



# Open Label Single-Arm Clinical Trial with Earvaru Beeja Kalka in the Management of Benign Prostatic Hyperplasia

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## ABSTRACT

Benign prostatic hypertrophy (BPH) is a common condition in the aging men along with lower urinary tract symptoms (LUTS). The prevalence of BPH is proportional to age. It affects 70% of men above 70 years. It is the increase in the number of stromal and glandular epithelial cells in the periurethral transitional zone of the prostate. It can be correlated to vatashtila one among the mutraghata. BPH can be managed by a conservative and surgical treatment which includes anti-androgen therapy, alpha-blockers, aromatase inhibitors, prostatectomy, laser therapy, microwave treatment. As the patients are fairly old these complications are liable to occur in early postoperative days. Even conservative therapy has disadvantages like administering anti-androgen therapy causes impotence, aromatase inhibitors which are widely used have to lead to certain side effects like lassitude, depression, gynecomastia. According to surveys, the socioeconomic burden of BPH is tremendous, costing over \$3 billion every year. In this situation, Ayurveda may be able to provide a treatment that is herbal and free from any adverse effects. This research work was carried out with the ultimate aim of finding the best cost-effective treatment of BPH in comparison with available Allopathic treatment. An extensive literature review reveals that Ervaru beeja kalka along with saindhava lavana and dhanyamla is an excellent remedy for mutraghata. Ervaru beeja kalka is an excellent mutrala, balya and dosha prashamana. Also, studies reveal that chemical constituents in cucumber seed can act on the signaling pathway of the proliferation of cancer cells in the prostate. Because of all these reasons, the present study of Earvaru beeja kalka on BPH was done.

**Key Words:** vatashtila, Ervaru beeja kalka, Benign prostatic hypertrophy, mutraghata.

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## INTRODUCTION

One of the most commonly seen diseases in the primary health care setting is urinary tract infections (UTIs), which is defined as any infection residing within the urinary tract. Both gram-positive and gram-negative bacteria can cause these types of infections. [1] Urinary tract stones after urinary tract infections and prostate pathologies are the third common disease of the urinary system. [2] Benign prostatic hypertrophy is a non-cancerous enlargement of the prostate gland. The prostate is a walnut-shaped structure that wraps around the first part of the urethra from the bladder neck [3]. It is the increase in the number of stromal and glandular epithelial cells in the periurethral

transitional zone of the prostate. It develops due to decreased level of testosterone and increased level of estrogen mainly the most potent form ie; estradiol. Mutraghata means mutravrodha, when dushita vata gets localized in between basti and guda, produce dense fixed firm glandular swelling known as vatashtila leading to obstruction of flatus, urine, and feces, abdominal distension and pain in the bladder region. BPH clinically manifests as LUTS, consisting of obstructive and irritative symptoms [4]. A weak stream of urine with interruption, straining and incomplete emptying of bladder are irritative symptoms. PH of the urine also affects the solubility of certain crystals, some of which deposit very fast in acid

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urine and some others in alkaline urine [5]. Prolonged obstruction may eventually lead to acute urinary retention, recurrent urinary tract infection (UTI), haematuria, bladder calculi, and renal insufficiency. In males, prevalence of BPH increase with age [6]. Benign prostatic hyperplasia affects 6% of the global population. After age 40, however, the prevalence of BPH increases sharply. Autopsy studies show an increase in histological prevalence in each decade after the age of 40.

**Aims:**

Primary objective: To evaluate the efficacy of Ervaru beeja kalka in Benign Prostatic Hyperplasia. Secondary Objective: To evaluate the efficacy of Ervaru Beeja Kalka in reducing the symptoms of BPH, the size of the prostate gland and post-void residual urine.

**MATERIALS AND METHODS:**

The present study was an open-label single-arm clinical study on the efficacy of Ervaru beeja kalka on BPH. The total duration of intervention was forty-five days ie: one and a half months. The patients were selected from OPD and IPD of Amrita Hospital, who were diagnosed as BPH patients and fulfilling the inclusion criteria. After being scrutinized, patients were registered under the present study with their informed consent. Data related to necessary investigations were obtained from the pathological laboratory attached to the hospital.

The study was conducted in Amrita Ayurvedic Hospital. The list of outcomes was a reduction in I-PSS (International Prostate Symptom Score), the volume of the prostate gland and PVRU (Post void residual urine). The interventions were tested using ultrasonography (USG). Drug Ervaru beeja and saindhava purchased from the local market and powdered. Dhanyamla was prepared according to the textual reference of Sahasra yoga under the direct supervision of Rasasastra & Bhaishajya Kalpana department faculties in Amrita School of Ayurveda.

**Inclusion criteria:**

A male patient of age group within 40 -70 years, Patients with signs and symptoms of BPH and USG diagnosed cases of BPH, Residual urine less than 100ml, Weight of prostate gland within 20 -80 gm and PSA less than 4ng/ml will be included.

**Exclusion criteria:**

Prostate cancer, Bladder neck stenosis, Catheterized patient, Prostatic calculi, Patient with systemic diseases like tuberculosis, hepatitis B, HIV and diabetic Mellitus. Diabetes mellitus refers to a disease that develops due to blood glucose being too high. [7]

**Assessment Criteria:**

The patient’s response was recorded based on subjective and objective parameters. The assessment was done with proper recording of scoring and measurements which are standard to the respective parameters. Subjective parameters: The symptoms of BPH were assessed by adopting international prostate symptom score (IPSS) according to American Urological Association: Incomplete Emptying, Frequency, Urgency, Weak Stream, Straining, Nocturia and Intermittency. Objective parameters: The objective parameters were obtained using ultrasound scanning of the prostate gland. The USG procedure was done before (0<sup>th</sup> day) and after the treatment plan (45<sup>th</sup> days) to assess the volume of the prostate gland and Post Void Residual Urine (PVRU)

**RESULTS:**

In the present study total, 30 patients were registered and 29 patients completed the study. The efficacy of the trial drug Ervaru beeja kalka was a statistical analysis of the relevant subjective and objective parameters that were done using SPSS VER. 24. A paired t-test was done to analyze the significance of parameters before and after changes. The twenty-nine patients have a significant mean reduction of I-PSS from 19.79 to 9.48 on the 45<sup>th</sup> day, which was statistically significant with p-value < .001. This shows that Ervaru beeja kalka was effective in the management of BPH.

**Table 1: Efficacy of treatment on I-PSS (N = 29)**

I-PSS	M	MD	SD	S E	t- value	df	P
BT (0 <sup>TH</sup> Day)	19.79	-	4.07	0.76	-		
AT (15 <sup>TH</sup> Day)	16.83	2.97	1.5	0.28	10.649	228	0.0001
AT (30 <sup>TH</sup> Day)	13.31	6.48	2.47	0.46	14.117		0.0001
AT (45 <sup>TH</sup> Day)	9.48	10.31	3.48	0.65	15.976		0.0001

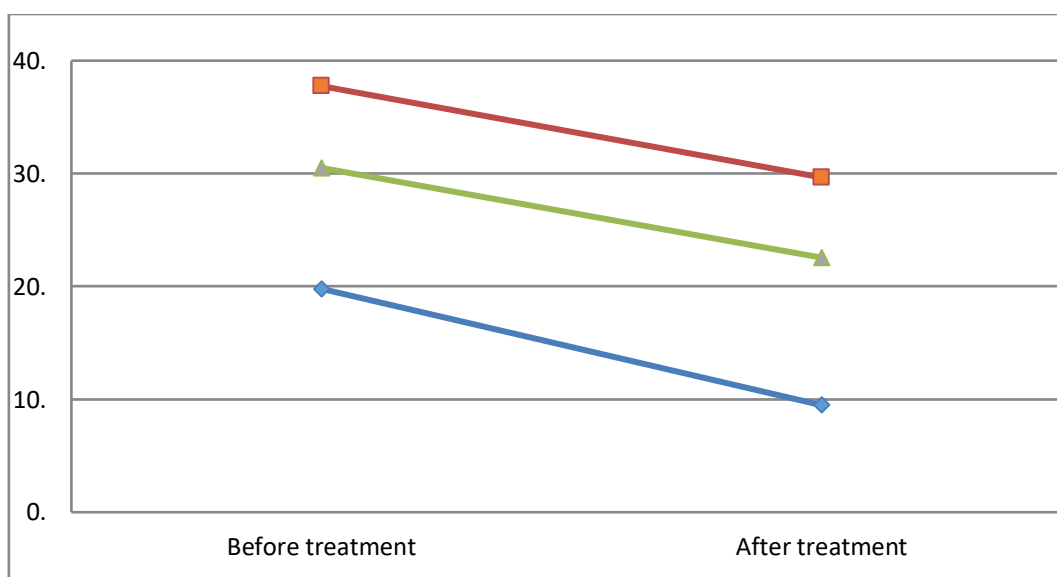
Prostate sizes of twenty-nine patients have a mean reduction from 37.75 to 29.66 on the 45<sup>th</sup> day, which shows a statistically significant with p-value < .001. This shows

that the present study was effective in reducing the size of the prostate gland. Post void residual urine of twenty-nine patients was reduced from 30 to 22.55 on the 45<sup>th</sup> day. This

means reduction with significant p-value < .001 shows  
 Ervâru Beeja Kalka was effective in controlling the PVRU.

**Table 2: Before and after treatment statistical analysis of objective parameters**

N =29		Mean	Mean difference	Std. Deviation	Std. Error	t- value	df	P-value
Size of Prostate	Baseline	30						
	BT	37.748	8.089	3.1666	0.5880	13.757	28	0.0001
	AT	29.659						
PVRU	Baseline	25						
	BT	30.497	7.944	3.9322	0.7302	10.88	28	0.0001
	AT	22.55						



**Figure 1: line diagram of before and after assessment of mean score of parameters**

**DISCUSSION:**

The present study was proposed to find out the efficacy of Ervâru beeja kalka in the management of BPH in thirty patients. Out of 29 patients, three got cured and 26 patients got moderate improvement in the size and symptoms of BPH. Benign Prostatic Hyperplasia was an age-related urinary disorder of men. Reason for the origin of Vâtâshfîlâ was angimandhya and deranged apâna vâta. Due to old age and improper food habits weakness of digestive power

happens, which leads to the ama formation. If this kind of nidhana continues will leads to ama in all dhatus. As purificatory mechanism urine also is filled with ama and can lead to infection. It will become an infective medium for bacteria, and create lower urinary tract infections and impacts the prostate. If the ama is not corrected, this will create an imbalance in cell division in the prostate. This imbalanced cell division along with decreased testosterone in aged men was a cause of prostate hyperplasia

	I-PSS	Prostate volume	PVRU
Before treatment	19.79	37.748	30.497

Consumption of cucumber seed improves overall digestion. Ervâru Beeja Kalka improves prostate health: by balancing Apâna Vâta, which assists in urination, stop ama production, strengthening the immune system; cleansing the urine, rasa dhatu. Thus Ervâru Beeja Kalka was a Prostate Protector containing a sophisticated combination of herbs to balance testosterone production. It also helps in maintain normal prostate size and health by diuretic action, anti-inflammatory action and improves immunity. This drug inhibits various growth factors thus prevent hyperplasia. The phytoestrogenic effect helps to reduce luteinizing hormone, testosterone and prolactin in males. It has proved useful in improving the detrusor contractility and alters the bladder function. The maintenance of correct electrolyte concentrations in body fluids is vital and disorders in electrolyte balance, which use to diagnose changes in renal and metabolic function. [8]

Cucumbers seeds have both antioxidant and anti-inflammatory properties [9]. The extracts obtained from seeds help to scavenge free radicals. It also helps to improve the antioxidant property thus prevent pro-inflammation. Along with antioxidant property the cucumber seed supplies vitamin C, beta-carotene, and manganese.

Potential anti-cancer benefits of cucumbers were cucurbitacins and lignans. cucurbitacins belong to a triterpene. Fresh cucumber contains Cucurbitacins a, b, c, d, and e. Researchers prove that cucurbitacins prevent several signaling pathways of cancer cell proliferation and survival. Thus it helps in preventing the proliferation of prostate hyperplasia. Lignans phytonutrients of cucumber provide an anti-cancerous effect. These lignans act with the help of bacterias in the intestinal mucosa. When we consume plant bacterias will hold of these lignans and they convert it into enterolignans such as enterodiols and enterolactone. Enterolignans will bind to estrogen receptors and produce both pro-estrogenic and anti-estrogenic action. Thus helps to a reduced risk of developing estrogen-related cancers in a site like a breast, ovary, uterus, and prostate. These phytonutrients maintain the normal hormone level and prevent benign growth.

The action of saindhava was improving digestion and appetite, which means it helps in ama pachana along with Ervâru. Saindhava lavana is vrishya thus stimulate and maintain reproductive hormones in a normal range. It is also vibhandaghna in action, which means remove the obstruction by normalizing the srôta. It can be applied in the case of urinary obstruction. The antioxidant property of saindhava helps to get rid of toxic minerals by improving blood circulation and mineral balance [10]. Also, the lavana rasa helps in the reduction of increased vâta.

Dhanyamla has the properties of amla rasa, Snigdha Guna; Uśna Veerya and Amla Vipaka which regain the normalcy of apâna vâta. Teekshna guna improves digestion and

reduces ama formation and abdominal distention. Amla vibhagha helps in maintaining the electrolyte balance. All together the trial drug was acting in multifactorial level Agni deepthi, sroto vishudhi, and vâta anulomana

## CONCLUSION:

The present clinical study was statistically analyzed and discussed to obtain a conclusion that, the mean age group with the highest incidence of BPH was between 60 -70 years and more in person with increased Vata. It was found that after the completion of intervention most of the patients got moderately improvement in subjective and objective parameters. No untoward effects of the drug were noted during treatment. In this study, three patients got completely cured and twenty-six patients got moderately improved. These results brought to the conclusion that Ervaru beeja kalka was effective in the management of BPH.

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