

Is Retrograde Intrarenal Surgery with Semi-rigid Ureterorenoscope Feasible for Isolated Renal Pelvic Stones?

© Fatih Tarhan¹, © Bilal Eryıldırım¹, © Erdinç Dinçer¹, © Burcu Hancı Sevinç¹, © Kemal Sarıca²

¹University of Health Sciences Türkiye, Kartal Dr. Lütfi Kırdar City Hospital, Clinic of Urology, İstanbul, Türkiye

²Biruni University Faculty of Medicine, Department of Urology, İstanbul, Türkiye

What's known on the subject? and What does the study add?

Retrograde intrarenal surgery using with flexible ureterorenoscope and Holmium laser lithotripsy has become one of the standard treatments for patients with upper urinary tract stones. However, the small size of the working channels of flexible ureterorenoscope and the high cost are disadvantages. It has been suggested that semirigid urethroscope may be effective as an alternative to solve this problem. In this study, we found that semirigid urethroscope had a lower success rate and a higher complication rate compared to flexible ureterorenoscope. Therefore, we concluded that semirigid urethroscopy is unsafe and unsuccessful in the treatment of pelvic stones.

Abstract

Objective: We compared the success and complication rates of retrograde intrarenal surgery (RIRS) performed with semi-rigid ureterorenoscopy (srURS) or flexible ureterorenoscopy (fURS) for isolated renal pelvic stones.

Materials and Methods: A total of 247 patients who underwent RIRS with fURS (n=179; group 1) or srURS (n=68; group 2) were included in this study. Various factors related to patients, stones and surgical procedures were evaluated retrospectively.

Results: There was no difference between the patient groups according to mean age (49.12±1.10 years vs 49.59±1.60 years, p=0.745), gender distribution (p=0.152), mean hounsfield unit values (941±31.41 vs 1036±44.47 p=0.077), and mean hospitalization time (3.57±0.19 days vs 4.59±0.57, p=0.224). In group 1, the mean stone size (14.5±0.73 mm vs 15.5±0.62 mm, p=0.019) was statistically lower and the operative time (79.73±3.38 min vs 70.65±8.61, p=0.041) was statistically higher than those of group 2. The overall success rate in group 1 and group 2 was 93.9% and 63.6%, respectively (p<0.0001). The complication rate in group 2 (23.5%) was higher than that of the group 1 (12.3%) (p=0.047).

Conclusion: According to our results, the success rate of srURS was lower and the complication rate was higher than that of fURS. Therefore, we conclude that srURS was unsafe and unsuccessful for use in the treatment of pelvic stones. Prospective studies involving intrarenal pressure measurement and cost analysis must reach a conclusion in this respect.

Keywords: Urolithiasis, nephrolithiasis, ureteroscopy, retrograde intrarenal surgery

Introduction

The main goal in the treatment of renal stones is to attain the greatest stone-free status with minimal morbidity (1). Retrograde intrarenal surgery (RIRS) with holmium laser lithotripsy has become one of the standard treatments for patients with upper urinary tract stones (2,3). RIRS with a flexible ureteroscope (fURS) has been widely adopted and has become an effective, safe option in primary care for upper urinary tract stones smaller

than 2 cm (4,5). The use of ureteral access sheaths (UAS) is also recommended during the treatment of kidney stones with fURS (4). On the other hand, it has been reported that the use of UAS may cause serious injuries to the ureter (6).

Although fURS is a safe and effective method for the treating of renal pelvic stones, it also has some disadvantages. The small size of the working channels of the fURS only allows the use of small stone baskets and laser fibers. High cost due to low

Correspondence: Fatih Tarhan MD, University of Health Sciences Türkiye, Kartal Dr. Lütfi Kırdar City Hospital, Clinic of Urology, İstanbul, Türkiye

Phone: +90 532 722 34 35 **E-mail:** tarhanf@yahoo.com **ORCID-ID:** orcid.org/0000-0001-8168-0420

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physical durability remains a major disadvantage (7). Disposable devices developed to solve this problem, unfortunately, cannot eliminate the problem (8).

Semirigid ureteroscope (srURS) application is not preferred in the treatment of the renal stones due to its limited maneuverability and difficult access to the calyces. Furthermore, infectious complications and kidney damage directly related to increased intrarenal pressures may occur during srURS procedures (9). However, previous studies have reported that some patients with renal pelvis stones can be treated with srURS (10,11). The advantage of using srURS in these patients is that it allows for larger sized working equipment due to the wider working channel and a better visualization can be achieved with a high irrigation flow rate (10).

In this retrospective study, we performed RIRS with srURS or fURS for the treatment of isolated renal pelvic stones that were resistant or unsuitable for extracorporeal shock wave lithotripsy (ESWL). We evaluated the success and the complication rates of srURS and fURS.

Materials and Methods

A total of 335 patients with isolated renal pelvis stones who had undergone RIRS between January 2015 and December 2018 were assessed for participation in this study. Sixty-seven patients were excluded because they did not meet the inclusion criteria. A total of 267 patients who underwent RIRS with srURS or fURS were included in the study. RIRS was performed using fURS (group 1) in 179 patients and with srURS (group 2) in 88 patients. In 20 patients (22.7%) in group 2, the treatment was started with srURS and was proceeded to fURS since the stone or renal pelvis could not be accessed using srURS. Therefore, the data of these patients were not analyzed further. As a result, a total of 247 patients were included in the study.

Patients' data were analyzed retrospectively from hospital medical databases. Patients over the age of 18 with renal pelvis stones, either refractory or not suitable to ESWL, were included in the study. Patients with non-opaque stones, caliceal stones, solitary kidney, ureteropelvic junction obstruction, ureteral strictures, congenital anomalies, bilateral cases, neurogenic lower urinary dysfunction, and those who received immunosuppressive therapy and pregnant patients were excluded from the study. This study was achieved accordance to Helsinki Declaration (193/2013). The study was approved by our Institutional Review Board (22.07.2020-2020/514/182/8), and written informed consent was obtained from all patients before the treatment.

The diagnosis of urolithiasis was made by imaging methods such as kidney-ureter-bladder radiography (KUB), ultrasonography

and low-dose, non-contrast computed tomography (CT). However, all patients were evaluated preoperatively by CT. The longest dimension of a stone was calculated as the stone size. Preoperative medical history, physical examination, comorbidities, the presence of DJ stents and results of complete blood count, plasma urea and creatinine values, clotting profiles, urinalysis and urine cultures were noted. Data of postoperative body temperature, blood pressure, heart rate and respiratory rate were recorded. The patients were evaluated comparatively in terms of demographic findings (age, gender), CT attenuation values of the stones [Hounsfield Unit (HU)], stone size, and procedures (duration, hospital stay, additional surgical interventions, stone-free rate, and complication rates).

Urine cultures of all patients were sterile before RIRS procedure. Patients with the positive urine cultures were treated with appropriate antibiotics and operated after control urine cultures were sterile. Anticoagulant drugs were discontinued 5-7 days before the procedure. A preoperative Double-J (DJ) stent was not placed to patients routinely, it was applied in the presence of kidney obstruction and infection.

All surgical procedures were performed under general anesthesia in the lithotomy position. Intravenous antibiotic prophylaxis (third generation intravenous cephalosporin) were administered one hour before general anesthesia induction and continued for 3 days postoperatively. The guidewire (0.035 inch, polytetrafluoroethylene coated flexible type guidewire, Boston Scientific, Marlborough, Massachusetts, USA) was placed in the upper urinary tract under fluoroscopic control using a 6/7.5 Fr srURS (Fiber-ureterorenoscope Richard Wolf, Germany).

In those who underwent RIRS with srURS, it was entered into the system with the guidance of the guidewire. The stones were fragmented with a holmium YAG laser (Sphinx Jr, LISA, Germany) using a 272 μm holmium laser fiber (Flexifib, LISA, Germany) with an energy 0.5-0.8 Joule and a frequency of 12-15 Hertz until it was considered small enough to pass spontaneously. A zero tip nitinol basket was used to remove the stone fragments. In patients undergoing RIRS with fURS, at first a 9.5/11 Fr UAS (Flexor Cook Medical, Bloomington, Indiana, USA) and then subsequently a 7.5-Fr fURS (Karl Storz Flex-X2, Tuttlingen, Germany) were placed in the system. An irrigation fluid (saline) bag was placed 80 cm above patient's level and a manual hand pump was used to increase the pressure of the irrigation fluid if necessary. The stones were fragmented using the same method as for srURS. At the end of the RIRS procedure, the ureter was checked and the fURS was removed under vision.

When srURS/fURS could not be introduced to the ureter because of ureteral orifice stenosis, the ureteral orifice was dilated with a balloon (UroMax Ultra, Boston Scientific, Marlborough, MA, USA). In cases where srURS/fURS could not reach the upper

urinary system, a DJ stent was placed into the ureter and procedure was repeated 2 or 3 weeks later.

The procedure was terminated after the stone-free status was confirmed by both ureterorenoscopy and fluoroscopy. At the end of the operation, DJ stent or ureter catheter was inserted in cases of ureteral trauma, residual fragments, bleeding, ureteral wall edema, a large stone burden (>1.5 cm), a longer operative time (>60 min), repeated access, impacted calculi, a recent history of urinary tract infection, and renal functional impairment. The operation time was calculated as the time from the ureteroscopy entry into the ureteral orifice until the completion of the stent placement. The DJ stent was removed approximately 2-3 weeks after surgery in case of complete stone clearance.

Postoperative complications were scored according to the modified Clavien-Dindo classification (MCCS) (12). Complications such as postoperative fever, sepsis, and septic shock were categorized as infective complications. Postoperative fever was defined as an increase in body temperature to >38 °C, which continued for 48 hours. Sepsis was considered in the presence of a source of infection and systemic inflammatory response syndrome (having two or more of the following criteria: temperature <36 °C or >38 °C; heart rate >90/min; respiratory rate >12/min or PaCO₂<32 mmHg; white cell count >12.000 or <4.000/mm³). Severe sepsis was described as sepsis with organ dysfunction. Septic shock was accepted as an acute circulatory failure condition characterized by permanent arterial hypotension. Definitions of temporary and permanent hematuria defined by Mandal et al. (13) were accepted.

A KUB was performed on the first postoperative day to assess the location of the DJ stent and to check for the presence of residual stone. The patients were evaluated with KUB and/or urinary ultrasound in the first postoperative month and with low-dose non-contrast CT in the third postoperative month. The success rate in the third month after surgery was evaluated.

The results were classified as 'stone free (absence of any stone fragments)', "clinically insignificant residual fragments (CIRFs) (the ≤4 mm non-obstructed asymptomatic residual stones) (7)" or "residual stones" (the >4 mm or symptomatic stones). success has been determined as stone-free status or the presence of CIRF.

Statistical Analysis

The patients' data were presented as percentages, mean ± standard error. D'Agostino & Pearson test was performed to determine whether the data followed a Gaussian distribution or not. Fisher exact probability test was used to compare the categorical variables. Student's t-test or Mann-Whitney U test was used to compare the two groups. Point-biserial correlation analysis was used for nominal/quantitative scale data, and Phi correlation analysis was used for nominal/nominal scale data (<https://www.socscistatistics.com/>). A multivariate logistic regression analysis was performed to identify factors potentially affecting the success and complications. Receiver operating characteristic plots were used to define the detection cut-off. Statistical calculations, except point-biserial and Phi correlation, were made using MedCalc® Version 20.010-64-bit software (<https://www.medcalc.org> free trial). P<0.05 was considered statistically significant.

Results

The demographic data of the patients, characteristics of the stones and the procedures are given in Table 1. The mean stone size of the fURS group was statistically lower than that of the srURS group (p=0.019). The operative time of the fURS group was statistically longer than that of the srURS group (p=0.041). There were no differences between the groups in terms of other parameters (p<0.05) (Table 1).

The postoperative complications of the patients are shown in Table 2. There were no major ureteral injury in patients.

Parameters		Group 1 (fURS)	Group 2 (srURS)	p*
Age		49.12±1.10	49.59±1.60	0.745*
Gender	Female	108/179	34/68	0.152**
	Male	71/179	34/68	
Preoperative DJ stent		48/179 (26.80%)	14/68 (20.59%)	0.411**
Stone size		14.5±0.73	15.5±0.62	0.019*
Hounsfield unit		941±31.41	1036±44.47	0.077*
Operative time		79.73±3.38	70,65±8.61	0.041*
Hospitalization time		3.57±0.19	4.59±0.57	0.224*
Balloon dilatation		31/179 (17.3%)	10/68 (14.7%)	0.705**
Postoperative DJ stent/ureter catheter		148/179 (82.7%)	63/68 (96.6%)	0.067**

DJ: Double J, *Mann-Whitney-U, **: chi-square, fURS: Flexible ureterorenoscopy, srURS: Semi-rigid ureterorenoscopy

The overall complication rate in the srURS group (23.5%) was higher than that in the fURS group (12.3%) ($p=0.047$). The most common complications were ureteral stones requiring intervention in 14 patients (5.7%) and transient hematuria in 13 patients (5.3%). Emergency DJ stent or nephrostomy was applied to 12 patients, and endoscopic stone treatment was performed in 2 patients because to the ureteral stones. There were no statistically significant differences between the groups in terms of the rate of additional interventions ($p=0.066$). Infective complications were seen in 6 patients (3.4 %) in group 1 and 5 patients (7.4 %) in group 2 ($p=0.181$). A statistically significant difference was not found between the groups in terms of transient hematuria ($p=0.757$). Persistent hematuria was not observed in any patient. There was no grade 4 or 5 complications according to MCCS. (Table 2).

As seen in Table 3, the mean HU value was lower and the mean operative time was longer in patients with complications ($p<0.05$). No differences were observed in the development of complications in terms of gender ($p=0.668$) and the presence of preoperative DJ stents ($p=0.621$) (Table 3).

While there was a positive correlation between the development of complications and the type of operation ($\phi=0.165$; $p=0.009$), and the operative time ($r_{pb}=0.281$; $p=0.003$), there was a negative correlation between the HU value and the development of complications ($r_{pb}=-0.172$; $p=0.015$). Logistic regression analysis revealed only the operative time as a statistically significant factor associated with complications [odds ratio 1.027, 95% confidence interval (CI) 1.0063-1.0473, $p=0.010$]. The optimal threshold of the operation

time for complications was >85 min (sensitivity 87.50% and specificity 60.64%; 95% CI 50.0-70.6). The HU cut-off level for complications was calculated as ≤ 570 (sensitivity 46.15% and specificity 81.44%, 95% CI 74.7-87.0) (Table 4).

The stone-free, CIRFs, and the residual stone rates were 80.4% ($n=144$), 13.4% ($n=24$), 6.1% ($n=11$) in the fURS group. In the srURS group, the stones of 77.3% of the patients could be achieved and the treatment was successful in 82.4% of the patients. However, when patients whose stones could not be achieved with srURS were added to the srURS failure rate, the stone-free, CIRF, and residual stone rates were found to be 56.8% ($n=50$), 6.8% ($n=6$) and 36.4% ($n=32$) in the srURS group, respectively. In this case, the overall success rate was 93.9% ($n=168$) in the fURS group and 63.6% ($n=56$) in the srURS group. A statistically significant difference was observed between the two groups in terms of success rates ($p<0.0001$).

As shown in Table 5, the mean stone size was larger and the mean operative time was longer in patients with unsuccessful treatment than the patients with successful treatments ($p<0.05$). There was no difference in the success rate in terms of gender ($p=0.335$) and the presence of preoperative DJ stents ($p=0.751$). Negative correlations were found between the success of treatment with the stone size ($r_{pb}=-0.277$; $p=0.00007$) and with the operative time ($r_{pb}=-0.249$; $p=0.016$). Logistic regression analysis did not reveal any statistically significant factors associated with treatment success. The optimal threshold of the operation time was ≤ 80 min (sensitivity 68.33% and specificity 61.90%; 95% CI 55.0-

Table 2. The distribution of complications between groups according to the modified Clavien-Dindo classification

Degree	Complication	Overall (n=247) n (%)	fURS (n=179) n (%)	srURS (n=68) n (%)	p*
1	Temporary hematuria	13 (5.3)	9 (5.0)	4 (5.9)	0.757
1	Fever	1 (0.4)	0 (0)	1 (1.5)	0.181
2	UTI, pyelonephritis, SIRS, sepsis	10 (4.0)	6 (3.4)	4 (5.9)	
3a	DJ stent or nephrostomy	12 (4.9)	7 (3.9)	5 (7.4)	0.066
3b	Endoscopic stone treatment	2 (0.8)	0 (0)	2 (2.9)	
Total		38 (15.4)	22 (12.3)	16 (23.5)	0.047

UTI: Urinary tract infection, SIRS: Systemic inflammatory response syndrome, DJ: Double J. *chi-square

Table 3. Characteristics of patients with and without complications

	Patients with complications (n=36)	Patients without complications (n=211)	p*
Age	49.42±3.11	49.20±0.92	0.948
Hounsfield unit	771.2±81.90	986,8±25,72	0.019
Stone size	15.88±1.48	13.79±0.38	0.159
Operative time	111.3±10.76	76.00±3.10	0.005
Hospitalization time	7.25±1.56	3.45±0.15	0.028

*Mann-Whitney U

79.7) for success. The cut-off level of stone size for success was calculated as ≤ 12 mm (sensitivity 56.52% and specificity 69.41 %, 95% CI 58.5-79.0) (Table 5).

Discussion

There are few studies in the literature regarding the use of semirigid ureteroscopy in the treatment of renal stones. The first reported study was conducted by Nakayama (14) in 1998 using rigid ureterorenoscopy and ultrasonic lithotripter in 10 patients with renal pelvis stone. In this series, 70% success rates and urinary extravasation as a complication were reported. Subsequently, Ebert and Schafhauser (15) in 2008 treated kidney stones with srURS and laser by repositioning the stones into the renal pelvis in 12 patients. The overall success rate was 92%, and no complications were reported. Bryniarski et al. (16) treated 32 patients with renal stones larger than 2 cm with srURS and lasers in 2012. The success rate was determined as 75% and they did not report any serious complications. Mursi et al. (17) reported the results of RIRS with srURS in 15 patients with renal pelvis stones in 2013. The success rate was reported as 53%.

There are only two studies comparing the success of srURS and fURS. Atis et al. (11) reported the results of RIRS with srURS in 47 patients with isolated renal pelvic stones in 2012. Stone could be reached with srURS in 53% of the patients. The success rate was reported as 76% in the srURS group and 86.4% in the fURS group. There was no significant difference between the groups

in terms of stone-free rates, complication rates, and length of hospital stay. In another study, Sürer et al. (10) reported that 88 patients with isolated 1-2 cm diameter renal pelvis stones underwent RIRS by laser using rigid URS in 2015, and 55% of these patients could be treated without fURS. The success rate was reported as 83% in the srURS group and 87% in the fURS group. No major complications have been reported in this study (10).

It was reported that the predictors of reaching the stone during RIRS with srURS were the female gender (10,11), the patients' height (10), and the lower degree of hydronephrosis (10). However, the success rates in gender groups both in this study and in the Atis et al. (11) study were similar. Additionally, Atis et al. (11) reported that the degree of hydronephrosis did not affect stone-free rates in both groups.

The rate of access to renal pelvis stones (77%) in this study was higher than those of other studies (10,11). This might be due to the use of srURS with a small diameter. The success rate of RIRS with srURS in this study was lower than those of other studies previously conducted (10,11,14-16). A disadvantage of srURS is that it has a limited maneuvering capacity. When stone fragments migrated to the calyx, srURS could not access the stone. Thus, RIRS with srURS could lead to a lower stone-free rate than fURS. In the literature, comparable to our results, the operation time of the fURS group was reported to be longer than that of the srURS group (11). It was reported that there was a negative correlation between the success and

Table 4. Results of correlation analysis for success and complication of treatment

Factors	Complication		Success	
	r_{pb}/ϕ	p	r_{pb}/ϕ	p
Age	0.005*	0.943	0.087*	0.222
Gender	-0.033**	0.399	0.066**	0.350
Preoperative DJ stent	0.031**	0.629	0.009**	0.893
Method of RIRS	0.165**	0.009	-0.092**	0.807
Hounsfield unit	-0.172*	0.015	0.114*	0.147
Stone size	0.106*	0.099	-0.277*	0.00007
Operative time	0.281*	0.003	-0.249*	0.016

*Point-biserial correlation (rpb), **Phi correlation (ϕ), DJ: Double J, RIRS: Retrograde intrarenal surgery

Table 5. Characteristics of patients with successful and non-successful treatment

	Patients with successful treatment (n=224)	Patients with unsuccessful treatment (n=23)	p*
Age	50.17 \pm 1.30	47.79 \pm 1.44	0.222
Hounsfield unit	989.9 \pm 36.35	912.3 \pm 38.41	0.153
Stone size	12.45 \pm 0.47	15.69 \pm 0.68	0.0001
Operative time	72.73 \pm 4.36	89.62 \pm 5.34	<0.0001
Hospitalization time	3.72 \pm 0.23	3.88 \pm 0.40	0.326

*Mann-Whitney U

the stone size in RIRS (18). In our study, it was found that there was a moderate negative correlation between the success of treatment and the stone size and the operative time. In our study, unlike other studies, complications were given according to MCCS.

Complication rates in the srURS group were higher than those in the fURS group ($p < 0.047$). Our complication rates (15.4%) were consistent with the complication rates of RIRS in the literature (13,19,20). According to our findings, low HU value (≤ 570), long operation time (> 85 min), and performing RIRS with srURS are associated with complications. Some studies found that the development of complications related to RIRS was affected by the stone size and the duration of the operation (19,21). In addition, the development of infective complications was associated with a long operative time (60 min) and high stone burden (22,23). Another disadvantage of srURS is the possibility of developing complications secondary to intrarenal reflux, which might develop due to increased intrarenal pressure during the procedure (9,24).

An interesting finding of our study was that a weak negative correlation was found between the HU value of the stone and the development of complications. The reason for developing more common complications in patients with low HU values might be that these were infection stones. Furthermore, this situation could be confirmed by performing a stone analysis.

Study Limitations

Despite these strengths, our study had some limitations. First, the study was retrospective nature. The second limitation was that there was no intrarenal pressure measurement was during RIRS. Lastly, the cost analysis has not been done.

Conclusion

In our study, srURS may be sufficient for the fragmentation of stones when stone can be achieved with srURS in 82% of patients. However, the overall success rate of srURS was lower and the complication rate was higher than that of fURS. Therefore, we conclude that srURS is unsafe and unsuccessful for use in the treatment of pelvic stones. Prospective studies involving intrarenal pressure measurement and cost analysis must reach a conclusion in this respect.

Ethics

Ethics Committee Approval: The study was approved by our Institutional Review Board (22.07.2020–2020/514/182/8).

Informed Consent: Written informed consent was obtained from all patients before the treatment.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: F.T., B.E., K.S., Concept: F.T., B.E., K.S., Design: F.T., B.E., K.S., Data Collection or Processing: F.T., E.D., B.H.S., Analysis or Interpretation: F.T., B.E., E.D., B.H.S., K.S., Literature Search: F.T., E.D., B.H.S., Writing: F.T., B.E., E.D., B.H.S., K.S.

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