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The Efficacy and Safety of Radiation-Free Retrograde Intrarenal Surgery: A Prospective Multicenter-Based, Randomized, Controlled Trial

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Study Need and Importance: Fluoroscopy is usually required during retrograde intrarenal surgery (RIRS). Although fluoroscopy is considered necessary for effective and safe RIRS, there is growing awareness regarding radiation exposure risk to patients and surgeons. However, there are no prospective, multicenter-based, randomized, controlled trials comparing the success rates or safety between radiation-usage (RU) and radiation-free (RF) RIRS.

What We Found: Of the 140 consecutive randomized participants, 128 patients completed this study (RF: 63; RU: 65). The success rate (78% vs 80%, $P = .8$) were not significantly different between the RF and RU groups. The rate of high-grade (grade 2-4) ureter injury was not significantly higher in the RF group compared to the RU group (4.8% vs 3.1%; Table). In RF RIRS, the success rate was noninferior compared to RU RIRS (the difference was 2.2% [95% CI, 0.16-0.12]).

Limitations: Limitations of the study include a relatively small cohort, the absence of long-term complication data, and variations in the types of rigid ureteroscopes, ureteral access sheaths, and flexible ureterorenoscopes. Most participants had a single uncomplicated stone, making RF RIRS manageable for experienced urologists.

Interpretation for Patient Care: The success rate of RF RIRS was not inferior, and the rate of high-grade ureteral injury was not significantly different compared to RU RIRS. This study demonstrated that RF RIRS can be effectively and safely performed in uncomplicated cases of renal stones.

Table. *Postoperative Outcomes Between Radiation-Free and Radiation-Usage Groups*

	Radiation-free group (n = 63)	Radiation-usage group (n = 65)	*P* value
Success, No. (%)	49 (78)	52 (80)	.8
Ureter injury, No. (%), grade			.7
0	53 (84)	54 (83)	
1	7 (11)	9 (14)	
2	2 (3.2)	2 (3.1)	
3	1 (1.6)	0 (0)	
High-grade ureter injury, No. (%)	3 (4.8)	2 (3.1)	.6

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The Efficacy and Safety of Radiation-Free Retrograde Intrarenal Surgery: A Prospective Multicenter-Based, Randomized, Controlled Trial

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Purpose: Fluoroscopy is usually required during retrograde intrarenal surgery (RIRS). Although fluoroscopy is considered necessary for effective and safe RIRS, there is growing awareness regarding radiation exposure risk to patients and surgeons. We conducted a multicenter-based, randomized, controlled trial to compare the safety and effectiveness of radiation-free (RF) RIRS with radiation-usage (RU) RIRS for kidney stone management.

Materials and Methods: From August 2020 to April 2022, patients with a unilateral kidney stone ($\leq$20 mm) eligible for RIRS were prospectively enrolled in 5 tertiary medical centers after randomization and divided into the RF and RU groups. RIRS was performed using a flexible ureteroscope with a holmium:YAG laser. The primary end point of this study was the success rate, defined as complete stone-free or residual fragments with asymptomatic kidney stones $\leq$ 3 mm. The secondary end point of this study was ascertaining the safety of RF RIRS. The success rates were analyzed using a noninferiority test.

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Ethics Statement: This study was approved by the Institutional Review Board of Kyungpook National University Hospital, Daegu, Republic of Korea (IRB No. KNUH 2020-05-0051-002). All patients were provided with written informed consent after a thorough explanation of the procedures.
Author Contributions:
Conception and design: Chung, B. S. Kim.
Data analysis and interpretation: Chung, Kang, B. S. Kim.
Data acquisition: Kang, Jung, Oh, H. W. Kim, Shin.
Drafting the manuscript: Chung, B. S. Kim.
Critical revision of the manuscript for scientific and factual content: Chung, B. S. Kim.
Statistical analysis: Chung, Kang.
Supervision: Chung, B. S. Kim.
Drs Chung and B. S. Kim had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Data Availability: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Editor's Note: This article is the first of 5 published in this issue for which Category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 821 and 822.

Results: Of the 140 consecutive randomized participants, 128 patients completed this study (RF: 63; RU: 65). The success rates (78% vs 80%, $P = .8$) were not significantly different between the groups. The rate of high-grade (grade 2-4) ureter injury was not significantly higher in the RF group compared to the RU group (RF = 3 [4.8%] vs RU = 2 [3.1%], $P = .6$). In RF RIRS, the success rate was noninferior compared to RU RIRS (the difference was 2.2% [95% CI, 0.16-0.12]).

Conclusions: This study demonstrated that the surgical outcomes of RF RIRS were noninferior to RU RIRS.

Key Words: kidney stone, radiation-free, randomized controlled trial

SIGNIFICANT innovative changes in the treatment of kidney stones have occurred in the last 30 years, including extracorporeal shock wave lithotripsy, percutaneous nephrolithotomy, and retrograde intrarenal surgery (RIRS).[1] Despite these changes, the essential goals of kidney stone management remain the same: maximize stone-free rate (SFR) and minimize surgery-related morbidity. Recently, RIRS has especially become popular in stone management for several reasons, including minimal invasiveness, patients' early discharge, lower complication rates, and favorable success rates.[2] In general, RIRS has been performed under fluoroscopy guidance. The radiation exposure during RIRS with the frequent use of fluoroscopy can cause potentially harmful effects to patients and surgeons. Ionizing radiation is mainly concerned with cancer risk that develops due to cellular damage and the expression of affected nuclear material.[3]

Therefore, decreasing unnecessary radiation exposure as well as ensuring the success rate of RIRS should be key points for protecting patients and surgeons. Radiation-free (RF) RIRS has been described in adult and pediatric urology.[1,4-7] However, there are no prospective, multicenter-based, randomized, controlled trials (RCTs) comparing the success rates or safety between radiation-usage (RU) and RF RIRS. We hypothesized that RF RIRS is noninferior to RU RIRS and compared the safety and efficacy of RF RIRS with RU RIRS using a multicenter-based RCT.

MATERIALS AND METHODS

Ethical Approval

From the relevant Institutional Review Boards of each participating center, approval for the study was obtained. The present trial was approved by the Institutional Review Board of Kyungpook National University Hospital, Daegu, Republic of Korea (IRB No. KNUH 2020-05-0051-002). The study was carried out in accordance with the guidelines of the Declaration of Helsinki. All patients were provided with written informed consent after a thorough explanation of the procedures.

Study Design, Setting, and Study Population

The study was registered on the Clinical Research Information Service (protocol ID: KCT0005400), and we conducted the present study following the CONSORT (Consolidated Standards of Reporting Trials) guidelines.[8] In this prospective, multicenter RCT, all patients aged $\geq$ 20 years who were scheduled to undergo elective RIRS were enrolled. The inclusion criteria were as follows: (1) patients with unilateral $\leq$ 2 cm renal stones diagnosed by CT before RIRS and (2) patients who agreed to participate. The exclusion criteria were as follows: (1) previous urinary stone–related surgery, (2) history of pelvic surgery or radiation, (3) pregnancy, (4) with ureteral stone, (5) with suspected urothelial carcinoma on preoperative CT scan, and (6) did not agree to an informed consent.

From August 2020 to April 2022, 5 centers prospectively screened 161 patients and finally enrolled a total of 140 patients. Figure 1 shows the flow diagram depicting the allocation of patients who were enrolled in this trial. Surgeons at each of the 5 centers had more than 300 RIRS experiences. All patients underwent CT scans for evaluation of kidney stones within 1 week before RIRS. Stone size was measured by the greatest diameter on any view of the CT scan. In cases of multiple kidney stones, the summation of the greatest diameter of each stone was determined as the maximum stone size. For stone volume measurement, we used the 2D volume measurement[9]: (length) $\times$ (height) $\times$ (width) $\times$ 0.52. Definition of ureteral injuries were as follows[10]: grade 0: no lesion found or only mucosal petechiae; grade 1: ureteral mucosal erosion without smooth muscle injury; grade 2: ureteral wall injury, including mucosa and smooth muscle, with adventitial preservation (periureteral fat not seen); grade 3: ureteral wall injury, including mucosa and smooth muscle, with adventitial perforation (periureteral fat seen); and grade 4: total ureteral avulsion. Portable C-arm fluoroscopy was used in low-level control mode (8 pulses/s; 98 kV and 3.8 mA) during RIRS in the RU group. A calculation of the radiation exposure time (RET) was programmed in the portable C-arm. A special radiologic technician recorded the RET.

Randomization

For the primary end point, the trial was designed with the aim of demonstrating noninferiority with the success rate in RF vs RU after RIRS. Based on previous reported data,[11] we estimated an 83% SFR in the RU group. Then, using a noninferiority margin of 20% for comparing difference of proportions, and allowing for a 10% attrition rate, we aimed to accrue 100 patients or 50 in each arm of the study ($\alpha = .05$, $1\text{-}\beta = 0.8$). We increased this to 140 for attrition to the primary outcome. The sample size was calculated using Software PASS2008 (NCSS, LLC Kaysville, Utah). The noninferiority margin was set at 20% on the basis of a study done by Dasgupta et al.[12]

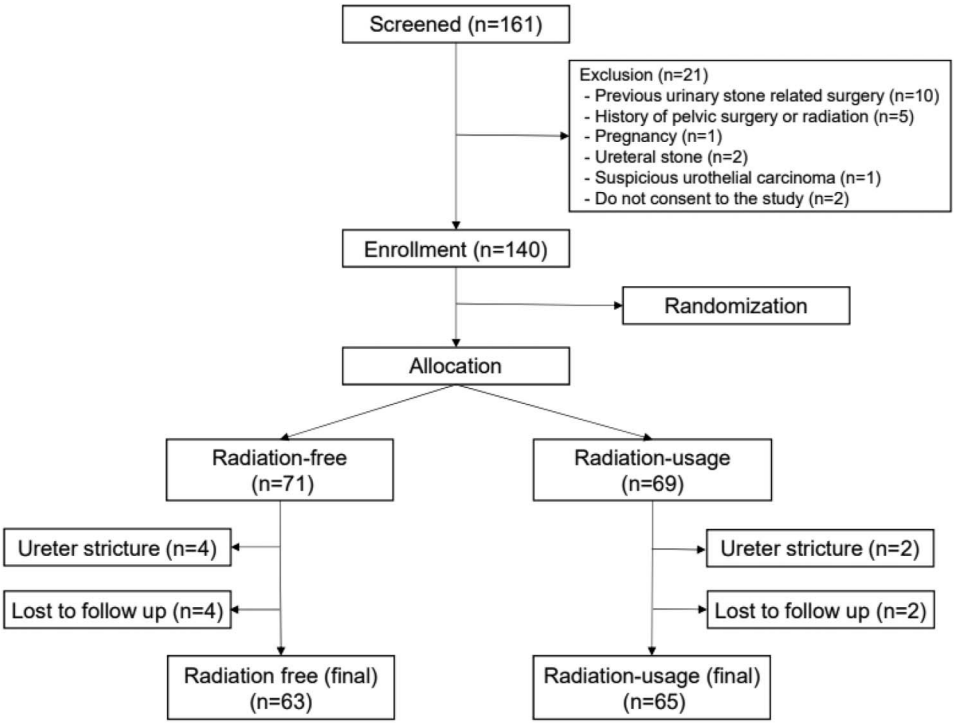

Figure 1. A flow diagram depicting the allocation of patients in this study.

All 140 patients were assigned to each group using a randomization table for even allocation among the 5 clinical trial institutions. The random assignment table was stored in a sealed state by the research director at the central medical institution and distributed in block units upon request from the testing institution. The randomization table was generated using the randomization code through the PROC PLAN function of the statistical software SAS, version 9.4 (SAS Institute Inc, Cary, North Carolina). According to the Cochrane Collaboration's tool for assessing the risk of bias, the risk of bias in the present study was modulated by random sequence generation, allocation concealment, blinding of patients, each center, and outcome data.[13]

Procedure

In this study, prestenting before RIRS was not performed (Supplementary Material, https://www.jurology.com). In the RU group, RIRS followed the standard protocol, with the initial guidewire, ureteral access sheath (UAS), and double-J stent placement guided by fluoroscopy. The flexible ureterorenoscope location and presence of remnant stones (in radiopaque cases) were confirmed with fluoroscopy. For the RF group, RIRS was performed with first-look ureteroscopy using a semirigid ureteroscope under general anesthesia in all cases.[14] A hydrophilic guidewire was advanced to the ureter through the semirigid ureteroscope in the lithotomy position, following which the semirigid ureteroscope was advanced to the upper ureter or renal pelvis and the ureteral length was measured. After a hydrophilic guidewire was left in the renal pelvis as a safety wire, a superstiff guidewire (Amplatz Super Stiff, Boston Scientific, Malborough, Massachusetts) was placed and a UAS was inserted along the superstiff guidewire under direct vision of a semirigid ureteroscope introduced beside the UAS into the bladder to observe whether the UAS was properly inserted through the ureteral orifice without twisting in the bladder. An 11F/13F UAS was mainly used, and a 10F/12F UAS was used when the ureter seemed narrow through first-look semirigid ureteroscopy or an 11F/13F UAS was not passed. The flexible ureterorenoscope was introduced through the UAS, and lithotripsy of the kidney stone was initiated using a holmium:YAG laser. The settings of the laser ranged from 0.3 to 1.5 J and 10 to 30 Hz depending on the stone density or the surgeon's preference. There were no differences in settings of laser energy between both groups. All procedures were done by fragmentation technique. After lithotripsy, stone fragments were extracted a using stone basket and the UAS was retrieved, and the ureteral injury was diagnosed and graded by surgeons using semirigid ureteroscopy. Then, a PTFE (polytetrafluoroethylene; Boston Scientific, Malborough, Massachusetts) guidewire was placed once again, and a double-J stent was inserted along the PTFE guidewire after removing the safety guidewire under the direct vision of a semirigid ureteroscope side to the stent. The location of the distal tip of the stent was adjusted under the direct vision of semirigid ureteroscopy. In the RF group, all previously mentioned procedures were conducted without fluoroscopy. The double-J stent was removed 1 to 3 weeks after the operation, routinely.

Assessment of Outcomes

The primary end point of this study was the success rate as determined by a CT scan at postoperative month 1. The definitions of success depended on the radiological findings and complete stone-free or residual fragments with asymptomatic kidney stones $\leq$ 3 mm.[15,16]

Table 1. *Patients' Baseline Characteristics in Radiation-Free and Radiation-Usage Groups*

	Radiation-free group (n = 63)		Radiation-usage group (n = 65)	
Age, median (IQR), y	60	(53, 68)	60	(53, 67)
Gender, No.				
Male	35		38	
Female	28		27	
BMI, median (IQR), kg/m^2	25.7	(23.3, 27.5)	25.0	(23.3, 27.7)
Hypertension, No. (%)	32	(51)	28	(43)
Diabetes mellitus, No. (%)	18	(29)	14	(22)
Preoperative ESWL, No. (%)	7	(11)	1	(1.5)
Radio-opacity, No. (%)				
Radiolucent	12	(19)	8	(12)
Radiopaque	51	(81)	57	(88)
Stone laterality, No. (%)				
Left	31	(49)	35	(54)
Right	32	(51)	30	(46)
Stone location, No. (%)				
Renal pelvis	40	(64)	33	(52)
Upper calyx	6	(9.5)	7	(11)
Middle calyx	0	(0)	2	(3.1)
Lower calyx	17	(27)	19	(29)
Multiple	0	(0)	4	(6.2)
Maximal diameter, median (IQR), mm	12.0	(9.4, 16.0)	13.0	(9.0, 15.5)
Stone volume, median (IQR), cc	0.66	(0.50, 0.97)	0.67	(0.31, 0.93)
Hounsfield units mean, median (IQR)	840.0	(606.0, 1162.5)	923.4	(577.2, 1229.0)
Hounsfield units SD, median (IQR)	142.0	(78.8, 419.4)	117.2	(73.5, 258.4)
Prostate size (men only), median (IQR), cc	25	(23.5, 32)	25	(24, 30)
BPH, No. (%)[a]	21	(29)	9	(26)

Abbreviations: BPH, benign prostatic hyperplasia; ESWL, extracorporeal shock wave lithotripsy.
[a] Prostate size > 30 cc, men only.

The secondary end point of this study was to compare the incidence rate of postoperative high-grade (grade 2-4) ureter injury between RF and RU RIRS. The presence of ureter injury and the grade of injury were evaluated using semirigid ureteroscopy following lithotripsy.

Statistical Analysis

Continuous variables are presented as median and IQR (25th, 75th percentile). Categorical variables are presented as counts (percentages). Given our continuous postoperative outcomes were all nonnormally distributed, Mann-Whitney tests were performed to compare group differences (operation time, hospital stay, RET, and radiation exposure dose). The categorical type tested the ratio difference through a χ^2 test. Although significant in the χ^2 test, if more than 20% of cells had an expected frequency of less than 5, the Fisher exact test was performed. A noninferiority test was used to evaluate whether RF RIRS had noninferiority to RU RIRS. Statistical analyses were performed using IBM SPSS Statistics 27 (IBM Corp, Armonk, New York). The level of statistical significance was set at $P < .05$.

RESULTS

Of the 140 consecutive randomized participants, there were cases of ureteral stricture where the semirigid ureteroscope was unable to engage under direct vision in the RF group (n = 4) and RU group (n = 2). In those cases, we performed retrograde pyelogram using fluoroscopy to see the length of ureteral stricture, and those patients dropped out. Six patients dropped out because they did not undergo postoperative CT scans to determine remnant stones. Finally, 128 patients completed this study (RF 63; RU 65; Figure 1). The baseline characteristics of the participants in each group are presented in Table 1. Table 2 shows the postoperative outcomes. No patients showed ureteral stent malposition in the RF group. Only 1 patient needed adjuvant treatment in the RU group. There were no significant differences in the proportion of stone composition between the 2 groups. The overall perioperative complication rate was 5.5% (7/128). The median operative time was 47 (IQR 34, 70) minutes and the overall success rate was 79% (101/128).

The success rate was not statistically different between the 2 groups (78% vs 80%, $P = .8$); in the RF group, the success rate was noninferior compared to the RU group (the difference was 2.2% [95% CI, 0.16-0.12], with the lower bound of the 95% CI inside the threshold for noninferiority; Figure 2).

Overall ureter injury cases were 16% in RF and 17% in RU. Proportion of ureter injury grades[10] between the 2 groups were not significantly different. No ureter injury was observed in 107 patients (84%) and the rate of high-grade (grade 2-4) ureter injury was not significantly higher in the RF group compared to the RU group (4.8% vs 3.1%, $P = .6$; Table 2).

DISCUSSION

This study, a pioneering prospective, multicenter, noninferiority RCT, compared the efficacy and safety of RF RIRS with RU RIRS. Our findings show that RF RIRS is noninferior to RU RIRS in success rate.

Table 2. *Postoperative Outcomes Between Radiation-Free and Radiation-Usage Groups*

	Total (n = 128)		Radiation-free group (n = 63)		Radiation-usage group (n = 65)		*P* value
Success, No. (%)	101	(79)	49	(78)	52	(80)	.8[a]
Ureter injury, No. (%), grade							.7[b]
0	107	(84)	53	(84)	54	(83)	
1	16	(13)	7	(11)	9	(14)	
2	4	(3.1)	2	(3.2)	2	(3.1)	
3	1	(0.8)	1	(1.6)	0	(0)	
High-grade ureter injury, No. (%)[c]	5	(3.9)	3	(4.8)	2	(3.1)	.6[a]
Other perioperative complications, No. (%)	7	(5.5)	4	(6.3)	3	(4.6)	.7[a]
Operation time, median (IQR), min	47	(34, 70)	45	(30, 70)	50	(34.5, 72.5)	.3[d]
Hospital stay, median (IQR), d	3	(3, 4)	3	(3, 4)	3	(3, 3)	.16[d]
Radiation exposure time, median (IQR), s	2	(0, 10)	0		10	(8, 15)	< .001[d]
Radiation exposure dose, median (IQR), mGy	0.09	(0, 0.71)	0		0.71	(0.66, 0.98)	< .001[d]
Need for additional treatment, No. (%)	1	(0.78)	0	(0)	1	(1.5)	1[a]
Stone analysis, No. (%)							.8[b]
N/A	5	(3.9)	2	(3.2)	3	(4.6)	
Calcium oxalate	110	(86)	54	(86)	56	(86)	
Uric acid	9	(7.0)	4	(6.3)	5	(7.7)	
Struvite	3	(2.3)	2	(3.2)	1	(1.5)	
Carbon apatite	1	(0.8)	1	(1.6)	0	(0)	

Abbreviations: N/A, not applicable.
[a] Fisher exact test
[b] Pearson χ^2 test.
[c] Ureter injury grade 2 to 4.
[d] Mann-Whitney test.

This suggests that consistent whole calyx examination using a scope before surgical completion in the RF RIRS group contributed to these outcomes.

A long-standing basic principle of RIRS is to perform the RIRS under fluoroscopic guidance.[17] However, as RIRS treatment for urinary stones has become more popular and has been used widely in recent decades, the hazard of radiation exposure has emerged as a clinical issue both on the part of patients and urologists.[18-21] In addition, patients with urinary stones may require repeat CT scans and stone-related treatments, such as extracorporeal shock wave lithotripsy, RIRS, and percutaneous nephrolithotomy.[22,23] Therefore, efforts to reduce patients' radiation exposure are necessary.

With significant technological advances in endoscopic equipment,[24] RIRS has been performed without fluoroscopic guidance in uncomplicated kidney stones. In 2015, Olgin et al first introduced complete fluoroscopy-free ureteroscopic stone surgery in 50 patients.[25] However, this retrospective study has a high possibility of selection bias as randomization was not performed while grouping the patients.

Peng et al evaluated 140 patients who underwent RF RIRS for renal stones.[4] The SFR was 95.7% at 1 month postoperatively without major intraoperative complications. Alma et al retrospectively analyzed RF RIRS.[1] At postoperative month 1, the SFRs were 92.2% and 90.8% (P = .724) in the RU and RF groups, respectively. However, these 2 retrospective studies also have a possibility of selection bias.

Güner and Günaydin compared RF (n = 67) and RU RIRS (n = 58) groups involving patients with < 20 mm of kidney stones prospectively, which was the first randomized prospective trial.[7] No statistically significant differences were found between the

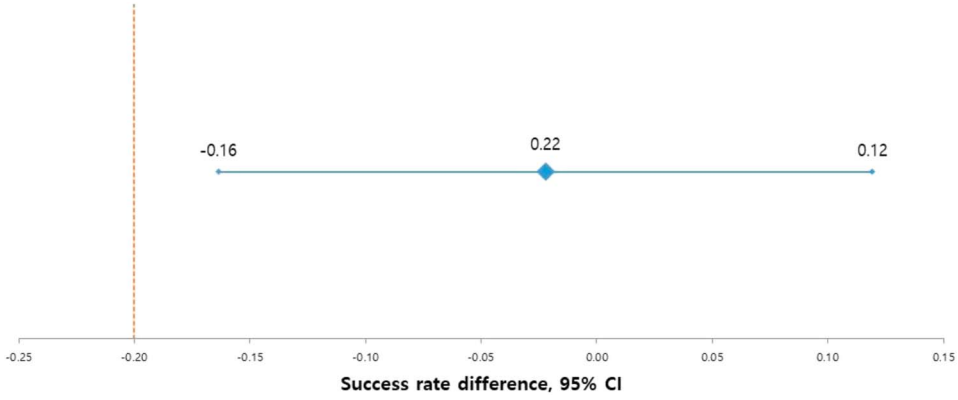

Figure 2. Success rate differences with 95% CIs. The noninferiority margin was set at 0.2 (20%).

2 groups in terms of hospital stay, operative time, SFR, complication rate, analgesic usage, need for additional treatment, and visual analog scale score. However, not specifying the exact randomization method, a relatively small cohort, and a single-center design were all limitations of this study.

Despite the prevailing preference for RU RIRS among urologists due to concerns about guidewire and UAS placement, confirming flexible ureterorenoscope positioning, and postsurgery stent placement, our experience shows that proper guidewire positioning can be achieved with a first-look, semirigid ureteroscope. Active dilation of the ureteral orifice and ureter is also possible incidentally. Furthermore, using a superstiff guidewire and an appropriately sized UAS, fluoroscopy-free UAS placement is feasible. Introducing a semirigid ureteroscope into the bladder alongside the UAS during placement ensures safe and easy positioning without fluoroscopy. While fluoroscopy may aid beginners in cases of complex calyceal anatomy or extensive stone dust, experienced surgeons can achieve efficient lithotripsy and satisfactory outcomes without fluoroscopy guidance. Similarly, double-J stent placement, with ureter length estimation using a semirigid ureteroscope and accurate guidewire placement, can be performed safely and accurately without fluoroscopy. Direct visualization through a semirigid ureteroscope during double-J stent placement ensures smooth advancement and proper distal tip positioning, avoiding malpositioning.

Although this RF RIRS technique can be safely performed by experienced surgeons, it is necessary to use a semirigid ureteroscope. There can be a concern for additional use of instruments and consequently more medical costs. However, because fluoroscopy and cystoscopy can be omitted with this RF RIRS technique, more instrumental or economical burdens may not be introduced with this RF RIRS technique. Another advantage of RF RIRS is no need for wearing radiation protectors for surgeons and assistants, and a disadvantage is impossibility of simultaneous ureteral balloon dilation in case of ureteral stricture.

Limitations of the current study include a relatively small cohort, the absence of long-term complication data, and variations in the types of semirigid ureteroscopes, UASs, and flexible ureterorenoscopes. Most participants had a single uncomplicated stone, making RF RIRS manageable for experienced urologists. However, dealing with multiple complicated stones or less experienced urologists may pose challenges with the RF RIRS technique, warranting exploration in future studies. Nonetheless, considering the growing necessity of conducting a multicenter, prospective RCT to evaluate RF RIRS,[6] our study showed valuable results.

CONCLUSIONS

We demonstrated that RF RIRS was noninferior to RU RIRS in terms of efficacy in patients with $\leq$ 20 mm kidney stones. Without the guidance of fluoroscopy, endourologists with sufficient experience can perform RIRS safely and efficiently with similar success and complication rates to RU RIRS if they follow our several suggested steps. However, considering the RF RIRS is not always available, we should keep in mind not only the RF technique, but also seeking RU as low as reasonably achievable during RIRS when fluoroscopy is necessary. Further studies, including a larger cohort with longer follow-up periods for RF RIRS, will help clarify these essential findings.

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EDITORIAL COMMENT

We read with great interest the paper by Chung et al that investigated the outcomes of radiation-free retrograde intrarenal surgery (RIRS) for the management of renal stones.[1] Ten years ago, when we first advocated for this technique, it was met with significant resistance and criticism from many in the field. This study, with its prospective randomized multicenter design, greatly advances our understanding of radiation-free RIRS by demonstrating no differences in success rates, operative times, ureteral injuries, or complications when compared to standard RIRS.

Although we strongly applaud the efforts of the authors to achieve the Holy Grail of no radiation exposure, we suspect that several surgeons reading this manuscript may be concerned that they will also be compelled to perform radiation-free RIRS. As the authors point out, the patients were carefully selected and the surgeons performing radiation-free RIRS were highly experienced and utilized techniques that may seem challenging to others. Although zero fluoroscopy is achievable, we would be the first to acknowledge that zero fluoroscopy should never be placed above the importance of a safe surgery with a good patient outcome.

Despite employing radiation-free techniques for over a decade, we still keep the C-arm in the room available for use should any question regarding the procedure arise. Several strategies for minimizing radiation during ureteroscopy have been published and can be implemented by most urologists in most patients. These include distance, shielding, employing visual and tactile feedback, and use of low-dose and single pulse fluoroscopy settings.[2,3]

To conclude, we congratulate the authors on this important trial which demonstrates the safety and efficacy of fluoroless RIRS. We completely agree with the authors' conclusion that when radiation-free techniques are not feasible, urologists can still minimize the radiation risks by adhering to the ALARA principle (as low as reasonably achievable).

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