



Finasteride and Tamsulosin Combination in Benign Prostatic Enlargement in a Tertiary Hospital

Binod Bade Shrestha,¹ Mikes Karmacharya¹

¹Department of Surgery, Manipal College of Medical Sciences, Pokhara, Nepal.

ABSTRACT

Introduction: Due to aging of the general population, prevalence of Benign Prostatic Enlargement is increasing. Symptoms of BPE may vary between the patients. Aim of the study was to analyze and compare the usefulness of combination drugs therapy and monotherapy after a trial period of six months.

Methods: Out of 100 male patients aged 45 years and above diagnosed with BPE, 92 were included in the study. Patients were randomized using computer generated random number table. Of which, 47 patients received combination therapy with Tamsulosin plus Finasteride and 45 patients received monotherapy with Tamsulosin once daily at bed time.

Results: The baseline demographic variables were comparable in both groups. The decrease in the total American Urological Association symptom score was statistically significant in the combination group ($p < 0.0001$) as compared to monotherapy ($p = 0.0715$) respectively. There was a statistically significant reduction in the residual urine volume with combination therapy ($p < 0.0001$) than in patients with monotherapy ($p = 0.1271$).

Conclusions: The combination therapy is effective in decreasing the irritative and obstructive symptoms in patients with BPE than monotherapy.

Keywords: AUA symptom score; benign prostatic enlargement; finasteride; post voidal residual urine; tamsulosin.

INTRODUCTION

Benign enlargement of prostate (BPE) is a common problem in aging males. At the age of 40, 5 to 10% of men have prostate enlargement whereas at 80 years, prevalence is as high as 80%.¹ However the size of

prostate correlates poorly with severity of symptoms such that patients with huge palpable prostate may be asymptomatic whereas those with small prostate may have severe symptoms.^{2,3}

Correspondence: Dr. Binod Bade Shrestha, Department of Surgery, Manipal College of Medical Sciences, Phulbari - 11, Pokhara, Nepal. Email: badebinod@hotmail.com, Phone: +977-9841308692.

The impact of Lower Urinary Tract Symptoms (LUTS) on patient's quality of life is variable. It is not directly related to any measurable physiological factors. The patient's perception of severity of condition and the degree to which it interferes with his lifestyle should be the primary consideration in choosing therapy.

We conducted a study to evaluate the efficacy of Tamsulosin plus Finasteride and Tamsulosin alone in the management of patients with BPE.

METHODS

After getting approval from Institute's Ethics Committee and obtaining written informed consent from patients, randomized trial was conducted in 100 patients from September 2013 to August 2014. Patients were randomized into two groups using computer generated random number tables such that 50 patients received combination drug therapy of Tamsulosin 0.4 mg plus Finasteride 5mg and remaining 50 patients received monotherapy with Tamsulosin 0.4 mg every day at bed time for a duration of six months.

Patients aged 45 years and above with symptomatic BPE as categorized by American Urological Association (AUA) symptom scoring system were included in the study.⁴

Patients with diabetes mellitus, prostate and bladder carcinoma, prostatitis, neurogenic bladder, stricture urethra, vesical calculus, and those on drugs likely to affect bladder function, were excluded from the study.

Study procedures: All patients presenting to the surgical outpatient department (OPD) of Manipal Teaching Hospital with symptoms of BPE were initially examined by the surgical resident in training under the supervision of consultant of General Surgery. All patients underwent an ultrasonography (USG) of abdomen and pelvis to assess the post voidal residual volume (PVRV) in milliliter (ml). Patients were interviewed with questionnaire as per AUA scoring and results recorded.

Follow-up and assessment: The patients were followed up for six months and AUA symptom score evaluation was recorded. A complete clinical and ultrasonography examination was carried out.

Statistical analysis was done using SPSS 17. Changes in various parameters from baseline values to values after six month were evaluated by using student t test.

The minimum level of significance was fixed at 95% confidence limit and a p value of <0.05 was considered significant.

RESULTS

Out of 100 patients, eight underwent surgery, three from combination therapy and five from monotherapy for recurrent retention of urine and were excluded from study. The baseline demographic age details showed no significant difference between the two groups. Mean age was 57.27 years in monotherapy group and 60.49 years in combination group (Table 1).

Table 1. Comparison of AGE between two groups.

Variables	Combination Group	Monotherapy Group	P value	CI
Mean	60.49	57.27	0.1265	-0.93 to 7.37
SD	9.06	10.94		
N	47	45		

CI: confidence interval; N: number of patients; SD: standard deviation

Almost all patients showed some symptomatic relief by beginning of second month in combination group. Further improvement in all parameters was evident by the end of six month. The total AUA score decreased from 18.02 to 12.12 ($p < 0.0001$) in combination group whereas with monotherapy it decreased from 16.62 to 15.31 ($p = 0.0715$), with percentage of change being 32.74% and 7.88% in combination group and monotherapy respectively (Table 2, Figure 1).

Table 2. Comparison of AUA score between two groups.

AUA Score	Combination group	Monotherapy group
Onset (mean \pm SD)	18.02 \pm 3.49	16.62 \pm 3.87
Six months (mean \pm SD)	12.12 \pm 2.68	15.31 \pm 3.36
p value	<0.0001	0.0715
Confidence interval (CI)	-0.125 to 2.92	-4.44 to -1.93

AUA: American Urological Association, CI: confidence interval; SD: standard deviation

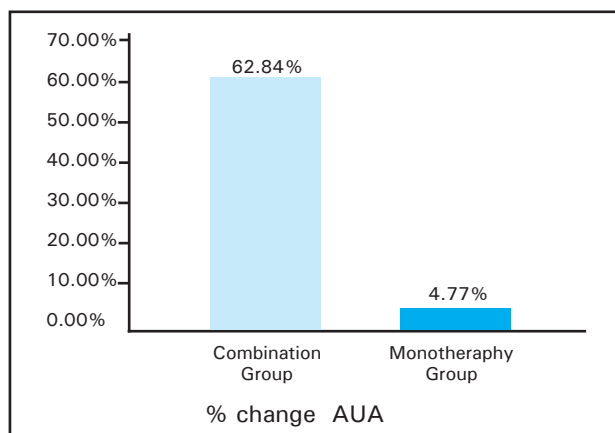


Figure 1. Comparison of AUA (American Urological Association) score between two groups.

The mean residual urine volume decreased from 120.87 to 44.92 ml in combination group whereas 100.34 to 95.55 ml in monotherapy group. There were significant reduction from baseline to the end of six month in combination groups ($p < 0.0001$) with mean percentage of change 62.84% in combination group whereas only 4.77% in monotherapy group (Table 3).

Table 3. Comparison of PVRV (ml) score between two groups.

PVRV	Combination group	Monotherapy group
Onset (mean \pm SD)	120.87 \pm 80.19	100.34 \pm 40.43
6months (mean \pm SD)	44.92 \pm 27.19	95.55 \pm 45.34
P value	<0.0001	0.1271
CI	-5.992 to 47.015	-66.03 - -35.22

CI: confidence interval; SD: standard deviation, PVRV: post voidal residual volume

DISCUSSION

BPE is one of the most common conditions affecting elderly males with a resultant impact on the surgical practice as elderly constitute an increasing population throughout the world. A decade back, surgery and

watchful waiting were the only treatment options available for BPE. However, at present era medical management is widely accepted modality of treatment and 80% of the population can be treated with medication.^{5,6}

Alpha blockers are the mainstay of treatment. Alfuzosin-uroselective alpha-1 blocker, Tamsulosin-prostate specific alpha-1a blocker and Finasteride-5 alpha reductase inhibitor are mostly used for the management of BPE.

Results from the Medical Therapy of Prostatic Symptoms (MTOPS) trial, emphasize the superiority of combination therapy (alpha blocker plus 5 alpha reductase inhibitor) over individual drug treatment which is in accordance to the finding of our study.⁷ In the current study, the significant reduction in the AUA symptom score at the end of six month in combination group indicate that Finasteride plus Tamsulosin provide significant symptomatic relief in BPE, which may be due to a significant reduction in the prostate size as well as increased contractility of urinary bladder. The beneficial effect of combination therapy is due to the synergistic action of its ingredients which also helped to decrease PVRV significantly. However in contrast to study by Hasan M et al, there is no clinically significant improvement in symptoms in patients treated with Tamsulosin alone.⁸ At present only combination therapy with 5alpha-reductase inhibitors with alpha-adrenergic antagonists is recommended in clinical practice guidelines.⁹

In this study we have not evaluated the incidence of side effects, urinary flow rate and change in the quality of life.

CONCLUSIONS

Our study has also shown a promising result in decreasing the irritative and obstructive symptoms both subjectively and objectively in patients treated with combination drug therapy. Thus the combination therapy might be recommended for treating patients with symptomatic BPE.

REFERENCES

- Berry SJ, Coffey OS, Walsh PC, Ewing LL. The development of human benign prostatic hyperplasia with age. *J Urol*. 1984;132(3):474-9.
- Christensen MM, Reginald CB. Clinical manifestations of benign prostatic hyperplasia and indications for therapeutic intervention. *Urol Clin North Am*. 1970; 7(3):509-16.

3. Jensen KME, Bruskewitz RC, Iversen P, Madsen PO. Significance of prostatic weight in prostatism. *Uro Int*. 1983;38(3):173-8.
4. Barry MJ, Fowler FJ Jr, O'Leary MP, Bruskewitz RC, Holtgrewe HL, Mebust WK. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. *Med Care*. 1995 Apr;33(4 Suppl):AS145-55.
5. Chirikos TN, Sanford E. Cost consequences of surveillance, medical management or surgery for benign prostatic hyperplasia. *J Urol*. 1996;55(4):1311-6.
6. Di-Silverio F, Sciarra A, Di-Nicola S, Casale P, Buscarini M, Di Chiro C, et al. Is medical therapy an expensive way for delaying surgery in BPH patients? *Minerva Urol Nefrol*. 1995;47(4):177-84.
7. Logan YT, Belgeri MT. Monotherapy versus combination drug therapy for the treatment of benign prostatic hyperplasia. *Am J Geriatr Pharmacother*. 2005 Jun;3(2):103-14.
8. Hasan M, Parveen F, Shamsuzzaman AK, Kibria. Comparison of efficacy between Tamsulosin and Finasteride on symptomatic Benign Prostatic Hyperplasia. *Mymensingh Med J*. 2007 Jul;16(2):154-9.
9. Chung DE, Kaplan SA. Current role for combination therapy in male LUTS. *Arch Esp Urol*. 2010 Jun;63(5):323-32.