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A CLINICAL STUDY TO EVALUATE THE COMBINED EFFICACY OF *DASHMOOLADI KWAATH* AND *TRIKANTAKAADI GUGGULU* IN *VAATASTHEELA MOOTRAGHATA* (BPH)

Sweta Rautela[1]*, Dr. Sunil K. Gupta[2] and Dr. Shivam Shukla[3]

[1]PG Scholar., P.G. Dept of Shalya Tantra, [2]Professor., P.G. Dept. of Shalya Tantra Gurukul Campus, Haridwar, Uttarakhand Ayurved University, Uttarakhand, India.

[3]PG Scholar Department of Shalya Tantra Gurukul Campus Haridwar, Uttarakhand Ayurveda University.

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***Corresponding Author**
Sweta Rautela
PG Scholar., P.G.Dept of Shalya Tantra, Gurukul Campus, Haridwar, Uttarakhand Ayurved University, Uttarakhand, India.

ABSTRACT

Vaatastheela is one of the urological disorders belonging to the group of urinary pathologies called *Mootraghata*, all of which have a characteristic feature of urinary obstruction, as mentioned in *Sushruta Samhita*. The condition is found to bear resemblance to BPH (Benign Prostatic Hyperplasia) of modern on the basis of its symptoms and anatomical similarities. BPH is a common disease among the old age group characterized by enlargement of prostate, which produces lower urinary tract symptoms and obstruction of urine, further with many other complications. Very common after 50 years age in men. Many formulations are mentioned in various ancient texts regarding *Vaatastheela* and these can be used to treat the condition. Among the various formulations mentioned *Dashmoolaadi Kwaath* and *Trikantakaadi guggulu* are also indicated in *Mootraghata*. Both the drugs are mentioned in *Yogaratnakar*. A clinical trial was done among 30 patients diagnosed of signs and symptoms of *Vaatastheela* (BPH) to evaluate the combined efficacy of both the formulations on the symptoms of *Vaatastheela* and assessment was done on the basis of subjective and objective parameters. Changes in subjective parameters by IPSS index and QOL score and of objective parameters by (USG) was observed both before and after treatment. From the final results of the study, after analysis it was observed that both the drugs were effective in treating *Vaatastheela* (BPH) and combined effect showed symptomatic relief in the patients.

KEYWORDS: *Vaatastheela, Mootraghata, Dashmoolaadi Kwaath, Trikantakaadi Guggulu.*

INTRODUCTION

Ageing is an inevitable process. Age-related disorders are very common and BPH (Benign Prostatic Hyperplasia) is one of the most prevalent age related condition. In this disease development of nodules occur within the prostate gland (an accessory gland of the male reproductive system[1]) which causes the enlargement of stromal and epithelial elements of the gland. As the disease progresses, the gland enlarge resulting in various effects like compression of prostatic urethra and development of BOO[2] (Bladder outflow obstruction). BPH produces obstructive as well as irritative symptoms of lower urinary tract due to enlarged gland. The choice of treatment is Surgery but has various complications and also high risk factor in the concerned age group. So, medical management is being tried from a long time to find an effective, reliable method. On the basis of signs and symptoms and anatomically the disease *Vaatastheela Mootraghata* mentioned in *Ayurvedic* Texts closely resembles to BPH. *Vaatastheela* is a *Vaata* dominant disease, which succeeds with old age. Incidence of both the diseases *Vaatastheela* and BPH is seen in old age. *Acharya Sushruta* has described *Vaatstheela* (BPH) as a condition which occurs due to vitiation of *Apaan Vaayu* and this vitiated *Vaata* occupies the space in between the *Shakrith Marga* (rectum) and *Basti Pradesha* (urinary bladder) leading to the formation of *Ashteelavat Ghana Granthi* (stone like, dense and firm glandular growth) which is *Achala* (movable) and *Unnata* (elevated).[3] This growth causes *Vin, Mutra and Anila Sanga* (obstruction to the flow of urine, faeces and flatus) and also *Adhyamana* and *Vedana* at *Basti Pradesha* (distension of bladder and pain in the bladder).

AIMS AND OBJECTIVES

1. To evaluate the combined efficacy of *Trikantakaadi Guggulu&Dashmoolaadi Kwaath* in the management of *Vaatastheela Mootraghata.*
2. To develop a cost - effective,simpler and non-invasive treatment for the management of *Vaatastheela.*
3. To document the changes on Assessment parameters.
4. To report any adverse effects of the drugs, if seen.

MATERIALS AND METHODS

Selection of Patients- A total of 30 patients of *Vaatastheela* (BPH) were selected from the O.P.D/I.P.D of the hospital of Uttarakhand Ayurved University, Gurukul Campus who were

ready to give their consent for the study and those fulfilling the eligibility criteria for the study.

Inclusion Criteria

- Patients with signs and symptoms of *Vaatastheela* (BPH).
- Patient with age group between 50 to 80 years.
- Patient with mild, moderate and severe BPH as per the American Urological Association Symptom score index.
- USG of bladder suggestive of residual urine range 50-150ml.
- USG suggestive of increased prostate weight or size.

Exclusion criteria - Patient with severe cardio vascular, renal disorders and Patient with infective diseases like HIV and HBsAg were excluded along with Known cases of CA Prostate and Stricture urethra.

Investigations -Routine blood investigations and S.Urea, S.creatnine, Urine(Routine& Microscopic), PSA and USG (KUB).

Preperation of Drugs

Trikantakaadi Guggulu- *Trikantak, Haritaki, Amalaki, Vibhitaki, Shunthi, Marich and Pippali* were taken. The drug was prepared according to the classical method which was described in Yogratnakar.[5] A total of 5 kg weight of *Gokshur (panchang)* was taken and grinded till fine coarse powder was formed and then boiled in 8 times of water till it remain 1/8th (decoction). After formation of the *Kwaath,* it is filtered and then ¼ th of the quantity of *Gokshur, Shuddha Guggulu* is added to it. It is further boiled. When the *Kwaath* becomes paste like, then fine powder of *Amalaki* (Emblica Officinalis), *Haritaki* (Terminalia chebula), *Vibhitaki* (Terminalia bellerica), *Shunthi* (Zingiber officinalis), *Maricha* (Piper nigrum), *Pippali* (Piper longum), *Musta* (Cyperus rotundus) are mixed in the *Kwaath* with whole quantity equal to the *Shuddh Guggulu.* Then after 500 mg tablets were made from the mixture and advised as two B.D. after meal.

Method of administration: 2 tab 500 mg each. BD for 60 days

Dashmooladi Kwaath - All the contents of *Dashmoola* were taken in equal quantity. 16 times to it water is added, and boiled till 1/4 th of water remains. Then, the liquid is filtered and after adding *Shilajatu* and *Sharkara* as *Prakshepa*, it is used for drinking.

Method of administration: 30 ml BD for 60 days.

Subjective Parameters

Clinical features of BPH as recommended by the American Urological Association, as mentioned below, were taken as subjective parameters which were Incomplete emptying, Frequency, Intermittency, Urgency, Weak stream, Straining, Nocturia and QOL (Quality of Life.

Table no. 1: showing the IPSS score index.

Symptoms	Never	Less than one in 5 times	Less than half the time	About half the time	More than half the time	Almost always
Incomplete Emptying	0	1	2	3	4	5
Frequency	0	1	2	3	4	5
Urgency	0	1	2	3	4	5
Straining	0	1	2	3	4	5
Weak stream	0	1	2	3	4	5
Intermittency	0	1	2	3	4	5
	None	One time	Two time	Three time	Four times	Five times
Nocturia	0	1	2	3	4	5

The score is interpreted as; Mild (1-7), Moderate (8-19) and Severe(20-35)

QOL Score

Q .If you were to spend the rest of your life with your current urinary condition,just the way it is, how would you feel about it?

Table no. 2: showing the QOL score index.

Delighted	Pleased	Mostly Satisfied	Mix	Mostly Unsatisfied	Unhappy	Terrible
0	1	2	3	4	5	6

Objective parameters - Prostate weight and size and PVRU.

Grading for PVRU

Grade 0 –less than 25ml, Grade 1 – 25-50ml, Grade 2 – 51 to 100ml., Grade 3 – 101 to 150ml., Grade 4 -151 to 200 ml and Grade 5: Above 200ml.

Grading for prostate weight

Grade 0 – Less than 25 gm, Grade 1- 25-35gm, Grade 2-36-45gm, Grade 3: 46-55gm And Grade 4: Above 55 gm.

Overall Assessment of The Therapy

Unchanged : 0% relief in symptom

Mild improvement : 01-25% relief in symptom

Moderate Improvement: 26- 50% relief in symptoms

Marked improvement : 51 -75% relief in symptom

Excellent improvement : 76- 99% relief in symptom

Completely Cured: 100% relief in symptoms

Distribution of Patients according to Complaints

In the Present clinical study 28(93.33%) patients presented with the complaint of the symptom of frequency, 21(70%) with incomplete emptying, 27 (90%) had complaint of urgency, 27(90%) of straining, 27 (90%) of weak stream,24 (80%) with straining and 29 (96.66) had complaint of Nocturia.

Distribution of patients according to QOL score -In the present clinical study 1 (3.33%) had score 1 (pleased),04 (13.33%) had score 2 (mostly satisfied),05 (16.66%) had score 03, 14 (16.66%) patients had score 04 (mix -equally satisfies & dissastisfied), 5 (16.66%) patients had score (05) unhappy and 01 (3.33%) had score 6 i.e. (Terrible).

Prostate size wise distribution of 30 patients

In the present study 14 (46.66%) patients were having Grade 1 enlargement of Prostate (25-35gm), 07 (23.33%) were having Grade 2 enlargement (36-45gm), 04 (13.33%) were having grade 3 enlargement and 04 (13.33%) were having grade 4 enlargement (above 55 gm).

Post voidal residual urine volume

In the present study PVRU less than 25 ml was observed in 15 patients (50%) patients. From 25-50 ml in 04 patients (13.33%) patients, 51-100 ml in 04 patients (13.33%), 101-150ml in 02 (6.66%) patients, 151-200 ml in 04 (13.33%) patients, above 200 ml in 01 (3.33%) patients.

RESULTS

Table no.3: showing Effect of therapy over subjective Parameters.

Subjective Parameters

Variable	Mean			Relief %	Result	
	BT	AT	D			
Incomplete Emptying	2.09	0.76	1.33	63.63%	<0.0001	ES
Frequency	2.28	0.85	11.43	62.5%	<0.0001	ES
Urgency	3.22	1.33	1.89	58.62%	<0.0001	ES
Straining	2.519	1.148	1.370	55.88%	<0.0001	ES
Weak stream	2.929	1.143	1.786	60.97%	<0.0001	ES
Intermittency	3.07	1.11	1.963	63.85%	<0.0001	ES
Nocturia	2.82	1.13	1.69	59.75%	<0.0001	ES
QOL	3.7	2.433	1.267	34.28%	<0.0001	ES

Table no 4: showing result over Objective Parameters (Prostate weight).

N	Mean weight	Relief %	t	Df	p	Result
29	0.842	25.45%	6.141	28	<0.0001	E.S.

Table no 5: showng results overPost void residual urine.

N	Mean weight	Relief %	t	Df	p	Result
15	1.133	37.77%	3.371	14	0.0046	V.S.

Table no- 6: showing Overall effect of treatment.

Observation	Percentage	No. of patients
No relief	0%	00
Mild relief	1-25%	02
Moderate relief	26-50%	11
Significant relief	51-75%	14
Excellent relief	76-99%	03
Completely cured	100%	00

Probable mode of action of Drugs Combined effect of the contents of Drugs on *Vaatastheela* *Trikatu* by their *Deepan- Paachan* properties regulate the *Agni*, increase the *Jatharagni* and *Dhatwagni* and decrease the *Granthi*. *Mustak* have *Laghu, Ruksha Guna, Katu, Tikta Rasa, Sheet Virya* and *Katu Vipaka* has *Kapha Shamak* and diuretic property. The drugs like *Gokshur, Triphala, Gambhari* have *Madhur Vipaaka* and thus would have helped in *Vaatanuloman* (*Rasa Vasishik*) and corrected the *Viguna Apaan Vaayu* Use of *Raasayan* drugs like *Gokshur, Shilajatu, Amalaki, Haritaki* etc would have accelerated the process of correction of pathology, and by their anti- ageing actions would have helped in the symptoms. Dashmoola have *Ushna Virya, shothhar action* that acts on vitiated *Vaata* and

normalize the obstructed *Gati* of *Vaata Dosha* and is beneficial in *Apaan Vaayu Vaigunya* In combination both the drugs acts by *Shothgana, Mootrala, Vaata-Kaphashamak, Srortoshodhak, Krimighn* and *Vaatanulomana* properties.

On modern aspect we can say that drugs would have worked by their anti-inflammatory, muscle relaxant and diuretic properties. And the anti- bacterial properties of drugs would have prevented the further infection of urinary tract. These drugs would have worked locally as well as systematically and relieved the congestion of the enlargement of the gland and reduced the swelling.

CONCLUSION

The disease Vaatastheela (BPH) is age dependent. It resembles on the basis of its signs and symptoms to BPH. Both the trial drugs i.e. *Trikantakaadi Guggulu* and *Dashmoolaadi Kwaath* were safe and effective in treatment of *Vaatastheela* (BPH). The combined drugs had better effect on Grade 1, Grade 2 than grade 3 and Grade 4 prostato-megaly. Though the drug had mild relief in prostato -megaly, but had checked further growth of Prostate. Significant symptomatic relief was seen in patients in symptoms like frequency, urgency, Intermittency, straining, weak stream, nocturia. Better Results have been obtained on subjective parameters than objective parameters. Working on large sample with long duration of treatment may help to bring better results. This same trial should be conducted with longer follow up to observe for any relapse in symptoms.

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