

“CLINICAL EVALUATION OF PATALYADI KSHAR IN THE MANAGEMENT OF VATASHTHEELA W.S.R. TO BENIGN PROSTATIC HYPERPLASIA”

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Abstract — Benign prostatic hyperplasia (BPH) is the most common condition in ageing men, associated with lower urinary tract symptoms (LUTS). In Ayurveda, Vatashtheela disease closely resembles with Benign Prostatic Hyperplasia of modern medicine in its signs and symptoms. A clinical trial was conducted in this study group of 30 males diagnosed with symptomatic Benign Prostatic Hyperplasia (Vatashtheela). Patients were selected randomly irrespective of their religion, race, occupation etc. They were administered Patalyadi Kshar, a herbal formulation, at a dose of 1 capsule each Bid a day 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. Analysis of result showed improvement in Vatashtheela (BPH). Finally study concluded that Patalyadi Kshar is effective for symptomatic relief in Vatashtheela (BPH).

Index Terms — Benign Prostatic Hyperplasia (BPH), Vatashtheela, Patalyadi Kshar.

I. INTRODUCTION

No one can deny that Ayurvedic approach towards the disease is holistic. Numerous therapeutical modalities have been advocated by our Acharyas in the management of each and every disease, but their efficacy need re-establishment by means of thorough and intensive researches.

Vatashtheela is a hard, elevated, mobile swelling. It is one of the thirteen types of Mootraghata. Earliest reference regarding urinary disorders is available in Atharvaveda. Sushruta (1500 BC) in his Sushruta samhita has elaborately explained about Vatashtheela. Vatashtheela reflects the symptoms similar to the Lower Urinary Tract Symptoms (LUTS) and may be co-related with the disease Benign Prostatic Hyperplasia (BPH) in modern parlance. Vatashtheela is a condition of obstructive uropathy (mechanical) which may present with either partial or complete retention of urine. The disease, Vatashtheela has been the subject of study in the

previous years and has shown encouraging results by Ayurvedic management.

BPH is a benign enlargement of prostate gland which shows histological excessive growth of prostatic nodules. BPH expresses both the obstructive and the irritative features of the urinary system. BPH affects the urethra and later on the bladder, and even kidneys are adversely effected retrogradely. Urinary retention - acute or chronic, is another form of progression. However, B.P.H. is a slow progressive disease and the management is achieved by either conservative or surgical methods.

The surgical procedure like prostatectomy as well as modern conservative management have many complications such as: haemorrhage, incontinence of urine, retrograde ejaculation, impotence, stricture of urethra, epididymitis, infection, stricture of bladder neck, gynaecomastia 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 Patalyadi Kshar, contains seven 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 Department Rishikul Campus (Haridwar) Uttarakhand Ayurved University. The duration of the study was fixed as 3 months.

II. AIMS & OBJECTIVES

- 1) To study aetiopathogenesis, signs & symptoms of the Vatashtheela (BPH).
- 2) To evaluate the efficacy and safety of Patalyadi kshara in management of Vatashtheela (BPH)
- 3) To establish the use of urodynamics in lower urinary tract symptoms.

III. MATERIAL & 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.

IV. PREPARATION OF DRUG

Trial drug Patlyadi kshara was prepared as per classical method mentioned in Sushruta's First of all panchang (whole plant) of Patla, Yava, Paribhadra, Tila was taken, in equal quantity and burn. Now mix it in six times water than its quantity. Now filtered it 21 times. Further boiled it in low temperature fire. Time comes when it is like paste then about 250 mg capsules are formed. Fine powder is also made of daalchini, Ela, and Pippali after taking each in equal quantity and about 1 gram capsules are formed..

DOSE: Table No. 1

Dose	One capsules BID
Time of administration	After meal
Anupana	Luke warm water
Duration	3 months

Laboratory Investigation

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

V. CRITERIA FOR ASSESSMENT

1. 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. Table No. 2 International Prostate Symptom Score (IPSS)

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%

VI. OBSERVATIONS & RESULTS:

Table No 3. Symptom Wise Distribution

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

TABLE NO.7- TOTAL EFFECT OF THERAPY OVER PROSTATE SIZE/VOLUME

Para meter	Mean		X	% relief	S D	S E	t – va lu e	p – va lu e	Signi fican ce
	B T	A T							
PRO STA TE SIZE/ VOL.	45 .0 3	42 .1 6	2. 8 6	6. 37	7. 4 7	1. 4 6	1. 95	>0 .0 5	N.S

TABLE NO. 4- EFFECT OF THERAPY ON OBJECTIVE PARAMETER (Qmax)

No.of days	Mean		Mean diff	% relief	SD	SE	t – value	p – value	Signifi cance
	BT	AT							
15 days	2.80	2.65	0.15	5.47	0.73	0.14	1.07	>0.05	N. S
30 days	2.80	2.03	0.76	27.39	1.03	0.20	3.80	<0.001	H.S
45 days	2.80	1.61	1.19	42.46	0.93	0.18	6.47	<0.001	H.S
60 days	2.80	1.50	1.30	46.57	0.92	0.18	7.18	<0.001	H.S
75 days	2.80	1.00	1.80	64.38	1.13	0.22	8.14	<0.001	H.S
90 days	2.80	0.88	2.00	71.23	1.16	0.22	8.74	<0.001	H.S

The initial mean score of Qmax was observed 2.80, which was brought down to 2.65 after 15

days, 2.03 after 30 days, 1.61 after 45 days, 1.50 after 60 days, 1.00 after 75 days, 0.88 after 90 days of treatment with 71.23 % relief. The test of significance shows that treatment was highly significant over objective parameter.

Summarized results after completion (90 days) of treatment:

TABLE NO. 5-TOTAL EFFECT OF THERAPY OVER IPSS

Symptoms	Mean		X	% relief	SD	SE	t – value	p – value	Significa nce
	BT	A.T							
Incomplete emptying	4.11	0.88	3.23	78.50	0.65	0.12	25.28	<0.001	H.S
Frequency	3.69	0.80	2.88	78.12	0.65	0.12	22.53	<0.001	H.S
Intermittency	3.84	0.88	2.96	77.00	0.95	0.18	15.75	<0.001	H.S
Urgency	3.50	0.61	2.88	82.42	0.95	0.18	15.45	<0.001	H.S
Weak stream	4.12	0.75	3.37	81.81	1.20	0.24	13.67	<0.001	H.S
Straining	3.04	0.75	2.29	75.34	0.95	0.19	11.76	<0.001	H.S
Nocturia	3.57	0.88	2.69	75.26	0.67	0.13	20.20	<0.001	H.S

The trial drug depicted highly significant (p< 0.001) results over all the mentioned symptoms.

TABLE NO.6- TOTAL EFFECT OF THERAPY OVER MAXIMUM FLOW RATE VALUE (QMAX)

Para mete r	Mean		X	% relief	S D	S E	t – va lu e	p – val ue	Signif icance
	B T	A T							
Q - MA X	2. 8 0	0. 8 8	2. 0 0	71 .2 3	1. 1 6	0. 2 2	8. 74 1	<0. 00 1	H.S

The initial mean score of Qmax was 2.80 which came down to 0.88, and test of significance shows that it was highly significant.

The initial mean score was 45.03 which came down to 42.16 and test of significance shows that it was non-significant

TABLE NO. 8- OVERALL EFFECT OF THERAPY

Result on effect of therapy	Effect	
	No .of Pt.	%
Complete cured	0	0
Marked Improvement	17	65.38
Moderate Improvement	08	30.76
Mild Improvement	01	3.84
Unchanged	0	0

The above table shows the overall effect of trial drug . Out of 26 patients, 17 patients i.e. 65.38% revealed marked improvement, 08 patients i.e. 30.76 % have shown moderate improvement and 1 patient i.e. 3.84 % have shown mild improvement after completion of the course.

VII. 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.

A. 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- Relief seen in incomplete emptying was 78.50%.(Table No. 25.). This change was statistically highly significant (p <0.001).It can be concluded

that Patalyadi Kshar was effective in providing relief in symptom of incomplete emptying.

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. Frequency was regressed by 78.12%. Relief seen was highly significant ($p < 0.001$). (Table No.26). Thus Patalyadi Kshar proved to be effective, as is evident from the relief seen.

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. Relief seen in weak stream was 81.81%, which is highly significant ($p < 0.001$). (Table No.29). This proves that Patalyadi Kshar provided higher efficacy in stream changes.

Effect on Nocturia - This is the most irritating symptom which sends the patient of BPH to the doctor in search of relief. Nocturia was relieved by 75.26%. (Table No. 23, 31) Relief seen was highly significant. This proves that Patalyadi Kshar significantly relieved Nocturia).

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. Relief seen in the symptom of urgency was 82.41%. This result was highly significant ($p < 0.001$) (Table No. 23, 28). Hence it can be inferred that Patalyadi Kshar is capable of relieving symptom of urgency.

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. Relief seen in the symptom was 75.34% which was highly significant ($p < 0.001$) (Table No. 23, 30). This observation tends to suggest that Patalyadi Kshar was better in relieving the symptom of straining.

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. Intermittency was relieved by 77%. (Table No. 23, 27). Hence it can be concluded that Patalyadi Kshar is effective in relieving the symptom of intermittency.

Improvements in IPSS justify the efficacy of drugs used in present study.

B. 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)

The initial mean score of maximum flow rate was observed 2.80, which was brought to 0.88 after completion of treatment with 71.23% relief. The test of significance shows that treatment was highly significant ($p < 0.001$). Qmax presents the overall effect of BPH symptom so, it shows improvement due to action of all the properties of the used indigenous drug which are Lekhan (Katu Tikta Rasa, Laghu Guna), Shoshan (Kashaya Rasa, Ruksha Guna) and Vilayana (Ushna Virya) property of Patalyadi Kshar which reduces the size of prostate and so, reduces the symptom.

Effect on Prostate Size / volume. The initial mean score of prostate size was 45.03 which was brought to 42.16 after completion of treatment with 6.37% reduction in size which is statistically insignificant. Out of 26 patients the USG of 6 patients show reduction in weight /volume of prostate while 10 patients unchanged and rest 10 patients slightly increased.

VIII. TOTAL EFFECT OF THERAPY:

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

Maximum improvement was seen in 17 patients (65.38%). Moderate improvement was observed in 08 patients (30.76%). While mild improvement was observed in only 01 patients i.e. 3.84%.

Overall assessment indicates that Patalyadi Kshar was very effective in relieving symptoms. During the whole course of therapy no adverse or toxic effect was seen.

DISCUSSION ON PROBABLE MODE OF ACTION OF FORMULATION: –

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, lekhan, sophahara, mootrala and bastishodhana along with deepana-pachana karma were selected, these properties help 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.

IX. MODE OF ACTION OF PATALYADI KSHAR

A. According to Ayurveda:

The classical formulation of Patalyadi Kshar was selected in BPH; because it is described in Mootraghatapratishedhiyaadhya of Sushruta Uttaratantra Chapter 58.. The ingredients of Patalyadi Kshar are Patala, Yavakshar, Paribhadra, Tila, Ela, Twak, Pippali.

The maximum ingredients in this formulation have katu, madhura & tikta rasa; ruksha & teekshna guna; ushna veerya and katu vipaka. 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 led 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.

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 Patalyadi Kshari are clinically proven as a safe and effective therapy in the management of Vatashtheela i.e. BPH. The selected formulations for clinical trial i.e. Patalyadi Kshar had shown VataKaphashamaka action and Mootrala, Deepana, Paachana, Lekhana and Bastishodhana properties and may be held responsible for breaking the sampraapti of Vatashtheela/ BPH as well as correction in imbalanced level of sex hormones and improving bladder functions by improving bladder muscle tone.

The fourth chapter has contained some important and productive discussion about the disease and the probable mode

of action of the selected formulas. The data obtained after the clinical trial were discussed thoroughly under this section. Lastly, total study is summarized here concisely, and a conclusion is drawn.

X. 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. The dose of Patalyadi Kshar can be increased for better result

3. 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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