# Can Endoscopic Papillary Large Balloon Dilation (EPLBD) Decrease the Need for Mechanical Lithotripsy in Patients with Giant Biliary Stones?

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## Abstract

**Introduction:** About 10% to 15% of patients with choledocholithiasis develop a giant calculus, defined as one that measures more than 10 mm to 15 mm. Removal of these stones can be problematic even for experienced endoscopists. Almost all patients with this pathology can be treated endoscopically: most are removed with sphincterotomies, mechanical lithotripsy (ML) or large balloon papillary dilatation (LBPD). LBPD has been shown to be effective in handling giant calculi and decreases the need for ML.

**Objectives:** The aim of this study was to determine the prevalence of giant choledocholithiasis at HUS between 2009 and 2014, the frequency of successful endoscopic treatment, and the frequency of surgery in these cases. We also evaluated factors associated with the use of lithotripsy to remove giant biliary calculi.

**Materials and Methods:** This study is a case-control study of patients who had giant calculi and underwent ERCP at the HUS between 2009 and 2014. Calculi larger than 10 mm were defined as giant. Cases were patients who underwent lithotripsy while controls were those who did not require lithotripsy. The results for continuous variables are presented as means or medians and their respective measures of dispersion while results for categorical variables are presented according to tests of normality or as frequencies and percentages. A logistic regression analysis was used to determine factors associated with lithotripsy. Biologically plausible variables and those that had statistically significant differences in the bivariate analysis ($p < 0.200$) were included. The results are presented as adjusted odds ratios (ORA).

**Results:** Between 2009 and 2014, a total of 1403 ERCPs were performed. Giant calculi were found in 198 (14.1%) of these procedures. Giant choledocholithiasis was more common in female patients than in male patients. The patients' mean age was 66.6 years. The average diameter of the common bile duct was 18 mm, and the average diameter of the stones was 18 mm. Ninety-nine percent of these patients underwent sphincterotomies, 28% required ML, 48% underwent LBPD, 5.5% required ML and LBPD, and 30.8% required biliary stents and more than one ERCP for the resolution of choledocholithiasis. In 89.9% of cases, endoscopic management was successful. Only 10.1% of the total number of patients required surgery. Complications occurred in 9.0% of the cases: 6 cases of pancreatitis, 7 cases of bleeding, 2 impacted cannula and 1 perforation. In the bivariate analysis, LBPD was a protective factor against the need for ML (ORA 0.07-IC 95% 0.025-0.194) and choledochal size was a predictor a need for MM ($p < 0.05$).

**Conclusions:** In our series the prevalence of giant choledocholithiasis and the success of endoscopic management are similar to those reported in the literature. Sphincterotomies, ML and LBPD were effective for managing giant calculi. Choledochal size is a predictor of a need for ML while performance of LBPD decreased the need for ML.

## Keywords

Choledocholithiasis, giant calculi, mechanical lithotripsy, large balloon papillary dilation.


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## INTRODUCTION

Gallstone disease affects more than 20 million adults in North America, with an annual cost of $6.2 billion. (1) Approximately 85% to 90% of gallstones can be removed with a balloon or a basket after a sphincterotomy or endoscopic papillary large balloon dilation (EPLBD). (1, 2) Approximately 10% to 15% of patients with choledocholithiasis present a giant calculus, defined as one that measures more than 10 mm to 15 mm (Figure 1). Removal of these can be problematic even for experienced endoscopists. Almost all patients with this pathology can be treated endoscopically, and most of the calculi are extracted by performing a sphincterotomy, mechanical lithotripsy (ML) or endoscopic papillary large balloon dilation (EPLBD). (1, 3, 4 , 5)

**Figure 1.** Giant biliary calculus

ML was first described in 1982 and has historically been the most frequently used technique for management and extraction of giant stones. It has had success rates of 79% to 92%. Failures in calculus extraction with this technique are due to calculus impaction in the common bile duct. Calculi larger than two cm are predictors of failure. The incidence of complications with its use varies between 6% and 13%, and pancreatitis and bleeding are the most frequent. (1, 5) We have previously reported our success rate with ML to be 89%, and calculi sizes of more than 24 mm were similarly predictive of failure. (6)

EPLBD was introduced as an alternative to sphincterotomies for patients with small to moderate stones (4 mm to 10 mm). However, this procedure is associated with a high risk of pancreatitis and need for additional ML. (7, 8) EPLBD for the removal of stones larger than 10 mm and/or multiple gallstones after limited or small sphincterotomies was first described in 2003 by Ersoz et al.. It has been shown to be effective for managing giant stones and, according to some studies, decreases the need for ML. (3, 4, 8) This method combines the advantages of sphincterotomies and EPLBD and increases the rate of stone extraction while decreasing the complications of sphincterotomies alone and EPLBD alone. (7) It is performed using balloons that measure 12 mm to 20 mm and leads to a wider papillary aperture than those obtained with sphincterotomy alone or EPLBD alone. The technique allows extraction of calculi without the need for ML and, therefore shortens the time of the procedure and irradiation. (1, 8, 9, 10, 11, 12)

## OBJECTIVES

The aims of this study were to determine the prevalence of choledocholithiasis with giant stones in patients at the HUS between 2009 and 2014, to determine the frequency of successful endoscopic management, to determine the need for surgical management, and to evaluate factors associated with the use of lithotripsy to remove giant stones from the biliary tract.

## MATERIALS AND METHODS

We retrospectively reviewed the clinical records of patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) during the period between January 2009 and December 2014. The prevalence of giant stone choledocholithiasis was calculated using a definition for giant calculi as those larger than 10 mm . A retrospective case-control study was performed with cases defined as patients who had undergone lithotripsy and controls defined as those who did not require this procedure. The procedures were performed by gastroenterologists from the Hospital Universitario de la Samaritana, a fourth-level referral center for the department of Cundinamarca, Colombia. Two Olympus duodenoscopes, a GIF-Q180V and a TJF-Q180V were used in the procedures. The results for continuous variables are presented as means or medians with respective dispersion measures indicated according to normality tests. Frequencies and percentages are used for categorical variables. A logistic regression analysis was

performed with the main objective of determining factors associated with lithotripsy. These included biologically plausible variables and variables which showed statistically significant differences in bivariate analysis (p <0.200). The results are presented as adjusted odds ratios (ORA).

## RESULTS

A total of 1,403 ERCPs were performed between 2009 and 2014. Of these, 198 (14.1%) had giant stones. The average age was 66.67 years, and 70.7% of the patients were women while 29.3% were men. The median diameter of the common bile duct was 18 mm, with an interquartile range (IQR) of between 15 and 20 mm. Table 1 summarizes findings for the total population. In addition to the group of patients who underwent lithotripsy, the failure rates and cases of partial lithotripsy are shown.

**Table 1.** General characteristics of patients included

| Characteristic | Valor |
|---|---|
| Age in years (mean ± SD) | 66.68 ± 15.71 |
| Bile duct size in mm (median, IQR) | 18 (16-20) |
| Largest diameter of calculus in mm (median, IQR) | 18 (15-21) |
| Smallest diameter of calculus in mm (median, IQR) | 15 (13-18) |
| EPLBD, n/N (%) | 95/198 (48.0) |
| Papillotomy, n/N (%) | 196/198 (99.0) |
| Balloon, n/N (%) | 122/198 (61.6) |
| Basket, n/N (%) | 164/198 (82.8) |
| Stent, n/N (%) | 61/198 (30.8) |
| Surgery, n/N (%) | 19/198 (10.1) |
| Lithotripsy, n/N (%) | 56/198 (28.3) |
| Lithotripsy failed, n/N (%) | 7/56 (12.5) |
| Partial lithotripsy, n/N (%) | 5/56 (8.9) |

SD: standard deviation; IQR: interquartile range

The average diameter of the common bile duct was 18 mm, and the average diameter of the stones was also 18 mm. Ninety-nine percent of the patients underwent sphincterotomies, 28% required ML, 48% underwent EPLBD, 5.5% required ML and EPLBD, and 30.8% required biliary stents and more than an ERCP for the resolution of choledocholithiasis. In 89.9% of cases, endoscopic management was successful while 10.1% required surgery. Nine percent of the cases had complications which included six cases (3.0%) of pancreatitis, all of which were mild; seven cases (3.5%) of bleeding from the area of the papillotomy, none of which required surgery; two (1.0%) impacted baskets, and one case of perforation (0.5%) who received conservative medical management. Both cases of impacted baskets occurred in patients who underwent ML: one was resolved with the emergency lithotripter and the other was resolved with surgery.

There were no mortalities associated with the procedure.

Bivariate analysis evaluated whether EPLBD behaves as a protective factor against the need for lithotripsy. EPLBD was found to be protective factor against the need for ML (AOR = 0.07, 95% CI: 0.025 to 0.194), and the size of the common bile duct was found to predict a need for ML (p <0.05).

Tables 2 and 3 present the results of the bivariate analysis with crude ORs, and the results of the logistic regression. The analysis was adjusted according to the other variables included in the study which were susceptible to confusion or interaction and according to those which showed significant differences in the bivariate analysis.

## DISCUSSION

About 10% to 15% of patients with choledocholithiasis have a giant stone. The extraction of these stones can be problematic even for experienced endoscopists. In our series, the prevalence of giant stones in patients undergoing ERCP due to choledocholithiasis was 14.1% (n = 198).

**Table 2.** Bivariate analysis

| Variable | Lithotripsy | | p | OR (95% CI) |
|---|---|---|---|---|
| | Yes | No | | |
| Age, years (mean ± SD) | 66.86 ± 14.5 | 66.61 ± 16.20 | 0.920* | NC |
| Choledochal size in mm (median, IQR) | 19.0 (17.0-22.0) | 18.0 (15.0-20.0) | 0.013^ | NC |
| Largest diameter of the calculus in mm (median, IQR) | 19.0 (15.0-23.0) | 18.0 (15-20) | 0.149^ | NC |
| Smallest diameter of the calculus in mm (median, IQR) | 15.0 (14.0-18.5) | 15.0 (13.0-18.0) | 0.394^ | NC |
| Male, n/N (%) | 16 (27.6) | 42 (72.4) | 0.889⁺ | 0.952 (0.481-1.885) |
| EPLBD. n/N (%) | 5 (5.3) | 90 (94.7) | 0.000⁺ | 0.057 (0.021-0.151) |

*Student's T test for differences of means; ^Mann-Whitney U test. ⁺ Chi² test

**Table 3.** Variables associated with the outcome of required lithotripsy

| Variable | AOR (95% CI) | p |
|---|---|---|
| Age | 0.998 (0.972-1.023) | 0.857 |
| Male | 0.619 (0.268-1.422) | 0.619 |
| Choledochal size | 1.117 (1.004-1.242) | 0.041 |
| Largest diameter of calculus | 0.996 (0.932-1.065) | 0.908 |
| EPLBD | 0.070 (0.025-0.194) | 0.000 |

AOR: adjusted odds ratio

This figure is similar to those reported in the literature. Our success rate with endoscopic management was 89.9%, and only 10.1% of the patients required surgical management. ML was performed in 28.3% of the cases, and its success rate was 89% as previously reported. Since 2011, the year in which we using EPLBD, this procedure has been performed in 48% of patients. From the beginning, our need for ML decreased, and only 5.5% of patients required EPLBD and ML. The size of the common bile duct was a predictor of the need for ML.

EPLBD after limited or small sphincterotomies for removal of stones larger than 10 mm and for removal of multiple gallstones was first described in 2003 by Ersoz et al. (1, 8, 9, 12) A larger opening of the biliary orifice is created with a large diameter balloon (12 mm to 20 mm) to simplify removal of giant and difficult bile duct stones and as an alternative to ML which is time consuming and can generate impaction or fracturing of the Dormia basket all of which increase the risk of adverse events. Sphincterotomy prior to EPLBD is recommended since it is believed decrease risk of pancreatitis following the procedure (Figure 2). (8, 9, 13, 14) It can be used as the initial method giant stones have been found in images or when conventional removal with a sphincterotomy and basket have failed. (14, 15, 16)

Factors associated with risks of adverse events resulting from the procedure include the size of the sphincterotomy, the diameter of the balloon used, and the manner of inflation of the balloon. (8, 9, 14) The diameter of the distal bile duct is the most important factor involved in selection of the diameter of the balloon to be used since dilation beyond the diameter of the bile duct increases the risk of perforation. For this reason, the maximum diameter of inflation of the balloon must not exceed the largest diameter of the distal common bile duct. Although diameters of the balloons for EPLBD range from 12 mm to 20 mm, 12 mm to 15 mm are used in most cases balloons in order to prevent adverse events (Figure 3). Rapid and forced inflation of the balloon through a narrow distal bile duct can lead to perforation and bleeding. The balloon should always be inflated slowly and gradually until its waist disappears (Figure 4). If the waist

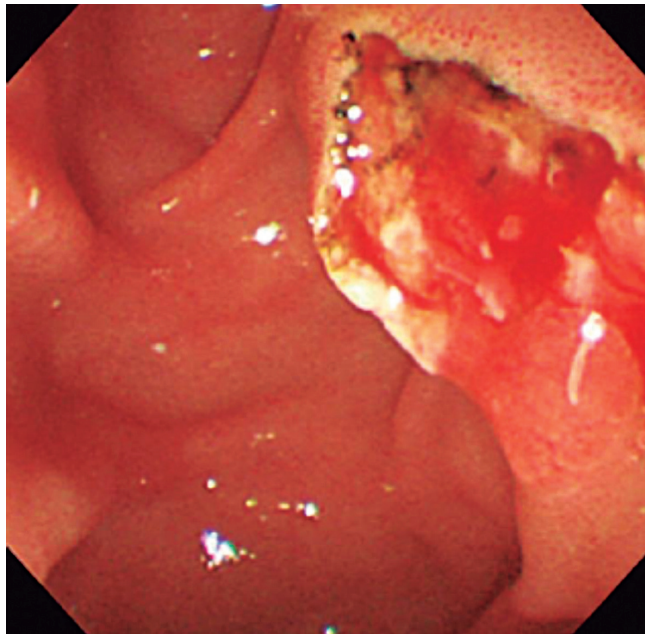

**Figure 2.** Medium sphincterotomy

**Figure 3.** Endoscopic Large Balloon Papillary Dilation (EPLBD)

of the balloon does not disappear, an occult biliary stenosis may be present. Dilation should stop at this point, and the balloon should be deflated to avoid risk of complications. In patients with evident biliary stenosis, or ducts that do not dilate, EPLBD is not recommended due to the risk of perforation. (17, 18) The usual duration of the EPLBD is

**Figure** 4. Dilation (waist of balloon)

30 to 60 seconds after the waist disappears, although studies report durations of dilation ranging from 10 seconds to 180 seconds. (14, 18) Additional studies are required to establish the optimal duration of dilation. In our series, the dilation time was 60 seconds.

ML has been shown to be a time-consuming technique which is related to adverse events such as impaction of the basket and bile duct injury. (14) It has been proposed that the widened papillary orifice created with EPLBD facilitates the removal of large stones and reduces the need for ML. Some metaanalyses have reported that EPLBD has reduced the need for ML more than have sphincterotomies alone, (8, 19, 20, 21) but metaanalyses have not reported any significant differences and consider that this statement is only speculation. (22) In our series, EPLBD was a strong protective factor against the use of ML as shown in both the multivariate analysis and the logistic regression.

The overall rate of adverse events including pancreatitis, bleeding and perforations is lower for EPLBDs than for sphincterotomies alone. This can be seen in four metaanalyses that have compared EPLBD plus sphincterotomy with sphincterotomy alone. (14, 19, 21, 22, 23) Analysis of subgroups in a large-scale multicenter case-control study of 946 patients has shown that calculi larger than 16 mm, cirrhosis, and total sphincterotomies were factors independently associated with adverse events. In addition, EPLBD does not increase the risk of pancreatitis. A systematic review of EPLBD studies has shown that pancreatitis occurred in 2.4% of patients who underwent EPLBD plus sphincterotomy. (14) A possible mechanism for reducing the rate of pancreatitis is the radial force exerted towards the bile duct and away from the pancreatic orifice during sphincterotomy dilation which produces a smaller periampullary lesion around the pancreatic duct. (13, 14) Nevertheless, it is believed that sphincterotomies have a limited role in preventing pancreatitis in patients with EPLBD, since patients with EPLBD without sphincterotomies do not have increased risk of pancreatitis. Another hypothesis about the mechanism of pancreatitis postulates that the amount of manipulation with Dormia basket and extraction balloon is reduced for both EPLBD with sphincterotomy and EPLBD without sphincterotomy because the papillary orifice is sufficiently large (Figure 5). This resulting in less periampullary trauma, less edema and lower risk of pancreatitis. This may explain why dilation with smaller caliber balloons (<10 mm) has higher risks of causing lesions of the orifice of the ampulla. These lesions could be caused by passage of instruments for extraction of stones through an inadequately enlarged orifice. (14)

In our series, the complication rate was consistent with that reported in the literature. There were six mild cases of pancreatitis (3.0%); two cases of impacted baskets (1.0%), both of which occurred in patients who underwent; and one perforation (0.5%) which was not associated with EPLBD but rather with the fin of a biliary stent and which was managed conservatively.

**Figure 5.** Papillary orifice following dilation

## CONCLUSIONS

The prevalence of giant stones and endoscopic management's success rate in our institution are similar to those reported elsewhere in the literature. EPLBD with medium sphincterotomy is a safe procedure, and EPLBD is a strong protective factor against the use of lithotripsy. This can reduce endoscopic time and the complications derived from this therapy as well as the additional costs.

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