

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF VARUN SHIGRU GHANA VATI WITH HELP OF UROFLOWMETRY IN THE MANAGEMENT OF VATASHTHILA W.S.R. TO BPH

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ABSTRACT

In Ayurveda, *Vatashthila* is one among the 12 types of *Mutraghata* (obstructive uropathy) disorders elaborated in the *Sushruta Samhita*. *Vatashthila* disease closely resembles Benign Prostatic Hyperplasia (BPH) of modern medicine in its signs and symptoms. Total 20 patients were selected for study. Patient was selected randomly irrespective of their religion, race, occupation etc. In BPH irritative and obstructive symptoms like frequency, urgency, staining, weak stream, incomplete emptying, nocturia, residual urine and uroflow rate were observed over the 3 month of treatment and for one month of follow up from onset of treatment. Observations were made & results were analyzed with the help of unpaired 't' test at 0.05 level of significance.

Keywords: Benign Prostatic Hyperplasia (BPH), *Asthila*, *Vatashthila*,

INTRODUCTION

In *Ayurvedic* classics *Mutraghata* gives the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria *Mutraghata* is predominantly due to the *Vata Dosha*.¹The *Vata Dosha* is responsible to expel the urine output timely & uniformly. If *Vata* gets vitiated, it causes various diseases related to *Basti* & produces *Mutraroga* such as *Prameha*, *Ashmari*, *Mutraghata*, *Mutrakruchha* etc. In *Ayurveda* the *Vatashtheela Vyadhi* which is a type of *Mutraghata* may have some similarity with BPH on the basis of symptoms like *Achala Unnata Granthi* (singly movable & elevated), *Vinmutranilasanga* (retention of urine, faeces & flatus), *Bastiadhmana* (distension of the urinary bladder), *Vedanacha-*

parabastou (excruciating pain in the bladder).² BPH is most common benign tumor in male, and its incidence is age related. Risk factors for the development of the BPH are poorly understood. Some studies have suggested genetic predisposition and some have noted racial differences.³ BPH is a senile disorder and chiefly affects individuals above the age of 50 years. The symptoms are those of bladder outflow obstruction, with increased frequency of micturition, dribbling, hesitancy, and the features of chronic urinary retention. In the classics there is no explanation about *Sadhyaasadhyata* for *Vatashthila*. But by considering, in general *Mutraghata* are difficult to cure due to involvement of *Basti marma*. Where as in

contemporary system of medicine, there are no satisfactory treatment modalities in controlling the symptoms and preventing the complications of the BPH. Acharya Sushruta decided general line of management of all type of *Mutraghata* by use of *Kashaya, Kalaka, Avaleha, Kshar, Madhya, Aasava, Swe-dana, Basti* and *Uttarbasti*.⁴ Hence here is an attempt made with different Ayurvedic conservative modalities to find a superior solution for maintaining the normal life in of elderly males.

AIMS & OBJECTIVES

- To study etiopathogenesis, signs & symptoms of the BPH & *Vatashthila*.
- To study efficacy of *Varun Shigru Ghana Vati* with uroflowmetric evaluation.
- To establish and encourage the use of herbal medicine in different urological problem related with old age.

MATERIAL & METHODS

Present clinical study has been carried out in the OPD & IPD level in the *Shalyatantra* department of Rishikul Campus Haridwar of Uttarakhand Ayurved Universi-

ty Dehradun. Patients were selected irrespective of their religion, race, occupation etc., fulfilling the selection & eligibility criteria & informed written consent was taken. Total number of 20 patients was studied.

PREPARATION OF DRUG

Trial drug *Varun Shigru Ghana Vati* was prepared as classical method mentioned in *Sharangdhar Samhita*⁵ First of all, fresh bark of *Varun* (*Crataeva nurvala*) and *Shigru* (*Moringa oleifera*) were taken and dried, then measure 5kg each. Now grind it till *Yavakut* after that allowed boiling it in 40 liters water till it remain ¼th (10 liter) of the initial volume. The decoction is prepared. Now filtered the *Kwatha* and further allow boiling, time comes when *Kwatha* is like paste then this material is dried in oven and make the *Ghana Vati* when material is of suitable consistency. Weight of each *Ghana Vati* is 500 mg.

DOSE: Standard dose is decided by boiling 50 ml *Varun Shigru Kwatha* till it becomes paste like and then make the *Vati* of this paste. Weight of this *Vati* is 500 mg.

Dose	500 mg BD
Time of administration	Before meal
Anupana	<i>Koshnaja</i>
Duration	3 months

Laboratory Investigation

1. Complete blood count
2. Sr. Creatinine
3. Urine Routine & microscopic
4. Blood Urea
5. Prostate Specific Antigen (If Required)
6. Ultra Sonography

Physical examination

- 1) Measurement of residual urine by catheterization
- 2) Uroflowmetry

- 3) Digital rectal examination

Inclusion criteria

- 1) Patient age group of 50-80 year.
- 2) Patient with mild and moderate symptoms according to questionnaire for American urological association score given for BPH.
- 3) Patients of *Samanya Lakshana's* of *Vatashthila*.

Exclusion of criteria

- 1) Patient having acute urinary retention, stricture of urethra, Ca. prostate, congenital

contracture of bladder neck, bladder polyps, cystitis, Hydronephrosis, Urolithiasis.

2) Patient with severe systemic disease like cardiac disease, Diabetes Mellitus, Renal failure, HIV- Immuno compromised patients must be excluded.

CRITERIA FOR ASSESSMENT-

Symptoms	Score /Grade
Incomplete emptying	Not at all 0/G0
Frequency	1 time in 5 micturition 1/G1
Intermittency	Less than half the time 2/G
Urgency	About half the time 3/G3
Weak stream	More than half the time 4/G4
Straining	Almost always 5/G5
Nocturia	

Grading on the basis of total score of IPSS (maximum score 35)

SYMPTOM SCORE:

- <7 -Mild
- 7-19 -Moderate
- >19 -Severe

2. Objective Parameter: -Maximum Flow Rate is objective parameter.

Grading –

- >15 ml/s - G0
- 13 to 15 ml/s - G1
- 10 to 12ml/s - G2
- 07 to 09 ml/s - G3
- < 07 ml/s - G4

Parameters of assessment: -The progress of therapeutic regimen was assessed on subjective and objective parameters. Interna-

1. Subjective parameters: The symptoms of BPH were recorded on the basis of International prostate symptom score and analysis was done on the standard method of statistics. **Table No.2 International Prostate Symptoms Score (IPSS)⁶**

tional prostate symptoms score was taken for subjective assessment and Maximum Flow Rate is objective parameter.

Assessment of total effect of therapy: -The overall assessment was calculated on the basis of average improvement in terms of percentage relief of scores.

- 1. Complete remission - 100%
- 2. Marked improvement - 75% to 100%
- 3. Improvement - 50% to 75%
- 4. Mild improvement - 25% to 50%
- 5. Unchanged - Below 25%

OBSERVATIONS & RESULTS:

Table No. 3 Symptom Wise Distribution-

Symptom	No. of patients	% of patients
Incomplete emptying	18	90
Frequency	20	100
Intermittency	17	85
Urgency	19	95

Weak stream	20	100
Straining	17	85
Nocturia	19	95

Table no. 4 effect of therapy on objective parameter

No.of days	Mean		Mean diff	% relief	SD	SE	t-value	p-value	Significance
	BT	AT							
15 days	2.25	1.75	0.5	22.22	0.51	0.11	4.35	<0.001	H.S
30 days	2.25	1.4	0.85	37.77	0.48	0.10	7.76	<0.001	H.S
45 days	2.25	0.95	1.3	57.77	0.47	0.11	12.36	<0.001	H.S
60 days	2.25	0.60	1.65	73.33	0.67	0.15	11	<0.001	H.S
75 days	2.25	0.40	1.85	82.22	0.74	0.17	11.10	<0.001	H.S
90 days	2.25	0.35	1.90	84.44	0.71	0.16	11.83	<0.001	H.S
	AT	F							
F	0.35	0.2	0.15	30.00	0.37	0.08	1.83	<0.01	S

The initial mean score of Qmax was observed 2.25, which was came down to 1.75 after 15 days, 1.4 after 30 days, 0.95 after 45 days, 0.60 after 60 days, 0.40 after 75 days, 0.35 after 90 days of treatment with 84.44% relief. The test of significance shows that treatment was highly significant over objective parameter. After completion of therapy when trail drug stopped, initial mean score

of objective parameter which was 0.35 came down to 0.20 along with 30% relief in objective parameter at the end of follow up period of one month. Here the test of significance showed that it was significant over urgency.

Summarized results after completion (90 days) of treatment:

Table No. 5 Total effect of Therapy over IPSS

Symptoms	Mean		X	% relief	SD	SE	t-value	p-value	Significance
	B.T	A.T							
Incomplete emptying	3.9	0.55	3.35	85.89	1.08	0.24	13.75	<0.001	H.S
Frequency	3.7	1.1	2.6	70.00	1.04	0.23	11.11	<0.001	H.S
Intermittency	3.25	0.35	2.9	89.23	1.37	0.31	9.45	<0.001	H.S
Urgency	3.15	0.50	2.65	84.12	1.22	0.27	9.66	<0.001	H.S
Weak stream	4.4	0.45	3.95	89.77	1.09	0.25	16.07	<0.001	H.S
Straining	2.55	0.25	2.30	90.19	0.73	0.16	14.03	<0.001	H.S
Nocturia	2.90	0.90	2.00	68.96	0.97	0.21	9.18	<0.001	H.S

The trial drug depicted highly significant ($p < 0.001$) results over all the mentioned symptoms.

Table no.6 Effect of therapy at the end of follow-up

Symptoms	Mean		X	% relief	SD	SE	t – value	p – value	Significance
	AT	F							
Incomplete emptying	0.55	0.5	0.05	50%	0.22	0.05	1	>0.05	N.S
Frequency	1.1	1.05	0.05	33.33	0.22	0.05	1	>0.05	N.S
Intermittency	0.35	0.20	0.15	75	0.37	0.08	1.8	<0.05	S
Urgency	0.5	0.3	0.2	80	0.41	0.09	2.18	<0.05	S
Weak stream	0.45	0.20	0.25	71.42	0.55	0.12	2.03	<0.05	S
Straining	0.25	0.25	0	0	0.45	0.10	0	>0.05	N.S
Nocturia	0.90	0.80	0.10	33.33	0.30	0.06	1.45	>0.05	N.S

The initial mean score of different IPSS in follow up period was observed as follows –

- Over incomplete emptying initial mean score was 0.55 which was came down to 0.50 within 30 days of follow up, the test of significance shows that it was non-significant over symptom.
- Over frequency, the initial mean score was 1.1 which came down to 1.05, and test of significance shows that it was non-significant over symptom.
- Over intermittency, the initial mean score was 0.35 which came down to 0.20 and test of significance showed it significant over symptom.
- Over urgency, the initial score was 0.50 which was down to 0.30 and the test of significance showed it significant over symptom.

- Over weak stream, the initial mean score was 0.45 and it came down to 0.20 and the test of significance showed it significant over symptom.
- Over straining, the initial mean score was 0.25 and it remains unchanged and test of significance was non-significant over symptom.
- Over nocturia, the initial mean score was 0.90 and it came down to 0.80 and test of significance shows that it was significant within follow up period.

Table no. 7 Total effect of therapy over maximum flow rate value

Parameter	Mean		X	% relief	SD	SE	t – value	p – value	Significance
	BT	AT							
QMAX	2.25	0.35	1.9	84.44	0.71	0.16	11.83	<0.001	H.S

The initial mean score of Qmax was 2.25 which came down to 0.35, and test of significance shows that it was highly-significant.

Table no. 8 Overall effect of therapy (IPSS)

Result on effect of therapy	Effect over IPSS	
	No .of Pt.	%
Complete cured	0	0
Marked Improvement	12	60
Moderate Improvement	5	25
Mild Improvement	3	15
Unchanged	0	0

The above table shows the overall effect of trial drug on Qmax .Out of 20 patients, 12 patients i.e. 60.00% revealed marked improvement, 5 patients i.e. 25.00% have shown moderate improvement and 3 patients i.e. 15% have shown mild improvement, among all the 20 patients none of the patient

was completely cured but all the patients showed significant changes in IPSS after completion of the course as well as follow up period.

Table no. 9 Overall effect of therapy (Qmax)

Result on effect of therapy	Effect over Qmax	
	No .of Pt.	%
Complete cured	0	0
Marked Improvement	5	25
Moderate Improvement	11	55
Mild Improvement	4	20
Unchanged	0	0

The above table shows the overall effect of trial drug on Qmax. Out of 20 patients, 11 patients i.e. 55.00% revealed moderate improvement, 5 patients i.e. 25.00% have shown marked improvement and 4 patients i.e. 20.00% have shown mild improvement after completion of the course as well as follow up period.

symptoms & seeking a safe & effective treatment for easy life. In this situation, the medicinal treatment may play an important role.

Mode of Action of Varun Shigru Ghana Vati: This formulation contains *Varun* (Cratogeomomma nurvala) and *Shigru* (Moringa oleifera) which is prescribed in treatment of *Mutraghata*, *Mutrakrichhra*, *Vatarog*, *Prameha* and *Vidridhi*. The ingredients in this formulation have *Ushna Virya*, *Kashaya*, *Madhura* & *Tikta Rasa*, *Ruksha*, *Ushna* & *Teekshna Guna*, and *Katu Vipaka* over all. With these properties, *Varun Shigru Ghana Vati* exerted pharmacological actions like *Deepana*, *Aama Pachana*, *Mutrala Lekhana*, *Shothahara*,

DISCUSSION

BPH is a common ailment of elderly population and an advisable treatment of choice is surgery, which is mentally & physically painful. Due to number of complications of operative surgery in old age, old persons avoid operative treatment for their BPH

Vilayana and Srotoshodhana etc. Further, due to these actions, Sanga is removed in Mutravaha Srotasa particularly at Basti Shira leads to reduction in size of the enlarged prostate and simultaneously correction of Agni Dusthti take place. As Mutravaha Srotasa becomes free from Avarodha (in the form of Aghata) or Avarana caused by vitiated Kapha, the vitiated Vata comes to normal state. Thus, it normalized the physiology of Apana Vayu, resulted proper evacuation of Mutra in the form of increased urine flow rate and decreased post-voidal residual urine volume. Because of improvement in Jatharagni due to Deepana-Pachana effect of drugs, Dhatvaagnies also had come down in normal state. The function of Basti Snayu might have been improved due to correction of Mamsadhatvaagni. Finally, Mamsa and Medo Vriddhi had been returned to normal state due to normalization of Dhatvagni, and ultimately lead to reduction in enlarged prostate size because of Aama Pachana, Lekhana and Sophahara action of ingredients.

The pharmacological studies on Varun and Shigru are shown potent diuretic effect and anti-inflammatory, antimicrobial, CNS stimulant, smooth muscle relaxant, 5- Reductase inhibitor, juvenile hormonal activity.

The effects of Shigru on serum concentration of ACTH, TSH, LH & FSH, adrenal, testosterone and estradiol hormones as well as its diuretic effect are well studied and is shown significant action on increasing the LH and testosterone level on administration of it. Shigru pharmacologically acts either by direct effect on gonads or through certain hormone present in body.

Shigru has 59 active principles in which three i.e. oleic acid, palmitic acid, stearic acid acts as 5- reductase inhibitor.⁷ As mentioned in modern review that 5- reductase is responsible for formation of DHT from testosterone and responsible for BPH with aging, so Shigru with the help of these three alkaloids inhibit the 5- reductase as well as prostate size.

Shigru also has -sitasterol which is antigonadotropic.⁸ It causes regression of enlarged prostate.

Shigru possess anti-proliferative and anti-estrogenic properties. It also shows an important role of natural antioxidant and as adjuvant to enhance the anticancer potential of AP9-cd and more likely other anti-neoplastic therapeutics.

Varun causes apoptosis in cancer cells via Betulinic acid⁹ – induced cell death in human prostate cancer cells. The isolated compounds from crataeva nurvala species of Varun has been tested against human prostate cancer¹⁰, it has shown moderate antiproliferative effects on human prostate cancer cell as well as inhibits the expression of androgen receptors.

Varun shows diuretic, estrogenic, smooth muscle relaxant and juvenile hormone mimicking activities and study reveals that its ability to inhibit the enzyme xanthine oxidase (XO) and to exert apoptotic effect on cancer cells.¹¹

Varun due to triterpene is good in improving the detrusors tone i.e. the musculature of urinary bladder along with the anti-infective properties.

So, based on above results of pharmacological studies and clinical results in present

study, it can be hypothesized that the formulation of *Varun Shigru Ghana Vati* may act on symptoms of BPH by reducing size of prostate via anti-proliferative, anti-inflammatory¹², anti-tumour, 5 - reductase inhibitor anti-estrogenic and enhancing apoptosis effect. Further it may be attributed to improving urine flow and reducing post-voidal residual urine as well as producing diuretic effect and increasing LH & testosterone levels and correcting the HPG axis as well as relaxing smooth muscles of prostate & internal urethral sphincters.

Discussion on effect of therapy –

The effect of therapy was analyzed by specially designed scoring pattern for IPSS, Uroflowmetry and student “t” test of significance was applied for that purpose.

Effect of therapy on symptomology (IPSS):

- The result shows that there was highly significant improvement ($p < 0.001$) observed in the symptom of incomplete emptying it may be due to *Mutral (Madhura Rasa)* property of *Varun*. *Varun* decreases post voidal residual urine and improves bladder tonicity.
- There was highly significant improvement ($p < 0.001$) observed in the symptom Intermittency. It may be due to *Shrotoshodhak* property of *Shigru* which is due to *Laghu* and *Tikshna Guna* of *Shigru*. Also due to anti-inflammatory property of *Shigru* and weight reducing property of prostate of *Varun*.
- The result was highly significant ($p < 0.001$) in the symptom Urgency. It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa,*

Ruksha Guna) and *Vilayana (Ushna Virya)* property of *Varun* and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Shigru* which reduces the size of prostate and so, reduces the symptom. Also due to reduction of prostate weight by anti-androgenic activity of *Varun*.

- The result shows that there was highly significant improvement ($p < 0.001$) observed in the symptom Weak stream. It may be due to *Lekhan* and *Shrotoshodhak* property of *Shigru* which is due to *Laghu* and *Tikshna Guna* of *Shigru*. Also due to bladder tone improvement and weight reduction of prostate by *Varun*.
- In the symptom Straining the result was also statistically highly significant ($p < 0.001$). It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)* *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Varun* and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Shigru* which reduces the size of prostate and so, reduces the symptom. Also due to reduction of prostate weight by anti-androgenic activity of *Varun*.
- It was observed that improvement in the symptom Nocturia was also statistically highly significant ($p < 0.001$). It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Varun* and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Shi-*

gru which reduces the size of prostate and so, reduces the symptom.

Effect of therapy on objective parameter (Qmax) -

The initial mean score of maximum flow rate was observed 2.25, which came to 0.35 after completion of treatment with 84.44% relief. The test of significance shows that treatment was highly significant ($p < 0.001$). Qmax presents the overall effect of BPH symptom so, it shows improvement due to action of all the properties of the used indigenous drug which are *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Varun* and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* and *Vilayana (Ushna Virya)* property of *Shigru* which reduces the size of prostate and so, reduces the symptom. *Lekhan* and *Shrotoshodhak* property of *Shigru* which is due to *Laghu* and *Tikshna Guna* of *Shigru*, also due to bladder tone improvement and weight reduction of prostate by *Varun*. *Mutral (Madhura Rasa)* property of *Varun*. *Varun* decreases post voidal residual urine and improves bladder tonicity.

Discussion on results:

IPSS: After the treatment, it was observed that 60.00% of patients had shown marked improvement and 25.00% of patients had shown moderate improvement, 15.00% of patients had shown mild improvement and no patient was completely cured in IPSS after completion of course & follow up period.

Qmax: Overall, 25.00% of patients had shown marked improvement and 55.00% of patients had shown moderate improvement, 20.00% of patients had shown mild im-

provement and no patient was completely cured in objective parameter (Qmax) after completion of course & follow up period. These results are probably due to the combined effect of trial drug i.e. *Varun Shigru Ghana Vati* has got potent *Vata-Kapha Shamaka* properties due to its *Pachana, Bastishodhana, Mutral, Grahee, Pramathee* and *Vata-Kapha Shamaka* pharmacological actions which played vital role in breaching *Samprapti* of *Vatashthila*. Increase in maximum urine flow rate was observed due to normalization of the functions of the *Apana Kshetra* produced by the *Mutral, Pramathee, Pachaneeya, Bastishodhana, Vata Shamaka* effect of drug.

Results also depends on the compliance of patient that, had he took medicine routinely or not? So, may be the results got better than this.

CONCLUSION

Use of *Varun Shigru Ghana Vati* in BPH is cheap effective and easily palatable for patients. Use of *this Vati* in early stage of BPH can prevent the further progressive pathology of disease. *Varun Shigru Ghana Vati* gives symptomatic relief in irritative symptoms like urgency, frequency, nocturia as well as in obstructive symptoms like straining, weak stream and incomplete emptying of bladder. Most of the patients having associated symptoms i.e. constipation and *Varun Shigru Ghana Vati* showed marked improvement for constipation.

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