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Comparison of tamsulosin with tadalafil versus tamsulosin alone in patients with benign prostatic hyperplasia

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ABSTRACT

Objective: The objective of the study is to compare the use of tamsulosin with tadalafil versus tamsulosin alone in the medical treatment of patients with benign prostatic hyperplasia (BPH) in Jos, using International prostate symptom score (IPSS), quality of life (QoL) scores, and maximum flow rate (Qmax).

Material and Methods: A randomized longitudinal study among 56 consented patients with BPH at the Jos University Teaching Hospital. Patients had the IPSS questionnaire and QoL scores and Qmax assessed at baseline. Thereafter, patients were randomized into groups A (tamsulosin and tadalafil) or B (tamsulosin only) and reassessed after 12 weeks of therapy. Data were recorded in a structured proforma, and the Statistical Package for the Social Sciences version 23 was used for data collation. Results were presented in tables and a Student *t*-test was used for the analysis. A $P < 0.05$ was considered significant.

Results: A total of 56 patients were studied with age ranging from 48 to 89 years, with a mean age of 61.82 ± 8.71 years. At baseline, the mean IPSS, QoL score, and Qmax for Group A were 14.28 ± 4.19, 4.29 ± 0.46, and 10.29 ± 3.05 and for Group B were 16.32 ± 2.83, 4.68 ± 0.72, and 7.43 ± 3.91. The assessment 12-week post-treatment showed that the mean IPSS, QoL score, and Qmax for patients in Group A were 9.73 ± 3.18, 3.19 ± 2.40, and 12.22 ± 2.97 and Group B were 11.18 ± 3.38, 2.89 ± 0.93, and 9.68 ± 2.95, respectively. Comparing the response to treatment in the two treatment groups using IPSS, QoL score, and Qmax, IPSS (1.618, $P = 0.112$) and QoL score (0.611, $P = 0.544$) were not statistically significant. However, the response in Qmax was statistically significant (3.191, $P = 0.002$).

Conclusion: While combination therapy and tamsulosin monotherapy had a similar effect in improving IPSS and QoL scores, only the combination of tamsulosin with tadalafil had a significant effect in improving urine flow rate (Qmax).

Keywords: Benign prostatic hyperplasia, Comparison, Lower urinary tract symptoms, Tadalafil, Tamsulosin

INTRODUCTION

Benign prostatic hyperplasia (BPH) is believed to be the most common benign tumor affecting men.[1] The occurrence rises increasingly with age, with over 70% of men aged 70 and older showing histologic signs. It is a histological diagnosis marked by a rise in the number of epithelial

and stromal cells within the transitional zone and the peri-urethral region of the prostate gland, leading to increased smooth muscle tone, urethral narrowing, and obstruction of urine flow.[1,2]

An enlarged prostate frequently leads to bladder outlet obstruction, which results in lower urinary tract symptoms (LUTS). These symptoms are categorized into voiding (such as hesitancy, weak urinary stream, intermittency, straining, and the sensation of incomplete bladder emptying), storage (including frequency, urgency, nocturia, and urge incontinence), and post-micturition (like post-void dribbling). All these symptoms negatively impact the quality of life (QoL) for those affected.[3,4]

BPH can be managed effectively using non-pharmacological, pharmacological, or surgical methods. While surgery is still regarded as the most definitive treatment for BPH, the potential risks, complications, and expenses associated with this procedure have led to an increased interest in effective and safe non-invasive treatments such as medication.[3] At present, there is a diverse range of medications available for managing BPH, and there is significant interest in examining their comparative effectiveness and safety. Selective α1-adrenoceptor antagonists are viewed as the primary option in pharmacologic therapy for patients, with tamsulosin demonstrated to offer symptomatic relief for BPH with once-daily administration.[5]

Phosphodiesterase type 5 inhibitors such as tadalafil play a role in the treatment of LUTS due to BPH and this is presumed to be through relaxation of smooth muscles in the bladder neck, urethra, and prostate induced by the nitric oxide/cyclic guanosine monophosphate (NO/cGMP) signal pathway.

Recently, its use either as monotherapy or combined with alpha-blockers has been associated with significant improvement in LUTS attributable to BPH by a large body of clinical studies.[6]

This study helps to objectively assess the efficacy of combination therapy with tamsulosin and tadalafil compared to tamsulosin only among African men with LUTS due to BPH. This is based on the need for readily available, effective treatment with significantly improved QoL outcomes for patients. Findings from this study will contribute to the armamentarium of effective drug combinations available to the urologist. In addition, there is a dearth of studies on the subject in the African sub-region, a vacuum this study aimed to fill.

MATERIAL AND METHODS

A prospective randomized longitudinal study was conducted over a 1-year period among 56 new consented patients with the diagnosis of LUTS due to BPH at the Jos University Teaching Hospital. The criteria for study inclusion were patients with IPSS scores ≤20, patients who had bothersome symptom scores of ≥4 that impacted negatively on QoL and those committed to medical therapy during the period of the study.

The following group of patients were excluded; patients already on medical therapy for BPH, patients with BPH and severe comorbidities such as diabetes, malignancy, hepatic or cardiovascular diseases, patients with absolute indication for surgical intervention, and those on nitrate drugs.

The instruments used for this study included the IPSS questionnaire, proforma, and uroflowmetry machine (NIDHI Flow-814). Patients had the IPSS questionnaire, QoL scores, and maximum flow rate (Qmax) assessed at baseline. A simple random sampling technique using a table of numbers was electronically generated. Using the software www.randomizer.org, 28 patients were allotted to the tamsulosin-with tadalafil group (Group A) and the same number to the tamsulosin only group (Group B). The subjects were then enrolled after consenting, their serial numbers already indicating the medication treatment as electronically generated. The treatment for the patients in study Group A was tamsulosin 0.4 mg with tadalafil 5 mg daily, while those in study Group B received only 0.4 mg of tamsulosin. After 12 weeks of treatment, the subjects were reassessed. The data collected from the participants were analyzed statistically using the Statistical Package for the Social Sciences version 23 software. The results were displayed in the form of tables. A student *t*-test was employed for the analysis, with a $P < 0.05$ deemed significant.

RESULTS

A total of 56 participants who provided consent and satisfied the inclusion criteria were included in the study. The ages of the subjects ranged from 48 to 89 years, with a mean age of 61.82 ± 8.71 years as shown in Table 1.

Table 1: Age of study participants with benign prostatic hyperplasia (*n*=56).

Age (years)	Frequency	Percentage
Mean±SD	61.82±8.71	
Age group		
≤50	5	8.9
51–60	20	35.7
61–70	23	41.1
>70	8	14.3
Total	56	100

SD: Standard deviation

Table 2: IPSS, QoL score, Qmax in the two groups of patients (Tamsulosin with Tadalafil vs. Tamsulosin alone) with LUTS due to BPH at baseline.

Parameters	Group		Total	*t*-test	*P*-value
	Tamsulosin with tadalafil	Tamsulosin alone			
IPSS (Storage)	7.04±2.66	8.50±3.09	7.77±2.95	1.902	0.062
IPSS (Voiding)	7.57±2.44	7.75±4.19	7.66±3.40	0.195	0.846
IPSS (Total)	14.25±4.19	15.39±2.73	14.82±3.55	1.210	0.231
QoL score	4.29±0.46	4.50±0.58	4.39±0.53	1.536	0.130
Qmax	10.29±3.05	9.11±2.50	9.70±2.83	1.580	0.120

QoL: Quality of life, LUTS: lower urinary tract symptoms, BPH: Benign prostatic hyperplasia, Qmax: Maximum flow rate, IPSS: International prostate symptom score

Table 3: IPSS, QoL score, and Qmax in the two groups of patients (Tamsulosin with Tadalafil vs. Tamsulosin alone) with LUTS from BPH after 12 weeks of treatment.

Parameters	Group		Total
	Tamsulosin with Tadalafil	Tamsulosin alone	
IPSS (Storage)	4.88±2.52	5.93±1.94	5.43±2.28
IPSS (Voiding)	4.92±2.10	5.21±3.17	5.07±2.68
IPSS (Total)	9.73±3.18	11.18±3.38	10.48±3.34
QoL score	3.19±2.40	2.89±0.93	3.04±1.80
Qmax	12.22±2.97	9.68±2.95	10.93±3.20

QoL: Quality of life, LUTS: lower urinary tract symptoms, BPH: Benign prostatic hyperplasia, Qmax: Maximum flow rate, IPSS: International prostate symptom score.

Table 4: Comparison of response to treatment from baseline at 12 weeks post-treatment using IPSS, QoL score, and Qmax among those treated in Group A.

Parameters	Period		*t*-test	*P*-value
	Baseline	After 3 months of treatment		
IPSS (Storage)	7.04±2.66	4.88±2.52	5.132	0.001
IPSS (Voiding)	7.57±2.44	4.92±2.10	8.922	0.001
IPSS (Total)	14.25±4.19	9.73±3.18	8.458	0.001
QoL score	4.29±0.46	3.19±2.40	2.332	0.028
Qmax	10.29±3.05	12.22±2.97	5.780	0.001

QoL: Quality of life, Qmax: Maximum flow rate, IPSS: International prostate symptom score.

At baseline, the mean total IPSS, QoL score, and Qmax in the two groups were as shown in Table 2. No statistical differences were noted.

As shown in Table 3 at 12 weeks of treatment, the QoL score and Qmax were higher in Group A than in Group B; however, the reverse was the case for IPSS.

Table 4 shows significant clinical and statistical differences in total IPSS, QoL score, and Qmax in Group A after 3 months of treatment.

Table 5: Comparison of response to treatment from baseline at 12 weeks post-treatment using IPSS, QoL score, and Qmax among those treated in Group B.

Parameters	Period		*t*-test	*P*-value
	Baseline	After 3 months of treatment		
IPSS (Storage)	8.50±3.09	5.93±1.94	5.795	0.001
IPSS (Voiding)	7.75±4.19	5.21±3.17	4.251	0.001
IPSS (Total)	15.39±2.73	11.18±3.38	7.596	0.001
QoL score	4.50±0.58	2.89±0.93	9.066	0.001
Qmax	9.11±2.50	9.68±2.95	0.98	0.336

QoL: Quality of life, Qmax: Maximum flow rate, IPSS: International prostate symptom score.

Table 6: Comparison of response to treatment in the two treatment groups using IPSS, QoL score, and Qmax after 12 weeks of treatment.

Parameters	Group		*t*-test	*P*-value
	Tamsulosin with Tadalafil	Tamsulosin alone		
IPSS (Storage)	4.88±2.52	5.93±1.94	1.713	0.093
IPSS (Voiding)	4.92±2.10	5.21±3.17	0.395	0.694
IPSS (Total)	9.73±3.18	11.18±3.38	1.618	0.112
QoL score	3.19±2.40	2.89±0.93	0.611	0.544
Qmax	12.22±2.97	9.68±2.95	3.191	0.002

QoL: Quality of life, Qmax: Maximum flow rate, IPSS: International prostate symptom score.

In comparing the total IPSS, QoL score, and Qmax among patients in Group B at 3 months post treatment, there was a significant clinical difference in IPSS, significant statistical difference in QoL score, however neither for Qmax [Table 5].

When total IPSS, QoL score, and Qmax are compared in the two groups after 3 months of treatment, only Qmax was statistically significant [Table 6].

DISCUSSION

The study compared the response to treatment in two groups of patients on medical therapy with tamsulosin combined with tadalafil versus tamsulosin only using IPSS, QoL score, and Qmax.

Fifty-six (56) patients with LUTS due to BPH were studied. Most of the patients presented in the seventh decade of life. This is similar to what was obtained in Ghana in a study by Yeboah where the predominant age range with BPH was in the 60–69 years age group.[7] From this study, the mean age and standard deviation of patients with BPH were 61.82 ± 8.71 years. This aligns with the results from Ojewola *et al*. in southwestern Nigeria, which reported a mean age of 64.3 ± 12.6 years, as well as the study by Bechara *et al*. in Argentina, which found a mean age of 63.7 years.[8,9] This supports the notion that BPH is a condition associated with advancing age.

The mean IPSS, QoL score, and Qmax at baseline for patients in the tamsulosin plus tadalafil group (Group A) were 14.28 ± 4.19, 4.29 ± 0.46, and 10.29 ± 3.05, while that for tamsulosin only group (Group B) were 15.39 ± 2.73, 4.50 ± 0.58, and 9.11 ± 2.50, with a total mean noted to be 14.82 ± 3.55, 4.39 ± 0.53, and 9.70 ± 2.83, respectively. This result is consistent with the observations made by Bechara *et al*., who reported a mean IPSS of 19.4, QoL score of 4.1, and Qmax of 9.6.[9] This may imply that patients with LUTS due to BPH with mild-to-moderate symptoms and bothersome scores greater than four at diagnosis are more likely to have significant obstruction.

The assessment at 12-week/s post-treatment showed that the mean IPSS, QoL score, and Qmax for patients in the tamsulosin plus tadalafil group (Group A) was 9.73 ± 3.18, 3.19 ± 2.40, and 12.22 ± 2.97, while that for tamsulosin only group (Group B) was 11.18 ± 3.38, 2.89 ± 0.93, and 9.68 ± 2.95, with a total mean noted to be 10.48 ± 3.34, 3.04 ± 1.80, and 10.93 ± 3.20, respectively. As per American Urological Association (AUA) guidelines, a change of 3 points from the baseline IPSS is deemed significant. The results of this study aligned with the clinically relevant enhancement in total IPSS for both groups,[10] i.e., tamsulosin with tadalafil (−4.52) and tamsulosin only (−4.21). This finding is in tandem with observations made by Singh *et al*. in the study conducted in India. Also noted, there was some improvement in the QoL scores and Qmax in both groups of patients following interventions with medical therapy.[10,11]

Comparison of response to treatment from baseline to 12-week post-treatment using IPSS, QoL score, and Qmax among those treated using the t-test showed significant improvement in Group A that was statistically significant; IPSS (8.458, P = 0.001), QoL score (−2.332, P = 0.028), Qmax (5.780, P = 0.001). However, in Group B while there were statistically significant improvements in IPSS (7.596, P = 0.001) and QoL score (9.066, P = 0.001), the improvement in Qmax (0.98, P = 0.336) was not statistically significant. This finding corroborates some observations made by Bechara *et al*. in the pilot study conducted in Argentina involving twenty-seven patients.[9]

CONCLUSION

This study has affirmed that there is a consistent clinically meaningful improvement of symptoms in patients with LUTSs due to BPH who have mild-to-moderate symptoms with a significant degree of bothersomeness as evidenced by total IPSS, QoL scores, and Qmax who are on medical therapy with either combination drugs using tamsulosin and tadalafil or monotherapy with tamsulosin.

The study revealed that the use of a combination medical therapy with tamsulosin and tadalafil or tamsulosin monotherapy has a similar effect in improving IPSS and QoL score; however, the combination of tamsulosin with tadalafil has a better effect in improving urine flow rate (Qmax) compared to tamsulosin when used alone. This may prove beneficial in a selected group of patients with BPH who have significant obstruction to urine flow.

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