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Sphincterotomy plus large balloon dilation *versus* sphincterotomy alone for the extraction of complex lithiasis: A prospective analysis

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ABSTRACT

Background and purpose: Mid-size sphincterotomy associated with large balloon dilation is an alternative to wide sphincterotomy to remove complex lithiasis. However, which of the two techniques is most effective remains unclear. Hence, we conducted this study to compare both methods prospectively.

Method: Since January 2012 until March 2014, 133 consecutive patients with complex stones were included. Group A underwent mid-size sphincterotomy associated with large balloon dilation and group B underwent wide sphincterotomy alone. Success rates were assessed for: Extraction of stones, ductal patency rate, the use of mechanical lithotripsy, dose, time and dose per radioscopy area as well as procedure-related complications.

Results: Group A comprised 44 patients and group B comprised 69 patients. Overall success rate for extraction was 86.4% in group A and 70% in group B ($p = 0.069$). In giant lithiasis, effective extraction was 89.3% in group A and 58.6% in group B ($p = 0.019$). Use of mechanical lithotripsy was 15.9% and 30.4%, respectively ($p = 0.142$). Total radiotherapy dose was 39.8 mGy *vs.* 26.2 mGy, respectively ($p = 0.134$). Complications occurred in 6.8% and 5.5% of the procedures in each group, without significant differences among them ($p = 0.856$).

Conclusion: Sphincterotomy plus large balloon dilation is more effective and equally safe than conventional sphincterotomy for the management of giant main bile duct lithiasis.

Key words: Sphincterotomy. Large balloon dilation. Complex lithiasis.

INTRODUCTION

Wide sphincterotomy (ES) is the endoscopic technique used most often to extract stones from the biliary tree. Although this technique has been widely accepted since implemented in 1974 (1,2), 15% of extractions can prove difficult when stones are large (> 20 mm), multiple (> 3), or when their shape and changes in the distal main bile duct cause a mismatch between contents and container (tapering

or tortuosity). Also, extracting complex stones increases procedure time and exposure to radiation, as well as the need for mechanical lithotripsy (ML). Ersoz et al. (3) were the first to show that the use of large dilation balloons (LBD), after a mid-size ES, is useful for the extraction of difficult stones. Since then, several studies have been published suggesting the procedure is safe and effective. However, most data were generated from retrospective series and only a few were prospective studies (4-9). We compared conventional ES with ES plus LBD (ES/LBD) and assessed the efficacy and safety of the procedure, time, dose, and dose per area (DPA) of radioscopy, as well as related complications.

METHODS

We prospectively and comparatively assessed a cohort of patients with difficult biliary lithiasis at the Department of Endoscopic Cholangiography of a large referral hospital from January 2012 to March 2014.

Patients were divided into two treatment groups: Group A: ES/LBD and group B: wide ES.

Patients included had difficult lithiasis (i.e., giant and/or multiple complex) and had not undergone prior treatments to the biliary tree.

Giant lithiasis was defined as stones larger than 20 mm, and multiple complex lithiasis was that with a "Stone Index" greater than 4. This index was published in 2010 by Dr. Horiuchi et al., and is calculated adding the diameter of each of the stones measured in cm times the number of stones. For example: A patient with 4 stones (one of them measuring 0.5 cm in size and the other three measuring 1.5 cm each) has an index of 5 ($[1 \times 0.5 \text{ cm}] + [3 \times 1.5 \text{ cm}]$) (10).

Overall therapeutic success was considered as complete extraction of the stones, and success in ductal patency was defined as successful drainage of the biliary tree by stone extraction or placement of a plastic stent.

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The size of the stones was assessed in two ways: By digital measurement with the C arm, or using the size of the duodenoscope as a reference. In this latter case, the magnification generated by radioscopy was corrected by the following mathematical calculation: Actual diameter of the stone = (diameter measured by imaging x actual diameter of the duodenoscope)/measured diameter of the duodenoscope (rule of three).

The size of the ES was defined according to the distance cut from the ostium to the transverse fold. The ES was small when it involved 1/3 of that distance, mid-size when it involved 2/3 and wide when it reached the transverse fold.

The following were considered exclusion criteria: Coagulation abnormalities (INR > 1.5), thrombocytopenia (< 50,000 platelets), prior ES, anatomic abnormalities of the biliary tree (Billroth II, hepatojejunostomies), intrahepatic lithiasis and biliary tree stenoses.

In each group the following rates were assessed: Ductal patency, complete extraction of main bile duct lithiasis, use of ML, placement of plastic stents, time, dose and radioscopy DPA, and related complications.

Post-retrograde cholangiography pancreatitis was defined as a threefold rise in the normal amylase value associated to abdominal pain in the 24 hours following the procedure. Cholangitis was diagnosed by an increase in white blood cell count associated with fever and jaundice. Perforations were diagnosed when there was air in the peritoneal cavity or the retroperitoneal space, by abdominal CT and a consistent clinical presentation.

The study was approved by the Hospital's Ethics Committee. All patients included gave their informed consent. The protocol complies with the ethical guidelines of the Declaration of Helsinki of 1975 (1983 revision).

Description of the procedure

All endoscopies were performed under deep sedation and orotracheal intubation. In cases with a preserved gallbladder, antibiotic prophylaxis consisted of one dose of IV ampicillin-sulbactam.

Endoscopic cholangiography was performed with a therapeutic duodenoscopy equipment (4.2 mm channel). The contrast medium used for cholangiography was 68% Ioversol, 320 mg/ml, in a 50% dilution. All ES were performed with cut current (electrosurgical unit). Two experienced endoscopists (performing more than 300 exams per year) were in charge of the procedures. After cannulating the biliary tree with a sphincterotome and a guidewire, the cholangiogram was performed and stone characteristics were evaluated.

Group A underwent a mid-size ES followed by balloon dilation (12 to 20 mm). The balloon diameter was selected according to size of the distal main bile duct. Inflation with contrast was performed under radioscopy and endoscopic guidance, until the notch disappeared. Once appropriate dilation was achieved, the balloon was kept inflated for 60 seconds (Fig. 1).

Group B underwent wide ES.

In both cases, stones were removed with an extracting balloon or a Dormia basket.

In both groups, ML was used as needed.

When complete removal of stones could not be achieved, a 7-10 F plastic biliary stent was placed, and patients were scheduled to undergo a new procedure during the subsequent 6-8 weeks.

Patients were followed via telephone contact or clinic visits within one week of the study and at 30 days.

Evaluation

The number and size of the stones, the method used in the index cholangiography and the success in extracting all stones and achieving patency of the biliary tree were documented, as well as the use of ML and plastic stents. Radioscopy time was calculated automatically by the operating room fluoroscopy machine, as were the radiation dose and DPA. All fluoroscopy images were digitized and archived.

Statistical analysis

Data obtained were reported as mean, median, 95% confidence interval, standard deviation and range or percentages as appropriate. The statistical analysis of the results obtained was performed with SPSS software, version 20.0. The chi² or Fisher's test were used to compare categorical variables, as appropriate. For quantitative variables, the Student's t test or Mann-Whitney's test were used depending on whether the distribution was normal or non-parametric, respectively. A *p* value < 0.05 was considered to be statistically significant.

RESULTS

A total of 850 endoscopic cholangiographies were performed between January 2012 and March 2014. Among them, 113 (14.5%) fulfilled the inclusion criteria for this study. No patients were lost to follow-up, since all of them were contacted personally and/or via telephone calls as previously explained.

In group A, 44 procedures were performed, while 69 procedures were performed in group B. No demographic differences were observed between both groups (Table I).

For group B patients, mean inflated balloon diameter was 13.6 mm.

There were no differences among both groups regarding the number or size of the main duct stones or the Stone Index.

Biliary patency was achieved in 100% of patients in group A and in 97.1% of patients in group B; the difference between groups was not significant (*p* = 0.683).

Although the rate of complete stone removal in the first endoscopy tended to be higher with LBD (86.4% vs. 70%), this difference was not statistically significant (*p* = 0.069).

When only patients with giant stones were analyzed, (28/44 in group A and 29/69 in group B), successful removal was significantly greater in the group undergoing ES/LBD: Group A, 89.3% and group B, 58.6% (*p* = 0.019).

In cases in which complete ductal patency could not be achieved, 7 or 10 F plastic stents were placed; this was required in 13.6% of patients in group A (6 patients) and in 27.5 % of patients (19 patients) in group B; *p* = NS.

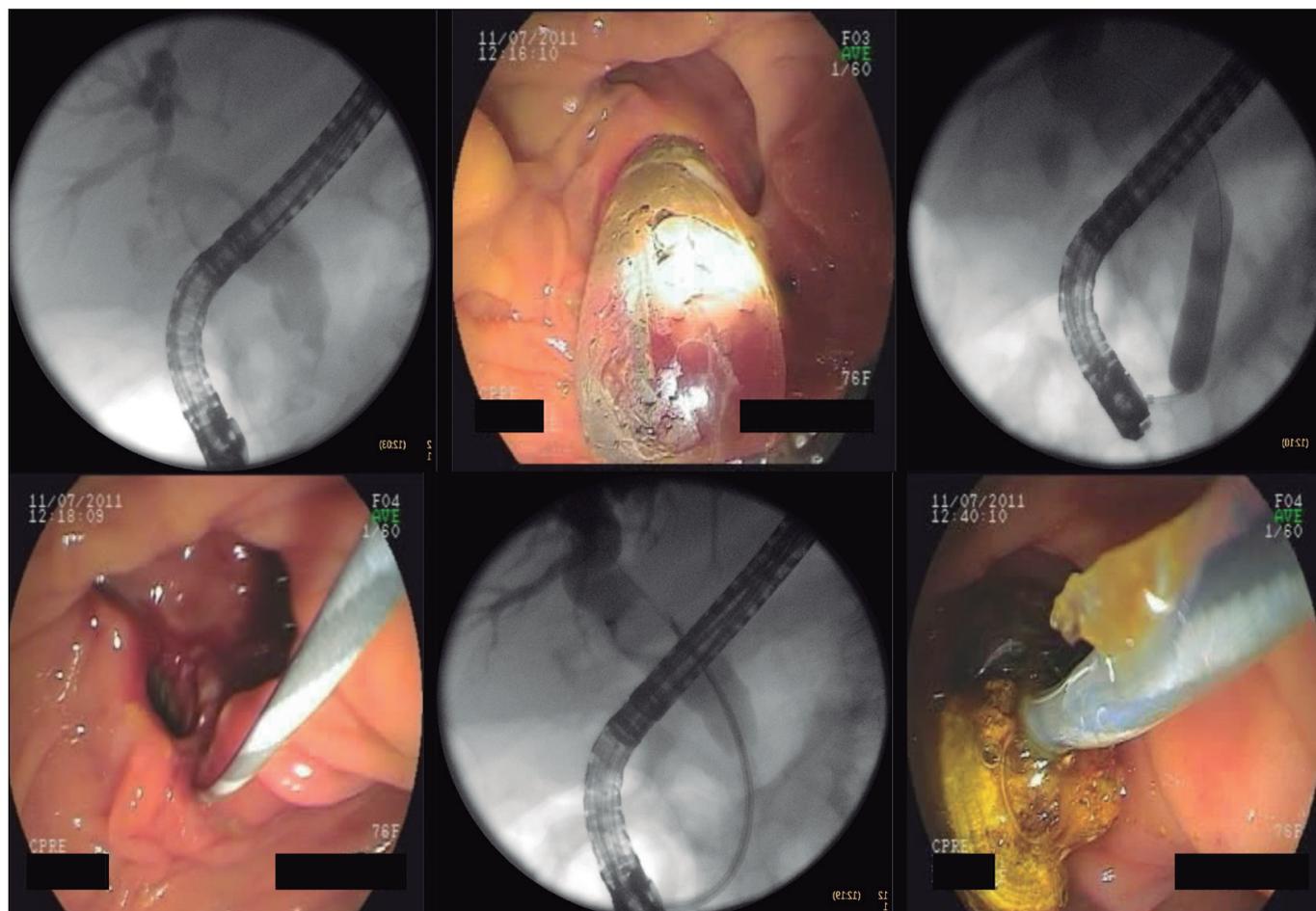


Fig. 1. Main bile duct lithiasis measuring 15x20 mm in a patient with an intradiverticular papilla and tapering of the distal biliary duct. ES, progressive biliary dilatation (15 mm), ML and extraction.

Table I. Demographic variables

Variable	ES/LBD	ES	p
Number of procedures	44	69	n/a
Age (years)			
Mean (range)	56.7 (21-88)	54.3 (23-86)	ns
Sex (F/M)	31/13	46/23	ns

ES: Sphincterotomy; LBD: Large balloon dilation; n/a: Not applicable; ns: Non-significant.

Patients were reintervened endoscopically 6 to 8 weeks later.

As to ML, it was used more often in the group undergoing wide ES (30.4% vs. 15.9%), but without significant difference between groups ($p = 0.142$).

When radiology related variables were assessed, no differences between both groups were found (Table II).

Regarding complications, no difference was found between groups; 6.8 % in the group ES/LBD (2 mild pancreatitis and 1 cholangitis) and 5.8% in the ES group (1 perforation, 2 cholangitis and 1 trapped basket). All com-

plications were resolved conservatively and there were no ERCP-related deaths.

We did not perform a multivariate analysis, since the number of events was small and relevant variables were symmetrically distributed.

Results of the analysis are summarized in the flow diagram shown in figure 2.

DISCUSSION

Difficulty in extracting stones from the biliary tree is determined by the number, size and shape of the stones, as well as the diameter and position of the distal main bile duct. Thus, a 10 to 15% failure rate occurs when the conventional ES technique is used. In order to overcome this, various extraction techniques have been implemented.

In 2003, Ersoz et al. described LBD after performing a mid-size ES (3), and their method proved effective for the extraction of biliary stones. Since then, many studies have been published showing a success rate of 83 to 100% using 12 to 20 mm diameter to extract stones measuring 13 to

Table II. Comparison of radiation exposure with both procedures

Radiation	ES/LBD	Wide ES	<i>p</i>
Time in seconds (median, 95% CI)	228 (157.5-371.3)	422 (302-479)	0.079
Dose (mGy) (median, 95% CI)	26.2 (19.4-43.4)	39.8 (27.9-59.9)	0.134
DPA (mGy/m ²) (median, 95% CI)	0.59 (0.39-0.96)	0.69 (0.48-1.02)	0.724

ES: Sphincterotomy; LBD: Large balloon dilation; DPA: Dose per area.

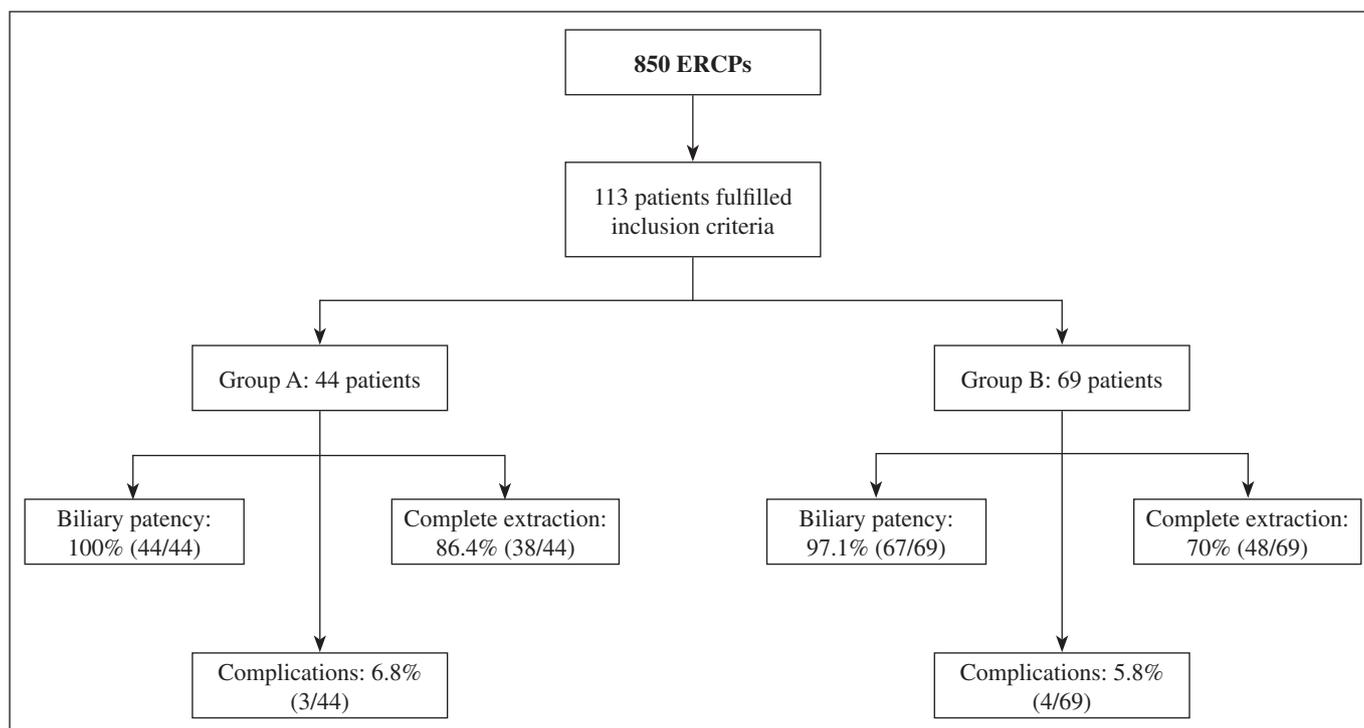


Fig. 2. Flow diagram: Results.

16 mm (11-15). In all studies except one (16), the need for ML was less than 10%.

When ES is performed for giant stones, the risk of complications such as perforation and bleeding increases (17-19).

In our study, ES plus LBD allowed a complete extraction of stones during the first session in 86.4% of cases; among them additional ML was used in 15.9%. These results are in agreement with those previously published (6,11,20). Regarding the higher rate of ML in our study as compared to other published data, we believe that it could be related to the large stone size in our patients (> 20 mm and a Stone Index > 4), rather than to the technique employed, since there were no significant differences among both groups.

Our data suggest that successful extraction rates are higher and the use of ancillary methods such as ML is lower when using the ES/LBD technique, although in none of the two cases did the difference reach statistical significance.

Among the subgroup of patients with giant stones, successful extraction was significantly better in group B.

In the present series, although the group undergoing wide ES required a longer procedure time, DPA and total radiation dose, the difference between groups was not significant. We believe that this may be related to the higher rate of ML in this group. Exposure to radiation is a serious issue affecting endoscopists, the operating room staff and patients. Uradomo et al. observed in his study (21) that ML is the method with the highest radiation exposure. Hence, if the use of dilating balloons decreases the rates of ML, it would add the indirect benefit of decreasing radiation exposure for everyone involved.

Procedure-related complications were 6.8 and 5.8% in groups A and B respectively. Although differences between groups are not significant and average rates do not differ from those published in the literature, it is worth noting that in the group undergoing wide ES there was one case of perforation and one case of basket entrapment, while the two cases of pancreatitis in the study occurred in the group of balloon dilation. The pathophysiology of these complications could be related to the respective techniques.

Perforation was due to a maximum ES and subsequent biliary instrumentation to extract a giant stone, while the two pancreatitis could have been due to involvement of the pancreatic sphincter during dilation. Regarding this last point, we should underscore that as stated by Heo et al. in their paper (13), performing a minimal ES before dilation results in separation of the pancreatic and biliary orifices that could decrease the incidence of this complication.

As a strength of this study, we would like to emphasize the characteristics of the stones included (20 mm and a Stone index > 4), since most published studies include stones > 10 mm but < 20 mm in size, and do not specify the characteristics of multiple lithiasis.

As limitations, we mention that this was a non-randomized study, which entails a potential source of bias. The lack of statistical power seen in the analysis of results is related to the small sample size of the study.

CONCLUSION

The ES/LBD technique is a simple, safe and effective method for the removal of difficult lithiasis. With this technique, dose and time of radiation can be reduced, as well as the need to perform ML. Future prospective and randomized studies with adequate sample size will be useful to further clarify the differences between both techniques.

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