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Effect of Tamsulosin Alone & Tamsulosin-Dutasteride Combination Therapy on Sexual Function in Men with Benign Prostatic Enlargement

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ABSTRACT

Background: Benign prostatic enlargement (BPE) is frequently observed in aging men. An association exists between lower urinary tract symptoms (LUTS) and sexual dysfunction resulting from BPE.
Objective: To compare the effect of Tamsulosin alone and Dutasteride in combination with Tamsulosin on men's sexual function (ejaculatory function, libido) for managing LUTS secondary to BPE.
Method: This quasi-experimental study was carried out at department of Urology, Nishtar Hospital Multan (2021-22) on 138 BPE patients in 2 equal groups. Group A was given Tamsulosin (0.4mg) and group B received combination of Tamsulosin and Dutasteride (0.4mg/0.5mg) at bedtime. Patients were followed in OPD at 3, 6, 9 and 12 months of study and each patient filled questionnaires on every visit of international prostate scoring system (IPSS), International Index of Erectile Function (IIEF-5) and Premature Ejaculation diagnostic tool (PEDT) to assess the sexual adverse effects. Data was analyzed in SPSS v25 using t-test for quantitative and chi-square for qualitative variables; $p \leq 0.05$ was considered significant**.** Ethical approval was obtained from institutional committee.
Results: Mean IPSS score in group A was 9.63±2.69 and in group B was 7.57±2.18 (p-value=<0.001). The mean Erectile dysfunction score in group A was 15.78±3.17 and in group B was 9.29±1.76 (p-value=<0.001). The mean ejaculation dysfunction score in group A was 8.92±2.19 and in group B was 12.39±2.02 (p-value=<0.001).
Conclusion: While treating LUTS in patients with BPE, although combination therapy of Tamsulosin and Dutasteride is better, it has significant adverse effects on sexual activity compared to Tamsulosin monotherapy**.**
Keywords: Tamsulosin, Dutasteride, Lower Urinary Tract Symptoms, Benign Prostatic Enlargement, Ejaculatory Dysfunction.

INTRODUCTION: Benign prostatic enlargement (BPE) is one of the most common conditions in older men [1]. It results from dihydrotestosterone acting on the aging prostate, causing changes in both stromal and epithelial components. This leads to uncontrolled proliferation of connective tissue, smooth muscle, and glandular epithelium within the transitional zone [2]. In men aged 50 years and older, the prevalence of BPE is estimated between 50% and 75%, rising markedly to about 80% in individuals over the age of 70 [3]. This condition commonly results in lower urinary tract symptoms (LUTS). Similarly, the frequency of LUTS ranges from 44% among men of 40 to 59 and rises to 70% in those over 80 [4]. LUTS may result in complications including urinary tract infections, urinary retention, bladder calculi, and even renal failure [5]. Tamsulosin is an α_{1A}-selective blocker with a plasma half-life of approximately 15 hours. Its effectiveness is notably higher in

inhibiting the contraction of prostate smooth muscle compared to other α1-selective blockers. This enhanced efficacy makes it a commonly preferred option for managing BPE symptoms over other drugs in the same class [6]. Dutasteride is a 5α-reductase inhibitor (5-ARI) that targets all three isoforms of the enzyme responsible for converting testosterone into dihydrotestosterone, a key contributor to prostate enlargement. Dutasteride undergoes hepatic metabolism and has a half-life measured in weeks [7]. The troublesome LUTS caused by BPE often lead patients to seek medical help. Multiple treatment options are available, including monotherapy with either Tamsulosin or Dutasteride, or a combination of both. Although these drugs substantially relieve LUTS associated with BPE, sexual dysfunction including decreased libido, erectile dysfunction, and premature ejaculation, remains a major concern for patients and can even lead to discontinuation of therapy [8,9]. Despite both Tamsulosin and Dutasteride are well established in the management of LUTS due to BPE, their impact on sexual function is assessed in limited research from Pakistan. Comparative data on monotherapy versus combination therapy in sexually active men is limited too.

The purpose of this study is to compare Tamsulosin alone or Tamsulosin-Dutasteride combination therapy on sexual function outcomes in sexually active men with lower urinary tract symptoms attributed to benign prostatic enlargement.

METHOD: This quasi Experimental study was carried out in the department of Urology, Nishtar Hospital Multan in 2021-22. Patients who had been sexually active within the past four weeks and expressed intent to remain sexually active for the next six months, aged ≥40 years, with diagnosed BPE, an IPSS ≥12 (at screening), prostate volume ≥40 grams (assessed by pelvic ultrasound), and a total serum PSA level ≤4 ng/ml (at screening) were included in this project. Patients with a total serum PSA level >4 ng/ml (at screening), diagnosed with prostate cancer, or suffering from chronic kidney disease, liver disease, diabetes mellitus, hypertension, or a history of prostate surgery, as well as those with preexisting erectile dysfunction, were excluded. The sample size was determined using expected mean difference of 3 in such groups, 0.05 significance level, 95% confidence level, and 80% power of the study, and the sample size came out to be 44 in each group (104 total) as a minimum sample size and we increased the sample size to 138 [11].

A non-probability convenience sampling technique was used to recruit participants for the project. Informed consent was obtained prior to their enrollment. They were divided into two groups as described in table 1.

Table 1: Intervention Protocol

Group A (n=69)	Patients took Tamsulosin 0.4 mg once at night for one year [11].
Group B (n=69)	Patients took Tamsulosin 0.4mg and Dutasteride combination 0.5mg once a day at night for 12 months [12].

Patients were contacted telephonically to remind them of follow-up visits and were examined in the outpatient department in the 3rd, 6th, 9th, and 12th months of the study. Each patient completed the Urdu versions of the IPSS (International Prostate Symptom Score), IIEF-5 (International Index of Erectile Function – 5-item version), and PEDT (Premature Ejaculation Diagnostic Tool) forms at every scheduled visit to assess erectile dysfunction, ejaculatory disorders, and decreased libido in the combination therapy group (Group B) versus the Tamsulosin monotherapy group (Group A). Non-sexual side effects that include headache, orthostatic hypotension, asthenia and cardiovascular effects were also recorded and had been managed symptomatically. Patients having non-sexual severe side effects were dropped from study [13,14]. Data was analyzed by using IBM SPSS version 25. Quantitative data was presented in the form of Mean ± S.D. Qualitative data was analyzed through chi-square test and quantitative data through t-test. *P*-value ≤ 0.05 was considered as significant. Ethical approval for the study was granted by the Institutional Ethics Committee (letter #15226/NMU&H, Dated: 12-08-2020).

RESULTS: Each group consisted of 69 patients, with a mean age of 59.36 ± 8.00 years in Group A and 60.91 ± 10.61 years in Group B. No patient discontinued medication or missed scheduled follow-up visits. Data was recorded at baseline and at 3, 6, 9, and 12 months. Table 2 summarizes the inter-group comparison of IPSS,

IIEF, and PEDT scores at baseline and follow up intervals. The corresponding trends in IPSS, IIEF, and PEDT are illustrated in Figure 1, Figure 2, and Figure 3, respectively.

Table 2: Inter group Comparison of IPSS, IIEF and PEDT at baseline and follow up periods

Time	Groups	IPSS Mean ± SD	*p* value	IIEF score Mean ± SD	*p* value	PEDT Mean±SD	*p* value
Baseline	Group A	25.23±3.99	0.130	18.46±2.61	0.261	8.87±1.99	0.122
	Group B	26.32± 4.38		18.96±2.52		8.30±2.26	
03 Month	Group A	18.96±4.67	<0.001	18.75±3.42	0.001	9.13±2.31	0.044
	Group B	15.97± 3.46		16.96±2.50		9.93±2.31	
06 Month	Group A	11.42± 3.06	0.015	18.09±3.32	<0.001	9.55±2.44	<0.001
	Group B	10.09±3.31		12.61±1.68		12.48±2.08	
09 Month	Group A	9.81± 2.87	<0.001	17.21±3.25	<0.001	9.0±2.08	<0.001
	Group B	7.85±2.28		10.53±1.62		12.36±2.03	
12 Month	Group A	9.63±2.69	<0.001	15.78±3.17	<0.001	8.92±2.19	<0.001
	Group B	7.57±2.18		9.29±1.76		12.39±2.02	

Figure 1: Mean IPSS score over time in Group A and Group B

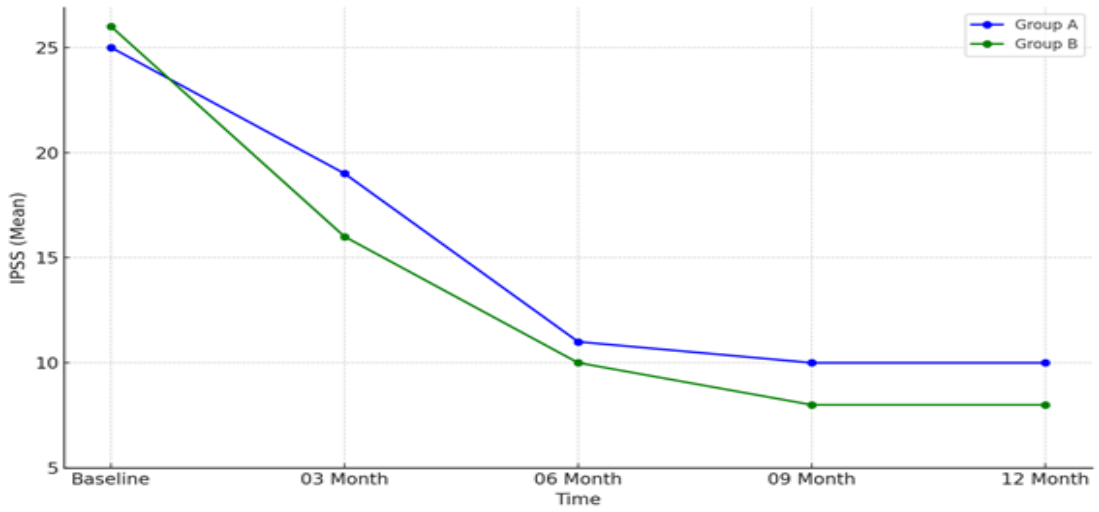


Figure 2: Mean IIEF score over time in Group A and Group B

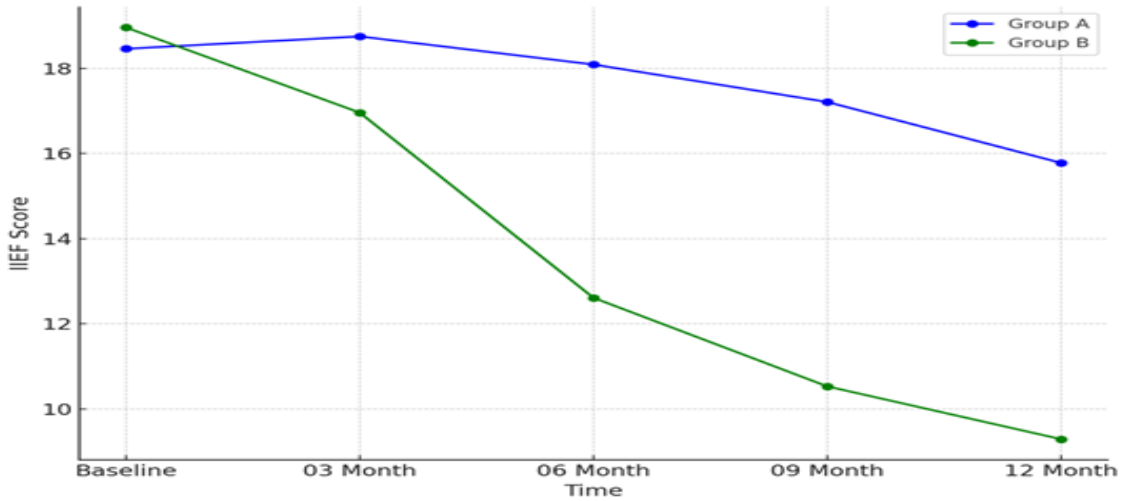
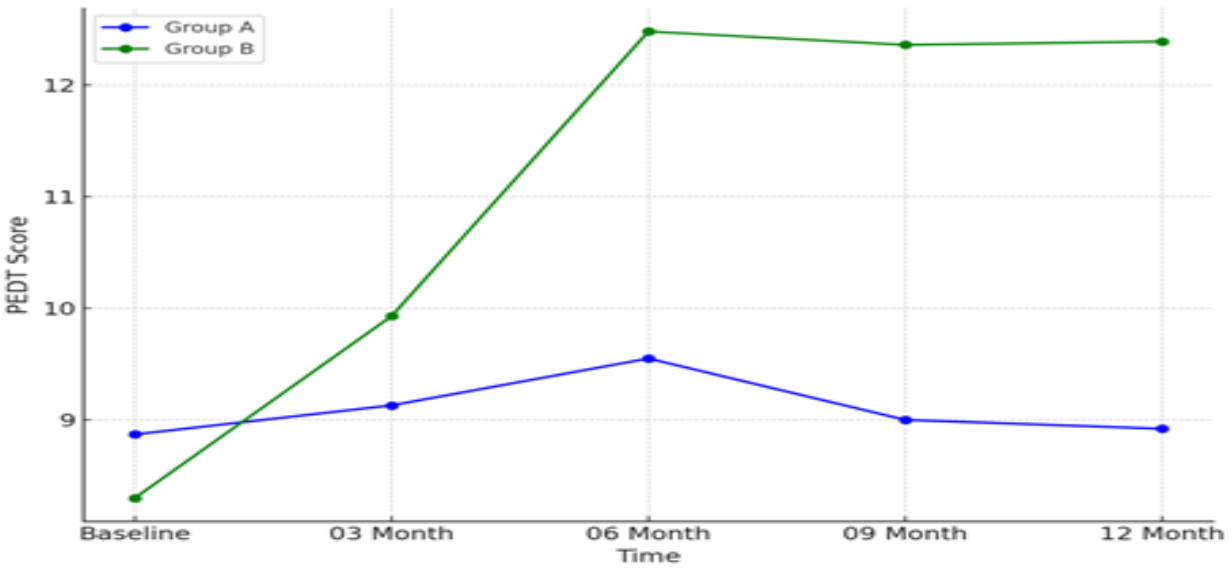


Figure 3: Mean PEDT score over time in Group A and Group B



DISCUSSION:

Due to BPE, LUTS are very prevalent in older men. Tamsulosin alone or in combination with Dutasteride is a common drug choice for these patients [15]. This study of the combination of Tamsulosin and Dutasteride (0.4 mg/0.5 mg) daily showed significantly better assessment using IPSS and ED scores compared to the Tamsulosin 0.4 mg daily group. However, in terms of ejaculatory dysfunction, the group receiving 0.4 mg of Tamsulosin daily experienced significantly fewer side effects compared to the combination of Tamsulosin and Dutasteride (0.4 mg/0.5 mg) daily. Similar results were found in the research by Zhongbao, which showed that combining Tamsulosin and Dutasteride had a better therapeutic impact for BPH while also increasing the risk of sexual adverse effects (OR, 0.56; $p < 0.001$) compared to the placebo group [16]. Likewise, the CombAT study led by Roehrborn et al. (2014) also strengthened the results of this project and highlighted the potential benefits of using a combination approach to manage BPH more effectively. Their study demonstrated that the combination therapy provided superior outcomes, including a significant improvement in clinical symptoms measured by the International Prostate Symptom Score (IPSS), with a difference of 4 points. Additionally, the combination therapy led to a remarkable 68% reduction in the incidence of acute urinary retention and a 71%

reduction in the need for surgical intervention after eight months of treatment compared to Tamsulosin alone. These findings highlight the potential benefits of using a combination approach to manage BPH more effectively [17]. Moreover, the results of the research work by Abou Farha were also parallel to our findings: patients with BPE using the combination of Tamsulosin experienced more sexual side effects.[8] Haque also confirmed that combining Tamsulosin and Dutasteride for patients having LUTS (moderate to severe) with larger prostate glands (>40 mL), high prostate-specific antigen levels (>1.6 ng/ml), and a reduced urine flow rate is a more effective therapeutic option ($p < 0.001$) in Asian people suffering from moderate-to-severe LUTS/BPH, as compared to Tamsulosin monotherapy [18]. On further exploration, it was found that the research project by Ajay Anand claimed that α-blocker monotherapy or add-on therapy with Dutasteride may also lead to failure i.e., in cases of large-sized prostates, intravesical projection, and raised serum PSA, surgical treatment should be considered [19]. Their findings not only positively attribute to this project but also guide early switching to surgical options if medical therapy fails. In contrast to our findings, the 2021 research work of Lulic found that in patients of Korean origin, there is no difference in erection or ejaculation problems in either group—those using Tamsulosin monotherapy or in combination with Dutasteride [20]. Likewise, Hisanori evaluated 81 patients with BPE who were taking Dutasteride for one year and concluded that Dutasteride did not lead to sexual dysfunction [21]. These contrary findings open the debate and leave space for further research on the same subjects to public a final conclusion. Our study has limitations. It was a single centered study and was not blinded by adding placebo.

CONCLUSION:

The study concludes that combining Tamsulosin with Dutasteride provides greater therapeutic benefit for managing lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) compared to Tamsulosin monotherapy; however, this improved efficacy is accompanied by a higher risk of sexual side effects.

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