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Effect of Tamsulosin on Clearance of Stone Fragments after Shockwave Lithotripsy for Renal & Ureteric Calculi. Does it Make a Difference? [Version 1, 1 Approved with Reservation]

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Abstract

Objective: The aim of this study is to assess effect of tamsulosin on clearance of stone fragments after shockwave lithotripsy(SWL) for renal & ureteric calculi.
Patients and Methods: Between November 2010 & April 2012, a total of 50 patients with solitary, radio-opaque renal or ureteral stones measuring ≤ 2 cm were treated by ESWL using Dornier SII lithotripter with a maximum of 4 sessions. Patients were divided into 2 equal groups; group (A) were taken tamsulosin plus diclofenac sodium and group (B) were taken diclofenac sodium alone. Post-treatment KUB were used to evaluate clearance of stone fragments.
Results: There was no statistically significant difference between both groups as regard clearance of stone fragments (100% versus 96% respectively p= 0.312); however group (A) had less requirements of analgesics (888 mg versus 1470 mg p= 0.001); also group (A) had less incidence of stienstrasse (4% versus 24%, p= 0.042).
Conclusion: Addition of tamsulosin drug to the patients after extracorporeal shockwave lithotripsy (ESWL) did not have significant effect on the clearance of stone fragments, however it reduced the analgesic requirements & occurrence of stienstrasse.

Abbreviations

ESWL: Extracorporeal Shockwave Lithotripsy; **SWL:** Shockwave Lithotripsy; **MET:** Medical Expulsive Therapy; **KUB:** Kidney, Ureter and Bladder Plan X-Ray

Introduction

Urinary stone disease is one of the most common urinary, affecting 5–10% of the population [1]. Since the early of eighteenth, extracorporeal shockwave lithotripsy (ESWL) has become one of the initial treatment for patients with kidney and ureteric calculi. Even with the refinement of current endourological methods for stone removal, ESWL remains the primary treatment for most patients with uncomplicated calculi [2].

Medical expulsive therapy (MET) has gained increasing attention in the last decade as promise in facilitating spontaneous clearance of the fragments after SWL for renal or ureteric calculi [3-5]. It has been suggested that the administration of alpha-adrenoreceptor antagonists (alpha-blockers) or calcium channel blockers augments stone expulsion rates and reduces colicky pain [6]. The role of alpha blockers as an adjunctive to ESWL for renal stones has emerged and is generally accepted for the last few years. However there is paucity of studies that have delved into the role of alpha blockers beyond just stone clearance [3,4,7].

However it remains unclear whether tamsulosin as adjuvant treatment for patients after ESWL, for ureteric and renal stone, would improve the stone free rate. A prospective randomized study was thus planned to evaluate the Effect of Tamsulosin on Clearance of Stone Fragments after Shockwave Lithotripsy for Renal & Ureteric Calculi.

Patients and Methods

A total of 50 patients with a single renal or ureteric calculus 20mm or less were enrolled in this prospective randomized controlled study was conducted at our hospital Between November 2010 & April 2012, underwent ESWL using Dornier SII lithotripter with a maximum of 4 sessions. The patients were randomly divided into 2 groups: group (A) formed of 25 patients received NSAID in the form of Diclofenac Na 50mg tds on demand with tamsulosin 0.4 mg once daily, and group (B) formed of 25 patients received Diclofenac Na 50mg tds on demand as a control group. Both groups received 75mg of Diclofenac Na ampule i.m on demand.

All patients signed consent before procedure and they were informed about all possible side effects.

All patients were followed up by KUB 2 weeks after each session of ESWL for clearance of stone fragments. The results of both groups were compared to each other as regard expulsion rate, analgesic requirement, and incidence of stienstrasse after ESWL.

The success of our study is defined as stone-free status or presence of clinically insignificant residual fragments (which defined as asymptomatic fragments 3 mm or less in diameter).

Failure was defined as failed ESWL after 4th session or the need for auxiliary procedure after any session (ureteroscopy, or percutaneous nephrolithotripsy performed for residual calculi or steinstrasse).

Data were analyzed by using the Chi-square test for categorical variables and T-test for continuous variables. Differences resulting in $p < 0.05$ were considered statistically significant.

Results

The mean age in group A 39.92+11.78 year and 38.76+11.035 in group B, so There is no statistically significant difference in both groups as regard mean age distribution(P= 0.72).

Female patients were 48% of group A and 32% of group B, while the male patients were 52% of group A and 68% of group B which revealed there is no statistically significant difference in both groups as regard sex distribution(P= 0.248).

The mean stone size was 10.76+2.85 mm in group A and 10.88+3.618 mm in group B. There is no statistically significant difference in both groups as regard the mean stone size in both groups (P= 0.897).

The stone size below 10mm was 60% of the cases in group a and 64% in group B, but stone size more than 10mm were 40% of cases in group A and in group B 36%, so There is no statistically significant difference in both groups as regard the stone size in both groups (P= 0.771).

Table 1: Stone size (<10 mm and >10 mm) in both groups.

Stone size in mm		Groups					
		Group A		Group B		Total	
		N	%	N	%	N	%
<or =10 mm		15	60.00	16	64.00	31	62.00
>10 mm		10	40.00	9	36.00	19	38.00
Total		25	100.00	25	100.00	50	100.00
Chi-square	X^2	0.085					
	P-value	0.771					

There is no statistically significant difference in both groups as regard the stone location. In which ureteric stone was 40% of cases in group A and 52% in group B, but renal stone was 60% in group A and 48% in group B (P=0.395).

Table 2: Stone location in both groups.

Stone location (ureter or kidney)		Groups					
		Group A		Group B		Total	
		N	%	N	%	N	%
ureter		10	40.00	13	52.00	23	46.00
kidney		15	60.00	12	48.00	27	54.00
Total		25	100.00	25	100.00	50	100.00
Chi-square	X^2	0.725					
	P-value	0.395					

After first session of ESWL radiological results revealed stone free were 60% of the patients in group A and 52% in group B (P= 569) . There is no statistically significant difference

in both groups as regard the clearance of stone fragments after 1st session in both groups.

Table 3: Radiological results after 1st session of ESWL in both groups.

PUT after 1st session		Groups					
	Group A		Group B		Total		
	N	%	N	%	N	%	
Stone free		15	60.00	13	52.00	28	56.00
Failed		10	40.00	12	48.00	22	44.00
Total		25	100.00	25	100.00	50	100.00
Chi-square	X^2	0.325					
	P-value	0.569					

There was no statistically significant difference in the stone free rate between stone size < or =10 mm (36% in group A and B) & stone size > 10 mm (24 in group A & 16% in group B) after 1st session in both groups (P= 1.000 & P= 0.571).

Table 4: Percentage of stone free cases in comparison with stone size after 1st session in both groups.

PUT After 1st session		Stone size							
	< or =10mm		>10mm		Total		Chi-square		
	N	%	N	%	N	%	X^2	P-value	
Group A	Stone free	9	36.00	6	24.00	15	60.00	0.000	1.000
	Failed	6	24.00	4	16.00	10	40.00		
Group B	Stone free	9	36.00	4	16.00	13	52.00	0.322	0.571
	Failed	7	28.00	5	20.00	12	48.00		

There is statistically significant difference in both groups as regard the stienstasse after 1st session as stienstasse occurred in one case only (4%) in group (A) & six cases (24%) in group (B) with (P =0.042).

Table 5: Radiological results after 1st session of ESWL in both groups as regard stienstrasse.

Stienstrasse at lower ureter after 1ST session		Groups					
	Group A		Group B		Total		
	N	%	N	%	N	%	
No		24	96.00	19	76.00	43	86.00
Yes		1	4.00	6	24.00	7	14.00
Total		25	100.00	25	100.00	50	100.00
Chi-square	X^2	4.153					
	P-value	0.042					

There is no statistically significant difference in both groups as regard the clearance of stone fragments after 2nd session. It was 100% in group A and 92% in group B with P= 0.149.

In group B there is one patient (4%) needing 3rd session of ESWL and another one patient (4%) in the same group needs 4th session to get free stones.

There is statistically significant difference in both groups as regard the analgesic requirement as much lower need of analgesic requirement in group (A) which The mean cumulative diclofenac dose (mean analgesis) was 888+134 mg.while in group B was 1470+484 mg (P<0.001).

Table 6: Radiological results after 2nd session of ESWL in both groups.

PUT after 2nd session		Groups					
	Group A		Group B		Total		
	N	%	N	%	N	%	
Stone free		25	100.00	23	92.00	48	96.00
Failed		0	0.00	2	8.00	2	4.00
Total		25	100.00	25	100.00	50	100.00
Chi-square	X^2	2.083					
	P-value	0.149					

Table 7: Analgesic requirement in both groups.

Groups	analgesic requirement in mg					T-test	
	Range			Mean	± SD	t	P-value
Group A	700mg	-	1200mg	888mg	± 134.07	-5.79	<0.001*
Group B	800mg	-	2650mg	1470mg	± 484.12		

There was no statistically significant different between both groups as regard clearance of stone fragments (100% versus 96% respectively p= 0.312); However group (A) had less requirements of analgesics (888 mg versus 1470 mg p= 0.001); Also group (A) had less incidence of stienstrasse (4% versus 24% , p= 0.042).

Discussion

The main goal of renal stone treatment is obtaining maximum stone clearance with minimum morbidity. So ESWL has allowed to manage most of patients with renal stones with minimally invasive fashion.

ESWL has introduced as non-invasive treatment of renal and ureteral stone. Recently ESWL has become the first choice modality for management of renal stones <2.0cm [8].

The using alpha 1 adrenergic antagonists in medical expulsion therapy due to their effect to inhibit basal tone and peristaltic ureteral contractions, which dilating the lumen of ureter and it increase the fluid bolus volume facilitating calculi passage through the ureter to the bladder[3,9]. It also effects on the C fibers blocking pain conduction [10]. Of the available α1-blockers,

Tamsulosin is chosen for this study as it is a combined α1A and α1D-selective adrenergic antagonist.

Although from previous studies there is still no definite number of ESWL that should be administered for ureteric ore renal calculi before alternative treatments are used [11,12] , in the present series we considered absent or poor fragmentation after four ESWL sessions as a failure.

In our study, there is no statistically significant difference between both groups as regards patients' characteristics, stone diameters and session details. All patients had the same follow up protocol performed by the same team, so the risk of bias in our study was limited. These results of the present study are

coincident with most of the previous studies for the absence of associations between the age and sex of the patient, side and nature of the stone, [12–14].

In our study there was no statistically significant difference between both groups as regard clearance of stone fragments (100% versus 96% respectively p= 0.312) ; This result was comparable to the results obtained by Graves et al [15] in a cohort of 64 patients with lower ureteric calculus found a statistically similar success rate in patients with or without tamsulosin (66.6% vs 58.1%, P> 0.05). also in accordance with Vineet et al., [16] which were (94.1% and 84.6%; P = 0 .14) ; and the results obtained by Gupta ., et al [17] which were (63% versus 52% ; p < 0.05) .

However these results were not comparable to that obtained by Bhagat et al [7] reported an improved success rate with tamsulosin in 60 patients with renal and ureteral stones undergoing ESWL (96.6% vs 79.3%, P=0.04). Giovanni Gravina et al., [18] which were (78.5% versus 60%; p =0.037) .

As one of advantage of adjunctive tamsulosin treatment in the present and other studies [7,5,19] is the significant reduction in the need for analgesics. In our study there was statistically significant reduction in the analgesic requirement in group (A) than the control group (888 mg versus 1470 mg p<0.001).

These results are matched with Hassan Ismail [20], The mean diclofenac dose was 380 mg/patient in group 2 and 750 mg/patient in group1 (P = 0.004)

These results were also comparable to the result obtained by Giovanni Gravina et al [18] which was 375 mg for tamsulosin group versus 675 mg for the control group (P=0.001); and the results obtained by Gupta ., et al [17] which was 57mg for tamsulosin group versus 119 mg for the control group (p=0.02). Also Aurorino et al [4] study revealed significantly lower incidence of analgesic requirement (9% vs 31%) and admission for colic(9% vs 21%) in patients receiving tamsulosin . In a metanalysis, Hollings worth et al [15] reported consistent benefit of tamsulosin in different pain parameters in patient of renal as well as ureterolithiasis with SWL.

In our study occurrence of stienstrasse at lower ureter was much lower in tamsulosin group (1/25patient) than the control group (6/25) patients (p= 0.04). All patients managed by another session of ESWL & all became stone free.

These results are more statistically significant compared to results obtained by Vineet et al., [16] in which 2/51 patients in group 1 (tamsulosin) and 9 /65 patients in group 2 (control) were developed stienstrasse (P= 0.10) and the results obtained by Bhagat et al. [7] in which steinstrasse was observed in 8/30 patients in the placebo group and 10/30 patients in the tamsulosin group.

In the present study group (A) had less incidence of stienstrasse than group B (4% versus 24% , p= 0.042). Which coincides with result of Syed Saeed et al. (10), the incidence of steinstrasse was higher in the control than in study group 15(25%) vs 6(10%) respectively, (p<0.03) .

Conclusion

Addition of tamsulosin drug to the patients after ESWL did not have significant effect on success and stone-free rates. However, it significantly reduced the analgesic requirements and was associated with significantly fewer complications, especially steinstrasse.

Conflict of Interest

None.

Source of Funding

None.

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