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Outcome of Digital Cholangioscopy and Laser Lithotripsy for Impacted Biliary Stones

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Abstract

Background and Aims Impacted stones in the bile duct are difficult to extract, and are predictor of failure of conventional endoscopic retrograde cholangiopancreatography techniques including mechanical lithotripsy and large balloon dilatation. Intracorporeal lithotripsy may be an effective technique for these stones. The aim of this study is to report the efficacy and safety of intracorporeal laser lithotripsy for impacted stones in the bile duct.

Method This study is retrospective analysis of prospectively collected data. Patients with impacted stones in the bile duct underwent cholangioscopy with spyglass DS system and laser lithotripsy. Outcome measures were proportion of patients with complete clearance of bile duct after the first session, number of sessions required for complete clearance, and the complications.

Results Forty-three patients (27 female) with mean age of 56.12 ± 15.16 years underwent digital cholangioscopy and laser lithotripsy. Mean bilirubin value was 1.8 ± 1.6 mg/dL, 20 (46.51%) patients had single stone, 35(81.39%) patients had only bile duct stones, and 8 (18.61%) patients had additional stones in cystic duct or intrahepatic biliary radical. Mean size of largest stone was 16.2 ± 4.4mm. Average duration of the procedure was 69.11 ± 28.12minutes, and complete clearance was achieved in 41/43 (95.34%) patients after the first session. Mean number of sessions required for complete clearance was 1.02 ± .26. Postprocedure cholangitis occurred in one patient.

Conclusion Intracorporeal laser lithotripsy is an effective and safe modality for the clearance of impacted bile duct stones.

Keywords
- cholangioscopy
- impacted biliary stones
- laser lithotripsy

Introduction

Endoscopic sphincterotomy (EST) is considered the method of choice for clearing bile duct stones.[1] By using EST and standard endoscopic maneuvers up to 90% of bile duct stones can be removed.[2] Rate of successful extraction declines with increasing size of the stone.[3] Stone more than 15 mm in size is considered difficult to remove with standard methods and

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both large balloon dilatation and mechanical lithotripsy have been used for the clearance of these stones. Impacted stones with size larger than distal common bile duct (CBD) are a predictor of failure for mechanical lithotripsy, and failure rate of up to 80% has been reported for these stones.[4] Further options are surgery, extracorporeal or intracorporal lithotripsy, and long-term stent placement. Surgery has associated morbidity; extracorporeal lithotripsy may increase the morbidity as it requires multiple sessions and nasobiliary drain placement. Intracorporal lithotripsy has gained popularity because of single-session treatment and high efficacy. At our center, we are treating impacted stones with digital cholangioscopy and laser lithotripsy. The aim of this study is to evaluate the efficacy and safety of intracorporal lithotripsy in patients with impacted biliary stones.

Patients and Methods

This study is a retrospective analysis of prospectively collected data at tertiary care center of North India. Data of all the patients who underwent digital cholangioscopy and laser lithotripsy from June 2017 to December 2019 was prospectively collected. Information regarding demographic, procedural, follow-up clinical detail was retrieved. Institute review board approved the study (EC/04/19/1519).

Inclusion and Exclusion Criteria

All the patients with impacted stones (►**Fig. 1**) treated with intracorporal lithotripsy with digital cholangioscopy and laser lithotripsy were included in the analysis. Stone was defined as impacted if all the following criteria were present: (1) stone size larger than the CBD size below the stone, (2) inability to grasp the stone with basket or mechanical lithotripter due to limited space between stone and bile duct wall, and (3) inability to move the stone up in proximal bile duct.

Patients with isolated intrahepatic stones or cystic duct stones were excluded from the analysis. Other exclusion criteria were patients with coexisting liver disease, chronic kidney disease stage IV and V, platelet count less than 50,000/mm^3, international normalized ratio more than 1.5, and pregnancy.

Procedural Details

Informed consent was obtained from all the patients. Procedures were performed under moderate sedation with midazolam and pentazocine. If the procedure time was expected to be more than 1 hour, or at the anesthetist discretion, lithotripsy was performed under general anesthesia with endotracheal intubation. Therapeutic duodenoscope with 4.2mm channel (TJF Q180V, Olympus, Tokyo, Japan) was used for endoscopic retrograde cholangiopancreatography (ERCP). After CBD cannulation (►**Fig. 1A**) obtaining the cholangiogram (►**Fig. 1B**), further assessment and decision were taken depending upon the stone size and lower CBD diameter. If stone appeared larger than lower CBD, partial sphincterotomy (half of length of the intraduodenal part of sphincter, Ultratome XL, Boston Scientific, Massachusetts, United States) and balloon dilatation (CRE Boston Scientific, Massachusetts, United States) were performed. Ampullary and bile duct dilatation were performed using the

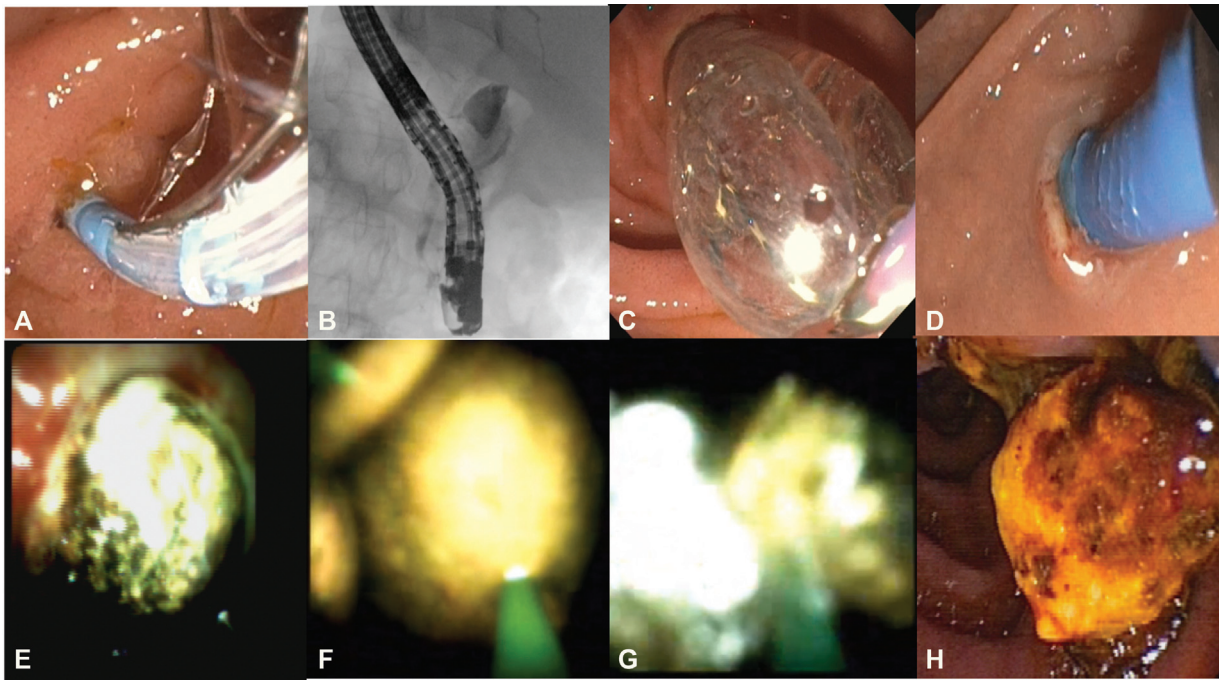

Fig. 1 **(A)** Selective common bile duct (CBD) cannulation. **(B)** Impacted stone at junction of bile duct and cystic duct with nondilated lower bile duct seen on cholangiography. **(C)** Balloon dilatation of ampulla. **(D)** Cholangioscope inserted into the CBD. **(E)** Visualization of CBD stone using cholangioscope. **(F)** Laser inserted through the working channel of the scope. **(G)** Stone fragmented using laser. (**H**) Stone retrieval from CBD using ballooning and basketing.

10-, 12-, or 15-mm balloon (►**Fig. 1C**), depending upon the size of lower CBD. Sphincterotomy extension was not done in patients who had undergone sphincterotomy previously, and only the balloon dilatation of papilla was performed. Mechanical lithotripsy (LithoCrush V, BML V242QR-302, Olympus, Tokyo, Japan) was attempted next. If mechanical lithotripsy failed, and proximal bile duct was dilated, attempt was made to push the stone in upper bile duct followed by repeat attempt of mechanical lithotripsy. In case of failure to push the stone in upper CBD, cholangioscopy and laser lithotripsy were the next step. In few patients, where proximal bile duct was also nondilated, upfront cholangioscopy and lithotripsy were performed without attempting mechanical lithotripsy. Cholangioscopy was performed with spyglass DS system (Spyscope DS, digital controller, access and delivery catheter, Boston Scientific, Massachusetts, United States), equipped with irrigation and aspiration system. Single or two operator cholangioscopy was performed depending upon the complexity of the procedure. Cholangioscope was introduced through the 4.2 mm working channel of duodenoscope by free-hand technique (►**Fig. 1D**), and the stone was visualized (►**Fig. 1E**). In case of sharp angulation at papilla, cholangioscope was introduced in CBD over the wire (0.025, Visiglide, Olympus, Tokyo, Japan). Laser fiber (200 or 365 µ) was introduced through the spyscope working channel (►**Fig. 1F**), and up to 16W (Auriga, Holmium Laser, Boston, Massachusetts, United States) energy was delivered for lithotripsy (►**Fig. 1G**). Continuous irrigation was done to clear the vision field. Crushed stone fragments were removed (►**Fig. 1H**) with balloon sweep (Extractor Pro XL, Boston Scientific, Cork, Ireland), basket trawl (Dormia, Olympus, Tokyo, Japan) and if required, mechanical lithotripsy. Bile duct clearance was confirmed both by cholangioscopy and contrast injection and was followed by stent placement in the bile duct.

Study outcome were the proportion of the patients with complete ductal clearance at the end of the first session of laser lithotripsy, mean number of sessions required to achieve the complete ductal clearance, and the adverse events. Complete ductal clearance was defined as absence of stone in bile duct and biliary radicals confirmed by cholangioscopy and contrast injection. Any episode of pancreatitis, cholangitis, and leak related complications was recorded. Peter Cotton definition was used to define the complications.[5]

Table 1 Demographic and baseline characteristics ($n = 43$)

Age (years), mean (SD)	56.12 ± 15.16
Male, *n* (%)	16 (37.20%)
Total bilirubin (mg/dL), mean (SD)	1.8 ± 1.6
White blood cell count n/mm,^{3} mean (SD)	$11.72 \pm 2.17 \times 10^3$
Alkaline phosphatase (IU/L), mean (SD)	281.12 ± 409.20
Previous sphincterotomy, *n* (%)	30 (69.76%)
Previous cholecystectomy, *n* (%)	18 (41.86%)

Abbreviation: SD, standard deviation.

Sample size calculation was based on results of previous study,[6] which has shown efficacy of 86% for first session clearance with laser lithotripsy. With a precision of 10% and confidence interval of 95%, calculated sample size was 46. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean and standard deviation. SPSS software version 17.0 was used for analysis

Results

During the study period between July 2017 and December 2019, 43 patients (27 female; mean age 56.12 ± 15.16 years) underwent digital cholangioscopy and laser lithotripsy for impacted stones in the bile duct. Demographic and baseline data are mentioned in ►**Table 1**. Thirty (69.76%) patients had attempt at stone removal at other center, and were refereed for complete bile duct clearance. In 38(88.37%) patients, moderate sedation was used. General anesthesia with endotracheal intubation was required in five (11.63%) patients. Procedure related details are mentioned in ►**Table 2**.

Table 2 Intraprocedural findings during ERCP and cholangioscopy ($n = 43$)

No of stones $n = 43$	Single, *n* (%) Multiple, *n* (%)	20 (46.51%) 23 (53.49%)
Location of stone $n = 43$	Common bile duct only, *n* (%) Common bile duct and cystic duct, *n* (%) Common bile duct and intrahepatic duct, *n* (%)	35 (81.39%) 3 (6.97%) 5 (11.62%)
	Diameter of largest stone, mm, (mean ± SD)	16.2 ± 4.4
Complete stone clearance	Total, *n* (%) Stones only in bile duct, *n* (%) Bile duct stones with cystic duct stones, *n* (%) Bile duct stones and intrahepatic stones, *n* (%)	41/43 (95.34%) 35/35 (100%) 3/3 (100%) 03/05 (60%)
Procedure time (mean ± SD)	Mean procedure time, minutes Stones only in bile duct Bile duct stones with cystic duct stones Bile duct stones and intrahepatic stones, *n* (%)	69.11 ± 28.12 65.1 ± 19.95 82.5 ± 38.89 85 ± 35.35

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; SD, standard deviation.

Thirty-five (81.39%) patients had stones only in bile duct, and eight (18.61%) patients had stones additionally in either cystic duct or intrahepatic biliary radical. Mean size of largest stone was 16.2 ± 4.4mm. Eight patients (18.6%) had largest stone more than 20 mm in size. Three patients had stricture in the lower bile duct; in all the patients, narrowing was seen at single site. Mechanical lithotripsy was attempted initially in 25 (58.13%) patients, and in rest of the patients cholangioscopy and laser lithotripsy were performed as upfront procedure. Balloon (10, 12, and 15 mm) was used for papillary dilatation in 3 (6.97%), 36 (83.72%%), and 4 (9.30%) patients, respectively.

Cholangioscopy visualization and targeting of the stone were successful in all the patients. Complete clearance was achieved in 41/43 patients (95.3%) after a single session. Two patients required one additional session; both these patients had intrahepatic stones also. Procedure was stopped in both the patients because of prolonged duration. Both the patients underwent one more session of cholangioscopy and laser lithotripsy after 2 weeks, and ducts were cleared. Mean number of sessions required for complete clearance was $1.02 \pm .26$. The mean duration of procedure from scope insertion to withdrawal was 69.11 ± 28.12 minutes. Duration of procedure in patients with isolated CBD stones was lower than those associated with cystic duct and intrahepatic stone. One patient developed cholangitis after the procedure, and improved with intravenous antibiotics. None of the patient had pancreatitis or leak related complication.

Discussion

ERCP and CBD clearance is the treatment of choice for CBD stones. Conventional methods of CBD clearance with sphincterotomy or sphincteroplasty have been the standard of care and have been successful in 85 to 90% of patients. Multiple stones (more than 3 in number), stone size more than 15mm, impacted stones, barrel-shaped stones, and intrahepatic or intracystic stones are predictors of difficult ERCP and also predictors of failure of conventional ERCP. Stricture below the stone and periampullary diverticulum also contribute to difficulty of the procedure.[7] As the stone is larger than the size of CBD below, balloon sweeps and basket trawls usually fail to remove the stone from the CBD. In these cases, stones need to be fragmented before the extraction. Mechanical lithotripsy is the next step in most of the circumstances, failing which, extracorporeal and intracorporeal lithotripsy are the alternatives. Mechanical lithotripsy also fails in the impacted stones because of difficulty in opening the basket around the stone.[4] Chang et al[8] analyzed data of 304 patients and concluded that stone impaction and narrowed lower CBD are important predictor of failure of mechanical lithotripsy. The introduction of cholangioscopy has been a great advancement in field of therapeutic ERCP. With the help of laser fiber introduced through the cholangioscope, difficult CBD stones can be pulverized. There is paucity of literature describing outcomes of cholangioscopy-guided laser lithotripsy in impacted CBD stones and we hereby describe our experience.

In this study, we focused on patients with impacted stones that is an important predictor for failure of conventional ERCP and also mechanical lithotripsy. We could achieve CBD clearance in about 95.3% of patients in a single session, while two patients required one additional session for ductal clearance. Prolonged procedure time was the reason for incomplete clearance in these patients. Maydeo et al[9] published a large series on the use of spyglass direct visualization system and holmium laser. Authors performed laser lithotripsy in 60 patients with large CBD stone, and single session clearance was possible in 83.33% of cases. Wong et al[10] published a series of 17 patients with complicated biliary stones, and 8 patients with impacted stone; overall clearance was 94% with median of one procedure. Navaneethan et al[6] published data of laser lithotripsy in 36 patients with difficult biliary or pancreatic stones, in which 36% stones were impacted. Complete duct clearance in one session was accomplished in 31/36 (86.1%) patients. In our study, we could also achieve a higher rate of stone clearance after first session. There are possibly two reasons for this. First, cholangioscopy and lithotripsy were performed by two operators in certain cases, as the one operator may find it difficult to maneuver two scopes, especially in technically difficult cases, where sharp angulations are required. Second, the use of general anesthesia with endotracheal intubation in few patients, where the prolonged procedure was anticipated.

Our study also included patients with cystic duct stones and intrahepatic along with CBD stones. About 11.6% of patients had intrahepatic stones and 6.97% of patients had associated cystic duct stones in our study. We could achieve clearance of all cystic duct stones along with the CBD stones. In a recent study by Pawa et al,[11] cholangioscopy with EHL was performed in 18 procedures to achieve cystic duct stone clearance. Cystic duct stone clearance was achieved in all patients and our findings are similar to the study. Two patients with intrahepatic stones required additional session of ERCP, and the reason was anticipated long duration for the procedure. In both the patients, complete clearance could be achieved during second session.

Higher rate of complications has been reported after cholangioscopy as compared to standard ERCP.[12] In our study, one patient developed cholangitis. Biliary stent was placed in all the patients to prevent the cholangitis. Goenka et al[13] described in their study an overall adverse event rate of 11.94%. Patients had acute pancreatitis, bleeding, and transient fever. Navaneethan et al[6] described cholangioscopy-related adverse events in three patients (2.9%) including cholangitis in two patients and postprocedure pancreatitis in 1 patient.

Strength of this study is the uniform and large number of cases with impacted stones with nondilated lower CBD. These are the most difficult stones to remove from the bile duct and are common cause of failure of conventional methods including mechanical lithotripsy and sphincteroplasty. More than one session is often required when conventional techniques are used. Treating these stones in a single session with cholangioscopy-guided laser is often

possible saving time and cost of an additional procedure. We have been thus able to demonstrate safety and efficacy of cholangioscopy and laser lithotripsy in impacted CBD stones.

Being a retrospective study, there are certain inherent limitations of the study. Certain parameters like exact stone size or the stone number and the complications may have been misinterpreted or missed. To conclude, our study has shown high efficacy and safety of digital cholangioscopy with spyglass DS system and holmium laser in patients with impacted bile duct stones.

Conflict of Interest
None declared.

References

1 Kawai K, Akasaka Y, Murakami K, Tada M, Koli Y. Endoscopic sphincterotomy of the ampulla of Vater. Gastrointest Endosc 1974;20(04):148–151
2 Binmoeller KF, Brückner M, Thonke F, Soehendra N. Treatment of difficult bile duct stones using mechanical, electrohydraulic and extracorporeal shock wave lithotripsy. Endoscopy 1993;25(03): 201–206
3 Lauri A, Horton RC, Davidson BR, Burroughs AK, Dooley JS. Endoscopic extraction of bile duct stones: management related to stone size. Gut 1993;34(12):1718–1721
4 Garg PK, Tandon RK, Ahuja V, Makharia GK, Batra Y. Predictors of unsuccessful mechanical lithotripsy and endoscopic clearance of large bile duct stones. Gastrointest Endosc 2004;59(06): 601–605
5 Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 2010;71(03):446–454
6 Navaneethan U, Hasan MK, Kommaraju K, et al. Digital, single-operator cholangiopancreatoscopy in the diagnosis and management of pancreatobiliary disorders: a multicenter clinical experience (with video). Gastrointest Endosc 2016;84(04):649–655
7 Stefanidis G, Christodoulou C, Manolakopoulos S, Chuttani R. Endoscopic extraction of large common bile duct stones: a review article. World J Gastrointest Endosc 2012;4(05):167–179
8 Chang WH, Chu CH, Wang TE, Chen MJ, Lin CC. Outcome of simple use of mechanical lithotripsy of difficult common bile duct stones. World J Gastroenterol 2005;11(04):593–596
9 Maydeo A, Kwek BE, Bhandari S, Bapat M, Dhir V. Single-operator cholangioscopy-guided laser lithotripsy in patients with difficult biliary and pancreatic ductal stones (with videos). Gastrointest Endosc 2011;74(06):1308–1314
10 Wong JC, Tang RS, Teoh AY, Sung JJ, Lau JY. Efficacy and safety of novel digital single-operator peroral cholangioscopy-guided laser lithotripsy for complicated biliary stones. Endosc Int Open 2017;5 (01):E54–E58
11 Pawa R, Dorrell R, Pawa S. Endoscopic management of cystic duct stones and Mirizzi's syndrome: experience at an academic medical center. Endosc Int Open 2022;10(01):E135–E144
12 Sethi A, Chen YK, Austin GL, et al. ERCP with cholangiopancreatoscopy may be associated with higher rates of complications than ERCP alone: a single-center experience. Gastrointest Endosc 2011;73(02):251–256
13 Goenka MK, Shah BB, Rodge GA, et al. Efficacy and safety of cholangioscopy guided laser lithotripsy for difficult bile duct stones - a prospective study from a tertiary care centre in Eastern India. Arab J Gastroenterol 2021;22(02):111–114

