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Extracorporeal shock wave lithotripsy as monotherapy for vesical calculi

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Abstract

Background Extracorporeal shock wave lithotripsy (ESWL) is a well-established non-surgical treatment of urolithiasis. ESWL as a monotherapy to treat vesical calculi is still unfamiliar among many urologists, despite its early introduction in the 1990's. ESWL monotherapy for vesical calculi was performed in our study in a unique fashion in supine position with full bladder unlike any other previous reported studies.

Methods We aimed this study to report our experience with ESWL as a monotherapy in treating urinary bladder stones with a unique technique. A total of 29 patients with vesical calculi were treated with ESWL monotherapy from May 2021 to January 2023 using Dornier delta lithotripter in the supine position with the full bladder without per urethral catheterisation. Patients with stone size > 2.5cm or Hounsfield units > 1200 were excluded. Stone clearance was assessed with the help of fluoroscopy and ultrasonography on a second visit on day 7 after the procedure. Patients were followed up for 3 months.

Results The mean size of vesical calculus was 1.6 cm (SD 0.32), and the mean Hounsfield unit was 940 HU (SD 86.61). None of the study subjects required surgical intervention. The stone clearance was obtained in 93.1% after a single session. The remaining two patients (6.9%) required one more session of ESWL following which stone clearance was obtained. One patient had acute urinary retention, and five (17.2%) patients had mild haematuria.

Conclusion ESWL monotherapy is a safe and effective treatment option for vesical calculi, with minimal or no patient discomfort, when done in supine position without routine per urethral catheterisation as described in the study. It should be considered more often by practicing urologists for vesical calculi.

Keywords Vesical calculi, ESWL, Monotherapy, Urolithiasis

1 Background

The search for lesser invasive treatments for urinary stone disease led to the discovery of extracorporeal shock wave lithotripsy (ESWL). Being an OPD procedure and not requiring anaesthesia coupled with the high success rate made ESWL patients' preferred choice whenever feasible. Although, initially started for renal pelvic calculi, ESWL has set foot into the treatment modalities of upper ureteric and vesical calculi in the present day.

The problem being mobility of bladder stones, ESWL was not used for bladder calculi initially. But advent of advanced ESWL machines solved this issue. Despite the initial studies on effectiveness of ESWL in vesical calculi in 1990's, ESWL is lesser-known treatment option among urologists for vesical calculi [1–3]. Hence, we aimed to study our experience of ESWL monotherapy for vesical calculi.

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2 Methods

The study was aimed to analyse our experience with ESWL monotherapy for vesical calculi. A prospective study was designed, and approval was sought from the institutional ethical committee. We included all the patients with single vesical calculi consenting for the study during May 2021 to January 2023. Exclusion criteria considered were coagulopathy, stone characteristics-HU > 1200, calculi > 2.5 cm and patients with history and physical examination findings suggestive of stricture urethra.

A total of 29 patients with vesical calculi were included and treated with ESWL monotherapy during the study period. Before the procedure, complete clinical evaluation with computed tomography (CT KUB) and ultrasonography (USG KUB) was performed in all the patients (Fig. 1). All the subjects were treated with ESWL monotherapy without any intravenous (IV) analgesia or sedation or spinal anaesthesia. Oral analgesics and rectal suppositories were given as and when required for analgesia. Dornier delta lithotripter with rotatable treatment arm was used with patients in supine Trendelenburg position in full bladder (Fig. 1). No routine per urethral catheterisation was done before or during the procedure. Patients were asked to drink plenty of fluids and hold urine for at least 2 h before the procedure. The procedure was performed by dedicated personnel using standard ramping up protocol, slow firing rate and with dynamic stone localisation throughout the procedure. After the procedure, patients were advised to void through a strainer for one week, to aid collection of stone fragments (Fig. 1). Stone clearance was assessed with the help of fluoroscopy and USG KUB on second visit on day 7 after the procedure. Patients were followed up for 3 months. Parameters evaluated are stone characteristics, number of ESWL sessions required, number and voltage of shockwaves used per session, failure of stone fragmentation, maximum fragment size and complications like acute urinary retention and haematuria. Failure is defined as need for surgical intervention.

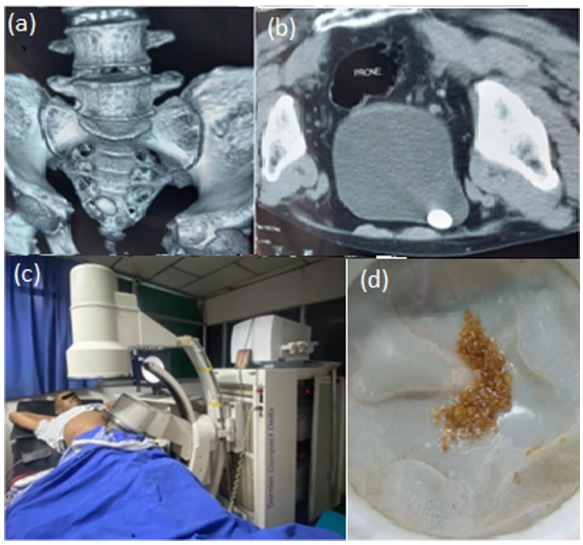

Fig. 1 **a**, **b** CT KUB showing vesical calculus, **c** a patient undergoing ESWL with a Dornier Delta lithotripter. **d** stone fragments voided in the strainer

Data were entered into Microsoft Excel data sheet and were analysed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables. Correlations were performed with Pearson correlation coefficient. *P* value (Probability that the result is true) of < 0.05 was considered as statistically significant after assuming all the rules of statistical tests. Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyse data.

3 Results

All the subjects were male, and mean age was 53.69 ± 9.72 years. Although age was not an exclusion criterion, there were no paediatric patients with vesical calculi during the study period.

Three (10.3%) subjects were found to have oedematous VUJ (vesicoureteral junction) on USG suggesting passed off calculus. Although the stone size was smaller (mean size of 1 cm) in such patients, the patients didn't opt for watchful waiting due to the severity of irritative symptoms from the calculus passed off from VUJ. Clinical and radiological evidence of prostatomegaly was found in 14 (48.3%) subjects with mean prostate size measuring 44.1cc on transabdominal USG.

None of the study subjects had chronic history of obstructive lower urinary tract symptoms. Four (13.7%) study subjects presented with strangury, one with acute retention of urine and the rest presented with acute history of obstructive lower urinary tract symptoms. Table 1 shows the demographical characteristics of study subjects. The preprocedural CT KUB showed the mean size of vesical calculus to be 1.6 cm (SD 0.32) and the mean Hounsfield unit of 940 HU (SD 86.61). Mean voltage of shockwaves used was 14.9 kV (SD 0.618), and mean number of shockwaves used per stone was 2525 (SD 593.95). Table 2 represents the detailed statistical data of the study. All patients except two of them, had complete stone clearance on day 7. The two patients (6.9%) required one more session of ESWL following which stone clearance was confirmed on USG and fluoroscopy. Only one (3.4%) patient had acute urinary retention

Table 1 Demographic data

	Number (n)	Per cent (%)
Age		
≤ 40 years	2	6.9
41–50 years	10	34.5
51–60 years	9	31.0
> 60 years	8	27.6
Total	29	100.0
Etiology		
None identified	12	41.4
Prostatomegaly	14	48.3
Oedematous VUJ (? passed out ureteric calculus)	3	10.3
Total	29	100.0

Table 2 Statistical data of various parameters

	Minimum	Maximum	Mean	Std. deviation
Size of vesical calculus (cm)	1.00	2.30	1.6	0.32
HU of stone	720	1126	940	86.62
Number of shock waves	1960	4000	2525	593.95
Voltage of shock waves (kV)	14	16	14.90	0.618

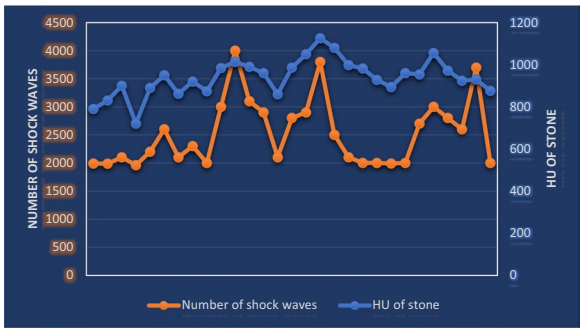

Fig. 2 Chart showing correlation between HU of stone and number of shock waves

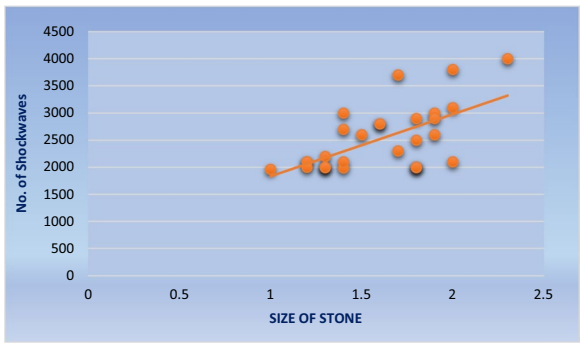

Fig. 3 Scatter plot showing correlation between size of vesical calculus and number of shock waves

which was managed by per urethral catheterisation and five (17.2%) patients had mild haematuria, managed conservatively. All of the subjects were managed with analgesics in the form of oral tablets and rectal suppositories as and when required. None of them required intravenous (IV) sedation or analgesia. Stone fragments collected were very fine. None of the patients in the study required surgical intervention.

There was positive strong correlation (Pearson correlation coefficient *r* value 0.64) between HU of stone and number of shock waves which was statistically significant ($p < 0.001$) depicted in Fig. 2. There was positive correlation (*r* value 0.61) between size of vesical calculus and number of shock waves which was statistically significant ($p < 0.001$) as depicted in Fig. 3

4 Discussion

ESWL was introduced in humans in early 1980's after successful attempts in dogs. In a few years following its introduction, ESWL soon became one of the common treatment modalities for urolithiasis [4]. ESWL was initially used to address renal pelvic calculi and later was also used to treat upper ureteric calculi [5, 6]. Shortly, it has developed into one of the most preferred treatment modalities for urolithiasis among patients [7].

ESWL in bladder calculi, started as an adjuvant procedure before performing endoscopic surgical treatment [2, 8]. Few studies were reported using ESWL as monotherapy for vesical calculi, as early as early 1990's [1, 9]. Despite its early debut, ESWL as a monotherapy is not well known and practiced less commonly by urologists. This might be partly due to varied concerns including success of procedure, possibility of repeated sessions. Hence, we aimed this study to evaluate our experience with ESWL in vesical calculi as a viable option for monotherapy.

Various lithotripters were developed from the first human prototype, Dornier HM1 (Human Model 1). The lithotripters have gone through various upgradations from the first serial lithotripter, the Dornier HM3 to the current fourth-generation lithotripters [10]. The present generation ESWL machines use EMSE 180 technology which helps in deeper penetration of shock waves. The 15 kW X-ray generator along with alternative ultrasound imaging modality in the present day, ESWL machines helps in better stone localisation. The Optivision technology present in the newer ESWL machines enhances strength of shockwaves at the focal point (stone) by optimizing the coupling at the treatment head. The flexible

treatment head which can be compressed against the skin over the vesical stone limits the stone mobility. Since, we perform the procedure with full bladder, and in supine Trendelenburg (15°–20°) position, the vesical stone comes closer to the lower abdominal wall. The positioning of the patient, flexible treatment head, enhanced coupling, dual imaging modalities, EMSE 180 and Optivision technologies in the newer machines makes ESWL for vesical calculi more effective.

While addressing bladder calculi, many centres perform the procedure in prone position with an indwelling Foleys catheter [3, 11, 12]. In our centre, with the availability of rotatable arm in Dornier Delta lithotripter, we attempted the procedure in supine position. In supine position, the coupling cushion of treatment head will be pressed against the anterior abdominal wall, thereby the urinary bladder. This apposition partly restricts the vesical calculus mobility when compared to prone positioning where the treatment head is placed against the spine. The supine positioning also provides the added advantage in a subset of patients with respiratory insufficiency and various musculoskeletal disorders. The supine positioning opens the door for ESWL to many more patients with vesical calculi. In our experience, we did not find an indwelling per urethral catheter necessary.

The stone localisation was dynamic throughout the procedure. The standard ramping up protocol, and shock wave delivery at slow rate along with dynamic stone localisation by dedicated personnel might have contributed to the high success rate in our study.

We observed the highly fine fragmentation of stones in the study subjects, which might have led to lesser complications like mild haematuria (17.2%) and acute urinary retention (3.4%). Despite of not having routine per urethral catheterisation, we observed acute retention of urine in only 3.2% of patients. This very small subgroup of patients with acute retention can be managed with simple measures like urethral catheterisation.

The patients with prostatomegaly were treated with alpha-blockers and dutasteride was added as appropriate after the ESWL. The highly fine fragmentation led to the smooth clearance of the calculus without much complications in these subjects.

Patients with history suggestive of stricture urethra such as chronic history of thin stream and other obstructive lower urinary tract symptoms or local examination findings such as meatal stenosis and induration were excluded from the study. The evaluation for bladder outlet obstruction prior to ESWL is best relied on history and physical examination findings. The further investigations to evaluate lower urinary tract obstruction should be avoided in presence of vesical calculus since it leads to false findings. Uroflowmetry, postvoid residual volume or urodynamic evaluation will yield false findings in the presence of vesical calculus. Hence, the patients with prostatomegaly on ultrasonography were treated with alpha-blockers ± dutasteride and were planned to be evaluated further for bladder outlet obstruction due to prostatomegaly after stone clearance.

In 41.4% of the patients, the cause for the vesical calculi couldn't be identified on initial evaluation. Further evaluation in the form of urethrography, diagnostic cystoscopy and urodynamics can be employed in such patients to identify the hidden cause.

The satisfactory success rate of ESWL in our study, i.e. 93.1% after single session and 100% after two sessions is encouraging.

The significantly less morbidity of ESWL monotherapy when compared to various endoscopic and open procedures is well known. ESWL is the least morbid of all the interventions for vesical calculi including mini cystolithotomy (under local anaesthesia) due to its complete non-invasive nature and not requiring any anaesthesia. The cost-analysis comparing various interventions was not assessed in this study, but we believe ESWL to be a cost-effective procedure for vesical calculi in selected patients which needs to be evaluated further in future studies.

However, when considering ESWL for vesical calculi, it is essential to counsel patients about the very low risk of failure or need for repeated sessions. Patients should also be informed about significantly lower morbidity and low incidence of minor complications like mild haematuria or temporary irritative symptoms or acute retention of urine.

Its non-invasive nature, the fact that it does not require hospital admission or anaesthesia, and the very short duration of the procedure, coupled with rapid symptomatic relief and good success rate, make ESWL unique and preferable treatment modality in appropriately selected patients. It is only prudent to present ESWL as a preferred modality for patients with single vesical stone < 2.5 cm and with no significant past history of lower urinary tract obstruction.

5 Conclusions

ESWL is a safe and effective procedure for treatment of single vesical calculi < 2.5 cm and with no significant bladder outlet obstruction. ESWL as treatment modality for monotherapy of vesical calculi (bladder stones) is less familiar among urologists. It is essential to present ESWL as an option in patients with single vesical calculi < 2.5 cm without significant history of lower urinary tract obstruction after counselling the patient about very low risk of failure with single session or need for multiple sessions. Our study shows that ESWL monotherapy

is a viable, non-invasive, outpatient procedure with minimal/no patient discomfort and high success rate. Also, it is not necessary to catheterise the patient during or after the procedure as a routine practice. The supine position paves the way for ESWL to be applicable to more patients with vesical calculi. We found it can also be used in patients with mild-to-moderate prostatomegaly. In essence, ESWL can enhance the patient's comfort as it offers advantages such as OPD/day care procedure, supine position during procedure, simple oral analgesia without sedation or intravenous analgesia. Hence, young urologists should not hesitate to consider ESWL as a monotherapy for bladder calculi in selected patients.

Abbreviations

ESWL	Extracorporeal shockwave lithotripsy
HU	Hounsfield units
USG KUB	Ultrasonography of kidneys, ureters and bladder
CT KUB	Plain computed tomography of kidneys, ureters and bladder
OPD	Outpatient department

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None.

Author contributions
BM collected and analysed the data and drafted the manuscript. AN collected the data and drafted the manuscript. NK contributed the concept and design of the study and reviewed the manuscript. TI, JV, NK and JN did the literature search and helped in data acquisition. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Ethics approval obtained from the institutional ethical committee. Reference number- SIMS&RC/IEC/02/2023. Ethics committee name- Sapthagiri Institute of Medical Sciences & Research Centre Institutional Ethics Committee. Informed written consent to participate in the study was provided by all participants.

Consent for publication
Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient.

Competing interests
The authors declare that they have no competing interests.

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