ORIGINAL ARTICLE

Homoeopathic medicines in the management of benign prostatic hyperplasia: A multi-centric prospective observational study

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Objectives: The primary objective of this study was to determine the therapeutic usefulness of a group of predefined trial medicines in benign prostatic hyperplasia. The secondary objective was to check the progression of disease by evaluating changes in prostate volume (PV), post-void residual urine (PVRU) and peak urine flow rates (Qmax and Qavg in ml/sec).

Methods: In a multi-centric observational study, 231 patients suffering from benign prostatic hyperplasia (BPH) having prostate volume > 20 mL and prostate specific antigen (PSA) ≤ 4 ng/mL were enrolled at 5 Institutes/Units under Central Council for Research in Homeopathy (CCRH). Symptoms were analyzed using the American Urological Association Symptom Index (AUASI). Parameters like PSA, Prostate volume, Post void residual urine, Qmax, Qavg were also analyzed. Twenty pre-defined homoeopathic medicines were short-listed for prescription after repertorizing the pathological symptoms of BPH. The appearance of any change (relief/worsening)/status quo was immediately followed by placebo/ change in potency/change in remedy. The follow-up period was for one year. The analysis was done as per intention to treat principle. Statistical analysis was done using SPSS version 16.

Results: The data of 187 patients out of 231 enrolled was analyzed. The non-parametric Friedman test was applied to test for significant difference in AUASI score reported over 12 months (baseline, 3 months, 6 months and 12 months). There was a statistically significant reduction in AUASI score (median change of 13 points, p= 0.0001) on completion of one year of treatment. A total of 10 out of 20 pre-defined medicines were prescribed to 187 patients. The medicines found to be most useful in this study are: *Thuja (27 out of 53; 51%), Sulphur (26 out 46; 56.5%), Pulsatilla (34 out of 46; 74%), Lycopodium.(7 out of 13; 54%).*There was a mean reduction of 2.3 ml in prostate volume, which was significant satistically (p=0.005).

Conclusion: Homoeopathic medicines significantly improved lower urinary tract symptoms in men with BPH. Placebo-controlled trials are needed to evaluate their efficacy and effectiveness.

Keywords: benign prostatic hyperplasia; homoeopathy; Lycopodium; observational study; Pulsatilla; Sulphur; Thuja

INTRODUCTION

Benign prostatic hyperplasia (BPH) develops in almost all elderly men.[1] Based on the prevalence, BPH appears to be a disease when benign prostatic enlargement (BPE), obstruction (BPO), or lower urinary tract symptoms (LUTS) appear. One-third to one-half of men with BPH develops BPE, approximately half of men with BPH–LUTS have BPO, and up to 40% of men in a community have LUTS.[2] LUTS is the most frequent cause of annoyance and decreased quality of life and associated with health-seeking behaviour.[3] Various therapeutic modalities opted are medications (include 5 α Reductase inhibitor, α-blocker), balloon dilation, and watchful waiting.[4] Men with clinical BPH are best treated initially with α-blocker to relieve LUTS. Although combination therapy (α-Blocker and 5 α-Reductase inhibitor) does decrease disease, the clinical relevance and cost-effectiveness of this outcome in clinical BPH are highly questionable.[5] Researchers in their recent

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findings suggest treatments tailored to individual cases so as to optimize efficacy and minimize side effects from therapy.[6] However, a prolonged intake is associated with an increased risk of sexual dysfunction, ejaculatory dysfunction, decreased libido and impotence[7], thus reporting unsatisfactory outcomes, consequential to unmet medical needs and significant impact on the Quality of Life.[8] Surgical measures that are minimal invasive like transurethral laser ablation of the prostate, transurethral resection of prostate, though beneficial, but are much costly, have diminished the quality of life in terms of peri-operative and post operative complications.[9,10]

Homoeopathy is the second-most widely used CAM in healthcare systems according to the World Health Organization.[11] A survey by Singh et al[12] showed that 12.6% of the Indian population prefers homoeopathy amongst the AYUSH system in India, which has scope in managing chronic diseases.[13-16] Homoeopathic preparations showed significant effects in in-vivo[17] and in-vitro studies[18] for prostatic cancer. Observational study conducted[19], case series[20] and reports[21-23] by researchers throw light on the usefulness of homoeopathy in BPH. The Central Council for Research in Homoeopathy (CCRH) had carried out preliminary study on symptomatic BPH with positive effects (unpublished data). The Council then took up a multi-centre study to evaluate the usefulness of a group of pre-defined homoeopathic medicines in BPH patients as a primary objective**.** The secondary objective was to check the progression of disease by evaluating changes in prostate volume (PV), post-void residual urine (PVRU) and peak urine flow rates (Qmaximum and Qaverage in mL/sec).

MATERIAL AND METHODS

Study design

This prospective multi-centric observational study was carried out between October 2005 to September 2010 at five Institutes/Units selected keeping in view the adequacy of the manpower, facilities of lab investigations and the willingness of the research personnel at the institute. These Institutes and Units were: Central Research Institute (H), Noida; Regional Research Institute (H), Gudivada; Clinical Research Unit (H), Siliguri and Tirupathi and Homoeopathic Drug Research Institute, Lucknow and were governed by CCRH. The patients were treated for a period of one year. Investigators with experience of five or more years were trained in the protocol. The study met the Council's ethical clearance and followed the declaration of Helsinki[24] and Good Clinical Practices of India.[25] Informed consent was obtained from all the patients before their enrolment. The symptoms and signs of these patients were rated using the American Urological Association Symptom Index (AUASI).[26]

Patients

Patients with 50 years and above having sign and symptoms of BPH, Prostate Specific Antigen (PSA) level ≤4 ng/ml, smooth, firm and elastic enlargement of prostate on digital rectal examination and PV >20ml on ultrasonic examination were included. Patients with complete retention of urine ≥ 24 hours, complications from benign neoplasms needing hospitalization, history of prostatic carcinoma and other possible causes such as urinary tract infection, neurogenic bladder, or urethral stricture were excluded.

Procedure for selection of pre-defined trial homoeopathic medicine

Table 1a and 1b shows the procedure for selection of pre-defined trial medicines by repertorizing the symptoms of BPH[27] using the Complete Repertory from CARA software.[28] Twenty medicines of both first (3 points) and second grade (2 points) mentioned against the rubrics 'Prostate, swelling' and 'Prostate, enlargement' were shorted: *Pulsatilla (Puls.), Conium maculatum (Con.), Digitalis purpurea (Dig.), Calcarea carbonica (Calc.), Baryta carbonicum (Bar-c.), Chimaphilla (Chim.), Staphysagria (Staph.), Thuja occidentalis (Thuj.), Apis mellifica (Apis), Sulphur (Sulph.), Argentum nitricum (Arg-n.), Selenium (Sel.), Lycopodium (Lyc.), Pareira brava (Pareir.), Mercurius solubilis (Merc.), Silicea (Sil.), Nitric acid (Nit-ac.), Hyoscyamus (Hyos.), Medorrhinum (Med.) and Phosphorus (Phos.).*

Selection of medicine and follow-up

The selection of the specific medicine for each patient was on the basis of the highest value on repertorization of the presenting signs and symptoms, further guided by the characteristic mental/emotional and physical attributes of the patient. The investigator was free to change the prescription up to three times, including the first prescription. However, if the selected medicine based on individualization was not one of those included in the pre-defined trial medicines then the patient was not included in the study.

The prescription of the selected medicine started with 30CH potency, in a single dose (four pills of globule No. 30) followed by placebo (four pills of unmedicated globules No. 30), daily. Follow-up was weekly for the first month, fortnightly for the next second months and thereafter monthly till 12 months. Clinical assessment was done by the investigator and urologist/surgeon at each centre and uroflometry was conducted by the urologist/surgeon.

Table 1a: Symptoms for selection of pre-defined trial medicine for Benign Prostatic Hyperplasia

Symptom	Complete Repertory		
	Rubric	Sub rubric	Code
Smooth, firm, elastic enlargement of the prostate	**PROSTATE**	**SWELLING (21)***	**1a**
		ENLARGEMENT (94)	**1b**
Hesitancy/straining	**URINATION**	retarded, must wait for urine to start (77)	2a
		retarded, must wait for urine to start; press, must; prostate affections, in (1)	2b
		retarded, must wait for urine to start; press, must; a long time before he can begin (47)	2c
Intermittent voiding		interrupted, intermittent (50)	3a
		spurting stream (12)	3b
		interrupted, intermittent; spurts, in swelled prostate, with each spurt cutting pain (1)	3c
A diminished stream		Thin stream (31)	4a
		Feeble stream, slow, weak (81)	4b
Incomplete emptying		Unsatisfactory (64)	5a
		Unsatisfactory; feeling as if urine remained in urethra (26)	5b
Post void leakage		Dribbling by drops; enlarged prostate, with (17)	6a
		Dribbling by drops; urination, after (45)	6b
		Unsatisfactory; bladder were not emptied, as if, with dribbling (1)	6c
Nocturia		Frequent; night (147)	7a
		Frequent; old people; enlarged prostate, with (2)	7b
		Frequent; prostate affections, with (5)	7c
Urgency		URGING to urinate, morbid desire; sudden; hasten to urinate, must, or urine will escape (62)	8
Retention		RETENTION of urine; enlarged prostate, from (19)	9

**Figure in parentheses indicated no. of medicines in Complete Repertory*

Any change (improvement/deterioration) triggered the administration of placebo or change in potency (from 30C to 200C or 1M) or change in remedy following the guidelines of Hahnemann[29]and Kent.[30]

Plan of treatment

The plan of treatment was based on the guidelines of the American Urological Association (AUA).[25]

i **Plan I:** *Mild to moderate intensity (AUASI: 0-19)*:

- 1st phase treatment – "Watchful waiting". Placebo plus pelvic floor exercises were advised till there was improvement as per the AUASI score, which was determined at two week's interval. In case of no improvement, the 2nd phase treatment was given.
- 2nd phase treatment – Indicated pre-defined trial medicine along with the general management.

ii **Plan II:** Severe intensity (AUASI score: 20-35):

Patients with severe AUASI score were advised for non-medicinal management as mentioned below, along with the indicated medicine.

Non-medicinal management

The following non-medicinal management were advised: to urinate when they first got the urge; to discontinue tobacco, alcohol and caffeine, especially after dinner; not to drink a lot of fluid at once and to avoid drinking fluids within two hours of bed time; not to take over-the-counter cold and sinus medications that contain decongestants and antihistamines, as these can increase BPH symptoms; to keep themselves warm by exercising regularly and to reduce stress,

Table 1b: Selection of pre-defined trial medicine for Benign Prostatic Hyperplasia

Medicine→	Puls	Con	Dig	Calc	Bar-c	Chim	Staph	Thuj	Apis	Sulph	Arg-n	Sel	Lyc	Pareir	Merc	Sil	Nit-ac	Hyos	Med	Phos
Total Score/ rubrics/sub rubrics covered→ Code↓	26/13	17/09	17/09	12/05	10/05	11/06	23/14	22/13	18/11	18/08	16/10	15/09	14/08	13/09	13/06	12/08	12/06	11/06	10/06	09/07
1a	2	2	2	0	0	3	1	1	0	0	0	1	0	0	0	0	0	0	1	0
1b	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Score/rubrics/sub rubrics covered→ Code↓	21/11	12/07	12/07	09/04	07/04	06/04	20/12	19/11	16/10	16/07	13/08	12/07	12/07	11/08	11/05	09/06	10/05	09/05	07/04	07/06
2a	1	0	2	1	0	0	1	2	2	1	1	2	3	2	0	2	2	0	1	0
2b	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
2c	0	0	0	0	0	2	0	1	2	0	0	0	1	1	0	0	2	2	0	0
3a	2	3	0	0	0	0	0	2	1	2	1	0	2	1	0	0	0	0	1	1
3b	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3c	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4a	2	0	0	0	0	1	2	2	1	2	0	0	0	0	2	0	2	0	0	0
4b	1	0	2	0	0	1	1	1	2	3	3	2	1	1	3	1	2	0	2	1
5a	1	1	0	2	0	0	2	2	0	2	2	2	1	0	1	1	0	2	0	1
5b	0	0	1	0	0	0	2	2	0	0	2	2	0	0	0	1	0	0	0	0
6a	2	0	2	0	1	0	2	0	0	0	0	1	0	1	0	0	0	0	0	0
6b	0	2	1	3	2	0	2	2	0	0	1	2	1	2	0	1	0	0	0	1
6c	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
7a	3	2	1	3	3	0	1	2	2	3	1	1	3	0	3	3	2	2	3	1
7b	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7c	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0
8	3	0	0	0	1	0	1	2	2	3	2	0	0	2	2	0	0	2	0	2
9	2	1	3	0	0	2	3	0	2	0	0	0	0	1	0	0	0	1	0	0

nervousness and tension which lead to more frequent urination; to perform Kegel exercises for strengthening pelvic muscles.

Outcome Assessment and Statistical analysis

The outcome status of the treatment was calculated using the formula:

$$\text{Outcome} = \frac{Baseline\ AUASI\ score - AUASI\ score\ at\ end}{Baseline\ AUASI\ score} \times 100$$

Changes were graded as *marked* (75% to < 100%), *moderate* (50% to < 75%), *mild improvement* (25% to < 50%), *improvement not significant* (< 25%), *static* (no change), and *worse* (increase in AUASI).

Statistical analysis (SPSS version 16) followed the intention to treat approach: patients who had at least one visit, apart from baseline, were included under intention to treat (ITT) analysis. The last observation carry forward (LOCF) was used to fill the missing values. Parametric tests were used for continuous data and non-parametric tests were used for ordinal data. The formula for Effect size calculation was: Effect size= $\frac{Z}{\sqrt{N}}$, where Z is the Z score and N is the total number of observations.[31] They are classified as r= 0.5, large; r < 0.3, medium; r =0.1, small. P-value < 0.05 was considered significant.

RESULTS

Disposition of patients

A total of 762 patients were screened; 231 patients

fulfilled the inclusion criteria. 44 out of 231 patients were excluded from analysis as mentioned in Figure 1. 187 patients were analyzed as per ITT. The baseline characteristics of the patients are given in Table 2. Mild, moderate and severe intensity of patients as per AUASI were 11(6%), 36(19%) and 140(75%) respectively. Objective findings (pre & post) could be analyzed as follows: PV (n=186 patients), PVRU (n=184 patients), PSA (n=104 patients), Peak urine flow rates (n=22 patients). Out of 20 pre-defined medicines, only 10 pre-defined medicines were used, on the basis of individualization.10 medicines which were not used in the study are *Dig., Calc., Bar-c., Chim., Sel., Pareir., Sil., Nit-ac., Hyos. and Med.* Henceforth the result will reflect the information related to 10 pre-defined medicines used.

Figure 1: Flow of patients in the study

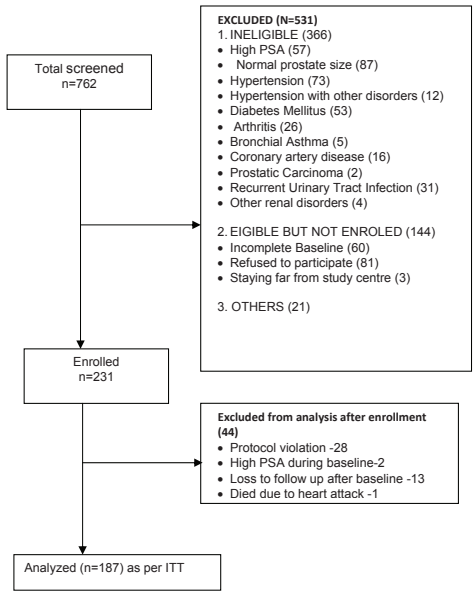

Table 2: Characteristics of study patients at Baseline

Variable	No. of patients (n),%	Mean(sd)/Median(Q1 to Q3)
Noida	51(27.3)	
Gudivada	66(35.3)	
Tirupathi	36(19.3)	
Lucknow	33(17.6)	
Siliguri	1(0.5)	
Age in yrs	187(100%)	64(8)
Range		
• 50-64	86(46%)	54.4(4.2)
• 65-80	99(53%)	69.8(4.2)
• 81>	2(1%)	84.5(0.7)
Duration of BPH in yrs	187(100%)	3.7(2)
Co-morbid disease		
• Diabetes	12(6%)	
• Hypertension	08(4%)	
Body Mass Index (kg/m^2)		
• <25	125(67%)	21.8(2.5)
• 25-29	44(23%)	26.7(1.03)
• ≥30	18(10%)	31(1.5)
AUASI		
• AUASI Intensity -Mild (0-7)	11(6%)	4(2 to 4)
• AUASI Intensity -Moderate (8-19)	36(19%)	13.5(10.25 to 17)
• AUASI Intensity Severe (20-35)	140(75%)	23(21 to 27)
• AUASI Intensity Mild –Moderate (0-19)	47(25%)	12(8 to 16)
• AUASI total score	187(100%)	21(19 to 25)
• AUASI storage score	185(99%)	10(8 to 13)
• AUASI voiding score	181(97%)	11(7 to 15)
Individual symptom score of AUASI		
• Incomplete emptying	150(80%)	4(1to 5)
• *Frequency*	174(93%)	4(3 to 5)
• Intermittency	129(69%)	3(0 to 5)
• *Urgency*	159(96%)	4(2 to 5)

• Weak stream • Straining • *Nocturia (times per night)*	170(91%) 101(54%) 170(91%)	4(2 to 5) 1(0 to 3) 3(2 to 5)
Prostate gland		
• Prostate Specific Antigen (ng/mL)	187(100%)	1.34(0.9)
• Prostate volume (mL)	187(100%)	35(15)
• Post void residual urine (mL)	187(100%)	73(78.5)
Uroflometry • Qmax (mL/s) • Qavg (mL/s)	 63(34%) 63(34%)	 16(9.7) 5.8(4)
Others		
• Serum Creatinine (mg/dL)	180(96%)	1.1(0.6)
• Blood urea (mg/dL)	180(96%)	31(9)

Data are presented in n(%),Mean(sd), Median(Q1 to Q3)

Changes in subjective parameter (Primary outcome)

Table 3 summarizes the results of Friedman's test for AUASI total score, individual symptoms, and different grades of intensity based on AUASI score over 12 months. There was a statistically significant reduction in all the subjective parameters. AUASI total score was reduced significantly (median reduction: 10, 12, and 13 points at 3 months , 6 months and 12 months respectively; p=0.0001). Voiding (questions 1, 3, 5 and 6 of AUASI) and storage symptoms (questions 2, 4, and 7 of AUASI) occurring due to BOO (Bladder outlet obstruction) were analyzed and found to be reducing significantly (p= 0.0001).

Table 3: Subjective changes in the patients (Freidman test)

Parameter	Mdn(Q1 to Q3)				Chi square	df	p-value
	Baseline	3rd month	6th month	12th month			
AUASI score • Mild (0-7)	4(2 to 4)	4(1 to 5)	2(1 to 4)	3 (1to 4)	2.9	3	0.4
• Moderate (8-19)	13.5(10.25 to 17)	8(5.25 to 11.75)	7(5 to 14.5)	7(5.25 to12)	24.9	3	**0.0001**
• Severe (20-35)	23(21 to 27)	14 (8 to 19)	11(7 to 17)	10(6 to16)	236.6	3	**0.0001**
• Mild –Moderate (0-19)	12(8 to 16)	7(4 to 11)	6(4 to 12)	6 (4 to 9)	25.63	3	**0.0001**
AUASI total score	21 (19 to 25)	11(6 to 17)	9(6 to 16)	8(5 to15)	252.6	3	**0.0001**
AUASI storage score	10(8 to 13)	5 (3 to 9)	5 (3 to 8)	4 (2 to 7)	261.6	3	
AUASI voiding score	11(7 to 15)	5(3 to 9)	5 (3 to 9)	4 (2 to 9)	164.5	3	
Symptoms of AUASI • Incomplete emptying • *Frequency* • Intermittency • *Urgency* • Weak stream • Straining • *Nocturia (times per night)*	 4(1 to 5) 4(3 to 5) 3(0 to 5) 4(2 to 5) 4(2 to 5) 1(0 to 3) 3 (2 to 5)	 1(0 to 3) 2(1 to 4) 1(0 to 3) 1(0 to 4) 2(1 to 5) 0(0 to 1) 1(1 to 3)	 1(0 to 3) 3(1 to 2) 1(0 to 2) 1(0 to 3) 2(1 to 4) 0(0 to 1) 1(1 to 3)	 1(0 to 2) 1(1 to 3) 1(0 to 2) 1(0 to 2) 2(0 to 4) 0(0 to 1) 1(0 to 2)	 173.4 199.6 97.5 209 107 73 215	 3 3 3 3 3 3 3	

At 12 months, mild, moderate and marked improvement was observed in 33 (17.6% of 187), 65 (34.8% of 187) and 45 patients (24% of 187) respectively. Non-significant, static and worsening of symptoms was found in 22 patients (12% of 187), 12 patients (6.4% of 187) and 10 patients (5.3% of 187) respectively (Table 5). None of the patients from mild (n=05) and moderate intensity group (n=06) who had Plan I treatment and prescribed placebo till the end were worsened. No adverse events were noted during the study.

Changes in objective parameters (secondary outcome)

Table 4 summarizes the results of paired t test for objective changes from baseline to 12th month. There was significant reduction in PV (3 ml, p=0.005), PSA (-0.24 ng/mL, p=0.01) and serum creatinine (p=0.01). However, insignificant statistical change was found in PVRU (p=0.06), Qmax (p=0.39), Qavg (p=0.15) and BUN (p=0.21).

Table 4: Changes in objective parameters

Parameter	Difference (Baseline-12 months)	95% CI of the Difference		t	df	p-value
	Mean (sd)	Lower	Upper			
Ultrasonography						
• PV/mL(n=186)	2.3 (11.2)	0.7	3.9	2.8	185	**0.005**
• PRU/mL(n=184)	9.5(69.8)	-0.6	19.6	1.8	183	0.06
Uroflometry, mL/sec						
• Qmax (n=22)	-2.3 (12.6)	-7.9	3.20	-0.8	21	0.39
• Qavg (n=22)	1.6(4.9)	-.61	3.8	1.5	21	0.15
PSA , ng/mL (n=104)	-0.24 (0.9)	-0.4	-0.06	-2.6	103	**0.01**
BUN,mg/dL(n=95)	1.4(10.5)	-0.8	3.5	1.3	94	0.21
Serum creatinine,mg/dL(n=94)	0.1(0.4)	0.02	0.17	2.4	93	**0.01**

PSA- Prostate specific antigen, BUN- Blood Urea Nitrogen, PV- Prostate volume, PRU- Post void residual urine

Table 5: Outcome status of predefined Homeopathic medicine and intensity of BPH

		N	Outcome, n					
			Marked	Moderate	Mild	Not Significant	Static	Worse
Medicine								
Thuj.		53	9	18	9	9	4	4
Sulph.		46	11	15	7	6	3	4
Puls.		46	13	21	7	2	1	2
Lyc.		13	4	3	4	2	0	0
Con.		6	1	2	1	1	1	0
Staph.		5	1	2	1	0	1	0
Merc.		5	2	2	1	0	0	0
Others		2	2	0	0	0	0	0
Total		176	43	63	30	20	10	10
Intensity of disease								
Mild	Placebo	5	2	0	1	0	2	0
	Medicine	6	1	0	0	0	4	1
	Total	11	3	0	1	0	6	1
Moderate	Placebo	6	0	2	2	2	0	0
	Medicine	30	4	12	2	4	3	5
	Total	36	4	14	4	6	3	5
Severe		140	38	51	28	16	3	4
Grand total		187	45	65	33	22	12	10

Effect of medicines

Out of 187 patients analyzed, 47 patients (11 mild, 36 moderate) had Plan I treatment whereas 140 severe patients had Plan II treatment at baseline. The changes in AUASI score was compared with baseline value in subsequent follow ups. Patients who improved/ maintained status quo in their AUASI score (5 mild, 6 moderate out of 47) were further kept on placebo whereas 36 patients (6 mild, 30 moderate) with increased AUASI score were prescribed the pre-defined trial medicines. 93% of patients (140 patients of severe BPH, 30 moderate BPH, and 6 mild BPH) required a homoeopathic medicine for their suffering. 23 patients in placebo group were changed to medicine group within three months of treatment, 05 patients within 6 months of treatment and 07 patients within 12 months of treatment. Table 5 shows the useful homoeopathic medicines. Frequently prescribed medicines producing marked and moderate improvement are *Thuj. (27 / 53; 51%), Sulph. (26 /46; 56.5%), Puls. (34 / 46;74%), Lyc. (7 / 13; 54%)*. A total of 55 patients required a change of prescription from baseline; 36 patients from mild and moderate BPH and 19 patients of severe BPH.

Effect size

Individualized homoeopathic treatment has large effect size at 3 months (Mdn = 11, Z = -10.47, r = 0.54, p =0.0001) and this was maintained up to 12 months (Mdn=4, z=-10.61, r=-0.5, p = 0.0001).

DISCUSSION

This study has thrown some light on the effect of homoeopathic medicines in BPH. The positive aspects are: firstly, medicines were prescribed following homoeopathic principle of individualization[29] and at the same time, following the treatment guidelines of AUA.[26] Secondly, previous research has suggested that a clinically meaningful change in symptoms of BPH requires a change in the AUASI score of at least three points.[32] In our study too, it was found that there was a reduction of 13 points in the AUASI score after one year.

Medicines have shown relief in both the voiding and storage symptoms in patients with LUTS and BOO, thought to be associated with BPH. Ten pre-defined medicines covered the prescribing totality of 176 patients. Four homoeopathic medicines covered approximately 81% of the prescriptions. Despite the individualized nature of homoeopathic treatment, it appears that clinical pathway to specific prescription exists, which is in consonance with the findings of Riley et al.[33] The most useful medicines that yielded marked and moderate improvement are *Thuja, Sulphur, Pulsatilla* and *Lycopodium.*

The review of literature shows that α1 adrenergic receptor blockers are not able to significantly alter PSA, and PV.[34] But in this study, it is observed that homeopathic medicines were able to change significantly the PV, maintain serum PSA till 12 months of treatment but no change was observed in post-void residual urine, Qmax and Qavg. Further research in a controlled setting is required to explore this area. Homeopathic medicines had no measurable effect on the urinary flow rates as pre- and post-comparison was done in 22 patients only.

The natural history of a disease refers to the progression of the untreated disease over time. Clinical endpoints of progression for BPH are bladder dysfunction manifested by incomplete emptying or detrusor instability, severe BOO, acute urinary retention, recurrent UTI, sepsis, chronic renal insufficiency, bladder stones, incontinence, and hematuria.[35,36] Such complications were not observed in this study.

There are limitations and drawbacks too. 60 patients gave their consent to participate but failed to report after enrolment. Patients of elderly age showed their difficulty for regular follow-up. Lastly, the investigators' bias cannot be ignored.

CONCLUSION

Homeopathic medicines significantly improved LUTS in men with BPH. Placebo-controlled trials are needed to evaluate the efficacy and effectiveness.

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उद्देश्यः अध्ययन का प्रांरभिक उद्देश्य सुसाध्य प्रोस्टेटिक अतिवृद्धि के उपचार में उपयोगी पूर्व चिन्हित होम्योपैथी औषधियों के एक समूह की चिकित्सीय उपयोगिता का निर्धारण करना था। अध्ययन का द्वितीय उद्देश्य प्रोस्टेट वोल्यूम (पी वी), पोस्ट–वायड अवशिष्ट मूत्र (पी वी आर यू) और मूत्र प्रवाह दर (क्यूमेक्स एवं क्यूवीसी एम एल/सेकण्ड) में मूल्यांकन द्वारा रोग के विकास का परीक्षण करना था।

पद्धतिः केन्द्रीय होम्योपैथी अनुसंधान परिषद् द्वारा एक बहु केन्द्रिक प्रेक्षणात्मक अध्ययन किया गया जिसके अन्तर्गत परिषद् के 5 संस्थानों/इकाई में सुसाध्य प्रोस्टेट अतिवृद्धि से पीड़ित 231 मरीजों का नामांकन किया गया जिनका प्रोस्टेट वोल्यूम <20 एमएल और प्रोस्टेट विशेष एंटीजन (पी एस ए) ≤4 एन जी/एम एल था। लक्षणों का विश्लेषण अमेरिकन यूरोलोजिकल एसोसिएशन सिस्टॉम इंडेक्स (ए यू ए एस आई) द्वारा किया गया। मापदण्ड जैसे पी एस ए, प्रोस्टेट आकार, पोस्ट–वायड अवशिष्ट मूत्र क्यूमेक्स, क्यूवेग भी विश्लेषित किया गया। सुसाध्य प्रोस्टेट अतिवृद्धि के रोग लक्षणों के रेपरट्राइजेशन के उपरांत बीस पूर्व चिन्हित होम्योपैथी औषधियों को चुना गया। रोग अवस्था (राहत/बिगड़ना) होने पर प्लासिबो/पोटेंसी उपचार में तुरंत परिवर्तन किया गया। अनुवर्तन काल एक वर्ष का था। होम्योपैथी सिद्धान्तों के अनुसार विश्लेषण किया गया। एपीएसएस वर्जन 16 का उपयोग करते हुए सांख्यिकीय विश्लेषण किया गया।

परिणामः नामांकित 231 मरीजों में से 187 मरीजों के आंकड़ों का विश्लेषण किया गया। 12 महीनों (बेसलाइन, 3 महीनों, 6 महीनों और 12 महीनों) में एयूएएसआई स्कोर में आये महत्त्वपूर्ण अन्तर के परीक्षण हेतु गैर–पैरामेट्रिक फ्राइडमैन परीक्षण उपयोग में लिया गया। एक वर्ष के उपचार के पूर्ण होने पर एयूएएसआई स्कोर (13 बिन्दुओं का मध्यम परिवर्तन, पी= 0.0001) में सांख्यिकीय महत्त्वपूर्ण रूप से कमी पायी गईं। पूर्व चिन्हित 20 औषधियों में से 10 औषधियां 187 मरीजों को सेवन हेतु दी गई। इस अध्ययन में अत्यधिक उपयोगी पाई गयी औषधियां : थुजा. (53 में से 27, 51%), सल्फर (46 में से 26, 56.5%), पल्साटिला (46 में से 34,74%), लाइकोपोडियम (13 में से 7,54 प्रतिशत) थीं। प्रोस्टेट के आकार में 2.3 एमएल की कमी हुई जो की सांख्यिकीय (पी=0.005) रूप से बहुत महत्त्वपूर्ण है।

निष्कर्षः सुसाध्य प्रोस्टेट अतिवृद्धि से पीड़ित पुरूषों में निम्न मूत्र मार्ग लक्षणों में होम्योपैथी औषधि ने महत्त्वपूर्ण सुधार किये। प्रभावकारिता एवं प्रभाव के मूल्यांकन हेतु प्लासिबो नियंत्रित परीक्षण किये जाने की आवश्यकता है।

खोजशब्दः होम्योपैथी, सुसाध्य प्रोस्टेट अतिवृद्धि, प्रेक्षणात्मक अध्ययन, थुजा, सल्फर, पल्साटिला, लाइकोपोडियम।