

A CLINICAL STUDY WITH VARUNADIKWATH AND GOKSHURADI GUGGULU IN THE MANAGEMENT OF 'MUTRAGHATA' W.S.R. TO BPH

AnkurSinghal¹, Komal Gupta²

¹Associate Professor, Department Of Kayachikitsa, V.Y.D.S.A.M., Khurja, Bulandshahr, Uttar Pradesh, India

²Senior Medical Officer, Devnandini Hospital, Hapur, Uttar Pradesh, India

Email:drankursinghal2015@gmail.com

ABSTRACT

B.P.H. is condition related to ageing process and most frequently seen in men in 7th, 8th, 9th decade, but also occurs in 6th and even 5th decade of life. Surveys have found a high prevalence of moderate to severe obstructive symptom in men over 50, which increases with age. This has a significant impact on the health of older men and health-care costs. Notably, increase in Benign Prostate Hypertrophy and lower urinary tract symptoms such as urgency, dribbling micturition, hesitancy, and increase frequency of micturition are on rise, occurring within the context of an aging global population. In Ayurvedic classics the term *Mutraghata* is related with the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria. In relation to BPH condition, there is no permanent and safe cure with modern medicine, except surgical resection of prostate, which is also having complication thereafter. So there is an urgent need of non-invasive treatments and pharmacological treatment that can promise a healthy aging. Keeping the above factors in consideration a study was carried out with Ayurvedic formulations, mentioned in classics, to assess the efficacy and to achieve a friendly treatment protocol. A clinical study was conducted in VYDSAM, Khurja with an objective to assess the efficacy of *GokshuradiGuggulu* and *Varunadikwath* in the management of *Mutraghata* w.s.r. BPH in 28 patients divided into two groups. A marked clinical improvement was noticed with combined use of *Gokshuradiguggulu* and *Varunadikwath*, as compared to *GokshuradiGuggulu* alone.

Keywords: *Mutraghata*, *GokshuradiGuggulu*, *VarunadiKwath*, BPH

INTRODUCTION

BPH is a common and progressive disease of aging men and the prevalence of BPH increases with age.¹ Around 50% of men above 65 years of age (more than 80% among men 70-79 years of age) suffer some symptoms of BPH.² Over the coming years, however, an increasing number of patients may report prostatic problems as the world's population is aging.

According to Ayurveda, the *Vatashtheela* and *MutrAGRAnthi* which are the types of *MutrAGhata* may be correlated with BPH on the basis of similarity of symptoms. According to Ayurveda classics *MutrAGhata* is a diseased condition where 'retention of urine' is the cardinal feature, whereas in *MutrAKricchArA*, difficulty in micturition is the typical characteristic feature. Obstruction and hence retention of urine may be caused by occlusion of the urinary tract or inflammation in the urinary pathway. Often injury, constriction/compressed stones or any other possible foreign bodies may result in this pathological condition.

MutrAGhata is predominantly a *VatAdosha* disorder. Vitiated *Dosha* travel through the *SukshmaSiras* and *Dhamani* to get Lodged in (*KhavaigunayaSthana*) i.e. *Basti* where upon further vitiation of *Vata* leads to *VimargaGamaNa* and therefore *MutrAGhata*.

The pharmacological approaches for the treatment of BPH according to modern science include the use of agents that either reduces the tone of Prostatic smooth muscle or the size of the Prostate. As this disorder appears to be hormone dependent condition, the modern investigators have primarily focused on endocrinal therapies which are having many compli-

cations such as loss of libido , impotence and gynaecomastia.

So it is the need of the hour to understand BPH in terms of Ayurveda so that an uncomplicated and patient friendly treatment can be advised to the patients.

Keeping all these facts in mind a clinical study "A Clinical Study with *VarunadiKwath* and *GokshuradiGuggulu* in the Management of *MutrAGhata* w.s.r. to BPH" was designed. *Gokshuradi guggulu*³ and *Varunadi kwath*⁴ seems to be appropriate drugs according to Ayurvedic classics in relation to the management of *MutrAGhata* . Hence they had been taken for the present clinical study.

AIMS AND OBJECTIVES

1. To study the *MutrAGhata* w.s.r. to Benign Prostate Hypertrophy according to Ayurvedic classic and modern science.
2. To evaluate the clinical efficacy of *VarunadiKwath* And *Gokshura Guggulu* in the management of *MutrAGhata* w.s.r. to BPH.

MATERIAL AND METHODS:

Clinical Study:-The patients attending the O.P.D. & I.P.D. of VYDSAMC and Hospital OPD, were selected for the Clinical Study and were selected irrespective of their Age, Religion, Race, Occupation etc., fulfilling the Criteria of selection and eligibility for the present study.

Total No. Of Patients: 28

Group A: 14 (*Gokshuradi Guggulu*)

Group B: 14 (*Gokshuradi Guggulu* and *VarunadiKwath*)

CRITERIA FOR THE SELECTION OF THE PATIENTS:

The patients were randomly selected and diagnosed on the basis of both the Subjective and Objective criteria of *Mutraghata*- BPH. Some patients with greater degree of Bladder outlet obstruction, acute retention of urine requiring catheterization and those with Impeding upper urinary tract affections were excluded from the study.

PLAN OF WORK:

1. A thorough history, General examinations, and Systemic examinations were conducted and duly recorded in the special proforma prepared for the study. The International Prostate Symptom Score based on the 'American Urologists Association' score-sheet was used to assess the Subjective complaints Before, During and After the schedule.
2. **Investigations:-**
 - (a) Digital and Ultrasonography examination of the Prostate gland.
 - (b) Residual urine volume assessment by Ultrasonography.
 - (c) Routine Hematological, Urine and Stool examinations with Specific Bio-chemical evaluation of Blood urea, Serum creatinine, Serum acid phosphatase and Serum alkaline phosphatase were carried out.
3. The selected patients were subjected to administration of *VarunadiKwath* and *Gokshuradi Guggulu*. A special *Pathya* regimen was advised to be followed throughout the entire schedule.

The schedule was designed as follows:-

- (1) Initially upon registration of the patient, up to the period of complete history taking, physical examinations and investigative procedures, the patients were advised to follow a '*Pathya*' regimen consisting of the following in their daily routine- *Takra, Kshira, Masha Yusha, Dadhi, MudgaYusha and UshnaJala* - (*Bh. R. MutraghataAdhikara*). The *Pathya* regimen was advised to be followed throughout the entire treatment.
- (2) *GokshuradiGuggulu* in the dosage of 500mg TDS, orally for 30 days after Food with lukewarm water.
- (3) *Gokshuradi Guggulu* in dosage of 500mg TDS after food and *VarunadiKwath* in dosage of 10-15ml twice a day with equal amount of water for 30 days after Food.

CRITERIA OF ASSESSMENT:

The effect of therapy was assessed as:-

- Group - I. After the completion of *Gokshuradi Guggulu* schedule of 30 days.
- Group - II. After the completion of *Gokshuradi Guggulu* and *VarunadiKwath* schedule of 30 days.
1. Improvement in the symptomatology of the disease based on International Prostate symptom score sheet (prepared by American Urologists Association).
 2. Assessment of Residual Urine Volume.
 3. Measurement of Prostatic enlargement by digital and Ultrasonographic methods.
 4. Urinary Sepsis and its Culture, wherever it is necessary.
 5. Assessment of Laboratory investigations. The Obtained Results have been discussed

and analyzed on the following parameters

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FOLLOW- UP STUDY: Duration of the follow-up study was **3 months** after the completion of treatment schedule.

OBSERVATIONS

Table 1: Chief Complaints of 28 Patients of *Mutraghata*

Chief complaints	Group – I		Group - II		Total	
	No. of patients	Percentage	No. of Patients	Percentage	No. of Patients	Percentage
Frequency	14	100	14	100.00	28	100
Urgency	11	78.57	10	71.42	21	75
Nocturia	14	100	13	92.85	27	96.4
Hesitancy	13	92.85	08	57.14	21	75
Weak urinary stream	10	71.42	10	71.42	20	71.41
Dysuria	12	85.71	13	92.82	25	89.26
Haematuria	01	7.14	02	14.28	3	10.71
Burning micturition	09	64.28	11	78.58	20	71.41
Incomplete voidance	14	100	09	64.28	23	82.12
Dribbling micturition	08	57.18	09	64.28	17	60.7
Pain in lower abd.	02	14.28	07	50.00	9	32.14
Terminal dribbling	08	57.18	05	35.71	13	46.42

Table 2: Assessment of Residual Urine Volume in 28 Patients Of *Mutraghata*

Residual urine	Group - I		Group - II		Total	
	No. of patients	Percentage	No. of patients	Percentage	No. of patients	Percentage
50 - 100 ml	0	00	00	00	0	0
100 - 150 ml	1	7.14%	8	57.14%	9	32.14%
150-200 ml	10	71.42%	4	28.57%	14	50%
> 200 ml	3	21.42%	2	14.28%	5	17.85%

Table 3: Effect of *Gokshuradi Guggulu* on Individual Symptoms of 14 Patients Of *Mutraghata*

Symptoms	Mean score		% of relief	S.D ±	S.E ±	T	P
	B.T.	A.T.					
Incomplete voiding	2.67	1.50	43.82	0.40	0.16	7.00	< 0.001
Frequency	2.56	1.44	44.48	0.60	0.20	5.54	< 0.001
Intermittency	3.60	2.60	27.78	0.70	0.31	3.16	< 0.001
Urgency	2.57	1.43	44.44	0.37	0.14	8.00	< 0.001
Nocturia	2.00	1.14	42.86	0.37	0.14	6.00	< 0.001
Had to strain	2.00	0.89	55.56	0.78	0.26	4.26	< 0.001
Weak urine stream	4.93	3.93	20.28	0.76	0.13	5.12	< 0.001

Table 4: Effect of Gokshuradi Guggulu & Varunyadi Kwath on Individual Symptoms Of 14 Patients of Mutraghata

Symptoms	Mean score		% of relief	S.D ±	S.E ±	t	P
	B.T.	A.T.					
Incomplete voiding	1.57	0.29	80.67	0.80	0.21	5.67	< 0.001
Frequency	2.79	0.71	74.55	1.49	0.40	5.20	< 0.001
Intermittency	1.36	0.21	84.56	0.86	0.23	4.95	< 0.001
Urgency	1.64	0.36	78.05	0.91	0.24	5.26	< 0.001
Nocturia	2.79	0.71	74.55	1.79	0.48	5.24	< 0.001
Had to strain	1.64	0.43	73.78	0.80	0.21	5.67	< 0.001
Weak urine stream	1.36	0.36	73.53	1.11	0.30	3.37	< 0.01

Table 5: Effect of Gokshuradi Guggulu on Residual Urine Volume of 14 Patients of Mutraghata

Parameter	Mean score		% of relief	S.D ±	S.E ±	T	P
	B.T.	A.T.					
Residual urine vol.	178.78	85.71	52%	25.55	6.83	13.62	< 0.001

Table 6: Effect of Gokshuradi Guggulu And Varunadi Kwath on Residual Urine Volume of 14 Patients of Mutraghata

Parameter	Mean score		% of relief	S.D ±	S.E ±	t	P
	B.T.	A.T.					
Residual urine vol.	155.35	36.00	78.82	18.66	4.98	23.92	< 0.001

Table 7: Effect of Treatment on Prostate Size in 28 Patients of Mutraghata

Sr. No.	Group – I		Group – II	
	B.T. (in mm)	A.T. (in mm)	B.T. (in mm)	A.T. (in mm)
1	37 x 35 x 45	40 x 38 x 42	65.3 x 50.3 x 42.5	61.9 x 49.8 x 39.7
2	43 x 39 x 42	48 x 40 x 36	60 x 56 x 53	61.8 x 53.2 x 51.2
3	46 x 52 x 56	50 x 53 x 47	51 x 49 x 33.3	53 x 46 x 32.4
4	56 x 38 x 58	52 x 40 x 51	58.5 x 57.8 x 57.2	57.6 x 58 x 53
5	48 x 42 x 50	50 x 40 x 47	45.2 x 38.6 x 37.5	47 x 28 x 41
6	62 x 50 x 44.5	58 x 52.3 x 42.5	56 x 46 x 41	51 x 55 x 56
7	41.4 x 40.6 x 35	42 x 39.6 x 34.5	46 x 35 x 33	45 x 32 x 28
8	48 x 37 x 33	48.5 x 37.5 x 34	49 x 45 x 39	47 x 42 x 44
9	44 x 48 x 55	43 x 49 x 53.0	46 x 52 x 56	46 x 54 x 55
10	50 x 36 x 36	49 x 36 x 35.3	56 x 28 x 40	49 x 28 x 38
11	49.8 x 38.9 x 33.9	42.2 x 41.3 x 39.1	49 x 45 x 43	46 x 46 x 44
12	46 x 42 x 37	46 x 43 x 38	48 x 39 x 44	44 x 42 x 46
13	50.7 x 52.7 x 44.2	50.7 x 52.7 x 44.2	32 x 39 x 40	34 x 32 x 38
14	41 x 36 x 28	41.5 x 36 x 29	59 x 57 x 58	60 x 55 x 60

Table 8: Total Effect of the Gokshuradi Guggulu treatment –Subjective Parameters

Result	No. of patients	Percentage
Complete remission	00	00
Marked improvement	07	50.00%
Improved	07	50.00%
Unchanged	00	00

Table 9: Total Effect of the Gokshuradi Guggulu And Varunadi Kwath treatment– On Subjective Parameters

Result	No. of patients	Percentage
Complete remission	08	57.14%
Marked improvement	06	42.85%
Improved	00	00
Unchanged	00	00

Table 10: Total Effect of The Gokshuradi Guggulu Treatment – Objective Parameters

Parameter	Complete remission	Marked improvement	Improved	Unchanged
Size of prostate	00	03	06	05
Percentage	00	21.42%	42.86%	35.71%
Residual urine volume	00	04	09	01
Percentage	00	28.57%	64.28%	7.1%
Urine flow rate	03	07	04	00
Percentage	21.42%	50%	28.57%	00

Table 11: Total Effect of the Gokshuradi Guggulu And Varunadi Kwath treatment – Objective Parameters

Parameter	Complete remission	Marked improvement	Improved	Unchanged
Size of prostate	00	06	07	01
Percentage	00	42.85%	50.00%	7.14%
Residual urine volume	04	06	01	-
Percentage	28.57%	42.86%	7.14%	
Urine flow rate	07	05	02	-
Percentage	50.0%	35.71%	14.28%	-

Laboratory investigation

The hematological, biochemical, urine and stool investigations were recorded and they were within normal limits in all the patients taken for the study.

DISCUSSION

Acharya Charaka states the importance of three *Marmas*, that the *Basti*, *Hridaya* and *Shiras* are the three vital points, as the *Prana* sheltered in them. Any affliction of these leads to vitiation of *Vata* etc. factors and may be fatal to life.⁵

In *Maharogadhyaya Acharya Charaka* quotes –That the natural action of *Vata*, moving from one bodily organ to another are the manifestation causes of looseness, dislocation, expansion, obstruction, circular movement, piercing pain etc.⁶ These are the actions which help the physician to diagnose a disease as predominated by *Vata*.

Acharya Sushruta further substantiated the above concept, he says that the vitiated *Vata* lodged in the *Basti* and *Guda* leads to grave diseases.⁷ Thus from all the above references it becomes clear that it is the "*Vata*" which is mainly responsible for the manifestation of *Basti* disorders. This "*Vayu*" may be provoked either by endogenous or exogenous factors. "*Mutravegavarodah*" is one such factor, which leads to vitiation of *Vata*. The voluntary suppression of urge of micturition, is quite a painful stimulus to the *Basti*, as is commonly experienced by everybody. This act of suppression, has to be present over a long period of time in a person to bring about the vitiation of *Vata*, to the extent that it manifests in *Mutraghata*. Here, postponing the urge leads to discomfort in the region of *Basti* and symptoms of obstructed flow or painful micturition may manifest.

As said, this vitiated '*Vayu*' gets lodged in '*Basti*' to produce altered functions. As already known '*Basti*' is an *Ashaya* (an element of *Vata*) and is structurally made up of '*Snayu*' (another element of *Vayu*).

This concept of '*Vata*' getting lodged in the '*Basti*' can be interpreted as *Vayu* getting lodged in '*Snayu*' which commonly referred to as '*Snayugata Vata*'. In this way, the sympto-

matologies of '*Snayugata Vata*'⁸ can be applied to *Basti*.

Reverting back to the "*Mutravegavarodha*", in the literary study "*Vata*" has been related to the "Neural stimuli" or nervous system in general.

These assumption and facts give rise to hypothesis that constant suppression of the urge of micturition leads to extreme *Vata* vitiation, which in turn leads to '*Gatavata*' in the '*Snayu*' of the '*Bastimarma*' and produces the morbid conditions of instability, hyperactivity or hypo activity, thereby bringing about a disturbance in the normal evacuation of urine.

Therefore, it can be put that "*Mutramargavarodha*" leading to "*Vataprakopa*" leads to deranged functioning of '*Snayu*' located in the *Basti*, which manifests as altered functioning of *Basti*.

Now, when scrutinizing different varieties of "*Mutraghata*", it becomes quite evident that the symptomatology is not given with reference to age, sex, or chronicity and hence, it becomes all the more troublesome to correlate a single variety to that of BPH.

From the above discussion, the following inferences may most probably be a suitable description in helping to identify the entity of BPH in our classical texts:-

- (a) The symptomatology of BPH in relation to the size of the gland is uncertain & hence the patients present themselves with varied symptoms.
- (b) The types like- *BastiKundalika*, *Mutragranthi*, *Mutrotsanga* & *Ashtheelamay* just be the various stages of *Mutraghata*, which a patient presents himself.

(c) The presence of obstructive symptoms is a must for the diagnosis of BPH and these cannot be found in the *Mutraukasada*, *Ushnavata* etc. types and hence cannot be considered here.

(d) The presence of enlargement is provided in “*MutrAGRAnthi*” & “*Ashtheela*” varieties, which again rules out the possibilities of “*VataBasti*”, “*Mutrajathara*” etc. types, which can probably be included safely under the “Neurogenic disturbances of the bladder”.

Thus it can be concluded that a single entity simulating BPH cannot be identified in our texts and rather the various stages of Benign Prostatic Hyperplasia have been recorded in *MutrAGRAnthi*, *Bastikundalika*, *Mutrotsanga* and *Ashtheela* varieties. Therefore one has to carefully elicit the history, symptomatology and confirm by physical examination to arrive at labeling a patient as a case of BPH.

EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS ON 14 PATIENTS OF BPH TREATED WITH GOKSHURADI GUGGULU:

43.82% relief was observed in Incomplete voiding, followed by 44.48% relief in Frequency, 27.78% in Intermittency, 44.44% in Urgency, 42.86% in Nocturia, 55.56% in Straining and 20.28% in Weak urine stream. All these values were statistically highly significant ($P < 0.001$).

These effects can be analyzed based on the mode of action of therapy administered.

EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS ON 14 PATIENTS

TREATED WITH GOKSHURADI GUGGULU AND VARUNADI KWATH

80.67% relief was observed in incomplete voiding followed by 74.55% relief in frequency, 84.56% relief in Intermittency, 78.05% relief in Urgency, 74.55% relief in Nocturia, 73.78% relief in Straining and 73.53% relief in Weak urine stream. All these values were statistically highly significant ($P < 0.001$).

Week wise improvement in the symptomatology of prostatism is as follows:

Urgency, Dysuria and Burning micturation was relieved in the **first week** followed by Constipation, Nocturia and Hesitency in the **second week**. In the **third week**, Urinary Stream was improved along with the improvement in the incomplete voidance, Retention of urine and Dribbling micturation.

Subjective parameters:

In Group - I, i.e. patient treated with *Gokshuradiguggulu* shows relief of up to improvement (50%) and marked improvement (50%) where as in Group - II when the oral supplements is combined with the *Varunadi Kwath*, the relief is increased up to complete remission (57.14%) and marked improvement (42.85%).

None of the patient remained unchanged in both the groups.

Objective parameters:

1) Size of prostate

It is clear that the size of prostate does not achieve the level of complete remission in both the cases but with the administration of *Varunadi Kwath* in the Group - II, the effect of

oral supplement seems to increase many folds. But the natural course of the disease is such that it either progresses gradually over a period of time or stays dormant for years and occasionally regresses too. Hence it is very difficult to claim that the therapy caused the regression of the Prostatic size and few more studies may be required to prove this. But however it is stated that the symptomatology of Prostate is not related with the size of the Prostate as many men with larger Prostate remain asymptomatic, where as those with slightly enlarged prostate may experience severe symptoms.

All the patients have registered relief rate of approx 45-60% in almost all the parameters assessed. The investigation of prostate gland size by ultrasonography is an observer based reading, and therefore, there is always a possibility of an error.

2) Residual urine volume:

It is evident from the comparison that effect of combination therapy is more significant than *Gokshuradi Guggulu* alone.

This is because of the fact that detrusor tone was improved and complete emptying was taking place.

Probable action of *Gokshuradi Guggulu*

Gokshuradi Guggulu (a combined Ayurvedic preparation) is a well-known and commonly used medicine in diseases of *MutravahaSrotas*. It is specially indicated in *Prameha*, *Mutrakricha* and *Mutraghata* along with other indications of *Mutra* and *Shukravaha Srotasa*.³ *Gokshura*, the main ingredient, is well

known for its *Rasayana* effect, especially on *MutravahaSrotas*. *Guggulu* (*Commiphoram ukul*), another main ingredient, is also *Rasayana* and it has *Lekhana* (scraping) effect also. In addition, *Guggulu* has *Tridosahara* property also, by which it pacifies all the three *doshas*. *Gokshuradi Guggulu* (containing mainly *Gokshura*, *Guggulu*, *Triphala*, *Trikatu*, *Musta*) are having *Sothhara*, *Vatahara*, *Mootrala*, *Lekhana* and *BastiShodhan* property. All the above said symptoms are due to vitiated *Vata* situated in the *Basti* and the formulation by virtue of its above said action bring backs the aggravated *Vata* to normal and breaks the *Dosa-Dushya Sammurcchana*. The use of "*Pathya*" such as *Kshira*, *Mudgayusha*, *Mashyusha*, *Dadhi*, *Takra* and *UshnaJala* predominantly alleviates *Vata* and each of them has got "*Bastishodka*" property and thus fortifies the action of *Gokshuradi Guggulu*.

Probable Action of *Varunadi Kwath*

'*Varunadi Kwath*', formulation explained by *Chakradatta*⁴, possess all the needful properties like *Kaphahara*, *Lekhana* and *Mutrala*. *Varun* as the main ingredient of *Varunadi Kwath* is used for *kaphavikara*, *medovikara*, *mandagni*, *urusthambha*, *shirashool*, *gulma* and *antravidradhi*.⁹

The ingredients of the compound pacify *KaphaDosh* by virtue of their *RukshaGuna*, *KatuVipaka* and *UshnaVirya* and also show "*Lekhana*" property due to *UshnaVirya*. The *Lekhana Karma* is again enhanced by famous *LekhanaDravya* i.e. *Yavakshara*, which is one ingredient in it. The *Vatanulomana*, *Shothahara* and *Mutrala* properties of ingredients

helps to relieve pain and *SthanikaSotha*. *Jwara* is also relieved due to the *Jwarahara* action of *Pashanbhed*, *Varun* and *Shunthi*. *Deepana* property of drug helps to increase the *Agni*, which further check the formation of *Ama* at-*Jatharagni* level. Remaining drugs of the compound act as *Mutrala* (diuretic) by virtue of their '*SheetaVirya*' and *Madhur Rasa*.

Varuna due to triterpene is good in improving the detrussors tone i.e. the musculature of urinary bladder along with the anti-infective properties.

Prostatic secretions are slightly acidic and Campbell, the God of urology, says that basic drug would be more positively charged in acidic prostatic fluid than in the blood. So, slight changes in the pH can have significant effect on the non-ionic diffusion, enzymes and hormones.

The above composition is basic in nature so it will definitely increase the bioavailability of the active components in the prostatic cells enhancing the overall activity of the compound.

*Acharya Charaka*¹⁰ in *Sutra Sthana* has described "*KsharaPunstavaUpghatinamShershta*"

The *Punstava Shakti* seems to be the testosterone. As described in *Vishnu Purana* and confirmed in the recent era by Campbell that every foetus tends to be a female till it is stopped by testosterone signifies the facts that testosterone can be compared with *Punstava-Shakti*. This testosterone is responsible for the increase in the size of prostate. *Ksharas* may be able to decrease its level by its anti-androgenic effect and therapy hampering the pathogenesis of BPH.

CONCLUSION

In the present study a marked clinical improvement was noticed with combined use of *Gokshuradi Guggulu* and *Varunadi Kwath* as compared to *Gokshuradi Guggulu* alone, in the management of *Mutraghata* w.s.r. BPH.

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