

## Original Research Article

# A comparative clinical evaluation of outcome of medical and surgical management of symptoms due to benign prostatic hyperplasia

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## ABSTRACT

**Background:** Benign hypertrophy of prostate is common disorder and benign neoplasm of man above 50 years of age. Around 30% patients with benign hypertrophy of prostate lower urinary tract symptoms (LUTS) but all symptoms may not be due to benign hypertrophy of prostate (BHP). Present study has been designed for comparative evaluation of the outcome of medical and surgical management of symptoms, due to benign prostatic hyperplasia by using IPSS (international prostate score) and quality of life score as tool.

**Methods:** In present study patients with LUTS, clinically diagnosed by per rectal digital examination and transrectal ultrasonographically confirmed cases of enlargement of prostate are enrolled for this study. Patients enrolled were divided equally in three groups.

**Results:** After six month the mean IPSS score in silodosin (Sd) group was  $6.55 \pm 0.86$  and in Sd+Dutasteride (Dt) group it was  $5.09 \pm 1.12$ . After six months mean IPSS score in Sd+Dt group was  $5.09 \pm 1.12$  and in TURP group it was  $2.44 \pm 0.59$ .

**Conclusions:** Single drug treatment with silodosin is associated with slow and less improvement in IPSS score in comparison with silodosin and dutasteride. But the response to TURP was better and faster than medical management.

**Keywords:** Benign prostatic hyperplasia, TURP, Medical management, Comparison

## INTRODUCTION

Benign hypertrophy of prostate is common disorder and benign neoplasm of man above 50 years of age. Enlargement of prostate consist of stromal and epithelial hyperplasia leading to formation of discrete nodule in periurethral region of prostate.<sup>1</sup> This pathological changes become important as enlarged prostate has intimate anatomical relation with bladder neck. The incidence of benign hypertrophy of prostate is 50% in patients above 50 years of age and it rise to 75% in eighth decade. Around 30% patients with benign hypertrophy of prostate LUTS but all symptoms may not be due to BHP. Various type of dysfunction of smooth muscle of lower urinary tract may be responsible for that. LUTS is a symptom

complex characterised as poor and/or intermittent stream, straining, prolonged micturition, feeling of incomplete bladder emptying, dribbling collectively called as obstructive symptoms and frequency, urgency, urge incontinence, and nocturia called as storage or irritative symptoms.<sup>2,3</sup> Based on pathogenesis of BHP two approach of medical management is used, first is to reduce the volume of gland for that two 5-ARIs that is finasteride and dutasteride are used second is to dilate the prostatic urethra for that and five  $\alpha$ -blockers that is terazosin, doxazosin, tamsulosin, alfuzosin, and silodosin are used. Last three decade has revolutionised the treatment modalities.<sup>3</sup> Even with the development in the field of surgical management TURP still considered being gold standard for management of BHP. With the development in the field of surgery HOLEP has become

treatment of choice for men seeking surgical relief for BPH related LUTS and the gold standard for the 21<sup>st</sup> Century but due to recourses and other issue TURP is still gold standard.<sup>4</sup> In last two decades numerous randomized, placebo-controlled clinical trials have been conducted to evaluate the safety and efficacy of these drugs. Lepor H et al. has concluded that combination of drugs with different mechanisms of action will likely show additive clinical effectiveness.<sup>5</sup> Cambio AJ, Evans CP et al. medications are equally efficacious for treating BPH, terazosin and doxazosin have higher adverse effect profiles (namely, orthostatic hypotension) than do other medications from this class.<sup>6</sup> Keeping in view of that present study has been designed for comparative evaluation of the outcome of medical and surgical management of symptoms, due to benign prostatic hyperplasia by using IPSS and QOL as tools.

## METHODS

This is prospective observational analytical cross sectional study conducted in the department of general surgery and urology Konaseema institute of medical science, Amalapuram, Andhra Pradesh from February 2018 to May 2020.

### Selection of patients

In present study patients with LUTS clinically diagnosed by per rectal digital examination and transrectal ultrasonographically confirmed cases of enlargement of prostate are enrolled for this study based on following exclusion and inclusion criteria. Inclusion criteria were, age more than 50 years and diagnosed cases of BHP. Exclusion criteria were, neurological causes of bladder dysfunction, Ca prostate, renal and bladder stone, cystitis with haematuria. Present study was approved by institutional ethics committee. A written informed consent was obtained from all patients before enrolling them for study.

Based on inclusion and exclusion criteria sixty patients with clinically and radiologically established BHP were enrolled for this study. The patients with LTUS were accessed with IPSS score.<sup>7</sup> Patients enrolled was divided equally in three groups. All data of patient were collected on predesigned Performa. Patients with volume of prostate more than 40ml were given silodosin 4 mg and

dutasteride 0.5mg combination was enrolled and called Sd+Dt group. Patients with volume of prostate less than 40 ml were given single drug silodosin 4 mg once daily was enrolled and called Sd group. Patients with recurrent urinary tract infection, acute obstruction and high IPSS were enrolled for surgical management were included in TURP group. Patients enrolled in this group were undergone transurethral resection of prostate under anaesthesia and standard surgical procedure was followed for each patients. All patients were evaluated for IPSS score at first month, second month, forth month and at sixth month. At the start of study base line score of IPSS were measured and was calculated at each visit. At the end of study QOL score was calculated and compared between the groups. Any drug reaction or intolerance to drug was noted and evaluated. All patients on drug therapy were advised to report for any drug reaction.

### Statistical analysis

Data was collected on excel sheet and analysed by SPSS software version 17. For analysis of data chi square test, paired t-test and one way ANOVA was used. The p value less than 0.05 were considered statistically significant.

## RESULTS

In present twenty six months study we have enrolled sixty students for evaluation of outcome of medical and surgical management of symptoms, due to benign prostatic hyperplasia.

As per (Table 1), we have found that mean age of patients in Sd group was 60.44±7.53 years, in Sd+Dt Group it was 59.95±4.97 years and in TURP Group it was 63.1±3.85 years. All three groups of patients were similar to each other with respect to age as p-value was 0.170912. The basal IPSS score was 10.45±1.80 in Sd group, 10.75±2.21 in Sd+Dt group and 24.5±5.60 in TURP group. The IPSS group was significantly higher in TURP group as p-value was less than 0.05. The basal quality of life score was 1.28±0.98 in Sd group, 1.31±0.92 in Sd+Dt group and 4.47±1.17 in TURP group. The mean prostatic volume was 37±1.84 in Sd group, 44.91±2.596 in Sd+Dt group and 50.6±4.42 in TURP group. All groups were statistically different from each other with respect to basal QOL score and mean volume of prostate. The p value was less than 0.05.

**Table 1: Basal parameters of patients in various treatment group.**

Variable	Sd group	Sd+Dt group	TURP group	P value
Age in years (mean±SD)	60.44±7.53	59.95±4.97	63.1±3.85	0.170912
Number of patients	20	20	20	--
Basal IPSS	10.45±1.80	10.75±2.21	24.5±5.60	<0.00001
Basal QOL score	1.28±0.98	1.31±0.92	4.47±1.17	<0.00001
Mean prostate volume (ml)	37±1.84	44.91±2.596	50.6±4.42	<0.00001

Sd = silodosin group, Sd+ Dt (silodosin plus dutasteride), TUR = (transurethral resection of prostate).

As per (Table 2), regarding comparison between two medical management group that is Sd group and Sd+Dt group, The IPSS score was  $10.33 \pm 0.98$  in Sd group and  $10.12 \pm 1.24$  in Sd+Dt group which is not significant statistically. The mean of IPSS score was decreased second month in both group that is  $9.11 \pm 1.54$  and  $8.28 \pm 1.51$  but p-value is 0.055 which is not significant. In fourth month the mean IPSS score in Sd group was  $8.57 \pm 1.49$  and in Sd+Dt group it was  $7.1 \pm 1.04$ . This difference was statistically significant ( $p=0.001047$ ). After six month the mean IPSS score in Sd group was  $6.55 \pm 0.86$  and in Sd+Dt group it was  $5.09 \pm 1.12$ . This difference was statistically significant ( $p=0.00004$ ).

**Table 2: Comparison between improvement of IPSS score between Sd and Sd+Dt group.**

Time in months	Sd group	Sd+Dt group	p-value
Basal IPSS	$10.45 \pm 1.80$	$10.75 \pm 2.21$	0.493312
First month	$10.33 \pm 0.98$	$10.12 \pm 1.24$	0.24156
Second month	$9.11 \pm 1.54$	$8.28 \pm 1.51$	0.055698
Fourth month	$8.57 \pm 1.49$	$7.1 \pm 1.04$	0.001047
Sixth month	$6.55 \pm 0.86$	$5.09 \pm 1.12$	0.000046

As per Table 3, represent comparison between improvement of IPSS score between Sd and TURP group as per this table after one month mean IPSS score in Sd group was  $10.33 \pm 0.98$  and in TURP group it was  $4.10 \pm 1.09$ . This difference was statistically significant ( $p<0.00001$ ). After two months mean IPSS score in Sd group was  $9.11 \pm 1.54$  and in TURP group it was  $3.65 \pm 0.85$ . This difference was statistically significant ( $p<0.00001$ ). After four months mean IPSS score in Sd group was  $8.57 \pm 1.49$  and in TURP group it was  $2.56 \pm 0.56$ . This difference was statistically significant ( $p<0.00001$ ). After six months mean IPSS score in Sd group was  $6.55 \pm 0.86$  and in TURP group it was  $2.44 \pm 0.59$ . This difference was statistically significant ( $p<0.00001$ ).

**Table 3: Comparison between improvement of IPSS score between Sd and TURP group.**

Time in months	Sd group	TURP group	P value
Basal IPSS	$10.45 \pm 1.80$	$24.5 \pm 5.60$	$<0.00001$
First month	$10.33 \pm 0.98$	$4.10 \pm 1.09$	$<0.00001$
Second month	$9.11 \pm 1.54$	$3.65 \pm 0.85$	$<0.00001$
Fourth month	$8.57 \pm 1.49$	$2.56 \pm 0.56$	$<0.00001$
Sixth month	$6.55 \pm 0.86$	$2.44 \pm 0.59$	$<0.00001$

As per (Table 4), after one month the mean of IPSS score in Sd+Dt group was  $10.12 \pm 1.24$  and in TURP group it was  $4.10 \pm 1.09$ . This difference was statistically significant ( $p<0.00001$ ). After two months mean IPSS score in Sd+Dt Group was  $8.28 \pm 1.51$  and in TURP group it was  $3.65 \pm 0.85$ . This difference was statistically significant ( $p<0.00001$ ). After six months mean IPSS score in Sd+Dt group was  $5.09 \pm 1.12$  and in TURP group

it was  $2.44 \pm 0.59$ . This difference was statistically significant ( $p<0.00001$ ).

**Table 4: Comparison between improvement of IPSS score between Sd+Dt and group.**

Time in months	Sd+Dt group	TURP group	p-value
Basal IPSS	$10.75 \pm 2.21$	$24.5 \pm 5.60$	$<0.00001$
First month	$10.12 \pm 1.24$	$4.10 \pm 1.09$	$<0.00001$
Second month	$8.28 \pm 1.51$	$3.65 \pm 0.85$	$<0.00001$
Fourth month	$7.1 \pm 1.04$	$2.56 \pm 0.56$	$<0.00001$
Sixth month	$5.09 \pm 1.12$	$2.44 \pm 0.59$	$<0.00001$

Regarding drug reactions with medical management group dizziness was present in 2 patients in Sd group and 4 patients in Sd+Dt group. Postural hypotension was present in 4 patients in Sd group and 3 patients in Sd+Dt group. Urinary incontinence was present in 2 patients in Sd group and 4 patients in Sd+Dt group. Decreased libido was present in 1 patient in Sd group and 3 patients in Sd+Dt group. This finding was not significant statistically (Table 5). After six month QOL score was measured in all group. The mean of quality of life score in Sd group was  $0.87 \pm 0.41$  in Sd+Dt group it was  $0.77 \pm 0.67$  and TURP group it was  $0.66 \pm 0.21$ . The difference between these group was not statistically significant (Table 6).

**Table 5: Adverse drug reaction developed in medical management group.**

Reactions	Sd group	Sd+Dt group	P value
Dizziness	2	4	0.691964
Postural hypotension	4	3	Chi-
Urinary incontinence	2	4	square-
Decreased libido	1	3	statistic is 1.4581

**Table 6: Comparison of Quality of life score between group.**

Time	Sd group	Sd+Dt group	TURP group	P value
Basal QOL	$1.28 \pm 0.098$	$1.31 \pm 0.92$	$4.47 \pm 1.17$	0.0001
Sixth month	$0.87 \pm 0.41$	$0.77 \pm 0.67$	$0.66 \pm 0.21$	0.1154

## DISCUSSION

Present study has been designed to evaluate the outcome of medical and surgical management of symptoms, due to benign prostatic hyperplasia. Patients enrolled for this study were divided in three study groups and mean age of patient in medical management group were  $60.44 \pm 7.53$  years and  $59.95 \pm 4.97$  years. In surgical management group it was  $63.1 \pm 3.85$  years. This finding is supported by the work of Sha et al. and Shrivastav et al.<sup>8</sup> Basal IPSS score of patients in TURP group was  $24.5 \pm 5.60$

which significantly higher than medical management group that is  $10.45 \pm 1.80$ . Huang et al. in his study has reported that International prostate symptom score-storage symptom score (IPSS-S) was 10.38 for medical management and 25.02 for surgical management group.<sup>9</sup> This finding supports our study. This finding also corroborates with the finding of Hagiwara et al.<sup>10,11</sup> The mean of prostatic volume in medical management group was lower than surgical management which is similar to the work of Macey et al.<sup>12</sup>

The improvement in IPSS score was better in combination of drug group in first two months but in fourth and sixth month IPSS score was significantly decreased in combination therapy (silodosin and dutasteride) group. This finding is supported by the work of Roehrborn et al.<sup>13</sup> The improvement in IPSS score was significantly better from first month by TURP then silodosin and combination of silodosin and dutasteride. This finding is supported by the work Huang Shei-Wei et al and Macey et al.<sup>11,12</sup>

Dizziness and postural hypotension are most common adverse drug reaction in both medical management group medical but urinary incontinence and decreased libido was common in silodosin and dutasteride. This finding is supported by the work of Zaman Huri et al. and Jiwrajka et al.<sup>14,15</sup> In our study we have observed that quality of life score was improved in all three group but the improved in QOL for TURP group was better than medical management.

## CONCLUSION

From our study we can conclude that single drug treatment with silodosin is associated with slow and less improvement in IPSS score in comparison with silodosin+dutasteride. But the response to TURP was better and faster than medical management. Silodosin+dutasteride is associated with adverse drug reaction in more number of patients in comparison to single drug silodosin. Quality of life score was improved in all patients but it was more improved in TURP patients.

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