

The health outcome after homeopathic treatment in cases of BPH and LUTS: a prospective clinical study.

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Abstract:

Introduction: Benign Prostatic Hyperplasia (BPH) and Lower Urinary Tract Symptoms (LUTS) are the uprising disease maladies troubling most of the old age population with much distress and irritability. Major surgical procedures without much adverse events gain a popularity of treatment choice. Nevertheless complementary medicine also ranks better in offering the non invasive solution with safety and efficacy. Homeopathy is also one of them frequently prescribed and accepted by the community for relief and cure.

Material and Methods: Total 66 men above 40 years were enrolled in this study. All the patients were examined and screened with I-PSS score chart at base line. Three patients with very low and three with very high I-PSS score were excluded from the study. All the patients were followed up for a single time after 15 days from baseline visit. For the same visit the I-PSS score was taken again to compare from initial visit. The homeopathic medicine was prescribed in oral dosage form on 4 globules for a single time. Medicines prescribed on the basis of principle of individualization according to homeopathic philosophy.

Result: The I-PSS score and Quality of Life both were found to be improved significantly ($P < 0.001$) with homeopathic treatment.

Conclusion: From the present study it could be concluded that homeopathic treatment is effective therapeutic modality to improve the quality of life and symptomatic relief in men with BPH and LUTS.

Keywords: Benign prostatic hyperplasia, Homeopathic medicine, International Prostate Symptom Score, Lower urinary tract symptoms, Quality of Life, Questionnaires, Urinary bladder,

Abbreviations: BPH: Benign Prostatic Hyperplasia, I-PSS: International Prostate Symptom Score, LUTS: Lower Urinary Tract Symptoms, QOL: Quality Of Life

Introduction:

Benign prostatic hyperplasia is a bothersome progressive disease affecting specifically to geriatric population [1]. It is commonly associated with moderate to severe lower urinary tract symptoms such as urinary urgency, frequency, incomplete bladder emptying, intermittent flow of stream and nocturia [2]. This condition becomes clinically noticeable only when it is intermingled with complex lower urinary tract symptoms. Owing to clinical scenario not all men with positive histological hyperplasia suffer from benign enlargement of prostate [3,4]. Relation with Lower Urinary Tract Symptoms (LUTS) also does not explain the presence of hyperplasia in all cases necessarily. Multiple studies demonstrated the correlation between age and markers of Benign Prostatic Hyperplasia (BPH) progression [5,6].

Since last few years there is considerable reduction in popularity of surgical management of symptoms associated with BPH and rising uptake of medical treatment signifies the better health outcome [7, 8]. Alpha-blockers and 5-alpha-reductase inhibitors are not only the

great treatments but also running prescriptions [9-12]. Plant extracts (Phytomedicines) and complementary medicines somehow created a better effective model for palliation without much adverse events [13-15]. Homeopathy offers a good treatment option which treats the man in disease on individualistic approach [16-18]. Specialty of homeopathic treatment in clinical management belongs to its rational selection of appropriate similimum and exact dose [19, 20]. *Conium maculatum*, *Thuja occidentalis*, *Staphysagria*, *Pareira brava* are few of the indicated remedies for prostate diseases specifically in homeopathy [21, 22].

The present study was designed to evaluate the efficacy of some homeopathic medicine in improvement of the quality of life and symptomatic relief in men with BPH and LUTS.

Material and methods:

This health outcome research study was conducted with already well proven and marketed homeopathic medicines according to guidelines mentioned in Homeopathic Pharmacopoeia of India, 1974. Study was conducted in

Sanjeevan Homeopathic Clinic and Research Centre, Pune, Maharashtra State, India from July 2007 to January 2012. The radiologically known diagnosed cases of BPH were included in this study with significant LUTS. Total 66 men above 40 years were enrolled in this study. All the patients were examined and screened with I-PSS score chart at base line^[23, 24]. Three patients with very low and three with very high I-PSS score were excluded from the study from ethics point of view. All the patients were followed up for a single time after 15 days from baseline visit. For the same visit the I-PSS score was taken again to compare from initial visit. The homeopathic medicine was prescribed in oral dosage form on 4 globules for a single time. Homeopathic medicines were selected according to homeopathic materia medica and philosophy i.e. on the basis of totality of symptoms^[25]. Medicine selected was different for every patient on the basis of individualization. All the patients completed a study course. No adverse event and lost to follow up was recorded during the discourse.

Statistical Analysis:

The general characteristics of the enrolled patients were described using summary statistics (i.e. mean and SD). The association between the quality of life rating and the I-PSS severity was analyzed using GraphPad Prism 5.0 software (GraphPad, San Diego, USA). The level of statistical significance was taken at $P < 0.05$ using student's 't' test and multiple comparison test to judge the difference between various groups.

The total I-PSS score was categorized in the standard way, using 0-7 to denote mild symptoms, 8-19 to denote moderate symptoms, and 20-35 to denote severe symptoms. Box plots were used to show the distribution of values for those variables whose mean differed across the I-PSS categories. Because the total I-PSS score was the sum of the individual question scores, multiple linear regressions were used to assess whether the total I-PSS score was related to a combination of FV variables. Stepwise regression was used to find the most parsimonious model.

Both instruments define nocturia as the number of nocturnal voids. This enabled us to examine whether self reported values were overestimated. Multiple regressions was used to assess the degree of underreporting and whether this might be explained by perceived quality of life as measured using the AUA-QoL. All other I-PSS questions ask patients to rate symptom burden as: 0 for "not at all," 1 for "less than one in five times," 2 for "less than half the time," 3 for "about half the time," 4 for "more than half the time," and 5 for "almost always." This scale was not equivalent to the scales used by the FV variables, and this difference could weaken the association between similar questions. In the case of urgency, this possibility could be examined by transforming the variable into an equivalent scale. First, the percentage of the total voids that were urgent was calculated. The transformed variable was then defined based on increasing 20% point intervals (0% was assigned a score of 0, 1-20% was assigned a score of 1, and soon).

Results:

A total of 66 respondents participated in the study; Table 1 shows the socio-demographic data of these groups. The mean age was 48.65 yrs (SD: 12.07 and range: 36-60). Mean weight of the patient was 61.26 Kg (SD: 13.72 and range: 43-90). The Pulse of the patient was 76.42 per min (SD: 13.19 and range: 52-102). The systolic blood pressure was 125 mmHg (SD: 20.21 and range: 68-174). The 79.39 mmHg was diastolic blood pressure (SD: 11.44 and range: 60-110).

Table 1. Patients Characteristics (n= 66)

Patients Characteristics	Mean \pm S. D.
Age (yrs)	48.65 \pm 12.07
Weight (Kg)	61.26 \pm 13.72
Pulse (per min)	76.42 \pm 13.19
Systolic Blood Pressure (mmHg)	125 \pm 20.21
Diastolic Blood Pressure (mmHg)	79.39 \pm 11.44

Based on responses to questions of the I-PSS, most of the 46.66% patient with BPH reported that more than half of the time they had a sensation of not emptying their bladder completely after finished their urination and about 35.00% of the patient reported that about half of the time they had a sensation of not emptying their bladder completely after finished their urination over the past month before treatment. After treatment with homeopathic medicine this ratio was changed and 35.00% of the patient reported that less than half the time they had a sensation of not emptying their bladder completely after finished their urination over the past month. (Figure 1)

Before treatment with homeopathic medicine the 36.66% of the patient reported that more than half the time they had to urinate again less than 2 hours after finishing their urination whereas 35.00% of the patient reported that about half the time they had to urinate again less than 2 hours after finishing their urination over the past month. However this ratio was changed and 46.66% of patient reported that more than half the time they had to urinate again less than 2 hours after finishing their urination, 35.00% of the patient reported that about half of the time they had to urinate again less than 2 hours after finishing their urination over the past month after treatment with homeopathic medicine. (Figure 1)

The 48.33% of the patient reported that about half the time they found that they stopped and started again several times when they urinated and 20.00% of the patient reported that more than half the time they found that they stopped and started again several times when they urinated over the past month before treatment with homeopathic medicine. However, treatment with homeopathic medicine resulted changed in this ratio. 15.00% of the patient reported that they did not suffered from any stopped and started again several times of urination phenomenon and 13.33% of the patient reported that less than one in five times they found that they stopped and started again several times when they urinated over the past month. (Figure1)

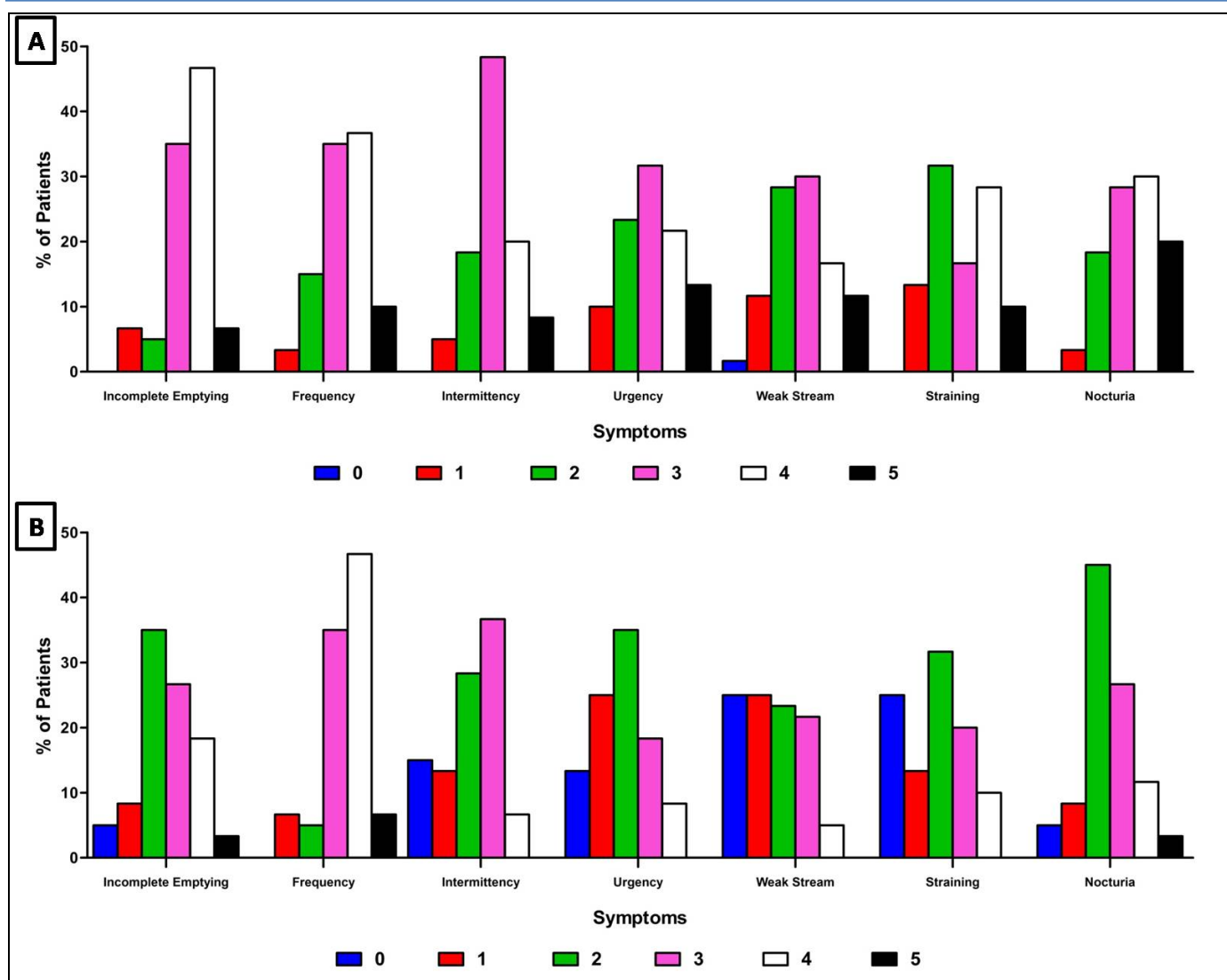


Figure 1. Responses to the I-PPS questions before treatment (A) and after treatment (B); higher scores indicate a greater negative impact of urinary symptoms; percentages might not total 100% due to rounding.

As depicted in Figure 1, before treatment with homeopathic medicine the 13.33% of the patient reported that almost always they found it difficult to postpone urination and 31.66% of the patient reported that more than half the time they found it difficult to postpone urination. After treatment with homeopathic medicine this scoring of the "Urge to Urinate" has been changed and 25.00% of the patient reported that less than one in five times they found it difficult to postpone urination and 13.33% of the patient reported that did not find any difficulty to postpone urination.

Almost 30% of the patients LUT feel that less than half the time or about half the time they had a weak urinary stream before the starting of the homeopathic treatment. Around 25% of the patient reported that treated with homeopathic medicine resulted in repairment of their weak urinary stream as they did not find any difficulty in urination or at the most less than one in five times they found weak urinary stream. (Figure 1)

As shown in Figure 1, the 31.66% of the patient reported that less than half the time had to push or strain to begin urination and 28.33% of the patient reported that more

than half the time had to push or strain to begin urination before starting of the homeopathic treatment. After treatment with the homeopathic medicine this score has been changed and 25.00% of the patient reported that they did not need to push or strain to begin their urination.

Almost 30.00% of the patient reported that either more than half the time or almost always they need to get up to urinate from the bed at night i.e. nocturation before treatment with homeopathic medicine. Treatment with homeopathic medicine changed this ratio and 45.00% of the patient reported that less than half the time they need to get up to urinate from the bed at night. (Figure 1)

The significant decreased ($P < 0.001$) in the incomplete emptying, intermittency, urgency, weak streaming, straining and urinating at night score was observe after the treatment with homeopathic medicine as compared to before treatment with homeopathic medicine. Treatment with homeopathic medicine failed to produce any significant recovery in the frequency of urination when compared with before treatment of homeopathic medicine. (Figure 2)

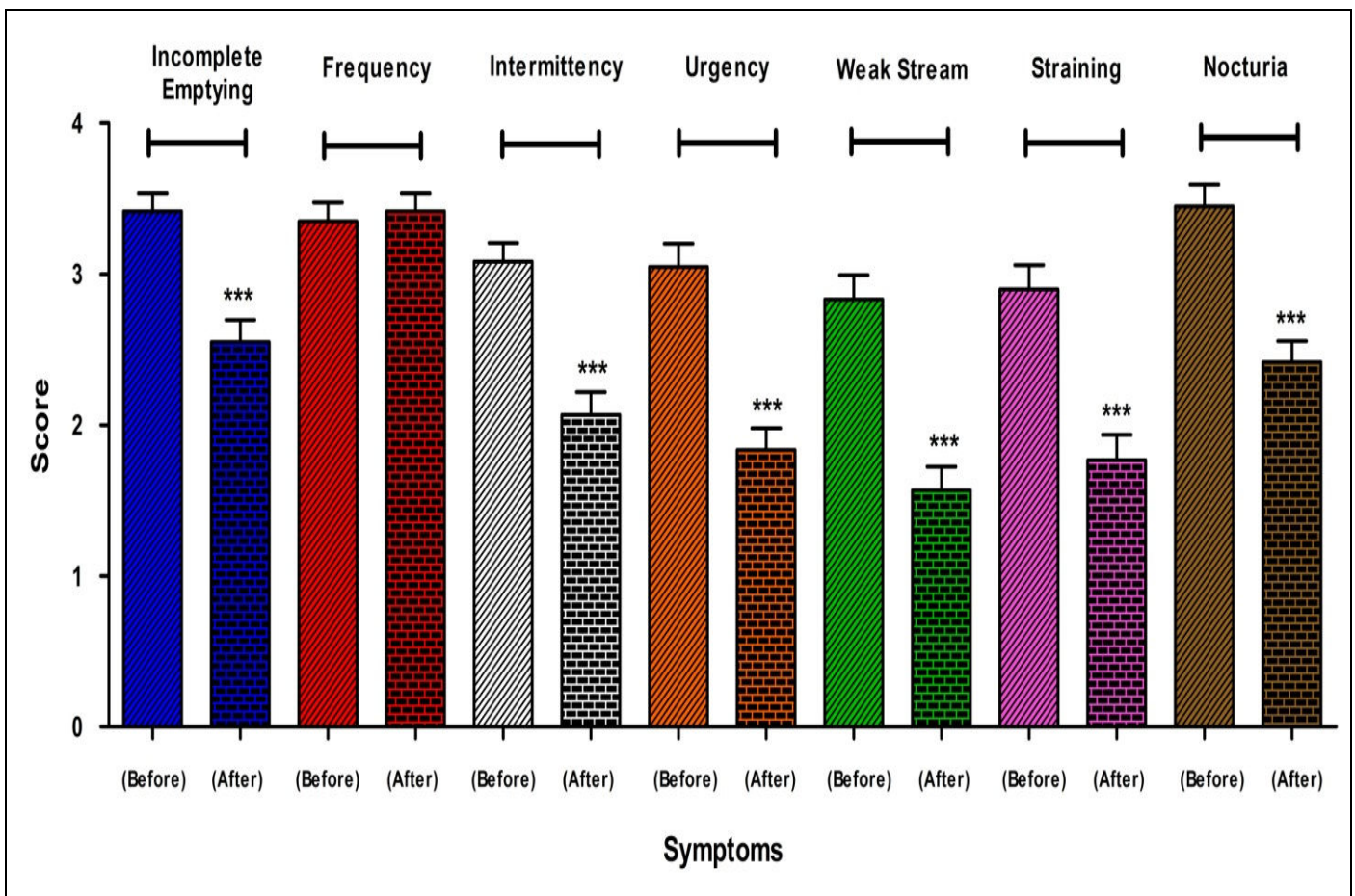


Figure 2. Effect of homeopathic medicine on Lower Urinary Tract Symptom before and after treatment

As depicted in Figure 3, the significant decreased ($P < 0.001$) in the total IPSS score was observed after homeopathic medicine treatment (22.02 ± 4.55) as compared to before homeopathic medicine treatment (14.50 ± 5.62).

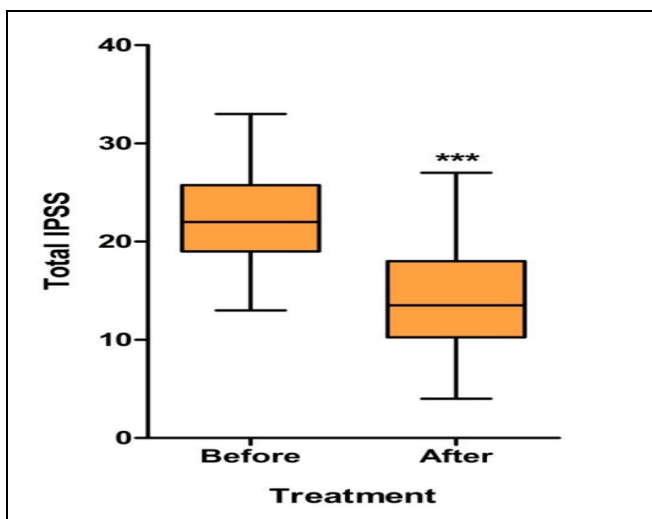


Figure 3. Effect of homeopathic medicine on total I-PSS score before and after treatment

The Quality of Life score after homeopathic medicine treatment (4.43 ± 0.98) was significantly improved ($P < 0.001$) as compared to Quality of Life score before homeopathic medicine treatment (3.06 ± 1.19). (Figure 4)

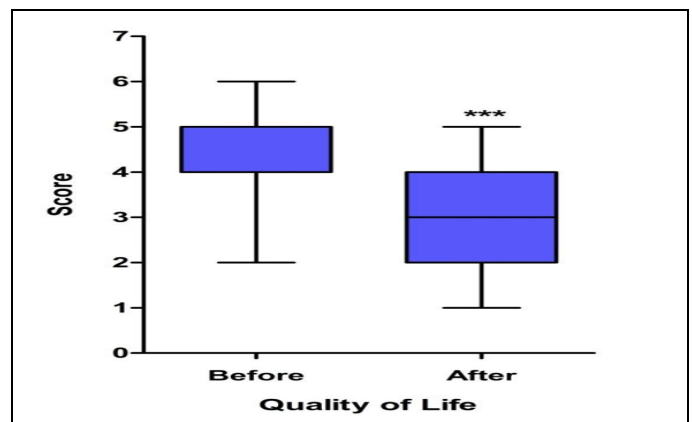


Figure 4. Effect of homeopathic medicine on Quality of Life before and after treatment

Discussion:

In this study I-PSS score was reduced significantly with homeopathic individualized treatment based on totality of symptoms and cardinal principles. Homeopathic treatment for LUTS need not contain the specific therapeutic agent in particular and management in general rather it signifies its specialty through the integration of number of medicines to derive the palliative as well as curative effect. Our study represented the positive health outcome through holistic approach in improving the quality of life in aged population having moderate to severe impairment in day-to-day work out because of BPH. Although the mechanism is still unknown that how does it works, such glimpse of studies helps in inducing the appropriate phenomena to work up on. Collectively this study has

measured the output in terms of score and quality of life individually helped in focusing the functional disability because of BPH and also added the unbiased results for define treatment effectiveness and regimen.

Chief investigating tool in this case from beginning was validated I-PSS score to increase the weight of study in terms of direct objective evidence and scalar measurements for ease of statistical analysis. Health outcome research design was especially selected for noninvasive study design and reducing the safety concerns. Although the homeopathic medicines didn't caused any major disturbance in a study still to minimize the chance of disharmony the already practicing drugs were used in entire treatment plan.

The pharmacotherapy of BPH has not advanced and there are much less approved therapies to improve the long-term prognosis of BPH. Recently many therapeutic strategies have been utilized in clinical trials for the treatment of BPH and LUTS^[26,27]. Many outcome studies have been carried out in the Pune region for various disease^[28-32]. Herbal moieties (phytomedicines), complementary medicines including homeopathic medicines have been successfully screen for the treatment of various disease complications without much side effect which is the major drawback for the synthetic chemical moieties^[33-44]. Hence, this homeopathic treatment would be better and effective treatment to improve the quality of life with the patient of BPH and LUTS.

Conclusion:

From the present study it could be concluded that homeopathic treatment is effective therapeutic modality to improve the quality of life and symptomatic relief in men with BPH and LUTS.

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