

## Clinical Research

### Management of bladder stones: the move towards non-invasive treatment

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#### ABSTRAK

**Latar belakang:** Batu buli merepresentasikan sekitar 5% dari semua kasus batu saluran kemih. Penanganan batu buli terus berkembang dari operasi terbuka, intracorporeal lithotripsy dan extracorporeal shock wave lithotripsy (ESWL). ESWL adalah sebuah modalitas yang menjanjikan dalam penanganan batu buli karena dapat ditoleransi dengan baik dan lebih sederhana. Penelitian ini dilakukan untuk mengumpulkan data yang dapat menggambarkan keamanan dan efektifitas dari ESWL dalam penanganan batu buli.

**Metode:** Studi ini merupakan sebuah studi retrospektif yang mengambil data dari rekam medis 92 pasien yang didiagnosa batu buli di Rumah Sakit Cipto Mangunkusumo (RSCM) dari Januari 2011 sampai April 2015. Data yang dikumpulkan meliputi usia pasien, jenis kelamin, jenis batu, prosedur yang dilakukan dan status disintegrasi batu, lama rawat dan komplikasi yang mungkin terjadi. Semua data dianalisis secara statistik menggunakan SPSS versi 20.

**Hasil:** Mayoritas pasien menjalani prosedur ESWL (49 dari 92, 53,3%). Angka bebas batu untuk tindakan ESWL, intracorporeal lithotripsy, dan sectio alta adalah 93,9%, 97,0% dan 100% secara berurutan. Salah satu pasien harus mengulang prosedur ESWL. Rerata ukuran batu ditemukan paling kecil pada kelompok ESWL bila dibandingkan dengan kelompok intracorporeal lithotripsy dan sectio alta (2,5 cm±2,0 cm vs 4,8 cm±3,7 cm vs 7,4 cm±5,4 cm secara berurutan). Prosedur ESWL dilakukan pada klinik rawat jalan.

**Kesimpulan:** ESWL dapat direkomendasikan sebagai modalitas terapi yang efektif dan non-invasif dalam penanganan batu buli dengan angka bebas batu yang cukup baik (93,9%) Tindakan ESWL bisa dilakukan di poliklinik rawat jalan dengan komplikasi yang minimal.

#### ABSTRACT

**Background:** Bladder stone accounts for 5% of all cases of urolithiasis. Bladder stones management has evolved over the last decades from open bladder surgery (sectio alta) to intracorporeal cystolithotripsy as well as extracorporeal shock wave lithotripsy (ESWL). ESWL presents to be a promising modality in the management of bladder calculi due to its simplicity and well tolerability. This study is thus conducted to present data on the safety and effectiveness of ESWL in the management of bladder stone patients.

**Methods:** This is a retrospective study evaluating the medical records of 92 bladder calculi patients admitted to Cipto Mangunkusumo General Hospital (RSCM) from January 2011 to April 2015. Patient's age, gender, type of stone and procedure being done, status of stone disintegration, length of hospital stay, and any complications that may occur are noted down and statistically analyzed using SPSS v. 20.

**Results:** Majority of the patients underwent ESWL (49 out of 92, 53.3%). The stone free rates for ESWL, intracorporeal lithotripsy, and sectio alta are 93.9%, 97.0% and 100% respectively. One patient had to repeat ESWL. The ESWL group had the smallest stone size average compared to the intracorporeal lithotripsy and section alta group (2.5 cm±2.0 cm vs 4.8 cm±3.7 cm vs 7.4 cm±5.4 cm respectively). The ESWL sessions were conducted in the outpatient clinic, and thus no hospital stay was required.

**Conclusion:** ESWL can be suggested as an effective non-invasive approach in the disintegration of bladder stone of ≤25 mm with a promisingly high stone-free rate (93.9%) Furthermore, ESWL can be performed on an outpatient basis with minimal complications.

**Keywords:** Bladder stone, cystolithotripsy, ESWL, sectio alta

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The advent of antimicrobial treatment and improvement in nutritional intake has played a significant role in reducing the incidence of bladder stones in the last couple of decades. Nowadays, bladder stones or calculi represent approximately 5% of all cases of urolithiasis.<sup>1</sup> Formations of bladder calculi are usually facilitated by the presence of bladder outlet obstruction, neurogenic voiding dysfunction, infection, as well as foreign objects.<sup>2</sup> Some other additives, for example in melamine-containing milk, had also been reported to cause formation of melamine-uric acid vesical stone in a child.<sup>3</sup>

Management options for bladder calculi are varied, and novel approaches have been developed in the last decades. Nevertheless, an ideal single approach to achieve stone clearance remained debatable due to the variations in stone burden and patient characteristics.<sup>2</sup> In general, *sectio alta* is usually reserved for pediatric bladder stone and evacuation of large calculi (stone size >4 cm).<sup>2</sup> This approach may also be indicated in hard stones that are refractory to endoscopic procedures. On the other hand, transurethral approach for bladder stone clearance provides an attractive alternative because it requires no incision (as it uses normal orifice) and permits the use of diverse tools for stone fragmentation. These include mechanical stone crusher, ultrasound, pneumatic and electrohydraulic lithotriptors, and combined ultrasonic/pneumatic lithotripsy device and laser energy sources, each of them with its own advantages and disadvantages.<sup>2,4-6</sup> Alternatively, extracorporeal shock wave lithotripsy (ESWL) also presents a promising management for bladder stones due to its simplicity and tolerability. It is especially indicated in high-risk patients who are poorly tolerant to operative procedures.<sup>2</sup> Additionally, ESWL is usually performed on an outpatient basis, does not require anesthesia and avoids prolonged urethral instrumentation.<sup>7,8</sup> Many previous studies presented promising data on its efficacy as a monotherapy in bladder stone.<sup>9-11</sup> Therefore, this retrospective study is conducted to explore the safety and effectiveness of bladder stone management in the Cipto Mangunkusumo General Hospital (RSCM) who underwent ESWL.

## METHODS

This is a retrospective study evaluating the medical records of patients who were admitted at the Cipto Mangunkusumo General Hospital with the diagnosis of bladder stones from January 2011 to April 2015. The confidentiality of the subjects identities was guaranteed. Case of bladder stones were diagnosed radiographically either by plain radiography or ultrasonography. Data regarding patient's age, gender, type of stone, type of procedure being done, status of stone disintegration, days of hospital stay, and any complications that may occur are noted down. The Ethics Committee of the Faculty of Medicine, University of Indonesia, with regards of the protection of human rights and welfare in medical research, has carefully reviewed and approved this study with Ethical Clearance (No. 446/UN2.F1/ETIK/2016).

Patients who underwent ESWL were treated on supine position using PiezoLith 3,000 Plus –Richard Wolf. The number of shocks delivered in each session ranges from 4,000 to 6,000 shocks. After undergoing ESWL, the patients were re-evaluated by ultrasonography or plain abdominal radiograph at two weeks interval. Second ESWL session was indicated or conducted in the presence of significant stone fragment (>5 mm). Patients not undergoing ESWL underwent either intracorporeal lithotripsy procedure using electro-pneumatic lithotripter (ELMED VIBROLITH) or cystolithotomy/*sectio alta*.

The data gathered in this study are analyzed using SPSS Statistics 20. The average age, stone size, and hospital stays in between different treatment groups (ESWL, intracorporeal lithotripsy, and *sectio alta* group) will be statistically analyzed using one way Anova to test whether there are statistically significant difference in various treatment groups in terms of average age, stone size, and duration of hospital stays. Post Hoc test will then be conducted to show the difference between treatment groups.

## RESULTS

From January 2011 to April 2015, 92 patients had been admitted to the Cipto Mangunkusumo

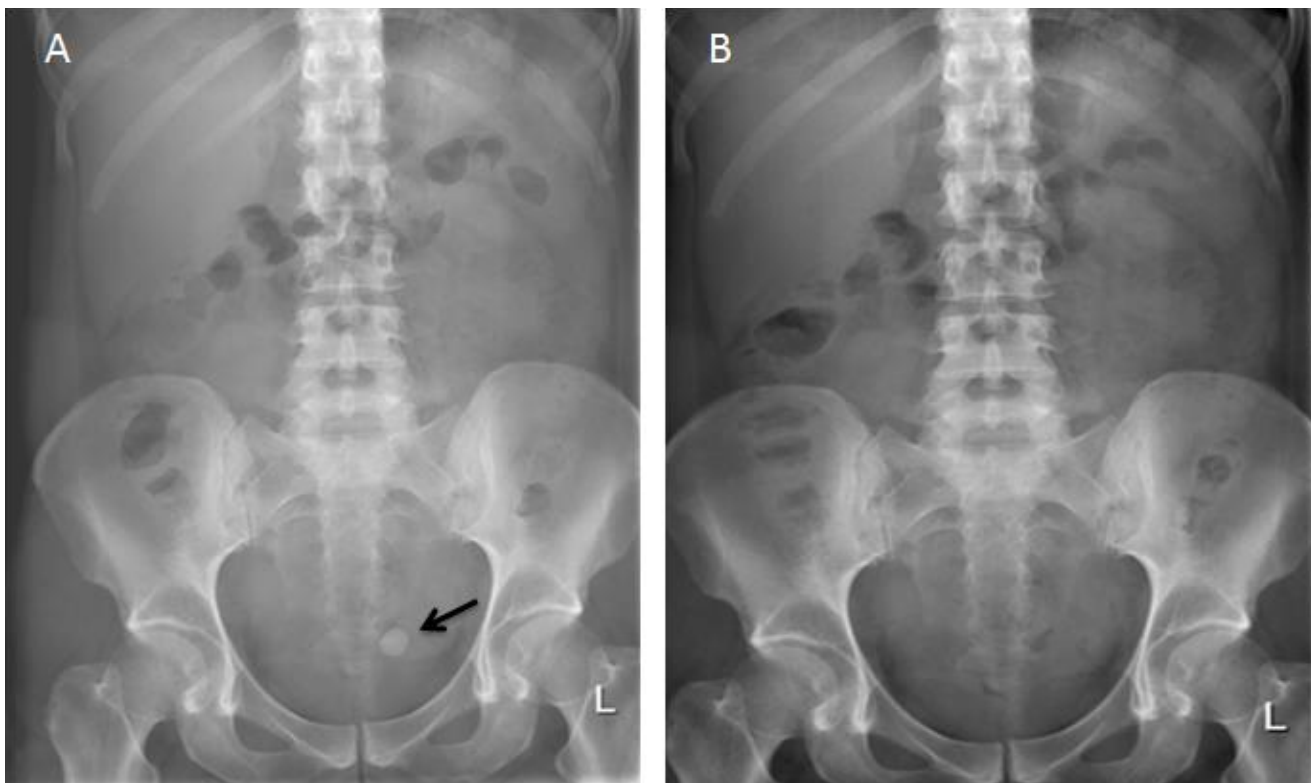
General hospital with diagnosis of bladder stone. They were mostly male patients (83 patients out of 92, 90.2%) with the average age around 51.3 ( $\pm 14.4$ ) years old. 78.3% (n=72) underwent plain abdominal imaging whereas only 8.7% (n=8) of them underwent ultrasonography (USG) examination. The rest of the patients underwent both radiographic examinations before being treated. The stones found from these patients are predominantly radiopaque (88 out of 92, 95.7%) and solitary in nature (84 out of 92, 91.3%) as shown in Table 1.

Majority of the patients admitted with bladder stone were managed by ESWL (49 out of 92, 53.3%) followed by intracorporeal lithotripsy (33 out of 92, 35.9%). Sectio alta was only performed in 10 out of 92 patients (10.9%). The stone free rate for ESWL, intracorporeal lithotripsy, and sectio alta are 93.9%, 97.0%, and 100% respectively (Table 2). Following the procedure, surgical site infection accompanied with fever was noted in one patient (1 out of 10, 10%) in sectio alta group (Table 3).

Overall, 49 patients out of 92 were treated with ESWL. One of these patients underwent ESWL

**Table 1.** Demographic characteristics

Demographic characteristics	(n = 92)
Patient's age (years)	51.3 $\pm$ 14.4
Gender	
Male	83 (90.2%)
Female	9 (9.8%)
Radiologic examination	
Plain radiograph	72 (78.3%)
USG	8 (8.7%)
Plain radiograph + USG	12 (13.0%)
Type of stone	
Radioopaque	88 (95.7%)
Radioluscent	4 (4.3%)
Number of stones	
Single	84 (91.3%)
Multiple	8 (8.7%)
Status of stone fragmentation	
Stone free	88 (95.7%)
Stone fragments present	4 (4.3%)



**Figure 1.** (A) Plain X-ray of patient with bladder stone (as indicated by black arrow); (B) Plain X-ray two weeks after last extra-corporeal shockwave lithotripsy (ESWL) session

for more than one session due to the presence of residual stone fragments two weeks post ESWL. The remaining patients underwent either intracorporeal lithotripsy or cystolithotomy. In general the average age of patients in ESWL and intracorporeal lithotripsy treatment group are similar ( $53.4\pm 10.8$  and  $53.2\pm 2.6$  years old, respectively) and older than patients undergoing sectio alta ( $36.9\pm 22.9$  years old). One way Anova test shows that the mean age in between these three treatment groups are significantly different ( $p=0.004$ ). However, Post Hoc test results have been inconclusive.

The average stone size was found to be the largest in patients undergoing sectio alta and the smallest in the ESWL group ( $7.4\pm 5.4$  and  $2.5\pm 2.0$

respectively). Similarly, there was also significant difference in the average stone size (cm) in between the three groups. Tamhane Post Hoc test shows that this significant difference lies between ESWL and Intracorporeal lithotripsy group ( $2.5\pm 2.0$  vs  $4.2\pm 2.8$  respectively,  $p=0.014$ ). ESWL was conducted in an outpatient setting therefore no hospital stay was required. On the contrary, the average days of hospitalization were  $4.8\pm 3.3$  and  $10.9\pm 8.2$  days for Intracorporeal lithotripsy and sectio alta group respectively. On the other hand, however, Post Hoc test did not show significant difference in the duration of hospital stay between intracorporeal lithotripsy and sectio alta group. In general, patients who underwent sectio alta had longer duration of hospital stay (Table 4).

## DISCUSSION

Bladder calculi represents approximately 5% of all cases of urolithiasis<sup>1</sup> with unique predisposing factors in different age groups and gender.<sup>2,3,12-14</sup> In the early days, bladder calculi was first evacuated by open bladder surgery/sectio alta.<sup>15</sup> Further development of endourology technique had also contributed greatly in the transurethral management of bladder stones (intracorporeal lithotripsy). Intracorporeal lithotripsy had also been commonly performed simultaneously with trans-urethral resection of prostate (TURP) in male patients of older population with history of bladder outlet obstruction caused by benign enlargement of prostate glands.<sup>5</sup> Nevertheless, it is still being questioned whether performing TURP simultaneously with transurethral cystolitholapaxy is superior to medical therapy for benign prostate hyperplasia (BPH) alone.<sup>16</sup>

Both sectio alta and transurethral approach of stone evacuation are more advantageous than ESWL in the fragmentation of larger bladder stones. Nevertheless, both procedures have

**Table 2.** Stone-free rate of each procedure

Type of procedure	(n=92)	Stone-free rate
ESWL	49 (53.2%)	93.9% (46/49)
Intracorporeal lithotripsy	33 (35.8%)	97.0% (32/33)
Cystolithotomy/ sectio alta	10 (10.8%)	100.0% (10/10)

ESWL=extracorporeal shockwave lithotripsy

**Table 3.** Procedural complications

Complications	ESWL (n=49)	Sectio alta (n=10)	Intracorporeal lithotripsy (n=33)
Fever	0(0.0%)	1(10.0%)	0(0.0%)
UTI	0(0.0%)	0(0.0%)	0(0.0%)
Urethral injury	-	0(0.0%)	0(0.0%)
Stone fragment impaction	0(0.0%)	0(0.0%)	0(0.0%)
Uncontrolled bleeding	-	0(0.0%)	0(0.0%)
Surgical site infection	-	1(10.0%)	-
Bladder perforation	-	0(0.0%)	0(0.0%)

ESWL=extracorporeal shockwave lithotripsy; UTI=urinary tract infection

**Table 4.** Comparison between ESWL patients and patients from other treatment groups

	ESWL	Intracorporeal lithotripsy	Cystolithotomy/ sectio alta	p
Patients (n)	49	32	10	-
Age of patients (year)	$53.4\pm 10.3$	$53.2\pm 12.5$	$33.5\pm 22.8$	0.004
Stone size (cm)	$2.5\pm 2.0$	$4.2\pm 2.8$	$7.4\pm 5.4$	<0.001
Hospital stay (days)	0	$4.8\pm 3.3$	$10.9\pm 8.2$	-

ESWL=extracorporeal shockwave lithotripsy

also a number of disadvantages since they must be performed under anesthesia, and long tedious postoperative hospital stay is inevitable. Additionally, transurethral approach also has several additional disadvantages such as longer operating time, hematuria, risk of bladder perforation, and potential urethral injury as their disadvantages.<sup>7,17</sup> ESWL, on the contrary, is a non-invasive modality that utilizes high energy acoustic pulses generated outside the body.<sup>18</sup> The effective applications of ESWL in disintegrating both radiopaque and radiolucent renal stones (e.g. uric acid stones) have been well described.<sup>19</sup> Kostakopoulos et al,<sup>11</sup> Al-ansari et al,<sup>20</sup> and Telha et al<sup>21</sup> have also mentioned ESWL's role as a monotherapy in bladder stones fragmentation. The use of ESWL as a monotherapy in bladder stones, however, still has some controversial issues to address. The first is the fact that the recurrence rate of bladder stone after ESWL monotherapy is not well determined yet. This raises some debates on how long a patient needs to be followed up after an ESWL session.<sup>9</sup> Secondly, there has also been some controversies regarding the proper patient positioning during the ESWL session. Some authors suggested a prone position<sup>17</sup> while others recommended conducting the session in a supine position.<sup>10</sup> Some authors preferred supine position because they assumed that in prone position, the sacrum might hinder stone fragmentation to some extent.<sup>21</sup>

In this study, 49 out of 92 patients underwent ESWL with stone-free rate of 93.9%. The stone-free rate observed in this study is comparable to the results gathered by El-Halwagy et al<sup>8</sup> and Telha et al<sup>21</sup> with stone-free rate of 96.6% and 95.5%.<sup>8,21</sup> One case series of twenty patients with bladder stone with concurrent paraplegia have demonstrated 100% stone-free rate after ESWL session.<sup>22</sup> The stone free rate of ESWL compared favorably to patients who underwent either intracorporeal lithotripsy or sectio alta (stone-free-rate of 97% and 100% respectively). Both these studies mentioned above, included patients in which ESWL is the first procedure performed for bladder stone management. This provides some suggestions that ESWL may be recommended to patient as the first line therapy before looking at other more invasive approaches. In this study, the success of ESWL in bladder stone treatment may be affected by the stone diameter. Apparently, the stone diameter of patients who underwent

ESWL are significantly smaller than the patients undergoing intracorporeal lithotripsy and sectio alta ( $2.5\pm 2.0$  vs  $4.2\pm 2.8$  vs  $7.4\pm 5.4$  respectively,  $p=0.004$ ). This finding in mean stone diameter in patients undergoing ESWL was similar to the study conducted by El-Halwagy et al<sup>8</sup> ( $2.6\pm 1.0$  cm) and Kilciler et al<sup>22</sup> ( $2.9\pm 0.6$ ). The smaller diameter of bladder stone in patients undergoing ESWL may be one of the determinants in the success rate. Other possible factors that may play a role in successful stone fragmentation in ESWL include the presence of bladder outlet obstruction and stone composition.<sup>2</sup> Nevertheless, bladder outlet obstruction has been proven to have limited effect in ESWL's success rate of stone fragmentation.<sup>8</sup> Additionally, in this study, patients underwent ESWL on the outpatient basis, and thus no hospital stay was required. Moreover, after each ESWL session, clearance of stone fragments did not require any placement of urinary catheters.

This study, however, has a number of limitations. Firstly because this study is retrospective by nature. Confounding factors that may affect treatment's success rate could not be minimized. Therefore, the impact of stone composition, urinary tract infection (UTI), stone burden, and presence of bladder outlet obstruction (BOO) on the treatment outcome could not be addressed. Secondly, this study also has a limitation in presenting the data of the recurrence rate of bladder stone after ESWL monotherapy. Additionally, this study also has limited data on the comorbidities in patients indicated to undergo ESWL treatment. These limitations can be tackled effectively if future studies in regards to ESWL monotherapy in bladder stone cases are conducted prospectively.

In summary, ESWL is a promising modality in the fragmentation of bladder stones. It provides a relatively high stone-free-rate (93.9%), can be done on an outpatient basis, and at the same time minimizes the need for anesthesia and urethral instrumentation with minimal complications. Therefore, ESWL can be suggested as a definitive treatment in patients with bladder stone of  $\leq 25$  mm in size especially in those with high anesthetic complications.

#### **Conflicts of interest**

The authors affirm no conflict of interest in this study.

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