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A randomised controlled clinical study to evaluate the efficacy of *nagaradi ghana vati* and *kurantika kashaya* in *mutrashmari*

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ABSTRACT

BACKGROUND: *Mutrashmari* is an important disorder of the *Mutravaha Srotas* described in Ayurvedic classics under *Ashmari Roga,* characterized by the formation and accumulation of urinary calculi, leading to symptoms such as *Mutrakrichra* (dysuria), *Mutradhara Sanga* (obstruction/interruption of urinary flow), *Sarujamutra* (painful micturition), and *Adhmana* and Basti Shoola. The clinical manifestations of *Mutrashmari* closely resemble urolithiasis, a common urological disorder characterized by the formation of calculi within the urinary tract. The recurrent nature of stone formation, associated pain and urinary complications, along with the limitations and recurrence associated with conventional management, necessitate the exploration of safe and effective Ayurvedic therapeutic approaches. Ayurvedic classics have described various *Aushadha Chikitsa* for the management of *Ashmari*, with emphasis on *Mutrala*, *Ashmaribhedana* and *Shothahara* actions.

The present study was undertaken to evaluate the efficacy of *Nagaradi Ghana Vati* administered with *Kurantika Kashaya* as *Anupana* as the trial intervention and to compare it with *Gokshuradi Guggulu* administered with *Varunadi Kashaya* as *Anupana* as the standard treatment in the management of *Mutrashmari*.

OBJECTIVE: To evaluate and compare the efficacy of trial drug *Nagaradi Ghana vati* with *anupana Kurantika Kashaya* and standard drug *Gokshuradi Guggulu* with *anupana Varunadi Kashaya.*

MATERIALS AND METHOD: 40 patients of *Mutrashmari* were selected those fulfilling the diagnostic and inclusion criteria. Patients were randomly assigned into two equal groups A and B. The overall treatment effect between the groups was

statistically analysed using the Mann-Whitney U test, while within the group comparison were performed using Wilcoxon Signed-Rank test.

RESULT: Both groups showed significant improvement in all parameters ($p<0.05$), with group A showing comparatively better efficacy.

KEYWORDS: *Mutrashmari, Urolithiasis, Gokshuradi Guggulu, Varunadi kashaya, Nagaradi Ghana vati, Kurantika kashaya.*

INTRODUCTION

Acharya Sushruta described *Mutrashmari* as one of the *Ashta-Mahagadas*[1]. It gives dreadful pain to patient like *Yama*[2] (god of death). In modern it can be correlated with urolithiasis.

Urolithiasis a pathological condition of the urinary system where aggregation of urinary crystalloids takes place anywhere in the urinary tract, i.e. from the kidney to urinary bladder.

In India, approximately 5 to 6 million patients suffer from renal calculi[3] and at least 1/1000 of Indian population needs hospitalization due to renal stone disease[4]. The incidence of calculi varies as per geographical distribution, sex and age group. The recurrence rate is 50 to 80%. Male population are more frequently affected than the female and their ratio is 2:1[5]. The incidence is still higher in the age group between 30 to 45 years because of busy life style and suppression of urges and incidence declines after age of 50[6]. Stones get forms gradually in human body and occur at several sites particularly in Kidney, Urinary bladder and Ureter. Among all the urological problems most painful condition is *Mutrashmari*.

Ayurveda classical literature has emphasized many *Nidana* (cause) of *Mutrashmari* such as *Asamshodhana* (improper body detoxification) is prime one. Other causes explained are,*Ativyama* (excessive exercise), *Apathya Sevana* (improper food habits), *Vidahi Ahara*, *Teekshnoushadha* (sharp, penetrating drugs), *Rooksha Ahara* (dry food), *Atiadhwa* (over walk) , *Nidra Alpata* (sleep deprivation) , *Lavana Ahara* (salty food)[7].

In contemporary sciences some of the factors responsible for *Mutrashmari* formation are emphasized like, Unhealthy life style, sleeplessness,, heavy consumptions of fast food, preserved foods, deficiency of vitamin A, And family history of renal calculi.[8]

Mutrashmari is associated with agonizing pain over *Nabhi (umbilicus), Basti (urinary bladder), Sevani* and *Sevani* and *Medhra (penis and other genital organs)* during micturition, *Mutradharasanga* (obstruction to Flow of urine), *Sarudhiramutrata (blood* stained urine), *Atiruk* during *ayasa* (severe pain on exertion such as travelling etc.)[9,10]

The available treatment modalities in contemporary methods for urolithiasis are more expensive, can't be afford by all people and there are high chances of re-occurrence of calculi. The prevalence of urolithiasis is increasing worldwide, contributing to as inevitable health burden to all age groups. It is of paramount urgency for us to make tremendous public health efforts to solve this problem.

The trial drug *Nagaradi Ghana Vati*[11] having key ingredients as *Shunti, Varunamoola twak, Gokshura, Pasanabheda, Kakamachi* is selected for this research work which are having properties of *Mutrala, Ashmari Bhedana, Basti Shodhana, Shothhara, Mutra Virechaniya, Vedanasthapana, Anulomana, Deepana, Pachana . Kurantika*[12] (Celosia argentia) having the properties as *Ashmari*

Bhedana, Basti Shodhana. Hence here by making an effort to manage the condition of *Mutrashmari* by my trial drug *Nagaradi Ghana Vati* with fresh *Kurantika Kashaya* in comparison with proven drug *Gokshuradi Guggulu*[13] with *Varunadi Kashaya*[14] which is already being practiced by Ayurveda practitioners.

MATERIALS AND METHODS

OBJECTIVE:

1. To evaluate the efficacy of *Nagaradi Ghana Vati* with *anupana* of *Kurantika Kashaya* in *Mutrashmari*.
2. To evaluate the efficacy of *Gokshuradi Guggulu* with *anupana* of *Varunadi Kashaya* in *Mutrashmari*.
3. To compare the efficacy of *Nagaradi Ghana Vati* with *anupana* of *Kurantika Kashaya* and *Gokshuradi Guggulu* with *anupana* of *Varunadi Kashaya* in *Mutrashmari*.

SOURCE OF DATA

LITERARY SOURCE

Relevant *Ayurvedic*, Modern and Contemporary literature including journals and websites was reviewed and documented regarding the disease and drugs for the study.

PHARMACEUTICAL SOURCE

The formulation selected for this work *Nagaradi Ghana vati* and *Kurantika kashaya* were prepared in Rajarajeshwari Ayurvedic medical college pharmacy, as per the literature reference. Raw drugs were identified and purchased from authentic Ayurvedic pharmacy.

CLINICAL SOURCE

Patients diagnosed with *Mutrashmari* symptoms were selected from

- ✓ The outpatient department of Kayachikitsa of Rajarajeshwari Ayurvedic medical college and Hospital, Humnabad, Karnataka.
- ✓ Medical camps and other referrals.

METHOD OF COLLECTION OF DATA

Sample Size

A Minimum of 40 patients irrespective of gender, caste, religion, status and those fulfilling the diagnostic criteria and inclusion criteria of *Mutrashmari* will be selected. They will be randomly assigned into two equal groups (group A and group B)

- Study design: Randomised controlled clinical study
- Blinding: single blind
- Method of sampling: lottery method

Plan of Study

GROUP (A) {STANDARD DRUG}

- Sample size : 20 patients
- Drug : *Gokshuradi Guggulu vati*
- Dose : 500mg BD after food
- Duration : 30 days
- *Anupana*: fresh *Varunadi Kashaya*
- Dose: 1 PALA (50ML) BD
- Duration: 30 days

GROUP (B) {TRIAL DRUG}

- Sample size : 20 patients
- Drug: *Nagaradi Ghana Vati*
- Dose: 500mg BD after food
- Duration : 30 days
- *Anupana* : fresh *Kurantika kashaya*
- Dose: 1 PALA (50ML) BD
- Duration : 30 days

Observation Period

- Patients are observed on 0^{th}, 15^{th} and 30^{th} day of treatment to assess the progress.
- Follow up assessment will be done: on 45^{th} day

- Total study duration including follow-up: 45 days

Diagnostic Criteria

- Patient complaining of radiating type of pain from lower back to front at groin region, burning micturition, mild hematuria, nausea, vomiting, painful micturition .
- Presentation of calculi in USG (Abdomen and pelvis) size less than or equal to 7 mm

Inclusion Criteria

- Patients of either gender aged between 20 to 60 years.
- Patients who are having the clinical features of Mutrashmari.
- Calculi of the size equal to or less than 7 mm single or multiple in USG of abdomen and pelvis.
- Patients who did not want to undergo surgery.
- Patients who are unfit for surgical intervention will be taken for study.
- Patients having unilateral and bilateral renal stones.

Exclusion Criteria

- Age below 20 years and above 60 years.
- Calculus more than 7 mm in size.
- Patient known case of renal failure.
- Patient having history of chronic kidney diseases.
- Patient with uremia, pyuria, pyelonephrities, sepsis.
- Patient with systemic diseases.

Clinical Parameters For The Assessment Of Results

Assessment was done according to the signs and symptoms of the condition with the help of scoring pattern made based on detailed case performa.

SUBJECTIVE CRITERIA –

1) Pain
2) Burning Micturition
3) Dysuria
4) Tenderness in Renal Angle
5) Hematuria

OBJECTIVE CRITERIA

1) Site of stone
2) Number of stone
3) Unilateral and bilateral stones

INVESTIGATION

- ✓ Routine urine test, USG of abdomen and KUB X-ray were carried out whenever necessary.
- ✓ Assessment was carried out using standardised subjective and objective parameters, with the results subjected to statistical analysis.

STATISTICAL TEST

The treatment effect between the groups was statistically analysed using the Mann-Whitney U test, while within the group comparisons were performed using Wilcoxon Signed-Rank test.

RESULTS

Table No 1: effect of *Gokshuradi Guggulu* with *anupana Varunadi kashaya* in group A

Parameter	Mean BT	Mean AT	Median	SD	SE	Wilcoxon W	P VALUE	%	Result
Pain	2.85	0.7	1	0.47	0.082	-4.058	<0.001	75.4	Sig
Burning Micturition	2.6	0.55	1	0.51	0.114	-4.056	<0.001	78.8	Sig
Dysuria	2.5	0.5	0.5	0.51	0.115	-4.099	<0.001	80.8	Sig
Tenderness in Renal Angle	2.6	0.65	1	0.50	0.112	-4.056	<0.001	75.0	Sig
Hematuria	2.5	0.6	1	0.50	0.112	-4.056	<0.001	76.5	Sig
Site of stone	2.65	0.55	1	0.51	0.114	-3.994	<0.001	79.2	Sig
Number of stone	1.65	0.5	0.5	0.51	0.115	-3.906	<0.001	69.7	Sig

Table No 2: effect of Nagaradi Ghana vati with anupana Kurantika kashaya in group B.

Parameter	Mean BT	Mean AT	Median	SD	SE	Wilcoxon W	P VALUE	%	Result
Pain	3	0.85	1	0.224	0.05	-4.379	<0.001	71.7	Sig.
Burning Micturition	2.65	0.8	1	0.224	0.05	-4.042	<0.001	69.8	Sig
Dysuria	2.65	0.95	1	0.224	0.05	-4.099	<0.001	64.2	Sig
Tenderness in Renal Angle	2.65	0.95	1	0.227	0.15	-4.042	<0.001	66	Sig
Hematuria	2.75	0.95	1	0.224	0.05	-4.179	<0.001	65.6	Sig
Site of stone	2.75	0.95	1	0.224	0.05	-4.179	<0.001	65.6	Sig
Number of stone	1.65	0.5	0.5	0.513	0.11	-3.500	<0.001	55.6	Sig

Table no 3: effect of treatment of unilateral and bilateral stones

Renal stones		Unilateral	Bilateral	McNemar test Statistic	P value	Result
Group A	**BT**	9	11	6.125	0.013	Sig.
	AT	17	3			
Group B	**BT**	5	15	5.143	0.023	Sig.
	AT	12	8			

Table No 4, Comparative effect of Group A and Group B

Parameter	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	p value	Result
Pain	Group A	20	18	360	150.00	0.04	Sig.
	Group B	20	23	460			
	Total	40					
Burning Micturition	Group A	20	16.5	330	120.00	0.004	Sig.
	Group B	20	24.5	490			
	Total	40					
Dysuria	Group A	20	16	320	110.00	0.002	Sig.
	Group B	20	25	500			
	Total	40					
Tenderness in Renal Angle	Group A	20	17.5	350	140.00	0.019	Sig.
	Group B	20	23.5	470			
	Total	40					
Hematuria	Group A	20	17	340	130.00	0.009	Sig.
	Group B	20	24	480			
	Total	40					
Site of stone	Group A	20	16.5	330	120.00	0.004	Sig.
	Group B	20	24.5	490			
	Total	40					
Number of stone	Group A	20	16	320	110.00	0.002	Sig.
	Group B	20	25	500			

	Total	40					

Parameter	Group	Unilateral	Bilateral	Chi-square test Statistic	p value	Result
Renal stones	Group A	17	13	3.135	0.047	Sig.
	Group B	12	8			

Table No 5: Overall effect of Group A and Group B

Overall effect	Group A		Group B		Total	
	Frequency	Percentage	Frequency	Percentage	Freque-ncy	Percent-age
Marked Improvement (75% - 100%)	12	60	4	20	16	40
Moderate Improvement (50% - 75%)	8	40	16	80	24	60
Mild Improvement (25% - 50%)	0	0	0	0	0	0
No Improvement (0% - 25%)	0	0	0	0	0	0
Total	**20**	**100**	**20**	**100**	**40**	**100**

DISCUSSION

Mutrashmari is a well-described urinary disorder in *Ayurveda*, with *Sushruta* considering *Ashmari* among the *Ashtamahagada* owing to its severe pain and difficulty in management. The *Ayurvedic* concept of *Mutrashmari*, particularly the involvement of *Kapha* in stone formation, *Vata* in pain and obstruction, and vitiation of *Mutravaha Srotas*, shows conceptual similarity with the modern understanding of urinary calculi, in which urinary supersaturation, crystallization, urinary stasis and metabolic and dietary factors contribute to stone formation. The therapeutic principles described in the classics, including *Mutrala*, *Ashmarihara/Ashmaribhedana, Shothahara* and *Shoolahara* actions, provide a rational basis for the present clinical study.

The present randomized controlled clinical study compared the efficacy of *Gokshuradi Guggulu Vati* with *Varunadi Kashaya* (Group A) and *Nagaradi Ghana Vati* with *Kurantika Kashaya* (Group B) in 40 patients of *Mutrashmari* over 30 days. Both groups demonstrated statistically significant improvement in the assessed clinical parameters, indicating the therapeutic potential of both interventions. However, Group A showed comparatively greater improvement across the major subjective and objective parameters.

The demographic observations showed maximum representation in the 31–40-year

age group (47.5%) and male predominance (67.5%). These findings may be related to lifestyle-associated risk factors such as inadequate hydration, dietary irregularities, sedentary habits and occupational exposure to dehydration. However, these observations should be interpreted primarily as characteristics of the study population rather than definitive epidemiological associations.

Clinically, Group A showed 75.4% improvement in pain, 78.8% in burning micturition, 80.8% in dysuria, 75% in renal-angle tenderness and 76.5% in hematuria, whereas Group B showed 71.7%, 69.8%, 64.2%, 66% and 65.5% improvement, respectively. Stone-related parameters also improved, with Group A demonstrating 79.2% improvement in site of stone and 69.7% reduction in number of stones, compared with 64.8% and 55.6%, respectively, in Group B.

The superiority of Group A may be attributed to the complementary actions of *Gokshura*, *Guggulu* and *Varuna*. *Gokshura* provides *Mutrala* and *Vata-shamaka* effects, facilitating urinary flow and reducing urinary irritation, while *Guggulu* contributes *Lekhana, Shothahara* and *Srotoshodhana* actions. *Varuna*, a classical *Ashmaribhedana*/*Ashmarihara* drug, may facilitate fragmentation and expulsion of calculi. Collectively, these actions may reduce urinary stasis, inflammation, obstruction and stone burden.

Nagaradi Ghana Vati with *Kurantika Kashaya* also produced significant improvement, supporting its clinical usefulness in *Mutrashmari*. The formulation contains drugs such as *Shunthi, Varuna, Gokshura and Pashanabheda,* which collectively provide *Deepana-Pachana, Mutrala, Ashmaribhedana, Shothahara and Shoolahara* actions. *Kurantika Kashaya*, used as *Anupana*, may further support urinary flow, reduction of inflammation and relief of burning micturition and dysuria. Thus, Group B appears to act through a multidimensional approach involving *Mutravaha Srotoshodhana, Mutrala* and *Ashmarihara* actions.

The between-group analysis demonstrated statistically significant differences favouring Group A in pain, burning micturition, dysuria, renal-angle tenderness, hematuria, site of stone and number of stones. The Chi-square analysis for unilateral and bilateral stones was also significant ($p = 0.047$). Overall parameter-wise improvement was 76.5% in Group A compared with 65.4% in Group B. Furthermore, 60% of patients in Group A achieved marked improvement compared with 20% in Group B, while moderate improvement predominated in Group B. These findings indicate that although both interventions were beneficial, *Gokshuradi Guggulu Vati* with *Varunadi Kashaya* produced a comparatively superior therapeutic response.

From an *Ayurvedic* perspective, the therapeutic response may be understood through *Samprapti Vighatana.* The *Mutrala* action increases urinary flow and facilitates flushing of crystals and small calculi; *Ashmaribhedana/Ashmarihara* action may assist fragmentation and expulsion; *Shothahara* action reduces urinary tract inflammation and edema; while Shoolahara/*Vedanasthapana* action helps alleviate renal colic. These combined effects may account for improvement in pain, dysuria, burning micturition and stone-related parameters. From a modern pharmacological perspective, the observed

clinical response may correspond to diuretic, anti-inflammatory, antispasmodic and potential anti-urolithiatic activities; however, these mechanisms remain probable and require further experimental validation.

Thus, the present study demonstrates that both *Nagaradi Ghana Vati* with *Kurantika Kashaya* and *Gokshuradi Guggulu Vati* with *Varunadi Kashaya* are clinically beneficial in *Mutrashmari*. However, the comparatively greater improvement observed with Group A suggests that its combined *Mutrala, Ashmarihara/Ashmaribhedana, Shothahara* and *Shoolahara* actions may provide a more effective approach for reducing urinary symptoms and stone burden. The findings provide a clinical basis for further well-designed studies with larger sample sizes, longer follow-up and objective biochemical and radiological assessment.

CONCLUSION

The present randomized controlled clinical study demonstrated that both *Nagaradi Ghana Vati* with *Kurantika Kashaya* and *Gokshuradi Guggulu* with *Varunadi Kwatha* produced significant improvement in the clinical features and stone-related parameters of *Mutrashmari* (renal calculi ≤7 mm).

The therapeutic effects observed with both interventions may be attributed to their complementary *Mutrala, Ashmaribhedana, Ashmarihara, Shothahara, Vedanasthapana* and *Srotoshodhaka* properties, which may facilitate improved urinary flow, reduction of urinary obstruction and inflammation, and expulsion of calculi.

Comparatively, *Gokshuradi Guggulu* with *Varunadi Kashaya* demonstrated superior therapeutic efficacy over *Nagaradi Ghana Vati* with *Kurantika Kashaya* in the present study. These findings suggest that both treatment modalities have potential as conservative Ayurvedic approaches in the management of selected cases of Mutrashmari. Further studies with larger sample sizes, longer follow-up and objective biochemical and radiological assessment are warranted to substantiate these findings.

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