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Comparison of Retrograde Intrarenal Surgery with and Without Fluoroscopy for Renal Stone Treatment

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

Fluoroscopy is used when placing an access sheath in kidney stone surgery. In our study, we contributed to the literature by comparatively showing that operations can be performed effectively and safely without using fluoroscopy.

Abstract

Objective: To compare fluoroscopy-free retrograde intrarenal surgery (RIRS) with routine RIRS with fluoroscopy for urolithiasis treatment in terms of efficacy and safety. Prospective quasi-experimental study. Hitit University Çorum Erol Olçok Training and Research Hospital, Department of Urology, Çorum, Turkiye August 2019-2020.

Materials and Methods: Pre-operative and postoperative data for 98 patients who underwent RIRS using fluoroscopy and 100 patients who underwent RIRS without fluoroscopy were prospectively assessed. Patients who did not provide preoperative consent, were pregnant, or had a clotting disorder, active urinary system infection, or anatomic abnormalities such as ectopic kidney were excluded from the study. In the technique without fluoroscopy, the fluoroscopic device was ready for use in surgery; however, all manipulations were performed by all-seeing access without fluoroscopy. Patients beginning without fluoroscopy who required fluoroscopy were not included in the study.

Results: The mean stone size was 18.5±2.31 (5-30) mm (in the fluoroscopy group 17.2±25.3 mm, in the non-fluoroscopy group 19.8±20.9). Stone-free rates were similar between the groups (91% in the fluoroscopy group and 90% in the non-fluoroscopy group) (p=0.683). The mean duration of fluoroscopy use in the fluoroscopy group was 8.76±9.50 s. A Clavien 3b complication (perirenal hematoma) was observed in one patient (in the fluoroscopy group), which regressed with observation. Minor complications were observed in both groups: fever in 7 patients (3.6%), hematuria in 7 patients (3.6%), and steinstrasse in 1 patient (0.5%).

Conclusion: Fluoroscopy-free RIRS may be applied effectively and safely by endourologists for patients with urolithiasis, similar to the routine method with fluoroscopy.

Keywords: Renal calculi, endourology, fluorroscopy-free retrograde intrarenal surgery

Introduction

While urinary system stone disease is observed at rates of approximately 12%, the recurrence rate is 50% within 5-10 years (1). With today's technological developments, retrograde intrarenal surgery (RIRS) may be used effectively and reliably for the treatment of stones of various sizes in urinary tract stone disease (2). When compared with open and laparoscopic surgery and percutaneous nephrolithotomy, this technique is less invasive, has high success rates, and has become popular (3).

This commonly used surgical technique involves some potential risks such as complication risks linked to the use of the ureteral access sheath (UAS), and cancer and genetic mutations linked to fluoroscopy use (4). In recent studies, it has been aimed to

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use fluoroscopy at a minimal level to protect the healthcare staff and the patient in RIRS, but as the number of operations is rapidly increasing, the cumulative doses of radiation are becoming an increasingly important issue.

With the aim of reducing radiation received during operations, we previously developed a fluoroscopy-free RIRS technique called "all-seeing access" and presented it for use (5). In this study, we compared fluoroscopy-free (all-seeing access) and fluoroscopy RIRS in terms of success, complications, and fluoroscopy duration.

We showed that RIRS without fluoroscopy can be performed safely, effectively, and with low complication rates.

Materials and Methods

The study included 198 patients scheduled to undergo RIRS for kidney and proximal ureter stones from August 2019 to August 2020 at the Clinic of Urology Hitit University Faculty of Medicine Çorum Erol Olçok Training and Research Hospital, who read the voluntary consent form and agreed to participate. The study was conducted prospectively after ethics committee permission was obtained (Hitit University Faculty of Medicine Clinical Research Ethics Committee decision no: 47, date: 18.09.2019).

Patients who did not provide consent before the operation, who were pregnant, or who had a clotting disorder, active urinary tract infection, or anatomic anomalies such as ectopic kidney were excluded from the study.

The patients were divided into two groups (groups were determined by simple randomization): group 1 (non-fluoroscopy group, n=100) underwent surgery without fluoroscopy and group 2 (fluoroscopy group, n=98) were operated on using fluoroscopy. For all patients, demographic features, stone side and location, stone dimensions, preoperative imaging method, operation and fluoroscopy durations, preoperative Double J (DJ) stent and intraoperative UAS insertion, stone-free rates, pre- and postoperative creatine variations, hematocrit levels, number of sessions, and complication data were recorded.

Preoperatively, the patients were assessed by full blood count, serum creatinine, bleeding parameters, full urine test, and urine culture. Patients positive for urine culture were given antibiotic treatment for sufficient duration and had the procedure performed after a clean urine culture was obtained. All patients were assessed preoperatively using spiral non-contrast tomography. All patients had kidney, ureter, and bladder X-rays taken preoperatively and postoperatively. The stone size was recorded by calculating the largest diameter of the stone in millimeters.

In the first month postoperatively, kidney ureter-bladder (KUB) X-ray was performed for opaque stones; otherwise, urinary ultrasonography or non-contrast tomography was performed to assess residual stone status. If appropriate, DJ stents were removed from the patients, while a second session of RIRS was performed in patients with residual stones (larger than 4 mm).

Technique

In the operating room, a C-arm fluoroscopy device was always ready when the procedure began. All patients undergoing RIRS were administered general anesthesia by intubation or laryngeal mask. The operation was performed in the supine lithotomy position. All patients were initially entered with a 9.5 FR semirigid ureteroscope (Storz, Tuttlingen, Germany), and the lower end of the ureter was observed. The ureter was entered with the aid of a guide wire (0.035-inch hydrophilic material coated flexible tip guide wire, Cook Medical, Limerick, Ireland). The ureter was assessed in terms of width and narrowness up to the final point that the ureteroscope could access (preferably the renal pelvis). The patient group without fluoroscopy first had a flexible renoscope (Storz Flex-X2, Tuttlingen, Germany) passed through an access sheath (9.5 Fr), and thus the access sheath was on the flexible renoscope. Then, with all-seeing access, the flexible renoscope was sent into the ureter through the guide wire and to the kidney. The access sheath was inserted into the ureter above the flexible renoscope (Figure 1). The stones were fragmented using a laser (Sphinx 30 Litho, Holmium-YAG laser, pulse energy 0.5-4.0 J, frequency single 4-20 Hz pulse peak power 15 kW). At the end of laser lithotripsy, the stones were left to pass spontaneously, and a DJ stent was inserted. The flexible renoscope and access sheath were removed together under all-seeing access to assess possible ureter injury. Three weeks later, the DJ stents were removed under mask anesthesia.

For the patient group in which fluoroscopy was used, they were entered with the renoscope, and a guide wire was inserted into the ureter. After diagnostic renoscopy was performed by entering the ureter, the access sheath was advanced along the ureter under fluoroscopy above the guide wire using the classic method. After the routine stone-fracture procedure, a DJ stent was inserted under fluoroscopy, and the procedure was completed.

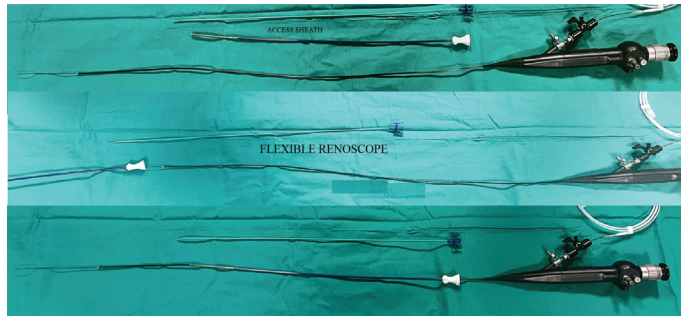

Figure 1. All-seeing access sheath insertion method

All patients underwent KUB X-rays on postoperative day 1, with hemogram and biochemistry examinations. Fever, pain, and hematuria were assessed. In the first postoperative month, a KUB X-ray was taken during the clinical check-up. If the stones were non-opaque, urinary ultrasound or tomography was performed, and residual stone presence was assessed. Complication and success rates were compared according to the use of the methods with and without fluoroscopy.

Statistical Analysis

Statistical analyzes were conducted using SPSS (Version 22.0, SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to determine the normality of distribution. Descriptive statistics for continuous data normally distributed are given as mean ± standard deviation, whereas continuous data not normally distributed are given as median (min-max), and categorical data are presented as number and percentage (%). Comparison of numerical variables between two independent groups used the independent groups t-test (Student's t-test) for data normally distributed and the Mann-Whitney U test for data not normally distributed. Relationships between categorical variables were examined using the chi-square test or Fisher's exact test linked to the number of data in the cells of cross tables. Statistical significance was assessed at $p<0.05$.

Results

In our research, among the 198 patients, the fluoroscopy group (n=98) comprised 33 women and 65 men, whereas the non-fluoroscopy group (n=100) comprised 36 women and 64 men. The mean age of the patients in the study was 48.22±14.42 (18-84) years. None of the patients received additional treatment. One patient had an ankylosing spondylitis diagnosis and 3 patients had a solitary kidney.

There were similar distributions for male and female rates in the research groups (p=0.731) (Table 1). The relationships between American Society of Anesthesiologists, previous stone surgery, stone localization, side, preoperative DJ stent placement, access use, and session numbers were not significant between the groups (p=0.058, p=0.375, p=0.671, p=0.306, p=0.958, p=0.277, p=0.078, respectively).

Patient age significantly differed between the groups (p=0.025) (Table 2). Stone sizes also significantly differed between the groups (p=0.002), as did operation duration (p=0.019). the number of stones was not significantly different between the groups (p=0.358).

The mean duration of fluoroscopy use in the fluoroscopy group was 8.76±9.50 (in non-fluoroscopy group was 0 s).

Table 1. Comparison of demographic data

		With fluoroscopy (n=98)	Without fluoroscopy (n=100)	p-value
		n (%)	n (%)	
Sex	Male	65 (50.4%)	64 (49.6%)	0.731[a]
	Female	33 (47.8%)	36 (52.2%)	
ASA	1	20 (69%)	9 (31%)	0.058[a]
	2	58 (47.9%)	63 (52.1%)	
	3	20 (41.7%)	28 (58.3%)	
Previous stone surgery	Yes	60 (52.2%)	55 (47.8%)	0.375[a]
	No	38 (45.8%)	45 (54.2%)	
Stone localization	Prox ureter	59 (51.8%)	55 (48.2%)	0.671[b]
	Pelvis-upper pole	33 (45.2%)	40 (54.8%)	
	Lower pole	4 (66.7%)	2 (33.3%)	
	Pelvis-lower pole	2 (40%)	3 (60%)	
Side	Left	46 (49.5%)	47 (50.5%)	0.306[b]
	Right	51 (51.5%)	48 (48.5%)	
	Bilateral	1 (16.7%)	5 (83.3%)	
Preoperative DJ	Inserted	12 (50%)	12 (50%)	0.958[a]
	Not inserted	86 (49.4%)	88 (50.6%)	
Session number	1	96 (51.3%)	91 (48.7%)	0.078[b]
	2	2 (20%)	8 (80%)	
	3	0 (0%)	1 (100%)	

[a]: Chi-square test, [b]: Fisher's exact test, DJ: Double J, ASA: American Society of Anesthesiologists

Table 2. Comparison age, stone sizes, the number of stones, the operation duration			
	With fluoroscopy (n=98)	**Without fluoroscopy (n=100)**	**p-value**
Age	45.90±13.97	50.49±14.55	**0.025**[a]
Stone sizes	1.72±2.53	1.98±2.09	**0.002**[b]
The number of stones	1.35±0.73	1.29±0.65	0.358[b]
The operation duration	42.62±14.75	46.29±15.75	**0.019**[b]
[a]: Chi-square test, [b]: Fisher's exact test			

Table 3. Stone-free comparison			
	With fluoroscopy (n=98)	**Without fluoroscopy (n=100)**	**p-value**
	n (%)	**n (%)**	
Stone Free	90 (91%)	90 (90%)	0.653
Residual stone	8 (9%)	10 (10%)	
Fisher's exact test			

A comparison of stone-free rates between the research groups is presented in Table 3. The relationship between being stone-free and the groups was not statistically significant (p=0.683).

A comparison of complication rates between the research groups is shown in Table 4. The relationship between hematoma (p=1.000), hematuria (p=0.27), fever (p=0.71), and steinstrasse (p=1.000) with the groups was not statistically significant.

Variations in hematocrit and creatine measurements before and after RIRS were not significantly different between the research groups (p=0.377, p=0.975, respectively).

Stone situation was evaluated with KUB in 150 patients, USG in 10 patients, and CT in 30 patients.

Discussion

Fluoroscopy is an important tool required in the operating room to safely perform endoscopic interventions. This tool is frequently used to insert a guide during renoscopy, insert and direct a UAS, and determine the location of renal stones in RIRS and other endoscopic operations (6). Despite these advantages during endoscopic surgery, ionizing radiation affects both the patient and operation room staff (surgeon, nurse, and anesthesiologist). With longer duration and higher dose, working in close proximity with continuous fluoroscopy may cause genetic changes and even cancer due to the cumulative radiation effect (7).

In the USA, cumulative radiation was shown to increase cancer risk by 0.4-0.9% (7,8). Another study by Hellawell et al. (9) showed very low radiation of 11.6 Gy for urologists during interventions; however, considering that an actively working surgeon may perform 500 operations per year, this rate reaches 5.6 Gy. They stated that this calculated radiation dose is more than half that of non-contrast tomography. Therefore, the issue of less frequent use of fluoroscopy has been raised with the aim of protecting both the patient and the surgical team from these harmful effects of radiation.

There are many publications with this aim in the literature. A 76-patient study by Kirac et al. (10) applied a reduced fluoroscopy method. With a direct view of the ureterorenoscope above the guide wire, the patients entered the renal pelvis and then inserted a UAS above the guide wire by tactile sensation. In 4 patients (5.4%), UAS placement could not be confirmed; therefore, single-shot fluoroscopy was used, and the mean fluoroscopy duration was 5.27±1.8 s. They reported complications in 5 patients (6.5%), with urinary tract infection in 2 patients, ureter injury in 1 patient, hematuria in 1 patient, and fever in 1 patient (10).

In another study by Hsi and Harper (11), in which 162 patients were operated on for 94 kidney stones, 26 proximal ureter stones, and 49 distal stones, tactile sensation and endoscopy

Table 4. Comparison of complications				
	Complications			
Operation method	**Hematoma number (n)**	**Hematuria number (n)**	**Fever number (n)**	**Steinstrasse number (n)**
With fluoroscopy n=98 (49%)	0	5 (2.5%)	4 (2%)	0
Without fluoroscopy n=100 (51%)	1 (1%)	2 (1%)	3 (1.5%)	1 (0.5%)
Total (n=198)	1 (0.5%)	7 (3.5%)	7 (3.5%)	1 (0.5%)
p-value	>0.99	0.27	0.72	>0.99
Fisher's exact test				

were used in an attempt to use less fluoroscopy. In 117 cases (75%) fluoroscopy was not used, while in 54% of cases with fluoroscopy used to confirm the stent placement, less than 2 s of fluoroscopy was used, while in 17 cases (11%) more than 5 s of fluoroscopy was used. In that study, 85% of fluoroscopy needs were reduced using tactile sensation and endoscopy, and they stated that this method could be used effectively and reliably (11).

Thus, attempts were made to perform surgery without fluoroscopy in several studies. However, UAS insertion with blind tactile sensation caused complications. With the "all-seeing access" method we developed, the UAS is not inserted with tactile sensation but with direct observation. Due to this method, in one group fluoroscopy was not used, whereas in the other group fluoroscopy was used for 8.76±9.50 s.

When the RIRS success rate was examined, stone-free rates were reported to be 73.6-94.1% in the literature (12). A 132-patient RIRC study by Fabrizio et al. (13) in India found that the success rate was 83% for upper calyx stones, 90% for middle calyx stones, 65% for lower calyx stones, and 87% for pelvic stones. A prospective study by Redondo et al. (14) evaluated 50 patients undergoing RIRS within 1 year and stated that the full stone-free rate after RIRS was 89.7%. Hyams et al. (15) reported that the stone-free rate was 95% with flexible ureteroscopy for proximal ureter stones smaller than 2 cm.

To determine the success and efficacy of RIRS, it was observed that the number of studies with lower success rates was particularly high for lower pole stones Fuchs and Fuchs (16) reported 60-80% stone-free rates for the treatment of lower pole stones with RIRS.

As shown by the studies, the full stone-free rates for adult patients after RIRS vary from 50% to 90%. This broad interval may be due to the radiological imaging method used to declare stone-free rates after operations and the lack of a standard definition for stone dimensions. In our study, when the stone-free rates in our patients were compared between the two methods, the difference was not significant. The group in which fluoroscopy was not used had a rate of 90%, whereas the rate for the group in which fluoroscopy was used was 91% (p=0.683). The reason for these success rates, which are similar and even better than those in the literature, may be that patients with lower pole stones, which have lower success rates, comprised only 6% of all patients.

A 635-patient RIRS study by Goldberg et al. (17) found that the operation duration was 53±19.4 min for stones smaller than 15 mm, whereas the duration for stones larger than 15 mm was significantly longer at 73.6±29.9 min. The size of the stone is stated to be a factor that lengthens the operation duration. In our study, the operation duration for the fluoroscopy group with stone size 17.2 (±25.3) mm was 42.62 min, whereasfor the non-fluoroscopy group with stone size 19.8 (±20.9) mm, the operation duration was 46.29 min. In our study, as the stone size increased, the operation duration was longer by a statistically significant degree (p=0.019).

A total of 11,885 prospective RIRS studies published by CROES were identified to have a general complication rate of 3.5%. According to the modified Clavien classification, 2.8% of these complications were degree 1 and 2 complications. In that study, mortality was reported in 5 cases due to sepsis, pulmonary embolism, multiple organ dysfunction, and cardiac reasons (18).

Xu et al. (19) published a 375-patient retrospective study assessing complications using the Clavien rating system for the effects of various factors. They stated that positive preoperative urine culture and lengthened operation duration were factors affecting complications. The mean case duration was 40 min, with fever observed in 13%, intraoperative hematuria in 7.7%, and significantly elevated creatinine in 6 patients.

In our study, preoperative routine urine cultures were obtained to verify a sterile urine and the patients were operated on. The mean operation duration was 40 min in both groups. Postoperatively, fever was observed in 7 patients (3.5%). They were treated with simple antipyretics. There was no significant difference between the groups (p=0.7195). Clavien grade 1 hematuria was observed in 23 patients (11%) and there was no significant difference between the groups for this complication (p=0.2766). Hematuria was observed in 5 patients in the group in which fluoroscopy was used (2.5%) and in 2 patients in the group in which it was not used (1%). Although there was no significant difference between the two groups (p=0.2766), we believe that inserting a UAS under all-seeing access is safer. Based on our clinical experience, stenosis of the ureter and kinking can be observed by eye when inserting the UAS using all-seeing access, and thus, the use of unnecessary force is avoided. In conclusion, the complication rates were lower. None of our patients had no significant changes in preoperative or postoperative creatinine or hematocrit levels (p=0.975).

The important complication, steinstrasse (Clavien 3b), was observed in 9 patients (0.6%) in a study including 1571 patients. The only variable affecting this complication was stone size (20). Again, another study of patients with 2-4-cm stone sizes observed that stone size being 4 cm or above and fragments larger than 1-2 mm were risk factors for the formation of steinstrasse. In our study, consistent with the literature, steinstrasse was observed in 1 patient (0.6%) with stones larger than 3 cm. The patient was treated by extraction of the stones endoscopically.

A subcapsular hematoma was observed in 1 patient (0.5%). An examination of the literature revealed that there was a probability of incidence in patients over 70 years of age, using anticoagulants, and with chronic renal disease, and this probability was less than 1%. It has been stated that the formation of abscesses, growth of hematoma, and disrupted hemodynamics should be corrected with open surgery (21). Contrary to the literature, despite our patient being young, having no comorbidity, and not using anticoagulants, subcapsular hematoma developed (22). The patient described flank pain on the first postoperative day, and non-contrast tomography imaging showed a hematoma. The patient was monitored with bed rest and empirical antibiotic treatment. The hematoma was reabsorbed without additional intervention. The reasons for this complication are considered to be that the stone was in the lower pole, parenchymal thinning occurred in the region linked to the stone, the stone was larger than 2 cm, and the operation lasted longer than 1 hour. In the literature, parenchymal rupture was emphasized to generally occur when working with high intrapelvic pressure (23). For this reason, a UAS should be used if possible, during RIRS, and high pressure should be avoided.

Because of this technique, it is thought that there is protection from the harmful effects of fluoroscopy and prevention of complications occurring due to blind UAS use during RIRS. When we prospectively investigated our patients undergoing RIRS with and without fluoroscopy, we did not find any statistically significant differences in terms of efficacy or complications between the methods. Thus, we showed that operations can be performed effectively and safely without using fluoroscopy. In addition, we protected the surgical team and the patient from the damaging effects of ionizing radiation.

Study Limitations

A limitation of this study is the small number of patients. Further prospective, randomized controlled studies are needed for RIRS without fluoroscopy to become more popular. Finally, multicenter studies will increase the evidence level.

Conclusion

In our study, groups operated on with and without fluoroscopy were prospectively investigated. Similar success and complication rates to those reported in the literature were obtained for our patients.

In RIRS without fluoroscopy, the f-URS acts as a guide to visually insert the UAS with all-seeing access, and it was concluded that it may be safely and effectively performed to protect the entire surgical team and the patient from the damaging effects of fluoroscopy.

RIRS without fluoroscopy was shown to be a method that may be chosen in clinics with high experience in the topic. With randomized, multicenter studies including more patients that will be performed on this topic, non-fluoroscopy RIRS may become a method that is routinely applied.

Ethics

Ethics Committee Approval: The study was conducted prospectively after ethics committee permission was obtained (Hitit University Faculty of Medicine Clinical Research Ethics Committee decision no: 47, date: 18.09.2019).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Concept: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Design: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Data Collection or Processing: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Analysis or Interpretation: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Literature Search: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B., Writing: M.S.Ç., M.E., C.A., M.M.B., M.Y., A.B.

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