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A clinical study to evaluate the combined effect of *Yavaksharayukta Swarnamakshika* with *Varanadi Kashaya* in benign prostatic hyperplasia

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ABSTRACT

Benign Prostatic Hyperplasia (BPH) is the adenomatous hyperplasia of the periurethral part of the prostate gland that occurs especially in men over 50 years old and that tends to obstruct urination by constricting the urethra. Overall nearly 80% of men will develop BPH, and as many as 30% will receive treatment for it. The present study was a clinical validation and standardization of Ayurvedic medicines which can provide an improved response to the disease as the present conventional practices are not satisfactory. The study design was interventional. Twenty patients satisfying the selection criteria were selected from the OPD of Government Ayurveda College, Trivandrum. 125 mg of *Swarnamakshika* and *Yavakshara* were advised to take with *Madhu*, followed by 48 ml of *Varanadikashaya* for a period of 45 days. Assessments were done before and after the study using assessment criteria. The study was statistically significant in symptomatic relief. The study therefore concludes that the combination is effective in the management of BPH.

Key words: BPH, *Swarnamakshikabhasma*, *Yavakshara*, *Varanadikashaya*, *Madhu*, IPSS score.

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is one of the most frequent diagnoses leading to the urology referral. It begins to develop before age 30, almost 10 % of men having histological evidence of BPH by 40 years of age, and 50% of men showing evidence by the age of 80.^[1] Overall nearly 80% of men will develop BPH, and as many as 30% will receive treatment for it. The complication of Bladder Outlet Obstruction (BOO)

includes acute and chronic retention, impaired bladder emptying, urinary infection, calculi, haematuria etc.^[2]

The treatments of BPH include pharmacological management and surgical procedures. Drugs used are alpha blockers and 5 alpha reductase inhibitors. Partial removal of prostate is needed in case of symptoms resistant to medical therapy.^[3] Surgical methods include transurethral resection of prostate (TURP) or transurethral ultrasound-guided laser induced prostatectomy (TULIP).^[4] Complications of TURP like procedures are retrograde ejaculation, erectile impotence, risk of reoperation (15% after 8-10 years) and morbidity rate.^[5]

In Ayurveda, diseases with urinary symptoms are scattered throughout various contexts in different classics. *Mutraghata*, *Mutrakrichra*, *Asmari* are the contexts which dealt with diseases of entire urinary system.^[6] The symptoms of BPH cannot be confined into a single disease. The symptoms are very similar to the *Lakshanas* (symptoms) produced by

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Mutravahasrotodushti (channels carrying urine)^[7] as well as seen in *Mutraghataprakarana* (diseases affecting urinary system).

The treatment of *Mutraghata* is *Mutakrichahara* treatments according to the vitiated *Dosha*, *Vasthi* and *Uthara Vasthi*.^[8] The basic treatment principle of BPH is *Vatakaphasamana* and *Srotorodhahara*. The drugs used should be having *Katu*, *Tikshna* and *Ushna Gunas*. In *Rasatarangini*, equal amount of *Swarnamakshika Bhasma* (Chalco pyrite) and *Yavakshara* (alkaline preparation of *Hordeum vulgare*) has been mentioned for *Darunamutrakrichra* (chronic urinary retention).^[9] *Darunamutrakrichra* can be taken as LUTS and associated urinary symptoms which are seen with BPH. *Varanadi Kashaya*^[10] is a commonly used medicine by practitioners in BPH. The clinical validation and standardization of these medicines can provide an improved response to the disease as the present conventional practices are not satisfactory.

AIM OF THE STUDY

To evaluate the effect of *Yavaksharayukta Swarnamakshika* with *Varanadi Kashaya* in Benign Prostatic Hyperplasia.

MATERIALS AND METHODS

Study population

Patients diagnosed with Benign Prostatic Hyperplasia attending OPD of Government Ayurveda College, Thiruvananthapuram satisfying inclusion and exclusion criteria.

Study design

The study was designed as a single group of interventional study.

Inclusion criteria

- Male patients aged 40-80 years having signs and symptoms of BPH with mild, moderate and severe symptoms of BPH as in IPSS Score
- Identified through USG Abdomino pelvis; Prostate volume above 20 cc

- Patients with PSA marker up to 4ng/ml

Exclusion criteria

- Known cases of liver disorders, cardiac complaints, acute renal failure.
- Any other structural/ functional bladder abnormalities.
- Acute & Chronic prostatitis.
- Prostate cancer
- Chronic bladder outlet obstruction
- Patients suggestive of surgery identified by the following symptoms:
 1. Recurrent gross hematuria
 2. Renal insufficiency secondary to obstruction
 3. Bladder diverticula
 4. Bladder calculi
 5. Permanently damaged or weakened bladder.

Drugs used

Swarnamakshika Bhasma^{[11],[12]} and *Varanadikashaya Choorna* were prepared in the Department of Rasasastra & Bhaishajya Kalpana, Government Ayurveda College, Trivandrum. *Yavakshara* was purchased from a genuine source and analyzed for purity according to API Standards.^[13]

Procedure

Patients were selected using study tools while keeping inclusion and exclusion criteria in mind. 125mg of each of *Swarnamakshika Bhasma* and *Yavakshara* were given as unit dosage form by wrapping in butter paper separately. *Madhu* (Honey) was given as *Sahapana* (vehicle) in dropper bottle and *Varanadikashaya Choorna* as *Anupana* (adjuvant) in coarse powder (mesh size 1.70 nm-355 micro)^[14] of 48g with instructions to prepare *Kashaya* (Aqueous extract of drugs) in zip lock cover. The *Kashaya*^[15] was prepared by boiling in 768 ml water which has to be reduced into 96ml and strained. The patients were advised to take unit dosage form of each

Swarnamakshikabhasma and Yavakshara in morning and evening after food followed by the intake of 48 ml Kashaya continuously for a period of 45 days. Patients were advised to follow diet and regimen. Assessment was done as per criteria.

Study tools

Case Proforma

Digital rectal examination (DRE)

Lab investigations

- Blood routine
- Urine routine
- Renal function test
- Liver function test
- PSA
- Ultrasonography

Assessment criteria

Changes in prostate volume USG Abdomino-Pelvis

Changes in IPSS Score

Table 1: IPSS Score - International Prostate Symptom Score (American Urological Association)

Symptoms	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always
Incomplete Emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish	0	1	2	3	4	5

urinating?						
Frequency Over the past month, how often have you had to urinate again less than 2 hours after you had finished urinating?	0	1	2	3	4	5
Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak Stream Over the past month, how often have you have a weak urinary stream?	0	1	2	3	4	5
Straining? Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5

Nocturia	None	Once	Twice	3 Times	4 Times	5 Times
Over the past month, how many times did you most typically get up each night to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5

Quality of life due to urinary symptoms

	Delighted	Pleased	Mostly satisfied	Mixed	Mostly unhappy	Unhappy	Terrible
If you were to spend the rest of the life with your urinary condition just the way it's now, how you feel about that?	0	1	2	3	4	5	6

Quality of life assessment index L =

The total score range from 0 to 35.

0-7 : Mildly symptomatic

8-19 : Moderately symptomatic

20-35 : Severely symptomatic

Ethical approval

Ethical approval was obtained from the Institutional ethical committee before the study. Details of study were explained and written consents were obtained from patients prior to study.

RESULTS AND DISCUSSION

20 patients satisfying both inclusion and exclusion criteria were consecutively selected for study.

Effectiveness of the treatment: The effectiveness of the treatment on various subjective & objective symptoms before the treatment and after the treatment was observed and the findings were analyzed statistically.

Effectiveness on clinical features by IPSS Score: Before treatment the mean of IPSS Score is 19.22 ± 5.5 and after treatment is 6.5 ± 4.6 . The result is statistically significant with p value 0.001.

Table 2: Effectiveness on clinical features by IPSS Score

	N	IPSS Score		Paired difference		Paired t test	
		Mean	SD	Mean	SD	t	p
BT	20	19.2	5.5	12.7	5.4	10.497	<0.001
AT	20	6.5	4.6				

Effectiveness in incomplete emptying: Before treatment 45% have Grade 5 and 35% have grade 0. After treatment 10% have Grade 5 and 65% have grade 0. So the improvement in incomplete emptying of bladder was statistically significant (p0.003)

Effectiveness in frequency: Before treatment 55% have Grade 5 and 0% have grade 0. After treatment 5% have Grade 5 and 25% have grade 0. So the

improvement in frequency was statistically significant (p 0.001)

Effectiveness in intermittency: Before treatment 20% have Grade 5 and 35% have grade 0. After treatment 0% has Grade 5 and 80% have grade 0. So the improvement in intermittency was statistically significant (p 0.001)

Effectiveness in urgency: Before treatment 40% have Grade 5 and 10% have grade 0. After treatment 10% has Grade 5 and 40% have grade 0. So the improvement in intermittency was statistically significant (p 0.001)

Effectiveness in weak stream: Before treatment 20% have Grade 5 and 60% have grade 0. After treatment 5% has Grade 5 and 70% have grade 0. So the improvement in weak stream was statistically significant (p 0.017)

Effectiveness in straining: Before treatment 15% have Grade 5 and 50% have grade 0. After treatment 0% has Grade 5 and 90% have grade 0. So the improvement in straining was statistically significant (p 0.005)

Effectiveness in nocturia: Before treatment 50% have Grade 5 and 10% have grade 1. After treatment 5% has Grade 5 and 15% have grade 1. So the improvement in straining was statistically significant (p 0.001)

Table 3: Effectiveness in symptoms according to IPSS Score

Symptoms	Wilcoxon Signed Rank Test	
	Z	P
Incomplete Emptying	2.949	0.003
Frequency	3.641	<0.001
Intermittency	3.201	0.001
Urgency	3.318	0.001
Weak Stream	2.388	0.017

Straining	2.82	0.005
Nocturia	3.775	<0.001

Effectiveness according to prostate size in USG: The mean prostatic volume before the treatment was 46.1 cc and after treatment the mean prostate volume changed to 47.9cc. The result is not statistically significant as the p value is 0.595

Table 10: Effectiveness according to prostate size in USG

	N	USG		Paired difference		Paired t test	
		Mean	SD	Mean	SD	t	p
BT	20	46.1	19.9	-1.8	15.3	-0.540	0.595
AT	20	47.9	24.7				

DISCUSSION

Benign prostatic hyperplasia is one of the most troublesome diseases causing discomfort for men in old age. The exact cause of BPH is still unknown. There is a connection with decrease in testosterone level as the age progresses. The absence of satisfactory treatment aids in modern medicine forces population to seek available resources. A number of formulations are currently in use in the successful treatment of BPH. In *Rasatarangini*, equal amount of *Swarnamakshika Bhasma* and *Yavakshara* has been mentioned for *Darunamutrakrichra*, which can be taken as LUTS and associated urinary symptoms.

The *Nidana-Samprapti* (pathophysiology) of BPH was more understandable in the light of *Mutravaha Srotas* and its *Dushti Lakshanas*. The *Vata-Kaphavardhaka Nidanas* cause *Vata-Kaphavidhi*. It in turn hampers *Agni* causing *Rasa-Mamsa-Medho Dushti*. The increased mass of prostate causes *Mutravahasrotorodha* (Obstruction of urinary channels) which in turn produces urinary (LUTS) symptoms. The treatment involves *Vata-Kaphahara, Kapha-Medoghna* and *Srotorodhahara*. *Swarnamakshika* is *Tridoshaghna* which normalizes

Tridosha Dushti. It cures urinary disorders (*Vividhavastivedana*) and is *Yogavahi*. It augments the actions of *Yavakshara* which is *Vata-Kaphahara*, *Mutrala* (Diuretic) and *Agnikrit* (Carminative). *Agnideepana* property of *Yavakshara* is due to its *Ushna*, *Teekshna* properties. It corrects *Agni* and causes *Srotovivarana* and *Srotosodhana*. The drugs in *Varanadi Kashaya* are *Katu*, *Ushna* and *Teeksna*, *Kapha-Medoghna*. They are *Deepana* (enhancing digestion), *Pachana* (Digestive), *Sothahara* (treatment for oedema) and have got particular effect on *Antahvidradhi* (Internal abscess). They reduce the mass while normalizing the *Agni*. The actions of the drugs are augmented by *Swarnamakshika* by *Yogavahiguna* (catalyst). The particular combination helps to maintain the prostate size even after the follow up period.

CONCLUSION

Benign Prostate Hyperplasia is a disease of old age and no particular etiology was found which has a direct relationship with the disease. There is no disease in Ayurvedic classics which exactly shows all the features of Benign Prostate Hyperplasia. In Ayurvedic terms, the disease shows *Mutravaha Srotodushti Nidanas*. *Yavaksharayukta Swarnamakshika* with *Varanadi Kashaya* is effective in relieving the urinary symptoms. The potassium content of *Yavakshara* regulates muscle contractions. Thus it decreases obstructive symptoms like weak stream, incomplete bladder emptying and nocturia. The potassium and sodium in body fluids regulates water and acid-base balance in body. Thus it decreases the irritative symptoms urgency, intermittency and frequency. It also decreases post voidal residue urine volume after treatment. Associated constipation seen in patients due to constant pressure in bladder neck by hypertrophied prostate which in turn pressurize rectum is relieved by *Yavakshara*.

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