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ORIGINAL PAPER

Constitutional, organopathic and combined homeopathic treatment of benign prostatic hypertrophy: a clinical trial

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Background: **Benign Prostatic Hypertrophy (BPH) is common in older men. This study compared homeopathic treatment strategies using constitutional medicines (CM) or organopathic medicines (OM) alone or in combination (BCOM) in patients suffering from BPH.**
Methods: **220 men aged 30–90 years were recruited in Odisha, India. Patients presenting symptoms of prostatism, with or without evidence of bladder outflow obstruction were included in the study. Patients with serum prostate specific antigen (PSA)> 4 nmol/mL, malignancy, complete urine retention, stone formation and gross bilateral hydronephrosis were excluded. Patients were sequentially allocated to OM, CM or BCOM. The main outcome measure was the International Prostate Symptom Score (IPSS).**
Results: **73, 70 and 77 patients respectively were sequentially allocated to OM, CM or BCOM. 180 patients (60 per group) completed treatment and were included in the final analysis. Overall 85% of patients showed improvement of subjective symptoms such as frequency, urgency, hesitancy, intermittent flow, unsatisfactory urination, feeble stream, diminution of residual urine volume but there was no reduction in prostate size. Treatment response was highest with BCOM (38.24%) compared to OM (31.62%) and CM (30.15%). Effect sizes were highest for the decrease in IPSS, residual urine volume and urinary flow rate.** *Homeopathy* (2012) **101**, 217–223.

Keywords: Homeopathy; Constitutional; Organopathic; Combined benign prostatic hypertrophy; Effectiveness; Treatment

Introduction

Benign Prostatic Hypertrophy (BPH) is a common problem in older men. From the age of 45 years, the prostate may undergo benign hyperplasia.[1] BPH usually occurs in males of 45–50 years old, ultimately involving 75% of the male population over 75 years of age.[2] BPH is characterized by a progressive swelling of the prostate causing symptoms of the lower urinary tract. Various plant derivatives, lipidosterolic extracts and drugs have been trialed to have an alternative to treat BPH against its surgical approach,[1–8] many cases eventually require surgery.

The homeopathic literature states that a number of constitutional as well as organopathic medicines (OM) are effective in treating patients suffering from BPH and claims good response at individual levels. But the results are too scanty and the claims not well documented. Homoeopathy considers disease a dynamic entity and the derangement of the whole man, expressed through the particular organs of the body, i.e. the 'whole man' is primarily diseased and individual organs/parts are only secondarily affected. It perceives each individual patient suffering from BPH as different from others suffering from the same disease,

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because individuals are unique by virtue of their peculiar mental states, physical attributes and particular characteristics. In short, it emphasizes, the 'person diagnosis', instead of the 'disease diagnosis'.

Constitutional medicines (CM) are selected on the basis of the peculiar, guiding and characteristic, whole person, physical and mental attributes of each individual patient. Constitutional homeopathic medicines include *Thuja*, *Conium*, *Sulphur*, *Lycopodium*, *Baryta carbonica*, *Natrum. muriaticum*, *Tuberculinum*, *Calcarea carbonica Carcinosin* and *Staphysagria*. While OM including *Sabal serrulata*, *Hydrangea*, *Chimaphilla*, *Solidago*, *Senecio*, *Triticum*, *Ferrum picricum* and *Picric acid* are said, in the homeopathic literature, to be effective in BPH cases.[9−13]

We hypothesized that simultaneous prescription of both constitutional and organopathic medicines (BCOM) may have better effect against BPH cases than either alone. The primary objective of this study was to compare the results of constitutional, organopathic and combined treatment of BPH. A secondary objective was to obtain a general picture of the response of BPH cases to homeopathic treatment.

Materials and methods

Ethical approval to conduct this study was undertaken from the research ethical committee of Dr. Abhin Chandra Homoeopathic Medical College & Hospital (Dr ACHMCH), Bhubaneswar, India. Informed consent was given by each patient. Advertisements placed in newspapers for treatment of BPH with free of cost, all total 284 patients were screened out of which 220 patients were registered for the study using systematic sampling. The study was conducted at the Dr ACHMCH, Bhubaneswar, India from April 2005 to April 2008.

Inclusion and exclusion criteria

Participants from all over the state of Odisha, India were considered suitable if they met diagnostic criteria for BPH. Men aged 30−90, presenting symptoms of prostatism, with or without evidence of bladder outflow obstruction were included in the study. Patients with serum prostate specific antigen (PSA) >4 nmol/mL, malignancy, complete urinary retention/stone formation and gross bilateral hydronephrosis were excluded from the study.

For screening of patients and follow-up, ultrasonography, serum PSA, blood electrolytes estimations were performed at Neelachal Hospital, Bhubaneswar, India. Uroflowmetry, urine test, blood and serum urea, creatinine and hemoglobin were performed at Dr ACHMCH, Bhubaneswar. Patients were diagnosed as suffering from BPH on the basis of obstructive symptoms (impaired size and force of urinary stream − weak stream, hesitancy of urination, intermittent and interrupted urination, terminal dribbling of urination, sense of incomplete bladder emptying and abdominal straining), irritational symptoms (nocturia, frequency of urination, urgency of urination/dysuria and dysuria), digital rectal characteristics (smooth/hard, elastic/non-elastic, nodulated/non-nodulated, mucosa free/plus, median sulcus felt/not felt etc.), ultrasonography (ultrasonography was performed to measure prostate size and residual urine volume (RUV). Prostate weight of 20 g and urine volume of 30 mL were taken as normal prostate size and normal RUV, respectively), urine flow rate (urine flow rate of ≥15 and ≥10 mL/sec were taken as maximum (Qmax) and average (Qavg) flow rate, respectively). Below the normal flow rate was taken to indicate obstruction.

Patients were stratified into four groups according to age (≤50, 51−60, 61−70 and >70 years). Within strata, patients were sequentially allocated to CM, OM and BCOM.

Allocation of medicines, potencies and repetition schedule

Patients were given either only CM or only OM or combinations of the above two types of medicines sequentially (Figure 1). After the data of 180 patients had been collected, the remaining patients continued to be followed in the outpatient department of the hospital, but are not included in this report.

CM were selected on the basis of the peculiar, guiding and characteristic physical and mental attributes of each individual patient. While prescribing the empirically used organopathic drugs, symptoms of each, though scanty, were taken into consideration. The CMs were prescribed in 30C, 200C, 1M, 10M, 50M and 50 millesimal potencies. The OMs were administered in mother tincture (MT) 6x and 6C (Table 7). The dose and repetition schedule was at the discretion of the treating doctor. Centesimal potencies were prescribed in single dose and repeated as and when required. For LM (50 millesimal) potencies, medicines were prescribed in divided doses, i.e. 30 mL of prepared potency divided into 16 doses. Patients were instructed to take LM potencies in 20 drops per dose. MTs of OM were prescribed in 5−10 drops dose, twice or thrice daily, for 2−4 weeks and repeated as required.

The patients were asked to return for assessment of their progress and prescription of medicines every 2−4 weeks. Ultrasound investigation and uroflowmetry were repeated every 6 months. Digital rectal examination, neurological examination, International Prostate Symptom Score (IPSS) and voiding chart were made at baseline and repeated at 6-month intervals. Lower urinary tract ultrasonsography was done in every case, upper tract imaging and cysto-urethroscopy were also performed when necessary. According to ultrasound findings, BPH was divided into four grades: I (25−34 g), II (35−49 g), III (50−74 g), IV (>75 g).

Assessment of outcomes

The IPSS was the main outcome criterion.[14] This scoring was measured to check the severity of symptoms only. According to their IPSS scores, patients were grouped into three categories, scores <7, 8−18 and >18 were considered mild, moderate and severely affected, respectively. No improvement and mild improvement cases were grouped together as 'failure' or 'negative response' group. Marked

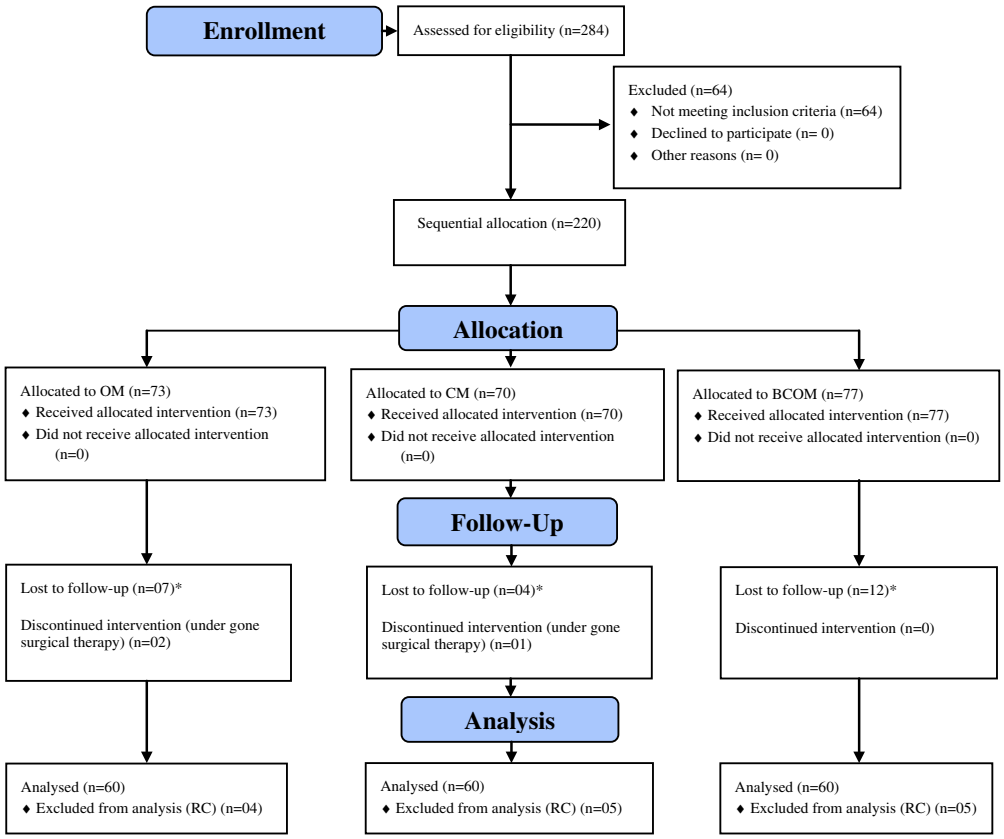

Figure 1 CONSORT flowchart of patients passing through the study. Patients were sequentially allocated to three groups. RC = recent cases, complete follow-up could not achieved during the study period of 3 years, *Patients were mostly from remote areas of Odisha state and the reasons for their drop out remained unclear as they did not respond to our calls.

and moderate improvement cases were taken as 'success' or 'positive response' group.

Statistical analyses

In CM, OM or BCOM groups, data of 60 patients (except Qmax and Qavg values) were presented as mean ± standard deviation (SD) for before and after comparison outcomes. Each set of data were tested for homogeneity of variance (Levene test) and normality (Lilliefors test) using interactive statistical calculation (statpages.org). Since the data were not normally distributed, non-parametric tests (χ^2 or Kruskal–Wallis at $p \leq 0.05$ significant level) were used. To compare the effects of medicines among groups, *Z*-test was performed. Proportion of success was calculated by dividing the number of cases having positive results by the total number of cases. The correlation co-efficient was calculated to determine the relation between age and prostrate size. Cohen's *d* test was performed to determine effect sizes, comparing before and after treatment time points. Cohen's *d* value ≤0.3 was considered a 'small effect', >0.30 to ≤0.49 'medium effect' and ≥0.5 was a 'large effect'.

Results

Of 284 patients who presented for treatment during the 3 years of study, 64 were excluded according to the exclusion criteria. Baseline characteristics of the included patients are given in Table 1. The treatment period varied from 6 months to 2 years depending upon the severity and recovery of the patients.

Dropped out cases

During the treatment period, out of 220 patients, 26 failed to return (Table 2). Three of these underwent surgical treatment and remainder (23 patients) dropped out for reasons which are unclear; they did not respond to our calls. Apart from the 26 dropped out cases, 14 were recent cases (presenting in 2008 and were excluded from the study). Most dropouts (16 out of 26) were within a month of starting treatment. Four cases were followed up for 2 months and six cases for 3 months. We excluded the data of drop out cases.

Demographics and age distribution of prostate gland

Initial characteristics of the patients are presented in Table 1. The highest and lowest number of patients was recorded from the age groups 60–69 and 30–39 years, respectively. Most of the patients were of average body built and were from urban area. Considering duration of illness, the highest number of patients had suffered from BPH symptoms for more than 3 years. Only six cases were of recent onset. Based on ultrasound findings, the highest numbers of cases were recorded to have grade I BPH, the lowest number had grade IV. Most patients had RUV of 30–100 mL and the lowest number of patients had RUV

Table 1 Patient characteristics at baseline

Characteristics/ groups		*Sub-groups or values*	*No. of patients*	*Percentage*
Demographics (age in years)		30–39 years	01	0.5
		40–49 years	08	4.4
		50–59 years	41	22.8
		60–69 years	86	47.8
		70–79 years	39	21.7
		80–89 years	05	2.8
	CM	63.60 ± 8.65 years	60	33.3
	OM	66.71 ± 8.20 years	60	33.3
	BCOM	66.73 ± 9.10 years	60	33.3
Habitats		Urban	167	92.8
		Rural	13	7.2
Body built		Obese	15	8.3
		Average	136	75.6
		Thin	29	16.1
Duration of symptoms		0.1–0.5 years	06	3.3
		0.6–1 years	31	17.2
		1–2 years	26	14.5
		2–3 years	27	15.0
		>3 years	90	50.0
Ultrasound (prostate weight)		Grade I (25–34 g)	81	45
		Grade II (35–49 g)	46	25.6
		Grade III (50–74 g)	38	21.1
		Grade IV (>75 g)	15	8.3
RUV		<30 mL	59	32.8
		30–100 mL	72	40.0
		100–200 mL	31	17.2
		>200 mL	18	10.0
IPSS value		Mild (0–7)	22	12.2
		Moderate (8–19)	104	57.8
		Severe (20–35)	54	30.0
Duration of treatment	CM	11.53 ± 5.92 months	60	33.3
	OM	11.08 ± 5.24 months	60	33.3
	BCOM	13.83 ± 4.68 months	60	33.3

No significant difference ($p > 0.05$) was observed between the three groups for the data (mean ± SD) of demographics (analysis of variance (ANOVA)) and duration of treatment (Kruskal–Wallis ANOVA).

>200 mL. The highest number of patients had moderate IPSS scores. The mean weight of the prostate (estimated from ultrasound) in age groups <50 years, 50–69 years, 60–69 years and ≥70 years was 28.18 ± 2.22, 38.90 ± 2.42, 54.18 ± 5.01 and 45.95 ± 2.72 g, respectively.

Outcomes

IPSS score: There was significant improvement of IPSS scores in all treatment groups. The improvement was greatest in BCOM group (Tables 3 and 4). The greatest decrease in IPSS (62%) was observed in the BCOM group in comparison to CM (56%) and OM (56%) groups. The effect sizes (Cohen's *d* value) for CM, OM and BCOM for IPSS were −1.43, −1.57 and −1.99, respectively.

Prostate size: Results in terms of prostate size are depicted in Tables 3 and 4. No statistically significant reduction in size of the prostate was observed. Only two cases belonging to OM group and three cases from BCOM group showed some improvement as regards size of the prostate as revealed from final ultrasound report. Three, two and three cases in CM, OM and BCOM groups were finally found to be upgraded to grade I, respectively. No case was improved at grade IV patients with regards to prostate size. The effect sizes (Cohen's *d* value) for CM, OM and BCOM for prostate were 0.01, 0.20 and −0.08, respectively.

RUV, and urinary flow: RUV decreased after the treatment in all groups. Tables 3 and 4 depict the change in RUV before and after treatment of the medicines in three groups. Prior to treatment, of 180 patients, 121 had RUV >30 mL. Of these 50 (41.32%) returned to the normal range after treatment. Improvement percent in the CM, OM and BCOM groups were 26.47, 51.11 and 42.85%, respectively. Four patients in the CM group, two in the OM group

Table 2 Baseline data on the 26 drop out patients

Age	*Size of prostate (g)*	*Residual urine (ml)*	*IPSS*	*Duration of treatment*	*Medicines*	*Group*
77	35	47	17	1 month	Con-0/1-0/2, Sabal ser- MT	BCOM
36	25	70	15	1 month	Lyssin0/1 to o/3, Hydrangea- MT	BCOM
52	75	171	24	3 months	Staph-0/1 to 0/6, phos- 0/1 to 0/4, Sabal ser- MT	BCOM
82	42	2	22	2 months	Merc.sol 0/1 to 0/4 Sabal ser- MT	BCOM
69	25	05	18	1 month	Staph-0/1 to 0/2, Picric acid-6	BCOM
60	82	43	15	1 month	Thuja-0/1 to 0/3, Picric acid-6	BCOM
75	29	05	12	1 month	Calcarea Carb-1M, Sabal Ser- MT	BCOM
67	425	48	13	3 months	Staph-1M, Thuja-0/1 to 0/6, Sabal ser- MT	BCOM
79	34	157	17	1 month	Staph-0/1 to 0/4, Sabal ser- MT	BCOM
64	131	63	12	3 months	Staph-0/1 to 0/6, Hydrangea- MT	BCOM
74	30	15	12	1 month	Thuja-1M, Sabal Ser- MT, Sulphur-30	BCOM
70	19	12	29	3 months	Thuja-1M, Medo-0/1 to 0/6, Sabal ser- MT	BCOM
78	25	33	16	1 month	Triticum repens- MT	OM
67	41	58	24	1 month	Sabal ser- MT	OM
66	38	70	13	1 month	Sabal ser- MT	OM
67	28	63	21	1 month	Senecio- MT	OM
73	35	09	12	3 months	Ferrum Pic-6X	OM
87	40	32	16	2 months	Hydrangea- MT	OM
63	39	57	13	2 months	Chimaphilla- MT	OM
52	23	222	24	1 month	Senecio- MT	OM
63	31	131	31	1 month	Sabal ser- MT	OM
88	46	13	22	3 months	Baryta Carb-0/1 to 0/6	CM
86	55	10	24	1 month	Staph-1M	CM
76	61	173	28	1 month	Staph-1M	CM
57	64	55	22	1 month	Staph-0/1 to 0/3	CM
80	28	12	08	2 months	Sulph-0/1-0/4	CM

Table 3 Effects of homeopathic treatment on patients with BPH

Groups	*IPPS*		*Prostate size (g)*		*RUV (mL)*		*Qmax (mL/sec)*		*Qavg (mL/sec)*	
	BT	*AT*	*BT*	*AT*	*BT*	*AT*	*BT*	*AT*	*BT*	*AT*
CM	14.26 ± 5.93	6.25 ± 5.33[c]	41.65 ± 22.90	41.85 ± 3.33[a]	70.43 ± 79.65	41.5 ± 40.44[b]	20.86 ± 8.99	28.06 ± 12.72[c]	9.31 ± 7.17	9.72 ± 5.31[a]
OM	15.70 ± 5.94	6.93 ± 5.31[c]	50.18 ± 23.64	53.58 ± 3.03[a]	104.28 ±131.44	64.67 ± 95.63[b]	17.26 ± 7.51	25.90 ± 13.33[c]	6.40 ± 3.11	6.90 ± 3.16[a]
BCOM	16.97 ± 6.19	6.47 ± 4.29[c]	47.08 ± 25.92	45.65 ± 6.66[a]	77.95 ± 77.46	40.52 ± 46.05[c]	18.19 ± 5.04	31.79 ± 12.23[c]	7.07 ± 3.66	9.07 ± 2.87[c]

Data are presented as mean ± SD. [a]Small, [b]medium, [c]large effect sizes (Cohen's *d* value) between before treatment (BT) and after treatment (AT). $n = 60$ in all cases except Qmax and Qavg where $n = 38$ for CM, $n = 32$ for OM and $n = 45$ for BCOM groups.

Table 4 Effects of OM, CM and BCOM on prostate weight, RUV and IPSS in benign prostate hypertrophy patients

Characteristics	*Improvement criteria*		*CM*		*OM*		*BCOM*	
			BT	*AT*	*BT*	*AT*	*BT*	*AT*
IPSS	Scored value	Mild (0–7)	09	44	09	42	04	40
		Moderate (8–19)	36	13	31	15	37	19
		Severe (20–35)	15	03	20	03	19	01
Prostate size	Prostate volume (converted into weight)	Gr I (25–34 g)	36	39	19	21	26	29
		Gr II (35–49 g)	11	09	18	18	17	15
		Gr III (50–74 g)	08	07	20	18	10	09
		Gr IV (>75 g)	05	05	03	03	07	07
RUV	Urine volume	>200 ml	07	03	06	04	05	01
		100–200 ml	05	04	14	03	12	05
		30–100 ml	22	18	25	15	25	18
		<30 ml	26	35	15	38	18	36

Data are presented as number of patients in each group before treatment (BT) and after treatment (AT) time points.

and four in the BCOM group with residual urine >200 mL exhibited remarkable improvement. The percentage who reverted to normal RUV in OM, CM and BCOM groups were 153, 35 and 100%, respectively. A 41, 38 and 48% decrease in RUV was observed in CM, OM and BCOM groups, respectively. The effect sizes (Cohen's *d* value) for CM, OM and BCOM for prostate were −0.46, 0.43 and −0.59, respectively (Table 6). Qmax and Qavg values improved in all the groups. The increase in Qmax was 38, 50 and 75% in CM, OM and BCOM groups, respectively. Cohen's *d* values for Qmax were 0.66, 0.80 and 1.47 in CM, OM and BCOM groups, respectively. Similarly, 4, 8 and 28% increase in Qavg value was observed in CM, OM and BCOM groups, respectively. Cohen's *d* values for Qavg were 0.07, 0.16 and 0.62 in CM, OM and BCOM groups, respectively.

Overall change: The results of the present study show that of 60 patients receiving CM, around 12% patients showed marked improvement, 60% showed moderate improvement, 22% showed mild improvement and only 6% patient showed no improvement. In OM group, out of 60 cases, 10% patients showed marked improvement, 58% showed moderate improvement, 27% showed mild improvement and only 5% showed no improvement. In the

Table 5 Effects of regimes in terms of positive and negative response. Mild and no improvement cases were designated as no response

Groups	*Positive response*	*Total*	*POS*
CM	43[a]	60	0.71
OM	41[a]	60	0.68
BOCM	52[b]	60	0.86
Total	136	180	0.75

Data are presented as numbers of patients in the respective groups. POS = proportion of success. Different superscripts indicate that data are statistically (χ^2 and *Z*-test) significant at 5% level ($Z < 1.96$ and $\chi^2 > 3.841$ for $n = 60$, $N = 120$) between the two compared groups.

Table 6 Cohen's *d* value for effect sizes by group and outcome measure

Group	*PW*	*RUV*	*IPSS*	*Qmax*	*Qavr*
CM	0.01	−0.46	−1.43	0.66	0.07
OM	0.20	−0.43	−1.57	0.80	0.16
BCOM	−0.08	−0.59	−1.99	1.47	0.62

PW = prostate weight, RUV = residual urine volume, IPSS = international prostate symptom score, Qmax = maximum urinary flow rate, Qavr = normal average urinary flow rate.

BCOM group of 60 patients, 15% showed marked improvement, 72% cases showed moderate improvement, 10% showed mild improvement and 2% patients showed no improvement.

Relative effectiveness of the three treatment schedules

Table 5 shows the proportion of the success in terms of positive and negative response of the medicines. It was found that the proportion of positive response was significantly higher in BCOM group than the other two groups. The proportion was 0.86, 0.71 and 0.68 in BCOM, CM and OM groups, respectively. The Chi-square values for the association between CM and OM, between CM and BCOM and between OM and BCOM groups were 0.158, 4.092 and 5.78, respectively. This signifies that there is no significant association between CM and OM groups of medicines and their effects. But a strong association exists between CM and BCOM and between OM and BCOM groups. Similarly, *Z*-test revealed that *Z* value between CM and OM, between OM and BCOM and between CM and BCOM groups were 0.397, −2.44 and −2.054, respectively. This signifies that there is no significant difference exists in efficacy between CM and OM groups while the efficacy of the BCOM groups is significant higher than the other two groups. Cohen's *d* values for effect sizes were highest in case of BCOM group in comparison to CM and OM groups for RUV and IPSS scores (Table 6).

Medicines prescribed

The numbers of prescriptions for each of the medicines and the distribution of potencies prescribed are given in Table 7.

Discussion

The present study aimed to compare organopathic (OM), constitutional (CM) homeopathic medicines alone, or in combination (BCOM) in the treatment of BPH of cases. Cristoni *et al.*[1] reported that after the age of 45 years, the prostate may undergo benign hyperplasia. Similarly, Caprino[2] opined that susceptibility of BPH in male starts at 45−50 years old and progressively involves 75% of the male population over 75 years age. The present study also supports the above fact that men of age group 60−69 were more prone to BPH followed by age group of 50−59 and 70−79 years.

Table 7 The number of prescriptions and potencies of homeopathic medicines prescribed in the study

Medicines	*CM group*		*OM group*		*BCOM group*	
	NP	*Potencies*	*NP*	*Potencies*	*NP*	*Potencies*
Thuja occidentalis	17 (10.17)	0/1-0/22, 200C, 1M, 10M, 50M	–	–	26 (17.21)	0/1-0/36, 1M, 10M, 50M
Conium maculatum	06 (3.59)	0/1-0/5, 200C, 1M, 10M, 50M	–	–	07 (4.63)	200C, 1M, 10M
Sulphur	18 (10.77)	0/1-0/20, 200C, 1M	–	–	18 (11.92)	0/1-0/17, 200C, 1M
Lycopodium clavatum	17 (10.17)	0/1-0/26, 1M	–	–	13 (8.60)	0/1-0/17, 1M
Staphysagria	24 (14.37)	0/1-0/20, 1M, 10M	–	–	23 (15.23)	0/1-0/24, 1M, 10M
Iodium	01 (0.59)	30C	–	–	00 (0.00)	–
Pulsatilla	19 (11.37)	0/1-0/12, 1M, 10M	–	–	08 (5.29)	0/1-0/20, 30C
Mercurius solubilis	05 (2.99)	0/1-0/13, 30C, 1M	–	–	03 (1.98)	0/1-0/16
Baryta carbonica	01 (0.59)	0/1-0/10	–	–	03 (1.98)	0/1-0/7, 30C, 200C, 1M
Natrium muriaticum	03 (1.79)	0/1-0/8, 1M	–	–	02 (1.32)	0/1-0/4, 1M
Lyssin	04 (2.39)	0/1-0/6	–	–	03 (1.98)	0/1-0/4, 200C
Tuberculinum bovinum	08 (4.79)	0/1-0/6, 200C, 1M	–	–	06 (3.97)	0/1-0/16, 200C, 1M, 10M
Calcarea carbonica	04 (2.39)	0/1-0/8, 200C, 1M	–	–	06 (3.97)	0/1-0/19, 1M
Gelsemium sempervirens	01 (0.59)	0/1-0/9	–	–	05 (3.31)	0/1-0/12, 200C, 1M, 10M
Nux vomica	07 (4.19)	0/1-0/18	–	–	04 (2.64)	0/1-0/4, 30C, 1M
Sepia officinalis	05 (2.99)	0/1-0/16	–	–	04 (2.64)	0/1-0/16, 1M
Causticum	03 (1.79)	0/1-0/14	–	–	01 (0.66)	200C
Medorrhinum	01 (0.59)	0/1-0/4	–	–	01 (0.66)	0/1-0/2
Argentum nitricum	03 (1.79)	0/1-0/3, 200C, 1M	–	–	02 (1.32)	0/1-0/10, 1M
Phosphorus	05 (2.99)	0/1-0/29, 1M	–	–	03 (1.98)	0/1-0/18, 200C
Nitricum acidum	04 (2.39)	0/1-0/18, 1M	–	–	03 (1.98)	0/1-0/9
Selenium	02 (1.18)	0/1-0/8, 1M	–	–	01 (0.66)	0/1-0/4
Carcinosin	09 (5.38)	0/1-0/13, 200C	–	–	09 (5.96)	0/1-0/15, 200C
Sabal serrulata	–	–	28 (44.58)	MT	31 (34.44)	MT
Hydrangea arborescens	–	–	11 (15.94)	MT	10 (11.11)	MT
Chimaphilla umbellata	–	–	07 (10.14)	MT	14 (15.55)	MT
Solidago vigra	–	–	02 (2.90)	MT	05 (5.55)	MT
Senecio aureus	–	–	06 (8.70)	MT	11 (12.22)	MT
Triticum repens	–	–	05 (7.25)	MT	04 (4.44)	MT
Ferrum picricum	–	–	09 (13.04)	6X	10 (11.11)	6X
Picric acid	–	–	01 (1.45)	6C	05 (5.55)	6C

NP = number of patients (%).

The results of the present study revealed that the number of negative improvement was least in BCOM group. It suggests that prescription of BCOM for BPH patients gives better result than CM or OM alone. Fortunately, no aggravation cases or adverse effects were complained by any of the patients after or during treatment schedule indicates homeopathic medicines as a promising alternative for treatment of BPH patients.

Three parameters: RUV, size of the prostate and IPSS were taken into account for assessment. IPSS is a subjective assessment based on patient reported symptoms. Other outcome measures are objective ones based on ultrasound findings and uroflowmetry. IPSS scoring suggests that BCOM groups showed more improvement than the CM and OM groups. Patients scoring 'severe' on IPSS showed remarkable improvement in BCOM groups in comparison to CM and OM. Of 121 patients having RUV more than normal (>30 mL), 50 reverted to the normal range after treatment.

No significant improvement in any of group occurred with respect to size of the prostate gland. It may be inferred that homeopathic treatment has no effect on the histoarchitecture of the gland in BPH. However there was a small, statistically non-significant reduction in prostate size in the BCOM group which may warrant further investigation. Other objective measures: RUV, Qmax and Qavg showed significant improvement, as did the IPSS scores. The reason for this disparity is not clear.

Limitations

A key weakness of this study is that it was not randomized, instead it used sequential allocation. Although no significant differences were observed between the groups in baseline data of the patients, it is possible that there were other, unrecorded between-group differences. The non-significantly longer treatment period in the BCOM group could have influenced the better improvement in this group in comparison to CM and OM groups.

Conclusions

Our results suggest that homeopathic combined constitutional and organopathic treatment has a greater beneficial effect on patients with BPH than either constitutional or organopathic treatment alone, in terms of subjective parameters, residual volume, uroflowmetry, although not in terms of prostate weight, estimated by ultrasonography. Further, randomized, studies of different homeopathic treatment strategies for BPH should be performed.

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References

1 Cristoni A, Di Pierro F, Bombardelli E. Botanical derivatives for the prostate. *Fitoterapia* 2000; **1**: S21−S28.
2 Caprino L. Drugs for the treatment of benign prostatic hypertrophy. *Minerva Urol Nefrol* 2000; **52**(2): 87−92.
3 Semino AM, Lozano OJL, Garcia CE, Tejeda BE, Romero RF. Symptomatic treatment of benign hypertrophy of the prostate. Comparative study of *prazosin* and *serenoa repens*. *Arch Esp Urol* 1992; **45**(3): 211−213.
4 Paubert-Braquet M, Richardson FO, Servent-Saez N, *et al*. Effect of *Serenoa repens* extract (Permixon) on estradiol/testosterone-induced experimental prostate enlargement in the rat. *Pharm Res* 1996; **34**(3−4): 171−179.
5 Paubert-Braquet M, Mencia HJM, Cousse H, Braquet P. Effect of the lipidic lipidosterolic extract of *Serenoa repens* (Permixon) on the ionophore A23187-stimulated production of leukotriene B4 (LTB4) from human polymorphonuclear neutrophils. *Prostaglandins Leukot Essent Fatty Acids* 1997; **57**(3): 299−304.
6 Nix JW, Carson CC. Medical management of benign prostatic hypertrophy. *Can J Urol* 2007; **1**: 53−57.
7 Stamatiou K. Management of benign prostatic hypertrophy-related urinary retention: current trends and perspectives. *Urol J* 2009; **6**(4): 237−244.
8 Mantovani F. *Serenoa repens* in benign prostatic hypertrophy: analysis of 2 Italian studies. *Minerva Urol Nefrol* 2010; **62**(4): 335−340.
9 Murphy RND. *Homoeopathic medical repertory.* New Delhi, India: B. Jain Publishers (P) Ltd, 1998, p. 1246.
10 Schroyens F. *Synthesis repertorium syntheticum*. New Delhi, India: B. Jain Publishers (P) Ltd, 2005, p. 970.
11 Knerr CB. *Repertory of Hering's guiding symptoms of our Materia Medica*. New Delhi, India: B. Jain Publishers (P) Ltd, 2002, p. 625.
12 Kent JT. *Kent's repertory of the homoeopathic Material Medica*. New Delhi, India: B. Jain Publishers (P) Ltd, 2004, p. 625.
13 Boericke W. *Organon of Medicine*. New Delhi, India: B. Jain Publishers (P) Ltd, 2004, p. 220.
14 Barry MJ, Fowler FJ Jr., O'Leary MP, *et al*. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J Urol* 1992; **148**(5): 1549−1557.