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G. Ravi Chandra Reddy

Clinical Research Unit (Homoeopathy), Tirupati, Andhra Pradesh, India

Praveen Oberoi

Central Council for Research in Homoeopathy, New Delhi, India


Vikram Singh

Central Council for Research in Homoeopathy, New Delhi, India

C. Nayak

Central Council for Research in Homoeopathy, New Delhi, India

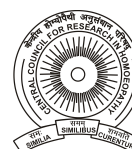
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Treating benign prostatic hyperplasia in elderly men with Homoeopathy- A series of eleven cases

Abstract

Background & Objectives: Benign prostatic hyperplasia is rarely life threatening, but often affects the individual's quality of life in varying degrees. The success rate in treating this condition with conventional therapy is limited and sometimes, treatment follows with side effects. If medical treatment fails, the physician determines the patient as a candidate for surgery. Though a few case records are documented in the past about the success of homoeopathic medicines in treating patients suffering from BPH, yet they lack proper quantitative assessment. Therefore, an observational study was undertaken with an objective to ascertain the usefulness of predefined homoeopathic medicines in the treatment of Benign Prostatic Hyperplasia. **Methods:** An open observational study was conducted by Central Council for Research in Homoeopathy including its Clinical Research Unit (Homoeopathy) at Tirupati (Andhra Pradesh) from Oct 05 to May '09. Clearance of the Ethical Committee and informed consents from the patients were obtained before initiation of the study. Eleven cases suffering from benign prostatic hyperplasia who followed up for one year were assessed on American Urological Association Symptom Index (AUASI) to quantify the severity of illness and assess the outcome. **Results:** Seven cases were relieved of their urinary symptoms with Pulsatilla nigricans and four cases with Thuja. In all the cases, reduction in AUA score was found. In 6 cases prostate volume was reduced; in 3 cases prostate size and volume increased, while in 2 cases prostate volume remained unchanged. **Conclusion:** The results of the study to determine the usefulness of the homoeopathic remedies in the treatment of Benign Prostatic Hyperplasia, although encouraging, are preliminary and the final analysis of the data of the multicentre study will help in reaching at a definitive conclusion.

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CLINICAL RESEARCH

Treating Benign Prostatic Hyperplasia in elderly Men with Homoeopathy – a series of eleven cases

G. Ravi Chandra Reddy¹, Praveen Oberaf¹, Vikram Singh², C. Nayak²

¹Clinical Research Unit (Homoeopathy), Tirupati, Andhra Pradesh

²Central Council for Research in Homoeopathy, New Delhi

Background & Objectives: Benign prostatic hyperplasia is rarely life threatening, but often affects the individual's quality of life in varying degrees. The success rate in treating this condition with conventional therapy is limited and sometimes, treatment follows with side effects. If medical treatment fails, the physician determines the patient as a candidate for surgery. Though a few case records are documented in the past about the success of homoeopathic medicines in treating patients suffering from BPH, yet they lack proper quantitative assessment. Therefore, an observational study was undertaken with an objective to ascertain the usefulness of predefined homoeopathic medicines in the treatment of Benign Prostatic Hyperplasia.

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Conclusion: The results of the study to determine the usefulness of the homoeopathic remedies in the treatment of Benign Prostatic Hyperplasia, although encouraging, are preliminary and the final analysis of the data of the multicentre study will help in reaching at a definitive conclusion.

Key words: benign prostatic hyperplasia; homoeopathy; pulsatilla; thuja.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is one of the most common benign neoplasms in elderly men. Enlargement of the prostate is nearly universal in aging men and is responsible for considerable disability. Hyperplasia usually begins by age of 45 years, occurs in the area of prostate gland surrounding the urethra, and produces urinary outflow obstructions^{1,2}.

The prevalence of histologically diagnosed prostatic hyperplasia increases with age, being 8% in age group

of 31 – 40, 40 - 50% in the men aged 51- 60 and over 80% in those more than 80 years old. Currently there are over 22 million men over the age of 50. With the increasing aging population, this number is expected to be nearly 45 million by the year 2010. In population – based studies, the prevalence of moderate to severe lower urinary tract symptoms (LUTS) and decreased peak urinary flow rates increases with age, and there is a modest co-relation among LUTS, peak flow rates and prostate volume³.

Although the precise etiology remains uncertain, alteration in testosterone, dihydro testosterone, and estrogen hormonal balance with aging are considered to cause BPH. Some experts believe that a family history of the condition increases a man's risk of developing BPH. Obesity and diabetes are the factors that potentially increase the risk of developing BPH

Address for Correspondence:

G. Ravi Chandra Reddy

Assistant Director (Homoeopathy),

Clinical Research Homoeopathy Unit (Homoeopathy),

Door No.6-1-61A, K.T. Road, Tirupati- 517 507, Andhra Pradesh

Email- crutpt@yahoo.co.in

and lower urinary tract symptoms (LUTS), while increased physical activity decreases the risk of BPH^{4,5,6}.

Significant enlargement of the prostate may occur before causing symptoms. Symptoms develop late because hypertrophy of the bladder detrusor compensates for urethral compression. The first symptoms of BPH are usually slow urinary flow, frequent urination, and the need to return to the bathroom shortly after voiding. Dysuria and urgency are signs of bladder irritation⁷. BPH usually results in a smooth, firm, elastic enlargement of the prostate. Conventional therapies like α -adrenergic blocking agents, 5 α -reductase inhibitors result in 25% shrinkage of the prostate gland and 20% improvement in the symptom scores. These drugs are expensive in comparison to their effectiveness⁸. Men undergoing prostatectomy may develop retrograde ejaculation, this occurs in about 65% of men after prostatectomy. Erectile impotence occurs in about 5% of men⁸. Moreover, patients with very mild symptoms of BPH receive little or no benefit from surgery.

Occasionally, BPH causes urine to be retained in the bladder. When this happens, urine backs up in the kidneys, which can result in kidney failure⁹. Testing blood level of creatinine with signs of BPH measures the kidney function. Creatinine levels may elevate in men as a result of an enlarged prostate that blocks urine flow⁵.

The Central Council for Research in Homoeopathy conducted this study from Oct.'05 to May '09 to study the usefulness of individualized homoeopathic medicines in treating BPH. This article reflects the interim analysis of the study at Clinical Research Unit (Homoeopathy), Tirupathi. The cases presented here are those where homoeopathic medicines have proved useful in the treatment of patients suffering from BPH.

Material and Methods

Study design

This article presents 11 cases that were enrolled at Clinical Research Unit (Homoeopathy), Tirupathi for the treatment of BPH. Clearance of the Ethical Committee and informed consents from the patients were obtained before initiation of the study. American Urological Association Symptom Index (AUASI)² was used to quantify the severity of illness and assess the

outcome. The prostate index score was divided according to the intensity of the disease into mildly symptomatic (1 – 7), moderately symptomatic (8 – 19) and severely symptomatic (20 – 35).

Study population

Eleven cases with the following inclusion criteria were included:

- Patients of 50 years and above with signs and symptoms of BPH
- PSA level equal to or below 4.0 ng/ml (To rule out malignancy at entry only)
- On Digital Rectal Examination (DRE): presence of smooth, firm and elastic enlargement of the prostate
- On ultrasonic examination: a swollen or enlarged prostate (more than 20 ml)

Cases with complete retention of urine for more than 24 hours, marked fluctuation of, or increase in the PSA level, benign neoplasms (except adenoma), fibroma and myoma of prostate, prostatic carcinoma, urinary tract infection, neurogenic bladder, or urethral stricture were excluded.

Selection of medicine

The selection of trial medicines was done by repertorising the symptoms of the BPH² with the help of Complete repertory. The medicines given in the first grade (3 points) and second grade (2 points) against the rubrics 'Prostate swelling' and 'Prostate enlargement' in the Repertory were shortlisted, which included *Pulsatilla nigricans*, *Conium mac.*, *Digitalis*, *Calc. carb.*, *Baryta carb.*, *Chimaphilla*, *Staphysagria*, *Thuja*, *Apis mel.*, *Sulphur*, *Argentum nit.*, *Selenium*, *Lycopodium*, *Prareira brava*, *Merc. sol.*, *Silicea*, *Nit. acid*, *Hyoscyamus*, *Medorrhinum* and *Phosphorus*. Out of these, each patient was administered the similimum, selected according to the totality of symptoms. The patients requiring other medicines beyond this pre-defined group were not included in the study.

Potency, dose and repetition

All the cases were given single dose of the indicated medicine. One dose consisted of four pills, size 30, followed by placebo. Follow-up of the cases and subsequent prescriptions were made following Kent's twelve observations. The indicated medicine was not

repeated till improvement stopped and the patient was kept on placebo. When improvement stopped, the same medicine was repeated in the same potency. When no further improvement occurred or improvement lasted for a very short period even after repeating the medicine in same potency, next higher potency of the same medicine was given.

Treatment plan

The treatment plan was based on the severity of the discomfort determined by the AUASI scoring method.

- (i) In discomfort of mild to moderate intensity (AUA Score 0-19), *the first phase treatment* i.e. watchful waiting and giving placebo (non-medicated globules) and conservative treatment (diet management and pelvic floor exercises) were carried out till such time that there was improvement in the prostatic hyperplasia and/or the American Urological Association (AUA) symptom index score for BPH.
- (ii) In case of no improvement, *the second phase treatment* was given i.e. the indicated medicine along with the general management.
- (iii) General management includes:
 - To urinate when you first get the urge.
 - To go to the bathroom when you have the chance, even if you don't feel a need to urinate.
 - To discontinue tobacco, alcohol and caffeine.
 - Especially after dinner, not to drink a lot of fluid all at once
 - To spread out fluid intake throughout the day.
 - To avoid drinking fluids within two hours of bedtime.
 - To reduce stress, nervousness and tension which can lead to more frequent urination.
 - To perform Kegel/pelvic strengthening exercises.

Outcome assessment

Outcome assessment was done by calculating the improvement percentage using the formula $[(\text{AUA symptom score at baseline} - \text{the AUA symptom score at completion}) / \text{AUA symptom score at baseline} \times 100]$; > 75% was considered as *marked improvement*, 50 to less than 75% was considered as *moderate*

improvement, 25 to less than 50% as *mild improvement*, less than 25% as *no significant improvement* and 0% as not improved or status quo and an increase in the symptom score from the baseline was counted as *worse*.

Results

Eleven patients as per the inclusion and exclusion criteria were followed up and studied. The incidence of BPH was predominant in 71 – 80 years of age group (n=5; 45%), followed by 61– 70 years age group (n=4; 36%) and 50 – 60 years age group (n=2; 18%). Duration of suffering ranged from less than 1 year to more than 10 years. All the cases were investigated for PSA and Ultrasonography at the baseline, 3 months and 1 year of treatment. Renal function tests, Urine analysis and DRE were done every 3 months till one year.

The subjects were evaluated at baseline and at completion of one year of the study. Difference between AUA score at baseline and at the end of the treatment was considered for the assessment of improvement, status as per the formula given under outcome assessment. According to AUASI (Table 1), seven patients were of severe intensity and four of moderate intensity at the baseline. After one year of treatment, eight patients became mild and three moderate.

On digital rectal examination at baseline, the prostate gland was severely enlarged in two patients, moderate to severely enlarged in two patients and moderately enlarged in seven patients. After one year of treatment, it was observed that seven patients had moderate enlargement and four patients had only mild enlargement. The consistency of prostate was found to be smooth, firm and elastic at baseline and this was maintained with similar consistency at the end of the treatment.

In four cases, that was mild to moderately symptomatic, first phase treatment i.e. "watchful waiting", was given, alongwith placebo and conservative treatment. But no improvement was found in regard to AUA symptom scores, prostate size and volume. These were then given second phase treatment with the indicated medicines. Following administration of the indicated medicine, improvement, with regard to AUA symptom scores, prostate size and volume was found.

An analysis of these results shows that two trial medicines, i.e. *Pulsatilla* and *Thuja*, were used more frequently during treatment of cases suffering from BPH. *Pulsatilla* was prescribed in seven patients, out of which four patients improved markedly and three showed moderate improvement. Similarly, *Thuja* was prescribed in four patients, out of which one patient improved markedly and moderate improvement was observed in the other three patients. Besides improvement in urinary symptoms related to prostate enlargement, improvement of associated diseases/complaints like osteoarthritis (n=6), polyarthralgia (n=1), cervical spondylosis (n=2), lumbago (n=3), peri-arthritis shoulder (n=2), acid peptic disease (n=6), renal calculi (n=4), tinea cruris (n=2), cholelithiasis (n=4), fistula-in-ano (n=1) and allergic rhinitis (n=1), was also observed.

Prostate volume was reduced in 6 patients, increased in three patients and remained status quo in two patients. In seven patients, PSA levels were decreased while in four patients, PSA levels were increased (but both the increase and decrease was within the normal limits, i.e. below 4.0 ng/ml). In all the patients, urine analysis was found within the normal limits at the baseline and at the end of the study; Serum creatinine levels were well maintained within the normal limits. In seven patients Hb% concentration raised (Table 2) after medication.

All the eleven cases required either *Pulsatilla* or *Thuja*. These medicines were prescribed in 30C potency, followed by 200C.

Pulsatilla was prescribed for the following symptoms:

- Mild and gentle temperament
- Aggravation from warmth
- Intolerance to meat
- Thirstlessness
- Desires open air
- Profuse perspiration
- Interrupted urination; dribbling urine by drops; feeble urine stream; unsatisfactory urination
- Frequent urination at night

Thuja was indicated when symptoms were:

- Forgetfulness and sluggish activity of mind
- Chilly patient
- Profuse perspiration
- Interrupted urination
- Incomplete emptying of bladder
- Urination dribbling
- Morbid urging to urinate
- Frequent urination at night
- Slow and weak urinary stream

Table 1: AUASI (At entry and End of study)

Symptoms	Score At Entry of Case														Score After 1 year of study of Case															
	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	BPH	
Incomplete emptying	2	3	4	4	4	4	4	4	4	4	4	4	4	4	4	3	2	5	0	1	0	2	0	1	2	1	0	1	1	
Frequency	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	2	1	1	2	2	2	2	2	0	2	1	3
Intermittency	0	3	4	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	1	1	0	1	1	1	1	1	1	1	2	
Urgency	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	1	1	0	1	1	1	1	1	1	1	1	
Weak stream	2	3	0	3	2	2	2	2	2	2	2	2	2	2	2	3	3	4	1	0	0	1	0	1	1	1	0	1	1	
Straining	2	2	0	1	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Nocturia	2	3	2	4	2	2	2	2	2	2	2	2	2	2	2	3	3	3	1	1	1	2	2	2	1	1	1	1	2	
Total AUA symptom score	14	20	17	22	22	22	19	26	22	21	14	23	6	5	2	9	6	7	8	5	5	6	7	8	5	5	6	10		

Table 2: Status of symptom scores, PSA, Prostate volume (PV), Post void residual urine (PVR), Serum Creatinine (SC) and Hb%

Case No.	At entry						After 1 year study						Degree of Improvement	
	AUA score	PSA (ng/ml)	PV (in ml)	PVR (in ml)	SC (mg/dl)	Hb. (gm%)	Medicine prescribed	AUA score	PSA (ng/ml)	PV (in ml)	PVR (in ml)	SC (mg/dl)		Hb. (gm %)
BPH 1	14	2.5	39.6	N.S.	1.2	10.8	Thuja	6	1.7	22	N.S.	1.21	13.6	Moderate
BPH 2	20	2.4	80	102	1.1	13.4	Puls.	5	0.5	16	200	1.1	13.8	Marked
BPH 3	17	1.5	83	N.S.	1.01	13.8	Puls.	2	2.0	75	75	0.81	14.2	Marked
BPH 4	22	0.6	30	N.S.	1	12.2	Thuja	9	0.5	32	N.S.	0.53	14.3	Moderate
BPH 5	22	1.1	40	N.S.	1.1	13.8	Thuja	6	1.7	50	121	0.91	14.2	Marked
BPH 6	19	0.7	24	N.S.	0.92	12.4	Thuja	7	2.5	24	N.S.	1.1	12.6	Moderate
BPH 7	26	1.5	72	52	1.34	13.2	Puls.	8	2.6	81	160	0.98	13.4	Moderate
BPH 8	22	1.5	40	N.S.	0.92	13.8	Puls.	5	0.5	19	N.S.	0.96	13.5	Marked
BPH 9	21	1.4	21	N.S.	1.13	13.6	Puls.	5	0.5	19	N.S.	1.28	13.8	Marked
BPH 12	14	0.6	32	N.S.	0.94	13.2	Puls.	6	0.5	32	N.S.	0.91	13.2	Moderate
BPH 13	23	0.8	48	N.S.	0.86	10.8	Puls.	10	0.5	30	N.S.	1.28	12.2	Moderate

(* Sig. - Significant or N.S. - Not Significant)

Discussion

The present study was intended to assess the usefulness of homoeopathic medicines in patients suffering from prostatic enlargement according to AUASI and urinary flow rates. The encouraging results of the present study support the findings of Arrighi *et al*⁶ of aging where the age-specific prevalence of pathologically defined BPH at autopsy correlates with the age in the study. This study also supports to a greater extent the study by Sarma A V *et al*⁷, which found the prevalence of moderate or severe lower urinary tract symptoms (LUTS) for men in the 5th, 6th, 7th and 8th decades of life.

According to the literature review, the incidence of obstructive symptoms of voiding decreases and the caliber of the urinary system increases with age and the same is made more certain in this study. BPH usually results in a smooth, firm, elastic enlargement of prostate, which was also found in this series of 11 patients⁷.

According to the homoeopathic literature by Boericke William, Pulsatilla nigricans is considered to be mainly a female remedy; despite that, it was indicated for seven males above 40 years of age in this study, who improved symptomatically as well as pathologically.

The urine flow was improved with reduction in prostate size and volume. Creatinine levels were well maintained within the normal limits reflecting normal functioning of kidneys. PSA levels were decreased in seven patients; thereby decreasing the risk of developing prostate malignancies. Weinstein's analysis of eight patients also shows the reduction of prostatic symptoms similar to the findings of this study. But this study deals with single individualized homoeopathic medicines, which relieved the patients of their prostatic troubles, whereas in the former study, the author had prescribed more than two medicines at different time intervals.

Prostate volume (PV) increased in 3 (27%) patients, remained the same in 2 (18%) and decreased in 6 (54%) patients. Changes in PV were not correlating with AUA score at the end of treatment, which was found to be reduced in all the 11 patients. The Post Void Residual urine (PVR) was found to be increased in four patients, out of whom two patients, had reduction in both AUA score and PV. PSA was found to be increased in four patients, out of whom three patients showed increase in prostate volume at the

end of treatment. Thus the baseline information related to AUASI, PSA, PV and PVR was not correlating with the investigations conducted at the end of the study, in some of the cases, which goes with the observations of Tsukamoto *et al*.

In none of the cases, under this study, there was any incidence of acute urinary retention, recurrent urinary tract infections or development of any new problem. With homoeopathic similimum, in seven patients, Hb% was found to be raised without taking any iron supplements. Thus, with homoeopathic treatment which is effective and cheaper, the number of surgeries conducted in treating the patients suffering from benign prostatic hyperplasia by modern treatment can be reduced.

Conclusion

The results of the study to determine the usefulness of the homoeopathic remedies in the treatment of Benign Prostatic Hyperplasia, although encouraging, are preliminary and the final analysis of the data of the multicentre study will help in reaching at a definitive conclusion.

Acknowledgments

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Conflict of interest: None declared

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