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### **Original Research Article**

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# Fluoroless versus conventional ureteroscopy: clinical outcomes, stone-free rate and complications

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#### **ABSTRACT**

**Background:** Urinary lithiasis is a prevalent condition worldwide, with recurrence rates up to 50% within five years. Ureteroscopy (URS) and retrograde intrarenal surgery (RIRS) are the preferred treatments for stones smaller than 20 mm, often involving radiation exposure. Fluoroless ureteroscopy (F-URS) has emerged as a potential method to reduce radiation-related risks for patients and healthcare personnel.

**Methods:** A retrospective, observational study was conducted, including patients over 18 years with ureteral or renal lithiasis treated with either F-URS (April 2022 to January 2023) or conventional ureteroscopy (C-URS) with fluoroscopy (January 2023 to January 2024). Data on stone-free rates (SFR), complications, surgical time, and radiation exposure were analyzed. Nominal variables were described with absolute and relative frequencies, while numerical variables were analyzed using means and standard deviations. Statistical comparisons were made using odds ratios (OR) with 95% confidence intervals (CI) and the Mann-Whitney U test.

**Results:** A total of 369 patients were included: 164 (44.44%) in the F-URS group and 205 (55.56%) in the C-URS group. The overall SFR was 76.96% (80.49% in F-URS versus 74.15% in C-URS; OR 0.70, 95% CI 0.42-1.14, p=0.152). Surgical time was longer in the C-URS group (75.15±41.34 min) compared to the F-URS group (65.59±36.03 min). Complication rates were similar between groups (15.85% versus 12.20%; OR 0.74, 95% CI 0.41-1.33, p=0.313). Radiation exposure for fourth-year residents averaged 1.17 mGy, decreasing progressively with training level.

**Conclusions:** F-URS is a safe and effective technique for treating ureteral and renal lithiasis, with comparable SFR and complication rates to conventional ureteroscopy. The reduction in radiation exposure benefits both patients and surgical staff. Although current guidelines do not explicitly endorse F-URS, it should be considered in teaching hospitals and complex cases where radiation minimization is a priority.

Keywords: Lithiasis, Endourology, Ureteroscopy, Retrograde intrarenal surgery, Radiation, Fluoroscopy

#### INTRODUCTION

Urinary lithiasis has a global prevalence of 2-20%, with 8.8% in the United States, 20% in America, and 8-15% in Asia.<sup>1</sup> Recurrence rate is up to 50% within 5 years.<sup>2</sup> Ureteroscopy (URS) and retrograde intrarenal surgery (RIRS) are the treatment of choice for renal and ureteral

stones smaller than 20 mm, with constant radiation exposure.

The reported complication rate ranges from 3.5% to 30%, with the modified Clavien classification system (MCCS), proposed by Mandal et al in 2012, being the most used system for reporting complications.<sup>3-9</sup>

Accumulated radiation exposure has been linked to the development of neoplasms and various diseases in the medium and long term, making fluoroless ureteroscopy a potential method to reduce the radiation risks associated with these procedures for both patients and healthcare staff. Radiation exposure during URS ranges from 1.2 to 29.7 mGy, with 20% of patients receiving more than 50 mSv in a single procedure. Factors such as stone size and location, the use of a ureteral access sheath, JJ stent placement, and the presence of hydronephrosis are associated with longer fluoroscopy times. 10-13

From April 2022 to January 2023, we performed fluoroless procedures for the treatment of ureteral and renal stones and from January 2023 to January 2024, procedures were conventional with fluoroscopy. An analysis of clinical outcomes was conducted to compare stone-free rates and complications.

The main objective of this study was to compare the stone-free rates and complication rates in adult patients with renoureteral lithiasis treated with F-URS and C-URS. Secondary objectives include characterizing the population with renoureteral lithiasis treated with F-URS and C-URS, comparing the proportion of SFR and the frequency of complications in adult patients with renoureteral lithiasis treated with F-URS and C-URS, and estimating the reduction of radiation exposure for healthcare personnel during procedures with and without fluoroscopy, and describing the surgical time required for each procedure.

#### Background

Urinary lithiasis is a common pathology worldwide, with a prevalence ranging from 2-20%, 8.8% in the United States, 20% in America, and 8-15% in Asia, and a recurrence rate of up to 50% within 5 years. The global incidence increased by 48.57% in 2019 compared to 1990, with a significant economic impact, leading to an estimated annual cost of \$5.3 billion in 2020.

There are different treatment options for renal and ureteral stones depending on their size and location. For stones smaller than 5-7 mm in the mid and lower ureter, conservative treatment with analgesia and alpha-blockers can be offered. For stones larger than 7-10 mm, definitive treatment options include extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS), percutaneous nephrolithotomy (PCNL), open surgery, laparoscopic surgery, or robotic surgery.

Currently, URS/RIRS is the gold standard for treating distal and proximal ureteral stones, as well as renal stones smaller than 20 mm, and renal stones larger than 20 mm where percutaneous surgery is contraindicated.<sup>5-7</sup>

Complication rate in the literature ranges from 3.5% to 30%. 8.9 According to the modified Clavien classification system (MCCS), perioperative complications are divided

into five grades, with grades 1 and 2 considered mild, and grades 3, 4, and 5 classified as major. Major complications require surgical, endoscopic, or radiological intervention and may be life-threatening.<sup>8</sup>

Complications can be classified as intraoperative, early postoperative (within three weeks), or late postoperative (after three weeks), and as major or minor.

In urology, ionizing radiation plays an important role, from diagnosis with computed tomography (CT) to intraoperative fluoroscopy exposure, affecting patients, surgeons, and staff involved in the procedure, including anesthesiologists and nurses. In some cases, CT is also used for postoperative follow-up to evaluate stone-free status after surgery.

Radiation exposure is measured by the absorbed energy per unit of body mass, expressed in milligrays (mGy), and different organs will absorb varying amounts of radiation, expressed in millisieverts (mSv).

Radiation exposure during URS ranges between 1.2 and 29.7 mGy, with 20% of patients receiving more than 50 mSv in a single procedure. Factors such as stone size and location, ureteral sheath use, JJ stent placement, and the presence of hydronephrosis are associated with longer fluoroscopy times. <sup>11-14</sup> Although the radiation dose in URS is low, recurrent stone formers can accumulate significant exposure. Fluoroless ureteroscopy (F-URS) aims to reduce radiation exposure in the operating room. Various protocols have shown reductions in radiation and fluoroscopy time of 65-70 seconds with proper surgical planning, pulsed fluoroscopy to avoid continuous fluoroscopy, and tactile feedback during the procedure. <sup>14</sup>

The ALARA principle (as low as reasonably achievable) was developed to minimize radiation risks based on optimization, justification, and limitation of exposure. As a general rule, radiation duration should be reduced using pulsed fluoroscopy, which takes about 5 images per second, compared to continuous fluoroscopy, which takes around 35 images per second. Staff should wear protective equipment such as lead aprons, neck shields, and goggles to reduce exposure by up to 70%. The use of dosimeters provides important information to encourage adherence to the ALARA principle.<sup>2,11,15</sup>

There are two types of radiation damage.

#### Deterministic (tissue reactions)

These occur from accumulated exposure, and the effect will become clinically visible if the radiation dose exceeds a threshold. The damage, expressed in DNA, is dose-dependent and increases in severity with greater radiation exposure. These effects are caused by cell death and include dermal injuries, cataracts, thyroiditis, bone marrow suppression, and hair loss. Such effects can be

seen in radiotherapy and interventional procedures guided by radiation.

#### Stochastic (cancer and heritable effects)

These do not require a radiation threshold; the probability increases with dose exposure and is proportional to the amount of radiation received. They can cause lung injury, cardiovascular effects, or gastrointestinal problems, usually manifesting years after the exposure.

This theory explains that any radiation exposure, even at low doses, carries a potential risk and can contribute to cancer development. It is estimated that 2% of new cancer diagnoses in the United States are associated with radiation exposure, particularly from CT scans. Additionally, a study conducted on cadavers estimated that 1 in 1,000 patients could develop skin cancer following a single ureteroscopy.<sup>2,11,15</sup>

The guidelines from the International Commission on Radiological Protection (ICRP) established a safe dose limit of 20 mSv per year over 5 years or 50 mSv in a single year, equivalent to 7-9 years of natural background radiation exposure or 2-3 abdominal and pelvic CT scans. Exceeding this limit increases the risk of cancer to 1 in 1,000. 15,16

Currently, protocols are in place to reduce radiation exposure during URS, F-URS protocols.<sup>14</sup> However, there is no current recommendation or contraindication in international guidelines regarding F-URS.

Emiliani et al provided several recommendations during ureteroscopy to minimize radiation use. When placing the safety guide, it should be advanced until slight resistance is felt or when the movement of the ureteral meatus is identified, indicating the ascent to the renal cavities. Additionally, some authors suggest measuring the guide concerning the patient's feet placed in the lithotomy position. It is recommended to perform a semi-rigid ureteroscopy to ensure the correct placement of the guide, identify ureteral stones, and perform passive dilation of the ureter to facilitate the ascent of a ureteral sheath. Care must be taken during this step; as ureteral injuries can occur. Some authors recommend using ureteral sheaths only if the patient previously had a JJ stent. The placement of the JJ stent at the end of the procedure should be done under direct visualization with cystoscopy, observing the distal mark in the ureteral meatus with possible ultrasound guidance.14

#### **METHODS**

This was a cross-sectional, observational, retrospective, study in the Hospital General Dr. Manuel Gea González. Patient records of individuals over 18 years of age diagnosed with ureteral or renal lithiasis were included. These patients underwent fluoroless ureteroscopy from April 2022 to January 2023 and conventional ureteroscopy

from January 2023 to January 2024. Selection criteria for this study included male or female patients who underwent URS or RIRS for the treatment of ureteral or renal lithiasis. Patients whose procedures were solely diagnostic or who had no stones identified at the time of the procedure were excluded.

A retrospective analysis of the procedures recorded in the urology department was conducted. From these records, the patient file numbers for those who underwent ureteroscopy during the different study periods were obtained.

Patient records were reviewed to assess eligibility based on selection criteria. Once identified, records were reviewed by the principal investigator and co-investigator to obtain information on variables using a specifically designed data capture sheet. For fluoroless procedures, records from April 2022 to January 2023 were reviewed, while those with fluoroscopy, from January 2023 to January 2024. Information related to surgical time, intraoperative complications, and stone-free status were collected from the surgical records.

CT scan was use for stone characteristics, location, number of stones and size was taking the maximum diameter of the stone. Immediate SFR was reported by the surgeon with nephroscopy at the end of the surgery and was confirmed with a CT scan 1 to 3 months after surgery. Evolution notes from clinical files were examined to document early or late postoperative complications, following the Clavien-Dindo classification, which is standardized in our hospital system.

Outcomes were assessed based on SFR, surgical time in minutes, and intraoperative and postoperative complications according to the modified Clavien-Dindo classification and hospital readmissions. A monthly record of radiation exposure was maintained using a dosimeter, and the cumulative radiation dose exposure for residents during the fluoroscopy and non-fluoroscopy periods was estimated.

Nominal variables were described using absolute and relative frequencies, and quantitative variables using means. A descriptive statistical analysis was performed using Stata version 15 for MAC. Categorical variables were described as percentages or proportions, and numerical variables with a Gaussian distribution were reported as means and standard deviations. The comparison between groups was done using odds ratios (OR) with 95% confidence intervals (CI); for ordinal variables, the Mann-Whitney U test was used. This was a retrospective, no-risk study guaranteeing patient confidentiality.

#### **RESULTS**

This study included 369 patients (47.15% women, 52.85% men) with a mean age of  $46\pm13.55$  years. Patients were

divided into fluoroless ureteroscopy (164, 44.44%) and conventional ureteroscopy (205, 55.56%). The mean surgical time was  $70.90\pm39.3$  minutes, with longer times in the conventional group ( $75.15\pm41.34$  min) compared to the fluoroless group ( $65.59\pm36.03$  min). In the fluoroless group, all patients had  $\leq 3$  stones, with 72.56% having a single stone and 50% having ureteral stones. In the conventional group, 3.9% had more than 4 stones, and 53.19% had renal stones. The most common procedure was RIRS in 48.23%, followed by URS in 31.43%, and combined URS + RIRS in 20.32% (Table 1).

**Table 1: Patient characteristics.** 

Categories	Conventional (n=205) (%)	Fluoroless (n=164) (%)
Sex		
Н	113 (55.12)	82 (50)
M	92 (44.88)	82 (50)
Age (years)	46.59 (±13.94)	45.32 (±13.05)
Number of stones		
1	154 (75.12)	119 (72.56)
2-3	43 (20.98)	45 (27.44)
4-6	8 (3.9)	
Location		
Distal	37 (18.04)	14 (8.5)
Mid	23 (11.21)	45 (27.4)
Proximal	36 (17.56)	22 (14.1)
Renal	109 (53.19)	83 (50)
Size (mm)	10.8 (30-2)	9.38 (18-4)
Surgery		
URSr	57 (27.8)	59 (35.97)
URSf	121 (59.02)	57 (34.75)
URSr + URSf	27 (13.18)	48 (29.28)

URS= Ureteroscopy, RIRS=retrograde intrarenal surgery, MM=millimeter

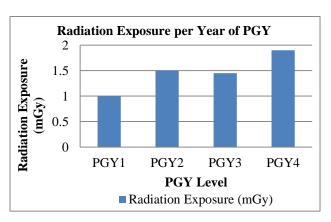


Figure 1: Radiation exposure measured in milligrays (mGy) for each level of postgraduate year (PGY) in urology residency.

The overall stone-free rate was 76.96%, with no significant difference between groups (80.49% fluoroless versus 74.15% conventional, OR 0.70, 95% CI 0.42-1.14, p=0.152). A total of 51 complications (13.82%) were

reported, with similar rates between groups (15.85% vs. 12.20%, OR 0.74, 95% CI 0.41-1.33, p=0.313). Most were Clavien-Dindo grade I, with one ureteral injury (grade III). Additionally, seven patients (13.72%) were readmitted for sepsis, and one (1.96%) required intensive care (grade IV) (Table 2). During fluoroscopy, radiation exposure was highest in fourth-year residents (1.17 mGy), followed by third-year (1.32 mGy), second-year (1.2 mGy), and first-year (0.97 mGy) (Figure 1).

Table 2: Intra and post-operative data.

Categories	Conventional (n=205) (%)	Fluoroless (n=164) (%)	P value	
Stone free rate	152 (74.15)	132 (80.49)	0.152	
Complica- tions	25 (12.20)	26 (15.85)	0.313	
Clavien-Dindo				
I	20 (9.75)	22 (13.41)		
II	3 (1.46)	3 (1.46)		
III	1 (0.48)	1 (0.6)		
IV	1 (0.48)			
Surgery time (min)	75.15 (±41.34)	65.59 (±36.03)		
Postoperative double J stent				
JJ	87 (42.43)	68 (41.46)		
Cumulative mGy				
PGY 1	1.17			
PGY 2	1.32			
PGY 3	1.2			
PGY 4	0.97			

Min=minutes, mGy=milligray

#### **DISCUSSION**

In this study, we evaluated the impact of fluoroscopy use on the surgical outcomes of patients with urinary lithiasis. The sample was divided into two groups: those who underwent fluoroless ureteroscopy and those who underwent conventional ureteroscopy, allowing a comparison of results.

We observed differences in the location and complexity of the stones between the two groups. Patients who underwent C-URS had more complex cases, with over four stones and a higher prevalence of renal stones, compared to the F-URS group, where all cases involved less than three stones.

Contrary to what Peng reported, we found longer surgical times in the conventional fluoroscopy group, likely due to the higher total number of stones, their complexity, the skill level of the operating team, and the fact that the procedures were performed in a teaching hospital where surgeries are carried out by different residents in training.<sup>2</sup> Another possible explanation could be the positioning of

the fluoroscopy equipment, which is handled by the medical team during the procedure.

In a study conducted by Aliaga et al, 105 patients who underwent F-URS were compared to 87 patients who underwent C-URS. The SFR in F-URS was 92.45%, and 94.25% in C-URS, with no statistically significant difference in complication rates of 2.9% versus 5.7%, respectively, similar to the rates reported in the literature. This shows that F-URS is a feasible and effective technique for treating ureteral stones.<sup>13</sup>

Tinoco et al also compared the results of F-URS and C-URS, finding similar SFR in both groups (90.1% in C-URS versus 82.5% in F-URS), with no significant difference in intraoperative complications, and similar postoperative complication rates (35% in C-URS versus 31.5% in F-URS), confirming the effectiveness and safety of fluoroless ureteroscopy in selected cases.<sup>17</sup>

The overall SFR was 76.96%, which was defined intraoperatively as fragments smaller than 3 mm and confirmed with postoperative CT between one and three months. Similar to Tinoco et al, we found no significant differences between the two procedures in terms of SFR (p=0.152) or intra- and postoperative complications (p=0.313), suggesting that fluoroscopy does not significantly improve these outcomes.<sup>17</sup>

Ahmed et al reported a 4.8% rate of ureteral injuries, whereas in our series, we encountered one case of a false passage, and one ureteral injury classified as grade III.<sup>4</sup>

RIRS was the most frequently performed procedure, with a higher number of cases in the conventional fluoroscopy group (59.02%) compared to the fluoroless group, where URS cases predominated (35.97%).

Patients and medical staff are exposed to a considerable amount of radiation during the diagnosis and treatment of this condition. A fourth-year urology resident in our hospital is exposed to an average annual cumulative radiation of 1.92 mGy, while third-year residents have an exposure of 1.45 mGy, second-year residents 1.49 mGy, and first-year residents 0.97 mGy, with a cumulative of 5.83 mGy.

Within the limitations of this study, it is a retrospective analysis relying on subjective reports of complications, and radiation exposure measurement largely depends on dosimeter usage during the procedure, as well as the use of protective equipment. These factors should be considered in future studies; however, the safety of the fluoroless surgery was demonstrated.

These findings suggest that the use of fluoroscopy during ureteroscopy does not confer a significant advantage in terms of surgical time, stone-free rates, or complications. Nonetheless, the choice of technique should be based on the surgeon's experience and the complexity of the stones.

Reducing radiation exposure may have positive benefits for both patients and surgical staff; it has been shown that simply alerting the surgeon can decrease the use of intraoperative fluoroscopy. This study provides evidence for future investigations.

#### **CONCLUSION**

This study demonstrates that ureteroscopy without fluoroscopy is a safe procedure for treating ureteral and renal lithiasis. This technique can be adopted in teaching hospitals when procedures are supervised, as it has shown an acceptable stone-free rate and minimal complication rate. However, current guidelines do not recommend this practice, so it should be employed in complex cases when available. Reducing radiation exposure may decrease associated side effects, providing positive benefits for both medical personnel and patients. Further studies should be conducted to support this evidence and encourage techniques that avoid fluoroscopy.

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Institutional Ethics Committee

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