



Cholangioscopy-Guided Lithotripsy in the Treatment of Difficult Bile Ducts Stones – Bulgarian and Egyptian Experience

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Abstract

Introduction: Up to 10% of bile duct stones are deemed 'difficult' because they cannot be extracted using standard endoscopic techniques. In these situations, cholangioscopy allows for stone fragmentation under direct visual control.

Aim: To evaluate the efficacy and safety of a digital single-operator cholangioscopy-guided lithotripsy in cases of difficult stones and to analyze factors related to adverse events and procedure time.

Materials and methods: A retrospective review of prospective databases from two tertiary referral centers was performed, which included 38 patients with difficult bile duct stones. All of the patients had previous endoscopic retrograde cholangiopancreatographies and at least one unsuccessful surgery to remove a stone. Following the standard protocol, we performed a digital single-operator cholangioscopy-guided lithotripsy using either electrohydraulic or laser lithotripsy. The main goal was to achieve ductal clearance, which was confirmed by a negative occlusive cholangiogram. We also investigated the occurrence of complications, the factors associated with them, and the variables influencing procedure duration.

Results: For the study period, 38 patients were treated with digital single-operator cholangioscopy-guided lithotripsy (33 with laser lithotripsy and 5 with electrohydraulic lithotripsy). Complete ductal clearance was achieved in 92.1% of cases, and in 78.9% of cases, it was accomplished in a single session. The average number of procedures until complete stone removal was 1.22 (1-3). The mean procedure times for electrohydraulic lithotripsy and laser lithotripsy was 83 minutes and 115 minutes, respectively. Complications, which were defined as mild, were observed in four (10.5%) patients. There was no correlation between age, size of stone, duration of the procedure and amount of saline used during lithotripsy and occurrence of complications. The presence of a stricture, barrel shaped or irregular shaped stones was associated with an increased risk of complications ($p < 0.05$). Large stones, multiple lithiasis, intrahepatic location, and failed previous EPLBD/ML were related to prolonged procedure time ($p < 0.05$).

Conclusions: A single-operator cholangioscopy-guided lithotripsy is a highly effective and safe procedure. The presence of a distal common bile duct stricture and complex shape of stones is associated with a higher risk of procedure complications.

Keywords

cholangioscopy, difficult stones, digital single-operator cholangioscopy, ERCP, lithotripsy, SpyGlass

Abbreviations:

ERCP: endoscopic retrograde cholangiopancreatography
CBD: common bile duct
POC: peroral cholangioscopy
SOC: single-operator cholangioscopy
D-SOC: digital single-operator cholangioscopy
LL: laser lithotripsy

EHL: electrohydraulic lithotripsy
EPLBD: endoscopic papillary large balloon dilation
ML: mechanical lithotripsy
ESGE: European Society of Gastrointestinal Endoscopy
ASGE: American Society of Gastrointestinal Endoscopy

INTRODUCTION

Endoscopic extraction is the preferred method for treating bile duct stones, with a success rate of more than 90%. Up to 10% of the bile duct stones cannot be extracted endoscopically despite using advanced techniques, such as endoscopic papillary large balloon dilation or mechanical lithotripsy. Stones are considered 'difficult' when they are larger than 15 mm, multiple, intrahepatic, located in the cystic duct, impacted or when they are associated with a distal stricture of the common hepatic duct or with altered anatomy.^[1] Other factors related to the difficulties of conventional extraction could be a sigmoid-shaped common bile duct, low take-off of the cystic duct, or the presence of a perampullary diverticulum. In these situations, different removal techniques are required.^[2] Peroral cholangioscopy offers the possibility of managing difficult stones with the advantage of direct visualization. They can be targeted and fragmented using electrohydraulic lithotripsy (EHL) or laser energy (LL) (Figs 1, 2). LL focuses laser light on the stone surface, creating gaseous collection of ions and free electrons (plasma), which expands and collapses. The induced mechanical shock wave leads to stone fragmentation. By EHL, sparks are generated in aqueous medium,

leading to formation of high frequency hydraulic pressure waves. These high frequency waves are absorbed by the stone and lead to its fragmentation.^[3]

AIM

The aims of the present study were to evaluate the efficacy and safety of D-SOC-guided lithotripsy using SpyGlass DS (Boston Scientific corp. Natick MA, USA) in cases of difficult bile duct stones, and to analyze factors related to adverse events and prolonged procedure time.

MATERIALS AND METHODS

We performed a retrospective review of prospective databases from two tertiary referral centers between February 2016 and April 2019. Thirty-eight patients with difficult bile duct stones, treated with D-SOC-guided LL or EHL, were included in the study. The procedures were performed in two centers: the Department of Interventional Gastroenterology at Acibadem City Clinic Tokuda Hospital in Sofia, Bulgaria, and the Department of General Medicine and

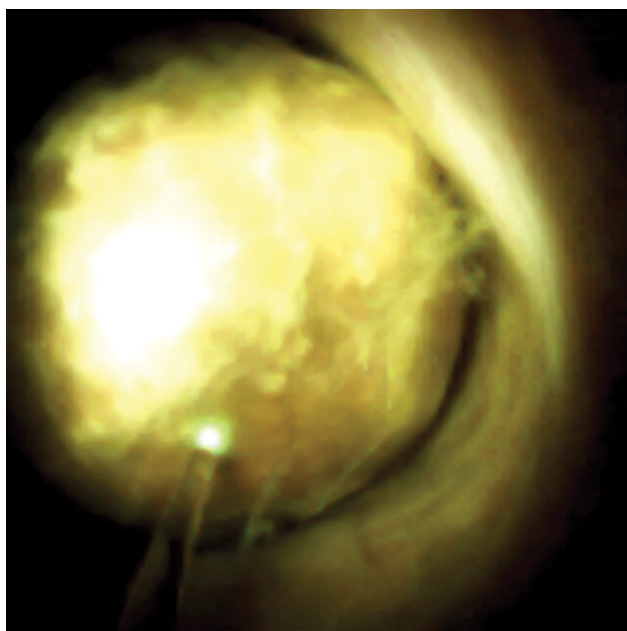


Figure 1. Cholangioscopic image of a common bile duct stone.

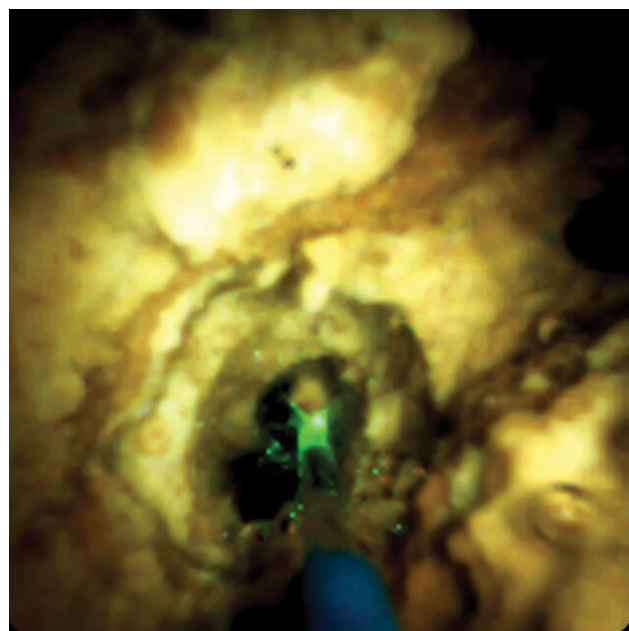


Figure 2. SOC-guided laser lithotripsy.

Gastroenterology at the National Hepatology and Tropical Medicine Research Institute of Cairo in Egypt.

Patients

All 38 patients had previously undergone biliary sphincterotomy and ERCP with a stone-removal attempt by an experienced endoscopist. In 74% of the cases, a previous ERCP with EPLBD and/or mechanical lithotripsy were performed without success in one of the two tertiary referral centers. The remaining cases were contraindicated for EPLBD due to association with a distal stricture. In two patients (5.2%), cholangioscopy was carried out as prompt salvage therapy because of impacted Dormia basket during an ERCP procedure. All patients met some of the widely accepted criteria for difficult biliary stones: large size (over 15 mm), multiple lithiasis (>3 stones), irregular or barrel-shaped stones, intrahepatic or cystic duct localization, localization over a stricture, presence of a duodenal diverticulum or previous surgery of the upper gastrointestinal tract.

Technical equipment

All cholangioscopies were performed with the second generation Spy Glass Digital Simple System– SpyGlass DS (Boston Scientific Corp.). A flexible 272- μ m fiber with 2–2.5 J, 6 Hz power settings was used for Holmium laser lithotripsy. An electrical spark (50–90 W) of 15 pulses/sec, and moderate power settings was used by a bipolar flexible 1.9 Fr fiber probe for EHL performance.

Procedure

The treatment consists in stone localization, visually controlled lithotripsy, and subsequent fragment removal. The stone fragments were extracted by standard technique. The procedure duration was defined as the time between biliary intubation and duodenoscope retrieval. Peri-procedural I.V. antibiotics were administered for all patients.

Outcomes

The primary endpoint of the study was successful stone removal. The complete bile duct clearance was proven by an occlusive cholangiogram. A clinical and laboratory follow-up of patients were performed within 30 days. An additional endpoint was to establish the incidence of complications and the factors associated with them. We also explored the variables affecting the procedure duration.

Statistical analysis

Python 3.6 package was used for statistical analysis, which included descriptive statistics, univariate and multivariate linear regression to establish complication-related factors. The Ordinary Least Squares linear model was used. A p value of <0.05 was considered statistically significant, with 95% confidence intervals calculated.

RESULTS

Between March 2016 and April 2019, 38 patients were treated with D-SOC-guided lithotripsy. The mean patient age was 63 years (range 24–91). The gender ratio was almost equal: 52.6% male, and 47.4% female.

Thirty-three patients were treated with LL and 5 patients with EHL. The mean procedure time for EHL was 83 minutes (35–120) and that for LL – 115 minutes (40–210). In all 38 (100%) cases, a localization and clear visualization of the stone were achieved during cholangioscopy. In 35 (92.1%) patients, the primary endpoint of complete ductal clearance was achieved. The remaining 3 of 38 patients with residual stones were planned for further procedures upon completion of the study. Complete stone removal within the first session was achieved in 30 out of 38 patients (78.9%); 4 patients required two procedures, 1 patients needed to have three procedures; thus, the average number of interventions needed for complete ductal clearance was 1.22. At the end of all procedures with incomplete stone removal, a plastic stent was placed and patients were scheduled for further lithotripsy after discussing the treatment options.

In 15 (39.5%) of the cases, the largest stone size was between 15 mm and 25 mm, and in the remaining 23 (60.5%), it was larger than 25 mm. Half of the patients (50%) had one biliary stone; the rest were with multiple lithiasis. The location distribution was as follows: 39.5% proximal bile ducts, 23.7% common bile duct, 10.5% intrahepatic lithiasis; in the rest of the cases, multiple locations were found. 23.6% of the patients featured altered anatomy or a duodenal diverticulum. A biliary stricture (inflammatory or iatrogenic) was observed in 37% of all patients.

Complication rate

Complications were observed in four (10.5%) patients. All were defined as mild according to the ASGE lexicon. None of them required surgical treatment and were conservatively managed within 3 days of prolonged hospitalization. We observed hemobilia during lithotripsy in two cases, which proved to be self-limiting (Fig. 3). One patient developed cholangitis after the lithotripsy. In one case, an intraprocedural microperforation of the common hepatic duct was noticed (Fig. 4). The patient remained asymptomatic after protective plastic stent placement for 2 weeks.

Predictive factors

We did not establish any significant association of the age of patient, size of stone, duration of procedure, and amount of saline used with the observed complications. We found a significant correlation between the development of complications and presence of biliary stricture (CI 0.135–0.436, $p < 0.05$). With regard to the shape, in our study, barrow and irregular stones were associated with increased presence of complications (Table 1).

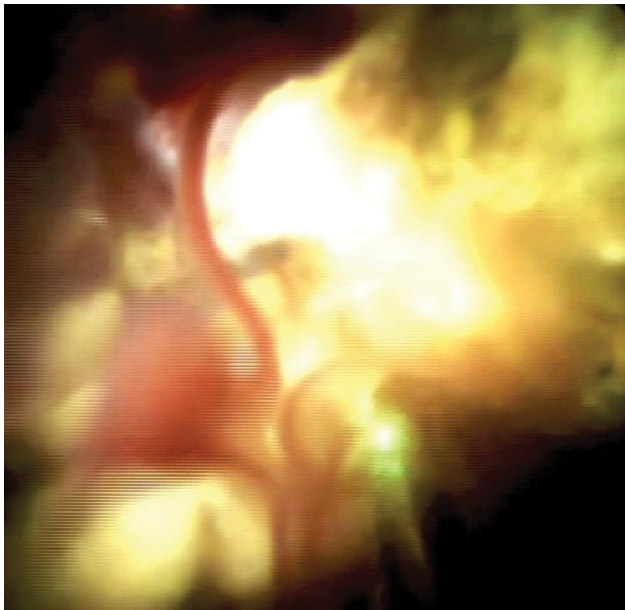


Figure 3. Hemobilia during SOC-guided LL.

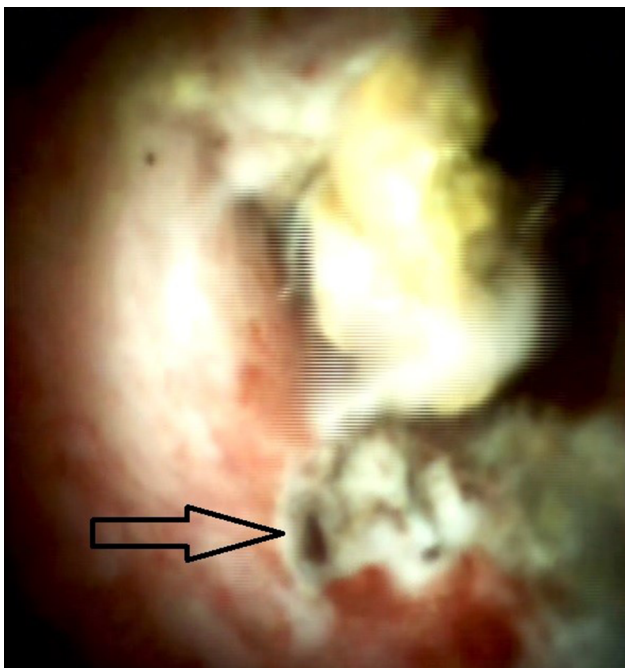


Figure 4. Small CBD perforation during SOC-guided LL.

Additionally, larger size, multiple lithiasis, intrahepatic localization, and failed previous EPLBD/ML were related to prolonged procedure time (over 90 minutes) (**Table 2**).

DISCUSSION

Lux et al. performed the first cholangioscopy-guided laser lithotripsy of a common bile duct stone in humans in 1986.^[4] Despite its reported high efficacy and safety, the procedure could not gain popularity for many years due to difficulties in using the available cholangioscopy platforms. With the implementation of the single-operator cholangioscopy, the intracorporeal lithotripsy became easier and widely available. Large amount of data has been collected proving its high efficacy and safety. Despite that, the exact place of the technique in the algorithm for treatment of difficult common bile duct stones remains unclear. The procedure is not yet fully standardized. There is not enough data to recommend or not recommend peri-interventional antibiotic administration, a specific technical setting, etc. It is not clear if EHL or LL is better. There are not enough studies comparing cholangioscopy-guided lithotripsy with conventional ERCP-based modalities.

According to the meta-analysis by Korrapati et al. including 31 studies evaluating the efficacy of cholangioscopy-guided lithotripsy, the overall stone clearance rate is 88%. The estimated technical success rate is 91%. The overall adverse event rate of POC is 7%. The collected data are before 2015 and the second generation SpyGlass DS (Boston Scientific corp.) was not available but according to this meta-analysis the highest technical success rate was demonstrated by the first generation SpyGlass (Boston Scientific corp.) compared with other cholangioscopy platforms available at that time.^[5]

A prospective study published in 2017 by Wong et al. evaluated the efficacy and safety of SpyGlass DS (Boston Scientific, Natick MA, USA) in the treatment of complicated biliary stones. Seventeen patients were included; the stone clearance rate was 94% over 1 median procedure. Adverse events were reported in 3 cases. The authors concluded that the technique was indicated in cases of impacted stones larger than the more distal CBD and choledocholithiasis, failing conventional extraction by mechanical lithotripsy.^[6]

Table 1. Factors associated with the risk of complications

	Complications analysis					
	R-squared	F-statistic	Coefficient	p-value	Confidence interval	
					0.025	0.975
Shape of stones	0.106	4.384	0.0424	0.043	0.001	0.083
Association with a stricture	0.286	14.8	0.2857	0	0.135	0.436
Number of stones	0.026	0.9801	0.0258	0.329	-0.027	0.079
Size of largest stone	0.066	2.608	0.0329	0.115	-0.008	0.074
Altered anatomy	0	0	0	1	-0.222	-0.222

Table 2. Factors associated with prolonged procedure time

	R-squared	F-statistic	Duration of procedure analysis			
			Coefficient	p-value	Confidence interval	
					0.025	0.975
Number of stones	0.769	76.59	57.9279	0	44.236	71.620
Size of largest stone	0.889	184.0	49.7414	0	42.156	57.327
Shape of stones	0.790	86.64	46.111	0	35.863	56.359
Proximal localization	0.700	53.62	137.2222	0	98.456	175.988
Failed EPLBD/ML previously	0.830	112.1	141.7500	0	114.052	169.448

In an observational study by Navaneethan et al.^[7], 31 patients with difficult stones underwent cholangioscopy-guided laser lithotripsy with SpyGlass DS (Boston Scientific Natick MA, USA). Complete ductal clearance was achieved in one session in 87.1% of cases. Median size of stones was 15 mm. Four patients required second endoscopic session. All of them had multiple stones (>3), which were removed successfully during the second endoscopy session using balloons or baskets. Adverse events were observed in 2.4%.^[7]

In a prospective study by Canena et al.^[8] including 17 consecutive patients with difficult bile duct and pancreatic stones reported about complete ductal clearance in one session in 94.1% and only one patient (5.9%) required additional 2 sessions. The authors favored holmium laser lithotripsy with regard to efficacy and shorter procedure time compared with EHL, but concluded that further studies comparing both methods were needed. Complications occurred in 6 patients (35.3%) incl. transient fever and post-operative pain. No serious adverse events were reported.^[8]

In a retrospective study by Shah et al.^[9], 28 patients underwent D-SOC for bile- or pancreatic duct stones. Complete ductal clearance was achieved in 100%, and in 89% of the cases it was done during the first session. Adverse events were noted in 3%, all of them classified as mild: 1 pancreatitis, 1 postoperative pain, and one cholangitis.^[9]

In a retrospective multicenter study by Turowski et al., 75 patients were indicated for D-SOC-guided lithotripsy, which was performed successfully in 71 patients (91.1%) with the need of 3 procedures (range 1–6). Four patients (8.1%) underwent cholecystectomy and surgical bile duct revision after failed endoscopic therapy. Adverse events were reported in 13.2% in this study; only 0.4% of them were classified as serious. Cholangitis was only 1% after peri-interventional antibiotic administration and 12.8% without antibiotics. The authors concluded that the adverse events could be significantly reduced by a single shot of antibiotic.^[10]

Gutierrez et al. examined 407 patients with difficult bile duct stones from 22 tertiary centers who underwent D-SOC-guided lithotripsy in a large multicenter retrospective study.^[11] 85.7% of them had a previous ERCP attempt with a failed stone extraction, 75% had more than one ERCP session. 75.2% were treated with EHL and 24.8% with LL. Technical success (complete ductal clearance) was achieved in 97.3% with a median number of sessions 1 (range 1-4).

Successful clearance in a single session was achieved 77.4%. Adverse events were noted in 15 patients (3.7%), 66.7% of them were classified as mild, and only 13.3% as severe. All were treated conservatively. This is the first study comparing ESWL and LL in terms of technical success, safety, and procedure time. No statistically significant differences were noted in the bile duct clearance rate, adverse events, and number of sessions. Procedure time was significantly longer in the EHL group (73.9 minutes vs. 49.9 minutes, $p < 0.001$). Difficult anatomy and difficult cannulation were only predictors associated with technical failure. Prior failed ERCP, more than one prior ERCP attempt and duration of the index D-SOC-guided lithotripsy were factors associated with the need of more than one session.^[11]

There are not many studies comparing D-SOC-guided lithotripsy with EPLBD and ML. A randomized controlled trial by Navaneethan et al.^[1] compared D-SOC with LL and endoscopic papillary large balloon dilation (EPLBD) including 66 randomized patients. More patients in the EPLBD group required mechanical lithotripsy (33.3 vs. 3%) or cross-over to SOC-LL (27.3 vs. 6.1%) to achieve ductal clearance. On multivariate logistic regression analysis in this study, stone-duct size ratio over 1.2 and not using SOC-LL were associated with treatment failure. The authors concluded that SOC-LL was most appropriate for difficult stones with distal strictures or in cases when the stone size exceeded that of the distal CBD.^[1]

In a randomized controlled trial by Franzini et al.^[12], D-SOC – EHL was compared with EPLBD. 100 patients were randomized in 2 groups – SOC-EHL and EPLBD. The initial overall complete stone clearance rate was 77.1% in the first and 72% in the second group. After a second session, the overall success rate achieved was 90.1% in both groups. No significant differences regarding technical success, radiation exposure, and adverse events between the two groups were noted. Procedure time was significantly longer in the SOC-EHL group.^[12]

In a randomized trial by Buxbaum et al.^[13], SOC-LL was compared with conventional therapy. Ductal clearance was achieved in 93% of patients with difficult stones who underwent SOC-LL, compared to only 67% of patients treated with EPLBD or ML. There was no significant difference in the fluoroscopy time, number of procedures, and adverse events between the two groups. The procedure time for the

SOC-LL group was significantly longer.^[13] The latter two studies were performed with the first-generation SpyGlass. It is still unclear if those data could be extrapolated to the new system (SpyGlass DS).

According to the recently published ESGE guidelines for treatment of common bile duct stones, SOC-EHL and LL are safe and effective treatment options in cases of difficult bile duct stones.^[14] In the newly published ASGE guideline in cases of difficult bile duct stones, EPLBD and cholangioscopy guided lithotripsy are equally recommended depending on availability, expertise, and choice.^[15] So the exact place of the procedure in the treatment algorithm of difficult bile duct stones remains unclear and not specified in both documents. Despite large amount of publications in the area, there is still not enough evidence to recommend the one technique over the other.

Our study demonstrates that SOC-guided lithotripsy is a highly effective procedure achieving complete ductal clearance in 92.1% of cases (the other patients were rescheduled for further endoscopic procedures upon completion of the study and none of them were referred for surgery). Complete stone clearance in one session was achieved in 79%. The average number of interventions needed was 1. These results do not differ from those published by other authors. All the patients had at least one previous attempt at stone extraction performed by experienced endoscopists practicing routinely EPLBD and ML or had contraindications to EPLBD. In our opinion, SOC-guided lithotripsy is the next step after EPLBD failure or in cases where EPLBD is contraindicated due to a distal CBD stricture.

Our study is the first to show that LL takes longer to perform than EHL. The probable reason for that is that more 'difficult' cases with large or multiple stones were referred for LL. Bigger size, multiple stones, intrahepatic location, and failed previous EPLBD/ LL are associated with prolonged procedure time according to our analysis.

Adverse events were reported in 10.5% of our cases, but all of them were mild and were managed conservatively. No severe adverse events that would require surgery or an ICU stay were noted. We did not find any correlation between age of patients, size of stones, duration of procedures, and amount of saline used during the interventions and occurrence of complications. Interestingly, we found that the presence of a distal CBD stricture is related with increased risk of adverse events ($p < 0.05$). According to our findings, barrel-shaped or irregularly shaped stones are also more likely to cause complications during SOC-guided lithotripsy ($p < 0.05$).

Our study has several weaknesses. One of them is its retrospective fashion. The lack of a control group is a significant limitation of the study. Despite the fact that all the included patients had at least one previous ERCP, there is no direct comparison between the different treatment options for difficult stones. Another weakness is that all procedures were performed only by two highly experienced endoscopists from two tertiary referral centers, and it is not clear if the data could be extrapolated and used in everyday practice.

CONCLUSIONS

SOC-guided lithotripsy is a highly effective and safe procedure that can be used as a second-line treatment in cases of EPLBD failure or as a first-line option in cases of large bile duct stones where EPLBD is contraindicated. The presence of a distal CBD stricture and the complex shape of the stones indicate a higher risk of complications.

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Литотрипсия под контролем холангиоскопии при сложном холедохолитиазе – опыт Болгарии и Египта

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Резюме

Введение: До 10% камней жёлчных протоков считаются «сложными», поскольку их невозможно извлечь с помощью стандартных эндоскопических методов. В этих ситуациях холангиоскопия позволяет провести фрагментацию камня под непосредственным визуальным контролем.

Цель: Оценить эффективность и безопасность однооператорной цифровой литотрипсии под контролем холангиоскопии при сложном холедохолитиазе и проанализировать факторы, связанные с побочными эффектами и длительностью процедуры.

Материалы и методы: Был проведён ретроспективный обзор проспективных баз данных из двух специализированных референс-центров, включавших 38 пациентов со сложным холедохолитиазом. Все пациенты ранее имели эндоскопическую ретроградную холангиопанкреатографию и как минимум одну неудачную операцию по удалению камня. Следуя стандартному протоколу, мы выполнили цифровую литотрипсию под контролем холангиоскопии с использованием либо электрогидравлической, либо лазерной литотрипсии. Главной целью было добиться клиренса протоков, что было подтверждено отрицательной окклюзионной холангиограммой. Мы также исследовали возникновение осложнений, факторы, связанные с ними, и переменные, влияющие на продолжительность процедуры.

Результаты: За исследуемый период 38 пациентам была проведена литотрипсия под цифровым однооператорным холангиоскопическим контролем (33 – лазерная литотрипсия и 5 – электрогидравлическая литотрипсия). Полное очищение протоков достигнуто в 92.1% случаев, а в 78.9% случаев – за один сеанс. Среднее количество процедур до полного удаления камней составило 1.22 (1-3). Среднее время процедуры электрогидравлической литотрипсии и лазерной литотрипсии составило 83 минуты и 115 минут соответственно. Осложнения, которые были определены как лёгкие, наблюдались у четырёх (10.5%) больных. Не выявлено корреляции между возрастом, размером камня, продолжительностью процедуры и количеством физиологического раствора, использованного при литотрипсии, и возникновением осложнений. Наличие стриктуры, камней бочкообразной или неправильной формы ассоциировалось с повышенным риском осложнений ($p < 0.05$). Крупные камни, множественные литиазы, внутрипечёночное расположение и неудачная предыдущая EPLBD/ML были связаны с увеличением времени процедуры ($p < 0.05$).

Заключение: Однооператорная литотрипсия под контролем холангиоскопии является высокоэффективной и безопасной процедурой. Наличие стриктуры дистального отдела общего жёлчного протока и сложной формы конкрементов связано с более высоким риском осложнений операции.

Ключевые слова

холангиоскопия, сложный холедохолитиаз, цифровая однооператорная холангиоскопия, ERCP, литотрипсия, SpyGlass