Original Research Article

Comparative Study on Efficacy of Dutasteride and Tamsulosin Combination vs. Trans Urethral Resection of Prostate (TURP) in Benign Prostatic Hyperplasia (BPH) Patients

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Abstract

BPH is one of the most common diseases among ageing men, affects more than half of men aged older than 50 years and nearly 90% of men over 80 years. BPH is one of the major causes of LUTS in men. The present study aimed to study the indications for medical management and surgery in BPH patients based on IPSS and maximal urinary flow rate (Q_{max}) and assesses the improvement in IPSS and Q_{max} after treatment with Dutasteride and Tamsulosin combination vs. TURP. Despite the treatment given in all the patients (50 cases, 100%) the obstructive symptoms were found to have a greater improvement than irritative symptoms. The present study concluded that despite the availability of various medical and minimally invasive surgical modalities even today TURP still remains the gold standard procedure for patients with clinically proven BPH causing moderate to severe LUTS.

Key words

BPH, Tamsulosin, Dutasteride, TURP, IPSS, Q_{max}.

Introduction

BPH is one of the most common diseases among ageing men, affects more than half of men aged older than 50 years and nearly 90% of men over 80 years [1, 2]. BPH is one of the major causes of LUTS in men [3].

Aim and objectives

- To study the indications for medical management and surgery in BPH patients based on IPSS and maximal urinary flow rate (Q_{max}).
- To assess the improvement in IPSS and Q_{max} after treatment with Dutasteride and Tamsulosin combination vs. TURP.

Materials and methods

Place of study: Mamata Medical College and Super Speciality Hospital, Khammam, India.
Duration of study: October 2017 to December 2019.
No of cases: 50 (25 medical management vs. 25 surgical management).

Inclusion criteria

- Age greater than or equal to 50 years.
- Peak urinary flow rate at least 4 ml/sec but not greater than 15 ml/sec; and voided volume is at least 125 ml.
- International Prostate Symptom Score of 12 or higher associated with moderate to severe symptoms.
- Ultrasonography showing prostate gland of size 30 to 50 cc (Grade II BPH).

Exclusion criteria

- Any prior medical or surgical intervention for BPH.
- Ultrasonography showing Intravesical protrusion of prostate.
- Patients with neurogenic bladder, prostate carcinoma, stricture urethra, bladder stone, recent gross hematuria, prostatic abscess were excluded from the study.

Methodology

A prospective comparative study of 50 patients who underwent treatment for BPH in Department of Urology at Mamata Medical College, Khammam was done. IPSS and Q_{max} were recorded in all the patients before and after 6 weeks of intervention. Comparison of the IPSS and Q_{max} before and after intervention to assess the improvement was done. IPSS questionnaire was downloaded online from AUA website [4] (https://www.auanet.org/Documents/practices-resources).

Results

The age group of patients was in the range of 50 to 80 years, with 20 cases (40%) in the age group of 70 years and above with a mean age of 66.92±8.23years.

Before start of medication, 25 cases were categorized as severely symptomatic IPSS group (score 20-35) with mean pre medication IPSS being 25.24±2.21, which when assessed 6 weeks after medication reduced to a mildly symptomatic group in 20 cases (80%) with a mean post medication score of 7.52±2.97 [3].

Before TURP, 25 cases were categorized as severely symptomatic IPSS group (score 20-35) with mean pre TURP IPSS being 25.6±2.06, which when assessed 6 weeks after TURP reduced to mildly symptomatic group in 20 cases (80%) with mean score of 7.44±2.76 which was superior in comparison to medical treatment.

Despite the treatment given in all the patients (50 cases, 100%) the obstructive symptoms were found to have a greater improvement than irritative symptoms [4].

The mean obstructive symptoms score pre-treatment was 14.52±2.0 for combination therapy and 14.92±1.79 for TURP, which reduced post treatment to a mean score of 2.6±2.12 for combination therapy and 2.4±1.98 for TURP, which was superior in comparison to medical treatment [4].

The mean irritative symptoms score pre-treatment was 10.72±1.22 for combination therapy and 10.86±1.78 for TURP, which decreased post-treatment.

Mean score of 5.28±1.7 for combination therapy and 5.04±1.75 for TURP, which was superior in comparison to medical treatment.

The mean score of quality of life pre-treatment was 4.1±0.02 for combination therapy and 4.44±0.01 for TURP, which when assessed post-treatment of 6 weeks had a mean score of 0.95±0.88 for combination therapy and 1±0.84 for TURP.

Of all the seven symptoms of IPSS, nocturia was found to have least improvement with any treatment having a mean pre-treatment score of 3.76±0.81 for combination therapy and 3.88±0.9 for TURP which when assessed 6 weeks after treatment had a mean post treatment score of 1.79±1.2 for combination therapy and 1.8±0.1 for TURP, which was similar in both groups.

Then mean Q_{max} pre-treatment was 9.56±2.94 for combination therapy and 9.64±2.54 for TURP, which when assessed post treatment of 6 weeks had a mean Q_{max} of 14.52±2.06 for combination therapy and 15.04±2.16 for TURP, which was superior to medical therapy group [5]. Results were tabulated as per **Table – 1 to 7** and **Graph – 1 to 7**.

Table – 1: Changes in Irritative symptom score in comparison to other studies.

Name of study	Pre ISS Combination therapy	Pre ISS TURP	Post ISS combination therapy	Post ISS TURP
Present Study	10.72±1.22	10.86±1.78	5.28±1.7	5.04±1.75
Dong, et al. [11]	10±3.8	10.4±3.4	5.3±1.9	5.4±1.85

Graph – 1: Changes in Irritative symptom score in comparison to other studies.

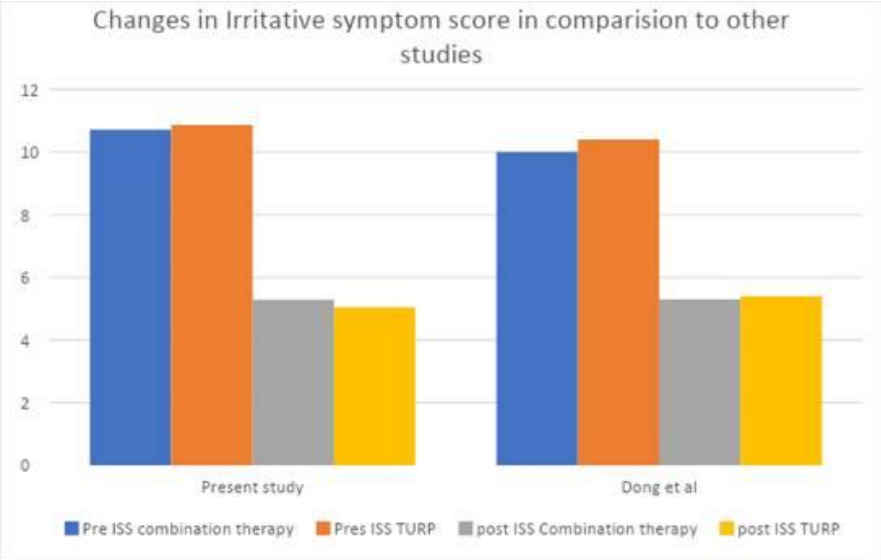


Table – 2: Changes in Obstructive symptom score in comparison to other studies.

Name of study	Pre OSS Combination therapy	Pre OSS TURP	Post OSS combination therapy	Post IOS TURP
Present Study	14.52±2.0	14.92±1.79	2.6±2.12	2.4±1.98
Dong, et al. [11]	13.6±6.0	13.8±4.7	3.7±4.1	2.3±3.7

Graph – 2: Changes in Obstructive symptom score in comparison to other studies.

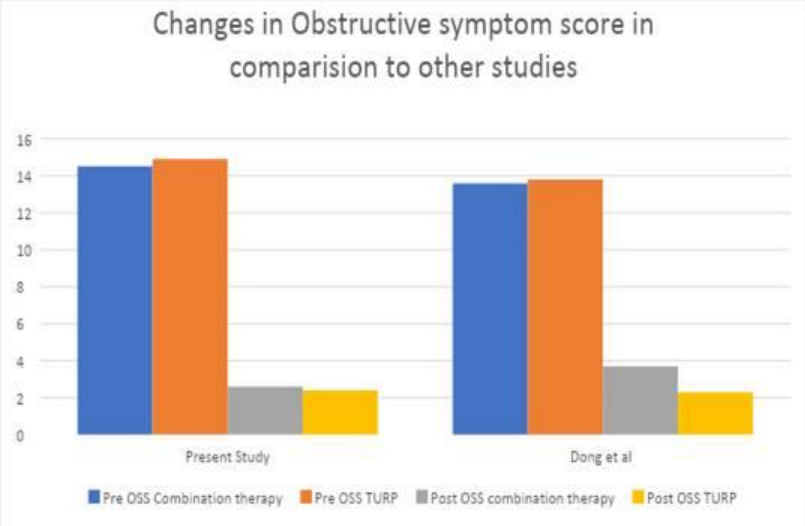


Table – 3: Changes in QOL score in comparison to other studies.

Name of study	Pre QOL Combination therapy	Pre QOL TURP	Post QOL combination therapy	Post QOL TURP
Present Study	4.1±0.02	4.44±0.01	0.95±0.88	1±0.84
Dong, et al. [11]	4.4±1.2	4.5±1.1	1.7±1.2	1.5±1.0

Graph – 3: Changes in QOL score in comparison to other studies.

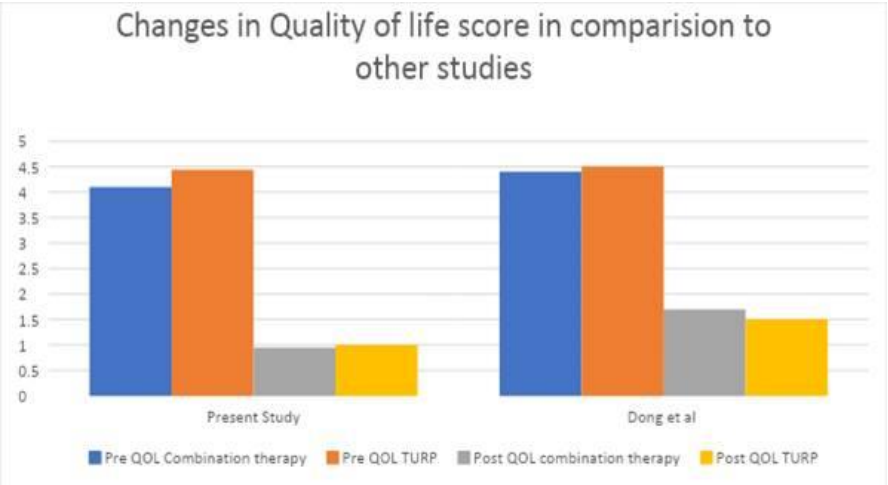


Table – 4: Changes in IPSS in comparison to other studies.

Name of study	Pre IPSS Combination therapy	Pre IPSS TURP	Post IPSS Combination therapy	Post IPSS TURP
Present Study	25.24±2.2	25.6±2.06	7.52±2.97	7.44±2.76
Vasileios Simaioforidis, et al. [7]	25.6±4.8	27.4±4.86	8.7±2.88	7.8±2.59
Dong, et al. [11]	22.8±7.9	23.4±6.9	9.1±7.8	8.6±4.5
Suhani, et al. [10]	25±1.7	29±2.2	11±2.8	10±2.9

Graph – 4: Changes in IPSS in comparison to other studies.

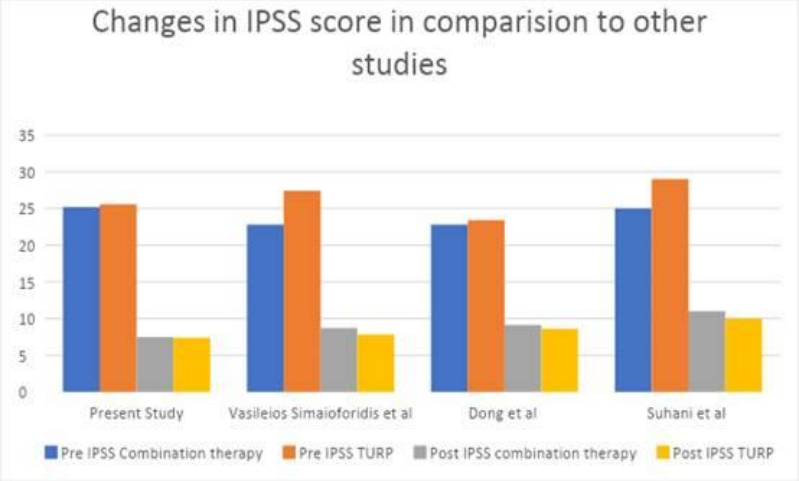


Table – 5: Percentage Change in IPSS in the present study in comparison to other studies.

Name of study	Combination therapy	TURP
Present Study	-34%	-36%
Roehborn, et al. [8]	-38%	-39%
Bozdar HR, et al. [9]	-30%	-34%
Djavan, et al. [12]	-37.7%	-41.8%

Graph – 5: Percentage Change in IPSS in the present study in comparison to other studies.

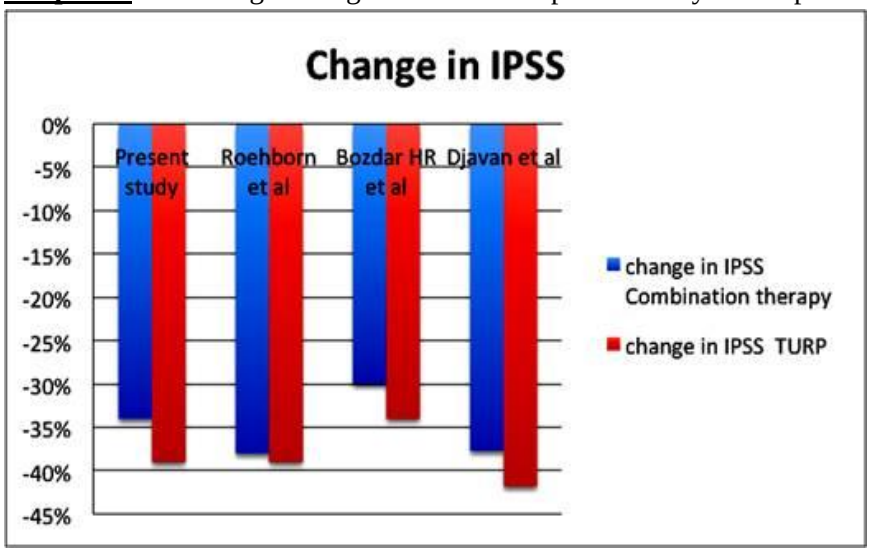


Table – 6: Change in Q_{max} in the present study in comparison to other studies.

Name of study	Combination therapy	TURP	Combination therapy	TURP
Present Study	9.56±2.94	9.64±2.54	14.52±2.06	15.04±2.16
Vasileios Simaioforidis, et al. [7]	9.5±1.69	9.4±2.16	15.1±8.1	14.9±8.8
Dong, et al. [11]	9.5±3.2	9.2±3.3	14.6±6.9	16.01±6.2
Suhani, et al. [10]	8.9±1.89	9.08±1.84	14.7±1.9	15.3±1.2

Graph – 6: Change in Q_{max} in the present study in comparison to other studies.

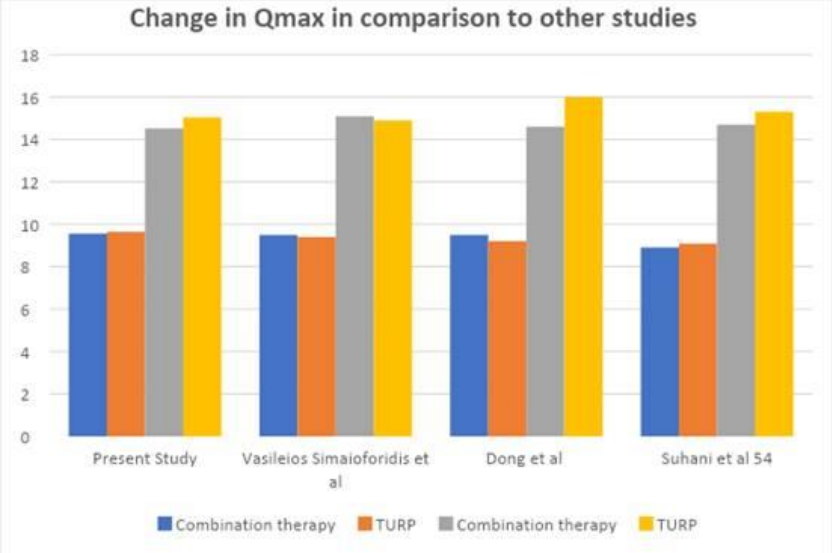
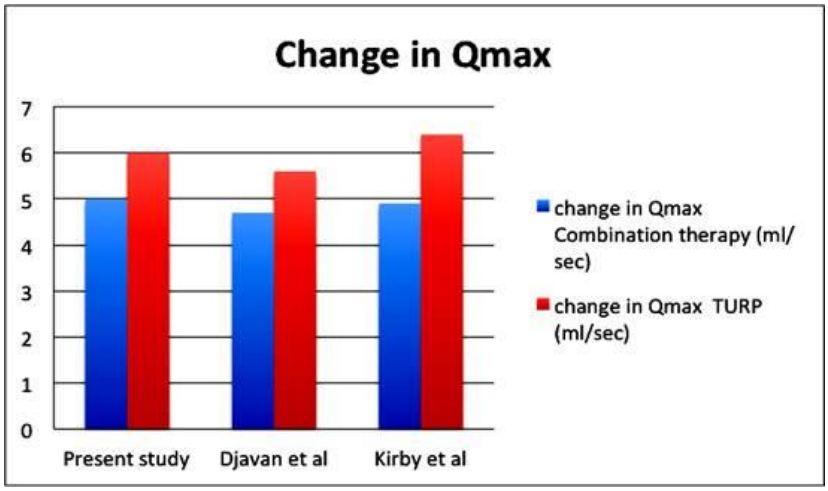


Table – 7: Improvement of Q_{max} in the present study in comparison to other studies.

Name of study	Combination therapy (ml/sec)	TURP (ml/sec)
Present Study	5	6
Djavan, et al. [12]	4.7	5.6
Kirby, et al. [9]	4.9	6.4

Graph – 7: Improvement of Q_{max} in the present study in comparison to other studies.



Discussion

In the present study, patients on combination therapy had a mean age of 67.36±9.2 years, which was in correlation to study by Vasileios Simaioforidis, et al. [7] where the mean age was 67.5 years and in Djavan, et al. [12] the mean age was 70years. In the study by Roehrborn, et al. [8] the mean age was 66.3 years.

In the present study, patients who underwent TURP had a mean age of 66.48±9.2 years, which was in correlation to study by Vasileios Simaioforidis, et al. [7] where the mean age was 69.8 years and in study done by Bozdar HR, et al. [6] mean age was 63.1±3.0 years whereas in study done by Dong, et al. [11] mean age was 68.5±7.6 years. In study by Suhani, et al. [10] the mean age was 65 years.

According to Djavan, et al. [12] TURP showed better improvement than medical therapy in decreasing frequent urination episodes by decreasing the irritation on bladder neck by enlarged prostate and improving bladder continence which was similar to findings noted in the present study.

In the present study it was found that deduction of the obstructive symptoms score was greater than the irritative symptoms score after treatment, which is in correlation to the study done by Dong, et al. [11].

In the present study, pre-treatment irritative symptoms score of 6-10 was seen in 13cases (52%) with mean score of 10.72±1.22 in combination therapy whereas post 6 weeks of therapy irritative symptoms score of 0-5 was seen in 14 cases (56%) in combination therapy with mean score being 5.28±1, which was in correlation to the study by Dong, et al. [11] (n=285) where a pre-treatment mean irritative symptoms score of 10±3.8 and post treatment mean score of 5.3±1.9 was noted.

In the present study, pre-treatment irritative symptoms score of 6-10 was seen in 13 cases (52%) with mean score of 10.86±1.78 in TURP patients whereas post 6 weeks of therapy irritative symptoms score of 0-5 was seen in 15 cases (60%) with mean score of 5.04±1.75 in TURP patients, which was in correlation to the study by Dong, et al. [11] (n=285) where a pre TURP mean irritative symptoms score of 10.4±3.4 and post TURP mean score of 5.4±1.85 was noted.

In the present study, pre-treatment obstructive symptoms score of 11-15 was seen in 17cases (68%) with mean score of 14.52±2.0 in patients on combination therapy whereas post 6 weeks of therapy obstructive symptoms score of 0-5 was seen in 23 cases (92%) in combination therapy with mean score being 2.6±2.12, which was in correlation to the study by Dong, et al. [11] (n=285) where pre-treatment mean obstructive symptoms score of 13.6±6.0 and post treatment mean score of 3.7±4.1 was observed.

In the present study, pre-treatment obstructive symptoms score of 11-15 was seen in 16 cases (64%) with mean score of 14.92±1.79 in TURP patients whereas post 6 weeks of therapy obstructive symptoms score of 0-5 was seen in 24 cases (96%) with mean score of 2.4±1.98 in post TURP patients, which was in correlation to study by Dong, et al. [11] (n=285) where pre TURP mean obstructive symptom score of 13.8±4.7 and post TURP mean score of 2.3±3.7 was observed.

In the present study, pre-treatment quality of life score of 4 was seen in 11 cases (44%) with mean score of 4.1±0.02 in patients on combination whereas post 6 weeks of therapy quality of life score of 0 was seen in 12 cases (48%) in patients on combination therapy with mean score being 0.95±0.88, which was in correlation to the study by Dong, et al. [11] (n=285) where a mean pre-treatment quality of life score of 4.4±1.2 and post treatment mean score of 1.7±1.2 was observed.

In the present study, pre-treatment quality of life score of 4 was seen in 12 cases (48%) with mean score of 4.44±0.01 in TURP patients whereas post 6 weeks of therapy quality of life score of 1 was seen in 10 cases (40%) with mean score of 1±0.84 in TURP patients, which was in correlation to the study by Dong, et al. [11] (n=285) where a mean pre TURP quality of life score of 4.5±1.1 and post TURP mean score of 1.5±1.0 was observed.

In studies by Dong, et al. [11] and Djavan, et al. [12] it has been observed that quality of life score had decreased significantly in medical therapy patients than those on TURP as TURP reduced urethral resistance [12] in BPH patients whereas combination therapy improved both detrusor contractility and decreased size of prostate gland [11], which was similar to the findings noted in the present study.

In the present study , pre-treatment IPSS score of 20-35 (severe) was seen in 25 cases (100%) with mean score of 25.24±2.21 in patients on combination therapy whereas post 6 weeks of therapy IPSS score of 0-7 (mild) was seen in 20 cases (80%) in patients on combination therapy with mean score being 7.52±2.97, which was in correlation to the study by Vasileios Simaioforidis, et al. [7] (n=66) where pre-treatment mean IPSS 25.6±4.8 and post treatment mean IPSS of 8.7±2.88 was observed. In studies by Dong, et al. [11] (n=285) and Suhani, et al. [10] (n=60) mean pre-treatment IPSS of 22.8±7.9 and 25±1.7, were seen respectively and post treatment mean scores of 9.1±7.8 and 11±2.8, were observed.

In the present study , pre-treatment IPSS score of 20-35 (severe) was seen in 25 cases (100%) with mean score of 25.6±2.06 in TURP patients whereas post 6 weeks of therapy IPSS score of 0-7(mild) was seen in 20 cases (80%) with mean score of 7.44±2.76 in TURP patients, which was in correlation to the study by Vasileios Simaioforidis, et al. [7] (n=66) where pre TURP mean IPSS 27.4±4.86 and post TURP mean IPSS of 7.8±2.59 was observed. In studies by Dong, et al. [11] (n=285) and Suhani, et al. [10] (n=60) mean pre TURP IPSS of 23.4±6.9 and 29±2.2 were seen respectively and post TURP mean scores of 8.6±4.5 and 10±2.9 were observed.

From various studies including the CONDUCT trial [8] combination therapy was found to reduce LUTS more effectively than other medical therapies because of synergistic mechanisms of component drugs [8] but improvement in IPSS was more in TURP patients as obstruction was relieved completely post-surgery in majority of patients [7].

In the present study, percentage of change in IPSS was -34% in combination therapy patients and -36% in TURP patients, which was in correlation with other studies done by Roehborn, et al. [8] (n=740) where improvement of -38% was seen with medical therapy and -39% with TURP, whereas according to Bozdar HR, et al. [6] (n=70) change in IPSS was -30% and -34% respectively, for medical and surgical therapy.

Various studies as well as the present study have concluded that despite availability of several newer drugs TURP still remains the gold standard for treatment of LUTS in BPH patients [6].

Pre-treatment Q_{max} of 6 to10 was seen in 12 cases (48%) with mean Q_{max} of 9.56±2.94 in patients on combination therapy whereas post 6 weeks of therapy Q_{max} of 16 to 20 was seen in 14 cases (56%) in patients on combination therapy with mean Q_{max} being 14.52±2.06, which was in correlation to study done by Vasileios Simaioforidis, et al. [7] (n=66) where pre-treatment mean Q_{max} of 9.5±1.69 and post treatment mean Q_{max} of 15.1±8.1 was observed. In studies by Dong, et al. [11] (n=285) and Suhani, et al. [10] (n=60) mean pre-treatment Q_{max} of 9.5±3.2 and 8.9±1.89 were seen respectively and post treatment mean Q_{max} of 14.6±6.9 and 14.7±1.9 were observed.

Pre-treatment Q_{max} of 6 to10 was seen in 19 cases (96%) with mean Q_{max} of 9.64±2.54 in TURP patients whereas post 6 weeks of therapy Q_{max} of 11 to 15 was seen in 13 cases (52%) with mean Q_{max} of 15.04±2.16 in TURP patients, which was in correlation to study done by Vasileios Simaioforidis, et al. [7] (n=66) where pre TURP mean Q_{max} of 9.4±2.16 and post TURP mean Q_{max} of 14.9±8.8 was observed. In studies by Dong, et al. [11] (n=285) and Suhani, et al. [10] (n=60) mean pre TURP Q_{max} of 9.2±3.3 and 9.08±1.84 were seen respectively and post TURP mean Q_{max} of 16.01±6.2 and 15.3±1.2 were observed.

The peak flow rates in various studies were slightly superior in TURP than medical therapy, because of immediate clearance of obstructive intravesical protrusion of prostate [6], apart from that there was no significant difference in peak

flow rates which was also noted in the present study.

In the present study change in Q_{max} was 5ml/sec in combination therapy patients and 6 ml/sec in TURP patients, which was in correlation with other studies done by Djavan, et al. [12] (n=309) where improvement of 4.7 ml/sec was seen with medical therapy in Q_{max} and 5.6 ml/sec with TURP, whereas according to Kirby, et al. [9] (n=52) change in Q_{max} was 4.9 ml/sec and 6.4 ml/sec respectively, for medical and surgical therapy.

Summary

The present study included 50 patients who were clinically proven cases of BPH to be evaluated using IPSS score before and 6 weeks after therapy.

Of the 50 patients treated at our hospital 25 patients were randomized to medical therapy and remaining 25 patients underwent TURP who were followed up 6 weeks after initiation of therapy.

The age group of patients was in the range of 50 to 80 years, with 20 cases (40%) in the age group of 70 years and above with a mean age of 66.92±8.23years.

Before start of combination therapy 25 cases were categorized as severely symptomatic IPSS group (score 20-35) with mean pre medication IPSS being 25.24±2.21, which when assessed 6 weeks after medication reduced to a mildly symptomatic group in 20 cases (80%) with a mean post medication score of 7.52±2.97.

Before TURP 25 cases were categorized as severely symptomatic IPSS group (score 20-35) with mean pre TURP IPSS being 25.6±2.06, which when assessed 6 weeks after TURP reduced to mildly symptomatic group in 20 cases (80%) with mean score of 7.44±2.76 which was superior in comparison to medical treatment.

Despite the treatment given in all the patients (50 cases, 100%) the obstructive symptoms were found to have a greater improvement than irritative symptoms.

The mean obstructive symptoms score pre-treatment was 14.52±2.0 for combination therapy and 14.92±1.79 for TURP, which reduced post treatment to a mean score of 2.6±2.12 for combination therapy and 2.4±1.98 for TURP, which was superior in comparison to medical treatment.

The mean irritative symptoms score pre-treatment was 10.72±1.22 for combination therapy and 10.86±1.78 for TURP, which decreased post-treatment to a mean score of 5.28±1.7 for combination therapy and 5.04±1.75 for TURP, which was superior in comparison to medical treatment.

The mean score of quality of life pre-treatment was 4.1±0.02 for combination therapy and 4.44±0.01 for TURP, which when assessed post-treatment of 6 weeks had a mean score of 0.95±0.88 for combination therapy and 1±0.84 for TURP.

Of all the seven symptoms of IPSS, nocturia was found to have least improvement with any treatment having a mean pre-treatment score of 3.76±0.81 for combination therapy and 3.88±0.9 for TURP which when assessed 6 weeks after treatment had a mean post treatment score of 1.79±1.2 for combination therapy and 1.8±0.1 for TURP, which was similar in both groups.

Then mean Q_{max} pre-treatment was 9.56±2.94 for combination therapy and 9.64±2.54 for TURP, which when assessed post treatment of 6 weeks had a mean Q_{max} of 14.52±2.06 for combination therapy and 15.04±2.16 for TURP, which was superior than medical therapy group.

Conclusion

The present study includes 50 patients who were clinically proven cases of BPH, of which 25

patients were subjected to combination therapy with Dutasteride (0.5 mg) and Tamsulosin (0.4 mg) while the remaining 25 patients underwent TURP. The efficacy of TURP and medical therapy was assessed using IPSS and Q_{max} pre-treatment and post 6 weeks of therapy.

The present study concluded that despite the availability of various medical & minimally invasive surgical modalities even today TURP still remains the gold standard procedure for patients with clinically proven BPH causing moderate to severe LUTS.

IPSS was of immense help in evaluating the efficacy of treatment with respect to following: -
All the patients were in severely symptomatic group as per IPSS pre-treatment assessment.

Post therapy when the patients were reassessed using IPSS 6 weeks after treatment and all the patients had improvement in their symptoms with majority of the patients being in the mildly symptomatic group.

The quality of life of all the patients improved after therapy when assessed using QOL score.

The improvement in the obstructive symptoms was greater than irritative symptoms after treatment.

Nocturia was the symptom that improved least with therapy in comparison with other symptoms.

From various studies including the CONDUCT trial [8] combination therapy was found to reduce LUTS more effectively than other medical therapies because of synergistic mechanisms of component drugs [8] but improvement in IPSS was more in TURP patients as obstruction was relieved completely post-surgery in majority of paitents [7].

Improvement of Q_{max} in various studies was slightly superior in TURP than medical therapy, because of immediate clearance of obstructive intravesical protrusion of prostate [6], apart from that there was no significant difference in peak flow rates which was also noted in the present study.

Several studies have shown that improvement in peak flow rate after TURP was due to large size of glands [10], resected rather than other factors, which was also noted in the present study.

There were some limitations in present study due to small sample size and single institutional study.

The present study would however, like to safely recommend that in all clinically proven cases of BPH with severe LUTS and candidates fit for surgical therapy, TURP (either monopolar or bipolar) is still the recommended treatment of choice especially in a tertiary care centre like ours in a rural setup which caters to wide range of geriatric patients with economic constraints.

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