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Original Article

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Comparative Study Between Dutasteride Monotherapy Versus Combination of Dutasteride and Tamsulosin in Management of BPH

Tawhid-Ul-Islam[1], Abu Bakar Siddique[2], Md. Nasir Uddin[3], Shahriar Md Kabir Hasan[4], AKM Anwarul Islam[5], Farhana Yesmin[6]

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Abstract

Objectives: *To evaluate whether combination therapy with Dutasteride and Tamsulosin is more effective than Dutasteride monotherapy for improving symptom of BPH.*

Patient and method: *This hospital based, prospective, randomized, comparative study will be conducted in Urology Dept. BMU from January 2011 to June 2012.Total 160 cases were selected according to inclusion and exclusion criteria. 80 case for combination therapy and 80 cases for monotherapy. Men 50-75 years with clinical diagnosis of prostatic hyperplasia, international prostate symptom score points 8 to 35, prostate volume 30 to 50 cc, total serum prostate specific antigen 1.5 to <4 ng/ml and peak urinary flow rate 5 to 15 ml/sec were randomized to 0.5 mg Dutasteride or the combination of 0.5 mg Dutasteride and 0.4 mg Tamsulosin on a daily for 12 months. Symptoms were assessed at 6 month and 12 months.*

Result: *Combination therapy resulted in significant improvements in symptoms. There was significantly greater improvement from baseline in Qmax, IPSS and Prostate Volume for combination therapy vs Dutasteride from month six. Drug related adverse events with combination therapy is not significant.*

Conclusion: *In men with moderate to severe lower urinary tract symptoms and prostate enlargement (30 cc or greater) combination therapy provides a significantly greater degree of benefit than Dutasteride monotherapy.:*

Keywords: BPH, DRE, IPSS, Qmax

Introduction:

Benign prostatic hyperplasia (BPH) is defined histologically by proliferation of the stromal and epithelial elements of the prostate (Bartsch et al 1979) and clinically it is characterized by lower urinary tract symptoms (LUTS). BPH is progressive in nature and may led to worsening of LUTS, flow rate, and serious complication such as acute urinary retention and need for surgery (Siami 2007). a blocker and 5-alpha reductase inhibitor have shown different abilities to influence likelihood of progression (Madersbacher 2007).

Combination therapy resulted in a greater improvement in symptom score statistically significant at six months than dutasteride monotherapy (Roehrborn et al. 2008). A subsequent analysis demonstrated that the benefits of combination therapy versus the monotherapy is significant in all men with a baseline prostate volume (PV) of at least 25cc (Kaplan 2006).

1987 Beside, review of different trials concluded that a PV at least 30cc and PSA level of at least 1.5 ng/ml could identify men at risk of BPH progression (Bartsch 2004). Thus the aim of this trial to investigate the efficacy and safety of combination therapy compared

1. Consultant Urologist, OSD DGHS, Dhaka, Bangladesh.
2. Associate Professor of Urology, Dhaka Medical College, Dhaka, Bangladesh.
3. Professor of Urology, Dhaka Medical College Hospital, Dhaka, Bangladesh.
4. Associate Professor of Urology, National Institute of Kidney Diseases & Urology, Dhaka, Bangladesh.
5. Ex-Chairman & Professor of Urology, Bangladesh Medical University (BMU), Dhaka, Bangladesh.
6. Assistant Professor of Surgery, OSD, DGHS attached to Bangladesh Medical University (BMU), Dhaka, Bangladesh.

Correspondences: Dr. Tawhid-Ul-Islam, Consultant Urologist, OSD DGHS, Dhaka, Bangladesh, Email: tawhid.uro@gmail.com.

with monotherapy alone, in men with moderate to severe BPH and at risk of disease progression- as identified by age ≥50years, moderate to severe symptoms, PV ≥30cc and PSA > 1.5ng/ml.

α-blocker providing a rapid onset of symptom relief and improvement in flow. Although they delay onset of AUR and reed for surgery but a-blocker do not reduce the overall risk of these events. On other hand 5 a-Reductase inhibitor provide long term improvement in symptoms and flow rate and reduce prostate volume, therefore the risk of BPH progression (Rocher et al. 2 Roehrborn 2002)

Keeping these views in mind, the present work has been carried out to evaluate the efficacy and safety of medical treatment of BPH with Dutasteride and Tamsulosin over effect of dutasteride alone.

Aims and Objectives

General Objective:

To compare the efficacy and tolerability of combination therapy of Dutasteride and Tamsulosin with Dutasteride monotherapy in the management of Benign prostatic hyperplasia.

Specific Objectives:

1) To observe the change in IPSS, Qmax and prostate volume using combination therapy of Dutasteride + Tamsulosin
2) To observe the change in IPSS, Qmax and prostate volume using Dutasteride monotherapy.
3) To compare the side effects of the both arms.

Variables:

a. International prostate symptom score (I-PSS)
b. Peak urinary flow rate (Qmax)
c. Prostate –volume by USG

Operational definition:

a) Satisfactory improvement of Qmax: 2.2 ml/s or more increase from baseline (Roehrborn et al. 1996).
b) Postural hypotension: A decrease in systolic blood pressure >20mmHg or a decrease in diastolic blood pressure >10 mmHg upon standing from the supine position (Lepor et al. 1996).
c) Hypotension: BP in lying position < 90/70 mm Hg (Lepor 1995).

Materials and Method:

Type of study: Randomized controlled trial.

Study period: January 2011 to June 2012

Place the Study: Department of Urology, Bangladesh Medical University (BMU) Hospital.

Study population:

Study population included the patients who attended the outpatient department of Urology complaining lower urinary tract symptoms (LUTS) due to BPH.

Sampling technique: Purposive random sampling technique was applied to collect the sample from study population.

Sample size:

$$n = \frac{P_1(1-P_1) + P_2(1-P_2)}{(P_1 - P_2)^2} \left(Z_\alpha - Z_\beta\right)^2$$

n=160

Group A = 80

Group B = 80

Study Design

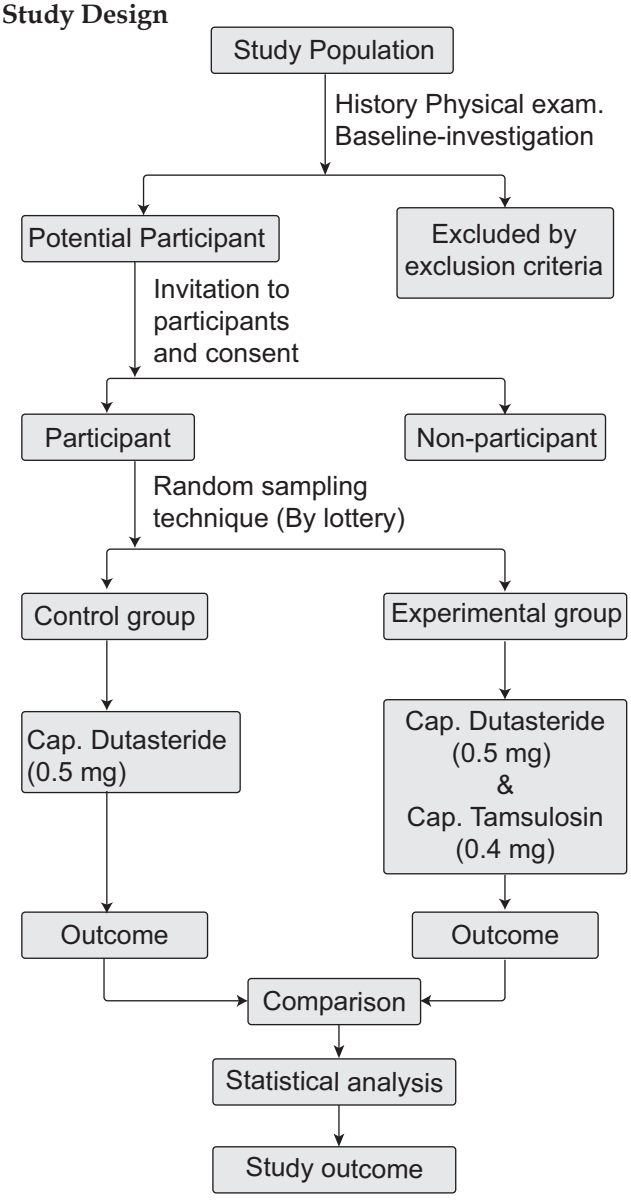

Fig.-1: *Flow chart of study design*

Inclusion criteria:

1. Moderate to severe LUTS
2. Clinically diagnosed case of BPH
3. Age: 50 to 75 years
4. Prostate size e"30 cc to 50 cc by USG
5. IPSS 8 to 35 points
6. Qmax = 5-15 ml/sec, voided volume: 150 ml
7. PSA (T) 1.5 to <4 ng/dl

Exclusion criteria:

1. PVR >250 ml
2. IPP (intravesical prostatic protrusion-median lobe)
3. Patient with refractory retention
4. History or evidence of carcinoma prostate
5. Previously operated patient (TURP, BNI, URETHROPLASTY, PELVIC SURGERY)
6. Neuropathic bladder, pelvic irradiation.

Procedure:

Each patient complained of LUTS were evaluated by history, physical examination, digital rectal examination (DRE), International Prostate Symptoms Scoring (I-PSS), Urinalysis, X-ray KUB, Ultra sonogram, Uroflowmetry and Serum prostatic specific antigen (PSA). By ultra-sonogram, volume of prostate or other pathology was determined.

These patients were then scrutinized according to inclusion and exclusion criteria. Also they were invited to participate and give consent. Those who meet these criteria, selected as baseline cases (Participant). Total 160 cases were selected purposively according to selection criteria.

Participants were randomly allocated in control (group-A) and experimental (Group-B) groups by lottery. Dutasteride 0.5mg was given to group-A and Combination of Tamsulosin 0.4mg+Dutasteride 0.5mg to Group-B. Each of the patients continued the therapy for 12 months and was, followed-up at 6 months (1st visit) and 12 months (End visit).

On each follow-up visit, each patient was evaluated by I-PSS, uroflowmetry to see peak urinary flow rate(Qmax), ultrasonogram to see prostate volume. During follow up each meticulously observed for any adverse event. A detail data sheet was compiled.

Data Collection & analysis:

Data were collected from data sheet, after collection, these were edited by meticulous checking and rechecking. Statistical Package for Social Science (SPSS), a statistical analysis package program version -18 was used. Measures of dispersion (mean, standard deviation) and the tests of significance (Student's paired "t" test and Student's unpaired "t" employed to examine the statistical significance of the study. A <0.05 was taken as minimum level of significance.

Result and Observation

Results at midterm (6 month) of study period:

A. Group-A (Dutasteride 0.5 mg) at six month follow up visit:

After 6 months treated with Dutasteride (0.5 mg), the mean values of IPSS Qmax and prostate volume were, 19.97±5.03 points, 13.89±1.42 ml/s, and 28.46±4.72 cc respectively. Mean value change of IPSS, Qmax and prostate volume were 2.7± 0.86 points, 2.94± 0.29 ml/s, 10.02±1.88 cc respectively in Dutasteride group. In comparison to baseline mean values, IPSS, Qmax and prostate volume values were of significant changes (P<0.05, in paired "t" test).

Table-I: *Results of Dutasteride (0.5 mg) Group-A at 6 month follow- up visit:*

Variables	Baseline (mean ±SD	Follow-up at 6 month (mean ± SD)	Change from baseline (mean±SD)	P (in the same group comparison with baseline)
IPSS (points)	22.67± 4.17	19.97± 5.03	2.7± 0.86	<0.05
Qmax (ml/s)	11.55 1.13	13.89± 1.42	2.34± 0.29	<0.05
Prostate volume (gm)	38.48± 5.60	28.46±4.72	10.02±1.88	<0.05

B. Group-B (Combination Group) at 6-month F/U visit:

After 6-months therapy, treated with combination (Dutasteride + Tamsulosin) drugs, the mean values of IPSS,

Qmax and prostate volume were, 17.67±4.17 points, 15.85±2.37 ml/s and 27.21±3.59 gms respectively. Mean value change of IPSS, Qmax and prostate volume were 4.53 0.3 points, 1.72± 1.32 ml /s and 10.56 ± 1.38 gm respectively in combination group. In comparison to baseline mean values, IPSS, Qmax and Prostate volume values were of significant changes (P < 0.05, in paired "t" test).

Table-II : *Results of combination drugs (Group B) at 6-month follow-up visit:*

Variables	Baseline (mean ±SD)	Follow-up at 6 month (mean ± SD)	Change from baseline (mean±SD)	P (in the same group comparison with baseline)
IPSS (points)	22.20± 4.47	17.67± 4.17	4.53± 0.03	<0.05
Qmax (ml/s)	12.67± 1.05	15.85± 2.37	3.18± 1.32	<0.05
Prostate volume (gm)	37.77± 4.97	27.21± 3.59	10.56± 1.38	<0.05

Results at end point (12 month) study period:

A. Group-A (Dutasteride 0.5 mg): at 12 month follow up visit:

At end point i.e., after 12 months, treated with Dutasteride (0.5 mg), the mean values of IPSS, Qmax and prostate volume were, 18.22 ± 5.15 points, 14.69 ±1.04 ml/s and 27.91± 4.71 cc respectively. Mean value change of IPSS, Qmax and prostate volume were, 4.45± 0.68 points 3.14± 0.09 ml/s and 10.57 ± 0.89 gm respectively in Dutasteride group. In comparison to baseline mean values, all the IPSS, Qmax and Prostate volume values were of significant changes (P<0.05, in paired "t" test).

Group-A at end point (12 month) follow-up visit:

Table-III: *Results of Dutasteride (0.5mg),*

Variables	Baseline (mean ±SD)	Follow-up at 6 month (mean ± SD)	Change from baseline (mean±SD)	P (in the same group comparison with baseline)
IPSS (points)	22.67± 4.17	18.22± 5.15	4.45± 0.68	<0.05
Qmax (ml/s)	11.55±1.13	14.69± 1.04	3.14± 0.09	<0.05
Prostate volume (cc)	38.48± 5.60	27.914.71	10.57±0.89	<0.05

Results at end point (12 month) study period:

B. Group B (Combination Group);

At the end point i.e., after 12-month therapy of combination drugs, the mean values of IPSS, Qmax and prostate volume were, 15.67± 4.17 points, 17.14± 5.51 ml/s and 26.71±3.62 cc respectively. Mean value change of IPSS, Qmax and prostate volume were, 6.53±0.12 points, 4.47± 3.46 ml/s and 11.06±1.35 cc respectively in combination group. In comparison to baseline mean values, all mean values of variables were of significant changes (P<0.05, in paired "t" test).

Table-IV: *Results of combination drugs (Group-B) at end point (12 month) follow-up visit.*

Variables	Baseline (mean ± SD)	Follow-up at 6 month (mean ± SD)	Change from baseline (mean±SD)	P (in the same group comparison with baseline)
IPSS (points)	22.20±4.47	15.67 ±4.17	6.53±0.41	<0.05
Qmax (ml/s)	12.67± 1.05	17.14± 5.51	4.47± 2.82	<0.05
Prostate volume (cc)	37.77± 4.97	26.71± 3.62	11.06 1.35	<0.05

Table-V: *Comparison of I-PSS between baseline and 6-month F/U visit in two groups:*

Patient group	Baseline IPSS mean±SD	IPSS at 6 month visit mean±SD	IPSS Change mean±SD	P (in the same group comparison with baseline)
Group-A(n=80)	22.67±44.17	19.97±5.03	2.27±0.86	0.001*
Group-B(n=80)	22.20±4.47	17.67±4.17	4.53±0.3	0.001*

*Significant

Table-VI *Comparison of IPSS between two mean at twelve months follow up visit in two groups.*

Patient group	IPSS at 6 month visit mean±SD	IPSS Change mean±SD	P (in comparison of mean IPSS between 2 groups)
Group-A(n=80)	18.22±5.15	4.45±0.68	0.04*
Group-B(n=80)	15.67 4.17	6.53±0.12	

*Significant

Table-VII: *Comparison of Qmax between baseline and 6 month follow- up visit in two groups.*

Patient group	Baseline Qmax mean± SD	Qmax at 6 month visit mean±SD	P (in the same group comparison with baseline) of Group A & B
Group-A(n=80)	11.55 ±1.13	13.89±1.42	0.001*
Group-B(n=80)	12.67±1.05	15.85±2.37	0.001*

*Significant

Table-VIII: *Comparison of Qmax between two mean at twelve months follow up visit in two groups.*

Patient group	Qmax at 12 month visit mean± SD	Qmax change mean± SD	P (in comparison of mean IPSS between 2 groups)
Group-A(n=80)	14.69±1.04	3.14±0.09	0.001*
Group-B(n=80)	17.14±5.51	4.47±2.28	

* significant

Table-IX: *Comparison of Prostate volume between baseline and 6 month follow-up visit in two groups:*

Patient group	Baseline prostate volume mean±SD	Prostate Volume at 6 month visit mean±SD	P (in the same group comparison with baseline) of Group A & B
Group-A(n=80)	38.48 5.60	28.46±4.72	0.001*
Group-B(n=80)	37.77±4.97	27.21±3.59	0.001*

* significant

Table-X: *Comparison of Prostate volume between two mean at twelve months follow up visit in two groups.*

Patient group	Prostate Volume at 6 month visit mean±SD	Prostate Volume change mean±SD	P (in comparison of mean IPSS between 2 groups)
Group-A(n=80)	27.91± 4.71	10.57±0.89	.74^{NS}
Group-B(n=80)	26.71± 3.62	11.06±1.35	

^{NS} Not significant

Table-XI : *Adverse effects observed in two groups.*

	Group-A (n=80)	Group-B (n=80)	P value
Complications	9(10.25%)	11(12.75%)	>0.05NS
Erectile dysfunction	3	2	
Retrograde ejaculation	1	2	
Altered libido	4	4	
Ejaculation failure	0	1	
Dizziness	1	2	

NS Not significant

Discussion

In this study Dutasteride 0.5mg and combination of Tamsulosin 0.4mg + Dutasteride 0.5 mg were given to 160 cases of moderate to severe symptom patients and were followed-up for 6 & 12 months to determine the efficacy of the drugs and to compare the outcome of monotherapy versus combination therapy.

In this study, all cases were purposively selected from out patient department of urology of BSMMU Hospital, age ranging from 50-75 years who had been suffering from LUTS due to BPH. The age range in a separate study done in 1997 was 50-85 years and have a diagnosis of LUTS suggestive of BPH (Abrams et al. 1997). In ComAT study age is e"50 years (Siami et al. 2007). All cases were supplied with a bengali version of I-PSS questionnaire (Salam 1999) and the scores at base line, at 6 month and at end point (12th month) were obtained for data analysis.

In group-A, mean I-PSS was 22.67 ± 4.17 point at base line, which became 19.97 ± 5.03 point at 6 month and 18.22 ± 5.15 point at end point (12 month) and therefore, mean changes of I-PSS was 2.7 ± 0.86 point at 6 month and 4.45 ± 0.68 point at end point. Mean improvement were 2.7±0.86 and 4.45±0.68 points respectively. 15.67 ± 4.19 point at end In group-B, mean I-PSS was 22.20 ± 4.47 point at base line, which became 17.67 ± 4.17 point at 6 month and point and therefore mean changes of I-PSS month and 6.53± 0.1 point at end point.

Hence a significant improvement of IPSS was found after 12 month of treatment with Dutasteride 0.5 (Group-A) and combination of Tamsulosin 0.4 mg + Dutasteride 0.5 mg therapy (Group-B) (P<0.001). Similar improvement were observed in a separate study that IPSS is decreased significantly after 12 months of treatment with combination of Dutasteride and Tamsulosin. The author found that mean changes of IPSS is -7.3 points for combination therapy and -6.4 points for Dutasteride (Roehrborn et al. 2010).

At 6 month mean improvement of IPSS in group-A was 2.7±0.86 and in Group B was 4.53±0.3. Combination therapy did significant improvement than Dutasteride monotherapy (P<0.04).

At 12 month mean improvement of IPSS in group-A was 4.45±0.68 and in group-B was 6.53±0.1. Again combination therapy significantly improve than dutasteride monotherapy (P<0.04).

Improvement of urinary flow was assessed by determining the peak urine flow rate (Qmax). In group-A, mean Qmax was 11.55 ± 1.13 ml/sec at base line, which became 13.89 ± 1.42 ml/sec at 6 month and 14.69 ± 1.04 ml/sec at end point and therefore mean changes of Qmax was 2.34 ± 0.29 at 6 month and 3.14 ± 0.09 ml/sec at end point.

In group-B, mean Qmax was 12.67 ± 1.05 ml/sec at base line, which became 15.85±2.37 ml/sec at 6 month and 17.14 ± 3.33 ml/sec at end point and therefore mean changes of Qmax was 3.18 ± 1.32 ml/sec at 6 month and 4.47±2.28 ml/sec at end point.

Hence a significant improvement of peak urine flow rate was found both after 6 month and 12 month treatment with 0.5 mg of Dutasteride (group-A) as well as in combination (group-B) in comparison to baseline.

In this study, the range of prostate volume was assessed by transabdominal ultrasonography which was 30 - 50 cc. In group-A, mean prostate volume was 38.48 5.60 cc at base line, which became 28.46 ± 4.72 cc at 6 month and 27.91 ± 4.71 cc at end point and therefore mean changes of prostate volume was 10.02 ± 1.88 cc at 6 month and 10.57±0.89 cc at end point.

In group-B, mean prostate volume was 37.77±4.97 cc at base line, which became 27.21±3.59 cc at 6 month and 26.71±3.62 cc at end point and therefore mean changes of prostate volume was 10.56 ±1.38 cc at 6 month and 11.06±1.35 cc at end point.

Hence prostate volume was reduced significantly in group-A and group-B after 6 and 12 months treatment in comparison to baseline (p<0.001)/But combination (group-B) therapy was not found to be superior to Dutasteride monotherapy in terms reducing prostate volume.

Hence in this study as well as other study done in different parts of world support that addition of 5a-

reductase inhibitors can reduce volume of prostate, which improve peak urine flow and decrease symptom.

Conclusion:

Combination therapy provided a significantly greater degree of benefit than Dutasteride monotherapy in terms of symptom, urinary flow and BPH related health status in men with moderate to severe LUTS and prostatic enlargement. Improvement was regardless of baseline prostate volume, Qmax, IPSS, age. Combination therapy provide rapid and durable symptom benefit in men with moderate to severe LUTS due to BPH, prostatic enlargement and at increased risk of progression.

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