Stone-Free Rate Differences in Kidney Stones Patients With and Without Tamsulosin After ESWL

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Effect of Testosterone Deprivation on Smooth Muscle-Collagen Ratio in Bladder Wall of Wistar Rats

Stone-Free Rate Differences in Kidney Stones Patients With and Without Tamsulosin After ESWL

Endothelin-1, Nitric Oxide, and Ratio of ET-1/NO in Erectile Dysfunction

Risk Factors for Urethrocutaneous Fistulas Formation After One Stage Hypospadias Repair

Comparison of Serum Sodium, Serum Potassium, and Blood Hemoglobin Changes After Transurethral Resection of The Prostate Between Irrigation With Normal Saline and Sterile Water

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Table of Contents

July 2011 Vol. 18 No. 2

ISSN: 2355-1402

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STONE-FREE RATE DIFFERENCES IN KIDNEY STONES PATIENTS WITH AND WITHOUT TAMSULOSIN AFTER ESWL

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ABSTRACT

Objective: *To determine whether the administration of tamsulosin, as adjunctive medical therapy, increases the efficacy of one session of extracorporeal shock wave lithotripsy (ESWL) to treat renal stones.* ***Material & Method:*** *A prospective randomized placebo controlled study enrolled 21 patients. They underwent a single ESWL session to treat solitary radiopaque renal stones 4 to 20 mm in diameter. After ESWL, the study group (11) received 0,4 mg tamsulosin daily and the control group (10) received placebo until stone clearance or a maximum period of 8 weeks. The primary endpoint was stone-free rate and parameters were stone size and clearance time.* ***Results:*** *The overall stone-free rate was better in the study group than in the control group (90,9% vs. 60,0%). The clearance time after 2, 4, 6 and 8 weeks was greater in the study group than in the control group (36,4%; 63,6%; 72,7% and 90,9% vs 30,0%; 50,0%; and 60,0% respectively) but statistically insignificant.* ***Conclusion:*** *Clinically, the results of our study have demonstrated that tamsulosin therapy, as an adjunctive medical therapy after ESWL, is more effective than lithotripsy alone for the treatment of patients with renal stones.*

Keywords: *Extracorporeal shock wave lithotripsy, tamsulosin, medical expulsive therapy, renal stones.*

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INTRODUCTION

Urinary tract stone disease is the third most common disease from the entire urinary tract abnormalities after urinary tract infections and prostate disorders.[1] In the United States the prevalence of urolithiasis is estimated at 10% to 15%.[2] In Indonesia, urinary tract stone disease still holds the largest share of total patients in urology clinic, with the precise incidence still undetermined.[3]

The discovery of ESWL (Extracorporeal Shock Wave Lithotripsy) is a revolutionary change in the therapy of kidney stones, compared to the main previous option of surgery. Twenty years after the introduction of ESWL and endourology, such as URS (ureterorenoscopy) and PNL (percutaneous nephrolithotripsy), the management of calyceal stones has changed drastically. Where in the era of 1970-1980s, open surgery was an option, it is rarely done today. Minimally invasive procedures are chose because of fewer complications compared to open surgery.[4]

ESWL is a non-invasive technology, first used in 1980. Thereafter ESWL has been used extensively throughout the world.[5] ESWL is preferred due to its non-invasive nature and limited morbidity compared to open surgery or other more invasive techniques. But in a setting of large, hard and multiple stones, ESWL may require multiple sessions, or surgery is required if complications arise, such as obstruction due to stone fragments.[6] American Urological Association (AUA) have published guidelines for the management of ureteric stones and kidney stones, in which stones of less than 20 mm can be subjected to ESWL.[7]

Studies on the use of tamsulosin on ureteral stone are various, especially for distal ureteric stones, considering α1-adrenergic receptors are the most numerous in the distal ureter.

The concept of using α1-adrenergic receptor antagonists as adjuvant therapy in ESWL therapy has been studied several times. A study comparing use of tamsulosin after ESWL of ureteral stones with control group without tamsulosin revealed the stone-free rate was 70,8% in tamsulosin group and 33,3% in group without tamsulosin.[8]

However, studies on tamsulosin as adjuvant therapy after ESWL on kidney stone are still limited. Gravina et al (2005), who conducted a study on the efficacy of tamsulosin after ESWL of kidney stones revealed, that after 12 weeks the stone-free rate was 78,5%, compared to the group without tamsulosin 60%. Effect of tamsulosin was better on larger stones (> 20 mm).[9]

OBJECTIVE

To determine stone-free rate and time to stone-free status in kidney stones patients subjected to ESWL with and without tamsulosin administration.

MATERIAL & METHOD

This study was a quasi-experimental study performed from January to July 2010. The samples in this study were patients diagnosed with kidney stones who performed ESWL in Soetomo Hospital Surabaya. Samples were randomly allocated into 2 groups, 10 individuals each. In Group 1 (tamsulosin group), after ESWL the patients took tamsulosin 0,4 mg once daily for 8 weeks, whereas in group 2 (control group) patients also underwent ESWL but received no adjuvant tamsulosin.

Criteria for inclusion in this study were (1) Patients diagnosed with calyx stone with size > 5 mm and ≤ 20 mm, (2) Age more than 18 years, (3) Serum creatinine below 1,7 mg/dL, (4) Normal routine blood tests, hemostatic function, and electrolytes, (5) Radiopaque stones, (6) Lower calyx stones, infundibulopelvic angle of more than 70°, infundibulum width more than 5 mm, and length of infundibulum less than 3 cm, (7) Subjected to IVP examination.

Five of 21 subjects in this study required repeat ESWL because until end of the 8th week of observation, there was still residual stone > 3 mm. No subject dropped out or developed complications that required treatment or surgery. Homogeneity test on stone diameter, age, gender, and location of the stone, showed no significant difference. Statistical analysis was performed descriptively and analytically. Difference in stone-free rate between treatment and control group was analyzed using two-layer Chi Square test. Observations were made at weeks 2, 4, 6, and 8.

RESULTS

The youngest subject was 19 years old while the oldest was 65 years old. The average age of 21 patients enrolled ranged 12,055 ± 49,14 years. The median age of the patients was 52 years. Most of the samples (57,1%) were male (Table 1). Stone location was mostly in the lower pole (57,1%) and a majority of stones was on the right side (71,4%).

Table 1. Characteristics of sex, stone location, and position.

Categories		Freq	%
Sex	Male	12	57,1
	Female	9	42,9
	Total	21	100,0
Store location	Lower	12	57,1
	Middle	7	33,3
	Upper	2	9,5
	Total	21	100,0
Position (right and left)	Right	15	71,4
	Left	6	28,6
	Total	21	100,0

Table 2. Comparison of stone-free rate in week 2.

Stone-free Incidence	Group		Total
	Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
Stone-free	4	3	7
	36,4%	30,0%	33,3%
No Stone-free	7	7	14
	63,6%	70,0%	66,7%
Total	11	10	21
	52,4%	47,6%	100,0%
χ^2		0,000	
Sig.		1,000	

Table 3. Comparison of stone-free rate in week 4.

Stone-free Incidence	Group		Total
	Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
Stone-free	7	5	12
	63,6%	50,0%	57,1%
No Stone-free	4	5	9
	36,4%	50,0%	42,9%
Total	11	10	21
	52,4%	47,6%	100,0%
χ^2		0,036	
Sig.		0,670	

Table 4. Comparison of stone-free rate in week 6.

Stone-free Incidence	Group		Total
	Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
Stone-free	8	6	14
	72,7%	60,0%	66,7%
No Stone-free	3	4	7
	27,3%	40,0%	33,3%
Total	11	10	21
	52,4%	47,6%	100,0%
χ^2		0,024	
Sig.		0,659	

Table 5. Comparison of stone-free rate in week 8.

Stone-free Incidence	Group		Total
	Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
Stone-free	10	6	16
	90,9%	60,0%	76,2%
No Stone-free	1	4	5
	9,1%	40,0%	23,8%
Total	11	10	21
	52,4%	47,6%	100,0%
χ^2		1,318	
Sig.		0,149	

In the 2nd week of observation (Table 2) clinical stone-free rate in tamsulosin group was better than control group (36,4% vs 30%), but not statistically significant (p = 1,000).

Clinical manifestations of tamsulosin were increasingly observable in week 4 (Table 3), where the stone-free rate reached 63,6%. It increased almost two fold compared to week 2, but significance was still higher than 0,05 (p = 0,670), which concluded there was no statistically significant difference between the two groups.

Table 6. Comparison of stone-free rates based on stone diameter in week 2.

Diameter categories				Group		Total
				Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
< 10mm	Week 2	Stone free	Count	4	3	7
			Expected count	3,5	3,5	7,0
			% within week 2	57,1%	42,9%	100,0%
		Stone present	Count	3	4	7
			Expected count	3,5	3,5	7,0
			% within week 2	42,9%	57,1%	100,0%
	Total		Count	7	7	14
			Expected count	7,0	7,0	14,0
			% within week 2	50,0%	50,0%	100%
> 10mm	Week 2	Stone present	Count	4	3	7
			Expected count	4,0	3,0	7,0
			% within week 2	57,1%	42,9%	100,0%
	Total		Count	4	3	7
			Expected count	4,0	3,0	7,0
			% within week 2	57,1%	42,9%	100,0%

The increase of stone-free rate on observation week 6 (Table 4), both in tamsulosin group and control group, was still observed (72,7% vs 60%). Tamsulosin group was clinically better than the control group. Significance value obtained in week-6 was 0,659, not much different from the results in week 4 and remained not statistically significant.

Observations until the end of week 8 (Table 5) revealed that the therapeutic effects of tamsulosin were clearly visible when compared with the control group. Stone-free rate of tamsulosin group increased compared to week 6, while the control group remained (90,9% vs 60%). But based on the calculation this difference remained statistically significant (p = 0,149).

The observation in week 2 (table 6) revealed that stone-free rate from both groups stratified based on stone diameter, for stone size ≤ 10 mm remained better in the tamsulosin group than in control group (57,1% vs 42,9%). However, those with stone diameter > 10 mm could not be analyzed because there was no change. Difference in stone-free rate of stones ≤ 10 mm for both groups was not significant (p = 1,000).

Stone-free rate in week 4 (table 7) in both groups had clinically remarkable increase (85,7% vs 71,4%) for stone with of size ≤ 10 mm compared with that in week 2, but the significance value between tamsulosin groups compared to control group was not high, which was 1,000 (p > 0,05).

Observation in week 4 for stone size > 10 mm showed that stone-free rate in tamsulosin group increased compared to controls (25% vs 0%), with significance value of 1,000. There was still no statistically significant difference between the two groups.

In week 6 (table 8), stone-free rate in tamsulosin group and control group was the same, 85,7%, for stone diameter ≤ 10 mm. The significance value obtained was 1,000 (p > 0,05), but showing no significant difference in stone-free rates in tamsulosin group and control group for stone diameter ≤ 10 mm.

For stone size > 10 mm statistical calculation for the two groups was not significant (p = 0,429), but the clinical significance of tamsulosin appeared better than that in control group. This was demonstrated by the increased stone-free rate (50% vs 0%).

Observations by the end of week 8 (table 9), showed the effect of tamsulosin therapy on stone size ≥ 10 mm was better than in controls, as shown by

Table 7. Comparison test of stone-free rates by stone diameter in week 4.

Diameter categories				Group: Tamsulosin (n = 11)	Group: No Tamsulosin (n = 10)	Total
≤ 10mm	Week 4	Stone free	Count	6	5	11
			Expected count	5,5	5,5	11,0
			% within week 4	54,5%	45,5%	100,0%
		Stone present	Count	1	2	3
			Expected count	1,5	1,5	3,0
			% within week 4	33,3%	66,7%	100,0%
	Total		Count	7	7	14
			Expected count	7,0	7,0	14,0
			% within week 4	50,0%	50,0%	100,0%
> 10mm	Week 4	Stone present	Count	1	0	1
			Expected count	,6	,4	1,0
			% within week 4	100,0%	0%	100,0%
		Stone present	Count	3	3	6
			Expected count	3,4	2,6	6,0
			% within week 4	50,0%	50,0%	100,0%
	Total		Count	4	3	7
			Expected count	4,0	3,0	7,0
			% within week 4	57,1%	42,9%	100,0%

increased stone-free rate to 100%, while in control group remained 85,7%. This difference was not statistically significant (p > 0,05).

Changes in stone-free rate in tamsulosin group were also seen on stone size > 10 mm (75% vs 0%), data showed that tamsulosin administration was clinically beneficial. However, this was not supported by statistical significance calculations. Significance value of 0,143 (p > 0,05) indicated no significant difference between the two groups.

Table 8. Comparison of stone-free rates based on stone diameter in week 6.

Diameter categories				Group		Total
				Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
≤ 10mm	Week 6	Stone free	Count	6	6	12
			Expected count	60,0	60,0	12,0
			% within week 6	50,0%	50,0%	100,0%
		Stone present	Count	1	1	2
			Expected count	1,0	1,0	2,0
			% within week 6	50,0%	50,0%	100,0%
	Total		Count	7	7	14
			Expected count	7,0	7,0	14,0
			% within week 6	50,0%	50,0%	100,0%
> 10mm	Week 6	Stone present	Count	2	0	2
			Expected count	1,1	,9	2,0
			% within week 6	100,0%	,0%	100,0%
		Stone present	Count	2	3	5
			Expected count	2,9	2,1	5,0
			% within week 6	40,0%	60,0%	100,0%
	Total		Count	4	3	7
			Expected count	4,0	3,0	7,0
			% within week 6	57,1%	42,9%	100,0%

Table 9. Comparison of stone-free rates based on stone diameter in week 8.

Diameter categories				Group		Total
				Tamsulosin (n = 11)	No Tamsulosin (n = 10)	
≤ 10mm	Week 8	Stone free	Count	7	6	13
			Expected count	6,5	6,5	13,0
			% within week 8	53,8%	46,2%	100,0%
		Stone present	Count	0	1	1
			Expected count	,5	,5	1,0
			% within week 8	0,0%	100,0%	100,0%
	Total		Count	7	7	14
			Expected count	7,0	7,0	14,0
			% within week 8	50,0%	50,0%	100,0%
> 10mm	Week 8	Stone present	Count	3	0	3
			Expected count	1,7	1,3	3,0
			% within week 8	100,0%	0,0%	100,0%
		Stone present	Count	1	3	4
			Expected count	2,3	1,7	4,0
			% within week 8	25,0%	75,0%	100,0%
	Total		Count	4	3	7
			Expected count	4,0	3,0	7,0
			% within week 8	57,1%	42,9%	100,0%

DISCUSSION

Researchers have reported study results of medications to minimize intrinsic factors that cause ureteric narrowing (ureteric peristalsis, spasm, and edema), thus increasing ureteric stone expulsion. Borghi and Porpligia reported a combination of nifedipine and corticosteroids improved mean time to expulsion of ureteric stones. Furthermore, the use of β-1 adrenergic antagonists for ureteral stones has been widely studied. In this study, researchers used tamsulosin, because it works well as a selective antagonist of α-1a and α-1d adrenoceptors, does not require dose titration and have minimal side effects.[9]

Urinary tract stone disease occurs more often in adult men than adult women. With a wide range of indicators, the incidence of urinary tract stones in men ranged from 2 to 3 times more frequently than in women.[10] The sample of this study showed that men had 1,3 times more susceptibility than women. It remains unclear why the stone tends to grow in lower calyx, although accumulation of stone fragments in this site is very likely related to gravity.

Time to stone-free state is one important indicator but is rarely measured in previous studies. The difficulty in this case is partly because the patients included in samples could not properly record the time and number of fragments expulsed,[9] and also due to the costs and effects of X-ray radiation and ultrasound scanning as a means of evaluating treatment results. Therefore, the remaining source that could be used to assess stone-free event was the regular intervals when the patient made a visit, i.e., in weeks 2, 4, 6, and 8 post-ESWL.

In this study there were no statistically significant difference in all comparisons of time to stone-free status in tamsulosin group compared to control group in week 2 (p = 1,0), week 4 (p = 0,670), week 6 (p = 0,659), and week 8 (p = 0,659). Observation to groups with and without tamsulosin regarding stone diameter, with diameter of ≤ 10 mm and 11-20 mm, showed no significant difference in all observations from week 2 to 8, both in groups with stone diameter of ≤ 10 mm and 11-20 mm. These results differed from previous studies. Seitz (2009) stated in his collaborative review that 19 out of 20 studies related to α-blockers with stones ≥ 5 mm (14 studies on ureteric stones, 3 studies on kidney stones) concluded that there was a significant advantage in stone expulsion rates.[11] Gravina (2005) and Bhagat (2007) in their research findings also stated that there were significant differences in stone with a diameter of> 10 mm.[9,12]

The results of this study showed that tamsulosin 0,4 mg as adjuvant therapy after ESWL on kidney stones in treatment group provided higher Stone-Free Rate (SFR) compared to the control group (90,9% vs 60%). Up to the end of week 8, Naja (2008) in similar studies found similar results in the administration of tamsulosin after ESWL for kidney stones in week 12 (94,1% vs 84,6%; p = 0,14).[13] This result is different from other existing studies. Gravina (2005) reported the success rate of one ESWL session for kidney stones with tamsulosin, in which the success was obtained in week 12 (78% vs 60%, p = 0,04), while Bhagat (2007) also reported significant results with tamsulosin administration for 4 weeks (96,6% vs 79,3%; p = 0,04).[9,12]

In general, previous studies showed better outcome of kidney stones treated with ESWL receiving tamsulosin as adjuvant therapy. In three studies, the clearance rate was higher after tamsulosin for 4 weeks compared to 12 weeks.[12,13] Therefore, it can be assumed that larger fragments in tamsulosin group were expulsed faster, producing better success rate than in control group, requiring no further ESWL sessions.

The results of time to stone-free in this study was not significant when compared to previous studies. This might be caused by the mean diameter of the stone. The mean stone diameter in this study was 8,91 ± 2,914 mm in tamsulosin group and 8,70 ± 2,003 mm in control group. Whereas, in previous studies by Gravina et al (2005), Bhagat et al (2007) and Naja et al (2008), stones in diameter of < 10 mm, the success rate in tamsulosin groups was not significant compared to that in control group.[9,12,13] Another possible cause of the insignificance in this study was the location of the stone. The locations of stone samples in this study were mostly in inferior calyx (12/21, 60%). Two of the three previous studies by Gravina et al (2005) and Naja et al

(2008) did not use stones in inferior calyx with the reason that the location did not have a beneficial effect from medications.[9,13]

Stone-Free Rate (SFR) for the inferior calyx stone varied between 67,8% (for ≤ 10 mm), 54,6% (11-20 mm) and 28,8% (> 20 mm).[8] Inferior calyx stone is a complex problem in the treatment of urinary tract stones with ESWL. First, many kidney stones originates from inferior calyx and its clearance rate tends to be lower compared to stones in other location. Second, stone fragments after ESWL, although originating from other calyces, tend to gather in the inferior calyx which is likely influenced by gravity.[14]

Anatomical-geometrical factor of the inferior calyx is also referred to as an important prognostic factor affecting clearance. Prognostic factors in question are infundibulo-pelvic angle, infundibular width and length.[15] Sampaio (1997) states that the favorable anatomical features of inferior calyx are infundibulo-pelvic angle of 90° or more, infundibular width of > 5 mm, and length < 30 mm. Sorenson and Chandhoke (2002) mentions that infundibulo-pelvic angle is favorable if > 70°,[16] while the width and length of infundibulum are similar to those in previous research.

Unfortunately, relationship between anatomical-geometrical factors of inferior calyx and clearance rate is still being debated in several studies. A comprehensive overview conducted by Danuser (2007) mentions that seven of the 11 studies found no relationship between infundibulum width and stone clearance. Positive relationship between long infundibulum and SFR was found in 6 of 12 studies, while those that found correlation between infundibulo-pelvic angle and SFR comprised 5 from 12 studies. Danuser, therefore, suggested that the relationship between anatomical-geometrical factors of calyx inferior with SFR is still not clear.[17] No strong evidence base as a reference for clinical practice exists that helps to predict the success of ESWL for inferior calyx.[14]

CONCLUSION

The results of this study indicate that clinical administration of tamsulosin as adjuvant therapy after ESWL is more effective than ESWL alone for treatment of kidney stones.

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PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9

PAGE 10

PAGE 11