

Is Fluoroscopic Imaging Mandatory for Endoscopic Treatment of Ureteral Stones?

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OBJECTIVE	To present the feasibility and safety of fluoro-less endoscopic treatment of ureteral stones to diminish radiation exposure of the patient and operating team, and to determine circumstances where a fluoroscopic imaging is mandatory.
METHODS	Between 2010 and 2011, 93 patients with ureteral calculi who underwent ureteroscopic treatment by experienced urologists were retrospectively evaluated. Manipulations, such as guidewire, ureteral stent insertion, and balloon dilatation were performed with visual and tactile cues. Patient demographics, need for fluoroscopic imaging, operation and fluoroscopy time, and complication and success rates were investigated.
RESULTS	The mean age of patients was 34.03 ± 12.09 years (range, 9-63 years). The mean stone size was 10.64 ± 3.16 mm (range, 6-17 mm). The stones were localized in the proximal, middle, and distal segments in 11, 30, and 52 patients, respectively. The mean duration of the operation was 34.51 ± 7.94 minutes (range, 24-55 minutes). Stone-free status was achieved for 90 patients (96.77%). Fluoroscopic imaging was required for 7 patients with a mean fluoroscopy time of 9 ± 4.72 seconds (range, 4-16 seconds) for the following reasons: stone migration to the kidney (3 patients), double collecting system with 2 ureters (1 patient), and ureteral orifice stricture extending to the upper segment (1 patient). No major complications were observed, but minor complications were observed in 11 patients (11.8%).
CONCLUSION	The ureteroscopic treatment of ureteral stones can be safely and effectively performed in experienced hands, with limited or no usage of fluoroscopy except in special circumstances, such as anatomic abnormalities, upper ureteral strictures, and impacted ureteral stones leading to ureteral tortuosity, kinking, and obstruction. UROLOGY 80: 1002–1006, 2012. © 2012 Elsevier Inc.

In recent years, treatment of urinary stone disease has dramatically improved because of technological developments. With the miniaturization of endoscopic instruments and advances in intracorporeal lithotripters, ureterorenoscopy (URS) has had a tremendous positive impact on treatment of ureteral stones.¹

Patients with urinary stone disease who undergo radiographic interventions and fluoroscopy guided endoscopic treatment modalities, such as percutaneous nephrolithotomy (PNL) and URS are potentially at a higher risk for the deleterious effects of radiation exposure (RE). In addition to the commonly known cumulative or deterministic effects of the radiation, the stochastic effects of ionizing radiation (which are not dose-dependent and do not have a threshold) may lead to genetic mutations and

cancer. With the increased concern for RE, the Alara principle — keep the exposure as low as reasonably achievable — is adopted by radiologists and urologists.²

Besides the classic protective measures, 2 studies published protocols to reduce RE during URS.^{3,4} Only 2 articles mention the feasibility of fluoro-less ureteroscopy for the treatment of ureteral stones.^{5,6} In this study, we aimed to present the feasibility and safety of X-ray free endoscopic treatment of ureteral stones to diminish RE to the patient and operating team, and to determine the circumstances in which fluoroscopic imaging is mandatory.

MATERIAL AND METHODS

Between September 2010 and August 2011, 93 consecutive patients with proximal or distal ureteral calculi resistant to shock wave lithotripsy (SWL) electively scheduled for ureteroscopic treatment were retrospectively evaluated. The procedures were performed in the same setting by 2 senior endourologists (A.T. and A.A.) with at least 4 years of experience with a minimum 50 URS procedures per year. Before surgery, each patient signed an informed consent form. Patient demographics, stone size and location, grade of hydronephrosis, need

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for balloon dilation or fluoroscopic imaging, operation and fluoroscopic screening time (FST), postoperative stenting, and complication and success rates were investigated.

Preoperative complete blood count, serum creatinine, platelet count, bleeding and coagulation profiles, and urine cultures were obtained from all patients. Radiological evaluations included intravenous urography and ultrasonography with the addition of noncontrast computed tomography in selected cases. Stone size was measured by the largest cross section on the kidneys, ureters, and bladder radiograph in patients with radio-opaque stones, and by noncontrast computed tomography in patients with radiolucent stones.

Operative Technique

With the patient under general or spinal anesthesia, all URS procedures were performed in the lithotomy position. The surgical team was protected with lead aprons and thyroid shields, and a mobile C-arm fluoroscopy system (Ziehm Solo, Ziehm Imaging, Nürnberg, Germany) was set ready to use in case fluoroscopic imaging was necessary. After a detailed cystourethroscopy procedure performed to rule out any urethral bladder pathology, the 0.035-inch guidewire that has a hydrophilic tip and stiff shaft (Sensor, Boston Scientific, Natick, MA) was gently inserted through the ureteral orifice with endoscopic visualization. The insertion was terminated if any difficulty arose. This difficulty may originate from the impaction of stone, ureteral stricture, or kinking. The 8F single channel semi-rigid ureterorenoscope (Karl Storz, Tuttlingen, Germany) was inserted through the orifice with the aid of a guidewire. In the presence of any stricture, ureteral balloon dilatation was performed with endoscopic visualization. Manipulations, such as guidewire, balloon dilatation, and ureteral stent or ureteric balloon insertion were performed with visual and tactile cues. Single-shot fluoroscopic screenings were taken when imaging was required. Stone disintegration was accomplished with a holmium laser until the stone was reduced to fragments that were easily and spontaneously passed. Indications for postoperative stenting were ureteral edema secondary to an impacted calculus, iatrogenic ureteral trauma (laceration or perforation), or a significant residual stone burden. Patients' radiological evaluation was done with plain film of the kidneys, ureters, and bladder that has 1.1 mSv estimated radiation dose for the average 70-kg patient,⁷ on postoperative day 1 to assess and document the success of the operation, the location of the double-J stent, and spontaneous passage of the stone fragments. Postoperative complications were grouped according to the Clavien Classification System.⁸

RESULTS

The mean age of patients was 34.03 ± 12.09 years (range, 9-63 years). The mean stone size was calculated to be 10.64 ± 3.16 mm (range, 6-17 mm). The stone localization was in the proximal, middle, and distal segments in 11, 30, and 52 patients, respectively (Table 1). The distribution of the patients classified regarding degree of hydronephrosis is summarized in Table 1.

The mean duration of the operation was 34.51 ± 7.94 minutes (range, 24-55 minutes). The average hospitalization time was 1.17 ± 0.48 days (range, 1-3 days). Stone-free status was achieved in 90 patients (96.77%). An additional procedure (SWL) was performed on 3 patients

Table 1. The demographic data of the patients

No. of patients	93
Mean age (y)	34.03 ± 12.09 (9-63)
Men/women	49/44
Mean stone size (mm):	10.64 ± 3.16 (6-17)
Stone location	
Distal	52
Middle	30
Proximal	11
Grade of hydronephrosis	
Nil	17
Mild	31
Moderate	32
Severe	13

Table 2. Perioperative findings and postoperative complications

Mean operation time, min	34.51 ± 7.94 (24-55)
Mean duration of hospitalization (days)	1.17 ± 0.48 (1-3)
Success rate (%)	90/93 (96.77)
Complications	11 (11.8%)
Proximal stone migration	3
Hematuria (Clavien grade I)	1
Mucosal injury	3
Urinary tract infection (Clavien grade II)	4
Need for C-arm fluoroscopy	7 (7.52%)
To confirm stone migration	3
Double collecting system with 2 ureter	1
Severe tortuosity of ureter with kinking	2
Ureteral stricture	1
Mean FST (for 7 patients) (seconds)	9 ± 4.72 (4-16)
Double-J stent insertion	19 (20.4%)
Severe mucosal edema	9
Mucosal injury	3
Ureteral stricture	7

FST, fluoroscopic screening time.

(3.22%) due to stone migration to the kidney. Perioperative findings are listed in Table 2.

A total of 11 complications (11.8%) were observed, none severe. In 1 patient, postoperative hematuria was resolved spontaneously with hydration (Clavien grade I complication). Three patients experienced mucosal injury during fragmentation of the stone and passage of the ureteroscope. The ureteral double-J stent was inserted in these patients and removed 2 weeks after the procedure. In 4 patients, fever and urinary tract infections were controlled with parenteral antibiotics (Clavien grade II complication). The ureteral double-J stent was inserted under direct vision in 19 patients (20.4%), over the guidewire inserted up to the kidney with indications of severe mucosal edema (n = 9), mucosal injury (n = 3), and ureteral stricture (n = 7).

The fluoroscopic imaging was required for only 7 patients (7.52%). The mean FST for these patients was 9 ± 4.72 seconds (range, 4-16 seconds). In 3 patients, single-shot fluoroscopic imaging was used to confirm stone migration. Retrograde pyelography was performed to confirm and evaluate the ureteral and kidney anatomy in 1 patient who had a double collecting system with 2 ureters. The ureteral balloon dilatation was performed under C-arm fluoroscopy in 1 patient who had ureteral orifice stricture extending to the upper segment of his ureter. In the other 6 patients, dilatation of the ureteral orifice was performed under direct vision. The advancement of the ureteroscope to the stone was accomplished under C-arm fluoroscopy with the guidance of a guidewire in 2 patients who had impacted ureteral calculi leading to tortuosity and kinking. The URS was successfully performed in 86 patients (92.4%) without need for fluoroscopic imaging.

COMMENT

Fluoroscopic imaging plays a key role during URS, PNL, and SWL. Fluoroscopy is used to guide the entire procedure and provide additional information to endoscopic imaging. Moreover, it increases the safety of the procedure.⁹ Despite these advantages, fluoroscopy has deleterious effects on the operating team and patient. Hellowell et al¹⁰ investigated staff radiation dosage during endourological procedures. They found that during standard radiation protection protocols, the surgeon received the maximum RE. They concluded that radiation doses were in the lower levels of acceptable annual dose limits for the surgeon, assistant, and nurse. Radiation doses of patients, however, was not evaluated in that study.

Although radiation doses and FST have been reduced by the new generation of modern digital fluoroscopy devices that have digital image capture, last image hold, and foot control features,¹¹⁻¹³ Krupp et al¹⁴ stressed that radiation emitted from fluoroscopy devices during URS should not be underestimated. In their study, organ-specific and tissue-specific radiation doses were measured during a simulation of ureteroscopy on cadavers, and they identified the cancer risks according to the mean radiation doses using a linear-no-threshold hypothesis. They found increased cancer rates ranging from 0.2 to 7.4 per 100 000 patients using the data from the Biological Effects of Ionizing Radiation VII report and International Commission on Radiological Protection publication 103.^{15,16} The posterior skin was found to have the highest relative risk of malignancy (0.25%). Another notable result of the study was that gonadal doses were significantly higher for women than for men. This is a very important finding because RE may lead to genetic mutations, particularly during a woman's reproductive years. In another recently published study, Jamal et al¹⁷ measured RE of patients who had undergone URS and PNL during the perioperative period. The operation-related dose for URS was calculated as 22.7 mGy.

With the increased awareness of deleterious effects of RE, minimizing RE has been regarded as a main aim. The literature details the results of studies using various strategies implemented to reduce RE. Ngo et al⁴ reported that providing surgeons with feedback on their fluoroscopy usage promoted decreased use of excessive and unnecessary use of fluoroscopic imaging and led to a 24% reduction in mean FST. They found that presence of hydronephrosis, the usage of ureteral access sheath and ureteral balloon, and necessity of a postoperative stent placement were the main factors for increased FST. In other studies, gender, stone location, length of surgery, surgeon experience, and the usage of flexible URS were found to be the main factors affecting FST during URS.^{13,18}

In another study, Greene et al³ implemented a protocol including laser-guided C-arm usage, designated fluoroscopy technician usage, and substitution of visual for fluoroscopic cues during ureteroscopy. Stents and guidewires were placed in the patients under direct visualization. Fluoroscopic imaging was used only when an obstruction was felt. The result was an 82% reduction in FST without affecting surgical outcomes. The mean FST was 15.5 seconds (range, 0-54 seconds) after the protocol. In their retrospective study, patients requiring ureteral balloon dilatation were excluded from analysis. The measures, such as use of a laser-guided C-arm and designated fluoroscopy technician usage instituted by Greene et al³ could be adapted for all fluoroscopy guided endoscopic procedures, such as PNL.

The studies of both Greene et al³ and Ngo et al⁴ included patients with renal stones who were treated with flexible URS. Use of fluoroscopy during endoscopic treatment of renal stone with flexible URS may be essential in some situations. Final placement of an access sheath or locating small stones in severely hydronephrotic kidneys requires fluoroscopic imaging. Fluoroscopy is a beneficial auxiliary imaging modality for localization of radio-opaque stones and helps renal mapping. During this period in our department, flexible ureteroscopy was not readily available; therefore, our study includes only patients with ureteral stones. They were all treated with semi-rigid URS. Although the use of flexible ureteroscopy is recommended for the treatment of proximal ureteral stones, the semi-rigid ureteroscope is safe even for proximal calculi in the absence of flexible instruments.^{1,19}

Mandhani et al⁵ reported results of their patients with distal ureteric stones treated with URS without fluoroscopic imaging. In their series (n = 110), C-arm fluoroscopy was used for only 6 patients (4%): for calcified ureteral orifice stricture (n = 1), for a duplex system (n = 1), because narrow and tortuous meatus caused difficulty in passing the balloon dilator (n = 3), and to confirm spontaneous stone passage (n = 1). Ureteric dilation was performed in 10 of their 13 cases by placing a balloon dilator under direct vision of ureteroscope. The placement of a double-J stent was also done under direct vision, with no need for fluoroscopy. No severe complications were reported during the X-ray free URS. Mand-

hani et al⁵ advocated using fluoroscopy in selected patients. Although this is the first reported study of URS with no fluoroscopic imaging, it includes only patients with distal ureteric stones. In our study, patients with proximal and distal stones were treated with URS with no fluoroscopic imaging. Fluoroscopy was required for only 7 patients (7.52%). For these patients, the mean FST was found to be 9 ± 4.72 seconds (range, 4-16 seconds). Although all distal ureteral and ureteral orifice strictures were dilated with balloons under direct vision, C-arm fluoroscopy was used for a patient with ureteral stricture extending to the upper levels. Additionally, fluoroscopic imaging was required in 2 patients who had impacted ureteral stones leading to ureteral kinking and obstruction, and in 1 patient who had a double ureter. We also used single-pulse fluoroscopic images in 3 patients to confirm stone migration to kidney. Despite its limited use of fluoroscopy in the present study, the fluoroscopy may be necessary for many cases with unpredictable and extraordinary situations.

Endoscopic procedures on pregnant women are performed with no fluoroscopic control to avoid deleterious effects of RE on her and fetus.²⁰⁻²³ A recently published meta-analysis asserted that safety of URS for ureteral stones in pregnant patients is not significantly different from safety of that procedure in nonpregnant patients.²³ In another study including pregnant women, the authors emphasize that placement of a ureteral-J stent without fluoroscopic imaging requires special care. In the presence of difficulty related to kinking of the guidewire during stent insertion, the authors suggest gentle withdrawal of the guidewire with equally gentle reinsertion of the stent to facilitate the procedure.²¹ In this series, ureteral stents were placed under direct visualization or ultrasonographic control. Ultrasonography is a popular and X-ray free imaging modality used alone or in conjunction with fluoroscopy to guide endoscopic procedures, such as PNL or URS.²⁴⁻²⁶ Although ultrasonographic-guided stent placement in pregnancy is a previously recognized safe method, it requires radiologic assistance and a portable ultrasound machine.²⁴ Our series had only 1 pregnant woman. With her, the procedure was performed entirely without any imaging modality. Placement of ureteral-J stent was performed with direct visualization and confirmed with ultrasonography.

The long duration of hospitalization in the present study is attributed to typical preference of our department. Most of the patients were discharged on postoperative day 1 after radiological evaluation and documentation.

Studies have shown that radiation-reducing measures or X-ray free URS have no impact on an operation's success, complication rate, or time, and adds no technical difficulty.^{3-6,23} Another factor, however, does affect course and outcomes of the surgery: the experience of the surgeon. In the present study, all of URS procedures were performed by senior endourologists with experience of a minimum 50 URS procedures per year. The use of fluo-

roscopy may be reduced as a surgeon becomes more experienced. Younger and less experienced urologists tend to overuse fluoroscopy to ensure that all steps of URS are being safely performed.⁹ To perform URS with no fluoroscopic control resembles driving at night with lights on that requires experience.

The retrospective and nonrandomized nature of the study and the lack of the patients treated with flexible ureteroscopy are considered as study limitations. The lack of information about the amount of RE is another limitation factor. The thermoluminescent dosimeters that directly measure RE dose were not routinely used for patients during URS because of its rarely and single-pulse use. Although FST is a not a good indicator of RE, it is accepted as a major predictor of individual RE that decreases in parallel to FST.³ In the study, FST was used as an indicator of RE to overcome this limitation. Another limitation factor is that the study included patients in a wide range of ages (range, 9-63 years). It is well known that children who undergo radiographic intervention are potentially at a higher risk of deleterious effects of RE than adults.²⁷

CONCLUSIONS

Fluoroscopic imaging has a key role during the endoscopic treatment of renal and ureteral calculi. However, all urologists should be informed about its potential risks of RE and the use the X-ray related imaging modalities rationally and consider the risk-to-benefit ratio. We have demonstrated that, in experienced hands, the ureteroscopic treatment of ureteral stones can be safely and effectively performed with limited or no usage of fluoroscopic imaging.

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EDITORIAL COMMENT

The drive to reduce radiation exposure to as low as reasonably achievable (ALARA) is one which is taking on ever-increasing importance in all medical fields. There are numerous ways we, urologists, can follow the ALARA principal; by collaboration with our radiologic colleagues for technique optimization, tracking our patients' exposures, using alternative nonionizing imaging modalities, and avoidance of unnecessary studies, in

doing so, we will be able to deliver the best health care possible while minimizing potential risks.

This study presents an option for complete avoidance of fluoroscopy during ureteroscopic stone fragmentation. Using tactile and visual cues, the surgeons were able to successfully avoid fluoroscopy in 92% of their patients, while safely and effectively treating the stones.

Although I agree with reducing dose whenever possible, dose reduction must be done safely and rationally. Most experienced urologists and endourologists will not expose patients to large amounts of radiation during a standard ureteroscopy. One recent study documents an average of 1.13 mSv for ureteroscopy in a male patient with a body mass index of 27.5 kg/m², equal to that of a kidneys, ureters, and bladder radiograph.¹ The same study's average fluoroscopy screening time was 47 seconds compared to 15 seconds in a previous report and 9 seconds in the present study.² Clearly, when ureteroscopy is performed thoughtfully, minimal fluoroscopy is used and patients' radiation exposure is minimal at worst.

I fear that by driving urologists to overly reduce the use of imaging in a safe, low risk, low radiation procedure may be potentially dangerous to the care of our patients. Brief confirmation of stone location, wire positioning, retrogrades for anatomic identification, and proper stent placement can help the treating physician avoid a multitude of potential complications. These complications can have a much greater impact on patients than the potential sequelae of 1 mSv or less of radiation exposure. Furthermore, the relationship between radiation exposure and malignant transformation is age-dependent. There are significant differences in risk between this studies' youngest patient (9 years old) and its eldest (63 years old). The latency time to development of malignancy from significant doses of radiation greatly reduces the excess relative risk of cancer formation as the patients' age. This is not to say that our middle-aged and elderly patients should not have reduction of exposure, but that the concerns are even less founded.

Fluoroscopy is a useful tool and should be used judiciously and intelligently to optimize our patients' outcomes. Whenever possible and reasonable, decrease the amount of time and energy emitted, but please do so with patient safety in mind.

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