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A Clinical Study to Evaluate the Efficacy of a Herbo-Mineral Formulation (PROSGUARD Capsule) in the Management of Benign Prostatic Hyperplasia (BPH)

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ABSTRACT

Benign prostatic hyperplasia (BPH) is a non-cancerous (benign) enlargement of the prostate gland. It is the most common cause of lower urinary tract symptoms (LUTS) in males such as increased frequency of urination, trouble starting to urinate, weak stream, post-micturition dribbling, inability to urinate, urinary incontinence, dysuria etc. Multiple surgical and non-surgical options are there for the treatment of BPH which have their own limitations. Hence to find out a safe, economic and suitable medical solution for BPH remains a challenging task. The present study was conducted to evaluate the efficacy of an Ayurvedic Herbo-mineral formulation (PROSGUARD Capsule) in the comprehensive management of BPH. For clinical trial 50 nos. of male patients with BPH were selected following criteria of inclusion. They were randomly assigned to the Trial Group & Control Group having 40 and 10 patients, respectively. The Trial Group was treated with PROSGUARD and the Control Group was treated with Tamsulosin for a period of 45 days. Subjective assessment was done by parameters like improvement in the International Prostate Symptoms Score (IPSS) and improvement in Quality of Life (QOL) Score, both of which are approved by American Urological Association. Parameters like reduction in Prostate size, reduction in Post Void Residual Urine (PVRU) volume based on USG findings and reduction in Prostate Specific Antigen (PSA) level were used for objective assessment. PROSGUARD was found to be effective in both subjective and objective criteria with statistical significance. The results of PROSGUARD were better than Tamsulosin in most of the parameters. Moreover, in terms of safety, tolerance and economy, PROSGUARD was far ahead of Tamsulosin.

KEYWORDS Herbo-mineral, Prosguard, BPH, Management

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common senile problem. It is also called benign enlargement of the prostate (BEP or BPE). BPH is a non-cancerous increase in size of the prostate gland[1]. The enlargement occurs due to hyperplasia of prostatic stromal and epithelial cells, resulting in the formation of large, fairly discrete nodules in the transition zone of the prostate[2]. BPH is the most common cause of lower urinary tract symptoms (LUTS), which are divided into storage, voiding, and symptoms which occur after urination[3]. Storage symptoms include the need to urinate frequently, waking at night to urinate, urgency (compelling need to void that cannot be deferred), involuntary urination, including involuntary urination at night, or urge incontinence (urine leak following a strong sudden need to urinate)[4]. Voiding symptoms include urinary hesitancy (a delay between trying to urinate and the flow actually beginning), intermittency (not continuous)[5] , involuntary interruption of voiding, weak urinary stream, straining to void, a sensation of incomplete emptying, and terminal dribbling (uncontrollable leaking after the end of urination, also called post-micturition dribbling)[6, 7, 8]. These symptoms may be accompanied by bladder pain or pain while urinating, called dysuria [9].

Adenomatous prostatic growth is believed to begin at approximately at the age of 30. An estimated 50% of men have histological evidence of BPH by the age of 50 years and 75% of men at the age of 80 out of this, BPH become clinically significant in 40–50% of cases [10].

BPH can be correlated with *Vatasthila* which comes under *Mootraghata* and it is caused due to vitiated *Vata* and *Kapha* which involve *Mootravaha Srotodushti.*

It is a very common problem of elderly men and no definitive conservative cure is available. However, a multiple options including surgical and minimal invasive methods are available at present for the management of BPH which have their own limitations. Hence it always remains a challenge to find out a safe, economic, suitable Medical management for BPH.

The present study is an *Ayurvedic* approach towards the comprehensive management of BPH. The drug Prosguard is a herbo-mineral preparation containing *Swarna Makshika Bhasma* (Oxide of Iron Pyrite), Praval (Coral) Pishti, *Shilajit (Asphaltum punjabianum), Kababchini (Piper cubeba), Khas (Vetiveria zizanioides), Sweta Chandan (Santalum album), Punarnava (Boerhaavia diffusa), Gokshura (Tribulus terrestris), Hapusha*

*(Juniperus communis)*and *Varuna (Crataeva nurvala)*, which are specially described by *Ayurvedic* classic for the treatment of *Mootraghata.*

MATERIALS AND METHODS

Following the criteria of selection, 50 cases of BPH patients were selected for the purpose of the study from the OPDs of Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha.

Inclusion Criteria

- Male patients in the age group of 40 to 80 years.
- Patients diagnosed as BPH by both clinical sign symptoms and USG were included

Exclusion Criteria

- Malignancy of Urogenital System
- Congenital deformities of Urogenital Tract
- PSA > 6.9 ng/ml (Maximum Normal Reference Range in patients between 70 – 79 years by De Antoni et al)
- Conditions like renal failure, ureteric calculus, renal calculus and chronic UTI
- Patients with Diabetes, Hypertension, Cardiac problems and Liver Diseases

Study Design

This was a prospective single blind, randomized and standard controlled, Phase –III clinical study.

Place and Duration of the Study

The 6 months study was conducted at Gopabandhu Ayurveda Mahavidyalaya& Hospital, Puri, Odisha, which is a premier Ayurveda institute in Eastern India.

Approval of Institutional Ethics Committee (IEC)

The project proposal was put for review before the Institutional Ethical Committee (IEC) and research work was started after obtaining clearance of the IEC on 28th May 2017.

Patient Selection, Grouping and Registration

Male patients, 50 nos. , were selected with their informed consent and randomly assigned into two groups by using computerized randomization method. General Examination and DRE was conducted for every patient in the study. Pathological Investigations and Ultrasonography (USG) were conducted as per the following protocol.

- FBS/PPBS (Done only once before treatment to exclude Diabetes)
- Urine RE & ME, PSA (Prostate Specific Antigen), LFT & RFT (Both before and after Treatment)

- USG (Both before and after Treatment)

All these information were recorded in a well-designed research case sheet. The patients were called for follow-up in every 15 days. All relevant informations were recorded in the case sheet at every follow up visit.

1. Group-I (Trial Group) – Included 40 patients who were treated with the Trial Drug (Prosguard Capsule) but there was a drop out of 2 patients in the mid of the trial. Hence, only 38 patients completed the trial.
2. Group-II (Control Group) – Included 10 patients who were treated with standard Control Drug (Tamsulosin). However, only 9 patients could complete the trial and 1 patient dropped out before completion of the study.

Drugs, Dose and Duration of Therapy

The Trial Drug was manufactured by GoodcarePharmaPvt. Ltd., Bagi Mouza, Bishnupur, 24 Parganas W.B and approved by Dept. of ISM, Govt. of West Bengal.

- Group-I (Trial Group) - Prosguard capsule was given in a dose of 2 capsules twice daily after food with water for a period of 45 days.
- Group-II (Control Group) - Tab. Tamsulosin 0.4 mg was given once daily after food with water for a period of 45 days.

Composition of the Trial Drug (Prosguard Capsule)

Each 550 mg Capsule contains	
Swarna Makshik Bhasma	225 mg
Praval Pishti	55 mg
Shudh Shilajit (Purified Asphaltum)	82 mg
Kababchini (*Piper cubeba*)	10 mg
Khas (*Veteveria zizanoides*)	10 mg
Sweta Chandan (*Santalum album*)	10 mg
Punarnava Ghanasatwa (Extract of *Boerhaavia diffusa*)	3 mg
Khas Ghanasatwa (Extract of *Veteveria zizanoides*)	2 mg
Gokshura (*Tribulus terrestris*)	70 mg
Hapusa Ghanasatwa (Extract of *Juniperus communis*)	55 mg
Varun Ghanasatwa (Extract of *Crataeva nurvala*)	28 mg

Assessment Criteria

Efficacy of Trial and Control Drug were assessed by improvement in IPSS rating scale score (Table – 1) given below which is approved by American Urological Association and USG findings (Prostate size & Post Void Residual Urine volume).

Table 1 IPSS Rating Scale

Symptoms	Never	Less than 1 time in 5 times	Less than half the time	About half the time	More than half the time	Almost all the time
Incomplete emptying	0	1	2	3	4	5
Increase frequency	0	1	2	3	4	5
Intermittency	0	1	2	3	4	5
Urgency	0	1	2	3	4	5
Weak stream	0	1	2	3	4	5
Straining	0	1	2	3	4	5
Nocturia	None	1 time	2 time	3 time	4 time	5 time
	0	1	2	3	4	5

Quality of Life (QOL) due to BPH was assessed by scoring system approved by American Urological Association (Table No - 2). Safety was assessed by incidence of adverse effects and laboratory evaluation of RFT, LFT with clinical biochemistry.

Table 2 Assessment of Quality Of Life Due To BPH

Quality of Life Due To Urinary Symptoms						
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?						
Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
0	1	2	3	4	5	6

Statistical Analysis

For assessing effect of therapy on each subjective and objective parameter, paired‘t’ test was applied as the test of significance. Statistical calculations were done online by using statistical software on www.graphpad.com.

OBSERVATION & RESULTS

Obesity, diabetes, physical inactivity and alcohol intake may substantially influence the risk of benign prostatic hyperplasia and lower urinary tract symptoms in older men[11]. Our observations in the present study with respect to risk factors were also in alignment with this reference (Table -3).

Table 3 Analysis of Risk Factors

RISK FACTORS	**TRIAL GROUP**		**CONTROL GROUP**	
	n	**%**	**n**	**%**
Positive Family History	9	23.68	3	33.33
Obesity	14	36.84	3	33.33
Alcohol Consumption	8	21.05	2	22.22
Sedentary Life Style	16	42.11	4	44.44
Prolonged Use of Beta Blockers	2	5.26	1	11.11

BPH is a disease predominantly found in the elderly males[12]. In the present study the sample size was dominated by elderly patients in the age group of 60 – 70 years in

both Trial Group (58%) and Control Group (55%).

As a protocol of the study 7 most frequently encountered subjective symptoms such as incomplete emptying, frequency of micturition, intermittency, urgency to pass urine, weak stream during urine output, straining during urination and nocturia (the complaint that the individual has to wake at night one or more times for voiding) were considered as subjective criteria to assess the outcome of the study. Every symptom was scored in a self assessment rating scale from 0 – 5 (IPSS) where "0" stands for no symptoms and "5" stands for having the symptoms most of the times. A total IPSS score was calculated by adding the individual scores. This exercise was done twice i.e. both before and after treatment to analyse the improvement.

Analysis of frequency of different symptoms in patients of both groups is summarised in Table – 4.

Table 4 Analysis of Subjective Symptoms

Symptoms	Group	n	%
Incomplete emptying	Group -I (TG)	38	100
	Group - II (CG)	9	100
Frequency	Group -I (TG)	38	100
	Group - II (CG)	9	100
Intermittency	Group -I (TG)	28	73.68
	Group - II (CG)	6	66.67
Urgency	Group -I (TG)	23	60.53
	Group - II (CG)	5	55.56
Weak stream	Group -I (TG)	27	71.05
	Group - II (CG)	7	77.78
Straining	Group -I (TG)	38	100
	Group - II (CG)	9	100
Nocturia	Group -I (TG)	33	86.84
	Group - II (CG)	7	77.78
Total IPS Score	Group -I (TG)	38	100
	Group - II (CG)	9	100

- Out of the above 7 symptoms, incomplete emptying, frequency and straining were invariably found in every patient of either group as these are quite troublesome for which the patient seeks medical advice.
- Nocturia was the second most common symptom followed by weak stream in both the groups. It means that the patient has to frequently wake up in the night for passing urine which interferes with his sleep quality. Disturbed sleep in old age can be a triggering factor for many other co-morbid conditions.
- Weak stream is due to partial blockage of the urinary passage because of swelled prostate gland.

- Urgency was the least frequently encountered symptom. Every patient of BPH may not feel the same urgency to pass the urine depending on the bladder capacity.

Both Prosguard and Tamsulosin were found to be effective in improving different symptoms of BPH.

The improvements were also statistically found to be extremely significant. Total IPS score was also extremely significantly reduced in both Trial & Control Groups. However, the results of Prosguard were found to be better in every subjective parameter as compared to Tamsulosin (Table – 5).

Table 5 Effectiveness of Trial Drug & Control Drug in Subjective Parameters

Parameter	Group		Mean ± SD	↓↑	d.f (n-1)	t - Value	p - Value	Interpretation
Incomplete emptying	Group -I (TG)	BT	4.12 ± 0.73	↓	37	24.71	< 0.0001	Extremely Significant
		AT	0.52 ± 0.48					
	Group - II (CG)	BT	4.29 ± 0.62	↓	8	10.45	< 0.0001	Extremely Significant
		AT	1.83 ± 0.74					
Frequency	Group -I (TG)	BT	4.51 ± 0.77	↓	37	22.72	< 0.0001	Extremely Significant
		AT	1.02 ± 0.72					
	Group - II (CG)	BT	4.07 ± 0.53	↓	8	10.22	< 0.0001	Extremely Significant
		AT	2.32 ± 0.73					
Intermittency	Group -I (TG)	BT	3.72 ± 0.79	↓	28	20.34	< 0.0001	Extremely Significant
		AT	0.88 ± 0.62					
	Group - II (CG)	BT	4.12 ± 0.71	↓	6	10.28	< 0.0001	Extremely Significant
		AT	1.98 ± 0.81					
Urgency	Group -I (TG)	BT	3.92 ± 0.91	↓	23	19.58	< 0.0001	Extremely Significant
		AT	0.98 ± 0.57					
	Group - II (CG)	BT	3.94 ± 0.77	↓	5	11.97	< 0.0001	Extremely Significant
		AT	1.72 ± 0.71					
Weak stream	Group -I (TG)	BT	3.38 ± 1.61	↓	27	9.52	< 0.0001	Extremely Significant
		AT	0.99 ± 0.53					
	Group - II (CG)	BT	3.65 ± 1.52	↓	7	7.18	< 0.0001	Extremely Significant
		AT	1.58 ± 1.08					
Straining	Group -I (TG)	BT	4.42 ± 0.71	↓	37	23.33	< 0.0001	Extremely Significant
		AT	0.86 ± 0.61					
	Group - II (CG)	BT	4.28 ± 0.86	↓	8	9.61	< 0.0001	Extremely Significant
		AT	1.46 ± 0.91					
Nocturia	Group -I (TG)	BT	3.33 ± 0.81	↓	33	20.72	< 0.0001	Extremely Significant
		AT	0.90 ± 0.61					
	Group - II (CG)	BT	3.33 ± 0.84	↓	7	10.61	< 0.0001	Extremely Significant
		AT	1.06 ± 0.62					

Total IPS Score	Group -I (TG)	BT	27.63 ± 2.44	↓	37	53.62	< 0.0001	Extremely Significant
		AT	4.55 ± 1.37					
	Group - II (CG)	BT	27.23 ± 2.41	↓	8	23.23	< 0.0001	Extremely Significant
		AT	6.67 ± 2.27					
SD : Standard Deviation, d.f : Degree of Freedom								

Prostate volume (in cc) and Post Void Residual Urine volume (PVRU in cc) were taken as two USG based objective parameters to evaluate the efficacy of Prosguard and Tamsulosin. As per most Indian Urologists Prostate size between 15 – 30 cc and post void urine volume up to 50 cc should be considered normal for Indian elderly population[13, 14]. Both Prosguard and Tamsulosin were found effective in reducing Prostate size and Post Void Residual Urine volume as measured by USG. But reductions in both parameters were higher in case of Trial Group taking Prosguard Capsule proving its superiority (Table – 6).

Table 6 Effectiveness of Trial Drug & Control Drug in Objective Parameters

Parameter	**Group**		**Mean ± SD**	**↓↑**	**d.f (n-1)**	**t - Value**	**p - Value**	**Interpretation**
Prostate Volume (in cc)	Group -I (TG)	BT	38.72 ± 15.11	↓	37	4.82	< 0.0001	Extremely Significant
		AT	21.95 ± 7.88					
	Group - II (CG)	BT	35.21 ± 9.29	↓	8	4.91	< 0.0001	Extremely Significant
		AT	28.61 ± 6.82					
Post Void Residual Urine Volume (in cc)	Group -I (TG)	BT	49.21 ± 33.31	↓	37	4.41	< 0.0001	Extremely Significant
		AT	24.53 ± 16.22					
	Group - II (CG)	BT	48.51 ± 11.43	↓	8	4.43	< 0.0001	Extremely Significant
		AT	27.71 ± 7.54					
SD : Standard Deviation, d.f : Degree of Freedom								

Table 7**Effect of Trial Drug & Control Drug on Quality of Life**

Parameter	**Group**		**Mean ± SD**	**↓↑**	**d.f (n-1)**	**t - Value**	**p - Value**	**Interpretation**
Quality of Life Due to BPH	Group -I (TG)	BT	4.82 ± 0.81	↓	37	14.99	< 0.0001	Extremely Significant
		AT	2.03 ± 0.68					
	Group - II (CG)	BT	4.71 ± 0.83	↓	8	9.91	< 0.0001	Extremely Significant
		AT	2.62 ± 0.63					
SD : Standard Deviation, d.f : Degree of Freedom								

Though BPH is a benign condition of the prostate, it remains challenging till date as it vastly interferes with the quality of life in elderly population. It also causes psychological and social embracement. Therefore, Quality of Life (QOL) was also taken as a subjective criterion to assess the outcome of the study. Quality of Life (QOL) significantly improved after treatment in both Trial and Control Group.

But the improvement was slightly better in Trial Group taking Prosguard Capsule (Table – 7). Both Prosguard and Tamsulosin were found to reduce PSA level significantly. However, the effect of Prosguard was marginally higher than Tamsulosin in reducing the level of PSA (Table -8).

Table 8 Effect of Trial Drug & Control Drug on Prostate Specific Antigen (PSA)

Parameter	Group		Mean ± SD	↓↑	d.f (n-1)	t - Value	p - Value	Interpretation
PSA (in ng/ml)	Group -I (TG)	BT	1.74 ± 1.12	↓	37	7.43	< 0.0001	Extremely Significant
		AT	1.09 ± 0.69					
	Group - II (CG)	BT	1.79 ± 1.18	↓	8	3.11	0.0144	Highly Significant
		AT	1.13 ± 0.65					

SD : Standard Deviation, d.f : Degree of Freedom

Considering improvement in subjective parameters, objective parameters and Quality of Life, the overall assessment of result was done for every patient. The overall improvement was categorized into four different categories e.g. Excellent, Good, Satisfactory and Unsatisfactory based on some predefined criteria (Table – 9). The percentage of Excellent, Good, Satisfactory and Unsatisfactory results in Trial Group were 55 %, 26 % and 19 % respectively whereas, in Control Group the percentages were 45 %, 33 % and 22 % respectively (Table – 10).

Table 9 Criteria for Overall Assessment

Overall Assessment Category	Reduction in Total IPSS Score	Reduction in Prostate Volume (in cc)	Reduction in Post Void Residual Urine Volume (in cc)	Improvement in Quality of Life	Reduction in PSA (in ng/ml)
Excellent	≥ 20	≥ 15	≥ 20	≥ 2	≥ 0.5
Good	15 - 19	10 - 14	15 - 19	1.5 - 1.9	0.3 - 0.4
Satisfactory	10 - 14	5 - 9	10 - 14	1.0 - 1.4	0.2 - 0.1
Unsatisfactory	< 10	< 5	< 10	< 1	< 0.1

Note: While categorizing, performances in Individual parameter were considered. In case of tie, performances in objective parameters were given preference.

Table 10 Overall Assessment of Patients

Category	Group - I (Trial Group)		Group - II (Control Group)	
	No. of Patients	Percentage (%)	No. of Patients	Percentage (%)
Excellent Improvement	21	55 %	4	45 %
Good Improvement	10	26 %	3	33 %
Satisfactory Improvement	7	19 %	2	22 %
Unsatisfactory Improvement	0	0 %	0	0 %

It was observed that the number of incidences of Adverse Drug Reactions (ADR) was more in case Tamsulosin. Few incidences of dizziness, drowsiness, nausea, headache, back pain and gastric Irritation were reported by the patients of

Control Group taking Tamsulosin. Nausea and Gastric irritation required medical intervention and oral antacid syrup was prescribed for the complaining patients. On the other hand Prosguard was found to be absolutely safe and well tolerated except few cases of occasional Gastric irritation which subsided on their own without any medical intervention. However, neither Prosguard nor Tamsulosin were found to alter LFT or RFT in patients.

DISCUSSION

In Ayurvedic literature, *Mutraghata* refers to obstructive uropathy which mainly causes obstruction or difficulties to urine outflow. According to commentator Dalhana, *Mutraghata* should be understood as *Mutraavarodha*[15].

The signs and symptoms of BPH closely resemble the description of *Vatastheela* which is one of the 13 types of *Mutraghata* as per *Charak Samhita* (*Cha. Si. 9/25-26*). *Vatastheela* is a *Tridoshaja Vyadhi* with *Vata* and *Kapha* predominance. Maharshi Charak has also advised to use *Mutravirechaniya dravyas* (Diuretics) for treatment of *Vatastheela*. Hence drugs with *Vata & Kapha* pacifying properties along with diuretic action should be used for treatment of BPH.

Prosguard is a combination of time tested herbs and mineral compounds satisfying the above therapeutic criteria. *Shudh Shilajit* (Purified Asphaltum), *Swarna Makshik Bhasma* (Oxide of Iron Pyrite) and *Praval Pishti* are good *Rasayanas* for *Mutravaha Srotas*. Kababchini (*Piper cubeba*) inhibits aromatase activity, which is responsible for transforming androgens into estrogens. Competitive binding assays also indicate that it binds to both human recombinant estrogen α and β receptors. Furthermore, it also inhibits the activities of cyclo-oxygenases (COX-1 and COX-2) and 5-lipo-oxygenase (5-LOX), also it attenuates the induction of interleukin 6 (IL-6) in differentiated THP-1 cells stimulated by lipopolysaccharide (LPS) [16]. These research findings support that Piper cubeba can be a potential therapeutic choice in BPH. Gokshura (*Tribulus terrestris*) has anti-inflammatory, smooth muscle relaxation, diuretic properties. It also reduces post void urine volume which makes it a good choice for BPH management[17].

Khas (*Veteveria zizanoides*) & Punarnava (*Boerhaavia diffusa*) are proven diuretic and anti-inflammatory drugs in Ayurveda. Hence logically they find an important place in the comprehensive management of BPH.

Sweta Chandan (*Santalum album*) & Hapusa (*Juniperus communis*) have

antiseptic, diuretic and cooling properties that make them useful to treat recurrent UTI which is a risk factor for BPH.

Cytometric studies have shown that Varun (*Crataeva nurvala*) improves bladder tone and post-prostatectomy atony of bladder. It has cytoprotective action which prevents UTI. It is also effective in prostatic hypertrophy[18].

There are no specific normal or abnormal levels of PSA in the blood. In the past, most urologists considered PSA levels of 4.0 ng/ml and lower as normal reference range in Indian patients[19]. Previous studies have reported that almost 64 % patients of BPH PSA concentrations above the 4 ng/ml threshold value[20]. Since there is influence of age on PSA, we have taken the reference range suggested by De Antoni et al in this study[21]. Moreover, PSA is a good marker for prostate volume. In this study it was observed that both Prosguard and Tamsulosin result in reciprocal reduction in Prostate size and PSA level.

The Therapeutic efficacy of Prosguard Capsule can be assigned to the synergistic effects of the combination of all the above herbs and mineral compounds.

CONCLUSION

Prosguard Capsule was not only effective in improving various sign and symptoms of BPH, but also reduced prostate size, post void urine volume and PSA level. In most of the parameters the results were better and in few parameters the results were comparable to that of Tamsulosin. Prosguard also improved the Quality of life which is a major concern in BPH patients. But in terms of safety and tolerance Prosguard was far ahead of Tamsulosin. Based on these findings of the present study it can be concluded that Prosguard capsule is an effective, safe and economical choice for medical management of BPH. However the authors would always welcome multi centric trials with larger sample for better evaluation of the product.

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