avoid the risk of perforation [17].

In a multicenter retrospective study conducted by PARK and al including 46 patients, a fatal perforation was noted in 2 patients following the use of a balloon with a diameter exceeding that of the CBD [13].

The inflation time is heterogeneous in the different studies and it varies from 10s to 180s, but most endoscopists use a duration less than 60s [14].

PASPATIS and al compared the dilation time of 30s vs 60s, this comparison showed no difference with regards to CBD vacuity and complications : pancreatitis, bleeding and perforation. A short inflation time does not appear to be associated with a high risk of hemorrhage [18].

The success rate of MDSO in our study was 96.1%. It remains comparable to that reported in the literature.

Two comparative retrospective studies have shown the significant superiority of sphincteroplasty over SE for the extraction of large stones with success rates of 84.2% vs 44.2%, $p < 0.001$ (49) and 87, 5% vs 74.0%, $p = 0.036$ respectively [19].

As has already been reported in several studies, MDSO compared to SE, makes it possible to reduce the use of ML as a second-line treatment [12,20,21]. In our series, no ML was necessary after sphincteroplasty.

Regarding the predictive factors of success or failure of MDSO, several variables were evaluated in our study such as age, sex, surgical history, acute pancreatitis, acute cholangitis, CBD diameter and possible presence of CBD stenosis or periampullary diverticulum.

Based on binary logistic regression and adjusting for different studied factors, none of his latest seemed to be associated with the success of this technique.

In the literature and to our knowledge, no previous study has evaluated these factors. Other studies have focused on the evaluation of post-sphincteroplasty complications (acute pancreatitis, hemorrhage, perforation and acute cholangitis).

Three randomized controlled trials compared the complication rate between 2 groups, the first was treated with EBS while the 2nd

group benefited from sphincteroplasty, they revealed no difference between the two techniques in terms of complications [22,23].

In our study no complications occurred in our patients, these results were similar to 3 studies that reported an overall complication rate of 0% [24-26].

Among the complications described, perforation is considered the most serious, but fortunately it remains rare, in fact 7 perforations (0.4%) have been reported in the literature (in 31 studies) [27].

The presence of CBD stenosis downstream of the stone seems to be a predictive factor for perforation and could be considered as a relative contraindication for MDSO [28].

In our experience sphincteroplasty was performed successfully and without complications in 5 patients, despite the presence of a caliber disparity between the distal portion of the CBD downstream of the stone and its proximal portion upstream of it.

The diverticulum is not a contraindication to sphincteroplasty, but it requires more careful dilation [28].

The most common complication of MDSO is represented by hemorrhage, it remains, however, minimal to moderate and can be curbed, generally, by conservative treatment. However, severe arterial bleeding, sometimes delayed, remains possible and may require surgery [29].

Conclusion

The sphincteroplasty is a safe and effective technique for the extraction of large stones from the CBD, it has reduced the use of ML while reducing the duration of the procedure with a high overall success rate.

In our study, complete extraction of large stones after sphincteroplasty was successfully performed in 96.1% of our patients without recourse to mechanical lithotripsy, with an overall rate of early complications of 0%.

Our study showed that none of the factors studied, namely age, sex, surgical history, acute pancreatitis, cholangitis, CBD diameter, biliary stenosis and periampullary diverticulum, were associated with success or failure of sphincteroplasty.

Bibliography

1. C H Oh and S H Dong. "Recent advances in the management of difficult bile-duct stones: a focus on single-operator cholangioscopy-guided lithotripsy". *Korean Journal of Internal Medicine* 36 (2021): 235-246.
2. A Katanuma., et al. "ENDOSCOPIC TREATMENT OF DIFFICULT COMMON BILE DUCT STONES: DIFFICULT BILE DUCT STONES". *Digestive Endoscopy* 22 (2010): S90-S97.
3. M Classen and L Demling. "Endoskopische Sphinkterotomie der Papilla Vateri und Steinextraktion aus dem Ductus choledochus". *DMW - Deutsche Medizinische Wochenschrift* 99 (1974): 496-497.
4. K Kawai., et al. "Endoscopic sphincterotomy of the ampulla of Vater". *Gastrointestinal Endoscopy* 20 (1974): 148-151.
5. G Stefanidis., et al. "Endoscopic extraction of large common bile duct stones: A review article". *World Journal Gastrointestinal Endoscopy* 4 (2012): 167-179.
6. S Ishii., et al. "Best Procedure for the Management of Common Bile Duct Stones via the Papilla: Literature Review and Analysis of Procedural Efficacy and Safety". *Journal Clinics Medicine* 9 (2020): 3808.
7. X M Yang., et al. "Endoscopic papillary large-balloon dilation following limited sphincterotomy for the removal of refractory bile duct stones: Experience of 169 cases in a single Chinese center: EPLBD facilitates stone removal". *Journal of Digestive Diseases* 14 (2013): 125-131.
8. T Ogura and K Higuchi. "A review of treatment options for bile duct stones". *Expert Review of Gastroenterology and Hepatology* 10 (2016): 1271-1278.
9. G Ersoz., et al. "Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract". *Gastrointestinal Endoscopy* 57 (2003): 156-159.
10. J H Kim., et al. "Endoscopic papillary large balloon dilation for the removal of bile duct stones". *World Journal of Gastroenterology: WJG* 19 (2013): 8580-8594.
11. D K Lee and J H Jahng. "Alternative methods in the endoscopic management of difficult common bile duct stones: endoscopic management of CBD stones". *Digestive Endoscopy* 22 (2010): S79-S84.

12. K Tsuchida, *et al.* "Comparison of the usefulness of endoscopic papillary large-balloon dilation with endoscopic sphincterotomy for large and multiple common bile duct stones". *BMC Gastroenterology* 15 (2015): 59.
13. SJ Park, *et al.* "Factors Predictive of Adverse Events Following Endoscopic Papillary Large Balloon Dilation: Results from a Multicenter Series". *Digestive Diseases and Sciences* 58 (2013): 1100-1109.
14. TH Kim, *et al.* "International consensus guidelines for endoscopic papillary large-balloon dilation". *Gastrointestinal Endoscopy* 83 (2016): 37-47.
15. D Karsenti, *et al.* "Complete endoscopic sphincterotomy with vs. without large-balloon dilation for the removal of large bile duct stones: randomized multicenter study". *Endoscopy* 49 (2017): 968-976.
16. G Grande, *et al.* "Dilation assisted stone extraction for complex biliary lithiasis: Technical aspects and practical principles". *World Journal of Gastrointestinal Endoscopy* 13 (2021): 33-44.
17. KH Lai, *et al.* "Reappraisal of endoscopic papillary balloon dilation for the management of common bile duct stones". *World Journal of Gastrointestinal Endoscopy* 7 (2015): 77-86.
18. G A Paspatis, *et al.* "Sixty- versus thirty-seconds papillary balloon dilation after sphincterotomy for the treatment of large bile duct stones: A randomized controlled trial". *Digestive and Liver Diseases* 45 (2013): 301-304.
19. T H Kim, *et al.* "Can a small endoscopic sphincterotomy plus a large-balloon dilation reduce the use of mechanical lithotripsy in patients with large bile duct stones?". *Surgery Endoscopy* 25 (2011): 3330-3337.
20. G Stefanidis, *et al.* "Large Balloon Dilation vs. Mechanical Lithotripsy for the Management of Large Bile Duct Stones: A Prospective Randomized Study". *American Journal of Gastroenterology* 106 (2011): 278-285.
21. U I Aujla, *et al.* "Endoscopic papillary large balloon dilatation with sphincterotomy is safe and effective for biliary stone removal independent of timing and size of sphincterotomy". *World Journal of Gastroenterology* 23 (2017): 8597-8604.
22. CM Kuo, *et al.* "The efficacy of limited endoscopic sphincterotomy plus endoscopic papillary large balloon dilation for removal of large bile duct stones". *BMC Gastroenterology* 19 (2019): 93.
23. XD Xu, *et al.* "Minor endoscopic sphincterotomy followed by large balloon dilation for large choledocholith treatment". *World Journal of Gastroenterology* 23 (2017): 5739-5745.
24. H G Kim, *et al.* "Small sphincterotomy combined with endoscopic papillary large balloon dilation versus sphincterotomy". *World Journal of Gastroenterology: WJG* 15 (2009): 4298-4304.
25. H G Yoon, *et al.* "Endoscopic papillary large balloon dilation for the management of recurrent difficult bile duct stones after previous endoscopic sphincterotomy: EPLBD for recurrent difficult CBD stones". *Digestive Endoscopy* 26 (2014): 259-263.
26. T Itoi, *et al.* "New large-diameter balloon-equipped sphincterotome for removal of large bile duct stones (with videos)". *Gastrointestinal Endoscopy* 72 (2010): 825-830.
27. G A Paspatis, *et al.* "Long-term recurrence of bile duct stones after endoscopic papillary large balloon dilation with sphincterotomy: 4-year extended follow-up of a randomized trial". *Surgical Endoscopy* 31 (2017): 650-655.
28. Y Feng, *et al.* "Comparison of endoscopic papillary large balloon dilation and endoscopic sphincterotomy for retrieval of choledocholithiasis: a meta-analysis of randomized controlled trials". *Journal of Gastroenterology* 47 (2012): 655-663.
29. B Maroy. "Life-threatening hemorrhage caused by balloon dilation after sphincterotomy for extraction of a large stone". *Endoscopy* 43 (2011): 94-95.