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A controlled clinical trial to evaluate the efficacy of *Kulatthadi Ghrita* in the management of *Mutrashmari* vis-à-vis Urolithiasis

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ABSTRACT

Mutrashmari is one of the most common conditions of *Mutravahasrotas*. The word *Ashmari* in *Sanskrit* denotes the stone or calculi and *Mutra* means urine. *Mutrashmari* is characterized by formation of stones anywhere in urinary tract. It is a dreadful condition and has potential to disturb the anatomy and physiology of the urinary system. Once it formed in the body it tends recurrence thus get difficult to cure. Hence it is included under *Ashtamahagada*. In modern medical system it is correlated with urinary calculi or Urolithiasis based on signs and symptoms. Factors such as diet, water, climate, geographical conditions will also play major role in causing *Mutrashmari*. Ayurveda basically aims at prevention of formation of *Mutrashmari* along with braking and flushing of existing calculi. In *Ayurveda* texts administration of oral medication in different forms such as *Ghrita*, *Kshara*, *Kashaya* and other *Shamanousadhi*, *Shodhana Karma* and *Shastra Karma* are emphasized for management of *Mutrashmari*. *Snehapana* is the basic principle in the management which is to be adopted in primary stage of *Mutrashmari*. In the present study *Kulatthadi Ghrita* having properties such as *Ashmaribhedana*, *Ashmari Patana* and *Mutrala* activities has been taken up as indicated in *Chakradatta* for *Ashmari*, along with *Nagaradi Kashaya* and *Badarashma Pishti*.

Key words: *Mutrashmari*, *Mutravahasrotas*, *Kulatthadi Ghrita*, *Urolithiasis*

INTRODUCTION

Mutrashmari is a very common worldwide problem, troubling mankind since ages and is one among the major reason for abdominal pain these days. It is *Kaphapradhana Tridoshaja Vyadhi* and included under

Ashtamahagada^[1] because of its *Marmashrayatwa*^[2] and various complications caused by the disease. Considering its clinical symptoms, *Mutrashmari* is compared to Urolithiasis. Urolithiasis is the third most common affliction of urinary tract after urinary tract infections and benign prostatic hypertrophy.^[3] There are different treatment modalities available in different systems of medicine such as flush therapy for stones less than 5mm and surgical procedures for larger stones. But they are quite expensive and pathogenesis behind the formation of calculi cannot be avoided. Even surgical methods available for the management of calculi such as ESWL, ureteroscopy, percutaneous nephrolithotomy etc.^[4] also fail to prevent recurrence and have got many complications such as sepsis, strictures etc. hence there is need for alternative treatment modalities which is cost effective and having very less or no complications. A number of

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Ayurvedic formulations have been used since past for managing *Mutrashmari*. One among such formulation is *Kulatthadi Ghrita*.^[5] Present study was conducted with the objective to evaluate the efficacy of *Kulatthadi Ghrita* in the management of *Mutrashmari vis-à-vis* Urolithiasis.

MATERIALS AND METHODS

The formulations used in the study i.e., *Kulatthadi Ghrita* and *Nagaradi kashaya* were manufactured by S.N. Pandit and son's Co. Pvt. Ltd, Mysuru, (a GMP certified pharmacy) were procured for the purpose of study. *Badarashma Pishti* manufactured by Shree Dhutapapeshwara Ltd. (a GMP certified pharmacy) was procured from available marketing sources for the purpose of study.

Study design

Double arm open labeled controlled clinical trial with pre and post-test study design.

Simple random sampling technique was employed.

The subjects fulfilling the diagnostic criteria of *Mutrashmari vis-à-vis* urolithiasis were assigned in two groups viz., Group A and Group B.

Total of 45 subjects, of *Mutrashmari vis-à-vis* Urolithiasis were randomly selected from OPD and IPD of Government Ayurveda Medical College, Mysuru and registered for the study. There were 22 subjects registered in Group A and 23 in Group B. by the end of the study there were 5 dropouts at different stage of the study. The study was completed in 40 subjects, 20 subjects in each group. The details of intervention is given below.

Table 1: Showing intervention in Group A and Group B

Group A	<ol style="list-style-type: none"> 30 ml of <i>Nagaradi Kashaya</i>^[6] with equal quantity of water, 350 mg <i>Yavakshara</i> and 3gm of <i>Guda</i> three times a day before food 250 mg of <i>Badarashma Pishti</i>^[7] with honey as <i>Anupana</i>, three time a day before food.
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Group B	<ol style="list-style-type: none"> 12gm of <i>Kulatthadi Ghrita</i> was administered with warm water as <i>Anupana</i>, before food, 2 times in a day. 30 ml of <i>Nagaradi Kashaya</i> with equal quantity of water, 350 mg <i>Yavakshara</i> and 3gm of <i>Guda</i> three times a day before food 250 mg of <i>Badarashma Pishti</i> with honey as <i>Anupana</i>, three time a day before food.
Duration of the intervention	30 days

Inclusion criteria

- Subjects of 18-60 years of age group irrespective of gender, caste, religion were included in the study.
- Both fresh and treated cases were taken for the study.
 - Definition of fresh cases includes freshly detected and untreated cases of *Mutrashmari vis-à-vis* Urolithiasis.
 - Definition of treated cases includes, already diagnosed and registered cases of *Mutrashmari vis-à-vis* Urolithiasis, who had voluntarily discontinued the treatment included with flush out period of 7 days, were included.
- Subjects with or without clinical features of *Mutrashmari* diagnosed with presence of urinary calculi (solitary or multiple) by radiological examination measuring 4-8mm anywhere in (KUB) kidney, ureter, and bladder were included in the study.

Exclusion criteria

- Subjects with acute symptoms like severe nausea and vomiting were excluded.
- Subjects with impaired renal function, renal failure, renal obstruction, severe hydronephrosis, and complications needing emergency surgical interventions were excluded.

- Subjects with association of any other severe systemic disorders that may interfere with the present intervention.
- Subjects suffering from severe hematuria were excluded.
- Pregnant and lactating women were excluded.

Diagnostic criteria

Diagnosis was made on the basis of ultrasonography or CT of Kidney, Ureter, Bladder (KUB) and clinical symptoms.

Assessment parameters

In the present study the assessment was carried out in the following schedule:

- Pre test assessment was done on 0 day before the commencement of intervention.
- Post test assessment was done on 31st day after the completion of intervention.

Data was collected according to case sheet proforma which was specially designed for the purpose of the study. Observations and assessment were done based on both subjective and objective parameters. Subjective parameters with gradating index included *Bastishoola*, *Mutradaha*, *Saraktamutrata* and *Mutrakrichra*. Objective parameter included USG of KUB region. Both Subjective and objective parameters were assessed before intervention (0 day) and after intervention (31st day).

Primary assessment parameters

- Ultrasonography of abdomen and pelvis were done before the beginning of intervention and after the completion of intervention. Following parameters were assessed
 - Number of stones.
 - Size of the stone.
 - Site of the stone.

Secondary assessment parameters

Table 2: Showing assessment parameters

<i>Shula in Nabhi</i> (umbilical region), <i>Basti</i> (supra pubic region), <i>Sevani</i> (perineal region), <i>Mehana</i> (genitalia).	S0 - None (absent) S1 - Mild (Occasionally Present but does not disturb day to day activities) S2 - Moderate (Present and disturbs day to day activities) S3 - Severe (Patient rolls over bed due to pain)
<i>Saraktamutrata</i> (Hematuria)	Sm0 - None (absence of RBC in urine) Sm1 - Mild (3-5 RBC in urine) Sm2 - Moderate (presence of 10-20 RBC in urine) Sm3 - Severe (presence of more than 20 RBC in urine)
<i>Mutrakruchrata</i>	Mk0 - None (Absence of symptom) Mk1 - Mild (Occasional pain during micturition) Mk2 - Moderate (Tolerable pain at starting and during micturition) Mk3 - Severe (Intolerable pain at starting and during micturition and prolonged after micturition)
<i>Mutradaha</i> (Burning micturition)	Md0 - None (Absence of burning sensation) Md1 - Mild (Rare burning in the morning or at starting micturition) Md2 - Moderate (Tolerable burning in the morning and at starting) Md3 - Severe (Intolerable burning in the morning at the starting of micturition and prolonged after micturition)

Assessment of overall effect of therapy

Complete Remission	Absence of calculi in USG of KUB and 100% relief in Chief complaints.
Marked improvement	Reduction in size of stone with more than 75% and less than 100% improvement in chief complaints was recorded as marked improvement.
Moderate improvement	Reduction in size of stone with 75% to 50% improvement in chief complaints was recorded as moderate improvement.

No improvement	No Reduction in size of stone and less than 25% improvement in chief complaints was recorded as no improvement.
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The Results were analyzed statistically by using, Chi square test, Paired sample “t” test, individual sample “t” test and Mann whitney U test as inferential statistics and mean, standard deviation, frequency, percentage as Descriptive statistics using SPSS for windows software.

OBSERVATIONS

In the present study it was observed that *Mutrashmari* was common in the age group of 30-50 years (55.6%), males (60%) were more affected than females (40%), it was mostly observed in employees (26.7%) and homemakers (24.4%) followed by farmers (17.8%) and labors (17.8%), incidence was more in lower middleclass population (82.20%) and was more in people with irregular dietary habits. Pain (57.8%) was the most predominant symptom observed in the study and other symptoms such as *Mutrakrichra* (4.4%), *Mutradaha* (2.2%), *Saraktamutrata* (15.6%) were observed in very less proportion of the study population.

In the present study, majority of subjects had calculi ranging between 4-6mm in diameter and multiple in number.

RESULTS

18 subjects in Group A and 18 subjects in Group B were presented with different grades of pain where both the groups showed highly significant result on pain relief with P value 0.000.

Table 3: Showing results on pain in Group A and Group B

Groups		Shoola (pain)		X2 value	P value	P value between the groups
		BT	AT			
Group A	Nil	2	20	32.727	0.000	0.317
	Mild	9	0			

Group B	Moderate	6	0	26.436	0.000
	Severe	3	0		
	Total	20	20		
	Nil	3	19		
	Mild	4	1		
Group B	Moderate	12	0		
	Severe	1	0		
	Total	20	20		

In Group A, 2 subjects had *Mutradaha* where as in group B, 1 subject was presented with *Mutradaha* and the results were non significant in both the groups with the P value 0.487 and 1.000 respectively.

Table 4: Showing results on Mutradaha Group A and Group B

Groups		Mutradaha		X2 value	P value	P value between groups
		BT	AT			
Group A	Nil	18	20	2.105	0.487	1.000
	Mild	2	0			
	Total	20	20			
Group B	Nil	19	20	1.026	1.000	
	Mild	1	0			
	Total	20	20			

3 subjects in Group A presented with the symptom *Saraktamutrata* which was mild, the result was clinically significant but statistically nonsignificant. No subject in Group B presented with *Saraktamutrata*.

Table 5: Showing results on Saraktamutrata Group A and Group B

Groups		Saraktamutrata		X2 value	P value	P value between groups
		BT	AT			
Group A	Nil	17	20	3.243	0.072	1.000
	Mild	3	0			

	Total	20	20		
Group B	Nil	20	20	-	0.231
	Total	20	20		

2 subjects in Group A and 1 subject in Group B were presented with mild degree of *Mutrakrichra*, the results were statistically non-significant with the P value 0.349 and 1.206 respectively.

Table 6: Showing results on *Mutrakrichra* Group A and Group B

Groups		<i>Mutrakrichra</i>		X2 value	P value	P value between groups
		BT	AT			
Group A		18	20	2.105	.349	1.000
	Mild	1	0			
	Moderate	1	0			
	Total	20	20			
Group B	Nil	19	20	1.206	1.000	
	Mild	1	0			
	Total	20	20			

Result on objective parameters

Number of calculi: Among 20 subjects in Group A, 12 had solitary kidney stone and 8 had multiple stones. After the completion of intervention, in 13 subjects' calculi were expelled and 7 subjects had single calculus at different locations of urinary system. Whereas in group B 10 subjects had single stone and 10 had multiple calculi. After intervention, 15 subjects had no calculi and 5 had single stone.

In Group A the mean value of number of stones was 1.65 before intervention and 0.35 after intervention whereas in Group B Mean value was 2.15 before intervention and 0.25 after intervention. Both the groups were statistically highly significant with P value 0.000.

Illustration 1: Result on number of stones (Group A)

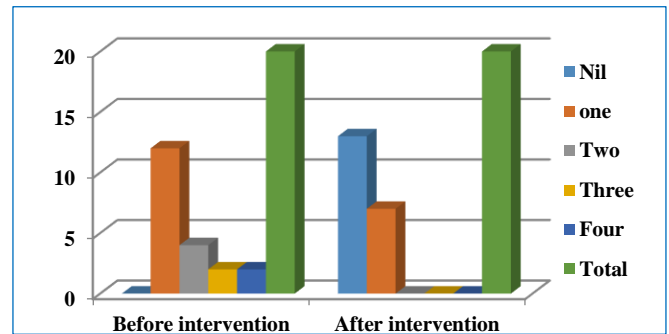
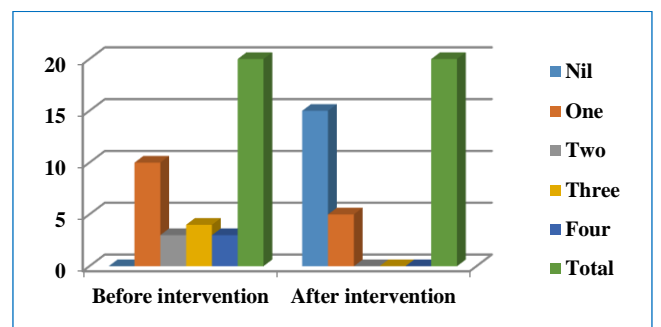


Illustration 2: Result on number of stones (Group B)



Size of Stone: In Group A before intervention 11 subjects had calculi measuring 4-6mm and 9 had calculi measuring 6-8mm. After intervention, there were 4 subjects with calculi measuring 4-6mm and 2 subjects had calculi of 6-8mm. The mean value was 2.45 which changed to 0.70 after intervention. In Group B 16 subjects had calculi measuring 4-6mm and 4 had calculi measuring 6-8mm before intervention. After intervention 15 subjects had no calculi, 1 was found to have calculus of 4mm size and 4 of them had calculi measuring 6-8 mm. The mean value was 2.20 before intervention which changed into 0.45 after intervention. Both the groups were statistically highly significant with P value 0.000.

Illustration 3: Result on size of stones (Group A)

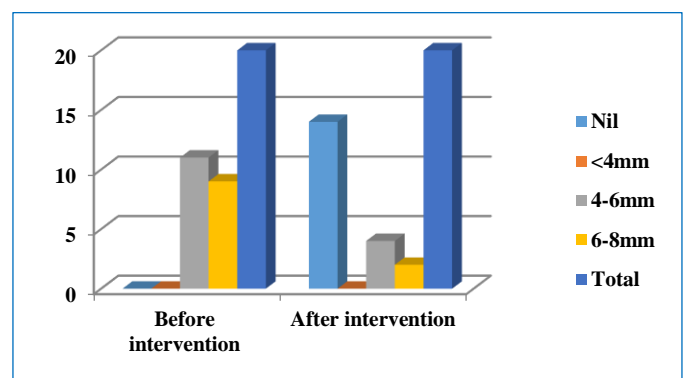
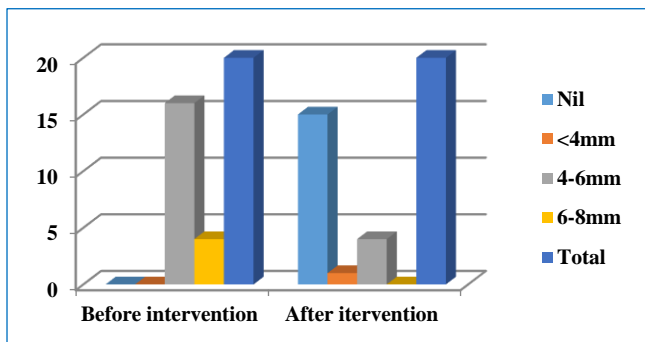


Illustration 4: Result on size of stones (Group B)



Site of stones: In 13 subjects of Group A the location of Stone was kidney, in 6 the location was ureter and 1 subject had stone in both kidney and ureter before intervention. Among them 13 subjects had no calculi after intervention and 7 had stones in kidney. The mean value of site of stones was 1.40 before intervention that changed to 0.35 after intervention. In Group B, 15 subjects had stone in kidney, 3 had in ureter and 2 had in both kidney and ureter before intervention. Among them 15 had no calculi after intervention and 5 had stone in kidney. The mean value was 1.35 before intervention and 0.25 after intervention. Both the groups were statistically highly significant with P value 0.000

Illustration 5: Result on the site of stones (Group A)

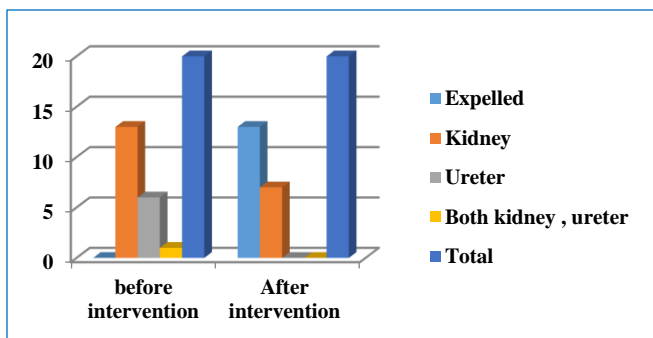
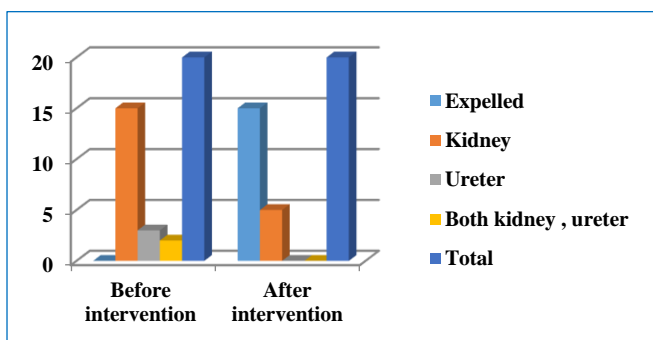


Illustration 6: Result on the site of stones (Group B)



DISCUSSION

Probable mode of action of drugs:

Table 7: Showing ingredients of the formulations

Kulatthadi Ghrita	Kulattha, Saindhava Lavana, Vidanga, Sharkara, Padmaka, Yavakshara, Kushmanda Beeja, Gokshura Beeja, Varuna Kwatha, Goghrita.
Nagaradi Kashaya	Shunthi, Varuna Twak, Gokshura, Pashanabheda, Bramhi
Badarashma Pishti	-

Kulatthadi Ghrita is Madhura, Tikta, Kashaya Rasa Pradhana which possess Laghu, Snigdha Guna, Ushna Veerya, Madhura Vipaka and Tridoshahara. It aids, Ashmari Bhedana, Mutrasanjanana, Basti Shodhana activity. As the formulation is in the form of Ghrita it is inferred to reduce Rukshata of aggregated particles there by produce smoothness to stone which enhances Ashmari Bhedana Karma of the drugs such as Varuna, Yavakshara and Kulattha helps in disintegration and dissolution of the calculi. Mutrala property of the drugs such as Gokshura, Kushmada, Vidanga, Padmaka will help in flushing out the disintegrated calculi. Further Deepana, Basti Samshodhana properties of Kushmada and Gokshura prevents formation of stones and thereby reduces the chance of recurrence.

Badarashma Pishti, another formulation in the intervention is fossilized tasteless stone. Studies indicated that Lapis judalicus powder can reduce the size of calcium oxalate stones due to presence of magnesium, which is a protective agent in calcium oxalate crystal growth. Moreover, its basic pH nature could be another inhibitor for stone production. Furthermore, SiO₂ can change calcium oxalate monohydrate to calcium oxalate dehydrate which is more soluble.

Nagaradi Kashaya has Kashaya, Tikta Rasa, Katu Vipka and Ushna Veerya. Ingredients of Nagaradi Kashaya such as Shunthi, Yavakshara and Bramhi have Shulahara property, which helps in reducing Shoola in Ashmari. Varuna, Pashanabheda and Yavakshara have

Ashmari Bhedana activity there by help in disintegration of calculi. *Gokshura* with its *Mutrala* property helps in expulsion of calculi. In addition to this it has *Kaphavatahara* action. Thus, with *Ashmaribhedana*, *Mutrala* and *Shulahara* properties, *Nagaradi Kashaya* acts against *Mutrashmari* by virtue of its *Dosha Pratyaneeka* and *Vyadhi Pratyaneeka* property.

CONCLUSION

In the present study, results obtained between the groups is non-significant. In spite of having almost similar results, Group A showed complete remission in 13 subjects and marked improvement in 7 of them whereas Group B showed complete remission in 15 subjects and marked improvement in 5 subjects. From the above data it can be concluded that, both the groups are equally effective in reducing the size of stones and relieving the symptoms. Till date there is no recurrence of *Mutrashmari* or symptoms of *Mutrashmari* are observed in the subjects involved in the study. With the obtained result it can be concluded that *Kulatthadi Ghrita* in combination with *Nagaradi Kashaya* and *Badarashma Pishti* can be administered safely and effectively in the management of *Mutrashmari*.

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