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EFFICACY OF INTERNAL ADMINISTRATION OF TILAKANDA KSHARA IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA- A PRE-POST STUDY

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ABSTRACT:

Background: Benign Prostatic Hyperplasia (BPH) is a prevalent, non-cancerous tumour affecting aging men, significantly contributing to lower urinary tract symptoms (LUTS) worldwide. This condition substantially impacts quality of life. Prevalence of histologic BPH with age is approximately 20% (41-50 years), 50% (51-60 years), and over 90% (above 80 years). Treatment modalities span from conservative management (watchful waiting) to medical therapy and Surgical intervention. According to *Ayurvedic* texts, *Mutra rogas'* severity manifests as *vibhanda* (obstruction), predominantly observed in *Mutraghata.* While no single disease mirrors Benign Prostatic Hyperplasia (BPH) exactly, *Mutragranthi*, described under *Mutraghata*, shares striking similarities. **Objectives:** To evaluate the efficacy of internal administration of *tilakanda kshara* in the management of Benign Prostatic Hyperplasia. **Materials and methods:** This is a single group pre- post interventional study conducted on 20 participants from OPD and IPD department of salya tantra, Govt Ayurveda College, Thiruvananthapuram. Participants diagnosed with BPH was subjected to internal administration of kshara for a period of 30 days. **Conclusion:** Most of the participants experienced significant relief from symptoms of BPH, even though there was no statistically significant reduction in prostate size. Furthermore, the post-void residual urine volume showed a significant reduction in most participants, both clinically and statistically. Therefore, it can be concluded that the internal administration of *Tila Kanda Kshara* with *Dadhi Mastu* is both clinically and statistically effective and can be considered a viable approach for the management of BPH.

Key words: *Benign prostatic hyperplasia, Mutragranthi, Tila Kanda kshara, Sesamum indicum*

INTRODUCTION

Benign prostatic hyperplasia (BPH) is non - malignant enlargement of the prostate gland and refers to the stromal and glandular epithelial hyperplasia that occurs in the transition zone of the prostate. Pathologically it causes obstruction of the lower urinary tract and manifests clinically with characteristic symptoms.[1] The development is influenced by a complex array of risk factors, including hormonal factors.[2] Testicular androgens play a crucial role in the development of benign prostatic hyperplasia. The clinical principles for evaluating BPH include medical history for assessing symptoms, medical conditions, and medications that may impact urinary function. Digital rectal examination helps to evaluate prostate size, shape, and consistency. Severity of the symptoms are assessed based on System score assessment. According to modern medical science, Watchful waiting is the conservative management approach for patients with mild to moderate urinary symptoms.[1] This strategy involves providing personalized lifestyle advice to help alleviate symptoms and reduce risk factors. Medical management includes using alpha blockers, 5-alpha-reductase inhibitors, Anticholinergic agents, IPDE5 (phosphodiesterase type 5 inhibitor) etc. Minimally invasive therapies are also advised when presented with moderate to severe symptoms**.** Most commonly used minimally invasive techniques includes transurethral needle ablation of the prostate (TUNA) and transurethral microwave thermotherapy (TUMT). Surgical interventions are usually adopted in moderate to severe BPH with complications. Open proctectomy is done on the basis of size of the gland. Transurethral laser approaches have also shown benefits in treating BPH.

Ancient India's Vedic era, circa 3000 BC, witnessed the dawn of medical and surgical practices, establishing a robust foundation for the diagnosis and treatment of urological disorders. Sushruta Samhita a pioneering work in surgery, offers a comprehensive and detailed explanation of the anatomy and physiology of the urinary system. While dealing with *mutrarogas* (urinary disorders), the intensity of *vibhanda* (obstruction) which is more seen in *Mutraghata*, a term comprising two words - *Mutra* (urine) and *Aghata* (obstruction) refers to the blockage of urine flow. Hence, it may be considered that the *Mutraghata* is a condition of some kind of obstructive uropathy which include both mechanical and functional causes. Among the 13 *Mutraghtas* mentioned, *Mutra granthi* is a *vata*-predominant disorder characterized by appearance of a small, hard, round, and immovable mass inside the urinary bladder's mouth and pain similar to that of a urinary stone.[3] While there isn't an exact correlation between *Mutra granthi* and any single disease, including benign prostatic hyperplasia (BPH). *Mutra granthi* seems to shares similar symptoms with BPH. Treatment principle mainly ensures on aspects like *Mutravahasrotosodhana* (purification of mutravaha srotas), *Vatanulomana, Agni deepana* and *Tridosha samana*. Management includes use of *kashaya, kalka*(paste*), sarpi*(ghee) *, bhakshya(* eatables *), lehya* (lickables*), ksheera paka (*medicated milk), *ksharam* preparations (alkaline

preparations), *madyam* preparations and *asava* preparations (self-generated alcoholic preparations).[4] The drug used in this study is mentioned in *Hareetha samhitha* 30th chapter *Mutrarodha chikilsa prakarana*. The current study evaluates the effect of internal administration of *tila kanda kshara* in cases of Benign Prostatic Hyperplasia.

OBJECTIVE

To evaluate the effect of internal administration of *tilakanda kshara* in reducing the symptoms, size of prostate and also reducing post void residual urine volume in Benign Prostatic Hyperplasia.

MATERIALS AND METHODS

Participants was recruited to the study after necessary examinations and investigations. Participants diagnosed with Benign Prostatic Hyperplasia fulfilling the inclusion and exclusion criteria was taken for the study. Then 500mg of *tilakanda kshara* with 5ml *dadhimastu* twice daily was given after food for a period of one month. Total duration of study was 60 days with a treatment period of 30 days and follow up period of 30 days.

Study design

Single group pre–post interventional study.

Study setting

OPD and IPD, Dept. of Salyatantra, Government Ayurveda College Hospital, Thiruvananthapuram**.** The study was conducted from May 10, 2023, to June 8, 2024.

Study population

Participants between the age group of 50-70 years, diagnosed with benign prostatic hyperplasia fulfilling the inclusion and exclusion criteria.

Sample Size – out of 24 samples screened , 20 were selected as pe inclusion and exclusion criteria and there was no drop out.

Inclusion Criteria

- Age between 50-70 years.
- Participants with symptoms of BPH, diagnosis confirmed by USG.
- Residual urine within 50-100 ml.

Exclusion Criteria

- Bladder neck stenosis
- Catheterized patients
- Known cases of Systemic disease like Tuberculosis, Hepatitis B, HIV, Cardiac diseases, Uncontrolled DM.

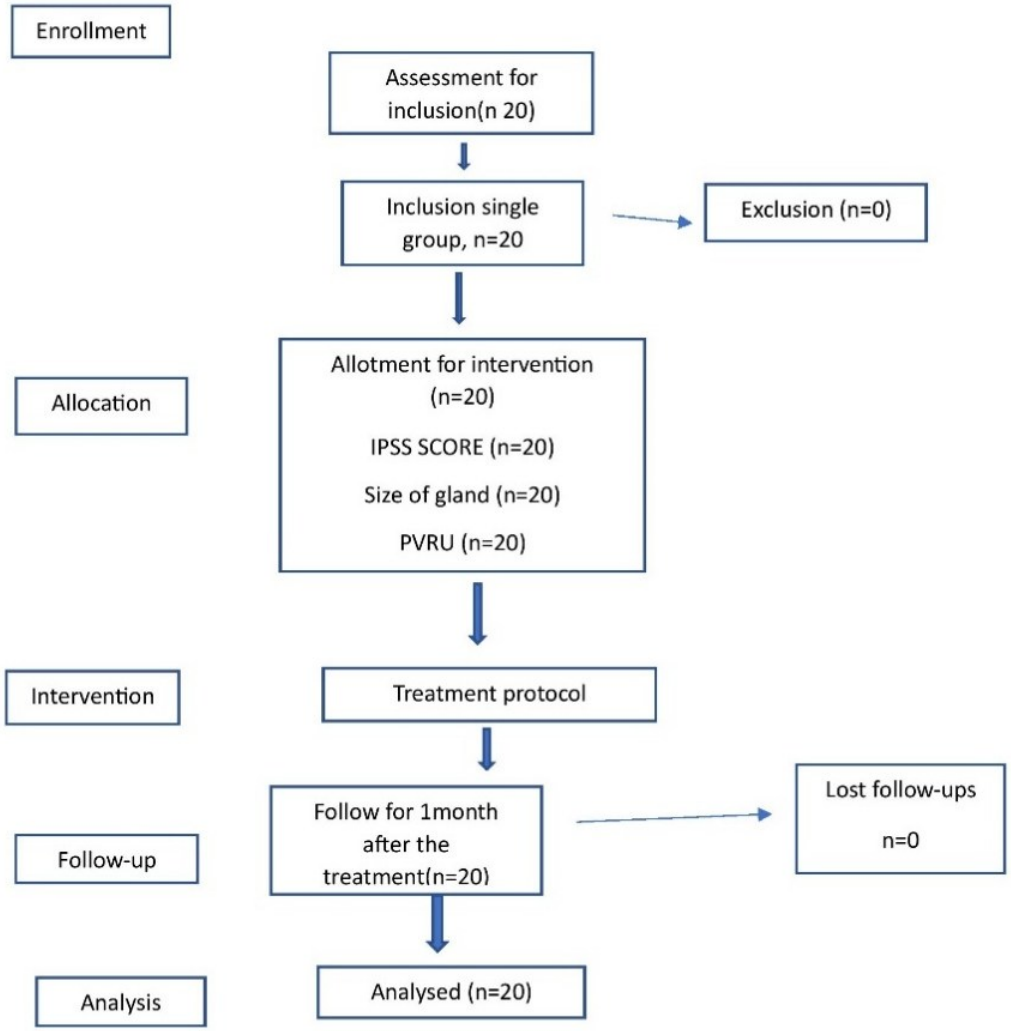
Preparation of Trial Drug

Preparation of *kshara was done* as per rasatarangani. From 30 kg of dried raw materials of tila kanda burnt in iron pan 8kg of white-greyish ash was obtained after self-cooling. Ashes were mixed with water and filtered through a clean cloth for21 times. Later heated to prepare kshara. Approximately 1 kg of kshara was obtained . it was stored in a glass jar under safe conditions.

Assessment

Effect of the drug is assessed by subjective and objective parameters. Subjective assessment of participants was done by International Prostate Symptom Score system(Table 1). It comprises the assessment of symptoms like incomplete emptying, frequency of micturition, intermittency, urgency, weak stream, straining and nocturia. Assessment was carried out on 0th day(before treatment period), 15th and 30thday(during treatment

period) and 45th and 60th day(during follow up period) respectively.



Flow Chart 1: CONSORT Flow Chart

Table 1: INTERNATIONAL PROSTATE SYMPTOM SCORE[IPSS]

Urinary symptoms	**Not at all**	**Less than 1 in 5 time**	**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 time
Nocturia	0	1	2	3	4	5

Total score:

- 1-7 mildly symptomatic/ asymptomatic
- 8-19 moderately symptomatic
- 20-35 more severely symptomatic

Objective assessment done by USG abdomen and pelvis to evaluate size of prostate gland and post void residual urine volume on 0th day (before treatment period) and 30thday (after treatment period).

Intervention

Participants were administered 500 mg of *Tila paneeya kshara* (alkali obtained from sesame plant) with 5ml dadhi mastu as anupana twice daily for a period of 30 days after food. Participants were advised to drink 3-4 L of water. And was advised to avoid hot and spicy food . Properties of *tila kshara* are given below (table 2).

Table 2 . Properties of tila kshara

Gunam	*teekshnam*
Karma	*mutra roga nibarhanam , asmari nasanam*

Dadhi mastu is the supernatant part of curd. Its properties are mentioned in Table.3

Table 3. Properties of dadhi mastu

Rasa	*Amla kasaya Madhura*
Guna	*Laghu*
Dosha karma	*Kapha vata samana*
Karma	*Srotovishodana , bhinatyasu mala, prahladana*

Data analysis

The data related to various assessments of both subjective and objective parameters, before and after treatment of 20 participants were taken for statistical analysis. The result of treatment was analysed through Wilcoxon Signed Rank Test statistically.

OBSERVATIONS AND RESULTS

1) Data on IPSS score

On analysing symptoms in IPSS score system, there were significant changes in symptoms both clinically and statistically. The mean IPSS score significantly decreased from 23.7 (SD: 3.6) before treatment to 16.0 (SD: 3.72) after treatment, and further to 5.35 (SD: 1.76) at follow-up. The Wilcoxon Signed-Rank Tests results show a statistically significant reduction in IPSS scores between both BT vs AT (Z-score: 3.96, P-value: <0.001) and BT vs AF (Z-score: 3.92, P-value: <0.001). These results indicate a significant improvement in symptom scores over time following treatment.

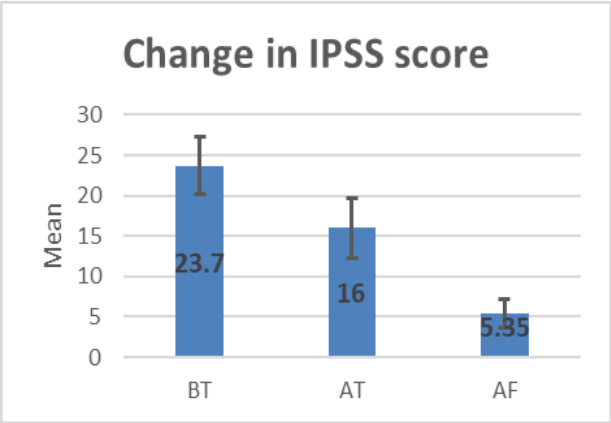
Table 4. Effectiveness of IPSS score

IPSS score	Mean	SD
BT	23.7	3.6
AT	16.0	3.72
AF	5.35	1.76

Table 5. Comparison for Wilcoxon Signed-Rank Test Results for IPSS score

Comparison	Z-score	P-value
BT vs AT	3.96	<0.001
BT vs AF	3.92	<0.001

Figure 1. Change in overall IPSS Score



2) Data on USG findings

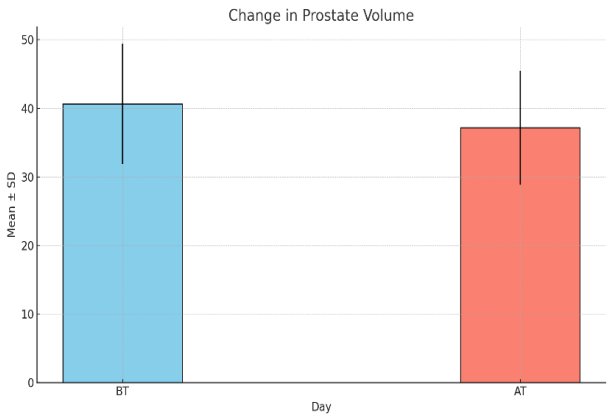
Objective assessment was done based on USG abdomen and pelvis. size of prostate gland and post void residual urine volume were assessed. Observations and subsequent results are enlisted below.

Change in prostate volume measured before treatment (BT) and after treatment (AT) - Initially, the average prostate volume was 40.63 with a standard deviation of 8.8, which significantly decreased to 37.17 with a standard deviation of 8.3 after treatment, as indicated by a T-score of 6.9 and a highly significant p-value of less than 0.001. This suggests a statistically significant reduction in prostate volume due to the treatment.

Table 6. effectiveness in prostate volume

Day	Mean	SD	P
BT	40.63	8.8	<0.001
AT	37.17	8.3	

Figure 2. change in prostate volume

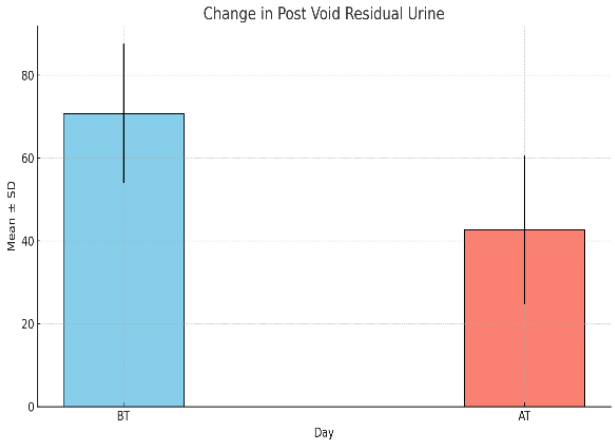


changes in post void residual urine- showing a decrease from a mean of 70.8 before treatment to 42.7 after treatment. The standard deviation also slightly increased post-treatment from 16.8 to 17.9. The T-score of 7.6 and the p-value of less than 0.001 indicate a significant reduction in residual urine volumes, demonstrating the effectiveness of the intervention in improving bladder emptying.

Table 7. effectiveness post void residual urine

Day	Mean	SD	P
BT	70.8	16.8	<0.001
AT	42.7	17.9	

figure 3 . change in post void residual urine volume



There were no adverse reactions found during the intervention.

DISSCUSSION

When considering the overall IPSS score, the study is found to be statically significant. marked decrease in IPSS scores suggests a significant therapeutic effect, with sustained improvement observed during follow-up. The mean IPSS score decreased from 23.7 (SD: 3.6) at baseline to 16.0 (SD: 3.72) after treatment, and further decreased to 5.35 (SD: 1.76) at follow-up, indicating substantial symptom improvement. The mean value of volume of gland dropped from 40.63 before study to 37.17 after study. The study showed a 4 cubic centimetre (cc) reduction in prostate volume after treatment, indicating a statistically significant decrease. Despite this modest size reduction, there was notable improvement in clinical symptoms. This suggests that the size of the prostate gland doesn't directly correlate with symptom severity.

Limitations or weaknesses 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.

Tila Kshara, a potent alkaline drug, possesses unique properties that help balance *Vata dosha* and promote *Vata Anulomana*. As per Vagbhata kshara belongs to *lavana varga,* which is having *lavana* as predominant *rasa* and does actions like destroying adhesions (*bandha*). It can increase digestion and brings about unctuousness.[5] The *mutra roga nibarhana* action of *tila kshara* along with the inherent properties like abrasive action of *kshara* helps to alleviate the urinary disorders.[6] *Ksharas* characteristics, including, *sukshma* (subtle), *vyavayi* (penetrating), and hot potency, contribute to its effectiveness. *Ushna veerya* of *kshara* along with the *snigdha guna* of *tila* helps in *vata anulomana*. *Aml*a and *Madhura rasa* of *dadhi mastu* can enhance the *vata samana* action and thus address the *apana vata vaigunyam* causing the pathology of the disease. The *lekhana* properties of *Kshara* can help to reduce abnormal tissue growth.[7] In this study during the intake of *tila kshara* along with *dadhi mastu* act as *vata kapha samana* and *srotoshodana* in action and helps in removal of metabolic waste products.

Drug is effective in reducing the storage symptoms like frequency of micturition, intermittency, urgency and nocturia. *Ksharana* and *lekhana* properties of *kshara* along with its *teekshna guna* helps to reduce the prostate gland's size, decreasing compression on the urethra and enhancing urine flow. Additionally, Tila is said to have anti-tumor effects, enhancing the drug's ability to prevent abnormal tissue growth.[8] Increased amount of residual urine volume can lead to infection and finally ending up in cystits like condition. Here the *vilayana* action of the *kshara* helps to reduce such inflammation. And also excess residual urine volume can stagnation of urine which eventually increases the viscosity of urine. *Ksharas sodhana* and *soshana* properties can prevent the formation of infection and inflammation due to the residual urine volume. Also the alkaline nature of *kshara* can manage the acidity of urine caused due to infections.[9]

Bhinathyasu Mala nature of the drug can helps in elimination of *mala* which is the metabolic waste products. The *mutrala* (diuretic action) of the drug can reduce the residual urine volume. *Srotosodhana* cleanses and clears the urinary channels, ensuring unhindered urine flow. The combined action of these properties helps alleviate obstruction, enabling a smooth and effortless flow of urine.

The study showed a 4 cubic centimetre (cc) reduction in prostate volume after treatment, indicating a statistically significant decrease. Despite this modest size reduction, there was notable improvement in clinical symptoms. This suggests that the size of the prostate gland doesn't directly correlate with symptom severity. It can also be noted *Ksharas* anti-testosteronic properties, may also contribute to reducing the size of the prostate gland by counteracting the effects of testosterone.[10]

Post-void residual urine (PVRU) refers to the amount of urine remaining in the bladder after. The study demonstrated a statically significant reduction in residual urine volumes, showcasing the effectiveness of the intervention in improving bladder emptying. This improvement can be attributed to the diuretic action of the drug, as well as its *Vata Anulomana* and *Kapha Vata* properties, which help regulate urinary flow and bladder function.

Oxidative stress and inflammation can cause significant tissue damage, leading to urinary dysfunction. Bladder outlet obstruction is a major contributor to these dysfunctions. The prominent chemical constituent, Sesamolin, in Tila possesses anti-inflammatory and antioxidant properties, which play a vital role in mitigating the severity of Benign Prostatic Hyperplasia (BPH). Sesamolin antioxidant properties enable the scavenging of free radicals, preventing harmful tissue damage and inflammation caused by oxidative stress. [11] This overall comprehensive effect improves quality of life and thus promote urinary health.

CONCLUSION

A majority of the participants experienced significant relief from symptoms of BPH, even though there was no statistically significant reduction in prostate size. Furthermore, the post-void residual urine volume showed a significant reduction in most participants, both clinically and statistically. The study was conducted on 20 participants, and no significant side effects were observed. Therefore, it can be concluded that the internal administration of *Tila Kanda Kshara* with *Dadhi Mastu* is both clinically and statistically effective and can be considered a viable approach for the management of BPH.

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