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A controlled clinical trial to evaluate the efficacy of *Tilanala Kshara* in the management of *Vatashteela* vis-a-vis Benign Prostatic Hyperplasia

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ABSTRACT

Background: Benign prostatic hyperplasia is the most common urological disease among elderly men, which is characterized by hypertrophic nodular changes of the prostate gland, which is located at the base of the bladder surrounding the proximal urethra. Gland grows at the rate of 2.4cm3/year after the age of 40 owing to the change in hormonal environment. In India, the prevalence rate is around 50% in men above the age of 65 years. The condition can be corelated to *Vatashteela* in Ayurveda based on the symptomatology. **Objective of the study:** To evaluate the efficacy of *Tila Nala Kshara* in the management of *Muthraghata* vis-a-vis BPH. **Materials and Methods:** A double arm open labelled clinical study with pre-post-test design was carried out at Government Ayurveda Medical College and Hospital, Mysuru. Data was collected as per the proforma prepared for the purpose of the study. *Tila Nala Kshara* was administered as intervention in 54 subjects and the control drug was *Gokshuradi Guggulu.* The data was analysed using SPSS descriptive and inferential statistics. **Results:** Among the objective parameters, change in prostate volume was significant between the groups with a P value 0.024. But for postvoid residual volume, the difference between the groups was not statistically significant. For subjective parameters which includes IPSS total and Quality of life scale, the difference between the groups was statistically nonsignificant. **Conclusion:** *Tilanala Kshara* when used along with *Gokshuradi Guggulu* was observed to improve general condition of the subjects to greater extent, which clearly implies the added effect of the trial drug.

Key words: *Vatashteela, BPH, Prostate, Tilanala Kshara.*

INTRODUCTION

Mutraghata comprises of a group of disorders related to *Basti* and *Mutravaha Srotas. Mutraghata* denotes a condition in which there is *Vibandha* in *Mutravaha Srotas* resulting in retention of urine.[1] Benign Prostatic Hyperplasia, which is generally abbreviated as BPH, is a disease, which is particularly seen in elderly men. It is considered as one of the major causes of lower urinary tract symptoms and bladder outflow obstruction. Among the varieties of *Mutraghata*, mainly *Vatashteela* resembles the condition of BPH. Histologically distinguishable BPH will be present in 8% of men aged 31-40 and progressively increases markedly with age to about 80% by the ninth decade of life. In India, the prevalence rate is around 50% in men above the age of 65 years.[2]

Although BPH is not a life-threatening condition, its impact on life can be significant, as it is the commonest cause for significant lower urinary tract symptoms (urgency, frequency, nocturia, incomplete evacuation of urine and weakness of urine stream) and bladder outflow obstruction in men.[3]

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In last three decades, despite of the intense research efforts to elucidate the underlying aetiology of prostatic growth in older men, the exact "cause and effect" relationship has not been established. Considering the limitations of the contemporary line of management, the present study was performed to evaluate the efficacy of *Tilanala Kshara* in the management of *Vatashteela* vis-à-vis BPH. *Kshara* is one among the treatment modalities mentioned in Ayurvedic *Samhita* for all types of *Muthraghata.*[4] *Tila Nala Kshara*[5] is the trial drug selected for the study along with *Gokshuradi Guggulu*[6] as the control drug. The drugs selected are indicated for *Mutravaha Sroto Vikara* including all varieties of *Muthraghata*. Hence the present study "The controlled clinical trial to evaluate the efficacy of *Tilanala Kshara* in *Vatashteela* vis-a-vis BPH" was carried out.

OBJECTIVE OF THE STUDY

To evaluate the efficacy of *Tila Nala Kshara* in the management of *Muthraghata* vis-a-vis BPH

MATERIALS AND METHODS

The materials used in the study were *Tila Nala Kshara* and *Gokshuradi Guggulu.*

Source of drug and method of preparation

Tila Nala for the preparation of *Tilanala Kshara* was procured from farmers of native Bannur district of Karnataka. *Tila* was dried and burnt at the native place itself and ash was collected. The preparation process was carried out at the inhouse pharmacy of GAMC and Hospital Mysuru.

Gokshuradi Guggulu Manufactured by GMP certified unit of Punarvasu Ltd. Nadiad, Gujarat and was procured from local vendors of Mysore.

Method of collection of data

Study design

Double arm open labelled control clinical trial with pre and post study design.

Sample size

Study comprised of 59 registered subjects (30 in trial group and 29 in control group) out of which 5 were drop outs. The study was completed on 54 subjects with 28 in trial group and 26 in control group.

Duration of intervention: 30 days

Inclusion criteria

1. Male Subjects belonging to age group of 40 to 70.
2. USG of bladder suggestive of residual urine volume up to 100ml.
3. Mild to moderate grades of BPH with prostate weight up to 75 gm
4. Both fresh and treated cases of *Vatashteela* vis-à-vis BPH

(Fresh cases included freshly detected and untreated cases of *Vatashteela* vis-à-vis BPH and treated cases included already diagnosed as *Vatashteela* vis-à-vis BPH, who had voluntarily discontinued the earlier treatment and were included with a flush out period of 7 days)

Exclusion criteria

1. Subjects with congenital hypothyroidism, chronic history of hypothyroidism (>5 yrs.) and secondary 1. Subjects suffering from malignancy, congenital deformities of urogenital tract or any other pelvic pathologies
2. Chronic UTI, urinary calculus, renal failure, urinary stricture
3. Systemic diseases like uncontrolled Diabetes mellitus (RBS range above 300mg/dl), Hypertension (stage 3 or above), Tuberculosis, hemiplegia, parkinsonism, and other disorders that may interfere with the present
4. intervention
5. Subjects with immune compromised conditions such as HIV
6. Subjects with USG findings suggestive of Hydroureteronephrosis
7. Subjects unfit for *Paneeya Kshara* intake such as acid peptic disorders

Diagnostic criteria

USG abdomen & pelvis and digital rectal examination

- International prostate symptom score (IPSS)

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- Scoring for prostate weight, Post void residual volume, size of prostate on DRE

Assessment Criteria

Primary assessment parameters

1. Assessment using IPSS was done.

IPSS assessment includes

- Incomplete emptying
- Frequency
- Intermittency
- Urgency
- Weak stream
- Straining
- Nocturia

2. Ultrasonography of abdomen and pelvis

Following parameters were assessed

- Prostate weight
- Prostate size
- Post void residual urine volume

Secondary assessment parameters

1. *Basti Shola*
2. *Mootra Rodha*
3. *Ghana Granthi*
4. *Basti Admaana*

Table 2: Shows the International prostate scoring scale.

International Prostate Symptom Score (IPSS) /American Urological Association Symptom Index (AUA-SI)

In the past one month	Not at all	Less than 1in 5 times	Less than half the time	About half the time	More than half the time	Almost always	Your score
Incomplete emptying	0	1	2	3	4	5	
Frequency	0	1	2	3	4	5	
Intermittency	0	1	2	3	4	5	
Urgency	0	1	2	3	4	5	
Weak stream	0	1	2	3	4	5	
Straining	0	1	2	3	4	5	
	None	Once	Twice	Thrice	Four times	Five or more	
Nocturia	0	1	2	3	4	5	
Total IPS score							

Score: 1-7: Mild 8-19: Moderate 30-35 : Severe

Quality of life due to urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy	Terrible
Score	0	1	2	3	4	5	6

Assessment schedule

Assessments were carried out 3 times during the course of intervention

Assessment using IPSS was done on (0th) day, (15th) day and on (30th) day of intervention.

Ultrasonography of abdomen and pelvis was done before the beginning of intervention and after the completion of intervention.

Statistical methods

The results were analysed statistically by using the following statistical methods:

Descriptive statistics - Mean, Standard deviation, Frequency, Percentage

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Inferential testing -

- Chi-square test, Wilcoxon signed rank test
- Repeated measures ANOVA, Mann Whitney U test
- Paired sample and individual sample "T" test

All the statistical methods were done using SPSS for windows

Intervention

Total duration of the intervention was 30 days. Intervention included,

Group A - 1gm of *Tilanala Kshara* in 2 equally divided doses after food with lukewarm water as *Anupana* and *Gokshuradi Guggulu* 3 gm in 3 equally divided doses after food with lukewarm water as *Anupana* were administered for 30 consecutive days.

Group B - *Gokshuradi Guggulu* 3 gm in 3 equally divided doses after food with lukewarm water as *Anupana* for 30 consecutive days was administered.

OBSERVATIONS

Age - 45 subjects were belonging to 61-70 years age group, 9 in 51-60 years and 5 were from 41-50 age group.

Occupation - 16 subjects were farmers, 12 subjects were engaged in bussiness, 11 were unemployed, 3 daily wagers and remaining 17 were having other occupations.

Fresh and treated cases - 39 fresh cases 20 treated cases were included.

Diet - 45 subjects were having mixed diet and remaining 14 were vegetarians.

Prostate size - Grade 1 enlargement was found in 50 subjects and grade 2 enlargement was seen in 9 subjects.

Residual volume - 23 subjects did not have any residual urine, 16 subjects had grade 1 PVRU and grade 2-4 grade 3-16

Enlargement of lobe - It was noted that the median and lateral lobes enlargement is the most common presentation.

Observations on clinical features of BPH

Among the symptoms of BPH, increased frequency of micturition was observed in 56 subjects, nocturia was seen in 44, weak stream in 37, urgency in 31 subjects, incomplete evacuation of urine in 22 and intermittency in 15 subjects

RESULTS

A total of 59 subjects were registered for the study, there were 5 dropouts. The results were obtained by assessing 54 subjects who have completed the study.

Result on prostate volume

A statistically highly significant change in Prostate volume was obtained in both the groups with P value <0.001 in both the groups. The mean volume of prostate was 45.29 and after intervention it came to 38.07 in trial group. The mean in control group was 33.81 and after intervention it was 31.19. The change in prostate volume between the two groups is statistically significant with a P value 0.024 with trial group having better result.

Result on Post void residual urine volume

A statistically significant change in Post residual urine volume was obtained in both the groups with a P value 0.022 in Trial group and 0.006 in Control group. Mean value was 33.75 in trial group before intervention and it came to 19.54 after intervention. A mean of 19.82 was observed before intervention in control group which came down to 13.54. The change in post void residual volume between the groups did not show any statistically significant difference with P value 0.421.

Result on IPSS total score

A statistically highly significant result in IPSS score was noticed in both the groups with P value<0.001 in Trial group and 0.002 in Control group. The change in IPSS score after the course of intervention was not statistically significant between the groups with a P value 0.541.

Result on Quality-of-life scale of IPSS

A statistically highly significant change in Quality of Life was obtained in both the groups with a P value <0.001.

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The change in quality of life after the course of intervention was not statistically significant between the groups with a P value 0.244.

Result on IPSS parameters

Among the sub parameters of IPSS, significant change between the groups were observed in urgency and nocturia. Frequency, intermittency, burning micturition, weak stream and straining didn't showed statistically significant difference between the groups.

Table 4: Showing results of overall assessment between the groups

Parameter	Prostate volume		Post void residual volume		IPSS total		IPSS QOL	
Groups	Trial	Control	Trial	Control	Trial	Control	Trial	Control
Pre - Mean	45.29	33.81	33.75	19.82	2.79	2.35	3.54	3.08
Post- Mean	38.07	31.19	19.54	13.54	2.04	1.92	2.57	2.04

DISCUSSION

Probable mode of action of *Tilanala Kshara*

Tila was the selected drug for *Kshara* preparation considering its *Vata Kaphahara* property which adds on to the property of *Kshara*. It is *Alpa Mootrakrit* and *Grahi.*[7] In BPH, where the major symptoms are increased frequency, urgency and nocturia these properties of *Tila* can come useful. The *Grahi* action of a drug usually can be assessed by the potency of the particular drug to increase the contractile tone of sphincter. This can be considered also for sphincters related to *Basti*. Along with *Vatagna* action*, Tila* is also *Balya* and *Agnideepana*. The *Balya* action could give strength to bladder muscles like detrusor which can improve symptoms like incomplete evacuation and urgency. The *Samprapthi* starts from *ama* formation and *Agnidushti,* hence the selected drug preferably should have *Agni Deepana* action also. *Snigda Ushna Guna* and *Ushna Veerya* also helps in *Vatanulomana* which enhances the overall effect of the intervention. Moreover, the antioxidant action of *Tila* also helps in free radical scavenging and there by protects the prostate tissue from damage.

Probable reasons for reduction in PVRU

In mean PVRU scores a significant decrease was observed after intervention in both the groups. When group-wise decrease was verified, a non-significant difference was observed between the groups. Drugs in *Gokshuradi Guggulu* might have produced strength to detrusor muscle to do sufficient contraction and *Kshara* helps for easy flow of urine out by keeping the bladder neck and prostatic urethra open. Even *Mutrala* and *Shothahara Karma* of the drugs might have acted to get the result.

Probable reasons for reduction in Prostate size

Even though both groups showed significant results, it was observed that Trial group had a better result in reducing the size of prostate. It could be because of the added *Lekhana* property from *Kshara*. It is also noted that few patients had also recorded an increase in the size of prostate. This could be due to the natural progressive course of the disease. The size either progresses gradually over a period of time or stays dormant for years.

CONCLUSION

Benign Prostatic Hypertrophy is having a wide spectrum of symptomatology. Even though it is very difficult to restrict and fit it into any single disease pathology as per Ayurvedic literature, in the present study BPH is considered as *Vatashteela* after analysing the *Vyutptti* of the term *Vatashteela, Nidana, Samprapti* and *Lakshana* of the disease *Vatashteela.* BPH is a *Vyadhi* of *Vridhavastha* where in *Vata* will be naturally in a predominant condition,[8] and the disease is more prevalent after the 6th decade, the age group in which *Shodhana* therapy is contraindicated. Hence *Shamana Oushadhi* have been selected for the controlled study. The Ayurvedic theory proposes predominance of *Vata* as age progresses and with increased *Rukshaguna* the manifestation of *Vatashteela* could be more. From the obtained data, it can be inferred that the size of prostate gland is not

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directly proportional with the intensity of symptoms including the post void residual volume of urine. But the severity of embarrassing symptoms was more in subjects with median lobe enlargement of prostate. Both groups showed significant results in both objective as well as subjective criteria. There was no statistically significant difference in results between the groups, but after looking at the mean differences of the objective parameters before and after the clinical trial, it can be inferred that the trial group had comparatively better outcome in majority of the parameters including size of the prostate, urgency and nocturia.

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