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The efficacy and safety of primary Retrograde Intrarenal Surgery (RIRS)

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ABSTRACT— Retrograde Intrarenal Surgery (RIRS) is an emerging minimally invasive method in the surgical treatment of kidney stones. It has rapidly become a preferred surgical technique owing minimally invasive surgical modality gap for small stones. The technique requires the simultaneous and effective use of laser energy, fluoroscopy, access sheaths, fiberoptic and digital technologies. The increasing experience with RIRS has created a tendency to simplify this complex process. There are several studies revealing that RIRS can be performed safely and effectively without these complex processes. Therefore the primary aims are to detect the safety and efficacy of the primary RIRS. From January 2022 to September 2022, the medical records of 58 patients who underwent RIRS for renal stones at Duhok hospitals prospectively evaluated. RIRS cases with stone sizes less than 25 mm and adult age group > 18 years with prior unstented ureters were included. Pediatric age patients, multi-stage procedures, documented ureteral strictures were excluded. Stone clearance rate; at the first session were 40 cases (68.97%) and at the Second session were 18 cases (31.03%). Complication rates; urosepsis 8 cases (13.79%), Ureteral contusion 4 cases (6.90%), and gross hematuria 4 cases (6.90%). The use of primary RIRS in unstented prior ureter is generally effective and safe and is not associated with higher complication rate.

KEYWORDS: RIRS; FURS; urolithiasis; kidney stone; stone clearance; complications.

1. INTRODUCTION

Stone formation is highly prevalent, with rates of up to 14.8% and increasing, and a recurrence rate of up to 50% within the first 5 years of the initial stone episode. Management of symptomatic kidney stones has evolved from open surgical lithotomy to minimally invasive endourological treatments leading to a reduction in patient morbidity, improved stone clearance rates and better quality of life. Prevention of recurrence requires behavioral and nutritional interventions, as well as pharmacological treatments that are specific for the type of stone [1]. With the aid of the recent technological developments; there have been rapid increasing options in the management of renal urolithiasis. Historically had been treated with open surgery, recently renal stones are often managed by extracorporeal shockwave lithotripsy (ESWL) and endoscopic operations. But recently minimally invasive surgery such as ESWL, percutaneous nephrolithotomy (PCNL), RIRS and laparoscopic surgeries are commonly used for the treatment of kidney stones. The most important one of the various clinical parameters that can affect the success of stone removal is the stone size [2]. Although ESWL and PCNL are mentioned in the guidelines as gold standard for the management of kidney stones, RIRS is accepted as another treatment modality in the European Association of Urology (EAU) guidelines [3]. The more commonly use of RIRS depends on not only the digital improvements in flexible Ureteroscopy (fURS) technology, but also the developments in deflection mechanism, mobility, ergonomics and durability. Meantime, with the addition of the developments in auxiliary devices and increase in surgical experience and compliance higher success rates have been achieved with RIRS in the management of renal stones [4]. Today, reaching the stone via a natural route and achieving a high success rate with a lower morbidity have led RIRS to become a commonly used and important treatment modality. The advantage of flexible ureteroscope over semirigid is the ability to inspect all renal collecting system and to diagnose and manage stones and even urothelial malignancy [5]. EAU recommends RIRS or (ESWL) as first line treatment option for kidney stones of diameter up to 20 mm and second line treatment of stones over 20 mm [6]. There are several studies revealing that RIRS can be performed safely and effectively without fluoroscopy or access sheath and the evidence is growing day by day. A recent systematic review and meta-analysis revealed that routine use of fluoroscopy doesn't influence the outcomes of RIRS [7]. Fluoroscopy have many advantages but the patients exposure to radiation and with surgeons and other staffs during the operation has become a problem [8]. The ureteral access sheath (UAS) allows fast, safe, and rapid repeated entrance into the collecting system, lowers the intrarenal pressure, improves visibility, and increases the ureteroscope lifespan. However, the safety of its routine use remains controversial; there are concerns related to UAS use about damage to the ureteric wall, ranging from urothelial abrasion to wall ischemia and ureteric avulsion [9]. The objective of this study was to conduct a modification of the RIRS technique, reduce the cost, and decrease radiation exposure, especially for the surgeon and intraoperative staff involved in a high-volume stone center. However, to the best of our knowledge, there are no published reports concerning the outcomes postoperative stone free rate and complications for the primary RIRS. In this study, we evaluated the efficacy and safety of primary RIRS for the treatment of renal stones.

Aim of the Study:
The primary aims are to detect the safety (urosepsis and ureteric injury and gross haematuria rates) and efficacy (stone clearance rate) of the primary RIRS (prior unstented ureter).

2. Materials and methods

From January 2022 to September 2022, the medical records of 70 patients who underwent RIRS for renal stones at Duhok city hospitals prospectively evaluated. RIRS patients with kidney stone sizes equal to or less than 20mm and adult age group > 18 years and Patients with prior unstented ureter were included. Exclusion criteria include: pediatric age groups, multi-stage procedure, documented ureteral strictures. Patients with inadequate data or lost during follow up had been excluded. In the final analysis 58 cases included only. The relevant clinical parameters were analyzed, prior to operation no double j stent inserted. The location, size of stones, duration of operation, and the method of stone removal had been evaluated. General information of patients with stones shown in table 1. Stone size was calculated as cumulative stone burden. RIRSs were performed under general anesthesia by multiple surgeons using a flexible dual channel ureteroscope with inserting two double j stent by semirigid ureteroscope. Next, Holmium laser lithotripsy is carried out and/or stone extraction with a basket device. At the end of the procedure, a double pigtail ureteral stent is left for 5-14 days. The evaluation done preoperatively by using non contrast computed tomography scan (NCCT). Follow up by laboratory tests and imaging kidney, ureter, bladder x-ray (KUB) and ultrasound, performed 2 weeks postoperatively to clarify the rate of stone clearance and 2 months after double j stent removal and in each follow up visit thereafter. The data such as age, gender, systemic conditions, operative time, perioperative complications such as perforation of ureter, hematuria and clinical follow-up had been collected. The primary aims were to evaluate the complication rates such as ureteral injury, urosepsis and gross hematuria and secondary outcomes are stone free rates, stones less than 4mm regarded as negligible development of all surgery was performed with the patient in the dorsal lithotomy position under general anesthesia. Fragmented stones were extracted by using a stone basket or irrigation.

2.1 Statistical analyses:

The comparisons of complications in patients with different medical and general information were examined in Pearson chi-squared tests. A significant level of difference was identified in a p value <0.05.

The statistical calculations were performed by JMP Pro 14.3.0.

2.2 Ethical approval:

The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It was carried out with patients verbal and analytical approval before sample was taken. The study protocol and the subject information and consent form were reviewed and approved by a local ethics committee according to the document number 1138 in 7/6/2022.

3. Results

General information of patients with stone disease, lists patient demographics and the baseline characteristics of the renal stones show in table 1.

Stone clearance rate at the first session were 40 cases (68.97%), and the Second session were 18 cases (31.03%) and p value was significant 0.0908. Lower pole stone clearance at the first session 10 cases (50%), renal pelvis 20 cases (76.92%), renal mid pole 8 cases (100%), Renal upper pole 2 cases (50%). Age category for stone clearance rate <31 years total number were 12 cases and at the first session were 4 cases (33.33%), and 8 cases (66.67%) at the second session, ≥ 31 years total 46 cases stone clearance at the first session 36 cases (78.26%), 10 cases (21.74%) at the second session. Association of stone clearance with general and medical characteristics among renal stone patients after RIRS and outcomes of RIRS in stone disease patients with different ages shows in table 2 and fig 1

Table 1: General information of patients with stone diseases

Characteristics (n=58)	**Statistics**	
	Number	**Percent %**
Sex		
Male	16	27.59
Female	42	72.41
Age (23-72 years)	45.31	15.35
Age category		
20-30	12	20.69
31-40	12	20.69
41-50	14	24.14
51-60	10	17.24
61-70	4	6.90
71-80	6	10.35
PMH		
Negative	34	58.62
Positive	24	41.38
PSH		
Negative	20	34.48
Positive	38	65.52
Stone size (6-23 mm)	13.91	4.61
The hardness of renal calculi (300-1300 HU)	723.79	231.01
left renal lower pole	12	20.69
Left renal midpole	8	13.79
left renal pelvis	12	20.69
right renal lower pole	8	13.79
right renal pelvis	14	24.14

Right renal upper pole	4	6.90
Fiber size (micrometer)		
200	56	96.55
270	2	03.45
Duration of operation (30-120 minutes)	Median: 60	IQR: 0
<1 hr.	16	27.59
≥1 hr.	42	72.41

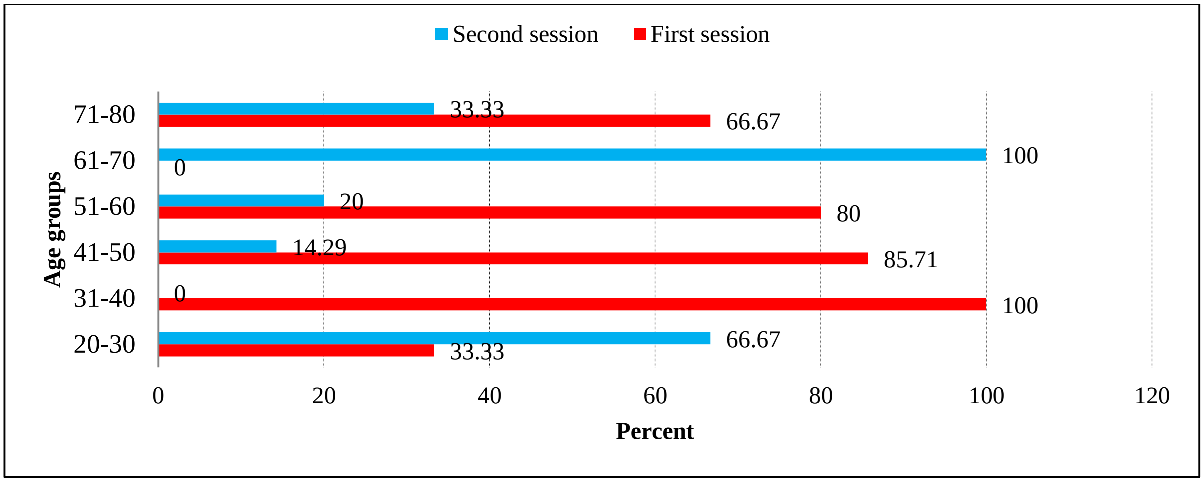

Fig 1: Outcomes of RIRS in stone disease patients with different ages

Table 2: Association of stone clearance with general and medical characteristics among renal stone patients after RIRS.

Characteristics (n=58)	The outcome of surgery no (%)		p-value (two-sided)
	First session 40 (68.97%)	Second session 18 (31.03%)	
Age category			
20-30	4 (33.33)	8 (66.67)	
31-40	12 (100)	0 (0.00)	
41-50	12 (85.71)	2 (14.29)	**0.0002**[a]
51-60	8 (80.00)	2 (20.00)	
61-70	0 (0.00)	4 (100)	
71-80	4 (66.67)	2 (33.33)	
Stone location			
left renal lower pole	6 (50.00)	6 (50.00)	
Left renal mid pole	8 (100)	0 (0.00)	
left renal pelvis	8 (66.67)	4 (33.33)	0.0908[a]
right renal lower pole	4 (50.00)	4 (50.00)	
right renal pelvis	12 (85.71)	2 (14.29)	
Right renal upper pole	2 (50.00)	2 (50.00)	
Fiber size (micrometer)			
200	38 (67.86)	18 (32.14)	1.0000[a]
270	2 (100)	0 (0.00)	
Power (joule) mean 9SD)	1.24 (0.25)	1.14 (0.32)	0.2949[b]
PMH			
Negative	22 (64.71)	12 (35.29)	0.4039[a]
Positive	18 (75.00)	6 (25.00)	

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PSH			
Negative	12 (60.00)	8 (40.00)	0.2843[a]
Positive	28 (73.68)	10 (26.32)	
Stone size	13.75 (4.86)	14.28 (4.12)	0.6905[b]
The hardness of renal calculi (HU) mean (SD)	772.86 (43.96)	618.19 (199.32)	**0.0003**[b]
Duration of surgery			
<1 hr.	12 (75.00)	4 (25.00)	0.7523[a]
≥1 hr.	28 (66.67)	14 (33.33)	

[a] Pearson chi-squared tests and [b] independent t-test were performed for statistical analyses.
The red bold numbers show the significant differences.

Overall complication rate: Urosepsis were 8 cases (13.79%) 2 cases at the first session (25%) and 6 cases at the second session (75%) with p value 0.0082. Most of cases of urosepsis their stones were located in the renal pelvis 6 cases (75%) and 2 cases in other renal locations (25%).The rate of urosepsis were high in very young ages <31 years 4 out of 12 cases (33.33%) and ≥ 31 years 4 out of 46 cases (8.69%). Urosepsis according to the duration of surgery increased by increasing the time < 60 min 2 out of 16 cases (12.5%) ≥ 60 min 6 out of 42 cases (14.28%). Ureteral contusion 4 cases (6.90%) 4 cases at first session (100%) and 0 case at second session. Gross hematuria 4 cases (6.90%) mostly associated with the cases of ureteral injury. Details of complications and Comparisons between the first and second clearance sessions shows in tables 3, 4 and figures 2, 3.

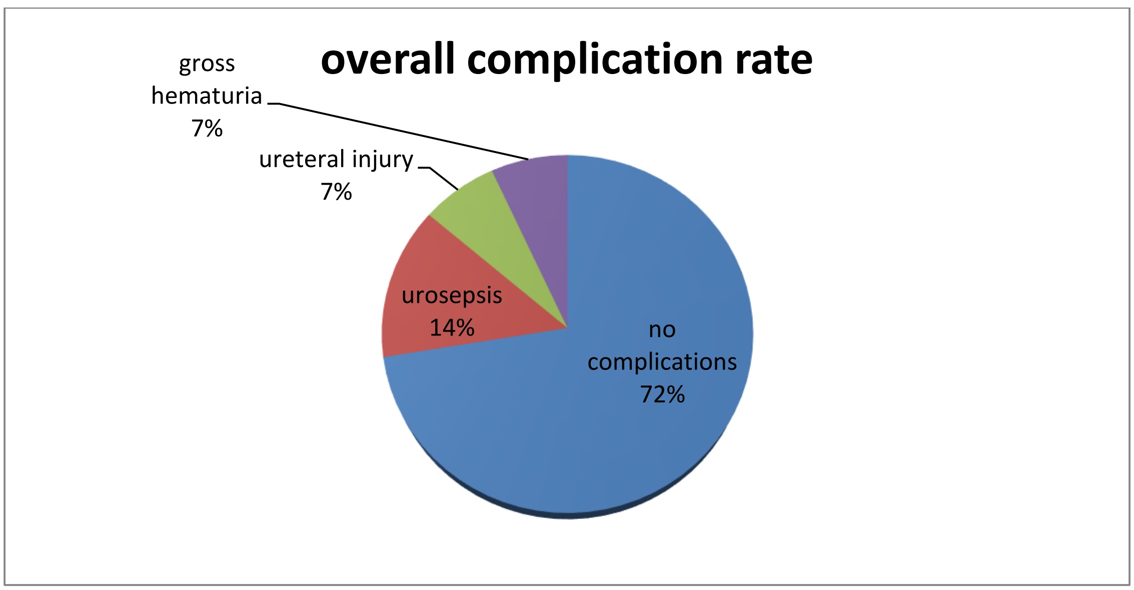

Fig 2: incidence of complication rate among patients with primary RIRS

Table 3: Factors associated with the incidence of Urosepsis in renal stone patients

Characteristics (n= 58)	Urosepsis		p-value (two-sided)
	Negative (n=50)	Positive (n=8)	
Age (years)	45.68 (14.71)	43.00 (19.96)	0.6507[b]
Age			
20-30	8 (66.67)	4 (33.33)	
31-40	12 (100)	0 (0.00)	**0.0176**[a]
41-50	14 (100)	0 (0.00)	
51-60	8 (80.0)	2 (20.00)	

61-70	2 (50.00)	2 (50.00)	
71-80	6 (100)	0 (0.00)	
PMH			
Negative	28 (82.35)	6 (17.65)	0.4491[a]
Positive	22 (91.67)	2 (8.33)	
PSH			
Negative	18 (90.00)	2 (10.00)	0.7015[a]
Positive	32 (84.21)	6 (15.79)	
Stone location			
left renal lower pole	12 (100)	0 (0.00)	
Left renal mid pole	8 (100)	0 (0.00)	
left renal pelvis	8 (66.67)	4 (33.33)	0.1288[a]
right renal lower pole	6 (75.00)	2 (25.00)	
right renal pelvis	12 (85.71)	2 (14.29)	
Right renal upper pole	4 (100)	0 (0.00)	
Fiber size (micrometer)			
200	48 (85.71)	8 (14.29)	1.0000[a]
270	2 (100)	0 (0.00)	
Duration of surgery			
<1 hr.	14 (87.50)	2 (12.50)	1.0000[a]
≥1 hr.	36 (85.71)	6 (14.29)	
Stone size	14.06 (4.75)	13.00 (3.78)	0.5507[b]
the hardness of renal calculi (HU)	669.13 (188.02)	775 (158.11)	0.1397[b]

[a] Pearson chi-squared tests and [b] independent t-test and were performed for statistical analyses.
The red bold numbers show the significant differences.

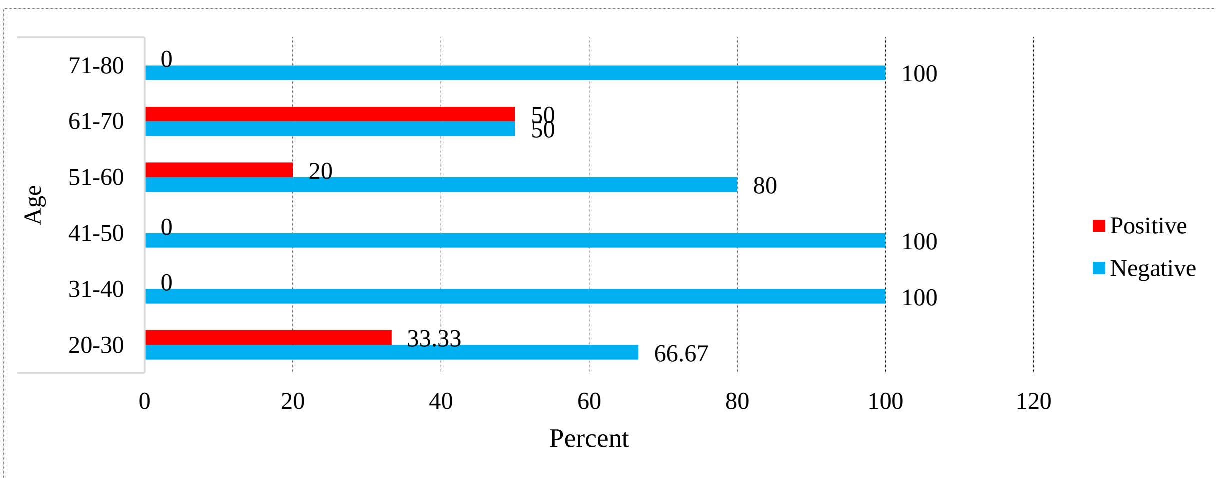

Fig 3: Incidence of Urosepsis in renal stone disease patients with different characteristics

Table 4: Factors associated with incidence of gross hematuria in renal stone patients

Characteristics (n= 58)	**Gross hematuria**		**p-value**
	Negative (n=30)	**Positive (n=28)**	
Age			0.3753[a]
20-30	10 (83.33)	2 (16.67)	
31-40	12 (100)	0 (0.00)	
41-50	12 (85.71)	2 (14.29)	
51-60	10 (100)	0 (0.00)	
61-70	4 (100)	0 (0.00)	
71-80	6 (100)	0 (0.00)	

PMH			0.6351[a]
Negative	31 (91.18)	3 (8.82)	
Positive	23 (95.83)	1 (4.17)	
PSH			1.000[a]
Negative	19 (95.00)	1 (5.00)	
Positive	35 (92.11)	3 (7.89)	
Stone location			**0.5560[a]**
left renal lower pole	10 (83.33)	2 (16.67)	
Left renal midpole	7 (87.50)	1 (12.50)	
left renal pelvis	12 (100)	0 (0.00)	
right renal lower pole	8 (100)	0 (0.00)	
right renal pelvis	13 (92.86)	1 (7.14)	
Right renal upper pole	4 (100.00)	0 (0.00)	
Fiber size (micrometer)			1.000[a]
200	52 (92.86)	4 (7.14)	
270	2 (100)	0 (0.00)	
Duration of surgery			0.5671[a]
<1 hr.	16 (100)	0 (0.00)	
≥1 hr.	38 (90.48)	4 (9.52)	
Stone size	14.06 (4.72)	12.00 (2.31)	0.3944[b]
hardness of renal calculi (HU)	688.82 (187.92)	762.50 (325)	0.4773[b]

[a] Pearson chi-squared tests and [b] independent t-test and were performed for statistical analyses.
The red bold numbers show the significant differences.

4. Discussion

In 1987, Bagley first introduced RIRS and reported the results of a flexible RIRS procedure [10]. Among the advances that have been made, the access sheath has played a significant role in RIRS. The access sheath allows the flexible URS to quickly and repeatedly enter the kidney and upper ureter and also reduces the risk of injury to the ureter. It also prevents pyelovenous reflux of large amounts of perfusion during surgery [11]. [12] reported that the failure rate for access sheath placement was approximately 15%.

But In our study, we don't used access sheath to decrease the rate of ureteral injury because of prior unstented and undilated ureter, we observed that the urosepsis rate was 13,9 % shown below in fig 4 which is higher comparatively to the studies whom used the ureteral access sheath, but ureteral injury rate was less 6,9%.

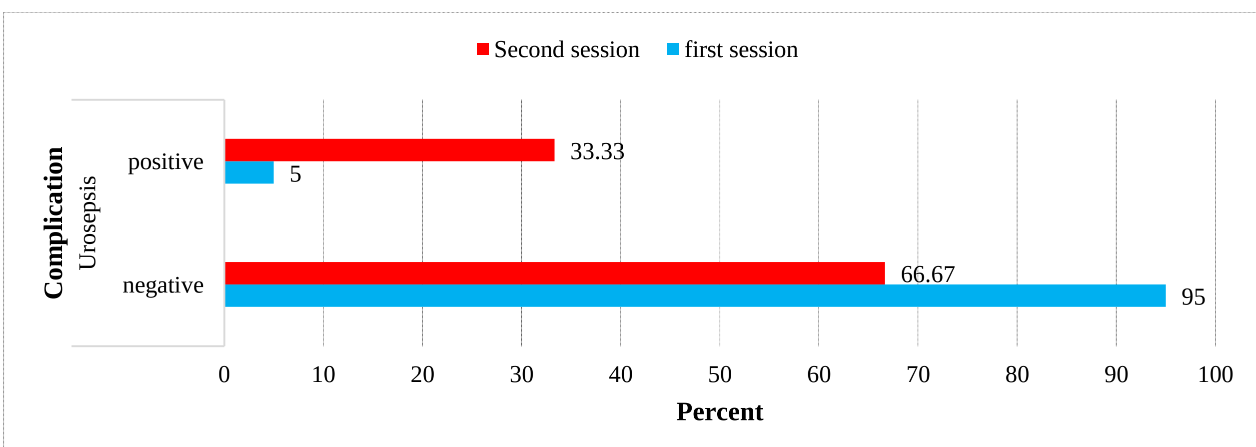

Fig 4: Complications in patients with first and second clearance sessions of RIRS

Several studies have reported that preoperative ureteral stenting affected the outcomes of patients who underwent RIRS [13]. But in our study the outcomes was near to the studies whom used preoperational stenting like stone clearance rate in the first session was 68, 97% and in the second session was 31.03%, Purlmutter et al. reported that preoperative stents dilated the ureter, passively affecting the outcomes of RIRS [14], while Rubenstein et al. reported that there was a significant effect on the stent and SFR [15]. However, Fabrizio et al. reported that preoperative ureteral stenting affected the expansion of the ureter but there was no significant correlation with stone clearance [16]. In our study, the SFR was 68, 97% in the first session and 31.03 % in the second session which shows in fig 5 below.

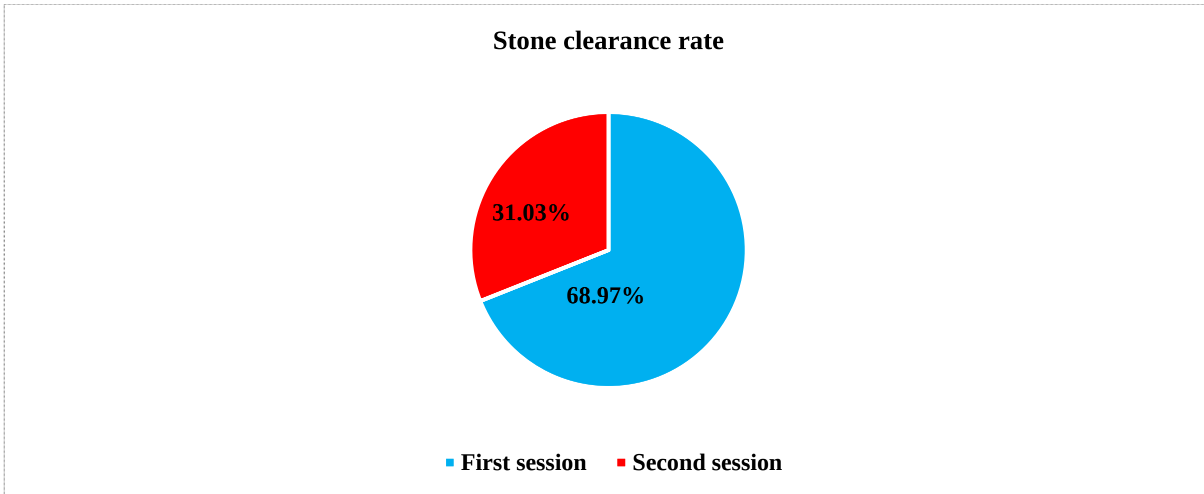

Fig 5: Incidence of stone clearance rate among patients with primary RIRS

These results indicate that preoperative ureteral stenting was not significantly associated with stone clearance. In multivariate logistic regression, stone characteristics such as size, density, and complexity affected the stone-free rate. In addition to stone characteristics, access sheath placement has been shown to affect the stone-free rate. Propensity score- matching results also showed that stone size, density, complexity, and access sheath placement were important predictors of SFRs. However, preoperative ureteral stenting had no significant effect on SFRs. Most RIRS surgeries are performed without preoperative ureteral stenting. In general, preoperative ureteral stenting is considered when UAS insertion is difficult or when it is difficult to insert flexible URS directly. Although ureteral preoperative stenting did not affect SFR, it increased the success rate of UAS insertion. This might be an important source for the prediction of patients who need preoperative stenting in the future.

In our study, patients in the first session had fewer overall complications than the stented second session , 5% urosepsis in first session versus 33,33% in the second session , but the rate of gross hematuria and ureteral injury mostly contusion was significantly higher in the first session versus the second session because the ureter was passively dilated in the second session .Similar to our results, Rubenstein et al. have also shown no significant difference in the rate of complications between the two groups [17]. Lee et al. have compared a short pre operation stenting group, a long preoperation group, and a no-stenting group and found no significant difference in overall complication among the three groups [18].

We acknowledge that our study had limitations. This study was not free from selection bias due to the use of multiple laser systems and laser fibers, multiple types of URS, and multiple surgeons. Therefore, a selection bias could have occurred. If these limitations are addressed in future studies, the results are expected to be more significant.

Table 5: Comparisons of complications between first and second clearance sessions of renal stone.

Complications (n=58)	Complications of all patients (n=58)	Outcome		p-value (two-sided)
		First session	Second session	
Urosepsis				
negative	50 (86.21)	38 (95.00)	12 (66.67)	**0.0082**
positive	8 (13.79)	2 (5.00)	6 (33.33)	
Ureteral contusion				
negative	54 (93.10)	36 (90.00)	18 (100)	0.2995
positive	4 (6.90)	4 (10.00)	0 (0.00)	
Gross hematuria				
negative	54 (93.10)	36 (90.0)	18 (100)	0.2995
positive	4 (6.90)	4 (10.0)	0 (0.0)	

Pearson chi-squared tests were performed for statistical analyses.
The red bold numbers show the significant differences.

In previous studies, there was no significant difference in operation time between with and without preoperative stents in patients with kidney stones [19]. A few studies reported the difference in operation time according to preoperative stent placement [20]. On the contrary, [20] reported that preoperative ureter stent insertion can significantly reduce operative time in patients with stones greater than 10mm. The difference in stone burden, the difference in diameter of the access sheath, In our opinion, once the FURS successfully arrived at renal pelvis, stone-free rate for renal calculi would be more likely affected by stone characteristics and pelvicalyceal anatomy rather than the existence of preoperative stenting and according to some published data. And the end reveals that preoperative unstinting of ureter had no major effects on complication rates and stone clearance rate and also decrease the patient's morbidity from repeated general anesthesia and decrease the cost also.

5. Conclusions

Our study reveals that preoperative stenting had no major effects on operative complications and outcomes such as SFRs, operative times, ureteral strictures. Therefor the use of primary RIRS in prior an unstinted ureter is safe and effective.

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