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Research Article

EFFECT OF *TRIKATVADI GUDIKA* ALONG WITH *GOKSHURA KWATHA* IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA - A PRE POST STUDY

Aswathy Krishnan[1]*, Deepa M S[2], Aneesh S[3]

*[1]PG Scholar, [2]Professor, Department of Shalyatantra, Government Ayurveda College, Thiruvananthapuram
[3]Professor & HOD, Department of Shalyatantra, Government Ayurveda College, Kannur, Kerala, India.

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ABSTRACT

Benign Prostatic Hyperplasia (BPH) is a non-malignant enlargement of the prostate gland leading to lower urinary tract symptoms (LUTS) in aging men. Conventional management involves alpha-blockers, 5-alpha reductase inhibitors and surgical procedures such as TURP, each with limitations and side effects. In Ayurveda, BPH can be correlated to *Mutraghata*, specifically *Mutragranthi* and *Vatashteela*, characterized by obstruction to urine flow and enlargement in the prostatic region. There are various *Yogas* mentioned for *Mutraghata* in Ayurvedic classics. One among them is administration of *Trikatvadi Gudika* along with *Gokshura Kwatha* which is explained in *Mutrakrichradhikara* of *Bhavaprakasa.* **Objectives:** To evaluate the effect of *Trikatvadi Gudika* along with *Gokshura Kwatha* in the management of Benign Prostatic Hyperplasia. **Materials and Methods**: An interventional single-arm open clinical trial was conducted in 25 male participants aged 41–75 years diagnosed with BPH based on clinical and ultrasonographic criteria. Patients were administered *Trikatvadi Gudika* (1.5 g) along with *Gokshura Kwatha* (48ml) and 6ml honey as *Anupana*, twice daily before food for 30 days. Follow-up was done for 30 days after treatment period. Assessment parameters included International Prostate Symptom Score (IPSS), prostate volume and post-void residual urine (PVRU). Data were analyzed using Wilcoxon signed-rank test and paired t test. **Results:** Significant reductions were observed in mean IPSS score, mean prostate volume and mean PVRU and no adverse effects were reported. **Conclusion:** *Trikatvadi Gudika* along with *Gokshura Kwatha* is effective and safe in reducing prostate enlargement and LUTS in BPH, highlighting a cost-effective conservative management option.

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a non-malignant enlargement of the prostate gland, characterized by proliferation of both epithelial and stromal cells within the periurethral zone. This enlargement typically leads to compression of the urethra, resulting in bladder outlet obstruction (BOO) and subsequent lower urinary tract symptoms (LUTS) such as weak urinary stream, frequency, urgency, nocturia and incomplete bladder emptying. BPH affects predominantly ageing men and is among the most common benign tumors encountered in clinical urology. The prevalence of BPH rises sharply with age, with studies indicating approximately 20% of men aged 41-50 years, 50% of men aged 51-60 and up to 90% of men over 80 years are affected.[1] Pathophysiologically, BPH development is strongly influenced by hormonal factors, particularly dihydrotestosterone (DHT), converted from testosterone by the enzyme 5-alpha-reductase in prostate tissue. DHT interacts with androgen receptors to induce prostatic cellular proliferation and enlargement.[2] Clinical assessment of BPH currently relies on symptom evaluation using validated tools like the International Prostate Symptom Score (IPSS), digital rectal examination (DRE), and objective diagnostic imaging including ultrasonography and uroflowmetry. The primary therapeutic aim is symptom relief and quality of life improvement

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through pharmacological agents or surgical intervention when necessary.[3] Conventional treatments have limitations such as side effects and contraindications in certain patient populations, prompting the exploration of complementary and alternative medicine options. In Ayurveda, BPH can be correlated with *Mutraghata*, particularly its subtypes *Mutragranthi* and *Vatashteela*, due to similarities in clinical features and anatomical considerations. Ayurvedic management principles focus on the restoration of normal urinary flow and alleviation of dosha imbalances causing obstruction. This study investigates the effect of *Trikatvadi Gudika* along with *Gokshura Kwatha* in managing BPH. These formulations contain herbs with *Mutrala* (diuretic), *Lekhana* (scraping), *Vibandhahara* (relieving obstruction), and *Vastisodhaka* (clearing urinary tract) properties. The study aims to determine their impact on clinical symptomatology and objective prostate parameters.

OBJECTIVES

To evaluate the effect of *Trikatvadi Gudika* along with *Gokshura Kwatha* in reducing the symptoms (assessed by International Prostate Symptom score {IPSS}), size of prostate gland and post void residual urine (assessed by USG) in Benign Prostatic Hyperplasia.

MATERIALS AND METHODS

Study Design

Single group pre – post interventional study.

The consort flow diagram of the study is provided in Chart 1.

Study Setting

OPD and IPD of Department of *Shalyatantra*, Govt. Ayurveda College, Thiruvananthapuram.

Study Population

Male participants between the age group of 41 to 75 years having Benign Prostatic Hyperplasia fulfilling the inclusion and exclusion criteria attending the OPD and IPD of Department of *Shalyatantra*, Govt. Ayurveda College, Thiruvananthapuram, were taken for the study.

Selection Criteria

Inclusion Criteria

- Age between 41 to 75 years.
- Sex – Male
- Participants with signs and symptoms of BPH, diagnosis confirmed by USG- Abdomen and pelvis.
- Volume of prostate gland within 25 - 60 ml.
- Residual urine within 50- 100ml
- Participants with PSA level < 4ng/ml.

Exclusion Criteria

- Known case of bladder neck stenosis and urethral stricture.
- Known case of prostate cancer
- Catheterized persons
- Known cases of systemic diseases like tuberculosis, Hepatitis B, HIV, cardiac diseases and diabetes mellitus.

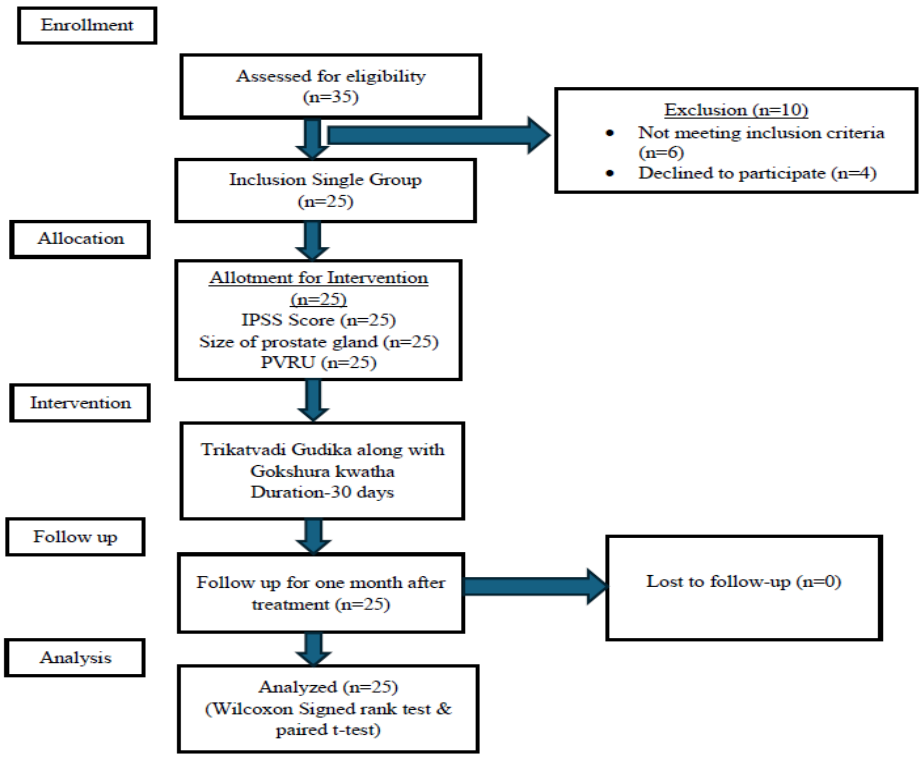


CHART 1: CONSORT FLOW CHART

Sample Size

25 participants were selected as per inclusion and exclusion criteria

Intervention

1.5g *Trikatvadi Gudika* mixed with 6ml of honey and taken along with 48ml *Gokshura Kwatha* at morning and evening before food for a period of 30 days and the effect was assessed.

Preparation of Drug

Trikatvadi Gudika

Ingredients and Measurements

Sunti (Rhizome), *Pippali* (fruit), *Maricha* (fruit), *Hareetaki* (fruit), *Bibhithaki* (fruit), *Amalaki* (fruit) and *Musta* (tuber) were taken in equal quantity and powdered. The *Sodhita guggulu* was also taken in quantity as that of other drugs. For that the quantity of raw *Guggulu* taken before the *Sodhana* procedure was decided based on the yield of *Guggulu* obtained after its *Sodhana* which was mentioned in previous research work.[4]

Figure 1: Ingredients of *Trikatvadi Gudika*

Preparation

- *Sodhana* of *Guggulu* was done by bounding the *Guggulu* in a cloth and then boiling in *Triphala kwatha* till the maximum portion of *Guggulu* enters into the liquid. The residue present in the bundle was discarded.[5]
- The liquid containing *Guggulu* was then heated until it acquired a thicker consistency.
- For the preparation of *Gudika*, powder of all the other drugs which was taken in equal quantities were added to the above mixture and stirred well. Then it is rolled into pills of 1.5 g size, dried and packed into tightly closed containers.

Figure 2: *Trikatvadi Gudika*

Figure 3: *Gokshura Kwatha Churna* in Packets

Preparation of *Gokshura Kwatha*

Dried fruits of *Gokshura* collected from a genuine source was crushed and dispensed in airtight packet of 48gm. Printed direction was given to the patient in regional language to make *Kashaya* each day by using 48gm of drug.

Kashaya preparing direction for one day- Take one packet of *Kashaya churna* (48gm), add 16 times of water (768ml) and reduce to 1/8th (96ml) in mild fire.[6] 48ml each was advised to be taken at morning and evening along with *Trikatvadi Gudika*.

Dose and Dosage Schedule

1.5gm *Trikatvadi Gudika* mixed with 6ml of honey and taken along with 48ml *Gokshura kwatha* at morning and evening before food for one month.

Study Duration

Total duration of study is 60 days (Treatment period-30 days and follow up period – 30 days)

Assessment

- Subjective assessment- 0th day, 15th day and 30th day. During follow up period - 45th day and 60th day.
- Objective assessment- 0th day and 30th day.
- Subjective assessment of participants- done by International Prostate Symptom Score (IPSS) System (Table no: 1)
- Objective assessment of participants – USG (Abdomen and Pelvis) was taken to assess the size of prostate gland and post void residual urine volume.

Table 1: International Prostate Symptom Score

Urinary symptoms	Not at all	Less than 1 in 5 times	Less than half the time	About half The time	More than half the time	Almost always
Incomplete emptying	0	1	2	3	4	5
Frequency	0	1	2	3	4	5
Intermittency	0	1	2	3	4	5
Urgency	0	1	2	3	4	5
Weak stream	0	1	2	3	4	5
Straining	0	1	2	3	4	5
	None	1 time	2 time	3 time	4 time	5 or more times
Nocturia	0	1	2	3	4	5

Total Score

Score 1-7 = Mildly symptomatic or asymptomatic

Score 8-19 = Moderately symptomatic

Score 20-35 = More severely symptomatic

Data Analysis

The quantitative variables were analysed using paired 't' test and the qualitative variables were analysed with Wilcoxon Signed Rank test.

Ethical Consideration

- Ethical clearance was obtained from the Institutional Ethics Committee, Government Ayurveda College, Thiruvananthapuram dated 12/10/2023 with Ref number IEC: 761-9/10/2023.
- Registration of the trial with Clinical Trials Registry of India (CTRI) was done prior to onset of study. Registration number is – CTRI/2024/09/092361.

OBSERVATIONS AND RESULTS

Data relating to clinical response

On analysing the data on IPSS Score, there were significant changes in symptoms both clinically and statistically. The mean score decreased from 24.5 at baseline (B.T) to 14.8 after treatment (A.T), and further to 9.64 at follow-up (A.F), indicating a marked reduction in symptom severity. The Wilcoxon signed-rank test results demonstrate highly significant improvements both immediately after treatment (A.T) and at follow-up (A.F) compared to baseline (B.T). In both comparisons, the Wilcoxon W value reached 325 with p-values less than 0.001, indicating that the reductions in IPSS scores were not only substantial but also statistically significant.

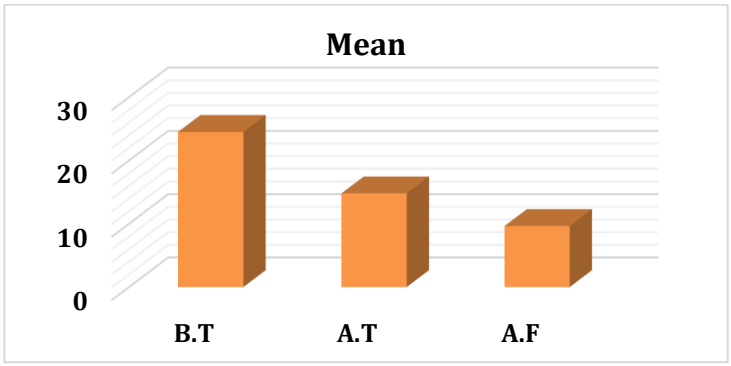
Table 2: Effectiveness on Overall IPSS Score

IPSS Score	Mean	S D
B T	24.5	4.63
A T	14.8	5.37
A F	9.64	5.20

Table 3: Wilcoxon Signed – Rank Test Results Comparison for Overall IPSS Score

Comparison		Statistic		P
BT	A T	Wilcoxon W	325	< .001
BT	A F	Wilcoxon W	325	< .001
Note. H_a $\mu_{\text{Measure 1 - Measure 2}} \neq 0$				

Graph 1: Change in Overall IPSS Score



Data relating to USG

Change in prostate volume was measured before and after treatment. Before treatment, the mean prostate volume was 46.7 cc with a standard deviation of 8.39. After treatment, the mean volume decreased to 38.2 cc with a standard deviation of 8.81. The paired t-test comparing prostate volume B.T and A.T yielded a statistically significant result, with a t-value of 6.27 and 24 degrees of freedom. The p-value was less than 0.001, indicating a highly significant difference between the two time points.

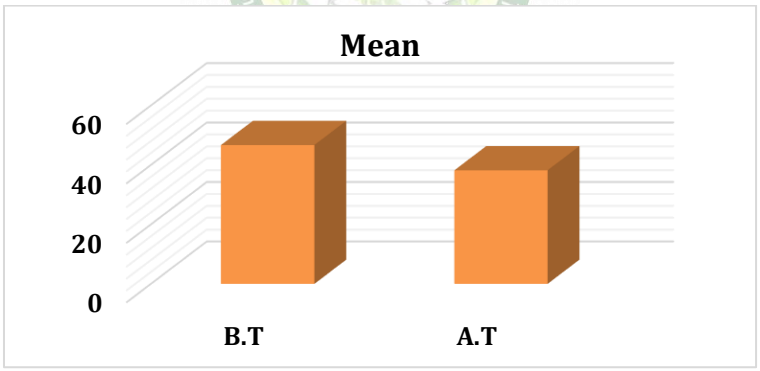
Table 4: Effectiveness on Prostate Volume

Prostate Volume	Mean	S D
BT	46.7	8.39
AT	38.2	8.81

Table 5: Paired T Test Results for Prostate Volume

		Statistic		DF	P
BT	AT	Student's t	6.27	24.0	< .001
Note. H_a $\mu_{\text{Measure 1 - Measure 2}} \neq 0$					

Graph 2: Change in Prostate Volume



The post void residual urine also decreased from 76.4 cc (B. T) to 52.9 cc (A.T). Although the standard deviation increased slightly (from 15.7 to 18.9), indicating more variability in post-treatment outcomes, the standard error remained relatively low, supporting the reliability of the mean estimates. The paired t-test comparing postvoid residual urine volume before and after treatment revealed a statistically significant reduction, with a t-value of 5.31 and 24 degrees of freedom.

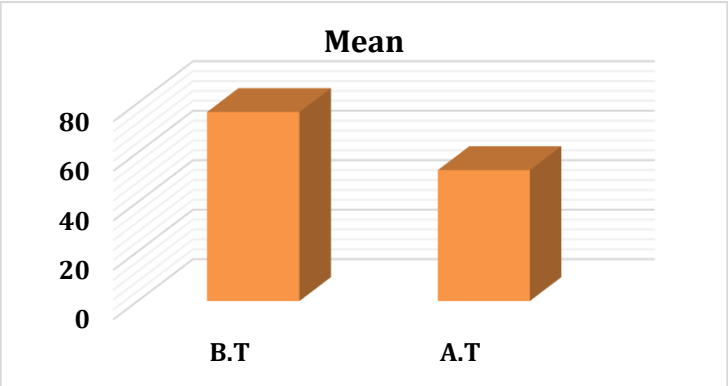
Table 6: Effectiveness on Post Void Residual Urine Volume

PVRU	Mean	S D
B T	76.4	15.7
A T	52.9	18.9

Table 7: Paired T Test Results for Post Void Residual Urine

			Statistic	DF	P
B T	A T	Student's t	5.31	24.0	< .001
Note. H_a $\mu_{\text{Measure 1 - Measure 2}} \neq 0$					

Graph 3: Change in Post Void Residual Urine



DISCUSSION

The results revealed significant improvement across all domains of IPSS. Every symptom domain showed substantial reduction in mean and median scores, and the grade distribution was shifted from severe baseline values to mild or no symptoms by completion of follow-up. Out of 25 participants, 22 patients showed a reduction in prostate size after treatment, 2 patients showed a mild increase in size (2 cc & 3 cc) after treatment and one patient had no change in prostate size. The average size of the prostate gland at baseline was 46.7 cc. After treatment, the mean size decreased to 38.2 cc, showing a clear reduction. Out of 25 participants, 21 patients showed a reduction in PVRU after treatment and 4 patients showed a mild increase in PVRU after treatment. Before treatment, the average post-void residual urine volume (PVRU) was 76.4 cc. After treatment, the average PVRU volume reduced to 52.9 cc, showing a clear improvement.

The *Nidanas* of BPH are similar to *Nidanas* of *Mutraghata* and *Mutrakrichra* and are attributed to an imbalance of *vata dosha*, specifically *Apana vaigunyam* which causes obstruction to the free flow of urine. *Trikatvadi gudika* is a combination of *Trikatu, Triphala, Musta* and *Guggulu.*[7]

Trikatu, composed of *Sunthi* (Zingiber officinale), *Maricha* (Piper nigrum) and *Pippali* (Piper longum), is characterized by *Katu rasa, Ushna veerya*, and *Tikshna–Sookshma guna* with *Kapha–vata hara* properties. These attributes enhance *Agni*, thereby improving digestion and metabolism. This in turn helps to minimize *Kapha* accumulation- a key factor contributing to the pathogenesis of Benign Prostatic Hyperplasia (BPH). Through its *Srotoshodhana* (channel-cleansing) and *Amapachana* (detoxifying) effects, *Trikatu* supports unobstructed urinary flow.[8] *Maricha* and *Pippali* are known to enhance bioavailability due to the presence of piperine. They also possess anti-inflammatory and smooth muscle relaxant actions, which may help to relieve bladder neck obstruction.

Haritaki exerts *Anulomana* action, facilitating toxin elimination and maintaining dosha balance, thus helping to relieve BPH-related symptoms. *Bibhitaki*, through its *Chedana* property, aids in the reduction of prostate size.[9] *Amalaki* functions as a *Rasayana*, nourishing the dhatus and maintaining tissue integrity. Its *Sheeta veerya* helps to soothe irritation in urinary pathways, easing symptoms like frequency and urgency. *Triphala* also contains β-Sitosterol, a phytosterol known to decrease prostate volume by modulating hormonal activity and inhibiting dihydrotestosterone (DHT) synthesis.[10]

Musta (Cyperus rotundus) possesses strong anti-inflammatory and *Sothahara* properties, helping to reduce stromal hyperplasia and glandular swelling. It promotes diuresis, aiding in the reduction of post-void residual urine (PVRU). By alleviating *Vata–Kapha* imbalance and clearing *Srotorodha* (obstructions), Musta enhances urinary flow, reduces frequency, and improves bladder emptying.[11]

Guggulu acts as *Kapha–Meda hara*, which assists in decreasing prostate enlargement. Its hypolipidemic activity contributes to the prevention of further glandular hyperplasia. Through its *Vatanulomana* property, it normalizes *Apana vayu,* leading to improved micturition and relief from symptoms like incomplete emptying, intermittency, and nocturia.[12]

Gokshura (Tribulus terrestris), being *Mutrala* and *Basti-shodhaka*, promotes free urinary flow and cleanses the *Mutravaha srotas*. It alleviates symptoms such as straining and the sensation of incomplete voiding. Owing to its *Rasayana* property, *Gokshura* maintains genitourinary health and supports prostate function. Its steroidal saponins exhibit anti-inflammatory and antioxidant effects, which help reduce prostatic swelling and improve overall urinary function.[13]

Madhu (honey) serves as the *Anupana* in this formulation. With *Kashaya–Madhura rasa* and *Ruksha guna*, it mitigates *Kapha* and *Ama*. Its *Lekhana* action aids in resolving tissue overgrowth and removing urinary obstructions, while its *Ropana* and immunomodulatory qualities support tissue repair and

decrease inflammation. Being *Srotoshodhaka*, honey enhances urinary flow by clearing the urinary pathway.[14]

Together, these ingredients work synergistically to reduce the symptoms, size of prostate gland and post void residual urine volume in patients with benign prostatic hyperplasia.

CONCLUSION

There were significant relief from symptoms of BPH as assessed by IPSS in all the participants both clinically and statistically. There was no much reduction in the size of prostate gland found as per USG clinically, but statistically seems to be significant. Post void residual urine volume found to be significantly reduced in majority of the participants both clinically and statistically.

In the study group, no side effects and adverse drug reactions were reported. Hence clinically and statistically it can be concluded that *Trikatvadi Gudika* along with *Gokshura Kwatha* given for a period of 30 days is effective in the management of benign prostatic hyperplasia. These results suggest that it can be used as a safe and effective non-surgical treatment, but larger controlled studies are needed to confirm these findings.

Limitations of the Study

- The study was conducted in small sample size.
- The duration of the study was only 30 days with a follow up for 30 days.

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***Address for correspondence**
Dr. Aswathy Krishnan
PG Scholar,
Department of Shalyatantra,
Government Ayurveda College,
Thiruvananthapuram, Kerala.
Email:
aswathykrishnan161@gmail.com

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