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Effectiveness and Safety of Bilateral Same-Session Ureteroscopy-A Prospective Study

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Abstract

Objective: To investigate the effectiveness and safety of Bilateral Same-Session Ureteroscopy (BSU) for urolithiasis in the contemporary endourology.

Material and Methods: Patients over 18 years old with bilateral urolithiasis in the upper urinary tract were selected under following criteria: total stone burden ≤40mm (accumulated diameter); size of single stone ≤20mm in the major burden side and ≤15mm in the minor; preoperative Serum Creatinine (sCr) normal. Patients were grouped into low burden (<20mm) and high burden (≥20mm) by overall stone burden. Parameters of operation and follow up were evaluated and compared.

Results: 32 cases (male19, female13; age 53.2±14.2yrs) were included from Jan 2013 to Dec 2014.Overall stone burden was 23.7±7.6 (14-40) mm, total stone number 109 (renal 78, ureteral 31). Operative time was 99.2±32.5 (50-175) mins, postoperative hospitalization 2.4±1.4 (1-6) days. Staged procedure took place in two cases. The immediate SFRs after first procedure and overall were 72.0% and 91.0%. However, the immediate SFRs in low burden and high burden were 100% and 50.0% (P=0.002) respectively. No significant sCr change was detected (p=0.711) and no major complications occurred.

Conclusions: BSU for selective cases with bilateral urolithiasis in the upper urinary could be redefined at contemporary endourology. From our study, it is effective and safe with high SFRs, no renal damage and minimal complications. Patients with low bilateral burden (<20mm) may benefit from the immediate stone clearance.

Introduction

Semi-Rigid Uretereoscopy (URS) is well acknowledged for the management of urolithiasis in the mid and lower ureter. With the recent development of Flexible Ureteroscopy (fURS) and laser technology, more intra-renal and proximal ureteral stones are successfully treated through natural lumen [1,2]. Bilateral Same-Session Ureteroscopy (BSU) possesses advantageous potentials, such as decreased procedure number and anesthesia, shorter hospital stay and lower cost. However, it was not widely practiced in older times, or even regarded as risky with higher chance of bilateral ureteral injury and other complications [3]. In the background of contemporary endourology, we sought to investigate the effectiveness and safety of BSU and designed this prospective study.

Material and Methods

Inclusions, grouping and exclusions

Patients with bilateral urolithiasis in the upper urinary tract were included by following criteria: age over 18 yrs old; overall stone burden(accumulated diameter) ≤40mm; size of single stone ≤20mm in the major burden side and ≤15mm in the minor; preoperative Serum Creatinine (sCr) level normal. If acute renal insufficiency by obstruction existed, the patient could be included when renal function resumed to normal after ureteral stenting. Patients were grouped into low burden (<20mm) and high burden (≥20mm) by overall stone burden. Patients of significant co-morbidities, severe hydronephrosis, or major renal or intrarenal deformities were excluded.

Procedure preparations

Demographics such as age, sex, Body Mass Index (BMI), blood chemistry, and etc. was acquired. Total stone burden was measured either by KUB+IVU or Non-Contrast Enhanced CT (NCCT) according to accumulated diameters. When urinalysis positive, urine culture was obtained and preoperative antibiotics applied. Apart from relieving obstruction, prestenting for passive ureteral dilation of 5-7 days was determined by the operating surgeon at the consideration of ureteral conditions and stone burden.

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Equipment and consumables

Semi-rigid URS (8/9.6F, Olympus), fURS(URF-P5, Olympus) and digital fURS (URF-V, Olympus) were used. Holmium laser system (Power Suite 100W, Lumenis) was for lithotripsy with 200μm or 365μm fibers. C arm (Siremobil Compact L, Siemens) was utilized in every procedure. 1000ml-bagged normal saline in pressurized cuff was for irrigation. 0.035' hydrophilic guidewire (nitinol, Bard), ureteral catheter (F5, Bard), ureteral access sheaths (AUS, F12/14 35cm COOK or F11/13 36cm Boston Scientific) and baskets (F1.7 Ngage, COOK or F1.9 Zerotip, Boston Scientific) were prepared.

Procedure

All procedures were performed by the same surgical team. Stone free status was defined as fragments <2mm. When the stone was in the distal ureter, semi-rigid URS was performed. For stones in the proximal ureter, semi-rigid URS was used first to break and then push back to the kidney. When stones were located inside the kidney or pushed back, fURS was performed under standardized manipulations as described elsewhere [4].

Setting of the holmium laser usually started at 3.6W(0.6J×6Hz), and ramped up as needed. After dusting and fragmentation, a basket was used to remove fragments bigger than 2mm. Staged procedure was considered by operation length, stone load, and intraoperative complications. Ureteral catheters or stents were placed bilaterally and removed in 24-72 hours or 2-4 weeks. sCr level was checked immediately after the procedure, and monitored continuously if elevated. KUB (radio-opaque) or NCCT (radiolucent) was taken in the first operative day and one month after stent or catheter removal. If patients did not come back timely, further evaluation was to be completed at later time. Patients with seeming intraoperative injuries should be followed up to 12m for late complications. Parameters, such as prestenting, operation time, procedure number, postoperative hospitalization, immediate and overall SFR, and early and late complications were recorded and compared.

Table 1: Patient's data and operative parameters.

Parameter	Result
Overall stone burden (mm)	23.7±7.6 (14~40)
Renal burden	15.4±9.7 (0~37)
Ureteral burden	8.2±7.2 (0~34)
Stone#	3.4±1.6 (2~10)
Renal stone#	2.4±1.7 (0~8)
Ureteral stone#	1.0±0.7 (0~3)
Prestenting	23/32 (71.9%)
Procedure#	1.1±0.2 (1~2)
Operation time (min)	97.7±32.0 (50~175)
Postoperative stay (day)	2.4±1.4 (1~6)
sCr preoperative (μmol/L)	78.3±15.0 (47.5~97.0)
sCr postoperative (μmol/L)	77.9±15.3 (35.4~111.0)
Immediate SFR after 1st procedure	23/32 (72.0%)
Overall SFR	29/32 (91.0%)
Complications	Hemorrhage 1, Fever 4

#-number, sCr-Serum Creatinine, SFR-Stone Free Rate

Data analysis

Statistical analysis was performed using SPSS 19.0 (SPSS, Inc, Chicago, IL). Demographic and other relevant parameters of low and high burden groups were compared by one-way ANOVA. Difference of sCr before and after was tested using paired T test. Chi-square test was used for comparing prestenting percentage, immediate and overall SFRs. $P < 0.05$ was regarded as statistically significant.

Results

At the approval from the Institutional Ethical Committee, 32 cases (male 19, female 14) were included from Jan 2013 to Dec 2014. Age 53.2±14.2 (19-79)y; BMI 25.6±3.1 (19.9-35.3)kg/m^2; overall stone burden 23.7±7.6 (14-40)mm; renal stones 15.4±9.7 (0-37)mm with 47.4% in the lower pole; ureteral stones 8.2±7.2 (0-34)mm with 51.5% in the proximal 48.5% in the distal. Total stone number 109, renal 78 (37 in the lower pole) and ureteral 31 (15 proximal and 16 distal). A concurrent strictured infundibulum in the lower pole was found in 1 case and an upper pole diverticulum with stones in another case. 2 cases had elevated sCr due to obstruction, which was relieved by stenting. 71.9% (23/32) cases received preplaced stents.

Totally, 34 procedures of URS with/or fURS were performed with 2 cases having a second staged procedure. Average operation time was 99.2±32.5 (50-175)mins, postoperative hospitalization 2.4±1.4 (1-6)days. No significant sCr changes was detected (P=0.711), preoperative 78.3±15.0 (47.5-97.0)μmol/L *vs.* postoperative 77.9±15.3 (35.4-111.0)μmol/L. Elevated sCr was found in 1 case and returned to normal in 2 weeks. Immediate SFR after the first procedure was obtained in 72.0% (23/32) and the overall SFR 91.0% (29/32). We had 3 cases with residual stones. In the first one, an asymptomatic upper pole diverticulum with stones was not found during the procedure. In the second case, a radiolucent stone in the lower pole was missed. The third case had discontinued procedure due to hemorrhage for incision of infundibulum to reveal an calyceal stone. Complications were observed in 5 cases, degreed as Clavien II in 4 (hemorrhage 1, and fever 3) and Clavien I in 1 (fever 1). In one case of fever, blood culture turned positive of E coli., but no signs of septic shock. The case of hemorrhage was the one of infundibulum incision. They were

Table 2: Comparisons between groups of low and high burden.

	Low burden	High burden	P
Sex	M8/14, F6/14	M11/18, F7/18	0.821
Age (y)	51.2±15.0	54.9±13.7	0.468
BMI (kg/m^2)	26.5±3.0	24.9±3.2	0.178
Overall burden	16.6±1.7	29.0±5.3	<0.001*
Stone #	2.9±1.4	3.8 ±1.8	0.096
Prestenting	7/14	16/18	0.015*
Procedure #	1.0±0.0	1.1±0.3	0.210
Operation time	73.9±14.3	116.1±29.8	<0.001*
Postop stay (day)	2.0±1.6	2.8±1.2	0.118
Immediate SFR	14/14	9/18	0.002*
Overall SFR	14/14	15/18	0.109
Complications	3/14	2/18	0.425

BMI-Body Mass Index, #-number, SFR-Stone Free Rate, *-as statistically significant

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all managed conservatively. During the median follow up of 20(7-30) months, no ureteral stricture was observed (Table-1).

14 and 18 cases were grouped into low and high burden respectively. In the high burden group, more preplaced stenting (88.9% *vs* 50.0%, P = 0.015) and longer operation time (116.1±29.8 *vs* 73.9±14.3mins, P<0.001) were observed, but much lower immediate SFRs after the first procedure than in the low burden group (50% *vs* 100%, P=0.002). Other parameters, such as age, sex, BMI, stone number, procedure number, postoperative hospitalization, overall SFR, and complications, were not significantly different in the two groups (Table-2).

Discussion

Effectiveness and safety of BSU has been in the argument for some time [3,5-9]. When compared with separate staged procedures, potential to reduce procedure number, operation time, anesthesia, hospitalization and cost is straightforward [3,5]. But in the previous publications, BSU was subject to bilateral ureteral surgical injuries [6,8]. 22% ureteral perforation rate was reported by Deliveliotis et al [5] using a F10.5-11 semi-rigid URS. And it was claimed BSU was only indicated bilateral distal ureteral stones [5,10]. However, due to the growth of industry and endourology, URS practice has very much improved. With the miniaturized endoscopy and experience accumulation, overall URS complication rate dropped to 5-9% and perforation less 2% [11]. Although good results were published for BSU by semi-rigid URS [12]or combined with fURS [13,15], those studies were retrospective, long in time gaps (5-15yrs) and of mixed lithotripsies, thus less coherent and promising, and we did not find any study about BSU last 3 years. In the current study, a prospective design was made up with careful inclusions and exclusions. Excellent URS and/or fURS together with holmium laser and modern consumables were used in all procedures, as the standard setup for contemporary endourology.

Factors, such as stone burden, composition, location and anatomy, may have impact on effectiveness [12,16]. For simplification, stone burden of accumulated diameters was taken as inclusion in the study. Single stone size was defined further based on our previous experience. Renal function is crucial as well. Although relief of bilateral obstruction was intriguing, acute renal insufficiency and anuria following BSU had been reported in those of preoperative elevated sCr [8]. For safety, only patients with normal preoperative sCr were included.

A significant percentage (71.9%) of patients received preplaced stents. This was due to the consideration of a wider ureteral diameter was required for multiple stones and repeated fragment retrievals. In our previous practice, failure of scope advance in an unprepared tight ureter was encountered as high as 10%. This led us to perform prestenting at a high rate when facing bilateral cases for maximal safety. In our series, 5-7 days of indwelling stents was sufficient for passive dilation, which helped to reduce the risk of ureteral injury and increased renal burden.

Intraoperatively, no anti-repulsion device was used for ureteral stones. If proximal, the stone was pushed back to the kidney. Laser setting usually started at 3.6w which was ramped up according to the stone hardness. It was our attempt to control the injury to the ureter by reducing intraureteral manipulations and low thermal effect on the ureter wall. For fragments or stones in the kidney, we followed the standard fURS practice described elsewhere [4]. AUS was placed in every procedure and 35-36cm AUS was used for multiple access and decreased intrarenal pressure [17]. From our experience, the tip of AUS over the level of iliac artery would be sufficient. Placing too much deeper might cause possible ureteral trauma and a collapsed intrarenal collecting system, interfering relevant manipulations. Intraoperative fluoroscopy was used in making key manipulations visible. Instead of continuous mode, intermittent paused exposure was applied to reduce the irradiation in the operating room.

Reported SFRs of BSU were 64~94.5% [9,12,14,15,18]. In our study, immediate SFR (72.0%) after first procedure and overall SFR (91.0%) was comparable to those in other reports. Fragment retrieval was performed with a basket as much as possible to ensure a good stone clearance [19]. This may explain that our operation time was relatively longer. However, when patients were grouped by stone burden, 100% immediate stone clearance was seen in low burden (<20mm). It is understandable that high burden is related with more operation time and a lower immediate SFR even though fragmentation was done as completely as possible. During immediate postoperative imaging, more fragments were left in high burden group and some might stay too close to be distinguished. For every patient, however, a good immediate SFR may relieve the patient's worry and sufferings from fragment expulsion.

No significant renal function damage was detected in our study, which was comparable to that by Huang et al [18]. Only 1 case experienced postoperative elevated sCr(111.0) and resumed to normal(81.0) in 2 weeks. In this case, operation time over 1 hour on each side was performed in order to reach an immediate stone free status. Thus, prolonged operation time should be avoided. Though complications took place in 17.8% (5/32), no severe life or organ threatening event happened and all managed conservatively. With the care to the ureter, no stricture was found postoperatively.

Our study is not without limitations. Due to the relatively small volume, a multivariant analysis to find out independent influencing factors on SFRs and complications could not be made. Renal scan to clarify detailed split renal function and a reliable intra-renal pressure sensing may help monitor and control the process of the procedure. Further studies may focus on these issues or randomized trials with a larger volume would be better to establish the fundamentals of BSU.

Conclusions

BSU for selective cases with bilateral urolithiasis in the upper urinary could be redefined at present endourology. From our study, it is an effective and safe treatment with excellent stone clearance, no adverse impact on renal function and minor complications. Apart from overall cost-effective potentials, patients of low bilateral stone burden(<20mm) may benefit from immediate stone clearance, minimizing the expulsion related sufferings and worries.

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