Original Article

# Homoeopathic treatment for lower urinary tract symptoms in men with benign prostatic hyperplasia: An open label randomised multicentric placebo-controlled clinical trial

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## Abstract

**Objectives:** The objectives of the study are to evaluate the effectiveness of Homoeopathic Constitutional remedy (HC) and Homoeopathic Constitutional + Organ remedy (HCOM) in comparison to Placebo (PL) in cases of benign prostatic hyperplasia (BPH) using International Prostate Symptom Score (IPSS), ultrasonographic changes in prostate volume, post-void residual urine, uroflowmetry and in WHO Quality of Life (QOL)-BREF. **Materials and Methods:** A multicentric, three-armed, randomised clinical trial was conducted at five centres. Patients were enrolled following the pre-defined inclusion and exclusion criteria, randomised into three groups in 2:2:1 ratio and were followed up for 6 months. The statistical analysis was done with modified intention-to-treat principle (mITT). **Results:** Out of 461 patients screened, 254 patients were enrolled in the study and 241 patients were analysed as per mITT. The mean changes in IPSS and QOL due to urinary symptoms from baseline to end of study had shown a positive trend in all the three groups. However, in HC group, the changes were more prominent as compared to the other two groups. There was no difference between HC and HCOM groups and they were equally effective in terms of managing lower urinary tract symptoms due to BPH. With regard to secondary outcome, there was no difference between the groups. The psychological, social and environmental domains of WHOQOL-BREF have shown positive trend, but there was no statistically significant difference in intervention groups. **Conclusion:** In this study, statistical significance was found in the IPSS in all the three groups but only in HC and not in any of the objective parameters.

**Keywords:** Homoeopathy, International Prostate Symptom Score, Post-void residual urine, Prostate volume, Uroflowmetry

## Introduction

Benign prostatic hyperplasia (BPH) is the most common condition in ageing men, associated with lower urinary tract symptoms (LUTS). Its prevalence increases with age, and the lifetime risk of developing histologically confirmed BPH has been approximately 8% between the ages of 31 and 40 years, 50% between 51 and 60 years, 70% between 61 and 70 years and 90% between 81 and 90 years.[1] Symptomatic (clinical) BPH is present in approximately 26% of the men in the fifth decade, 33% in the sixth decade, 41% in the seventh decade and 46% in the eighth decade of life and beyond.[2] The enlarged gland produces LUTS complex through two routes: (a) direct bladder outlet obstruction (BOO) from enlarged tissue (static component) and (b) from increased smooth muscle tone and resistance within the enlarged gland (dynamic component). Voiding symptoms have often been attributed

Access this article online

Quick Response Code:

Website: www.ijrh.org

DOI: 10.4103/ijrh.ijrh_36_18

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**Received:** 06.06.2018; **Accepted:** 07.09.2018



**How to cite this article:** Sharma B, Mehra P, Oberai P, Roja V, Reddy G, Arya DD, *et al*. Homoeopathic treatment for lower urinary tract symptoms in men with benign prostatic hyperplasia: An open label randomised multicentric placebo-controlled clinical trial. Indian J Res Homoeopathy 2018;12:113-24.

to BOO.[3] Although voiding symptoms (e.g., slow stream, hesitancy, intermittency and terminal dribble) occur with a greater frequency, storage symptoms (e.g., increased daytime frequency, nocturia, urgency and urinary incontinence) are considered to be most bothersome and interfere to a great extent with daily life activities of the patient and his partner's quality of life (QOL).[4]

The specific approach used to treat BPH depends on a number of factors such as age, prostate size, weight, prostate-specific antigen (PSA) level and severity of the symptoms. Alternative treatment modalities available for the moderate-to-severe symptoms of BPH include watchful waiting, allopathic drugs including alphablockers, 5alphareductase inhibitors (5ARIs), anticholinergic agents, their combination therapy and minimally invasive and surgical intervention.[5] The alpha adrenergic-blocking agents and 5ARIs result in 20% improvement in symptom scores and 25% shrinkage of prostate gland respectively. These drugs are expensive in comparison with their effectiveness, and 65% of men undergoing prostatectomy develop retrograde ejaculation and 5% men develop erectile impotence. Patients with very mild symptoms receive little or no benefit from surgery.[6,7]

An observational study carried out by Oberai *et al*.[8] had shown positive leads in managing the symptoms (LUTS) due to BPH with the use of constitutional/individualised homoeopathic medicine within 6 months of treatment. Another observational study by Gupta *et al*.[9] had also shown similar benefits. However, a non-randomised comparative study by Hati *et al*.[10] has shown some benefits with combination of organ-specific remedies along with constitutional homoeopathic medicines. The earlier told studies lagged control arm, thereby cause–effect relationship could not be established. The latter study had a comparator arm, but the major limitations of the study were sequential allocation instead of randomisation and non-significantly longer treatment period in both constitutional and organopathic medicines (BCOM) group, which could have influenced the better improvement in this group in comparison to constitutional medicine (CM) and organopathic medicine (OM) groups, which in turn brings bias to the results. Therefore, we compared the efficacy of the Homoeopathic Constitutional (HC) remedy and Homoeopathic Constitutional + Organ (HCOM) remedy against Placebo (PL).

## Materials and Methods

### Study design and setting

A multicentre, three-armed (HC remedy, HCOM remedy and PL), randomised PL-controlled study was conducted at five centres, namely Central Research Institute (H), Noida; Central Research Institute (H), Kottayam; Regional Research Institute (H), Gudivada; Clinical Research Unit (H), Port Blair and Clinical Research Unit (H), Tirupathi, among patients suffering from LUTS with BPH. Homoeopathic physicians with postgraduation in Homoeopathy and 15–20 years of professional experience, who consented, were involved as investigators at each centre (total 5 centres); four of these investigators had contributed in the previous observational study also. All of them were trained about the study protocol for screening, seeking informed consent, case taking, prescription and follow-up before implementation of the study. A consultant urologist was appointed for screening and assessing the cases during follow-up.

The investigators filled in the International Prostate Symptom Score (IPSS) at baseline and then every month till 6 months and the WHOQOL-BREF questionnaire was filled in at baseline and at 6 months. Ultrasonography (USG) to measure the prostate volume (PV) and postvoid residual urine (PVRU), PSA and uroflowmetry was done at baseline, 3 months and 6 months. The investigations done at baseline helped in screening the patients and also in assessing the changes during the trial.

Ethics Committee of the Council approved the study protocol and the study was registered in the 'Clinical Trial Registry - India': CTRI/2012/05/002649.

### Study duration

The study was conducted from July 2012 to July 2014, wherein the patients were treated for 6 months after enrolment.

### Study participants and eligibility criteria

The patients were screened in the outpatient departments of respective centres and as per the inclusion and exclusion criteria[11] and were enrolled and followed up for 6 months of the trial.

### Inclusion criteria

- Men aged between 50 and 80 years with signs and symptoms of BPH
- IPSS >7
- PSA ≤4 ng/ml
- PV >20 g/20cc/20 ml and
- Those who gave written informed consent.

### Exclusion criteria

Patients with serious underlying medical condition such as severe renal, hepatic disease and prostatic carcinoma; complete retention of urine for >24 h; other possible causes of the symptoms such as recurrent urinary tract infection, neurogenic bladder, or urethral stricture and those interested for surgery during the next 6 months were excluded from the study.

### Randomisation

Patients fulfilling the eligibility criteria were randomised into three groups as per random numbers generated with the help of www.randomizer.org. Patients suffering from LUTS with BPH fulfilling inclusion and exclusion criteria were enrolled and randomised to HC, HCOM and PL in the ratio of 2:2:1.

### Intervention

The site investigators were provided training before starting the study and a case report form for taking a complete history

of all the enrolled patients which included protocol, case recording and follow-up forms and guidelines for conducting the trial. Soon after a patient was enrolled, case taking was undertaken by the investigators at the respective study sites followed by analysis and evaluation of the symptoms as per the homoeopathic principles, and final selection of the remedy was based on the homoeopathic Materia Medica in case of HC medicines. Organ-specific homoeopathic remedies were selected as per the recommendations of the experts.

### Homoeopathic Constitutional group

In the HC group, medicine in LM potency was prepared as follows: one globule (poppy-seed size) of the medicine in desired LM potency was dissolved in 120 ml of distilled water, containing 2.4 ml (2% v/v) of dispensing alcohol, pre-mixed in it, followed by ten uniformly forceful downward strokes given against the bottom of the phial. The patients were instructed to take three tea spoonful (15 ml) of the medicine and mixed with 8 tea spoonful (40 ml) of water taken in a glass and stirred thoroughly. Out of the above medicinal solution, one tea spoonful (5 ml) is to be taken as one dose and rest of the medicinal solution of the glass is to be discarded. The same procedure as above was followed every time for each subsequent dose.

### Homoeopathic constitutional + organ-specific remedy group

In HCOM group, along with the above individualised homoeopathic remedy, the organ-specific remedies such as *Sabal serrulata* (SS) ø, *Hydrangea arborescens* ø, *Chimaphila umbellata* ø, *Berberis vulgaris* (BV) ø, *Ferrum picricum* (FP) 3X, *Pareira brava* ø, SS ø and *Solidago* ø were prescribed on the basis of indications [Appendix 1]. The dosage of mother tincture was ten drops in one ounce of water/twice/per day and for trituration, 2 grains/twice/per day.

### Placebo group

PL was given in the form of globules moistened with unsuccused dispensing alcohol with 90% Vol.

### Outcomes

Primary outcome was comparison of the changes in IPSS at 6 months between the groups i.e., HC versus PL group and HCOM versus PL group and HC versus HCOM group.

Secondary outcomes were to compare the changes in PV, PVRU, uroflowmetry ($Q_{max}$ and $Q_{avg}$) at 3$^{rd}$ month and 6$^{th}$ month from baseline and comparison of the changes in WHOQOL BREF at 6 months from baseline between the groups.

The IPSS is an 8-question written screening tool used to screen for, rapidly diagnose, track the symptoms of and suggest management of the symptoms of BPH. Seven questions concerned to urinary symptoms (incomplete emptying, frequency, intermittency, urgency, weak stream, straining and nocturia) and one question concerned QOL. Each question concerning urinary symptoms allows the patient to choose one out of six answers indicating increasing severity of the particular symptom. The answers are assigned points from 0 to 5. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic). Further, the range is graded to mild (0–7), moderate (8–19) and severe (20–35).[11]

WHO QOL–BREF questionnaire contains 26 questions which cover four domains namely, physical, psychological, social and environmental. The answers assigned to each question ranges from 0 to 5 i.e., worse to best. The raw scores calculated for all the four domains were computed and transformed into scores (0–100 scale).[12]

### Sample size

The sample size was calculated keeping in view the outcome of the earlier observational study on BPH of the Council.[8] The effect size in the previous study was found to be 0.6. Hence, in the present study, using effect size of 0.6, with power 90%, $\alpha = 0.05$ and HC: HCOM: PL ratio at 2:2:1, the sample size was calculated to be 90:90:45. Hence, a total of 225 samples were required. As the trial is multicentric, for equal distribution among six centres (study withdrawn from one centre) with 10% of dropouts, the total sample size was rounded to 42 per centre i.e., 17:17: 8. Hence, a total of 252 patients were to be enrolled in the study.

### Statistical methods

Reporting of the study is done as per the Consolidated Standards of Reporting Trials[13] guidelines and Reporting data on Homoeopathic Treatments.[14] Statistical Package for the Social Sciences (SPSS) version 20 for Windows was used for all the data analyses. The missing values were imputed with last observation carry forward method. Patients with incomplete baseline and protocol violation were not considered under intention-to-treat analysis, thus modified intention to treat (mITT) was used. The variables with baseline difference were analysed with analysis of covariance. Values with more than two readings were analysed with repeated measures ANOVA. $P < 0.05$ was considered statistically significant.

## Results

A total of 461 patients were screened out of which 254 were found eligible and after obtaining consent, randomised and allocated to receive one of the three interventions: HC group, $n = 103$; HCOM group, $n = 102$ and PL group, $n = 49$. In the HC group, one patient each did not complete the baseline and did not follow the protocol i.e., protocol violation, was excluded from the analysis. In the HCOM group, ten cases were excluded from the analysis due to protocol violation and in PL group, one case was excluded due to protocol violation. Thus, the data of 241 patients were analysed. All the patients with loss to follow-up were analysed under mITT protocol taking into consideration the last observation carry forward method. The flow of patients in the study is

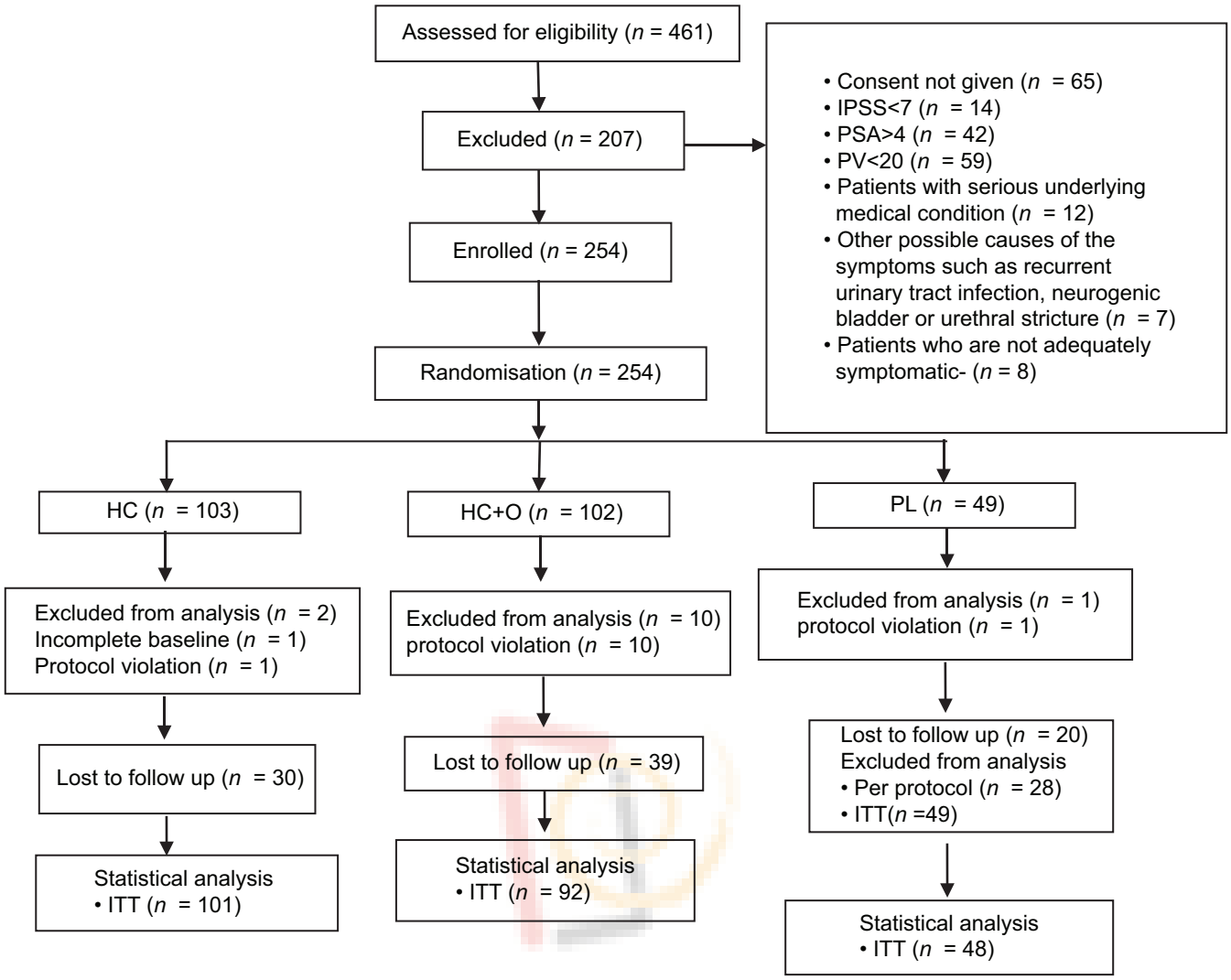


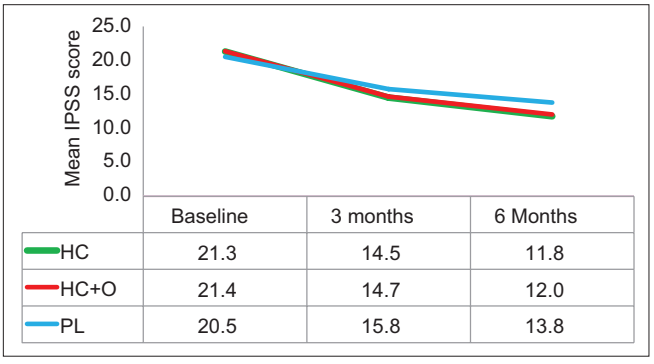

**Figure 1:** Participants flow diagram

depicted in Figure 1. The patients at baseline in all the three groups were comparable except for PV which was less in the PL group. Table 1 reflects the baseline characteristics of mITT population.

## Outcome analysis (modified intention-to-treat group)

The change in the IPSS score in all the three groups post-intervention at 6 months was analysed [Table 2]. The mean reduction (standard error) in IPSS at the end of month 6 from baseline was 10.4 (0.7), 10.2 (0.7) and 5.5 (0.8) in the HC, HCOM and PL groups, respectively. The difference between HC and PL was 4.9 (2.5–7.3), $P = 0.0001$. Similarly, the difference between HCOM and Pl was 4.7 (2.3–7.2), $P = 0.0001$.

There was no difference between HC and HCOM groups. Thus, both the groups were equally effective in terms of managing LUTS due to BPH. The mean changes of IPSS over a period of 6 months from baseline showed a positive pattern. However, in the HC group, the changes were more prominent as compared to the other two groups [Figure 2].




| | Baseline | 3 months | 6 Months |
|---|---|---|---|
| HC | 21.3 | 14.5 | 11.8 |
| HC+O | 21.4 | 14.7 | 12.0 |
| PL | 20.5 | 15.8 | 13.8 |

**Figure 2:** Mean changes of IPSS (ITT) over period for the three groups

On further comparing the category of intensity of symptoms as per IPSS from at the end of the treatment, it was found that in HC and HCOM groups, there was significant decrease in the number of patients in severe category, 58 and 59 at baseline to 04 and 12 at 6th month, respectively. Whereas in PL group, 12 patients remained severe at 6 months out of 25 patients at baseline [Table 3].

**Table 1: Baseline information of the participants**

| Variables | Modified ITT | | | |
|---|---|---|---|---|
| | HC (*n*=101) | HCOM (*n*=92) | PL (*n*=48) | *P* |
| Age (years) | 65.2±7.1 | 64.6±7.4 | 64.6±7.1 | 0.83 |
| Duration (years) | 4.6±4.0 | 4.3±4.4 | 4.4±3.4 | 0.92 |
| IPSS total score | 21.32±6.0 | 21.71±6.1 | 20.17±5.9 | 0.35 |
| QOL due to urinary symptoms | 4.43±1.0 | 4.24±1.0 | 4.04±1.1 | 0.09 |
| Incomplete emptying | 3.27±1.42 | 3.27±1.43 | 3.29±1.25 | 0.99 |
| Frequency | 3.55±1.53 | 4.0±1.27 | 3.42±1.40 | 0.03* |
| Intermittency | 2.86±1.56 | 3.0±1.59 | 2.56±1.70 | 0.31 |
| Urgency | 3.32±1.65 | 2.97±1.67 | 3.40±1.57 | 0.22 |
| Weak stream | 3.10±1.64 | 3.34±1.56 | 3.06±1.73 | 0.51 |
| Straining | 1.92±1.90 | 1.77±1.96 | 1.50±1.75 | 0.45 |
| PV (g) | 36.7±13.3 | 38.6±16.9 | 30.5±10.2 | 0.006 |
| PVRU (ml) | 58.9±61.2 | 63.9±69.8 | 60.4±69.1 | 0.872 |
| PSA (ng/ml) | 1.4±0.9 | 1.5±1.1 | 1.2±0.7 | 0.137 |
| $Q_{max}$ (ml/s) | 13.8±8.2 | 12.5±7.4 | 14.0±9.1 | 0.450 |
| $Q_{avg}$ (ml/s) | 5.7±4.0 | 5.0±3.3 | 6.1±4.5 | 0.250 |
| WHO QOL domains | | | | |
| Physical | 54.9±13.5 | 53.4±13.7 | 54.3±12.5 | 0.733 |
| Psychological | 57.0±13.3 | 57.2±12.5 | 55.7±12.2 | 0.813 |
| Social | 57.0±16.5 | 58.0±18.0 | 59.2±16.0 | 0.756 |
| Environmental | 56.5±18.2 | 56.9±18.2 | 56.5±18.5 | 0.978 |

Data presented as mean±SD and percentage as applicable. *$P$<0.05 will represent statistical significance. IPSS: International Prostate Symptom Score; QOL: Quality of Life due to urinary symptoms; PV: Prostate volume; PVRU: Postvoid residual urine; PSA: Prostate-specific antigen; $Q_{max}$ and $Q_{avg}$: Uroflowmetry; HC: Homoeopathic constitutional remedy; HCOM: Homoeopathic constitutional+organ remedy; PL: Placebo; SD: Standard deviation; ITT: Intention to treat

**Table 2: Primary and secondary outcomes at the end of 6 months as per modified intention-to-treat analysis**

| Variable | HC (*n*=101) | HCOM (*n*=92) | PL (*n*=48) | HC versus PL (95% CI) | *P* | HCOM versus PL | *P* |
|---|---|---|---|---|---|---|---|
| Primary outcome (change from baseline) | | | | | | | |
| IPSS total | 10.4 (0.7) | 10.2 (0.7) | 5.5 (0.8) | 4.9 (2.5-7.3) | 0.0001 | 4.7 (2.3-7.2) | 0.0001 |
| IPSS QOL | 1.5 (0.4) | −0.2 (1.3) | 0.7 (0.2) | 0.7 (−0.5-1.9) | 0.22 | −1.0 (−4.6-2.6) | 0.60 |
| Incomplete emptying | 1.9 (0.1) | 1.6 (0.2) | 0.9 (0.2) | 1.0 (0.4-1.5) | 0.0001 | 0.7 (0.1-1.2) | 0.02 |
| IPSS frequency | 2.0 (0.2) | 2.0 (0.2) | 0.9 (0.2) | 1.1 (0.5-1.6) | 0.0001 | 1.1 (0.5-1.7) | 0.0001 |
| IPSS intermittency | 1.6 (0.1) | 1.3 (0.2) | 0.5 (0.2) | 1.1 (0.6-1.6) | 0.0001 | 0.9 (0.3-1.4) | 0.002 |
| IPSS urgency | 1.9 (0.2) | 1.5 (0.1) | 0.9 (0.2) | 1.0 (0.5-1.5) | 0.0001 | 0.6 (0.1-1.1) | 0.01 |
| IPSS weak stream | 1.6 (0.1) | 1.4 (0.2) | 0.8 (0.2) | 0.8 (0.4-1.3) | 0.0001 | 0.6 (0.1-1.1) | 0.01 |
| IPSS straining | 1.4 (0.2) | 1.0 (0.2) | 0.4 (0.2) | 1.0 (0.5-1.5) | 0.0001 | 0.6 (0.1-1.0) | 0.01 |
| Secondary outcome (change from baseline) | | | | | | | |
| PV (in mL) | 2.0 (1.3) | 2.8 (1.5) | 1.5 (1.6) | 0.5 (−3.9-4.9) | 0.82 | 1.3 (−3.5-6.1) | 0.58 |
| PVRU | 10.2 (6.7) | 5.2 (5.1) | 16.6 (6.7) | −5.8 (−27.3-15.6) | 0.59 | −10.8 (−28.1-6.3) | 0.21 |
| $Q_{max}$ | −2.8 (0.9) | −2.8 (1.1) | −3.1 (1.8) | 0.2 (−3.5-4.0) | 0.89 | 0.2 (−3.8-4.3) | 0.90 |
| $Q_{avg}$ | 0.04 (0.4) | 0.3 (0.2) | −0.6 (0.5) | −0.5 (−1.9-0.8) | 0.44 | −0.2 (−1.3-0.8) | 0.60 |
| WHOQOL-BREF | | | | | | | |
| Physical | −5.1 (1.4) | −9.3 (3.2) | −2.1 (1.4) | −3.0 (−7.6-1.6) | 0.20 | −7.2 (−16.5-2.0) | 0.12 |
| Psychological | −2.3 (1.2) | −9.5 (8) | −3.5 (1.5) | 1.6 (−2.8-6.1) | 0.46 | −6.2 (−28.6-16.2) | 0.58 |
| Social | −0.9 (1.4) | −1.4 (1.3) | 1.1 (1.3) | −2.0 (−6.6-2.5) | 0.30 | −2.4 (−6.7-1.8) | 0.26 |
| Environmental | −2.7 (1.4) | −5.3 (1.3) | −5.9 (2.0) | 3.1 (−1.7-8.1) | 0.20 | 1.3 (−3.3-5.9) | 0.58 |

Data are presented in mean (SE). IPSS: International Prostate Symptom Score; QOL: Quality of Life due to urinary symptoms; HC: Homoeopathic constitutional remedy; HCOM: Homoeopathic constitutional + organ remedy; PL: Placebo; CI: Confidence interval; PV: Prostate volume; PVRU: Postvoid residual urine; $Q_{max}$ and $Q_{avg}$: Uroflowmetry; SE: Standard error

With regard to secondary outcome, there was no difference between the groups i.e., HC and PL for PV (0.5 [−3.9–4.9]; 95% confidence interval [CI]; $P$ = 0.82); PVRU (−5.8 [−27.3–15.6]; 95% CI; $P$ = 0.59); $Q_{max}$ (0.2 [−3.5–4.0]; 95% CI; $P$ = 0.89) and $Q_{avg}$ (−0.5 [−1.9–0.8]; 95% CI; $P$ = 0.44). Similarly, there was no difference between the HCOM

**Table 3: Comparison of International Prostate Symptom Score as per intensity of symptoms**

| Group | Intensity | Baseline | 3 months | | | 6 months | | |
|---|---|---|---|---|---|---|---|---|
| | | | Mild | Moderate | Severe | Mild | Moderate | Severe |
| HC | Mild | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Moderate | 43 | 11 | 31 | 1 | 16 | 24 | 3 |
| | Severe | 58 | 5 | 47 | 6 | 12 | 42 | 4 |
| | Total | 101 | 16 | 78 | 7 | 28 | 66 | 7 |
| HCOM | Mild | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Moderate | 33 | 4 | 29 | 0 | 14 | 18 | 1 |
| | Severe | 59 | 8 | 33 | 18 | 14 | 33 | 12 |
| | Total | 92 | 14 | 62 | 18 | 28 | 51 | 13 |
| PL | Mild | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Moderate | 23 | 3 | 19 | 1 | 5 | 16 | 2 |
| | Severe | 25 | 1 | 10 | 14 | 3 | 10 | 12 |
| | Total | 48 | 4 | 29 | 15 | 8 | 26 | 14 |

IPSS: 0-7 mildly symptomatic; 8-19 moderately symptomatic; 20-35 severely symptomatic. HC: Homoeopathic constitutional remedy; HCOM: Homoeopathic constitutional + organ remedy; PL: Placebo; IPSS: International Prostate Symptom Score

and PL groups for PV (1.3 [−3.5–6.1]; 95% CI; $P = 0.58$); PVRU (−10.8 [−28.1–6.3]; 95% CI; $P = 0.21$); $Q_{max}$(0.2 [−3.8–4.3]; 95% CI; $P = 0.9$) and $Q_{avg}$ (−0.2 [−1.3–0.8]; 95% CI; $P = 0.6$). Similarly, no difference was also observed between HC and HCOM [Table 2]. Trend line comparing the three groups is given at Figure 2.

Further, in the four domains of the WHOQOL-BREF, no significant changes in the domains were found [Table 2].

### Intervention (homoeopathic constitutional and homoeopathic constitutional + organ-specific remedy)

The medicines prescribed to patients in LM potency in HC group ranged from 0/1-0/26. The prescription made in the HC group is as follows: *Apis mellifica* ($n = 1$), *Cantharis* ($n = 1$), *Carbo veg* ($n = 1$), *Lycopodium* ($n = 49$), *Nux vomica* ($n = 2$), *Phosphorus* ($n = 5$), *Pulsatilla* ($n = 18$), *Silicea* ($n = 3$) and *Sulphur* ($n = 21$).

The medicines prescribed in HCOM group are *Calcarea carbonica* (CC) + SS ($n = 1$), CC + BV ($n = 1$), CC + FP ($n = 1$), *Lycopodium* + SS ($n = 12$), *Lycopodium* + BV ($n = 15$), *Lycopodium* + *Chimaphila* ($n = 1$), *Lycopodium* + FP ($n = 3$), *Lycopodium* + *Pareira brava* (PB) ($n = 4$), *Lycopodium* + *Solidago* ($n = 1$), *Lycopodium* + *Hydrangea* ($n = 1$), *Nux vomica* + FP ($n = 1$), *Nux vomica* + SS ($n = 3$), *Nux vomica* + PB ($n = 1$), *Phosphorus* + FP ($n = 1$), *Phosphorus* + *Hydrangea* ($n = 3$), *Phosphorus* + SS ($n = 5$), *Phosphorus* + BV ($n = 1$), *Phosphorus* + PB ($n = 2$), *Pulsatilla* + BV ($n = 4$), *Pulsatilla* + SS ($n = 9$), *Pulsatilla* + *Solidago* ($n = 1$), *Sulphur* + FP ($n = 2$), *Sulphur* + PB ($n = 2$), *Sulphur* + SS ($n = 9$), *Sulphur* + BV ($n = 5$), *Sulphur* + *Hydrangea* ($n = 1$), *Thuja occidentalis* + PB ($n = 1$), *Thuja occidentalis* + FP ($n = 1$).

The medicines which were prescribed to more than 10 patients were further analysed statistically (HC group included *Lycopodium* [$n = 49$], *Pulsatilla* [$n = 18$], *Sulphur* [$n = 21$] and in the HCOM group, *Lycopodium* + BV Ø [$n = 15$] and *Lycopodium* + SS Ø [$n = 12$]). The effectiveness of these drugs in bringing the change in the various components of IPSS and the investigational parameters was assessed, and it was found that the changes were statistically significant at 3 and 6 months in IPSS and QOL with the intervention of all these medicines [Table 4]. In addition, *Lycopodium* has helped in bringing about significant change in $Q_{max}$ values, *Lycopodium* + BV Ø has shown statistical change in $Q_{max}$ and $Q_{avg}$ values.

## Discussion

This study reflects the beneficial role of homoeopathic medicines either in single or in combination with organopathic remedies in alleviating the symptoms (LUTS) due to BPH. The patients with BPH who received HC/HCOM had significantly less symptom score and better functionality after 6 months of treatment than did patients who received PL.

The homoeopathic literature refers to a number of constitutional as well as organopathic medicines for the treatment of BPH. Several rubrics related to the symptoms of BPH with indicated constitutional remedies and organ remedies are mentioned in many repertories.[15-19] The medicines were prescribed after taking the totality of symptoms as per the homoeopathic principles. This study aimed to substantiate previous study results conducted by other researchers. One of the first observational studies validating the role of homoeopathic medicines on BPH was undertaken by Oberai *et al*.[8] under the Central Council for Research in Homoeopathy considering the clinical as well as laboratory/diagnostic parameters, wherein twenty preselected homoeopathic medicines were used. This study reported that *Lycopodium, Pulsatilla, Sulphur* and *CC* in 30C and 200C potencies were found useful in alleviating the LUTS associated with BPH.[20] However, this study was an open-label study with no limitations to the use of medicine or choice of medicine. The homoeopathic medicines prescribed in

**Table 4: Effect of intervention on the outcome variables**

| Medicine | Parameters | Mean±SD | | | Wilks' lambda | *F* | *P* |
|---|---|---|---|---|---|---|---|
| | | Baseline | 3 months | 6 months | | | |
| *Lycopodium* (*n*=49) | IPSS | 22.3±5.6 | 11.9±5.2 | 10.1±4.6 | 0.2 | 91.5 | 0.0001 |
| | QOL due to urinary symptoms | 4.5±0.9 | 2.6±1.2 | 2.3±0.9 | 0.2 | 59.2 | 0.0001 |
| | PV | 37.8±15.2 | 40.1±20.6 | 35.9±20.4 | 0.96 | 0.85 | 0.43 |
| | PVRU | 58.1±58.9 | 43.8±44.1 | 44.1±56.4 | 0.94 | 1.28 | 0.28 |
| | $Q_{max}$ | 14.4±9.1 | 16.2±10.9 | 17.0±10.0 | 0.92 | 2.01 | 0.14 |
| | $Q_{avg}$ | 5.5±3.5 | 5.7±4.3 | 5.8±3.9 | 0.99 | 0.13 | 0.87 |
| *Pulsatilla* (*n*=18) | IPSS | 22.2±6.7 | 13.4±5.4 | 12.6±7.3 | 0.38 | 12.9 | 0.0001 |
| | QOL due to urinary symptoms | 4.5±0.8 | 3.1±1.2 | 2.8±1.3 | 0.40 | 8.98 | 0.002 |
| | PV | 37.3±12.1 | 32.1±12.6 | 32.5±12.7 | 0.84 | 1.51 | 0.25 |
| | PVRU | 47.5±41.5 | 60.8±67.2 | 39.6±35.8 | 0.89 | 0.94 | 0.40 |
| | $Q_{max}$ | 14.3±7.5 | 13.8±7.7 | 14.9±7.7 | 0.97 | 0.17 | 0.83 |
| | $Q_{avg}$ | 5.4±4.1 | 5.2±3.5 | 6.0±4.1 | 0.95 | 0.38 | 0.68 |
| *Sulphur* (*n*=21) | IPSS | 19.1±6.2 | 11.3±4.8 | 9.3±5.2 | 0.20 | 31.6 | 0.0001 |
| | QOL due to urinary symptoms | 4.1±1.2 | 3.1±1.2 | 2.5±0.9 | 0.41 | 13.5 | 0.0001 |
| | PV | 32.6±7.5 | 33.8±21.4 | 31.1±9.8 | 0.90 | 0.30 | 0.72 |
| | PVRU | 79.1±79.6 | 61.3±53.1 | 67.9±55.3 | 0.95 | 0.47 | 0.62 |
| | $Q_{max}$ | 11.5±5.3 | 17.5±15.3 | 18.1±13.6 | 0.70 | 2.80 | 0.08 |
| | $Q_{avg}$ | 5.3±3.4 | 4.8±3.1 | 5.2±3.3 | 0.80 | 1.50 | 0.24 |
| *Lycopodium* + *Berberis vulgaris* (*n*=15) | IPSS | 25.3±6.2 | 14.9±6.6 | 9.7±4.4 | 0.19 | 26.12 | 0.0001 |
| | QOL due to urinary symptoms | 4.6±0.9 | 2.3±1.6 | 2.3±1.5 | 0.30 | 14.2 | 0.001 |
| | PV | 40.9±17.5 | 36.2±16.0 | 39.7±22.2 | 0.80 | 0.90 | 0.39 |
| | PVRU | 98.5±87.1 | 87.3±73.3 | 89.4±85.3 | 0.90 | 0.40 | 0.67 |
| | $Q_{max}$ | 10.6±6.5 | 15.93±11.7 | 14.3±8.3 | 0.54 | 5.50 | 0.01 |
| | $Q_{avg}$ | 3.7±3.1 | 5.5±5.9 | 5.1±4.1 | 0.80 | 1.50 | 0.25 |
| *Lycopodium* + *Sabal serrulata* (*n*=12) | IPSS | 24.6±5.6 | 17.3±7.7 | 15.6±8.4 | 0.60 | 7.7 | 0.009 |
| | QOL due to urinary symptoms | 4.3±0.9 | 2.9±0.9 | 2.8±1.2 | 0.40 | 6.5 | 0.01 |
| | PV | 36.5±10.1 | 37.4±17.4 | 34.1±13.2 | 0.90 | 0.50 | 0.59 |
| | PVRU | 87.7±73.9 | 85.1±72.2 | 90.9±77.2 | 0.90 | 0.20 | 0.84 |
| | $Q_{max}$ | 7.1±3.1 | 8.1±3.4 | 9.5±7.2 | 0.80 | 0.70 | 0.48 |
| | $Q_{avg}$ | 2.7±1.6 | 3.0±1.8 | 3.2±1.7 | 0.70 | 1.6 | 0.23 |

Data presented as mean±SD. IPSS: International Prostate Symptom Score; QOL: Quality of Life due to urinary symptoms; PV: Prostate volume; PVRU: Postvoid residual urine; PSA: Prostate-specific antigen; $Q_{max}$ and $Q_{avg}$: Uroflowmetry; SD: Standard deviation

this study were in concordance with the above study. Similarly, in the study conducted by Gupta *et al*.,[9] *Lycopodium* and *Pulsatilla* were the most frequently prescribed medicines. Reddy *et al*.[21] published a case series of 11 patients evaluated by AUASI score[9] and reported *Pulsatilla nigricans* and *Thuja occidentalis* 200C to be useful in reducing the AUASI score as well as PV. Thus, a comparison among the previous studies on all such aspects will be difficult.

Hati *et al*.[10] used (CM) or OM alone or in combination of BCOM to evaluate their role on symptoms of BPH using AUASI score. The major limitations of the study conducted by Hati *et al*. were sequential allocation instead of randomisation and non-significantly longer treatment period in the BCOM group, which could have influenced the better improvement in this group in comparison to CM and OM groups. Thus, the study reported that BCOM relieved a maximum number of patients. However, the present study was conducted with randomisation and equal time period of follow-up i.e., 6 months resulted in equal effects of HC and HCOM groups.

Hati *et al*.[10] in their study reported 38%, 50% and 75% increase in $Q_{max}$ in CM group, OM group and BCOM group, respectively, and $Q_{avg}$ increased by 4%, 8% and 28% in CM, OM and BCOM group, respectively, thereby increased effect in BCOM group (i.e., combination of HC and HCOM groups). However, in this study, $Q_{max}$ increased by 5.1%, 0.9% and 2.8% in HC, HCOM and PL groups, respectively. Thus, the results are discordant with respect to the combined intervention. Although the changes are not statistically significant ($P = 0.92$), the values reflect that HC group has an upper edge in bringing the change.

In the present study, the total IPSS showed statistically significant change in HC as well as HCOM group of medicines compared to PL. The comparative changes in the category of intensity in IPSS in the three groups clearly reflect that the changes found are not by chance but are due to the effect of the medicine administered. Comparing the symptoms of IPSS i.e., incomplete emptying, frequency intermittency, urgency, weak stream and straining, HC

group was found to have an edge over HCOM group. In the urinary flow, $Q_{avg}$ and $Q_{max}$ had increased, but there was no statistically significant result in HC and HCOM groups. The trials in conventional system have also shown changes in the overall IPSS but no statistically significant changes in the uroflowmetry.[22-25] There was no adverse event reported in the study, which further strengthens the fact that the homoeopathic intervention is safe.

In all the studies discussed, the HC remedies that were prescribed most frequently and found useful are *Lycopodium, Pulsatilla* and *Sulphur*. In the other group where HCOM was prescribed, SS and BV mother tinctures were prescribed, but patients who were prescribed *Lycopodium* + BV Ø showed changes in the uroflowmetry study as well. Further, pragmatic trial with longer follow-up and a parallel arm comprising of two groups, wherein one group had only HC drug and in the other, only organ remedy (SS/BV), may be taken up in future. A strategy may be framed to understand the potency and dosage which will help in not only relieving the symptomatology, but changes in the objective parameters may also be brought about in such cases.

All the domains of Model Validity of Homoeopathic Trials[26] are covered in this study and are amenable to homoeopathic intervention; the specific intervention used is consistent with homoeopathic principles, the rationale for the intervention used is supported by a significant body of homoeopathic practitioners, the main outcome measures reflect the key effects expected of the intervention used and is capable of detecting the change. Furthermore, the length of the follow-up for the main outcome is appropriate to detect the intended effect of the intervention used.

The overall risk of bias[26] appears to be minimal as only one domain (allocation concealment) out of six has high risk of bias. The primary objective i.e., comparison of IPSS, is subjective, but the secondary outcomes are objective and shall not be influenced by lack of blinding. In this study, the statistical significance is found in the IPSS in all the three groups but only in HC and not in any of the objective parameters.

### Limitations of the study

The limitation of the study was that it was not blinded. The inhibition for not making it blinded was the use of mother tinctures of organ-specific medicines in liquids of different colours and odours that could not be blinded. The homoeopathic principles were not compromised while prescribing the medicines in the HC group and, in the HCOM group, the organ-specific remedy was prescribed as per the homoeopathic indications only. Another shortcoming was that the duration of follow-up was also comparatively less than the other reported studies.

## Conclusion

Results of this study have shown that both HC and HCOM groups have shown symptomatic relief in patients with LUTS in BPH.

### Acknowledgement

The authors are thankful to Dr. Ritika Hassija Narula, Research Officer (H) for data verification of case records.

### Financial support and sponsorship

Nil.

### Conflicts of interest

None declared.

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## Appendix 1: Indications of organ remedies

| Name | Indications |
|---|---|
| *Sabal serrulata* (SS) | Nocturnal urination-increased |
| | Enuresis |
| | Difficulty in urination |
| | Cystitis |
| | Prostatic fluid discharge |
| | Loss of sexual power |
| *Chimaphila umbellata* | Urine scanty-with sediments, turbid, offensive |
| | Burning and scalding during urination |
| | Retention and feeling of a ball in perineum |
| | Urination better while standing with feet wide apart and body inclined forward |
| *Hydrangea* | Frequent desire |
| | Burning in urethra |
| | Urine difficult to start |
| | Gravel in urine |
| *Ferrum picricum* | Plethoric patients |
| | Pain along urethra |
| | Frequent urination at night, full feeling, smarting at neck of bladder and penis |
| | Retention of urine |
| *Calcarea iodata* | Scrofulous affections including thyroid and tonsil enlargement |
| *Eupatorium purpureum* | Diabetes |
| | Burning pain in urethra and bladder on urinating |
| | Flow insufficient |
| | Constant desire |
| *Pareira brava* (PB) | Constant urging; great straining; pain down thighs during efforts to urinate |
| | Can emit urine only when he goes on his knees, pressing head firmly against the floor |
| | Feeling of the bladder being distended and neuralgic plan in the anterior crural region |
| | Urethritis, with prostatic trouble |
| *Solidago* | Difficult and scanty urine |
| | Pain in kidneys extends forward to abdomen and bladder |
| | Clear and offensive urine |
| *Berberis vulgaris* (BV) | Sensation as if urine remained after urinating |
| | Urine with thick mucus and bright-red, mealy sediment |
| | Pain in bladder region. Pain in the thighs and lions on urinating |
| | Frequent urination; urethra burns when not urinating |

**बिनाइन प्रोस्टेटिक हाइपरप्लासिया से ग्रस्त पुरूषों में निचले मूत्र पथ के लक्षणों का होम्योपैथिक उपचारः एक खुला यादृच्छिक प्लेसबो नियंत्रित नैदानिक परीक्षण**

**उद्देश्यः** बिनाइन प्रोस्टैटिक हाइपरप्लासिया के मामलों में इंटरनेशनल प्रोस्टेट सिमप्टम स्कोर (आईपीएसएस), प्रोस्टेट मात्रा में अल्ट्रासोनोग्राफिक परिवर्तन, पोस्ट वोइड रेसिडूअल यूरिन, यूरोफ्लोमेट्रि और डब्ल्यूएचओ गुणवत्ता जीवन–बीआरईएफ द्वारा प्लेसबो (पीएल) की तुलना में होम्योपैथिक कांसिट्यूशनल रेमेडी (एचसी) और होम्योपैथिक कांसिट्यूशनल + ऑरगन रेमेडी (एचसीओएम) की प्रभावशीलता का मूल्यांकन।

**सामग्री और विधिः** पाँच केन्द्रों में एक बहुआयामी थ्री–आर्म यादृच्छिक नैदानिक परीक्षण आयोजित किया गया। रोगियों का नामांकन पूर्वनिर्धारित समावेश और निषेध मानदंडों का पालन कर किया गया। सभी को तीन समूहों में 2:2:1 के अनुपात में यादृच्छिक किया गया और छह महीने के लिए अवलोकन किया गया। सांख्यिकीय विश्लेषण, मॉडिफाइड इंटेशंन टू ट्रीट सिद्धांत से किया गया।

**परिणामः** जाँचे गए कुल 461 रोगियों में से, अध्ययन में 254 रोगियों को नामांकित किया गया, एमआईटीटी के अनुसार 241 रोगियों का विशलेषण किया गया। बेसलाइन से अध्ययन के अंत तक मूत्र संबंधी लक्षणों के कारण आईपीएसएस और जीवन की गुणवत्ता (क्यूओएल) में औसत परिवर्तन ने सभी तीन समूहों में सकारात्मक रूझान दिखाए। हालांकि, एचसी समूह में, अन्य दो समूहों की तुलना में परिवर्तन अधिक महत्वपूर्ण था। बीपीएच के कारण एलसीटीएस के प्रबंधन के मामले में एचसी और एचसीओएम समूह समान रूप से प्रभावी थे। डब्ल्यूएचओक्यूओएल बीआरईएफ के मनोवैज्ञानिक, सामाजिक और पर्यावरणीय श्रेत्रों ने सकारात्मक रूझान दिखाया, परंतु अंतःक्षेप समूहों में कोई सांख्यिकीय रूप से महत्वपूर्ण अंतर नहीं था।

**निष्कर्षः** इस अध्ययन के परिणाम बताते हैं कि बीपीएच में एलयूटीएस के रोगियों में एचसी और एचसीओएम समूह दोनों ही लक्षणात्मक राहत प्रदान करते हैं।

**Traitement homéopathique pour les symptômes de la voie urinaire inférieure chez les hommes atteints d'hyperplasie bénigne de la prostate: une étude clinique ouverte, randomisée, multicentrique, et contrôlée par placebo**

**RÉSUMÉ**

**Objectifs:** Évaluer l'efficacité du remède constitutionnel homéopathique (RCH) et celle du remède constitutionnel homéopathique + remède spécifique d'organe (RCHRO) par rapport à un placebo (PL) dans les cas d'hyperplasie bénigne de la prostate à l'aide du Score international des symptômes de la prostate (International Prostate Symptom Score (IPSS)), des changements échographiques du volume de la prostate, du résidu post-mictionnel, du débit urinaire et des documents de l'OMS sur la qualité de vie (WHOQOL BREF)

**Matériels et méthodes:** Une étude clinique randomisée, multicentrique et à trois volets a été menée dans cinq centres. Les patients ont été inscrits conformément aux critères prédéfinis d'inclusion et d'exclusion. Ils ont été répartis en trois groupes de façon aléatoire selon une proportion de 2:2:1 et ont été suivis pendant 6 mois. L'analyse statistique a été effectuée selon le principe de l'intention de traiter modifiée (ITTm).

**Résultats:** Parmi les 461 personnes dépistées, 254 patients ont participé à l'étude et 241 patients ont été analysés selon l'ITTm. Une tendance positive a été constatée chez les trois groupes concernant les changements moyens d'IPSS et de qualité de vie (QdV) causés par les symptômes urinaires du début à la fin de l'étude. Cependant, dans le groupe RCH, les modifications ont été plus importantes par rapport aux deux autres groupes. Les groupes RCH et RCHRO étaient aussi efficaces en termes de gestion des symptômes de la voie urinaire inférieure dus à l'hyperplasie bénigne de la prostate. Les domaines psychologiques, sociaux et environnementaux du WHOQOL BREF ont montré une tendance positive mais il n'y avait aucune différence statistiquement significative dans les groupes d'intervention.

**Conclusion:** Les résultats de cette étude montrent que le groupe RCH et le groupe RCHRO apportent tous les deux un soulagement symptomatique aux patients manifestant des symptômes de la voie urinaire inférieure dus à l'hyperplasie bénigne de la prostate.

**Tratamiento homeopático de los síntomas del tracto urinario inferior en varones con hiperplasia prostática benigna: ensayo clínico multicéntrico aleatorizado controlado con placebo y de diseño abierto**

**RESUMEN**

**Objetivos:** Evaluación de la eficacia del remedio homeopático constitucional (HC) y del remedio homeopático constitucional + orgánico (HCO) en comparación con el placebo(PL) en casos de hiperplasia prostática benignaaplicando los siguientes parámetros: utilizando el índice IPPS(*International ProstateSymptom Score*), cambios ecográficos en el volumen prostático, residuo postmiccional, uroflujometría y cuestionario de la calidad de vida de la OMS (WHOQOL–BREF).

**Material y métodos:** Se efectuó un ensayo clínico multicéntrico de tres brazos en cinco centros. Los pacientes fueron incluidos conforme a criterios predefinidos de inclusión y exclusión. A continuación, fueron aleatorizados en tres grupos en una relación de 2:2:1 y sometidos a un seguimiento de seis meses. Se realizó un análisis estadístico conforme al principio de intención de tratar modificado (IDTm).

**Resultados:** 254 de los 461 pacientes examinados fueron incluidos en el estudio. 241 pacientes fueron analizados conforme al protocolo de IDTm. Los cambios medios en el IPSS y la calidad de vida CdV debido a síntomas urinarios desde el principio hasta el final del estudio mostraron una tendencia positiva en los tres grupos. Sin embargo, en el grupo HC, los cambios fueron más prominentes en comparación con los otros dos grupos. La eficacia en los grupos HC y HCO fue equivalente en cuanto al control de los síntomas del tracto urinario inferior (STUI)a causa de la HPB. Los dominios psicológicos, sociales ambientales del WHOQOL BREF mostraron una tendencia positiva, pero no se dieron diferencias estadísticamente significativas entre los grupos de intervención.

**Conclusiones:** Los resultados de este estudio han evidenciado que tanto los grupos con HC como los HCO mostraron un alivio sintomático en pacientes con STUI en caso de HPB.

**Homöopathische Behandlung von Symptomen der unteren Harnwege bei Männern mit benigner Prostatahyperplasie: Eine offene, randomisierte, multizentrische, placebokontrollierte klinische Studie**

**ABSTRAKT**

**Ziel:** Um die Wirksamkeit von homöopathischenkonstitutionellenMitteln (HC) und homöopathischenkonstitutionellen + Organarzneimitteln (HCOM) imVergleichzu Placebo (PL) in Fällen von benignerProstatahyperplasiemit International Prostate Symptom Score (IPSS), sonographischeVeränderungen des Prostatavolumens, Post-Void-Residual-Urin, Uroflowmetrie und in WHO-Lebensqualität - BREF.

**Material und Methoden:** Eine multizentrische dreiarmige randomisierte klinische Studie wurde in fünf Zentren durchgeführt. Die Patienten wurden gemäß den vordefinierten Einschluss- und Ausschlusskriterien in drei Gruppen im Verhältnis 2: 2: 1 randomisiert und sechs Monate lang beobachtet. Die statistische Analyse wurde mit modifiziertem Intention-to-treat-Prinzip (MITT) durchgeführt.

**Ergebnisse:** Von 461 untersuchten Patienten wurden 254 Patienten in die Studie eingeschlossen, 241 Patienten wurden nach MITT untersucht. Die mittleren Veränderungen der IPSS und der Lebensqualität (LQ) aufgrund von Harnwegssymptomen vom Ausgangswert bis zum Ende der Studie hatten in allen drei Gruppen einen positiven Trend gezeigt. In der HC-Gruppe waren die Veränderungen jedoch im Vergleich zu den anderen beiden Gruppen ausgeprägter. HC- und HCOM-Gruppe waren gleichermaßen wirksam bei der Verwaltung von LUTS aufgrund von BPH. Die psychologischen, sozialen und ökologischen Bereiche des WHO-BVT-Merkblatts haben sich positiv entwickelt, aber es gab keinen statistisch signifikanten Unterschied in den Interventionsgruppen

**Schlussfolgerung:** Die Ergebnisse dieser Studie haben gezeigt, dass sowohl HC- als auch HCOM-Gruppen eine symptomatische Erleichterung bei Patienten mit LUTS bei BPH bewirken.

## 以順勢療法治療患有下泌尿道症候群伴隨良性前列腺肥大的男士：一個非盲隨機多中心安慰劑對照臨床試驗


## 摘要

**目的：**在良性前列腺增生的個案中，以國際前列腺症狀評分(IPSS)、超聲波檢查前列腺體積變化、排出後的餘尿量、尿流速圖和世界衛生組織生活質素問卷(BREF)來評估順勢療法體質療劑 (HC) 和順勢療法體質療劑 + 特定器官療劑(HCOM)對比安慰劑的有效性。

材料和方法：在五個中心進行一項多中心三比對組隨機臨床試驗。病人按預定的納入和排除標準進行登記，按2：2：1的比例隨機分成三組，並跟進六個月。並採用改良式治療意向分析法(mITT) 進行統計學分析。

**結果：**在篩選出來的461名病人中，254名病人參加了該項研究，而241名病人按照mITT進行了分析。從基線到研究結束時，泌尿系統症狀IPSS和生活質素(QOL)的平均數在所有三組中都顯示出傾向正面的改變。然而，HC組別比其他兩個組別有更顯著的改變。HC組和HCOM組對於由於良性前列腺肥大(BPH)引起的下泌尿道症候群 (LUTS)同樣有效。世界衛生組織生活質素問卷BREF的心理、社交及環境領域均呈正向趨勢，但在實驗組之間無統計上的顯著差異。

**結論：**本研究結果顯示HC組和HCOM組均能減輕BPH患者的LUTS症狀。