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### Stones and Endourology

Original article

# Comparison of safety and efficacy of tamsulosin, tadalafil, combinations and deflazacort in lower ureteric orifice negotiation by large size ureteroscope (8/9.8 Fr) prior to intracorporeal lithotripsy



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#### KEYWORDS

Hematuria;  
Negotiation;  
Ureteroscope

#### Abstract

**Objective:** To compare the safety and efficacy of tamsulosin, tadalafil, deflazacort and combination of tamsulosin with tadalafil in lower ureteric orifice negotiation by large size ureteroscope (8/9.8 Fr) prior to intracorporeal lithotripsy.

**Patients and methods:** In this prospective study, 180 patients presented with ureteric stone of size 8–15 mm were randomly assigned to 5 groups: tamsulosin (group A), tadalafil (group B), deflazacort (group C), combination of tamsulosin with tadalafil (group D) and placebo (group E). After 10 days of drug therapy 168 patients were underwent ureteroscopy and findings like endoscopic configuration of ureteric orifice, need for ureteric dilatation, ureteroscope negotiation, operating time, drug related side effect and procedural complication were noted in each group.

**Results:** All four groups (A, B, C, D) were significantly better than group E in terms of ureteric orifice appearance (wide) during endoscopy. Negotiation of ureteric orifice was easy in group A (70.59%), B (58.82%) and D (78.13%) as compare to group E (31.43%) which was statistically significant. Group A (32.35%) and D (34.38%) were statistically better with group E (62.86%) in terms of ureteral dilatation. Operative time was less in all four groups as compared to group E. All patients well tolerated the drugs with no serious side effects.

**Abbreviations:** PDE 5i, phospho diesterase 5 inhibitor; UVJ, ureterovesical junction.

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**Conclusion:** Both tamsulosin and tamsulosin with tadalafil helps in forward propagation of large size ureteroscope as compared to other groups with less operative time without any significant complications. So, we can conclude that tamsulosin alone can be helpful for lower ureteric orifice negotiation during intracorporeal lithotripsy with minimal side effects.

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## Introduction

Narrowest part of human ureter is the ureterovesical junction (UVJ) which provides difficulty in spontaneous stone expulsion as well as ureteroscope negotiation [1,2]. Peremans described the microanatomy of UVJ as three different zones namely the intramural and submucosal part of intravesical ureter and the extravascular ureter at ureteral hiatus [3]. Functionally, three different muscle groups with different innervations are present at UVJ namely the detrusor, inner and outer layer of ureter muscle and muscularis mucosae [4]. After the introduction of first rigid ureteroscope in 1980 by Perez Castro and Martinez Pineiro, several modification and miniaturization has been occurred for diagnostic and therapeutic accuracy that minimizing the morbidity but also compromises the visibility [5–7]. UVJ negotiation is an important part during ureteroscopy and many patients (almost 40–60%) may require dilatation of ureteric orifice for negotiation of large size ureteroscope (8/9.8 Fr) [8]. Various maneuvers have been described for UVJ negotiation (cases in which difficulty encountered during traversing the ureteric orifice) but none is free from complications [9].

A number of studies had found the role of  $\alpha$  blocker and phosphodiesterase inhibitors (PDE 5i) in ureteric calculus expulsion. Although  $\alpha$ -adrenergic receptors are distributed along the entire length of human ureter, highest concentration is present in the lower ureter. PDE 5i acts on nitric oxide/cyclic guanosine monophosphate (cGMP)-signaling pathway that will lead to increased levels of cGMP which is responsible for relaxation of the smooth muscle of ureter [10,11]. Antagonism of these receptors relaxes the ureteric smooth muscle, reduces ureteral spasm and promotes expulsion of calculi [12,13]. Ureteric calculus can lead to inflammatory reaction and mucosal edema and anti-inflammatory drugs like corticosteroid can reduce the inflammatory response thus increases stone expulsion [2,11,14].

Aim of our study was to compare the safety and efficacy of  $\alpha$  blocker (tamsulosin), PDE 5i (tadalafil), corticosteroid (deflazacort) and combination of  $\alpha$  blocker with PDE 5i (tamsulosin with tadalafil) in lower ureteric orifice negotiation by large size ureteroscope prior to intracorporeal lithotripsy.

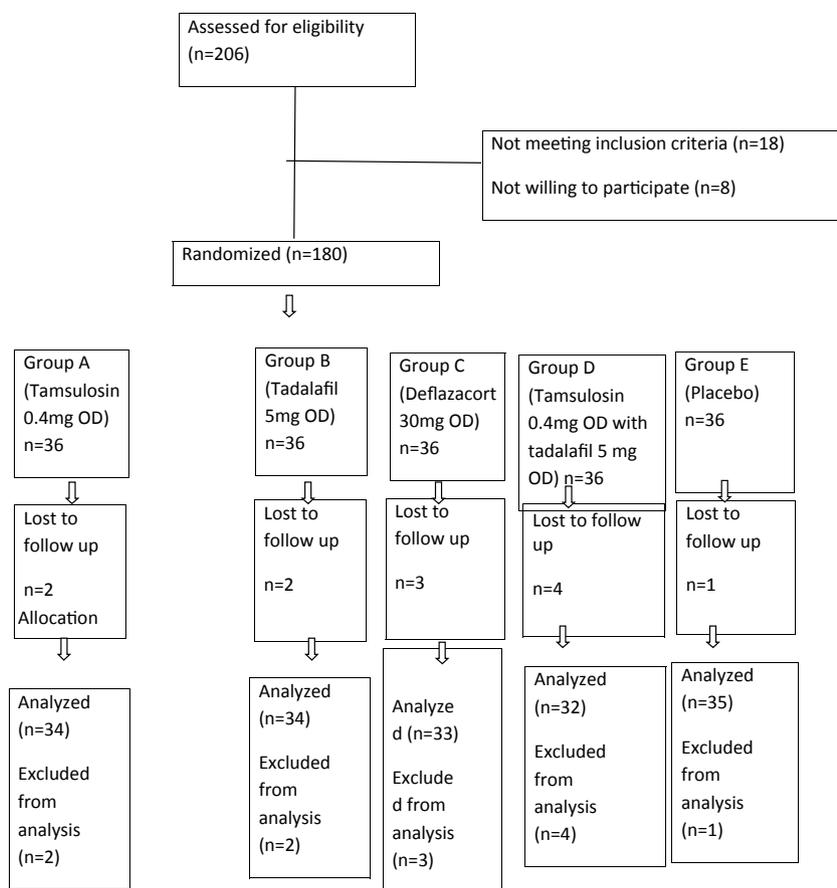
## Subjects and methods

After taking institutional review board approval (2701/MC/EC/2016), this prospective randomized double blind placebo controlled study was conducted in our department of urology from February 2016 to April 2017. Informed written consent was taken from all the study participants. A total of 206 patients aged 18–60 years

with an uncomplicated, single ureteric stone size 8–15 mm, located in either lower or mid ureter (up to upper border of sacrum) were included in this study. Patients either not meeting inclusion criteria or not willing to participate were excluded from this study (these patients were 26 in number). Patients who were ready to accept drugs like alpha blocker (tamsulosin), PDE5i (tadalafil), corticosteroids (deflazacort), combination (tamsulosin with tadalafil) and placebo (multivitamin) prior to surgery were included in this study. Patients with fever, moderate to gross hydronephrosis, presence of symptomatic bacteriuria, multiple or bilateral ureteric stones, stone located at VUJ, patients who passed stone spontaneously, patients with acute or chronic renal insufficiency, solitary kidney or congenital urinary abnormality were excluded. Patient having history of surgical interventions either open or endoscopic urinary tract surgery, diabetes, cardiac disease, bleeding diathesis, peptic ulcer or on concomitant treatment with drugs like alpha blocker, beta-blockers, calcium antagonists or nitrates, immunosuppressant without's, any malignancy, pregnant or lactating females and patient who demand immediate active intervention and not willing to participate were also excluded from this study. So, finally, 180 patients met the inclusion criteria and underwent intracorporeal ureteroscopic lithotripsy.

All patients satisfying inclusion criteria were randomized into five groups by use of sequentially numbered, opaque sealed envelopes (SNOSE) method [15]. Group A, B, C, D and E were given, Tamsulosin (0.4 mg OD), Tadalafil (5 mg OD), Deflazacort (30 mg OD), Tamsulosin (0.4 mg OD) + Tadalafil (5 mg OD) and placebo (multivitamin), respectively only for 10 days prior to surgery. All patients were informed about the side effects of the drugs. History and physical examination were done in all the patients. General characteristics of all patients were recorded like age, gender, side, size and location of calculus, height, weight and BMI. Investigations like serum creatinine, urinalysis with urine culture, ultrasonography, plain X-ray of the kidneys, ureter, and bladder (KUB) and computed tomography (CT) were done in every patient before surgery. The greatest dimension of the stone was taken into consideration as the stone size. Postoperatively, X ray KUB and ultrasonography were done in every patient to know the residual fragment.

Tab diclofenac 50mg was given in each group for pain relief as and when required. After 10 days of drug intake, patients of each group underwent cystourethroscopy. Ureteric orifice configuration (wide/narrow) was noted and then 0.035 Fr guide wire placed. After this, 8/9.8 Fr wolf ureteroscope was tried to insert into ureteric orifice over guide wire. If ureteroscope was negotiated easily into ureteric orifice without using any maneuver than procedure was considered as complete. If ureteroscope could not be negotiated through ureteric



**Figure 1** Showing study design of all groups.

orifice easily than dilatation was done up to 10Fr with nottingam ureteral dilator over guide wire, subsequently ureteroscope passed and stone removal done. At the end of procedure double J stent was placed in all patients (as a routine procedure in our institution). Both cystoscopy and ureteroscopy were done by single senior urologist only. Ureteric orifice configuration (wide/narrow), negotiation (difficult and easy), ureteric orifice dilatation required or not, operation time, procedural complication like mucosal injury/false passage, hematuria and fever, hospital stay, stone free rate and side effect of drug were noted in each group.

Statistical analysis was performed with the SPSS, Trial version 23 for Windows statistical software package (SPSS Inc., Chicago, IL, USA) and Primer. The Categorical data were presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data were presented as mean and standard deviation and were compared using by Students' *t*-test, ANOVA Test, post Hoc Test and Tukey Test to find out the most significant groups among all the groups. Probability *P* value <0.05 was considered statistically significant.

**Results**

**Fig. 1** shows the study design. Total 180 patient following inclusion criteria were randomly assigned into five groups. There was a dropout of two patients in group A and two in group B, three in group C, four in group D and one patient in group E. Reason for this dropout was unknown because patients didn't come for follow up.

So, 168 patients were left for final analysis out of which 34 patients were in group A, 34 in group B, 33 in group C, 32 in group D and 35 in group E.

**Table 1** shows the pre-procedural characteristics of all the study participants. No statistically significant differences were observed in basic parameters (like patient's age, gender, side of stone, body mass index, stone size, and location of stone) in all the groups.

**Table 2** shows the intra procedural characteristics of all the groups. Ureteric orifice was found wide in 25 (73.53%) cases of group A, 23 (67.65%) cases of group B, 15 (45.45%) cases of group C, 25 (78.13%) cases of group D and 7 (20%) cases of group E. Negotiation of ureteric orifice was easy in 24 (70.59%), 20 (58.82%), 19 (57.58%), 25 (78.13%) and 11 (31.43%) cases of group A, B, C, D and E, respectively whereas ureteral dilatation was required in 32.35% [11] cases of group A, 41.18% [14] cases of group B, 48.48% [16] cases of group C, 34.38% [11] cases of group D and 62.86% [22] cases of group E. Mean operative time was 34.41, 35.53, 36.12, 33.34 and 45.20 min in group A, B, C, D and E, respectively.

**Table 3** shows the statistical analysis of these findings (ureteric orifice appearance, negotiation and requirement of ureteral dilatation) between all five groups. With comparative analysis we found that all four groups (A, B, C, D) were statistically better than group E in terms of ureteric orifice appearance (wide) during endoscopy. However when we compare all these groups with each other, we found

**Table 1** showing the demographic data of all groups.

Parameters	Group A	Group B	Group C	Group D	Group E	P value
Number	34	34	33	32	35	
Age (years) (mean $\pm$ SD)	35.42 $\pm$ 11.4	32.78 $\pm$ 14.1	33.32 $\pm$ 10.9	36.6 $\pm$ 12.8	37.1 $\pm$ 10.9	0.488
Sex (Male/Female)	24/10	25/9	24/9	24/8	25/10	0.995
Side (Right/Left)	18/16	19/15	15/18	18/14	16/19	0.822
BMI kg/m <sup>2</sup> (mean $\pm$ SD)	23.42 $\pm$ 3.9	23.98 $\pm$ 4.2	22.7 $\pm$ 3.6	24.9 $\pm$ 4.1	22.9 $\pm$ 2.9	0.125
Location of calculus (Middle/Lower)	10/24	9/25	8/25	6/26	10/25	0.869
Size (mm) (mean $\pm$ SD)	10.2 $\pm$ 2.1	10.7 $\pm$ 2.9	12.0 $\pm$ 2.5	11.6 $\pm$ 2.9	11.3 $\pm$ 2.8	0.357

**Table 2** showing procedural characteristics and outcome of all groups.

Parameters	Group A (N = 34)		Group B (N = 34)		Group C (N = 33)		Group D (N = 32)		Group E (N = 35)	
	No	%								
<i>Ureteric orifice appearance during endoscopy</i>										
Narrow	9	26.47	11	32.35	18	54.55	7	21.88	28	80.00
Wide	25	73.53	23	67.65	15	45.45	25	78.13	7	20.00
<i>Negotiation of ureteric orifice by ureteroscopy</i>										
Difficult	10	29.41	14	41.18	14	42.42	7	21.88	24	68.57
Easy	24	70.59	20	58.82	19	57.58	25	78.13	11	31.43
<i>Ureteral dilation</i>										
Not required	23	67.65	20	58.82	17	51.52	21	65.63	13	37.14
Required	11	32.35	14	41.18	16	48.48	11	34.38	22	62.86
<i>Mean operative time <math>\pm</math> (min)</i>	34.41 $\pm$ 6.76		35.53 $\pm$ 6.99		36.12 $\pm$ 7.42		33.34 $\pm$ 6.15		45.20 $\pm$ .963	

**Table 3** Showing statistical analysis (P value) between all groups.

Parameters	A vs B	A vs c	A vs D	A vs E	B vs c	B vs D	B vs E	C vs D	C vs E	D vs E
<i>Ureteric orifice appearance during endoscopy</i>										
Narrow	0.79	0.036	0.88	0.00	0.39	0.49	0.01	0.014	0.047	<0.001
Wide										
<i>Negotiation of ureteric orifice by ureteroscopy</i>										
Difficult	0.44	0.39	0.67	0.003	0.88	0.15	0.041	0.13	0.054	<0.001
Easy										
<i>Ureteral dilation</i>										
Not required	0.62	0.27	0.93	0.02	0.72	0.75	0.39	0.36	0.82	0.03
Required										
<i>Mean operative time (min)</i>	0.963	0.848	0.970	0.001	0.997	0.699	0.007	0.484	0.023	0.000

that ureteric orifice was wide in more cases of group A and D in contrast to group C with statistically significant difference. Negotiation of ureteric orifice was easy in group A, B and D as compared to group E which was statistically significant. Although negotiation of ureteric orifice was easy in group C as compared to group E, it was statistically insignificant. Group A and D were statistically better with group E in terms of ureteric orifice dilatation; however group B and C didn't show statistical significant difference with group E. All four groups (Group A, B, C, D) showed statistically significant difference with group E in terms of operative time. When we compare all four groups (Group A, B, C, D) with each other, we didn't find any statistical significant difference between groups with regard to ureteric orifice negotiation, ureteral dilatation and operative time.

**Table 4** shows the procedural complications (gross hematuria, mucosal injury/false passage, fever), stone free rate and hospital

stay of patients in all groups. **Table 5** shows statistical analysis between all groups regarding these complications. Gross hematuria was noted in 7, 10, 9, 6 and 17 patients of group A, B, C, D and E, respectively. Similarly, mucosal injury/false passage was noted in 3, 5, 6, 2 and 11 patients of group A, B, C, D and E, respectively but statistical significant difference was found only between group A and D with group E in terms of false passage and gross hematuria. Post-operative fever was also noted in some of the patients of each group but not statistically significant. Stone free rate was also not significant between all the groups. Hospital stay was statistically significant between group A, C, and D when compare to group E.

**Table 6** shows the drug related side effects. Headache, backache and dyspepsia were higher in patients of Group B and D as compared to patient of Group A, B and E and was statistically significant ( $P$  value <0.05). Whereas dizziness and abnormal ejaculation was more

**Table 4** showing post procedural characteristics between all groups.

Parameters	Group A (N= 34)	Group B (N= 34)	Group C (N= 33)	Group D (N= 32)	Group E (N= 35)	P value
<i>Gross hematuria (&lt;24 h/&gt;24 h)</i>						0.16
<24 h	5	8	6	5	15	
>24 h	2	2	3	1	2	
No	27	24	24	26	18	
<i>Mucosal injury/false passage</i>						0.034
Not present	31	29	27	30	23	
Present	3	5	6	2	11	
<i>Fever</i>	3	2	4	1	8	0.08
<i>Stone free rate</i>						0.75
Free	32	31	30	30	30	
Residual	2	3	3	2	5	
<i>Hospital stay (in days)</i>	2.12 ± 0.33	2.21 ± 0.41	2.18 ± 0.39	2.13 ± 0.34	2.56 ± 0.93	0.004

**Table 5** showing statistical analysis (p value) between all groups regarding post procedural characteristics.

	A vs B	A vs c	A vs D	A vs E	B vs c	B vs D	B vs E	C vs D	C vs E	D vs E
<i>Gross hematuria (&lt;24 h/&gt; 24 h)</i>										
<24 h	0.83	0.87	0.83	0.034	0.79	0.59	0.89	0.56	0.56	0.036
>24 h										
No										
<i>Mucosal injury/false passage</i>										
Not present	0.7	0.44	0.94	0.03	9.95	0.475	0.15	0.27	0.29	0.019
Present										
<i>Fever</i>	1	0.97	0.65	0.65	0.64	0.98	0.09	0.37	0.054	0.057
<i>Stone free rate</i>										
Free	1	0.97	0.65	0.44	0.69	0.94	0.74	0.97	0.77	0.5
Residual										
<i>Hospital stay (in days)</i>	0.95	0.98	0.99	0	1	0.972	0.053	0.99	0.061	0.01

**Table 6** Showing drug related side effects between all groups.

	Group A		Group B		Group C		Group D		Group E		P value
	No	%									
Headache, backache	4	11.76	12	35.29	3	9.09	10	31.25	5	14.29	0.017
Dyspepsia	3	8.82	10	29.41	5	15.15	11	34.38	5	14.29	0.04
Abnormal ejaculation	3	8.82	2	5.88	1	3.03	4	12.50	1	2.86	0.46
Dizziness	5	14.71	4	11.76	4	12.12	6	18.75	4	11.43	0.902

common in Group A and D as compared to Group B, C and E which was statistically insignificant ( $P$  value  $>0.05$ ).

## Discussion

One of the narrowest part of the ureter is the UVJ and urologist often having difficulty to traverse ureteric orifice by ureteroscopy. For effective ureteroscopy crossing the ureteral orifice is basically a vital demonstration. Initially ureteroscopy was performed by Young in 1912 in an infant [16], however it was popularized in 1960s following advances in Dr. Hopkins rod-lens optical systems [17,18]. Miniaturization of ureteroscopy may lead to easy negotiation but with compromised visibility and efficacy for removal of calculi, on the other hand large size ureteroscopy require ureteric orifice dilatation [19,20]. To overcome the difficulty of ureteric orifice negotiation, numerous techniques had been employed in the form

of either passive dilatation (Double j stent) or active dilatation (balloon, metal, sequential fascial dilators, olives, etc.) but none of these are free from complications [19–21].

The alpha-1 A and D-adrenergic receptors are most populated adrenergic receptors in human ureter. Highest concentration of these  $\alpha$  receptors are in lower ureter as compared to upper and mid ureter [11,13]. Tamsulosin is most widely studied  $\alpha$  blocker for medical expulsive therapy and is highly selective  $\alpha$ 1a blocker so we used this drug for our study [22]. Gratzke et al. demonstrated the role of phosphodiesterase inhibitor on ureteric smooth muscle using sildenafil, vardenafil and tadalafil. As tadalafil is more selective PDE-5 receptor with less visual side effect [23,24], so we used this drug in our study at low dose [23,24]. Larger stones tend to cause inflammatory reactions in ureter and that submucosal edema in the vicinity of a stone may aggravate urinary obstruction and calculus retention.

Corticosteroids stabilize neutrophil lysosomes, therefore decreasing inflammation and edema related to mechanical irritation [25]. Deflazacort is a glucocorticoid and it has faster and potent anti-inflammatory action that can be achieved at a low dose [2]. Medical expulsive therapy for distal ureteric stones using combination of tamsulosin plus tadalafil is safe, effective and well tolerated with no serious adverse events [26].

To the best of our knowledge, this is the first kind of prospective study that assessed use of medications like  $\alpha$  blocker and PDE5i for ease of negotiation of larger size ureteroscope to improve stone access. Ureteric orifice was found narrow and negotiation of orifice was difficult in group E as compared to other groups. Elashry et al. used various size of ureteroscope (6.9Fr to 11.5Fr) in management of ureteric calculi. In their retrospective study they showed that ureteric orifice was dilated in 59.5% of cases, direct introduction of ureteroscope into ureter without dilatation was done in 24.9% of patients either using small size semi rigid ureteroscope or ureteral stenting preoperatively. Ureteric perforation was noted in 58 patients, out of which 40 was noted in cases where large size ureteroscope used (9Fr or larger). Similarly out of 18 cases of ureter avulsion, 17 were noted in cases of large size ureteroscope [27]. However, we used 8/9.8Fr wolf ureteroscope, so 62.86% patients require ureteric orifice dilatation in Group E as compared to 32.35%, 41.18%, 48.48% and 34.38% patients in Group A, B, C and D, respectively.

As shown by Lodh et al. the mean operative time was also higher group E as compared to other groups [2]. Reason for this may be the difficulty in ureteroscope negotiation and need for ureteral dilatation. In our study, high incidence (32.35%) of mucosal injury/false passage was noted in the group E as compared to other groups. This may be due to tight ureteric orifice and need for frequent dilation of ureteric orifice while entering through the inflamed ureteric orifice [28]. In their study of iatrogenic ureteric injury following URSL, Al-Awadi et al. found it as by considered it as one of the most common complications [29]. Some investigator reported higher incidence of complications like mucosal injury, hematuria and ureteral avulsion in patients who were treated with large size ureteroscope [30]. We also noted similar findings in group E as compared to other groups. Although some of our patients also noted complications during drug intake, these were not much severe and all patients tolerated drug.

Main limitation of our study was the small sample size, single center study, short follow up and subjective intraoperative findings like ureteric orifice appearance (narrow/wide) and orifice negotiation. Although the complications rate and need for dilatation was high and easy negotiation rate was low in our study as compared to some previous studies, we think that main reason of this was due to choosing a low threshold for reporting these complications as most of these complications were subjective in nature.

## Conclusion

We found that both tamsulosin and tamsulosin with tadalafil not only relax ureteral smooth muscle but also helps in forward propagation of large size ureteroscope as compared to deflazacort, tadalafil or placebo without any significant complications with less operative time. However, drug related side effect like headache and backache were more significant in combination group as compared to tamsulosin alone. So, we can conclude that tamsulosin alone can be

helpful for lower ureteric orifice negotiation during intracorporeal lithotripsy with minimal side effects.

## Authors' contributions

Rohit Bhattar – conception and design, drafting of the manuscript, acquisition of data.

Vinay Tomar – supervision and administrative support, critical revision of manuscript.

Sher Singh Yadav – administrative, technical or material support, critical revision of manuscript.

Anuradha Maheshwari – critical revision of manuscript.

## Conflict of interest

There is no conflict of interests for any of the authors.

## Source of funding

None.

## Consent from the patient

Informed written consent was taken from all the study participants.

## Ethical Committee Approval

The research committee approved this study with the approval number 2701/MC/EC/2016.

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