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Comparison of Safety and Efficacy of Tamsulosin alone and Combination of Tadalafil and Tamsulosin as Medical Expulsive Therapy for Ureteric Stone

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Abstract

Background and objectives: The medical expulsion therapy is essential to avoid invasive treatment of ureteric stones. The aim was to compare the safety and efficacy of Tamsulosin alone and combination of Tadalafil and Tamsulosin.

Methods: A retrospective cross-sectional study implemented in private clinic in Erbil city, Kurdistan Region-Iraq from 1st of February, 2022 to 31st of January, 2024 on one hundred and eighty-four patients with ureteric stones (92 patients with Tamsulosin only and 92 patients with Tadalafil & Tamsulosin). Post-treatment outcomes and adverse effects were assessed and managed accordingly.

Results: Number of analgesic injections were higher among patients treated by Tamsulosin only zero injection (39/92),1-3 times (44/92), and >3 times (9/92) while in Tamsulosin Tadalafil group were zero injection (65/92) , 1-3 times (24/92) and >3 times (3/92) with statistical value ($p<0.001$).also number of emergency visits were higher in Tamsulosin only group zero visit (57/92),1-3 visits (30/92),>3 visits (5/92) in compare to the Tamsulosin Tadalafil group zero visit(85/92) , 1-3 visits (5/92) and >3 visits (2/92) and the statistical value was ($p<0.001$). also, stone expulsion rates were higher with Tadalafil & Tamsulosin therapy (70/92) while in Tamsulosin only group (66/92) and the statistical value was ($p=0.02$). dizziness adverse effect was more with Tadalafil & Tamsulosin therapy (5/92) in compare to the Tamsulosin only were (0/92) with statistical value ($p=0.02$).

Conclusion: Tadalafil & Tamsulosin is safe and more effective in medical expulsion therapy of ureteric stones than Tamsulosin alone.

Keywords: Medical expulsion therapy, Tadalafil, Tamsulosin, Ureteric stone

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Introduction

Ureteric stone is a common disorder affecting all world population with big burden on healthcare system. This disease is characterized by evolving increasing in incidence and prevalence and accompanying different systemic diseases especially heart diseases, diabetes mellitus and metabolic syndrome.[1] The main risk factors of ureteric stones are chronic infection, cystinuria, hypercalciuria, low fluid intake, high salty diet, high protein diet, dehydration and inadequate urinary volume.[2] The prevalence of ureteric stones reached to 11% among males and 7% among females with incidence rate reaching to 0.5% in population of Western countries.[3] The ureteric stone is a frequent disease in Iraq with different distribution and stones compositions in various areas of the country.[4] The ureteric stones represented about 22% of urinary stones and about two thirds of detected ureteric stones were in distal portion of ureter.[5] These stones are usually presented by colicky pain and other symptoms like frequency and urgency.[6] Recently, different treatment options are used for ureteric stones from medical to surgical options which depend mainly on stones size.[7] Small stone size (<5 mm) had an acceptable odd of pass-through ureter (98%), while stones of large than that size (6 to10 mm) had odds of 47% to pass and in stones with larger (>10 mm) size, numerous surgical treatments are used such as extracorporeal shock wave lithotripsy, ureteroscopic lithotripsy, laparoscopic ureterolithotomy and percutaneous nephrolithotomy.[8] High chance of stones passage from distal ureter encouraged the physicians to use the medical expulsive therapy as a non-invasive option for small size distal ureteric stones.[9] The medical expulsive therapy is a medical treatment facilitates the stones passage and approved by American and European Guidelines.[3, 10] This treatment regimen involves different medicines like alpha adrenoreceptor antagonists, calcium channel blockers, prostaglandin inhibitors and phosphodiesterase type 5 inhibitors.[11,12] Nevertheless, the Tamsulosin (alpha adrenoreceptor antagonists) is the highly used treatment as medical expulsive therapy. Tamsulosin mechanism of action is thought to be as a relaxant of ureteric smooth muscles, as this drug blocks the alpha receptors of smooth muscles at end of ureter leading to passage of stone and minimizing expulsion time.[13] Tamsulosin is found to be effective expulsive therapy in ureteric stones.[13, 14] On other hand, some authors failed to prove the effectiveness of Tamsulosin in treatment of ureteric stones.[10] phosphodiesterase type 5 inhibitors are used in management of lower urinary tract symptoms of benign prostatic hyperplasia. They are newer treatment agents selected for expelling ureteric stones through breaking down of cyclic adenosine 3′,5′-monophosphate and cyclic guanosine 3′,5′-monophosphate leading to smooth muscle relaxation and facilitating stones passage. The Tadalafil was approved first prescribed for erectile dysfunction, leading to prostate smooth muscle relaxation and improving lower urinary tract symptoms in addition to its action on cavernous muscles.[15] Different literatures had shown that use of Tadalafil alone or in combination with Tamsulosin accelerating passage of ureteric stones, lowering time of expulsion and decreasing need for analgesic treatment.[12] Nowadays, the medical expulsive therapy is popular treatment of ureteric stones in Iraq with good outcomes reaching to 50% success rate after two weeks treatment.[16] Anyway, this treatment option is still new and needs further studies. This study aimed to compare the safety and efficacy of Tamsulosin alone and combination of Tadalafil and Tamsulosin as medical expulsive therapy for ureteric stones.

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Patients and methods

A retrospective observational cross-sectional study implemented in private clinic in Erbil city, Kurdistan Region-Iraq in duration of two years from 1st of February, 2022 to 31st of January, 2024. All male patients (females were excluded because of social issues that make the families not accept to give any medication with sexual effect to female members of their family) with ureter stones were the study population. Inclusion criteria were adult male patients (18-65 years) with ureteric stone with size ranging between 5 to 10 mm. Renal impairment, febrile urinary tract infection, hypersensitivity to the medications, single kidney, stone size larger than 10 mm and smaller than 5 mm, associated disorders with renal stone that need surgical intervention, bilateral ureteric stones and missing or incomplete saved data were the exclusion criteria. Ethical issues were subjected to approval of Ethical Committee of Hawler Medical University, hospital authority and confidentiality of data. A sample of one hundred and eighty-four patients with ureteric stones were treated with medical expulsive therapy (92 patients with Tamsulosin only and 92 patients with Tadalafil & Tamsulosin) was selected after eligibility to inclusion and exclusion criteria. Data of selected patients were collected respectively by researchers through reviewing their saved records that filled in a prepared questionnaire involving basic characteristics (age, stone site and size), symptoms following therapy (number of colicky pain attacks, number of analgesics injections and number of emergency visits) and adverse effects of medicines (dizziness, headache, backache, lower limb pain, dry ejaculation and hypotension). The ureter stones were diagnosed by researcher in the clinic in regard to clinical examination and imaging techniques. The medical expulsion therapy was prescribed by researcher. Post-treatment outcomes and adverse effects were assessed by the researcher and managed accordingly. Duration of treatment follow up was three weeks and any patient not pass the stone after three weeks managed by endoscopic intervention. The patient's data were entered and analyzed statistically by statistical package of social sciences program-26 with suitable categorical tests (chi square and fishers' exact tests) and continuous test (independent sample t-test) for statistical relationships. Significance level was ≤0.05.

Results

In this study, one hundred and eighty-four patients with ureteric stones were treated with medical expulsive therapy (92 patients with Tamsulosin only and 92 patients with Tadalafil & Tamsulosin). No significant differences were observed between patients of both study groups regarding age and stone site (p>0.05). Stones size was statistically higher among patients treated by tadalafil & tamsulosin therapy (p=0.001), Table (1).

Table (1): Distribution of basic characteristics according to study groups.

Variable	Study groups				P
	Tamsulosin		Tadalafil & Tamsulosin		
Age					0.6 NS
Mean±SD (years)	40.3±12.8		39.5±8.1		
Stone site	No.	%	No.	%	0.09 NS
Upper	29	31.5	19	20.7	
Lower	63	68.5	73	79.3	
Stone size					0.001 S
5-7 mm	74	80.4	54	58.7	
8-10 mm	18	19.6	38	41.3	

S=Significant, NS=Not significant.

No significant differences were observed between patients of both study groups regarding number of colicky pains following therapy (p=0.06). Number of analgesic

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injections was significantly higher among patients treated by Tamsulosin only (p<0.001). Also, the number of emergency visits following therapy was significantly higher among patients treated by Tamsulosin only (p<0.001), Table (2).

Table (2): Distribution of symptoms following therapy according to study groups.

Variable	Study groups				P
	Tamsulosin		Tadalafil & Tamsulosin		
Number of colicky pains	No.	%	No.	%	0.06 NS
Zero	33	35.9	47	51.1	
1-3 times	45	48.9	38	41.3	
>3 times	14	15.2	7	7.6	
Number of analgesic injections					<0.001 S
Zero	39	42.4	65	70.7	
1-3 times	44	47.8	24	26.1	
>3 times	9	9.8	3	3.3	
Number of emergency visit					<0.001 S
Zero	57	62.0	85	92.4	
1-3 times	30	32.6	5	5.4	
>3 times	5	5.4	2	2.2	

S=Significant, NS=Not significant.

There was a statistically significant association between dizziness adverse effect and Tadalafil & Tamsulosin therapy (p=0.02). No significant differences were observed between patients of both study groups regarding headache, backache, lower limb pain, dry ejaculation and hypotension adverse effects (p>0.05), Table (3).

Table (3): Therapy adverse effects according to study groups.

Variable	Study groups				P
	Tamsulosin		Tadalafil & Tamsulosin		
Dizziness	No.	%	No.	%	0.02 S
Yes	0	-	5	5.4	
No	92	100.0	87	94.6	
Headache					0.4 NS
Yes	3	3.3	5	5.4	
No	89	96.7	87	94.6	
Backache					0.1 NS
Yes	0	-	2	2.2	
No	92	100.0	90	97.8	
Lower limb pain					0.08 NS
Yes	0	-	3	3.3	
No	92	100.0	89	96.7	
Dry ejaculation					1.0 NS
Yes	2	2.2	2	2.2	
No	90	97.8	90	97.8	
Hypotension					0.17 NS
Yes	1	1.1	4	4.3	
No	91	98.9	88	95.7	

S=Significant, NS=Not significant.

There was a statistically significant association between higher expulsion rate and Tadalafil & Tamsulosin therapy (p=0.02). No significant differences were observed between patients of both study groups regarding time to expulsion and time of intervention (p>0.05), Table (4).

Table (4): Distribution of expulsion characteristics according to study groups.

Variable	Study groups				P
	Tamsulosin		Tadalafil & Tamsulosin		
Expulsion	No.	%	No.	%	0.02 S
Yes	66	71.7	70	76.1	
No	26	28.3	22	23.9	
Time to expulsion					0.15 NS
Mean±SD (days)	15.7±4.4		16.7±3.6		
Time of intervention					0.13 NS
Mean±SD (days)	17.7±5.2		15.3±5.9		

S=Significant, NS=Not significant.

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Discussion

Selecting the best option of medical expulsive treatment of ureteric stones is essential in avoiding surgical treatment and hence, preventing complications and saving cost.[17] In this study, there were no significant differences between patients of both study groups regarding age and stone site (p>0.05). These findings are parallel to results of different literatures comparing Tadalafil and Tamsulosin expulsive therapy.[12,13] However, the current study showed that stones size was statistically higher among patients treated by Tadalafil & Tamsulosin therapy (p=0.001). This finding is inconsistent with results of prospective study conducted in India which compared the efficacy of Tadalafil versus Tamsulosin therapy and the stones size was not statistically different between both groups .[18] This inconsistency might be attributed to high trust of combining Tadalafil & Tamsulosin therapy by physicians in our center. Present study found that number of analgesic injections need was significantly higher among patients treated by Tamsulosin only as compared to Tadalafil & Tamsulosin therapy (p<0.001). Similarly, a recent randomized controlled trial in Nepal found a statistically significant difference in analgesics need between patients with ureteric stones treated by Tamsulosin only as compared to Tadalafil & Tamsulosin therapy .[19] Our study also found that number of emergency visits following therapy was significantly higher among patients treated by Tamsulosin only as compared to Tadalafil & Tamsulosin therapy (p<0.001). This finding coincides with results of recent randomized placebo-controlled study conducted by El Hadj Sidi AM and et al which reported lower hospital visits among patients with ureteric stones treated by Tadalafil & Tamsulosin therapy in comparison to patients treated by tamsulosin only.[20] Although no statistical significance, the number of colicky pain perceived by patients with ureteric stones treated by Tadalafil & Tamsulosin therapy was lower than that perceived by patients treated by Tamsulosin only. Consistently, recent study by Reda A. et al found that number of colicky pain attacks for ureteric stones was statistically lower among patients treated by Tadalafil & Tamsulosin therapy in comparison to patients treated by Tamsulosin only .[21] In current study, there were no significant differences between patients of both study groups regarding headache, backache, lower limb pain, dry ejaculation and hypotension adverse effects (p>0.05). These findings are close to results of different literatures .[18, 19] In our study, there was a statistically significant association between dizziness adverse effect and Tadalafil & Tamsulosin therapy (p=0.02). This finding is inconsistent with results of a recent open-labelled, randomized, prospective study carried out by Neeli s. which reported high proportion of patients with dizziness after treatment with Tamsulosin therapy. However, this adverse effect in our study might be related to Tamsulosin drug effect.[22] In our study, there was a statistically significant association between higher expulsion rate and Tadalafil & Tamsulosin therapy (p=0.02). This finding is consistent with results of many literatures.[19, 21] Generally, many authors revealed higher efficacy and safety of Tadalafil monotherapy in distal ureteric stones in comparison to tamsulosin monotherapy.[23, 24]

Conclusion

In conclusion, the combination of Tadalafil & Tamsulosin is safe and more effective in medical expulsion therapy of ureteric stones than tamsulosin alone. The Tadalafil & Tamsulosin therapy is used for large stones and characterized by a smaller number of colicky pain attacks, number of analgesic injections and number of emergency department visits than Tamsulosin alone

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However, the dizziness is the adverse effect of Tadalafil & Tamsulosin.

Conflicts of interest

Declared none.

References

1.Ziemba JB, Matlaga BR. Epidemiology and economics of nephrolithiasis. Investig Clin Urol 2017; 58(5):299-306.
2.Eisner BH, Sheth S, Dretler SP, Herrick B, Pais VM. Abnormalities of 24-hour urine composition in first-time and recurrent stone-formers. Urology 2012; 80(4):776-9.
3.Pearle MS, Goldfarb DS, Assimos DG, Curhan G, Denu-Ciocca CJ, Matlaga BR, et al; American Urological Association. Medical management of kidney stones: AUA guideline. J Urol. 2014; 192(2):316-24.
4.Afaj AH, Sultan MA. Mineralogical composition of the urinary stones from different provinces in Iraq. The Sci. World J. 2005; 5(1); 24–38.
5.Puvvada S, Mylarappa P, Aggarwal K, Patil A, Joshi P, Desigowda R. Comparative efficacy of Tadalafil versus Tamsulosin as the medical expulsive therapy in lower ureteric stone: a prospective randomized trial. Cent European J Urol 2016; 69(1):178-82.
6.Kumar S, Jayant K, Agrawal S, Singh SK. Comparative efficacy of Tamsulosin versus Tamsulosin with Tadalafil in combination with prednisolone for the medical expulsive therapy of lower ureteric stones: a randomized trial. Korean J Urol 2014; 55(1):196-200.
7.Preminger GM, Tiselius HG, Assimos DG, Alken P, Buck C, Gallucci M, et al. 2007 guideline for the management of ureteral calculi. J Urol 2007; 178(1):2418-1734.
8.Wang Y, Chang X, Li J, Han Z. Efficacy and safety of various surgical treatments for proximal ureteral stone ≥10mm: A systematic review and network meta-analysis. Int Braz J Urol 2020; 46(1):902-26.
9.Pietropaolo A, Proietti S, Geraghty R, Skolarikos A, Papatsoris A, Liatsikos E, et al. Trends of 'urolithiasis: interventions, simulation, and laser technology' over the last 16 years (2000–2015) as published in the literature: a systematic review from European section of Urotechnology. World J Urol 2017; 35(1):1651–8.
10.Pickard R, Starr K, MacLennan G, Lam T, Thomas R, Burr J, McPherson G, et al. Medical expulsive therapy in adults with ureteric colic: a multi-Centre, randomized, placebo-controlled trial. Lancet 2015; 386(9991):341-9.
11.Shokeir AA, Tharwat MA, Abolazm AE, Harraz A. Sildenafil citrate as a medical expulsive therapy for distal ureteric stones: A randomised double-blind placebo-controlled study. Arab J Urol 2016; 14(1):1-6.
12.Özsoy M, Liatsikos E, Scheffbuch N, Kallidonis P. Comparison of Silodosin to Tamsulosin for medical expulsive treatment of ureteral stones: a systematic review and meta-analysis. Urolithiasis 2016; 44(1):491-7.
13.Hsu YP, Hsu CW, Bai CH, Cheng SW, Chen KC, Chen C. Silodosin versus Tamsulosin for medical expulsive treatment of ureteral stones: A systematic review and meta-analysis. PLoS One 2018; 13(1):43-7. e0203035.
14.Falahatkar S, Khosropanah I, Allahkhah A, Jafari A. Open surgery, laparoscopic surgery, or trans ureteral lithotripsy--which method? Comparison of ureteral stone management outcomes. J Endourol 2011; 25(1):31-4.
15.Shabsigh R, Seftel AD, Rosen RC, Porst H, Ahuja S, Deeley MC, et al. Review of time of onset and duration of clinical efcacy of phosphodiesterase type 5 inhibitors in treatment of erectile dysfunction. Urology 2006; 68(4):689–96. Available from: https://doi.org/10.1016/j.urology.2006.05.009/

16.Alwan MG, Nima MH, Alquraishi FS, Rashid NR. Deciding on a novel predictive value to gauge how well patients with lower ureteric stones respond to medical expulsive therapy. Urolithiasis 2024; 52(1):41-8.
17.Wood KD, Gorbachinsky I, Gutierrez J. Medical expulsive therapy. Indian J Urol 2014; 30(1):60-4.
18.Goyal SK, Singh V, Pandey H, Chhabra MK, Aggarwal SP, Bhat A. Comparative efficacy of Tamsulosin versus Tadalafil as medical expulsive therapy for distal ureteric stones. Urol Ann 2018; 10(1):82-6.
19.Gnyawali D, Pradhan MM, Sigdel PR, Parajuli P, Chudal S, Poudyal S, et al. Efficacy of Tamsulosin plus Tadalafil versus Tamsulosin as Medical Expulsive Therapy for Lower Ureteric Stones: A Randomized Controlled Trial. Adv Urol 2020; 20(1):32-8. 4347598.
20.El Hadj Sidi AM, Abdel Wehab T, El-Shazly AM, El Dakhakhni AS, Abdel-Azim AF. Efficacy of Silodosin versus Silodosin plus Tadalafil as Medical Expulsive Therapy for Lower Ureteric Stones: A Prospective Randomized Placebo Controlled Study. BMFJ 2023; 40(1):254-63.
21.Reda A, Kamel M, Loay M, Abdelsalam YM, Zarzour MA. Efficacy of the combination of Tadalafil and Tamsulosin versus tadalafil alone as a medical expulsive therapy for stone L1/3 ureter 10 mm or less: A prospective comparative placebo-controlled study. Curr Urol 2023; 42 (1):53–7.
22.Neeli S. Effect of Tamsulosin versus Tamsulosin plus Tadalafil on renal calculus clearance after shock wave lithotripsy: An open-labelled, randomised, prospective study. Asian J Urol 2021; 8(4):430-5.
23.Kc HB, Shrestha A, Acharya GB, Basnet RB, Shah AK, Shrestha PM. Tamsulosin versus Tadalafil as a medical expulsive therapy for distal ureteral stones: A prospective randomized study. Investig Clin Urol 2016; 57(5):351-6.
24.Ragheb AM, Mohamed AG, Mostafa AS, Abd Elatif A, Elmarakbi AA, Ibrahim RM, et al. Tadalafil versus tamsulosin for distal ureteric stone expulsion; a prospective randomized comparative study. Afr J Urol 2024; 30(1): 20-4. Available from: https://doi.org/10.1186/s12301-024-00425-2/