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Research Article

THE EFFECTIVENESS OF GOKSURADI GUGGULU AND VARUNADI KWATH WITH GOKSURADI GUGGULU IN THE MANAGEMENT OF MUTRASMARI W.S.R. TO UROLITHIASIS

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ABSTRACT

Introduction: *Mutrasmari* is considered as *Astamahagada* in Ayurveda in which there is formation of stone in the *Mutravaha srota*. It is an ancient disease with global distribution. The symptoms of *Mutrasmari* are excruciating pain in urethra, ureter, urinary bladder and over umbilical region, haematuria etc and later that may lead to emergence by the obstruction in urination. Hence on the basis of pathology and its clinical presentation the disease is correlated with Renal calculus or Urolithiasis in modern Urology.

Methodology: 38 patients diagnosed as *Mutrasmari* were randomly divided in two groups as per the lottery system of randomization. The patients of Group A were given 1000mg *Goksuradi guggulu* twice a day for 45 days. The patients of Group B were given 1000 mg of *Gokshuradi guggulu* along with 45 ml of *Varunadi kwatha* twice a day for 45 days. The patients of both the groups were advised to follow the dietary regimen and lifestyle modification. The effect of the intervention was assessed before and after treatment.

Result: The treatment outcomes were statically analyzed and found that both treatment groups were significant in relieving the symptoms like abdominal pain, burning micturition, dysuria and expulsion of renal culculi. 100% relief noted on *Surudhir mutrata* (Hematuria) where only single patient complaint had been registered as Hematuria in Group B. In case of *Mutradaha* (Burning micturition) there was mild improvement in group A and moderate improvement in group B. Similarly there was complete remission in *Mahati vedana* (Dysuria and Pain in abdomen) case in both Group A and Group B after the treatment. **Conclusion:** *Gokshuradi guggulu* along with *Varunadi Kwatha* shows more significant result than *Gokshuradi guggulu*.

INTRODUCTION

Asmari comprises of two words '*Asma*' and '*Ari*'. '*Asma*' means stone or a gravel and '*Ari*' means enemy. *Asmari* is a disease in which there is formation of stone, exerting great suffering to man like an enemy. Ayurveda considered *Asmari* mainly as '*Mutrasmari*'. It is a disease of *Mutravaha srotas* and considered as one of the '*Astamahagada*'^[1,2]. *Mutrasmari* is an ancient disease with global distribution. It refers to stones originating

anywhere in the *Mutravahasrota*. which is emerging as a sequel to deranged *Mutra pravritti* (Urination) leading to deterioration in urine secretion and micturition. i.e., one of the deadly diseases. The symptoms of *Mutrasmari* like excruciating pain over *Nabhi* (Umbilical region) *Vasti* (Urinary bladder) or at *Sevani* (ureter) and *Medra* (urethra) during micturition, sudden stoppage of urine flow, blood stained urine, twisting and slitting of urine^[3]. Hence

the disease entity can be co-related with the symptoms of Urolithiasis or Renal calculi of modern medicine.

Among all types of pain, abdominal pain drags not only patients attention but also the curiosity of the clinician. Renal calculi or stones are one among the cause for pain in abdomen and it is estimated that from 7-13% in North American, 5-9% in European, and 1-5% in Asian peoples are suffering from this misery^[4]. The National Health and Nutrition Examination Survey 2007-2010 shown the prevalence of kidney stones among American adults was 10.6% among men and 7.1% among women^[5]. The differences among countries reflect several lithogenic factors, including age, gender, dietary habits, fluid intake, climate, occupation and education level, socioeconomic status. The problem of stone is more predominant in the productive age groups^[6].

In the modern arena, surgical procedures remain the only treatment of choice and are not conducive enough as they hold the disadvantages of high expenditure, side effects and disease recurrence. It is in this dire situation, the desperate need to find conservative medicine which is an economical, effective, easily available and appropriate medicine to treat *Mutrasmari* which has very less disadvantages. In Ayurveda, various treatment modalities including number of drugs with medicinal preparations referred in different forms are mentioned. Taking all these points, the present clinical trial was planned with an aim to evaluate the efficacy of *Gokshuradi Guggulu*^[7] and *Varunadi Kwatha*^[8] in management of *Mutrasmari*.

Objectives of the Study

- To determine the effectiveness of *Gokshuradi guggulu* in the patients with *Mutrasmari*.
- To compare the effect of *Gokshuradi guggulu* and *Varunadi kwath* with *Gokshuradi Guggulu* in patients with *Mutrasmari*.

Ethical clearance: This study was approved by Institutional Review Board of Institute of Medicine Kathmandu with Ref no. 304 (6-11-F) 2/072/073.

MATERIALS AND METHODS

Selection of the patients

The study were conducted on 38 clinically diagnosed patients of '*Mutrasmari*' (Urolithiasis) selected from the OPD and IPD of Tribhuvan University Ayurveda Teaching Hospital Kirtipur Kathmandu and Nardevi Ayurvedic Hospital, Kathmandu.

Study Area: The sampling frame included all the patients of *Mutrashmari* visiting the OPD and IPD of TUATH Kirtipur, mobile Health camp (with urology department) within Kathmandu valley, Naradevi Ayurvedic Hospital between May 2016 to July 2016.

Sample Size: Sample size of 19 will be taken for each group. So total sample size is 38.

Inclusion Criteria

- Patient presenting with signs and symptoms of *Mutrashmari* (uninary calculi) are selected for study, irrespective of chemical composition of calculi.
- The age group of 16-70 years
- Urinary calculi measuring up to 10mm.
- Recurrent stones are also included in the study.
- Patient who are not willing to undergo invasive or non-invasive surgical intervention.

Exclusion Criteria

- Chronic systematic disease like diabetes mellitus, Human Immunodeficiency (HIV), Benign Prostate Hyperplasia (BPH), Renal failure, Tuberculosis, Polycystic kidney, Wilm's tumor and neoplasm.
- Disease related complications like Hydro-nephrosis, Uramia Dysuria etc.
- Renal calculi in pregnant women and lactating mother.

Criteria for diagnosis of *Mutrashmari*

Patients were diagnosed on the basis of clinical features, physical examination, lab investigation findings, and radiological evidence.

Research design

Open clinical trial, total 38 patients were selected and randomly categorized into two groups A and B.

Group A: 19 Patients were given *Gokshuradi guggulu* 1000 mg with luke warm water twice in a day for duration of 45 days.

Group B: 19 Patients were given *Gokshuradi guggulu* 1000 mg along with 45 ml of *Varunadi kwatha* twice a days for 45 days.

Observation period- Patients of both the group were advised for a follow up of every 15 days for 45 days, during treatment. Patients were advised to drink 3-4 liters of water and to consume *Yava*, *Godhuma*, *Shastika shali*, *Kushmanda* etc. with proper sleep and excretion of natural urges.

Follow up period: The patients were advised for follow up once in seven days to rule out any recurrence of symptoms. However patients were advised to report immediately if they noticed any real symptoms.

Criteria for examination and assessment

The assessment was done on the basis of relief in signs and symptoms of urolithiasis. Other investigation findings (laboratory as well as radiological) on the basis of specially designed research proforma through the scoring pattern.

Criteria for withdrawal

- During the course of trial if any serious condition or any serious adverse effects occur which require urgent treatment.
- Patients himself/herself want to withdraw from the clinical trial.

Method of Preparation of Trial Drug

Gokshuradi Guggulu^[7]- First *Gokshura kasaya* was prepared by boiling *Yavakut Goshura* with 10.24 liters of water reduced to 1/4th part. Then *kashaya* filtered and mixed with *Shuddha guggulu* and heated till it attain the solid consistency. Then *Sunti churna, Pippali churna, Maricha churna, Amalaki churna, Haritaki churna, Vibhitaki churna* and *Musta churna* were mixed uniformly and prepared the tablets of 500 mg and dry under shade.

Preparation of Varunadi kwath^[9]

Fresh *Varuna* tvak (12gm)+ *Sunthi* (2gm)+
Gokshura (10gm)



Added 8 times of their combined all of water



Boiled in *Mandagni* (low flame)



Reduced for 1/4 part and adding 500 mg of *Yavakshara* and 24 gm *Jaggery*



Kwath (decoction) is prepared

Duration of Clinical Trial and Follow up Study

- Duration of trial will be 45 days.
- Patient will be followed up after 15 days, after 30 days and after 45days.

Criteria for Assessment

During the trial patient will be assessed on the following parameters.

Subjective parameters

Mahati Vedana (Pain in Abdomen)

Sarudhira Mutrata (Hematuria)

Mutrakrichha (Dysuria)

Mutradaha (Burning micturation)

Objective parameters: It was based on various investigations like CBC, ESR, Urine R/M, X-Ray (KUB), USG Abdomen and pelvis.

The statistical analysis was done of these score before starting the treatment and after completion of the treatment.

Overall Assessment of the Therapy

For the assessment of overall effect of the treatment following four categories were taken for consideration.

Table 1: Shows assessment criteria for overall symptoms

S. No.	Overall assessment of the therapy	Remarks
1.	Complete remission	76-100 % relief
2.	Marked improvement	51-75 % relief
3.	Moderate improvement	25-50 % relief
4.	Mild improvement	< 25 % relief

Grading Criteria for Clinical Symptoms

Mahati vedana (Pain in abdomen)

- No *Mahati Vedana* (Pain in abdomen) - 0
- Mild *Mahati Vedana* (pain in abdomen)
- Present but does not disturb routine - 1
- Moderate *Mahati Vedana* (pain in abdomen) present which disturbs routine - 2
- Severe *Mahati Vedana* (pain in abdomen) patient rolls on bed due to pain - 3

Surudhira Mutrata (Hematuria)

- Absence of RBC in Urine - 0
- Microscopic Hematuria - 1
- Macroscopic Hematuria - 2
- Frank Hematuria - 3

Mutrakrichhra (Dysuria)

- Absence of pain during micturation - 0
- Mild pain during micturation - 1
- Moderate pain during micturation - 2
- Severe pain during micturation - 3

Mutradaha (Burning Micturation)

- Absence of burning during micturation - 0

- Mild burning during micturation - 1
- Moderate burning during micturation - 2
- Severe burning during micturation - 3

Objective parameters

- Size of stone
- Number of stone

OBSERVATION AND RESULTS

In the present study, maximum respondents were from 30-70 years age group constituting 57.9 % and only 42.1% were between age 16-30 years. Most of the respondents were from Brahmin chhetri group at about 44.7% followed by Janajati and Newar group at 26.3% and 21.1% respectively. Study result showed the about 52.2% of male respondents. Similarly 71.1% Hindu religion followers were included in the study followed by Buddhism at 26.3%. The research fortunately covered educated population on a study group, only about 5% respondents were illiterate. Majority of the respondents fall either in student (26.3%) or stay at home (26.3%) category. It was also observed that the chief complaints of respondents, majority

of them picked *Vastipida*, *Vasti-vedana*, *Mutrartyaga vedna*, *Nabhi vedhana*, *Mutrakricha*, *Arochak* during the time of history taking of the patients. Some of them opted for the multiple complaints to cause urolithiasis. 100% of respondents have been doing moderate types of physical activities whereas almost 94.7% respondents in both group A and group B, they preferred to have non veg food. Among several diseases UTI and hypertension are the most to note down as a past medical history and the trend is same in case of family history as well, which has been reported for BPH, Hypertension and Diabetes Mellitus in both group A and group B. Though family history does not play significant role

to cause urolithiasis, past personal history with UTI might affect patient for the management.

Along with the addition of addiction habit to them, only 10 % from group A and about 15.78 % from group B have found current alcohol consumption habit. No record of Tobacco chewing habit were found, where only 15% from group A and 10.5% from group B had smoking habit. Regarding the causes for Uro-lithiasis, *Kaphajanit ahara* and *Snighdabhojan* followed by *Diwaspana*, *Virudha ahara Kasayarasa* and *Kaphakarak vihar* respectively occupied the highest reason noted in this study.

After completion of 45 days of treatment the result was assessed with following manner.

Assessment on the basis of Subjective Criteria

Table 2: Presentation of Mahati Vedana (Pain in abdomen) in the patients of Group A and Group B

Clinical parameters	Before Treatment		After treatment	
	Group A	Group B	Group A	Group B
No pain	37%	16%	95%	79%
Mild Pain	53%	63%	5%	21%
Moderate Pain	5%	21%	0	0
Severe	5%	0	0	0

Table 3: Presentation of Sarudhira Mutrata (Haematuria) in the patients of Group A and Group B

Clinical parameters	Before Treatment		After treatment	
	Group A	Group B	Group A	Group B
Absence of RBC in urine	100 %	95%	100%	100%
Microscopic hematuria	0%	5%	0%	0%
Macroscopic hematuria	0%	0%	0%	0%
Frank hematuria	0%	0%	0%	0%

Table 4: Presentation of Mutrakrichchha (Dysuria) in the patients of Group A and Group B

Clinical parameters	Before Treatment		After treatment	
	Group A	Group B	Group A	Group B
Absence of Pain during micturation	58%	58%	95%	84%
Mild pain during micturation	42%	16%	5%	16%
Moderate pain during micturation	0	26%	0	0
Severe pain during micturation	0	0	0	0

Table 5: Presentation of Mutradaha (Burning Micturation) in the patients of Group A and Group B

Clinical parameters	Before Treatment		After treatment	
	Group A	Group B	Group A	Group B
Absence of burning during micturation	47%	5%	84%	68%
Mild burning during micturation	42%	84%	16%	32%
Moderate burning during micturation	11%	11%	0	0%
Severe burning during micturation	0	0	0	0

Assessment on the basis of Objective Criteria

Table 6: Stone Expulsion after treatment

Treatment schedule			Status after treatment								Remarks
			Expelled		Un-changed		Size reduced		Others		
			Single	Multiple	Single	Multiple	Single	Multiple	Single	Multiple	
Group A	Stone size	5-6mm	4	2	2	1	6	3		1	Different size of calculi in different location
		6-8 mm	0	1	1		2				
		8-10 mm	1				1				
		n.multiple	1				1				
Group B	Stone size	5-6mm	3	1			0	1	1		
		6-8 mm	6				1				
		8-10 mm	7				1				
		n.multiple	0				0				

The table no. 06 shows that 84 per cent of expulsion has done by the treatment Group B followed by 46 per cent by Group A and also expelled the one calculus of size 8-10 mm. In group A, 15.7% remains unchanged in single stone status where 5% unchanged in case of multiple stone. About 68% of calculi size has been reduced by Group A. Furthermore, Group B have witnessed high expulsion rate (84.2 %) as compared to Group A. 15. 8% of stone has fairly reduced its size under Group B category. Expulsion of calculi also depends on the presence of stone, its size and location.

Table 7: Paired Sample Test in Different variables before and after treatment in Group A and Group B

Variables	Group	Mean BT-AT	SD	SE mean	t	df	Sig. (2 tailed)
<i>Mahati Vedana</i> (Pain abdomen)	Gr. A	0.737	0.806	0.185	3.986	18	0.001
	Gr. B	0.842	0.375	0.86	9.798	18	0.000
<i>Sarudhir Mutrata</i> (Haematuria)	Gr. B	0.026	0.162	0.26	1.000	37	0.324
<i>Mutra Krichya</i> (Dysuria)	Gr. A	0.368	0.496	0.114	3.240	18	0.005
	Gr. B	.526	.841	.193	2.727	18	0.014
<i>Mutra Daha-</i> Burning Micturation	Gr. A	0.474	0.697	0.160	2.964	18	.008
	Gr. B	0.737	0.562	0.129	5.715	18	.000

There is significantly reduction in the severity of abdomen pain after administration of drug in both Group A and group B. It shows the strong evidence that there is significant difference ($p < 0.05$) between Group A and Group B in the reduction of abdominal pain. The change in this parameter is only in group B as it has registered only patient with microscopic hematuria (*Sarudhiramutrata*). The mean of *Mutra krichchha* before and after treatment is group A and group B is 0.368 and 0.526. There was significant reduction of *Mutrakrichchha* illness cases in both group A and Group B. The change in pain before and after treatment in both group A and group B were not significantly different. The significant reduction of *Mutradaha* cases were found in both group A and group B, before and after treatment; but are not significantly associated in both groups; P value in [Group A, $p=0.008$ and Group B, $p=0.000$].

Table 8: Independent Sample T test for comparing the reduction of Variables in Group A and Group B

	Levene's Test for Equality of Variances					t-test for Equality of Means		95% Confidence Interval of the Difference		
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
<i>Mahati vedana</i>	BT	1.321	0.258	-1.144	36	0.260	-0.263	0.230	-0.730	0.203
	AT	10.192	0.003	-1.441	36	0.158	-0.158	0.110	-0.380	0.064
<i>Surudhira mutrata</i>	BT	4.484	0.041	-1.000	36	0.324	-0.053	0.053	-0.159	0.054
	AT			-1.000	18.0	0.331	-0.053	0.053	-0.163	0.058
<i>Mutra krichchha</i>	BT	13.834	0.001	-1.124	36	0.268	-0.263	0.234	-0.738	0.212
	AT	4.867	0.034	-1.044	36	0.303	-0.105	0.101	-0.310	0.099
<i>Mutradaha</i>	BT	12.919	0.001	-2.098	35	0.043	-0.386	0.184	-0.759	-0.013
	AT	4.579	0.040	-1.067	33	0.294	-5.951	5.578	-17.299	5.397

Table 9: Summary of Subjective Assessment

Subjective Parameter	I Assessment		II Assessment		Group A	Group B
	Group A	Group B	Group A	Group B		
<i>Mahati vedana</i> (0-3)	15	20	1	4	93% (complete remission)	80% (complete remission)
<i>Sarudhir Mutrata</i> (0-3)	0	1	0	0	(complete remission)	100% cure
<i>Mutrakrichya</i> (0-3)	8	13	1	3	87% (complete remission)	76% (complete remission)
<i>Mutradaha</i> (0-3)	12	20	3	6	40% (Mild improvement)	50% (Moderate Improvement)

Table shows the 100% relief on *Surudhir mutrata* (Hematuria) where, only single patient complaint has been registered as *Hematuria* in group B, later which completely cured. In case of *Mutradaha* (Burning micturation) there was mild improvement in group A and moderate improvement in group B. Similarly there was complete remission in *Mahati vedana* (Dysuria and Pain in abdomen) case in both Group A and Group B after the treatment.

Table 10: Test the effectiveness of single drug -Goksuradi Guggulu and combined drug- Gokshuradi guggulu and Varunadi Kwath

Drug category	Stone expulsion after treatment			t	df	Sig (2 tailed)
	Expelled	Not Expelled	Total			
Group A	6	13	19	3.78	36	0.001
Group B	16	3	19			

Table no.10 displays the high expulsion rate after administration of the treatment Group B. There is significant evidence to support the high acceptance of combined drug for the effective management of urolithiasis.

DISCUSSION

In group A, out of 19 patients, 53% patients were persisted as mild pain and 5% of moderate pain before treatment which after treatment has reduced to 5% to the mild treatment and no moderate treatment found and the percentage in no pain has reached from 37 to 95% after treatment. Similarly, in group B, after treatment the proportion has reached to 79 % from 16 % and only 21% patients were persisted with mild pain which was 63% before treatment. *Sarudhiramutrata* (microscopic haematuria) found in only 5% of patients of treatment Group B and got complete relief after completion of treatment.

In group A, only 5% were persisted with moderate pain and 42 % were persisted with mild pain which after treatment has reduced to 5%.

Likewise, in group B, the percentage of no pain from 58% has significantly increased to 95% after treatment. None of them had listed as severe pain. In both group A and B, there is significant increase in no pain population.

Out of 19 patients in Group A, 11% have been grouped under moderate pain and 42% of Mild pain which respectively reduced to 16% (mild burning case) after the treatment. Additionally the percentage of no pain has reached up to 68% from 5% in Group B.

In group A, out of 19 patients, almost 47 % expulsion of stone observed and only 21% of unchanged status of stone (poor response) had seen. Whereas, in group B 84% of expulsion was done after administration of the drug. Statistical p

value if 0.01 denotes that in both group B the expulsion is high due to efficacy of drug.

Probable Mode of Action of Trial Drugs

Gokshuradi Guggulu - It is a herbal preparation containing *Sodhit Guggulu, Gokshura, Amalaki, Bibhitaki, Haitaki, Sunthi, Pippali Maricha* and *Musta*. It is indicated in *Prameha, Pradara, Vatarakta, Vutraghata* and *Ashmari*^[7]. *Gokshura* posses *Asmarighna* (lithotriptic) and *Mutral* (diuretic) properties which contains small quantity of essential oil, resins and nitrates^[10]. *Guggul* has *Vatashamaka* properties and its resin is antiseptic, enriches the blood, demulcent, antispasmodic, carminative^[11] *Musta* has diuretic action and act as stimulant^[12] that help expulsion of calculus.

Varunadi kwatha - It contains *Varuna, Gokshura, shunthi* and *Yavakshara* and having properties of *Chedana, Bhedana, Lekhana, Tridoshaghna, Mutrala, Anulomana, Krimighna, Kaphavataghna* property, that helps in breaking down the pathogenesis of *Ashmari* and *Granthi*^[13]. *Varuna twak* contains saponin and tannin. It is demulcent, diuretic, tonic and useful in calculus affections, disorders of urinary organs^[14]. *Yavakshara* is having pH 11.73. It neutralizes the acidic media and prevents calculus formation. Also being *Ruksha, Laghu, Teekshna* and *Shigragami* it reduces the growth of stone and favors its breakdown^[15].

CONCLUSION

Gokshuradi Guggulu and *Gokshuradi Guggulu* with *Varunadi kwatha* both are effective and economical alternative for management for *Mutrasmari* (Urolithiasis). The result of the study clearly highlighted the efficacy of *Gokshuradi guggulu* with *Varunadikwath* not only to increase the expulsion rate but also in reducing symptoms like pain abdomen, hematuria and dysuria and micturition.

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