

Prospective Evaluation of Bilateral Retrograde Intrarenal Surgery: Is It Really Safe?

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Abstract

Introduction: The aim of this study was to prospectively compare the outcomes of bilateral same-session retrograde intrarenal surgery (BSS RIRS) with unilateral RIRS and to compare the outcomes of first with second operated kidneys in BSS RIRS.

Subjects and Methods: Consecutive symptomatic adult patients with kidney stones up to 20 mm who accepted to be treated by RIRS were prospectively studied. Stone-free rate (SFR) was evaluated by non-contrast CT for each renal unit, and surgical complications were evaluated based on Clavien-Dindo classification.

Results: SFR (73.9% vs 76.1%, $p=0.830$) and hospitalization time (14.43 ± 18.81 hours vs 13.00 ± 4.89 hours, $p=0.564$) were similar between unilateral and BSS RIRS groups, with less consumption of disposable devices in BSS RIRS ($p=0.017$). Operative time was longer in BSS RIRS (61.24 ± 26.62 minutes vs 88.65 ± 33.19 minutes, $p<0.001$). Bilateral group had significant more overall complications by Clavien-Dindo classification than unilateral (15.9% vs 39.9%, $p=0.030$) and more emergency room (ER) visits (11.6% vs 34.8%, $p=0.026$). Moreover, although both groups temporarily increased creatinine levels, it was significantly higher in bilateral RIRS ($p=0.019$). First operated kidney outcomes were similar to second operated kidney outcomes of BSS RIRS.

Conclusion: Although BSS RIRS had similar SFR and consumed less disposable devices, it had a higher overall complication rate, a higher frequency of ER visits, and higher creatinine levels during follow-up than unilateral RIRS. There is no significant outcome difference between first and second operated kidneys in BSS RIRS.

Keywords: urolithiasis, retrograde intrarenal surgery, kidney calculi, bilateral

Introduction

RISING INCIDENCE OF urolithiasis worldwide increased overall costs of urinary stone treatment.^{1,2} Retrograde intrarenal surgery (RIRS) have been used more frequently for the treatment of kidney stones up to 20 mm due its high stone-free rate (SFR) and low complication rate.³ However, not only the financial cost per treatment has increased, but also ecological issues have emerged. Each RIRS produces alarming amounts of disposable devices waste discarded in the environment.⁴ Moreover, despite RIRS reduced patient suffering compared with non-minimally invasive procedures, many

patients still complain about pain leading to unplanned emergency room (ER) visits and loss of working days after RIRS.²

Treatment for urolithiasis should be efficacious, safe, and cost-effective. Based on the incidence of bilateral urolithiasis around 10%⁵ and the complication profile of RIRS, bilateral same-session (BSS) RIRS has been considered as an interesting way to save resources.

Bilateral procedures seem to be appealing, as they apparently save hospitalization time, working day loss, and disposable devices, but they may have more complications and a suboptimal performance due to staff tiredness compared with their unilateral counterparts. A few retrospective studies looked

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at bilateral RIRS outcomes. Moreover, there is no prospective study to evaluate the outcomes of BSS RIRS.^{6,7} The aim of this study was to prospectively compare the outcomes of BSS RIRS with unilateral RIRS and to compare the outcomes of first with second operated kidneys in bilateral RIRS.

Subjects and Methods

Consecutive symptomatic adult patients with kidney stones up to 20 mm who accepted to be treated by RIRS in our Institution from August 2016 to August 2017 were prospectively studied. Patients previously submitted to open kidney surgery or endourological procedures were excluded from the study. Patients with kidney malformations, hydronephrosis, with indwelling Double-J stent, or untreated urinary tract infection were also excluded from the study. The institutional ethics committee approved the study protocol (IRB No. 11851), and written informed consent was obtained from all patients according to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.

Demographic data and preoperative CT stone features were recorded from all patients. The CT exams were performed by using a 64-slice GE Lightspeed CT Scanner[®] (General Electric, USA) and a slice thickness of 1 mm. A senior radiologist evaluated all CT exams in the magnified (400%) bone window (width, 1600 UH/level, 500 UH) in the three axes. Stone size sum was considered the sum of the longest diameter of each stone in the renal unit

regardless of CT axes. Stone volume sum was calculated by using the sum of the volume of each stone in the renal unit using the ellipsoid formula as $\text{length} \times \text{width} \times \text{depth} \times \pi \times 0.167$. Stone density was measured by free hand region of interest determination coincident with the stone borders.

Operative technique of RIRS was described in detail in a previous publication.³ Irrigation was obtained by a bag of 1 L saline hanging 40 cm above the patient plus occasional flushes of saline with 20 mL syringe. The most symptomatic kidney was operated first when bilateral RIRS was planned. Every case was performed by using a reusable flexible ureteroscope URF-P5 (Olympus, JN). As a standardized method, in every unilateral RIRS the same disposable devices were used: nitinol 0.035" guidewire (Coloplast, DK), polytetrafluoroethylene (PTFE) 0.035" guidewire (Coloplast, DK), ureteral access sheath 10/12F×35 cm (Coloplast, DK), tipless basket 1.5F (Coloplast, DK), Double-J silicone stent 6F (Coloplast, DK), and 270 μ m Holmium laser fiber (Dornier, USA), one each. Extra disposable devices were available for the surgeon and used on demand for bilateral cases. Failure to pass the ureteral sheath was recorded, and a Double-J stent was placed on the renal unit. Disposable devices used in each procedure were recorded. Operative time was defined from the beginning of cystoscopy to the end of Double-J insertion for each renal unit. Double-J stent with an external string was placed at the end of RIRS in every renal unit. Ureteral lesions due to RIRS were evaluated according to the Post-Ureteroscopic Lesion Scale (PULS).⁸

TABLE 1. CLINICAL FEATURES OF UNILATERAL VS BILATERAL RETROGRADE INTRARENAL SURGERY

Feature	Unilateral RIRS	Bilateral RIRS	p
Gender, Female, N (%)	49 (71.0)	11 (47.8)	0.075
Age (mean \pm SD), years	47.54 \pm 14.56	44.39 \pm 12.82	0.331
Body mass index (mean \pm SD), kg/m ²	28.05 \pm 4.99	28.15 \pm 4.40	0.927
American Society of Anesthesiologists classification, N (%)			
I	27 (39.1)	11 (47.8)	0.272
II	36 (52.2)	8 (34.8)	
III	6 (8.7)	4 (17.4)	
Charlson, N (%)			
0	24 (34.8)	12 (52.2)	0.729
1	16 (23.2)	2 (8.7)	
2	12 (17.4)	5 (21.7)	
3	6 (8.7)	1 (4.4)	
4	5 (7.3)	2 (8.7)	
5	2 (2.9)	0 (0.0)	
6	1 (1.5)	0 (0.0)	
7	1 (1.5)	1 (4.4)	
8	1 (1.5)	0 (0.0)	
9	0 (0.0)	0 (0.0)	
10	1 (1.5)	0 (0.0)	
Pre-op creatinine (mean \pm SD), mg/dL	0.81 \pm 0.20	0.97 \pm 0.59	0.209
Pre-op VAS >3, N (%)	29 (42.0)	10 (43.5)	1
Stone size sum (mean \pm SD), mm	14.05 \pm 6.30	16.21 \pm 8.40	0.143
Stone volume sum (mean \pm SD), mm ³	495.71 \pm 515.92	347.47 \pm 390.81	0.083
Stone density (mean \pm SD), HU	1032.14 \pm 299.42	925.20 \pm 365.70	0.103
Inferior calix location, N (%)	22 (31.9)	8 (17.4)	0.083
Infundibulopelvic angle of the inferior calix (mean \pm SD), °	41.17 \pm 19.36	44.15 \pm 24.26	0.484
Stone composition			
Calcium oxalate monohydrate, N (%)	27 (39.1)	22 (47.8)	0.932
Calcium oxalate dihydrate, N (%)	36 (52.2)	20 (43.5)	
Calcium phosphate, N (%)	6 (8.7)	4 (8.7)	

RIRS=retrograde intrarenal surgery; VAS=visual analogic scale.

Patients were discharged on the same day except if visual analogic scale (VAS) for pain >3. Patients were maintained with standardized oral analgesics and antibiotics until removal of the Double-J stent on postoperative day (POD) 10.

All patients were re-evaluated on POD 3, POD 10, POD 30, and POD 90 by the same urologist. The SFR was evaluated on a POD 90 non-contrast CT by a senior radiologist for each renal unit. Surgical complications based on Clavien-Dindo classification during the 90 days of follow-up were recorded.⁹ Outcomes of BSS RIRS were compared with unilateral RIRS. Outcomes of the first operated kidney were compared with the second kidney in the BSS RIRS group.

Categorical data were reported as frequency and percentage, and continuous data were reported as mean and standard deviation. Categorical variables were compared by using the chi-square test, whereas continuous variables were compared by using the Student *t*-test for independent groups. Normal

distribution was validated with a histogram and box plot. SPSS® Statistics Version 20 (IBM Corp®, USA) was used for statistical analysis. Sample size of 23 patients for BSS RIRS and 69 patients for unilateral RIRS was calculated in a case-control study, with a 1:3 proportion, to a test power of 80% and an alpha error of 0.05 for an overall complication rate of 15% for unilateral RIRS and 40% for BSS RIRS.³

Results

One hundred one patients comprising a total of 127 renal units met the inclusion criteria for our study. Ureteral access sheath insertion was not accomplished in 12 out of 127 renal units, resulting in a failure rate of 9.4%. These renal units were managed with Double-J stenting for a second procedure and were excluded from this study. Failure in ureteral access sheath placement occurred in 5 out of 74 (6.8%) renal units of

TABLE 2. OUTCOMES OF UNILATERAL VS BILATERAL RETROGRADE INTRARENAL SURGERY

Feature	Unilateral RIRS	Bilateral RIRS	p
Operative time (mean ± SD), minutes	61.24 ± 26.62	88.65 ± 33.19	<0.001
Fluoroscopy time (mean ± SD), seconds	33.10 ± 26.62	47.13 ± 36.28	0.098
X-Ray dose (mean ± SD), mGy	1.15 ± 1.38	1.51 ± 1.22	0.244
Dose area product (mean ± SD), mGym ²	0.03 ± 0.07	0.03 ± 0.02	0.460
Disposable devices			
Ureteral dilation balloon, <i>N</i> (%)	1 (1.4)	0 (0.0)	0.017
Nitinol guidewire, <i>N</i> (%)	78 (113.0)	31 (67.4)	
PTFE guidewire, <i>N</i> (%)	77 (112.0)	30 (65.2)	
Ureteral access sheath, <i>N</i> (%)	69 (100.0)	23 (50.0)	
Tipless basket, <i>N</i> (%)	69 (100.0)	23 (50.0)	
Holmium laser fiber, <i>N</i> (%)	69 (100.0)	23 (50.0)	
Double-J stent, <i>N</i> (%)	74 (107.2)	53 (115.0)	
Hospitalization time (mean ± SD), hours	14.43 ± 18.81	13.00 ± 4.89	0.564
Creatinine (mean ± SD), mg/dL			
Immediate postoperative	0.89 ± 0.24	1.11 ± 0.64	0.023
POD 3	0.87 ± 0.22	1.18 ± 0.76	0.003
POD 10	0.82 ± 0.19	0.96 ± 0.46	0.034
POD 30	0.79 ± 0.17	0.93 ± 0.42	0.032
POD 90	0.79 ± 0.17	0.91 ± 0.43	0.068
Stone-free rate, <i>N</i> (%)			
0 mm	51 (73.9)	35 (76.1)	0.830
0–2 mm	5 (7.3)	4 (8.7)	0.712
>2 mm	13 (18.8)	7 (15.2)	0.802
Post-ureteroscopic lesion scale			
0	63 (91.30)	45 (97.83)	0.514
1	4 (5.80)	1 (2.17)	
2	1 (1.45)	0 (0.00)	
3	1 (1.45)	0 (0.00)	
Clavien-Dindo			
0	58 (84.1)	14 (60.1)	0.030
I	7 (10.1)	7 (30.4)	
II	4 (5.8)	1 (4.4)	
IIIa	0 (0.0)	0 (0.0)	
IIIb	0 (0.0)	1 (4.4)	
ER visits, <i>N</i> (%)	8 (11.6)	8 (34.8)	0.026
VAS >3, <i>N</i> (%)			
POD 3	43 (62.3)	15 (65.2)	0.083
POD 10	12 (17.4)	5 (21.7)	0.642
POD 30	1 (1.4)	2 (8.7)	0.090
POD 90	0	2 (8.7)	0.013
Double-J displacement before planned, <i>N</i> (%)	24 (34.8)	18 (39.1)	0.695

ER = emergency room; POD = postoperative day; PTFE = polytetrafluoroethylene.

planned unilateral RIRS and in 7 out of 54 (13.0%) renal units of planned bilateral RIRS ($p=0.234$). One patient who had planned for BSS RIRS was shifted to unilateral RIRS due to a failure in ureteral access sheath insertion in only one renal unit. As a result, 69 patients were evaluated in the unilateral RIRS group and 23 patients with 46 renal units were evaluated in the BSS RIRS group.

Clinical features of successful unilateral RIRS were compared with BSS RIRS (Table 1). Demographic data and stone characteristics were similar between groups.

Table 2 summarizes the comparative outcomes of unilateral and BSS RIRS. The SFR (73.9% vs 76.1%, $p=0.830$) and hospitalization time (14.43 ± 18.81 hours vs 13.00 ± 4.89 hours, $p=0.564$) were similar between unilateral and bilateral RIRS, with less consumption of disposable devices in the bilateral group ($p=0.017$). Disposable devices used in the first attempt to RIRS were reported in an intention-to-treat analysis, including all disposable devices used in failed RIRS. Nitinol guidewire, PTFE guidewire, and Double-J stents used in failed RIRS were reported (Table 2). Operative time was longer in bilateral RIRS (61.24 ± 26.62 minutes vs 88.65 ± 33.19 minutes, $p<0.001$).

The bilateral RIRS group had significantly more overall complications by Clavien-Dindo classification than unilateral RIRS (15.9% vs 39.9%, $p=0.030$) and more ER visits (11.6% vs 34.8%, $p=0.026$). Clavien-Dindo postoperative complications grade I occurred in seven patients in each group due to more analgesic requirements than originally prescribed, grade II occurred in four patients in the unilateral group and in one patient in the bilateral group due to urinary infection and the need for antibiotics, and grade IIIb occurred in one patient in

the bilateral group due to Double-J insertion. During follow-up, 16 patients, 8 each group, visited the ER. One patient from the unilateral group visited the ER four times for analgesics, six patients visited twice for pain in the bilateral group, and nine patients visited once. All patients were kept enrolled and followed according to the study design. Although the VAS curve for pain during the follow-up was similar between groups ($p=0.334$) (Fig. 1), at POD 90 more patients in the bilateral RIRS experienced VAS >3 than in the unilateral group ($p=0.013$). Although both groups temporarily increased creatinine levels from immediate postoperative (IPO) to POD 3, the creatinine curve for the entire follow-up was significantly higher in bilateral RIRS ($p=0.019$) (Fig. 2).

Further, operative time, SFR, and PULS classification of the first operated renal unit were similar to the second operated renal unit in bilateral RIRS (Table 3).

Discussion

This is the first prospective study to compare the outcomes of unilateral with BSS RIRS and to compare the outcomes of the first with second operated kidneys in bilateral RIRS for the treatment of kidney stones up to 20 mm. The BSS RIRS had similar SFR, consuming less disposable devices compared with unilateral RIRS; however, BSS RIRS had a higher overall complication rate, a higher frequency of ER visits, and higher creatinine levels during follow-up. Moreover, this study is the first to demonstrate no difference in outcomes between the first and second operated kidneys in BSS RIRS.

Many economical advantages are attributed to bilateral procedures, making this approach very attractive. Less

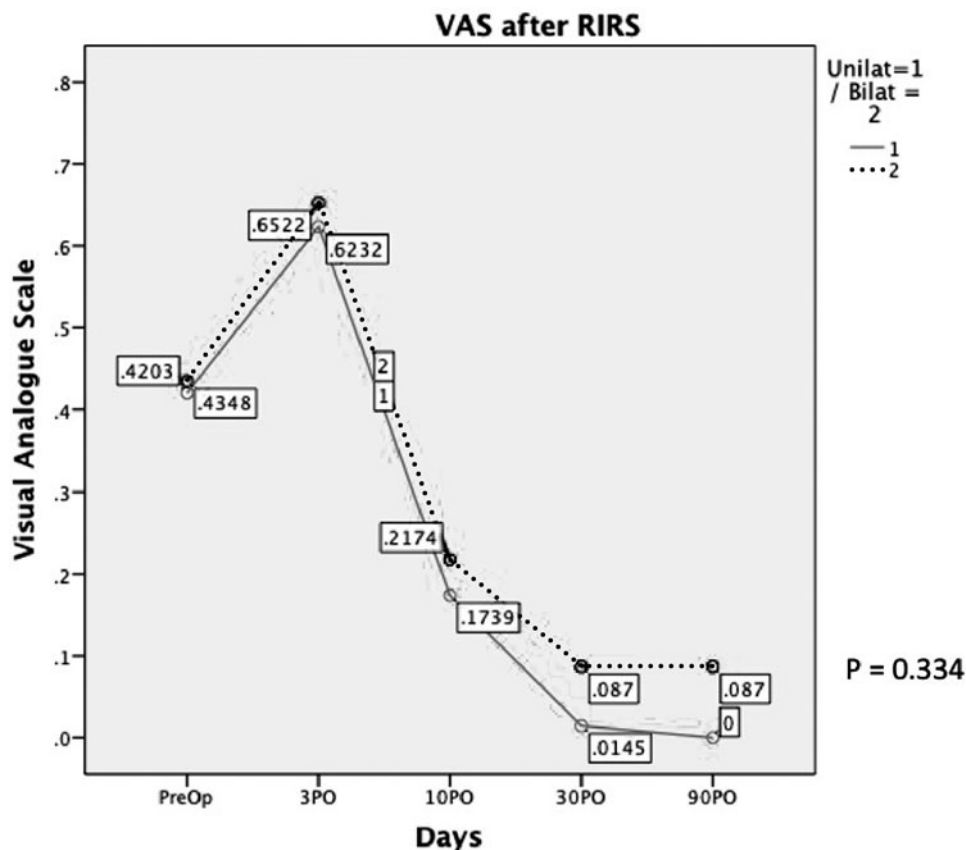
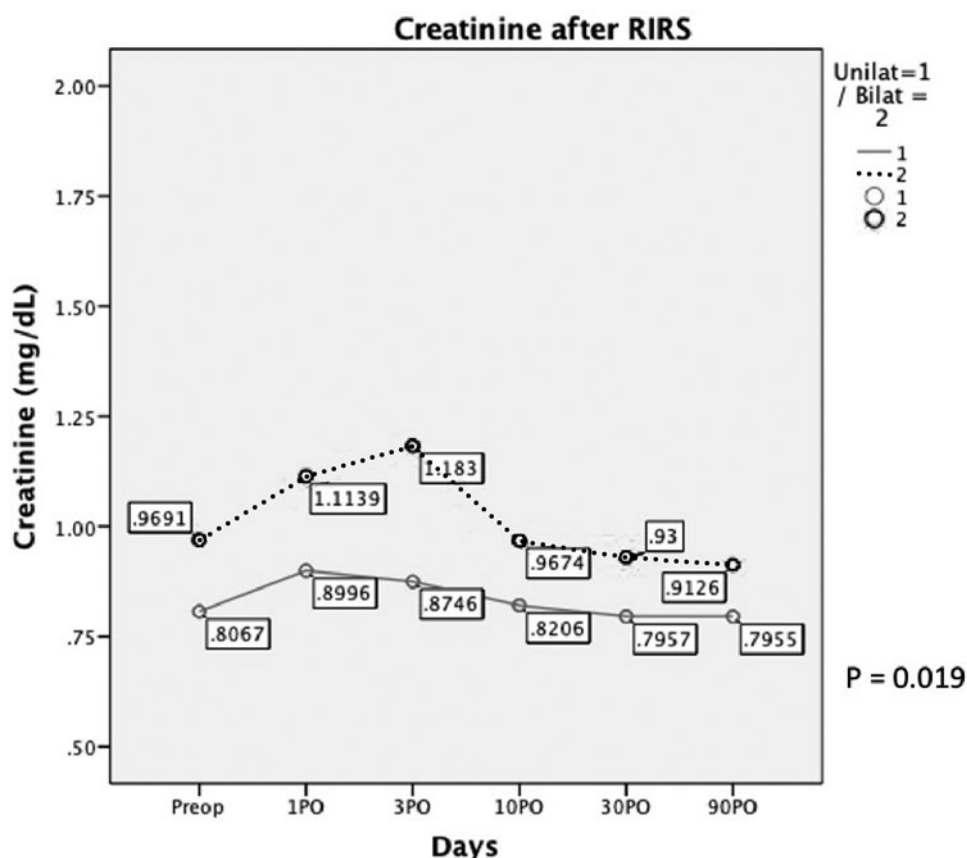


FIG. 1. Visual analogue scale for pain after unilateral vs bilateral same-session RIRS. RIRS=retrograde intrarenal surgery.

FIG. 2. Serum creatinine curve after unilateral vs bilateral same-session RIRS.



disposable devices consumption, less operation room expenditure, less hospitalization time, and fewer working days loss are expected benefits. Our study demonstrated less consumption of disposable devices in bilateral RIRS, similar hospitalization time, and less operation room expenditure for the renal unit.

However, SFR and surgical complications were poorly assessed since only retrospective studies evaluated bilateral RIRS. Three systematic reviews highlighted the lack of high-quality evidence on BSS RIRS in the management of urolithiasis.^{6,7,10} Previous retrospective series reported that SFR ranged from 42.0% to 92.8%.^{11–16} This wide range reflects the different image modalities used to evaluate this outcome. Lack of a comparative group makes these low-quality data. Only one retrospective study compared BSS RIRS with a matched control unilateral RIRS group at a 1:1 ratio. The

authors reported a similar SFR higher than 80% assessed by plain X-ray between groups and a very low Clavien-Dindo complication rate of 11.9% for bilateral RIRS and of 8.5% for unilateral RIRS with no major complications. Different from our study, all units had a stent placed before RIRS to reduce ureteral complications.¹⁷ Moreover, retrospective data tend to show fewer complications because of underreporting. Patient security is the main concern of bilateral RIRS since it may affect renal function. Therefore, to validate BSS RIRS, we need to evaluate prospective data.

Our study is the first to report the prospective outcomes of bilateral RIRS. Compared with the unilateral RIRS, the SFR evaluated exclusively by CT was similar but complications were significantly higher. Bilateral RIRS had significantly more overall complications by Clavien-Dindo classification than unilateral RIRS (15.9% vs 39.9%, $p < 0.001$), including

TABLE 3. FIRST VS SECOND OPERATED KIDNEY OF BILATERAL SAME-SESSION RETROGRADE INTRARENAL SURGERY

Features	First	Second	p
Stone volume sum (mean ± SD), mm ³	279.44 ± 329.93	415.51 ± 440.32	0.242
Stone density (mean ± SD, range), HU	946.57 ± 355.01	903.83 ± 382.83	0.697
Infundibulopelvic angle (mean ± SD), °	48.00 ± 26.88	40.30 ± 21.23	0.287
Operative time (mean ± SD), minutes	43.22 ± 21.67	45.43 ± 26.12	0.756
Stone-free rate, N (%)			
0 mm	17 (73.9)	18 (78.3)	1
0–2 mm	3 (13.0)	1 (4.4)	0.608
>2 mm	3 (13.0)	4 (17.4)	1
Post-ureteroscopic lesion scale			
0	22 (95.7)	23 (100.0)	0.312
1	1 (4.4)	0 (0.0)	

one Clavien-Dindo IIIb in the bilateral group, and more ER visits (11.6% vs 34.8%, $p=0.026$). We do acknowledge that the vast majority of postoperative complications were grade I due to the need for analgesics. However, in a prospective and standardized study such as ours, it is relevant and probably underreported in retrospective series. During follow-up, eight patients in each group visited the ER. One patient from the unilateral group visited the ER four times for analgesics and this case might be classified as personal sensitivity; however, six patients in the bilateral group visited twice for pain and nine patients visited once, two from the bilateral group and one from the unilateral group. Although the VAS curve for pain during the follow-up was similar between groups, at POD 90 more patients experienced VAS >3 in the bilateral RIRS.

Previous studies could not demonstrate a significant creatinine change after bilateral RIRS, although they reported an increase in creatinine levels.^{12–15,18} A retrospective series of 44 bilateral RIRS reported two cases of anuria in the only two patients left without a Double-J stent.¹⁹ Our study demonstrated that both groups temporarily increased creatinine levels from IPO to POD 3 and more importantly, the creatinine curve for the entire follow-up was significantly higher in bilateral RIRS even using Double-J stent in every operated renal unit. Although increased, mean creatinine levels remained in the normal range during the follow-up in both groups. Creatinine rise might be particularly relevant for patients with previous limited renal function. The small number of participants in this study prevented a multivariate analysis to identify which patients are at greater risk for a creatinine rise during follow-up. Our results demonstrated that bilateral RIRS is not entirely safe as previous retrospective studies reported.

This study also compared the outcomes of first with second operated kidneys of bilateral same-session RIRS. No significant difference in SFR, operative time, or PULS was demonstrated. Although not significant due to variation, mean stone volume sum difference between first and second operated kidneys was 30% but the operative time difference between first and second operated kidneys was only 5%. A combination of dusting and basketing techniques to treat a variety of multiple, single, soft, and hard stones in this prospective study was used. Therefore, many other stone factors than simply stone volume may influence operative time.

The small number of bilateral procedures is a limitation of our study. However, sample size was calculated to a test power of 80%. Another limitation is the study design. Patients with bilateral kidney stone disease were not randomized in same-session and staged RIRS. However, bilateral kidney stones are expected in around 10% of the patients and randomization in two groups would impair the study.

Conclusion

Although BSS RIRS had a similar SFR and consumed less disposable devices, it had a higher overall complication rate, a higher frequency of ER visits, and higher creatinine levels during follow-up than unilateral RIRS. There is no significant outcome difference between the first and second operated kidneys in bilateral RIRS.

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A.D.: Performed the research, designed the research study, analyzed the data, and wrote the article; F.C.M.T.: performed

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Abbreviations Used

BSS = bilateral same session

CT = computed tomography

ER = emergency room

IPO = immediate postoperative

PTFE = polytetrafluoroethylene

POD = postoperative day

RIRS = retrograde intrarenal surgery

SFR = stone-free rate

PULS = post-ureteroscopic lesion scale

VAS = visual analogic scale