Original Article

Efficacy of Spyglass-Guided Electrohydraulic Lithotripsy in Difficult Bile Duct Stones

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ABSTRACT

Background/Aims: We aimed to evaluate the efficacy and safety of Spyglass-guided electrohydraulic lithotripsy (EHL) for difficult common bile duct stones (CBD) not amenable to conventional endoscopic therapy. **Design:** A retrospective study evaluating the efficacy of Spyglass-guided EHL in treating difficult CBD stones, in a single tertiary care center. **Patients and Methods:** All patients who underwent Spyglass-guided EHL from 2012 to 2013 were compared with a historical cohort who had ECSWL. **Results:** A total number of 13 patients underwent Spyglass-guided EHL, 8 (61.5%) of them were males. The mean age was 46.5 ± 5.6 years. Bile duct clearance was achieved in 13 (100%) of them. Seventy-six percent required only one Endoscopic Retrograde Cholangiopancreatography (ERCP) to clear the CBD, 7.7% required two ERCPs, and 15.4% required three ERCPs. Adverse effects (cholangitis) occurred in one patient (10%), whereas only 30 patients (64.4%) of the ESWL group had complete CBD stone clearance. Thirty-seven percent required one ERCP to clear the CBD, 35.6% required two ERCPs, and 20% required three ERCPs. Adverse effects happened in seven (15.5%) patients, where five (11%) had cholangitis and two (4.4%) had pancreatitis. **Conclusion:** Although a retrospective design with a small sample size, we concluded that Spyglass-guided EHL is an effective procedure in treating difficult CBD stones.

Key Words: Biliary stones, ESWL, EHL, spyglass

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Most of the patients with extrahepatic bile duct stones are treated nonsurgically by endoscopic sphincterotomy (ES) and stone extraction with a basket or by an extraction balloon catheter. With the addition of mechanical lithotripsy, the success rate for endoscopic stone extraction may reach 95%.[1-3] Although conventional techniques for stone removal are highly effective, they may fail in up to 5% of patients with difficult bile duct stones.[4] In these cases, bile duct stones are impacted, lodged behind strictures, huge in size or located in regions of the biliary tree, which are difficult to target endoscopically. For this selected group of patients for whom all conventional endoscopic stone treatment devices have failed, shockwave technology has provided an approach to the fragmentation of difficult bile duct stones. Shockwaves can be generated with intracorporeal probes by direct contact with a high voltage discharge [electrohydraulic lithotripsy (EHL)] or a pulsed dye laser (laser lithotripsy), or outside the bile duct using an extracorporeal shockwave lithotripsy (ESWL).

A single-operator cholangioscopy (SOC) system (SpyGlass® Direct Visualization System, Boston Scientific Corp., Natick, MA, USA)[5,6] has overcome most of the conventional cholangioscopy limitations. A prospective observational feasibility study at two tertiary medical centers demonstrated that Spyglass cholangioscopy could provide adequate samples for histological diagnosis and successfully guide stone therapy.[6]

We aimed to evaluate the efficacy and safety of Spyglass-guided EHL for difficult common bile duct (CBD) stones not amenable to conventional endoscopic therapy and compared these results with a historical cohort of 45 patients who underwent Extracorporeal Shock Wave Lithotripsy (ESWL) in treating difficult CBD stones in the same center.

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PATIENTS AND METHODS

Definitions

A difficult CBD stone was defined as a stone that could not be removed from the bile duct despite ES, and using a basket, and/or balloon extractor, and/or mechanical lithotripter and/or after a balloon dilatation of the papilla of Vater. Success was defined as complete CBD clearance following either EHL or ESWL sessions. Treatment failure was defined as failure to remove the CBD stone after ESWL or Spyglass-guided EHL mandating another modality of treatment either surgery or permanent biliary stenting with stent exchange when deemed necessary. Dilated CBD was defined as mid common bile duct diameter of more than or equal to 7 mm.

Outcomes

The main outcome was to determine the efficacy of Spyglass-guided EHL in clearing difficult CBD stones in terms of success rate, number of sessions required, and complications. Secondary outcomes were to compare the efficacy of Spyglass-guided EHL to a historical cohort of difficult CBD stone patients who were treated with ESWL in the same center.

Study population

All patients' medical files of all patients who underwent Spyglass-guided EHL for treatment of difficult CBD stones at King Khalid University Hospital, from February 2012 to June 2013, were retrospectively reviewed and were followed up by retrospectively reviewing the files of all patients who underwent ESWL for difficult CBD stones from the year 2000 to January 2012.

Procedures

Electrohydraulic lithotripsy

An SOC system (Spyglass Direct Visualization System) would be introduced through the duodenoscope. The system features two separate dedicated irrigation channels and a four-way tip deflection capability for enhanced steerability. The Nortech AUTOLITH system (Northgate Technologies, Inc, Elgin, IL, USA) and a 1.9F probe were used in those patients undergoing electrohydraulic lithotripsy (EHL).

Once the stone was identified within a bile duct, an EHL probe was introduced through the working channel of the cholangioscope, with the tip positioned directly at the stone. Shockwaves generated by an electric spark (50-90 W) at the end of the probe were propagated through the aqueous medium to achieve stone fragmentation under visual guidance. Fragmented stones were then flushed out or removed by using a balloon and/or basket. Spyglass-guided EHL was introduced in our practice at King Khalid University Hospital from February 2012. This procedure was performed under conscious sedation by one of two experienced therapeutic endoscopists in our endoscopy unit (A.J. and M.A.).

Extracorporeal shock wave lithotripsy

ESWL was routinely used till the introduction of the Spyglass-guided EHL to our practice and it was carried out only when the CBD was deemed difficult according to the above criteria. A nasobiliary tube was placed to visualize the calculi during ESWL. ESWL was carried out with a third-generation lithotripter, which uses electromagnetic shock waves as a source of energy (Delta Compact, Dornier Medtech, Wessling, Germany). ESWL was carried out in the supine position. The shock wave energy settings (intensity and frequency) were adjusted to achieve successful fragmentation. ESWL was initiated at a setting of 1 (11,000 kV) and gradually increased to 4-5 (14 000-15 000 kV) over 5-7 min. A maximum of 5000 shocks were used per session, unless the stone fragmented earlier. The procedure would be called successful only when the CBD could be cleared after the ESWL session or after an urgent Endoscopic Retrograde Cholangiopancreatography (ERCP) with stones extraction using a balloon or a basket. The number of ESWL sessions depended on achievement of CBD clearance, and repeat ESWL sessions were done on consecutive days.

Data collection

Data collected included age, gender, body mass index, number of previous biliary interventions, number of stones, presence of a biliary stricture, baseline laboratory data before the first session of either ESWL or EHL, in addition to the procedure success rate, number of ESWL or EHL sessions needed, procedure-related complications, and number of patients requiring another modality of treatment.

Statistical analysis

Data analysis included descriptive statistics computed for continuous variables, including means, standard deviations (SD), minimum and maximum values, as well as 95% CI. Percentages and 95% confidence interval (CI) are used for categorical variables. Between-groups comparisons were performed using Chi-square, *t*-test, or Wilcoxon rank testing, as appropriate to evaluate the difference between the groups.

We used the software STATA 11.2 (Stata Corp, TX, USA) in our analysis. A statistical significance threshold of $P <= 0.05$ was adopted.

RESULTS

Spyglass-guided EHL

A total number of 13 patients underwent Spyglass-guided EHL, 8 (61.5%) of them were males ($P = 0.34$) with

a mean age of 46.5 ± 5.6 years. The mean of the total bilirubin was 41.1, CBD was dilated in 100% of the patients, and four of them (30.8%) had intrahepatic duct stones. Six patients (46.1%) had one stone, five (38.5%) had two stones, and two (15.4%) had three or more stones [Table 1].

The mean number of previous ERCP attempts prior to Spyglass-guided EHL was two. All patients (100%) had complete CBD clearance with no further interventions [Figure 1a-e], 10 patients (76.9%) required only one ERCP, one (7.7%) required two ERCPs, and two (15.4%) required four ERCPs with a mean of ERCP of 1.61 [Table 2].

Biliary stricture was seen in two patients (15.4%), one of them turned out to be cholangiocarcinoma based on histopathology.

Complications happened only in one (7.7%) patient who had cholangitis, which was treated with broad-spectrum antibiotics.

Extracorporeal shock wave lithotripsy

A total number of 45 patients underwent ESWL. Twenty-two patients (48.8%) were male with a mean age of 51.8 ± 2.7. The mean of the total bilirubin was 33.8, CBD was dilated on 41 (91%) of the patients and seven (15.6%) had intrahepatic duct stones. Eighteen patients (40%) had one stone, nine (20%) had two stones, and 19 (42.2%) had three or more stones [Table 1]. The mean number of previous ERCP attempts prior to ESWL was 1.6.

Only 30 patients (64.4%) had complete CBD stone clearance. ESWL failed to clear the CBD in 15 patients (35.6%), nine of them (20.4%) underwent surgery, four (9.1%) had permanent stents with stent exchange if deemed necessary, one (2.3%) had EHL, and one (2.3%) had laser lithotripsy through percutaneous choledocoscopy. Seventeen patients (37.8%) of the ESWL required one ERCP to clear the CBD, 16 (35.6%) required two ERCPs, nine (20%) required three ERCPs, one (2.2%) required four ERCPs and one (2.2%) required five ERCPs with a mean of ERCP of 0.93. Biliary stricture was seen in four patients (8.9%), all were benign.

Complications happened in seven (15.5%) patients, where five (11%) had cholangitis and two (4.4%) had pancreatitis.

Table 1: Descriptive analysis of ESWL and Spyglass

Variables	ESWL group (*n*=45)	EHL group (*n*=13)	*P*
Male (%)	48.9%	61.5%	0.34
Mean age (years)	51.9±2.7	46.6±5.6	0.5
Body mass index (mean)	26.9±0.9	34.8±3	0.14
Reason for initial hospitalization			
Cholangitis	27.2%	40%	0.44
Jaundice	79.5%	80%	1.00
Right upper quadrant pain	79.5%	50%	0.44
Mean total bilirubin	33.8±9	41.2±15	0.91
Mean ALP	160.1±27	284.2±51	0.86
Mean ALT	69.4±16	87.9±22.51	0.53
Mean AST	46.5±10	53.7±26	0.46
CBD dilated (above 7 mm)	91.1%	100%	0.20
CBD stricture	8.9%	15.4%	1.00
Number of CBD stones			
1	40.0%	46.1%	0.19
2	18.9%	38.5%	0.01
= or>3	41.1%	15.4%	0.43
Site of stones			
Intrahepatic	8.9%	7.7%	0.33
Extrahepatic	84.4%	69.2%	0.43
Both	6.7%	23.1%	0.67
Mean number of previous ERCP attempts	1.6±0.14	2±0.2	0.82

EHL: Electrohydraulic lithotripsy, ESWL: Extracorporeal shock wave lithotripsy, CBD: Common bile duct

Table 2: The patient's outcome of EHL versus ESWL

	ESWL group	EHL group	*P*
Mean number of ERC sessions	0.93	1.61	0.09
Complete CBD clearance	(30) 64.4%	13 (100%)	0.16
Failed CBD clearance	(15) 35.6%	0%	0.21
Surgery	(9) 20.4%	0%	0.16
Permanent stent (stent exchange if necessary)	(4) 9.1%	0%	NA
EHL after failed ESWL session	(1) 2.3%	0%	0.34
Percutaneous choledocoscopy using laser lithotripsy	(1) 2.3%	0%	0.34
Complications	(7) 15.5%	(1) 7.7%	0.22

CBD: Common bile duct, ERC: Endoscopic retrograde cholangiography, EHL: Electrohydraulic lithotripsy, ESWL: Extracorporeal shock wave lithotripsy

DISCUSSION

Biliary stones may be difficult to remove due to one or more factors related to the stone size, location, shape, being of hard consistency, or being impacted. Biliary stones that are difficult to extract using the conventional methods, can be removed by using a variety of techniques, including endoscopic papillary balloon dilatation, mechanical lithotripter, permanent stenting, ESWL under ultrasound or fluoroscopy guidance, EHL or laser lithotripsy using percutaneous cholangioscope or a "mother–baby" endoscopic system cholangioscope or more recently using SOC system, including Spyglass, or surgical intervention if necessary.[7-10] The effectiveness of ESWL, laser lithotripsy and EHL has been demonstrated in various studies.[9,11-14] In late 2006, the Spyglass was introduced to the market. Spyglass is an SOC platform and improves upon many shortcomings of the dual-operator systems.[15]

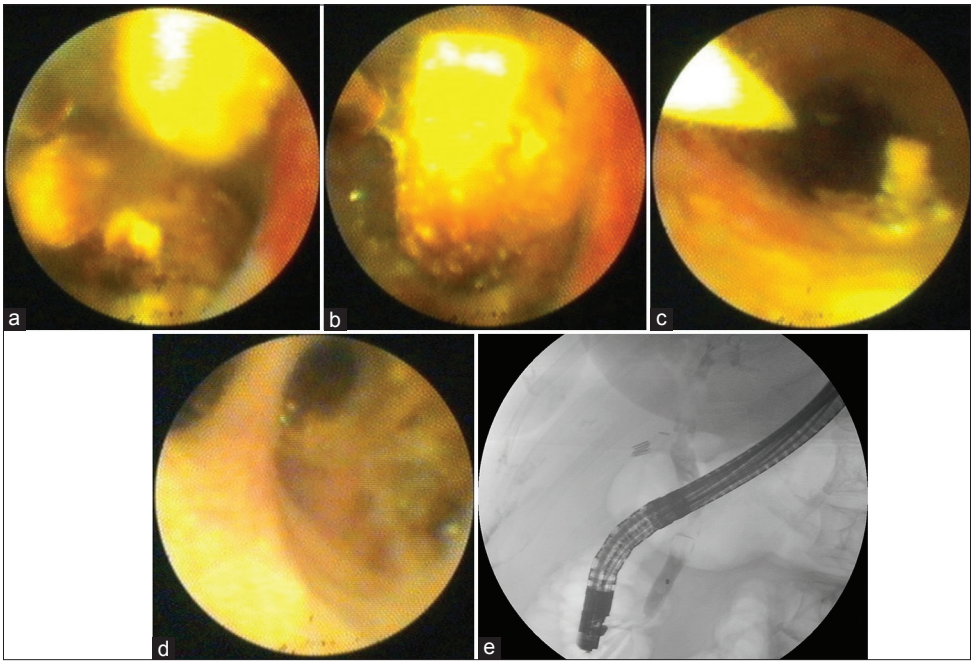

Figure 1: (a) Spyglass view of multiple large common bile duct stones. (b) Spyglass-guided electrohydraulic lithotripsy (EHL) with the tip of the catheter targeting a large common bile duct (CBD) stone. (c) Spyglass view post-EHL therapy of a CBD stone.(d) Spyglass view of the right and the left intrahepatic duct in a patient with multiple difficult intrahepatic and extrahepatic duct stones. (e) Cholangiogram showing numerous large CBD and common hepatic duct stones for which three ERCP attempts with conventional methods failed to clear the CBD

Although our study was a retrospective one with a small sample size, it is one of the few studies that showed the efficacy and safety of Spyglass-guided EHL in a well-defined population of difficult CBD stones, in addition, compared to our historical ESWL cohort, Spyglass-guided EHL showed its significant superiority. In this study, among 13 patients, we have found 100% CBD clearance rate in the EHL group, compared with 66.7% success rate among the historical ESWL cohort.

In 1995, Adamek *et al*. had compared the clearance rates of ESWL to EHL in 35 patients with difficult CBD stones, ESWL group had a success rate of 72%, whereas EHL group had a success rate of 76.5% with no significant difference between these two techniques.[16] Although their ESWL efficacy was comparable to our ESWL results, the EHL efficacy was below than reported in our study and in most recent studies, where a higher success rate for Spyglass-guided lithotripsy, ranging from 90% to 100%, has been documented in a number of series.[17-19] Importantly, complete stone clearance was achieved in only one session in the vast majority of cases.

Using EHL via a "mother–baby" endoscopic system in 94 patients with difficult CBD stones, Arya *et al*. showed a final stone clearance rate of 90% with a 13% complication rate.[20] Using an SOC-guided EHL system among 75 patients with difficult CBD stones, Farrell *et al*. had shown a 100% success rate with no complication,[21] which is consistent with our data.

In a recently published review by Karsenti *et al*., the success rate of ESWL varied from 70% to 90% for complete CBD clearance.[22] Among 313 patients with difficult CBD stones who underwent ESWL, Sackmann *et al*. achieved a stone clearance rate of 90% of patients,[23] whereas among 283 patients with difficult CBD stones, Tandan *et al*. achieved a complete clearance of the CBD in 84.4%.[24] These two studies have shown an overall success rate higher than ours; however, these rates were at the upper range of rates reported by other groups of investigators (52.5%-73%).[16,25,26] This variability might be secondary to the difference in the definition of the "difficult CBD stone" they have used and the sort of endoscopic maneuvers that were used prior to referral to ESWL or EHL.

In a prospective study of 60 patients comparing ESWL with intracorporeal laser lithotripsy, Neuhaus *et al*. showed that bile duct clearance was achieved in 22 of 30 patients (73%) in the ESWL group and in 29 of 30 patients (97%) in the laser lithotripsy group. In another study using an SOC-guided laser lithotripsy system among 13 patients with difficult CBD stones, Kim *et al*. have shown a success rate of 84.6%.[27] Although these results may suggest that EHL and laser lithotripsy have similar efficacies in managing difficult CBD stones, laser systems are considerably more expensive than EHL.[28]

Using Spyglass-guided EHL or laser therapy in 18 patients with difficult CBD, Moon *et al*. showed that it was successful in 16 out of 18 (89.9%) patients.[29]

There are some limitations in this study that are inherent to its design, that is, the retrospective nature of the study as well as the imbalance in the number of patients who underwent EHL and ESWL.

CONCLUSION

Spyglass-guided EHL is an effective alternative to ESWL and might be superior to ESWL in difficult CBD stones. Prospective trials factoring other variables including costs, complications, hospitalization time, and quality of life would be of value.

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