Is a Safety Guide Wire Necessary for Transurethral Lithotripsy using Semi-Rigid Ureteroscope? Results from a Prospective Randomized Controlled Trial

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Purpose: Experts recommend us to keep a safety guidewire during the process of upper urinary tract endoscopy, though there is a lack of high-level evidence to support the efficacy and safety of this opinion. This study was conducted to compare the outcome of ureteral stone breakage in the presence or absence of a safety guidewire.

Materials and methods: Patients candidate for endoscopic breakage of ureteral stone using a semi-rigid ureteroscope, were randomly assigned in two groups based on keeping a safety guidewire (group1) or removing the guidewire (group2) before the process of breaking ureteral stone by lithoclast. Demographic factors, history of previous stone treatment, kidney function, stone location, symptoms duration and severity were recorded for each patient. Primary outcomes included success rate of stone treatment and secondary outcomes included number of attempts to enter to ureter, success rate of ureteral entry, success rate of stone achievement, stone migration rate and the success rate of ureteral stent insertion.
The recorded data were entered to the SPSS software and descriptive statistical analysis including power calculation and non-inferiority design for the primary and secondary outcomes, was performed. P-value less than 0.05 was considered significant.

Results: From January 2016 till May 2018, 320 patients were randomized with 160 patients in each arm. Considering the cases who were missed due to follow-up loss, there were 153 patients in group 1 and 147 patients in group 2 at the end of the study. Baseline data were equally distributed in both groups. Based on the initial analysis, the studied variables had no significant difference between two groups; though, according to the subgroup analysis of patients with proximal ureter stones, patients in Group 1 had higher rates of ureteral injury comparing to the patients in Group 2 ($p = 0.03$).

Conclusion: According to our findings, keeping the safety guidewire through the process of endoscopic stone breakage (stone size: less than 1.5Cm) seems to add no significant benefit to the procedure outcome, while it increases the ureteral injuries in the proximal ureter stones, but not in mid or distal ureter stones.

Keywords: ureteroscopy; safety guide wire; randomized controlled trial

INTRODUCTION

During the past decade, we have witnessed a significant change in the treatment armamentarium and treatment algorithm for the management of urinary stones. On one hand, this has been fueled by the development of smaller sized endoscopic instruments for ureteroscopy, flexible endoscopes for retrograde intrarenal surgery, and miniaturization of percutaneous endoscopes[1-3]. On the other hand, the centralization of care has resulted in high volume centers with specialist care performed by surgeons with a high-level experience resulting in better surgical outcomes and fewer complications[4].
Guidelines recommend the use of a safety guidewire to secure safe access to the ureter during ureteroscopy for the treatment of urinary stones[5]. A possible ureteral lesion or even avulsion may result in a complicated procedure once a safety guidewire is not in place[6,7]. Regardless of the complication, the safety guidewire ensures the ability to place a ureteral stent at the end of a ureteroscopic procedure[8]. However, one may ask if the historical dogma of always using safety guidewires in endourologic procedures is still applicable? While nowadays, the endourological environment has raised the safety and precision of the procedure to a new level that may alleviate the routine use of a safety guidewire. On the other hand, some reports showed disadvantages regarding the use of safety guidewires during ureteroscopy[9]. The forces needed to insert and retract the endoscope during ureteroscopy with a safety guidewire in place are considerably higher when compared with procedures that not include a safety guidewire[10]. Although not completely confirmed, this fact raises the

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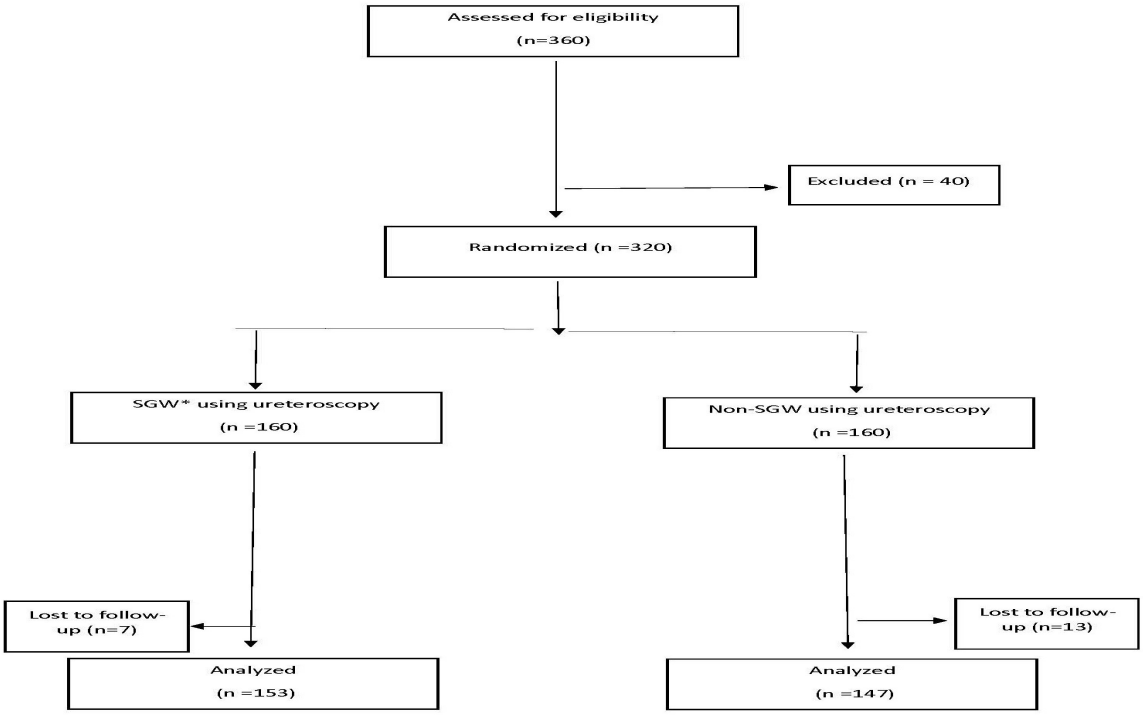

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram.
*SGW: Safety guide wire

question if actually, the placement of a safety guidewire could eventually increase the risk of harming the ureter in some patients[11].

Foregoing reports show successful ureteroscopy without any guidewire in place. However, none of them are high power randomized clinical studies and could not address the question of whether a safety guidewire is necessary during ureteroscopy or not. Therefore, this randomized clinical study was designed to compare the efficacy and safety of ureteroscopy with and without a safety guidewire in patients with ureteral stones.

METHODS AND MATERIALS

This prospective randomized trial was registered at http://www.clinicaltrials.gov (Unique Protocol ID: Q12133) and received approval from the Urology and Nephrology Research Center (UNRC) (Ethical code: IR.SBMU.UNRC.1396.41). The study was conducted from January 2016 to May 2018 and enrolled patients ($\geq$ 18 years old) with ureteral stones ($\leq$ 1.5 cm) that didn't pass the stone spontaneously within two weeks following diagnosis. Patients with ureter stones $\leq$ 1.5 cm, confirmed via ultra-sonography and non-contrast enhanced computed tomography (CT).

Exclusion criteria included pregnancy, pelvic kidney, transplant kidney, uncorrected coagulopathy, skeletal disorder, history of ureteral stenosis, history of ureteral surgery, positive urine culture, any urinary diversions and need for emergency ureteroscopy.

Of the 360 patients treated for ureteral stones during the study period, 40 patients were excluded because of exclusion criteria. Of the remaining 320 patients, 153 received ureteroscopy with a safety guidewire (group 1), and 147 received ureteroscopy without a safety guidewire (group 2). The discrepancy between the numbers is because of lost to follow-up (**Figure 1**).

Intravenous second-generation cephalosporin or ciprofloxacin was administered 30 minutes before the induction of anesthesia in all cases. All ureteroscopy started with an 8-french semi-rigid ureteroscope, and if there was stricture or tightness in moving the ureteroscope, a 6-french semi-rigid ureteroscope was also used.

Assessment baseline data including age, gender, body mass index, stone location, ureteral side, stone surface, the status of kidneys (single or double), degree of hydronephrosis (according to society of fetal ultrasound), pain severity and serum creatinine were captured. The pain was evaluated with a visual analog scale (VAS) with scores ranging from zero to 10 (0 for no pain and 10 for intolerable pain).

Based on a table of random numbers generated by random allocation software, the patients were assigned to two groups: ureteroscopy with safety guidewire versus ureteroscopy without safety guidewire and the surgeries were conducted by residents that had an experience of at least 100 ureteroscopy during their education. The pre-operative, baseline characteristics of the two groups are shown in **Table 1**.

The primary outcome was the rate of ureteral injuries. The ureteral injuries were graded according to the European Association of Urology guidelines: grade I: Mucosal abrasion; grade II: Ureteral perforation; grade III: Intussusception/avulsion. Secondary outcomes included peri-operative data (number of attempts to enter to the ureter, the success rate of ureteral entry, the success rate of stone access, stone migration rate, the success rate of ureteral stent insertion, operative time, conver-

Table1. The pre-operative, baseline characteristics of the two groups

Characteristic	Safety guide wire (n=153)	No safety guide wire (n=147)	*P* value
Age (year)	43.64 ± 12.66	41.99 ± 11.73	0.24
Gender (male)	124 (81%)	106 (72.1%)	0.08
BMI	28.2 ± 10.12	26.3 ± 9.31	0.35
Stone surface (mm2)	63.12 ± 9.12	56.14 ± 9.43	0.36
Time of symptom to treat (day)	25.16 ± 23.64	22.20 ± 33.68	0.38
Preoperative creatinine	1.39 ± 1.10	1.44 ± 1.90	0.77
Pain severity	1.91 ± 1.06	2.09 ± 1.03	0.37
Solitary kidney	8 (5.2%)	5 (3.4%)	0.57
History of stone treatment	18 (11.8%)	10 (6.8%)	0.17
History of abdominal surgery	28 (18.3%)	25 (17%)	0.88
Side of ureteral stone (right)	79 (51.6%)	64 (43.5%)	0.17
Ureteral stone location			
Proximal	33 (21.6%)	32 (21.8%)	0.25
Middle	55 (35.9%)	40 (27.2%)	
Distal	64(41.8%)	75 (51.0%)	
Severity of hydronephrosis			
No	7 (4.6%)	9 (6.2%)	0.86
1	57 (37.3%)	53 (39.5%)	
2	52 (34%)	47 (32%)	
3	30 (19.6%)	23 (15.6%)	
4	7 (4.6%)	10 (6.8%)	

Data was presented as n (%) and mean ± SD.
BMI: Body Mass Index

sion to open surgery) and postoperative data including 2 weeks and 3 months' success rate of stone treatment (residual stone < 4mm), pain severity, and presence of hydronephrosis.

The minimum number of required samples in each of the two groups using the following statistical relationship is 134 patients in each group[12]:

$$n \geq \frac{(z_\alpha + z_\beta)^2 (P_1(1-P_1) + P_2(1-P_2))}{(\varepsilon - \delta)^2}$$

$$P_1 = 0.50$$
$$P_2 = 0.60$$
$$\varepsilon = P_1 - P_2 = 0.1, \quad \delta = -0.05$$
$$\alpha = 0.05 \Rightarrow z_{1-\alpha} = 1.64$$
$$\beta = 0.20 \Rightarrow z_{1-\beta} = 0.84$$

Considering about 20% of the sample loss, 160 patients in each group were included.

Statistical analysis

Neither the examiner nor the patient was aware of the type of treatment that was used during the evaluation. Thus the data recorded for each follow-up evaluation were double-blind. If the data were distributed normally, we used an independent t-test to compare means. Otherwise, the Mann Whitney test was used. Categorical data were compared between groups using chi-square or Fisher exact tests. We performed analysis using SPSS software (version 20.0 for Windows). The statistical significance was set to $p < 0.05$.

Endoscopic Technique

All procedures were performed with 8 and 6 French (Fr) Wolf urethroscopes. In order to have a better visibility and smooth passage of devices such as Double-J

Table2. Peri and post-operative outcomes between two groups

Outcome	safety guide wire (n=153)	No safety guide wire (n=147)	*P* value
Size of ureteroscope			
6	24 (15.7%)	15 (10.2%)	0.17
8	129 (84.3%)	132 (89.8%)	
Number of attempts to enter to ureter	1.6 ± 1.3	1.5 ± 1.4	0.34
Success rate of ureteral entry	152 (99.3%)	145 (98.6%)	0.62
Success rate of stone achievement	147 (96.1%)	140 (95.2%)	0.78
stone migration rate	42 (27.5%)	29 (19.7%)	0.13
Success rate of ureteral stent insertion	152 (99.3%)	147 (100%)	0.99
Severity of ureteral injury*			
No	79 (51.6%)	93 (63.3%)	0.18
I	51 (33.3%)	40 (27.2%)	
II	20 (13.1%)	13 (8.8%)	
III	3 (2.0%)	1 (0.7%)	
Operative time (min)	24.5 ± 11.5	25.1 ± 10.7	0.65
2-week follow up			
Success rate of stone treatment	120 (78.4%)	124 (84.4%)	0.24
Pain severity	0.54 (0.63)	0.51 (0.61)	0.64
No hydronephrosis	93 (60.8%)	100 (68.0%)	0.58
3-month follow up			
Success rate of stone treatment	147 (96.1%)	143 (97.3%)	0.75
Pain severity	0.08 (0.28)	0.12 (0.32)	0.38
No hydronephrosis	148 (96.7%)	143 (97.3%)	0.79

Data was presented as n (%) and mean ± SD; *Ureteral injury as in European association guideline including I: Mucosal abrasion; II: Ureteral perforation; III: Intussusception / avulsion
Observation: hydronephrosis decreases with time.
Question: how many had hydronephrosis at baseline

Table 3. The pre-operative, baseline characteristics of the two groups for proximal ureteral stones

Characteristic	Safety guide wire (n=33)	No safety guide wire (n=32)	*P* value
Age (year)	43.75 ± 11.95	42.31 ± 13.30	0.65
Gender (male)	27(81.8%)	19 (59.4%)	0.047
BMI	26.9 ± 8.32	27.3 ± 10.11	0.43
Stone surface (mm2)	56.32 ± 11.10	52.13 ± 9.61	0.52
Time of symptom to treat (day)	20.15 ± 10.84	18.87 ± 13.30	0.67
Preoperative creatinine	1.35±0.7	1.58 ± 1.84	0.51
Pain severity	1.78±1.08	1.84 ± 0.98	0.83
Solitary kidney	1(3%)	2 (6.3%)	0.613
History of stone treatment	6(18.2%)	5 (15.6%)	0.783
History of abdominal surgery	1(3%)	6 (18.8%)	0.054
Side of ureteral stone (right)	21(63.6%)	15 (46.9%)	0.174
Severity of hydronephrosis			
No	2 (6%)	0 (0%)	0.269
1	10 (30.3%)	9 (28.1%)	
2	14 (42.4%)	14 (43.8%)	
3	6 (18.2%)	4 (12.5%)	
4	1 (3%)	5 (15.6%)	

Data was presented as n (%) and mean ± SD.
BMI: Body Mass Index

through the ureters, all procedures was operated initially by 8-Fr ureteroscope. The procedure was continued by a 6-Fr ureteroscope, in cases there was a clear stricture that make it difficult to pass through the ureter.. In the next step, cystoscopy was performed to visualize the bladder, exclude any gross lesion, and to localize the ureteric orifice. Then, a safety guidewire was passed through the ureteric orifice into the ureter,the ureteroscope followed the route and continued until reaching the stone. From this point forward, we divided the cases into two groups based on the presence or absence of safety guide wire in the process of stone breakage; For "Group 1" the guidewire was gently guided forward to pass the stone and was inserted in the ureter after the stone (and if it was not possible to pass the stone, the guidewire was inserted beside the stone). Ureteroscope was ejected and reinserted in the ureter using a new guidewire; By the next step, the stone was broken by Lithoclast, both guide wires were removed and the ureteral stent was inserted. For "Group 2" the guide wire and ureteroscope were guided through the ureter to the stone location, then the guide wire was removed and Lithoclast was installed to break the stone. Then, the ureteroscope and lithoclast were removed and the ureteral stent was inserted. The ureteral stent was removed after four to six weeks in both groups of patients.

RESULTS

The Consolidated Standards of Reporting Trials (CONSORT) diagram in Figure 1 shows the process for participant inclusion. The pre-operative such as the history of stone surgery, history of stone treatment, ureteral stone location, and ureteral stone side were not significantly different between the two groups ($p > 0.05$) (**Table 1**).

The severity of ureteral injury according to the European Association of Urology (EAU) grading was not significantly different between the two groups ($p = 0.18$). Peri-operative outcomes included the success rate of

Table4. Peri and post-operative outcomes between two groups for proximal ureteral stones

Outcome	Safety guide wire (n=33)	No safety guide wire (n=32)	*P* value
Size of ureteroscope			
6	8 (24.2%)	1 (3.1%)	0.03
8	25 (75.8%)	31 (96.9%)	
Number of attempts to enter to ureter	1.51±0.79	1.22±0.66	0.03
Success rate of ureteral entry	33 (100%)	32 (100%)	-
Success rate of stone achievement	32 (97.0%)	31(96.9%)	-
stone migration rate	14 (42.4%)	10 (31.3%)	0.44
Success rate of ureteral stent insertion	33 (100%)	32 (100%)	-
Severity of ureteral injury*			
No	15 (45.5%)	23 (71.9%)	0.03
I	12 (36.4%)	6 (18.8%)	
II	6 (18.2%)	3 (9.4%)	
III	0	0	
Operative time (min)	25.3±12.5	26.1±11.4	0.51
2-week follow up			
Treatment success rate	20 (60.6%)	26 (81.3%)	0.10
Pain severity	0.54 (0.56)	0.53 (0.62)	0.92
No hydronephrosis	21 (63.7%)	19 (59.4%)	0.37
3-month follow up			
Treatment success rate	30 (90.9%)	28 (87.5%)	0.71
pain severity	0.06 (0.24)	0.06 (0.25)	0.97
No hydronephrosis	32 (96.9%)	32 (100%)	0.53

Data was presented as n (%) and mean ± SD; *Ureteral injury as in European association guideline including I: Mucosal abrasion; II: Ureteral perforation; III: Intussusception / avulsion

stone achievement, stone migration rate, the success rate of ureteral stent insertion were not significantly different between the two groups (**Table 2**).
Post-operative follow-up showed no significant difference between two groups at 2 weeks and 3-month (**Table 2**). Also, we performed an outcome analysis based on the stone location. While there was no significant difference between the two groups with proximal ureteral stone (**Table 3**), a higher rate of injuries was found when using a safety guidewire compared to not using a safety guidewire in patients with proximal ureteral stone (**Table 4**) (p = 0.03).

DISCUSSION

This well-powered study confirms that overall outcomes of semirigid ureteroscopy (URS) not using a safety guidewire is not inferior to semirigid ureteroscopy using a safety guidewire. However, for patients with proximal ureter stones, the use of a safety guidewire resulted in a higher injury rate when compared to patients treated without a safety guidewire. This finding provides new insights into the position of the use of safety guidewire for semirigid ureteroscopy.
The use of a safety guidewire during endoscopic procedures in the upper urinary tract was originally intended to help straighten and stabilize the ureter, allow navigation through edematous, narrowed or otherwise defective sections, and facilitate placement of ureteral stents when necessary. Since the advent of ureteroscopy in the late 1980s, however, advances in technology have led to the development of a smaller caliber ureteroscope [(7)].
Besides, urologists have become increasingly experienced with ureteroscopic procedures, and some urologists forego the use of the safety wire in routine cases to improve visualization and manipulation of the ureteroscope. Ulvik and colleagues evaluated diversities in Norwegian urologists' personal preferences in the endoscopic management of ureteral calculi and showed a safety guidewire was routinely inserted alongside the ureteroscope by 79.3% of the physicians, while the rest employed a safety guidewire only in complicated cases [(13)].
Dickstein and colleagues have performed a retrospective chart review to determine the safety and feasibility of dispensing with the guidewire in patients undergoing ureteroscopy for renal or ureteropelvic junction stones and showed no intraoperative complications, including loss of access, ureteral perforation or the need for a percutaneous nephrostomy tube[(14)]. They concluded that the use of a safety guidewire is not necessary for routine cases of ureteroscopic laser lithotripsy in patients with an uncomplicated ureteropelvic junction or renal stones. However, they recommend that a safety wire should still be used in complicated cases, such as those involving encrusted ureteral stents, ureteral strictures, urinary diversions, or concomitant ureteral stones. However, this study is retrospective evaluation and suffers from a level of evidence to confirm this concept. Our study using randomized controlled design has shown, no inferiority in complication rates for not using a safety guidewire compared when using safety guidewire for ureteroscopy on the other hand higher rate of injuries was found in the safety guidewire group compared with non-safety guidewire groups in upper ureteral stones.
Eandi and colleagues examined a porcine animal model to evaluate the impact of the presence of a safety guidewire during ureteroscopy and showed the presence of a safety guidewire adjacent to the endoscope inhibits the passage of the ureteroscope in an in vitro animal model [(15)]. Ulvik and colleagues iv an in vivo study investigated whether the presence of a safety guidewire during ureteroscopy in a normal clinical setting will influence pushing and pulling forces exerted on a semirigid ureteroscope and showed the safety guidewire may even increase the risk of ureteral injuries[(9)].
Johnson and colleagues studied retrospectively a single-surgeon prospective database of flexible ureteroscopy and showed stone-free rates after primary treatment of ureteral calculi were 93, 96, and 100% for a proximal, middle and distal third location, respectively. Our results are in agreement with this study, but in a randomized controlled study manner and using semi-rigid ureteroscope[(16)].
There are only two comparative studies available in the literature that studied the role of a safety guidewire for semi-rigid and flexible ureteroscope. Moran and Bratslavsky[(17)] compared a total of 340 none using safety guidewire flexible ureteroscopy with 1,500 using safety guidewire laser lithotripsies. Targeted stone destruction occurred in 98% of these cases and the stone-free rates were lower (326/340) for those that did not use a safety guidewire. Failures in this cohort were infrequent and occurred in seven patients with high-grade obstruction and/or impacted calculi. On the other hand, in the entire series of 1,500 patients, the targeted stone destruction occurred in 98% and the stone-free rate was 96%, with results identical to the technique without the safety wire. There were no complications in the group without a safety wire secondary to loss of upper tract access.
In this study, only flexible ureteroscopy was performed, which is not available in all centers because of cost and special expertise and the design of the study is the collection of the data from non-randomize trials.
Ulvik et al. compared the results of URS for the treatment of ureteral stones at two different hospitals where the safety guidewire was either routinely used or omitted[(13)]. The reported success rates of passing the ureteroscope through the ureteral orifice, the ability to access the ureteral stone, and the ability to place a ureteral stent when needed after the endoscopy were not significantly different between the two groups of patients. There was no significant difference in the overall intraoperative complication rates at the two hospitals. The overall stone-free rates were 77.1% and 85.9% with and without the safety guidewire. According to the stone location, the stone-free rates were 61.2 and 70.2% for upper, 72.6, and 81.1% for mid, and 89.8 and 93.9% for distal ureteral stones with and without safety guidewire, respectively. A significant increase in the number of patients (14 patients, 3.4%) was found to have post endoscopic ureteral stenosis at the hospital where the safety guidewire was routinely used than at the hospital where a safety guidewire was omitted (six patients, 1.2%). Although this study confirms our results, it is obvious that this is not RCT and may contain many biases regarding patient selection, technical aspect, and level experience of operators.
Our results were in agreement with these two studies, however, we have not found any post-operative stenosis in our patients.
To our best knowledge, our study is the first randomized controlled trial comparing using or not using safety

guidewire in the new era of endourology practice. Moreover, the procedures were performed by residents. This makes the current data even more generalizable. It may be needed further study with a larger number of patients to evaluate this concept more precisely.
One of the limitations of the study is that the surgery was not performed by a specific surgeon. In addition, we can mention the other limitation is being small number of patients in each group.

CONCLUSIONS

Not using a safety guidewire has not resulted in inferior outcomes compared with using a safety guidewire in the endoscopic management of ureteral stones less than 1.5Cm.

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