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Clinical Research

Gokshuradi Vati and *Dhanyaka-Gokshura Ghrita Matra Basti* 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. Hence, to find out a suitable Ayurvedic approach, an effort has been made towards the management of BPH, In this study, 32 selected patients of *Mootraghata* at par to BPH were divided into three groups randomly and treated accordingly. In group A, *Gokshuradi* compound (GC) *Vati* (GV) 500 mg was given three times a day with luke-warm water after food; while in group B, *Dhanyaka-Gokshura Ghrita* (DGG) as *Matra Basti* (MB) of 60 ml, once in a day, just after lunch and combined therapy of both formulations in group C was administered. Out of 32 patients, total 30 patients (10 in each group) were completed the treatment course of 21 days. In results, 54.09% improvement was seen in group C, 45.67% in group A and 47.99% in group B. The size of prostate gland was found reduced highly significant in group C. Hence, it is concluded that combined therapy of GV and DGG MB is beneficial without developing any adverse drug reactions and can be prescribed safely for *Mootraghata* (BPH).

Key words: Benign prostatic hyperplasia, *Dhanyaka-Gokshura Ghrita, Gokshuradi* Vati, *Matra Basti, Mootraghata*

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 = 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 Gokshuradi Vati (GV) orally and Dhanyaka-Gokshura Ghrita (DGG) Matra Basti (MB) in the management of Mootraghata with reference to BPH.

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Materials and Methods

Selection of patients

Total 32 male patients having signs and symptoms of *Mootraghata* (BPH) were selected randomly from outpatient department of Shalya Tantra and from two special diagnostic camps irrespective of religion and occupation.

Inclusion criteria

- Male patients of age - 50 to 80 years.
- Patients having signs and symptoms of *Mootraghata* (BPH).

Exclusion criteria

- Patients not fulfilling age criteria and those suffering from malignancy, congenital deformities of urogenital tract,
- Systemic diseases such as uncontrolled hypertension, diabetes mellitus, liver, renal, and cardiac diseases.

Diagnostic criteria

Diagnosis was made on the basis of classical signs and symptoms of *Mootraghata*, per rectal digital examination and on the basis of the findings of Ultra Sonography for Kidney, Ureter, Bladder Region (KUB) and prostate.

Trial drugs

- GV: It contains *Punarnava* (*Boerhavia diffusa* L. nom. Cons.) and *Devadaru* (*Cedrus deodara* (Roxb.) G. Don) as additional *Kwatha Dravyas* to classical formulation of *Gokshuradi Guggulu*.[9] It was prepared as per *Guggulu Kalpana*.[10]
- DGG: In this formulation, *Dhanyaka* (*Coriandrum sativum* L.) and *Gokshura* (*Tribulus terrestris* L.) were used as *Kalka* and *Kwatha Dravya*; and cow ghee as *Sneha Dravya*.[11] It was prepared as per classical *Snehapaka Kapana*.[12]
- Both the drugs were prepared and supplied by the Pharmacy, Gujarat Ayurved University, Jamnagar.

Clinical study design

Grouping and posology

- Patients were divided into three groups by simple random sampling method:
  1. Group A: GV 500 mg was administered orally three times in a day, with luke-warm water, 30 min. after food.
  2. Group B: DGG was administered as MB of 60 ml, once in a day, just after lunch[13] possible at 12.30 pm.
  3. Group C: Combined therapy of GV and DGG MB was administered as per above mentioned schedule.
- Total duration of therapy in each group was of 21 days.
- Follow-up period was of 1 month.

Assessment criteria

- Subjective assessment of results was carried out by scoring pattern of symptoms of *Mootraghata*/BPH and by using International Prostate Symptom Score[14] sheet for subjective complaints.
- Objective assessment of results was done by Average Urine Flow Rate (AUFR) measurement and USG findings of prostate weight and Post-voidal Residual Urine Volume (PRUV) were considers as objective parameters [Table 1].

Statistical analysis

For assessing effect of therapy on each subjective and objective parameters, paired 't' test for significance was applied. For comparison among the three groups, for objective parameters un-paired '*t*' test is used whereas for subjective parameters Chi-square test with Yate's correction was adopted.

Observations and Results

Out of 32 patients, 10 in each group were completed the therapy and follow-up period. So, in this study, general observations were made on 32 patients as mentioned in Tables 2-4 and results were made on 30 patients as shown in Tables 5-12.

Discussion

Mootraghata (BPH) is a most common obstructive urological condition of old age. In pathophysiology of *Mootraghata*, there is involvement of *Mootravaha Srotasa* especially *Basti* (bladder). It may occur due to complex phenomena such as BOO, LUTS, and BPH. The symptoms of all types of *Mootraghata* may be classified under three groups for clinical assessment of BPH.

Voiding symptoms include *Pravaahato Shanaih Shanaih* (decreased urine flow rate/weak stream of urine), *Pravaahato Punah Punaha* (increased frequency/urgency of micturition), *Mootrasanga* (retention of urine, acute/chronic), *Srijeda-Alpaalpam* (scanty micturition/dribbling), *Adhahasroto Nirodhanam* (constipation), *Yobhuyah Srashtumichchhati* (hesitancy), etc., which are resembling with LUTS and BOO and generally exist in *Vatakundalika*, *Mootrasanga*, *Vatashtheela*, and *Mootrateeta* – all are the types of *Mootraghata*.

Findings of per rectal digital examination such as *Vritta Granthi* (round/oval shaped mass), *Sthira-Ghana-Astheela Vata Granthi* (hard/firm in consistency), and *Unnata Granthi* (convex surface), which are found in *Vatashtheela* and *Mootragrathi*. Hence, these types of *Mootraghata* may be related to be more nearer to the disease of BPH.

Table 1: Overall assessment of result

Result	Percentage	Subjective assessment criteria	Objective assessment criteria
Complete cure	100	In International prostate symptom score sheet and signs and symptoms of *Mootraaghaata* and/or BPH as per pro-forma	Reduction in weigh of prostate by USG Improvement in PRUV by USG Improvement in AUFR
Maximum improvement	>75 to<100		
Moderate improvement	>50-75		
Mild improvement	>25-50		
Unchanged	Up to 25		

BPH: Benign prostatic hyperplasia, PRUV: Post-voidal residual urine volume, AUFR: Average urine flow rate, USG: Ultrasonography

Table 2: General observations (*n*=32)

Observations	No. of patients (percentage)
Age (>60-80 years)	53.13
Nature of work and life style (sedentary)	84.38
Addiction (tobacco chewing or smoking)	59.37
History of Ayurvedic treatment for BPH	37.50
Chronicity (1-3 years)	43.57
Faulty dietetic habits (*Adhyashana* and *Vishamaashana*)	71.88
Vaatakapha Prakriti	56.25
Madhyama Kostha	46.88
Mandaagni	53.13
Vayataha (*Vriddhaavasthaa*)	68.75
Mootravaha Srotodusti	100.00
Nidaana (*Mooravegaavarodha*)	100.00
Retention time (h) for MB	06.75
Average *Vega* (numbers) after MB	01.30

BPH: Benign prostatic hyperplasia, MB: *Matra basti*

Table 4: General observations on objective findings (*n*=32)

Subjective	No. of patients	Percentage
Enlargement of prostate gland (both lateral lobe)†	21	65.62
Size of prostate gland (mild enlargement)†	21	65.62
Shape of prostate gland (oval)†	22	68.75
Surface of prostate gland (smooth)†	24	75.00
Upper border of prostate gland (reached with difficulty)†	19	59.38
Median groove of prostate gland (not palpable)†	22	68.75
Mild prostate enlargement (weight: Up to 45 g)‡	18	56.52
Moderate prostate enlargement (weight: >45 g)‡	22	43.48
PRUV (>60 cc to 90 cc maximum)‡	17	53.24
AUFR (3 to<7 ml/s)§	22	68.75

†Findings of per rectal digital examinations, ‡Findings of USG, §Findings on manual measurement, PRUV: Post-voidal residual urine volume, AUFR: Average urine flow rate, USG: Ultrasonography

Table 6: Effect of therapy on objective parameters in group A (*n*=10)

Objective parameters	% of relief	Mean difference±SEM	*t*	*P*
Prostate size (g)	20.71	09.33±2.220	4.203	<0.01
PRUV (ml)	06.55	03.75±8.059	0.465	>0.05
AUFR (ml/s)	39.52	02.43±0.313	7.805	<0.001

SEM: Standard error of mean, PRUV: Post-voidal residual urine volume, AUFR: Average urine flow rate

Table 3: General observations on subjective findings (*n*=32)

Subjective parameters	No. of patients	Percentage*
Increased frequency	32	100.00
Incomplete voiding	32	100.00
Weak stream	32	100.00
Hesitancy	32	100.00
Nocturia	31	96.88
Urgency	28	87.50
Dribbling	10	31.25

*Based on specially designed scoring pattern and assessed through International prostate symptom score

Table 5: Effect of therapy on subjective parameters in group A (*n*=10)

Subjective parameters	*n*	Mean difference±SEM	*T*	*P*
Increased frequency	10	0.8±0.133	9.000	<0.01
Incomplete voiding	10	0.7±0.213	3.279	<0.01
Weak stream	10	0.7±0.152	4.582	<0.01
Hesitancy	10	1.4±0.163	3.674	<0.01
Nocturia	10	0.8±0.133	6.000	<0.01
Urgency	07	1.1±0.260	4.381	<0.01
Dribbling	01	1.0±0.000		

SEM: Standard error of mean

Rest of symptoms of *Mootraghata* which are grouped under the findings of urine examinations such as *Mootram Haridram* (yellow urine), *Mootram Bahalam* (large quantity urine), and *Raktam Mootram* (reddish urine) are found in *Bastikundal*, *Mootrotsanga*, *Vatabasti*, *Mootrajathara*, *Ushnavata*, and *Mootraukasada* types of *Mootraghata*. These features are helpful in making differential diagnosis of BPH from other pathological conditions.

Out of total 32 patients registered in this study, maximum number of patients, i.e. 17 (53.13%) were found in age group of 60-80 years because it is the *Sheeryamanadhatvavastha* (elderly age) dominated by *Vata Prakopa*.Remaining patients were above 50 years, i.e. in *Vriddhavastha* (senile age), which is the natural period of *Vata Vriddhi* in the body.[15,16] Hence, it is attributed that the provoked *Vata* is a prime causative factor for manifestation of *Mootraghata*.[17] In this study, 59.37% patients had the history of tobacco chewing or smoking. As per the research studies on BPH in Europe, there is no strong evidence for smoking, tobacco chewing and high alcohol intake as the risk-factors for the causing BPH.[18] However in Ayurveda, it has been cited that *Teekshna Aushadha* or *Aahara*[19] (drugs/diet of strong potency like tobacco) are traced as the leading causative factors for *Mootraghata*. In the present research work, 71.88% patients had positive history of *Adhyashana* and *Vishamashana*. Such kind of dietetic habits lead to formation of *Kleda* and *Aama* in *Dhatus*[20] which might be produced *Srotoavarodha* in *Dhatu*. This phenomenon is treated as one of the important factors in the etiopathogenesis of *Mootraghata*. Maximum number of patients, i.e. 56.25% were belonging to *Vata-Kaphaja Prakriti*, the data itself revealed *Dosha* dominancy for individual

Table 7: Effect of therapy on subjective parameters in group B (*n*=10)

Subjective parameters	*n*	Mean difference±SEM	*t*	*P*
Increased frequency	10	1.5±0.224	6.708	<0.001
Incomplete voiding	09	1.1±0.147	8.315	<0.001
Weak stream	10	1.1±0.180	6.128	<0.001
Hesitancy	10	1.2±0.200	6.000	<0.001
Nocturia	09	1.0±0.261	4.264	<0.001
Urgency	10	0.6±0.163	3.674	<0.001
Dribbling	03	0.6±0.333	2.000	>0.05

SEM: Standard error of mean

Table 8: Effect of therapy on objective parameters in group B (*n*=10)

Objective parameters	% of relief	Mean difference±SEM	*t*	*P*
Prostate size (g)	18.08	07.77±03.384	2.296	<0.01
PRUV (ml)	23.91	17.82±13.058	1.365	>0.05
AUFR (ml/s)	31.65	02.04±00.325	6.555	<0.001

SEM: Standard error of mean, PRUV: Post-voidal residual urine volume, AUF: Average urine flow rate

Table 9: Effect of therapy on subjective parameters in group C (*n*=10)

Subjective parameters	*N*	Mean difference±SEM	*T*	*P*
Increased frequency	10	2.1±0.100	21.000	<0.001
Incomplete voiding	10	1.3±0.153	8.510	<0.001
Weak stream	10	1.1±0.100	11.000	<0.001
Hesitancy	10	1.2±0.133	9.000	<0.001
Nocturia	10	1.1±0.180	6.123	<0.001
Urgency	09	0.9±0.111	8.000	<0.001
Dribbling	06	0.8±0.167	7.000	<0.001

SEM: Standard error of mean

Table 10: Effect of therapy on objective parameters in group C (*n*=10)

Objective parameters	% of relief	Mean difference±SEM	*t*	*P*
Prostate size (g)	24.89	13.45±1.795	7.493	<0.001
PRUV (ml)	25.17	23.95±10.088	2.374	<0.01
AUFR (ml/s)	55.68	2.950±0.271	10.856	<0.001

SEM: Standard error of mean, PRUV: Post-voidal residual urine volume, AUFR: Average urine flow rate

in older age group and hence it can be presumed that *Prakriti* may play an important role for susceptibility or development of *Mootraghata*. Highest number of patients, i.e. 43.57% had chronicity of 1-3 years which suggests that *Mootraghata* is a slow and gradually disorder and had chronic history of onset [Table 2].

The result of study in group A showed statistically significant relief in all subjective parameters. Further, the trial formulation has given highly significant result by increasing AUFR; significant result was observed in reduction of prostate size while insignificant change was observed over PRUV. Overall, it was concluded that out of 10 patients, 3 patients (30.00%) were shown moderate improvement, while 7 patients (70.00%) were got mild improvement. These results were found due to GV, which possess properties such as *Vatakapha Shamaka*, *Lekhana*, *Pachana*, *Bastishodhana*, *Mootrala*, *Grahee*, *Pramathee* qualities and played vital role in breaching *Samprapti* of *Mootraghata* [Tables 5, 6, 12].

Table 11: Comparative mean effect of therapy in percentage (*n*=30)

Parameters (*n*=10)	Effect of therapy in percentage		
	Effect over subjective parameters (%)	Effect over objective parameter (%)	Overall average effect of therapy (%)
Group A	51.50	20.90	45.67
Group B	51.60	26.70	47.99
Group C	56.33	36.41	54.09

Table 12: Overall effect of therapy (*n*=30)

Result on effect of therapy	Group A		Group B		Group C		Total	
	No	%	No	%	No	%	No	%
Completely cured	00	00.00	00	00.00	00	00.00	00	00.00
Maximum improvement	00	00.00	00	00.00	00	00.00	00	00.00
Moderate improvement	03	30.00	04	40.00	07	70.00	14	46.67
Mild improvement	07	70.00	06	60.00	03	30.00	16	53.33
Unchanged	00	00.00	00	00.00	00	00.00	00	00.00
Total	10	100.00	10	100.00	10	100.00	30	100.00

In group B, all subjective parameters had showed highly significant ($P < 0.001$) relief except in dribbling of micturition feature, which was statistically insignificant. DGG MB showed highly significant result in AUFR, while significant result was found in the reduction in size of enlarged prostate gland and in feature of PRUV the result was insignificant. Finally, out of 10 patients, 4 patients (40.00%) had shown moderate improvement and 6 patients (60.00%) got mild improvement. The deranged function of *Apana Kshetra* would have been corrected by virtue of *Mootrala*, *Tridoshahara*, and *Basti Shodhana* properties of DGG MB. It may be attributed also that the nourishment of the nervous systems through Enteric Nervous System (ENS) and Central Nervous System (CNS) theory[21] would have been much impact on bladder physiology and in correction of pathogenesis of BOO [Tables 7, 8, 12].

Group C showed statistically highly significant relief in all subjective parameters. Combined therapy of GV and DGG MB in this group had shown highly significant improvement in urine flow rate and reduction in size of the prostate gland followed by significant reduction in PRUV. Overall in this group, out of 10 patients, 7 patients (70.00%) had got moderate improvement and 3 patients (30.00%) had shown mild improvement. Hence, group C showed better result in all parameters due to the synergistic effect of GV and DGG MB [Tables 9, 10, 12].

As per assessment, group C showed better improvement in objective parameters (36.41%) than group A (20.90%) and group B (26.70%). However, when data was analyzed statistically with un-paired '*t*'-test for three group comparison, insignificant difference was observed. In the same way, for subjective parameters, group C showed percentage wise better results, i.e. 56.33% than group A (51.50%) and group B (51.60%). However, when data was analyzed statistically with Chi-square test with Yate's correction; insignificant difference between all the groups was recorded [Table 11].

The *Samyak Yoga Lakshanas* of MB were observed in 95.00% of patients due to *Deepana*, *Pachana*, and *Niratyaya*[7] (without complications) effects of DGG MB. No adverse drug reactions were observed during this clinical study.

Conclusion

Gokshuradi Vati and *Gokshura-Dhanyaka Ghrita Matra Basti* are proven clinically to be safe and effective therapy in the management of *Vriddhavastha-Janya Mootraghata* i.e. BPH.

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हिन्दी सारांश

पौरुषग्रंथिवृद्धि में गोक्षुरादि वटी एवं धान्यकगोक्षुरघृत मात्रा बस्ति का चिकित्सीय अध्ययन

श्रेयस जी. भालोडिया, चतुर्भुज भुयाँ, संजयकुमार गुप्ता, तुकाराम एस. दूधमल

पौरुषग्रंथिवृद्धिजन्य मूत्राघात जो आधुनिक मतानुसार बी.पी.एच. से समानता रखता है, वृद्धावस्था में होने वाली एक प्रमुख व्याधि है, जिसका उपद्रव रहित चिकित्सीय उपाय आजतक उपलब्ध नहीं हो सका है । अद्यतन उपलब्ध शस्त्रकर्म की अपनी मर्यादाएँ एवं हानियाँ हैं। इसलिए आयुर्वेद द्वारा इस व्याधि की सुरक्षित, आसान एवं प्रभावी चिकित्सा की आशा करना स्वाभाविक है । इस अध्ययन में पंजीकृत किए गए कुल ३२ मूत्राघात के रोगियों को ३ वर्गों में बाँट कर चिकित्सा प्रबन्ध किया गया ।'अ'वर्ग में गोक्षुरादि वटी ५०० मि.ग्रा. दिन में तीनबार, भोजन के बाद, कोष्ण जल से; वर्ग 'ब'में धान्यकगोक्षुरघृत ६० मि.लि. मात्रा बस्ति के रूप में भोजनोत्तर, दोपहर में एकबार दिया गया तथा वर्ग 'स' में दोनो प्रकार की औषधियों का सम्मिलित प्रयोग किया गया । कुल ३० रोगियों में २१ दिन की यह चिकित्सा सम्पन्न करायी गयी । अध्ययन के अंत में वर्ग 'स' में ५४.०९%, वर्ग 'अ' में ४५.६७% तथा वर्ग 'ब' में ४७.९९% रोगियों में निर्धारित मापदण्डों के अनुसार लाभ पाया गया । वर्ग 'स'में पौरुषग्रंथि के प्रमाण में महत्वपूर्ण कमी पाई गई । अंतत: बी.पी.एच. जन्यमूत्राघात की चिकित्सा में संयुक्त रूप से प्रयुक्त गोक्षुरादि वटी एवं धान्यकगोक्षुरघृत मात्रा बस्ति की चिकित्सा का उत्तम प्रभाव पाया गया।