Research Article

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A CLINICAL STUDY ON THE EFFICACY OF PATALADI KASHAYA IN THE MANAGEMENT OF 'VATAShteela' VIS A VIS 'BPH' (BENIGN PROSTATIC HYPERTROPHY)

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ABSTRACT

In the present clinical study the cases of disease 'Vatashteela', which is a type of Mutraghata in terms of Benign Prostate Hypertrophy (BPH), were considered. The objective of the study was to assess the efficacy of Pataladi kashaya in Vatashteela 'vis a vis' BPH. Total 30 patients having signs and symptoms of 'Vatashteela' 'vis a vis' BPH were included according to criteria of AUA-SI (American Urological Association – Symptom Index), and also after diagnosing BPH by Digital Rectal Examination, and Ultrasonography of Abdomen and pelvis. Patients were assigned into a single group consisting of 30 patients for whom Pataladi kashaya 30 ml thrice a day before food with sukhoshna jala for 30 days was administered. Incomplete emptying, Frequency, Urgency, Intermittency, Straining, Weak stream and Nocturia were the Subjective parameters, data of which were collected before (day 0), during (day 15), after (day 30) and follow up (day 60). The objective parameters were residual urine, volume and size of the prostate. These data were collected before (day 0) and after (day 30) of the clinical trial. The analysis was done statistically by using Repeated Measure ANOVA, student 't' test and contingency co-efficient table. The statistical values showed significant results in subjective and objective parameters. In lateral lobe enlargement, symptoms were relieved to a greater extent compared to median lobe enlargement. Residual urine, volume of the prostate, obstructive symptoms showed marked improvement in many of the patients, and there was also significant decrease in size of the prostate. Overall assessment showed marked and moderate improvement in many patients. Pataladi kashaya is useful in reducing the signs and symptoms of 'Vatashteela' 'vis a vis' 'BPH' and even residual urine, volume and size of the prostate. Pataladi kashaya is beneficial due to its properties in improving obstructive symptoms and reducing the size of the prostate.

Keywords: Mutraghata, Vatashteela, BPH, Pataladi kashaya

INTRODUCTION

Increase in the size of the prostate gland in middle aged and elderly men is termed as Benign Prostatic Hypertrophy¹. It is one of the most common pathology with few complaints related to act of micturation. Dysuria, urgency, dribbling, incomplete emptying of bladder, nocturia, frequency are the symptoms of Prostatic hypertrophy². Symptoms improve or stabilize in 70-80 % of patients, 20-30 % require treatment because of worsening symptoms. These symptoms along with the increase in the size of the gland and hardness in middle aged and elderly men are almost similar to the description of "Vatashteela"³, one among the varieties of a major disease called Mutraghata⁴. A recent survey of WHO reveals that, above the age of 50 years, 50 % people are suffering from BPH. BPH is as high as 50 % at the age of 60 years and 90 % at the age of 85 years. It is observed that among the men above 80 years, 90 % show histological evidence of BPH, out of that 81 % have BPH related symptoms and 10 % suffer from urinary retention. It is having second highest incidence in the geriatric practice other than arteriosclerosis⁵. Despite intense research efforts, the exact cause, and effect relationship of prostatic growth has not been established. The current modalities of management are "wait-watchful" therapy and surgery (prostatectomy). Surgery is the second option for the treatment of the disease due to complications like

incontinence and impotence. However the complication associated with the surgical management of BPH, lead to a search for other alternative methods of management which are safer, simpler and economical. Considering the indication of 'Pataladi kashaya' in Mutraghata and after analysing the individual drugs of this formulation it has been selected for the clinical study.

MATERIALS AND METHODS

Inclusion Criteria

- Elderly male patients with clinical features of BPH
- Patients fulfilling the criteria for International Prostate Symptom Scoring (IPSS), Digital Rectal Examination (DRE) and Ultrasonography (USG)

Exclusion Criteria

- Patients in whom surgery is unavoidable
- Ca Prostate.
- Ca Rectum
- Neurogenic bladder
- Stricture Urethra
- Patients having any systemic diseases, which interfere with the course of treatment.

Diagnostic Criteria

- Subjective criteria - Classical Clinical features of BPH (Vatashteela)
- Objective criteria – DRE (Digital Rectal Examination), USG (Ultrasonography).

Parameters of the Study**Subjective Parameters**

Assessed by the American Urology Association - Symptom Index (AUA - SI)⁷.

Objective Parameters

- Measurement of prostatic enlargement by Digital rectal examination and Ultrasonography.
- Residual urine assessment by Ultrasonography.

Investigations

- Urine - Albumin, Sugar, Microscopic
- Ultrasonography of abdomen and pelvis

Study Design

Total 30 patients were assigned into a single group. Data were collected in the performa of the study. The study was compared with pre and post-test design. Study was carried out as per ethical guidelines with Institutional ethical clearance number 2441104.

Intervention

Oral administration of Pataladi kashaya in a dose of 30 ml thrice a day before food for 30 days with equal quantity of sukhoshna jala advised as anupana.

Assessment Criteria**AUA – SI**

Symptom	Assessment	Not at all	Less than 1 in 5 times	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying How often have you had a sensation of not emptying your bladder completely after you finish urinating?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Frequency How often have you had to urinate again less than two hours after you finished urinating?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Intermittency How often have you found you stopped and started again several times when you urinated?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Urgency How often have you found it difficult to postpone urination?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Weak stream How often have you had a weak urinary system?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Straining How often have you had to push or strain to begin urination?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Nocturia How many times did you most typically get up to urinate from the time you went to bed at night the time you got up in the morning?	Before	0	1	2	3	4	5
	After	0	1	2	3	4	5
Total Score	Before						
	After						

0-7	Mild
8-19	Moderate
20-35	Severe

Subjective findings were recorded before (day 0), during (15th day), and after (30th day) the intervention.

Objective Parameters

It includes the size of prostate by Ultrasonography and Digital Rectal Examination (DRE), Volume and Post voidal residual urine (PVRU) measurement through USG. Objective findings were recorded before (day 0) and after (30th day) the clinical trial.

Overall assessment**Complete relief**

100 % reduction in symptoms and PVRU

Marked relief

61 to 99 % reduction in symptoms and PVRU

Moderate relief

31 to 60 % reduction in symptoms and PVRU

Mild relief

16 to 30 % reduction in symptoms and PVRU

No improvement

Up to 15 % reduction in symptoms and PVRU

The data was analyzed by using 't' test, repeated measure ANOVA, and contingency co-efficient table analysis. The analysis was carried out by using SPSS for Windows (Statistical Presentation System Software) version 10.0 developed by SPSS Inc, New York (1999).

Table 1: Results of PVRU (Post Void Residual Urine)

Paired 't' test					
		Mean	N	Std. Deviation	Std. Error Mean
Pair	PVRU Before	108.3000	30	126.88092	23.16518
	PVRU after	71.3	30	94.9870	21.8789
Paired 't' test					
		Paired Differences Mean	T	Df	Sig (2-tailed)
Pair	PVRU Before – PVRU After	37	4.786	29	.000

Significance - < 0.000 (highly significant)

Table 2: Results of Volume

Paired 't' test					
		Mean	N	Std. Deviation	Std. Error Mean
Pair	Volume Before	39.2667	30	20.06186	3.66278
	Volume After	30.5667	30	17.05101	3.11307
Paired Samples Test					
		Paired differences mean	T	Df	Sig (2 tailed)
Pair	Volume Before – Volume After	8.7000	3.262	29	.003

Significance - < 0.003 (significant)

Table 3: Results of prostate size

Contingency co efficient test				
			Session	
			Before	After
Enlargement of Lobe	No enl	Count	0	16
		% of SESSION	0 %	53.3 %
	Med	Count	13	1
		% of SESSION	43.3 %	3.3 %
	lat lobe	Count	17	13
		% of SESSION	56.7 %	43.3 %
Total		Count	30	30
		% of SESSION	100.0 %	100.0 %
Symmetric Measures				
			Value	Approximate Significance
Nominal by Nominal		Contingency Coefficient	0.08	.003

Significance - < 0.003 (significant)

Table 4: Results of total IPSS Score

Descriptive Statistics			
	Mean	Std. Deviation	N
TOTBEF	21.4000	6.66230	30
TOTDUR	19.9667	6.43527	30
TOTAFT	14.6000	6.14537	30
TOTFU	9.1000	5.60388	30

Source	Type III Sum of Squares	Df	Mean Square	F	Significance
CHG	2825.400	3	941.800	138.852	.000
Error(CHG)	590.100	87	6.783		
Source	Type III Sum of Squares	Df	Mean Square	F	Significance
Intercept	31752.533	1	31752.533	235.869	.000
Error	3903.967	29	134.620		

Significance - <0.000 (highly significant)

Table 5: Results of incomplete emptying

		Sessions			
		Before	During	After	Follow Up
IE	NO	Count	10	10	15
		% of SESSIONS	33.3 %	33.3 %	50.0 %
	<1 in 5	Count	0	1	1
		% of SESSIONS	.0 %	3.3 %	3.3 %
	<1/2	Count	1	0	3
		% of SESSIONS	3.3 %	.0 %	10.0 %
	½	Count	0	1	11
		% of SESSIONS	.0 %	3.3 %	36.7 %
	>1/2	Count	2	4	1
		% of SESSIONS	6.7 %	13.3 %	3.3 %
	always	Count	17	14	3
		% of SESSIONS	56.7 %	46.7 %	10.0 %
	Total	Count	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.567	.000

Significance - < 0.000 (highly significant)

Table 6: Results Frequency

			Sessions			
			Before	During	After	Follow Up
FR	NO	Count	3	4	6	12
		% of SESSIONS	10.0 %	13.3 %	20.0 %	40.0 %
	<1 in 5	Count	1	1	1	0
		% of SESSIONS	3.3 %	3.3 %	3.3 %	.0 %
	<1/2	Count	0	0	2	2
		% of SESSIONS	.0 %	.0 %	6.7 %	6.7 %
	½	Count	0	2	11	10
		% of SESSIONS	.0 %	6.7 %	36.7 %	33.3 %
	>1/2	Count	0	3	2	3
		% of SESSIONS	.0 %	10.0 %	6.7 %	10.0 %
	always	Count	26	20	8	3
		% of SESSIONS	86.7 %	66.7 %	26.7 %	10.0 %
	Total	Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.563	.000

Significance - < 0.000 (highly significant)

Table 7: Results Intermittency

			Sessions			
			Before	During	After	Follow Up
INT	NO	Count	23	24	24	29
		% of SESSIONS	76.7 %	80.0 %	80.0 %	96.7 %
	<1 in 5	Count	1	0	0	0
		% of SESSIONS	3.3 %	.0 %	.0 %	.0 %
	<1/2	Count	0	1	0	0
		% of SESSIONS	.0 %	3.3 %	.0 %	.0 %
	½	Count	2	3	5	1
		% of SESSIONS	6.7 %	10.0 %	16.7 %	3.3 %
	>1/2	Count	1	0	1	0
		% of SESSIONS	3.3 %	.0 %	3.3 %	.0 %
	always	Count	3	2	0	0
		% of SESSIONS	10.0 %	6.7 %	.0 %	.0 %
	Total	Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.356	.292

Significance - < 0.292 (non significant)

Table 8: Results of Urgency

			Sessions			
			Before	During	After	Follow Up
UR	NO	Count	6	6	9	14
		% of SESSIONS	20.0 %	20.0 %	30.0 %	46.7 %
	<1/2	Count	0	1	1	2
		% of SESSIONS	.0 %	3.3 %	3.3 %	6.7 %
	½	Count	0	2	9	11
		% of SESSIONS	.0 %	6.7 %	30.0 %	36.7 %
	>1/2	Count	3	3	1	0
		% of SESSIONS	10.0 %	10.0 %	3.3 %	.0 %
	always	Count	21	18	10	3
		% of SESSIONS	70.0 %	60.0 %	33.3 %	10.0 %
Total		Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.507	.000

Significance - <0.000 (highly significant)

Table 9: Results of Weak Stream

			Sessions			
			Before	During	After	Follow Up
WS	NO	Count	9	9	11	20
		% of SESSIONS	30.0 %	30.0 %	36.7 %	66.7 %
	<1 in 5	Count	2	2	2	1
		% of SESSIONS	6.7 %	6.7 %	6.7 %	3.3 %
	<1/2	Count	1	0	1	0
		% of SESSIONS	3.3 %	.0 %	3.3 %	.0 %
	½	Count	1	4	12	8
		% of SESSIONS	3.3 %	13.3 %	40.0 %	26.7 %
	>1/2	Count	1	2	0	0
		% of SESSIONS	3.3 %	6.7 %	.0 %	.0 %
Total	always	Count	16	13	4	1
		% of SESSIONS	53.3 %	43.3 %	13.3 %	3.3 %
		Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.509	.000

Significance - < 0.000 (highly significant)

Table 10: Results of Straining

			Sessions			
			Before	During	After	Follow Up
STR	NO	Count	19	19	22	26
		% of SESSIONS	63.3 %	63.3 %	73.3 %	86.7 %
	<1 in 5	Count	0	1	2	1
		% of SESSIONS	.0 %	3.3 %	6.7 %	3.3 %
	<1/2	Count	1	1	0	0
		% of SESSIONS	3.3 %	3.3 %	.0 %	.0 %
	½	Count	1	1	3	2
		% of SESSIONS	3.3 %	3.3 %	10.0 %	6.7 %
	>1/2	Count	0	1	0	1
		% of SESSIONS	.0 %	3.3 %	.0 %	3.3 %
	always	Count	9	7	3	0
		% of SESSIONS	30.0 %	23.3 %	10.0 %	.0 %
	Total	Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.373	.197

Significance - <0.197 (non significant)

Table 11: Results of Nocturia

			Sessions			
			Before	During	After	Follow Up
NOCT	NO	Count	2	1	2	6
		% of SESSIONS	6.7 %	3.3 %	6.7 %	20.0 %
	<1 in 5	Count	0	0	0	1
		% of SESSIONS	.0 %	.0 %	.0 %	3.3 %
	<1/2	Count	0	0	5	3
		% of SESSIONS	.0 %	.0 %	16.7 %	10.0 %
	1/2	Count	3	4	8	15
		% of SESSIONS	10.0 %	13.3 %	26.7 %	50.0 %
	>1/2	Count	1	4	4	3
		% of SESSIONS	3.3 %	13.3 %	13.3 %	10.0 %
	always	Count	24	21	11	2
		% of SESSIONS	80.0 %	70.0 %	36.7 %	6.7 %
	Total	Count	30	30	30	30
		% of SESSIONS	100.0 %	100.0 %	100.0 %	100.0 %

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.550	.000

Significance - < 0.000 (highly significant)

Table 12: Results of Overall assessment

Improvement	Number and Percentage
No improvement	3 (10 %)
Mild	4 (13 %)
Moderate	12 (40 %)
Marked	11 (37 %)
Complete relief	0

RESULTS

A highly significant decrease was observed between before to after intervention in mean PVRU scores. Significance was found at 0.000 levels. From the mean values it is evident that a mean of 108.3 was observed before, which was decreased to 71.3 after the intervention. In mean Volume scores, a significant decrease was observed from before to after intervention at 0.003 levels. From the mean values it is evident that a mean of 39.26 was observed before, which was decreased to 30.56 after the intervention. A statistically significant result was observed in the enlargement of lobe on Digital Rectal examination (DRE) in both the groups, with p value of 0.003. It was observed that 43.3 % (13) patients had median lobe enlargement and 56.7 % (17) had lateral lobe enlargement, among which 53.3 % (16) patients enlargement reduced completely after the clinical trial. A highly significant decrease was observed from before to after intervention in mean total IPSS scores. F value (F = 235.869) for this decrease was found to be significant at 0.000 level. From the mean values it is evident that a mean of 21.4 was observed before, which was decreased to 14.6 after the intervention. The results on the subjective parameters showed a highly significant result with a 'p' value of 0.000 in incomplete emptying, frequency, weak stream, urgency and nocturia but a non significant result in straining and intermittency. The overall assessment showed, 11 (37 %) patients got marked relief, 12 (40 %) got moderate relief, 4 (13 %) patients got mild relief and 3 (10 %) patients got no improvement.

DISCUSSION

The result on PVRU might be due to the action of the drugs in the formulation which would have produced strength to detrusor muscle to do sufficient contraction. Even mutrala and shotha hara karma⁸ of the drugs might have acted to get the result. It can be understood that the shamana yoga used in the present study was helpful in reducing the size of the prostate by observing the results on the size of the prostate after the intervention. This can be attributed to drug in the formulation like patala, shyonaka and nimba which could probably reduce the size of stromal and epithelial cells of the gland. A highly significant decrease was observed from before to after intervention in mean total IPSS scores, and also showed

highly significant results on incomplete emptying, weak stream, frequency, urgency and nocturia and non significant results on intermittency, and straining. Results of Pataladi kashaya in these symptoms were due to its vatakaphahara⁹, shothahara, mutrala, basti shodhana and rasayana¹⁰ action. It was observed that the response was evident only after the 30 days of trial and after the follow up period, maximum result was obtained. Patients selected for the trial had 30 - 50 % relief in the symptoms as well as objective findings. Even the appetite and digestive capacity of the patients got increased and few were relieved from symptoms like angamarda, vibandha, adhmaana, probably due to the presence of triphala especially haritaki. Some patients complained of burning abdomen after consumption, may be because of pragbhakta administration, for which it was advised to take the kashaya after the food. Many patients felt difficult to consume because of the bitter taste of kashya mainly contributed by the ingredient Nimba.

CONCLUSION

Thus, Pataladi kashaya was proved to reduce the symptoms, as well as size and volume of Prostate and PVRU. Pataladi kashaya was observed to improve even general condition to a greater extent in this study.

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