

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *TRIKANTAKADI GUGGULU* IN THE MANAGEMENT OF *VATASHTHILA W.S.R. TO BENIGN PROSTATIC HYPERPLASIA (BPH)*

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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, Vatashtila disease closely resembles with Benign Prostatic Hyperplasia (BPH) 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 (Vatashtila). Patients were selected randomly irrespective of their religion, race, occupation etc. They were administered Trikantakadi guggulu, a herbal formulation, at a dose of 2 tablets Bid a day for three months and monitored at every 15 days interval during the study period. The irritative and obstructive symptoms of BPH (Vatashtila) 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 BPH (Vatashtila). Finally study concluded that Trikantakadi guggulu is effective for symptomatic relief in Vatashtila (BPH).

Index terms- Benign Prostatic Hyperplasia (BPH), Vatashtila, Trikantakadi guggulu, Urgency,

I. INTRODUCTION

Benign Prostatic Hypertrophy (BPH) is an ailment commonly encountered in aged males¹. It is a proliferative process that involves both the stromal and epithelial elements of the prostate. Its clinical manifestations include obstructive and irritative urinary tract symptoms, urinary retention, urinary tract infection². The standard line of treatment for BPH is surgery. However, the risk factor is high for patients in this age group who undergo prostatectomy³. Hence, the preferred line of treatment is medical therapy. Advances in the medical field in the coming years are bound to result in increased longevity and thereby the probable incidence of BPH will increase. In Ayurvedic classics *Mutraghata*⁴ gives the symptoms of lower urinary output either by retention, absolute or anuria. *Mutraghata* is predominantly due to the *Vata Dosha*.⁵ In Ayurveda the *Vatashtila*⁶ Vyadhi which is a type of *Mutraghata* may have some similarity with BPH on the basis

of symptoms like *Achala Unnata Granthi* (singly movable & elevated swelling), *Vinmutranilasanga* (retention of urine, faeces & flatus), *Bastiadhmana* (distension of the urinary bladder), *Vedanachaparabastou* (excruciating pain in the bladder) In the classics *Acharya Sushruta* decided general line of management of all type of *Mutraghata* by use of *Kashaya*, *Kalka*, *Avaleha*, *Kshar*, *Madhya*, *Aasava*, *Swedana*, *Basti* and *Uttarbasti*.⁸

Hence here is an attempt made with herbal conservative modalities to find a superior solution for maintaining the normal life in of elderly males.

II. AIMS & OBJECTIVES

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

III. MATERIAL & METHODS

A. Selection of patients:

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.

B. 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* (Symptoms) of *Vatashtila* (BPH).

C. 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.

D. Laboratory Investigation

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

E. Physical examination

- 1) Measurement of residual urine by Ultrasonography
- 2) Uroflowmetry
- 3) Digital rectal examination

F. Preparation of drug:

Trial drug *Trikantakadi guggulu* was prepared as per classical method mentioned in *Yogratnakara*⁹. First of all panchang (whole plant) of *Gokshur (Tribulus terrestris)* was taken, washed and dried, then measure by weight and taken 5 kg. Now grind it till *Yavakut i.e. coarse powder after that allowed boiling it in 40 liters of water till it remain 1/8th (5 liter) of the initial volume. The decoction is prepared, now filtered the Kwatha. Further mix it with 1.25 kg shuddha guggulu (Commiphora mukul) and boiled further. Time comes when Kwatha is like paste then fine powder of Aamalki (Embelica officinalis), Haritaki (Terminalia chebula), Vibhitaki (Terminalia bellerica), Sunthi (Zingiber officinale), Maricha (Piper nigrum), Pippli (Piper longum), Motha (Cyperus rotundus/esculentus) are mixed in it equal to guggulu in quantity. Then about 500 mg tablets are formed.*

G. DOSE

Table No. 1

Dose	Two Tablets BID (500 mg each)
Time of administration	After meal
Anupana	Like warm water
Duration	3 months

H. Criteria for assessment-

The progress of therapeutic regimen was assessed on subjective and objective parameters.

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 Symptoms Score (IPSS)¹⁰

Symptoms	Score /Grade
Incomplete emptying	Not at all 0/G0 1 time in 5 micturition 1/G1
Frequency	Less than half the time 2/G
Intermittency	About half the time 3/G3
Urgency	More than half the time 4/G4
Weak stream	Almost always 5/G5
Straining	
Nocturia	

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

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%

IV. OBSERVATION & RESULT

Table no. 3 Distribution of patients according to symptoms

Symptom	No. of patients	% of patients
Incomplete emptying	30	100
Frequency	30	100
Intermittency	25	83.33
Urgency	27	90
Weak stream	23	76.66
Straining	28	93.33
Nocturia	27	90

In this study, all 30 patients were suffering from frequency and Incomplete emptying followed by 27 patients (90%) of nocturia and urgency followed by 23 patients (76.66%) of weak stream. Straining & Intermittency was complaint of 28

patients (93.33%) and 25 patients (83.33%) respectively. **Table no. 4 Effect of therapy on Objective Parameter**

No. of days	% relief	t value	p value	Significance
15 days	43.82	5.76	<0.001	H.S
30 days	46.06	5.88	<0.001	H.S
45 days	51.68	7.38	<0.001	H.S
60 days	56.17	6.20	<0.001	H.S
75 days	60.67	7.30	<0.001	H.S
90 days	66.29	10.42	<0.001	H.S

Test of significance shows that it was highly-significant.

Table no. 5 Total effect of therapy over Subjective Parameter (IPSS)

Symptoms	% relief	t - value	p - value	Significance
Incomplete emptying	69.87	15.31	<0.001	H.S
Frequency	74.03	15.03	<0.001	H.S
Intermittency	85.48	7.91	<0.001	H.S
Urgency	75.00	7.37	<0.001	H.S
Weak stream	80.95	6.62	<0.001	H.S
Straining	77.10	12.46	<0.001	H.S
Nocturia	69.73	9.61	<0.001	H.S

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

Table no. 6 Overall effect of therapy (IPSS)

Result on effect of therapy	Effect over IPSS	
	No. of Pt.	%
Complete cured	0	0
Marked Improvement	16	53.34
Moderate Improvement	13	43.33
Mild Improvement	1	3.33
Unchanged	0	0

The above table shows the overall effect of trial drug on IPSS. Out of 30 patients, 16 patients i.e. 53.34% revealed marked improvement, 13 patients i.e. 43.33 % have shown moderate improvement and 1 patients i.e. 3.33 % have shown mild improvement, among all the 30 patients none of the patient was completely cured but all the patients showed significant changes in IPSS after completion of the course as well as follow up period.

Table no. 7 Overall effect of therapy (QMAX)

Result on effect of therapy	Effect over Qmax	
	No. of Pt.	%
Complete cured	----	----
Marked Improvement	04	13.33
Moderate Improvement	13	43.33
Mild Improvement	12	40
Unchanged	01	3.33

The above table shows the overall effect of trial drug on Qmax. Out of 30 patients, 04 patients i.e. 13.33 % revealed marked improvement, 13 patients i.e. 43.33 % revealed moderate improvement, 12 patients i.e. 40 % have shown marked improvement and 01 patients i.e. 3.33 % have shown no improvement after completion of the course.

V. DISCUSSION

BPH (*Vatashthila*) is a common ailment of elderly population and an advisable treatment of choice is surgery, which is mentally & physically painful. Due to number of complications of operative surgery in old age, old persons avoid operative treatment for their BPH symptoms & seeking a safe & effective treatment for easy life. In this situation, the medicinal treatment may play an important role.

Mode of Action of *Trikantakadi Guggulu*:

As per *Ayurvedic classics* the *Katu Vipaka* and *Ruksha Guna* might have acted in reducing the size of the prostate by their *Lekhana* properties. The *Vigunya Apana Vayu* is presumed to be corrected by *Madhura Vipaka* with the help of its *Anulomic* action (*Rasa Vaisheshika*). The associated symptom of *Pitta* may have been corrected by *Sheeta Virya* and *Madhura Vipaka* of drug. This result on signs & symptoms and IPSS proven that the trial drugs *have got potent Vatakapsha shamaka* properties due to its *Paachana*, *Bastishodhana*, *Mutrala*, and *Shoth hara* activity. This drug have *Vata-Kapsha shamaka* pharmacological actions which played vital role in breaching *Sampraapti* of *Vatashthila*. *Mutral* and *Rasayana* property of the drug may have accelerated the process of correction of pathology condition of *Ama* may have been digested by *Katu*, *Tikta Rasa* and *Ushna Virya* of the drug¹¹.

On modern parameter it can be postulated that the drug might have reduced the enlargement by its anti-inflammatory and muscle relaxant properties. Further urinary tract infection may have been controlled by the anti-bacterial properties inherited by the drug. The anabolic and cytoprotective properties might have accelerated the process of rehabilitation of mucosal lining of posterior urethra. Further these drugs may have acted locally as well as systematically in relieving the congestion of the enlarged gland and reducing its swelling also by correcting the normal function of *Apana Vayu* it might have helped in normalizing the act of micturition. Thus relieving the symptomatology related with BPH (*Vatashthila*). The enlarged

prostate gland size was decreased due to the *Lekhaneeya*, *Shothahara* and *Deepana-Paachana* properties of drugs by

correcting unbalanced *Dhaatvaagni and Strotosanga*. Increase in maximum urine flow rate was observed due to normalization of the functions of the *apaana kshetra produced by the - Mutrala, Paachaneeya, Bastishodhana, Vata shamaka effect of drug*.

Discussion on effect of therapy –

The effect of therapy was analyzed by specially designed scoring pattern for IPSS, Uroflowmetry and student “t” test of significance was applied for that purpose.

Effect of therapy on symptomology (IPSS):

- The result shows that there was highly significant improvement ($p < 0.001$) observed in the symptom of incomplete emptying it may be due to *Mutral (Madhura Rasa)* property of drug. Both decreases post voided residual urine and improves bladder tonicity.
- There was highly significant improvement ($p < 0.001$) observed in the symptom Intermittency. It may be due to *Shrotoshodhak* property of *Guggulu*. Also due to anti-inflammatory property of *Haritaki, Aamalki*.
- The result was highly significant ($p < 0.001$) observed in the symptom Urgency. It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of drug and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* which reduces the size of prostate and so, reduces the symptom.
- The result shows that there was highly significant improvement ($p < 0.001$) observed in the symptom Weak stream. It may be due to *Lekhan* and *Shrotoshodhak* property of *Guggulu*. Also due to bladder tone improvement and weight reduction of prostate by *Trikantak and Sunthi*.
- In the symptom Straining the result was also statistically highly significant ($p < 0.001$). It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and also *Lekhan (Katu Tikta Rasa)*, *Shoshan (Ruksha Guna)* and *Vilayana (Ushna Virya)* property of drug.
- It was observed that improvement in the symptom Nocturia was also statistically highly significant ($p < 0.001$). It may be due to *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of drug.

Effect of therapy on objective parameter (QMAX) -

- The initial mean score of maximum flow rate was observed 2.96, which was come to 1 after completion of treatment with 66.29 % 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 drug which are *Lekhan (Katu Tikta Rasa, Laghu Guna)*, *Shoshan (Kashaya Rasa, Ruksha Guna)* and *Vilayana (Ushna Virya)* property of drug.

VI. DISCUSSION ON RESULTS:

IPSS:

- After the treatment, it was observed that 53.34% of patients had shown marked improvement and 43.33% of patients had shown moderate improvement, 3.33% of patients had shown mild improvement and no patient was completely cured in IPSS after completion of course.

QMAX:

- Overall, 13.33% of patients had shown marked improvement and 43.33% of patients had shown moderate improvement, 40% of patients had shown mild improvement and 3.33% patient had shown no change in objective parameter (Qmax) after completion of course.

VII. CONCLUSION

Use of *Trikantakadi guggulu* in BPH (*Vatashtila*) is cheap, effective and easily palatable for patients. Use of it in early stage of BPH (*Vatashtila*) can prevent the further progressive pathology of disease. It gives symptomatic relief in irritative symptoms like urgency, frequency, nocturia as well as in obstructive symptoms like straining, weak stream and incomplete emptying of bladder. Most of the patients having associated symptoms i.e. constipation and *Trikantakadi guggulu* showed marked improvement for constipation. Both percentage wise and statistically, results are satisfactory in this study. This therapy is effective without an adverse effect.

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