

A SAFETY EVALUATION AND EFFICACY OF TABLET PROSCAREHILLS IN  
SUBJECT OF MILD TO MODERATE BENIGN PROSTATE ENLARGEMENTAjitkumar Harichand Mandlecha<sup>1\*</sup> and Gous Shaukatali Mujawar<sup>2</sup><sup>1</sup>BAMS, M. Phill (Musculoskeletal Disorder), Medical Director, Vishwanand Kendra Pune, Maharashtra, India.<sup>2</sup>BAMS, MD (Rasa Shastra), Research Head, Vishwanand Kendra Pune, Maharashtra, India.

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**ABSTRACT**

**Introduction:** Benign Prostatic Hyperplasia, which is generally abbreviated as BPH, is a disease, which is particularly seen in elderly men. It is considered as one of the major causes of lower urinary tract symptoms and bladder outflow obstruction. Among the varieties of Mutraghata, mainly Vatashteela resembles the condition of BPH. Histologically distinguishable BPH will be present in 8% of men aged 31-40 and progressively increases markedly with age to about 80% by the ninth decade of life. In India, the prevalence rate is around 50% in men above the age of 65 years. **Objective:** To Evaluate Safety and efficacy of Tablet Proscarehills in subject of mild to moderate Benin Prostate Enlargement. **Materials and Methods:** 30 subjects of mild to moderate benign prostate enlargement enrolled in the study. **Conclusion:** It is safe and effective in the treatment of benign prostatic hyperplasia (BPH).

**INTRODUCTION**

The prostate or gland plays a significant role in the male reproductive system. This gland, which is the size of a walnut, is situated below the bladder. Hyperplasia of the prostate most commonly involves the transitional zone (periurethral zone), affecting both the glandular and stromal tissue.

In India, multiple studies have indicated the prevalence of Benign Prostrate Hyperplasia (BPH) to be around 25%, 37%, 37% and 50% for the age group 40 – 49, 50 – 59, 60 – 69 and 70 – 79 years, respectively. By the age of 60 years, more than 50% of men would have some evidence of the disease. Worldwide, the prevalence of BPH generally varies from 20% to 62% in men beyond the age of 50 years.

Clinical BPH is defined as having at least two of the following features: (A) Moderate to severe lower urinary tract symptoms (LUTS) with International Prostate Symptom Score (IPSS) greater than 8 and (B) an enlarged prostatic volume > 30 mL) and (C) maximum urinary flow rate less than 15 mL/s.

According to Ayurveda, the Vatashteela and Mutragranthi which are the types of Mutraghata may be correlated with BPH on the basis of similarity of symptoms. According Ayurveda classics Mutraghata is a diseased condition where retention of urine is cardinal feature.

Vatashteela is predominantly a Vata – Kapha dosha disorder. The formulations have properties of pacifying Vata, Kapha, Vatanulomana, anti-inflammatory, scraping, and diuretic effects. Old people are seeking a safe and effective treatment to avoid complications from surgical therapy, and medical treatment cam plays an important role in this situation.

Keeping all these facts in mind “A clinical study -To Evaluate Safety and efficacy of Tablet Proscarehills in subject of mild to moderate Benin Prostate Enlargement” was designed.

**AIMS AND OBJECTIVES**

1. To Evaluate Safety and efficacy of Tablet Proscarehills in subject of mild to moderate Benin Prostate Enlargement.
2. To study the Vatashteela w.s.r to Benign Prostate Hypertrophy according to Ayurvedic classic and modern science.

**MATERIAL AND METHODS**

Clinical study – the patients attending the O.P.D. of Vishwanand Kendra, Pune, were selected for the clinical study fulfilling the criteria of selection and eligibility for present study.

Duration of study – 90 days

Number of subjects – 30

**Inclusion criteria**

1. Male Subjects belonging to age group of 50 to 70.
2. USG of bladder suggestive of residual urine volume up to 100ml.
3. Mild to moderate grades of BPH.

**Exclusion criteria**

1. Chronic UTI, urinary calculus, renal failure, urinary stricture
2. Systemic diseases like uncontrolled Diabetes mellitus (RBS range above 300mg/dl), Hypertension (stage 3 or above), Tuberculosis, hemiplegia, parkinsonism, and other disorders that may interfere with the present.
3. Subjects with immune compromised conditions such as HIV

4. Subjects with USG findings suggestive of Hydroureteronephrosis

**Diagnostic criteria**

1. Digital and ultrasonography examination of Prostate gland.
2. Residual urine volume assessment by ultrasonography.

**Interventions – orally**

Tablet Proscarehills was administered in dose of 500 mg, three times a day (TID) with luke warm water, half an hour before food.

**Assessment Criteria Primary assessment parameters**

1. Assessment using IPSS was done.

**IPSS assessment includes**

(International Prostate Symptom Score (IPSS) /American Urological Association Symptom Index (AUA-SI))

In the past one month	Not at all	Less than 1 in 5 times	Less than half time	About half the time	More than half the time	Almost Always	Your score
Incomplete emptying 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	
	None	Once	Twice	Thrice	Four times	Five or more	
Nocturia	0	1	2	3	4	5	
Total IPS SCORE							

**Score 1-7: mild 8-19: moderate 30-35: severe**

Quality of life due to urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy	terrible
Score	0	1	2	3	4	5	6

**OBSERVATIONS AND RESULT****Table 1: Effect of Tab. Proscarehills on individuals' symptoms of B.P.H.**

Symptoms	Mean score		% Of Relief	S.D	S.E	T	P
	B.T.	A.T.					
Incomplete voiding	2.67	1.50	43.82	0.40	0.16	7.00	<0.001
Frequency	2.56	1.44	44.48	0.60	0.20	5.54	<0.001
Intermittency	3.60	2.60	27.78	0.70	0.31	3.16	<0.001
Urgency	2.57	1.43	44.44	0.37	0.14	8.0	<0.001
Nocturia	2.00	1.14	42.86	0.37	0.14	6.0	<0.001
Had to strain	2.00	0.89	55.56	0.78	0.26	4.26	<0.001
Weak urine stream	4.93	3.93	20.28	0.76	0.13	5.12	<0.001

**Table 2: Effect of Tab. Proscarehills Prostate size.**

Parameter	Mean Score		% of relief	S.D.	S.E.	T	P
	B.T.	A.T.					
Prostate size	40.50	39.40	2.72	1.370	0.433	2.538	<0.01

**Table 3: Effect of Tab. Proscarehills on Residual urine volume of B.P.H.**

Parameter	Mean Score		% of relief	S.D.	S.E.	T	P
	B.T.	A.T.					
Residual urine volume	155.35	36.00	78.82	18.66	4.98	23.92	<0.001

**Table 4: Total effect of Tab. Proscarehills on B.P.H. Treatment objective parameters.**

Parameter	Complete remission	Marked improvement	Mild Improvement	Unchanged
Size of prostate in %	00	42.86	50.0	7.14
Residual urine volume in %	28.57	65.86	5.57	-

**DISCUSSION****Result on Quality-of-life scale of IPSS**

A statistically highly significant change in Quality of Life was obtained in subjects with a P value <0.001.

**Size of prostate**

The relief rate for almost all the parameters assessed has been approximately 45-60% for all patients. The overall result showed that 42.86% patients were shown marked improvement, 50.0% cases showed Mild Improvement and 7.14 % patients showed no improvement in Size of prostate.

**Residual urine volume**

In Objective Parameters highly significant result (<0.001) was observed in Average Urine Flow Rate (AUFR) and significant result (< 0.01) was found in reduction of Prostate Size.

28.57% patients were shown complete remission, 65.86% cases showed marked improvement and 5.57% patients showed Mild Improvement in Residual urine volume.

**Probable action**

All the above said symptoms are due to vitiated Vata situated in the Basti and the formulation by virtue of its above said action bring backs the aggravated Vata to normal and breaks the Dosa-Dushya Sammurcchana.

The Vatanulomana, Shothahara and Mutrala Sothhara, Vatahara, Mootrala, Lekhana and Basti Shodhan properties of ingredients helps to relieve pain and SthanikaSotha.

Varuna due to triterpene is good in improving the detrusors tone i.e. the musculature of urinary bladder along with the anti-infective properties. Punarnava and Ashwandha have rasayan property. Which helps to avoid recurrence of the ailment.

Prostatic secretions are slightly acidic and Campbell, the God of urology, says that basic drug would be more positively charged in acidic prostatic fluid than in the blood. So, slight changes in the pH can have significant effect on the non-ionic diffusion, enzymes and hormones. The above composition is basic in nature so it will definitely increase the bioavailability of the active components in the prostatic cells enhancing the overall activity of the compound.

**CONCLUSION**

This study provides the evidence in support of the potential efficacy of Tablet Proscare an proprietary

Ayurvedic medicines. It is safe and effective in the treatment of benign prostatic hyperplasia (BPH).

**REFERENCES**

- Bhat SA, Rather SA, Islam N. An overview of benign prostatic hyperplasia and its appreciation in Greco-Arab (Unani) system of medicine. *Asian J Urol*, 2022 Apr; 9(2): 109-118. doi: 10.1016/j.ajur.2021.05.008. Epub 2021 May 29. PMID: 35509487; PMCID: PMC9051355.
- McConnell JD, Roehrborn CG, Bautista OM, Andriole GL Jr, Dixon CM, Kusek JW, Lepor H, McVary KT, Nyberg LM Jr, Clarke HS, Crawford ED, Diokno A, Foley JP, Foster HE, Jacobs SC, Kaplan SA, Kreder KJ, Lieber MM, Lucia MS, Miller GJ, Menon M, Milam DF, Ramsdell JW, Schenkman NS, Slawin KM, Smith JA; Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *N Engl J Med*, 2003 Dec 18; 349(25): 2387-98. doi: 10.1056/NEJMoa030656. PMID: 14681504.
- Parsons JK. Modifiable risk factors for benign prostatic hyperplasia and lower urinary tract symptoms: new approaches to old problems. *J Urol*, 2007; 178: 395-401. 2.
- Bourke J, Griffin JP. Hypertension, diabetes mellitus and blood groups in benign prostatic hyperplasia. *Br J Urol*, 1987; 138: 795-797.
- Bhavamishra. In: Bhavaprakasha, Madhyama Khanda, Part-2, 36/41. 9th ed. Pandit Shri B S Mishra., editor. Varanasi: Chaukhamba Sanskrita Sansthana, 2005; 370.
- Sharangadhara. In: Sharangadhara Samhita. 1st ed. Pandita P S Vidhyasagar., editor. Varanasi: Chaukhamba Surbharati Prakashana, 2006; 212.
- Agnivesha. In: Charaka, Dridhabala, Charaka Samhita, Siddhi Sthana, Kalpana Siddhi, 1/20-21. Reprint. Vaidya Yadavaji Trikamji Acharya., editor. Varanasi: Chaukhamba Sanskrita Sansthana, 2002; 680.
- International Prostate Symptom Score (I-PSS) [accessed on 2010 Apr 12]. Available from: <http://www.urospec.com/uro/Forms/ipss.pdf>.
- Agnivesha. In: Charaka, Dridhabala, Charaka Samhita, Viman Sthana, Rogabhishajitiya Vimanam, 8/122. Reprint. Vaidya Yadavaji Trikamji Acharya., editor. Varanasi: Chaukhamba Sanskrita Sansthana, 2002; 280.
- Sushruta. In: Sushruta Samhita, Sutra Sthana, Aturopakramaniya, 35/29. Reprint. Vaidya Yadavaji Trikamji Acharya., editor. Varanasi: Chaukhamba Surbharati Prakashana, 2008; 155.