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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF DASAMOOLADI KWATH IN THE MANAGEMENT OF VATASTHILA WITH SPECIAL REFERENCE TO(BPH)

[1]*Dr. Abdul Khaleque, [2]Dr. Shyamanta Kalita and [3]Dr. Binod Kalita

[1]PG Scholar, Dept. of Kayachikitsa, Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati, Assam.

[2]Associate Professor and Head, Department of Kayachikitsa, Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati, Assam.

[3]Assistant Professor, Department of Shalya Tantra, Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati, Assam.

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***Corresponding Author**
Dr. Abdul Khaleque
PG Scholar, Dept. of Kayachikitsa, Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati, Assam.

ABSTRACT

Benign prostatic hyperplasia is an extremely common ailments in men by the age of 40 and this affect the quality of life. BPH is characterized by proliferation of both stromal and epithelial element with resultant enlargement of the gland and is clinically manifested as lower urinary tract symptoms (LUTS). In Ayurveda vatasthila resembles obstructive uropathy due to enlarged prostate on the basis of symptomatology. In vatasthila there is a growth in between rectum and urethra which leads to obstruction to urine flow. Surgical removal of prostate gland in BPH leads to various complication. So the present study was undertaken to evaluate the efficacy of dasamooladi kwath in the management of vatasthila or BPH. It is a single arm interventional clinical trial which was conducted at, Department of Kayachikitsa, Govt. Ayurvedic college and Hospital, jalukbari, Guwahati, Assam involving 20 patient. The objective of the study was to assess the efficacy of dasamooladi kwath on cardinal symtoms of vatasthila with special reference to BPH Known as lower urinary tract symptoms (LUTS) for 60 days. The patients showed marked improvement in the symptomatology indicating a need for further research emphasing the potential of dasamooladi kwath in BPH.

KEYWORDS: Benign Prostatic Hyperplasia, Vatasthila, Lower Urinary Tract Symptoms, Dasamooladi Kwath, Clinical Study.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is an extremely common abnormality. It is present in a significant number of men by the age 40, and its frequency rises progressively with age, reaching 90% by the the eight decade of life. BPH is characterized by proliferation of both stromal and epithelial elements, with resultant enlargement of the gland, and in some cases urinary obstruction. Although the cause of BPH remains incompletely understood, it is clear that excessive androgen dependent growth of stromal and glandular elements has a central role. BPH does not occur in males castrated before the onset of puberty or in men with genetic diseases that block androgen activity. Dihydrotestosterone (DHT), the ultimate mediator of prostatic growth, is synthesized in the prostate from circulation of testosterone by the action of enzyme 5 alpha reductase type 2. BPH contributes to the development of lower urinary tract symptoms (LUTS).[1] LUTS arising from lower urinary tract dysfunction, are further subdivided into obstructive symptoms (urinary hesitancy, straining, weak stream, terminal dribbling, prolonged voiding, incomplete emptying) and irritative symptoms (urinary frequency, urgency, nocturia, urge incontinece and small voided volumes). LUTS and other sequelae of BPH are not just due to mass effect, but also likely due to a combination of the prostatic enlargment and by the contraction of prostatic smooth muscle mediated by alpha adrenergic receptors and also due to age related detrusor dysfunction.[31]

With the advancement of time different conservative method like alpha blockers, 5-alpha reductase inhibitors, phosphodiesterase -5 inhibitors[3] along with surgical intervention like TURP, TUIP, TULIP, Prostectomy have been practiced for different grades of BPH.[4]

In classics of Ayurveda, the sign and symptoms of vatasthila has close resemblance with that of benign prostatic hyperplasia. Vatasthila is among, one of the various types of mutraghat diseases described vividly in sushruta samhita, charak samhita, astanga sangraha, astanga hridyam and madhav nidana. It is mainly considered as vatavydhai that is due to the excessive intake of food and indulgence of lifestyle that aggravates vata dosha that leads to a growth between rectum and urethra resulting in obstruction to urine flow and in severe case may stool.[256]

In spite of recent advances in western medicine the treatment protocol of BPH are not 100% effective in managing LUTS, rather a series of complication like retention of urine, sepsis, incontinence, haemorrhage has been observed. Hence considering this lacunae an effective treatment with the trial drug was planned for the study. The trial drug Dasamooladi kwath was selected from Yogratnakar, Mutraghat chikitsa.

MATERIAL AND METHOD

Aim and objective of the study: To assess the efficacy of dasamooladi kwath in the management of cardinal symtomps of vatasthila (BPH)

Study setting and selection of patient: patients were taken randomly based on the inclusion and exclusion criteria from the opd and ipd of department of kayachikitsa, Govt. Ayurvedic college, Guwahati Asssam.

Selection of the drug: The trial drug dasamooladi kwath was selected from Yogratnakar, Mutraghat chikitsa, chapter 5.[8]

Preparation of the trial drug

The trial drug were prepared in the State Ayurvedic Pharmacy, Govt. Ayurvedic college, Guwahati Asssam.

Ingredients of dasamooladi kwath[9]

Sl No	Drug	Botanical Name	Parts used	Quantity
1	Bilva	*Aegle marmelos*	Roots	1 Part
2	Agnimantha	*Premna integrifolia*	Roots	1 Part
3	Syonaka	*Oroxylum indicum*	Roots	1 Part
4	Gambhari	*Gmelina arborea*	Roots	1 Part
5	Patala	*Stereospermum sauveolens*	Roots	1 Part
6	Salaparni	*Desmodium gangeticum*	Roots	1 Part
7	Prisniparni	*Uraria picta*	Roots	1 Part
8	Brihati	*Solanum indicum*	Roots	1 Part
9	Kantakari	*Solanum xanthocarpum*	Roots	1 Part
10	Gokshura	*Tribulus terrestis*	Roots	1 Part

Prakshep dravya matra[9]

Prakshep dravya	Quantity
Silajit	1/16 th of kwath dravya
Sarkara	1/4 th of kwath dravya

The ingredients of the trial drug were individually taken in separate vessels and were examined for adulterants, impurities and cleaned properly and then subjected to dry for 2 days. Then shilajit was purified as per purification methods mentioned in classical text. Then the are coarsely powdered and converted to yavakut churna and mixed well according to the classical ratio.

The formulated yavakut churna thus obtained were given to the patients and were being instructed to prepare kwath from it.

Preparation of the kwath: 1 part churna + 8 part water ---> boil it in mild fire ---> evaporate it till reduced to ¼ th ---> filter---> use it when freash.

Sample size: 20 number of patients

Study design: Randomised open clinical trial.

- Dose: 50ml twice daily
- Route of administration :orally
- Time of administration : after food
- Duration : 30days

Inclusion criteria

- Patient diagnosed on the basis of LUTS, on digital rectal examination of enlarged prostate.
- USG suggestive of BPH upto grade 3
- Patients with age in between 40 years to 70 years
- Patients with considerable PSA level

Exclusion criteria

- Patient with grade 4 BPH
- Patient with high PSA
- Patient more than 70 years of old
- Patient with systemic disorder like uncontrolled diabetes mellitus, CKD, CLD, Cardiac illness.
- HIV positive, HBsAg positive, HCV positive cases with other STDs
- CA prostate

- Pinhole meatus

Assessment Criteria

The severity of the patient's condition was assessed using the International Prostate Symptom Score(IPSS).[7] The score thus obtained before and after the treatment was statistically analysed.

SYMTOMS: Straining.

QUESTION: How often have you had to push or strain to begin urination ?

Responses	**Score**
Not at all	0
Less than one fifth of the time	1
Less than half of the time	2
About half of the time	3
More than half of the time	4
Almost always	5

SYMPTOMS: Urgency

QUESTION: How often have you found it difficult to postpone urination?

Responses	**Score**
Not at all	0
Less than one fifth of the time	1
Less than half of the time	2
About half of the time	3
More than half of the time	4
Almost always	5

Symtoms: Hesitancy

Question: How often have you found that you stopped and started again several times when you urinated ?

Responses	Score
Not at all	0
Less than one fifth of the time	1
Less than half the time	2
About half of the time	3
More than half of the time	4
Almost always	5

SYMPTOMS: Incomplete emptying

QUESTION: How often have you had a sensation of not emptying your bladder completely after you finished urinating ?

Responses	Score
Not at all	0
Less than one fifth of the time	1
Less than half the time	2
About half of the time	3
More than half of the time	4
Almost always	5

SYMPTOM: Frequency

QUESTION: How often have you had to urinate again less than 2 hours after you finished urinating?

Responses	**Score**
Not at all	0
Less than one fifth of the time	1
Less than half the time	2
About half of the time	3
More than half of the time	4
Almost always	5

SYMPTOM: Weak stream

QUESTION: How often you had a weak urinary stream?

Responses	**Score**
Not at all	0
Less than one fifth of the time	1
Less than half the time	2
About half of the time	3
More than half of the time	4
Almost always	5

SYMPTOM: Nocturia.

QUESTION: How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

Responses	**Score**
Not at all	0
Less than one fifth of the time	1
Less than half the time	2
About half of the time	3
More than half of the time	4
Almost always	5

INVESTIGATION

USG KUB: USG KUB was done to assess prostate size to exclude grade 4 BPH and to rule out structural abnormalities in urinary tract.

PSA: PSA was measured to exclude patients with high elevated levels suggestive of prostate cancer or other prostatic pathology.

CBC: CBC was done to rule out infection anemia or other hematological abnormalities.

Statistical analysis

The analysis of the effect of the trial drug was done based on Student ‘’t’’ test applications. The efficacy of dasamooladi kwath was evaluated by comparing the results obtained before treatment (BT) and after treatment (AT).

Level of significance

Values

P=/>0.05 statistically not significant

P=/<0.005 statistically significant

P=/<0.01, p=/<0.001, p=/<0.0001 statistically highly significant

RESULTS

Table: Effect of dasamooladi kwath in the management of LUTS associated with BPH (n=20).

Symptom domain	Mean BT±SD	Mean AT±SD	Mean difference	t Value	P Value	Remarks
Straining	3.1±1.2	1.5±1.0	1.6	6.10	P<0.0001	S.H.S
Urgency	3.8±1.4	1.9±1.2	1.9	6.80	P<0.0001	S.H.S
Hesitancy	3.5±1.1	1.8±1.0	1.7	6.32	P<0.0001	S.H.S
Incomplete emptying	3.6±1.1	1.7±0.8	1.9	6.90	P<0.0001	S.H.S
Frequency	4.1±1.2	2.1±1.0	2.0	7.45	P<0.0001	S.H.S
Weak stream	4.0±1.3	2.0±1.0	2.0	6.75	P<0.0001	S.H.S
Nocturia	3.0±1.0	1.4±0.9	1.6	6.20	P<0.0001	S.H.S

INTERPRETATION

Straining: The mean symptom score before treatment was 3.1±1.2 which is reduced to 1.5±1.0 after treatment, with a mean difference of 1.6. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is effective in reducing straining in micturition.

Urgency: The mean symptom score before treatment was 3.8±1.4 which is reduced to 1.9±1.2 after treatment, with a mean difference of 1.9. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is effective in reducing urgency.

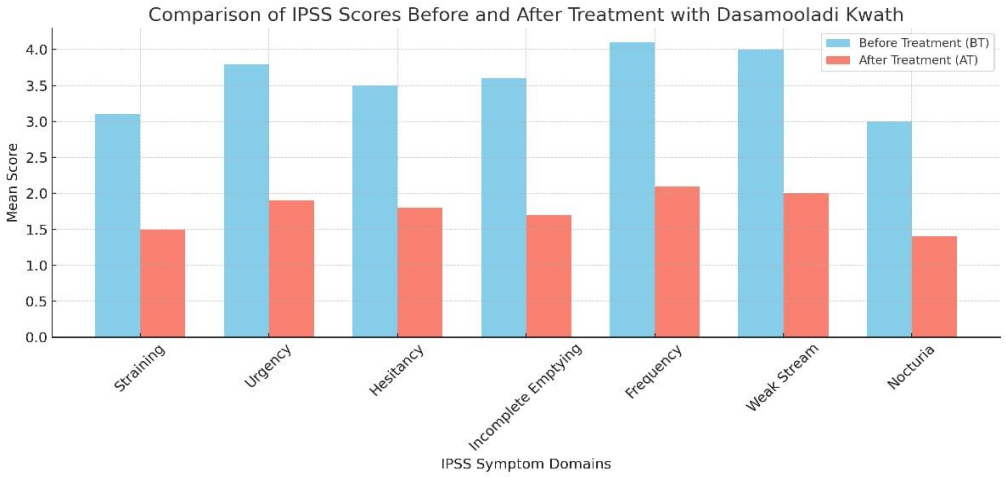
Hesitancy: The mean symptom score before treatment was 3.5±1.1 which is reduced to 1.8±1.0 after treatment, with a mean difference of 1.7. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath has a positive effect on hesitancy.

Incomplete emptying: The mean symptom score before treatment was 3.6±1.1 which is reduced to 1.7±0.8 after treatment, with a mean difference of 1.9. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is highly effective in managing the symptom of incomplete emptying in BPH.

Frequency: The mean symptom score before treatment was 4.1±1.2 which is reduced to 2.1±1.0 after treatment, with a mean difference of 2.0. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is effective in reducing frequency of urination in the patients of BPH.

Weak stream: The mean symptom score before treatment was 4.0±1.3 which is reduced to 2.0±1.0 after treatment, with a mean difference of 2.0. The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is effective in Improving urinary stream.

Nocturia: The mean symptom score before treatment was 3.0±1.0 which is reduced to 1.4±0.9 after treatment, with a mean difference of 1.6 The result was statistically highly significant at P<0.0001, indicating that dasamooladi kwath is effective in reducing nocturnal urinary disorder.



DISCUSSION ON TREATMENT

Dasamoola is a classical Ayurveda formulation which acts as vata kapha shamaka and sothahara. In the trial drug dasamooladi kwath, pure silajit as prakshep dravya enhances the bioavailablity of dasamoola specially on the mutravaha srotas. In BPH, Which is presented as lower urinary tract symptoms, the formulation reduces the obstruction and improves urinary flow with the combined effect of all the active ingredient of dasamooladi kwath through sothahara, Mutrala, vatanulomana, rasayana, and yogavahi karma. There for, dasamooladi kwath, through synergistic action of its 10 ingrients with silajit and sarkara as prakshep dravya, likely reduces LUTS in BPH by decreasing inflammation and congestion in the prostate, improving urinary flow,and pacifying apana vata.

CONCLUSION

Benign prostatic hyperplasia is common ailments in ageing males that significantly affects quality of life and the current modern pharmacological options only shows symptomatic relief which is accompanied by various adverse effect and the surgical removal of prostate shows severe complications. In this clinical study Dasamooladi kwath, demonstrated significant improvement in the main symtoms of BPH without adverse effect. It can therefore be considered as a safe and effective Ayurvedic management options for vatasthila or BPH, Justifying study on large scale of sample and experimental studies to decode its mechanism of action emphasizing the molecular pathway.

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