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A COMPARATIVE CLINICAL STUDY OF *VEERTARVADI GANA KASHAYA* AND *BASTI* THERAPY IN THE MANAGEMENT OF *VATASHTHEELA* WITH SPECIAL REFERENCE TO BENIGN PROSTATIC HYPERPLASIA

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ABSTRACT

B.P.H. is condition related to ageing process and most frequently seen in men in 7th, 8th, 9th decade, but also occurs in 6th and even 5th decade of life. Surveys have found a high prevalence of moderate to severe obstructive symptom in men over 50, which increases with age. This has a significant impact on the health of older men and health-care costs. Notably, increase in Benign Prostate Hypertrophy and lower urinary tract symptoms such as urgency, dribbling micturition, hesitancy and increase frequency of micturition are on rise, occurring within the context of an aging global population. In *Ayurvedic* classics the term *Vatashtheela* is related with the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria. In relation to BPH condition, there is no permanent and safe cure with modern medicine, except surgical resection of prostate, which is also having complication thereafter. So, keeping the above factors in consideration a study was carried out with *Ayurvedic* formulations, mentioned in classics, to assess the efficacy and to achieve a friendly treatment protocol. A clinical study was conducted in Rishikul Campus Haridwar, Uttrakhand Ayurved University with an objective to A Comparative clinical study of *Veertarvadi gana kashaya* and *Matra Basti* in the management of *Vatashtheela* w.s.r. to benign prostatic hyperplasia in 30 patients. Patients were selected randomly irrespective of their religion, race, occupation etc. and

divided into three groups. Treatment was given for three months and monitored at every 15 days interval during the study period. The irritative and obstructive symptoms of BPH (*Vatashtheela*) like frequency, urgency, staining, weak stream, incomplete emptying, nocturia, residual urine and uroflow rate were observed over the treatment.

KEYWORDS: *Vatashtheela, Veertarvadi Gana Kashaya, Matra Basti,* BPH.

INTRODUCTION

Sushruta, the pioneer of *Shalya tantra* (surgery) has enumerated the urology in his legendary text book of surgery, Sushruta Samhita by describing anatomy, physiology and pathology of many diseases related to urinary system like *Ashmaree* (urinary stone), *Mootrakrichchhra* (painful micturation), and *Mootraghata* (suppression or obstruction of urine) etc. with their management along with diseases of other systems. The description of *Basti* (urinary bladder), *Mootrotpatti* (formation of urine), *Mootravaha Srotasa* (urinary system) and *Shukravaha Srotasa* (reproductive system) is given in a concise way.

The word *Mootraghata* comprises of two different words i.e. "Mootra" and "Aghata", which stand for low urine output due to obstruction in the passage of urine.[1]

The clinical entity of "*Vatashtheela or Astheela*" has close resemblance to the disease benign prostatic hyperplasia.

The expense and complications associated with surgical treatment for benign prostatic hyperplasia (BPH) have led to a search for safe and effective medical therapies.[2] Benign prostatic hyperplasia is a non-malignant condition of nodular but symmetrical enlargement of the prostate in the peri-urethral region, likely due to androgen imbalances associated with aging. It is common in men over the age of 40, regardless of ethnic background. The incidence of BPH can be as high as 50% by the age of 60, and 90% by the age of 85.[3] This makes BPH a condition of increasing importance as the population ages. Due to its proximity to the urogenital tract, prostatic enlargement most commonly presents as obstructive lower urinary tract symptoms, although some are asymptomatic. Bladder outlet obstruction, causing incomplete emptying and subsequent rapid filling, results in urgency, frequency, and nocturia as the primary presenting complaints. The weak and reduced urinary stream in BPH produces hesitancy, intermittency and post-void dribbling. Urinary retention and stasis predi spose BPH patients to infection, which can cause bladder and upper urinary tract inflammation, as

well as calculus formation. In severe, prolonged obstruction, there is a risk of hydronephrosis and progressive renal failure and azotemia. There has been great interest in the effect of alpha1- adrenoceptor antagonists in the treatment of BPH. More selective and long-acting alpha1- adrenoceptor antagonists (terazosin and doxazosin) have also produced statistically and clinically significant improvements in signs and symptoms of BPH. These are also associated with side effects, such as dizziness, asthenia, peripheral oedema, postural hypotension, somnolence, and syncope.[4,5,6,7,8] Some studies have shown that 5α reductase inhibitors are effective in reducing the size of prostate, however these patients have to bear with long term side effects such as ejaculation disorders, loss of libido and impotence.[9]

The surgical procedures like prostatectomy have many comlications such as: haemorrhage, incontinence of urine, retrograde ejaculation, impotence, stricture of urethra, epididymitis, infection, stricture of bladder neck, orthostatic hypotension, dizziness etc.

Hence, Ayurveda may be more effective as well as safe for conservative management of *Vatashtheela*/B.P.H. The drug used in present study is *Veertarvadi Gana Kashaya*[10] and *Mulaka Taila.*[11] *Matra Basti*, both of these contains herbal drugs.

The nature of the study was entirely clinical, and importance was given on the relief of sign and symptoms. The patients for the clinical study were selected on the basis of a fixed criteria from the O.P.D. and I.P.D. of Shalya Tantra Department Rishikul Campus (Haridwar) Uttarakhand Ayurved University. The duration of the study was fixed as 3 months.

AIMS AND OBJECTIVES

1) To study aetiopathogenesis, signs & symptoms of the *Vatashthila* (BPH).
2) To compare the efficacy and safety of *Veertarvadi Gana Kashaya* and *Mulaka Taila Matra Basti* in management of *Vatashtheela* (BPH).

MATERIAL AND METHODS

Present clinical study has been carried out in the OPD & IPD in the Shalya tantra department of Rishikul Campus Haridwar, of Uttarakhand Ayurved University Dehradun. Patients were selected irrespective of their religion, race, occupation etc., fulfilling the selection & eligibility criteria & informed written consent was taken. Total number of 30 patients were studied.

Total No. Of Patients: 30

Group A: 10 (Veertarvadi Gana Kashaya) Group B: 10 (*Mulaka Taila Matra Basti*)

Group C: 10 (Combination of Group A and Group B)

Completeed 27 Patients, 9 Patients in each group, three patients LAMA. Laboratory

Investigation

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

Ultrasonography

Physical examination

1) Measurement of residual urine by Ultrasonography 2) Uroflowmetry

3) Digital rectal examination

Inclusion criteria

1) Patient age group of more than 50 year.
2) Patient with mild and moderate symptoms according to questionnaire as per American urological association score given for BPH.
3) Patients of Samanya Lakshana of Vatashthila (BPH).

Exclusion of criteria

1) Patient having acute urinary retention, stricture of urethra, Carcinoma 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.

Table No. 1: Grouping, Posology & Duration of Therapy.

Groups	Formulation	Route	Dose	Time	Duration
Group A	*Veertarvadi Gana Kashaya*	Orally	30 ml	BD	90 Days
Group B	*Mulaka Taila*	*Matra Basti*	50 ml	OD	90 Days (Three seating of 15 days duration with gap of 15 days in between
Group C	*Veertarvadi Gana Kashaya*	Orally	30 ml	BD	90 Days
	Mulaka Taila	*Matra Basti*	50 ml	OD	90 Days (Three seating of 15 days duration with gap of 15 days in between

Criteria for Assessment

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.

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. International 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	- 76% to 100%
3. Improvement	- 51% to 75%
4. Mild improvement	- 25% to 50%
5. Unchanged	- Below 25%

OBSERVATIONS AND RESULTS

Table No. 2: Symptom Wise Distribution.

Symptom	No. of patients	% of patients
Incomplete Emptying	**30**	**100**
Frequency	**30**	**100**
Intermittency	**25**	**83.33**
Urgency	**26**	**86.66**
Weak stream	**28**	**93.33**
Straining	**28**	**93.33**
Nocturia	**29**	**96.66**

RESULTS

Table No. 3: Effect Therapy on Subjective Parameters.

S. No.	Symptoms	Group	MEAN SCORE		N	Friedman's Test	P- Value	% Effect
			BT	AT				
1.	INCOMPLETE EMPTYING	A	6.28	1.83	9	45.962	0.000	70.8
		B	6.11	1.94	9	41.307	0.000	68.2
		C	6.83	1.44	9	49.051	0.000	78.9
2.	FREQUENCY	A	6.67	2.17	9	42.726	0.000	67.5
		B	6.56	2.17	9	41.458	0.000	66.9
		C	6.94	1.78	9	47.265	0.000	74.4
3.	INTERMITTENCY	A	6.67	2.06	9	44.446	0.000	69.2
		B	6.39	2.33	9	40.444	0.000	63.5
		C	6.83	2.11	9	45.661	0.000	69.1
4.	URGENCY	A	6.39	1.83	9	35.102	0.000	66.1
		B	6.22	2.67	9	27.735	0.000	51.8
		C	6.78	1.67	9	41.730	0.000	71.5
5.	WEAK STREAM	A	6.17	1.83	9	43.365	0.000	70.3
		B	6.39	2.67	9	32.580	0.000	58.3
		C	6.78	1.67	9	47.034	0.000	75.4
6.	STRAINING	A	5.83	1.94	9	29.083	0.000	66.7
		B	6.28	1.83	9	42.127	0.000	70.8
		C	6.28	1.72	9	44.848	0.000	72.6
7.	NOCTURIA	A	6.22	2.28	9	33.832	0.000	63.4
		B	6.67	2.61	9	40.043	0.000	60.8
		C	6.89	1.89	9	44.863	0.000	72.6

From above table we can observe that P-Values for Group A, Group B and Group C are less than 0.05 hence we conclude that effect observed in all three groups are significant.

Table No. 4: Effect of Therapy on Objective Parameter (Qmax).

Uroflowmetry	Group A	Group B	Group C
BT	6.22	6.22	6.39
AT	2.06	1.83	1.61
N	9	9	9
Friedman's Test	37.317	36.337	42.014
P-Value	0.000	0.000	0.000
% Effect	67.0	70.5	74.8

From above table we can observe that P-Values for Group A, Group B and Group C are less than 0.05 hence we conclude that effect observed in all three groups are significant.

Table No. 5: Total Effect of Therapy Over Prostate Size/Volume.

Prostate Size/Volume		Mean	N	SD	SE	t-Value	P-Value	Result
Group A	BT	46.4	9	12.3	4.1	1.000	0.347	NS
	AT	45.9	9	13.2	4.4			
Group B	BT	62.3	9	42.2	14.1	0.000	1.000	NS
	AT	62.3	9	42.2	14.1			
Group C	BT	47.5	9	19.5	6.5	1.396	0.200	NS
	AT	46.2	9	20.2	6.7			

Table No. 6: Compasison Among Group A, Group B & Group C.

	Group	N	Mean Rank	Kruskal Wallis	P-Value	Result
Incomplete Emptying	Group A	9	13.72	6.649	0.036	Sig
	Group B	9	9.89			
	Group C	9	18.39			
	Total	27				
Frequency	Group A	9	11.83	7.826	0.020	Sig
	Group B	9	10.67			
	Group C	9	19.50			
	Total	27				
Intermittency	Group A	9	15.56	4.304	0.116	NS
	Group B	9	9.83			
	Group C	9	16.61			
	Total	27				
Urgency	Group A	9	11.78	4.114	0.128	NS
	Group B	9	12.06			
	Group C	9	18.17			
	Total	27				
Weak Stream	Group A	9	12.17	9.094	0.011	Sig
	Group B	9	9.83			
	Group C	9	20.00			
	Total	27				
Staining	Group A	9	11.61	6.022	0.049	Sig
	Group B	9	11.61			
	Group C	9	18.78			
	Total	27				
Nocturia	Group A	9	11.61	9.987	0.007	Sig
	Group B	9	10.11			
	Group C	9	20.28			
	Total	27				
Uroflowmetry	Group A	9	13.17	10.019	0.007	Sig
	Group B	9	8.83			
	Group C	9	20.00			
	Total	27				

Table No. 7: Overall Effect of Therapy.

Result on effect of therapy	Group A		Group B		Group C	
	No. of Pt.	%	No. of Pt.	%	No. of Pt.	%
Complete cured	00	00	00	00	00	00
Marked Improvement	04	44.44	03	33.33	06	66.67
Moderate Improvement	04	44.44	04	44.44	02	22.22
Mild Improvement	01	11.11	02	22.22	01	11.11
Unchanged	00	00	00	00	00	00

DISCUSSION

Effect of Therapeutics on the Prostate Gland

All the patients were subjected to repeated per rectal digital examination to know the extent of the size and shrinkage of the gland. But the change were beyond the estimate, however no change in the consistency of the gland was observed in any of the patients.

Discussion on Parameters

1. **Subjective Parameter (IPSS) –** IPSS is a well-known internationally accepted scoring system which is taken as a major parameter for the present study. In the IPSS Incomplete emptying, Frequency, Intermittency, Urgency, Weak stream, Straining, and Nocturia are taken in account.

Effect on Incomplete emptying

Percentage effect on incomplete emptying in Group A was 70.8%, in Group B 68.2% and in Group C 78.9%. In Group A initial mean score was 6.28 which was reduced to 1.83, in Group B initial mean score was 6.11 which was reduced to 1.94, in Group C initial mean score was 6.83 which was reduced to 1.44(Table No.3) and we can observe that P-value for Group A, Group B and Group C are less than 0.05 hence we conclude that effect observed in all three Groups are significant.

Effect on Frequency of micturition

In BPH, hypertrophy of urinary bladder muscle occurs and bladder become hypertonic, that's why small amount of urine result as urge for micturition which leads to frequency of micturition. Percentage effect in Group A was 67.5%, in Group B 66.9% and in Group C 74.4%. In Group A initial mean score was 6.67 which was reduced to 2.17, in Group B initial mean score was 6.56 which was reduced to 2.17, in Group C initial mean score was 6.94 which was reduced to 1.78(Table No.3). Effect observed in all three Groups are significant.

Effect on Weak stream

Micturition at this stage is probably due to vesical introversion of the sensitive prostatic mucosa by intravesical enlargement of prostate due to its enlargement, elongation of prostatic urethra and diminution in its calibre. This change in urethra causes poor stream of urine. So, reduction in this symptom will show the reduction in the root cause of all these symptoms i.e. BPH. Percentage effect in Group A was 70.3%, in Group B 58.3% and in Group C 75.4%. In Group A initial mean score was 6.17 which was reduced to 1.83, in Group B initial mean score was 6.39 which was reduced to 2.67, in Group C initial mean score was 6.78 which was reduced to 1.67(Table No.3) and effect observed in all three Groups are significant.

Effect on Nocturia

This is the most irritating symptom which sends the patient of BPH to the doctor in search of relief. Percentage effect in Group A was 63.4%, in Group B 60.8% and in Group C 72.6%. In Group A initial mean score was 6.22 which was reduced to 2.28, in Group B initial mean score was 6.67 which was reduced to 2.61, in Group C initial mean score was 6.89 which was reduced to 1.89(Table No.3) and effect observed in all three Groups are significant.

Effect on Urgency

As the internal sphincter mechanism is deranged due to invasion of prostate into the bladder leading to the escape of little urine into the prostatic urethra, which is highly sensitive and cause urgency so, reduction in this symptom will show relief in BPH. Percentage effect in Group A was 66.1%, in Group B 51.8% and in Group C 71.5%. In Group A initial mean score was 6.39 which was reduced to 2.17, in Group B initial mean score was 6.22 which was reduced to 3.00, in Group C initial mean score was 6.83 which was reduced to 1.94(Table No.3) and effect observed in all three Groups are significant.

Effect on Straining

In case of BPH, bladder outlet resistance increases and calibre of prostatic urethra diminishes, so, patient of BPH strains during micturition to empty his bladder completely. Percentage effect in Group A was 66.7%, in Group B 70.8% and in Group C 72.6%. In Group A initial mean score was 5.83 which was reduced to 1.94, in Group B initial mean score was 6.28 which was reduced to 1.83, in Group C initial mean score was 6.28 which was reduced to 1.72(Table No.3) and effect observed in all three Groups are significant.

Effect on Intermittency

This symptom shows that the weak bladder muscle due to stasis, infection, straining, narrowing of urethra is unable to evacuate bladder completely in a single flow. Percentage effect in Group A was 69.2%, in Group B 63.5% and in Group C 69.1%. In Group A initial mean score was 6.67 which was reduced to 2.06, in Group B initial mean score was 6.39 which was reduced to 2.33, in Group C initial mean score was 6.89 which was reduced to 2.11(Table No.3) and we can observe that P-value for Group A, Group B and Group C are less than 0.05 hence we conclude that effect observed in all three Groups are significant.

1. Objective Parameter– Uroflowmeter

This will show the flow rate of urine which is a graphically presented, numerically evaluated method to represent the combined effect of symptoms of BPH (intermittency, straining, weak stream, frequency etc.). So, increase in flow rate will definitely show improvement in all these symptoms which is obviously due to enlarged prostate in the patient of BPH.

Effect on Maximum Flow Rate(Qmax)

Percentage effect on Qmax in Group A was 67.0%, in Group B 70.5% and in Group C 74.8%. In Group A initial mean score was 6.22 which was reduced to 2.06, in Group B initial mean score was 6.22 which was reduced to 1.83, in Group C initial mean score was 6.39 which was reduced to 1.61(Table No.4) and we can observe that P-value for Group A, Group B and Group C are less than 0.05 hence we conclude that effect observed in all three Groups are significant.

Effect on Prostate Size / volume

In Group A initial mean score was 46.4 which was reduced to 45.8, in Group B initial mean score was 62.3 which was remain 62.3, in Group C initial mean score was 47.2 which was reduced to 46.2(Table No.5) and we can observe that P-value for Group A, Group B and Group C are more than 0.05 hence we conclude that effect observed in all three Groups are non-significant.

Comparison among Group A, Group B and Group C

As the present study was comparative study and for comparison of the three groups, to find out which group was the best we have used another test Kruskall Wallis test. Following results were found in overall comparison:-

- On comparative assessment of % relief in subjective Parameters it was found that patients

got better relief in Group C than other two groups in the majority of symptoms namely incomplete emptying (78.9%), frequency of micturition(74.4%), urgency (71.1%), weak stream (75.4%), straining (72.6%) and nocturia (72.6%).

- The % relief in intermittency was better in Group A (69.2%) than Group B (63.5%) and Group C (69.1%).
- On comparative assessment of % relief b/w Group A and Group B in subjective parameters it was found that patients got better relief in Group A than Group B in majority of symptoms namely incomplete emptying (70.8%), frequency of micturition(67.5%), intermittency(69.2%), urgency (66.1%), weak stream (70.3%), and nocturia (63.4%).
- On comparative assessment % relief in straining b/w Group A and Group B, the relief was better in Group B (70.8%) than Group A (66.7%).
- On comparative assessment of % relief in objective Parameters (uroflowmetry/Qmax) it was found that patients got better relief in Group C (74.8%) than Group A (67.0%) and Group B (70.5%)
- Intergroup comparison of decrease in prostate size/vol. we found that there was no significant difference in three groups($p>0.05$).
- On inter group comparison by Kruskal wallis test it was found that Group C was statistically more significant than other two groups (p value < 0.05 and mean rank for Group C is more).
- On comparison b/w Group A and Group B by Kruskal Wallis test we observed that p-value is less than 0.05 and mean rank for Group A is more hance we conclude that Group A is statistically more significant than Group B.

Total Effect of Therapy

Mainly symptomatic criteria was adopted to assess the total efeect of the therapy along with reduction in size/volume of prostate.

In Group A maximum improvement was seen in 4 patients (44.44%). Moderate improvement was observed in 04 patients (44.44%). While mild improvement was observed in only 01 patients i.e. 11.11%. In Group B maximum improvement was seen in 3 patients (33.33%). Moderate improvement was observed in 04 patients (44.44%). While mild improvement was observed in only 02 patients i.e. 22.22%. In Group C maximum improvement was seen in 6 patients (66.67%). Moderate improvement was observed in 02 patients (22.22%). While mild

improvement was observed in only 01 patients i.e. 11.11%.

Thus we can conclude that the overall effect of Group C was best followed by Group A and Group B.

Discussion on Probable Mode of Action of Formulation

Vatashtheela (BPH) is a troublesome obstructive urological condition for the majority of elderly men in the society. The probable mode of action of both the trail formulations is discussed as mentioned below based on the results of therapy and its interpretation by Ayurvedic as well as modern pharmacology.

While selecting the formulations, a hypothesis was made that as per etio-pathogenesis of *Vatashtheela* described in Ayurvedic classics and equivalent pathology described in modern texts for BPH, there is deranged function of *Vayu*, particularly *Apana vayu* which is the prime causative factor and this perturbed *Vata* with *Kapha* manifest *Mootravaha srotodushti* as well *Khavaigunya* due to *dhatvagnimandya*. So, the drugs which have *Vata-kaphahara* properties like *srotoshodhana, lekhana, sophahara, mootrala* and *bastishodhana* along with *deepana-pachana karma* were selected, these properties helps to crack the *samprapti* of *Vatashtheela* as well as pathophysiology of BPH which is generally caused by disturbance in normal HPG axis and bladder outlet obstruction for manifestation of BPH.

Mode of Action of *Veertarvadi Gana Kashaya*
According to Ayurveda

The classical formulation of *Veertarvadi Gana Kashaya* was selected in *BPH;* because it is the wonderful combination designed by *Sushrut* for urinary channels. The component of *Veertarvadi Gana Kashaya* are so wonderfully collated by *Acharya Sushrut*, that it can be said complete regimen for urinary tract disorders. Total 19 contents in this preparation namely *Veertaru, Sahachardwaya, Darbha, Vrikshadani, Gundra, Nala, Kusha, Kasha, Ashmabheda, Agnimanth, Murva, Basuk, Vashir, Bhullaka, Kurantaka, Kamala, Kapotvanka* and *Gokshura.*

The maximum ingredients in this formulation have *Kashaya Rasa(65%), Madhura Rasa(45%) & Tikta Rasa(65%); Madhura Rasa* carried the *Vata-Pitta Shamaka* and *anulomana* property, *Tikta Rasa* having *Kapha-Hara* and *Deepana Pachana* property *and Kashaya Rasa* exhibit *Kapha-Pitta Shamaka. Laghu(85%)* and *Ruksha(35%) Guna; Kapha Shamaka* in nature, *Laghu Guna* carried the *Agni Deepana* and *Shrotoshodhana* properties,

Snigdha Guna(35%) is capable to relieving *Vata* and *Pitta. Katu Vipaka(60%); katu vipaka* is said to be normalising vitiated *Kapha.* These properties, exerted pharmacological actions like *agni deepana, ama pachana, mootrala, lekhana, shothahara, vilayana* and *srotoshodhana* etc. Further, due to these actions, *sanga* is removed in *mootravaha srotasa* particularly at *basti shira* leaded to reduction in size of the enlarged prostate and simultaneously correction of *agni dushti* took place. As *mootravaha 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*, results into proper evacuation of *mootra* in the form of increased urine flow rate.

Because of improvement in *jatharagni* due to *deepana & pachana* effect of drugs, *dhatvagnies* also had come down in normal state. The function of *basti snayu* might have been improved due to correction of *mamsa dhatvagni*. Finally, *mamsa* and *medo vriddhi* had been returned to normal state due to normalization of *dhatvagni;* and ultimately leads to reduction in enlarged prostate gland size because of *ama pachan, lekhana* and *sophahara* action of ingredients.

According to Modern

Maximum drugs in this formulation have anti-inflammatory, antoxidant and antimicrobial properties to eliminate the urinary infection and maintain the urinary pH. The anti-lithogenic and diuretic drugs are available here in formulation to minimize the chances of stone formation. The high proportion of diuretic drugs not only improves the kidney function but also promotes to enhance the normal metabolism of body. Anti-spasmodic drugs for action of smooth urinary stream flow may have alpha-blocker properties. The stress relieving drugs like *Brahmi* are used here to keep pacification and relaxation of mind along with the stress free internal urinary sphincter.

Mode of Action of Basti

In *Ayurvedic* classics *Aacharya* have explained action of *Basti* hypothetically with suitable analoges gives knowledge of different effects as follows.

The positional effect

The rationality behind the left lateral position is the *Gudavalee* become relaxed there by helps in administration of *Basti*. *Pakvashaya* resides in the left side so given *Basti Dravya* reaches the *Pakvashaya*. As it is the main seat of *Vata*, given drugs will counter act the *Vata Dosha*.

As trees irrigated in its roots yield branches with beautiful tender leaves, flowers and fruits in time and attain big stature in the same way *Anuvasana Basti* administered in the rectum yield significant results from head to toe.

Guda (Anus) is one of the *Pranayatana*, where all twelve *Prana* dwell predominantly. *Guda* (Anus) is a *Mamsa Marma* of *Sadyapranahara* type. Being a *Marma* it has roots of all four types of *Sira* embedded in it viz. *Vatavaha, Pittavaha, Kaphavaha and Shonitavaha*. Due to its *Sadyapranahara* nature, *Guda* (Anus) is highly sensitive. Even a mild stimulation to it, say, by *Basti* drugs and procedure may sensitize the whole body by vigorous action of *Vayu* through all the *Siras* present in the body.

This physiology confirms immediate and all pervasive action of *Basti* drugs even though the *Basti* lies in *Pakvashaya*.

Relations of Guda (Anus)

- *Apana Vayu* - Anus is the seat of *Apana Vayu*
- *Prana Vayu* - Being *Sadyapranahara Marma*
- *Vyana Vayu* - *Vyana* is all pervasive
- *Samana Vayu* - It moves all over the *Kostha.*
- *Pachaka Pitta* - Helps in digestion
- *Sira, Snayu, Sandhi, Asthi* - As it is a *Marma* and *Mamsa Sannipata*
- *Kala – Maladhara, Asthidhara and Majjadhara*.
- *Dhatu - Rasa, Rakta, Mamsa, Meda, Majja & Shukra.*

From the above-sited relevance it may be said that, *Basti* influences whole body. However, it acts mainly on the structures related to *Guda* (Anus). If *Apana* is controlled in its own abode other four *Vayus* can be bridled automatically. *Vagbhata* illustrated the whole phenomenon as follows *Basti*.

The drug effect

For particular disease, *Basti* should be prepared with drugs of choice for that disease. Action of *Basti* i.e., when *Lekhana Dravyas* are used, it does *Karshana* and when *Brihmana Dravyas* are used, they will do *Brimhana.* The drug we used for *Basti* is *Mulaka Taila.* Contents of drug are *Rasna, Sirisa, Mulethi, Shunthi, Sahachar Guduchi, Syonaka, Devdaru, Shampaka, Ashvagandha, Gokshur, Tila Taila, Sarvagandha Dravyas, Dadhi, Aarnal, Urad Kwath And*

Ikshu Rasa. The maximum ingredients in this formulation have *Katu Rasa, Madhura Rasa & Tikta Rasa; Madhura Rasa* carried the *Vata-Pitta Shamaka* and *Anulomana* property, *Tikta Rasa* having *Kapha-Hara* and *Deepana Pachana* property *and Katu Rasa* exhibit *Kapha Shamaka. Ama Pachana and Agni deepan, Laghu Guna; Kapha Shamaka* in nature, *Laghu Guna* carried the *Agni Deepana* and *Shrotoshodhana* properties, *Snigdha Guna* is capable to relieving *Vata* and *Pitta. Katu Vipaka; katu vipaka* is said to be normalising vitiated *Kapha.* These properties, exerted pharmacological actions like *agni deepana, ama pachana, mootrala, lekhana, shothahara, vilayana* and *srotoshodhana* etc. Further, due to these actions, *sanga* is removed in *mootravaha srotasa* particularly at *basti shira* leaded to reduction in size of the enlarged prostate and simultaneously correction of *agni dushti* took place. As *mootravaha 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*, results into proper evacuation of *mootra* in the form of increased urine flow rate.

Absorption and Influence of *Basti*

Basti is not merely the enema, one which exerts local cleansing effect, rather it is a highly complex, sophisticated and systemic therapy having wider range of therapeutic actions and indication. It exerts its action by endcolonic (action inside the colon), encolonic (action on tissues of colon) and diacolonic (for systemic action) ways.

A) Absorption

Basti may be absorbed by diffusion, filtration, osmosis or by adsorption depending upon substance used in it.

a) Drug absorption

- The rectum has rich blood & lymph supply.
- *Basti* drugs get absorbed via two routes:
  - Drug absorbed by upper haemorrhoidal vein goes into portal circulation.
  - Drug absorbed by middle and inferior haemorrhoidal veins is always absorbed without reacting with digestive enzymes and acids.

b) Electrolyte absorption

The ions like sodium (Na+), calcium (Ca) and potassium are absorbed and are essential for the generation of action potential, which is the main functional unit of nervous system. Here

are the mechanisms how they absorb from intestinal mucosa.

- Sodium (Na+) ions are absorbed by diffusion & active transport.
- Chloride (Cl^-) ions penetrates via passive diffusion and facilitated by sodium absorption
- Calcium (Ca) ions can be absorbed via active transport

c) Fat absorption

1) In *Anuvasana Basti*

The fat given by *Basti* stimulates cholecystokinin enzyme, which stimulates gall bladder to secrete the bile. Bile contains bile salts, 20-50 molecules of bile salt aggregate to form 'micelles' which have the ability to dissolve in water. The central part of micelles is fat soluble, so fatty acids & mono-glycerides dissolve in the centre of micelle. When they come in contact with the surface of epithelial cells, fatty acids & mono- glycerides diffuses into the cell leaving the micelles behind. In this way the absorption of fat takes place in *Anuvasana Basti.*

B) Influence on Bacterial Flora

- *Basti* influences the normal bacterial flora thus it increases the endogenous synthesis of Vitamin B12, Vitamin K etc. *Basti* makes the whole metabolism normal.
- Production of thiamine with the help of bacteria, which is necessary for nerve conduction and which is produced in large intestine, may be controlled by *Basti.*

CONCLUSION

There was no any untoward effect or adverse drug reaction (ADR) recorded during treatment & follow up among all the patients. Lastly, total study is summarized and concluded that oral use of *Veertarvadi Gana Kashaya and Matra Basti* of *Mulaka Taila* are clinically proven as a safe and effective therapy in the management of *Vatashtheela* i.e. BPH. Finally study concluded that there is best effect of Combination of both *Veertarvadi Gana Kashaya* and *Mulaka Taila Matra Basti* followed by *Veertarvadi Gana Kashaya* and *Mulaka Taila Matra Basti* for symptomatic relief in *Vatashtheela* (BPH). The selected formulations for clinical trial, had shown *VataKaphashamaka* action and *Mootrala, Deepana, Paachana, Lekhana and Bastishodhana* properties and may be held responsible for breaking the *sampraapti of Vatastheela*/ BPH as well as correction in imbalanced level of sex hormones and improving bladder functions by improving bladder muscle tone.

Suggestions for Further Study

1. In this study due to time bound sample size was very small. So, it requires further study on larger sample size to obtain more impressive results.
2. In this study, prostate size is measured through abdominal USG, but Trans-Rectal Ultrasound (TRS) can be proved more effective for accurate measurement of prostate size as well as for assessing effect of the therapy on BPH.

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