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A Prospective Randomized Comparative Study between the Effect of Silodosin and Tamsulosin on Expulsion of Lower Third Ureteric Stones

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objectives: To compare the efficacy of silodosin (8 mg) vs tamsulosin (0.4 mg), as a medical expulsive therapy (MET), in the management of distal ureteric Calculi (DUC) in terms of stone clearance rate and stone expulsion time.
Patients and Methods: A prospective randomised study was conducted on 130 patients, aged more than 18 years, who had unilateral DUS less than 1 cm. Patients were divided into two groups. Group A received silodosin (8 mg) and Group B received tamsulosin (0.4 mg) daily for 1 month. The patients were followed-up by urine analysis & serum creatinine. Kidney ureter bladder x-ray (KUB) (for detection of the stone size and site), Pelvi-abdominal ultrasound (U/S) (for diagnosis & monitoring of the degree of hydronephrosis), Non contrast spiral CT abdomen & pelvis (NCCT): for detection of site, size and density of the stone and detection of degree of hydronephrosis.
Results: There was a significantly higher stone clearance rate of 88.3% in Group A vs 68.3% in Group B. Group also showed a significant advantage for stone expulsion time but as regard analgesic use no significant difference between both groups.

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No severe complications were recorded during the treatment period. An ejaculation was recorded in 8 and 1 patients in Groups A and B, respectively. However, complication as headache hypotension are more common in group B, 4: 13 in group A and group B respectively.
Conclusion: Our data showed that silodosin is more effective than tamsulosin in the management of DUC for stone clearance rates and stone expulsion times. A multicenter study on larger scale is needed to confirm the efficacy and safety of silodosin.

Keywords: Silodosin; tamsulosin; distal ureteric stones.

1. INTRODUCTION

Urolithiasis is one of the most common disorders of urinary tract affecting about 5%-10% of the population [1].

The increasing prevalence of ureteric stone is a matter of concern in this era, and it may be linked to improved quality of life. The incidence varies with geographic location being greater in mountainous and desert areas that are found in Middle East, western India, southern United States, Scandinavia, Mediterranean, and Central Europe which probably reflects water and soil content as well as hot weather and dehydration that exist in these areas [2].

Renal stones are most prevalent between the ages of 20 and 40 years and are 3 times greater in men than women [2].

A watchful waiting approach has been reported to be associated with spontaneous stone expulsion in up to 50% of cases but some complications may occur such as urinary tract infections, hydronephrosis and colic events [3].

In recent years, the use of the expectant approach for distal ureteric stones has been extended to the use of adjuvant medical expulsive therapy (MET), that is able to reduce symptoms and facilitate stone expulsion.

In 1970, Malin et al. [4] demonstrated the presence of alpha and beta adrenergic receptors (AR) in the human ureter [4]. Alpha1 are the most abundant AR subtypes at the level of ureteric smooth muscle cells [5].

Itoh et al. [6,7] demonstrated that three types of alpha1 AR are expressed in the human ureter (alpha1A, alpha1B and alpha1D) [8].

Antagonists of these receptors have been proved to decrease ureteric basal tone, peristaltic activity, and contractions thus decreasing intraureteric pressure and increasing urine transport [9].

Three metaanalyses have confirmed a positive effect of alpha-blocker therapy on the stone expulsion rates [10].

Alpha-blockade has been proved to improve the likelihood of spontaneous stone passage, and to decrease both the time to stone passage and analgesic requirements [11].

According to European Association of Urology Guidelines, alpha-blockers or nifedipine are recommended for MET (grade of recommendation A) [12].

Patients who elect for MET should have well controlled pain, no clinical evidence of sepsis, and adequate renal functional reserve [12].

The alpha1A/D selective alpha-blocker tamsulo sin has been demonstrated to be a safe and effective drug that enhances spontaneous passage of distal ureteral stones sized 10 mm or smaller [6].

Recent studies have demonstrated that the alpha1A subtype plays the major role in mediating phenylephrine-induced contraction in the human isolated ureter [8].

Various studies compared alpha1A (AR) antagonist, silodosin with alpha1D (AR) antagonist revealing that silodosin was clinically superior for stone expulsion [13].

2. PATIENTS AND METHODS

This study included 130 patients who presented with symptomatic unilateral lower ureteric stone < 1cm during the period from January 2016 to June 2019 at TantaUniversity Hospitals.

2.1 Technical Design

All patients were enrolled from patients attending Urology Outpatient Clinic at Tanta University Hospitals.

2.2 Sample Size

130 patients, 65 patients in tamsulosin group and 65 patients in silodosin group.

2.3 Subjects Included in the Study

The cases of this study were randomly allocated into two groups:

Group A: (65 patients) received silodosin 8 mg controlled-release capsule once daily at constant time.

Group B: (65 patients) received tamsulosin 0.4mg capsuleonce daily at constant time.

Each group received treatment for a period maximally 1month during this period the patient evaluated weekly by history and every 2 weeks radiologicaly by US&NCCT for stone passage.

2.3.1 Inclusion criteria

- Age> 18 year old
- Unilateral distal ureteral single stone <1 cm in diameter

2.3.2 Exclusion criteria

- Multiple stones
- Bilateral ureteric stones.
- High gradehydronephrosis
- atient with single kidney.
- Pyonephrosis
- Impaired renal function serum creatinine>2 mg / dl.
- Pregnancy and lactating women.
- Associated ureteral pathology e.g. ureteral stricture.
- Cardiac patients.
- Hypersensitivity of the patient to the drugs.

2.4 Statistical Analysis

Data collected throughout included history, basic clinical examination, laboratory investigations and outcome measures uncoded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data, the following tests were used to test differences for significance: Differences between frequencies (qualitative variables) and percentages in groups were compared by Chi-square test. Differences between means (quantitative variables) IN two parametric groups by t test. P value was set at <0.05 for significant results &<0.001 for high significant result.

3. RESULTS

Time of stone expulsion and how many patients expelled stones in the study was illustrated in the Table 1.

From the Table 1, stone expulsion was observed in 51 patients (88.3%) from group (A) with average time of stone expulsion 9.53 day (±2.33) and in 41 patients (68.3%) from group (B) within average time of stone expulsion 12.47 days (±3.08).

There is statistically significant difference between group (A) which showed higher stone expulsion rate and group (B) that show lower stone expulsion rate. The 28 patients with failed stone expulsion underwent uretroscopy.

3.1 Clinical Data during Treatment

Clinical presentation of patients of both groups during follow up while they receiving treatment is observed as in the Table 2.

From the Table 2, there is no statistical significant difference was observed between both groups according to number of attacks of renal colic and visual analogue scale during treatment (P=0.138 & P=0.073 respectively).

Beside the visual analogue scale, the use of analgesia was observed to detect the severity of attacks of renal colic and loin pain during treatment; the mean dosage of sodium declofenac (in mg) per patient was 21(±6.2) in group A & 25 (±7.1) in group B. There is no significant statistical difference between both groups as regarding use of analgesia.

3.2 Complications among the Studied Groups

Complications among the patients of both groups during follow up while they receiving treatment is observed as in the Table 3.

As regarding side effects of the used drugs during follow up, there were 8 patients (24.24%) of group A (silodosin) were suffered from an ejaculation and only 1 (3.12%) patients in tamsulosin group. However according to side effects related to peripheral vasodilation there is 13 patients (21.7%) were complaining from

hypotension, headache, dizziness and nasal congestion, they treated symptomatically but silodosin group show lower number of patient complaining from these side effects (4 patients) (6.8%).

4. DISCUSSION

In this study, the stone clearance rate was significantly higher in the silodosin group compared with the tamsulosin group at (88.3% and 68.3% respectively), also the mean (SD) stone expulsion time was significantly shorter in the silodosin group compared with the tamsulosin group.

Kumar et al. [2], also confirmed the pervious results as they found that silodosin is better than tamsulosin in expulsion rate and time.Stone expulsion rate was 83.3% in the silodosin group and 64.4% in the tamsulosin group.

Hsu et al. [14] and Huang et al. [15], revealed that silodosin was more effective than tamsulosin in the expulsion rate and time, as the selectivity of silodosin for the α1A subtype was approximately 17-fold greater than that for tamsulosin, in other words, silodosin has a higher affinity for the α1A subtype than tamsulosin.

Dell'Atti [16] reportedthat expulsion rate of 80.3% in silodosin group whereas the tamsulosin group showed an expulsion rate of 61.2% (p= 0.003), resulting in a significant advantage in favor of silodosin [16]. Ahmed and Al-Sayed [17] reported that the stone expulsion rates for silodosin, tamsulosin and placebo groups were 86.2, 76.6 and 50%, respectively.The difference in silodosin and tamsulosin groups with respect to placebo group was significant (p= 0.0028) [17].

Itoh et al. [7] reported that In distal ureteral stones the stone expulsion rate was 55.6% for control group and 72.7% for silodosin group (P = 0.106), and the mean expulsion times were 13.40 ± 5.90 and 9.29 ± 5.91 days, respectively (P = 0.012) [7]. And Gupta et al. [18] reported that stone clearance rate at 82% and 58% for silodosin and tamsulosin respectively [18].

The mechanism could be explained by Rossi and Roumeguere, 2010, who stated that tamsulosin preferentially blocks alpha1A and alpha1D AR, with a 10-fold greater affinity than for alpha1B AR. In contrast, silodosin is highly selective for alpha1A AR, with a 162-fold greater affinity than alpha1B AR and about a 50-fold greater affinity than for alpha1D AR [19].

Table 1. Time and rate of stone expulsion in both groups of the study

		Group A	Group B	T	χ^2	P value
Time (per day)	Range	5-13	7-18	6.442		0.001*
	Mean±SD	9.53 ± 2.33	12.74 ± 3.08			
Success rate	No.(%)	51(88.3%)	41 (68.3%)		4.662	0.031*
Failure rate	No.(%)	9 (11.7%)	19 (31.7%)			
Total		60	60			

Table 2. Number of attacks of renal colic / patient

During treatment	Group A	Group B	T	P
No. of attacks of renal colic/patient (Mean ± SD)	0.82 ± 0.32	0.91 ± 0.34	1.492	0.138
Visual analogue scale (Mean ± SD)	2.13 ± 1.04	2.51 ± 1.23	1.831	0.073

Table 3. Complication among the patients of both groups during follows up

Complication	Group A		Group B		X2	P value
	N	%	N	%		
An ejaculation	8	24.24	1	3.12	6.068	0.014*
Dizziness	1	1.7	4	6.7	1.882	0.171
Nasal congestion	1	1.7	3	5	1.034	0.309
Postural hypotension	1	1.7	3	5	1.034	0.309
Headache	1	1.7	3	5	1.034	0.309

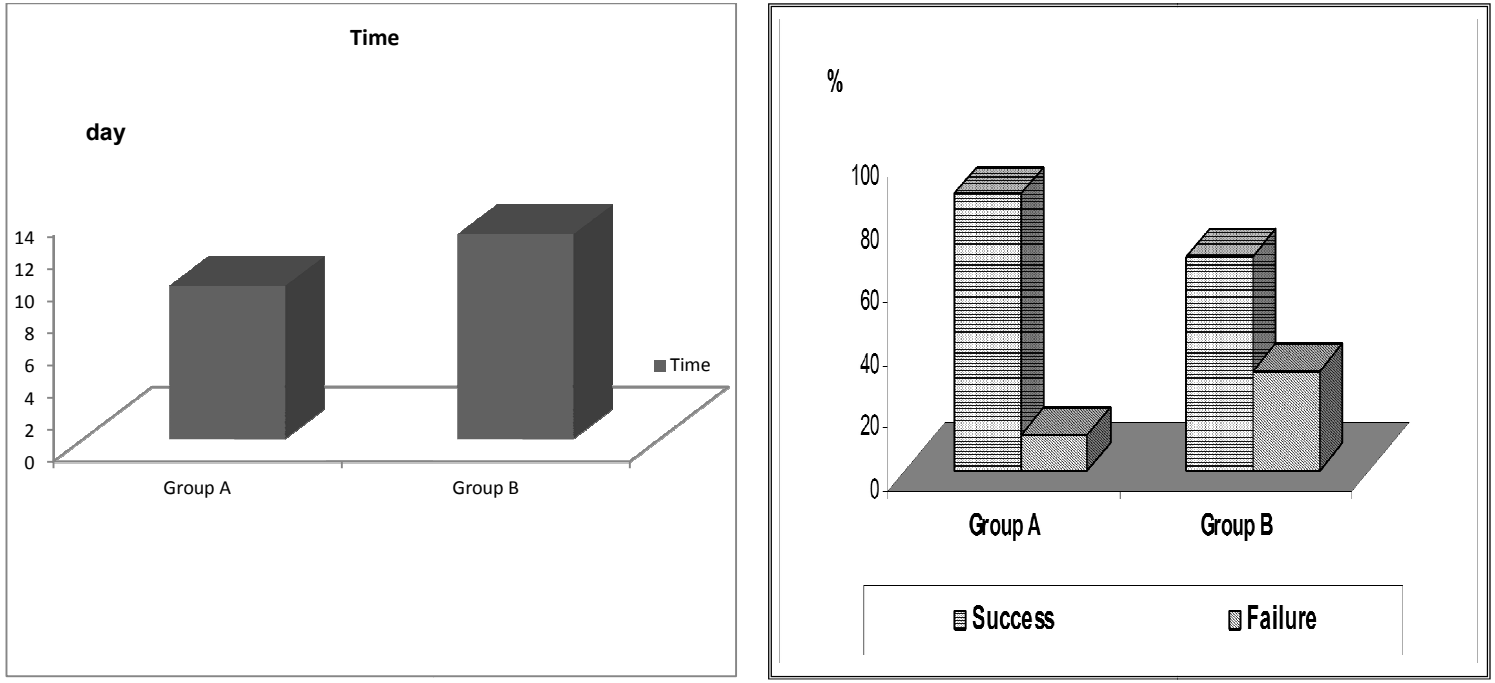

Fig. 1. This figure shows that the rate of stone expulsion was 88.30% in silodosin group and 68.3% in tamsulosin group

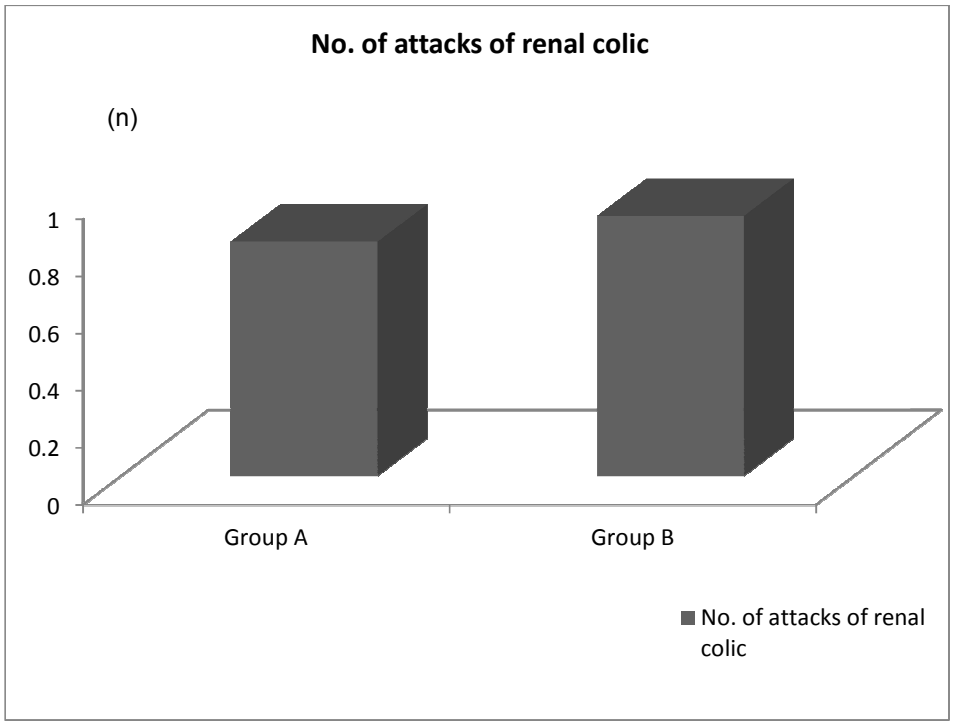

Fig. 2. This figure shows that there was no significant statistical difference among the studied groups regarding the number of attack of renal colic (p>0.05)

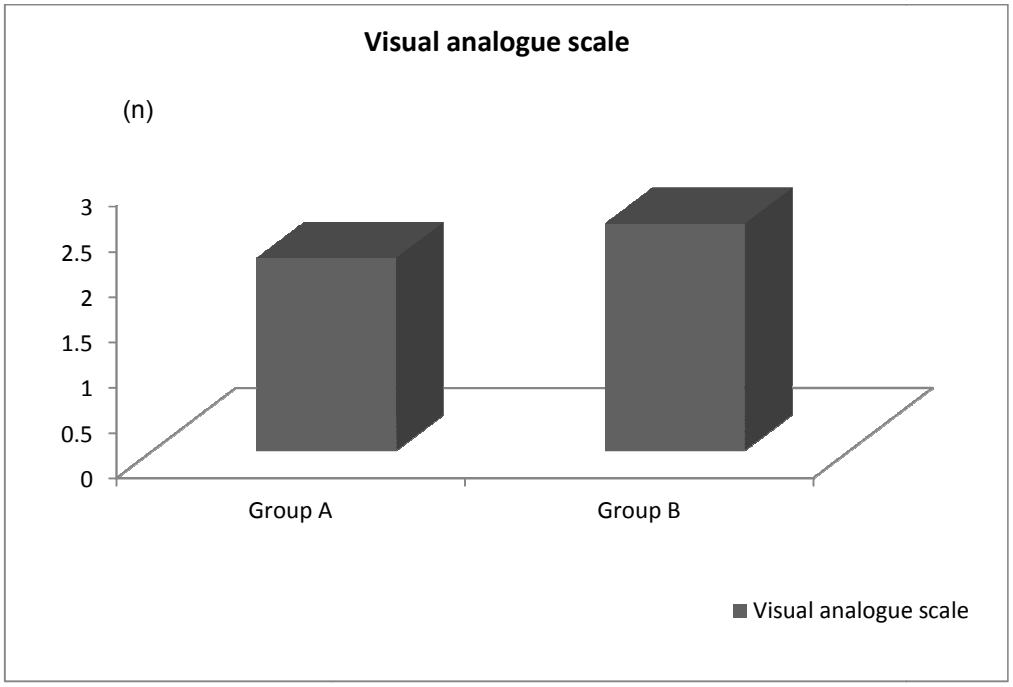

Fig. 3. This figure shows that there was no significant statistical difference among the studied groups regarding the Visual analogue scale (p>0.05)

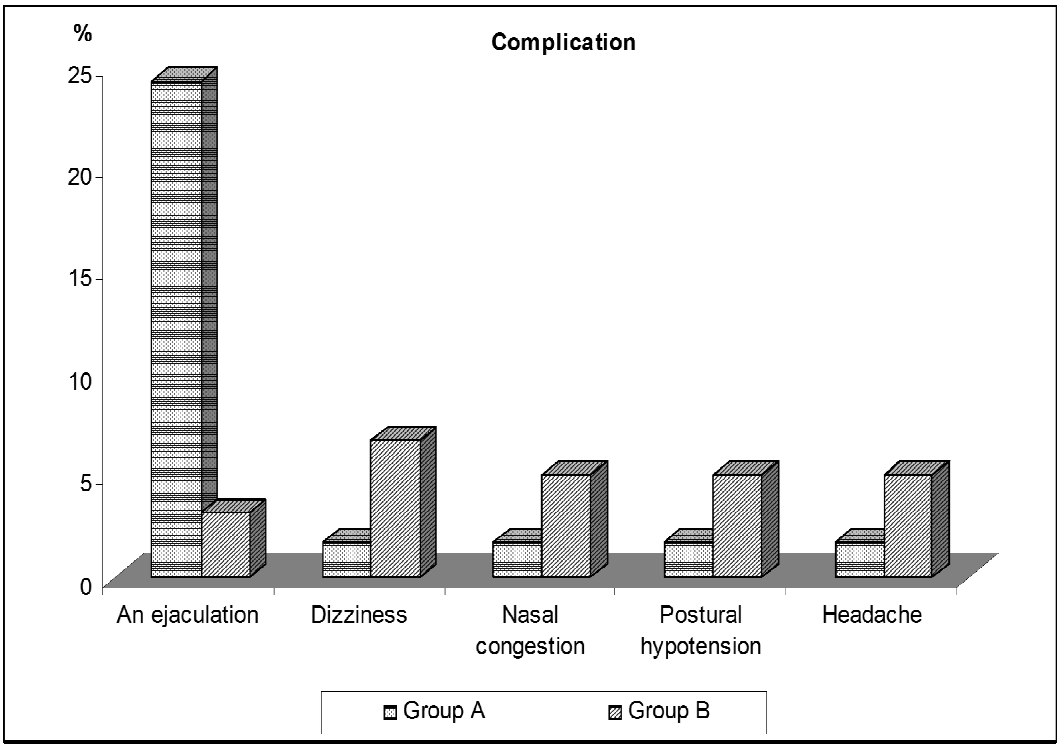

Fig. 4. Complication among the patients of both groups during follow up

In this study we found the mean of stone expulsion time was significantly shorter in silodosin group 9.53 days than tamsulosin group 12.74 days.

Elgalaly et al. [20] reported that mean stone expulsion time in silodosin significantly shorter than tamsulosin group at 12.5 days and 19.5 days respectively [20]. Kumar et al. [2] reported that the mean stone expulsion time of 14.8 days and 16.5 days for silodosin and tamsulosin respectively [2]. Özsoy et al. [21] reported that the mean expulsion time was 9.29 days for silodosin and 13.40 for tamsulosin group (P= 0.012) [21] Rathi et al. [22] reported that the expulsion time was significantly shorter in silodosin group and tamsulosin groups than in placebo group (p= 0.0097 and 0.026, respectively) [22]. Wang et al. [23] reported that the averageexpulsion time was significantly different with mean expulsion time 11 days for silodosin and 14 days for tamsulosin (P<0.001) [23].

However, Imperatore et al. [24], reported that there is non-significant difference of stone clearance rates and stone expulsion time between silodosin and tamsulosin.

The results of the present study showed a low mean number of pain episodes in the silodosin and tamsulosin groups, with no statistical significant difference between both groups.

In this study there was a low mean of pain episodes in silodosin (0.82%) than tamsulosin group (0.91%) which wasn't significantly different between silodosin group and tamsulosin group (P>0.05).

These results agreed by Yilmaz et al. [9] Ahmed and Al-Sayed [17], Arda et al. [25], Özsoy et al. [21], Al-Ansari et al. [26] and Agrawal et al. [27].

Kumar et al. [2] reported that the mean of pain episodes of (0.8%) and (1.7%) in silodosin and tamsulosin groups respectively which was none statically different [2]. And also Imperatore et al. [24] reported that there was no statically different between silodosin and tamsulosin groups regarding pain episodes of (1.6%) and (1.7%) respectively [24].

The results of the present work showed that side effects differ considerably between both silodosin group and tamsulosin group.

In this study we found that both drugs are well tolerated and safe, the most abundant complication is An-ejaculation which was reported in 8 patients (24.24%) for silodosin group and 1 patient (3.12%) in tamsulosin group. Which was statistically different (P=0.015).

Sertkaya and Ozkaya [28] have reported that silodosin is the most uroselective and effective agent for ejaculation, It is thought that the effect of silodosin on dry ejaculation is largely due to a peripheral effect rather than the central nervous system.

The an-ejaculation is attributed to smooth muscle relaxation in the vas deferens, bladder neck, prostate, seminal vesicles and urethra. It is reported that alpha1A-AR is mainly expressed in the bladder neck, vas deferens, and seminal vesicles, and mediates human vas deferens contraction Therefore, this adverse effect may be explained by the high alpha1A-AR subtype selectivity of silodosin [28].

Under normal conditions, in males, orgasm is in the same time as ejaculation. Orgasm occurs through the processing of sensorial stimulation of the pudendal nerve by the brain during events in the ejaculatory process [29].

In the case of Ejaculatory dysfunction, it has been suggested that sensorial stimulation of the pudendal nerve originates from urethral bulb muscle contraction caused by silodosin, thus allowing the orgasmic feeling in the absence of ejaculation [30].

Huang et al. [14] reported that silodosin has a higher incidence of abnormal ejaculation than tamsulosin [14].

Kumar et al. [2] reported that retrograde ejaculation was 15.6% for silodosin group and 11.2% for tamsulosin group which was none statically different [2]. Imperatore et al. [24] reported that retrograde ejaculation was statically different between silodosin group (8%) and tamsulosin group (2%) [24]. Dell'Atti [16] reported that significantly higher incidence of abnormal ejaculation in the silodosin group in comparison to the tamsulosin group with 22.7% and 10.2% of the patients having experienced the side effect, respectively ($p< 0.002$) [16].

This also explained by Shakir et al. [31], who stated that silodosin appears to relax the smooth muscles of the lower urinary tract and the genital tract enough to induce a retrograde ejaculation. This was reflected in the finding that the patients who had the greatest relief from the lower urinary tract symptoms had a higher likelihood of the retrograde ejaculation. This observation suggests that the retrograde ejaculation is actually an indirect indicator of the relaxation of the smooth musculature that silodosin induces.

Montorsi et al. [32] reported that a higher incidence of retrograde ejaculation in patients treated with silodosin but lower incidence of side effects related to peripheral vasodilation when compared to tamsulosin [32].

However there was another complication in this study as dizziness, nasal congestion, headache and postural hypotension is more common in tamsulosin group (21.7%) than silodosin group (6.8%).

These finding were agreed by Yoshida et al. [33] who stated that retrograde ejaculation is more common with silodosin treatment but postural hypotension and dizziness were more common with tamsulosin group.

In a study by Yu et al. [34], tamsulosin treatment resulted in a significant reduction in mean systolic blood pressure relative to the negligible change of silodosin.

Hsu et al. [13] has suggested that silodosin as a consequenceof its high subtype selectivity is less likely than tamsulosin to have significant cardiovascular side effects either when used alone or in combination with other agents, which may affect blood pressure, so The lower incidence of side effects related to peripheral vasodilation associated with silodosin use make it moresuitable for olderpatients.

5. CONCLUSION

In conclusion, silodosin is more effective than tamsulosin in the management of DUS for the stone clearance rate and stone expulsion time; and lower incidence of side effects related to peripheral vasodilation, however the higher incidence of an-ejaculation is the main drawback.

CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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