Clinical Research

Gokshuradi Vati and Dhanyaka-Gokshura Ghrita Matra Basti in the management of Benign Prostatic Hyperplasia

Shreyas G. Bhalodia, Chaturbhuj Bhuyan¹, Sanjay Kumar Gupta², Tukaram S. Dudhamal³

Lecturer, Department of Sharira Rachana, KVG Ayurveda Medical College, Sullia, Karnataka, ¹Director, Centre for Care of Ano-Rectal Research by Indian System of Medicine and Allied Sciences, Bhubneshwar, Odisa, ²Associate Professor and I/C Head, ³Assistant Professor, Department of Shalya Tantra, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India

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 lukewarm 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 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) and Bladder Outflow Obstruction (BOO), 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) in India. For this notorious problem there is no 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. 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.

In the context of manifestation of Mootraghata, developed due to deranged function of Vata, 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. Mootraghata can be correlated to BPH and is caused due to vitiated Vata and Kapha which involve Mootravaha Srotodushi. Present clinical study was planned as per management principles 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.

Address for correspondence: Dr. Shreyas G. Bhalodia, Block No 201, My Nest Apartment, N/R ICICI Bank, Motibag Road, Junagadh - 362 001, Gujarat, India. E-mail: shreyas.ayurved@gmail.com
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 Devadara (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 Snehataka 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 lukewarm 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[9] 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 considered 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 Mootраваха Srotasaa 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 Punah (increased frequency/urgency of micturition), Mootrasanga (retention of urine, acute/chronic), Sriyedas-Aalpaalpam (scanty micturition/dribbling), Adhahasroto Nirodhanam (constipation), Yobhuyah Srashtumichchhati (hesitancy), etc., which are resembling with LUTS and BOO and generally exist in Vatakundalika, Mootrasanga, Vatashtaala, 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 Umata Granthi (convex surface), which are found in Vatashtaala 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 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                                | 71.88                       |
| (Adhyashana and Vishamaashana)                         |                             |
| Vaatakapha Prakriti                                   | 56.25                       |
| Madhyma Kostha                                        | 46.88                       |
| Mandaagani                                            | 53.13                       |
| Vayataha (Vridhaavasthaa)                              | 68.75                       |
| Mootravaha Srotodusti                                 | 100.00                      |
| Nidaana (Moovegaavaardha)                              | 100.00                      |
| Retention time (h) for MB                              | 06.75                       |
| Average Vega (numbers) after MB                       | 01.30                       |

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

| Subjective parameters                          | 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      |

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, Mootraftathara, Ushnavata, and Mootraukasad 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 Vridhavastha (senile age), which is the natural period of Vata Vriddhi in the body. Hence, it is attributed that the provoked Vata is a prime causative factor for manifestation of Mootraghata. 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. However in Ayurveda, it has been cited that Teekshna Aushadha or Aahara (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 Vishamaashana. Such kind of dietetic habits lead to formation of Kleda and Aama in Dhatus which might be produced Srotoavardha 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, AUFR: 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 | <0.001 |
| 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

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

| Parameters | 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 |
|-----------------------------|---------|---------|---------|-------|
| Completely cured            | 00      | 00      | 00      | 00    |
| Maximum improvement         | 00      | 00      | 00      | 00    |
| Moderate improvement        | 03      | 04      | 07      | 14    |
| Mild improvement            | 07      | 06      | 03      | 16    |
| Unchanged                   | 00      | 00      | 00      | 00    |
| Total                       | 10      | 10      | 10      | 30    |

In older age group and hence it can be presumed that Prakriti may play an important role for susceptibility or development of Moortaghata. Highest number of patients, i.e. 43.57% had chronicity of 1-3 years which suggests that Moortaghata 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 Shama, Lekhaha, Pachana, Bastishodhaha, Mootrala, Grahee, Pramathee qualities and played vital role in breaching Samprapti of Moortraghata [Tables 5, 6, 12].

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 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 Nirayatad[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.

References

1. Sushruta, Sushruta Samhita, Uttar Tantra, Murtraghata Pratisedhayaya. 58/3‑4. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Surbarati Prakashana, Varanasi, 2008; 787.
2. Neal DE. The prostate and seminal vesicles. In: Williams NS, Bulstrode, O’Connell, editors. Bailey and Love’s Short Practice of Surgery. 25th ed. London: Hodder Arnold; 2008. pp. 1345.
3. Ibidem. Caukhambha Samhita, Madhyama Khanda; 197.
4. Sushruta, Sushruta Samhita, Uttar Tantra, Mutraghata Pratisedhayaya. 58/241‑243; 610.
5. Wein AJ, Kavoussi LR, Novick AC, Partin AW, Peters CA, editors. Campbell-Walsh Urology, 9th ed. Philadelphia: W.B. Saunders Company; 2007. pp. 1225.
6. Ibidem. Campbell-Walsh Urology; pp. 1999.
7. Agnivesha, Charaka, Dridhabala, Charaka Samhita, Siddhi Sthana, Dhamargava Kalpaadhyaya, 4/53. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Sanskrita Sansthana, Varanasi, 2002; 701.
8. Sushruta, Sushruta Samhita, Uttar Tantra, Murtraghata Pratisedhayaya, 58/27. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Surbarati Prakashana, Varanasi, 2008; 789.
9. Sharangadhara, Sharangadhara Samhita, Madhyama Khanda, 6/22. Edited by Pandita P S Vidhyasagar, 1st ed. Chaukhamba Surbarati Prakashana, Varanasi, 2006; 82.
10. Ibidem. Sharangadhara Samhita, Madhyama Khanda; 197.
11. Bhavanishra, Bhavaprakasha, Madhyama Khanda, Part‑2, 36/41. Edited by Pandit Shri B S Mishra, 9th ed. Chaukhamba Sanskrita Sansthana, Varanasi, 2005; 370.
12. Sharangadhara, Sharangadhara Samhita, Edited by Pandita P S Vidhyasagar, 1st ed. Chaukhamba Surbarati Prakashana, Varanasi, 2006; 212.
13. Agnivesha, Charaka, Dridhabala, Charaka Samhita, Siddhi Sthana, Kalpana Siddhi, 1/20‑21. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Sanskrita Sansthana, Varanasi, 2002; 680.
14. International Prostate Symptom Score (i‑PSS). Available from: http://www.urospec.com/uro/Forms/ipss.pdf [accessed on 2010 Apr 12].
15. Agnivesha, Charaka, Dridhabala, Charaka Samhita, Viman Sthana, Rogabishajiyatiyam Vimanan, 8/122. Edited by Vaidya Yadavaji Trikamji Aacharya. Reprint. Chaukhamba Sanskrita Sansthana, Varanasi, 2002; 280.
16. Sushruta, Sushruta Samhita, Sutra Sthana, Asupoparakramanayi, 35/29. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Surbarati Prakashana, Varanasi, 2008; 155.
17. Ibidem. Sushruta Samhita, Uttara Tantra, Mutraghata Pratisedhayaya, 58/26, 789.
18. Guidelines on BPH, European Association of Urology, 2009. p. 9. Available from: http://www.uroweb.org/. [accessed on 2010 Apr 25].
19. Agnivesha, Charaka, Dridhabala, Charaka Samhita, Chikitsa Sthana, Trinarmiya Chikitsa, 26/32. Edited by Vaidya Yadavaji Trikamji Aacharya, Reprint. Chaukhamba Sanskrita Sansthana, Varanasi, 2002; 599.
20. Ibidem. Charaka Samhita, Chikitsa Sthana, Trinarmiya Chikitsa, 26/241‑243; 610.
21. Vasudevan Nampoorthiri MR, Mahadevan L. Principles and Practice of Vasti. 3rd ed., Chennai: Sri Sarada Ayurvedic Hospital Publication; 2010. pp. 46.