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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF “KANCHNARA GUGGULU AND VIR-TARVADI GANA KASHAYA” IN MANAGEMENT OF B.P.H (BENIGN PROSTATE HYPERPLASIA)

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ABSTRACT

Medical as well as surgical treatment of Benign prostate hyperplasia, despite a long history of credentials and conduct, still poses a challenge to medical fraternity in terms of finding satisfactory cure of the disease. This clinical study was done to evaluate the synergetic therapeutic and clinical effect of the *Kanchnara Guggulu* with *Vir-tarvadi Gana Kashaya* in the management of Benign prostate hyperplasia (BPH). 28 patients of BPH vis-à-vis *Vatashthila* were studied, who were randomly selected. Modified Boyarsky scoring system and International prostate symptoms score was taken for subjective assessment. Ultrasonically assessed weight and size of prostate and post voidal residual urine were criterion for objective evaluation. The total IPSS was improved by 76.17% from 25.785 ± 3.224 to 6.142 ± 2.304 . The reduction in symptom score was highly significant ($t = 32.249$, $p < 0.001$). The score of “quality of life” had shown 80.58% improvement. The prostate weight was reduced by 3.01% from the mean value 48.978 ± 16.457 gm to 47.5035 ± 17.314 gm. The reduction in volume of post voidal residual urine from 47.893 ± 42.99 ml to 10.678 ± 16.129 ml was noted. The result shows that the action of drugs *Kanchnar Guggulu* and *Virtarvadi Gana Kashaya* are not only over physiologic component but also over the anatomical component of pathogenesis.

Keywords: Benign prostate hypertrophy, *kanchnar guggulu*, *virtarvadi gana kashaya*.

INTRODUCTION

The earliest descriptions about urinary retention (*Mutra Sanga*) and its surgical management by direct puncturing of bladder with *Shara Kanda* is available in *Atharva Veda*, i.e. in the Vedic period 2500 BC¹. Description of *Basti* and other related organs are also found from the *Yajurveda*².

Aggravated *Vata* localized inside the passage of faeces i.e. rectum and the urinary bladder produces a hard tumor, like the cobbler's stone, is immovable and bulged up, giving rise to obstruction of faeces, urine and flatus; develop flatulence and severe pain in urinary bladder, produces the disease called *Vatashthila*³. So, it is obvious that the disease, *Vatashthila* is a combination of anatomical mal-alignment and physiological mal-functioning derangement. *Charaka* also defines that *Vata* produces obstruction in urinary bladder and anal region. It blows them up forming a protruded stony mass; which is mobile in nature and causes extreme pain along with the obstruction in passage of urine and feces⁴. *Sushruta* says that cobble stone like hard tumor, extended to upward, protruded

and obstructing the out passages should be considered as *Vatashthila*⁵. *Sushruta* also elaborated at another place that the malpractice of inserting *Shooks* made of *Bhallataka* like poisonous and irregular substances inside the urethra, vitiates *Vata*; which produces hard *Pidika* known as *Ashthilika*⁶. *Sushruta* has adopted a common line of treatment in all the cases of urinary disorder. *Virechana Karma* after proper *Snehana-Swedana* followed by *Uttar Basti* is best modality⁷. Decoction, *Kalka*, ghee, *Avleha*, milk, *Kshar*, alcohol, *Upnaha Sweda*, *Uttar Basti*, *Sneha Virechana* and litholytic medication should be used in all types of urinary suppression⁸. *Charak* has indicated *Mutrakriccha Nashak Aushadhi* on the basis of vitiated *dosha* in body. *Basti* and *Uttar Basti* are recommended in all types of bladder disorders⁹. Surgical intervention has also been described in texts. Application of leech and excision of gland, like *Kaphaj Granthi* is indicated in recurrent variants of *Ashthila*¹⁰. *Vatashthila* can be correlated to Benign prostatic hyperplasia (BPH). BPH is the most commonly occurring benign proliferative abnormality found in any internal organ¹¹.

Autopsy studies have shown that 50% of 45-year-old men have histological evidence of BPH; this figure increases to nearly 90% of men in their ninth decade¹². BPH is found in about 50% of the male population in their fifth decade and shows a tendency to increase to 80% in men over 80 years of age¹³. One in every four men in the United States will require treatment for symptomatic relief of BPH by the time they reach age 80 years¹⁴.

The human prostate gland is a composite organ, made up of glandular and non-glandular components and composed of both epithelial and stromal cells¹⁵. 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 adulthood¹⁶.

This clinical trial was done to evaluate the synergetic therapeutic and clinical effect of the *Kanchnara Guggulu* with *Vir-Tarvadi Gana Kashaya* in the management of BPH.

MATERIALS AND METHODS

In this study, 30 patients, who had classical sign and symptoms of BPH vis-à-vis *Vatashthila* were studied, which were randomly selected from the O.P.D. and I.P.D. section of hospital. One patient was finally diagnosed as CA prostate, so he was excluded and one patient was defaulter during the course of study. Finally the 28 patients were studied (n=28). A special research performa was designed to standardize this explorative activity, on the basis of international parameters, which had also included all the specific constraints used in the standard *Ayurvedic* researches.

Inclusion criteria:- Diagnosed cases of BPH with lower urinary tract symptoms (LUTS) like incomplete emptying, nocturia, intermittency, urgency, weak stream, straining and frequency, age above 45 years, residual urine <100ml and digital rectal examination (DRE) suggesting enlarged prostate were included.

Exclusion criteria:- Cases with prostatic carcinoma, prostatitis, idiopathic bladder neck obstruction, bladder neck stenosis, bladder neck hypertrophy, prostatic calculi,

neurogenic bladder, renal failure-acute and chronic, urethral stricture, complications of BPH, severe symptoms of lower urinary tract symptoms (LUTS) and residual urine >100ml were excluded.

Diagnostic criteria:-

After examination, the patients having more than 20 gm prostate weight in ultrasonic examination were classified as follows:-

Grade 1	20 – 40 gm
Grade 2	41 – 60 gm
Grade 3	61 – 80 gm
Grade 4	more than 80 gm

Follow-ups of the patients:-

All the patients were asked first of all to report after 15 days after commencement of treatment. After 1st follow-up, all patients were re-evaluated after next 15 days. The clinical trial was further extended to two more follow-ups on the interval of one-one month to study on the long term basis.

Selection of drug: - All the drugs were collected from nearby regions in the *Hemant Ritu*, in month of November – December, 2007. Wet drug was dried in sunlight and then was properly formulated at a local pharmacy. The drugs were collected after proper identification.

Preparation of drug: -

(1) *Virtarvadi Kwath: -*

All the drugs were dried to evaporate the vapor contents present in it. Under proper hygienic control the drugs were crushed in the size of barley (*Yavakuta*) in the disintegrator machine. The *Yavakuta Kwatha* was packed in small packets consisting quantity of 210 gm each for the dosage of one week.

(2) *Kanchnar Guggulu: -*

All the raw materials except *Guggulu* were taken in rationale proportion and were crushed in the form of powder. The *Guggulu* of same quantity was dissolved in water properly. Then the previously formed powder was pulverized in this solution as a doughy mixture. Small pellets like tablets of the weight of 500mg were prepaid and get dried under direct sunlight.

Composition of <i>Viratarvaadi Gana Kashaya</i> (each 15 gm contains)				
Sr. No.	Name	Botanical name	Family	Quantity
1	<i>Virataru</i>	<i>Terminalia arjuna</i>	<i>Combretaceae</i>	0.789gm
2	<i>Sahachara dvaya</i> (blue)	<i>Barleria strigosa</i>	<i>Acanthaceae</i>	0.789gm
3	<i>Sahachara dvaya</i> (white)	<i>Barleria cristata</i>	<i>Acanthaceae</i>	0.789gm
4	<i>Darbha</i>	<i>Imperata cylindrica</i>	<i>Poaceae</i>	0.789gm
5	<i>Vrikshaadani</i> (vandaaka)	<i>Dendrophthoe falcata</i>	<i>Loranthaceae</i>	0.789gm
6	<i>Gundra</i>	<i>Cyperus rotandus</i>	<i>Cyperaceae</i>	0.789gm
7	<i>Nala</i>	<i>Arundo donax</i>	<i>Poaceae</i>	0.789gm
8	<i>Kusha</i>	<i>Desmostachya bipinnata</i>	<i>Poaceae</i>	0.789gm
9	<i>Kaasha</i>	<i>Saccharum spontaneum</i>	<i>Poaceae</i>	0.789gm
10	<i>Ashmabheda</i> (Controversial-Paashaanabheda)	<i>Bergenia ligulata</i>	<i>Saxifragaceae</i>	0.789gm
11	<i>Agnimantha</i>	<i>Premna integrifolia</i>	<i>Verbenaceae</i>	0.789gm
12	<i>Morata</i> (Controversial-Murva)	<i>Helicteres isora</i>	<i>Sterculiaceae</i>	0.789gm

13	<i>Vasuka – Vrihat maulshri</i>	<i>Osmanthus fragrans</i>	<i>Oleaceae</i>	0.789gm
14	<i>Vashira</i> (Controversial– <i>Apaamaarga</i>)	<i>Achyranthes aspera</i>	<i>Amaranthaceae</i>	0.789gm
15	<i>Bhalluka - Shyonaaka</i>	<i>Oroxylum indicum</i>	<i>Bignoniaceae</i>	0.789gm
16	<i>Kurantaka</i>	<i>Barleria prionitis</i>	<i>Acanthaceae</i>	0.789gm
17	<i>Indivara- Neel Kamala</i>	<i>Nelumbo nucifera</i>	<i>Nelumbonaceae</i>	0.789gm
18	<i>Kapotavankaa-Braahmi</i>	<i>Bacopa monnieri</i>	<i>Scrophulariaceae</i>	0.789gm
19	<i>Gokshura</i>	<i>Tribulus terrestris</i>	<i>Zygophyllaceae</i>	0.789gm

Composition of *Kanchnar Guggulu* (each 500mg contains)

Sr. No.	Name	Botanical name	Family	Quantity
1	<i>Kanchnar</i>	<i>Bauhinia purpurea</i>	<i>Caecalpinoideae</i>	22.7mg
2	<i>Haritaki</i>	<i>Terminalia chebula</i>	<i>Combretaceae</i>	22.7mg
3	<i>Vibhitaki</i>	<i>Terminalia bellerica</i>	<i>Combretaceae</i>	22.7mg
4	<i>Amalaki</i>	<i>Embllica officinalis</i>	<i>Euphorbiaceae</i>	22.7mg
5	<i>Pippali</i>	<i>Piper nigrum</i>	<i>Piperaceae</i>	22.7mg
6	<i>Maricha</i>	<i>Piper nigrum</i>	<i>Piperaceae</i>	22.7mg
7	<i>Shunthi</i>	<i>Zingiber officinale</i>	<i>Scitaminae</i>	22.7mg
8	<i>Varuna</i>	<i>Crataeva religiosa</i>	<i>Capparidaceae</i>	22.7mg
9	<i>Sukshma-Ela</i>	<i>Elettaria cardamomum</i>	<i>Scitaminae</i>	22.7mg
10	<i>Dalchini</i>	<i>Cinnamomum zeylanica</i>	<i>Lauraceae</i>	22.7mg
11	<i>Tejpatra</i>	<i>Cinnamomum tamala;</i>	<i>Lauraceae</i>	22.7mg
12	<i>Guggulu</i>	<i>Commiphora mukul</i>	<i>Burseraceae</i>	250mg

Dosage, method of administration and duration of treatment:-

(1) *Virtarvadi Kwatha*:-

The fully prepared *Kwath* material was taken 15 gm for a single dose. This amount was instructed to add with the 60ml water and boiled. When the volume of decoction remained 15 ml (i.e. 1/4th), it was filtered and taken by patient at *Sukhoshna* temperature. Two such dosages were advised to every patient.

(2) *Kanchnar Guggulu*:-

The two tablets were administered twice a day with Luke warm water or the above decoction.

Duration of treatment:-

The whole therapeutic regimen was administered for the period of thirty days. After this duration the 90 days follow-up was also given to appraise the long term effect of therapy.

Study design:-

It was a randomized single blind trial for the actual assessment in the symptomatic and objective evaluation in the patients of enlarged prostate.

Parameters of assessment:-

There were mainly two parameters to assess the progress of therapeutic regimen, one was subjective and another objective. Modified Boyarsky scoring system and International prostate symptoms score was taken for subjective assessment. Ultrasonically assessed weight and size, post voidal residual urine was another criterion for objective evaluation.

General parameters:-

The patients having the lower urinary tract symptoms were evaluated on the ground of two highly specific grading systems i.e. Modified Boyarsky score and International prostate symptom score.

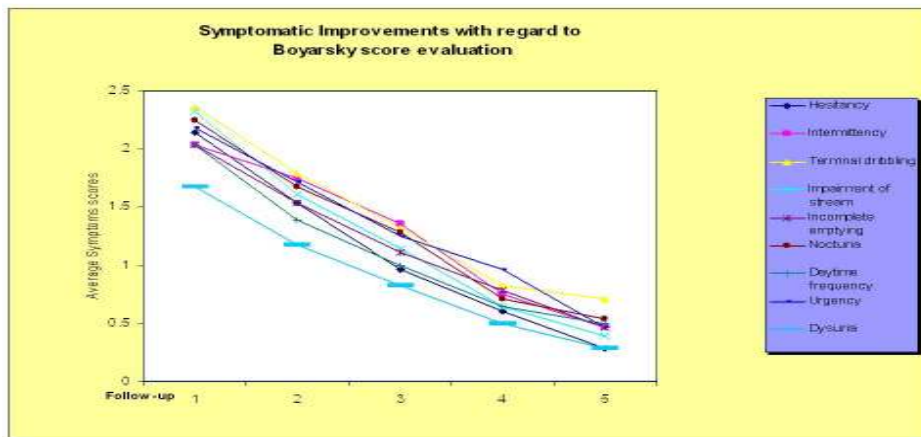
Assessment of total effect of therapy:-

The overall assessment was calculated on the basis of average improvement in terms of percentage relief of scores i.e. complete remission-100%,marked improvement-75% to 100%,improvement-50% to 75%,mild improvement- 25% to 50%,unchanged-below 25%. The paired ‘t’ test was applied to paired data of independent observations from the selected population, where each individual gave a pair of observations.

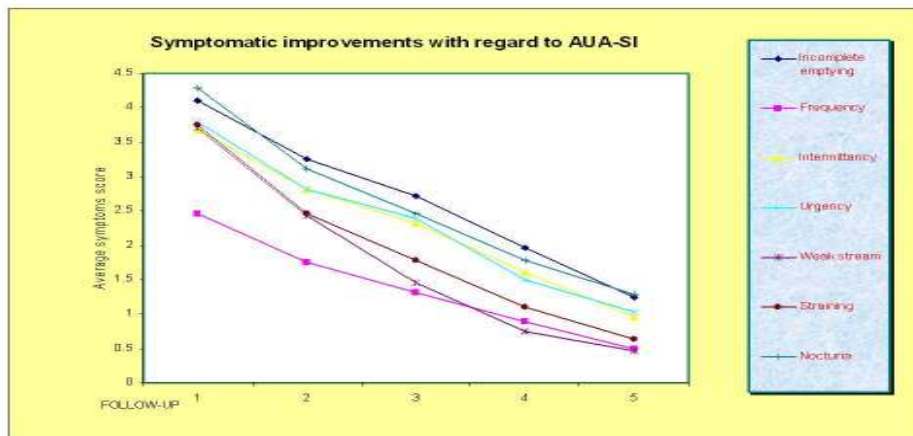
Observations

Effect of *Virtarvadi Kashaya* and *Kanchnar Guggulu* on cardinal symptoms of BPH as per the International symptoms scoring system:-

Sr. No.	Symptoms	Mean score		D	%	S.D. (±)	S.E.	t value	P value
		B.T.	A.T.						
1.	Incomplete emptying	4.107 ±0.916	1.25 ±0.844	2.857	69.56	0.8908	0.1683	16.976	<0.001
2.	Frequency	2.464 ±1.426	0.50 ±0.693	1.964	79.70	1.1700	0.221	8.888	<0.001
3.	Intermittency	3.678 ±1.123	0.964 ±0.922	2.714	73.79	0.8967	0.1694	16.022	<0.001
4.	Urgency	3.785 ±1.031	1.035 ±0.881	2.75	72.65	0.6852	0.1294	20.147	<0.001
5.	Weak stream	3.714 ±1.013	0.464 ±0.792	3.25	87.50	0.9371	0.1771	18.553	<0.001
6.	Straining	3.75 ±1.174	0.643 ±0.826	3.107	82.85	1.1333	0.2141	14.512	<0.001
7.	Nocturia	4.286 ±0.854	1.285 ±0.713	3.001	70.01	0.6666	1.2598	2.3813	<0.05
8.	Total	25.785 ±3.224	6.142 ±2.304	19.643	76.17	3.2227	0.6090	32.249	<0.001
9.	Quality of life	4.964 ±0.881	0.964 ±0.881	4.0	80.58	1.0184	0.1924	20.790	<0.001



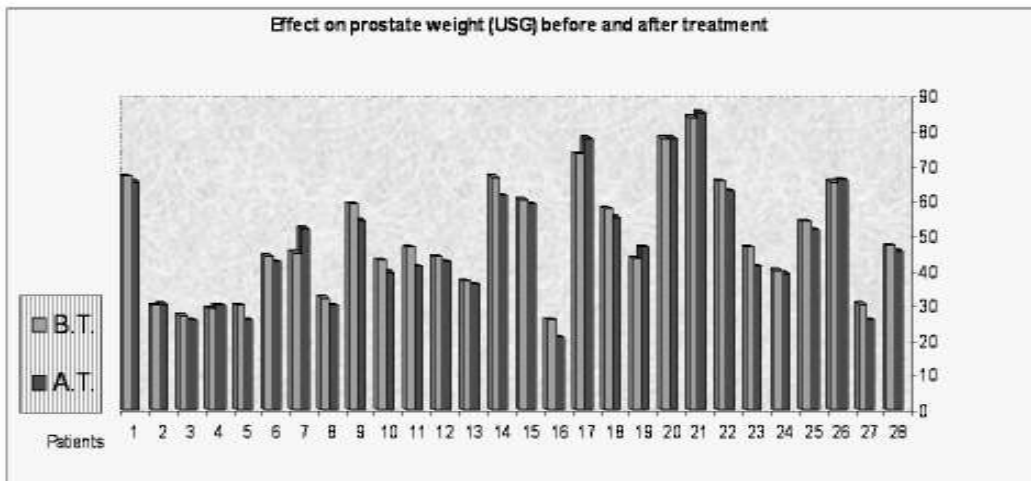
The graph showing the all nine symptoms with regard to Boyarsky score evaluation



The graph showing the all seven symptoms with regard to IPSS:

Effect of *Virtarvadi Kashaya* and *Kanchnar Guggulu* on prostate weight and post void residual urine measured by ultra-sound:-

Sr. No.	Criteria	Mean value		D	%	S.D. (±)	S.E.	t value	p value
		B.T.	A.T.						
1.	Prostate weight(gm)	48.978 ±16.457	47.5035 ±17.314	1.4745	3.01	3.0411	0.5747	2.566	<0.01
2.	Post-voidal residual urine(ml)	47.893 ±42.99	10.678 ±16.129	37.215	77.70	37.043	7.0004	5.3160	<0.001



The graph showing prostate weight and post void residual urine measured by ultra-sound

RESULTS

MODIFIED BOYARSKY SCORE

All the obstructive symptoms were collectively scored as 11.036 ± 2.21 B.T. and 2.321 ± 1.24 A.T. The 78.96% reduction in obstructive symptom was noted. The S.D. of data from mean value was ± 2.291 . The effect of drug was found to be highly significant against obstructive symptoms ($t=20.13$; $p < 0.001$).

Irritative symptoms were collectively improved by 78.07%. The S.D. from mean value of difference was ± 1.56 . The total score was improved by 78.58% from 19.179 ± 3.07 to 4.107 ± 1.93 . The t value was 25.706 against degree of freedom equal to 27 (p value < 0.001).

INTERNATIONAL PROSTATE SYMPTOMS SCORE (IPSS)

Thus the total score was improved by 76.17% collectively from 25.785 ± 3.224 to 6.142 ± 2.304 . The reduction in symptom score was highly significant ($t = 32.249$, $p < 0.001$).

The added score by WHO is "quality of life", which had shown 80.58% improvement. The data are highly significant ($t=20.790$, $p < 0.001$).

OBJECTIVE CRITERIA:-

The prostate weight was reduced by 3.01% from the mean value 48.978 ± 16.457 gm to 47.5035 ± 17.314 gm. The S.D. from mean difference was observed as ± 3.0411 . The calculated t value was 2.566 against the degree of freedom 27 ($n=28$). The observation for the reduction in prostate size and weight is significant ($p < 0.01$). The reduction in volume of post voidal residual urine from 47.893 ± 42.99 ml to 10.678 ± 16.129 ml was noted ultrasonically. This improvement was calculated about 77.7%. The result is highly significant ($p < 0.001$).

DISCUSSION

The categories of prescription medications currently available for treating BPH are $\alpha 1$ -adrenergic antagonists (e.g., tamsulosin) and 5α -reductase inhibitors (e.g., finasteride). These medications act on dynamic and static components of bladder outlet obstruction. A meta-analysis by Djavan and Marberger reviewed the randomized controlled trials of the $\alpha 1$ -adrenergic antagonists used for treatment of BPH¹⁷.

The Medical Therapy of Prostatic Symptoms (MTOPI) trial involved 3407 men with BPH who were randomized to placebo, doxazosin, finasteride, or combination therapy. Significant findings were a 66% reduction of clinical progression with combination therapy ($P < .001$), a reduced risk of acute urinary retention or need for invasive therapy with combination therapy ($P < .001$), and improved symptom scores with invasive therapy ($P < .001$)¹⁸.

Herbal medicines used to treat BPH include derivatives from African star grass, African plum tree bark, rye grass pollens, stinging nettle, and cactus flower. Saw palmetto is considered safe, and available evidence supports its effectiveness. In a large European trial by Carraro et al, 1098 men were randomized to saw palmetto or finasteride having same improvement in symptom scores^[19]. Furthermore, a meta-analysis by Boyle et al showed that compared with placebo,

saw palmetto improves peak urinary flow rates and reduces nocturia in men with BPH²⁰.

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* (237 mg three times /day) was given to 899 tribal people of India bearing simple goiter. They were also asked to apply *Kanchnar* ointment simultaneously. 90 to 100% improvement was observed in the swelling of the gland in 163 patients, a 50 to 100% improvement was seen in 148 patients, and up to a 50% improvement was observed in 149 patients²¹.

Its specific indication is in *Gundmala*, severe form of *Apache*, *Arbuda*, *Granthi*, *Vrana*, *Gulma*, *Kushtha* and *Bhagandara*²². The benign hyperplasia of prostate is also a type *Granthi*. 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 *Mootrasthila* 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 adulthood¹⁶.

It is very much likely to support the concept that the incidence of *Asthithila* is promoted by embryonic precursor after vitiation of *Kapha* and *Rakta Dosh*. These *Dosha* get aggravate in old age and develop *Kaphaj Granthi* like growth. *Rakta* also gets involve 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 major component isolated from *Varuna* is lupeol, which is used to treat hypercrystalluria, hyperoxaluria and hypercalciuria. Lupeol also possesses antipyretic, analgesic, antiinflammatory activity²³.

The essential oil of the *Tejpatra* leaves is medicinally used as carminative, antifatulent, diuretic²⁴. *Ayurveda* describes the use of leaves of *Tejpatra* in the treatment of ailments such as anorexia, bladder disorders, and dryness of mouth, coryza, diarrhea, nausea and spermaturia²⁵.

Trikatu, i.e. *Pippali*, *Maricha* and *Shunthi* are typical complementary component whose benefit is to increase the bioavailability, enhance absorption of the other active ingredients and prevents gastrointestinal side effects.

Antifertility effects of *Terminalia* species have been reported on mammals²⁶. Administration of *Emblica officinalis* (500 mg/kg) significantly prevents the restrain-stress induced oxidative stress and elevation in LPO (Lipid per-oxidation) and corticosterone levels²⁷. This plant exhibits a variety of pharmacological effects including anti-inflammatory, anti-pyretic, anti-oxidant, anti-carcinogenic, and anti-mutagenic effects²⁸. *T. bellerica* extract exhibited anti-proliferative effects in several cancer cell lines including Shiongi 115, breast cancer MCF-7, prostate cancer PC-3 and DU-145 cells²⁹. *T. chebula* is used in cough, asthma, piles and urinary diseases.

The principle ingredients of *Kanchnar* (*Bauinia verigata*) are β -sitosterol, lupeol, kaempferol 3-glucoside. The extract of *Kanchnar* stem bark has shown anti cancerous activity against epidermal carcinoma. It has also shown the excellent effect on goiter and other nodular fibrotic growths.

Ela (*Eletteria cadamomum*) has α - & β - terpeneols, camphene, nerol, saibene etc. as major chemical constituents. Its specific action on cardiac disorders, respiratory infections and dysurea has been proved. *Dalchini* is also known to cure cough, headache, cardio respiratory disorders, genitourinary disorders and helminthic infestations.

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*.

The medicinal efficacy of *Brahmi* (*Bacopa monniera*) is extensively reported for treatment of epilepsy, insomnia and anxiety and as a mild sedative and memory enhancer. The biological activities of *N. nucifera*, such as anti-diarrheic, psychopharmacological, hypoglycemic, hypolipemic, anti-pyretic and antioxidant activities have been reported.

Nagarmusta is mostly useful in supporting healthy genitourinary system. Studies are also being conducted on hepatoprotective properties³⁰. *Arjuna* is a heart tonic that has been

used to support the cardiovascular functions since ancient times with known cardio-protective effects. A slight increase in the HDL-to-total cholesterol ratio and an overall improvement in the cardiovascular profile have been reported³¹.

Gokshura is a mild diuretic widely used to promote the flow of urine, cools and soothes the membranes of the urinary tract and inhibits the production of oxalate, a substance that cause micro-crystals. It contains saponins that may improve the heart function by dilating coronary arteries, thereby boosting circulation to the heart. In China, 406 patients were treated with these saponins and their EKG improved in 67% of the cases³².

Acetone extract of the root bark of *B. ligulata* has been subjected to preliminary pharmacological investigations. The extract was devoid of possessing antilithiatic activity but exhibited a mild diuretic effect when tested on rats and dogs³³.

The chloroform extract of *H. isora* exerted a significant antispasmodic effect on ileum contractions induced by Ach, histamine and barium chloride (IC₅₀ = 90.64, 73.12 and 115.2 μ g/ml, respectively). Furthermore, the chloroform extract of *H. isora* provoked a concentration-dependent inhibition of spontaneous contractions of guinea pig ileum with potencies comparable to those of papaverine³⁴.

β -Sitosterol, barlacristone, cristabarlone, acetylbarlein, apigenin present in *Barleria* species are effective to provide *Kapha-Vata Hara* property. *Kusha*, *Kasha*, *Nala* and *Darbh* are the component of *Trinapanchmoola Kashaya*. This group of drugs has shown an excellent diuretic property. Bufotenine, dehydrobufotenine, bufotenidine, gramine, donaxarine, donaxaridine are present as chief chemical constituents in it. β -Sitosterol, luteolin, aphelandrine, ganikarine, premnaspodiene are the main acting component of *Agnimantha* (*P. integrifolia* Linn.), which are responsible for its anti-inflammatory property.

Ethanol extract of *Vaska* (*Osmanthus fragrans* Lour.) has considerable anti-microbial activity against gram-positive (*S. aureus* and *B. cereus*) and gram negative bacteria (*S.typhi*).^[35]

The diuretic activity of saponin mixture of *Achyranthes aspera* Linn was associated with increase in excretion of sodium and potassium in urine as found with acetazolamide. The *Oroxylum indicum* has p-coumaric acid, scutellarein-7-rutinoside, prunetin, β -sitosterol which is might responsible to show anti-androgenic and anti-inflammatory character.

Present evaluation indicates clinically beneficial effect of *Virtarvadi Kashaya* and *Kanchnar Guggulu* and safety as far as its anti-androgenic effect is concerned. It is possible that the beneficial effects seen with *Virtarvadi Kashaya* and *Kanchnar Guggulu* may be a sum total effect of these ingredients. This study also indicates safety of *Virtarvadi Kashaya* and *Kanchnar Guggulu*, and also they do not have any adverse effect.

CONCLUSION

The excellent action of *Virtarvadi Kashaya* and *Kanchnar Guggulu* might have been due to their synergistic effect both on hormonal and physiological level due to their anti-

androgenic, anti-inflammatory, anti-biotic, anti-mutagenic, anti-spasmodic, anti-fibroblastic and other growth factors. The mode of action of these formulations is also over the psychological component of the patients. The stress relieving elements, for both on brain and urinary sphincters are present to rationalize the action. The phyto-estrogens present in these formulations may play a role in reducing and inhibiting the prostate size.

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