



Research Article

MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA (GRADE I & II) BY PHYTOTHERAPY

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ABSTRACT

Benign prostatic hypertrophy (B.P.H) is a common condition in men above 50 years of age & 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. The clinical feature of B.P.H. includes incomplete emptying, frequency, intermittency, weak stream, straining & nocturia. Modern treatment though effective in treating symptoms has a number of side effects such as Sexual dysfunction, Postural hypotension, Asthenia and Dizziness etc. Similarly, surgical procedures such as prostatectomy, laser treatment & transurethral resection of the prostate (TURP) are costly & associated with a high risk of complications and morbidity. Hence, there is definite need to explore and evaluate the efficacy of Ayurvedic medicines in the management of B.P.H.

This B.P.H can be correlated with *Vata-ashthila*, described by Sushruta. Herbal drugs mentioned in the management of *Vata-ashthila* not only take care of symptoms but also aims to break the pathology & improves quality of life of patient. So, this clinical study was done to establish an Ayurvedic conservative treatment for B.P.H – Grade I & II, which is cost effective, free from adverse reactions and side effects of Allopathic drugs.

An open randomized controlled clinical trial was conducted with Group A (phytotherapy) comprised of *Ghana* of *Ashwagandha*, *Varun*, *Gokshur*, *Haritaki* & *Punarnava*, whereas, in Group B - α 1 blocker (Tamsulosin hydrochloride) was selected.

The comparative analysis of results in both Group-A & B, revealed that the total effect of the therapy was same in both the groups. In Group A, 26.66% patients were Cured, 63.33% were relieved, 10% patients were markedly improved. Similarly, in Group B, 30% patients were Cured, 66.66% were relieved, 3.33% patients were markedly improved. This proves that the Phytotherapy combination does give the patients the same expected relief like modern drug i.e. Tamsulosin hydrochloride.

KEYWORDS: Benign Prostatic Hypertrophy, α 1 blocker- Tamsulosin hydrochloride, *Sushrut Samhita-Vata ashthila*, *Ashwagandha*, *Varun*, *Gokshur*, *Haritaki*, *Punarnava*.

INTRODUCTION

Benign prostatic hyperplasia (B.P.H) is a common condition in men above 50 years of age & 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.^[1] It 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.^[2]

The aetiology of B.P.H. is unknown. One hypothesis infers that the prostate converts testosterone to a more powerful androgen, 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.^[3]

Due to the enlargement of prostate gland, a group of symptoms develop which are called as prostatism. The clinical feature of B.P.H. includes incomplete emptying, frequency, intermittency, weak stream, straining & nocturia. For Curative relief – 5 alpha reductase inhibitors like Finasteride and Dutasteride whereas, for Symptomatic relief – Alpha blockers like Terazosin, Doxazosin, Tamsulosin, and Alfuzosin is given. However, long-term

therapy is required to maintain the benefits these medicines, along with side effects and adverse effects like Sexual dysfunction, Postural hypotension, Asthenia and Dizziness etc.^[4]

Further, there are various surgical procedures like prostatectomy, laser treatment & microwave treatment. However, transurethral resection of the prostate (TURP) has been the mainstay of treatment. But, surgery is associated with a high risk of complications and morbidity, including haemorrhage, infection, epididymitis, renal failure, stricture of the bladder neck, impotence etc. Additionally, about 20 to 25% of patients do not have a long-term satisfactory outcome surgery.^[5]

This provides opportunity to Ayurvedic fraternity to explore and evaluate the efficacy of herbal drugs in the management of B.P.H. Ayurveda looks at this senile problem in a different way. There is a lot of similarity between *Vata-ashthila* described by Sushruta and Benign Prostatic Hyperplasia. *Vata-ashthila* is said to develop due to vitiated *Vata* 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.^[6,7,8]

Herbal drugs advocated in Ayurvedic texts not only takes care of symptoms of B.P.H. but also aims to break the pathology & improves quality of life of patient. Hence, this study was conducted to evaluate efficacy of Phytotherapy treatment comprising *Ghana* of *Ashwagandha*, *Varun*, *Gokshur*, *Haritaki* & *Punarnava* in the patients of B.P.H. (Grade I & II). The statistics revealed that the Phytotherapy combination effectively reduced the symptoms of B.P.H. & works out as good as the highly selective α 1 blocker (Tamsulosin hydrochloride).

AIMS AND OBJECTIVES

1. The study primarily aims at evaluating the treatment's result in B.P.H. (Grade I & II).
2. To establish an Ayurvedic conservative treatment for B.P.H – Grade I & II, which is cost effective, free from adverse reactions and side effects of Allopathic drugs.

MATERIALS AND METHODS

Type of study- Open Randomized Controlled Clinical Trial

Centre of study- Dr. D.Y.Patil Ayurvedic Hospital, Navi Mumbai, India.

Sample size – 60 patients (30 in each group)

Grouping of the patients – Randomly selected patients were divided into two groups

Group A –Phytotherapy combination,

Dose-Two tablets twice a day with Luke warm water.

Group B – Capsule of Tamsulosin Hydrochloride,

Dose- 1 Capsule of 0.4 mg at night.

Duration of treatment - 3 months

Follow Up – Every 3 weeks

Drug profile

Group A - Phytotherapy combination. The ingredients of this herbal formulation are.

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

All above mentioned herbal drugs taken in specified quantity and *Ghan vati* is prepared.

Group B – Tamsulosin hydrochloride (Symptomatic relief – Alpha blockers)

Criteria for the Selection of the Patients

Inclusive criteria

- Male patients about the age of 50 yrs
- Prostate size - Grade I & II

Exclusive 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

- 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).
- P.S.A (Prostate specific antigen)
- AUA Score (American Urological Association Symptom Score)

Table 1: Parameters of American Urological Association (A.U.A) Symptom Score

Sr. No.	Symptoms	Not at all	Less than 1 in 5 times	Less than 1/2 the time	About 1/2 the time	More than 1/2 time	Almost always
1	Incomplete emptying	0	1	2	3	4	5
2	Frequency	0	1	2	3	4	5
3	Intermittency	0	1	2	3	4	5
4	Urgency	0	1	2	3	4	5
5	Weak stream	0	1	2	3	4	5
6	Straining	0	1	2	3	4	5
7	Nocturea	0	1	2	3	4	5

Total score

1. 0-7 : Mildly symptomatic
2. 8-19 : Moderately symptomatic
3. 20-35 : Severely symptomatic

Assessment of Efficacy of Therapy

The assessment of effect of therapy was totally based on the standard AUA symptom score. Symptomatic relief of the patient was the main aim. The effect of therapy was assessed in terms of Cured, Relieved, Markedly improved, Improved, and Unchanged.

1. **Cured** – 100% relief, in all symptoms was considered as totally cured.
2. **Relieved** – 75% to 100% relief in the symptoms
3. **Markedly Improved** – 50% to 75% relief in the symptoms

4. **Improved** – 25% to 50% relief in the symptoms

5. **Unchanged** – Less than 25% or no relief symptoms was considered as unchanged.

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 patients were asked for the compliance of the tablet and side effects or the adverse effect if any, faced by the patients. No such adverse effects were found and so the treatment was then continued and patient was 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 final results were found out. The

Institutional Ethical Committee clearance reference number for this study is DYPUSA/16/12.

STATISTICAL ANALYSIS

A) Parametric tests for objective Parameters (Quantitative Data i.e. Improvement in Physical parameters & improvement in hematological parameters)

B) Non -Parametric test for subjective parameters (Qualitative Data i.e. Relief in Symptoms)

OBSERVATION

The Statistical analysis of symptoms of patients of B.P.H in Group- A, by Wilcoxon - matched - pairs Signed - ranks test is as below.

Table 2: Statistical analysis of symptoms of patients of B.P.H in 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					

The Statistical analysis of symptoms of patients of B.P.H in Group- B, by Wilcoxon - matched - pairs Signed - ranks test is as below:

Table 3: Statistical analysis of symptoms of patients of B.P.H in 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					

RESULT

Comparative analysis of results in both Group-A & B, revealed that the total effect of the therapy was same in both the groups. 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. This shows that the Phytotherapy combination does give the patients the same expected relief like modern drug i.e., Tamsulosin hydrochloride.

Table 4: Table showing comparative results both in Group- A & B, using 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

Assessment of objective parameters

This assessment of study was based on the improvement in AUA Score. The parameters considered were Incomplete Emptying, Frequency, Intermittency, Urgency, Weak stream, Straining and Nocturea exclusively. However, surprisingly observed improvement in some other objective parameters like BUN, Weight of prostate, Post Void Residual Urine Volume (PVR) with Group A. These findings, though, not relevant to study, as they were not included as parameters to be studied, still they are mentioned here in brief, just to reveal the significance of Phytotherapy.

1. 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.

2. Weight of prostate- Mean Wt of prostate in gms 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.

3. 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

Patients were asked for the follow up for 6 months. For 3 months they were on medicine & for the remaining 3 months without medicine for the follow up.

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.

Group A: Phytotherapy combination - The patients of Group- A were found to have complete symptomatic relief. No adverse effects were observed in Group -A patients. Further, 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 and giving the

treatment for a longer period of a time to assess its efficacy in also reducing the size and weight of the prostate to establish drug for curative relief.

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 the bed time. Dizziness was seen in some patients, but that did not disturb the routine work of the patient much.

Patients' showed satisfactory relief during the treatment but after stopping the treatment, symptoms re occurred in most of them which reveals that long term therapy is required in Group- B category.

Probable mechanism of Action of Phytotherapy

Ashwagandha (*Withania somnifera*) – The drug is *Kapha-Vata shamak* and effective in *Granthishotha* and *Mootraghata* like condition.^[9]

Previous research work reveals that *Ashwagandha* plays main role in reducing prostatic congestion & regularizes hormonal metabolism. It has immunomodulatory effect on prostate & Suppresses Androgen biosynthesis. ^[10, 11, 12]

Varun (*Crataeva nurvela*)- It is *KaphaVata -shamaka Pittavardhak*, effective in *Vranshoth*, *Vidradhi*, *Gulma*, *Ashmari*, *Bastishool* and *Mootrakrichra*.^[13]

Research conducted proves that it exhibits 5- α reductase enzyme inhibitory activity. It also has Lithotriptic, Diuretic, Disinfectant, Anti inflammatory action.^[14, 15, 16]

Gokshura (*Tribulis terrestris*) - *Gokshur* is *Vata Pitta - shamaka*, effective in conditions such as *Nadidaurbalya*, *Ashmari*, *Mootrakrichra* *Bastishoth*.^[17]

It exhibits 5- α reductase enzyme inhibitory activity. It acts on the mucous membrane of the urinary tract. It contains potassium and other salts which increases volume of urine.^[18, 19, 20]

Haritaki (*Terminalia chebula*)- *Haritaki* is *Tridosha - shamaka*, specially *Vatashamaka*, effective in *Shoth*, *Ashmari*, *Vedanayuktavikara*, *Vrana*, *shoola*, *Gulma*, *Mootrakrichchra* and *Mootraghata*. According to Ayurvedic concepts it is the best '*Vatanulomak*' drug. ^[21]

This drug is Diuretic, Anti-inflammatory, Antiseptic, Antimicrobial, Antifungal Antibacterial, Antispasmodic.^[22, 23, 24]

Punarnava (*Boerhavia diffusa*)- It posses *Tridosha* – *shamaka* property and effective in *Shoth* and *Mootrakrichchra*.^[25]

It contains alkaloids, β -sitosterol, ursolic acid, Vitamins D, and E. It helps to regulate production of polyamine and prostaglandins which are powerful immuno-suppressants produced in the prostate & also support and balance the healthy flow of urine by toning smooth muscles located in the urino-genital system and reducing inflammation of the urethra and prostate.^[26, 27]

Limitation & Scope for further research

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 to observe any untoward effects.

There is a need to evaluate the efficacy of this combination in reducing the size and weight of the prostate giving curative relief along with the symptomatic relief to the patients of Benign Prostatic Hyperplasia.

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 α 1 blocker, Tamsulosin hydrochloride. The number of patients Cured, Relieved, Markedly improved and Improved were almost equal in number.

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 and decrease in the post void residual urine volume. Furthermore, it relieves irritative symptoms like increased urine frequency, urgency and nocturia. Similarly, it relieves obstructive symptoms like hesitancy, poor and intermittent flow and incontinence. It also prevents U.T.I associated with B.P.H, safe with no adverse effects, cost effective as compared to modern drugs and improves the quality of life of patient with B.P.H.

Further research is needed using standardized preparations of Phytotherapy combination to determine its long-term effectiveness and ability to prevent BPH complications.

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