

Research Article

Fluoroless Ureteroscopic Lithotripsy for the Treatment of Ureteral Stones: The Feasibility and Safety Study in A Large Consecutive Cohort

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Abstract

Objective: To present the feasibility, efficacy and safety of fluoroless ureteroscopic lithotripsy for the treatment of ureteral stones.

Patients and methods: From Jan 2010 to Dec 2015, 536 consecutive patients with ureteral stones underwent ureteroscopic lithotripsy using fluoroless technique were enrolled. Patient characteristics, intraoperative and postoperative parameters were reviewed.

Results: The mean age of patients was 52.10 ± 18.03 years. The stone laterality was in the left, right, and bilateral in 240, 291, and 5 patients, respectively. The stone located in the proximal/middle ureter in 213 cases, while 328 cases were located in the distal ureter. The mean stone size was 13.04 ± 3.27 mm and hydronephrosis was observed in 473 cases (87.43%). The mean operative time was 28.50 ± 9.94 min. Stone free status was achieved in 518 cases with a successful rate of 95.75% using fluoroless technique. Fluoroscopy was employed in 22 cases, and perioperative complications occurred in 62 cases (11.46%).

Conclusions: Fluoroless ureteroscopic lithotripsy was safe and effective for the treatment of ureteral stones. The placement of guidewires, ureteral stent, ureteral access sheath or even ureteral dilation could be done under direct visual without image guidance; however, a fluoroscopy-guided technique should not hesitate to be used if the urologists felt any difficulties or uncertainties.

Keywords: Fluoroless Technique; Ureteroscopic Lithotripsy; Ureteral Stone

Introduction

With the advances in instruments, ureteroscopic lithotripsy has become one of the first line therapies for the treatment of ureteral stones. Intraoperative fluoroscopic imaging routinely plays an important role during ureteroscopic lithotripsy for visualization and guidance; however, it makes the patient, urologist, and operating room staff exposed by the radiation [1]. Although the intraoperative radiation exposure is relatively low compared to radiation levels during CT scan, the effects are cumulative [2]. In fact, any radiation exposure may lead to genetic mutation and

cancer since there is no threshold below which potentially harmful effects do not occur [3].

With the increasing awareness for radiation exposure, the As Low as Reasonably Achievable (ALARA) principle is adopted by urologists, and the necessity to reduce the risks to patients and medical professionals is well understood [4]. To minimize or avoid the hazards of radiation, protocols were published to reduce exposure during ureteroscopic lithotripsy [5, 6]. Several researches even discuss the feasibility of fluoroless ureteroscopy for the management of ureteral stones, but only in small case series [7-9]. The purpose of this study was to present the feasibility, efficacy and safety of radiation free ureteroscopic lithotripsy for the treatment of ureteral stones.

Patients and Methods

From Jan 2010 to Dec 2015, 536 consecutive patients with ureteral stones underwent ureteroscopic lithotripsy in our institution were enrolled in this retrospective study. Diagnosis evaluation of ureteral calculi consisted of a thorough history taking, physical examination, routine laboratory examinations (including complete blood count, serum creatinine, bleeding and coagulation profiles, urine test and cultures), and radiological evaluations. Stone size, stone location and associated hydronephrosis were measured by ultrasonography, the Kidneys, Ureters and Bladder Radiography (KUB), Intravenous Urography (IVU) and/or non-contrast Computed Tomography (CT). Stone size was calculated by multiplying the two largest cross-sectional dimensions on KUB in patients with radio-opaque stones and by CT in patients with radiolucent stones. Preoperative variables for all patients were reviewed, including age at time of surgery, gender, stone size and location, and grade of hydronephrosis. Intraoperative variables reviewed included total operation time, estimated blood loss, intraoperative complications. Postoperative variables reviewed included length of postoperative hospital stay, postoperative complications, and stone-free rates (defined as no residual stone > 2 mm).

Technique for Fluoroless Ureteroscopic Lithotripsy

Before surgery, KUB was performed for preoperative imaging assessment in each patient. The procedure was performed in the lithotomy position under general anesthesia. The 8F semi-rigid ureteroscope (Karl Storz, Tuttlingen, Germany) was introduced into the bladder. After locating the desired ureteral orifice, the safety guidewire (Cook Medical, Bloomington, IN) was gently manipulated into the ureteral orifice with endoscopic visualization until any resistance could be felt, then slightly move back the guidewire. The resistance might originate from the stone, ureteral stricture or kinking. The semi-rigid ureteroscope was inserted through the orifice under direct vision with the aid of safety guidewire. Once the stone was identified, holmium laser was used to treat the stone. Lithotomy was accomplished when the stone was reduced to small fragments that were easily and spontaneously passed. Due to concern for ureteral inflammation and edema after operation, ureteral stent was temporarily placed in all patients using fluoroless stent placement technique. Once lithotomy was completed, the ureteroscope was moved forward to the ureteropelvic junction level to ensure there were no residual stones. After that, the flexible safety wire guide tip was passed to the renal pelvis through operation channel of ureteroscope under the direct vision. Next, the ureteroscope was re-introduced into the bladder alongside the previously placed safety guidewire, which had been confirmed ureteroscopically to be placed into the pelvis. After estimating the proper stent length using a baseline imaging, a ureteral stent (Cook Medical, Bloomington, IN) was used and the stent was passed over the flexible safety guidewire using a

stent advancer under ureteroscopic observation (4.7-6F, 22-32cm). Once the distal end of the stent had been reached the orifice, the urologist should stop passing the stent. The stent advancer was used to stabilize the stent and the guidewire was removed, allowing the distal coil to form in the bladder under direct visualization. At last, the ureteroscope was positioned in the bladder neck to confirm the distal coil was in right position. Radiological evaluation was performed 2-3 weeks after operation to assess the location of the stent and the passage of the stone fragments before removing the ureteral stent.

Results

A total of 536 patients were enrolled in this study with a mean age of 52.10 ± 18.03 years (range 15-86 years). The stone laterality was in the left, right, and bilateral in 240, 291, and 5 patients, respectively. The stone located in the proximal/middle ureter in 213 cases, while 328 cases were located in the distal ureter. The mean stone size was 13.04 ± 3.27 mm (range 8-21 mm) and hydronephrosis was observed in 473 cases (87.43%). The mean operative time was 28.50 ± 9.94 min (range 15-80 min). The mean duration of hospitalization was 3.51 ± 1.17 days (range 2-7 days). Stone free status was achieved in 518 cases with a successful rate of 95.75% (Table 1).

Characteristics	n=536
Age (yr)	52.10 ± 18.03 (15-86)
Gender	
Male	306
Female	230
Stone laterality	
Left	240
Right	291
Bilateral	5
Stone location	
Proximal/mid-ureter	213
Distal ureter	328
Stone size (mm)	13.04 ± 3.27 (8-21)
Associated hydronephrosis	473 (87.43%)
Operative time (min)	28.50 ± 9.94 (15-80)
Success rate	95.75% (518/541)
Need for fluoroscopic screening	22(4.07%)
Hospital stay	3.51 ± 1.17 (2-7)
Complications	
Stone migration	31
Mucosal injury	5
Ureteral perforation	1
Hematuria	19
Urinary tract infection	9
Ureteral stent migration	6

Table 1: Patient characteristics.

Fluoroscopy was employed in 22 cases, 7 for dilation, 13 for the placement of ureteral access sheath due to stone migration to the pelvis and further flexible ureteroscopy needed, 2 for anatomic abnormality (1 for double collecting system and 1 for ureteral kink, which lead to difficulty in placing guidewire). Perioperative complications occurred in 62 cases (11.46%). Severe complication was observed in 1 case who was converted to open operation due to ureteral perforation. Stone fragments migration occurred in 31 cases and additional flexible ureteroscopy were performed in these cases. The ureteral access sheath was successfully placed in 18 cases using fluoroless technique. The ureteral stent migration (retrograde into the ureteral orifice) was observed in 6 cases and ureteroscopy was employed for removing the stent.

Discussion

Fluoroscopy is commonly used during ureteroscopic lithotripsy to guide the entire procedure and provide additional information, which may increase the safety of the operation. However, fluoroscopy has deleterious effects on the patient and medical staff by putting them at the risk of radiation exposure [1]. Although fluoroscopy time and radiation doses have been reduced with the application of the new digital fluoroscopy devices, radiation exposure during ureteroscopic lithotripsy should never be underestimated. The radiation exposure for a patient receiving ureteroscopy ranges from 2.5 to 100 mSv [10]. Moreover, the effects are cumulative, and many patients with ureteral stones require multiple ureteroscopic lithotripsy and radiographic examination. Krupp et al. measured organ-specific and tissue-specific doses during a simulation of ureteroscopy on cadavers to fluoroscopy [2]. They estimated that increased cancer rates ranging from 0.2 to 7.4 per 100 000 patients as a result of radiation induced cellular injury, and the highest cancer risk increase was seen at the posterior skin (104 additional cancers per 100,000).

Since there is rising concern over the deleterious effects of radiation exposure, minimizing radiation exposure during ureteroscopic lithotripsy has become a main issue. Several studies evaluated the risk factors for increased radiation exposure during ureteroscopy, and found obesity was the one of the main risk factors. Larger patients experienced higher radiation dose rates under fluoroscopy, and severe obesity was associated with 3-fold higher radiation dose rate [11]. The usage of ureteral balloon for dilation during the operation was also a main risk factor [12]. Moreover, fluoroscopy time might be decreased by an experienced surgeon and dedicated C-arm technician [13]. In the field of cardiology, reported a 50% reduction in radiation exposure with a 15-hour educational course and standardized technical recommendations [14]. While in the field of endourology, Weld et al. established a program called Safety, Minimization, and Awareness Radiation Training (SMART), which was composed of radiation safety training, instruction on

minimizing fluoroscopy use during ureteroscopy, and participation in a monitoring program. The authors compared the fluoroscopy time in urology residents with or without SMART program and the results revealed that SMART reduces fluoroscopy time by 56% [15]. To reduce the radiation exposure, pulsed fluoroscopy technique was introduced in clinical practice. Pulsed fluoroscopy delivered less radiation compared with continuous fluoroscopy at each site, including anterior and posterior skin, and kidney. It was reported that pulsed fluoroscopy reduced fluoroscopy time by 76% and radiation dose by 64% in comparison with continuous fluoroscopy. When evaluated by blinded urologists, more than 90% of them considered pulsed fluoroscopy images were adequate for most tasks of ureteroscopy [16]. Since fluoroless operation has been successfully performed in several previous image-guided procedures, such as interventional cardiac ablation surgery and endoscopic retrograde cholangiopancreatography, we realized that ureteroscopic lithotripsy could be performed completely without fluoroscopic imaging.

Fluoroless ureteroscopic lithotripsy was first reported [17] in 2007 but was recommended only in selected patients. This study enrolled only patients with distal ureteral stones (below the sacroiliac joint). The results demonstrated that complete clearance of distal ureteral stones could be achieved without fluoroscopy in 99 out of 110 patients. Only 6 patients underwent fluoroscopy during the operation: 3 cases for difficulty in placing the dilator, 1 case for ureteral orifice stricture, 1 case for a double collecting system, and 1 case for the confirmation of spontaneous stone passage. Moreover, Ureteral dilation was performed in 13 cases in this study and 10 of them (76.92%) were done without fluoroscopy, which indicated that dilation under direct vision of ureteroscope was safe in selected patients. In our study, ureteral dilation was performed in 12 cases and 7 of them were performed under the guidance of fluoroscopy. In our opinion, fluoroscopy should be employed if the urologist felt any uncertainties of during the dilation procedure.

[9] performed ureteroscopic treatment in 93 consecutive patients with ureteral stones, which located in proximal(n=11), middle(n=30), and distal(n=52) segments. They achieved Stone-free status in 90 patients (96.77%) with only 7 patients required intraoperative fluoroscopy. Hsi and Harper [18] treated 162 consecutive ureteroscopic procedures using two taps of fluoroscopy at the time of the procedure. In their report, no fluoroscopy was used for the ureteroscopy, but limited fluoroscopy was required for stent placement. Wayne Brisbane et al. reported a technique placing ureteral stent without image guidance, and they found ureteral stent placement without fluoroscopic guidance is feasible [19]. In our study, we placed ureteral stent under direct visual without image guidance and evaluated the stent migration rate 1-month after surgery. The results showed that the stent retrograde migration occurred only in 6 cases (6/541) and ureteroscopy

was performed in these cases for removal of the stent. These findings demonstrated the reliability of placing the stent without the guidance of fluoroscopy. [7] further expanded the potential application of fluoroless ureteroscopy. Their study enrolled 50 consecutive patients underwent completely fluoroless ureteroscopy with the comparison of 50 conventional, fluoroscopy-guided ureteroscopies performed in the same time period. The completely fluoroless ureteroscopy was performed by inserting guidewires and instruments using tactile feedback, direct visualization, and external visual cues to substitute for fluoroscopy. The results demonstrated that a completely fluoroless technique is feasible and effective for the treatment of calculi throughout the entire upper urinary tract. Although in relatively small case series, these previous innovative studies have already demonstrated the safety and efficacy of fluoroless ureteroscopic lithotripsy. In our retrospective study, the results showed that fluoroless ureteroscopic lithotripsy could achieve high success rate (95.75%) in the treatment of ureteral calculi without increasing the complication rate in a large consecutive case cohort.

Intraoperative ultrasound guidance was regarded as an alternative to fluoroscopy during ureteroscopy. In 2014, a prospective randomized controlled trial reported [8] enrolled 50 patients with symptomatic ureteral stones ≤ 8 mm and assigned to either ultrasound or fluoroscopy-guided ureteroscopy (25 patients per arm). No difference in stone-free rates, operative time, or complication rates were observed between the two groups. However, completely fluoroless technique had some certainly advantages compared with ultrasound guided procedure. One reason was intraoperative ultrasound required unique instrument and skill not always available in the operating room. Moreover, ureteral stents might be difficult to identify using ultrasound. Furthermore, it was reliable to assess the residual stone size [20], place the ureteral stent [7, 19], or even perform the ureteral dilation [17] under the direct visual during the procedure, thus making the fluoroless ureteroscopic lithotripsy as safe and effective as fluoroscopy-guided operation according to the present study and previous reports.

Although our study demonstrated favorable outcomes could be achieved by completely fluoroless technique in a large consecutive cohort, the retrospective and nonrandomized nature were considered as study limitations. Multi-center randomized controlled clinical trial was needed for further investigation. Certainly, the intent of this study was not to advocate fluoroless ureteroscopy in any condition. If the urologists felt any difficulties or uncertainties in placing the guidewire, assessing the residual stone size, placing the ureteral stent, and performing the dilation, they should not hesitate to convert to a fluoroscopy-guided technique.

Conclusions

Fluoroless ureteroscopic lithotripsy was safe and effective for the treatment of ureteral stones. The placement of guidewires,

ureteral stent, ureteral access sheath or even ureteral dilation could be done under direct visual without image guidance; however, a fluoroscopy-guided technique should not hesitate to be used if the urologists felt any difficulties or uncertainties.

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