

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

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## ABSTRACT

**Background:** This study is conducted to investigate the effectiveness of extracorporeal shockwave lithotripsy (ESWL) after biliary stent placement compared to biliary stent placement alone in difficult common bile duct stones.

**Method:** This is a retrospective cohort study using medical record data from the Gastrointestinal Endoscopy Center Registry of Dr. Cipto Mangunkusumo General National Hospital. We retrospectively evaluated 126 subjects with difficult bile stones. The subjects were divided into two groups: subjects subjected to biliary stent placement only and subjects who underwent ESWL procedure after the biliary stent placement. The effectiveness of the procedures was measured in the form of total clearance of bile stones.

**Results:** A total of 126 subjects were included in this study, including 72 subjects who underwent ESWL procedure after biliary stent placement and 54 subjects who underwent biliary stent placement only. The effectiveness of ESWL after biliary stent placement in achieving total clearance was 69.1%, and the effectiveness of biliary stent placement in achieving total clearance was 64.8%. The ESWL procedure as adjuvant therapy after biliary stent placement did not provide a statistically significant difference ( $p = 0.703$ ; 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 after biliary stent placement has the same level of effectiveness as biliary stent placement alone.

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

## ABSTRAK

**Latar belakang:** Penelitian ini dilakukan untuk mengetahui efektivitas extracorporeal shockwave lithotripsy (ESWL) setelah pemasangan stent bilier dibandingkan dengan hanya pemasangan stent bilier saja pada kasus batu saluran empedu yang sulit.

**Metode:** Penelitian ini merupakan penelitian kohort retrospektif dengan menggunakan data rekam medis

dari Pusat Endoskopi Saluran Cerna RSUPN Dr. Cipto Mangunkusumo. Kami mengevaluasi 126 subjek dengan batu empedu sulit secara retrospektif. Subjek dibagi menjadi dua kelompok yaitu subjek yang hanya dilakukan pemasangan stent bilier dan subjek yang menjalani prosedur ESWL setelah pemasangan stent bilier. Efektivitas dari prosedur diukur dalam bentuk klirens total batu empedu.

**Hasil:** Sebanyak 126 subjek diikutsertakan dalam penelitian ini, termasuk 72 subjek yang menjalani prosedur ESWL setelah pemasangan stent bilier dan 54 subjek yang 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 ( $p = 0,002$ ).

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

**Kata kunci:** extracorporeal shockwave lithotripsy, stent bilier, batu saluran empedu, batu empedu

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is still the treatment of choice in patients with common bile duct stones with an 80–90% success rate.<sup>1</sup> However, in around 10–15% of patients with common bile duct stones, the stones cannot be extracted because of the size, shape, multiple numbers, or the location of stones.<sup>2</sup> Thus, ERCP alone is inadequate, and other modalities are needed for the management of the difficult common bile duct stones. There are various modalities for difficult common bile duct stones management. The options ranging from non-surgery to surgery. Nowadays, non-surgical therapy is the first choice, given the greater morbidity of the surgical approach. Non-surgical treatment modalities include endoscopic papillary balloon dilatation, mechanical lithotripsy, laser lithotripsy, electrohydraulic lithotripsy, extracorporeal shock wave lithotripsy (ESWL), and biliary stent placement.<sup>3</sup> In 1989, Sauerbruch et al reported the use of ESWL for common bile duct (CBD) stone achieving 90% fragmentation.<sup>4</sup> Previous studies on ESWL for difficult CBD stone showed a 73–84% rate of bile duct clearance.<sup>5</sup> Currently, there is no study comparing ESWL and stenting only for difficult CBD stones. Therefore, this study is conducted to determine the effectiveness of ESWL after biliary stent placement compared to biliary stent placement alone in difficult CBD stones.

## METHODS

This study is a retrospective cohort study that observed the effectiveness of total stone clearance

from ESWL procedure as adjuvant therapy after biliary stent placement in subjects 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. The inclusion criteria of this study were adult subjects over the age of 18 years with difficult stones, that is, by definition: (1) Stone size more than 15 mm; (2) Multiple stones; (3) Bile duct stenosis; (4) History of surgery, or with the most recent definition; (5) Subjects with stones that cannot be extracted by conventional ERCP methods and were difficult to extract by operators. All subjects included had undergone biliary stent placement and continued with ESWL. Exclusion criteria was if the data is not sufficient for analysis.

## Interventions and Outcomes

The subjects in biliary stent placement only groups were subjects who underwent plastic biliary stent placement only using single or double stent types, and stones removal through ERCP. Meanwhile, the subjects in ESWL adjuvant group were subjects who underwent the ESWL procedure after biliary stent placement or ERCP was performed. 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 in around 3–6 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

Statistical package for social sciences (SPSS) version 20.0 was used for all statistical analyses. We performed normality test. Data with normal distribution were shown in number (percentage), while data with skewed distribution were shown in median (min-max). Chi-square test was used and relative risk was obtained to determine the difference in effectiveness between ESWL adjuvant therapy vs. bile stenting placement only.  $P < 0.05$  is considered significant.

## RESULTS

### Baseline Characteristics of Research Subjects

In this study, 126 subjects were evaluated, with 54 subjects in biliary stent placement only group and 72 subjects in ESWL adjuvant group. The mean age of the subjects with difficult stones was  $50 \pm 19.2$  years, with more females than male subjects (54% and 46%, respectively).

Based on the number of stones, single stones were found in 43 subjects (34.4%) and multiple stones in 82 subjects (65.6%). Most of the subjects had stones in the choledochal duct based on stone location (102 subjects, 84.3%). Periampullary diverticula were found in 15 subjects (11.9%), common bile duct stenosis was found in 16 subjects (12.7%), papillary vascular abnormalities were found in 10 subjects (7.9%), and history of cholecystectomy was found in 4 subjects (3.2%).

The mean body mass index (BMI) in this study was  $23.1 \pm 4.1$  kg/m<sup>2</sup>. The use of 600–750 mg of ursodeoxycholic acid (UDCA) per day was found in 71 subjects (56.3%). Plastic stent was used in all subjects; most of the stent used was Tannenbaum plastic stents in 46 subjects (37.4%). On subjects who underwent the ESWL procedure after biliary stent placement, the ESWL sessions were given three times with a mean shock of 4,667 Hz. The power given for each session was 17 and 18 times 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 and Table 2.

**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)
≥ 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)
≥ 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

**Table 2. Basic characteristic of ESWL procedures and stenting**

Characteristics	Stenting and ESWL (N(%))	Stenting (N(%))
Cannulation		
Difficult	12 (83.3)	4 (7.4)
Easy	60 (16.7)	50 (92.6)
Stent type		
Tannenbaum	28 (38.9)	18 (35.3)
Double pigtail	19 (26.4)	9 (17.6)
Single pigtail	3 (4.2)	4 (7.8)
Cotton leung	22 (30.6)	20 (39.2)
Balloon size (mm)	15 (12–18)	15 (12–18)
Stent diameter (Fr)	10 (7–10)	10 (7–10)
Stent length (cm)	9 (4–15)	9 (6–15)
ESWL session	3 (1–10)	
ESWL shock (Hz)	4667 (4000–5000)	
Power per session in rate I	18 (16–20)	
Power per session in rate II	17 (15–21)	
Second session of ERCP (Months)	3 (3–6)	3 (3–6)

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%. There was no statistical difference in the total clearance effectiveness in both groups ( $p = 0.703$ ; RR = 1.050; 95% CI: 0.816–1.351). The comparison of effectiveness between ESWL procedure after biliary stent placement and biliary stent placement only in achieving total clearance of difficult stones can be seen in Table 3.

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 4.

## DISCUSSION

Difficult stones cannot be extracted with ERCP only but require additional therapy, including lithotripsy, biliary stent placement, or surgery. Surgical therapy is not the first choice therapy, due to high complication, mortality, and morbidity rates. With the development of technology, non-surgical methods were also rapidly developing. In subjects with difficult stones, non-surgical management options include the biliary stent placement, mechanical lithotripsy, and ESWL.<sup>4,6</sup>

ESWL is usually performed in patients with large CBD stones that are not extractable with conventional techniques. ESWL is also indicated in patients with retained stones after cholecystectomy, and is useful in patients who refuse or unfit for surgery. ESWL is contraindicated in patients with coagulative disorders and acute cholangitis. However, if those conditions are treatable, then ESWL can be performed after they are treated.<sup>7</sup>

In this study, 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. Of 126 subjects with difficult stones, total clearance was found in 49 subjects (69.1%) in the ESWL adjuvant group and 35 subjects (64.8%) in the biliary stent placement only group ( $p = 0.703$ ; RR = 1.050; 95% CI: 0.816–1.351).

From a total of 126 subjects, 72 subjects underwent ESWL procedure after biliary stent placement. 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. In this study, the final outcome was stone total clearance to assess the effectiveness of ESWL as adjuvant therapy after biliary stent placement.

**Table 3. The bivariate analysis of effectiveness between ESWL adjuvant and biliary stent only for difficult common bile duct stones**

Variable	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)		

ESWL: extracorporeal shockwave lithotripsy

**Table 4. 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)		
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

The amount of ESWL shock and sessions in this study was similar to the research conducted by Tandan et al, with the difference in the amount of power per minute given. In the study conducted by Tandan et al, the ESWL session was given three times, the shock given per session was a maximum of 5000 shocks, and power 90 times/minute; and the outcome of ductal clearance after ESWL procedure. After evaluation with ERCP, 239 subjects (84.45%) achieved total 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.<sup>5</sup> When compared with Tandan et al, the power given in this study was 17 times/minute, which was very low compared to a dose of 90 times/minute in Tandan et al study.

Tao et al conducted a similar study with Tandan et al in 2017 regarding the effectiveness of the ESWL and ERCP sessions on difficult stone subjects before and after ESWL using the same dose, power 90 times per minute, and 4000–5000 Hz shock. Tao et al conducted research on 231 subjects, with total ductal clearance of stones as the main outcome. In this study, the second and third ESWL sessions achieved total clearance. However, some patients underwent ESWL until the seventh session.<sup>8</sup>

Compared to the research conducted by Tao et al, the shock given and the ESWL session in this study were similar, but the power per minute given was lower. The effectiveness of ESWL as adjuvant therapy in this study was not statistically significant. It can be caused by the amount of power per minute given below the standard dose, compared to other studies that used power 60–90 times/minute. Other studies in ESWL for urinary stones also obtained 60–90 shocks/minute as the ideal shockwave for lithotripsy.<sup>9–11</sup>

Factors influencing the effectiveness of ESWL as adjuvant therapy after biliary stent placement in achieving total clearance of difficult stones have not been thoroughly analysed. However, influencing factors found in several studies including stone type, stone shape, number of stones, location of stones (proximal to the bile duct stenosis), anatomical

abnormalities of the biliary system, type of ESWL machine used, and body mass index (BMI).<sup>7,8,12</sup>

In this study, BMI was found to be a factor related to the effectiveness of ESWL or total clearance in ESWL after biliary stent placement. This study obtained similar result to the study conducted by Frank et al in 2014, which examined the total clearance in 73 difficult stone subjects who underwent ESWL procedure.<sup>13,14</sup> 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.<sup>15</sup>

Obesity is also an established risk factor for failed ESWL for renal and ureter stones. BMI is an independent risk factor for successful ESWL because ESWL efficacy is influenced by the skin-to-stone distance, which increases in obese patients due to the thicker layer of subdermal fat. The fatty tissue in obese patients might also cause poorer detection of the stones.<sup>16</sup>

In this study, pancreatitis after ERCP procedure was found in a small number of subjects, and the complications can be appropriately managed. At the same time, severe complications such as biliary sepsis to mortality were not found in this study. Other complications in subjects who underwent ESWL procedure include perirenal hematoma, biliary obstruction, intestinal perforation, necrotic pancreatitis, pain, ecchymosis at the site of the ESWL, and haemobilia.<sup>7,8,17</sup> This study could not find detailed data of complications experienced in subjects who underwent ESWL after biliary stent placement; thus, the other complications cannot be explained in detail.

In this study, 26 subjects did not complete treatment. These subjects had no total clearance data. These subjects who did not complete treatment had the same basic characteristics as the subjects studied and analysed, including 13 subjects who underwent biliary stent placement only and 13 subjects who underwent ESWL after biliary stent placement.

The limitation of this study includes some incomplete data, especially data regarding the type of ESWL machine, stone type, and complications from ESWL. Since this is a retrospective study using

registry data from our endoscopy center, there was no randomization of subjects who underwent biliary stent placement with ESWL and subjects who underwent biliary stent placement only, increasing the risk of bias.

## CONCLUSION

For the extraction of common bile duct difficult stones, ESWL as adjuvant therapy after biliary stent placement has the same effectiveness in achieving total clearance compared to biliary stent placement only. For further clinical application, still needs other prospective studies using different power of ESWL for difficult common bile duct stones to achieve higher clinical efficacy.

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