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Research Article

EFFICACY OF *GOKSHURADI GUGGULU, SHUDHA SILAJIT* AND *DASHMOOL GHRUTA* IN BENIGN PROSTATIC HYPERPLASIA (*ASTHEELA*) – AN OPEN OBSERVATIONAL STUDY

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ABSTRACT

Objective: To assess the clinical efficacy of *Goksuradi gugulu, Shudha Silajeet* and *Dashamula ghruta vasti* in the management of *Astheela* (BPH).

Materials and Method: This is an interventional, open, perspective, non-controlled, single group assigned study, designed to evaluate efficacy of Ayurvedic medicine on BPH (*Astheela)* studied on 40 patients. The study period was 84 days.

Results: MFRml/S (Maximum flow rate) at base line was 12.1400 which was increased to 13.9475 ml/S at 84th day after treatment. Similarly the mean PVR (Post void Residual Urine) at base line was 147.5750ml which was reduced to 89.7500 ml after 84 days of treatment. The mean MLP (Median Lobe Projection) before treatment was 7.0375mm which was reduced to 6.5300mm, which is not statistically significant. The Mean Prostate Weight at base line was 38.0250 which was reduced to 37.9250 after treatment and was not statistically significant. The effect on symptoms was found to be satisfactory. The percentage of recovery in intermittent flow of urine was 96.15, in Poor flow of urine was 31.21. Similarly the percentage of recovery in incomplete emptying of bladder, dribbling of urine, retention of urine, urge incontinence, frequency was 95.24, 93.75, 83.34, 90, 97.44 and 92.6 respectively which was statistically significant. But no change in nocturnal incontinence was found.

KEYWORDS: Benign Prostatic Hyperplasia, BPH, *Astheela, Gokshuradi Guggulu, Shudha Silajit, Dashmool Ghruta*.

INTRODUCTION

Benign Prostatic Hyperplasia also referred as Benign Prostatic Hypertrophy, is a non-malignant enlargement of the prostate gland affecting aging men and is responsible for compromises in the quality of life in the geriatric population[1]. Histologically Benign prostatic hyperplasia is characterized by a coalescence of atrophy and proliferation in prostatic glandular and stromal tissue**.** Post-mortem studies show that the first signs of BPH appear before the age of 40 years, followed by a rapid increase in prevalence with age and 80% of 80-year-olds have evidence of BPH [2]. In Ayurveda this disease clinically simulate with *Astheela.* It is described under one of the 13 types of *Mutraghata* (Obstructive Uropathy)[3]. The goal of BPH treatment is to reduce excessive cell growth. Recent clinical trials have suggested that 5α-reductase inhibitors and long acting α1-adrenergic antagonist drugs are effective in the treatment of BPH. But, these drugs have frequent adverse effects (headache, dizziness, hypotension, fatigue, reduced libido, impotence, breast tenderness, breast enlargement, and reduced sperm count), which are major limitations for long-term usage.[4] Due to these limitations, extensive research work was done and some Ayurvedic formulations have been shown beneficial in the management of BPH. In Ayurvedic texts so many drugs are available for the management of *Astheela* The drugs which are having *Vrishya* and *Rasayan* property that is anti-ageing action anti-inflammatory drugs (*Shothnashak*) to minimize the size of BPH, *Vata* and *Kapha shamak* to pacify vitiated *Doshas* and, diuretic (*Mutrala*) action were selected for the study. *Gokshura, Shilajatu* and *Dashmulas* are having these properties and hence these were selected.[5,6,7] This study was planned to evaluate the efficacy of Ayurvedic Medicine with *Vasti* (Therapeutic purgation) in BPH (*Astheela*).

OBJECTIVES OF THE STUDY

Primary Objective of the study is to assess the clinical efficacy of *Goksuradi gugulu*, *Shudha Silajeet* and *Dashamula ghruta vasti* (Therapeutic purgation) in the management of BPH *(Astheela*).

MATERIALS AND METHODS

Study Design

This is an interventional, open, perspective, non-controlled, single group assigned study, designed to evaluate efficacy of Ayurvedic medicine. The total treatment period was 84 days. The patients were recruited at the outpatient department of Central Ayurveda Research Institute for Cardiovascular Disease, New Delhi India.

Inclusion criteria

Male of 40-80 years of age, who understand and have the ability to sign written informed consent prior to study having moderate to severe BPH, whose post void residual volume (PVR) < 250ml and the patients AUA (American urological association) symptom score index mild (0-7 points) to moderate (8-19 points) were included in the study.

Exclusion criteria

Patients with prostate and bladder carcinoma, prostatitis, neurogenic bladder, stricture urethra, diabetes mellitus, vesicle calculus were excluded from the study. Patients with severe Cardiovascular, kidney or liver disorders, and patients indicated for surgery with refractory retention and recurrent or persistent gross hematuria were excluded from the study.

Study procedure

At the initial visit, a detailed medical history, with special emphasis on history of urinary symptoms (urgency, frequency, nocturia, hesitancy, straining, intermittency, terminal dribbling and sensation of incomplete voiding) was taken from all patients. All patients underwent a thorough systemic examination, which was followed by ultra-sonography of kidney urinary bladder and prostate region for determining prostate size, presence of nodule, asymmetry and tenderness. Routine biochemical blood tests (Hb, TLC and DLC) and specific tests of renal safety like urea, creatinine was done for all patients. The prostate volume and Post void residual urine was determined by abdominal ultrasound and/or Trans rectalultra-sonography.

Drug intervention

All patients were advised to consume 1gm tablet of *Goksuradi gugulu, Shudha Silajeet* 500mg twice in a day after food for a period of 84 days followed by *Dashmulghruta vasti* (20ml) once in a day. All the medicines were procured from IMPCL that supplied to attached pharmacy in this Hospital.

Method of Administration of *Vasti*

On the day before administration of *Vasti* the patients were asked to take light diet. Then the patients were made to lie in left lateral position where the left lower extremity straight and right lower extremity flexed on knee and hip joint. The patient's left hand was kept under his head. Light massage was done in anal region for 2 minute. Then 20ml of luke warm *Dashmool ghruta* was taken in enema syringe. The syringe was fixed with a rubber catheter lubricated with *Dashmool ghruta*. Rubber catheter was inserted into the anus of the patient up to the length of 4-5 inches. Caution was taken not to enter the air in to the anus. The patients were asked to take deep breath while introducing the catheter and drug. After the administration of *Vasti*, patient was advised to lie in supine position and patient's buttocks were gently tapped and waist region was kept slightly raised. After few minute the patients were advised to get up from the table and take rest.

Follow-Up and Assessment

All patients were followed for a period of 84 days. At each 14th day follow-up visit, the AUA (American urology association Table no 1) symptom score and prostate size was evaluated and recorded. A complete clinical, biochemical and ultra-sonographic examinations was carried out at the end of the 84th day. The changes in subjective and objective parameters were enumerated in Table no 3, 4, 5.

Table 1: American Urological Association BPH Symptom Score Index Questionnaire

	Not at all	less than 1 time in 5	less than ½ the time	about ½ the time	more than ½ the time	almost always	Your Score
Incomplete Emptying Over the last month how, often have you had a sensation of not emptying your bladder completely after you finish	0	1	2	3	4	5	
Frequency During the last month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	

I**ntermittency** During the last month, how often have you stopped and started again several time when you urinate	0	1	2	3	4	5	
Urgency During the last month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
Weak Stream During the last month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining During the last month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	
Nocturia During the last month, how many times did you most typically get up to urinate from the time you I went to bed until the time you got up in the morning?	0	1	2	3	4	5	

Add the score for each number above, and write the total in the space to the right Symptom Score =

1-7 Mild, 8-19, Moderate, 20-35 Severe.

Adverse Events

Patients were specifically questioned as per a pre-determined list of common symptoms. Patients were also encouraged to volunteer information that they considered to be adverse events (AE) or a side effect (SE).

Withdrawals

Patients could withdraw voluntarily or at the discretion of the Investigator.

Table 2: Demographic Data

Variables	**N (%)**	**Mean ± SD**
Age		55.1 ± 7.96
BMI(Kg/m$^{2)}$		25.49 ± 3.12
Habitat		
Urban	25 (62.5)	
Semi urban	14 (35)	
Rural	1 (2.5)	
Economic Status		
Above poverty Line	36 (90)	
Below poverty line	4(10)	
Occupation		
Desk Work	35 (87.5)	
Field work with physical labor	5 (12.5)	
Dietary Habits		
Veg	4 (10)	
Non Veg	36(90)	
Prakriti		
Vataj	11(27.5)	
Pittaja	03(7.5)	
Kaphaja	15(37.5)	
Vatta pitta	03(7.5)	
Vata kaphaj	05(12.5)	
Pitta kaphaj	03(7.5)	

RESULT

Table 3: Showing Symptom wise Observation in Studied Case

Symptoms	Base line (n)	After 84 days	Percentage of Recovery
Hesitancy	29	02	93.10
Difficult in micturition	39	02	94.87
Intermittent flow of urine	26	01	96.15
Poor flow of urine	16	11	31.25
Incomplete emptying of bladder	21	01	95.24
Dribbling of urine	16	01	93.75
Retention of urine	06	01	83.34
Nocturnal incontinence	02	02	00
Urge incontinence	10	01	90
Frequency	39	01	97.44
Nocturia	27	02	92.6

Efficacy of Trial Drugs on Outcome Measures

The outcome measures were compared from baseline to end of the treatment. The mean total MFRml/S (Maximum flow rate) at base line was 12.1400 which was increased to 13.9475 ml/Sat 84th day after treatment. Similarly the mean PVR (Post void Residual urine) at base line was 147.5750 ml which was reduced to 89.7500 ml after 84 days of treatment. The mean MLP (Median lobe projection) before treatment was 7.0375mm which was reduced to 6.5300mm after 84 days of treatment and was found statistically significant. The Mean Prostate Weight at base line was 38.0250 which was reduced to 37.9250 after treatment which was not statistically significant. The effect on symptoms on the basis of AUA score was found to be satisfactory. The percentage of recovery in hesitancy was 93.10 after 84 days, percentage of recovery in difficult in micturition 94.87. The percentage of recover in intermittent flow of urine was 96.15. The percentage of recovery in poor flow of urine was 31.21. Similarly the percentage of recovery in incomplete emptying of bladder, dribbling of urine, retention of urine, urge incontinence, frequency was 95.24, 93.75, 83.34, 90, 97.44 and 92.6 respectively. But no change in nocturnal incontinence was found. The subjective findings were analyzed and enumerated in Table no. 5. The two-tailed P value is less than 0.0001 by conventional criteria in sign and symptoms, this difference is considered to be extremely statistically significant so far as clinical features are concerned. So far as USG findings are concerned P value is significant in MFR ML/S, PVR ml. MLP, while p value is not significant in prostatic weight.

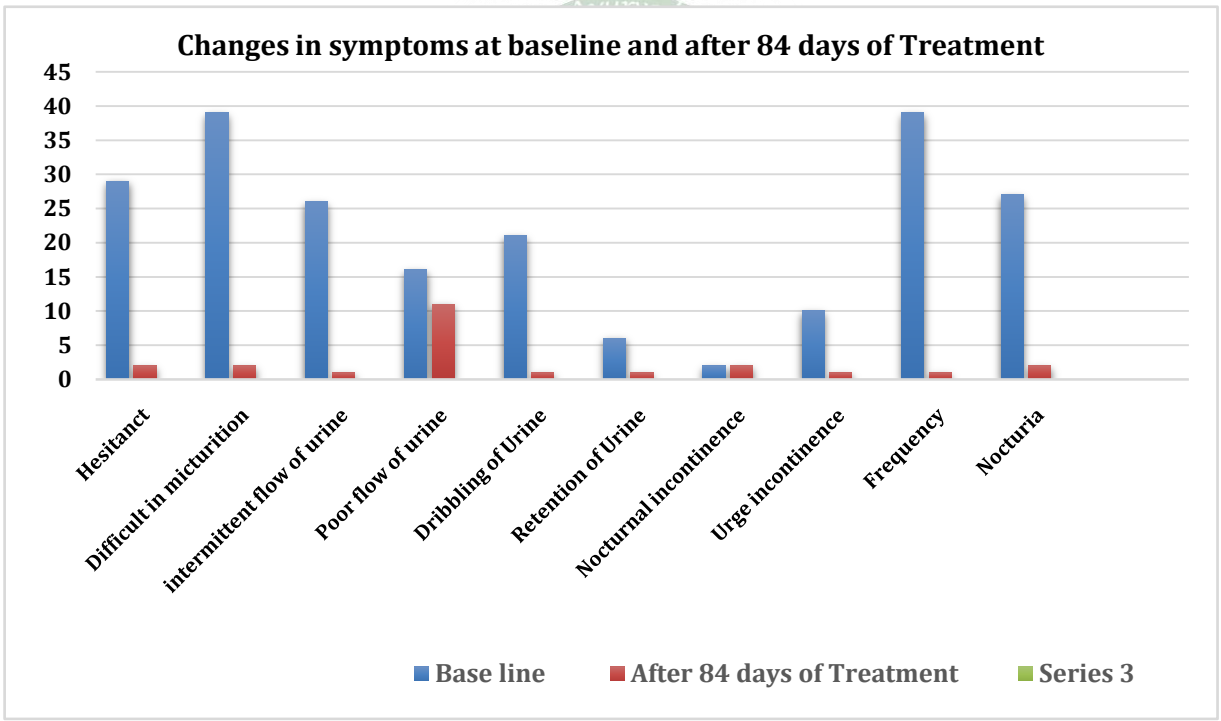
Table 4: Ultra Sonographic Findings

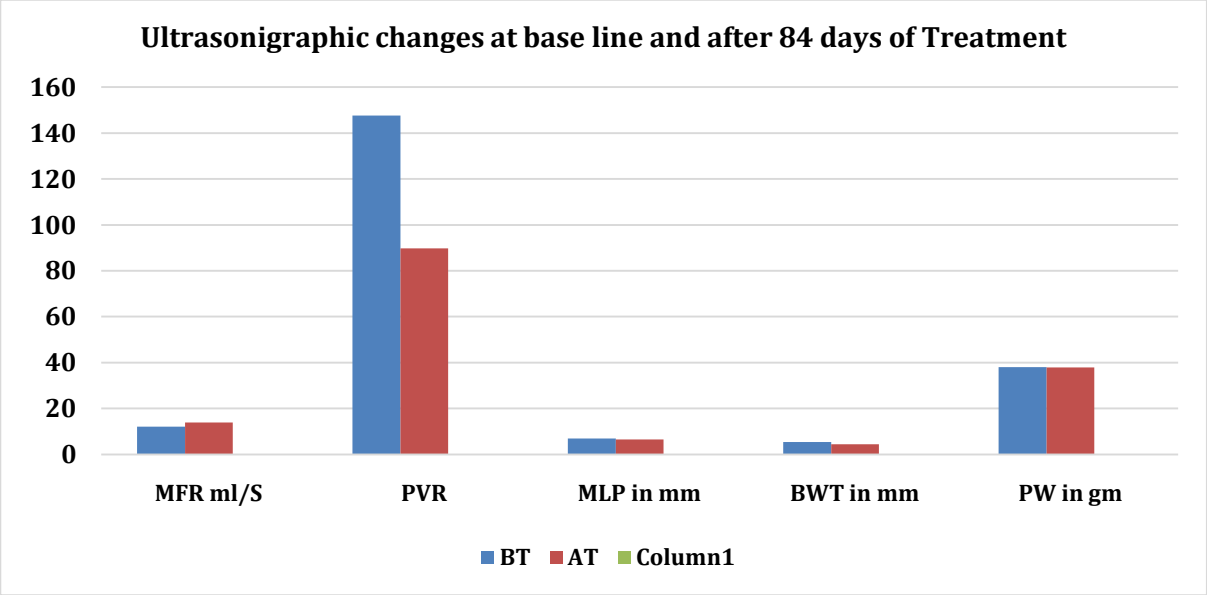
Variables		Mean	Std. Deviation	Std. Error Mean	p-value	t-value	Significant
MFR ml/S	BT	12.1400	3.51800	0.55624	0.0001	2.3829	Significant
	AT	13.9475	3.26159	0.51570			
PVR ml.	BT	147.5750	7.68578	1.21523	0.0001	39.4877	Significant
	AT	89.7500	5.16770	0.81709			
MLP In mm.	BT	7.0375	.56961	0.09006	0.0003	3.7842	Significant
	AT	6.5300	.62847	0.09937			
BWT in mm.	BT	5.5000	.24807	0.03922	0.0001	18.3335	Significant
	AT	4.5775	.19934	0..03152			
PW in gm.	BT	38.0250	1.62493	0.25692	0.8177	0.2312	Not Significant
	AT	37.9250	2.20009	0.34786			

(MFR= Maximum flow rate, PVR= Post Void residual volume, MLP=Median lobe projection, BWT= Bladder wall thickness, PW=Prostate Weight. BT-Before Treatment, AT-After Treatment

Table 5: Efficacy in Clinical Features

		Mean	Std. Deviation	Std. Error Mean	p-value	t-value	Significant
Frequency During the last month	BT	2.77	0.919517	0.145388	P<0.0001	8.8903	Highly significant
	AT	0.97	0.891196	0.140910			
Intermittency	BT	2.6	0.900142	0.142325	P<0.0001	9.8590	Highly significant
	AT	0.8	0.723240	0.114354			
Weak Stream	BT	2.45	0.932325	0.147413	P<0.0001	10.639	Highly significant
	AT	0.58	0.594622	0.095215			
Incomplete Emptying	BT	2.55	0.814924	0.128850	P<0.0001	11.234	Highly significant
	AT	0.7	0.648469	0.102532			
Nocturia	BT	2.57	0.675106	0.106743	P<0.0001	13.055	Highly significant
	AT	0.7	0.607643	0.096076			
Straining	BT	1.7	0.939175	0.148496	P<0.0001	5.8945	Highly significant
	AT	0.65	0.622237	0.098384			
Urgency	BT	2.65	0.699816	0.110650	P<0.0001	11.932	Highly significant
	AT	0.8	0.686873	0.108604			





DISCUSSION

In this study effect of *Gokshuradi guggulu*, *Sudha Silajeet* and *Dashmula ghruta vasti* was tried. So as far as demographic data is concerned [Table -2] it has been found that the disease predominantly found in the older age group. In this study the mean age was 55years. The disease is more prevalent in higher BMI subjects. In this study the mean BMI was 25.49. In this study the urban population was 62.5%, semi urban population was 35% and rural population was 2.5%. So far as the economic status of the subjects is concerned 90% subjects were above poverty line and only 10% subjects were below poverty line. In this study 87.5% of study subject's occupation was desk work which indicates that the disease is more prevalent in sedentary lifestyle population. *Prakriti* of the subjects are also studied. In this study 37.5% were *Kaphaj prakriti*, 27.5% subjects were *Vataj Prakriti* 12% were *Vatakaphaj Prakriti*. So it can infer that the disease is *Vata* and *Kapha* dominated disease. There was a significant reduction in the mean symptom score [Table 3]. The ultra-sonographic examination revealed a significant reduction in the post-void residual urine volume [Table no. 4] BWT (Bladder Wall Thickness) and significant increase in the urinary MFR (Maximum Flow Rate). *Gokshuradi Guggulu* contains *Guggulu* as chief ingredient. *Guggulu* having *Laghu*, *Tikta guna, katu tikta Rasa, Ushana Veerya* pacifies *Vata dosha.* Due to *Tikshna guna* it causes *Srotas shudhi*.[8] It also contains *Trikatu,* due to its *Tikshana guna ushana veerya* pacifies *Vata* and *Kapha dosha* hence reduce the pain.[9] *Mustak* having *Laghu, Rukshya guna, Katu Tikta Rasa, Katu Vipaka & Sheeta Veerya* therefore it has *Kapha Shamaka* and diuretic property[10,11] and hence increases the MFR and decreases the PVR. *Gokshuradi Guggulu (Tribulus terrestris)* possesses diuretic, anti-inflammatory, and muscle relaxation actions, which has been used in genitourinary infections, painful micturition, dysuria and benign prostatic hyperplasia (Singh *et al.,* 1991; Tomova 1987). It also possesses alpha-adrenoceptor antagonistic and 5-alpha reductase enzyme inhibitory activities. This was also reported by *Sahu,* M et. al, Medicine update 2003. The above effects are also possibly due to guggulsterones present in the drug *Guggulu.* It may reduce the level of pro-inflammatory cytokines. Guggulusterone is also able to reduce the Cyclo-oxygenase-2 (COX2) mRNA level and suppress its TNFα mediated induction (activation)[12,]. *Dasha mula ghruta* possesses anti-inflammatory property and hence reduces MLP (Medial Lobe Projection) and BWT (Bladder Wall Thickness) and also having action on prostatic weight. *Dasha mula Ghruta* also relaxes the smooth muscles of prostate and bladder neck hence improves the urine flow and reduces bladder neck obstruction, improves the urinary flow rate while reducing post-void residual urine. *Sudha Silajeet* possesses antimicrobial property and is useful in controlling symptoms of urinary tract infections and is beneficial in uropathy. It additionally possesses immuno modulatory effects and hence inhibits prostatic stromal proliferation and possibly averts the reoccurrence of the diseases. *Sudha Shilajatu* has multipurpose therapeutic uses after administered with different *Anupan. Rasa Tarangini* gave detailed description of different uses of *Shilajatu*. If taken with *Dashmula* it cures the *Mutraghat* and *Astheela* [13].

CONCLUSION

Thus, *Gokshuradi Gugulu Sudha Silajeet* followed by *Dashmul ghruta vasti* is effective in controlling the symptoms of BPH, improving the

maximum flow rate. It has significant effects in controlling the symptoms but very negligibly reduce the prostate weight and it is not statistically significant. During the treatment no any side effects or, adverse effects were found. The treatment was well tolerated and accepted by the patients. Thus, these compound medicines can be considered as treatment of choice in the management of patients with symptomatic BPH.

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