



Shock wave lithotripsy versus endoscopic cystolitholapaxy in the management of patients presenting with calcular acute urinary retention: a randomised controlled trial

Mohamed Ali¹ · Abdelwahab Hashem¹ · Tamer E. Helmy¹ · Tamer Zewin¹ · Khaled Z. Sheir¹ · Ahmed A. Shokeir¹

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Abstract

Purpose Shock wave lithotripsy (SWL) in treatment of bladder and urethral stones was not precisely determined. The objective of this study is to compare the efficacy and safety of SWL versus visual cystolitholapaxy in the management of calcular acute urine retention.

Methods From March 2015 to February 2017, a randomised controlled study was conducted on 100 patients for whom urethral catheter fixed for acute retention of urine due to urethral or vesical radio-opaque stone(s) ≤ 2 cm. Patients were randomised to either SWL group ($n = 50$) or visual cystolitholapaxy (endoscopy group) ($n = 50$).

Results No statistically significant differences between the pre-operative parameters of both groups were found. The mean stone diameter was 12.2 ± 3 mm and 12.2 ± 3.2 mm in SWL and endoscopy groups, respectively (p value = 0.4). The overall success rates of SWL group were 94% (47 of 50 patients) and endoscopy group were 98% (49 of 50 patients). SWL failed in 3 patients (6%); these 3 patients underwent cystolitholapaxy and were rendered free of stones. Intra-operative and post-operative complications were comparable between both groups (p value = 0.5 and 1, respectively). One patient had bladder perforation in the endoscopy group and was managed conservatively.

Conclusions SWL mono-therapy is safe, non-invasive and as effective as visual cystolitholapaxy in management of patients presenting with acute urine retention by vesical or urethral stones 2 cm or less and could be useful for patients unwilling/unfit for general anaesthesia.

Keywords Urinary retention · Bladder stones (BS) · Shock wave lithotripsy (SWL) · Cystolitholapaxy · Urolithiasis

Introduction

Bladder stones (BS) are classified as migrant, primary idiopathic and secondary. Migrant BS are formed in the upper tract and passed to the bladder, whereas primary BS are associated with nutritional deficiencies. Secondary BS are complications of underlying conditions such as bladder outlet obstruction (BOO), neurogenic bladder, bladder diverticulae and foreign bodies [1].

Although shock wave lithotripsy (SWL) is currently the least invasive and ideal therapy for most of upper urinary tract stones, SWL usage for bladder and urethral stones

is very limited [2]. Endoscopic and to lesser extent, open manipulation are the traditional methods of urethral and BS management. However, these techniques require anaesthesia, hospitalisation and are associated with some morbidities such as haematuria, bladder perforation and urethral injury [3, 4].

By reviewing the previous reports [5], the indications of SWL in treatment of urethral and BS were not precisely determined and without strong level of evidence. To the best of our knowledge, this is the first randomised controlled trial (RCT), comparing the efficacy and safety of SWL versus endoscopic cystolitholapaxy for the treatment of patients who presented with calcular acute urinary retention.

✉ Abdelwahab Hashem
abdelwahab_hashem@yahoo.com

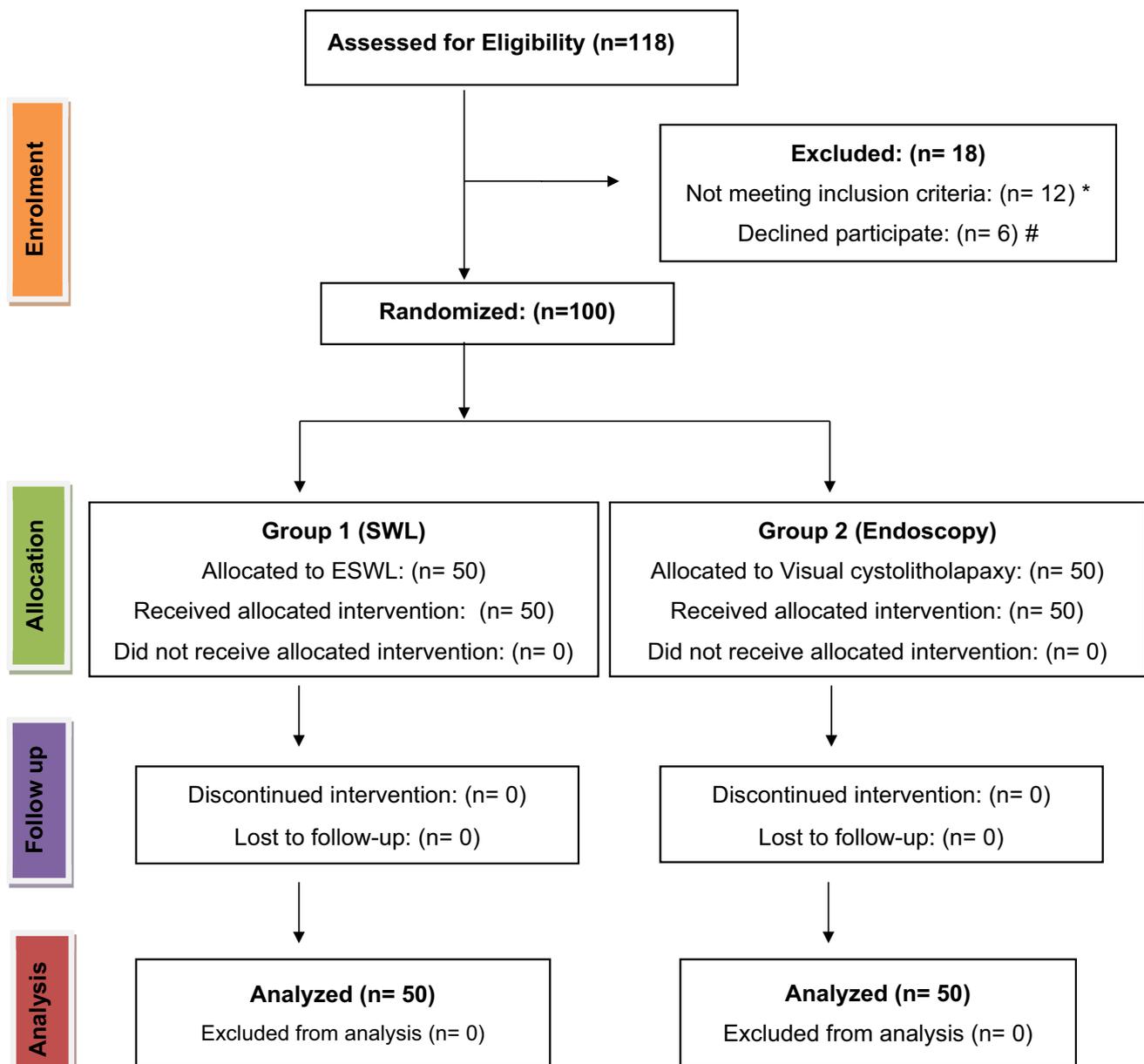
¹ Urology and Nephrology Center, Mansoura University, Mansoura, Egypt

Materials and methods

Patients

A RCT was conducted between March 2015 and February 2017 and was registered in Clinicaltrials.gov with ID: NCT02594631; a total of 118 male patients were

diagnosed at emergency room (ER) with acute retention of urine as a result of urethral or BS at Mansoura urology and nephrology centre. Only 100 patients aged between 18 and 60 years and with radio-opaque stones 2 cm or less in greatest dimension were eligible for participation in the study after success of fixation of urethral catheter at the ER, because 12 patients did not meet the inclusion criteria. The CONSORT flowchart for study participants is shown



* 8 patients had prostate size ≥ 80 gm, 3 patients had BS > 2 cm and 1 patient had radiolucent BS

6 patients refused to be randomised and prefer endoscopic management

Fig. 1 CONSORT flowchart for study participants. *Eight patients had prostate size ≥ 80 g, 3 patients had BS > 2 cm and 1 patient had radiolucent BS. #Six patients refused to be randomised and prefer endoscopic management

in Fig. 1. Exclusion criteria were bladder cancer, bladder replacement, radiolucent stone(s), more than two stones or BOO due to marked enlarged prostate ≥ 80 g, prostate cancer, stricture urethra or external urethral meatus stenosis. The primary endpoint was to assess the stone-free rate (SFR) at 1 month. The secondary endpoint was to assess the peri-operative complications.

Procedure

After urethral lubrication with 20 ml of lubricating gel, patients who had a successful trial of fixation of a silicon Foley's catheter (16 F) were included in the trial. No blinding (masking) was done in this RCT, and randomisation was performed using computer generated, sequential numbering and patients were allocated to receive either SWL (SWL group) ($n=50$) or visual cystolitholapaxy (Endoscopy group) ($n=50$). All patients were evaluated by a complete history and physical examination, urine analysis, urine culture, coagulation profile, complete blood count and serum creatinine level. Imaging included a plain abdominal film (KUB X-ray) for stone opacity assessment, 3D-abdominal and pelvic ultrasonography (US). Prostate size was automatically measured using Philips iU22 US machine.

All patients of the SWL group were treated in the supine position using the Dornier Gemini Lithotripter, under IV sedoanalgesia, and no prophylactic antibiotic was given unless indicated by positive urinalysis and culture. Endoscopy group patients were treated using Karl Storz cystoscope and Mauermayer stone forceps, under spinal anaesthesia with prophylactic antibiotic. None of the endoscopy group patients had concomitant prostate resection, if BOO was present.

After the initial SWL session, the urethral catheter was removed, provided that disintegration of BS was evident on fluoroscopy and there was no haematuria. In the endoscopy group, the patients were hospitalised till urethral catheter removal on the next day. Patients who had BOO because of prostate were discharged on alpha-blocker to be followed up at our prostate unit, for later management. Success was defined as bladder free of clinically insignificant residual fragment (CIRF) < 4 mm by US and KUB.

Follow-up

The patients were seen 1 week and 1 month after the procedure, and a KUB and US were performed. If a significant residual stone ≥ 4 mm was present in SWL group, the patient underwent another SWL session. Fortunately, we did not miss any patient during follow-up visits. The procedure was considered failed if no or inadequate stone fragmentation ≥ 4 mm and/or no clearance were observed

after three sessions, and the patient was scheduled for visual cystolitholapaxy.

Statistical analysis

From previous reports, the success rate for the SWL in treating BS was around 70%. Assuming type I statistical error of 5% and type II statistical error of 20%, we planned to obtain a power of 80% (using G power program). According to [2–4, 6, 7], the expected difference between the SWL group and the endoscopy group would be 25% and a sample size of 50 patients in each arm would be powered 80% to detect the difference with the account for 15% losses (e.g. patient who may miss follow-up).

The data were collected into IBM SPSS 20 program (IBM Corporation; Armonk, New York, USA). Categorical variables in the groups were compared using chi-square test. Continuous variables were compared using Student's *t* test. A *p* value < 0.05 was the cutoff for significance of the differences between the groups.

Results

The comparison of the pre-operative parameters between the two groups did not reveal any statistically significant differences (Table 1). The SFR of SWL group was 94% and that of endoscopy group was 98% ($p=0.3$). One session of SWL was sufficient to disintegrate and clear stones in 43 patients (86%), while 2 patients required 2 sessions (4%) and another 2 patients required 3 sessions (4%) (Table 2).

The mean number of shocks was 3402 ± 1452 , the median energy was 141.2 J, and the mean treatment duration was 44 ± 11 min. The median number of sessions was 1 (range 1–3). SWL failed in treatment of three patients (6%): two patients (4%) were failure of clearance even after achieving adequate fragmentation and one patient (2%) had no fragmentation at all. These patients underwent cystolitholapaxy and were rendered free of stones. We did not use any complementary endoscopic procedures for evacuation of the stone fragments, and they were left for spontaneous passage in the other successful patients (94%).

In SWL group, sessions were performed on outpatient basis, while in the endoscopy group, patients were hospitalised for 1 day, unless complicated. Intra-operative and post-operative complications were comparable between both groups (Table 2). All complications are of grade I based on Clavien–Dindo classification. In all patients of both groups who developed haematuria, it was self-limited and resolved within 12 h with adequate hydration. One case of the cystolitholapaxy group was complicated by bladder perforation with extrusion of the stone in front of Denonvilliers' fascia (Fig. 2) and was managed conservatively in the form

Table 1 Patients' and stones' descriptive data

	SWL group (n=50)		Endoscopy group (n=50)		p value
	Mean ± SD	N (%)	Mean ± SD	N (%)	
Age (years)*	43.5 ± 11.8		45.1 ± 10		0.4
ASA score**					
ASA I		39 (78%)		37 (54%)	0.9
ASA II		11 (22%)		13 (26%)	
BMI (kg/m ²)*	29.7 ± 4.4		29.4 ± 4.2		0.7
Past history of LUT surgery**		4 (8%)		1 (2%)	0.3
Prostate size: g***, median (min–max)	33 (15–70)		33 (15–75)		0.8
Pre-operative UTI**		10 (20%)		11 (22%)	1
S. uric acid (mg/dl)*	5.8 ± 1.3		5.9 ± 1.6		0.6
Haemoglobin (gm/dl)*	14.4 ± 1		14.2 ± 1.5		0.5
Prothrombine concentration (%)*	94 ± 6		92.8 ± 8.4		0.2
Hounsfield unit (HU)*	773 ± 165		804 ± 175		0.37
Stone length (mm)*.#	12.2 ± 3		12.2 ± 3.2		0.97
Stone width (mm)*.#	8.3 ± 2.6		8.9 ± 2.5		0.27
Stone type**					
Migratory		35 (70%)		30 (60%)	0.3
Primary idiopathic		0 (0%)		2 (4%)	
Secondary		15 (30%)		18 (36%)	
Stone nature**					0.2
Denovo		41 (82%)		42 (84%)	
Recurrent		9 (18%)		8 (16%)	
Stone number**					1
Single		49 (98%)		48 (96%)	
Two stones		1 (2%)		2 (4%)	

*Independent sample *T* test

**Chi-squared test

***Mann–Whitney *U* test

#Represent the maximal values for the stone or the largest one

of prolonged urethral catheterization (14 days), as it was asymptomatic.

Discussion

The choice of surgical approach and method of BS extraction have been determined by the availability of equipment, surgical experience, underlying comorbidities and stone characteristics (e.g. size and type) [8]. SWL could be an alternative option for the BS management [2, 4, 9]. Though secondary BS could be an indication for prostate surgery, Millan-Rodríguez successfully eliminated BS ≤ 4 cm² in 93% of the patient with BOO using SWL. Only 8% of the patients needed subsequent prostate surgery later on [3]. With the previous prospective study, we had level 2 evidence that BS are not an absolute indication for transurethral resection of the prostate (TURP), if the stones are < 4 cm² [5]. Fragmentation had been satisfactory in most of the series published for SWL for BS, reaching between 72.2% and

100% with effect of some factors in prognosis as the size of the BS, getting better results when BS had smaller size [3]. This rate decreased to about 25% if the BS would be larger than 6 cm [8]. In spite of the reports revealing that the success of the procedure is directly related to the size of the BS [4], in the current study, we found that the need for extra sessions of SWL and the failure were not related to the size of the BS and this finding may be explained by limiting the BS size to ≤ 2 cm in the our selected patient.

In the literature, SWL was a reasonably effective option for treatment of BS with SFR ranging 66–100% [5]. The SWL SFR for BS depending on its volume; 92% in BS smaller than 1 cm², 73% in 1–2 cm², 57% in 2–3 cm² and 42% in larger than 3 cm² [10]. Frabboni et al. used SWL for BS and had stone-free rate of 66% of the obstructed patients and 96% of the unobstructed patients [11]. Al-Ansari et al. studied 64 patients who presented with urethral or BS to the emergency department with acute urine retention and were treated with SWL; the stone-free rate was 98.4% [2]. In our study, radio-opaque BS ≤ 2 cm in greatest diameter and not

Table 2 Peri-operative complications and outcomes of both groups

	SWL group (<i>n</i> = 50), <i>N</i> (%)	Endoscopy group (<i>n</i> = 50), <i>N</i> (%)	<i>p</i> value
Intra-operative complications*			
Bladder mucosal injury	–	2 (4%)	0.5
Perforation	0 (0%)	1 (2%)	
Urethral injury	–	1 (2%)	
Post-operative complications*			
Haematuria	10 (20%)	8 (16%)	1
Urine retention	1 (2%)	0 (0%)	
Abdominal pain	0 (0%)	1 (2%)	
Overall	11 (22%)	9 (18%)	0.3
Stone free after 1st ses- sion*	43 (86%)	–	
Stone free after 2nd ses- sion*	2 (4%)	–	
Stone free after 3rd ses- sion*	2 (4%)	–	0.3
Overall stone free*	47 (94%)	49 (98%)	
Failure*	3 (6%)	1 (2%)	

*Chi-squared test

**Fig. 2** Pelvic NCCT showing extrusion of stone in front of Denonvilliers' fascia after bladder perforation as cystolitholapaxy complication; yellow arrows 1—urinary bladder, 2—the extruded stone, 3—Denonvilliers' fascia, 4—rectum

more than 2 stones in number were treated efficiently by SWL reaching an overall success rate of 94%.

Regarding the efficacy of endoscopic management for BS in the current literature, the SFR is about 83–100% [12–16]. Cystolitholapaxy group in this trial had a SFR 98%. Comparing the both modalities in our RCT: SWL and cystolitholapaxy in the management of patients presenting

with calculi acute urinary retention, we obtained SFR 94% versus 98%, respectively ($p = 0.3$). The higher SFR in our study is due to stone size ≤ 2 cm in greatest diameter. The advantage for SWL—although SWL require ionising radiation for localization—include outpatient treatment under sedoanalgesia, and options for repeated treatments, while the cystolitholapaxy was carried out under spinal anaesthesia [2, 17, 18]. However, SWL had some disadvantages; multiple therapeutic sessions may be necessary and no available management of the BS aetiology as BOO by prostate resection simultaneously.

Endoscopic cystolitholapaxy was reported to have a complication rate up to 25%, including urethral injury, vesical perforation and residual lithiasis, whereas SWL had up to 13% complication that required endoscopic procedures [8]. Data from a recent study reported that no pelvic haematoma or other complications were found, even for a patient who required 3 sessions, and the haematuria that developed in some patients was self-limiting, managed conservatively in all cases [4]. In this RCT, the complication rate was 20% and 18% for the SWL and cystolitholapaxy groups, respectively ($p = 0.79$). Bhatia and Biyani revealed that the complications as well as the hospital stay are tripled in the endoscopic extraction compared with the SWL for BS [7]. In our study, SWL was done as outpatient procedure. Endoscopic cystolitholapaxy had 1-day hospital stay, except for the patient of bladder perforation that was kept inpatient for 5 days.

Although this study is a RCT, it still has some limitations including: exclusion of stone > 2 cm that could make SWL to be less effective, the lack of a chemical analysis of the disintegrated stones, the omission of cost analysis and the number of patients in our study was not adequate to study the factors predicting the success of SWL in treatment of BS, so investigators are invited to carry out a study of good number of cases that can achieve such a goal.

Conclusions

SWL mono-therapy is safe, non-invasive and as effective as visual cystolitholapaxy in management of patients presenting with acute urine retention by vesical or urethral stones 2 cm or less in greatest dimension and could be useful for patients unwilling/unfit for anaesthesia.

Author contributions Ali M: patients' follow-up, data collection and manuscript writing. Hashem A: manuscript re-writing, revision and editing. Helmy T: supervision on patients' follow-up and data collection and manuscript revision. Zewin T: patients follow-up and protocol writing. Sheir KZ: SWL session supervision and statistical analysis. Shokier AA: study chief and supervision of study and manuscript revision.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and animal rights All procedures in this study involving human participants were in accordance with the ethical standards of the institutional committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

- Philippou P, Volanis D, Kariotis I, Serafetinidis E, Delakas D (2011) Prospective comparative study of endoscopic management of bladder lithiasis: is prostate surgery a necessary adjunct? *Urology* 78(1):43–47
- Al-Ansari A, Shamsodini A, Younis N, Jaleel OA, Al-Rubaia A, Shokeir AA (2005) Extracorporeal shock wave lithotripsy monotherapy for treatment of patients with urethral and bladder stones presenting with acute urinary retention. *Urology* 66(6):1169–1171
- Millan-Rodriguez F, Izquierdo-Latorre F, Montlleó-González M, Rousaud-Barón F, Rousaud-Barón A, Villavicencio-Mavrich H (2005) Treatment of bladder stones without associated prostate surgery: results of a prospective study. *Urology* 66(3):505–509
- El-Halwagy S, Osman Y, Sheir KZ (2013) Shock wave lithotripsy of vesical stones in patients with infravesical obstruction: an underused noninvasive approach. *Urology* 81(3):508–510
- Wong M, Omar M, Azhari N, Geavlete P, Haupt G, Kuo T et al (2008) Bladder calculi an evidence-based review. In: Densted J, Khoury S (eds) 2nd International Consultation on Stone Disease. Health Publications, Paris, pp 297–303. <http://www.icud.info/PDFs/Stone-Disease.pdf>. Accessed 1 Apr 2018
- Delakas D, Daskalopoulos G, Cranidis A (1998) Experience with the Dornier lithotripter MPL 9000-X for the treatment of vesical lithiasis. *Int Urol Nephrol* 30(6):703–712
- Bhatia V, Biyani C (1994) A comparative study of cystolithotripsy and extracorporeal shock wave therapy for bladder stones. *Int Urol Nephrol* 26(1):27–31
- García JC, González CE, Cabrera JP, Rodríguez JM, Calahorra FF, Vela RN (2003) Bladder calculi. Is extracorporeal shock wave lithotripsy the first choice treatment? *Arch Esp Urol* 56(10):1111–1116
- Bhatia V, Biyani C (1993) Extracorporeal shock wave lithotripsy for vesical lithiasis: initial experience. *BJU Int* 71(6):695–699
- Rodríguez FM, Ruiz JT, Llauradó HL, Barón FR, Malet JM, Latorre FI et al (2001) Tratamiento de la litiasis vesical mediante litotricia extracorpórea por ondas de choque. *Actas Urol Esp* 25(7):504–509
- Frabboni R, Santi V, Ronchi M, Gaiani S, Costanza N, Ferrari G et al (1998) Echo-guided SWL of vesical stones with Dornier MPL 9000 lithotripter in obstructed and unobstructed patients. *J Endourol* 12(1):81–86
- Asci R, Aybek Z, Sarikaya S, Buyukalpelli R, Yilmaz A (1999) The management of vesical calculi with combined optical mechanical cystolithotripsy and transurethral prostatectomy: is it safe and effective? *BJU Int* 84:32–36
- Shah HN, Hegde SS, Shah JN, Mahajan AP, Bansal MB (2007) Simultaneous transurethral cystolithotripsy with holmium laser enucleation of the prostate: a prospective feasibility study and review of literature. *BJU Int* 99(3):595–600
- Chtourou M, Younes AB, Binous M, Attyaoui F, Horchani A (2001) Combination of ballistic lithotripsy and transurethral prostatectomy in bladder stones with benign prostatic hyperplasia: report of 120 cases. *J Endourol* 15(8):851–853
- Pearle M (1999) Holmium: YAG lithotripsy for large renal and bladder calculi strategies for efficient lithotripsy—comment. *Mary Ann Liebert Inc Publ, Larchmont*
- Sinik Z, Isen K, Biri H, Kupeli B, Sozen S, Deniz N et al (1998) Combination of pneumatic lithotripsy and transurethral prostatectomy in bladder stones with benign prostatic hyperplasia. *J Endourol* 12(4):381–384
- Bhatia V, Biyani CS (1994) Vesical lithiasis: open surgery versus cystolithotripsy versus extracorporeal shock wave therapy. *J Urol* 151(3):660–662
- Kostakopoulos A, Stavropoulos NJ, Makrichoritis C, Picramenos D, Deliveliotis C (1996) Extracorporeal shock wave lithotripsy monotherapy for bladder stones. *Int Urol Nephrol* 28(2):157–161