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A COMPARATIVE STUDY OF ROHITAKARISTA AND KANCHNAAR GUGGULA IN THE MANAGEMENT OF MOOTRAGHATA W.S.R TO BENIGN PROSTATE HYPERPLASIA

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a disease affecting male population after the age of 50 years. The prostate gland is a male reproductive organ which physiologically undergoes significant growth during fetal development and puberty. At the end of the puberty prostate gland reaches maturation stage and maintains the same unless benign Prostatic Hyperplasia develops which causes increase in size and weight of the prostate gland after the first five decade of life.

BPH can be defined as "A histological process that over time may result in both anatomic and physiologic changes in the prostate gland and entire lower urinary tract. BPH is a disease where adenomatous enlargement of the periurethral prostate gland causes obstruction of the urethra and bladder outlet.

The enlarged gland puts pressure on the urethral passage and due to obstruction of urethra there is development of numerous urinary symptoms. These symptoms include both obstructive and irritative features such as - frequency of micturition, nocturia, urgency, sensation of poor bladder emptying, intermittent stream of urine or dribbling micturition, poor flow of urine, hesitancy etc.

If we go through the Ayurvedic classics, the diseases related to clinical symptoms of BPH are found placed under the heading of Mutraghata. Various diseases mentioned under this group

produce the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria.

Diseases described under Mutraghata are predominantly due to the vitiation of Vata Dosha. Apana Vata (which is one among 5 types of Vata Dosha) is responsible for normal act of micturition when it is in Samya Avastha (In state of normalcy). When there is vitiation of Apana Vata it results in development of various disorders affecting the Mutravahasrotas like Prameha, Ashmari, Mutraghata, Mutrakrichha etc.

Need of Study

- In spite of surgical advancement and conservative management in modern sciences still it is not possible to treat BPH effectively.
- In modern medicine the management of BPH is either through a surgical approach (e.g., open prostatectomy, transurethral resection of prostate, cryo therapy, etc.) or by conservative treatment using drugs (e.g., chemotherapy, hormonal therapy, etc.).
- Among the many approaches, prostatectomy is the best, but it is associated with many complications, e.g., postoperative morbidity, impotence, retrograde ejaculation, etc.
- The second most acceptable procedure is TURP, transurethral resection of prostate, which is also not free from complications, with the cumulative probability of re-operation estimated to be around 15% at 5–8 years after TURP.
- The surgical approach has provided a great deal of relief for many people but, as mentioned earlier, there are many associated complications.
- In case of hormonal therapy, although there are some advantages, but many complications like loss of libido, impotence, gynecomastia, etc also exist. Generally, the conservative treatments mentioned above have to be continued indefinitely and, therefore, they can be expensive.
- In this scenario it is possible that Ayurveda provides a treatment that proves to be effective as well as safe in conservative management of Astheela/B.P.H.
- Oral medicines based on the principles of ayurveda may be efficacious in the treatment of these disorders.
- So the present study is an attempt to evaluate Ayurvedic therapy in the management of BPH according to treatment principles mentioned in Ayurvedic classics

AIMS AND OBJECTIVES

The aims and objectives of present study were as follows-

- To study the conceptual details of the disease vataastheela as per Ayurvedic literature and correlate it with bph.
- To find out an easily available and considerably low cost, safe and effective remedy for treatment of bph.
- To compare the clinical effect of *the rohitakarista* and *kanchnaar guggula* in management of vatastheela wsr to BPH.

Other objectives of the present clinical trial were as follows-

- To break the pathogenesis of BPH on modern concept with ayurvedic formulation.
- To improve the quality of life of BPH patients.

2. Disease Review

(A) Ayurvedic review

If we go through the Ayurvedic classics, the diseases related to clinical symptoms of BPH are found placed under the heading of Mutraghata. Various diseases mentioned under this group produce the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria.

Classification of Mootraghata

In the classics 13 types of mootraghata have been recognized which are mentioned in the following table in as per acharya.

Table 1: Various texts.

Types of Mootraghata	S.S. (S.S.U.58/3-4,787)	C.S. (C.S.Si.9/25, 26,719)	A.H. (A.Hr.Ni.9/2-3)	M.N. (1/505)	G.N.	B.P.
Vatakundalika	✓	✓	✓	✓	✓	✓
Vatashthila	✓	✓	✓	✓	✓	✓
Vatabasti	✓	✓	✓	✓	✓	✓
Mootrajathara	✓	✓	✓	✓	✓	✓
Mootrasanga	✓	✓	✓	✓	✓	✓
Mootrakshaya	✓	✓	✓	✓	✓	✓
Mootragranthi	✓	✓	✓	✓	✓	✓
Mootrashukra	✓	✓	✓	✓	✓	✓
Ushnavata	✓	✓	✓	✓	✓	✓
Mootroukasada (pittaja)	✓	✓	✓	✓	✓	✓
Mootroukasada (kaphaja)	✓	✓	✓	✓	✓	✓
Mootratita	✓	-	-	-	✓	✓

Table 2: According to dosha.

Dosha	Types of Mootraghata
Vataj	Vatakundalika, Vatashthila, Vatabasti, Mootratita, Mootrjathara, Mootrasanga, Mootrashukra, Vidvighata, Bastikundala
Pittaj	Pittaj Mootroukasada
Kaphaj	Kaphaj Mootroukasada
Vatakaphaja	Raktagranthi, Mootroukasada
Vatapittaja	Ushnavata

Table 3: According to special symptoms.

Types of Mootraghata	Symptoms				
	Obstruction	Pain	Frequency	Burning	Haematuria
Vatakundalia	✓	✓	✓	-	-
Vatashthila	✓	✓	-	-	-
Vatabasti	✓	✓	-	-	-
Mootratita	✓	✓	✓	-	-
Mootrajatara	✓	✓	-	-	-
Mootrasga	✓	✓	✓	-	-
Mootrakshaya	-	✓	-	✓	-
Mootragranthi	✓	✓	✓	-	✓
Mootrasukra	-	-	-	-	-
Ushnavata	-	✓	✓	✓	✓
Mootroukasada– (Pittaja)	-	-	-	✓	-
Mootroukasada– (Kaphaja)	-	✓	-	-	-
Bastikundala	✓	✓	-	-	-

The exact correlation of the BPH can be done by Vataastheela according to ayurvedic classics.

Vatastheela

Nidana

- vayur Ntrmaiïtm! i.e. vitiated vata situated inside the granthi (prostate gland).

Samprapti

- zk«NmagRSy bSteí AiólavÏ< ¢iNw i.e. the vitiated vata gets lodged between the bladder and rectum and produces the stony hard swelling i.e. enlargement of prostatic tissue.

Lakshana

- clm! %Út¢iNw (Single, movable and elevated)
- "n ¢iNw (Hard to firm in consistency)
- iv{mUÇainls¼ (Retention of urine, feces and flatus)

- □biSt==Xman! (Distention of the urinary bladder)
- □vedna c pra bStaE (Excruciating pain in the bladder).

Table 5: Correlation of various types of mootraghata considering pathogenesis & clinical manifestation.

S.N.	Mootraghata	Correlation
1	Vatakundalika	Bladderneck contracture and spasm of vesico urethral Junction
2	Vatashthila	Benign prostatic hyperplasia
3	Vatabasti	Bladder outlet obstruction like bladder neck contracture, acute prostatitis, benign prostatic hyperplasia, impaction of stone, bladder neck stenosis, bladder neck hypertrophy etc.
4	Mootratita	Chronic retention/ hyper reflexic neurogenic bladder/ hypotonic or atonic bladder/ altered bladder neuro physiologic condition.
5	Mootrajathara	Neurological origin like vertebral disease, neurological diseases affecting lumbosacral plexus, neurogenic bladder conditions.
6	Mootrotsanga	Stricture urethra at the level of bladder neck, proximal or distal urethra, or at the level of glans penis.
7	Mootrasankshaya	Oliguria
8	Mootragranthi	Acute prostatitis impacted vesical calculi at bladder neck, Vesical benign/malignant growth at neck region.
9	Mootrashukra	Retrograde ejaculation may be due to neurological pathology leading to incompetant internal sphincter. Trauma or iatrogenic leading to damage of internal urethral and sphincter or obstruction beyond the level of prostatic urethra.
10	Ushnavata	Inflammatory condition of bladder i.e cystitis.
11	Pittaja Mootroukasada	Crystallurea, severe infective urethritis
12	Kaphaja Mootroukasada	Phosphateuria
13	Vidvighata	Colovesical or rectovesical fistula of various Aetiologies
14	Bastikundala	Atonicity of bladder.

B. Modern review

Benign Prostatic Hyperplasia

A non malignant enlargement of the prostate gland, caused by excessive growth of prostatic nodules, is the most common benign neoplasm of aging men.

Pathology of BPH[28]

BPH first develops in the periurethral transition zone of the prostate. The transition zone consists of two separate lobules of tissue immediately external to the preprostatic sphincter. The main ducts of the transition zone arise on the lateral aspects of the urethral wall at the point of urethral angulation near the verumontanum. Proximal to the origin of the transition

zone ducts are the glands of the peri-uretheral zone, which also undergo hyperplastic growth. Stromal/ smooth muscles extra cellular matrix and epithelial nodules develop in these zonal compartments, leading to an overall increase in the size of the gland. As the prostate enlarges, the peripheral zone, the most common site for the development of prostatic adenocarcinoma, is compressed between the transition zone and the capsule of the gland.

One of the unique features of the human prostate is the presence of the prostatic capsule, which prays an important role in the development of prostatism. In the dog, the only other species known to develop naturally occurring BPH, symptoms of prostatism rarely develop because the canine prostate lacks a capsule. Presumably the capsule transmits the pressure of tissue expansion to the urethra, leading to an increase in urethral resistance.

Growth of the prostate is aging men is not a uniform process. Some patients develop global‖ enlargement of the entire gland, while others develop more prominent growth of specific regions of the gland. Extensive growth of the peri- urethral zone may lead to a ―middle lobe‖ and a resulting ball valve type of obstruction.

Smooth muscle cells within the prostatic capsule, stroma and bladder neck have a high density of alpha1-adrenergic receptors on their surface. Thus, tone in the prostatic urethra is influenced by the degree of adrenergic stimulation to the gland, which contributes in a dynamic way to outflow obstruction.

The bladder‘s initial response to prostatic enlargement is the development of compensatory muscular hypertrophy. Intravesical pressure increases to maintain flow in the face of outflow resistance. Unfortunately the adaptation is not perfect: bladder hypertrophy leads to urinary frequency and urgency. In advanced cases, the bladder wall becomes fibrotic, losses compliance and fails to empty completely. The development of post voiding residual urine however is common and doesn‘t invariably lead to urinary retention and hydronephrosis.

The molecular pathogenesis of BPH is uncertain. It is clear that the process requires aging and testicular androgens. BPH doesn‘t develop in men castrated before puberty. Testosterone (T), produced by testicular leydig cells, is the major androgen in the circulation. After T diffuses into the prostate cell, most of it is converted into a much more potent androgen, dihydrotestosterone (DHT), by the enzyme 5 reductase. The importance of this amplification step in growth of the prostate is clear from studies of patients with deficiency of the 5

reductase enzyme who have virtually absent prostate. Both T and DHT bind to the androgen receptor to stimulate androgen dependent cell growth and inhibit the programmed cell death seen on androgen withdrawal. Although androgens do not cause BPH, DHT plays a central role in the pathogenesis of the disease.

Patho-Physiology of BPH[30]

The pathophysiology of BPH is a complex phenonmenon. Prostatic hyperplasia increases urethral resistance, resulting in compensatory changes in bladder function. The prostatic adenoma obstructs the urinary flow in two ways. First, the enlarged prostate itself possess a static obstruction caused by the increased bulk of tissue from new cells growing in the peri-uretheral region. Second, a dynamic obstruction believed to be a secondary contraction of smooth muscle fibers compressing the urethra & bladder neck. The smooth muscles in the adenoma & anterior prostatic capsules are rich in alpha – adrenergic receptors and stimulation of these receptors results in a contraction or increase in tone of muscles. Obstruction induces changes in detrusor function, compounded by age related changes in both bladder & nervous system functions, leads to urinary frequency, urgency and nocturia, the most bothersome BPH related complains.

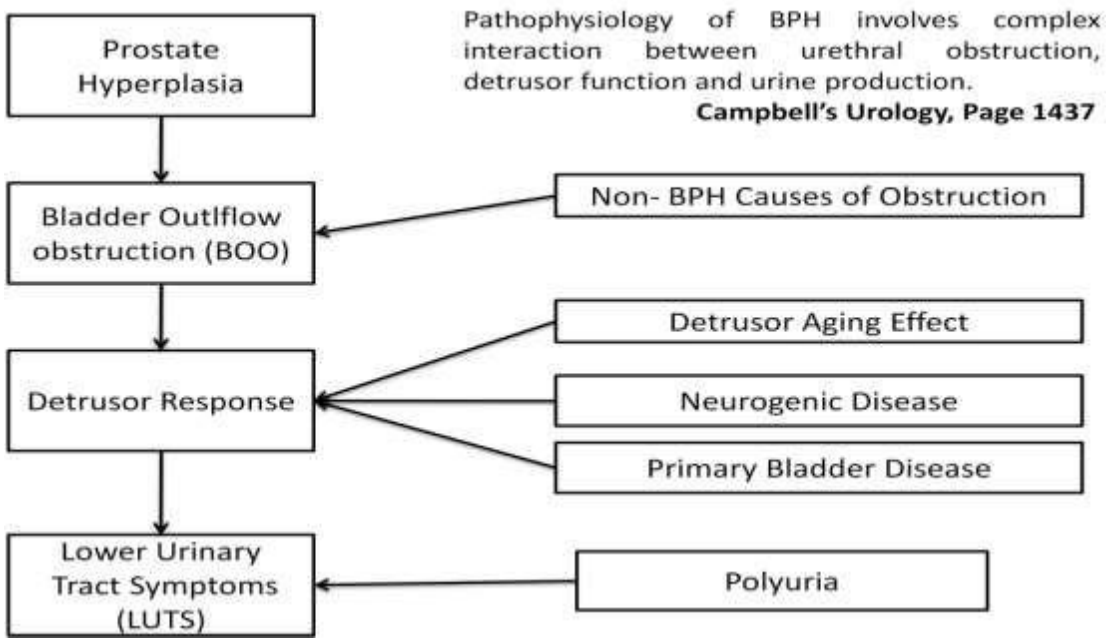

Figure - Pahtophysiology of BPH & its Complex.

Clinical Features of BPH

The symptoms of BPH mainly arise due to obstruction of urinary stream and seldom occur before age of 50 years. The researchers have suggested that severity of the symptoms is not

correlated with the size of the prostate. The severity of clinical symptoms experienced by an individual patient may also fluctuate unpredictably, as stress, cold and the use of adrenergic agents may cause symptoms to worsen.

It is important to realize that the relationship between anatomical prostatic enlargements, LUTS and urodynamic evidences of BOO is complex.[31] Pathophysiologically, BOO may be caused in part by increased smooth muscle tone, which is under control of adrenergic agonists.

1. Impact of anatomical factors

a. Urethra

i. The prostatic urethra is enlarged, sometimes twice than its normal length, but it does not become narrow anatomically.

ii. The normal posterior curve may be so exaggerated that is required a curved catheter to negotiate it.

iii. When only one lateral lobe is enlarged, distortion of prostatic urethra is occurs.

b. Urinary Bladder

i. If BPH causes BOO, the musculature of the bladder hypertrophy to overcome the obstructions and appears trabiculated.

ii. Significant BPH is associated with increased blood flow and the resultant veins at base of bladder are apt to cause haematuria.

2. Lower Urinary Tract Symptoms (LUTS)

Urologists prefer the term LUTS and discouraging the use of term prostatism‘. LUTS is usually assessed by means of scoring systems which gives a semi objective measure of severity of urinary obstruction. LUTS can be described as follows:-

Voiding Symptoms

- Hesitancy (worsened if bladder is very full)
- Poor flow (unimproved by straining)
- Intermittent stream (stops & starts stream)
- Dribbling (after micturation urine drops)
- Incomplete voiding (sensation of poor bladder emptying)
- Episodes of frequent retention of urine

Storage Symptoms

- Frequency (more time urination)
- Nocturia (increased urination of night)
- Urgency (unable to control urination)
- Urge incontinence (if try to control urination takes place)
- Nocturnal incontinence (incontinence during night)

3. Bladder Outflow Obstruction (BOO)

This is an urodynamics concept based on the combination of low flow rate of urine in presence of high voiding pressures. It can be diagnosed definitely only by pressure flow studies. BOO may result also from detrusor muscle instability, neurological dysfunction and weak bladder contraction. It has been proven urodynamically that BOO may occur due to BPH, Bladder Neck Stenosis, Bladder Neck Hypertrophy, Prostate Cancer, Urethral Stricture, Neuropathic conditions etc.

Primary effects of BOO on Urinary Bladder is

- Urinary flow rate decreases
- Voiding Pressure Increases Long Term Effects of BOO:
- The bladder may decompensate so that detrusor contraction becomes progressively less efficient and residual urine develops.
- Bladder becomes more irritable during filling with a decrease functional capacity partly caused by detrusor over activity.

Besides from symptoms of BOO, it may causes complications like

- Acute Retention of Urine
- Chronic Retention of Urine
- Impaired Bladder Emptying
- Haematuria
- Pain

Other than pain due to retention, these are not symptoms of BOO, and its presence could be prompted the exclusion of acute retention, UTI, stones, carcinoma of prostate and carcinoma *in situ* of bladder.

Other Symptoms of BPH[32]

- **Dysuria** – due to increased urethral resistance and derangement of internal urethral opening function.
- **Pain** - due to secondary changes caused by BPH.
- **Prostatism** –The features of prostatism reflect which are classified in two groups as mentioned below:

1. Obstructive

a. Poor flow, which does not improve rather worsen by straining
b. Dribbling
c. Hesitancy

2. Irritative

a. Increased frequency with nocturia
b. Urgency
c. Nocturnal incontinence of urine (Enuresis)

Secondary Effects of Prostatic Enlargement[33]

- **On ureters and kidneys**: Increase in the intavesical pressure causes gradual dilation of the ureters due to back pressure followed by ascending infection or more rarely from the blood stream; acute or chronic pyelonephritis may supervene.
- **On sexual organs:** In early stages of prostatic enlargement there is increased libido and later, impotence is the rule.

Drug Review

Selection of drug

The drug selected for the clinical study is having various drugs with wide range of actions in the body mentioned in *Ayurveda* and other research works. This formulation is described in *Ayurvedic* text. An *Ayurvedic* formulation *Kanchnaar guggula and Rohitakarista* was prepared for the management of Benign Prostatic Hyperplasia with consideration of following qualities -

- *Rasayana* properties
- *Mutral* effect (Diuretic properties)
- Anti-inflammatory and Antispasmodic properties
- *Vata* and *Kapha Shamaka* properties

- ***Rohitakarista***

Rohitakarista is prepared by the combination of 11 drugs, the main content of *Rohitakarista* is *rohitaka,* other contentsare *Panchkol (pippali, pippalimool, chavya, chitarka, shunthi), Trijata (dalcheeni, sukshm ela), Dhataki and Amalaki.*

Ingredients

S.No	*Sanskrit name*	*Part used*	*Latin name*	*Required*	*Used in kalpana as*
1.	*Rohitaka*	Stem	*Tecoma undulate*	5kg	*Yavakuta churna*
2.	*Dhatki*	Flower	*Woodfordia fruticose*	750gm	*Yavakuta churna*
3.	*Pippali*	Fruit	*Piper longum*	50gm	*Yavakuta churna*
4.	*Pippalimool*	Root	*Piper longum*	50gm	*Yavakuta churna*
5.	*Chavya*	Root	*Piper rectrofractum*	50gm	*Yavakuta churna*
6.	*Chitrakamool*	Root	*Plumbago Zeylanica*	50gm	*Yavakuta churna*
7.	*Shunthi*	Root	*Zingiber Officinale*	50gm	*Yavakuta churna*
8.	*Tejpatra*	Leaf	*Cinamomum zeylanicum*	50 gm	*Yavakuta churna*
9.	*Dalchheni*	Bark	*Cinamomum Zeylanicum*	50 gm	*Yavakuta churna*
10.	*Sukchm Ela*	Fruit	*Eletaria cardamomum*	50 gm	*Yavakuta churna*
11.	*Amalaki*	Fruit	*Umbelica Officinale*	50 gm	*Yavakuta churna*
12.	*Haritaki*	Fruit		50gm	*Yavakuta churna*
13.	*Bibhitaki*	Fruit		50gm	*Yavakuta churna*
14.	*Pure water*			52lit	
15.	*Gud*			10kg	

B. Kanchanar Guggulu

The classical formulation of *Kanchanar Guggulu*[23] was selected in *BPH.* Because it is prescribed in management of Gandamala, Apachi, Arbuda, Granthi etc. It is made up of *Kanchanar twak, Triphala, Trikatu, Varun, Ela, Twak, Patra*. Due to its *vatakaphahara, shothahara, lekhana and mootrala* effect and these are considered for better result in *mootraghata* and termed it as *Kanchanar Guggulu.*

Ingredient

S.No.	Sanskrit Name	Part Used	Latin Name	Required Quanity	Use in Kalpana as
1	*Kanchanar*	Bark	*Bauhinia variegata Blume.*	200gm	*Churna*
2	*Triphala*	Compound Formulation as per Classics		120gm	*Churna*
3	*Trikatu*			60gm	*Churna*
4	*Varun*	Bark	*Crataeva nurvala*	20gm	*Churna*
5	*Ela*	Seed	*Eletaria cardamomum Maton.*	5gm	*Churna*
6	*Twak*	Bark	*Cinnamomum zeylanicum Blume.*	5gm	*Churna*
7	*Tejpatra*	Leaf	*Cinnamomm tamal Buch. Ham.*	5gm	*Churna*
8	*Guggulu*	Resin	*Comiphera mukul*	415gm	Shuddha, Binding Agent
9	Pure Water	-	-	Q.S.	-

MATERIAL AND METHODS

The present study has been carried out on 40 patients of *Mutraghata* (Benign prostate hyperplasia). Patients presenting with the different symptoms of prostatism viz. dribbling, hesitancy, urgency, intermittency, dysuria, frequency, nocturia and weak stream etc. were selected irrespective of their Age, Religion, Race, Occupation etc. fulfilling the criteria of selection and eligibility for the present study.

Source of Data

- ✓ Patients were selected from OPD and IPD of hospital of university college of ayurveda, jodhpur.
- ✓ Literary data were collected from all *Samhita's* modern books of surgery, *Nighantu's*, Journals, Magazines, Seminars, Conferences and Web sites.
- ✓ Raw drugs were collected and preparation of *Guggula kalpana(Kanchnaar guggula), Arista(Rohitakarista)* was done under the supervision of *Rasa shastra* and *Bhaishajya kalpana* specialist from pharmacy of university college of ayurveda, Jodhpur.
- ✓ Patients were diagnosed clinically and radiologically from attached laboratory of the hospital.

Method of Study

It is an open clinical trial where the patients were selected on simple randomised sampling technique after being diagnosed by clinically and by ultra sonography. Conceptual Study of the disease in detail has been carried out, and the details of preparation of *Kanchnaar guggula* and *Rohitakarista*, Dose and, Route of administration procedure as per the texts have been incorporated.

Clinical Examination

Careful medical history was taken pertaining to the illness and scoring of the symptoms was done on the basis of International Prostatic Symptom Score (IPSS), by asking specific questions as per the format, thorough clinical examination, abdominal examination was done specially for kidneys and bladder conditions. Digital rectal examination was done in all the patients for the assessment of the condition of the prostate.

Digital Rectal Examination

Patient was kept in left lateral position with extended left lower limb and flexed right knee and hip towards chest. Patient was asked to be in relaxed state. Then gloved and lubricated

index finger was introduced gently and prostate was palpated anteriorly for its size, consistency, tenderness, symmetry, surface, median sulcus (palpable or not), upper limit (reachable or not) and rectal mucosa (free or fixed).

***Prakriti* Analysis**

Each and every patient was assessed for his body constitution i.e. *Deha Prakriti* on the basis of specific proforma.

Investigations

- **Haematological:** Total leucocyte count, differential leucocyte count, haemoglobin percentage, erythrocyte sedimentation rate.
- **Biochemical:** Blood urea, Blood sugar estimation, Serum creatinine level.
- **Urological:** Urine for routine and microscopic examination.
- **Ultrasonography**: Transabdominal ultrasonography was done for all the registered patients for the assessment of the condition of the kidneys, ureters, urinary bladder, weight of the prostate and post voidal residual urine.
- **Kidneys & Ureters-** Hydronephrosis, Hydroureters, presence of calculus, renal diseases etc.
- **Bladder-** Bladder diverticula, Trabeculation, wall thickening, cystitis etc.
- **Prostate size-** Prostate weight was calculated by the formula 0.55 x D_1 x D_2 x D_3 (D_1, D_2 and D_3 are dimensions of prostate in cms.) and on the basis of the prostate weight grading was done as follows-

Grade I	-	20-30 gm.
Grade II	-	30-40 gm.
Grade III	-	40-50 gms.
Grade IV	-	<50 gms

- **Post void residual urine**- Residual urine was estimated after voiding.
- **Prostate Specific antigen (PSA):** PSA was estimated in suspected patients to exclude the CA prostate.

Plan of Clinical Study

- Informed consent was obtained from every patient.
- Patients were managed on an outpatient basis unless hospitalization was necessary.
- Clinical evaluation and assessment was planned every fifteenth day.
- Patients were instructed to avoid all other form of medicament during the course of

treatment.

- In the event of any other illness, the patients were directed to report the scholar immediately.

Withdrawal criteria

- Development or occurrence of life threatening illness.
- Severe side effect of drug during trial.
- Need of other medication arises.
- Avoidance of follow-ups by patients.

Clinical Study

The selected (40)patients were divided into two equal groups(group A & group B) 20 patients of group A were subjected to oral administration of *Kanchnaar guggula (SHA.SA/MA/7/95-98)* and 20 patients of group B were subjected to oral administration of *Rohitakarista* (B.R/YAKRIT PLEEHA CHIKITSA/228-231) which were prepared as per AFI standards and used for the trial.

- **Group-A:** 20 patients were treated with *Kanchnaar guggula* 1000 mg. orally before meal with lukewarm water two times a day for 60 days.
- **Group-B:** 20 patients were treated with *Rohitakarista* 20ml orally after meal with equal quantity of water twice daily for 60 days.
- **Follow up period:** 1 month

Selection Criteria of the Patient Inclusive Criteria

- USG suggestive of BPH
- Pre diagnose case of BPH
- Patient who are not willing for surgery
- Post voidal Residual urine upto100ml.
- Frequency of urine > 2 times and < 5 times in night.

Exclusive Criteria

- Patient having carcinoma of prostate, acute retention of urine and severe urinary tract infection, urethral stricture, tuberculosis, renal failure, diabetes mellitus.
- Patients having other systemic pathology
- Patients currently using any other conservative treatment for BPH

- Residual urine volume > 200ml.
- Patients who are not willing to give informed consent.

Subjective Criteria

- Frequency.
- Urgency.
- Nocturia.
- Feeling incomplete evacuation of bladder.
- Urge incontinence.
- Strangury.
- Straining.
- AUA (IPSS)Score.

Objective Criteria

- Digital rectal examination
- USG(KUB region)-

a) Change in prostate volume(Weight)

b) Residual urine

Plan of Work

Thorough history, general examination and Systemic examination were conducted and duly recorded in the special proforma prepared for the study. The International Prostate Symptom Score based on the 'American Urologists Association' score-sheet was used to assess the Subjective complaints before, during and after the schedule.

Investigations

- Post voidal residual urine, size of the prostate by USG.
- X-ray KUB (if necessary).
- Haematological investigations such as HB:/:, CBC, ESR, biochemical investigations such as serum creatinin, serum calcium, RBS, uric acid, urine examinations such as Routine & MICROSCOPIC examination of urine.
- Serum PSA test, Serum Alkaline phosphate (if necessary).

Criteria of Assessment

The effect of therapy was assessed in two phases:

Both groups, the observations were assessed on(BT) 0^{TH} AT -15^{th} 30^{th}, 45^{th} day and 60^{th} day. Group -A. After the completion of oral administration of Kanchnar guggula schedule. Group -B. After the completion of oral administration of Rohitakarista schedule.

Assessment of Result

For the purpose of the assessment of result some grade points were used considering the severity of different sign and symptoms as follows.

Sign	Grade	Grade Point
+++	G_3	3
++	G_2	2
+	G_1	1
-	G_0	0

Clinical assessment of results per the following criteria

After the treatment schedule on the basis of –The clinical assessment was done after every 15days interval up to 60 days. The initial finding through clinical signs & symptoms were compared with the result of progress every week up to 60 days. Grading & Grouping according to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the patients in the clinical study and finally the assessment as a whole was presented in percent value.

In order to present the study in scientific manner the statistical assessment of the result was done, the mean ± S.E of each sign & symptom before treatment has been compared with Mean± S.E value of the after treatment, two way anova(f test) is used for the purpose of the test of significance and the effectiveness of the both the groups assessed through p- value.

1. Improvement in the symptomatology of the disease based on International Prostate symptom score sheet (prepared by American Urologists Association).
2. Assessment of Residual Urine Volume.
3. Measurement of Prostatic enlargement by digital and Ultrasonographic methods. The Obtained Results have been discussed and analyzed on the following parameters

Subjective Parameter

- **Mild improvement:-** 25-50% relief in the complaints of the patients.
- **Moderate improvement**:- More than 50% relief in the complaints of the patients.
- **Maximum** - upto 75% relief in the complaints of the patients. **Complete relief**: - 100% relief in the complaints of the patients. **Unchanged:** No relief in the complaints of the

patients

- **Objective Parameters:-Mild Improvement:**- 25-50% improvement in the post voidal residual urine volume and other investigations respective / irrespective to the reduction in the size of the Prostate.
- **Moderate improvement**:- More than 50% improvement in the post voidal residual urine volume, other investigations respective / irrespective to the size of the Prostate.
- **Maximum-** upto 75% improvement in the post voidal residual urine volume, other investigations respective / irrespective to the reduction in the size of the Prostate.
- **Complete relief**:- 100% reduction in the size of the enlarged Prostate and 100% improvement in post voidal residual urine volume.
- **Unchanged:** No changes in the Residual urine volume and other investigations respective / irrespective to the reduction in the size of the Prostate.

Follow- Up Study

- **Treatment Period**: 60 days
- **Follow-Up Period**: 30 day

DISCUSSION

Discussion stays an all important step and an integral part of a study as it helps in exploring the hidden and enigmatic subjects and bridges the gap, to draw any conclusion subsequently.

The various clinical manifestations of urinary system are categorized into obstructive and non-obstructive pathologies in Ayurveda. The obstructive urinary conditions are described under the heading *Mootraghata*. *Mootraghata*, a clinical entity predominated by the symptoms of "*AGHATA*" (either suppression or obstruction) to the outflow of urine mainly due to vitiated "*VAYU'*. *Astheela* is one amongst twelve types of *Mootraghta*. This condition is also referred as *Vatastheela*.

The disease Vatastheela, one of the 13 *Mootraghta* disorders, can be correlated with BPH on the basis of its *Sthana* (place), which is between *Guda* and *Basti*, and also on the basis of the correspondence of the signs and symptoms. Most of the features of *Vatastheela* described by *Sushruta*, such as retention of urine (*Mutrasanga*), pain in suprapubic region etc., are similar to the symptoms of BPH. Benign Prostatic Hyperplasia (BPH) is a common ailment affecting one third of men over fifty, half of all men over sixty and ninety percent of all men over the age of eighty five. Like grey hair, balding or wrinkles, BPH enlargement of the prostate gland

is a part of the ageing process. As the boomer generation turns sixty, the incidence of BPH is increasing and so is awareness of the value of CAM (complementary and alternative) disciplines in its management.

The condition is referred to as benign to distinguish it from malignant condition of the prostate. The use of the word "benign" does not however imply that BPH is not a troublesome and possibly dangerous condition. Whenever there is a *gulma* a tumour or space occupying lesions & symptoms will arise due to blocking of channels. In the case of BPH, it is the urethra, the inlet of *mutravahasrotas*, (urine carrying channels) which is partially or fully blocked, leading to significant symptoms.

Currently available conventional treatment options for the management of BPH in modern Medicine include medications and surgery. The adverse effects of the medical treatment include headache, dizziness, hypotension, fatigue, reduced libido etc. The surgical procedure aims at removal of prostate gland partially or completeby different approaches. Due to advanced age of the patient and associated other diseases surgical interventions have limitations. Surgical procedures will overcome the Prostatic obstructive pathology but poses greater threat to life during surgery, as well as, the early and delayed surgical complications often makes life of the sufferer more miserable. So there is a constant effort for a search of a non surgical approach in the management of BPH.

Although various clinical trials have been carried out with many modalities with good results, a pioneer attempt has been made to evaluate the efficacy of *Kanchnaar guggula* 1000mg and *Rohitakarista* 20ml twice a day for 60 days in the management of BPH according to treatment principles mentioned in *Ayurvedic* texts. Then patients were assessed after treatment on the same parameters & follow-up was done for four weeks. The efficacy of the drug was assesses with the help of paired,"t test". The obtained results are very much encouraging and hence, further strengthen the principles of "*Chikitsa Sutra*" of *Ayurveda* in managing a disease. The obtained observations and results are discussed herewith.

Discussion of Demographic Observations

- **Age:** Out of 40 patients, maximum 26 (65%) belongs to the age group of 60-75 years followed by 08 (20%) of 45-60 years group, and 06(15%) are between 75-90years. In *Ayurveda* under *vridhavasta* in which predominance of *vata* which is responsible for the vitiation of the *vata dosa* which is responsible for the formation of *Mootraghta*.

- **Religion:** Out of 40 patients, maximum 38 (95%) were Hindus followed by 02 (05%) who were muslims and 00(00%) were sikhs. This reflects the geographical preponderance of the particular region rather than any specific affirmative reason of the disease with the religion.
- **Marital Status**: Out of 40 patients, all patients (100%) were married and no one (00%) was unmarried. This confirms that the celibacy status does not have any relationship with the disease.
- **Socio - Economic Status**: Out of 40 patients, 26 patients (65%) were from Above poverty line, followed by 14 patients (35%) were belongs to below poverty line. Although the socio- economic status has nothing to do with the disease, it just reflects the country‟s state of affairs and also the section of society attending the hospitals.
- **Habitat**: Out of 40 patients, 12 patients (30%) were from urban area followed by 28 patients (70%) from the rural area. This again has got no relation with the disease but it reflects the rural predominance in the country.
- **Occupation**: Out of 100 patients, 26 patients (65%) were agriculture, 06 patients (15%) were belongs to business, 08 patients (20%) were from private /govt /Retd employees, 00 (00%) patients were drivers, followed by 00 (00%) were related to other group. Most of the patients in this study Private /Govt /Rtd Employees, Agriculture, Business people. In India retirement period around 60 years so it is nothing to correction with age and mode of work, In case nature of work who has with sedentary lifestyle prone for the vitiation of kapha, with the old age predominance of vata both dosas might have prone to Mootraghta.
- **Dietetic Habits**: Out of 40 patients, 28 patients (70%) were vegetarians followed by 12 patients (30%) who were taking mixed diet. This reflects the cultural tradition of the religion and has got nothing to do with the manifestation of the disease.
- **Sleep Pattern**: Maximum number of patients, 25 (80%) were having disturbed, having disturbance in sleep pattern in accordance with predominance of the Nocturia. Followed by 08(25%) patients having sound sleep.
- **Prakriti**: The patients were analyzed on the basis of their body type. The Prakriti examination was done with the help of appropriate Prakriti analysis proforma (as in appendix). Vata Pittaja Prakriti were maximum (45%) percentage, followed by Vata Kaphaja Prakriti (32.5%), and Pitta Kaphaja Prakriti patients (22.5%) percent. This may indicate that Vata predominance in old age i.e cause for the manifestation of mootraghata.

- **Chronicity**: Out of 100 patients, patients (45%) were recorded chronicity of Zero months to 1 year of duration after diagnosing BPH, followed 30 patients (30%) were having Chronicity upto 13 months to 24 months, 10 patients (15%) were reported to have chronicity in between 25 months to 48 months.

In early stage of BPH, patient ignores the disease due to less sign & symptoms and patient does not feel troublesome from the disease. So usually patients Approaches to the doctor when presenting with severe sign and symptoms.

Discussion on Subjective Parameters

AUA Score

- **In Group A** the mean of improvement in AUA Score before and after treatment were 16.75 & 8.60, the percentage of relief about 48.65%, the 't' value was 17.92 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in AUA Score before and after treatment were 18.70 & 7.80, the percentage of relief about 58.28%, the 't' value was 10.04 and 'p' value was less than 0.001, which was statistically highly significant.

Strangury

- **In Group A** the mean of improvement in strangury before and after treatment were 2 & .85, the percentage of relief about 57.5%, the 't' value was 10.258 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in strangury before and after treatment were 1.95 & .85, the percentage of relief about 56.41%, the 't' value was 11.00 and 'p' value was less than 0.001, which was statistically highly significant.

Frequency

- **In Group A** the mean of improvement in Frequency before and after treatment were 2.05 & 1.00, the percentage of relief about 51.21%, the 't' value was 9.200 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in Frequency before and after treatment were 2.20 & .85, the percentage of relief about 61.36%, the 't' value was 10.283 and 'p' value was less than 0.001, which was statistically highly significant.

Urgency

- **In Group A** the mean of improvement in urgency before and after treatment were 2.10 & 1.00, the percentage of relief about 52.38%, the 't' value was 15.98 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in urgency before and after treatment were 2.05 & .700, the percentage of relief about 65.85%, the 't' value was 12.33 and 'p' value was less than 0.001, which was statistically highly significant.

Straining

- **In Group A** the mean of improvement in straining before and after treatment were 1.95 & .70, the percentage of relief about 64.10%, the 't' value was 12.58 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in straining before and after treatment were 2.15 & .60, the percentage of relief about 72.09%, the 't' value was 13.58 and 'p' value was less than 0.001, which was statistically highly significant.

Nocturia

- **In Group A** the mean of improvement in Nocturia before and after treatment were 1.55 & .60, the percentage of relief about 61.29%, the 't' value was 10.78 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in Nocturia before and after treatment were 1.65 & 0.55, the percentage of relief about 66.66%, the 't' value was 15.98 and 'p' value was less than 0.001, which was statistically highly significant.

Urge of incontinence

- **In Group A** the mean of improvement in urge of incontinence before and after treatment were 1.75 & 0.60, the percentage of relief about 65.71%, the 't' value was 14.038 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in urge of incontinence before and after treatment were 1.60 & 0.50, the percentage of relief about 68.75%, the 't' value was 15.98 and 'p' value was less than 0.001, which was statistically highly significant.

Feeling incomplete emptying of bladder

- **In Group A** the mean of improvement in Feeling incomplete emptying of bladder before and after treatment were 1.45 & 0.55, the percentage of relief about 62.06%, the 't' value

was 13.077 and 'p' value was less than 0.001, which was statistically highly significant.

- **In Group B** the mean of improvement in Feeling incomplete emptying of bladder before and after treatment were 1.90 & 0.75, the percentage of relief about 60.52%, the 't' value was 14.03 and 'p' value was less than 0.001, which was statistically highly significant.

Discussion on the objective parameters

Size of prostate

- **In Group A** the mean of improvement in size of prostate before and after treatment were 2.16 & 2.10, the percentage of relief about 2.77%, the „t" value was 1.76 and pvalue was greater than 0.05, which was statistically not significant.
- **In Group B** the mean of improvement in size of prostate before and after treatment were 1.88 & 1.84, the percentage of relief about 2.12%, the 't' value was 1.42 and p value was greater than 0.05, which was statistically not significant.

Post voidal residual urine

- **In Group A** the mean of improvement in post voidal residual urine before and after treatment were 2.05 & 0.9, the percentage of relief about 56.09%, the 't' value was 14.038 and 'p' value was less than 0.001, which was statistically highly significant.
- **In Group B** the mean of improvement in post voidal residual urine before and after treatment were 1.95 & 0.70, the percentage of relief about 64.10%, the 't' value was 12.58 and 'p' value was less than 0.001, which was statistically highly significant.

DISCUSSION ON RESULTS

Frequency of micturition was the commonest problem encountered in the present study which was due to the enlargement of prostate causing irritation to the bladder and prostatic urethra. The Group treated with the Rohitakarista got maximum relief due to its action over Apana Vayu. The symptom–complex of frequency, urgency, incontinence, straining and strangury related to prostatic hypertrophy was relieved to a greater extent.

Micturition is a complex function. Since last 10-15 years emphasis on micturition has shifted away from mere neuro-anatomy to neurophysiology and pharmacology. Multiple complex factors must work together in proper coordination for the normal.

Normal micturition is affected in causes of perianal pathology, postoperative pain conditions and physiologically also in unfavorable social circumstances, where obstruction is not the

cause for voiding difficulty. According to Ayurveda this complex mechanism is totally controlled by functions of Apana Vayu. In proper micturition act the normal functions of this is very essential. When there is vitiation of Apana Vayu it results in various dysfunctions of act of micturition. Pacification of this has been advocated for the normalization of the micturition act. So it can be understood that Apana Vayu plays important role in proper micturition and vitiation of this may lead to disturbances of normal neurophysiology and neuromuscular coordination of micturition.

In this study *Kanchnaar Guggula* and *Rohitakarista* has been proved to have effects on various subjective and objective parameters.

Ingredients of *Kanchnaar Guggula* and *Rohitakarista* have following properties

- Anti-inflammatory & Antispasmodic
- Antibacterial
- Diuretic
- Nervine tonic
- Bladder tonner
- Tumor regression
- Antioxidant activity
- *Vata – kapha pradhana, tridoshahara*

Probable Mode of Action

Mootraghata (BPH) is a troublesome obstructive urological condition for the majority of elderly men in the society. The probable mode of action of both the trail formulations is discussed as mentioned below based on the results of therapy and its interpretation by Ayurvedic as well as modern pharmacology.

While selecting the formulations, a hypothesis was made that as per etio- pathogenesis of *mootraghata* described in Ayurvedic classics and equivalent pathology described in modern texts for BPH, there is deranged function of *vayu*, particularly *apana vayu* which is the prime causative factor and this perturbed *vata* with *kapha* manifest *mootravaha srotodushti* as well *khavaigunya* due to *dhatvagnimandya*. So, the drugs which have *vata-kaphahara* properties like *srotoshodhana, lekhana, sophahara, mootrala* and *bastishodhana* along with *deepana-pachana karma* were selected, these properties helps to crack the *samprapti*.

The classical formulation of *Kanchanar Guggulu* and *Rohitakarista* was selected in *BPH;* because *Kanchnaar Guggula* is prescribed in management of Gandamala (Goiter), Apachi (Lymphadinitis), Arbuda (Tumor), Granthi (Swelling) etc and *Rohitakarista* is prescribed in Pleeha(spleenomegaly), Gulma, Udar roga, Astheela, Shotha(Inflammation) etc. The ingredients of Kanchanar Guggulu are Kanchanar twak, Triphala, Trikatu, Varun, Ela, Twak, Patra and ingredients of Rohitakarist are Rohitaka, Pippali, Pippalimool, Chavya, Chitaraka, Shunthi, Dhataki, Daalcheeni, Ela, Tejpatra, Amalaki.

The entire ingredients in this formulation have kashaya, madhura & tikta rasa; ruksha, ushna & teekshna guna; ushna veerya and katu vipaka. These properties, exerted pharmacological actions like agni deepana, ama pachana, mootrala, lekhana, shothahara, vilayana and srotoshodhana etc. Further, due to these actions, sanga is removed in mootravaha srotasa particularly at basti shira leaded to reduction in size of the enlarged prostate and simultaneously correction of agni dushti took place. As mootravaha srotasa becomes free from avarodha (in the form of aghata) or avarana caused by vitiated kapha, the vitiated vata comes to normal state. Thus, it normalized the physiology of apana vayu, results into proper evacuation of mootra in the form of increased urine flow rate and decreased post-voidal residual urine volume.

Because of improvement in jatharagni due to deepana & pachana effect of drugs, dhatvagnies also had come down in normal state. The function of basti snayu might have been improved due to correction of mamsa dhatvagni. Finally, mamsa and medo vriddhi had been returned to normal state due to normalization of dhatvagni; and ultimately leads to reduction in enlarged prostate gland size because of ama pachan, lekhana and sophahara action of ingredients.

To concise the group B treated with Rohitakarista showed máximum result in reducing the urgency of micturition compared with group A treated with Kanchnaar Guggula. The group B treated with Rohitakarista showed Second maximum result in reducing the the frequency of micturition compared with group A treated with Kanchnaar guggula. Urge of incontinence and incomplete emptying of bladder was reduced significantly in both the groups. The responce over strangury was encouraging in group A in comparison with Group B. The responce over straining and nocturia was encouraging in group B in comparison with Group A. AUA score questionres comprises of all the above said symptoms. The statistical significance of these questionaires, have showed overall satisfactory.

SUMMARY

This thesis work titled "A comparative study of "*Rohitakarista* and *Kanchnaar Guggula* in the management of *Mootraghata* w.s.r to Benign prostate hyperplasia" comprises of Introduction, Disease review (*Ayurveda* and modern review), Drug review, Clinical study, Observation & Results, Discussion and Conclusion.

- **Introduction** highlights the importance of *Āyurveda*, a few words about the presentation and manifestation of *Mootra vikaras*, BPH and its incidence & treatment modalities employed. The selection of the treatment for trial, need of the present study and intention of the study, aims and objective of the study, Plan of the study and related previous research work to the study are also included in this chapter.
- **Disease review** gives a detailed description of History, Etymology, *Nidāna, Pūrvarūpa, Rūpa, Saṃprāpti, Sādhyāsādhyata* and *Cikitsa* of mootraghata. The anatomy of Lower urinary tract is discussed in detail. This chapter also includes a description of Definition, History, Epidemiology, Pathology, Symptoms, Diagnosis, Investigations and Treatment of BPH.
- **Drug review** includes the ingredients of *Kanchnaar Guggula* and *Rohitakarista* with *Rasa, Guna, Veerya, Vipaaka, karma* and its chemical compositions are explained in detail.
- **Clinical study** describes Selection of the patients, diagnostic criteria, inclusion and exclusion criteria, materials and methods of the trial and assessment criteria. A clinical study was conducted on 40 patients in 2 groups. After registration, patients were randomly distributed into two Groups as Group A and Group B having 20 patients each.
- **Study design:** The present clinical study comprise of 40 patients. They were be divided into two groups as Group-A, Group-B.

- **Group-A:** 20 patients were treated with *Kanchnaar Guggula* 1000 mg orally two times a day for 60 days.
- **Group-B:** 20 patients were treated with *Rohitakarista* 20ml orally twice daily for 60 days.

Follow up period: 4 weeks.

Various observations regarding incidence of disease study in age, occupational status, *Prakruti* etc. are tabulated and represented graphically**.** Observations on statistical analysis are also included. All the cardinal signs and symptoms were scored according to the

severity grade. The clinical responses of the therapy in both groups were assessed on the basis of change in the severity score after the treatment.

RESULTS

The group B treated with *Rohitakarista* showed máximum result in reducing the urgency of micturition compared with group A treated with *Kanchnaar Guggula*. The group B treated with Rohitakarista showed Second maximum result in reducing the the frequency of micturition compared with group A treated with *Kanchnaar guggula*. Urge of incontinence and incomplete emptying of bladder was reduced significantly in both the groups. The responce over strangury was encouraging in group A in comparison with Group B. The responce over straining and nocturia was encouraging in group B in comparison with Group A. AUA score questionres comprises of all the above said symptoms. The statistical significance of these questionaires, have showed overall satisfactory results.

- **Discussions** of all the sections of the study are explained and discussed with the reasoning. It also deals with major results obtained regarding probable mode of action of both the drugs over.
- **Conclusion of the study says** *Kanchnaar Guggula* and *Rohitakarista* proves safe and cost effective remedy for the management of BPH. There is a Need of regular medications to prevent the symptoms as well as for the better life style. Also makes elective surgical intervention as treatment choice for the patients.

CONCLUSION

BPH (Benign prostrate hyperplasia) is comparable with *Mootraghata* in *Ayurveda*. The ancient system of medicine prescribes non surgical therapy, which is quite acceptable from the patient's point of view. On the basis of present study the following conclusions can be drawn.

- BPH is a natural development in elderly persons, but produces the symptoms of distress and discomfort which completely change the whole life style of an individual.
- The development of symptoms like frequency of micturition, hesitancy, urgency, strangury, increased nocturia, and suppression of urine and occasionally acute retention of urine- all these make the life of the sufferer very uncomfortable necessitating immediate remedial measures.
- All the patients of group 'A' and Group B reflected statistically significant reduction in assessment criteria i.e. emptying of bladder, frequency, urgency, straining, nocturia. The

quality of life improved with the reduction in symptom score (IPSS), Post voidal Residual urine.

- Ayurvedic treatment with *Kanchnaar Guggula* and *Rohitakarista* can make quite a significant difference to improve the lifestyle of the sufferer.
- No adverse effect was reported during and after completion of the treatment. So *Kanchnaar Guggula* and *Rohitakarista* can be taken without any complication.
- The Drugs advised in contemporary system of medicine has shown adverse effects, so to prevent those adverse effects *Kanchnaar Guggula* and *Rohitakarista* proves safe and cost effective remedy for the management of BPH.
- In the follow up period patients developed the symptoms gradually as before, so it concluded that it needs regular medications to prevent the symptoms as well as for the better life style.
- The trial groups showed significant reduction in post voidal Residual urine which makes elective surgical intervention as treatment choice for the patients.