The Evaluation of the Result of Warm Normal Saline Irrigation in Ureteral Endoscopic Surgeries: A Randomized Clinical Trial

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Purpose: Transurethral lithotripsy (TUL) is a major modality for the endoscopic management of ureteral stones. Ureteral spasm makes access for ureters difficult, which causes impaction of the ureteroscope, ureteral dislodge, and a low success rate of endoscopic surgeries. This study described the outcomes of a new endoscopic surgical experience by use of 40-degree warm saline irrigation during TUL compaired with routine ambient air irrigation in TUL.

Materials and methods: In this randomized clinical trial from 2014 to 2015, 150 patients with ureteral stone with balanced randomization were divided into two parallel groups. Patients underwent TUL in the first group with 20–25 degree saline irrigation and in the second group with 40-degree saline irrigation. One surgical team with the same semi-rigid instrument performed all TULs and the other steps were similar in both groups. Complete stone fragmentation was measured as the primary outcome and the duration of procedure, retrograde stone migration and all and any intraoperative complications were the secondary measurements.

Result: While comparing warm saline irrigation with cold saline irrigation, the rate of access to upper ureter was 95% versus 72%, stone retropulsion frequency was 10.7% versus 30.7% and the stone-free rate was 96% versus 76% respectively ($P < .05$). There was no ureteroscope impaction and ureteral dislodge in both groups.

Conclusion: Using warm saline irrigation in endoscopic surgeries results in better surgical outcomes including a lower ureteral spasm rate, greater ureteral muscle relaxation and better access to the upper ureteral zone, and a lower rate of complications, such as ureteroscope impaction, ureteral dislodge and stone retropulsion.

Keywords: lithotripsy; ureteroscopy; ureteral dislodge; warm saline; irrigation.

INTRODUCTION

Endoscopic ureteral surgeries are the most common urologic surgeries, including diagnostic ureterostomy, strictures and obstruction treatments, stone lithotripsy, resection and fulguration of ureteral tumors.[1] Urolithiasis is a common urological problem. Ureteral stones can cause severe morbidity and pain. After failed medical therapy and if intervention is indicated, then various modalities would be available, such as extra corporeal shock wave lithotripsy (ESWL) and ureteroscopic management.[1–3] The choice of intervention depends on many factors, including stone size and location, available instruments and surgical team experience. Transurethral lithotripsy (TUL) is a major modality for endoscopic management of ureteral stones. One of the risk factors in difficult access of ureters is ureteral spasm, which causes the impaction of the ureteroscope, ureteral dislodge, and a low success rate of endoscopic surgeries. Difficult access and retrograde stone migration are two main problems during TUL, which could require additional instruments such as ureteral dilators, stone retrieval devices, or additional procedures like Re-TUL or ESWL[4, 5], which can cause additional morbidity and cost. By the invention and use of new endoscopic instruments, ureteral endoscopic surgeries are more common. Nowadays, diagnostic ureteroscopy, TUL, ureteral stones, treatment of ureteral obstructions and resection and fulguration of ureteral tumors are the most common endoscopic urologic surgeries.

Transurethral lithotripsy is one of the best modalities for ureteral stone management. TUL with semi-rigid ureteroscope is one of the most common techniques for this purpose. However, difficult ureteral access and retrograde stone migration are some of the common problems associated with this method.[5–7] Additional medications or interventions like tamsulosin therapy, lidocaine jelly, Dj placement, re-TUL or ESWL could be necessary to manage migrated or residual fragments.[2,9-14] There are some maneuvers, such as the reverse Trendelenburg position, to prevent stone retropulsion, and there are some devices like stone baskets, N-trap and stone cone that can solve the problem. All of these entail additional morbidity and costs.[2,4,8,15,16] The thickening of the tip to the end of the ureteroscope instrument may result in ureteral spasm and ureteroscope impaction, and result in ureteral spasm and difficultness in procedures of endoscopic surgery. In such situations, ureteral dislodge may occur as well. Since 1993, with the use of the first pneumatic lithoclast device in Iran in the urological department of Ghaem Hospital in Mashhad, ureteral endoscopic surgeries began, and everyday, many patients underwent TUL and other endoscopic procedures. After a few years, we found out that in cases of cold water irrigation during TUL, we had more ureteral spasms around the ureteroscope instrument, which led to lower access to the upper ureter. We also had two

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Table 1. Demographic characteristics of patients in the intervention and control groups

		Ambient air group (Group 1)	40°c irrigation fluid (Group 2)	*P*-value
sex	Female Number (%)	32 (42.7)	25 (33.3)	0.23
	Male Number (%)	43 (57.3)	50 (66.7)	
Age, years; mean (SD)		33.4 (8.6)	35.9 (8.8)	0.08

cases of ureteroscope impaction in the ureter, which resulted in ureteral dislodge during 10 years. In the last two decades, with the use of warm 40-degree saline irrigation during TUL, we had better surgical outcomes, and ureteral dislodge or ureteroscope impaction were not seen. In this study, we describe our experience and outcomes of warmed saline irrigation during semi-rigid ureteroscopy and TUL in patients with ureteral stone.

PATIENTS AND METHODS

Study population

The participants of this study were patients who were diagnosed with ureteral stone. From May 2014 to May 2015, 150 consecutive patients with 170 ureteral stones were treated at our Urologic Department with pneumatic TUL (TULp). Active urinary tract infection, pregnancy, bilateral stones or single functional kidney were the exclusion criteria. In this study, the criteria for successful operation are the small size of the remaining stone (less than 4 mm) and patients without urinary tract obstruction and hydronephrosis and those totally asymptomatic. Sample size was determined based on the study of John TT, with the statistical formula of comparable proportions with a dichotomous outcome between two samples: Type I error of 0.05 and Type II error of 0.2, $p1 = 0.87$ and $p2 = 0.68$. These resulted in 75 samples in each group.

Study design

This study was a prospective single-center, parallel-group randomized clinical trial with balanced randomization. The block size was 4 and all possible balanced combinations of assignment within the block were calculated. Blocks were then randomly chosen to determine the patients' assignment into the groups: all block sizes were the same and the SPSS software was used for block randomization.

After the local ethics committee's approval and informed consent, the patients included were randomly allocated into two groups using block randomization method, so that each group contained 75 patients. Patients and analyzers were blinded to the randomization group. The co-researcher determined patient allocation and one assistant with the surgeon made the interventions and measured outcomes.

Patients who underwent TULp with ambient temperature irrigation (22–24°C) were assigned to Group 1, and patients who underwent TULp with warmed irrigation fluid (40□C) were assigned to Group 2. In all patients, routine complete blood count, blodd urea nitrogen, Creatinine, urine analysis and culture were performed preoperatively, and prophylactic intravenous antibiotics were administered. Using general anesthesia in the lithotomy position, a semi-rigid ureteroscopy was performed (8–8.9 semi-rigid ureteroscope–Wolf, Germany), and safety wire was placed. After ureteral access and identification of the stone in the ureter, the stone

Table 2. Results of 40°c warmed irrigation fluid versus ambient air group

			Ambient air group (Group 1)	40°c irrigation fluid (Group 2)	*P*-value
Stone side	Right	35	38		0.62
		46.7%	50.7%		
	Left	40	37		
		53.3%	49.3%		
Stone location	Upper ureter	7	8		0.65
		9.3%	10.7%		
	Mid ureter	23	18		
		30.7%	24.0%		
	Lower ureter	45	49		
		60.0%	65.3%		
Fragmentation / migration	Complete with out migration	52	67		0.002
		69.3%	89.3%		
	Incomplete or migrated	23	8		
		30.7%	10.7%		
stenting	none	51	65		0.006
		68.0%	86.7%		
	dj	24	10		
		32.0%	13.3%		
complications	no	50	59		0.09
		66.7%	78.7%		
	yes	25	16		
		33.3%	21.3%		
Stone free at 2w	free	57	72		< 0.001
		76.0%	96.0%		
	residue	18	3		
		24.0%	4.0%		
Re TUL/ ESWL	no	57	72		< 0.001
		76.0%	96.0%		
	yes	18	3		
		24.0%	4.0%		

Table 3. Comparison of complications between 2 groups

			complications				Total
			none	bleeding	failed access	mucosal tear	
group	ambient air	Count	50	12	7	6	75
		% within group	66.7%	16.0%	9.3%	8.0%	100.0%
	40°C	Count	59	14	0	2	75
		% within group	78.7%	18.7%	0.0%	2.7%	100.0%
	Total	Count	109	26	7	8	150
		% within group	72.7%	17.3%	4.7%	5.3%	100.0%

was fragmented by pneumatic device (TULp). All steps were similar in Group 1 and 2. The only difference was the irrigating fluid temperature. The duration of the procedure, complete stone fragmentation, retrograde stone migration and any intraoperative complications were recorded for each patient. The next day, KUB was performed to assess the probable stone migration or residual stone fragments. Two weeks later, patients were re-evaluated by sonography and spiral CT scan.

Outcome assessment

Complete stone fragmentation was measured as the primary outcome and the duration of procedure, retrograde stone migration and any intraoperative complications were the secondary measurements.

Data analysis was performed using SPSS software (Statistical Package for the Social Sciences, V. 16.0; SPSS Inc., Chicago, IL, USA), by using *T*-test and chi-squared test. A *P*-value less than 0.05 was considered statistically significant.

RESULTS

Of 150 patients, 93 (62%) were male, and 57 (28%) were female. The mean age of the participants was 34.06 years (SD = 9.4), with no significant difference between male and female (**Table 1**).

In both groups, the locations of stones were in similar sites of ureter (*P* =. 65) and the location of stones in both groups was not significantly correlated with the results (**Table 2**).

The mean (SD) of stone size in Group 1 (cold saline irrigation) was 8.7(1.8) millimeters, while in Group 2 (warm saline irrigation), it was 9.8(2.5), (*P* = .001). Since the mean size of stones in the 40-degree irrigation fluid group was greater than in the control group, this showed that even in larger stones, the use of warm saline irrigation was more successful.

Warmed irrigation fluid improved TULp results. The rates of re-intervention (Re TUL or ESWL) was 24% and 4% in Groups 1 and 2 respectively. The mean (SD) time of TULp in Group 1 was 27.6 (6.6) minutes while in Group 2 it was 24.4 (69), (*P* = .004). Two weeks later, TULP stone-free rates by KUB/USG or CT were 76% in Group 1 and 96% in Group 2. We analyzed data on the time of operation, stone-free rates at two weeks, rates of complications, and need to re-intervene in both groups. The rates of complications (bleeding, failed access, mucosal tear) were 33.3% and 21.32% in Groups 1 and 2. The rate of access to the upper ureter with warm saline irrigation was 95% against 72% with cold saline irrigation. Lower stone retropulsion with warm saline irrigation was 10.7% against 30.7% with cold saline irrigation. We have not seen any uretrescope impaction and ureteral dislodge in both groups.

DISCUSSION

By using warm saline irrigation in endoscopic surgeries, we described better surgical outcomes: these included lower ureteral spasm rate, more ureteral muscle relaxation, and better access to the upper ureteral zone and lower rate of complications like uretroscope impaction and ureteral dislodge. In this study, we used warmed irrigation fluid during TULp to improve ureteral access, prevent stone retropulsion and increase stone free rate, with minimal cost and morbidity. We compared these outcome measures between two groups. Group 1, with ambient temperature irrigation fluid, and Group 2, with 40□C irrigation fluid. The results were in favor of Group 2, which showed better ureteral access, lower stone retropulsion, and a greater stone-free rate. Also, the mean operative time was in favor of Group 2. This demonstrates warmed irrigation fluid as an effective way to improve TULp results. There were some limitations to our study. We did not have access to flexible ureteroscopy and could not compare our results with it. We also feel that a larger series is required to confirm our results. We did not have a flexible ureteroscope and that was the main limitation of our study. However, flexible ureteroscopy is more expensive, and a well-done TULp could be an acceptable alternative to laser lithotripsy, and is also more cost-effective.

The reason of these method success is due to ureteral muscle relaxation with use of warm saline irrigation. This may facilitate ureteroscope passage and better stone access and also no use of high pressure saline irrigation, which may lead to the stone being pushed back. This ureteral dilatation may also facilitate spontaneous passage of small stones.(20)

In the study performed by Basiri and coworkers, stone removal was performed by the use of balloon for ureteral dilatation and electrohydraulic and basket combination in 60 patients: the rate of success was 84.6%, which was lower than our success rate (96% of our patients were stone-free).(17)

In another study by Tanagho and coworkers in general urology stone removal by basketing under fluoroscopy, a 60–70% success rate was reported, which, too, was lower than our success rate.(18)

In another study by Takashi Yagisawa and coworkers in 2001, they describe the 91% rate of succession in traditional ureteroscopic pneumatic lithotripsy, which was lower than our success rate as well.(19)

According to the same paper with the same method is used in this study, comparison of the results is not possible.

CONCLUSIONS

We found that warmed irrigating fluid (40°C) can improve TULP results in terms of ureteral access, preven-

tion of stone retropulsion, and the stone-free rate. It entails no additional cost or morbidity for patients.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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