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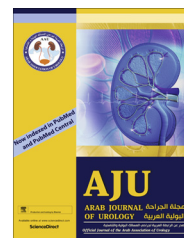


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Bilateral same-session ureterorenoscopy: A feasible approach to treat pan-urinary stone disease



**Bora Özveren^{a,*}, Murat Tugrul Eren^b, Hakan Özveri^a, Uğur Altuğ^a,
Ahmet Şahin^a**

^a Department of Urology, Acibadem University School of Medicine, Istanbul, Turkey

^b Vocational School of Health Services, Acibadem University, Istanbul, Turkey

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KEYWORDS

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Bilateral;
Kidney stones, ureter stones;
Flexible ureterorenoscopy;
Treatment outcomes

ABBREVIATIONS

ASA, American Society of Anesthesiologists;
BSSU, bilateral same-session ureteroscopy;
KUB, kidney–ureter–bladder radiograph;
LOS, length of hospital stay;

Abstract Objectives: To assess treatment effectiveness and safety of bilateral same-session ureterorenoscopy (BSSU) for the management of stone disease involving the entire urinary system.

Patients and methods: We reviewed the records of 64 patients who underwent BSSU for the treatment of bilateral ureteric and/or kidney stones. Size, number, location per side, and the total burden of stones were recorded. Data on stenting, lithotripsy, and stone retrieval, and details of hospital stay and operation times were investigated. Treatment results were assessed using intraoperative findings and post-operative imaging. The outcome was considered successful in patients who were completely stone-free or who had only residual fragments of ≤ 2 mm.

Results: The outcome was successful in 82.8% of the patients who received BSSU (54.7% stone-free and 28.1% insignificant residual fragments). The success rate per renal unit was 89.8%. There were no adverse events in 73.4% of the patients. The most common intraoperative complication was mucosal injury (36%). The complications were Clavien–Dindo Grade I in 9.4% and Grade II in 7.8%. Grade IIIa and IIIb (9.4%) complications required re-treatments. Statistical evaluation showed no association between complication grades and stone, patient, or operation features. Stone burden had no negative impact on BSSU results. The presence of impacted proximal ureteric stones was significantly related to unsuccessful outcomes.

* Corresponding author at: Acibadem Altunizade Hospital, Tophanelioglu Cad, Okul Sok No:1, 34662 Uskudar, Istanbul, Turkey. Fax: +90 (216)4284444.

E-mail address: ozverenb@yahoo.com (B. Özveren).

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PCNL, percutaneous nephrolithotomy;
SFR, stone-free rate;
SWL, shockwave lithotripsy

Conclusion: BSSU is safe and effective for the management of bilateral urolithiasis. BSSU can prevent recurrent surgeries, reduce overall hospital stay, and achieve a stone-free status and complication rates that are comparable to those of unilateral or staged bilateral procedures.

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Introduction

The treatment of bilateral urolithiasis has traditionally been staged procedures due to concerns of the possible simultaneous traumatising of both sides of the urinary system. Currently, in cases of bilateral ureteric stone impaction, semi-rigid ureteroscopy is often attempted bilaterally in a single stage [1–3]. Flexible ureterorenoscopy is usually carried out for ipsilateral nephrolithiasis whilst treating ureterolithiasis [4–6]. Reports on the efficiency of a single-stage, bilateral ureteroscopic treatment of stones in the entire urinary system are still scarce.

Owing to the improvement of endoscopic technology and skills, the treatment of all stones in the entire urinary tract has become an attainable goal in a single operative session. Bilateral same-session ureterorenoscopy (BSSU) has been proposed to reduce overall operative times and anaesthetic requirements, which are factors associated with increased morbidity [1–3,5–9]. In our practice, patients recommended to undergo ureteroscopic stone treatment have been counselled on the option of undergoing BSSU for all stones of clinically significant size. This approach may be warranted urgently or as elective management of bilateral symptomatic or asymptomatic stones. As 32–58% of asymptomatic stones of significant size cause symptoms or require intervention within several years, we have aimed to clear all accessible stones in the urinary tract in a single operative session [10–11].

In the present study, we analysed our experience with BSSU used for the treatment of stone disease involving the whole urinary system. We investigated the clinical operative data and perioperative course of this approach to determine its effectiveness and safety.

Patients and methods

From 2010 through 2016, 64 adult patients underwent BSSU. The indications for the procedure were bilateral nephrolithiasis, bilateral ureteric obstruction, and unilateral ureteric obstruction with ipsilateral/contralateral kidney stones. Patients with pan-urinary stones were deemed suitable for BSSU depending on clinical judgements of safety, indication, patient preference, and the failure of previous treatments.

Pre- and postoperative evaluation

Surgical planning involved imaging with unenhanced CT, ultrasonography, and/or a kidney–ureter–bladder radiograph (KUB). Stone size was measured as the greatest dimension in millimetres, and stone burden represented the sum of all the maximum sizes of stones at the given location. Patients were preoperatively tested and treated to ensure sterile urine. Informed consent of patients suitable for BSSU was taken after a comprehensive discussion of the procedure.

Treatment success was intraoperatively assessed by endoscopy and postoperatively assessed by radiological imaging. KUB/ultrasonography was done at ≤ 4 weeks of a patient's operation. The outcome was considered successful in patients who were totally stone free or who had only residual fragments of ≤ 2 mm too small for retrieval.

Complications were assessed according to the modified Clavien–Dindo grading system. All abrasions, thermal injuries, and submucosal false passages were defined as mucosal injuries. Perforation encompassed injuries caused by misguided wires, laser fibres, or accessory instruments through the ureteric wall; the propulsion of stone fragments through the ureter/collecting system; or defects of any size on the ureteric wall created by dilatation or passage of a ureteroscope or access sheath. Intrarenal urothelial tears, incisions, and punctures were also described as perforations.

The operation (OR) time denoted the whole interval of anaesthesia, which began with induction and consisted of the positioning and preparation periods and the duration of the endoscopic operation, and which ended with the extubation of the patient.

Techniques and instruments

BSSU was carried out under general anaesthesia, and all patients received i.v. cephalosporin or aminoglycoside for prophylaxis. Semi-rigid 8–9 F, Digital or Flex X2 7-F (Storz®) flexible ureteroscopes were used by three experienced endourologists. Several instruments (baskets, graspers, etc.) were used for stone extraction and/or positioning depending on the surgeon's choice. Ureteric access sheath (11/13 F or 12/14 F) was not the standard technique in BSSU cases and used upon the

discretion of the surgeon depending on the burden and location of kidney stones.

Intracorporeal lithotripsy was performed by holmium laser, pneumatic and electrohydraulic fragmentation. Ureteric access sheaths were used depending on the surgeon's discretion and were used particularly if the stone burden was large or a prolonged procedure was anticipated. The BSSU procedure was started from either the obstructed side or the side with the greater stone burden.

Institutional Review Board permission to extract and review our prospectively maintained electronic database was obtained.

Statistical analysis

Statistical analyses were performed using PASS 2008 and NCSS 2007 Statistical Software® (Utah, USA). Continuous variables were compared using the nonparametric Mann–Whitney *U*-test. Categorical variables were compared using Pearson's chi-squared test, the Fisher–Freeman–Halton test, Yates' continuity correction, and Fisher's exact test. Spearman's correlation analysis was conducted to measure the degree of association between variables. A $P < 0.05$ was considered statistically significant.

Results

In total, 64 adult patients (21 females and 43 males) aged between 27 and 80 years (median 47 years) with bilateral ureter and/or kidney stones underwent BSSU.

Stone characteristics

The stone characteristics are presented in Table 1. In all, 46 patients (71.9%) harboured multiple stones (range 3–10) in their entire urinary system, whilst 28.1% had single stones on both sides. The average stone count was 4.25 per patient. There were both renal and ureteric stones in various anatomical locations in 35 patients (54.7%). In all, 10 patients (15.6%) had only renal stones and 19 patients (29.7%) had only ureteric stones bilaterally. There were both renal and ureteric stones in various locations in 35 patients (54.7%). The mean (range) stone burden was 29.87 (11–82) mm per patient.

Operation data

A flexible ureteroscope was exclusively or additionally required in 75% of the patients. Both semi-rigid and flexible instruments were used in about half of the patients (51.6%; Table 2).

The median OR time was 107.5 min. Four patients with concomitant urological procedures (three photoselective laser vaporisation of the prostate and one

Table 1 Stone characteristics.

Characteristic	Right (<i>n</i> = 64)	Left (<i>n</i> = 64)	All units (<i>n</i> = 128)
Stone count, <i>n</i>			
Median (IQR)	2 (2)	1.5 (2)	2 (2)
Mean (SD)	2.20 (1.39)	2.04 (1.31)	2.12 (1.35)
Stone count, <i>n</i> (%)			
1	27 (42.2)	32 (50.0)	59 (46.1)
2	14 (21.6)	12 (18.8)	26 (20.3)
3	14 (21.9)	10 (15.6)	24 (18.8)
≥4	9 (14.2)	10 (15.6)	19 (14.8)
Stone location, <i>n</i> (%)			
Renal	21 (32.8)	26 (40.6)	47 (36.7)
Distal ureter	20 (31.3)	16 (25.0)	36 (28.1)
Distal ureter + renal	8 (12.5)	6 (9.4)	14 (10.9)
Proximal ureter	6 (9.4)	13 (20.3)	19 (14.8)
Proximal ureter + renal	9 (14.1)	3 (4.7)	12 (9.4)
Stone burden, mm			
Median (IQR)	12 (8)	13 (10.5)	26.5 (16.75)
Mean (SD)	15.16 (9.78)	14.68 (8.36)	29.87 (14.96)

fulguration of multiple bladder lesions lasting 255, 160, 130, and 100 min, respectively) were excluded from the OR time analysis. One patient with proximal ureteric stenosis required a lengthy endoscopic procedure to access the stone, and this procedure lasted the longest (240 min) out of the cases included in the study group. The statistical analysis revealed a significant positive correlation between stone burden and OR time ($P < 0.05$; Table 3).

Intracorporeal lithotripsy was not needed in 7.8% of the patients. A laser lithotripter was not amongst the operative armamentarium in seven (11%) patients. Stone retrieval equipment was not required in 20% of the patients.

Most of the patients undergoing BSSU (93.8%) did not have preoperative ureteric stents (Table 2). Postoperative stents were placed in 86% of the patients. Of the patients without postoperative stents, four were treated for bilateral kidney stones. In the remaining patients without stents, the unstented units were treated for ureteric stones only. The duration of stenting was determined on a per case basis, which ranged from 1 to 4 weeks.

Complications

The most common intraoperative complication was mucosal injury (36%). There were perforations in 9.4% of the patients (Table 2). Most of these perforations were minor and involved injuries of the ureteric smooth muscle and the urothelial wall inside the collecting system due to extraction and lithotripsy. Only one procedure was abandoned due to severe (full-thickness) ureteric

Table 2 Operation data.

Variable	Value
Ureterscopy, <i>n</i> (%)	
Semi-rigid	16 (25)
Flexible	15 (23.4)
Both	33 (51.6)
Lithotripsy, <i>n</i> (%)	
None	5 (7.8)
Holmium laser	52 (81.2)
Pneumatic/electrohydraulic	7 (11)
Baskets, <i>n</i> (%)	
Not used	13 (20.3)
Used	51 (79.7)
Preoperative stent, <i>n</i> (%)	
None	60 (93.8)
Unilateral	2 (3.1)
Bilateral	2 (3.1)
Postoperative stent, <i>n</i> (%)	
None	9 (14.1)
Unilateral	14 (21.9)
Bilateral	41 (64.1)
Complications*, <i>n</i> (%)	
Mucosal injury	23 (35.9)
Perforation	6 (9.4)
Avulsion	0
Fever/sepsis	3 (4.7)
Prolonged haematuria	12 (18.8)
Severe pain	17 (26.6)
Clavien–Dindo grade, <i>n</i> (%)	
0–II	58 (90.6)
III	6 (9.4)
> III	0
LOS, days, <i>n</i> (%)	
1	55 (85.9)
2	8 (12.5)
3	1 (1.6)
Median (IQR)	1 (0)
Mean (SD)	1.15 (0.40)
ASA score, <i>n</i> (%)	
I	42 (65.6)
II	21 (32.8)
III	1 (1.6)
Median (IQR)	1 (1)
Mean (SD)	1.35 (0.51)
OR time (4 cases with concomitant urological procedures excluded), min	
Median (IQR)	107.5 (50)
Mean (SD)	112.50 (38.21)

* Multiple observations per case.

Table 3 Analysis of OR time with relation to stone factors.

Variable	OR time	
	<i>r</i> ^c	<i>P</i>
Stone count	0.096	0.448
Stone burden, mm	0.384	0.002*

^c Spearman's Correlation quotient.

* *P* < 0.05.

impacted bilateral ureteric stones in the remaining two patients, one of which was further complicated by ureteric stenosis. The OR times of these three patients were 150, 120, and 240 min, respectively. All three patients were successfully treated with broad-spectrum antibiotics.

The length of hospital stay (LOS) was 1 day for 85.9% of the patients. The causes of extended LOSs were unalleviated pain in three patients, fever in three, macroscopic haematuria in one, and unspecified patient preference in two. Re-admissions (6.3%) were due to pain or fever in three patients and oliguria in one. This oliguric renal insufficiency resulted from bilateral urinary obstruction by a stone street comprised of gravel after an uncomplicated unstented BSSU for a 9-mm proximal ureteric stone and bilateral nephrolithiasis, with a total stone burden of 29 mm and 16 mm on each side. This patient's renal function quickly normalised after re-look ureteroscopy.

There were no adverse events in 47 patients (73.4%). Complications, which were defined according to the modified Clavien–Dindo classification, were Grade I in six patients (9.4%) and Grade II in five (7.8%). Therefore, 90.6% of the patients had either no or minor (Grade ≤ II) complications. In the remaining six patients (9.4%), the complications were Grade IIIa or IIIb. Three patients had undergone extracorporeal shock-wave lithotripsy (SWL) treatment for residual or migrated stones (Grade IIIa). The Grade IIIb complications required re-operations for residual stones and obstructing fragments. A statistical evaluation did not show any association between the Clavien–Dindo complication grades and stone, patient, or operation features (*P* > 0.05; Table 4).

Success

There was a successful surgical outcome in 82.8% of the patients. After BSSU, 35 patients were completely stone free (54.7%), and 18 had only residual fragments of ≤2 mm (28.1%). When the surgical outcomes were re-evaluated per renal unit treated, the overall success rate was 89.8% (Table 5).

Unsuccessful results comprised 11 patients with unreachable or residual stones of significant size. Two patients were treated during a period when a flexible ureteroscope was not available to pursue migrated frag-

perforation during stone extraction, which was managed with long-term ureteric stenting.

There was prolonged macroscopic haematuria in 19% of the patients. Nearly a quarter of patients reported severe pain after the procedure.

Three patients (4.6%) had postoperative high-grade fever (>38.0 °C). One of these patients had multiple renal stones with a total burden of 66 mm. There were

Table 4 Modified Clavien–Dindo's complication grading with regard to patient, stone and operation factors.

Variable	None or Grade < III (<i>n</i> = 58) [‡]	Grade ≥ III (<i>n</i> = 6)	<i>P</i> ^a
Age, years			
Mean (SD)	48.05 (12.67)	52.17 (9.85)	0.327
Median (IQR)	47 (21)	49 (19.8)	
ASA score			
Mean (SD)	1.34 (0.51)	1.59 (0.55)	0.427
Median (IQR)	1 (1)	1.5 (1)	
OR time, min			
Mean (SD)	109.26 (34.28)	141.67 (60.39)	0.231
Median (IQR)	105 (47.5)	130 (105)	
Stone count			
Mean (SD)	4.35 (2.16)	3.33 (1.75)	0.245
Median (IQR)	4 (4)	2.5 (3.3)	
Stone burden, mm			
Mean (SD)	29.39 (14.34)	34.16 (21.34)	0.764
Median (IQR)	26 (16.5)	25 (38.8)	

^a Mann–Whitney *U*-test.[‡] Grade 0, I and II complications were seen in 71.9% (46/64), 10.9% (7/64) and 7.8% (5/64) of patients, respectively.**Table 5** Treatment success.

Surgical outcome	Unsuccessful, <i>n</i> (%)	Successful, <i>n</i> (%)
Stone free		35 (54.7)
RF* ≤ 2 mm		18 (28.1)
Unreachable/residual stones	11 (17.2)	–
Success per case	11 (17.2)	53 (82.8)
Success per renal unit	13 (10.2)	115 (89.8)

* RF, residual fragments that were too small for retrieval.

ments. Statistical analysis did not reveal any significant association between BSSU success rates and patient age, American Society of Anesthesiologists (ASA) score, OR time interval, or the use of laser lithotripsy. Although stone count and burden did not have any impact on treatment results, the presence of proximal ureteric stones was significantly related to unsuccessful outcomes ($P < 0.05$; Table 6).

When the former and latter (in chronological order) patients in the study group were further analysed, there were treatment failures in 25% of the patients (eight of 32) compared to 9.4% (three of 32) amongst the second half of cases.

Discussion

The guidelines on the management of stones of various sizes and locations are methodically updated parallel to the progress of endourological expertise and clinical evidence. However, there is currently no consensus on the

Table 6 Treatment success rates with regard to patient, stone and operation factors.

Variable	Unsuccessful (<i>n</i> = 11)	Successful (<i>n</i> = 53)	<i>P</i>
Age			
Mean (SD)	47.18 (11.22)	48.69 (12.74)	0.859
Median (IQR)	45 (19)	49 (20.5)	
ASA score			
Mean (SD)	1.27 (0.46)	1.37 (0.52)	0.568
Median (IQR)	1 (1)	1 (1)	
OR time (min.)			
Mean (SD)	134.00 (54.55)	108.20 (33.14)	0.183
Median (IQR)	120 (85)	102.5 (45)	
Laser lithotripsy, <i>n</i> (%)			
Unavailable	3 (27.3)	9 (17.0)	0.418 ^b
Available	8 (72.7)	44 (83.0)	
Stone count			
Mean (SD)	4.00 (2.32)	4.30 (2.11)	0.526 ^a
Median (IQR)	3 (4)	4 (3)	
Stone burden (mm)			
Mean (SD)	37.72 (24.41)	28.21 (11.87)	0.545 ^a
Median (IQR)	24 (46)	27 (16)	
Stone location, <i>n</i> (%)			
Renal	6 (12.8)	41 (87.2)	0.443 ^c
Distal ureter	3 (21.4)	11 (78.6)	0.708 ^c
Distal ureter + renal	6 (13.9)	31 (86.1)	0.720 ^c
Proximal ureter	7 (36.8)	12 (63.2)	0.022 ^{d,*}
Proximal ureter + renal	1 (8.3)	11 (91.7)	0.690 ^d

^a Mann–Whitney *U*-test.^b Fisher–Freeman–Halton test.^c Yates' continuity correction.^d Fisher's exact test.* $P < 0.05$.

best practice for the management of bilateral urinary stones. The review of our present results of the use of a single BSSU procedure for the treatment of bilateral pan-urinary stone disease revealed a successful outcome rate of 82.8%.

Various options are available for the treatment of patients with bilateral renal stones, including bilateral SWL, staged or synchronous percutaneous nephrolithotomy (PCNL), and PCNL combined with ureterorenoscopy. Perry et al. [12] stated that bilateral synchronous SWL is a safe and effective monotherapy for bilateral urolithiasis, with a bilateral stone-free rate (SFR) of 60% after one treatment. However, additional procedures were required in 16% of cases due to significant residual stone disease or obstruction during follow-up. Stone size and number independently increased the probability of treatment failure. For patients with large bilateral renal stones, synchronous bilateral PCNL may be offered. In a review by Williams and Hoenig [13], the overall outcomes for synchronous bilateral PCNL revealed high SFRs (95–97%), low complication rates

(9–12%), short LOSs (4–6 days), and low blood transfusion rates. In a study comparing 150 simultaneous bilateral and 300 unilateral PCNLs, Holman et al. [14] concluded that similar complication rates (14.3% vs 11.3%, respectively) showed that the single-session bilateral PCNL is no more hazardous than separate PCNLs for bilateral kidney stones, alongside the clear advantages of single anaesthesia, less medication, shorter LOS and convalescence, considerable cost-effectiveness, and reduced loss of working days. Silverstein et al. [15] also commented on similar benefits, together with total blood loss and total OR time, making synchronous bilateral PCNL an attractive option for select patients with large renal stone burdens. However, in patients with multiple difficult to access renal stones and particularly patients with renal stones that are accompanied by ureteric stones, the effective clearance of stones may not be accomplished by synchronous bilateral PCNL or SWL.

Considerable data have accumulated to advise BSSU as a treatment for bilaterally obstructing ureterolithiasis. A recent meta-analysis of 11 studies (431 patients), which assessed the treatment of ureteric calculi, revealed an overall SFR of 82% (varying from 52% to 90%) for BSSU [16]. The overall complication rate of BSSU remained at 17%. Amongst these, the incidences of pain, postoperative fever, and gross haematuria were 20%, 4% and 4%, respectively. Other complications including urosepsis, urinary infection, mucosal laceration, stone migration, and ureteric perforation accounted for 6% of the total complications.

Contemporary studies of the use of BSSU to treat multiple stones at different locations in the urinary tract are limited, with existing studies reporting on a total of <250 patients [2–5,17–21]. The heterogeneity of stone characteristics makes comparing the results of published series difficult. In these studies, the SFRs have ranged widely between 52% and 92.8%, and these rates are inversely associated with a mean stone burden of >20 mm, a higher proportion of impacted proximal ureteric stones, and lower pole renal stones [2,3,5,9]. The varied outcomes of the current BSSU studies may be attributable to patient diversity and inconsistent methodologies. Our present success rate per case is augmented to 89.8% when reassessed on a per renal unit basis. Redefining the size of insignificant residual fragments and longer follow-up periods might further influence the SFR. In the present study, we did not detect any significant association between BSSU success and total stone burden in pan-urinary stone disease. We attained a favourable success rate despite a large number and volume of stones (Table 6) and a high proportion (70%) of nephrolithiasis in our patient population. Our present analysis also revealed that our BSSU success rate considerably increased over time, which is a result that is probably related to technical advancements and surgical experience.

The prevalent use of JJ stents in our patients probably lead to a higher incidence of postoperative prolonged haematuria and pain. Hollenbeck et al. [2] noted that patients were more likely to have postoperative complications when ureteric stents were not placed after BSSU. Due to concerns about simultaneous renal damage resulting from bilateral urinary obstruction, JJ stents should be used in all BSSU patients. Our experience showed that postoperative stenting is appropriate when bilateral renal stones are treated by laser dusting or fragmenting. In addition, the treatment of impacted stones, the use of access sheaths, major ureteric damage, and prolonged operations may oblige post-procedural stenting. The interval of stenting was determined arbitrarily in the absence of established guidelines. Presently, we keep pull-string JJ stents for a week in uncomplicated cases.

A unilateral ureteroscopy intraoperative complication rate of 6.3% and a postoperative complication rate of 3.5% were reported by de la Rosette et al. [22] in a prospective study. Early studies associated the BSSU procedure with higher complication rates, but recent studies have mostly reported minor complications ranging from 17% to 50.8% [16–23]. Even though we observed low-grade complications, as defined using the Clavien–Dindo classification system, the specific rates of pain, perforation, haematuria, and mucosal injury remained relatively high. All the current BSSU literature pertains to retrospective data, which is naturally prone to bias and some uncertainty in terms of adverse events, including perforations. The characterisation and reporting of endourological complications still lacks standardisation, the lack of which hinders the interpretation of surgical performance [24,25]. By implementing the modified Clavien–Dindo system, we could observe that most of the recorded complications did not correspond to any deviation from the ideal postoperative course of BSSU. Apparently, mucosal injuries or minor perforations had no impact on the safety of BSSU. On the other hand, we regarded the necessity of the secondary treatment of residual stones after BSSU as failure to cure complications rather than auxiliary procedures contributing to success rates.

The present study had limitations. The retrospective review of an uncommon surgical approach is subject to bias in patient selection. Our study group comprised patients who underwent BSSU for varied combinations of bilateral pan-urinary stones. The stone characteristics are broadly heterogeneous in terms of burden, location, and complexity. However, we believe that this heterogeneity of pan-urinary stone disease in our study group denotes the originality of our report. Reports of BSSU in the literature are usually composed of either ureter/ureter or kidney/kidney stones, but 55% of our patients had bilateral kidney and ureteric stones in various locations of the upper urinary system. The execution of

BSSU may have also varied throughout the time interval of the study and with surgeon experience. The definition and reporting of success, complications, and follow-up were not standardised and may therefore be misleading. Most patients were not tested for renal function changes immediately after surgery. In two early cases with bilateral ureteric stones, stone migration was the cause of residual fragments. As a flexible ureterorenoscope was not available at that time, these patients' procedures were unsuccessful, and re-operations (i.e. SWL) were necessary. In general, the contraindications for a BSSU procedure are no different than those for a unilateral ureteroscopy, which are untreated UTI, urosepsis, and uncorrected bleeding diathesis. Furthermore, the experience of the surgical team and availability of the appropriate instruments are of the utmost importance for a successful outcome.

Conclusion

BSSU is a challenging endourological procedure. However, through the constant improvement of endoscopic technology and with the right expertise and experience, this procedure can now be performed successfully and safely. With a success rate of 82.8%, our study has presented further evidence concerning the effectiveness of this contemporary single-session approach to bilateral, pan-urinary stone disease. Nevertheless, prospective randomised studies are urgently needed to determine the best practice for the use of BSSU in the management of complex urolithiasis.

Conflict of interest

None.

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