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A CLINICAL STUDY TO EVALUATE THE EFFECT OF NAGARADI KWATHA AND CHANDRAPRABHA VATI IN MOOTRASHMARI W.S.R. TO UROLITHIASIS

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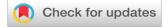
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ABSTRACT

Ashmari is the formation of stone in *Mootravaha srotas*, resulting in severe pain as given by the enemy. It is an effect of the complex, physicochemical process that involves a sequence of events in the formation of any urinary stones, including urinary saturation, supersaturation, nucleation and growth of crystals, aggregation and retention of crystals, and finally, stone formation. It affects about 12% of the world's population at some stage in their lifetime in all age groups, sexes, and races but occurs more frequently in men than women aged 20 to 49 years. In India, about 12% of the total population is expected to have urinary stones in their life, out of which 50% may end up with loss of kidney function. Contemporary treatment such as Lithotripsy (ESWL), Percutaneous Nephrolithotomy (PCNL), Retrograde Intra-renal surgery (RIRS), and Laparoscopic Ureter lithotomy adopted in the condition of Urolithiasis is quite costly with high incidence of recurrence. For the present study, Nagaradi Kwatha and Chandraprabha Vati were administered for 14 days. Each patient was observed on the 0-day, 7th, and 15th day of drug intervention with said parameters. The study showed significant clinical improvement in reducing the shoola, mootradosha, Kruchramutrata, and Sarakta mootrata and showed good response in disintegration and the expulsion of Ashmari.

Keywords: Ashmari, Mootrashmari, Nagaradi kwatha, Chandraprabha vati, Urolithiasis.

INTRODUCTION

Ashmari is a calculus that develops in the urinary system. Clinically, it may present with Shoola (pain) in Kati and Kukshi Pradesh. Later, it results in passing a weak stream of urine and burning micturition. Urolithiasis affects about 12% of the world population at some stage in their lifetime in all age groups, sexes, and races but occurs more frequently in men than women between the ages of 20 to 49 years. In India, about 12% of the total population is expected to have urinary stones in their life out of which 50% may end up with loss of kidney function. Without treatment, the recurrence rate for calcium oxalate stone is about 10% in one year, 35% at five years, and 50% at ten years. Acharya Sushruta emphasized early stone management with conservative treatment and reserved the operative procedures for large stones. The use of Nagaradi kwatha in Ashmari is mentioned in Chakradatta in Ashmari Adhikar. It is selected as all the drugs have Ashmari Nashana, vatanulomana, Motorola, etc properties. draprabhavati is mentioned in Sharangadara Samhitha Madyama khanda is also indicated for Mootravahasrotovikaras and all types of Ashmari. The drugs mentioned in Chandraprabha vati have Vatakaphahara and Mootrala properties. This clinical study tests the effects of Nagaradi kwatha and Chandraprabha vati as internal medications in Mootrashmari (Urolithiasis). The present intervention in treating Mootrashmari (Urolithiasis) is simple, readily available, and economical.

AIMS AND OBJECTIVES OF THE STUDY:

To evaluate the effect of *Nagaradi kwatha* and *Chandraprabha vati* in *Mootrashmari* (Urolithiasis).

MATERIALS AND METHODS:

SOURCE OF DATA: Thirty patients of *Mootrashmari* will be selected from the IPD and OPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi.

SOURCE OF DRUG: Medicines required for the treatment will be prepared in Shri Dharmasthala Manjunatheshwara Ayurveda Pharmacy Udupi

METHODS OF COLLECTION OF DATA:

After obtaining consent, thirty patients diagnosed with Mootrashmari (Urolithiasis) will be selected for clinical study. Patients of either sex between 18 or 60 years of age will be chosen. They will be treated with the oral administration of Nagaradi Kwatha and *Chandraprabha Vati*.

STUDY DESIGN: A prospective, single-group, open-labeled clinical study with pre-test and post-test design.

INTERVENTION: *Nagaradi Kwatha* (30ml) with *Guda* (3 grams) will be administered with two tablets of *Chandraprabha vati* (750mg) in the morning, afternoon, and evening before food to each patient for 14 days.

OBSERVATION PERIOD: Each patient will be observed on the 0day, 7^{th and} 15th day of drug intervention with said parameters.

DIAGNOSTIC CRITERIA: OBJECTIVE CRITERIA:

Ultrasonography (USG) of Abdomen and Pelvis -This is considered as primary criteria for diagnosis to evaluate-

- ➤ Size of stone
- > Site of the stone
- ➤ Number of stones

SUBJECTIVE CRITERIA:

- > Shoola (Pain)
- > Saraktamutrata (Haematuria)
- ➤ Mootrakrichhrata (Dysuria)
- ➤ Mootradaha (Burning micturition)

INCLUSION CRITERIA:

- Patients of either sex between the age group of 18 to 60 years.
- Asymptomatic patients who are diagnosed with Urolithiasis.
- Symptomatic Patients with solitary or multiple urinary calculi.
- All patients with individual stone size less than 10 mm.

EXCLUSION CRITERIA:

- Patients are aged below 18 years and above 60 years.
- Stone size is more than 10 mm.

- Staghorn calculus and other impacted stones.
- Gross hydronephrosis.
- Stone with urinary infections, diabetes mellitus, and other systemic diseases.
- Malignancy.
- Impaired Renal Function.
- Patients are already on diuretics.
- Patients undergoing treatment for any other serious illness.

ASSESSMENT CRITERIA: SUBJECTIVE PARAMETERS:

The criteria of assessment will be.

- > Shoola (Pain)
- > Saraktamutrata (Haematuria)
- > Mootrakrichhrata (Dysuria)
- ➤ *Mootradaha* (Burning micturition)

OBJECTIVES PARAMETERS:

The objective parameter considered for the study will be recorded by Ultrasonography (USG) of the Abdomen and Pelvis for the presence of stones before and after treatment for statistical analysis.

- > Number of stones
- ➤ Site of stone
- > Size of stone

The assessment will be done on

- Day 1- before treatment (BT)
- Day 15- after treatment (AT)

STATISTICAL ANALYSIS:

Paired t-test and Wilcoxon signed rank test for statistical analysis will be used.

INVESTIGATIONS:

- ➤ Hb%
- TC, DC
- > RBS
- Urine analysis (routine and microscopic)
- ➤ USG (abdomen and pelvis)
- > RFT (if necessary)

ASSESSMENT OF INTERVENTION:

Assessment Criteria	0 day	7 th day	15 th day
Pain			
Dysuria			
Frequent micturition			
Hematuria			
Burning micturition			
Fever			
Nausea and vomiting			

BASED ON RADIOLOGICAL GRADING OF ASSESSMENT CRITERIA:

Pain in abdomen:

No pain (VAS 0)	0	
Mild pain (VAS 1-3)	1	
Moderate pain (VAS 4-6)	2	
Severe pain (VAS 7-9)	3	
Worst pain (VAS 10)	4	

Haematuria:

No reddish tinge	0	
Dark yellow with reddish tinge	1	
Red colour	2	

Dysuria:

No pain	0
Occasionally bearable pain (mild)	1

Often bearable pain (moderate)	2	
Intolerable severe pain (severe)	3	

Frequency of micturition (Day):

3-5times	0
6-8times	1
8-10times	2
more than 10times	3

Frequency of micturition (Night):

0-1times	0	
2-4times	1	
5-7times	2	
more than 7times	3	

Burning micturition:

No burning	0	
Occasionally bearable burning (mild)	1	
Often bearable burning (moderate)	2	
Intolerable severe burning (severe)	3	

Size and expulsion of stone:

Expulsion of stone	0	
Decrease in size more than 50%	1	
Decrease in size less than 50%	2	
No change in size	3	

Hydronephrosis:

Absent	0	
Mild	1	
Moderate	2	

CRITERIA FOR ASSESSMENT OF OVERALL RESULT:

- 1. Unchanged- no change in Mootrashmari and symptoms
- 2. Improved- change in size and site of Mootrashmari and improvement in symptoms.
- 3. Completely relieved- absent of Mootrashmari and symptoms.

OBSERVATIONS AND RESULTS:

The treatment was given for two weeks, and the observations of objective and subjective criteria were recorded at each follow-up of 7-day intervals. All cases were analyzed about Age, Sex, Diet, Addiction, Occupation, presenting complaints, size, site, and Number of stones present, dissolved, and expelled. The peak incidence of urolith was found in the 30-60 years of age group (83.33%), in males (76.7%), in non-vegetarians (73.3%), in Addicted people (30%), the majority of 46.7% of patients belonged to a middle class, the incidence of kidney stone was (65.8%). The common presenting complaint like pain, haematuria, dysuria, frequent micturition, burning micturition, fever with chills and nausea & vomiting were

100%, 13.3%, 20%, 23.3%, 36.7%, 16.7%, and 16.7% respectively.

TABLE NO 1: EFFECT ON PAIN (WILCOXON SIGNED RANK TEST)

Parameter	Negat	ive Ranks	,	Positive Ranks			Tie	Z value	P value	Interpretation
Pain	N	MR	SR	N	MR	SR				
0 to 7 th day	28	14.50	406.00	0	.00	.00	2	-5.07	.000	H.S.
Pain 0to15 th day	29	15.00	435.00	0	.00	.00	1	-4.80	.000	H.S.

TABLE NO 2: EFFECT ON DYSURIA (WILCOXON SIGNED RANK TEST)

Parameters	Nega	Negative Ranks Positive Ranks			Positive Ranks			Z value	P value	Interpretation
Dysuria	N	MR	SR	N	MR	SR				
0 to 7 th day	3	2.00	6.00	0	.00	.00	1	-1.73	.083	N.S.
Dysuria	4	2.50	10.00	0	.00	.00	0	-2.00	.046	Significant
0to15 th day										

TABLE NO 3: EFFECT ON BURNING MICTURITION (WILCOXON SIGNED RANK TEST)

Parameters	arameters Negative Ranks		Positi	Positive Ranks		Tie	Z value	P value	Interpretation	
Burning micturi-	N	MR	SR	N	MR	SR				
tion	7	4.00	28.00	0	.00	.00	1	-2.53	.011	Significant
0 to 7 th day										
Burning micturi-	8	5.00	45.00	0	.00	.00	0	-2.71	.007	Significant
tion										
0to15 th day										

TABLE NO 4: EFFECT ON HAEMATURIA (WILCOXON SIGNED RANK TEST)

Parameters	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Haematuria	N	MR	SR	N	MR	SR				
0 to 7 th day	5	3.00	15.00	0	.00	.00	1	-2.24	.025	Significant
Haematuria 0to 15 th day	5	3.00	15.00	0	.00	.00	1	-2.24	.025	Significant

TABLE NO 5: EFFECT ON SIZE OF STONE (PAIRED T-TEST)

Size of stone	Mean value	Difference in Mean	Paired t-tes	st	Interpretation			
			%	S.D.	S.E.M.	T	P	
BT	5.05	2.14	42.38	2.42	.38	5.48	.000	H.S.
AT	2.91			3.40	.53			

TABLE NO 6: EFFECT ON NO. OF STONE (PAIRED T-TEST)

No. of	Mean	Difference in	Difference in Paired t-test						
stone		Mean	%	S.D.	S.E.M.	T	P		
BT	1.36	.633	46.54	.49	.089	4.82	.000	H.S.	

A	ΓΙ	.73		.69	.126		

DISCUSSION

Effect on Shool (Pain):

Among the 30 patients in the study, all the 30 had pain. Reduction in pain was found to be 85%, as statistically highly significant as P<0.0001. The mean score for pain before the treatment was 2.00, which decreased on the 7th and 15th day of treatment to 0.97 and 0.30, respectively. This shows that pain reduced drastically during the first week and continued to reduce in the subsequent week.

Effect on Mootrakrichhrata (Dysuria):

The symptoms were in 4 patients among 30 patients. A reduction in the Mootrakrichhrata by 80% was statistically significant as the P value was 0.046. The mean score for Mootrakrichhrata before the treatment was 2.50, which decreased on the 7th and 15th day of treatment as follows: 1.75 and 0.5, respectively. Four patients had bearable pain during micturition before the therapy, which was reduced in the second week of medication.

Effect on Mootradaha (Burning micturition):

The symptoms were in 11 patients among 30 patients. Reduction in the Mootradaha by 88.36% was found to be statistically significant as the P value is 0.007. The mean score for Mootradaha before the treatment was 1.89, which decreased on the 7th and 15th day of treatment as follows: 0.87 and 0.22, respectively. Eight patients had occasional burning--micturition before the therapy, which reduced in the 2nd week of medication.

Effect on Sarakta Mootrata (Haematuria):

The symptom of Saraktamootrata was in 6 patients out of 30 patients. In the present study, a 71.8% reduction in Saraktamootrata was seen, statistically significant for the improvement as the P value is 0.025. The mean score for Saraktamootrata before the treatment was 1.17, which decreased on the 7th and 15th day of therapy to 0.33. Among six patients of Saraktamootrata, all had dark yellow with reddish tinge urine before the medication. This symptom had maximum reduction in the first week of the treatment and became nil at the end of 2nd week.

Effect on Reduction in the size of stone

In this study, a 42.38% reduction was seen in the size of the stones, which is statistically highly significant as P=0.000. There was a total of 41 stones in the 30 patients. Among them, 11 patients had bilateral, and 19 patients had unilateral renal stones. The majority of the single stones are upper calyx kidney stones. The maximum size of the stone noted before the treatment was 10mm, which was reduced to 9.6mm after the treatment. Among the 19 patients with unilateral stones, in 13 patients, complete expulsion of the stone was seen after the treatment. Among 11 patients with bilateral stones, two patients had complete expulsion of stone in one side of the kidney, and there was a reduction in the size in the other kidney. Expelled stores have an average length of 3-4mm.

Effect on Reduction in the number of stone

The present study shows a 46.32% reduction in the number of stones in the USG abdomen, which is statistically highly significant for the improvement as P=0.000. In the present study, the maximum number of stones is single. Among the 30 patients, in 13 patients, all the calculi had been expelled, and no calculi were found in the USG.

THE OVERALL ASSESSMENT:

The overall assessment was done as 43.3% of patients had been relieved entirely, 46.7% showed improvement, and 10% remained unchanged. The drugs are considerably effective in reducing symptoms and treating the disease.

DISCUSSION ON PROBABLE MODE OF ACTION OF THE FORMULATIONS: NAGARADI KWATHA:

Sushruta gives importance to Shleshma as the causative dosha for Ashmari. The primary cause of Ashmari is an aggregation of Kapha-Pradhana Doshas in Mutravaha Srotas. The drugs used to treat Ashmari should possess the properties to inhibit the process and correct the pathology involved in the formation of Ashmari, i.e., Samprapti Vighatana and "Nagaradi Kwatha" are two. The ingredients of this formulation are readily available and cost-effective.

Table 7: Probable mode of action

Drug	Action
Nagar (Z. officinale)	Shoolprashamana, Kapha-vatashamaka
Varun Tvak (C. nurvala)	Tridoshghna, Ashmaribhedana, Mutrala
Gokshur (T. terrestris)	Ashmarighna, Bastishodhana,
	and Vatashamaka, Mutrala
Pashanabheda (B. ligulata)	Ashmaribhedana and
	Bastishodhana, Mutrala, Shoolaghna
Kakamachi (Solanum nigrum)	Tridoshghna, Bhedana, Mutrashodhana
Gud (jaggery)	Ashmaribhedana, Mutrakrichrahara, Vataghna and Bastishodhaka
Yavakshara (K2CO3)	Mutrakricchra, Asmaribhedana

The Litholytic activity of Nagaradi kwatha is caused by the components' combination of Mutrala, Bastishodhana, Anulomana, Deepana, Pachana. Shothhara, and Kapha-Vata Shamak. Gokshura is crucial for boosting urine production and clearing the urinary system because of its Bastishodhak and Mutrala qualities. It is utilized as Mutrakrichra, Ashmari, and Prameha in the classical Ayurvedic literature to treat various urinary system illnesses. One of the ingredients of Nagaradi kwatha is Yavakshara, which has qualities like Lekhana, Chedana, Bhedana, Mutrala, and Kapha-Shamata and is naturally alkaline. As a result, it aids in neutralizing acidic media, avoids stone formation, and reduces Mutrashmari. The Vatanulomana, Shothahara, and Mutrala properties of ingredients help to relieve pain and retention of urine; the Deepana property of drugs helps to increase the Agni, which further checks the formation of Ama at the Jatharagni level. Stone might be dissolved due to the Ashmari-Bhedana or Ashmarihara property of the ingredients present in Nagaradi kwatha.

CHANDRAPRABHA VATI:

It is an herbal-mineral combination proven safe for renal function and is recommended for use in Mutra-krichhra (dysuria) and Ashmari (urinary calculi). It contains Shilajitu, a preferred medication for the treatment of Bastigatavyadhi. Camphor (Cinnamomum camphora), a product component, has anti-inflammatory, antibacterial, diuretic, and other beneficial properties for urinary tract infections. Oth-

er ingredients, such as Yavakshara (alkalized barley preparation) and Sarjikakshara, are alkaline and used to cure Ashmari and Mutrakrichra by lowering the acidity of urine. It functions as an alkalizer and aids in the breakdown of renal calculi since it contains potassium chloride, potassium sulfate, potassium bicarbonate, and potassium carbonate.

CONCLUSION

The following conclusions were drawn from the present clinical study-

- ➤ The present study observed that Mootrashmari was common in the 30-60 age group; males were more affected than females. Occupation-wise, it was more common in businessmen and laborers, more in the middle class, and more in people with mixed dietary habits who drank less fluids.
- ➤ When administered internally, Nagaradi kwatha and Chandraprabha vati showed significant clinical improvement in reducing the shoola, mootradaha. Kruchramutrata and Saraktamootrata.
- ➤ The treatment effectively reduces the size of stones in almost all patients, and 46% of patients had expelled entirely all calculi. Further, in no patient did the calculi size increase, or the occurrence of new calculi was observed.
- Nagaradi kwatha and Chandraprabha vati are simple to administer, palatable, and free from adverse effects. Hence, it can be adopted for the treatment of Mootrashmari.

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