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EFFECT OF KANCHANAR GUGGULU IN THE MANAGEMENT OF VATASHTHEELA W.S.R. TO BENIGN PROSTATIC HYPERPLASIA (B.P.H.)- A RANDOMISED CONTROLLED TRIAL.

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Abstract : BENIGN PROSTATIC HYPERPLASIA (B.P.H.) is a histological process that over the time may result in both anatomic and physiologic changes in the prostate gland and entire lower urinary tract. Benign Prostatic Hyperplasia (B.P.H.) is a disease where adenomatous enlargement of 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; development of numerous urinary symptoms. In *Ayurveda* the *Vatashtheela (B.P.H)* which is the type of *Mootraghata* (obstruction) may be correlated with BPH on the basis of similarity of symptoms. *Mootraghata* means *Mootravarodh* i.e. low urine output due to obstruction in passage of urine. Acharya Sushrut described 12 types of *Mootraghata* which reflect the symptom of retention of urine, incomplete voiding, dribbling, hesitancy, incontinence of urine etc, i.e. feature of lower urinary tract symptom (LUTS) and Bladder Outflow Obstruction (BOO), which can be correlated with Benign Prostatic Hyperplasia in modern prevalence. As per studies, pathogenesis of BPH is well compared with *samprapti* of *Granthi* and *Arbuda*. Hence the drugs prescribed for the management of *Granthi* and *Arbuda* can be used in relieving the symptoms of BPH. *Kanchanar Guggulu* is well established drug in the management of *Granthi* and *Arbuda*. *Kanchanar* itself is *Granthighna* and *Arbudaghna* as well as *Guggulu* acts as *Vata pacifying agent*. So, in present article, the reassessment of *Kanchanar Guggulu* has been done in the management of Benign Prostatic Hyperplasia as it helps to reduce the size of prostate gland resulting in sympotomatic relief.

Key-words - *Mootraghata*, Benign Prostatic Hyperplasia, *Kanchanar Guggulu*

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INTRODUCTION

Ayurveda deals with the healthy life of human being. Moreover, it is concerned with the life without disease. While describing the aim of *Ayurveda*, *Acharya Sushruta* said that the treatment of diseased person and maintenance of health of human being are aims of *Ayurveda*. But they gave importance to treatment of diseased person first.[1]

Acharya Sushruta has described 4 types of diseases[2]: -

1)*Aagantu vyadhi* 3) *Manas vyadhi*

2)*Sharir vyadhi* 4) *Swabhavik vyadhi*

So, we can conclude that, in the present era, the category *swabhavik vyadhi* constitute age related disorders[3]. *Vata* is predominantly present in the old age. Likewise, Benign Prostatic Hyperplasia is also a disease which is found in old aged males above 50 years.

Benign Prostatic Hyperplasia (B.P.H.) is a disease where adenomatous enlargement of prostate gland causes obstruction of the urethra and bladder outlet. The enlarged gland puts pressure on the urethral passage and causes obstruction of urethra; and develops numerous urinary symptoms; includes both obstructive as well as irritative symptoms. Obstructive symptoms include hesitancy, weak urine stream & dribbling micturition etc. whereas irritative symptoms include urgency, frequency, incomplete voiding, nocturia etc. It's clinical manifestations worsen the quality of life of patient; but it is not as much life threatening condition.

Benign Prostatic Hyperplasia (B.P.H.) can be managed by conservative likewise surgical management. Medical management is Suggested for mild to moderate BPH; which includes Alpha blockers, or 5 alpha reductase inhibitors or both within the combination; But various side effects like headache, restlessness, insomnia, decreased libido, vertigo, dizziness, abnormal ejaculation, postural hypotension, retrograde ejaculation etc. are noted due to use of these drugs. If the symptoms are not minimized with the conservative treatment or in severe BPH, patient has to recommend for surgery like prostatectomy or Trans Urethral Resection of Prostate (TURP), LASAR Prostatectomy etc. But because it could be a disease which is found in old aged persons, patient might not be suited surgery because of various problems or known history of uncontrolled diabetes,

hypertension, respiratory disorder etc. Even if the surgery is done, there are high chances of complications. Early complications include hemorrhage which needs transfusion, clot retention, bladder neck stenosis etc. Whereas the late complications include erectile dysfunction, secondary growth, post TURP syndrome, urethral strictures (narrowing) which resulting in a 'split stream' of urine, incontinence, impotency etc. Considering these complications, recurrence & cost of surgery, it is the necessity of society to evaluate an another option for this senile disease.

Here, *Ayurveda* has got definite contribution which inspires us to search out solution. In *Sushruta Samhita*, Disease of *Mutravaha strotas* are broadly classified in 2 groups as *Mootratipravrutti* and *Mootralpapravrutti*.[4]

Mootralpapravritti again categorized into *Mutraghata* and *Mootrakrichra*. *Mutraghata* means low urine output, weak urine flow due to obstruction in passage of urine; *Mootrakricchhrata* represents *kricchhrata* (difficulty in micturition) is that the common feature. Symptoms of Benign Prostatic Hyperplasia are described under *Mutraghata*.

There are 12 varities of *Mutraghata*; one in all them is *Vatashtheela*, having symptoms as:

When abnormally increased *Vata dosha* (vitiated *Apana Vayu)* takes place in between the *Basti* and *Guda*; this *sthansanshraya* results into formation of thick dence firm glandular swelling or mass. It is hard in consistency & mainly obstructs urinary outflow. During this regard, further increase withinin the size of *Vatashtheela* will subsequently obstructs the passage of urine, stool & flatus (*Vinmutrasanga*), also causes *Adhmana, Ruja*, Weak urine flow because of obstruction in passage of urine and dribbling micturition. This ultimately ends up in chronic retention of urine and distention of abdomen[5]. These symptoms of *Vatashtheela* are just like the lower urinary tract symptoms (LUTS) caused by BPH.

Various *Ayurvedic* drugs were studied previously as a conservative measure and are found effective also. But since problem is incredibly much severe, we can study the consequences of assorted other drugs or therapies also for conservative management. In *Sushrut Samhita*, *Vatashtheela* is grouped under the title of *Mutraghata*. Various decoctions, medicated *ghee*, medicated milk,

kshar, madya, asava, uttarbasti which are enriched with various drugs will be used for treatment of *Mutraghata*.[6]

it's possible that *Ayurveda* similarly as modern medicine provides a treatment that proves to be effective yet as safe in conservative management of *Vatashtheela* (Benign Prostatic Hyperplasia). Benign Prostatic Hyperplasia (B.P.H.) is mostly treated with surgery; but as described above surgeries create a lots of complications like bleeding, acute cystitis, acute epididymitis, delayed wound healing, decreased libido, stricture of urethra erectile dysfunction, secondary growth, post TURP syndrome, urethral strictures (narrowing) leading to a 'split stream' of urine, incontinence, impotency and some times death also. Considering these complications, recurrence & cost of surgery, it is the need of society to search an alternative option for this senile disease. Hence non invasive and internal medication have definite role in management of Benign Prostatic Hyperplasia (B.P.H.).

Consistent with *Acharya Sharangdhar*, *Kanchanar Guggulu* is well established drug within the management of *Granthi* and *Arbuda*[7]. *Kanchanar* itself is *Granthighna* and *Arbudaghna* also as *Guggulu* acts as Vata pacifying agent.[8] So *Kanchanar Guggulu* is used for BPH. Some trials for BPH were conducted with different *ayurvedic* drugs and *Kanchanar Guggulu* but trial of only *Kanchanr Guggulu* is yet to be done. Cost of treatment modality is very much less as compared to other conservative and surgical management. So, in this research study we have decided to evaluate the effect of *Kanchanar Guggulu* in BPH in comparison with Tamsulosin Hydrochloride as a control group.

MATERIALS AND METHODS

A) Inclusion Criteria:

1) Diagnosed patients of Benign Prostatic Hyperplasia of age group between 50 to 80 years.
2) Uncomplicated BPH.
3) Selection will be irrespective of gender, religion, education and socioeconomic status.

B) Exclusion Criteria:

1) Prostatitis.
2) Patient with prostatic carcinoma
3) Complicated BPH
4) Patients with Immunocompromised diseases like uncontrolled Diabetes Mellitus, AIDS, Malignancy and Renal failure.

ASSESSMENT CRITERIAS

- **Subjective Criteria:-**

INTERNATIONAL PROSTATE SYMPTOM SCORE(IPSS)

The American Urologic Association (AUA) symptom index was developed as a standardized instrument to assess the degree of bladder outlet obstruction in men. It is widely used and consists of intermittency, urgency, weak stream and straining with each graded with a score of 0-5 total score ranges 0-35. The International Prostate Symptom Score (IPSS) can be utilized to measure the severity of lower urinary tract symptoms.

IPSS	Severity
0 to 7	Mild
8 to 19	Moderate
20 to 35	Severe

7 questions assess emptying, frequency,

Table showing severity of International Prostate Symptom Score (IPSS)

- **Objective Criteria:**

Urine flow rate - measured by **Uroflowmetry**.

Uroflowmetry measures the flow of urine. It tracks how fast urine flows, how much flows out, and how long it takes. It is a non invasive technique to measure urine flow rate in one complete cycle of micturition by the electronic device. It's a diagnostic test to assess how well the urinary tract functions. By measuring the average and top rates of urine flow, this test can show an obstruction in urinary tract such as an enlarged prostate.

Uroflowmetry is performed by having a person urinate into a special funnel that is connected to a measuring instrument. The measuring instrument calculates the amount of urine, rate of flow in seconds, and length of time until completion of void. This information is converted into a graph. The information helps to evaluate function of lower urinary tract or helps to determine if there is an obstruction of normal urine outflow.

Overall Assessment Criteria:

Criteria of assessment was based on improvement in subjective and objective parameters after the treatment.

Selection of Patients:

1. Total 64 patients of Vatashtheela were selected from OPD and IPD of Shalyatantra department of Shri Ayurved Mahavidyalaya, Nagpur.

2. The registered patients were randomly allocated into 2 groups each consisting of 32 patients. Informed, written and valid consent of patient was taken prior to commencement of clinical trials.

3. A standard case record form was maintained.

The study was approved by Institutional Ethics Committee (IEC), before starting the the clinical trial.

Materials:

Among 64 registered patients in Group A (n=32), patients of Vatashtheela were treated with Kanchanar Guggulu; and in Group B (n=32), patients of Vatashtheela were treated with Tablet Tamsulosin Hydrochloride.

Methodology

- **GROUP A (Trial Group):**

32 patients with signs and symptoms of *Vatashtheela* (Benign Prostate Hyperplasia) were administered with *Kanchanar Guggulu Vati* which is purchased from standardize company.

Dose: 500mg BD

Anupana: *Koshna jala*

Route of administration: Oral

- **GROUP B (Control Group):**

32 patients with signs and symptoms of *Vatashtheela* (Benign Prostate Hyperplasia) were treated with Tablet Tamsulosine Hydrochloride which is purchased from standardize company.

Dose: 0.4 mg at night

Anupana: *Jala*

Route of administration: Oral

Duration of treatment:

30 Days

Follow up period:

0^{th}, 15^{th} & 30^{th} day

Statistical Tests:

Two independent samples are there, hence t test will be used and chi square test will be used to access the significance of proportion between the two groups within the group.

Comparison

Before and after treatment comparison will be done by paired t test in each group separately. P value < 0.05 will be considered statistically significant for all comparison.

Formula for sample size:

N={Z 1-α sqrt* 2P(1-P)} +Z 1-β sqrt*P1 (1-P1) +p2(1-p2)} 2/(p1-p2) 2

Where ,p=mean of two proportion ,p1=group A ,p2=group B

OBSERVATIONS AND RESULTS

Table Comparative analysis of Subjective criteria between two groups

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Incomplete evacuation	Group A	32	34.00	1088.00	464.000	0.49009
	Group B	32	31.00	992.00		
	Total	64				
Frequency of micturition	Group A	32	39.59	1267.00	285.000	0.00047
	Group B	32	25.41	813.00		
	Total	64				
Intermittency of micturition	Group A	32	32.59	1043.00	509.000	0.96494
	Group B	32	32.41	1037.00		
	Total	64				
Urgency of micturition	Group A	32	37.34	1195.00	357.000	0.01992
	Group B	32	27.66	885.00		
	Total	64				
Weak stream of urine	Group A	32	38.50	1232.00	320.000	0.00415
	Group B	32	26.50	848.00		
	Total	64				
Straining duuring micturition	Group A	32	35.88	1148.00	404.000	0.01096
	Group B	32	29.13	932.00		
	Total	64				
Nocturia	Group A	32	31.50	1008.00	480.000	0.60327
	Group B	32	33.50	1072.00		
	Total	64				

Mann Whitney U test is carried for comparison between Group A and Group B. From above table, we can observe that, P-Value for almost parameters is less than 0.05. Hence, we can conclude that, there is significant difference between Group A and Group B.

Further, we can observe that, mean rank for Group A is greater than Group B. Hence, we can conclude that, effect observed in Group A is better than Group B. Hence Group A i.e. *Kanchanar Guggulu* is more significant than Group B i.e. Tamsulosin Hydrochloride in management of *Vatashtheela* i.e. Benign Prostatic Hyperplasia (B.P.H.).

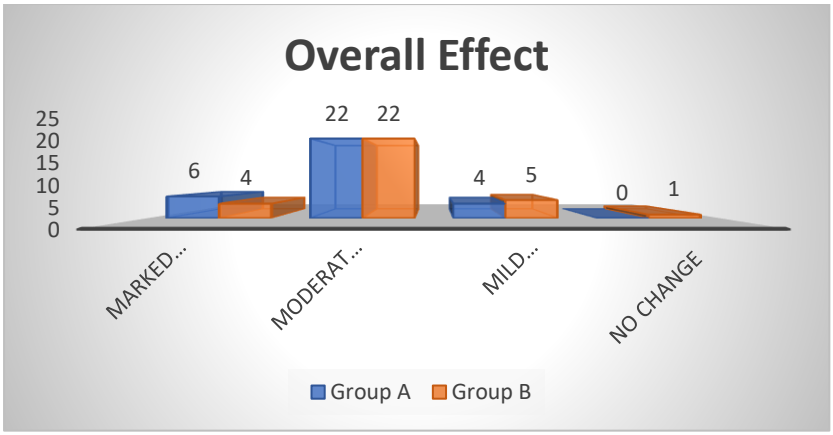
Comparative analysis of Objective criteria between two groups

Variable	Group	N	Mean	SD	SE	t-Value	P-Value
Maximum flow rate (ml/sec)	Group A	32	10.75	13.76	2.43	1.742	0.087
	Group B	32	5.56	9.72	1.72		
Maximum flow time (sec)	Group A	32	5.97	13.33	2.36	0.457	0.649
	Group B	32	4.78	6.32	1.12		

Unpaired t-test is carried for comparison between Group A and Group B. From above table, we can observe that, P-Value is greater than 0.05. Hence we can conclude that, there is no significant difference between Group A and Group B.

Overall effect of therapy in both the groups

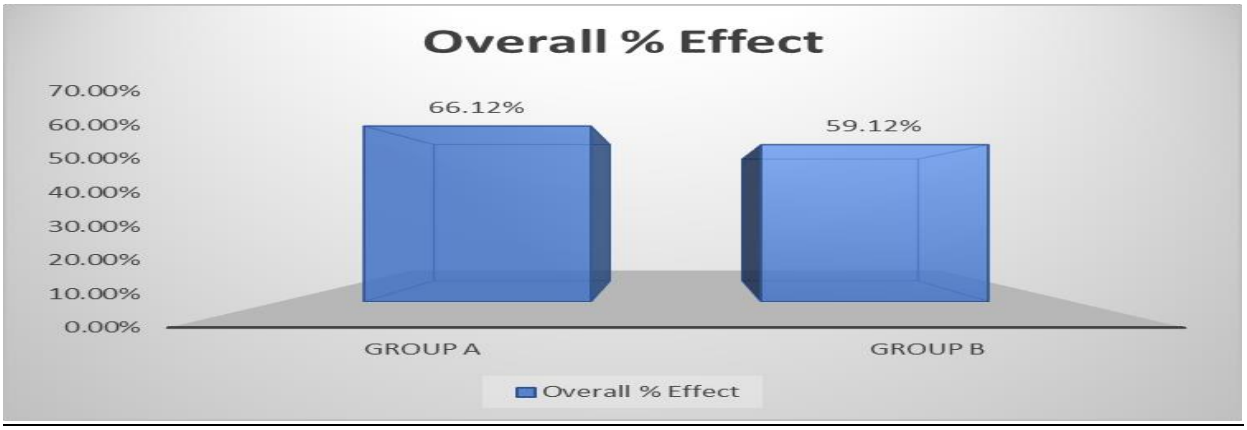
Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	6	18.75%	4	12.50%
Moderate Improvement	22	68.75%	22	68.75%
Mild Improvement	4	12.50%	5	15.63%
No Change	0	0.00%	1	3.13%
TOTAL	32	100.00%	32	100.00%



Overall effect observed in Group A is Marked improvement in 18.75% and 12.50% in group A and B respectively; Moderate improvement in 68.75% in both the groups; Mild improvement in 12.50% and 15.63% in Group A and Group B respectively; No change in 0% and 3.13% in Group A and Group B respectively. Hence Group A i.e. Trial drug *Kanchanar Guggulu* is significantly more effective in patients with *Vatashtheela* i.e. Benign Prostatic Hyperplasia (B.P.H.) rather than Group B i.e. Control group of Tab. Tamsulosin Hydrochloride.

Overall % effect of therapy in both the groups

	Group A	Group B
Overall % Effect	66.12%	59.12%



Overall percentage effect observed in Group A (66.12%) is better than Group B (59.12%). Hence, *Kanchanar Guggulu* is significantly effective in management of *Vatashtheela* i.e. Benign Prostatic Hyperplasia (B.P.H.) rather than Tablet Tamsulosin Hydrochloride.

DISCUSSION

Mutraghata means obstruction of urine flow. Symptoms of *Mutrghata*, and Per rectal findings are similar to symptom of BPH. In moderm medicine, BPH treated either conservative treatment i.e. hormonal therapy or surgical treatment i.e. Prostatectomy, LASER Prostatectomy, Prostatic stents etc. But there are many complications like Loss of libido, gynecomastia, post TURP syndrome, urethral strictures (narrowing) leading to a 'split stream' of urine, urinary incontinence, impotency, erectile dysfunction, recurrent infrction, bladder change, retrograde ejaculation, bleeding during surgery which may requires transfusion etc. so, Ayurvedic approach i.e *Kanchanar Guggulu* is helpful, clinically safe, effective and it is better option to treat *Mutraghata* (BPH) and beneficial for old age. Most of the contents in *Kanchanar Guggulu* have *Katu Rasa*, *Ruksha* and *Laghu Guna*, *Ushna Virya*, *Madhura Vipaka* and property of *Vatakaphahara*. The properties like *Rasayana*, *Vayasthapana*, *Medohara*, *Krimighna*, *Lekhana*, *Shothaghna* and *Vata-Kapha Shamana* are helpful to act on various changes in BPH. The tremendous action may be due to anti-androgenic, anti-inflammatory, antibiotic, anti-mutagenic and anti-fibroblastic properties of *Kanchanar Guggulu*. After completion of this clinical study it will be helpful to understand the effect of *Kanchanar Guggulu* in the remission of obstructive and irritative symptoms of *Vatashtheela* i.e. Benign Prostatic Hyperplasia.

CONCLUSION

Mutraghata is a group of obstructive uropathy disorders, has been dealt in detail in almost all ancient treatises. In which the *Vatashtheela* is the condition which is similar to the BPH in respective of obstructive as well as irritative phases. The total effect of the *Kanchanar Guggulu* has provided considerably significant relief on subjective as well as objective parameters. The subjective complaints were relieved highly significant in the range. Moderate improvement is seen on criterias after the treatment.

According to statistical analysis performed above, we can conclude that,

the total effect of both drugs have provided significant relief on subjective as well as objective parameters.

In comparison we have observed that, effect observed in Group A is better than Group B in management of *Vatashtheela*. Hence it is proved that is, *Kanchanar Guggulu* is significantly effective in the management of *Vatashtheela*.

In the present clinical study, only *Kanchanar Guggulu* is used. It can be supplemented by other drugs or formulations or procedures which helps dravya to reach at the microcellular level and get more significant effects on remission of above said subjective and objective criterias. In this study, effects of *Kanchanar Guggulu* were studied for 30 days and it was very significant in symptoms of BPH. So this treatment modality can be further studied for longer duration for more acurate and reliable results of ayurvedic treatment for BPH. Cap. Tamsulosin HCl acts through systemic circulation. Further Tamsulosin is used as single drug in this clinical trial. It may be effective in combination with 5α reductase inhibitors. C. Tamsulosin HCl may be effective when used for about 2-3 months.

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