

A RANDOMIZED CONTROLLED STUDY TO EVALUATE THE EFFICACY OF PROSTOCARE (HERBO-MINERALO COMPOUND) IN THE MANAGEMENT OF PAURUSH GRANTHI SHOTH W.S.R. (B.P.H. GRADE I & II)

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ABSTRACT

Benign Prostate Hypertrophy (B.P.H.) is a most common condition seen in ageing men above 50yrs old, characterised by non malignant enlargement in Peripheral Transitional Zone of Prostate gland. Clinically it manifests symptoms of disturbed LUTS (Lower Urinary Tract Symptoms) comprising *incomplete emptying of bladder, intermittency, straining, frequency, urgency, weak stream and nocturia*. Mild LUTS (Lower Urinary Tract Symptoms), reasonable flow rates (>10ml/s) and good bladder emptying Residual Volume (<100 ml) can be managed conservatively with two classes of *Pharmacological agents*. *Alpha-Adrenergic blocking agents* inhibit contraction of smooth muscles and the other class *5-Alpha Reductase inhibitors* inhibit the conversion of testosterone to DHT (*dihydrotestosterone*). Though these drugs are uroselective they involve many adverse effects such as *Postural Hypotension, Retrograde Ejaculation, Asthenia, Dizziness* etc. However severe symptoms with low maximal flow rate (<10ml/s) and residual volume (100-250 ml) causing BOO (Bladder Outlet Obstruction) strongly require surgical intervention with *Prostatectomies* as they fail to respond well with drug therapy, which may be used as a spacing for postponing surgery. TURP (Trans Urethral Resection Of Prostate) is considered as a gold standard procedure in the Management of Severe Grade III and IV B.P.H.(Benign Prostate Hypertrophy) with BOO (Bladder Outlet Obstruction). Post operative complications of TURP (Trans Urethral Resection Of Prostate) involves *Retrograde ejaculation, impotence, failed primary procedure seen in 15-18% cases demands repeat procedure, damage to sphincter mechanism causing urinary incontinence, urethral stricture* etc. Acharya Sushruta has described 12 types of Mutraghata (*Obstructive Uropathy*) out of which *Vatashtila (prostatomegaly)* is the commonly found in day-to-day practise. As the name suggests the main factor (dosha) in *Vatashtila (prostatomegaly)* is Vata and symptoms suggests that it occurs in Basti which is sthan of Apanvayu. So because of dushti of Apan Vayu obstruction, Dribbling micturition and Hesitancy develops which is known as *Vata-ashtila (prostatomegaly)* and which can be easily correlated with B.P.H. (Benign Prostate Hyperplasia). Considering all these, pitfalls

the present study was taken up with the objective of evaluating efficacy of *Tab.Prostocare* (Herbo-Mineralo Compound) in the management of BPH Grade I & II (Benign Prostate Hyperplasia). The efficacy of treatment was assessed through symptom score sheet IPSS (International Prostate Symptom Score Sheet) and improvement in LUTS (Lower Urinary Tract Symptoms) with follow up every 15 days. The study proved statistically significant result in reducing LUTS (Lower Urinary Tract Symptoms) secondary to BPH (Benign Prostate Hyperplasia). The results revealed that the estimated treatment showed statistically highly significant improvement ($p<0.01$) in reducing all seven symptoms of BPH (Benign Prostate Hyperplasia) assessed through IPSS (International Prostate Symptom Score Sheet) and found effective in reducing overall IPSS score (International Prostate Symptom Score Sheet)

Keywords: *Tab. Prostocare, Vata-ashtila, Management of B.P.H (Benign Prostate Hyperplasia, IPSS (International Prostate Symptom Score Sheet)*

INTRODUCTION

Ayurveda deals with the healthy life of human being. Moreover it is concerned with the disease free. Acharya sushruta has described diseases in 4 types *Agantuj vyadhi* (Traumatic disorders), *Manas vyadhi* (Disorders of Mind), *Sharir vyadhi* (Disorders of Body) and *Swabhavik vyadhi* (Age Related Disorders)¹

Swabhavik vyadhi constitute age related disorders like osteoarthritis, cataract, presbyopia etc. Vata is predominantly present in the old age. Likewise, Benign Prostatic Hyperplasia is also a disease which is found in old aged males. It is the common disease which occurs in men more than 50 years of age. The disease - Benign Prostatic Hyperplasia is characterized by the obstructive as well as irritative symptoms. Obstructive symptoms include hesitancy, weak urine stream & dribbling micturition etc. whereas urgency, frequency, nocturia may be categorized under the variety of irritative symptoms. Although Benign Prostatic Hyperplasia is not as much life threatening condition, its clinical manifestations worsen the quality of life of patient.

The present modern conservative treatment includes use of either alpha blockers or 5 alpha

reductase inhibitors or both in the combination. But various side effects like headache, restlessness, insomnia, decreased libido, vertigo, dizziness, abnormal ejaculation, postural hypotension, asthenia etc. are noted due to use of these drugs. If the above said symptoms of Benign Prostatic Hyperplasia are not minimized, then patient has to opt for surgery like prostatectomy or resection of prostate.

Prostatectomy or Trans Urethral Resection of Prostate (TURP) is the primary approach to Benign Prostatic Hyperplasia. But as it is a disease which is found in old aged persons, patient may not be fit for surgery due to various problems or known history of diabetes, hypertension, bronchial asthma etc. Even if the surgery is done, there are high chances of complications. Early complications include hemorrhage, clot retention, bladder neck stenosis, sphincter mechanism damage causing post TURP incontinence etc. whereas, the late complications include recurrence, erectile dysfunction, secondary growth, urethral stricture, recurrent UTIs etc. Considering the complications, recurrence & cost of surgery, it is the need of society to evaluate an alternative option for this senile dis-

ease. Here, Ayurveda has got definite contribution which encourages us to find solution. In Ayurved Samhitas, symptoms of Benign Prostatic Hyperplasia are described under *Mootraghata*. There are 12 types of *Mootraghata*; one of them is *Vatashtila*.

In *Vata-ashtila* the abnormally increased *vata dosha* is accumulated in the narrow space of neck of urinary bladder & around the anal canal. This *sthansanshraya* in the vicinity results into formation of thick lump like swelling or mass. It is hard in consistency & mainly obstructs urinary outflow. In this regard, further increase in the size of *vatashtila* will subsequently obstructs the passage of urine, stool & flatus.² This ultimately results in chronic retention of urine & pain & distention of abdomen. The symptoms of *vatashtila* are like the lower urinary tract symptoms caused by BPH. In *sushrut samhita*, *vatashtila* is grouped under the title of *Mootraghata* (Obstructive Uropathy)

While working in our Hospital we came across large number of patients suffering from enlargement of Prostate. Hence B.P.H has been subject of study in previous years and research scholars have provided enthusiastic results with the help of Ayurvedic preparations. On the basis of same with the aim to keep a step forward the present study has been planned.

AIM

A Randomized Controlled Study to Evaluate the Efficacy of Prostocare (Herbo-Mineralo Compound) in the Management of Paurush Granthi Shoth (w.s.r. BPH Grade I & II)

OBJECTIVES OF STUDY:

- To improve symptom score in patients with severe LUTS secondary to BPH (Assessed through IPSS).

- To provide cost effective treatment in patients of BPH.
- To establish the product as a first line of therapy among different herbal compounds used in BPH worldwide.

TYPE OF STUDY: Randomized Controlled Study

MATERIALS & METHODS:

SOURCE OF DATA: The Patients collected from inpatient & outpatient department of Dr. D. Y. Patil Ayurvedic Hospital by simple random sampling procedure, according to the selection criteria. All the patients were divided into two equal groups 30 in each.

DRUG AND DOSAGE:

60 patients suffering from *Paurush Granthi Shoth* (Gr I & II) in an age group of 50-70 yrs were selected randomly and were subjected to clinical study. The selected patients were categorised in 2 groups of 30 in each.

- Group A: Tab. Prostocare 500mg

Each 500mg Tablet containing

<i>Ashwagandha Ghana</i>	100mg
<i>Triphala Ghana</i>	100mg
<i>Dashamula Ghana</i>	100mg
<i>Varuna Ghana</i>	100mg
<i>Shuddha Shilajit</i>	100mg

Administration:- Per Orally (2tab twice a day before meals)

Anupan- Koshna Jala

Duration – 3 months

- Group B: Cap. Tamsulosin 0.4mg

Administration:- Per Orally (Once a day at bed time)

Duration – 3 months

Follow up - Thorough Clinical history will be recorded before the treatment that is on zero day. Changes with the treatment will be as-

sessed through symptom score sheets and improvement in LUTS with follow up after every 15days.

Advice: Avoid alcohol, tea, coffee and reduce fluid intake after 8pm.

Tab. Prostocare 500mg was prepared from Chaitanya Pharmaceutical Nashik according to

Methodology:

Drug Profile

Drug	Doshagnata	Karma	Pharmacological Activities
Ashwagandha (<i>Withania somnifera</i>) ³	Vatakaphagna	Rasayan, Balya, Vajikaran, Vrushya, Shothahara, Deepan, Anuloman and Shoolprashaman	Diuretic, Immunomodulatory, Anti-inflammatory, Anti-spasmodic
Triphala ³ Haritaki- <i>Terminalia chebula</i> Amalaki- <i>Phyllanthus emblica</i> Bibhitaki- <i>Terminalia belerica</i>	Tridosahar, Kaphapitta shamak	Lekhan, Sanshodhan, Sanshaman, Anuloman, Krimighna, Rasayan	Anti-oxidant, Anti-inflammatory, Anti bacterial, Anti septic
Dashamula ³ • Bruhat Panchamula Bilva (<i>Aegle marmelos</i>) Agnimantha (<i>Premna mucronata</i>) Shyonak (<i>Oroxylum indicum</i>) Paatla (<i>Stereospermum suaveolens</i>) Gambhari (<i>Gmelina arborea</i>) • Laghu Panchamula Shaalparni (<i>Desmodium gangeticum</i>) Prshnaparni (<i>Uraria picta</i>) Bruhati (<i>Solanum indicum</i>) Kantakari (<i>Solanum xanthocarpum</i>) Gokshur (<i>Tribulus terrestris</i>)	Kaphavata shamak Vatapitta shamak	Shothahar, Shulahar	Analgesic, Anti-inflammatory, Smooth muscle relaxant
Varuna ³ (<i>Crateva nurvala</i>)	Vatakaphagna	Mutrala, Mutrjanan, Krimighna, Shotaghna, Ashmaribhedan, Shotaghna, Anuloman, Deepan, Jwaraghna	Diuretic, Lithotriptic, Antibacterial, Anti-inflammatory, stimulant,
Shuddha Shilajit ⁴ (Black butimen)	Vatakaphagna	Chedan, Shoshan, Lekhan, Parama Rasayan, Yogavahi, Mutral	Diuretic, lithotropic, Antiseptic, Tonic, Rejuvenative

the standard procedure of Ghana Vati preparation mentioned in Sharangdhar Samhitha.

Ethical Clearance for the study was taken from Institutional Ethical Committee DYP AYU. PG/2014-15/20-9-2015.

SELECTION CRITERIA:

INCLUSIVE CRITERIA:

- Male patients around the age of 50-70yrs of age

➤ Patients with signs and symptoms of B.P.H.

EXCLUSIVE CRITERIA:

- Complicated BPH(Grade III) with BOO, CA prostate, Diabetes Mellitus, Oliguria, Stric-

ture Urethra, Major diseases like HIV, Liver Cirrhosis, Kochs, IHD, Nephrotic Syndrome.

- Patients with CKD(Chronic Kidney Disease) on Dialysis
- Patients with suspected Neuropathic lesions such as in Diabetes, Tabes Dorsalis, Strokes, Parkinsons etc
- Patients with chronic retention (residual volume >250ml)
- Patients encountering recurrent episodes of retention and presented as Acute Urinary Retention

ASSESSMENT CRITERIA:

- Subjective criteria.- According to International Prostate Symptom Scorings (I.P.S.S) system.
 - Objective criteria. - By:
 - USG-(Prostate)
 - Prostate size.
 - Residual volume of urine
- AUA (American Urological Association) or IPSS Symptom Score⁵

Sr. No	Symptoms	Not at All	Less than 1 in 5 times	Less than ½ the time	About ½ the time	More than ½ 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.	Nocturia	0	1	2	3	4	5

SYMPTOM SCORE:

1-7 (Mild)

8-19 (Moderate)

20-35 (Severe)

DIAGNOSTIC CRITERIA

➤ Signs & Symptoms :-

- Increased frequency of urination with increased Nocturnal Volume
- Urgency and hesitancy(worsened if bladder is full)
- Incomplete emptying of bladder with intermittent stream
- Weak stream (poor flow-unimproved by straining)

INVESTIGATION

Essential Blood tests:

- CBC with ESR, BUN, Sr .Creat
- Blood Sugar 1) Fasting 2) PPBS
- Urine Routine and microscopic
- USG- Prostate with post void residual volume before and after T/t
- Sr.PSA

ASSESSMENT RESULT

Assessment Result was made before and after treatment on the basis of gradation which is mentioned above in subjective and objective parameters. The assessment of the effect of therapy was totally based on the standard AUA/IPSS sheets .Symptomatic relief of the patient was the main aim and the effect of therapy was assessed in terms of⁶

Cured	100% relief in symptoms
Relieved	75 to 100% relief in symptoms
Markedly improved	50 to 75% relief in symptoms
Improved	25 to 50% relief in symptoms
Unchanged	<25% or no relief to symptoms

OBSERVATIONS & RESULT:

The efficacy of T. Prostocare and C. Tamsulosin has been studied in 60 patients of BPH. These patients were divided into two groups viz

Group A: Tab. Prostocare 500mg and Group B: Cap. Tamsulosin 0.4mg

The observed data is grouped under two headings- Demographic analysis and clinical efficacy of treatment during study.

Demographic analysis-

Age Wise:- The age wise distribution of 60 patients was divided into five groups 5 patients (8.3%) belonged to age group 50-54yrs, 9 patients (15.0%) belonged to age group 55-59yrs, 15 patients (25%) belonged to age group 60-64yrs, 21 patients(35.0%) belonged to age group 65-69yrs and 10 patients (16.7%) belonged to age group 70-74yrs

Religion wise:- Out of 60 patients observed and selected in the study 43 patients (71.7%) were Hindu,9 patients (15.0%) were Muslim, 2 patients (3.3%) were Christian and 6 patients (10.0%) were Buddhist.

Education wise:-Out of 60 patients observed, 7 patients (11.6%) were illiterate, 37 patients (61.66%) were educated upto H.S.C, 10 patients (16.66%) were graduates and 6 patients (10%) were post graduates.

Marital Status:- Out of 60 patients observed all the 60 patients 100% were married. Unmarried patients were not found during the study

Occupation wise:- Out of 60 patients observed,10 patients (16.7%) were businessman,

33 patients (55%) were retired people and 17 patients (28.3%) were in service.

Addiction:- Out of 60 patients observed, 9 (15.0%) patients had addiction of Alcohol, 14 (23.3%) patients had addiction of Tobacco, 3 (5.0%) patients had addiction of Cigarette and 34 (56.7%) patients found to have no addiction.

Diet:- Out of 60 patients observed, 15 patients (25%) were vegetarians and 45 patients (75%) were non- vegetarians

Duration of Disease:- Out of 60 patients observed,23 (38.3%) patients were found to be facing symptoms of BPH since less than 1year and 37 (61.7%) patients were found to be facing symptoms of BPH since 1yr and above.

Prakruti wise:- Out of 60 patients observed, 3 (5.0%) patients had *Kaphapitta prakruti*, 9 (15.0%) patients had *Kaphavata prakruti*, 3 (5.0%) patients had *Pittakapha prakruti*, 5 (8.3%) patients had *Pittavata prakruti*, 21 (35.0%) patients had *Vatakapha prakruti* and 19 (31.7%) patients had *Vataapitta prakruti*.

Koshtha wise:- Out of 60 patients observed, 32 (53.3%) patients had *Krura Koshtha*, 4 (6.7%) patients had *Mrudu Koshtha* and 24 (40%) patients had *Madhyam Koshtha*

Agni wise:- Out of 60 patients observed, 29 (48.3%) patients had *Madhyam Koshtha* ,3 (5.0%) patients had *Sama Koshtha* ,14 (23.3%) patients had *Tikshna Koshtha* and 14 (23.3%) patients had *Visham Koshtha*

Assessment of Results

Table 1: Before and after experiment of Patients in Group A

Parameters	Experiment	Group A - Code (%)					
		Not at all	Less than 1 in 5 times	Less than 1/2 the time	About 1/2 the time	More than 1/2 the time	Almost always
Incomp Emptying	Before	0(0.0%)	0(0.0%)	13(43.3%)	16(53.3%)	0	1(3.3%)
	After	14(46.7%)	16(53.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Frequency	Before	1(3.3%)	21(70.0%)	8(26.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	After	22(73.3%)	8(26.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Intermittency	Before	1(3.3%)	17(56.7%)	12(40%)	0(0.0%)	0(0.0%)	0(0.0%)
	After	18(60.0%)	12(40%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Urgency	Before	0(0.0%)	0(0.0%)	23(76.7%)	6(20.0%)	1(3.3%)	0(0.0%)
	After	21(70%)	9(30%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Weak Stream	Before	0(0.0%)	0(0.0%)	20(66.7%)	9(30%)	1(3.3%)	0(0.0%)
	After	19(63.3%)	11(36.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Straining	Before	2(6.7%)	3(10%)	18(60%)	6(20%)	1(3.3%)	0(0.0%)
	After	23(76.7%)	7(23.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Nocturia	Before	5(16.7%)	5(16.7%)	8(26.7%)	11(36.7%)	1(3.3%)	0(0.0%)
	After	20(66.7%)	10(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

Out of 30 patients in group A assessing the symptomatic relief for Seven Parameters of IPSS scores ranging from 0 to 5 for each parameters

Result: Above table shows that Tab. Prostocare is having effect on all 7 parameters of IPSS and shows effect on reducing AUA score.

Table 2: Wilcoxon Test (Group A)

Parameters Group A	Wilcoxon sign rank test (Z)	P-value	Significant at 5% level
Incomp Emptying	5.103	P<0.001	Yes
Frequency	5.063	P<0.001	Yes
Intermittency	4.994	P<0.001	Yes
Urgency	5.260	P<0.001	Yes
Weak Stream	5.104	P<0.001	Yes
Straining	4.840	P<0.001	Yes
Nocturia	4.462	P<0.001	Yes

Result: Above Table shows statistically highly significant at 0.01% level i.e., p<0.001 for all

seven parameters of IPSS. Hence Phytotherapy is effective in reducing all 7 symptoms of IPSS.

Table 3: Before and after experiment of Patients in Group B

Parameters	Experiment	Group B - Code (%)					
		Not at all	Less than 1 in 5 times	Less than 1/2 the time	About 1/2 the time	More than 1/2 the time	Almost always
Incomp Emptying	Before	0(0.0%)	3(10.0%)	17(56.7%)	8(26.7%)	1(3.3%)	1(3.3%)
	After	14(46.7%)	15(50.0%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)
Frequency	Before	0(0.0%)	8(26.7%)	14(46.7%)	6(20.0%)	2(6.7%)	0(0.0%)
	After	24(80.0%)	5(16.7%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)

Intermittency	Before	0(0.0%)	5(16.7%)	16(53.3%)	7(23.3%)	2(6.7%)	0(0.0%)
	After	18(60.0%)	11(36.7%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)
Urgency	Before	0(0.0%)	6(20.0%)	15(50.0%)	7(23.3%)	2(6.7%)	0(0.0%)
	After	19(63.3%)	10(33.3%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)
Weak Stream	Before	0(0.0%)	6(20.0%)	16(53.3%)	6(20.0%)	2(6.7%)	0(0.0%)
	After	21(70.0%)	9(30.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Straining	Before	0(0.0%)	8(26.7%)	16(53.3%)	4(13.3%)	3(10.0%)	0(0.0%)
	After	20(66.7%)	10(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Nocturia	Before	0(0.0%)	8(26.7%)	18(60.0%)	2(6.7%)	1(3.3%)	1(3.3%)
	After	21(70.0%)	9(30.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

Out of 30 patients in Group B assessing the symptomatic relief for Seven Parameters of IPSS scores ranging from 0 to 5 for each parameters

Result: Above table shows that C. Tamsulosin (Group B) is having effect on all 7 parameters of IPSS and shows effect on reducing AUA score.

Table 4: Wilcoxon Test (Group B)

Parameters Group B	Wilcoxon sign rank test (Z)	P-value	Significant at 5% level
Incomp Emptying	4.932	P<0.001	Yes
Frequency	4.945	P<0.001	Yes
Intermittency	4.950	P<0.001	Yes
Urgency	4.950	P<0.001	Yes
Weak Stream	4.871	P<0.001	Yes
Straining	4.881	P<0.001	Yes
Nocturia	4.903	P<0.001	Yes

Result:- Above Table shows statistically highly significant at 0.01% level i.e., p<0.001 for all

seven parameters of IPSS. Hence C. Tamsulosin is effective in reducing all 7 symptoms of IPSS.

Table 5: Laboratory investigation before and after experiment of Patients: Group A

Parameters Group A	Experiment	N	Mean	Stdev	Paired T test	P_value	Significant at 5% level
Hb	Before	30	12.4700	1.9193	3.887	.001	Yes
	After	30	12.8200	1.6541			
RBC	Before	30	4.1200	.6150	2.193	.036	Yes
	After	30	4.2167	.4594			
WBC	Before	30	6753.3333	1572.5519	0.548	.588	No
	After	30	6803.3333	1386.5072			
Blood Sugar Level Fasting	Before	30	100.1000	13.3219	0.306	.762	No
	After	30	99.7000	14.2929			
Blood Sugar Level PP	Before	30	121.3333	19.7839	0.964	.343	No
	After	30	119.9333	16.4860			
ESR	Before	30	18.1000	13.3555	0.147	.884	No
	After	30	18.3333	8.9648			
Sr. Creatnine	Before	30	.9600	.1850	1.439	0.161	No
	After	30	.9533	.1833			

Bun	Before	30	18.5267	3.2344	0.690	.496	No
	After	30	18.3333	2.2944			
Epithelial cells	Before	30	.8000	1.3995	3.131	.004	Yes
	After	30	.0000	.0000			
Pus Cells/Bacteria	Before	30	2.2333	4.4387	2.757	0.010	Yes
	After	30	.0000	.0000			
RBC	Before	30	0.06667	.3651	1.000	.326	No
	After	30	.0000	.0000			
Sr PSA	Before	30	2.8670	.9888	12.234	<0.001	Yes
	After	30	1.6233	.6621			
Size of prostate in cm ³	Before	30	68.2804	13.3396	3.240	.003	Yes
	After	30	64.4660	10.7907			
Weight of Prostate	Before	30	34.1000	5.1149	1.379	.178	No
	After	30	33.6800	5.9928			
Post Void Residual Volume (ml)	Before	30	67.0667	35.7404	12.379	<0.001	Yes
	After	30	7.9000	10.6717			

Result: Above investigational findings shows **statistically significant results** on Haemoglobin (p value 0.001), Pus cells (p value 0.010) and epithelial cells in Urine (p value 0.004), Sr. PSA (p value <0.001), Size of Prostate (p value 0.003) and Post Void Residue (p value <0.001). While **statistically insignificant results** on Total WBC count (p value 0.588), ESR (p value 0.884), Blood Sugars Fasting (p value 0.762) and Post Prandial (p value 0.343), Sr. Creat (p

value 0.161), BUN (p value 0.496) and on Weight of Prostate (p value 0.178)

Hence we conclude that Group A phytotherapy is effective in raising Haemoglobin and reducing Sr. PSA, Size of Prostate, Post Void Residual Volume and epithelial cells, pus cells in urine

No effect of drug is seen on weight of prostate, Blood sugars (Fasting, Post- prandial), Sr. Creat, BUN, Total WBC count and ESR

Table 6: Laboratory investigation before and after experiment of Patients: Group B

Parameters Group B	Experiment	N	Mean	Stdev	Paired T test	P_value	Significant at 5% level
Hb	Before	30	12.2000	1.2515	0.165	.870	No
	After	30	12.1867	1.2264			
RBC	Before	30	4.1100	.2808	1.795	0.083	No
	After	30	4.1000	.2767			
WBC	Before	30	6440.0000	1638.8810	0.940	.355	No
	After	30	6510.0000	1481.4601			
Blood Sugar Level Fasting	Before	30	94.2000	9.0987	0.084	.934	No
	After	30	94.2667	8.6421			
Blood Sugar Level PP	Before	30	122.7000	6.9140	0.112	.911	No
	After	30	122.8000	6.8602			
ESR	Before	30	14.2333	7.5278	0.405	.689	No
	After	30	13.9667	5.4487			
Sr. Creatinine	Before	30	.8800	.1669	0.320	.752	No
	After	30	.8733	.1484			

Bun	Before	30	18.7000	1.8411	0.361	.721	No
	After	30	18.6000	1.4044			
Epithelial cells	Before	30	.9333	1.5071	2.045	.050	Yes
	After	30	.2000	1.0954			
Pus Cells/Bacteria	Before	30	1.0667	2.3771	2.458	.020	Yes
	After	30	.0000	.0000			
RBC	Before	30	.0000	.0000	-	-	No
	After	30	.0000	.0000			
Sr PSA	Before	30	2.8857	1.0114	12.363	<0.001	Yes
	After	30	1.3967	.5922			
Size of prostate in cm ³	Before	30	68.7608	16.4009	1.597	1.21	No
	After	30	72.0149	14.5154			
Weight of Prostate	Before	30	37.2133	7.7708	0.384	.704	No
	After	30	37.2467	7.7707			
Post Void Residual Volume (ml)	Before	30	64.2000	48.0434	3.007	.005	Yes
	After	30	33.0333	35.5620			

Result: Above investigational findings shows statistically significant results on Pus cells (p value 0.020), epithelial cells in Urine (p value 0.050), Sr. PSA (p value <0.001) and Post Void Residue (p value 0.005).

While statistically insignificant results were obtained on Total WBC count (p value 0.355), ESR (p value 0.689), Blood Sugars Fasting (p value 0.934) and Post Prandial (p value 0.911), Sr. Creat (p value 0.752), BUN (p value 0.721),

Size of Prostate (p value 1.21) and on Weight of Prostate (p value 0.704)

Hence we conclude that C. Tamsulosin Group B is effective in reducing Sr. PSA, Post Void Residual Volume and epithelial cells, pus cells in urine.

No effect of drug is seen on weight of prostate, Blood sugars (Fasting, Post-prandial), Sr. Creat, BUN, Hb, Total WBC count, ESR and Size of Prostate.

Table 7: Effect on General AUA symptom Group A & Group B

S.N.	Symptoms	Group-A - Treatment				Group-B-Treatment			
		Before	After	Difference (BT-AT)	%	Before	After	Difference (BT-AT)	%
1	Incomp Emptying	79	16	63	79.7	70	17	53	75.7
2	Frequency	67	8	59	88.1	62	7	55	88.7
3	Intermittency	71	12	59	83.1	66	13	53	80.3
4	Urgency	68	9	59	86.8	65	12	53	81.5
5	Weak Stream	71	11	60	84.5	64	9	55	85.9
6	Straining	61	7	54	88.5	60	10	50	83.3
7	Nocturia	58	10	48	82.8	59	9	50	84.7

Table 8: Showing Total Effect of Therapy in Group –A & Group – B

Effect	Group-A	Percentage	Group-B	Percentage
Cured	9	30.0	7	23.3
Relieved	20	66.7	20	66.7

Markedly Improved	1	3.3	3	10.0
Improved	0	0.0	0	0.0
Unchanged	0	0.0	0	0.0
Total	30	100.0	30	100.0

Out of 30 patients Observed in Group A

9 patients (30.0%) were cured, showed 100% relief in the symptoms of B.P.H by AUA score.

20 patients (66.7%) were relieved, showed 75 to 100% relief in the symptoms of B.P.H by AUA score.

1 patient (3.3%) was markedly improved, showed 50 to 75% relief in the symptoms of B.P.H by AUA score.

Out of 30 patients Observed in Group B

7 patients (23.3%) were cured, showed 100% relief in the symptoms of B.P.H. by AUA score
20 patients (66.7%) were relieved, showed 75 to 100% relief in the symptoms of B.P.H by AUA score

3 patients (10.0%) were markedly improved, showed 50 to 75% relief in the symptoms of B.P.H by AUA score

Table 9: Independent T Test applied to Post Void Residual Volume and Sr. PSA

Parameters	Group	N	Mean (Diff. Value of reduction)	Stdev (Diff. Value)	T test	P-value	Significant at 5% level
Postvoid residue	Group –A	30	59.1667	26.1799	2.453	0.017	Yes
	Group – B	30	31.1667	56.7712			
Sr PSA	Group –A	30	1.2467	.5551	-1.549	0.127	No
	Group – B	30	1.4900	.6572			

Result:- The above table shows the reduction value before and after experiment in group A and group B. Only Post void residue is statistically significant at 5% level i.e., $P < 0.05$ in group A and group B. The mean difference of Group A is more than Group B, Hence Group A is much effective in reducing Post Void Residual Volume than Group B. But Sr PSA is not statistically significant at 5% level i.e., $P > 0.05$ in group A and group B. In Sr PSA mean difference of Group B is more than Group A, Hence Group B is more effective in reducing Sr PSA than Group A.

DISCUSSION

The main aim of treatment was –

- 1) To provide symptomatic relief and
- 2) Prevent U.T.I associated with B.P.H, to prolong surgery as far as possible, to improve quality of life of the patients.

PROBABLE MODE OF ACTION-

According to Ayurvedic view pathology behind symptoms due to benign enlargement of prostate (*Vata- ashtila*) is mostly based upon vitiation of *Vata pradhan Tridosha* and obstruction in the *Mutravaha srotas*.

Hence the treatment should be aimed at maintenance of *Dosha samya* and *srotoshodhan*.

1. Increase in Urine Flow Rate and Urine Volume

Shuddha Shilajit and *Varuna* are *Mutral* (Diuretic) dravyas, *Dashmool* is an excellent *Vataghna dravya* which controls the vitiated *Vata* and this effectively increases the urine flow rate and thus reduce the symptoms like Intermittency, Urgency, Weak stream, Incomplete emptying and Straining. *Triphala* is a good *anuloman dravya*. In *Vata-ashthila apanvayu* gets vitiated causing different symptoms. As *triphala* is *vatanulomak* and it specially acts on

apan vayu, it will control the vitiated apan vayu thus reducing the symptoms of the patients of *Vata-ashthila*. All these drugs in the Phytotherapy combination ultimately increase the urinary flow rate and thus reduce the post void residual urine volume.

2. Antibacterial activity:-

Triphala, *Varuna* and *Ashwagandha* has good antibacterial activity (*krimighna*). This helps in curing the U.T.I. and Cystitis associated with B.P.H. and so reduces burning micturation.

3. Antioxidant activity:-

Ashwagandha, *Triphala* & *Shuddha Shilajit* have potent Antioxidant properties. These are good *Rasayan Dravyas* also. So they give the expected strength to the affected organ and thus help in curing the symptoms of B.P.H. They also give general strength and increase the immunity power in the old age of patients of B.P.H.

4. Anti inflammatory activity:-

Dashmool, *Varuna* & *Ashwagandha* possess anti inflammatory activity. *Dashmool* is a good *shothahar dravya* so it reduces this *shotha* and reduces the obstruction in the pathway of urine and increases the rate of flow of urine. As narrated in *Bhavprakash Varuna* is *Mutrajanana*, *Mutrala* and *Shothaghna* so it will reduce the obstruction in the pathway of urine and will increase the urine flow rate. *Ashwagandha* has astringent action so it is useful in reducing the prostatic congestion. This will reduce the inflammation, reducing the obstruction in the pathway of urine.

5. Analgesic and Antispasmodic activity:-

Dashmool is an excellent *Vataghna dravya*, so it will control the vitiated vata and thus act as an analgesic (*shoolghna*) and antispasmodic drug in the combination.

6. Effect on Vata Dosha:-

Ashwagandha and *Dashmool* are *Vataghna dravyas* due the *vatahar guna* they possess. This will act on the vitiated vata dosha and thus cure the symptoms of *Vata-ashthila*. *Triphala* is a good *Vatanuloman dravya*, it will act on the vitiated *apan vayu* and thus reduce the symptoms of *Vata-ashthila*.

7. Effect on Hormonal Imbalance:-

One of the reasons of prostatic enlargement is the imbalance between the testosterone and oestrogen hormone. As the age advances the level of testosterone hormone decreases and as a result estrogen hormone dominates the individual. It is under the influence of this estrogen hormone the enlargement of prostate takes place. As per the research paper available on net by Abdel-magied EM, Abdel Rohman HA, Harazem they conclude in their research that *Ashwagandha* increases the serum testosterone level. So this might reduce the imbalance between the testosterone and estrogen and reduce the symptoms of B.P.H. This is the possible mechanism of action kept forward for the results obtained in the patients of Group A (Tab.Prostocare). This Phytotherapy combination has already proven its symptomatic relief in the patients of B.P.H (Grade I & II) in this study, also reduce the size and PVR of the Prostate except Weight of Prostate giving curative relief in the patients of Benign Prostatic Hypertrophy

8. Effect on Size of Prostate:- *Triphala* and *Shuddha Shilajit* both in combination synergistically performs *lekhan karya* and helps in reducing size of Prostate in Grade I and Grade II Prostatomegaly.

Actions of Tamsulosin

This is uroselective $\text{Alpha}_{1A}/\text{Alpha}_{1D}$ blocker hence appears to cause fewer vascular side effects. It causes the smooth muscles of Prostate

and Bladder neck to relax and thus increases the urine flow rate. Since activation of Alpha₁ adrenoceptors in bladder trigone, prostate and prostatic urethra increases smooth muscle tone, their blockade relaxes these structures, reducing dynamic obstruction, increasing urinary flow rate and causing more complete emptying of bladder in many patients of BPH. The Alpha₁ blockers afford faster (within 2 weeks) and greater symptomatic relief compared with Finasteride.⁷

Elaboration of Cost Effectivity

Tab. Prostocare comparative with Cap. Tamsulosin 0.4mg is much cost effective as 15capsules strip of Cap. Tamsulosin 0.4mg (URIMAX 0.4) costs 165 INR i.e. per tablet 11 rupees costing. Whereas Tab. Prostocare 15,000 tablets were prepared along with raw materials, processing, manufacturing, storage and packaging for 15,000 INR i.e. 1 rupee per tablet. Hence Tab. Prostocare is much cheaper compared to Cap. Tamsulosin 0.4mg.

CONCLUSION

Our Aim was to see whether this Phytotherapy combination works out as good as the highly selective Alpha₁Adrenoceptor blocker, Cap. Tamsulosin 0.4mg. The statistics obtained clearly show equivalent results of the Phytotherapy combination. Therefore, on the basis of analysis of the recorded observations and results, there is no hesitation to state that a Phytotherapy Combination has definite effect on Benign Prostate Hypertrophy (Grade I & II) in reducing LUTS and could therefore provide an alternative for the existing modalities of its management.

From the results obtained in the study we can conclude that:-

- 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 nocturea.
- 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.

FUTURE SCOPE AND LIMITATIONS:

Further Scope of study

Tab. Prostocare 500mg is statistically and equally effective to Cap. Tamsulosin in reducing LUTS secondary to BPH (Grade I & II), as in our study the sample size was less, this study needs more elaboration at multicentric levels with Uroflowmetry Studies.

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