

## VARUNA SHIGRU GUGGULU AND BALA TAILA MATRA BASTI IN THE MANAGEMENT OF MOOTRAGHATA (BENIGN PROSTATIC HYPERPLASIA) - AN OBSERVATIONAL CLINICAL STUDY

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### ABSTRACT

**Background:** Benign Prostatic Hyperplasia is one of the major clinical conditions related with ageing process in men. It affects the quality of life and causes physical and mental stress to the patient. According to Ayurvedic principles, vitiated *Kapha* and *Vata doshas* are responsible for the pathology of benign prostatic hyperplasia. **Aim:** To evaluate the clinical effect of *Varuna Shigru Guggulu* and *Bala Taila Matra Basti* in the management of *Mootraghata* w.s.r. to BPH. **Material & Methods:** The study was open prospective in which 50 patients having signs and symptoms of *Mootraghata* / BPH were randomly selected from OPD and IPD of *Shalya Tantra* of research hospital. In the, herbal drug *Varuna Shigru Guggulu* (500 mg three times orally), and the *Bala Taila Matra Basti* (60 ml once daily, through rectum route) tried in this study. The treatment was given for 30 days and assessed as per gradation adopted. **Statistical analysis used:** The obtained data of all patients was statistically analyzed by paired 't' test for objective parameters and wilcoxon signed rank test for subjective parameters and laboratory investigations. **Results and Conclusion:** *Varuan Shigru Guggulu* orally and *Bala Taila Matra Basti* was tried in 50 patients as observational study which showed good result in symptomatic management of BPH. Hence study has concluded that *Varuna Shigru Guggulu & Bala Taila Matra basti* is safe and effective in *Mootraghata*.

**Keywords:** Ayurveda, *Bala Taila*, Benign Prostatic Hyperplasia, *Matra Basti* , *Mootraghata*

### INTRODUCTION

Benign prostatic hyperplasia (BPH) is very common disease of aged male persons. Some recent epidemiological studies have revealed that, to a large extent lifestyle factors associated with metabolism including obesity, blood glucose, exercise, and diet also contribute substantially to the development of

these conditions.<sup>[1]</sup> The prevalence of histopathologic BPH is age-dependent, with initial development usually after 40 years of age<sup>[2]</sup> and more than 50% of men in their 60s and upto 90% of men in their 70s and 80s have some symptoms of BPH.<sup>[3]</sup> The disease refers to the adenomatous enlargement of the peri

urethral tissue of prostate gland, leading to obstruction of the urethral passage and outlet of bladder neck. The enlarged prostate creates pressure on the urethra causing obstructive urinary symptoms like increased frequency of urination, dysuria, urinary urgency, nocturia and dribbling of urine etc. [4] International surveys have found a high prevalence of moderate to severe obstructive symptoms in men over the age of fifty years. [5] In modern medicine the management of BPH is either by conservative treatment using drugs (e.g. hormonal therapy, chemotherapy etc.) or through a surgical approach (e.g. open prostatectomy, transurethral resection of prostate-TURP, cryotherapy, etc.). [6] In old age the surgery is associated with many complications like postoperative morbidity, impotence, retrograde ejaculation. [7] In case of hormonal therapy there are complications like loss of libido, impotence, gynaecomastia and moreover, it is also very expensive. In *Ayurvedic* classics *Mootraghata* is explained as having symptoms of low urinary output either by retention, absolute or relative anuria or oliguria. *Mootraghata* is predominantly due to the *Vata Dosha* in general and *Apana Vayu* in particular. [8] The *Apana Vayu* is responsible to expel the urine timely & uniformly. If *Vata* gets vitiated, it causes various diseases related to *Basti* & produces *Mootraroga* such as *Prameha*, *Ashmari*, *Mootraghata*, *Mutrakrichchra* etc. In *Ayurveda*, *Mootraghata* has some similarity with BPH on the basis of symptoms like *Achala Unnata Granthi* (immobile & elevated), *Vinmutranilasanga* (retention of urine, feces & flatus), *Bastiadhmana* (distension of the urinary bladder), *Vedanachaparabastou* (excruciating pain in the bladder). [9] *Basti (Matra Basti)* is authentic treatment for vitiated *Vayu* in which there is no strict restriction. [10] So, for the *Vata dosha*, *Basti* in general and *Matra Basti* in particular may be helpful in reducing the size of the prostate and enhancing the tone of urinary bladder. Considering this concept in mind, this study using *Varuana Shigru Guggulu* orally and *Bala Taila Matra Basti* was tried in 50 patients as clinical with following Aims & Objectives.

**Aim & Objectives:** To evaluate clinical efficacy of *Varuna Shigru Guggulu* and *Matra Basti* of *Bala Taila* in the management of *Mootraghata* w.s.r. to BPH.

**Materials and Methods:** 50 patients having signs and symptoms of *mootraghata* / BPH were randomly selected from OPD and IPD of I.P.G.T. & R.A. Hospital, Jamnagar. The trial formulations *Bala Taila* & *Varuna Shigru Guggulu* were prepared and supplied by Pharmacy of Gujarat Ayurveda University, Jamnagar. Ethical clearance was obtained from Institutional Ethics Committee (no.PGT/7A/Ethics/2014-15/ 2652, dated 18/12/2014.) before commencement of the study. Informed consent was taken from each registered patient before starting the treatment. The trial is also registered to Clinical Trial Registry of India (CTRI/2015/10/006279) retrospectively.

**Inclusion Criteria:** Patients of age more than 40 years having signs and symptoms of *Mootraghata* (BPH) were included in this study. Controlled cases of Diabetes and controlled Hypertension patients have been also included in this study.

**Exclusion Criteria:** Patients below 40 years of age were excluded. Patients suffering from malignancy, Systemic diseases like Uncontrolled Hypertension (HT) & Diabetes Mellitus (DM), Tuberculosis (TB), Paralysis, and Parkinsonism etc. were excluded from study.

**Interventions:** *Varuna Shigru Guggulu* was administered in dose of 500 mg, orally three times (TID) for 30 days with luke warm water, half an hour before intake of food., *Bala Taila* was administered in 60 ml once daily as *Matra basti*, for 30 days just before breakfast. (*Matra Basti*- through rectum route)

**Procedure of *Matra Basti*:** In most of the patients *Matra basti* was administered indoor i.e. *Shalya* male ward and adopted standard procedure of *Matra basti* was followed. [11]

**CRITERIA FOR ASSESSMENT:** The assessment was done on the basis of subjective parameters [12] and objective parameters [13] and the data was analyzed statistically.

## DISCUSSION

The concept of nodular hyperplasia in pathology of BPH has been established but its exact cause is still unknown.<sup>[14]</sup> In fact, the development of BPH is multifactorial phenomenon as there is no strong evidence for risk factors like smoking, vasectomy, obesity or high alcohol intake for developing clinical features of BPH.<sup>[15]</sup> The *Mootraghata* in Ayurveda is a broad term and it can be considered as a syndrome, because it covers most of the pathological entity of the urinary system as twelve types.<sup>[16]</sup> These types may be correlated with three major groups of modern parlance i.e. Neurogenic Bladder Disturbances (NBD), Bladder Outflow Obstruction (BOO) & Lower Urinary Tract Symptoms (LUTS).

Most of the patients in this study (66.00%) were from the age-group of 61-80 years as BPH is a disease related to aging. 54.00% of patient had chronicity of more than a year of BPH which suggest the slow progressive nature of BPH. 82.00 % of patients belonged to *vata-kaphaja prakriti* which is an important risk factor for susceptibility or development of *mootraghata*. (Table no. 1) The symptoms of BPH like, nocturia, increased frequency, dysuria, incomplete voiding and weak stream was observed in more than 60% of patients as these are cardinal symptoms of BPH (Table no. 2). The per rectal digital examination findings of BPH like enlargement of lobes- bilateral, smooth-surface, upper border-unapproachable, median groove-not palpable, soft-consistency, free-rectal mucosa and size of prostate as mild were observed in most of the patients. These findings are suggestive that the selected patients had the benign enlargement of prostate and there was no possibility of them malignant being (Table no.3).

In this study, highly significant result ( $P < 0.001$ ) was observed in International Prostate Symptoms Score (IPSS) (Table no.4). In Objective Parameters highly significant result ( $P < 0.001$ ) was observed in Average Urine Flow Rate (AUFR) and in reduction of Prostate Size. Also, in Post voidal residual urine (PVRU), 50.00 % patients showed improvement (Table no. 5). In this study significant result ( $P < 0.05$ ) was found in Serum prostate specific antigen (PSA) and Serum

testosterone levels shows that this drug is very effective in BPH (Table no. 6). The overall result showed that 28.00 % patients with maximum improvement, 54.00 % cases with moderate improvement and 16.00 % patients showed mild improvement in signs and symptoms. A complete cure was not observed in any of the patients while one patient found unchanged during therapy. So it can be said that study showed positive effect in the management of BPH (Table no. 7). *Varun Shigru Guggulu* and *Bala Taila Matra Basti* gives effective result in irritative symptoms like urgency, frequency, nocturia as well as in obstructive symptoms like straining, weak stream and incomplete emptying of bladder.

### Discussion on probable mode of action:

The trial formulation (*Varuna Shigru Guggulu*) contains *Varun (Crativa nurvala)*, *Shigru (Moringa oliefera)* and *Guggulu (Commiphora Mukul)* which is prescribed in treatment of *Mutrakrichhra*, *Vataroga*, *Prameha* and *Vidridhi*. The ingredients in this formulation have *Ushna Virya*, *Kashaya*, *Madhura & Tikta Rasa*, *Ruksha*, *Ushna & Teekshna Guna*, and *Katu Vipaka*. With these properties, *Varun Shigru Guggulu* exerted pharmacological actions like *Deepana*, *Aama Pachana*, *Mutrala*, *Lekhana*, *Shothahara*, *Vilayana* and *Srotoshodhana* etc. Further, due to these actions, *Sanga* is removed in *Mutravaha Srotasa* particularly at *Basti Shira* which leads to reduction in size of the enlarged prostate with simultaneous correction of *Agni Dusthti*. 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*, which in 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 attained normal state. The function of *Basti Snayu* might have been improved due to correction of *Mamsadhatvaagni*. Finally, *Mamsa* and *Medo Vriddhi* returned to normal state due to normalization of

*Dhatvagni*, which 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* have shown potent diuretic activity above with anti-inflammatory, antimicrobial, CNS stimulant, smooth muscle relaxant, 5- $\alpha$  reductase inhibitor,<sup>[17]</sup> 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 to have 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 of which three i.e. oleic acid, palmitic acid, stearic acid acts as 5- $\alpha$  reductase inhibitor. As mentioned in modern review the 5- $\alpha$  reductase is responsible for formation of DHT from testosterone and responsible for BPH with aging, so *Shigru* with the help of these three alkaloids inhibits the 5- $\alpha$  reductase as well as prostate size. *Shigru* also has  $\beta$ -sitosterol which is antigonodotropic.<sup>[18]</sup> It causes regression of enlarged prostate. *Shigru* possess anti-proliferative and antiestrogenic properties. It also shows an important role of natural antioxidant and acts as an adjuvant to enhance the anticancer potential of AP9-cd and more likely other anti neoplastic therapeutics. *Varun* causes apoptosis in cancer cells through Betulinic acid<sup>[19]</sup> induced cell death in human prostate cancer cells. The isolated compounds from *Crataeva nurvala* species of *Varun* have been tested against human prostate cancer,<sup>[20]</sup> it has shown moderate anti proliferative 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 the study reveals that its ability to inhibit the enzyme xanthine oxidase (XO) and to exert apoptotic effect on cancer cells.<sup>[21]</sup> *Guggulu* causes apoptosis in cancer cells via **guggulsterone** induced cell death in human prostate cancer cells. The isolated compounds from *Commiphora opobalsamum* species of *guggulu* have

been tested against human prostate cancer; it has shown to have moderate anti-proliferative effect on human prostate cancer cell as well as inhibits the expression of androgen receptors.<sup>[22]</sup>

In *Bala Taila* only two drugs *Atibala* (*Abutilon indicum*) and *Tila Taila* (*Sesamum indicum* Linn.) are used. In the management of *Mootraghata*, it is clearly mentioned to use *Taila* as *Sneha Dravya* in the forms of *Pana*, *Abhyanga* as well as *Basti*.<sup>[23]</sup> Beta Sitosterol has been identified as the active ingredient in *Atibala* (*Abutilon indicum*).<sup>[24]</sup> It is proved scientifically that beta sitosterol has anti-inflammatory effects (through interference with prostaglandin metabolism) and anti-androgenic or anti-estrogenic effect.<sup>[25]</sup> The active chemical component beta sitosterol in any herb is proved very effective in BPH. *Tila taila* (*Sesamum indicum*) has linoleic acid and oleic acid as a chemical component.<sup>[26]</sup> They are inhibitors of both 5- $\alpha$  reductase and  $\alpha$  blockers activity.<sup>[27]</sup> The inhibition of 5- $\alpha$  reductase controls the conversion of testosterone to Dihydrotestosterone (DHT). So controlling DHT ultimately controls the further growth of prostate gland and produces relief in the symptoms.

## CONCLUSION

The study concludes that *Varuna Shigru Guggulu* and *Bala Taila Matra Basti* are very effective in BPH patients. Use of this therapy in early stage of BPH can prevent the further progressive pathology of disease. Important thing to note is that no adverse effect was reported throughout the study. Therefore, these formulations can be used for the BPH with great confidence.

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## OBSERVATIONS AND RESULTS:

**Table 1:** Observation on demographic data (n=50)

Observation	No. of Patients	%
Age (61 to 80)	33	66.00
Religion (Hindu)	48	96.00
Socio economic status (Lower Middle Class)	33	66.00
Occupation (Retired)	40	80.00
Education (Literate)	37	74.00
Diet habit ( <i>Samasana</i> )	30	60.00
<i>Agni</i> ( <i>Samagni</i> )	26	52.00

Bowel habit (Regular)	41	82.00
Prakriti (Vata-kapha)	41	82.00
Table No 2 – Symptoms		
Symptoms	No. of Patients	%
Nocturia	41	82.00
Increased Frequency	42	84.00
Dribbling	30	60.00
Haematuria	1	02.00
Burning Micturition	16	32.00
Dysuria	45	90.00
Incomplete Voiding	37	74.00
Weak Stream (Stop & Start)	50	100.00
Urgency	25	50.00
Chronicity ( Above 1 year)	27	54.00

**Table 3:** Observation on Local Findings (n=50)

Observations	No. of Patients	%
Enlargement of Lobes (Bilateral)	43	86.00
Shape (Round)	43	86.00
Surface (Smooth)	49	98.00
Upper Border of gland (Unreached)	29	58.00
Median groove (Not palpable)	40	80.00
Mobility ( Fixed)	50	100.00
Rectal Mucosa (Free)	50	100.00
Consistency (Soft)	30	60.00
Tenderness (Absent)	47	94.00
Size of Prostate (Mild)	27	54.00

**Table 4:** Effect of Therapy on IPSS (Subjective Parameters) (n=50)

International Prostate Symptoms Score (AUA)	Mean Score		n	% Relief	SD	SEM	W	T	P
	BT	AT							
Incomplete emptying	3.8	0.7	50	80.83	1.996	0.282	741	741	<0.001
Frequency	4.1	0.8	50	79.61	1.738	0.246	903	903	<0.001
Intermittency	4.3	0.9	50	79.17	1.762	0.249	903	903	<0.001
Urgency	2.5	0.4	50	80.95	2.204	0.312	325	325	<0.001
Weak stream	4.9	1.2	50	73.88	1.563	0.221	1081	1081	<0.001
Straining	4.5	0.8	50	80.70	1.435	0.203	1081	1081	<0.001
Nocturia	3.6	1.2	50	64.44	1.518	0.215	820	820	<0.001
Quality of life	4.9	1.5	50	69.35	1.053	0.149	1275	1275	<0.001

**Table 5:** Effect of Therapy on Objective Parameters (n =50)

Objective Parameters	Mean Score		% Relief	SD	SE	t	P
	BT	AT					
Prostate Size & Volume	50.08	48.62	2.91	4.883	0.691	2.114	<0.001
Post voidal Residual Urine Volume	26.10	21.12	19.08	30.37	4.296	1.159	>0.05
Average Urine Flow Rate	2.87	4.52	57.52	1.013	0.143	11.526	<0.001

**Table 6:** Effect of therapy on Laboratory Investigations (n =50)

Investigations	Mean Score		% Relief	SD	SEM	t	P
	BT	AT					
FBS	86.98	86.44	3.93	26.89	3.804	0.931	> 0.05
S. Alkaline Phosphatase	51.72	50.00	3.33	12.88	1.822	0.944	> 0.05
S. PSA	3.33	3.00	9.28	1.631	0.238	1.409	> 0.05
S. Testosterone	507.13	514.96	1.54	166.21	23.51	-0.333	> 0.05
Blood Urea	30.44	31.60	-3.81	11.00	1.556	-0.746	> 0.05
S. Creatinine	1.2	1.2	0.63	0.347	0.049	0.163	> 0.05

**Table 7:** Overall Effect of therapy (n =50)

Parameters	Effect on Subjective parameters (IPSS)		Effect on Objective Parameter		Overall Effect of therapy	
	n	%	n	%	n	%
Overall Effect of therapy						
Complete cured	3	6	0	00.00	0	00.00
Maximum Improvement	21	42	0	00.00	14	28
Moderate Improvement	23	46	0	00.00	27	54
Mild Improvement	2	4	6	12	8	16
Unchanged	1	2	44	88	1	2

**Source of Support: Nil**

**Conflict Of Interest: None Declared**

How to cite this URL: Joyal Patel: Varuna Shigru Guggulu And Bala Taila Matra Basti In The Management Of Mootraghata (Benign Prostatic Hyperplasia) - An Observational Clinical Study. International Ayurvedic Medical Journal {online} 2019 {cited August, 2019} Available from: [http://www.iamj.in/posts/images/upload/1299\\_1305.pdf](http://www.iamj.in/posts/images/upload/1299_1305.pdf)