

**RANDOMISED CONTROLLED CLINICAL TRIAL OF NARAYAN
TAILA UTTARBASTI IN VATASHTHILA WITH SPECIAL
REFERENCE TO BENIGN PROSTATIC HYPERPLASIA**

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ABSTRACT :

Benign prostatic hyperplasia is a common disease with well defined age incidence. The present modern established conservative management includes use of α blockers and 5 α reductase inhibitors. But both of drugs cause various side effects. As it is a senile disease, people may not be fit for TURP or prostatectomy. In *Ayurved Samhitas*, symptoms of Benign Prostatic Hyperplasia are described under *Mootraghata*. There are 12 types of *mootraghata*; one of them is *Vatashthila*. Various ayurvedic drugs were studied previously as a conservative measure & are found effective also. But since the incidence of this disease is very much, we can study the effects of various other drugs or therapies also as conservative management. Though *uttarbasti* is a traditionally used therapy, it's efficacy is not yet evaluated with *Narayan Taila* in benign prostatic hyperplasia. *Uttarbasti* is a non invasive procedure. Moreover the cost of this treatment modality is very much less as compared to other conservative or surgical managements. Use of *Uttarbasti* may avoid surgery which ultimately results in increased quality of life of patients. So, in the present clinical study, efficacy of *Narayan taila Uttarbasti* in *Vatashthila* with special reference to Benign Prostatic Hyperplasia is evaluated. At the end of study, it is found that *Narayan taila Uttarbasti* is found effective in BPH than that of C.Tamsulosin HCl with respect to frequency, urgency, nocturia & force of urine stream. Also *Narayan taila Uttarbasti* is found effective in reducing the post void residual urine volume. Thus, at the end of study, it is concluded that there is much more increase in the quality of life of patients due to this non invasive treatment modality.

Key words: *Mootraghata, Vatashthila, Uttarbast, Narayan taila, Benign Prostatic Hyperplasia*

INTRODUCTION: *Ayurveda* deals with the healthy life of human being. Moreover it is concerned with the disease free life^{1,2}. The disease - Benign Prostatic Hyperplasia^{3,4} is characterized by the obstructive as well as irritative symptoms. Obstructive symptoms include hesitancy, weak urine stream & dribbling micturition etc. whereas urgency, frequency, nocturia may be categorized under the variety of the irritative symptoms. Although Benign Prostatic Hyperplasia is not as much life threatening condition, it's clinical

manifestations worsen the quality of life of patient. The present modern conservative treatment includes use of either ⁵alpha blockers or 5 alpha reductase inhibitors or both in the combination. But various side effects like headache, restlessness, insomnia, decreased libido, vertigo, dizziness, abnormal ejaculation, postural hypotension etc. are noted due to use of these drugs. If the abovesaid symptoms of Benign Prostatic Hyperplasia are not minimized, then patient has to opt for surgery like

prostatectomy or resection of prostate. Prostatectomy or Trans Urethral Resection of Prostate (TURP) is the primary approach to Benign Prostatic Hyperplasia. But as it is a disease which is found in old aged persons. Patient may not be fit for surgery due to various problems or known history of diabetes, hypertension, bronchial asthma etc. Even if the surgery is done, there are high chances of complications. Early complications include hemorrhage, clot retention, bladder neck stenosis etc. The late complications include recurrence, erectile dysfunction, secondary growth, urethral stricture, infection etc. Considering the complications, recurrence & cost of surgery, it is the need of society to evaluate an alternative option for this senile disease. Here, Ayurveda has got definite contribution which encourages us to find solution. In Ayurved Samhitas, symptoms of Benign Prostatic Hyperplasia are described under *Mootraghata*. There are 12 types of *mootraghata*; one of them is *Vatashtihila*^{6,7}:

The abnormally increased *vata dosha* is accumulated in the narrow space of neck of urinary bladder & around the anal canal. This *sthansanshraya* in the vicinity results into formation of thick lump like swelling or mass. It is hard in consistency & mainly obstructs urinary outflow. In this regard, further increase in the size of *vatashtihila* will subsequently obstructs the passage of urine, stool & flatus. This ultimately results in chronic retention of urine & pain & distention of abdomen. The symptoms of *vatashtihila* are like the lower urinary tract symptoms caused by BPH.

In *sushrut samhita*, *vatashtihila* is grouped under the title of *mootraghata*. The general treatment for *mootraghata* is described in *Uttartantra*⁶: Various decoctions, medicated ghee, medicated milk, *kshar*, *madya*, *asava*, *uttarbasti* which are enriched with various drugs can be used for treatment of *mootraghata*.

In *vata vyadhi chikitsa*, *prashasti* of *Narayan taila* is described in *Sharangdhara Samhita*⁸ as: *Narayan taila* can be used for *navan nasya*, oleation, *basti* and also for internal use. *Narayan taila* normalizes the vitiated *vata dosha* which is abnormally spreaded all over the body. Hence *Narayan taila* is the best remedy for *vata vyadhi*.

Though *uttarbasti* is a traditionally used therapy, it's efficacy is not yet evaluated with *Narayan taila* in benign prostatic hyperplasia. Cost of the treatment modality is very much less as compared to other conservative and surgical management. So, in this clinical study, we have decided to evaluate clinical efficacy of *Narayan taila Uttarbasti* in *Vatashtihila* with special reference to Benign Prostatic Hyperplasia.

AIMS AND OBJECTIVES:

- **Aim:-** To evaluate clinical efficacy of *Narayan taila Uttarbasti* in *Vatashtihila* with special reference to Benign Prostatic Hyperplasia.
- **Objectives:-**
 - The study anatomy and physiology of *Ashthila* & *Basti* in detail.
 - To study pathology, signs and symptoms of *Vatashtihila* with special reference to Benign Prostatic Hyperplasia in detail.
 - To study the effects of *Narayan taila uttarbasti* in *Vatashtihila* with special reference to Benign Prostatic Hyperplasia.

- Comparative statistical analysis of effects of *Narayan taila uttarbasti* and C. Tamsulosin Hydrochloride 0.4 mg.

MATERIALS & METHODS:

Material:

1) Criteria for Selection of Patients:

A) Inclusion Criteria:

Patient diagnosed as case of BPH (wt. of prostate – upto 50 gms) with following symptoms:-

- 1) Weak stream of urine
- 2) Hesitancy
- 3) Urgency of micturition
- 4) Nocturia
- 5) Increased frequency of micturition
- 6) Male patients of age 50-80 years.

B) Exclusion criteria:

- 1) Known case of malignant prostatic enlargement
- 2) Known case of BPH along with urethral stricture.

2) Narayan Taila: For uttarbasti, *Narayan taila* is used, which is the proprietary product of *Aushadhi-bhavan, Ayurved Sewa Sangh, Ayurved Mahavidyalaya, Nashik*. It is prepared according to reference from *Bharat Bhaishajya Ratnakar (iii)*⁹.

CLINICAL METHODS: The study was conducted in O.P.D. and I.P.D. of *Shalyatantra in Arogyashala Rugnalaya, A.S.S Ayurved Mahavidyalaya, Nasik*. Total 60 patients were selected randomly. Patients were divided in two groups

namely Experimental group (Group A) & Control group (Group B) with 30 cases in each group.

1) GROUP A (EXPERIMENTAL GROUP): 30 patients with signs and symptoms of *vatashtihila* (Benign Prostate Hyperplasia) were administered *Uttarbasti* with *Narayan taila*. *Uttarbasti* was carried out in minor operation theatre under strict aseptic condition.

- Dose: As per requirement of patient, maximum upto 20ml.
- Regime: 3 sittings of *uttarbasti* (each containing 3 uttarbasti) with gap of 3 days.
- Duration of study: 15 days.
- Follow up: 0th, 5th, 10th & 15th day.

2) GROUP B (CONTROL GROUP): 30 patients with signs and symptoms of *Vatashtihila* (Benign Prostate Hyperplasia) were treated with Tab. Tamsulosine Hydrochloride.

- Dose: 0.4 mg at night⁵
- Duration of study: 15 days.

SYMPTOMATIC CLINICAL ASSESSMENT:

A. OBJECTIVE CRITERIA:

Post void residual urine volume- measured by infant feeding tube. This is evaluated both before & after treatment. Assessment of effect of therapy is done according to gradation based on reduction in the post void residual volume after the treatment.

Post voidal residual urine	Gr	BT 0 th day	AT ₁ 5 th day	AT ₂ 10 th day	AT ₃ 15 th day
Nil(up to 30 cc)	0				
>30to 60cc	1				
>60to 90cc	2				
>90to120cc	3				
>120cc	4				

S.N.	Assessment	Reduction in residual urine volume
1)	Uttam Upashaya	> 75%
2)	Madhyam Upashaya	50% to 75%
3)	Alpa Upashaya	25% to 50%
4)	Heena/Anupashaya	< 25%

B. SUBJECTIVE CRITERIA:

No.	Criteria	Gradation	Score
1)	Frequency	Normal frequency of micturition Patient micturating once in every 2 hour Patient micturating once in every 1 hour Patient micturating once in every 1/2 hour	0 1 2 3
2)	Urgency	No urgency of micturition Can hold urine till reaching toilet Can't hold urine till reaching toilet Can't hold urine or soiling cloths	0 1 2 3
3)	Force of stream	Stream reaches beyond the toilet pan Stream reaches in the toilet Stream just in front of the feet Very weak stream	0 1 2 3
4)	Nocturia	No nocturnal micturition Once in night One to three times in night More than three times in night	0 1 2 3

INVESTIGATIONS:

Following investigations will be carried out for patients treated in the proposed study.

1) Complete Blood Count

2) Urine- routine and microscopic

3) Serum Creatinine

4) Blood Sugar Level (Random)

5) Serum PSA (if required)

6) Ultra Sono Graphy - Abdomen and Pelvis with post void residual urine

OBSERVATIONS AND RESULTS:

Statistical analysis of Post void residual volume

No.	Symptom	χ^2	df	Table χ^2 value	Probability	Result
1)	Frequency	10.00	2	5.99	P<0.05	Significant
2)	Urgency	13.30	2	3.84	P<0.05	Significant
3)	Force of Stream	22.42	3	7.81	P<0.05	Significant
4)	Nocturia	7.84	2	5.99	P<0.05	Significant

Paired 't' test:

Postvoid residual volume	
SD	25.55
SE	6.61
t ₅₈	3.201
t _{table}	2.05
P	<0.05

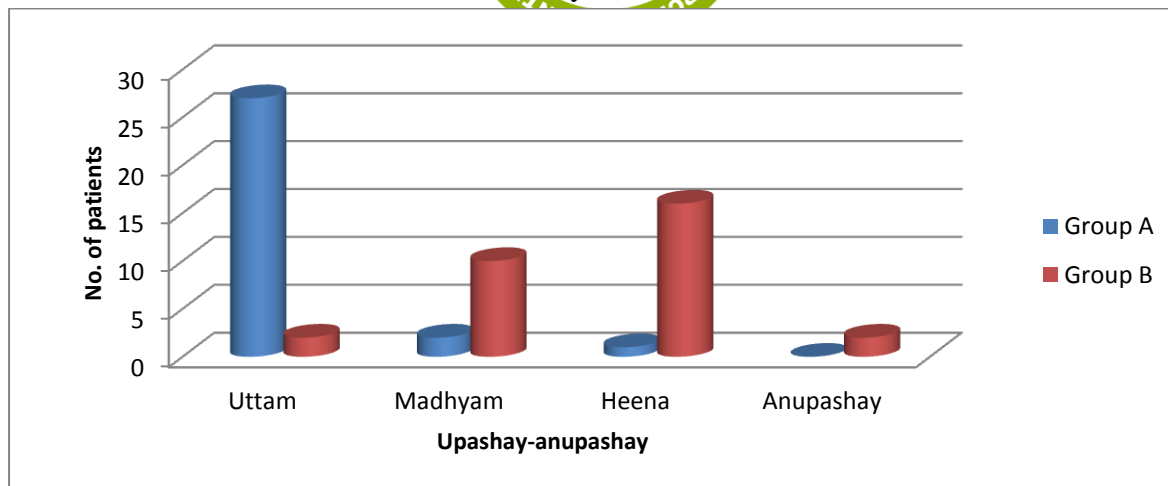
Unpaired 't' test:

Post void residual volume		
	Group A	Group B
Mean	20	-1.16
SD	6.82	35.48
SE	1.24	6.48
t ₂₉	16.12	-0.17
t _{table}	2.05	2.05
P	<0.05	<0.05

According to statistical analysis, we can infer that *Narayan Taila Uttarbasti* is more effective in reducing the post void residual urine volume than that of C. Tamsulosin Hydrochloride.

DISTRIBUTION OF PATIENTS ACCORDING TO TOTAL EFFECT OF THERAPY:

From the above graphical representation, we can see the Gr.A i.e. *Narayan Taila Uttarbasti* is more effective than that of C. Tamsulosin Hydrochloride.



DISCUSSION: Complete assessment of all the patients is done by using various standard statistical methodology with each and every follow up. Following discussion is made after the whole assessment.

1) **Frequency of micturition:** There is no significant difference at the level D5. But after that, the significant

results are shown at the level of D10 and D15. At the end of the treatment, from Gr. A, 21 patients show *uttam upashaya*, 5 patients show *madhyam upashaya* & 4 patients show *alpa upashaya*. Interestingly no any patient has shown *anupashaya*. This infers that *Narayan taila Uttarbasti* is effective in reducing the frequency of

micturition. The *Narayan Taila* instilled by *Uttarbasti* acts on the sensitive prostatic mucosa. Thereby it oleates the prostatic mucosa & hence it may minimize sensitivity. Thus frequency of the micturition is reduced.

2) **Urgency of micturition:** There is significant difference at the level of all the follow ups of the clinical study. At the end of the treatment, from Gr. A, 25 patients show *uttam upashaya*, 3 patients show *madhyam upashaya* & 2 patients show *alpa upashaya*. Likewise frequency, here in this symptom also, no patient has shown *anupashaya*. This infers that *narayan taila uttarbasti* is also effective in reducing the urgency of micturition. The *narayan taila* acts on the internal sphincter. Due to action of *narayan taila* on internal sphincter, it's function to hold & control urge of micturition may improve because of tonocytivity of internal sphincter. So there is no any escape of urine in the prostatic urethra. By this mechanism, urgency of micturition is reduced.

3) **Force of urine stream:** The force of urine stream goes on increasing day by day by *uttarbasti*. After completion of the treatment, 23 patients from Gr. A, show *uttam upashaya* while 3 patients show *madhyam upashaya* & 4 patients show *alpa upashaya*. In this symptom also, no patient has shown *anupashaya*. *Narayan taila*, instilled by *uttarbasti* acts on internal sphincter of urinary bladder & the urethra. Thereby *narayan taila* decreases the urethral resistance. Also it relieves the obstruction of internal urethral orifice. The prostatic mucous membrane is sensitized by the vascular introversion in BPH. The *narayan taila* minimizes this sensitivity, thereby reducing the irritability of the urinary bladder. For *uttarbasti*, the infant

feeding tube is inserted per urethra. This relieves the per urethral obstruction. So all these mechanisms enhance force of urine stream.

4) **Nocturia:** In this clinical study, *Narayan Taila Uttarbasti* is found efficient in reducing the nocturia of the patients. In the benign prostatic hyperplasia, this symptom arises due vascular introversion of sensitive prostatic mucous membrane due to it's upward enlargement. *Uttarbasti* instills *Narayan Taila* in the urinary bladder & in the urethra. So *narayan taila* acts on the prostatic mucous membrane, thereby it causes the soothing effect & finally reduces it's sensitivity. So by this way, nocturia is reduced.

5) **Residual Urine Volume:** There is significance change at the level of D15 in the experimental group in the residual urine volume. The paired and unpaired 't' test shows that the calculated 't' value is much greater than that of table 't' value. Due to enlargement of prostate, urinary flow is obstructed. To compensate urethral resistance, detrussor muscles become hypertrophied & in the advanced stage, they become exhausted & atonic. This leads to the stagnation of urine in the urinary bladder & residual urine volume is increased. As the *uttarbasti* delivers *Narayan Taila* in the urinary bladder, it nourishes as well as rejuvenates the exhausted detrussor muscles. Hence it ultimately results in the less amount of residual urine volume.

DISCUSSION REGARDING TOTAL EFFECT OF THERAPY:

• Experimental Group:

After studying all the data thoroughly, it is observed that, out of 30 patients in experimental group, 27 (90.00%) received *uttam upashaya*. The 2

(6.66%) patients received *madhyam upashaya* while 1 (3.33%) patient received *alpa upashaya*.

• **Control Group:**

Whereas in control group, only 2 (6.66%) patients got *uttam upashaya*, 10 (33.33%) patients got *madhyam upashaya*, 16 (53.33%) patients got *alpa upashaya* and 2 (6.66%) had *anupashaya*.

PROBABLE MODE OF ACTION OF

UTTARBASTI: ⁹*Narayan taila* possesses *vata-kapha shamak*, *mrudukara*, *sara*, *sukshma*, *vikasi* & *vranaropak* qualities. It softens the tissue, can penetrate upto the deeper cells & hence increases elasticity. It heals as well as promotes regeneration of the tissue. In benign prostatic hyperplasia, volume of prostate gland is increased. It can be due to *shotha* induced by *kapha dosha* or *vyasa* induced by *vata dosha*. As *narayan taila* is *vata-kapha shamak*, it pacifies them. So it is observed that patients who were treated with *narayan taila uttarbasti*, do not show increase in the volume of prostate. On the other aspect, patients who are treated with C. Tamsulosin Hydrochloride show increase in the volume of prostate.

In the act of *uttarbasti*, *narayan taila* is instilled in the vicinity of urinary bladder along with the urethra. The *taila* which is instilled in the urinary bladder, is absorbed by mucosa & detrussor muscles of urinary bladder. The *poorana* of *basti* is done by *narayan taila* according to *Upasnehan Nyaya*. The detrussor muscles which become hypertrophied or atonic in case of benign prostatic hyperplasia, are nourished & rejuvenated by *narayan taila*. Hence frequency & urgency of micturition are minimized. Also it helps to improve force of urine stream. The mechanism of

detrussor muscles is regained, resulting in lower amount of residual urine volume.

The *narayan taila* possesses *ropan* quality i.e. wound healing property. Due to action of *narayan taila*, the eroded prostatic mucous membrane is healed. It arrests dilatation of prostatic venous plexuses, thereby causes arrest of haematuria.

CONCLUSION: The nutshell conclusion can be drawn as the *Narayan Taila Uttarbasti* is effective in reducing all the symptoms of *Vatashtihila* as compared to the C. Tamsulosin Hydrochloride 0.4 mg. As the statistical analysis proves the same which states that the hypothesis behind the study is found to be correct. But it will need further evaluation on large sample size & for more duration also, so that it may be worth in the management of Benign Prostatic Hyperplasia i.e. *Vatashtihila*.

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