Comparison of Two Different Retrograde Intrarenal Surgical Techniques: Is It Mandatory to Use Fluoroscopy During Retrograde Intrarenal Surgery?

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Purpose: To evaluate the efficacy and reliability of fluoroscopy-free retrograde intrarenal surgery.

Materials and Methods: A retrospective evaluation was made of the data of 226 patients who underwent RIRS as kidney stone treatment between May 2015 and May 2017. When evaluation was made acccording to the exclusion criteria, the study continued with a total of 190 patients including 103 in whom fluoroscopy was used (Group 1) and 87 who underwent a fluoroscopy-free procedure (Group 2).

Result: Group 1 patients comprised of 56 males and 47 females with a mean age of 41.5 ± 13.9 years. Group 2 patients comprised of 48 males and 39 females with a mean age of 42.6 ± 15.2 years. The mean stone size was 14.3 ± 2.7 mm in Group 1 and 14.1 ± 2.8 mm in Group 2. The mean operating time was calculated as 63.6 ± 8.2 minutes in Group 1 and 65.7 ± 9.7 minutes in Group 2. In Group 1, the success rate was determined as 83.5% on postoperative day 1 and as 92.2% in the postoperative first month. In Group 2, these rates were 81.6% and 90.8% respectively. No statistically significant difference was determined between the groups in respect of stone size (P= .752), operating time (*P* = .108) and postoperative first day (*P* = .732) and first month success rates (*P* = .724).

Conclusion: Fluoroscopy-free RIRS is a surgical technique with a high rate of success that can be applied safely to be able to protect patients at high risk of radiation and the surgical team, particularly in centers with high patient circulation.

Keywords: flexible ureteroscopy; fluoroscopy-free RIRS; kidney stone; nephrolithiasis; radiation exposure

INTRODUCTION

The primary aim of kidney stone treatment is to obtain the maximum stone-free rate with minimum morbidity. There have been significant changes in the treatment of kidney stones in the last 30 years. While treatment in the past was only applied with open surgery, treatment options have now become less invasive with percutaneous nephrolithotomy (PCNL), shock wave lithotripsy (SWL) and retrograde intrarenal surgery (RIRS). In the last decade in particular, the use of RIRS has become more popular for reasons including that it is less invasive, patients can be discharged early, there are low complication rates and success rates are high.[1-2]

However, the exposure to low-dose radiation with the frequent use of fluoroscopy imaging at different stages of RIRS could create potentially harmful effects for the patient and the surgical team in the future. The most significant concern related to ionized radiation is the risk of cancer, which may develop as a result of cellular damage and the expression of affected nuclear material.[3,4] The Ionizing radiation (IR) exposure of stone forming patients are depending on three factors. First one is the diagnostic procedures. According to current EAU guidelines, non-contract CT scan is the preferable imaging method for the patients with renal colic. Secondly, IR exposure of the treatment; all surgical treatment modalities uses IR. Third, during follow-up IR exposure is needed. Within these factors only modifiable factor is the treatment factor. Radiation free treatment modalities such as US-guided SWL and PCNL are more preferred to reduce IR doses both in patients and doctors. Several urology centres have reported reduced or fluoroscopy-free and flexible ureteroscopic studies to decrease fluoroscopic exposure because of these potential risks.[5,6] The urologists have concerns on flexible ureterorenoscopy(URS) without fluoroscopy guidance. Thus, we aimed to compare the feasibility, reliability and outcome of conventional RIRS and fluoroscopy free RIRS.

MATERIAL AND METHODS

Study population

A retrospective evaluation was made of the data of 226 patients who underwent RIRS as kidney stone treatment between May 2015 and May 2017. Decision of RIRS and the guidance method, with or without fluoroscopy were made by the patient as a result of a patient-doctor consultation. The procedure was performed to patients whom had signed the inform consent. Preoperative evaluation of the patients was made based on non-contrast computed tomography (NCCT) and kidney-ure-

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Table 1. Demographics and clinical data

Characteristics[a]	Group 1(N=103)	Group 2(N=87)	*P* value
Age(years)	41.5 ± 13.9	42.6 ± 15.2	0.604
Sex			
Male	47	39	0.912
Female	56	48	
BMI (kg/m^2)	23.7 ± 2.6	23.6 ± 2.4	0.954
Stone diameter(mm)	14.3 ± 2.7	14.1 ± 2.8	0.752
Stone location			
Renal pelvis	59	42	0.622
Middle calyx	22	22	
Upper calyx	9	11	
Lower calyx	13	12	
Operation side(%)			
Right	49(47.57)	41(47.12)	0.951
Left	54 (52.42)	46(52.87)	

Abbreviation: BMI, Body Mass Index
[a]Data are presented as mean ± SD or number (percent)

ter-bladder (KUB). All patients were operated by surgeons with at least ten years of endourological surgery experience. One surgeon performed RIRS under fluoroscopy guidance (H.E) and the other performed RIRS without fluoroscopy (E.A). The patients who were conventionally operated with RIRS under fluoroscopy guidance formed group 1 and the patients who were operated with RIRS without fluoroscopy fromed group 2. All patients were operated with a flexible ureterenoscopy with 7.5 Fr tip and 8.5 Fr shaft diameter (Karl Storz, Flex x 2, Tutlingen, Germany).
For both groups, the exclusion criteria were defined as a paediatric age group, coagulation disorder, previous renal or ureter surgery, urinary system obstruction (ureteropelvic or ureterovesical junction obstruction etc.), elevated creatinine level (>2mg/dL), anatomic disorder of the urinary system (double-collecting system, horseshoe kidney etc), those with multiple stones, those with non-opaque stones. When evaluation was made according to the exclusion criteria, the study continued with a total of 190 patients including 103 in whom fluoroscopy was used (Group 1) and 87 who underwent a fluoroscopy-free procedure (Group 2). The patients were evaluated preoperatively with routine anesthesia tests. Stone dimensions were measured preoperatively on NCCT and the greatest diameter was calculated with digital measurement.

Outcome assessment

RIRS was accepted as successful in patients determined as completely stone-free during follow-up, or with clinically insignificant residue (< 3mm). The treatment was accepted as unsucessful in patients who required additional treatment (SWL or URS) because of clinically significant residue (≥ 3mm) or the development of complications due to RIRS. When there was a neeed to use fluoroscopy in Group 2 patients, the treatment was accepted as unsuccessful. The residual fragments were evaluated with KUB on posoperative day 1 and one month later with KUB and/or NCCT.

Fluroscopy- free surgical technique

All the operations were operated under general anesthesia in the lithotomy position. Before RIRS, the ureter was evaluated with semi-rigid URS. During diagnostic URS a working guide-wire (0.038-inch superstiff guide-wire, Cook Urological, Bloomington, IN, USA) was placed in the renal pelvis by advancement with a 7.0 Fr ureteroscope (Karl Storz, Tutlingen, Germany) as far as the ureteropelvic junction (UPJ). During diagnostic URS, the length between the external ureteral meatus and the ureter superior (UML) end was calculated by subtracting the length of the ureteroscope remaining outside the external meatus from the length of the ureteroscope. Then, a 9.5/11.5 Fr ureteral access sheath (UAS) (Cook Flexor, Cook Urological, Bloomington, IN, USA) was placed by advancement according to the defined length. When placing the UAS, it was advanced by sliding over the guide-wire only, without applying any tactile force. By advancing a flexible URS (Karl Storz, Flex x 2, Tutlingen, Germany) within the UAS, the UPJ was passed and the renal pelvis was entered.
Following examination by direct observation of all the calyces of the kidney, stone fragmentation was fragmented with a Ho-YAG laser (Sphinx, Lisa, Germany). By using high frequency and low energy (30 Hz, 0.5 J) for stone fragmentation, dusting was applied. At the end of fragmentation, a guide-wire (0.038 in floppy tip guide-wire, Cook Urological) was advanced to the renal pelvis within the flexible URS and the UAS was removed together with the ureteroscope for evaluation of ureter damage. At the end of the operation, a double J (DJ) stent was applied. These stents were removed after one-month with flexible cystoscope under local anesthesia. The operating time was calculated as the period between the start of URS and the placement of a DJ stent.
For both procedures, in cases where the ureteroscope could not be advanced to the UPJ during diagnostic URS (eg, ureteral stricture, ureteral resistance), the operation was terminated by applying a DJ stent for passive ureteral dilation and the procedure was reperformed after two weeks.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) 20 software (SPSS Inc.Chicago, IL). The Shapiro Wilk test was used to assess the conformity of the data to normal distribution and all normally distributed data were presented as mean ± standard deviation (SD). The Student's t-test was used for parametric variables, and the Mann Whitney U-test was used for nonparametric variables. For multivariate analyses, the linear regression analysis test

Table 2. Perioperative and postoperative findings

Characteristics[a]	Group 1(N:103)	Group 2(N:87)	*P* value
PUD	22	21	0.648
Operation time (min)	63.6 ± 8.2	65.7 ± 9.7	0.108
POSR on first day (%)	83.5	81.6	0.732
POSR on first month (%)	92.2	90.8	0.724

Abbreviations: PUD, Passive ureteral dilatation; POSR, Postoperative success rate
[a]Data are presented as mean ± SD or number (percent)

was used. A value of $p < 0.05$ was considered statistically significant.

RESULTS

Group 1 patients consisted of 56 males and 47 females with a mean age of 41.5 ± 13.9 years. Group 2 patients consisted of 48 males and 39 females with a mean age of 42.6 ± 15.2 years. The mean stone size was 14.3 ± 2.7 mm in Group 1 and 14.1 ± 2.8 mm in Group 2. In terms of age and stone size, there was no significant differences between two groups. The statistical evaluation of the demographic data and stone parameters is shown in **Table 1**.

The UML was calculated as 37.8 ± 2.5 cm in males and 29.1 ± 2.5 cm in females in Group 2. A DJ stent was placed for passive ureteral dilation because of ureteral resistance during UAS placement in 22 patients in Group 1 and in 21 patients in Group 2. The mean operating time was calculated as 63.6 ± 8.2 minute in Group 1 and 65.7 ± 9.7 minute in Group 2. In Group 1, the success rate was determined as 83.5% on postoperative Day 1 and it is increased to 92.2% in the postoperative first month. In Group 2, these rates were 81.6% and 90.8% respectively. The mean time of fluoroscopy usage in Group 1 was 16.82 ± 6.65 second. For 1 (1.1%) patient of Group 2, pyelography had to be applied using fluoroscopy intraoperatively due to stone location in the upper pole of the kidney that could not be visualized. As bifid pelvis was determined in this patient, the operation was continued using fluoroscopy. No statistically significant difference was determined between the groups in respect of operating time, and postoperative first day and first month success rates. The intraoperative and perioperative parameters and the statistical evaluations of these variables are presented in **Table 2**.

Multivariate linear regression analysis was performed to evaluate the factors which affected success of the operation. As a result of this analysis, stone location in the lower pole of the kidney (P = 0.000) was found to be significant predictive factor for success on postoperative Day 1, and mean stone size (P = .001) was a significant predictive factor for success in the first month.

In group 1:

Minimal mucosa injury (Clavien 1) developed in 6 (5.8%) patients in Group 1. These patients were treated with DJ stent insertion which was routinely performed and no further treatment were applied. SWL was applied to 5 patients (4.9%) who were accepted as unsuccessful, a second RIRS procedure was applied to 2 and in 1 asymptomatic patient with 5.5 mm residual lower pole stone and monitored. Postoperative fever (> 38˚C) developed in 5 patients (4.9%), mild hematuria in 10 patients (9.7%) and flank pain in 19 patients (18.4%) who responded to non-steroidal anti-inflammatory treatment.

In group 2:

Minimal mucosa injury (Clavien 1) developed in 5 patients (5.7%) in Group 2. These patients were treated with DJ stent insertion which was routinely performed and no further treatment were applied. SWL was applied to 3 patients who were accepted as unsuccessful, a second RIRS procedure was applied to 3 and ureteroscopic stone treatment was applied to 1 patient because of 'steinstrasse' in the ureter. Postoperative fever (> 38˚C) developed in 3 patients (3.4%), mild hematuria in 7 patients (8.04%) and flank pain in 12 patients (13.8%) who responded to non-steroidal anti-inflammatory treatment. The complications for both groups according to the modified Clavien's classification are shown in **Table 3**.

DISCUSSION

Fluoroscopic imaging has been used routinely for many years to increase surgical success, collector system anatomy and safety in urological operations. However, in centers with high patient circulation, complications which could develop in the long-term related to the use of fluoroscopy are a source of concern for the whole operating team. The most serious complication which could develop related to fluoroscopy use is cancer, as a result of cellular damage and affected nuclear material[3,4]. In studies conducted on this subject, it has been reported that there could be serious side-effects of fluoroscopy usage[7,8].

The International Commission on Radiation Protection has reported that exposure to radiation should not exceed 20 mSv per year over 5 years and should not exceed 50mSv in any single year to avoid the harm-

Table 3. Postoperative complications

Characteristics[a]	Group1(N:103)	Group 2(N:87)	Clavien' score	P Value
Fever	5	3	1	0.495
Flank pain	19	12	1	0.387
Hematuria	10	7	1	0.689
Mucozal injury	6	5	1	0.982

[a]Data are presented as mean ± SD or number

ful effects of radiation [8]. To protect the surgical team in urological operations from the effects of low-dose radiation, equipments are used such as a scopy apron, gloves, neck guard, testes protector and glasses etc. Despite all the biosafety equipment available to medical teams, the cumulative deleterious effects of radioactivity cannot be ignored. Fluoroscopes emit doses of approximately 5 rads per minute and minifluoroscopes can cause serious and irreversible damage to health [9,10]. In a recent study it was reported that even in optimal conditions, the protective equipment of gloves and glasses could reduce the radiation exposure at the rate of 69.4% and 65.6% respectively [11]. In this context, it is evident that all the operating team, especially in centres with high patient circulation are vulnerable to develop complications which are associated with low-dose radiation.

As a result of concerns related to fluoroscopy usage in urological stone treatment, firstly, reduced fluoroscopy came into use and recently, there have been publications related to completely fluoroscopy-free operations. In a study by Greene et al., the duration of fluorosopy was reduced by 82% during ureteroscopy and it was concluded that similar success rates were achieved with the use of reduced fluoroscopy compared to conventional ureteroscopy and that it was a reliable procedure [12]. Later, Olgin et al. reported that fluoroscopy-free ureteroscopy applied to the upper urinary system was effective and could be applied. Thus, the conclusion was reached that exposure to radiation had been completely removed for the patient and operating team and this technique could be applied to pregnant patients, children and patients with recurrent stones[6].

In RIRS, the use of reduced fluoroscopy or completely fluorosopy-free has come to prominence for reasons such as the developments in laser and optic technology, reduced calibration of the instruments and increased endoscopic experience of urologists. Kiraç et al. used single-dose fluoroscopy at the UAS placement stage in RIRS and reported a success rate of 88.5% in UAS placement and 82.9% stone-free rate (SFR). Additional fluoroscopic imaging was necessary in only 5.2% [13]. Peng et al. then described a fluoroscopy-free RIRS technique. In that study, the mean stone size was 14±4 mm and 85% SFR was reported on postoperative Day 1 and 95.7% SFR in the first month. The mean operating time was 74.5 minute and fluoroscopy was used in only 1 patient because of a double collecting system. It was concluded that fluoroscopy-free RIRS is possible and can be employed by experienced surgeons[14]. In the current study, the success rates were determined as 83.5% on postoperative Day 1 and 92.2% in the first month in Group 1 and as 81.6% and 90.8% respectively in Group 2. It was necessary to use fluoroscopy intraoperatively in only 1 patient of Group 2 (1.1%).

In conventional RIRS, fluoroscopic imaging is used at different stages of the operation. It is used especially at the stage of UAS placement and at the stages of defining the localization of the stone within the kidney and for flexible ureteroscope. Under fluoroscopy guidance, the UAS is advanced and access to the kidney is provided. Fluoroscopic imaging at this stage contributes nothing to the safety of the procedure but only shows the localization of the UAS [15]. In the technique used in the current study, first diagnostic URS was applied and after calibration of the ureter and determination of the UML, then the UAS was placed.

The patient group of the current study included patients with a single stone in the kidney, pelvis or any calyx. As the patients only had a single stone, no difficulties were experienced related to the localization of the ureteroscope and the stone within the kidney. However, when there are multiple stones in the kidney, it could be considered more difficult, the fluoroscopy-free RIRS technique could still be applied. This would be the subject of a different study. The rates of success in Group 2 in the current study are similar in general to the results of conventional RIRS in literature [16-18]. This is due to the basis of the current study being the visual evaluation of the urinary system at every stage of the operation. It is thought that this visual evaluation could provide the high success rate.

Complications occurring in RIRS are most often related to injuries in the ureter. Although the vast majority of injuries are related to the use of UAS, it is known that the injury is not directly related to the diameter of the UAS used[19]. While Kiraç et al. reported ureter injury at 1.3%[13]. Peng et al. reported general complications as 2.9% Clavien 1 and 0.7% Clavien 2[14]. Oguz et al. determined a total intraoperative complication rate of 30%, the majority of which were low level. The most frequent intraoperative complication was mild haematuria at 9.5%, followed by superficial mucosal injury at 4.3% and severe mucosal injury at 1.3%[3]. In the current study, all the ureter injuries (5.8% in Group 1, 5.7% in Group 2) were at a treatable level and no additional surgical intervention was necessary in any patient where injury developed (Clavien 1).

Limitations of the current study include the following: the retrospective design, the fact that patients were operated by two surgeons and no inclusion of long-term complications. However, as one of the first studies related to fluoroscopy-free RIRS, this study can be considered to contribute to literature in respect of allaying the concerns of all the operating team, particularly in centers with high patient circulation,

CONCLUSIONS

Fluoroscopy-free RIRS is a surgical technique with a high rate of success that can be applied safely to be able to protect patients at high risk of radiation and the surgical team, particularly in centers with high patient circulation.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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