



## A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF KSHARAPIPALI AND MAHODARAHARA KASHAYA IN VATASHTHEELA W.S.R. TO BENIGN PROSTATIC HYPERPLASIA – A CASE SERIES

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### ABSTRACT

Vatashteela is one among 12 types of *Mutraghata*, characterized by aggravated Vata that localizes between the *basti* and *shakrutmarga*, forming a dense, stone-like glandular swelling, leading to obstruction of *vit*, *mutra* and *anila* with *adhmana* and *teevraruja* in *basti*, mirroring symptoms of Benign Prostatic Hyperplasia (BPH). BPH primarily affects older males, presenting with increased frequency, urgency, hesitancy, incomplete voiding, and a weak urine stream. Conventional BPH treatments such as anti-androgens, alpha-blockers, and surgery carry risks of side effects and complications, emphasizing the need for effective conservative management. Acharya *Vangasena* has described *Ksharapippali* in his treatise *Cikitsasaara Sangraha* and mentioned that it is effective in treating in *Vatashteela*. This study was undertaken to know the efficacy of *Ksharapippali* in *Vatashteela* and the results were compared with *Mahodarahara Kashaya*, a formulation from *Sahasrayoga* used as a standard in previous research. Hence an attempt is made to review about the Clinical efficacy of these formulations in the present article.

**KEYWORDS:** *Vatashteela*; *Ksharapippali*; *Mahodarahara Kashaya*; Benign Prostatic Hyperplasia.

### INTRODUCTION

Acharya Sushruta, known as the pioneer of surgery, comprehensively described urology in his treatise *Sushruta Samhita*. He identified urinary disorders like *Mutraghata* (urinary obstruction), *Mutrakrichchhra* (dysuria), and *Ashmari* (renal calculi), along with their effective management. In the *Uttaratantra*, he elaborated on obstructive and irritative urinary bladder symptoms under the category of *Mutraghata*. Among its 12 types, *Vatashteela* closely resembles Benign Prostatic Hyperplasia (BPH) in modern medicine.

*Vatashteela* arises from deranged *Apana Vayu* and vitiated *Kapha* and *Pitta*, which produce *Ama* and obstruct urinary channels (*Srotorodha*). Aggravated *Vata* settles between the bladder (*Basti*) and rectum (*Shakrut Marga*), forming a dense glandular swelling. This results in symptoms like urinary retention, incomplete voiding, urgency, hesitancy, weak stream, and straining, which align with BPH.

BPH, a common uropathy in elderly males, is characterized by an enlarged prostate compressing the urethra. Its prevalence increases with age, affecting 8% of men in their 40s, 50% in their 60s, and 80% in their

80s. Symptoms include urgency, frequency, hesitancy, weak stream, dribbling, and incomplete voiding. BPH is primarily managed through  $\alpha$ 1A-adrenoreceptor blockers, 5 $\alpha$ -reductase inhibitors, or a combination of both. However, these medications often cause side effects like dizziness, decreased libido, and gynecomastia. Surgical interventions, including Transurethral Resection of the Prostate (TURP) and laser therapies, carry risks like erectile dysfunction, retrograde ejaculation, and severe complications, particularly in older patients with comorbidities.

Ayurveda offers a conservative, non-invasive, and cost-effective approach to managing *Vatashteela*. Treatment for *Mutraghata* are applicable to *Vatashteela*, that include *Nidana Parivarjana*, *Shodhana*, *Shamana* and *Rasayana*. Specific therapies include *Snehana*, *Swedana*, *Virechana*, and *Uttarabasti*. Herbal formulations like *Ksharapippali* and *Mahodarahara Kashaya* have shown promise in alleviating symptoms.

*Ksharapippali*, described by Acharya Vangasena in *Chikitsasaara Sangraha*, contains diuretic (*Mutrala*) herbs like *Bala* and *Manakanda*, alongside *Shirisha*, *Chitraka*, *Varuna*, and *Punarnava*, which contain  $\beta$ -

sitosterol.  $\beta$ -sitosterol improves urinary symptoms and flow measures, making it effective for BPH. *Kshara* preparations are considered superior among treatments for their potency and versatility.

A comparative clinical study was undertaken to evaluate the efficacy of *Ksharapippali* against *Mahodarahara Kashaya* in managing *Vatashteela* with reference to BPH. This study focused on subjective and objective parameters, offering a safe, non-invasive, and portable treatment alternative to conventional therapies.

The findings highlight Ayurveda's potential to manage *Vatashteela/BPH* effectively, minimizing side effects and addressing the limitations of modern surgical and pharmacological approaches.

### OBJECTIVES OF THE STUDY

- 1) To evaluate the effectiveness of *Ksharapippali* in the management of *Vatashteela* w.s.r to benign prostatic hyperplasia.
- 2) To evaluate the effectiveness of *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to benign prostatic hyperplasia.
- 3) To evaluate the comparative effectiveness of *Ksharapippali* and *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to benign prostatic hyperplasia.

### HYPOTHESIS

#### NULL HYPOTHESIS

- There is no significant effect of *Ksharapippali* in the management of *Vatashteela* w.s.r to BPH.
- There is no significant effect of *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to BPH.
- There is no significant difference between the effect of *Ksharapippali* and *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to BPH.

#### ALTERNATE HYPOTHESIS

- There is significant effect of *Ksharapippali* in the management of *Vatashteela* w.s.r to BPH.
- There is significant effect of *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to BPH.
- There is significant difference between the effect of *Ksharapippali* and *Mahodarahara Kashaya* in the management of *Vatashteela* w.s.r to BPH.

### METHODOLOGY

#### SOURCE OF DATA

Patients with clinical features of *Vatashteela* w.s.r. to BPH viz., increased frequency of micturition during day and night, urgency, hesitancy, incomplete voiding of urine will be selected from IPD and OPD of Sri Jayachamarajendra Government Ayurveda and Unani Hospital, Bengaluru.

### METHOD OF COLLECTION OF DATA

A total of 40 patients presenting with the clinical features of *Vatashteela* (Benign prostatic hyperplasia) mentioned in inclusion criteria and confirmed case of BPH by USG were taken for the study.

### INCLUSION CRITERIA

- Subject with signs and symptoms of *Vatashteela* (BPH).
- Subject with mild to moderate BPH with score 1-19, as per The International Prostate Symptom Score index.
- Diagnosed case of BPH by USG.

### EXCLUSION CRITERIA

- Subject with malignancy.
- Subject more than 80 years of age.
- Subject with severe cardio vascular, Renal or Hepatic disorders, uncontrolled Hypertension & Diabetes mellitus.
- Subjects with immune compromised diseases.
- Subject with USG findings suggestive of severe Hydronephrosis.
- Post-void Residual urine volume more than 150ml as assessed by USG of Abdomen and pelvis.

### SAMPLING PROCEDURE

A total of 40 cases *Vatashteela* (Benign Prostatic Hyperplasia) after considering the above-mentioned criteria were included for the study. The 40 cases included were randomly allotted into two groups namely Group-A & Group-B with 20 patients in each group.

### STUDY DESIGN

**GROUP-A:** In this group 20 patients were treated with *Ksharapippali*. It was orally administered in the dose of 500 mg, twice daily after food with go ghrita as anupana for 28 days.

**GROUP-B:** In this group of 20 patients were treated with *Mahodarahara kashaya*. It was orally administered in the dose of 25ml twice daily before food for 28 days.

Observation with respect to changes in both the groups, the subjective Parameters was assessed before treatment, on 14th day, on 28th day and Objective parameters was assessed before and after the treatment, the same was recorded in the proforma of case sheet specially prepared for the study.

### ASSESSMENT CRITERIA

#### SUBJECTIVE PARAMETERS

Subjective parameters are assessed through International Prostate Symptom Score (IPSS), by AUA

Total International Prostate Symptom Score

1-7 : mild symptoms

8-19 : moderate symptoms

20-35 : severe symptoms

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score
Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	

	None	Time 1	Time 2	Time 3	Time 4	times or more 5	Your score
Nocturia Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5	

### OBJECTIVE PARAMETER

#### ➤ Ultrasonography

A detailed USG of both abdomen and pelvis was carried out before and after the treatment in relation to the post void residual urine and size of the prostate.

- Post void Residual Urine
- Prostate Size (Volume)

### OBSERVATION AND RESULTS

Statistical analysis: Statistical results of administration of Ksharapippali in Group A and Mahodarahara Kashaya in Group B of subjects suffering from Vatashteela before

and after treatment are analyzed and the results of subjective & objective parameters of clinical study obtained before and after treatment were analyzed statistically using IBM SPSS Statistics Software. The effect of treatment on different subjective and objective parameters were assessed after treatment and the values obtained were subjected to statistical tests to compare the mean values within the group and between the groups.

Statistical test for between the groups: 1. Mann Whitney 'U' test 2. Wilcoxon test.

### 1) INCOMPLETE EMPTYING OF THE BLADDER

Table no.1 - Effect of treatment on incomplete emptying of bladder Between Group A and Group B.

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	19.30	386.00	16.55	331.00	15.85	317.00
Group B	20	21.70	434.00	24.45	489.00	25.15	503.00
Test Statistics							
		BT	D14			AT	
Mann-Whitney U		176.000	121.000			107.000	
Wilcoxon W		386.000	331.000			317.000	
Z		-.688	-2.253			-2.806	
P value (2-tailed)		.492	.024			.005	

Since p values > 0.05, the level of significance for BT; there is no sufficient evidence to reject the null

hypothesis for BT.

The Mann-Whitney U test results show no significant differences in incomplete emptying grades between Group A and Group B at baseline (BT,  $p = 0.492$ ). However, significant differences emerged at Day 14

(D14,  $p = 0.024$ ) and after treatment (AT,  $p = 0.005$ ), with Group A displaying lower mean ranks (16.55 for D14 and 15.85 for AT) than Group B. This suggests that Group A experienced a more substantial treatment effect on incomplete emptying over time.

## 2) INCREASED FREQUENCY OF MICTURATION

**Table no.2 - Effect of treatment on frequency of micturition Between Group A and Group B**

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	20.95	419.00	18.68	373.50	15.78	315.50
Group B	20	20.05	401.00	22.33	446.50	25.23	504.50
Test Statistics							
		BT		D14		AT	
Mann-Whitney U		191.000		163.500		105.500	
Wilcoxon W		401.000		373.500		315.500	
Z		-.335		-1.416		-3.074	
P value (2-tailed)		.738		.157		.002	

Since  $p$  values  $> 0.05$ , the level of significance for BT & D14; there is no sufficient evidence to reject the null hypothesis for BT & D14.

The Mann-Whitney U test results show no significant differences in frequency grades between Group A and

Group B at baseline (BT,  $p = 0.738$ ) and Day 14 (D14,  $p = 0.157$ ). However, a significant difference was observed after treatment (AT,  $p = 0.002$ ), with Group A having a lower mean rank (15.78) than Group B (25.23). This indicates that Group A experienced a greater treatment effect on frequency by the end of the intervention.

## 3) URINARY INTERMITTENCY

**Table no.3 -Effect of treatment on urinary intermittency between group A and group B**

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	19.83	396.50	16.75	335.00	15.78	312.50
Group B	20	21.18	423.50	24.25	485.00	25.23	507.50
Test Statistics							
		BT		D14		AT	
Mann-Whitney U		186.500		125.000		102.500	
Wilcoxon W		396.500		335.000		312.500	
Z		-.440		-2.191		-2.911	
P value (2-tailed)		.660		.028		.004	

Since  $p$  values  $> 0.05$ , the level of significance for BT; there is no sufficient evidence to reject the null hypothesis for BT.

The Mann-Whitney U test results show no significant difference in intermittency scores between Group A and Group B before treatment (BT,  $p = 0.660$ ), indicating both groups started similarly. However, significant

differences were found at Day 14 (D14,  $p = 0.028$ ) and after treatment (AT,  $p = 0.004$ ), with lower mean ranks in Group A (16.75 for D14 and 15.63 for AT) compared to Group B (24.25 for D14 and 25.38 for AT), suggesting that Group A experienced a more substantial effect from the treatment over time. This highlights the effectiveness of the intervention in improving intermittency, particularly for Group A.

## 4) URGENCY TO MICTURATE

**Table no.4 -Effect of treatment on urgency to micturate between group A and group B.**

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	22.75	455.00	19.08	381.50	16.90	338.00
Group B	20	18.25	365.00	21.93	438.50	24.10	482.00
Test Statistics							

	BT	D14	AT
Mann-Whitney U	155.000	171.500	128.000
Wilcoxon W	365.000	381.500	338.000
Z	-1.333	-.896	-2.192
P value (2-tailed)	.182	.370	.028

Since p values > 0.05, the level of significance for BT & D14; there is no sufficient evidence to reject the null hypothesis for BT & D14.

The Mann-Whitney U test results show no significant differences in urgency grades between Group A and Group B at baseline (BT, p = 0.182) and Day 14 (D14, p

= 0.370). However, a significant difference was found after treatment (AT, p = 0.028), with Group A demonstrating a lower mean rank (16.90) compared to Group B (24.10). This suggests that Group A experienced a greater treatment effect on urgency by the end of the intervention.

## 5) WEAK STREAM OF URINE

**Table no.5 -Effect of treatment on weak stream of urine between group A and group B.**

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	20.40	408.00	18.03	360.50	16.40	328.00
Group B	20	20.60	412.00	22.98	459.50	24.60	492.00
Test Statistics							
		BT	D14	AT			
Mann-Whitney U		198.000	150.500	118.000			
Wilcoxon W		408.000	360.500	328.000			
Z		-.060	-1.583	-2.593			
P value (2-tailed)		.953	.113	.010			

Since p values > 0.05, the level of significance for BT & D14; there is no sufficient evidence to reject the null hypothesis for BT & D14.

### Conclusion

The Mann-Whitney U test shows no significant differences in weak stream grades between Group A and

Group B at baseline (BT, p = 0.953) and Day 14 (D14, p = 0.113). However, a significant difference emerged after treatment (AT, p = 0.010), with Group A demonstrating a lower mean rank (16.40) compared to Group B (24.60). This suggests that Group A experienced a greater treatment effect on weak stream by the end of the intervention.

## 6) STRAINING TO MICTURATE

**Table no.6 -Effect of treatment on straining to micturate between group A and group B.**

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	18.58	371.50	17.40	348.00	17.00	340.00
Group B	20	22.43	448.50	23.60	472.00	24.00	480.00
Test Statistics							
		BT	D14	AT			
Mann-Whitney U		161.500	138.000	130.000			
Wilcoxon W		371.500	348.000	340.000			
Z		-1.118	-1.873	-2.870			
P value (2-tailed)		.263	.061	.004			

Since p values > 0.05, the level of significance for BT & D14; there is no sufficient evidence to reject the null hypothesis for BT & D14.

### Conclusion

The Mann-Whitney U test shows no significant differences in straining between Group A and Group B at baseline (BT, p = 0.263) and Day 14 (D14, p = 0.061).

However, a significant difference emerged after treatment (AT, p = 0.004), with Group A showing lower mean ranks (17.00) compared to Group B (24.00), indicating Group A experienced a greater treatment effect on straining by the end of the study.

## 7) NOCTURIA

Table no.7 -Effect of treatment on Nocturia between group A and group B

Ranks		BT		D14		AT	
Groups	N	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Group A	20	21.73	434.50	17.60	352.00	15.23	304.50
Group B	20	19.28	385.50	23.40	468.00	25.78	515.50
Test Statistics							
		BT		D14		AT	
Mann-Whitney U		175.500		142.000		94.500	
Wilcoxon W		385.500		352.000		304.500	
Z		-.725		-1.723		-3.093	
P value (2-tailed)		.469		.085		.002	

Since p values > 0.05, the level of significance for BT & D14; there is no sufficient evidence to reject the null hypothesis for BT & D14.

## Conclusion

The Mann-Whitney U test results show no significant differences in nocturia between Group A and Group B at

baseline (BT, p = 0.469) and Day 14 (D14, p = 0.085). However, a significant difference was observed after treatment (AT, p = 0.002), with Group A exhibiting lower mean ranks (15.23) compared to Group B (25.78). This indicates that Group A experienced a more pronounced treatment effect on nocturia.

## 8) TOTAL IPSS

Table no.8 -Effect of treatment on total IPS Score between group A and group B.

Group Statistics					
Groups		N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	20	13.05	3.14	0.70
	Group B	20	13.40	3.00	0.67
D14	Group A	20	8.75	2.83	0.63
	Group B	20	11.40	2.66	0.60
AT	Group A	20	3.70	2.47	0.55
	Group B	20	7.40	2.37	0.53

Independent Samples Test						
Total IPSS Score		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	T	Df	P value (2-tailed)
BT	Equal variances assumed	.132	.719	-.361	38	.720
	Equal variances not assumed			-.361	37.923	.720
D14	Equal variances assumed	.117	.734	-3.052	38	.004
	Equal variances not assumed			-3.052	37.868	.004
AT	Equal variances assumed	.007	.932	-4.830	38	.000
	Equal variances not assumed			-4.830	37.933	.000

Since p values > 0.05, the level of significance for BT; there is no sufficient evidence to reject the null hypothesis for BT.

The independent samples t-test showed that after treatment, Group A had a 71.64% reduction in Total IPSS

score (mean: 13.05 to 3.70, p = 0.000), while Group B experienced a 44.26% reduction (mean: 13.40 to 7.40, p = 0.004). This indicates that the treatment was significantly more effective in Group A, providing 62% more symptom relief than Group B.

## 9) POST VOID RESIDUAL URINE

Table no.9 -Effect of treatment on Post void residual urine between group A and group B.

Group Statistics					
Groups		N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	20	65.30	45.03	10.07
	Group B	20	70.50	39.66	8.87
AT	Group A	20	29.85	30.43	6.80

	Group B	20	45.45	21.40	4.79
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Independent Samples Test						
PVR Urine(in ml)		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	T	Df	P value (2-tailed)
BT	Equal variances assumed	.523	.474	-.388	38	.701
	Equal variances not assumed			-.388	37.404	.701
AT	Equal variances assumed	2.400	.130	-1.875	38	.068
	Equal variances not assumed			-1.875	34.105	.069

Since p values > 0.05, the level of significance for BT & AT; there is no sufficient evidence to reject the null hypothesis for BT & AT.

The independent samples t-test comparing post-void residual (PVR) urine between Group A and Group B showed that Group A had a 54.29% reduction in PVR (mean: 65.30 to 29.85), while Group B experienced a

35.53% reduction (mean: 70.50 to 45.45). Although Group A showed greater improvement, the difference between the groups was not statistically significant (p = 0.068). This means Group A had a 52.78% greater reduction in PVR compared to Group B, highlighting a more substantial improvement in Group A's urinary function after treatment.

## 10) PROSTATE SIZE

Table no.10 -Effect of treatment on Prostate size between group A and group B

Group Statistics					
Groups		N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	20	42.55	15.37	3.44
	Group B	20	34.65	6.37	1.42
AT	Group A	20	35.15	14.79	3.31
	Group B	20	31.90	6.75	1.51

Independent Samples Test						
Size of Prostate(in Vol)		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	T	Df	P value (2-tailed)
BT	Equal variances assumed	21.429	.000	2.124	38	.040
	Equal variances not assumed			2.124	25.339	.044
AT	Equal variances assumed	23.338	.000	.894	38	.377
	Equal variances not assumed			.894	26.586	.379

Since p values > 0.05, the level of significance for AT; there is no sufficient evidence to reject the null hypothesis for AT.

The treatment effect on prostate size was evaluated using the independent samples t-test. Group A's mean prostate size decreased from 42.55 to 35.15, resulting in a 17.65%

reduction, while Group B's mean size went from 34.65 to 31.90, reflecting a 7.93% reduction. The t-test indicated a significant difference in prostate size before treatment (p = 0.040), but not after (p = 0.377). Ultimately, Group A achieved 9.72% more relief in prostate size compared to Group B post-treatment.

## ASSESSMENT OF TOTAL EFFECT OF TREATMENT

Table no.11 - OVERALL RESPONSE IN GROUP A AND GROUP B.

Response	GROUP A		GROUP B	
	No. of patients	%	No. of patients	%
No response	0	0.0	0	0.0
Poor response	0	0.0	1	5.0
Mild response	2	10.0	4	20.0
Moderate response	7	35.0	7	35.0
Good response	11	55.0	8	40.0
Total	20	100.0	20	100.0

Chi-square value	Df	p-value
2.14	3	0.54

With a p-value of 0.544, there is no statistically significant difference in response rates between Group A and Group B

## DISCUSSION ON RESULTS

Effect of treatment on subjective and objective parameters.

**Incomplete emptying of Bladder:** Group A showed 57.5% improvement in incomplete emptying, while Group B had 55.1% improvement, both with a highly significant response ( $p < 0.001$ ). Group A exhibited a more pronounced effect.

**Frequency of Micturition:** Group A showed a 64% improvement in urinary frequency, while Group B had a 56% improvement. Both groups demonstrated highly significant results ( $p < 0.001$ ), Group A demonstrated a more significant effect.

**Intermittency:** Group A achieved a 51.8% improvement in urinary intermittency, while Group B showed a 46% improvement. Both groups were highly significant ( $p$ -value of 0.000), indicating effective treatments, especially in Group A.

**Urgency:** Group A had a 56.8% improvement in urinary urgency, while Group B showed a 41.6% improvement. Both groups were highly significant ( $p$ -value of 0.000), with Group A demonstrating greater effectiveness.

**Weak stream:** Group A experienced a 50.3% improvement in weak urinary stream, while Group B showed a 34.2% improvement. Both groups had highly significant results ( $p$ -value of 0.000), Group A displayed a more marked effect.

**Straining:** Group A had a 32.7% improvement in straining, while Group B achieved a 34.8% improvement. Both groups showed highly significant results ( $p$ -value of 0.000), with Group B slightly outperforming Group A.

**Nocturia:** Group A experienced a 62.5% improvement in nocturia, while Group B showed a 49% improvement. Both groups had significant results ( $p$ -value of 0.000), with Group A demonstrating greater effectiveness.

**Total IPSS:** Group A demonstrated 71.6% improvement on Total IPS Score, while Group B showed an improvement of 45%. Both groups exhibited highly significant results with a  $p$ -value of 0.000, indicating effective treatments, with Group A significantly surpassing Group B.

**Post void residual urine volume:** Group A demonstrated a 54.3% improvement in post void residual

urine volume, while Group B had a 35% improvement. Both groups exhibited highly significant results ( $p$ -value of 0.000), emphasizing the effectiveness of the treatments, particularly in Group A.

**Prostate size:** Group A showed a 17.3% reduction in enlarged prostate size, while Group B had an 8% reduction. Both groups demonstrated highly significant results with a  $p$ -value of 0.000, indicating the effectiveness of the treatments, especially in Group A.

## Discussion on Overall results of the study

### Overall effect on Group A (Ksharapippali)

In Group A, among 20 patients, 55% showed a good response, 35% had a moderate response, and 10% experienced a mild response, with no cases of poor or no response. Specifically, 11 patients experienced significant improvement in obstructive and irritative urinary symptoms within 28 days, 7 patients had moderate symptom reduction, and the remaining 2 patients saw mild improvement within the same period.

### Overall effect on Group B (Mahodarahara Kashaya)

In Group B, out of 20 patients, 40% showed a good response, 35% had a moderate response, 20% experienced a mild response, and 5% had a poor response, with no cases of no response. Specifically, 8 patients demonstrated significant improvement in obstructive and irritative urinary symptoms within 28 days, 7 had moderate symptom reduction, 4 experienced mild reduction, and 1 patient showed poor improvement over the same period.

## DISCUSSION ON PROBABLE MODE OF ACTION OF DRUG

### Probable mode of action of Ksharapippali

Ksharapippali, a formulation explained by Vangasena indicated in Vatashteela.

Most of the drugs possess ushna veerya, katu, tikta rasa and vatanulomaka, guna, mutrala, mutrajanana properties. All of this ultimately helps restore the normal function of Apana Vata, ensuring proper regulation of shukra, shakrit and mutra visarjana, thereby relieving obstructions. As a result, urine is evacuated efficiently, which may significantly reduce obstructive symptoms such as incomplete bladder emptying, weak urine flow, intermittency, straining, and post-void retention.

Pharmacologically most of the drugs possess anti-inflammatory properties. Drugs like Bala, Manakanda, Punarnava, Varuna and Yavakshara are diuretics and Sirisha, Citraka, Varuna, Punarnava, Ajagandha contain chemical constituents like  $\beta$ -sitosterol. Various study shows  $\beta$ -sitosterol has been proved potential in reducing BPH by improving urologic symptoms and flow measures. Ksharapippali prepared using the ingredients listed above is a potent formulation in treating Vatashteela (BPH). This can significantly reduce obstructive symptoms like incomplete bladder emptying, weak stream, intermittency, straining, and post-void



retention. Ksharapippali has the mutrala effect. Pharmacologically, many of these drugs also possess anti-inflammatory and anti-tumor activities, aiding in the management of Vatashteela.

#### **Probable mode of action of Mahodarahara Kashaya**

Most of the drugs used have ushna veerya, katu and tikta rasa, and vatanulomaka properties, along with mutrala, nutrajanaka, and bastishulahara actions. These help restore the normal function of Apana Vata, relieving obstructions and ensuring proper urine evacuation. This can significantly reduce obstructive symptoms like incomplete bladder emptying, weak stream, intermittency, straining, and post-void retention. Yava kshara, enhances the drug's mutrala effect. Pharmacologically, many of these drugs also possess anti-inflammatory and anti-tumor activities, aiding in the management of Vatashteela.

#### **CONCLUSION**

- ❖ Following conclusions were drawn from the present clinical study titled "A comparative clinical study to evaluate the efficacy of Ksharapippali and Mahodarahara Kashaya in Vatashteela w.s.r to Benign Prostatic Hyperplasia" which was carried out on 40 patients of Vatashteela.
- ❖ Out of the 40 patients of *Vatashteela* with special reference to Benign Prostate Hyperplasia included in this study, 20 patients were treated with *Ksharapippali* under group A and 20 patients were treated with *Mahodarahara Kashaya* in group B.
- ❖ The overall observation in the study revealed that *vatashteela* (BPH) was common in the age group of 40-80 years, the maximum number of Subjects were under the age group of 60-70 years of age, maximum number of Subjects were Hindus and from the middle class, having Mixed diet and with duration of the disease within 1 year and with increased frequency, urgency, intermittency and nocturia as chief complaints.
- ❖ BPH is a disease which gives rise to various urinary features and are mainly divided into obstructive and irritative symptoms. The action of drug on both obstructive and irritative symptoms was significant in both Group A and Group B.
- ❖ In the present study, the effect of the treatment in both the groups has shown statistically highly significant results in both subjective and objective parameters.
- ❖ Group A was comparatively better than Group B in parameters like frequency, intermittency, urgency, weak stream, nocturia both clinically and statistically. While both the groups showed approximately similar results in parameters like incomplete voiding and straining.
- ❖ Statistically, when mean rank were compared between 2 groups, Effect of drug on frequency, intermittency, urgency, weak stream, nocturia in both groups was not

significant, the subjects under Group A showed better response.

- ❖ The overall effect of the treatment was statistically insignificant ( $p=0.40$ ), with only a slight difference from reaching significance when comparing Group A, and Group B.
- ❖ However, comparative statistical analysis of the overall effect of both the groups shows that Group A where patients treated with *Ksharapippali* was more effective than Group B with *Mahodarahara Kashaya*.
- ❖ No adverse effects were observed in both the groups during the course of the study.
- ❖ During the Study period no escalation of symptoms were observed.
- ❖ During the observational period no reoccurrence of symptoms was observed.
- ❖ Based on observation and result, following hypothesis can be accepted-
- ❖ There is significant effect of *Ksharapippali* in *Vatashteela* w.s.r to Benign Prostatic Hyperplasia.
- ❖ There is significant effect of *Mahodarahara Kashaya* in *Vatashteela* w.s.r to Benign Prostatic Hyperplasia.
- ❖ There is no significant difference between the effect of *Ksharapippali* and *Mahodarahara Kashaya* in *Vatashteela* w.s.r to Benign Prostatic Hyperplasia.

#### **SCOPE FOR FURTHER RESEARCH**

- ❖ A similar study can be conducted on large population.
- ❖ The study can be extended over a longer period to achieve more comprehensive results.
- ❖ To comprehend the mechanism of urodynamic effects of therapy, urine flow rate should be assessed using automated uroflowmetry.

Since the clinical study was conducted on a limited, its results cannot be deemed conclusive. A multicentre study with a larger sample size would be more credible for establishing efficacy.

## Preparation of the Drugs



Ingredients of Ksharapippali



**Finely powdered ingredients of Ksharapippali**



**Preparation of Ksharapippali**



**Final Product  
Ksharapippali**



**Ingredients of Mahodarahara Kashaya**



**Coarsely powdered ingredients**



**Final Product**

**Mahodarahara Kwatha churna**

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