

## HYPOPLASTIC EFFECT OF PROSTOWIN VATI AND VASTIKARMA IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA

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### ABSTRACT

60 Patients were selected for the clinical study in 3 groups and 20 patients were in each group. The quality of life improved with the Prostowin Vati and Ksheerabala oil Vasti with the reduction in symptom score (IPSS and DPSS), Residual urine, Micturition time and improvement in Average flow rate. Old persons refuse operative treatment for their BPH symptoms and seeking a safe and effective treatment for easy life. In this situation the medicinal treatment may play an important role.

**Keywords:** Straining, Intermittency, International prostate symptom scoring system (IPSS), Danish Prostate Symptom scoring system (DPSS), Residual

### INTERODUCTION

Benign prostatic hyperplasia is a disease of old male person when their hair becomes gray and scanty and when a white zone is formed at the margin of the cornea. This disease refers to the adenomatous enlargement of the periurethral prostate gland, promoting obstruction of the urethra and bladder opening. As men age, the prostate gland increases in size, making BPH one of the most common age-related conditions in men. The enlarged gland puts pressure on the urethra, acting like a partial clamp and thus causing numerous urinary symptoms. BPH is a progressive disease, but it does not usually cause problems until late in life.

B.P.H. is a condition intimately related to ageing and most frequently seen in men in 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> decade but also occurs in 6<sup>th</sup> and even 5<sup>th</sup> decade of life. International surveys have found a high prevalence of moderate to severe obstructive symptoms in men over 50, which increase with age. Symptoms of BPH vary in severity and include frequent urination, nocturia (excess urination at night), urinary urgency or hesitancy, painful and difficult urination (dysuria) and incomplete urination, Inflammation and infection of prostatic tissues may also be present.

प्रस्तुत शोध प्रबन्ध में 60 रोगियों पर तीन वर्गों (प्रत्येक वर्ग में 20 रोगी) में प्रोस्टाविन वटी एवं क्षीरबला तैल का चिकित्सात्मक अध्ययन किया गया। प्रोस्टाविन वटी एवं क्षीरबला तैल रोगियों के आई. पी. एस. एस. और डी. पी. एस. एस. स्कोर को कम करने में, मूत्रावृत्ति कम करने में और अवषेष मूत्र की मात्रा कम करने में एवं प्रोस्टेट ग्रन्थि का भार कम करने में लाभदायक है। वृद्धावस्था में शल्य कर्म कराने में भय एवं शारीरिक दुर्बलता, आर्थिक असमर्थता एवं आधुनिक समाज में वृद्धों के प्रति असहयोग को ध्यान में रखते हुए अष्टौला वृद्धि में औषध प्रोस्टाविन वटी एवं क्षीरबला तैल का प्रयोग अतिलाभदायक है।

### NEED AND SIGNIFICANT OF PRESENT RESEARCH WORK

In modern surgical therapy for BPH, the patient may suffer from following complications:

Retrograde ejaculation- 65%

Erectile impotence - 5%

Clot retention, stricture, incontinence, infection, perforation of prostatic capsule, haemorrhage are other complications.

Problems with urination can be very distressing and severely affect quality of life, although individual response to these symptoms varies widely. Some men can tolerate very uncomfortable sensations of abnormal urination, while other men seek relief from mild symptoms. Men are more apt to tolerate voiding symptoms (intermittent flow, hesitancy before urinating) and seek help for storage symptoms (urgency, frequency, urination at night). Voiding symptoms, however, may indicate an obstruction blocking the bladder, which if extensive can severely reduce urine flow and cause other complications. Due to these complications and ignorance of operative therapy in old age, old persons refuse operative treatment for their BPH symptoms and seeking a safe and effective treatment for easy life. In this situation the medicinal treatment may play an important role.

### Aims and Objective

The main aims and objective of present study were as follow-

- Evaluation of efficacy of an Ayurvedic formulation Prostowin vati in the management of BPH.
- Evaluation of efficacy of Vata Samak Vasti (Ksheerabala taila) treatment in the management of BPH.
- Evaluation of efficacy of combined therapy in BPH based on various parameters.

The other objectives of the present clinical trial were as follow-

- To reduce the severity of symptom of BPH patient with Ayurvedic medicine
- To break the pathogenesis of BPH on modern concept with Ayurvedic formulation
- To improve the quality of life of BPH patients

### Selection of drug

The drug selected for the clinical study was with multifactorial action.

**Prostowin vati** was deigned and prepared for the management of Benign Prostatic Hyperplasia with consideration of following qualities -

- Vrishya and Rasayana properties
- Diuretic properties
- Anti-inflammatory and Antispasmodic properties
- Vata and Kapha samak properties
- 5- $\alpha$  reductase inhibitor activity
- **Contents of Prostowin vati-**

S.N.	Name of drug	Bot. Name	Family	Part used
1.	Erand	Ricinus communis	Euphorbiaceae	Root
2.	Bal haritaki	Terminalia chebula	Combretaceae	Fruit
3.	Punarnava	Boerhavia diffusa	Nyctaginaceae	Root
4.	Varuna	Crataeva novella	Capparidaceae	Bark
5.	Kapikachhu	Mucuna prurita	Leguminosae	Seed
6.	Amalaki	Emblica officinalis	Eurphobiaceae	Fruit
7.	Ashwagandh	Withania somnifera	Solanaceae	Root
8.	Peet kusmanda	Cucurbita maxima	Cucurbitaceae	Seed
9.	Trapush	Cucumis sativus	Cucurbitaceae	Seed
10.	Shilajatu	Asphaltinum punjabinum		Niryas
11.	Yava	Foeniculum vulgare		Kshara

ksheer-bala oil was used for vasti treatment in present study.

Name of drug	Bot. name	Family	Part used
Bala	Sida cardifolia	Malvaceae	Whole plant
Taila	Sesamum indicum	Pedaliaceae	Seed oil
Godugdha	Cow milk		

- Protowin vati and Ksheerbala oil was prepared in the pharmacy of national institute of Ayurveda, Jaipur

#### MATERIAL AND METHODS

##### Inclusion criteria

- Patients above the age of 40 years
- Patients having benign growth only
- Patients unfit for surgery
- BOO due to BPH only

##### Exclusion criteria

- Patients having acute retention and severe UTI, Diabetes,
- Prostatic carcinoma, Prostatitis, C.A. bladder, Neurogenic bladder,
- Stricture of urethra, Vesicle calculus

##### Criteria of grading the patients

- Grade I - If the weight within 29 gm of Prostate gland.
- Grade II - 29 - 59 gm.
- Grade III - 59-89 gm.
- Grade IV - More than 89 gm.

**Grouping-** All 60 patients were divided in 3 groups -

- Group -A - Patients treated with Prostowin vati only.
- Group-B - Patients treated with Ksheer Bala taila vasti only.
- Group-C- Patients treated with combined (Prostowin vati and Ksheer Bala taila vasti) therapy.

- Dose of drug :2 tab. tid
- Dose of oil for vasti :50 ml / day
- Duration of drug administration: Three months
- Duration of vasti treatment : One month

##### Subjective parameters

- Over symptoms like Incomplete evacuation, Frequency, Intermittency, Urgency, Weak urine stream, Straining and Nocturia
- International prostate symptom scoring system(IPSS)
- Danish Prostate Symptom scoring system(DPSS)

##### Objective parameters-

- Digital rectal examination
- USG (KUB region)-
  - a) Change in prostate volume (Weight)
  - b) Residual urine
- Average flow rate
- Micturition time

##### Prostate weight

Weight of prostate (in gm.)= 0.55 × Length (D<sub>1</sub>) × Width (D<sub>2</sub>) × Height (D<sub>3</sub>)

##### Residual urine

Residual urine (ml)= Length (D<sub>1</sub>) × Width (D<sub>2</sub>) × Height (D<sub>3</sub>)/2

##### Measurement of Average flow rate and Micturition time

Average flow rate (ml/second)=Total urine passed (in ml) / Total Micturition time (seconds)

#### ESTIMATION OF RESIDUAL URINE



Equipments



Holding of Penis



Introduction of Xylocaine Jelly



Filled Jelly



Insertion of Catheter



Catheter Attached With Urobag

#### PROCEDURE OF VASTI KARMA



Vastikarma Materials



Filling of Oil



Insertion of Catheter



Pushing of Oil

## CLINICAL STUDY

## Summarized result on subjective parameters of group-A

Parameters	Mean B.T.	Mean A.T.	% Improv.	t- value	p-value
Incomplete evacuation	3.55	1.6	54.93	10.5634	< 0.001
Frequency	3.25	1.45	55.38	9.6567	< 0.001
Intermittency	2.80	1.15	58.93	7.4694	< 0.001
Urgency	3.05	1.40	54.10	9.9039	< 0.001
Weak stream	3.45	1.70	50.72	12.2549	< 0.001
Straining	3.80	1.75	53.95	11.1051	< 0.001
Nocturia	3.30	1.60	51.52	8.2324	< 0.001
IPSS	23.20	10.65	54.10	19.7825	< 0.001
DPSS(Symptoms severity)	20.80	9.60	53.85	18.244	< 0.001
DPSS(Degree of Bothering)	19.25	9.10	52.73	13.8889	< 0.001

In group-A the maximum relief was observed in intermittency symptom (58.93%) and minimum in symptom of weak stream (50.72%). The overall IPSS improvement was 54.10%. The percentage relief in DPSS (symptom severity) was 53.85% and in degree of bothering was 52.73%. The improvements were highly significant in all symptoms

## Summarized result on Objective parameters of group-A

Parameters	B.T.	A.T.	% Improv.	t- value	p-value
Weight	38.2	33.25	12.95	6.3789	< 0.001
Residual urine	107.5	52.25	51.40	8.8403	< 0.001
Voided volume	191.75	218.75	14.08	9.9111	< 0.001
Micturition time	55.45	38.15	31.9	11.0571	< 0.001
Average flow rate	3.47	5.89	69.4	14.64	< 0.001

In all objective parameters of group-A, the maximum percentile improvement was noticed in average flow rate (69.4%) followed by in Residual urine (51.40%).

## Summarized result on subjective parameters of group-B

Parameters	B.T.	A.T.	% Improv.	t- value	p-value
Incomplete evacuation	3.4	2.1	38.24	7.9365	< 0.001
Frequency	3.30	2.00	39.39	7.2544	< 0.001
Intermittency	3.15	1.65	47.62	7.8125	< 0.001
Urgency	3.10	1.50	51.61	9.4899	< 0.001
Weak stream	3.15	1.65	47.62	7.549	< 0.001
Straining	3.10	1.80	41.94	7.2545	< 0.001
Nocturia	2.80	1.70	39.29	8.9069	< 0.001
IPSS	22	12.4	43.64	25.751	< 0.001
DPSS(Symptoms severity)	19.70	12.70	35.53	16.3094	< 0.001
DPSS(Degree of Bothering)	18.10	11.45	36.74	11.6157	< 0.001

In group-B the maximum relief was observed in urgency symptom (51.61%) and minimum in symptom of incomplete evacuation (38.24%). The overall IPSS improvement was 43.64%. The percentage relief in DPSS (symptom severity) was 35.53% and in degree of bothering was 36.74%. The improvements were highly significant in all symptoms.

## Summarized result on Objective parameters of group-B

Parameters	B.T.	A.T.	% Improv.	t- value	p-value
Weight	41.7	38.6	7.43	5.9319	< 0.001
Residual urine	109.25	63.75	41.65	10.2112	< 0.001
Voided volume	199.75	224.75	12.52	11.036	< 0.001
Micturition time	58	44.55	23.19	11.6683	< 0.001
Average flow rate	3.48	5.09	46.55	15.3419	< 0.001

In all objective parameters of group-B, the maximum percentile improvement was noticed in average flow rate (46.55%) followed by in Residual urine (41.65%).

## Summarized result on subjective parameters of group-C

Parameters	B.T.	A.T.	% Improv.	t- value	p-value
Incomplete evacuation	3.4	1.1	67.65	12.8348	< 0.001
Frequency	2.85	0.90	68.42	9.233	< 0.001
Intermittency	2.75	0.95	65.45	10.4834	< 0.001
Urgency	2.95	0.90	69.49	9.7064	< 0.001
Weak stream	3.00	0.90	70.00	11.0178	< 0.001
Straining	3.00	0.95	68.33	8.7308	< 0.001
Nocturia	3.00	1.10	63.33	8.3224	< 0.001
IPSS	20.95	6.8	67.54	23.4349	< 0.001
DPSS(Symptoms severity)	18.80	7.40	60.64	23.8544	< 0.001
DPSS(Degree of Bothering)	17.70	7.05	59.71	21.5805	< 0.001

In group-C the maximum relief was observed in weak stream symptom (70.00%) and minimum in symptom of nocturia (63.33%). The overall IPSS improvement was 67.54%. The percentage relief in DPSS (symptom severity) was 60.64% and in degree of bothering was 59.71%. The improvements were highly significant in all symptoms.

#### Summarized result on Objective parameters of group-C

Parameters	B.T.	A.T.	% Improv.	t- value	p-value
Weight	37.85	28.1	25.76	16.0104	< 0.001
Residual urine	117.5	47	60	15.0451	< 0.001
Voided volume	203	249	22.66	15.3129	< 0.001
Micturition time	60.1	41.25	31.36	13.5758	< 0.001
Average flow rate	3.41	6.04	77.13	18.2408	< 0.001

In all objective parameters of group-C, the maximum percentile improvement was noticed in average flow rate (77.13%) followed by decrease in Residual urine (60%).

The subjective and objective parameters were further analyzed on the basis of prakriti of patients.

#### OBSERVATION AND RESULT

##### IPSS

The mean IPSS was maximum in group-A of 60-69 yrs age group (23.38) and minimum in 70-above age group (23). The maximum improvement in group-A was noticed in 70-above age group (57.26%).

In group-B the maximum improvement in IPSS was also in 70-above age group (44.75%). The percentile relief in IPSS increased as age increases in this group.

Where as in group-C maximum IPSS improvement was observed in 50-59 yrs age group (70.93%). Particularly in this group, decrease in percentile relief in IPSS was observed as age increases.

##### Weight of Prostate

Most of the patients of all groups were with second grade of BPH. The maximum weight was 54 g and minimum was 25 g, the prostate weight reduction was maximum in 50-59 yrs of group-C (28.48%). As the age increases less effect of therapy was noticed in group-C i.e. 60-69yrs-26.77% and in 70-above- 22.21%

##### Residual Urine

64.17% relief was noticed in group-C patients of 60-69 yrs age group. The minimum relief in residual urine of group-C was in 70-above age group (55.07%). In 50-59 yrs age group the maximum relief was observed in group-A patients (57.82%) and minimum relief was observed in group-B patients of 60-69 yrs age group (39.34%).

##### Micturition Time

In all groups, before treatment mean micturition time ranges from 53-60 sec. whereas after treatment it was between 37-46 sec. The maximum percentile reduction in micturition time was in group-A of 50-59 yrs (33.52%) and minimum was in same age group of group-B (20.84%).

##### Average flow rate

The average flow rate was almost same in all groups and age groups but maximum mean value observed in group-A of 60-69 yrs (3.63ml/sec).

The maximum percentile increase in average flow rate was in group-C patients- 81.37, 76.48 and 75.73% according to increasing age group.

The group-B patients showed nearly same percentile relief in 50-59 and 60-69 yrs age groups. 70-above age group patients of group-B get maximum relief (54.44%).

The incidence and results are analyzed on the basis of patient's prakriti.

##### IPSS

The maximum mean IPSS observed in group-A was of kaphaja prakriti (24.6), in group-B and C of pittaja prakriti 24.5 and 21.17 respectively. So all groups showed severe symptom according to IPSS.

The pittaja prakriti patients got less relief in all the groups especially in group-B (37%).

##### Weight of Prostate

The maximum percentile weight reduction was noticed in group-C of vatika patients (28.65%). In group-A maximum relief in kaphaja patients (19.8%) and minimum in paittika patients (9.92%). The group-B patients relieved less in this contrast. Kaphaja patients of group-B got only 2.4% reduction whereas pittaja patients with 10.14% and vatika with 7.57% in weight reduction.

##### Residual urine

The mean residual urine reduced well in group-C patients. The maximum relief observed in kaphaja prakriti patients of group-C (66.27%) followed by vatika patients (63.16%). Whereas in group-A vatika patients got maximum relief of 57.98% followed by kaphaja prakriti (51.58%).

The trend of residual urine reduction of group-C was observed in group-B also. Here vatika patients got 49.34%, kaphaja patients-40% and pittaja prakriti patients got 24.13% relief.

##### Micturition Time

The group-A patients showed maximum reduction in micturition time of vatika prakriti patients (36.91%) and vatika patients of group-C got 35.21% relief, which was maximum relief in group-C of all prakriti.

Vatika patients of group-B got 28.13% relief, which was maximum in this group and minimum was of kaphaja prakriti patients 17.99% only.

##### Average flow rate

Vatika patients of group-C showed maximum increase in average flow rate 88.05% in all groups and pittaja patients of this group relieved 63.10% whereas kaphaja prakriti patients got 71.46% relief.

In group-A vatika patients relieved 83.57% in average flow rate followed by kaphaja patients (57.44%). In group-B patients maximum relief was noticed in pittaja patients (36.62%).

#### CONCLUSION

In present clinical study Evaluation of efficacy of an Ayurvedic formulation Prostowin vati and Ksheerabala oil Vasti in the management of BPH had done. The conclusions of study are as follow-

The BPH is a disease of elderly person and more prevalent in vatika and kaphaja individuals. The development of symptoms like incomplete evacuation, frequency, hesitancy, weak stream, nocturia etc. make the life of the sufferer very uncomfortable desiring immediate remedy for that.

The non-invasive and non-surgical therapy (Prostowin vati and Ksheerabala oil Vasti) suggested in present study has provided better non-hormonal alternative therapy to the BPH patients without any adverse effect.

The Prostowin vati formulation selected on the basis of pathogenesis involved in the BPH is very effective in reducing the symptoms of BPH.

The drug show better results with the Vatasamaka vasti treatment especially in weight reduction of prostate may be due to some hypoplastic effects.

The quality of life improved with the Prostowin Vati and Ksheerabala oil Vasti with the reduction in symptom score (IPSS and DPSS), Residual urine, Micturition time and improvement in Average flow rate.

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