

CLINICAL EVALUATION OF KANCHNAAR GUGGULU AND VARUNA KWATH CHURNA IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA

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ABSTRACT :

Benign Prostatic Hyperplasia (BPH) is a burning senile problem of elderly men and no definitive conservative cure is available. The present available surgical and minimal invasive methods have their own limitations. Researchers, in the field of ayurveda, have been working to provide an acceptable treatment for this condition, based on ayurvedic principles. Various researches carried out in this regard been proved to be effective with encouraging results. Keeping in consideration the results of previous researches a clinical trial of *Kanchnaar guggulu* and *Varuna kwath churna* was planned by Central Council for Research in Ayurveda and Siddha, New Delhi under Department of AYUSH, Ministry of Health & Family Welfare, and Government of India. Results of the trial were assessed on various parameters viz. American urology association (AUA) Symptoms Score, size of the prostate and volume of the post-void residual urine, Quality of life etc. There was improvement in various symptoms and results were also statistically significant. , Hence, it is concluded that combined therapy of *Kanchnaar guggulu* and *Varuna kwath churna* is beneficial without developing any adverse drug reactions and can be prescribed safely for *Mootraghata* (BPH).

Key words: Benign prostatic hypertrophy, BPH, Mutraaghata, Mutrakrichhra, Vatastheela, Kanchnaar Guggulu, Varuna kwath churna.

INTRODUCTION: The term *Mootraghata* stands for low urine output due to obstruction in the passage of urine. It can be considered as a syndrome, because it covers most of the pathological entity of the urinary system into 12 types [1] except urolithiasis and reflect the symptoms of retention of urine, incomplete voiding, dribbling, hesitancy, increased frequency of micturition, weak stream, and nocturia. These features are related to the Lower Urinary Tract Symptoms (LUTS) [2] and Bladder Outflow Obstruction (BOO), [3] hence, it can be co-related with the disease Benign Prostatic Hyperplasia (BPH) at modern parlance.

BPH is a senile disorder of the geriatric men with histologically proven high incidence of 92.97% ($n_0 = 185$) and 93.3% ($n = 200$) [4] in India. For this notorious problem there is no concrete conservative measure available until now. BPH involves multi-factorial pathogenesis caused by not only involvement of prostate and bladder, but also involves the hypothalamus-pituitary-gonads axis. The scope for medical therapy is still high because of the limitation of surgical approaches due to greater morbidity and failure to consistently achieve a successful outcome. [5] Therefore, to find out solutions through minimal invasive surgical techniques and

use of phytotherapeutic treatment as an alternative approach for BPH has been taken as a research problem in this particular field. In this regard, for the treatment of LUTS/BPH, phytotherapeutic agents in USA have gained widespread usage since 1990. ^[6]

In the context of manifestation of *Mootraghata*, developed due to deranged function of *Vayu*, particularly *Apana Vayu* leads to this condition. The authentic treatment for deranged *Vata* is the *Basti* and among them the *Matra Basti* (MB) is a safe one, which can be adopted without any restriction. ^[7] *Mootraghata* can be correlated to BPH and is caused due to vitiated *Vata* and *Kapha* which involve *Mootravaha Srotodushti*. Present clinical study was planned as per management principles ^[8] to evaluate the clinical efficacy of *Kanchnaar guggulu* and *Varuna kwath churna* in the management of *Mootraghata* with reference to BPH.

AIMS AND OBJECTIVES:

- Detaile study of mootraghata explained in ayurvedic, modern and releavent text journals etc.
- To know the efficacy of the Kanchnaar Guggulu and Varuna Kwath Churna in the management of mootraghata

MATERIALS AND METHODS:

Study design: A prospective observational clinical study with single group.

Source of Data: 50 Patients were registered in the trial from outpatient P.G.department of Shalya Tantra, National institute of Ayurveda Jaipur,among them 10 patients were dropped out.

DISTRIBUTION OF PATIENTS:

All 40 patients were studied in a single group

TRIAL DRUGS:

1.Kanchanara Guggulu^{[9][10]} :

1 gm after food with lukewarm water for 12 weeks

Prepared by Indian medicine pharmaceuticals limited batch no. AGU 11

2.Varuna Kwath Churna^[11]

25 gm BD before food with lukewarm

Prepared by Aryavaidyasala kottakal Batch no. 20008

OUTCOMES:

1.PRIMARY OUTCOME MEASURE

- Reduction in AUA score^[12] during the period of 12 weeks
- Change in quality of patients (QOL) index^[13]

2. SECONDARY OUTCOME MEASURE

- Reduction in post voidal residual volume of urine

Improvement in the Peak flow rate.

STUDY SCHEDULE

- **screening:** Informed consent and laboratory investigations
- **On baseline :** Demographic and medical history, clinical examination, assessment of Ayurvedic parameters, QOL index ,AUA score issue of drugs
- **On day 14th 28th 42nd 56th 70th** : clinical examination, AUA score, concomitant medication,Rescue mediacation, ADR, drug compliance issue of trial drugs.
- **On day 84th :** Lab investigation, clinical exam., Ayurvedic parameters, QOL index, AUA score, concomitant medicine, rescue medicine, ADR drug compliance
- **On 16th week follow up:** clinical examination QOL index AUA score

TIMELINES:

Treatment period: 12 weeks

Follow-up period: 4 weeks

INCLUSION CRITERIA:

- Patients with Age b/w 45-70 year

- Patients with AUA symptom score ≥ 8 and ≤ 21
- Rectal examination consistent with BP
- Prostate volume > 30 cc
- PSA < 4 ng/ml
- Urine flow rate > 5 to < 15 ml/sec. for 2 void
- Willing and able to participate in the study for 16 weeks

EXCLUSION CRITERIA:

- Patient with severe BPH (AUA score > 21)
- Patient currently using any other form of medical therapy for BPH/hair loss
- Patient with H/O of TURP
- Serum PSA > 4 ng/ml
- Chronic retention of urine(post voidal urine volume > 150 ml)
- Refractory bactreuria
- Patient with persistent gross haematuria
- Patient with evidence of malignancy
- patient with poorly controlled diabetes mellitus
- patients with poorly controlled hypertension
- patients on prolonged (≥ 6 weeks) medication with corticosteroids, anti-depressants, anticholinergics, etc. or any other drugs that may have an influence on outcome of the study.
- patients suffering from major systemic illness necessitating long term drug treatment(Rhematoid Arthritis, Tuberculosis, Psycho-Neuro-Endocrinial disorders etc.
- Patient who have a past H/O of Atrial fibrillation, Acute coronary syndrome, Myocardial infarction, Stroke or Severe Arrhythmia in last 6 months.
- Symptomatic patient with clinical evidence of Heart failure.

- Patients with concurrent serious hepatic disorder (defined as AST and/ or ALT) total billirubin, Alkaline phosphatase > 2 times upper normal limit or renal disorder(defined as S.creatinine > 1.2 mg/ml), severe pulmonary dysfunction(uncontrolled Bronchial Asthma and/or COPD, or any other condition that may jeopardize the study.

- Alcoholic and drug abusers.
- H/O hypersensitivity to any of the trial drugs.
- Patients who have completed participation in any other clinical trial during the past six (06) months.
- Any other condition which the Principal Investigator thinks may jeopardize the study.

INVESTIGATIONS:

UROFLOWMETRY

ULTRASOUND-WHOLE ABDOMEN (with special reference to Prostate)

HAEMATOLOGICAL:

Haemoglobin%, Total leucocyte count, Differential leucocyte count, Erythrocyte sedimentation rate Blood Sugar fasting

BIOCHEMICAL: Blood Urea, Serum Uric acid, Serum creatinine, SGOT, SGPT ,Total protein (albumin, globulin, Serum Bilirubin Serum Alkaline phosphatase, Serum PSA

URINE ANALYSIS:-R/E: WBC, RBC Protein, Sugar

Urine culture

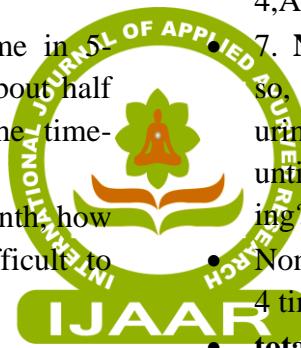
OBJECTIVES

Primary Objective: To assess the clinical efficacy of *Kanchanaar Guggulu* and *Varuna Kwath Churna* on **AUA symptom score** in the patients of BPH.

- 1. **Incomplete emptying:** Over the past month, how often have you had a sensation of not



- emptying your bladder completely after you finished urinating?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 2. **Frequency:** Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 3. **Intermittency:** Over the past month, how often have you found that you stopped and started again several times when you urinated?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 4. **Urgency:** Over the past month, how often have you found it difficult to postpone urination?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 5. **Weak-stream:** Over the past month, how often have you had a weak stream?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 6. **Straining:** Over the past month, how often have you had to push or strain to begin urination?
- Not at all-0, Less than 1 time in 5-1,Less than half the time-2,About half the time-3,More than half the time-4,Almost always-5
- 7. **Nocturia:** Over the past month or so, how many times did you get up to urinate from the time you went to bed until the time you got up in the morning?
 - None-0,1 time-1, 2 times-2, 3 times-3, 4 times-4,5 or more times-5
- total AUA score = _____



OBSERVATION AND RESULTS

Table no.1: Observations of total registered patients.

Findings	Predominance	Percentage
Age	65-70 yrs. Age group	52.50%
Sharirik Prakriti	Pitta-Kaphaja	40.00%
Socio-economic status	APL	65.00%
Dietary habits	Vegetarian	85.00%
Chronicity of disease	Up to 1	57.50%
Addiction	None	65.00%
Occupation	Desk Worker	62.50%
Prostate grade(weight)wise	II(30-50gms)	92.50%
Involved prostate lobes	Lateral	50.00%
Severity of AUA	8-19	82.50%

Table no.2The Comparison of AUA Score on base line to all follow up

Comparison	Mean Diff.	% Change	S.D.±	S.E.±	t	p	Significance
0 & 84 th day	6.275	38.975	2.5216	0.3987	15.73	<0.001	H.S.

Table no.3.Changes in Chief Complaints of 40 patients.

Chief Complaints	No. of Patients having this Complain Before Treatment	No. of Patients having this complain After Treatment
Frequency	40	40
Abdominal Blotting	19	7
Urgency	33	4
Pain In Lower Abdomen	17	3
Straingury	4	14
Feeling Of Incomplete Evacuation	37	4
Nocturia	35	36

Table no.4.Summarized result on different parameters

Parameters	Mean B.T.	Mean A.T.	SD	SE	t- value	p-value
AUA	16.1)	9.825	2.5216	0.3987	16.394	<0.001(HS)
QOL	4.775	2.575	0.7232	0.1144	19.238	<0.001(HS)
Frequency	3.275	2.600	0.7299	0.1154	5.849	<0.001(HS)
Incomplete evacuation	1.325	0.1750	1.122	0.1774	6.482	<0.001(HS)
Intermittency	2.325	0.1775	0.7494	0.1185	4.642	<0.001(HS)
Urgency	2.450	0.3000	0.9213	0.1457	14.760	<0.001(HS)
Weak stream	2.475	1.575	0.9282	0.1468	6.132	<0.001(HS)
Straining	2.125	1.650	0.6400	0.1012	4.694	<0.001(HS)
Nocturia	2.125	1.725	0.9554	0.1511	2.648	<0.01 (S)
Residual urine volume	35.29	18.2	29.531	4.669	3.660	<0.001(HS)

Prostate weight	36.508	34.375	3.9929	0.6313	3.3778	<0.001 (HS)
Peak flow rate in	11.26	14.60	2.854	0.4513	7.4014	<0.001 (HS)
Average flow rate	4.965	6.325	1.6394	0.2592	5.2467	<0.001(HS)
Serum PSA	2.9425	2.4	0.3752	0.0593	8.1748	<0.001(HS)

DISCUSSION ON OBSERVATION :

Age incidence: All the patients were categorized in 3 age groups viz. 45-55 yrs, 55-65 yrs and 65-70 yrs.. In present clinical study most of the selected cases of BPH were between the 65-70 of age group (52.5%). The BPH incidence increases with the increase in age (Tsukamoto et al. 1995a). The clinical diagnosis of BPH made entirely on the basis of a history and physical examination. In the Baltimore longitudinal study of aging 69% of men aged 61-70 were given the clinical diagnosis of BPH, where as the prevalence of pathologic BPH in this decade was estimated to be 70.7%.

Prakriti incidence: The maximum number of patients was of Pitta kaphaja prakriti (40 %), followed by Vatta kaphaja prakriti (32.50 %). BPH is the disease of old age and according to Ayurvedic principle there is kaphaja predominance in all normal and abnormal growths.

Socio-economic status: On the basis of socioeconomic status patients were divided in two groups- Above poverty line and below poverty line. The parameter was monthly income of patients. The maximum number of patients were above poverty line (65%) and 35% were from below poverty line. The N.I.A., Jaipur hospital situated near lower and middle-income

group so probably this factor increases the middle and lower class patient incidence.

Diet relation: According to above table the most of patients was vegetarian (85.00%). In modern literature no specific type of diet correlation was described in relation to BPH prevalence. In present clinical study only four Muslim patients were registered, rest are Hindus who are mostly vegetarian.

Chronicity relation: On the basis of Chronicity of BPH all the patients were divided in four groups. There was no any significant variation. The maximum number of patients was with less than 1-year Chronicity (57.50%) of BPH symptoms. Nowadays patients are so much aware about his health problem and BPH destroys quality of life very much, so patients in early stage of BPH, When diagnosed as a BPH patient, seek alternative treatment for the improvement of their quality of life.

AUA Score : The AUA (American urology association) is recommended as a symptom scoring instrument to be used for baseline assessment of the severity in each patient presenting with prostatism. The grades were done on the symptoms score index for the assessment of the therapy. In this study 82.50% patients were having severe grade AUA score and 17.50% had

moderate grade score. None of the patients included with mild grade score as inclusion criteria.

By analyzing the above it is evident that AUA score improved after treatment. Improvement in AUA score may be related to multiple actions of the used formulation *Kanchnaar guggulu* and *Varuna kwath churna* on the urinary system which relieved the symptoms of the BPH. The comparison between baseline with each follow up has been done highest change in % of AUA score is between Baseline (0th Day) and 84th day that is last day of treatment is seen that is 38.975% and which is statistically highly significant.

QUALITY OF LIFE INDEX(WHO)

QOL score is also a question based tool for the assessment of severity of botheration to the patient due to enlargement of the prostate gland. On the basis of score patients were asked for thinking about life with symptoms of BPH.

80.00% patients were having QOL score 5 (unhappy) & 6 (terrible) and 17.50% patients had score 3 (mixed) 4 (dissatisfied).

Response of therapy on QOL Score:

There was reduction in severity of botheration after treatment. Results were statistically highly significant. Results may be due to the drugs used in the trial were effective on urinary disorders.

Response of therapy on residual urine volume: Failure to empty the bladder may result from an atonic bladder or a bladder outlet obstruction. Normally 100% of normal men have postvoidal residual urine volume less than 12 ml. (Di Mare et al, 1963). In this study assessment of postvoidal residual urine volume was done by ultrasonography. Reduction in PVR is an important criteria for the assessment of response of therapy.

In this study there was no change in PVR in 32.5% patients whereas it increased in 05% patients and in 62.5% patients there was reduction in PVR. Results were found statistically highly significant.

Response of therapy on prostate weight :

In men between 31-50 years doubling time of prostate weight is 4.5 years, whereas in between 51-70 years doubling time is 10 years. Average of 6 ml. of prostate volume increases in duration of 10 years (C.U.) Therefore it is clear that between 3rd to 5th decade rate of prostatic growth is at peak when compare to later decades of life i.e. after 5th decade. But symptoms become more severe as age advances. This is because of age related bladder function changes. Prostate weight is calculated on the basis of three dimensions of the prostate.

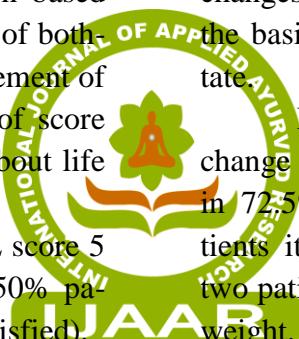
In this study patient there was no change in prostate weight after treatment in 72.5% patients whereas in 22.5% patients it was decreased. There were only two patients (5%) with increase of prostate weight. Results were statistically highly significant.

Response of therapy on Peak flow rate of urine:

The Uroflowmetry findings are nonspecific for causes of symptoms of lower urinary tract. Abnormal flow may be because of obstruction or detrusor hypo contractility. The peak flow rate more specifically identifies the patients with BPH than does the average flow rate. (C.U.). There was no change in peak flow rate only in 2.5% patients after treatment whereas it was increased in 97.50% patients and there was no patient with decreased peak flow rate. Results were statistically highly significant.

Response of therapy on average flow rate:

Average flow rate of urine was in-



creased after the treatment. Results were also statistically highly significant.

Response of therapy on Serum PSA Level

Serum: PSA level were decreased after the treatment. Results were also statistically highly significant.

In this study assessment of the efficacy of the therapy was done on various subjective and objective parameters in the patients suffering from the symptoms of the BPH. On analysis of the previous discussion it is clear that there was positive response of therapy.

PROBABLE MODE OF ACTION:

Effects of *Kanchnar Guggulu* on Gross Urinary physiology w.s.r. to prostate:

Prepared from gum resin of *Commiphora mukul* and bark powder of *Bauhinia variegata*, *Kanchnara Guggulu*. Its specific indication is in *Gundmala*, severe form of *Apache*, *Arbuda*, *Granthis*, *Uvana*, *Gulma*, *Kushtha* and *Bhagandara* 22. The benign hyperplasia of prostate is also a type *Granthis*. The overall pathological phenomena of BPH also show the same kind of fibrotic growth in prostatic parenchyma. As the pathology of BPH, the fact revealed that the prostatic growth factor was found through sequence analysis to be basic fibroblastic growth factor (FGF). In addition to FGF, other heparin-binding growth factors (fibroblastic growth factor), transforming growth factors (TGF-13), and epidermal growth factor (EGF) have been found in hyperplastic BPH tissue. It is likely that growth factors play some role in the pathogenesis of BPH. It is quit possible that *Kanchnar Guggulu* may work to overcome the fibroblastic growth factor (FGF) or some other.

In the context of *Utpatti* of *Basti* and *Guda* it has been told that, they are the

Prasada Bhaga of *Rakta* and *Kapha*. This *Prasada Bhaga* gets *Pachymana* by *Pitta* and in this process *Vata* helps *Pitta* to potentiate the action. *Mootrasthila* occurs in between *Basti* and *Guda* region and this phenomenon has influence on the disease manifestation of *Mootrashtela* also.

The epithelial budding and glandular morphogenesis in BPH are similar to those in embryonic tissue, a process generally forbidden in adult organs, leading to the suggestion that BPH is the result of a “reawakening” of the embryonic inductive potential of prostatic stroma in adulthood 16. It is very much likely to support the concept that the incidence of *Ashthila* is promoted by embryonic precursor after vitiation of *Kapha* and *Rakta Dosha*. These *Dosha* get aggravated in old age and develop *Kaphaj Granthi* like growth. *Rakta* also gets involved in pathogenesis, as the aging prostate maintains a high level of dihydrotestosterone (DHT), as well as a high level of androgen receptor; thus, the mechanisms for androgen dependent cell growth are maintained.

Most of the drugs present in *Kanchnar Guggulu* have *Katu Rasa*, *Ruksha* and *Laghu Guna*, *Ushna Virya*, *Madhura Vipaka* and the property of *Kapha-Vata Hara*. Major proportion of *Madhura*, *Tikta* and *Kashaya Rasa* containing drug is also present. The properties like *Rasayana*, *Vayasthapana*, *Medhohara*, *Krimighna*, *Lekhana*, *Shothaghna* and *Vata-Kapha Shaamana* are helpful to act on various changes in BPH. *Commiphora mukul* contains compounds called guggulsterones, which range from E to Z. It inhibits tumor cell proliferation, induces S-phase arrest, and promotes apoptosis through activation of c-Jun N-terminal kinase, suppression of Akt pathway, and

down regulation of antiapoptotic gene products.

The action of *Kanchnar Guggulu* on enlarging prostate is proved in present clinical trial. The size reduction in prostate is noted about 3.01%. This tremendous action may be due to anti-androgenic, anti-inflammatory, antibiotic, anti-mutagenic and anti-fibroblastic properties of *Kanchnar Guggulu*.

Effects of *Virtarvadi Gana Kashaya*:

The most of the constituents of this *kashaya* are having the *Madhura*, *Tikta* and *Kashaya Rasa*. Subsequently, the *Pitta* pacifying action is the chief pharmaco-dynamics of formulation. Due to occurrence of *Pitta hara* drugs in majority, the *Shita Virya* is predominantly present in formulation. The ultimate *vipaka* is *Katu Pradhan*. This group of drugs has shown an excellent diuretic property, anti-inflammatory, anti-androgenic property.

Present evaluation indicates clinically beneficial effect of *Kanchnar Guggulu* and *Varuna kwath churna* and safety as far as its anti-androgenic effect is concerned. This study also indicates safety of *Kanchnar Guggulu* and *kwath churna*, and also they do not have any adverse effect.

CONCLUSION:

- The trial drugs have been proved to be effective on various subjective and objective parameters in the management of BPH.
- The quality of life (QOL) improved with the reduction in symptom score (AUA), reduction in Prostate weight, Residual urine, and improvement in Peak & Average flow rate.
- So it can be concluded that (*Kanchnaar guggulu* and *Varuna kwath churna* if together used in patients of BPH,

it helps to improve the quality of life of the patients by reducing the AUA, QOL, prostate weight, post-void residual urine and increase in peak flow rate of urine thus providing relief from the symptoms of BPH.

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