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Original Article

Comparison of the Tamsulosin and Tolterodine Effectiveness in Stent-Related Symptoms Reduction

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HIGHLIGHTS

- A combination of Tamsulosin and Tolterodine could significantly reduce all stent-related symptoms except urgency.
- Solitary use of neither Tamsulosin nor Tolterodine was superior to the control group.

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ABSTRACT

Introduction

To compare the effectiveness of tamsulosin and Tolterodine in reducing stent-related symptoms with each other and with the control group we performed this randomized clinical trial.

Methods

150 patients after successful first-time transurethral lithotripsy (TUL) for unilateral ureteral stones were elected for the study 17 patients were excluded in the first allocation. Other patients were randomized (With balanced blocked randomization) into three groups. In group 1, 41 patients received Tamsulosin (Omnicep) 0.4mg once a day for a month and in group 2, 42 patients received tolterodine (Detrusitol) 2mg once a day for a month. In group 3, which was our control group, 50 patients received a placebo once a day for a month. Clinical stent-related symptoms questionnaires at the first visit (day 10) and before removing themes stent were completed. Two urine tests and an x-ray of the abdomen in the first visit have been performed.

Results

Despite the remarkable decrease in the severity of stent-related symptoms other than urine urgency in the control group (p -value<0.05), solitary use of neither tamsulosin nor tolterodine was superior to the control group, and also, they were not superior to each other with respect to improving double-J stent-related symptoms (p -value>0.05).

Conclusions

The results of our study show that administration of tolterodine and tamsulosin to reduce stent-related symptoms do not have superiority to each other and the control group.

Keywords: Ureteral Stent; Tamsulosin; Tolterodine

Introduction

The indications of inserting double-J stents through cystoscopy have been expanded in the last decade and they play a mandatory role in a wide spectrum of situations that cause urinary obstruction (1, 2). In these situations,

double-J stents provide drainage for urine to flow into the bladder properly, and hence, the risk of kidney damage would be minimized. In addition to kidney damage, urinary extravasation (that is prevalent following surgery and trauma) will be hampered by using these stents (3).

Even though the insertion of double-J stents is of proven value in managing several urological problems, they are accompanied by some complications including, but not limited to, urinary infection, pain, discomfort, lower urinary tract symptoms (LUTS) (4, 5). The complications of double-J stents, which impact patients' quality of life and sexual function, have been the subject of several recent studies (6).

Although the mechanisms behind stent-related symptoms are still under debate, the spasm of the lower ureter and irritation of the trigon by the stent are the possible explanations for the pain and LUTS. Therefore, it was hypothesized that anticholinergics, analgesics, oral alpha-1 antagonists can be utilized to reduce the severity of pain and LUTS (7, 8). Among mentioned drugs, more promising outcomes have been reported when alpha-1 antagonists' drugs were applied. Tamsulosin is one of the most popular alpha-1 antagonists. It affects the D subtype of alpha-1 receptors, which makes it more specific with the least side effects. Tolterodine is one of the specific anticholinergic medications. This drug has more effect on the bladder than salivary glands. So it had fewer side effects than older drugs such as oxybutynin (4, 9).

We designed a prospective study to compare the effect of Tolterodine and Tamsulosin with each other and the control group on six frequent stent-related symptoms in patients who received double-J stents after undergone transurethral lithotripsy (TUL) surgery.

Methods

This was a double-blinded clinical trial was performed between 2016-2019, on patients who were candidates for TUL surgery for unilateral ureteral stones and did not have kidney stones over 18 years and under 50 years of age were included in the study. Our exclusion criteria include symptoms of benign prostatic hyperplasia (International prostatic symptoms score > 8), pregnancy, history of any disease and treatment for prostatitis and cystitis and urinary symptoms, chronic flank pain, ureteral stent insertion in any of the ureters, recent urinary tract infection, concomitant use of another group of drugs, chronic gastrointestinal pain, psychological diseases, malignancy, history of allergy or complications of tamsulosin or tolterodine. Before performing TUL, the type of medication or placement in the control group was determined randomly and patients were provided with the necessary information about receiving the drug and the need for relevant follow-up. If they did not need to perform another procedure such as extracorporeal shock wave lithotripsy, ureteroscopy, or TUL, they would be included in the relevant group.

First, a total of 150 patients were a candidate for our study, but, 17 patients due to not meeting our inclusion criteria were excluded from the present study before

randomization. Written informed consent was obtained from patients before starting the study. Our patients were randomized (With balanced blocked randomization with 4 units in each block) into three groups. In group 1, 41 patients received Tamsulosin (Omnicep) 0.4mg once a day for a month and in group2, 42 patients received tolterodine (Detrusitol) 2mg once a day for a month. In group 3, which was our control group, 50 patients received a placebo once a day for a month. Patients in all 3 groups were given 10 tablets of Cefixime 400 mg and 20 tablets of Naproxen 500 mg. Patients were required to take one Cefixime daily and were allowed to take naproxen as a painkiller every 12 hours for pain and discomfort. These patients had a face-to-face visit 10 days after surgery and they asked about stent-related symptoms and abdominal and pelvic X-ray, urine analysis, and culture were obtained. Patients were excluded from the study if the patient was dissatisfied with the medication, improper use of medication, inappropriate double-J stent location, or urinary tract infection. According to previous studies, the extraction time of ureter stents was 28 days after the stent insertion and if double-J stents were extracted at another time, the patient would be excluded from the study. Before double-J stents were extracted, stent-related symptoms were asked and questions were asked about how to take the medication.

In our center, 8Fr ureteroscopes and 6Fr pneumatic lithoclast (Karl Storz Company, Germany) and 4.8Fr Double-J (DJ) stent used for patients. The DJ embedding indication is determined by the center's experienced specialist based on the patient's condition. Patients who needed double-J stent due to severe damage of the ureter were excluded from our study. Patients admitted to the study underwent general or spinal anesthesia at the discretion of the anesthesiologist. Extracting double-J stent was performed at the appointed time with local anesthesia.

The designed questionnaire measured the severity of six clinical symptoms attributed to stent ureter in several studies. Symptoms include suprapubic pain, burning when urinating, abdominal pain, flank pain, frequent urination, and hematuria. The scoring for suprapubic pain, dysuria, and flank pain was performed using the following formula: 0: asymptomatic, 1: mild, 2: moderate, 3: severe. For urgency on a 0-2 scale, 0: none, 1: sometimes, 2: most of the time or always, for urgency on a scale 0-3, 0: never, 1: 1-3 times a day, 2: 4-6 times a day, 3: more than 6 times a day, and for hematuria on a scale 0-3, 0=no hematuria, 1=microscopic hematuria, 2=occasional macroscopic hematuria, and 3=permanent or associated macroscopic hematuria.

Statistical analysis

Quantitative variables of this study including age, stone

size, and the number of tablets of analgesic medication were analyzed by ANOVA test. Nominal qualitative variables including sex, side, and location of stones were analyzed by Chi-square test. The Kruskal–Wallis test was used for comparison among three groups. The Wilcoxon test was used to test the severity of stent-related symptoms within each group. The results were significant when the p -value <0.05 for all variables. Our data were analyzed by SPSS version 18.

Results

From 133 patients were enrolled in the study, a total of 23 patients, including 2 patients in the Tamsulosin group (Group 1), 2 patients in the Tolterodine group (Group 2), and 19 patients in the control group (Group 3) excluded from the study (Figure 1). Group 1 (39 patients) consisted of 32 (82.1%) male and 7 (17.9%) female with the mean age of 37 ± 7.81 (ranges 21-48 years), group 2 (40 patients) consisted of 34 (85%) male and 6 (15%) with the mean age of 37.3 ± 7.59 (ranges 19-49 years), and group 3 (31 patients) consisted of 26 (83.9%) male and 5 (16.1%) female with the mean age of (ranges 20-48 years). With respect to age, sex, size and side of the stone, double-J stent duration, and the number of tablets of analgesic medication, there were no significant differences among groups (Table 1).

According to the completed questionnaires, 85.5%

of patients had at least one of the clinical symptoms in the first 10 days and 58.2% at the time of double-J stent extraction. The most common complaint of patients in the first visit was suprapubic discomfort (72.7%), which along with frequent urination (52%) was the most common complaint of patients until stent extraction. In the second visit, suprapubic pain (62%) was the most prevalent symptom alike to the result of the first visit, however, hematuria (42%) was the second prevalent symptom.

The results of the questionnaires were examined the first visit (the tenth day after double-J stent insertion) (Table 2) and before the extraction of the double-J stent (Table 3) between the three groups in terms of significant statistical differences with the Kruskal Wallis test, which did not make any significant difference regarding stent-related symptoms (p -value >0.05) (Table 2 and 3).

Discussion

To the best of our knowledge, the result of this prospective randomized trial study, which showed despite the remarkable decrease in the severity of stent-related symptoms other than urine urgency in the control group, solitary use of neither tamsulosin nor tolterodine was superior to the control group, and also, they were not superior to each other with respect to improving double-J stent-related symptoms.

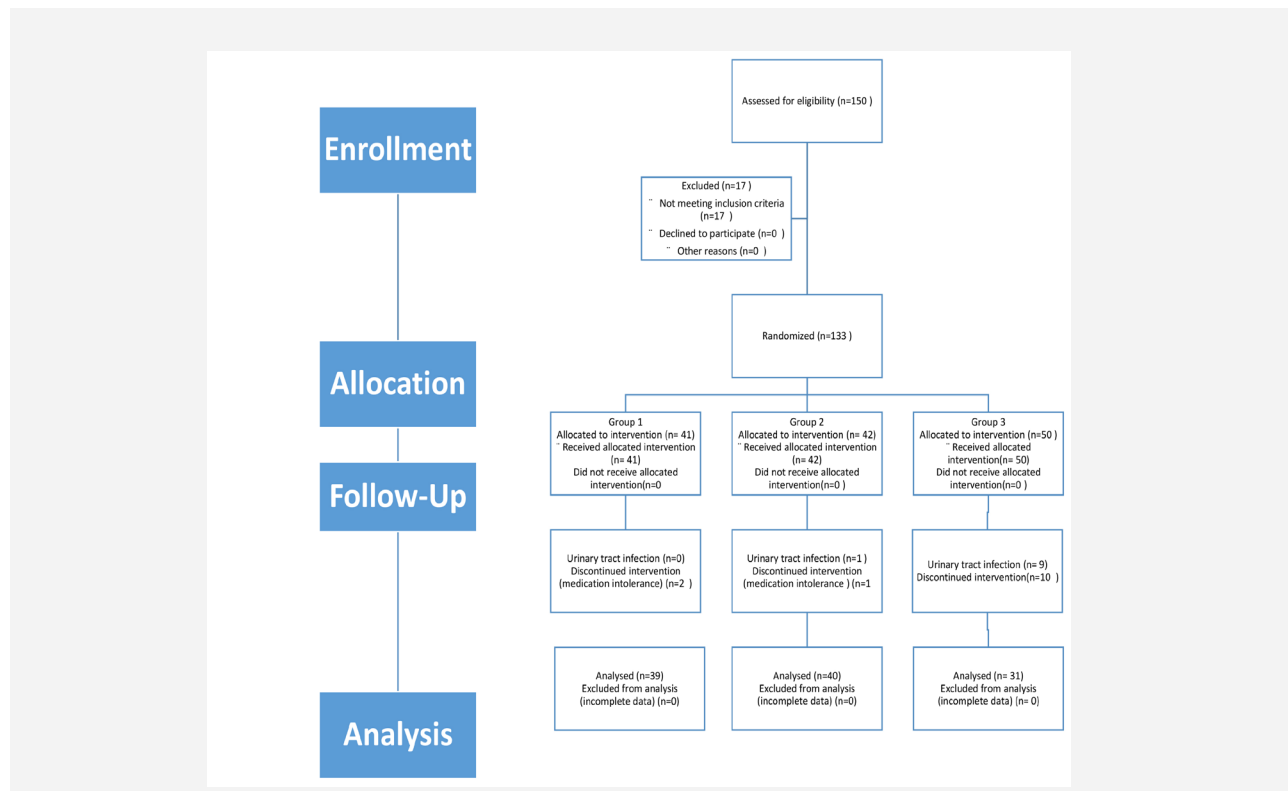


Figure 1. CONSORT diagram of the study

Table 1. Basic characteristics of the patients

Characteristic	Tamsulosin	Tolterodine	Control	Total	p-value
Number patients	39	40	31	110	
Age (SD) (years)	37.0 (7.81)	37.3(7.59)	35.6(6.93)	36.6(7.45)	0.679
Gender					
Male (%)	32(82.1)	34(85)	26(83.9)	92(83.6)	0.948
Female (%)	7(17.9)	6(15)	5(16.1)	18(16.4)	
Side					
Proximal (%)	13(33.3)	13(32.5)	13(41.9)	39(35.5)	0.659
Middle (%)	11(28.2)	7(17.5)	6(19.4)	24(21.8)	
Distal (%)	15(38.5)	20(50.0)	12(38.7)	47(42.7)	
Mean stone Size (SD) (cm)	9.1 (1.60)	9.1 (2.56)	8.7 (1.98)	9.0(2.09)	0.663
Stone Side					
Right (%)	28(71.8)	25(62.5)	21(67.7)	74(67.3)	0.714
Left (%)	11(28.2)	15(37.5)	10(32.3)	36(32.7)	
Days of DJ having (SD)	28.1 (1.15)	28.4 (1.05)	28.3 (0.90)	28.2 (1.05)	0.482
No. of analgesics (capsules or tablets)	14.4 (4.03)	14.2 (3.89)	16.4 (2.66)	14.9 (3.74)	0.023

Nowadays, placement of double-J stents is being frequently practiced in the management of several urological diseases, nevertheless, it could result in a variety of morbidities, which might necessitate stent to be removed (10-12). It has been postulated that the majority of stent-related symptoms are unwarranted and have a great influence on performance and quality of life in 45% to 80% of patients(6, 13), Consequently, lots of attempts have been made to restrict morbidities. Currently, most of the patients (approximately 85%) had at least one of the symptoms in the first visit after double-J stent insertion and the most prevalent symptom was suprapubic discomfort (72.7%), and frequency (52%). Scarneci and colleagues investigated 1520 patients with indwelling ureteral stents and similar to our result, the frequency was the second most common symptom among patients, however, dysuria was the first (14).

Fully understanding the precise pathophysiology of stent-related symptoms will aid us to improve the available stents or/and use proper drugs to diminish symptoms. The spasm of lower ureter and irritation of neurons, which are mainly located in the bladder trigone submucosa and contain α -1D receptors, is the probable reason for LUTS and pain related to stents. Flank pain in patients with stents can be explained by urine reflux from the bladder into the kidney (15, 16).

According to a study of Lang et al., resolving stent-related pain likely attributes to both relaxation in the lower ureter's smooth muscle and a decrease in motility of the ureter (17, 18). Another study in which, assess the effect of α -1 blockers on stent-related symptoms, stated that this category of the drug especially tamsulosin brings about a

reduction in voiding pressure and urine reflux subsequent relaxation of bladder neck (19).

Tolterodine is a well-known muscarinic receptor antagonist agent with a broad indication for urinary disorders primarily unstable bladder and improves symptoms related to the overactive bladder (20). Additionally, stent-related symptoms are virtually alike to symptoms of overactive bladder thereby, several studies have been performed to validate the potential of these agents to attenuate stent-related symptoms (21). Although Norris et al., claimed that oxybutynin (anticholinergic drug) has not shown any significant differences in stent-related symptoms when it compares to placebo, the result of their study is not completely reliable due to limitation in the number of patients enrolled in the study (22). Despite that study, oxybutynin compare to placebo, was efficient in reducing bladder discomfort following the result of Agarwal and colleagues' study (23). In our study, the result of the administration of Tolterodine in terms of improving stent-related symptoms was not satisfactory.

Tamsulosin, which inhibits α -1 adrenoceptor antagonist, is the most potent agent used with the purpose of a better urine flow through relaxing in the smooth muscle of the prostate, bladder, and proximal urethral (24) and the optimal benefits of tamsulosin allocated to patients with benign prostatic hyperplasia. Applying tamsulosin in patients with stents would offer advantages in terms of alleviating stent-related symptoms originates from the resemblance of benign hyperplasia prostate symptoms and stent-related symptoms. Wang et al., assess the impact of tamsulosin on stent-related symptoms in a prospective randomized study and they demonstrated that

Table 2. Comparison of stent-related symptoms in all groups 10 days after stent insertion

Total		Type of Drug/Control				p-value*
		Total	Tamsulosin	Tolterodine	Control	
Dysuria After 10 days of TUL	No	52	22	18	12	0.344
		47.3%	56.4%	45.0%	38.7%	
	Mild	48	13	20	15	
		43.6%	33.3%	50.0%	48.4%	
	Moderate to Severe	10	4	2	4	
		9.1%	10.3%	5%	12.9%	
Hematuria After 10 days of TUL	No	62	23	20	19	0.811
		56.4%	59.0%	50.0%	61.3%	
	Microscopic	39	12	17	10	
		35.5%	30.8%	42.5%	32.3%	
	Macroscopic-No Clot	9	4	3	2	
		8.2%	10.3%	7.5%	6.5%	
Loin Pain After 10 days of TUL	No	46	20	15	11	0.028
		41.8%	51.3%	37.5%	35.5%	
	Mild	59	14	25	20	
		53.6%	35.9%	62.5%	64.5%	
	Moderate to Severe	5	5	0	0	
		4.5%	12.8%	0.0%	0.0%	
Supra pubic pain After 10 days of TUL	No	30	13	14	3	0.066
		27.3%	33.3%	35.0%	9.7%	
	Mild	69	21	23	25	
		62.7%	53.8%	57.5%	80.6%	
	Moderate to Severe	11	5	3	3	
		10%	12.8%	7.5%	9.7%	
Frequency (willing to void <2hr after voiding) After 10 days of TUL	No	58	18	25	15	0.349
		52.7%	46.2%	62.5%	48.4%	
	1-3 times	39	13	13	13	
		35.5%	33.3%	32.5%	41.9%	
	>4 times	13	8	2	3	
		11.8%	20.5%	5.0%	9.7%	
Urgency (feeling urgency to void) After 10 days of TUL	No	87	29	33	25	0.518
		79.1%	74.4%	82.5%	80.6%	
	Yes	23	10	7	6	
		20.9%	25.6%	17.5%	19.3%	
	Not Sure	32	9	16	7	
		29.1%	23.1%	40.0%	22.6%	
	No	13	5	1	7	
		11.8%	12.8%	2.5%	22.6%	

*TUL: Transurethral Lithotripsy

Table 3. Comparison of stent-related symptoms in all groups before stent extraction

Total		Type of Drug/Control				p-value*
		Total	Tamsulosin	Tolterodine	Control	
Dysuria After 30 days of TUL	No	90	33	35	22	0.180
		81.8%	84.6%	87.5%	71.0%	
	Mild	20	6	5	9	
		18.2%	15.4%	12.5%	29.0%	
Hematuria After 30 days of TUL	No	87	30	33	24	0.836
		79.1%	76.9%	82.5%	77.4%	
	Microscopic	23	9	7	7	
		20.9%	23.1%	17.5%	22.6%	
Loin Pain After 30 days of TUL	No	94	35	33	26	0.664
		85.5%	89.7%	82.5%	83.9%	
	Mild	16	4	7	5	
		14.5%	10.3%	17.5%	16.1%	
Supra pubic pain After 30 days of TUL	No	58	22	23	13	0.504
		52.7%	56.4%	57.5%	41.9%	
	Mild	49	16	16	17	
		44.5%	41.0%	40.0%	54.8%	
	Moderate to Severe	2	1	1	0	
		1.8%	2.6%	2.5%	0.0%	
Frequency (willing to void <2hr after voiding) After 30 days of TUL	No	93	33	36	24	0.422
		84.5%	84.6%	90.0%	77.4%	
	1-3 times	16	6	4	6	
		14.5%	15.4%	10.0%	19.4%	
	>4 times	1	0	0	1	
		0.9%	0.0%	0.0%	3.2%	
Urgency (feeling urgency to void) After 30 days of TUL	No	101	37	39	25	0.046
		91.8%	94.9%	97.5%	80.6%	
	Yes	9	2	1	6	
		8.2%	5.1%	2.5%	19.4%	

*TUL: Transurethral Lithotripsy

stent-related pain, loin pain will decrease remarkably if tamsulosin is prescribed for patients with ureteral stents (25). In our study, tamsulosin similar to tolterodine did not show any superiority when it compares to placebo.

Recently, evaluating the effect of the combination of

tamsulosin and tolterodine on stent-related symptoms has been of interest to researchers. The outcome of the tamsulosin and solifenacin combination on 327 patients was more satisfactory than the control group or either drug alone following Shalaby et al., the study (26), and

this point was emphasized by Tehrani et al., who investigated the combination of terazosin and tolterodine (27). But, the result of this combination therapy in a short time was unmet in the Sivalingam et al., the study (28).

The strength of our study was the type of our study which was a randomized trial study and we demonstrated that against all the odds, both tamsulosin and Tolterodine have not potential advantageous in comparison to placebo. However, we acknowledge that our study had some limitations. First, lack in the number of patients who were enrolled in our study, and different results may have occurred in our study that contained more patients. Second, the stents that were used for our patients were similar in material and design, but different in size in the control group in comparison to the Tamsulosin group and Tolterodine group. There is an ongoing debate concerning the characteristics of stents. Candela et al., illustrated that differences in the length and composition of stents would not influence stent-related symptoms (29). On the other hand, Ho and his associations proposed that the suitable length of the stent is the most important factor in diminishing stent-related symptoms (30). Further randomized studies are needed with a larger sample size to investigate this topic.

Conclusions

Some studies have been conducted to assess the tamsulosin and tolterodine to reduce stent-related symptoms. The results of our study show that administration of either tolterodine or Tamsulosin to reducing stent-related symptoms do not have superiority to each other and the control group.

Authors' contributions

SMKA is the principal investigator who supervised the project, SAM run the project and surgery process. SSTZ and MHR wrote the manuscript and AFY edited that.

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Conflict of interest

All authors declare that there is not any kind of conflict of interest.

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There was no founding.

Ethics statement

The study was done under the Tehran University of Medical Sciences Ethical Committee (IR.TUMS.SINAHOSPITAL.REC.1399).

Data availability

Data will be provided by the corresponding author on request.

Abbreviations

DJ	Double-J
TUL	Transurethral lithotripsy
LUTS	Lower urinary tract symptoms

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Author (s) biosketches

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