

Effectivity of Extracorporeal Shock Wave Lithotripsy (ESWL) and Stenting vs. Stenting Only for Difficult Common Biliary Duct Stones: A Retrospective Analysis

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) alone may not be sufficient for treating difficult common bile duct stones. To address this challenge, several other modalities exist, including extracorporeal shock wave lithotripsy (ESWL) and biliary stent placement. This study aims to investigate the effectiveness of ESWL following biliary stent placement, in comparison to biliary stent placement alone, in the treatment of difficult common bile duct stones.

Methods: A retrospective cohort study was conducted using medical record data from the Gastrointestinal Endoscopy Center Registry of Dr. Cipto Mangunkusumo General National Hospital. This study evaluated 126 subjects with difficult bile stones, who were divided into two groups: one group received biliary stent placement alone, while the other underwent extracorporeal shock wave lithotripsy (ESWL) following biliary stent placement. The effectiveness of each treatment was assessed based on the rate of complete clearance of bile stones.

Results: Of the total participants, 72 underwent ESWL following biliary stent placement, while 54 received biliary stent placement alone. The rate of complete stone clearance was 69.1% in the ESWL group and 64.8% in the stent-only group. However, the addition of ESWL as an adjuvant therapy did not result in a statistically significant improvement ($p = 0.703$; 95% CI: 0.816–1.351). Normal body mass index was a factor that influences the effectiveness of ESWL after biliary stent placement ($p = 0.002$).

Conclusion: The ESWL procedure as adjuvant therapy following biliary stent placement has the same level of effectiveness as biliary stent placement alone.

Keywords: Biliary stent, common bile duct stones, extracorporeal shockwave lithotripsy, gallstones

ABSTRAK

Latar belakang: Endoscopic retrograde cholangiopancreatography (ERCP) saja mungkin tidak cukup untuk menangani kasus batu saluran empedu yang sulit. Terdapat beberapa modalitas lain untuk mengatasi masalah ini, seperti extracorporeal shockwave lithotripsy (ESWL) dan pemasangan stent bilier. Penelitian ini dilakukan

untuk mengetahui efektivitas ESWL setelah pemasangan stent bilier dibandingkan dengan hanya pemasangan stent bilier saja pada kasus batu saluran empedu yang sulit.

Metode: Penelitian kohort retrospektif menggunakan data rekam medis dari Registrasi Pusat Endoskopi Gastrointestinal Rumah Sakit Umum Pusat Nasional Dr. Cipto Mangunkusumo dilakukan untuk mengevaluasi 126 subjek dengan batu empedu yang sulit diatasi. Subjek dibagi menjadi dua kelompok: kelompok pertama hanya menjalani pemasangan stent bilier, dan kelompok kedua menjalani prosedur ESWL setelah pemasangan stent bilier. Efektivitas dari prosedur diukur dalam bentuk klirens total batu empedu.

Hasil: Sebanyak 72 subjek menjalani prosedur ESWL setelah pemasangan stent bilier, sementara 54 subjek hanya menjalani pemasangan stent bilier. Efektivitas ESWL setelah pemasangan stent bilier dalam mencapai klirens total adalah 69,1% dan efektivitas pemasangan stent bilier dalam mencapai klirens total adalah 64,8%. Prosedur ESWL sebagai terapi tambahan setelah pemasangan stent bilier tidak memberikan perbedaan yang bermakna secara statistik ($p = 0,703$; 95% CI: 0,816–1,351). Indeks massa tubuh yang normal merupakan faktor yang mempengaruhi efektivitas ESWL setelah pemasangan stent bilier ($p = 0,002$).

Kesimpulan: Prosedur ESWL sebagai terapi tambahan setelah pemasangan stent bilier memiliki tingkat efektivitas yang sama dengan pemasangan stent bilier saja.

Kata kunci: Stent bilier, batu saluran empedu umum, litotripsi gelombang kejut ekstrakorporeal, batu empedu

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) remains the treatment of choice for patients with common bile duct stones, with a reported success rate of 80-90%.¹ However, in approximately 10-15% of cases, stone extraction is unsuccessful due to factors such as size, shape, number, or location of the stones.² In these instances, ERCP alone is inadequate, and additional treatment modalities are needed for the management of the difficult common bile duct stones. A variety of options are available, ranging from non-surgical to surgical approaches.

Nowadays, non-surgical therapy is the first choice, given the greater morbidity of the surgical approach. These non-surgical modalities include endoscopic papillary balloon dilatation, mechanical lithotripsy, laser lithotripsy, electrohydraulic lithotripsy, extracorporeal shock wave lithotripsy (ESWL), and biliary stent placement.³ In 1989, researchers reported the use of ESWL for common bile duct (CBD) stone, achieving a 90% fragmentation rate.⁴ Previous studies on ESWL for difficult CBD stone showed a 73-84% rate of bile duct clearance.⁵ However, to date, there have been no studies directly comparing ESWL with biliary stent placement alone for the management of difficult CBD stones. Therefore, this study was conducted to determine the effectiveness of ESWL following biliary stent placement compared to biliary stent placement alone in patients with difficult CBD stones.

METHODS

Study Design

This study employed a retrospective cohort design to evaluate the effectiveness of total stone clearance achieved by ESWL as an adjuvant therapy following biliary stent placement in patients with difficult common bile duct stones.

Population

The subjects of this study were included from the registry data of the Gastrointestinal Endoscopy Center of Dr. Cipto Mangunkusumo Hospital, Jakarta, from April 2015 to September 2019. Inclusion criteria were adult patients aged 18 years and older with difficult bile duct stones, defined as follows: (1) stone size greater than 15 mm; (2) presence of multiple stones; (3) bile duct stenosis; (4) history of biliary surgery; or (5) stones that could not be extracted using conventional ERCP techniques and were deemed difficult by the operator. All included subjects had undergone biliary stent placement, followed by ESWL. Subjects were excluded if their medical records lacked sufficient data for analysis.

Interventions and Outcomes

Subjects in the biliary stent placement-only group underwent plastic stent placement using either a single or double stent, followed by stone removal through ERCP. In contrast, subjects in the ESWL adjuvant group received ESWL therapy after biliary stent placement or ERCP. On average, these subjects

underwent three ESWL procedures. The primary outcome was the total clearance of bile stones. Both groups were evaluated at the same time, approximately 3 to 6 months after the procedures. The protocol of this study has been approved by The Ethics Committee of the Faculty of Medicine Universitas Indonesia with protocol number 19-06-0691.

Statistical Analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 20.0. A normality test was conducted to determine the distribution of the data. Variables with a normal distribution were presented as mean (\pm standard deviation) or number (percentage), while those with a skewed distribution were reported as median (range). The chi-square test was used to compare the effectiveness between ESWL as adjuvant therapy and biliary stent placement alone. Relative risk (RR) was calculated, and a p-value of less than 0.05 was considered statistically significant.

RESULTS

Baseline Characteristics of Research Subjects

A total of 126 subjects were evaluated in this study, with 54 in the biliary stent placement-only group and 72 in the ESWL adjuvant group. The mean age of the subjects with difficult stones was 50 ± 19.2 years. The study population consisted of slightly more female than male subjects, accounting for 54% and 46%, respectively.

Based on the number of stones, 43 subjects (34.4%) had single stones, while 82 subjects (65.6%) presented with multiple stones. In terms of location, the majority of stones were found in the choledochal duct (102 subjects, 84.3%). Additional findings included periampullary diverticula in 15 subjects (11.9%), common bile duct stenosis in 16 subjects (12.7%), papillary vascular abnormalities in 10 subjects (7.9%), and a history of cholecystectomy in 4 subjects (3.2%).

The mean body mass index (BMI) of subjects in this study was 23.1 ± 4.1 kg/m². A total of 71 subjects (56.3%) received ursodeoxycholic acid (UDCA) at a daily dose of 600–750 mg. All subjects were treated with plastic biliary stents, with Tannenbaum stents being the most commonly used type (46 subjects, 37.4%). Among those who underwent ESWL following biliary

stent placement, the procedure was typically performed in three sessions, with a mean shock frequency of 4,667 Hz. The power applied during each session ranged from 17 to 18 impulses per minute. Complications in the form of pancreatitis before the procedure were found in 37 subjects (29.4%), and pancreatitis after the procedure was found in 10 subjects (8%). All subjects in both groups were re-evaluated through ERCP at intervals of 3 to 6 months. Basic characteristics in each group are shown in **Table 1**.

Table 1. Baseline characteristics of research subjects

Characteristics	Stenting and ESWL (N(%))	Stenting (N(%))
Gender		
Male	28 (38.9)	30 (55.6)
Female	44 (61.1)	24 (44.4)
Age (years)		
< 50	9 (12.5)	16 (29.7)
\geq 50	63 (87.5)	38 (70.3)
Ductal clearance		
Completely cleared	49 (68.1)	35 (64.8)
Failed clearance	23 (31.9)	19 (35.2)
Stone amount		
Single	25 (34.7)	18 (34)
Multiple	47 (65.3)	35 (66)
Stone location		
Choledochal duct	58 (80.6)	44 (81.5)
Common hepatic duct	8 (11.1)	3 (5.6)
Intra hepatic duct	2 (2.8)	5 (9.3)
Pancreatic duct	1 (1.4)	0 (0)
Periampullary diverticula		
Yes	10 (13.9)	5 (9.3)
No	62 (86.1)	49 (90.7)
Biliary ductal stenosis		
Yes	5 (6.9)	11 (20.4)
No	67 (93.1)	43 (79.6)
Abnormality of ampulla of Vater		
Normal	64 (88.9)	52 (96.3)
Abnormal	8 (11.1)	2 (3.7)
Cholecystectomy history		
Yes	33 (4.2)	1 (1.9)
No	69 (95.8)	53 (98.1)
Ursodeoxycholic acid treatment		
Yes	36 (50)	35 (64.8)
No	36 (50)	19 (35.2)
Comorbid		
Hypertension	4 (5.6)	9 (16.7)
Diabetes mellitus	1 (1.4)	3 (5.6)
Chronic kidney disease	1 (1.4)	1 (1.9)
Coronary heart disease	0 (0)	2 (3.7)
Body mass index		
18–24.9 (normal)	38 (52.7)	37 (68.6)
25–29.9 (overweight)	34 (47.3)	16 (29.6)
\geq 30 (obesity)		1 (1.80)
Pancreatitis before ERCP		
Yes	21 (16.7)	16 (12.7)
No	51 (40.5)	38 (30.1)
Pancreatitis after ERCP		
Yes	5 (3.95)	5 (3.95)
No	67 (53.2)	49 (38.9)

ESWL: extracorporeal shockwave lithotripsy; ERCP: endoscopic retrograde cholangiopancreatography

Effectiveness between ESWL Adjuvant Therapy and Biliary Stent Placement Only for Difficult Common Bile Duct Stones

In this study, the total clearance for subjects in ESWL adjuvant group was 69.1%, while the total clearance for subjects in biliary stent placement-only group was 64.8%. The difference in effectiveness between the two groups was not statistically significant ($p = 0.703$; RR = 1.050;

95% CI: 0.816–1.351). A detailed comparison of the effectiveness of ESWL following biliary stent placement versus biliary stent placement alone in achieving complete clearance of difficult stones is presented in **Table 2**.

Body mass index was found to be a factor related to total clearance of ESWL after biliary stent placement. Subgroup analyses of ESWL after biliary stent placement are shown in **Table 3**.

Table 2. The Bivariate Analysis of Effectiveness Between ESWL Adjuvant and Biliary Stent Only for Difficult Common Bile Duct Stones

Variables	Total ductal clearance		RR (95% CI)	p
	Yes	No		
Biliary stent placement and ESWL	49 (69.1)	23 (31.9)	1.050 (0.816–1.351)	0.703
Biliary stent placement only	35 (64.8)	19 (35.2)		

ERCP: endoscopic retrograde cholangiopancreatography

Table 3. Subgroup Analysis of the ESWL After Biliary Stent Placement Effectiveness

Characteristics	Biliary stent placement with ESWL		RR (95% CI)	p
	Total ductal clearance n (%)	Failed clearance n (%)		
Age				
< 50 years	5 (55.6)	4 (44.4)	1.257 (0.685–2.306)	0.454
≥ 50 years	44 (69.8)	19 (30.2)		
BMI				
< 18 (underweight)	0 (0.0)	0 (0.0)		
18–24.9 (normal)	32 (84.2)	6 (15.8)	1.730 (1.207–2.478)	0.002*
25–29.9 (overweight)	17 (50.0)	17 (50.0)		
≥ 30 (obesity)	0 (0.0)	0 (0.0)		
Biliary ductal stenosis				
Yes	2 (40.0)	3 (60.0)	0.570 (0.193–1.687)	0.319
No	47 (70.1)	20 (29.9)		
Stone amount				
Single	14 (56.0)	11 (44.0)	0.752 (0.511–1.106)	0.110
Multiple	35 (74.5)	12 (25.5)		
Stone location				
Choledochal duct	39 (67.2)	19 (32.8)	-	0.673
Common hepatic duct	5 (62.5)	3 (37.5)		
Intra hepatic duct	2 (100.0)	0 (0.0)		
Periampullary diverticula				
Yes	7 (70.0)	3 (30.0)	1.033 (0.665–1.605)	1.000
No	42 (67.7)	20 (32.3)		
Abnormality of ampulla of vater				
Abnormal	7 (87.5)	1 (12.5)	1.333 (0.972–1.829)	0.422
Normal	42 (65.6)	22 (34.4)		
Cholecystectomy history				
Yes	3 (100.0)	0 (0.0)	1.500 (1.269–1.772)	0.546
No	46 (66.7)	23 (33.3)		
Ursodeoxycholic acid				
Yes	25 (69.4)	11 (30.6)	1.042 (0.759–1.430)	0.800
No	24 (66.7)	12 (33.3)		
Balloon size				
≤ 15 mm	5 (50.0)	5 (50.0)	0.700 (0.322–1.522)	0.622*
> 15 mm	5 (71.4)	2 (28.6)		

Characteristics	Biliary stent placement with ESWL		RR (95% CI)	p
	Total ductal clearance n (%)	Failed clearance n (%)		
Stent diameter				
≤ 10 French	8 (66.7)	4 (33.3)	0.976 (0.631–1.508)	1.000*
> 10 French	41 (68.3)	19 (31.7)		
Stent length				
≤ 9 cm	2 (66.7)	1 (33.3)	0.979 (0.433–2.214)	1.000*
> 9 cm	47 (68.1)	22 (31.9)		
ESWL session				
< 2 session	2 (66.7)	1 (33.3)	0.950 (0.419–2.152)	1.000*
≥ 2 session	40 (70.2)	17 (29.8)		
ESWL shock				
≤ 4000 Hz	4 (80.0)	1 (20.0)	1.084 (0.675–1.741)	1.000*
> 4000 Hz	31 (73.8)	11 (26.2)		
Power per session in rate I				
≤ 18 times/minute	32 (74.4)	11 (25.6)	0.997 (0.818–1.216)	1.000
> 18 times/minute	3 (75.0)	1 (25.0)		
Power per session in rate II				
≤ 17 times/minute	34 (75.6)	11 (24.4)	1.060 (0.855–1.268)	0.450
> 17 times/minute	1 (50.0)	12 (50.0)		

(*): statistically significant; ESWL: extracorporeal shock wave lithotripsy; RR: risk ratio; BMI: body mass index

DISCUSSION

There was no statistically significant difference in achieving total clearance effectiveness between subjects who underwent ESWL procedure after biliary stent placement compared to subjects who underwent biliary stent placement only. The ESWL sessions given were three times, with 4000–5000 Hz shock given and 17–18 times/minute power per ESWL session. Subjects with difficult stones were then re-evaluated with ERCP every three months after the ESWL procedure.

The number of ESWL sessions and shock parameters used in this study were consistent with previous research, where ESWL was administered three times per patient, with up to 5,000 shocks per session and a power setting of 90 impulses per minute. In comparison, the power applied in this study was significantly lower, at 17 impulses per minute. Following evaluation with ERCP, 239 subjects (84.45%) achieved complete bile duct clearance, with 35 subjects (12.36%) achieved partial clearance, and 9 subjects (3.18%) did not achieve total clearance. The complications found were mild. Haemobilia was found in 45 subjects (15.90%), with mild haemobilia in 34 subjects (12.01%). Cholangitis was found in 11 subjects (3.88%) and recovered with antibiotics administration. Post-ERCP pancreatitis was found in 10 subjects (3.53%) with a length of hospital

stay of 1–3 days. Skin purpura was found in 21% of post-ESWL subjects. The skin purpura did not require therapy and had disappeared within one week. No mortality was found in this study. Comparing with previous study, the power given in this study was 17 times/minute, which was very low compared to a dose of 90 times/minute.⁵

A study conducted in 2017 also evaluated the effectiveness of ESWL and ERCP in patients with difficult bile duct stones, using similar shock parameters—4,000 to 5,000 Hz and a power setting of 90 impulses per minute. That study included 231 subjects and focused on total ductal clearance as the primary outcome. The results showed that complete clearance was typically achieved during the second or third ESWL session, although some patients required up to seven sessions.⁸ the number of ESWL sessions and shock frequency used in the present study were similar; however, the power applied per minute was notably lower. This reduced power setting may explain why the effectiveness of ESWL as an adjuvant therapy in this study did not reach statistical significance. Previous research on ESWL for urinary stones also supports the use of 60–90 impulses per minute as the optimal shockwave frequency for effective lithotripsy.^{9–11} Factors influencing the effectiveness of following biliary stent placement in achieving complete clearance of difficult stones have not

been fully explored. However, several studies have identified potential contributing factors, including stone type, shape, number, location (particularly proximal to bile duct stenosis), anatomical abnormalities of the biliary system, the type of ESWL machine used, and body mass index (BMI).^{7,8,12}

Body mass index (BMI) was identified as a factor associated with the effectiveness of ESWL in achieving total stone clearance following biliary stent placement. This finding is consistent with a study by Frank et al. (2014), which evaluated 73 patients with difficult bile duct stones who underwent ESWL.^{13,14} Lenze et al found 66 subjects (90%) achieved total clearance, three subjects achieved partial clearance, and four subjects (6%) did not achieve total clearance; thus, surgical procedures were performed. Subjects who achieved total clearance underwent ESWL with a shock dose of 3000 shocks, power 60-90 shock/minute. In subjects who did not achieve total clearance, subjects were overweight and obese. Meanwhile, subjects with normal BMI or underweight managed to achieve total clearance, with $p = 0.035$ in subjects with overweight and obesity compared with normal BMI.¹⁵ Obesity is also a well-established risk factor for failed ESWL in the treatment of renal and ureteral stones. BMI is considered an independent predictor of ESWL success, largely due to the increased skin-to-stone distance in obese individuals, which reduces the energy delivered to the stone. Additionally, excess adipose tissue may impair stone visualization, further compromising treatment efficacy.¹⁶

Biliary stenting alone has also proven effective for managing difficult bile duct stones, as demonstrated in this study. Supporting evidence comes from a study by Horiuchi et al., which evaluated the role of biliary stenting as an alternative to stone clearance in elderly patients with common bile duct (CBD) stones. Patients treated with stenting alone experienced significantly shorter procedure times (approximately 21 minutes vs. 44 minutes) and reduced hospital stays (3.8 vs. 6.5 days), without an increased risk of adverse events during an average follow-up of 1.5 years. Notably, the need for additional endoscopic procedures and one-year mortality rates were comparable between the stenting and stone removal groups. These findings suggest that in elderly or high-risk patients, simple biliary stenting can offer safe and

effective palliation for large or multiple CBD stones. It presents a practical alternative when definitive stone extraction is challenging or carries elevated procedural risks.¹⁸

Pancreatitis following ERCP procedure was found in a small number of subjects in this study and was appropriately managed without serious complications. Importantly, no cases of severe adverse events such as biliary sepsis or mortality were reported. Importantly, no cases of severe adverse events such as biliary sepsis or mortality were reported.^{7,8,17} This study was unable to obtain detailed data on complications experienced by subjects who underwent ESWL following biliary stent placement; therefore, specific adverse events could not be described in detail. Additionally, a total of 26 subjects did not complete the treatment and were excluded from the final analysis due to the absence of total clearance data. These subjects were evenly distributed between the two groups, with 13 in the biliary stent placement-only group and 13 in the ESWL adjuvant group. Importantly, their baseline characteristics were comparable to those of the subjects included in the analysis.

This study had several limitations, including incomplete data on key variables such as the type of ESWL machine used, stone characteristics, and specific complications related to the ESWL procedure. As a retrospective study utilizing registry data from our endoscopy center, there was no randomization between subjects who underwent biliary stent placement alone and those who received ESWL as adjuvant therapy. This lack of randomization increases the potential for selection bias and limits the ability to draw definitive conclusions regarding comparative effectiveness.

CONCLUSION

For the extraction of common bile duct difficult stones, ESWL as adjuvant therapy following biliary stent placement has the same effectiveness in achieving total clearance compared to biliary stent placement only. However, for broader clinical application, further prospective studies are needed, particularly those exploring different ESWL power settings, to optimize treatment efficacy in patients with difficult bile duct stones.

Conflict of Interest

The authors declare that there are no conflicts of interest related to this study.

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Author Contribution

All authors contributed to this manuscript.

Data Availability

The data that support the findings of this study are contained within the article.

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