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Review Article

RANDOMISED CONTROLLED CLINICAL TRIAL OF GOKSHUR, VARUN, SHATAVARI & SAHACHAR CHOORNA IN VATASHTHILA i.e. BENIGN PROSTATIC HYPERTROPHY.

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ABSTRACT:

The present study was conducted to evaluate clinical efficacy of *Gokshur, Varun, Shatavari & Sahachar choorna in Vatashthila*[1] *i.e.* Benign Prostatic Hypertrophy in patients who cannot afford surgical management for the same. The diagnosis of Benign Prostatic Hypertrophy was established by inclusion & exclusion criteria as determined.

Total 60 patients were included in the study with dividation in two groups as, Group A - 30 patients on *Gokshur, Varun , Shatavari & Sahachar choorna* total 10 gm/ day in divided two dosages. Group B - 30 patients on Cap. Tamsulosin Hydrochloride 0.4 mg at night. (for 42 days). All serving patients were assessed weekly till 42 days.

At the end of 42 days in group A respectively 60%, 70% , 50% 80% improvement in the symptoms frequency, urgency, force of urine stream & haematuria, so far as in group B respectively 33.33%, 36.67%, 56.67% & 33.33%. Significant difference was observed in residual urine volume as t58 = 3.40 with P<0.05 (in group A & group B) .

Hence it can be concluded that, *Gokshur, Varun , Shatavari & Sahachar choorna* is viable therapeutic option in treatment of Benign Prostatic Hypertrophy as compared to Cap. Tamsulosin Hydrochloride 0.4 mg. It will be the treatment of choice in Benign Prostatic Hypertrophy to make surgery as an option, but required to be studied on large sample size.

KEY WORDS: Health preservation, lifestyle, lifestyle disorders, regimen, stress, sadvritta

INTRODUCTION:

Being the commonest geriatric problem & difficulty in recognition of cause and effect relationship, Benign Prostatic Hypertrophy became a crucial problem to the world… BPH is very uncommon in men younger than the age of 30 but then increases steadily in an almost linear manner In fact approximately 90% of men in their 80s[2]. .Though the standard line of treatment for Benign Prostatic Hypertrophy is surgery, only 25% will require it . Until recently prostatectomy & watchful waiting are widely accepted options to treat Benign Prostatic Hypertrophy .This reason have lead us to haunt for remedy. We evaluated the efficacy of *Gokshur,* Varun , *Shatavari* & *Sahachar choorna*[3] in Vatashthila i.e. Benign Prostatic Hypertrophy.

Material & Methods-

60 patients of Benign Prostatic Hypertrophy were enrolled for the study based on inclusion & exclusion criteria.

Inclusion Criteria –

- **Sex** – Male (Obvious)
- **Age**[4] – 50yrs to 70 yrs
- **Marital Status** – Both married and unmarried.

Symptoms [5] –

1. Reduced urinary flow or force
2. Urgency in urine
3. Hesitancy in urine
4. Haematuria
5. Retention of urine
6. Nocturia
7. Increased frequency of urine

Exclusion Criteria –

K/C/O Malignant prostatic enlargement

BPH along with complication like stricture urethra , CRF ,DM etc.

Patient suffering from Autoimmune disease

They are divided in two groups.

Group A -

30 patients on *Gokshur,* Varun , *Shatavari* & *Sahachar choorna* total 10 gm/ day in divided two dosages for 42 days.

Group B -

30 patients on Cap. Tamsulosin Hydrochloride 0.4 mg at night, for 42 days.

Dose and Root of Administration:-

Group A

- Dose - 10 gm choorna per day in divided 2 doses before meal.
- Route of administration - Oral.
- Anupan – Koshna Jala.

Group B

Cap. Tamsulosin hydrochloride 0.4 mg in night with water

Weekly assessment done , accordingly all the signs & symptoms were recorded. On the basis of clinical study, occurrence of various incidences statistical analysis done.

Assessment Criterion

Objective criterion:

Before subjecting the patient to clinical trials, residual urine volume i.e. post voiding was measured using disposable infant feeding tube under strict aseptic condition. Also after completion of treatment residual urine was measured using same method and accordingly patient is assessed for result.

Symptomatic clinical assessment will be done as follows:

1) Frequency :

3+ : Nocturnal frequency increased disturbing sleep of patient.

2+ : Day time increase in frequency every 1 hr.

1+ : Patient urinating every four hours

0 : Regular or frequency not increased.

2) Urgency :

3+ : Patient cannot hold urine or soiling clothes.

2+ : Patient cannot hold urine till he reaches toilet

1+ : Patient can hold urine till he reaches toilet

0 : No urgency.

3) Force of urine stream :

3+ : Soiling or at feet or very weak stream

2+ : Just in front of feet

1+ : In the toilet pan

0 : Beyond toilet pan

4) Haematuria :

3+ : Frank haematuria for every micturition

2+ : Intermittent or once per day

1+ : Casual or once a week

0 : Nil.

Degree of BPH:

Degree of BPH was clinically assessed as follows

1) Third Degree BPH :

Severe enlargement of prostrate having total score – 9 to 12

2) Second Degree BPH :

Moderate enlargement of prostrate having total score – 4 to 8

3) First Degree BPH :

Mild enlargement of prostrate having total score – 1 to 3.

Activity performed:

- Informed consent
- Examination of patient & history of patient was noted.
- Signs & symptoms of Vatashthila according to criterion were taken into consideration.

Discontinuation Criteria :

- Incidence of any acute or life threatening disease
- Incidence of any such disease or situation which prevents the subject from attending more than 3 interim examination.

Criteria for relief in percentage :

With follow up, study progress was observed and analyzed to assess benefit and improvement of condition.

Uttam Upashaya : 3+ to 0, 2+ to 0, 1+ to 0

i.e. from initial gradation to 0

Madhyama Upashaya : 3+ to 2+/ 2+ to 1+

Anupashaya : No change in gradation.

Dropout:

Those patients who left the treatment before advised duration or who did not follow the instruction were considered as dropout.

RESULT :

Mean of all symptoms were compared with the help of Chi-square test [6].

FREQUENCY OF URINE:

Gradation	Group A			Group B		
	D_0	D_{21}	D_{42}	D_0	D_{21}	D_{42}
Uttam	(Grade I) 11	5	18	(Grade I) 12	4	10
Madhyam	(Grade II) 14	13	9	(Grade II) 11	10	8
Anupashaya	(Grade III) 5	12	3	(Grade III) 7	16	12

Table No. 1: Frequency of Urine

Day	c^2	df	Table c^2 value	Probability	Result
D_{21}	1.05	2	5.99	P>0.05	Not Significant
D_{42}	8.2	2	5.99	P< 0.05	Significant

Table No. 2:

	Uttam	Madhyam	Anupashaya	c^2	df	P	Result
Gr.A	18	9	3	8.2	2	P<0.05	Significant
Gr.B	10	8	12				

Table No. 3: Comparison of symptom Frequency of urine of Gr. A & Gr. B.

URGENCY OF URINE:

Gradation	Group A			Group B		
	D_0	D_{21}	D_{42}	D_0	D_{21}	D_{42}
Uttam	(Grade I) 13	7	21	(Grade I) 14	5	11
Madhyam	(Grade II) 10	12	6	(Grade II) 6	11	9
Anupashaya	(Grade III) 7	11	3	(Grade III) 10	14	10

Table No. 4: Urgency of Urine

Day	c^2	df	Table c^2 value	Probability	Result
D_{21}	1.06	2	5.99	P>0.05	Not Significant
D_{42}	7.48	2	5.99	P< 0.05	Significant

Table No. 5:

	Uttam	Madhyam	Anupashaya	c^2	df	P	Result
Gr. A	21	6	3	7.48	2	P<0.05	Significant
Gr. B	11	9	10				

Table No. 6: Comparison of symptom Urgency of urine of Gr. A & Gr. B.

FORCE OF URINE STREAM:

Gradation	Group A			Group B		
	D_0	D_{21}	D_{42}	D_0	D_{21}	D_{42}
Uttam	(Grade I) 11	7	15	(Grade I) 12	8	17
Madhyam	(Grade II) 12	11	6	(Grade II) 12	13	6
Anupashaya	(Grade III) 7	12	9	(Grade III) 6	9	7

Table No. 7: Force of Urine Stream

Day	c^2	df	Table c^2 value	Probability	Result
D_{21}	1.03	2	5.99	P>0.05	Not Significant
D_{42}	0.375	2	5.99	P> 0.05	Not Significant

Table No. 8:

	Uttam	Madhyam	Anupashaya	c^2	df	P	Result
Gr. A	15	6	9	0.375	2	P>0.05	Not Significant
Gr. B	17	6	7				

Table No. 9: Comparison of symptom force of urine of Gr. A & Gr. B.

HAEMATURIA:

Gradation	Group A			Group B		
	D_0	D_{21}	D_{42}	D_0	D_{21}	D_{42}
Uttam	(Grade I) 8	10	24	(Grade I) 6	8	10
Madhyam	(Grade II) 12	12	3	(Grade II) 10	14	12
Anupashaya	(Grade III) 10	8	3	(Grade III) 14	8	8

Table No. 10: Haematuria

Day	c^2	df	Table c^2 value	Probability	Result
D_{21}	0.37	2	5.99	P>0.05	Not Significant
D_{42}	12.22	2	5.99	P< 0.05	Significant

Table No. 11:

	Uttam	Madhyam	Anupashaya	c^2	df	P	Result
Gr. A	24	3	3	12.22	2	P<0.05	Significant
Gr. B	10	12	8				

Table No. 12: Comparison of symptom Haematuria of Gr. A & Gr. B.

Residual Urine Volume :

Difference of residual urine volume before & after treatment (in ml)			
Group A		Group B	
Frequency	No.of patients	Frequency	No.of patients
10-30	10	10-30	23
30-60	18	30-60	7
60-90	2	60-90	0

Table No. 13: Residual Urine Volume

$c^2 = 11.96$

df =2

Table c^2 value = 5.99

Probability = P < 0.05

Result = Significant

Predominance of vegavrodhjanya hetu was observed in study (52%). Majority of the patients were in age group from 65 to 70 years (51.66%).

Group A-

At the end of study 18 out of 30 patient showed uttam upashaya in frequency (60%) , 21 out of 30 patient with uttam upashaya in urgency (70%), 15 out of 30 patient with uttam upashaya in force of urine stream (50%), 24 out of 30 patient showed uttam upashaya in haematuria (80%).

Group B-

For frequency uttam upashaya observed in 10 out of 30 (33.33%), in the part ofurgency 11 out of 30 patient showed uttam upashaya(36.67%), for force of urine stream uttam upashaya in 17 out of 30 (56.67%) & for haematuria it was 10 out of 30 (33.33%).

For residual urine volume group A showed significant result.

DISCUSSION:

Discussion regarding clinical parameters:

1) **Discussion regarding Frequency of Micturition:** There is no significant difference at D_{21} (c^2 =1.05,df 2) but significant difference at D_{42} (c^2 =8.02 df 2)in trial & control group in frequency of micturition.

2) **Discussion regarding Urgency of Micturition:** There is no significant difference at D_{21} (c^2 =1.06,df 2) but significant difference at D_{42} (c^2 =7.48 df 2) in trial & control group in frequency of micturition.

3) **Discussion regarding Force of Urine Stream:** There is no significant difference at D_{21} (c^2 =1.03,df 2) & also no significant difference at D_{42} (c^2 =0.375 df 2) in trial & control group in frequency of micturition.

4) **Discussion regarding Haematuria:** There is no significant difference at D_{21} (c^2 =0.37,df 2) but significant difference at D_{42} (c^2 =12.22 df 2) in trial & control group in frequency of micturition.

5) **Discussion regarding Residual Urine Volume:** There is significant difference at D_{42} (c^2 =11.96 df 2) in trial & control group in residual urine volume.

Probable mode of action of drug

Gokshur, Varun, Shatavari & Sahachar in combination have its action on lower urinary tract symptoms mostly of which are irritative in nature than obstructive.

Gokshur by its guru,snigdha guna,madhur rasa & madhur vipaka inhibits the vata dosha with its guna laghu, ruksha & chala guna. Ultimately helps in reducing symptoms of prostatic enlargement like increased frequency of micturition, urgency. By snigdha guna soothes the smooth muscles of urethra by relaxing it & maintains the flow of urine stream by local diuretic action. Also it enhances the secretion of testosterone which ois responsible for BPH in low levels.

Tribulus terrestris is a testosterone enhancer. Tribulus terrestris saponins appear to bind with the receptors of the hypothalamus that detect sex hormones. It in-part blocks the receptors leading to the hypothalamus misinterpreting the body's sex hormone levels as being lower than they really are. The hypothalamus signals to start the production of Luteinizing hormone (LH). When LH levels are increased, the natural production of testosterone also increases.

Varun by its own property of ashmaribhedan helps in dissolving the bond between vata & kapha which is responsible for appearance of vatashthila like Ghana, achala granthi. Tikta rasa, katu vipaka & ushna virya acts like strotoshodhan which cleans the way for urine. Also with the help of tikta rasa & katu vipaka by acting on, stagnated urine resulting in urinary infection same pathology in formation of ama in amashaya, ama dosha in urine reduces the chances of infection. Kashaya rasa by its astringent action helps in toning of urethra which becomes lengthened in BPH.

Shatavari by its guru, snigdha guna, madhur rasa, madhur vipaka acts on vata resulting in antispasmodic effect. Also it is balya which gives power to smooth muscles in prostate, prostatic urethra & bladder wall helps in increasing force of mictirition.

Sahachar by its madhur rasa & ushna virya acts on vata & byits tikta rasa & katu vipaka acts on kapha ultimately resulting in dissolution of vata-kapha bandha.

As above all drugs being given orally they are coming through all stages of pachana & starts its action from level of pakwashaya, vata sthana, helps in proper formation of urine, then the local action of above drugs take place.

Koshna jala anupana is helpful in absorption & increases the bioavailability of drugs which enhances the action of these drugs.

All the patients in the study were of Benign Prostatic Hypertrophy & none of these patients any sign of malignancy was discernible. Patients in group A & group B were comparable with respect to age, etiological factor & various other parameters of assessment. Patients in group A had better results than group B .

Gokshur, Varun , *Shatavari* & Sahachar in combination exerts its action on lower urinary tract syndrome mostly of which are irritative in nature than obstructive.

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