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“The Physician who studies the  
Science of Medicine from the lips of  
his preceptor, and practices medicine  
after having acquired experience in his  
art by constant practice, is the true  
Physician”

- *Susrutha Samhitha*

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# MANAGEMENT OF BPH BY PHYTOTHERAPY

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## ABSTRACT:

Benign Prostatic Hypertrophy (BPH) is a common condition in men above 50, characterized by a non-malignant enlargement of the prostate. The clinical features include incomplete emptying, frequency, intermittency, weak stream, straining & nocturia.

Ayurveda looks at this senile problem in a different way. This B.P.H. can be correlated with *Vata-ashthila*, described by Acharya Sushruta. Drugs advocated in Ayurvedic texts not only take care of the symptoms, but also aims to break the pathology. All this has inspired us to conduct clinical trials of Phytotherapy treatment comprising *Ghana* of *Ashwagandha*, *Varun*, *Gokshur*, *Haritaki* & *Punarnava* in the patients of B.P.H. The statistics obtained revealed that the Phytotherapy combination (Tab. EASYPROST) effectively reduce the symptoms of B.P.H. and worked as good as the highly selective  $\alpha_1$  blocker (Tamsulosin hydrochloride).

**KEY WORDS:** Benign Prostate Hypertrophy, Prostate surgery,  $\alpha_1$  blocker - Tamsulosin hydrochloride, *Vata-ashthila*, *Varun*, *Gokshur*, *Haritaki* & *Punarnava*.

**Introduction: Benign Prostatic Hypertrophy (B.P.H.)** is characterized by a non-malignant enlargement of the prostate resulting from excessive cellular growth of both the glandular and the stromal elements of the gland. Due to the enlargement of prostate gland, a group of symptoms develop which is called as Prostatism.

**Prostatism is divided into two groups:**

Obstructive	Irritative
Hesitancy – worsened if the bladder is very full	Frequency
Dysuria - Poor flow – unimproved by straining	Nocturia
Intermittent stream – stops and starts	Urgency
Dribbling – including after micturition	Urge incontinence
Episodes of near retention	Nocturnal incontinence
Sensation of poor bladder emptying	

**Aetiology of B.P.H.:** The aetiology of BPH is unknown. One hypothesis infers that the prostate converts testosterone to a more powerful androgen called Dihydrotestosterone (DHT), which stimulates cell growth in the tissue that lines the prostate gland (the glandular epithelium) and is the major cause of the rapid prostate enlargement.

**Incidence and Epidemiology:** Benign Prostatic Hypertrophy (BPH) is a common condition in older

men; approximately 50% of men aged 60 years and 90% of those aged 85 years present with BPH. In India, prostatic hypertrophy is common over the age of 60 years.

## Established Treatment of B.P.H.

**Conservative medical management** - For Curative relief – 5 alpha reductase inhibitors like Finasteride and Dutasteride and for Symptomatic relief – Alpha blockers like Terazosin, Doxazosin, Tamsulosin, and Alfuzosin are given. However, these medicines have got side effects and adverse effects like Sexual dysfunction, Postural hypotension, Asthenia and Dizziness, etc. Similarly, long-term therapy is required to maintain the benefits.

**Surgical procedures** - Supra pubic Prostatectomy, Retro pubic Prostatectomy, Transurethral prostatectomy, Perineal prostatectomy, Laser treatment & Microwave treatment. However, TURP, i.e. transurethral resection of the prostate, has been the mainstay of treatment.

**B.P.H. and Ayurveda:** There is a lot of similarity between *Vata-ashthila* described by Acharya

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Sushruta and B.P.H. *Vata-ashthila* is said to develop due to vitiated *Vayu* which gets lodged in the space between *Basti* and *Guda* and gives rise to a hard, thick cystic (*Granthi sadrushya*) structure, which is non-shifting in character and produces various obstructive and irritative urinary symptoms and cause pain in the bladder. These symptoms and cystic (*Granthi sadrushya*) structure can be correlated with B.P.H.

**Need for Herbal approach in the Management of BPH:** In patients of BPH, treating only the symptoms is not sufficient. Modern medicines, though effective, have a number of side effects. Similarly surgical techniques demand not only money factor, but also there are many other complications after surgery. Additionally, about 20 to 25% of patients do not have a long-term satisfactory outcome from surgery.

Herbal drugs advocated in Ayurvedic texts not only takes care of symptoms of BPH, but also aims to break the pathology & improves quality of life of patient with B.P.H. Similarly, Phytotherapy gives curative relief along with the symptomatic relief to the patients of B.P.H. They are cost effective and free from any adverse effect.

**Aims and objectives of the study:**

- The study entitled “Randomized Controlled clinical study of Phytotherapy combination (Tab. EASYPROST) in the patients of B.P.H. (Grade I & II)” primarily aims at evaluating the treatment result in B.P.H.
- First line therapy – To substitute Medical Therapy for Surgery in the patients of B.P.H. – Grade I & II, free from adverse reactions and side effects of Allopathic drugs.
- Economic Therapy – To give cost effective treatment in the patients of B.P.H.

**Materials and Methods**

- Title of the study - “Randomized Controlled clinical study of Phytotherapy combination (Tab. EASYPROST) in the patients of B.P.H. (Grade I&II)”.

- Type of study - Open Randomized Controlled Clinical Trial.
- Centre of study - Dr. D. Y. Patil Ayurvedic Hospital, Nerul, Navi Mumbai.
- Sample size - 60 (30 + 30)
- Grouping of patients – Randomly selected patients were divided into:
  - Group A – Tab. EASYPROST (Phytotherapy combination)
  - Group B – Capsule of Tamsulosin Hydrochloride 0.4 mg
- Duration of treatment - 3 months for both the groups.
- Follow Up – Every 3 weeks.

**Criteria for the selection of the patients**

**Inclusion criteria:** Male patients around the age of 50, Prostrate size Grade I & II

**Exclusion criteria:** Complicated B.P.H. with Grade III, Ca prostate, Diabetes Mellitus, Oliguria, Stricture Urethra, Major disease like HIV, Liver cirrhosis, Koch’s, IHD, Nephrotic syndrome, etc.

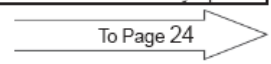
**Baseline assessment & Investigations:**

**Investigations:** All Routine investigations CBC, ESR, BSL, BUN, Sr. Creatinine, Urine R/M, etc., Digital rectal examination (DRE), USG for prostate to observe weight and size of the prostate, Post-void residual urine volume (before and after treatment), PSA (Prostate specific antigen) and AUA Score (American Urological Association Symptom Score).

**Assessment of Efficacy of Therapy**

The assessment of the effect of therapy was totally based on the standard AUA symptom score. Symptomatic relief of the patient was the main aim and the effect of therapy was assessed in terms of:

Cured	100% relief, in all symptoms.
Relieved	75% to 100% relief in the symptoms.
Markedly Improved	50% to 75% relief in the symptom.
Improved	25% to 50% relief in the symptoms.
Unchanged	Less than 25% or no relief to symptoms



## Drugs and Doses

**Group A** - Tab. **EASYPROST** (Phytotherapy combination) - Two tablets twice a day for three months, with luke warm water.

1. *Ashwagandha Ghana* (*Withania somnifera*) - 100mg
2. *Varun Ghana* (*Crataeva nurvala*) - 100mg
3. *Gokshura Ghana* (*Tribulis terrestris*) - 100mg
4. *Haritaki Ghana* (*Terminalia chebula*) - 100mg
5. *Punarnava Ghana* (*Boerhavia diffusa*) - 100mg

**Group B** – (Alpha blocker) - Capsule of Tamsulosin Hydrochloride 0.4 mg 1 H.S. for three months.

## Drug Profile:

Drug	Doshagnata	Rogagnata	Pharmacological activities
<i>Ashwagandha</i> ( <i>Withania somnifera</i> )	<i>Kapha Vata - shamak</i>	<i>Granthishotha Mootraghata</i>	Antibacterial, Immuno modulatory, Antitumor, Antioxidant, Anti-inflammatory, Antispasmodic, Analgesic, Cytoprotective
<i>Varun</i> ( <i>Crataeva nurvala</i> )	<i>Kapha Vata - shamak Pittavardhak</i>	<i>Vranshoth, Gulma, Vidradhi, Shool, Ashmari, Bastishool, Mootrakrichra</i>	Diuretic, Lithotropic, Antibacterial, Anti-inflammatory, Stimulant, Astringent, Spasmolytic, Corticosteroid like activity
<i>Gokshura</i> ( <i>Tribulis terrestris</i> )	<i>Vata Pitta - shamak</i>	<i>Nadidaurbhaya, Ashmari, Mootrakrichra, Bastishoth</i>	Diuretic, Aphrodisiac, Anti-inflammatory, Lithotropic, Astringent, Analgesic, Antirheumatic, Muscle relaxant Excellent result in UTI
<i>Haritaki</i> ( <i>Terminalia chebula</i> )	<i>Tridosha - shamak, especially Vata shamak</i>	<i>Shotha, Ashmari, Vedanayuktavikara, Vrana, Shoola, Gulma, Mootrakrichra, Mootraghata</i>	Astringent, Diuretic, Anti-inflammatory, Antiseptic, Antifungal, Antibacterial, Laxative, Carminative, Digestive, Antispasmodic
<i>Punarnava</i> ( <i>Boerhavia diffusa</i> )	<i>Tridosh shamak</i>	<i>Shoth, Mutrakrichra</i>	Diuretic, Hepatoprotective, Anti-inflammatory, Antibacterial, Antifibrinolytic, Antiviral agent

## Group B

### Tamsulosin hydrochloride (Symptomatic relief – Alpha blockers)

This drug relaxes smooth muscles, especially in the urinary tract and prostate. Helps relieve BPH

symptoms, but do not reduce the size of the prostate. Helps to improve urine flow and reduce risk of bladder obstruction. Also, it increases the urine flow rate significantly in 90 minutes after administration of a single dose.

**Adverse effects:** Postural hypotension, retro-grade ejaculation, dizziness, asthenia.

**Indications and usage:** Treatment of symptoms of Benign Prostatic Hyperplasia.

**Dosage and administration:** PO 0.4 mg/day, administered approximately 30 minutes following the same meal each day. If the patient fails to respond after 2 to 4 weeks, the dose may be increased to 0.8 mg/day.

**Method:** A good clinical examination was done and patients with Grade I & II of B.P.H were selected in the study randomly. After starting the treatment, patients were called for visit after 1 week and were asked for the compliance of the tablet and side effects or the adverse effect, if any. No such adverse effects were found and so the treatment was then continued with the patient thoroughly examined in every 3 weeks. The AUA Score was assessed and a Digital rectal examination was carried out in 3 weeks. Statistical analysis was done from the data obtained and final results were found out.

## Statistical Analysis

**Parametric tests** for objective Parameters (Quantitative Data, i.e. Improvement in Physical parameters & improvement in haematological parameters)

**Non –Parametric test** for subjective parameters (Qualitative Data, i.e. Relief in Symptoms)

## Observation and Results

### Assessment of observed Parameters

Table showing effect on general AUA symptom (Score of 30 patients of B.P.H.)

GROUP A						GROUP B					
Sr. No.	Symptoms	BT	AT	Difference	% of Relief	Sr. No.	Symptoms	BT	AT	Difference	% of Relief
1	Incomplete Emptying	45	3	42	93.33	1	Incomplete Emptying	48	6	42	89.36
2	Frequency	95	24	71	74.73	2	Frequency	103	28	75	72.81
3	Intermittency	38	4	34	89.47	3	Intermittency	37	2	35	94.59
4	Urgency	86	11	75	87.20	4	Urgency	78	6	72	92.30
5	Weak stream	58	7	51	87.93	5	Weak stream	65	9	56	86.15
6	Straining	40	7	33	82.50	6	Straining	58	5	53	91.37
7	Nocturea	88	21	67	76.13	7	Nocturea	84	17	67	79.76

#### WILCOXON TEST

Sr. No.	Symptoms	Group A	Group B
1	Incomplete Emptying	3.51 P<0.001	3.72 P<0.001
2	Frequency	4.78 P<0.001	4.78 P<0.001
3	Intermittency	3.51 P<0.001	3.62 P<0.001
4	Urgency	4.62 P<0.001	4.62 P<0.001
5	Weak stream	4.19 P<0.001	4.45 P<0.001
6	Straining	3.62 P<0.001	4.45 P<0.001
7	Nocturea	4.87 P<0.001	4.62 P<0.001

#### STATISTICAL ANALYSIS OF SYMPTOMS OF PATIENTS OF B.P.H.

##### GROUP A

Sr. No.	Symptoms		Mean	SD	Diff SE	Sum of all signed ranks	No. of pairs	Value of 'Z'	P
1	Incomplete Emptying	BT	1.5	1.59	0.27	136	16	3.51	<0.001 Highly Significant
		AT	0.1	0.40					
		DIFF	1.4	1.52					
2	Frequency	BT	3.16	0.93	0.16	465	30	4.78	<0.001 Highly Significant
		AT	0.8	0.71					
		DIFF	2.36	0.92					
3	Intermittency	BT	1.26	1.48	0.22	136	16	3.51	<0.001 Highly Significant
		AT	0.13	0.43					
		DIFF	1.13	2.25					
4	Urgency	BT	2.86	1.43	0.21	406	28	4.62	<0.001 Highly Significant
		AT	0.36	0.61					
		DIFF	2.5	1.19					
5	Weak stream	BT	1.93	1.38	0.21	276	23	4.19	<0.001 Highly Significant
		AT	0.23	0.50					
		DIFF	1.7	1.20					
6	Straining	BT	1.33	1.42	0.19	153	17	3.62	<0.001 Highly Significant
		AT	0.23	0.50					
		DIFF	1.1	1.09					
7	Nocturea	BT	2.93	1.52	0.20	406	27	4.87	<0.001 Highly Significant
		AT	0.7	0.79					
		DIFF	2.23	1.13					

## GROUP B

Sr. No.	Symptoms		Mean	SD	Diff SE	Sum of all signed ranks	No. of pairs	Value of 'Z'	P
1	Incomplete Emptying	BT	1.6	1.45	0.23	171	18	3.72	<0.001 Highly Significant
		AT	0.2	0.40					
		DIFF	1.4	1.27					
2	Frequency	BT	3.43	0.93	0.11	465	30	4.78	<0.001 Highly Significant
		AT	0.93	0.73					
		DIFF	2.5	0.62					
3	Intermittency	BT	1.26	1.20	0.20	153	17	3.62	<0.001 Highly Significant
		AT	0.06	0.25					
		DIFF	1.2	1.12					
4	Urgency	BT	2.6	1.03	0.20	406	28	4.62	<0.001 Highly Significant
		AT	0.2	0.40					
		DIFF	2.4	1.10					
5	Weak stream	BT	2.16	1.14	0.16	351	26	4.45	<0.001 Highly Significant
		AT	0.3	0.53					
		DIFF	1.86	0.89					
6	Straining	BT	1.93	1.14	0.18	351	26	4.45	<0.001 Highly Significant
		AT	0.16	0.37					
		DIFF	1.76	1.00					
7	Nocturea	BT	2.8	1.12	0.14	406	28	4.62	<0.001 Highly Significant
		AT	0.56	0.67					
		DIFF	2.23	0.81					

### Other Significant Observations:

**BUN:** Mean BUN level in Group A, before treatment was 18.52 + 3.23 and after treatment was 18.33 + 2.29 where  $t=0.68$ ,  $P>0.05$ , which was statistically insignificant.

**Weight of prostate:** Mean Wt. of prostate in grams in Group A, before treatment was 33.74 + 11.24 and after treatment was 33.72 + 11.26 where  $t=1$ ,  $P>0.05$ , which was statistically insignificant.

**Post Void Residual Urine Volume (PVR):** Mean PVR in ml in Group A, before treatment was 64.4 + 59.71 and after treatment was 29.9 + 37.59 where  $t=7.99$ ,  $P>0.001$ , which was statistically significant.

## DISCUSSION

### Group A: Phytotherapy combination

- Patients were asked for the follow up after 6 months, some of them regularly visited the O.P.D. for 6 months.

- In the data collected, majority of the patients were found in between 60-70 years - 32 patients (53.33%). This shows that B.P.H. is a geriatric problem.
- Out of 60 patients observed 34 patients (56.66%) were retired people. This shows that B.P.H. is the disease of retirement.
- The patients of Group A (Phytotherapy combination) were found to have complete symptomatic relief.
- No adverse effects were observed in Group A patients.
- They did not have any recurrence of the symptoms after stopping the treatment.
- This Phytotherapy combination has already proven its symptomatic relief in the patients of B.P.H. (Grade I & II) in this study, but further evaluation should be done by taking a large sample size.

- It is felt that this combination would also reduce the size and weight of the prostate giving curative relief along with the symptomatic relief to the patients of Benign Prostatic Hypertrophy by giving the treatment for a longer period of a time.

#### **Group B: Alpha blocker -Tamsulosin Hydrochloride**

- In order to avoid the side effect, postural hypotension, etc. the patients were advised to take the capsule at bed time.
- Dizziness was seen in some patients, but that did not disturb the routine work of the patient much.

#### **Impact of Phytotherapy combination (Group A): Controlled Group (Group B)**

- The total effect of the therapy was same in both the groups.
- The number of patients Cured, Relieved, Markedly improved and Improved were almost equal in number.
- This shows that the Phytotherapy combination does give the patients the same relief like Tamsulosin hydrochloride.

#### **CONCLUSION**

- The Phytotherapy combination gave remarkable results by reducing the symptoms of B.P.H. The statistics obtained clearly

shows that the Phytotherapy combination works out as good as the highly selective  $\alpha$  1 blocker, Tamsulosin hydrochloride.

- Total effect of the therapy in Group A, 8 patients (26.66%) were Cured, 19 (63.33%) were relieved, 3 (10%) were markedly improved. In Group B, 9 patients (30%) were Cured, 20 (66.66%) were relieved, 1 (3.33%) was markedly improved.
- From the results obtained in the study we can conclude that The Phytotherapy combination gives -
  - Significant improvement in the AUA symptom score
  - Increase in the urine flow rate
  - Increase in the void volume
  - Decrease in the post void residual urine volume
  - Relieves irritative symptoms like increased urine frequency, urgency and nocturia.
  - Relieves obstructive symptoms like hesitancy, poor and intermittent flow and incontinence.
  - Prevents U.T.I associated with B.P.H.
  - Safe with no adverse effects.
  - Cost effective, as compared to modern drugs.
  - Improves the quality of life.

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