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COMPARISON THE TREARMENT RESULTS OF TAMSULOSIN AND DOXAZOSIN IN THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERTROPHY

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ABSTRACT

Background: The incidence of LUTS related to benign prostate hyperplasia (BPH) increases to 70% by the age of 80, which seriously affects the quality of life. Moreover these symptoms are associated with substantial personal and social problems. Although there are several options of drugs for treatment the LUTS related to BPH, a1-blockers are still the first-line drugs, and doxazosin and tamsulosin are the most popular ones worldwide. **Objective:** This study aims to evaluate the effectiveness and the safety of the tamsulosin and doxazosin in management of lower urinary tract symptoms associated with benign prostatic hypertrophy, and determine which one is more effective than the other. **Methods and materials:** Patients aged between 50-80 years and diagnosed with benign prostate hyperplasia (BPH) with International Prostatic Symptom Score (IPSS) total symptom score >8 were included. A total of 100 patients were randomized to treatment with 4mg of doxazosin daily (n = 50) or 0.4 mg of tamsulosin daily (n = 50) for 12 weeks. Efficacy was assessed at 0 weeks,6 weeks and 12 weeks of treatment ,using total IPSS, storage subscore and voiding subscore to determine changes in LUTS and urinary flow rates. Adverse events (AE) were recorded at each visit based on patient reports. QOL was assessed by the 'quality of life due to urinary symptoms' question from the IPSS questionnaire. **Results:** The total IPSS, voiding IPSS and storage IPSS each had decreased significantly after 12 weeks of treatment in the doxazosin group (P<0.05). However, only the T-IPSS had decreased significantly after 12 weeks of treatment in the tamsulosin group (P<0.05),while the decrease occurred in V-IPSS and S- IPSS in the tamsulosin group had no significance (P>0.05). However the improvement occurred in the QOL was significant in either the doxazosin and tamsulosin groups (P<0.05). **Conclusion:** Our results show superior efficacy of doxazosin over tamsulosin in terms of S-IPSSS and V- IPSS. Thus, doxazosin is superior to tamsulosin in the management of LUTS in patients with BPH.

KEYWORDS: Doxazosin, Tamsulosin, BPH, IPSS.

INTRODUCTION

Many men over the age of forty suffer from Lower urinary tract symptoms (LUTS) due to various reasons.[1],[2] These causes include in general the following : benign prostate hyperplasia (BPH), overactive bladder, urinary tract infection, tumors, stones, or functional disorders of the lower urinary tract.[3] Among them benign prostate hyperplasia is considered one of the most common causes that lead to LUTS by causing benign prostatic enlargement and/or bladder outlet obstruction. Hence, several LUTS occur, ranging from hesitancy, poor urine stream, daytime frequency, or nocturia to hematuria and ejaculation disorders.[4][5][6]

The incidence of LUTS related to benign prostate hyperplasia (BPH) increases to 70% by the age of 80, which seriously affects the quality of life. Moreover these symptoms are associated with substantial personal and social problems.-

Lower urinary tract symptoms (LUTS) related to benign prostate hyperplasia (BPH) can be treated by conservative, pharmacological, or surgical methods.

Antagonists of a1-adrenoceptors (a1-blockers) are an effective and safe option for relief the LUTS related to BPH.

Treatment modalities for LUTS/BPH in general and the number of drugs in particular have evolved extensively during the last 3 decades. Based on current guidelines, a1-blockers including alfuzosin, doxazosin, silodosin, tamsulosin, and terazosin are strongly recommended as

first-line drug treatment for men with moderate to severe LUTS related to BPH.

Pharmacological treatment is strongly recommended for moderate-to-severe LUTS related to BPH in all current guidelines.[9][10][11]

The currently available oral drugs for LUTS related to BPH include a1- blockers, 5a-reductase inhibitors, muscarinic receptor antagonists, phosphodiesterase type 5 inhibitors, and plant extracts. Although there are several options of drugs, a1-blockers are still the first-line drugs for treatment the LUTS related to BPH, and doxazosin and tamsulosin are the most popular ones worldwide.[12],[13]

METHODS AND MATERIALS

This prospective study has been conducted in urology department at Tishreen University Hospital from 2023 to 2024.

Patients aged between 50-80 years and diagnosed with benign prostate hyperplasia (BPH) with International Prostatic Symptom Score (IPSS) total symptom score ≥8 mL/s were included.

Exclusion criteria were: previous prostate surgery; presence of a prostatic stent, microwave therapy or balloon dilatation, suspected malignancy findings on digital rectal examination any known causes other than prostatic hyperplasia for urinary symptoms or reduction in flow rate existing hypotension (sitting blood pressure <90/60 mmHg) or orthostatic hypotension, acute urinary retention, bladder stones, recurrent urinary tract infections (more than three within the last year), large bladder diverticulum, prostate malignancy or prostate-specific antigen (PSA) >10 ng/mL, uncontrolled or poorly controlled diabetes mellitus, hepatic or renal dysfunction, history of congestive heart failure, abnormal erythrocyte findings on dipstick for reason other than BPH, concomitant therapy with agents known to affect vesicourethral function (anticholinergics, cholinergics or other a-blockers), or concomitant therapy with 5-a reductase inhibitors or antiandrogens during the study or 6 months before the study and presence of contraindication for either tamsulosin and doxazosin .

A total of 100 patients were randomized to treatment with 4mg of doxazosin daily (n = 50) or 0.4 mg of tamsulosin daily (n = 50) for 12 weeks.

The initial visit (week 0) included the collection of baseline information, such as demographics, medical history, physical examination, assessment of the total IPSS, voiding IPSS, storage IPSS, QOL, PSA test and prostate ultrasound examination. Patient visits occurred at study entry (week 0), and after 6 weeks and 12 weeks of treatment.

Efficacy was assessed using total IPSS, storage subscore, voiding subscore, and Q-max to determine changes in LUTS and urinary flow rates. Adverse events (AE) were recorded at each visit based on patient reports. QOL was assessed by the 'quality of life due to urinary symptoms' question from the IPSS questionnaire.

RESULTS

100 patients were enrolled and randomized into two treatment groups (50 patients in the tamsulosin group and 50 patients in the doxazosin group). Patient demographics and baseline characteristics for age, total IPSS, voiding IPSS, storage IPSS, QOL, prostate volume, and PSA level are presented in Table 1. There were no significant differences between the two groups in any baseline parameters.

Table 1: Baseline characteristics of 100 patients.

Variable	Tamsulosin	Doxazosin	p-value
Mean age(y)	65.14±6.2	63.25±5.4	0.1
Prostate volume(ml)	50.67±10.1	49.19±8.9	0.2
PSA (ng/ml)	1.29±0.8	1.26±0.4	0.1
Total IPSS	17.81±6.8	19.65±7.9	
voiding IPSS	9.57±4.9	10.21±5.2	
storage IPSS	8.24±2.8	9.44±3.2	
QOL	3.79±1.4	4.31±1.2	0.9

***PSA:** Prostate specific antigen, **IPSS**: International Prostatic Symptom Score, **QOL**: quality of life**, Q-max**: maximum urinary flow rate.

The total IPSS, voiding IPSS and storage IPSS each had decreased significantly after 12 weeks of treatment in the doxazosin group (P<0.05). However, only the total IPSS had decreased significantly after 12 weeks of treatment in the tamsulosin group (P<0.05),while the decrease occurred in voiding IPSS and storage IPSS in the tamsulosin group had no significance (P>0.05).

However the improvement occurred in the QOL was significant in either the doxazosin and tamsulosin groups (P<0.05) (Table 2).

However, no important changes had observed in prostate volume and PSA in both the the doxazosin and tamsulosin groups.

There was no significant differences of the AEs reported between the doxazosin and tamsulosin groups. Ejaculation disorders was the most common AE in both the doxazosin and tamsulosin groups, followed by dizziness (table3). Most AEs were mild or moderate in severity.

Table 2: Mean change from baseline of efficacy parameters.

Parameter		doxazosin	p-value	tamsulosin	p-value
Total IPSS	0 week	19.65±7.9	0.02	17.81±6.8	0.09
	6 weeks	17.05±7.7		16.62±6.9	
	12 weeks	16.21±8.1		16.04±7.1	
Voiding IPSS	0 week	10.21±5.2	0.04	9.57±4.9	0.2
	6 weeks	9.01±6.1		9.37±5.2	
	12 weeks	7.99±5.9		8.87±4.9	
Storage IPSS	0 week	9.44±3.2	0.04	8.24±2.8	0.8
	6 weeks	8.36±4.1		7.92±3.3	
	12 weeks	7.46±3.9		7.78±2.7	
QOL	0 week	4.31±1.2	0.0001	3.79±1.4	0.0001
	6 weeks	2.48±1.4		1.88±1.2	
	12 weeks	1.08±0.6		0.89±0.1	

Table 3: Incidence of adverse events.

AE	doxazosin	tamsulosin	p-value
Headache	5(10%)	6(12%)	0.2
Dizziness	9(18%)	8(16%)	0.8
Chest pain	3(6%)	4(8%)	0.1
Ejaculation disorders	13(26%)	15(30%)	0.2
Ejaculation	2(4%)	4(8%)	0.4
Flu-like symptom	6(12%)	2(4%)	0.08
Asthenia	1(2%)	3(6%)	0.1

***AE:** adverse events.

DISCUSSION

Many studies had compared the efficiency between doxazosin and tamsulosin. Kirby et al, reported that the efficacy of doxazosin is superior to that of tamsulosin in the management of patients with BPH.[14] They found that 4mg daily of Doxazosin-GITS was more effective than 0.4 mg daily of tamsulosin (p = 0.019 between-group difference for total IPSS; p = 0.001 for irritative subscore; p = 0.045 for obstructive subscore) after 8 weeks of treatment.

Chung et al, also found that, 4mg daily of doxazosin-GITS was significantly more rapid onset of efficacy and similar AEs compared with 0.2 mg daily of tamsulosin in BPH patients with LUTS.[15]

Our present study revealed that doxazosin had advantages in terms of IPSS-S and IPSS-V.

Other studies are in line with our results, where doxazosin demonstrated a superior improvement in IPSS in comparison to other a1- blockers and 5a-reductase inhibitors as mono-drug therapy.[16]

However, Pompeo et al reported that 4mg daily of doxazosin GITS and 0.4 mg daily of tamsulosin improved IPSS with no significant differences between groups.[17]

Moreover, Rahardjo et al reported that 0.2 mg daily of tamsulosin was more effective than 2mg daily of doxazosin in the treatment of LUTS due to BPH.[18]

These different results may be due to the variety in either the dose of the used drugs and the period of the study.

The European Association of Urology (EAU) had reported in Guideline on Male LUTS that a1-receptors are not only located within the prostate but also in the bladder, spinal cord, and other places could also be related to LUTS.[19]

This supremacy of doxazosin could be due to the nonspecifity of it as an a1-blocker, while tamsulosin is a relatively specific a1A-blocker.[20][21]

The present study demonstrated no statistically significant differences in AEs incidences between those two drugs, both of which were well tolerated by patients.

A standard treatment option for individual patients is still lacking[20] and, therefore, a systematic comparison of widely used formulations of a1- blockers is necessary.

CONCLUSION

Our present study reported that doxazosin had better efficiency compared to tamsulosin.

More multicenter randomized control studies with larger sample sizes with high quality are required to support our conclusions.

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