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# Ureteroscopy in patients with coagulopathies is associated with lower stone-free rate and increased risk of clinically significant hematuria

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## ABSTRACT

*Purpose:* Patients with coagulopathy are at increased risk of peri-operative hemorrhage. The aim of the present study was to compare ureteroscopy (URS) in these high risk patients to those with normal bleeding profile.
*Materials and Methods:* Twelve patients with coagulopathies (Group I) undergoing 17 URS were included in the study [3 for biopsy of ureteral lesions and 9 for Holmium Laser Lithotripsy (HLL)]. A patient had Child B (MELD 11) cirrhosis, 6 patients were on warfarin, 3 patients on ASA, 1 patient on ASA and clopidogrel, and the last patient was on heparin. URS in Group I was performed without correction of coagulopathy. Group II consisted of 32 patients with normal bleeding profile who underwent 34 URS concurrently.
*Results:* Group I included 4 ureteral biopsies in 3 patients with suspicious ureteral lesions and 13 URS for HLL in 9 patients with nephrolithiasis. There were no significant differences between the two groups in terms of patient age, sex, percent of renal stones, median operative and fluoroscopy times. When compared with Group II, Group I had significantly larger median stone size (9.2 vs. 14.0 mm, p = 0.01) and significantly lower stone-free rate after first URS (94.1% vs. 69.2%, p = 0.04). However, after second URS, stone-free rates were comparable in both groups (92.3% vs. 100%, p = 0.9). Two (16.7%) patients with coagulopathy were readmitted due to gross hematuria. There were no post-operative complications in Group II.
*Conclusions:* Although URS in selected patients with coagulopathies is safe, it is associated with significantly lower stone-free rates and higher readmissions due to gross hematuria.

## ARTICLE INFO

***Key words:***
Ureteroscopy; lithotripsy; calculi; ureter; hematologic diseases

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## INTRODUCTION

Anticoagulants and antiplatelet agents are commonly used for prophylaxis of cardiovascular, cerebrovascular or venous thrombotic disease and post-implantation of mechanical valves and stents (1). Peri-operative management of these anti-coagulated patients presents a dilemma to the surgeon since patients on chronic anticoagulation therapy have multiple comorbidities thus increasing risks of adverse thromboembolic events following perioperative cessation of anticoagulation (2). Furthermore, surgery may have thrombogenic nature and a potential hypercoagulable state that

may result from a rebound increase in clotting factors after discontinuation of these drugs (3). Withdrawal of antiplatelet agents in the perioperative period is associated with higher risks than the maintenance of these medications (4). Several studies have reported coronary stent thrombosis after premature discontinuation of antiplatelet agents (5-7), resulting in increased post-operative myocardial infarction, peri-operative cardiac mortality, and overall mortality (5,6,8). Therefore, peri-operative maintenance on anti-platelet agents is recommended for low-hemorrhagic risk procedures after drug-eluting stents (9). Extracorporeal shock wave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL), laparoscopic or open stone surgery are contraindicated in patients with coagulopathies (10). Traditionally, bleeding diathesis is corrected and the anticoagulation therapy is withheld prior to any urological intervention to minimize surgical hemorrhage (11). However, despite pre-operative correction and apparently normal clotting parameters, patients with coagulopathy have a higher rate of complications and lower efficacy of SWL (12). The safety of URS and holmium laser lithotripsy in patients with coagulopathies without correction of the abnormality have been reported in 3 retrospective studies (10,13,14). Therefore, the aim of the present study was to expand the indications for URS in patients with coagulopathies and compare their outcome with concurrent patients with normal clotting parameters.

## MATERIALS AND METHODS

Retrospective review of prospectively collected data of patients undergoing URS by a single surgeon (SA) between July 2009 and January 2011 was performed. Twelve patients with coagulopathies undergoing 17 URS comprised Group I [3 for biopsy of ureteral lesions and 9 for Holmium Laser Lithotripsy (HLL)]. Thirty-two concurrent patients with normal clotting parameters who underwent URS and HLL served as the control group (Group II). All patients had routine pre-operative evaluation that included complete blood count, prothrombin time, partial thromboplastin test and International Normalized Ratio (INR). Pre-operative patient information including age, sex, stone/tumor size and location, co-morbidities, and indications for anticoagulation of patients with coagulopathies were collected. Intra-operative information such as operative time, fluoroscopy time, use of access sheath, stone-free status and any complications were recorded immediately post-operatively on research data forms. Post-operative outcome and complications especially hemorrhagic and thromboembolic events were recorded from office and hospital charts.

## TECHNIQUE

All ureteroscopies were performed under general anesthesia in lithotomy position. All patients received broad spectrum antibiotic prophylaxis. Under sterile conditions, cystoscopy was performed and Sensor™ (Microvasive Boston Scientific, Natick MA, USA) was inserted. At this point semi-rigid URS was performed to identify and address ureteral stones/tumors. Ureteral lesions were biopsied using Piranha™ cold-cup biopsy forceps (Boston Scientific, Natick MA, USA). Ureteral stones were lithotripsied using Holmium: YAG laser with either 200µ or 365µ laser fibers at 10W setting. Stones were fragmented and basked out using Zero Tip™ basket (Boston Scientific, Natick, MA, USA). Whenever possible, stones were fragmented and removed rather than pulverized. When the rigid ureteroscope did not reach the stone, then a second wire was placed, a 14-16 Peel-Away (Cook Urological, Inc., Spencer, Indiana, USA) ureteral access sheath was placed and a 7.5F Storz Flex-X™ ureteroscope was used for proximal ureteral stones and renal stones. At the end of the procedure, a 6F double pigtail indwelling ureteral stent was placed. When the vision became poor or URS took longer than 2 hours, a staged URS was scheduled. When patients were deemed stone-free ureteroscopically (≤ 3 mm), stents were removed a week later. Otherwise, patients were followed by serial KUB to assure stone-free status (≤ 3 mm) prior to removal of the ureteral stent. When significant residual fragments remained, a repeat flexible URS and basketing of stone fragments was scheduled a month later.

### Statistical Analysis

Data were analyzed using the commercially available Statistical Package of Social Sciences for Windows (SPSS, Chicago, IL), version 17. Descriptive data were presented in terms of percentages, range, medians and standard deviations. Continuous variables such as length of surgery, fluoroscopy time and stone size were compared with the Mann-Whitney U test. Fisher's exact test was used for categorical variables with two-tailed $p < 0.05$ being statistically significant.

## RESULTS

Twelve patients with coagulopathies with a median age of 63.5 years were included in Group I (9 males and 3 females). In terms of coagulopathy, a patient had Child B (MELD 11) cirrhosis with thrombocytopenia, 6 patients were on warfarin [4 for Deep Vein Thrombosis (DVT), 1 for atrial fibrillation, 1 for mechanical aortic valve], 3 patients were on acetylsalicylic acid (ASA) and another patient was on combination of ASA and clopidogrel for coronary artery disease and coronary stents, and the last patient was on low molecular weight heparin (Tinzaprin) for recent DVT/PE (Table-1).

A total of 17 URS with HLL or biopsies of suspicious ureteral lesions were performed in 9 and 3 patients, respectively. URS in Group I was performed without correction of coagulopathy or suspension of their anti-coagulation therapy. For the 9 patients with coagulopathies undergoing URS and HLL, the median maximum stone diameter was 14 mm (5 - 22 mm). However, 6 out of the 9 patients had significant stone burden including a lower pole partial staghorn (Table-1). When visibility was poor, a staged URS was performed to obtain stone-free status. Therefore, 2 out of 9 patients (22.2%) underwent a second URS and one patient required a third URS to achieve stone-free status. In one of the three patients with ureteral lesions undergoing URS and biopsy, the first biopsy was inconclusive. Therefore, a repeat URS with biopsy was performed.

Group II consisted of 32 patients undergoing 34 URS and HLL for 45 stones. There were no significant differences between the two groups in terms of patient age, sex, percent of renal stones, median operative time and fluoroscopy time (Table-2). However, Group I patients had significantly larger median stone size when compared with Group II (14.0 vs. 9.2 mm, $p = 0.01$) (Table-2). Due to poor vision, 3/12 (25%) patients in Group I and 2/32 (6%) patients in the control Group II underwent second URS to achieve stone-free status ($p = 0.11$). Stone-free rate after first URS was significantly lower in Group I compared with Group II (69.2% vs. 94.1%, $p = 0.04$). However, after the second URS, the stone-free rates were comparable in both groups (92.3% vs. 100%, $p > 0.05$). Calcium oxalate monohydrate represented the most common stone composition in both groups (67% and 43% respectively) followed by uric acid stones.

No patient had significant gross hematuria during the immediate post-operative period in both groups. However, the median post-operative level of hemoglobin significantly decreased in patients with coagulopathies when compared with controls (0.8 vs. 0.2 g/dL; $p = 0.001$).

Two patients (22 %) from Group I (patients 3 and 4) on warfarin therapy were readmitted for management of gross hematuria. Patient #3 in Group I was readmitted on post-operative day 47 post URS and biopsy of invasive TCC. Patient #4 in Group I had an INR of 3.14 and was readmitted on post-operative day 6 post URS and HLL. Both patients underwent continuous bladder irrigation and their anti-coagulants were withheld till hematuria resolved. They did not require transfusions. There were no post-operative complications in Group II.

## DISCUSSION

Ureteroscopy and holmium laser lithotripsy achieve a high stone-free rate of over 97% in ureteral calculi with only 6% of patients requiring an additional procedure (15). With increasing experience and miniaturization of flexible ureteroscopes, indications for URS have expanded to include large renal stones, children, pregnant women, and patients with coagulopathy (16). This is because endoscopic procedures with

**Table 1 - Characteristics of patients with coagulopathies (Group I) and indications of URS.**

| Pt. No. | Age | Sex | Type of coagulo-pathy | Anticoagulant/ bleeding diatheses | Indications of URS | No of URS | Stone composition / pathology |
|---|---|---|---|---|---|---|---|
| 1 | 59 | F | DVT | Warfarin | Partial staghorn stone (22 X 22 mm) | 2 | Uric acid dihydrate |
| 2 | 62 | M | DVT | Warfarin | UPJ stone (20X13 mm) | 1 | Struvite |
| 3 | 86 | M | Atrial fibrillation + DVT | Warfarin | Mid-ureteral mass (40X 20 mm) | 1 | High grade invasive TCC |
| 4 | 47 | M | Mechanical aortic valve | Warfarin | Lower pole stones (18 & 12 mm) | 3 | Calcium oxalate monohydrate |
| 5 | 78 | M | Recent atrial fibrillation | Warfarin | Obstructing UPJ stone (11X6mm) + renal gravel | 1 | Uric acid dihydrate |
| 6 | 58 | M | Coronary disease and stent | ASA | Distal ureteral stone (10X5 mm) | 1 | Carbonate apatite + Calcium oxalate |
| 7 | 70 | M | Coronary disease and stent, ESRD | ASA | Mid ureteral lesion (10mm) | 2 | Cytological atypia Ureteritis |
| 8 | 52 | M | Recent DVT/ PE | LMW heparin (Tinzaprin) | Lower pole kidney stones (14X10 and 9X7 mm) with UPJ stone (8X6 mm) | 2 | Calcium oxalate monohydrate |
| 9 | 62 | F | Child B, MELD 11 hepatic cirrhosis | Thrombo-cytopenia | UPJ stone (10 mm) and lower pole stone (5 mm) | 1 | Calcium oxalate monohydrate |
| 10 | 63 | M | Bilateral DVT | Warfarin | Upper ureteral stone (5 mm) | 1 | Calcium oxalate monohydrate |
| 11 | 44 | F | Coronary stent | ASA + Clopidogrel | Upper ureteral lesion | 1 | Chronic inflammation |
| 12 | 59 | M | Recent MI and CABG | ASA | Lower pole kidney stone (8 mm) | 1 | Calcium oxalate monohydrate |

**ASA:** acetyl salicylic acid; **DVT:** Deep Vein Thrombosis; **ESRD:** End Stage Renal Disease; **PE:** Pulmonary embolism; **MI:** myocardial Infarction; **CABG:** Coronary Artery Bypass Graft; **LMW:** low molecular weight; **UPJ:** uretero-pelvic junction; **PE:** pulmonary embolism; **PLT:** platelets; **POD:** post operative day; **TCC:** Transitional Cell Carcinoma

**Table 2 - Comparison of patients undergoing URS and laser lithotripsy.**

| Variable | Group I (n = 9) | Group II (n = 32) | P- Value |
|---|---|---|---|
| Median Age (yrs) | 60.0 | 53.5 | 0.27 |
| Male gender | 7 (78%) | 19 (59%) | 0.49 |
| Percent Renal Stones (# renal/ total) | 8/14 (57%) | 18/45 (40%) | 0.35 |
| Median stone size (mm) | 14 | 9.2 | 0.01 |
| Stone-free rate After 1st URS | 69.2% | 94.1 % | 0.04 |
| Stone-free rate After 2nd URS | 92.3 % | 100% | 0.9 |
| Median URS time (min.) | 60 | 60 | 0.21 |
| Median Fluoroscopy time (Sec) | 63 | 114 | 0.24 |

**Group I:** patients with coagulopathies; **Group II:** patients with normal clotting parameters.

low risk of hemorrhage such as URS and HLL can be performed without discontinuation of anticoagulation therapy (17). Thus, URS and HLL may be the only option for these patients with coagulopathies since they are often poor candidates for SWL or PCNL due to hemorrhagic and thromboembolic complications (10,13).

In the present study, 6 out of 9 patients (patients 1, 2, 4, 5, 8, 9) in Group I undergoing URS and laser lithotripsy had significant stone burden (Table-1). Traditionally, these patients would be treated with PCNL with correction of the coagulopathy. Discontinuing and re-initiating anticoagulation therapy in these high risk patients may have increased risk of hemorrhagic and thromboembolic complications. PCNL with reversal of anticoagulation has been previously described in 27 such high risk patients (2). However, two patients (7%) developed post-operative hemorrhage with one patient requiring angio-embolization. Another patient (4%) developed DVT with pulmonary embolism on POD 4 requiring IVC filter since he had developed hemorrhage when anticoagulation was initiated (2). Furthermore, the expense of bridging therapy (with low molecular weight heparin or intravenous heparin) is considerable (10). Therefore, the present study expands the indications for URS in patients with coagulopathies to those who are traditionally treated with PCNL with reversal of their anti-coagulation. This would be ideal for patients who cannot safely undergo withholding of anticoagulation.

The first series describing URS in patients with coagulopathies was by Kuo et al. (Table-3) (14). Eight patients with stone disease and 1 patient with upper tract TCC were treated by URS with the holmium laser (14). Six out of 7 patients who underwent laser fragmentation for calculi were stone free at 1 month, and no tumor recurrence was noted in the patient with TCC (follow-up of 4 months). One patient only had a post-operative bleeding complication related to the procedure, involving an episode of oliguria secondary to a small ureteral clot that was resolved with diuretics. Watterson et al. reported on a series of 25 patients who were anticoagulated either pharmacologically or by underlying systemic diseases (13). The overall stone-free rate after a single ureteroscopic procedure was 93%. There were no hemorrhagic complications in patients undergoing laser lithotripsy. One patient who underwent electrohydraulic lithotripsy developed a retroperitoneal hematoma necessitating transfusion (Table-3). Therefore, electrohydraulic litho-

**Table 3 - Comparison between the present series and previous published studies.**

| Study | No of Patients | Type of Study | Remarks | Complications |
|---|---|---|---|---|
| Kuo et al. (14) | 8 patients for urolithiasis + 1 upper pole TCC | Retrospective over 11 month period | Thrombocytopenia was corrected in I patient before URS | 1 Ureteral bleeding and 2 non-urological complications. |
| Watterson et al. (13) | 25 (30 URS for 29 stones) | Retrospective in 2 tertiary stone centers over 5.5 years | URS and HLL (20 ureter+ 9 kidney) Thrombocytopenia was corrected in one patient before URS | Retroperitoneal Hemorrhage in one patient (EH lithotripsy) |
| Turna et al. (10) | 37 URS+ HLL Renal calculi | Retrospective in 2 centers over 7 years | URS on active anticoagulants | Post operative hematuria > 3 days in 3 patients |
| Present series | 17 URS (HLL in 9 and biopsies in 3 patients) | Retrospective over 18 months | URS on active anticoagulants | Post operative hematuria in 2 patients requiring CBI |

**CBI:** continuous bladder irrigation; **HLL:** Holmium laser lithotripsy; **TCC:** Transitional cell carcinoma; **URS:** Ureteroscopy; **EH:** Electrohydraulic

tripsy must be avoided in this highly selected group of patients with coagulopathies (18). The Holmium: YAG laser has the ability to fragment calculi of all compositions including calcium oxalate monohydrate and it is an ideal intracorporeal lithotripter for ureteral calculi with a high success rate and low morbidity (19). Moreover, the Holmium: YAG laser has haemostatic properties that would be beneficial for treating patients with bleeding disorders (20). Therefore, it is ideal for fulguration of bleeders during biopsy of ureteral lesions in patients with coagulopathies.

Turna et al. compared a group of 37 patients on aspirin, clopidogrel, or warfarin with a cohort of matched controls without coagulopathy and found similar stone-free rates (81.1% versus 78.4%, p = 0.7) (10). However, the peri-operative hemoglobin change was significantly higher in the anticoagulated group (6 g/L vs. 2 g/L, p < 0.0001). In that study, there were no procedures terminated because of poor visibility. The authors reported 3 cases of hematuria of more than 3 days in patients with coagulopathies (Table-3).

In the present study, after the first URS, the stone-free rate was significantly lower in Group I when compared with Group II (69.2% vs. 94.1%, p = 0.04). This could be related to the fact that patients in Group I had significantly larger median stone size (14 vs. 9.2 mm. p = 0.01). Furthermore, two thirds (6 out of 9) of patients had significant stone burden that are ideally managed by PCNL. In the present study Group I, 2 out of 9 (22.2%) patients underwent a second URS and one patient required a third URS to achieve stone-free status. However, after a second URS, the stone-free rates were comparable in both groups (92.3% vs. 100%, p > 0.05). Similarly, in the study by Watterson et al., there was a second URS in 5 patients. Furthermore, in that study, a thrombocytopenic patient had correction of thrombocytopenia prior to URS. Thus, although URS and HLL are safe in these highly selected patients with coagulopathies, they may require more than one URS session for stone clearance. Larger sample size is required to verify these results.

Previous reports of URS and laser lithotripsy in patients with coagulopathies did not report stone composition. In the present series, most of the stones in both groups (67% in Group I and 43% in Group II) were composed of calcium oxalate monohydrate, which is one of the hardest stones to fragment (21). Therefore, this may have contributed to the lower stone-free rate in Group I.

Except for one patient reported by Kuo et al., there are no other reports in the literature about safety of URS and ureteral biopsy in patients with coagulopathies (14). In the present study, 3 patients underwent ureteral biopsies safely and efficiently while they were on anticoagulants. One of them developed a late hematuria (after 47 days). This was an 86-year old man on warfarin for repeated bilateral DVT and atrial fibrillation in addition to past medical history of hypertension, diabetes mellitus, and chronic renal failure. His preoperative INR was 2.89. After his diagnostic URS and biopsy, he underwent external beam radiotherapy for his 4 cm mid-ureteral invasive TCC. Therefore, his delayed hematuria could be related to other factors than the procedure itself such as the invasive TCC, indwelling ureteral stent, or radiation ureteritis. The other 2 patients underwent 3 ureteral biopsies on 3 occasions without complications indicating the safety of ureteroscopic biopsies in these patients with coagulopathies.

There are several limitations of the present study. Although the data were collected prospectively, this still remains a retrospective review of highly selected small cohort of patients with coagulopathies undergoing URS. Furthermore, the cohort with coagulopathies was diverse with multiple different therapies (antiplatelet and anticoagulation (Coumadin, LMW heparin)) undergoing two different procedures (biopsy and lithotripsy). Another limitation was that the INR on the day of the URS was not confirmed to be in the therapeutic level. It was only checked in the pre-operative evaluation.

## CONCLUSIONS

Although URS in selected patients with coagulopathies is safe, it is associated with significantly lower stone-free rates and higher readmission for management of gross hematuria. Prospective randomized studies with and without correction of the coagulopathy is needed to weigh the risks and benefits of correcting anticoagulation during ureteroscopy and laser lithotripsy or biopsy of ureteral lesions.

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## ABBREVIATIONS

ASA: acetyl salicylic acid
CBI: Continuous Bladder Irrigation
DVT: Deep Vein Thrombosis
ESRD: End Stage Renal Disease
HLL: Holmium Laser Lithotripsy
INR: International Normalized Ratio
LMW: low molecular weight
PCNL: Percutaneous Nephrolithotomy
PE: Pulmonary Embolism
PLT: platelets
POD: post operative day
SWL: Extracorporeal Shockwave Lithotripsy
TCC: Transitional Cell Carcinoma
UPJ: uretero-pelvic junction
URS: ureteroscopy

## CONFLICT OF INTEREST

None declared.

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## EDITORIAL COMMENT

A clinical problem that troubles urologists is how they should treat patients on anticoagulants. Interruption of anticoagulation therapy for elective urologic procedures in these patients generates a complex situation in which competing risks of thrombosis and bleeding must be weighed up; when anticoagulation is discontinued patients are at risk of cardiovascular complications, and when it is restarted they are at risk of hemorrhage (1,2). There is an increasing interest in the evaluation of the risk of operating on patients on ongoing anticoagulation due to technological advances (e.g. laser prostatectomy) and the growing aging population who suffers from cardiovascular co-morbid-

ities. However, the safety and efficacy of different procedures have not been well documented.

In the present study, Elkoushy et al. compared the outcomes of ureteroscopy (URS) in patients with coagulopathies with those with normal bleeding profile. It was found that although URS in selected coagulopathic patients was safe, it was associated with significantly lower stone-free rates and higher re-admission for gross hematuria. The main limitations of the study included its retrospective nature, the diversity of the study population (patients under different drugs with different properties) and the small number of patients enrolled (e.g. one could argue that the difference in patients who underwent 2nd URS due to poor vision did not reach statistical significance due to the small sample size). However, this study is useful because the authors add their experience to the limited existing literature and provide information which help urologists to better inform their patients about the potential risks and benefits of URS without stopping anticoagulation.

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