# **Original Article**

# Role of homoeopathic medicines in prostate enlargement: A retrospective observational study

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# **Abstract**

**Background:** Prostatic enlargement (prostatomegaly) is a common condition in aging men which can be progressive and lead to acute urinary retention and ultimately need for surgery. Although clinical evidence of disease occurs less commonly, symptoms of prostatic obstruction are also age related and if untreated affect quality of life. Patients with huge prostatic enlargement mostly undergo surgical intervention. **Objective:** To assess the usefulness of homoeopathic medicines in patients with huge prostatomegaly, a clinical study was conducted at Gaurang Clinic and Centre for Homoeopathic Research, Lucknow, India. **Materials and Methods:** A total of 116 patients have been shortlisted with prostate weight above 50 g, out of which 61 were found fit for the study. The medicines have been selected on the basis of principles of Homoeopathy. Prostate weight and postvoid residual urine (PVRU) on ultrasonography were assessed before and after treatment. **Results:** After comparing pre- and post-treatment results, the difference in mean values of prostate weight and PVRU were  $67.47 \pm 2.78-60.15 \pm 3.62$  (P < 0.001) and  $91.61 \pm 11.91-65.94 \pm 9.01$  (P = 0.009), respectively, which were found statistically significant. *Lycopodium* (n = 21), *Pulsatilla* (n = 7), and *Nux vomica* (n = 3) were found to be most useful medicines. **Conclusion:** Results obtained from the study are encouraging with findings that almost 64% of patients reduced their prostatic weight significantly. However, such study with inclusion of more parameters is needed for further validation of the role of homoeopathic medicines.

Key words: Homoeopathy, Lycopodium, Post void residual urine volume, Prostate weight, Prostatomegaly, Pulsatilla, Retrospective study

# INTRODUCTION

Prostatic enlargement (prostatomegaly) is one of the most common conditions in elderly men. This condition is rarely life-threatening but often affects the individual's quality of life in varying degrees. As men age, the incidence of prostatomegaly increases. Autopsy data indicate that over 90% of men >80 years of age have histological evidence of benign enlargement of the prostate.<sup>[1]</sup>

About 75% of men >50 years of age have symptoms arising due to prostatic enlargement and 20%–30% of men reaching 80 years of age require surgical intervention for its management. [2,3] It affects the quality of life similar to other chronic diseases such as diabetes mellitus, hypertension, and heart disease. [4,5] Even depression of mood is supposed to occur more in patients of prostatomegaly. [6] Patients with classical symptoms of prostatic enlargement are treated with  $\alpha$ -blockers to relieve in lower urinary tract symptoms. Even  $\alpha$ -blockers in combination with 5  $\alpha$ -reductase inhibitor are able to decrease the disease up to some extent, but their cost-effectiveness is still questionable [7] and even

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Website:
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DOI:
10.4103/0974-7168.194323

their prolonged use can cause sexual dysfunction and ultimately affects quality of life. [8] Surgical interventions, though beneficial, are costly and have their own complications. [9,10] Prevention of disease progression is one of the main goals of treatment.

Homoeopathy is based on natures law of cure which implies "A weaker dynamic affection is permanently extinguished in the living organism by a stronger one, if the latter (whilst differing in kind) is very similar to the former in its manifestations" means that the similar remedy is able to cure the patient because in nature too it has been observed that a weaker disease is automatically removed if the same patient contracts a similar but stronger disease. [11] Today, Homoeopathy is the 2<sup>nd</sup> most used health-care system in the world. [12]

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 $\label{eq:how-to-cite-this-article:} How to cite this article: \mbox{ Gupta G, Singh S. Role of homoeopathic medicines in prostate enlargement: A retrospective observational study. Indian J Res Homoeopathy 2016;10:266-71.}$ 

Gupta *et al.*<sup>[13,14]</sup> published their clinical work on benign prostatic hyperplasia and had shown the usefulness of homoeopathic medicines. Patients with more than 20 g of prostate in ultrasonography were enrolled in the study, and prostate weight was the only parameter for assessment of treatment. No literature is available on role of homoeopathic medicines in patients with enlarged prostate with more than 50 g of weight so far in which two parameters, i.e., prostate weight and postvoid residual urine (PVRU), have been taken together. Taking presence and severity of symptoms into consideration, cases of huge enlargement of the prostate mostly undergo surgical intervention. Drug treatment can defer surgical intervention in prostatomegaly and is widely practiced.

### **Objective**

To assess the usefulness of homoeopathic medicines in patients with huge prostatomegaly, a clinical study was conducted at Gaurang Clinic and Centre for Homoeopathic Research, Lucknow, India.

# MATERIALS AND METHODS

The study was conducted at Gaurang Clinic and Centre for Homoeopathic Research, Lucknow. Cases were shortlisted from the outpatient department record files from April 1995 to June 2015.

To assess the status of progression of disease, per abdominal ultrasonography for prostate weight and PVRU volume was done at registration and after every 3 months till the patient continued treatment.

More than 50 g of prostate weight on ultrasonography was the only inclusion criterion for the study.

A total of 667 cases of benign prostatic hyperplasia screened during the period, out of which 116 patients have been shortlisted with more than 50 g of prostate weight on ultrasonography. Rest 551 cases excluded due to prostatic weight <50 g on ultrasonography. Out of 116 who have been shortlisted, 61 found fit for the study as their pre- and post-treatment ultrasonography reports were kept safe in files [Figure 1].

Out of 55 patients who were dropped out, 22 were excluded due to unavailability of pre- or post-ultrasonography reports (though their case file was complete and findings were written manually) and 33 were excluded due to unavailability of PVRU volume in either pre- and/or post-treatment ultrasonography reports provided by an ultrasonologist.

The age of all 61 patients shortlisted for the study at the time of registration ranged from 50 to 86 years with mean ( $\pm$  standard error [SE]) of 66.66  $\pm$  1.07 years.

The selection of constitutional medicine was done by repertorizing the rubrics obtained from life space investigation guided by totality of presenting signs and symptoms on the basis of "Principle of Similia,"<sup>[11]</sup> using complete repertory with the help of Hompath Classic software in every case.<sup>[15]</sup>

Selected constitutional medicine was dispensed in 30C, 200C, and 1000C potency according to the need of individual case, followed by placebo twice daily. *Sabal serrulata* mother tincture was given in every case due to its unquestioned value in prostatic enlargement.<sup>[16]</sup> A periodic biweekly or monthly follow-up of the cases was done till entire duration of treatment. The repetition of dose of selected medicine/second prescription was based on the response of the patient to the first prescription as mentioned in Kent's 12 observations.<sup>[17]</sup>

The average follow-up period of the whole study was 228 days, with mean ( $\pm$  SE) of 311.90  $\pm$  31.42 days. Taking the views from ultrasonologists, changes more than 2 g in pre- and post-treatment prostate weight was considered for assessment of treatment. Decrease and increase of prostate weight more than 2 g in posttreatment ultrasonography reports in comparison to pretreatment report were considered as case of improvement and worsened, respectively, while changes within 2 g were considered as status quo.

# **Statistical Analysis**

Data were summarized as mean  $\pm$  SE. Pre- and post-treatment data were compared by paired *t*-test. A two-tailed P < 0.05 was considered statistically significant. Analyses were performed on IBM SPSS Statistics software (Windows version 17.0).

# RESULTS

The pre- and post-treatment prostate weight and PVRU of all 61 patients are summarized in Table 1. Paired t-test for the difference in mean of pre- and post-treatment prostate weight was found statistically significant (P < 0.001). Difference in mean of pre- and post-treatment PVRU also was found statistically significant (P < 0.009). After treatment, both prostate weight and PVRU were found to be decreased. On comparing, paired t-test showed significant decrease in both mean weight (10.9%) (mean  $\pm$  SE:  $67.47 \pm 2.78$  vs.  $60.15 \pm 3.62$ , mean difference [MD] =  $-7.32 \pm 1.91$ , t = 3.83, P < 0.001) and PVRU (28.0%) (mean  $\pm$  SE:  $91.61 \pm 11.91$  vs.  $65.94 \pm 9.01$ , MD =  $-25.67 \pm 9.49$ , t = 2.70, P = 0.009).

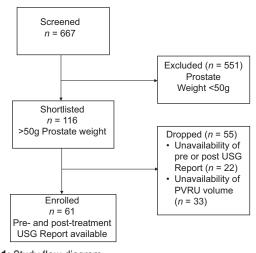


Figure 1: Study flow diagram

The age and duration of treatment of patients ranged from 50 to 86 years and 78 to 1288 days, respectively, with mean ( $\pm$  SE) of  $66.66 \pm 1.07$  years and  $311.90 \pm 31.42$  days, respectively, and median of 65 years and 228 days, respectively.

Out of 61 patients, 39 (63.89%) improved, 7 (11.48%) remained status quo, and 15 (24.6%) worsened.

The details of prescribed medicine are summarized in Table 2 which shows that two medicines were frequently prescribed to patients. These were *Lycopodium* (49.2%) and *Pulsatilla* (16.4%) accounting for 65.6% of the total medicines prescribed.

The data of patients who were dropped out are given below. Total number of patients was 22; the age and duration of treatment of patients ranged from 41 to 90 years and 20 to 1426 days, respectively, with mean ( $\pm$  SE) of  $70.82 \pm 2.60$  years and  $279.55 \pm 59.25$  days, respectively, and median of 74 years and 208 months, respectively.

After treatment in 22 cases, prostate weight decreased while PVRU increased. On comparing, paired t-test showed significant decrease (24.5%) in mean weight (mean  $\pm$  SE:  $66.11 \pm 2.82$  vs.  $49.90 \pm 4.12$ , MD =  $-16.21 \pm 3.16$ , t = 5.13, P < 0.001). However, mean PVRU did not differ between the two periods (mean  $\pm$  SE:  $118.78 \pm 31.17$  vs.  $122.88 \pm 24.39$ , MD =  $4.10 \pm 34.84$ , t = 0.12, P = 0.908), rather it increased by 3.3%.

At final evaluation of 22 patients, 18 (81.8%) showed improvement, 2 (9.1%) patients worsened, and 2 (9.1%) remained status quo.

# DISCUSSION

This was a retrospective study which has shown positive results in both diagnostic parameters of prostatomegaly, i.e., weight of prostate and PVRU.

This was a unique type of work in Homoeopathy as patients having enlarged prostate more than 50 g on ultrasonography have been included in the study. In the present study, the mean  $\pm$  SE of the first parameter (prostate weight) at entry and end of follow-up was  $67.47 \pm 2.78$  and  $60.15 \pm 3.62$ , respectively. The result showed decrease of 10.9% in prostate weight which is statistically highly significant (P < 0.001). Similarly, the means ( $\pm$  SE) of PVRU at entry and the end of follow-up were  $91.61 \pm 11.91$  and  $65.94 \pm 9.01$ , respectively. This also showed decrease of 28% in PVRU which is also statistically significant (P = 0.009). The results support the fact that homoeopathic medicines are useful in reducing the prostate weight and PVRU in cases of prostatomegaly.

In the previous work of Gupta et~al., [18,19] both parameters, prostate weight and PVRU, were decreased after homoeopathic treatment; however, in the present study, pre- and post-treatment difference in prostate weight is statistically more significant (P < 0.001) as it was only significant decrease in previous studies (P < 0.01) by Gupta et~al. [17,18] and (P = 0.005) by Oberai et~al. [20] Similarly, pre- and post-treatment changes in PVRU were not statistically significant (P > 0.05) in the previous studies by Gupta et~al. [18,19] and (P = 0.06) by Oberai et~al. [20] while it is statistically significant (P = 0.009) in the present study. Constitutional medicine along with organopathic medicine may be the reason for better results as it was prescribed in every case in the present

Table 1: Pre- and post-treatment status (mean  $\pm$  standard error, n=1) P **Outcome measures Pretreatment** Post-treatment Change (post-pre) Paired (t) Weight (g) 67.47±2.78 (51-152) 60.15±3.62 (7-166) -7.32±1.91 (-44-30) 3.83 < 0.001 PVRU (ml) 91.61±11.91 (0-400) 65.94±9.01 (0-390)  $-25.67\pm9.49$  (-390-150) 2.70 0.009

SE: Standard error, PVRU: Postvoid residual urine

Medicines	Number of patients (%)	Response of medicine		
		Improvement	Status quo	Worsened
Acid phos	1 (1.6)	1	0	0
Arsenic album	4 (6.6)	2	0	2
Calcarea carb	4 (6.6)	1	1	2
Carcinosin	1 (1.6)	1	0	0
Causticum	1 (1.6)	0	0	1
Lycopodium	30 (49.2)	21	5	4
Natrum muriaticum	4 (6.6)	1	1	2
Nux vomica	3 (4.9)	3	0	0
Pulsatilla	10 (16.4)	7	0	3
Silicea	1 (1.6)	0	0	1
Thuja occidentalis	2 (3.3)	2	0	0

study.<sup>[21]</sup> Another reason for the better response in the present study may be of variable time frames of follow-up according to the demand of case, whereas in the previous studies, this time was limited to 1 year only.

For clinical improvement status, International Prostate Symptom Score was assessed in every follow-up in the previous study by Gupta *et al.*,<sup>[17,18]</sup> while in the present study, it was not universally followed in every case hence not taken as parameter for clinical improvement though more than 75% patients reported improvement in classical symptoms such as increased frequency of urination, hesitancy, and urgency before urination.

The most useful trial medicines in this study were *Lycopodium* and *Pulsatilla*, which are common to the constitutional medicines used in the previous studies by Gupta *et al.*,<sup>[18,19]</sup> Oberai *et al.*,<sup>[20]</sup> and Reddy *et al.*<sup>[22]</sup> However, in the present study, *S. serrulata* mother tincture was also prescribed to the patients which was not used in the previous studies by Gupta *et al.*,<sup>[18,19]</sup> Oberai *et al.*,<sup>[20]</sup> and Reddy *et al.*<sup>[22]</sup>

The above findings suggest that addition of *S. serrulata* mother tincture with homoeopathic constitutional medicines produced better response to the treatment by not only checking but also reverting the progression of prostatic enlargement effectively.

# CONCLUSION

The outcome of this evidence-based study is encouraging. It proves that Homoeopathy can provide a safe, nonsurgical, and effective treatment to cases of huge prostatomegaly. However, randomized control trials are needed to further validate the role of homoeopathic medicines in case of huge prostatomegaly.

# **Financial Support and Sponsorship**

Nil

#### **Conflicts of Interest**

There are no conflicts of interest.

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#### Klinische Studie zur Prostatahyperplasie

Hintergrund: Eine Vergrößerung der Prostata (Prostatahyperplasie) ist bei älteren Männern häufig zu finden. Sie kann progressiv sein, zu akuter Harnverhaltung führen und schließlich einen operativen Eingriff nötig machen. Obwohl die Erkrankung sich klinisch weniger oft beweisen lässt, sind die Symptome der prostatabedingten Harnentleerungsstörung altersabhängig und beeinträchtigen unbehandelt die Lebensqualität. In aller Regel werden Patienten mit einer Prostatahyperplasie operativ behandelt.

**Ziel:** Um den Nutzen homöopathischer Arzneien in Patienten mit einer Prostatahyperplasie zu beurteilen, wurde eine Studie an der "Gaurang Clinic" und am "Centre for Homoeopathic Research" in Lucknow, Indien durchgeführt.

**Methode:** Insgesamt kamen 116 Patienten mit einem Prostatagewicht von über 50 Gramm in die engere Wahl. Davon wurden 61 für die Studie ausgewählt. Die Arzneien wurden nach den Grundsätzen der Homöopathie ausgewählt. Prostatagewicht und Restharnmenge (PVRU) wurden vor und nach der Behandlung mittels Ultraschall bestimmt.

**Ergebnisse:** Der Vergleich der Resultate vor und nach den Behandlung zeigte Unterschiede, die eine statistische Relevanz zeigen in der Prostatagröße und bei der Restharnmenge  $67,47 \pm 2,78 - 60,15 \pm 3,62$  (p<0,001) und  $91,61 \pm 11,91 - 65,94 \pm 9,01$  (p=0,009). *Lycopodium* (n=21), *Pulsatilla* (n=7), *Nux vomica* (n=3) zeigten sich als die nützlichsten Mittel.

**Fazit:** Die Ergebnisse der Studie sind ermutigend und zeigen, dass sich bei fast 64% der Patienten das Prostatagewicht signifikant reduzierte. Studien dieser Art mit mehr Parametern sind zur weiteren Validierung der Rolle homöopathischer Arzneien nötig.



# Hipertrofia prostática enorme- Estudio clínico RESUMEN

**Fundamento:** El engrosamiento de la próstata (prostatomegalia o hipertrofia prostática) es una patología habitual en varones de edad avanzada que puede progresar y dar lugar a una retención urinaria aguda, por lo que, al final, se hace necesario intervenir quirúrgicamente. Si bien la evidencia clínica de la enfermedad es menos frecuente, los síntomas de la obstrucción prostática también están relacionados con la edad y, si no se tratan, pueden afectar a la calidad de vida los pacientes con una hipertrofia prostática enorme han de someterse en su mayoría a una intervención quirúrgica.

**Objetivo:** Evaluar la utilidad de los medicamentos homeopáticos en pacientes con una hipertrofia prostática importante. Se realizó un estudio clínico en la Clínica Gaurang y enel Centro de Investigación Homeopática, Lucknow, India.

**Métodos:** Un total de 116 pacientes fueron preseleccionados por un peso prostático por encima de 50 gramos. 61 de estos pacientes cumplían los criterios para ser incluidos en el estudio. Los medicamentos se selecionaron conforme a los principios de la homeopatía. Antes y después del tratamiento se evaluaron el peso prostático y la orina residual postmiccional (ORPM) por ecografía..

**Resultados:** Tras comparar los resultados pre y post-tratamiento, la diferencia en los valores medios del peso prostático y la ORPM fueron de  $67,47 \pm 2,78 - 60,15 \pm 3,62(p<0,001)$  y de  $91,61 \pm 11,91-65,94 \pm 9,01(p=0,009)$  respectivamente, lo que fue estadísticamente significativo. Los medicamentos más útiles fueron *Lycopodium*(n=21), *Pulsatilla* (n=7) y *Nux vomica* (n=3).

**Conclusiones:** Los resultados obtenidos en el estudio han sido muy alentadores ya que en casi un 64 % de los pacientes se redujo significativamente el peso de la próstata. Sin embargo, es necesario incluir más parámetros para seguir validando la función de los medicamentos homeopáticos.

# प्रोस्टेट में विशालकाय वृद्धि -एक नैदानिक अध्ययन

पृष्ठभूमिः वृद्धावस्था के साथ प्रोस्टेट में वृद्धि पुरुषों में एक सामान्य स्थिति है जोकि बढ़ती जा सकती है और तीव्र मूत्र प्रतिधारण की समस्या और अंत में शल्य चिकित्सा की आवश्यकता उत्पन्न कर सकती है। यद्यपि रोग का नैदानिक साक्ष्य कम ही देखने में आते हैं, प्रोस्टेट की रुकावट के लक्षण भी आयु संबंधी होते हैं और अगर चिकित्सा न की जाए तो जीवन की गुणवत्ता पर भी प्रभाव डाल सकते हैं। प्रोस्टेट में विशालकाय वृद्धि के रोगी को अधिकतर शल्य चिकित्सा का सहारा लेना पड़ता है।

**उद्देश्यः** प्रोस्टेट में विशालकाय वृद्धि के रोगियों में होम्योपैथी की उपयोगिता के आंकलन के लिए, गौरांग क्लिनिक और होम्योपैथी शोध केंद्र, लखनऊ, भारत में एक नैदानिक अध्ययन आयोजित किया गया।

पद्धति/विधिः कुल 116 रोगियों को छांटा गया जिनके प्रोस्टेट का भार 50 ग्राम से अधिक था, उनमें से 61 अध्ययन के लिए उपयुक्त पाए गए. औषिधयों का चयन होम्योपैथी के सिद्धांतों के आधार पर किया गया। चिकित्सा से पूर्व और पश्चात अल्ट्रासोनोग्राफी पर प्रोस्टेट के भार और रिक्ति पश्चात शेष मूत्र पोस्ट वोयड रेजीड्यूल यूरिन (पीवीआरयू), का आंकलन किया गया।

**परिणाम:** चिकित्सा के पूर्व और पश्चात के परिणामों की तुलना के बाद, प्रोस्टेट भार और पीवीआरयू के औसत मूल्य का अंतर क्रमशः  $67.47 \pm 2.78 - 60.15 \pm 3.62$  (पी < 0.001) और  $91.61 \pm 11.91 - 65.94 \pm 9.01$  (पी = 0.009), था जोकि सांख्यिकीय रूप से महत्वपूर्ण पाया गया। लाइकोपोडियम (सं=21) पल्साटिल्ला (सं=7) तथा नक्स वोमिका (सं=3) को सबसे कारगर औषधियों के रूप में पाया गया।

निष्कर्षः इस जांच-परिणाम के साथ कि लगभग 64 प्रतिशत रोगियों के प्रोस्टेट भार में उल्लेखनीय कमी आई, इस अध्ययन के परिणाम उत्साहजनक हैं। फिर भी, होम्योपैथी औषधियों की भूमिका की आगे पृष्टि हेत् अधिक मानकों को शामिल कर ऐसे अध्ययन की आवश्यकता है।

