

EFFECTS OF TAMSULOSIN 0.2 MILIGRAM AND TAMSULOSIN 0.4 MILIGRAM ON LOWER URINARY TRACT SYMPTOM SCORE OF USSQ IN PATIENTS WITH INDWELLING DJ STENTS

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ABSTRACT

Objective: To assess the difference in the administration of 0.2 mg and 0.4 mg tamsulosin to the patient's complaint with DJ stent based on USSQ parameters. **Material & Methods:** This was a prospective study conducted in Hasan Sadikin Hospital Bandung from October to December 2017. A total of 60 patients with indwelling DJ stents randomly divided into 2 groups (n=30). The first group was given tamsulosin 0.2mg daily and the second group was given tamsulosin 0.4 mg daily. LUTSs before and after tamsulosin administration for a week were evaluated in both groups using USSQ. Percentage decreases in USSQ score in both groups were then compared using Mann Whitney Test. **Results:** In group I, USSQ score means were 31.9 (20.0-40.0; SD 31.9) before tamsulosin 0.2 mg administration and 26.1 (15.0-35.0; SD 5.6) after tamsulosin 0.2 mg administration. Comparison test before and after tamsulosin 0.2 mg administration showed significant decrease in USSQ score. In group II, USSQ score means were 38.9 (31.0-44.0; SD 2.9) before tamsulosin 0.4 mg administration and 16.7 (13.0-21.0; SD 1.8) after tamsulosin 0.4 mg administration. Comparison test before and after tamsulosin 0.4 mg administration showed significant decrease in USSQ score. The percentage decreases in USSQ score were 18.7% in group I and 56.9% in group II. Different test score before and after treatment for both groups showed p-value<0.05. Scoring results after treatment showed the effectiveness of tamsulosin 0.4 mg was better than tamsulosin 0.2 mg. **Conclusion:** LUTS is the most common stent-associated symptom (SAS) in patients with indwelling DJ stent. Independent administration of tamsulosin 0.2 mg and 0.4 mg significantly alleviated SAS. Tamsulosin 0.4 mg had better effectiveness in alleviating SAS compared to tamsulosin 0.2 mg.

Keywords: Stent-associated symptom, tamsulosin, USSQ.

ABSTRAK

Tujuan: Menilai perbedaan administrasi 0.2 mg dan 0.4 mg Tamsulosin terhadap keluhan pasien dengan DJ stent berdasarkan parameter USSQ. **Bahan & Cara:** Studi prospektif dilakukan di RS Hasan Sadikin Bandung pada periode Oktober-Desember 2017. Total 60 pasien dengan DJ stent yang secara acak dibagi menjadi 2 kelompok (n=30). Kelompok pertama diberikan 0.2 mg Tamsulosin dalam sehari dan kelompok kedua diberikan 0.4 mg Tamsulosin dalam sehari. LUTSs sebelum dan setelah administrasi Tamsulosin selama seminggu dievaluasi di kedua kelompok menggunakan USSQ. Persentase penurunan nilai USSQ pada kedua kelompok kemudian dibandingkan dengan tes Mann Whitney. **Hasil:** Pada kelompok I, nilai USSQ sebesar 31.9 (20.0-40.0; SD 31.9) sebelum administrasi 0.2 mg Tamsulosin dan 26.1 (15.0-35.0; SD 5.6) setelah administrasi 0.2 mg Tamsulosin. Perbandingan tes sebelum dan setelah administrasi 0.2 mg Tamsulosin menunjukkan penurunan yang signifikan dalam nilai USSQ. Pada kelompok II, nilai USSQ sebesar 38.9 (31.0-44.0; SD 2.9) sebelum administrasi 0.4 mg Tamsulosin dan 16.7 (13.0-21.0; SD 1.8) setelah administrasi 0.4 mg Tamsulosin. Perbandingan tes sebelum dan setelah administrasi 0.2 mg Tamsulosin menunjukkan penurunan yang signifikan dalam nilai USSQ. Persentase penurunan nilai USSQ sebesar 18.7% pada kelompok I dan 56.9% pada kelompok II. Nilai tes yang berbeda sebelum dan sesudah pengobatan untuk kedua kelompok menunjukkan p-value <0.05. Hasil penilaian setelah pengobatan menunjukkan efektivitas 0.4 mg Tamsulosin lebih baik daripada 0.2 mg Tamsulosin. **Simpulan:** LUTS adalah stent-associated symptom (SAS) yang paling umum pada pasien dengan DJ stent. Administrasi independen dari 0.2 mg dan 0.4 mg Tamsulosin secara signifikan mengurangi SAS. 0.4 mg Tamsulosin memiliki efektivitas yang lebih baik dalam mengurangi SAS dibandingkan dengan 0.2 mg Tamsulosin.

Kata Kunci: Stent-associated symptom, tamsulosin, USSQ.

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INTRODUCTION

Double J (DJ) stent was developed by Finney and Hepperlen in 1978 and is currently used by urologists in all parts of the world. The use of DJ stents in kidney stone surgery in America in 2006 reached 16% of 166.000 cases. DJ stents are used to relieve ureteric obstruction, postoperative drainage, and urinary diversion.^{1,2} Causes of intrinsic obstruction are usually caused by stones, tumors, or strictures while extrinsic causes are caused by suppression of tumors, blood vessels, retroperitoneal fibrosis, enlarged lymph nodes. Relieving obstruction with stent placement can be done temporarily until definitive treatment is done, or permanent if definitive therapy is not possible.

Besides being useful, it turns out that DJ stents can also give complications to patients including migration of stents, urinary tract infections, encrustation, neglected stents, and symptoms of LUTS. Complications that occur can give patients discomfort, called stent-associated symptom (SAS). Pathophysiological explanations have not been fully obtained, but SAS is thought to be caused by irritation of the bladder mucosa, especially the trigone region due to the distal part of the stent, urinary reflux, and smooth muscle spasm. In the use of DJ stents in the ureter, hematuria, urgency, frequency, dysuria, bladder pain, and flank may occur. Lower urinary tract symptoms (LUTS) are reported to reach 80% in patients who use DJ stents.³

Joshi and colleagues developed the ureteral stent symptom questionnaire (USSQ) for evaluation of symptoms and the effect of ureter stent on quality of life.² USSQ was used by filling in and divided into 6 areas of urinary symptoms, pain, general health, work performance, sexual life and quality of life.³

α 1-Adrenoceptor is found in the ureter, with the highest density in the distal ureter. Administration of α 1-Adrenoceptor antagonists dilates the ureteral tract and reduces cramps by inhibiting basal tone and reducing the frequency of ureteral peristalsis. This is expected to reduce stent-associated symptoms. Tamsulosin is a selective α 1A- and α 1D-adrenoceptor antagonist, which can relax smooth muscle in the prostate, bladder neck, and distal ureter. Tamsulosin is used to treat cases of benign prostatic hyperplasia but can also be used as a therapy for distal ureteral stones with certain indications.⁴

The use of α blockers to reduce symptoms of stent discomfort has also been recommended by

EAU. The use of tamsulosin can reduce the symptoms of LUTS, improve general conditions and improve work performance.

Based on this background, the central theme of this study is Double Pigtail Stent or better known as Double J (DJ) stents which can provide complications in patients including migration of stents, urinary tract infections, encrustation, neglected stents, and symptoms of LUTS. Complications that occur can give patients discomfort, especially in cases of the stent-associated symptom (SAS). Joshi and colleagues developed a ureteral stent symptom questionnaire (USSQ) for evaluation of symptoms and the effect of ureter stents on quality of life. α 1-Adrenoceptor is found in the ureter, with the highest density in the distal ureter. α 1-Adrenoceptor antagonists dilate the channel and reduce cramps by inhibiting basal tone and ureteral peristalsis frequency, which is expected to reduce stent-associated symptoms. Tamsulosin is a selective α 1A- and α 1D-adrenoceptor antagonist, which can relax smooth muscle in the prostate, bladder neck, and distal ureter. The use of tamsulosin can reduce the symptoms of LUTS, improve general conditions and improve work performance. At present, tamsulosin is available in 2 doses, namely 0.2 mg and 0.4 mg and there are no studies that determine which dose is more effective.

OBJECTIVE

The researchers wanted to assess the difference in the administration of 0.2 mg and 0.4 mg tamsulosin to the patient's complaint with DJ stent based on USSQ parameters.

MATERIAL & METHODS

This study is a prospective cohort study. The subjects of the study were patients who used the DJ stent and were given tamsulosin therapy at a dose of 0.2 mg and 0.4 mg at Hasan Sadikin Hospital in Bandung for 1 week. A unilateral ureterorenoscopy is performed using a fiber-Uretero-Renoscope ultrathin 4.5/6.5 Fr brand Richard Wolf. The ureteral catheter used is a 4.7 Fr-sized double J (DJ) brand with a length that is adjusted to the patient's height. All patients underwent URS procedures with spinal anesthesia.

Samples were taken by the permutation block randomization technique. The sample was then evaluated using a USSQ assessment and compared between the two doses of administration.

The results of the study were processed using SPSS version 20.0 and described in the form of tables and diagrams. This study was conducted in the urology polyclinic of Hasan Sadikin Hospital, Bandung. Data collection and processing takes 3 months from October 2017 to December 2017.

Patients who became inclusion in the study were patients who underwent ureterorenoscopy surgery (URS) with the unilateral insertion of a urinary indwelling stent (DJ Stent), patients with a minimum height of 150 cm and a minimum weight of 50 kg, the stent material used was size 5 Fr polyethylene. While the exclusion criteria were URS postoperative UTI, patients with LUTS symptoms due to benign prostate enlargement under alpha-blocker therapy, diagnosis of Overactive Bladder under anticholinergic therapy, and patients with prostate malignancy and bladder, urethral stricture, urinary incontinence, prolonged use of NSAIDs, with post-URS complications (ureteral perforation), and patients with bilateral ureteral stent placement.

RESULTS

Analysis of the data to be released is the population and gender of the patient, and descriptive analysis in the form of mean, standard deviation, maximum and minimum values, frequency distribution, and analysis used to see the results of the USSQ questionnaire on LUTS complaints between giving 0 tamsulosin, 2 milligrams and Tamsulosin 0.4 milligrams dose in patients using DJ Stent. The study sample consisted of 30 patients using 0.2 mg of Tamsulosin and 30 patients using Tamsulosin at a dose of 0.4 milligrams. This experiment was conducted twice with pretest and

post-test design to fulfill the assessment results. The questions raised in this study were 11 questions.

From the results of the patient data recapitulation obtained data on the characteristics of the patient with the number of male correspondents as many as 30 people and women as many as 30 people. Based on age, the average age of the correspondent was 51.75 ± 9.95 years, with the youngest age being 28 years and the oldest was 72 years.

This analysis is used to see whether there is a significant difference in the use of Tamsulosin dose 0.2 mg before (pretest) compared to after (post test). The following are the results of the average calculation, standard deviation, minimum value and maximum score of the scoring results in the Tamsulosin group with a dose of 0.2 mg.

Based on the table above, of the 30 samples tested, the data before being treated with a minimum score of 20.0 is a maximum of 40.0, averaging 31.9 with a standard deviation of 31.9. While after being treated the minimum score changed to 15.0, the maximum was 35.0, the average was 26.1 with a standard deviation of 5.6. After doing descriptive statistical analysis, then proceed with the normality test.

Normality test is used to see whether the distribution of data comes from normal distribution or not. Besides, the normality test is also useful to determine the right type of analysis using parametric or non-parametric analysis. If the data is not normally distributed, then the analysis uses non-parametric test using the Wilcoxon test, but if the data is normally distributed, the analysis uses parametric test using paired t-test. The following are the results of the normality test results of the USSQ

Table 1. Patients Characteristics.

Characteristics	Total	Group Tamsulosin 0.2 mg	Group Tamsulosin 0.4 mg
Gender			
Male	30	15	15
Female	30	15	15
Mean Age	51.75	51.17	52.33

Table 2. Before and after scores in the Tamsulosin 0.2 mg trial.

	N	Minimum	Maximum	Mean	Std Deviation
Before	30	20.0	40.0	31.9	4.4
After	30	15.0	35.0	26.1	5.6

questionnaire before and after the trial group Tamsulosin dose 0.2 mg.

Table 3. Data Normality Test.

Group	Shapiro-Wilk		
	Statistic	Df	p-value
Before	0.938	30	0.080
After	0.940	30	0.093

Based on the table above, the data before and after treatment the p-value value is greater than 0.05, meaning that the data before and after treatment has a normal data distribution. Because the data has a normal data distribution, the comparison test uses a paired t-test.

Table 4. Comparison Test of USSQ Tamsulosin 0.2 mg Scoring.

Group	Mean	p-value	Info
Before	31.9	0.000*	Different +
After	26.1		

Based on the table above, the comparison test between before and after being given tamsulosin 0.2 mg dose showed a p-value of 0.000. Because the p-value (0.000)<0.05 means that there is a difference in scores between before and after being treated. In other words, there is an effect of giving 0.2 mg tamsulosin to changes in scoring results with a significant reduction.

This analysis is used to see whether there is a significant difference in the use of Tamsulosin dose 0.4 mg before (pretest) compared to after (post test). The following are the results of the average calculation, standard deviation, minimum value and maximum score of the results of the scoring in the Tamsulosin group at a dose of 0.4 mg.

Based on the table above, of the 30 samples tested, the data before being treated with a minimum score of 31.0 maximum was 44.0, the average was 38.9 with a standard deviation of 2.9. While after being treated the minimum score changed to 13.0,

the maximum was 21.0, the average was 16.7 with a standard deviation of 1.8. After doing descriptive statistical analysis, then proceed with the normality test.

Normality test is used to see whether the distribution of data comes from normal distribution or not. Besides, the normality test is also useful to determine the right type of analysis using parametric or non-parametric analysis. If the data is not normally distributed, then the analysis uses non-parametric test using the Wilcoxon test, but if the data is normally distributed, the analysis uses parametric test using paired t-test. The following are the results of the normality test results of the USSQ questionnaire before and after the Tamsulosin trial dose of 0.4 mg:

Table 6. Data Normality Test.

Group	Shapiro-Wilk		
	Statistic	Df	p-value
Before	0.964	30	0.398
After	0.942	30	0.101

Table 7. Comparison Test of USSQ Tamsulosin Scoring 0.4 mg.

Group	Mean	p-value	Info
Before	38.9	0.000*	Different +
After	16.7		

Based on the table above, the comparison test between before and after being given tamsulosin 0.4 mg dose showed a p-value of 0.000. Because the p-value (0.000)<0.05 means that there is a difference in scores between before and after being treated. In other words, there is an effect of giving 0.4 mg tamsulosin to changes in scoring results with a significant reduction.

After being tested in each treatment group, then proceed with testing whether there are differences in USSQ scores before and after treatment in each treatment group. For this reason, testing was done by comparing the results of the

Table 5. Before and after scores on the Tamsulosin 0.4 mg trial.

	N	Minimum	Maximum	Mean	Std Deviation
Before	30	31.0	44.0	38.9	2.9
After	30	13.0	21.0	16.7	1.8

Table 8. USSQ Scoring Results Tamsulosin group 0.2 mg and 0.4 mg.

Group		Before	After
Dosage 0.2 mg	Mean	31.9	26.3
	Std. Deviation	4.4	5.6
	N	30	30
Dosage 0.4 mg	Mean	38.9	16.7
	Std. Deviation	2.9	1.8
	N	30	30

USSQ scoring before treatment in the group that used 0.2 mg of Tamsulosin with 0.4 mg of Tamsulosin and then re-tested the USSQ scoring after treatment. The following are the results of descriptive analysis of the results of the USSQ scoring before and after treatment in each treatment group.

Based on the table above, in the experimental group tamsulosin 0.2 mg, the data before treatment averaged 31.9; standard deviation is 4.4; while data after treatment averages 26.3; standard deviation is 5.6. In the tamsulosin 0.2 mg experimental group, the data before treatment averaged 38.9; standard deviation 2.9; while data after treatment averages 16.7; with a standard deviation of 1.8. After the descriptive analysis is known, then the analysis is continued by testing the normality of the data.

Normality test is used to see whether the distribution of data comes from normal distribution or not. Besides, the normality test is also useful to determine the right type of analysis using parametric or non-parametric analysis. Because what will be tested in this section is the pre-treatment scoring results in the group using tamsulosin 0.2 mg compared to the pre-treatment scoring results using tamsulosin 0.4 mg and to test the scoring results after treatment in the group using tamsulosin 0.2 mg compared with the results of scoring after treatment using tamsulosin 0.4 mg, if the data is not normally distributed, the analysis uses a non-parametric test using the Mann Whitney test, but if the data is

Table 9. Data Normality Test.

Group		Shapiro-Wilk		
		Statistic	Df	P-value.
Before	0.2 mg	0.938	30	0.080
	0.4 mg	0.964	30	0.398
After	0.2 mg	0.940	30	0.093
	0.4 mg	0.942	30	0.101

normally distributed then the analysis uses parametric tests using unpaired t-test (independent t-test) The following are the results of the normality test.

Based on the table above, the results of the scoring data in the Tamsulosin treatment group at a dose of 0.2 mg and the Tamsulosin group at 0.4 mg dose had a p-value of more than 0.05. Thus the comparison test analysis uses an independent t-test (independent t-test). The next analysis is to calculate the comparison test using the t-test as follows.

Table 10. Comparative Test of USSQ Scoring in Tamsulosin 0.2 mg and Tamsulosin 0.4 mg.

Group	Group	Mean	p-value	Info
Before	0.2 mg	31.9	0.000**	Different +
	0.4 mg	38.9		
After	0.2 mg	26.1	0.000**	Different +
	0.4 mg	16.7		

Based on the table above, the results of the different test scores before and after treatment between tamsulosin dose 0.2 mg and tamsulosin dose 0.4 mg each showed a p-value of 0.000, because of the p-value <0.05 means that there is a difference meaningful results of USSQ scoring before and after treatment between groups of tamsulosin dose of 0.2 mg and Tamsulosin dose of 0.4 mg. Scoring results after treatment showed the effectiveness between tamsulosin dose 0.2 mg and 0.4 mg against changes in scoring results with the conclusion that those who use tamsulosin dose 0.4 mg is better than using tamsulosin at a dose of 0.2 mg.

This analysis is intended to calculate the percentage change (difference) of USSQ scoring results before and after treatment. For more details, be explained in the following discussion.

Based on the table above, the percentage change in decline between before and after being treated in the group using Tamsulosin dose 0.2 mg

Table 11. Percentage of Change (Difference) in USSQ Scoring in Tamsulosin 0.2 mg and Tamsulosin 0.4 mg.

Group		Before	After	% Change
Tamsulosin dosage 0.2 mg	Mean	31.9	26.1	-18.7
	Std. Deviation	4.4	5.6	11.8
	N	30	30	30
Tamsulosin dosage 0.4 mg	Mean	38.9	16.7	-56.9
	Std. Deviation	2.9	1.8	5.8
	N	30	30	30

Table 12. Normality Test Percentage of Change in USSQ Scoring Results

Group		Shapiro-Wilk			Info
		Statistic	Df	P-value.	
Pre-post	Dosage 0.2 mg	0.906	30	0.012	Not Normal
	Dosage 0.4 mg	0.950	30	0.165	Normal

Table 13. Comparative Test of Percentage of Change in USSQ Scoring Results.

Group		Mean %	p-value	Info
% Change	Dosage 0.2 mg	-18.7	0.000*	Different +
	Dosage 0.4 mg	-56.95		

was 18.7%. While the percentage change in decline between before and after being treated in the group using Tamsulosin dose of 0.4 mg was 56.9%, this figure is much higher than the dose of 0.2 mg. To find out the analysis used using the t-test or the Mann Whitney test, normality tests were carried out as above.

Based on the table above it can be seen that the distribution of data for the percentage change in the results of USSQ scoring shows a varied distribution, meaning that there is data that is normally distributed and there is also data that is not normally distributed. With the provision, if the p-value is above 0.05, the data is normally distributed and vice versa if the p-value is below 0.05, then the data is not normally distributed. Because the data distribution was not uniform, the analysis continued with the Mann Whitney test analysis.

Based on the table above, it was concluded as follows that there were significant differences in the results of USSQ scoring between those using Tamsulosin at 0.2 mg and Tamsulosin at 0.4 mg (p-value 0,000). The percentage difference is quite large, namely -18.7% for Tamsulosin dose of 0.2 mg and -56.95% for Tamsulosin dose of 0.4 mg. From all of these analyzes, it can be concluded that the

administration of Tamsulosin 0.4 mg dose has a better effect compared with Tamsulosin dose of 0.2 mg.

DISCUSSION

Lower urinary tract symptoms (LUTS) are complaints that are often experienced by adult men with a major impact on the quality of life (QoL), and substantial and social personal output. LUTS occurs in men and women according to increasing age.⁵

DJ stents can provide complications in patients including migration of stents, urinary tract infections, encrustation, neglected stents, and symptoms of LUTS. Complications that occur can give patients discomfort, called stent-associated symptom (SAS). Pathophysiological explanations have not been fully obtained, but SAS is thought to be caused by irritation of the bladder mucosa, especially the trigone region due to the distal part of the stent, urinary reflux, and smooth muscle spasm. In the use of DJ stents in the ureter, hematuria, urgency, frequency, dysuria, bladder pain, and flank may occur. Lower urinary tract symptoms (LUTS) are reported to reach 80% in patients who use DJ stents.

α 1-Adrenoceptor is found in the ureter, with the highest density in the distal ureter. Administration of α 1-Adrenoceptor antagonists dilates the ureteral tract and reduces cramps by inhibiting basal tone and reducing the frequency of ureteral peristalsis. Use of α inhibitors to relieve SAS is recommended by the EAU guideline.^{4,5}

Tamsulosin is a selective α 1A and α 1D adrenoceptor antagonist. The standard tamsulosin regimen used to treat LUTS in the western population is 0.4 mg once daily. But a lower dose of tamsulosin 0.2 mg daily is the standard regimen used for Asian populations. Because tamsulosin is one of the most commonly used drugs in the initial treatment of LUTS, many clinicians often decide to use tamsulosin 0.2 mg monotherapy. Increasing dosage is an attractive alternative.⁶ Several factors that must be considered to increase the dose of tamsulosin 0.4 mg for LUTS patients due to less effective administration of tamsulosin 0.2 mg are:

1. Safety from increasing doses

We know that the safety of increasing the dose by seeing it does not get worse after the increase in the dose.

2. Effectiveness

In some studies, it was seen that there was an increase in Qmax with the improvement of LUTS symptoms. Besides, the administration of tamsulosin 0.4 mg improved the improvement of subjective symptoms assessed from the IPSS questionnaire. However, proper counseling and education before the dose increase needs to be done.⁶

The results of the comparative test study of the results of scoring before and after the tamsulosin group at a dose of 0.2 mg showed that the results were not in accordance with the existing theory that the LUTS symptoms of the Asian population can be overcome with tamsulosin 0.2 mg even though there are also some refractory individuals or failed with the dosage treatment.

The results of the comparative test study of the results of scoring before and after the tamsulosin group at 0.4 mg showed that these results are in accordance with the existing literature that an increase in tamsulosin dose of 0.4 mg for LUTS

patients due to less effective administration of tamsulosin 0.2 mg provide significant improvement in LUTS symptoms both subjectively and objectively (scoring system).

CONCLUSION

Lower urinary tract symptoms are the most common complication of using DJ stents. Administration of tamsulosin 0.2 mg or 0.4 mg can significantly reduce SAS. Tamsulosin 0.4 mg has a better effect on reducing SAS compared with tamsulosin 0.2 mg. Further research with a larger number of subjects is still needed.

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