

A Comparative Clinical Study to Evaluate the Efficacy of Traikantaka Ghrita and Tila Nala Kshara in Mutrashmari W.S.R. To Urolithiasis – A Case Series

Dr. Vikas warad¹, Dr. Srinivas masalekar²

¹Post Graduate Scholar, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, India.

²Professor & HOD, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, India

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ABSTRACT:

Ashmari is one of the Mutravahasrothogata Vikara. Due to severe pain associated with the condition, complications produced and very difficult to treat, Acharya Sushruta has mentioned it as one among Astamahagada¹ and calls it as “Antakapratima” which means Swaroopa of Yama. In Ayurvedic literature Mootrashmari is classified based on Lakshana’s of Dosha & Ashma. There is striking similarity between the signs and symptoms and the morphology of stone in Ashmari mentioned in literature to that of Urolithiasis. The clinical manifestations like dysuria, pain abdomen, haematuria and burning micturition are also same. Urolithiasis is 3rd most common disease of urinary tract. The recurrence rate of urolithiasis is approximately 50% within 5 yrs. Renal calculi affects one in 20 at some time or other in their lives to a negligible or noticeable extent. Conservative management of contemporary sciences are not that much helpful in preventing and recurrences and surgical management like PCNL, Uteroscopy, Pyelolithotomy, Nephrolithotomy, Partial Nephrectomy, Nephrectomy and Nephrostomy. Even though they are useful & provide immediate relief, they involve considerable amount of risk and the rate of recurrence is also high as much as 50%. Hence an attempt is made to review about the Clinical understanding of these conditions in the present article.

Key words- Mutrashmari, Urolithiasis, Ashtamahagada, Dysuria.

I. INTRODUCTION

Since ages human race is constantly challenged by diseases & it is an uphill task to

combat them. Ashmari is one among the Muthravahasrothovikara. It is associated with formation of stone in the urinary tract resulting in severe pain. The severity of the pain is compared to the pain as if it given by an enemy. Acharya Sushrutahas mentioned it as one among Ashtamahagada and calls it as “Antakapratima²” which means swaroopa of Yama. Elaborate description of Mutrashmari is available in Sushruta Samhita (1500B.C) and in many of the Ayurveda treatises. Charaka has advised medical management and Sushruta advised both conservative management and surgical removal of stone.

Urolithiasis is a disease which has high morbidity and socio-economic impact and low mortality. Urolithiasis is the third most common disease of urinary tract preceded by urinary tract infections and prostate diseases. The peak age of incidence is generally between the 3rd – 5th decade. Prevalence rate of 1-5% are reported in Asia, 12% in India. Among the affected population, 5% may end up with renal damage. The ratio of incidence of calculi is more in male compared to female i.e., 3:1. Without treatment, the typical patient has a 10% risk of recurrence at 1 year, 35% at 5year and nearly 50% at 10years.

According to Ayurveda, Srotovaigunya resulting from Dushitha Kapha which will be localised in Basti in association with Pradushitha Vata and Pitta is the cause for the formation of Ashmari. At first, vitiation of dosha occurs in the Mutravaha Samsthana, may be catalysed by the presence of an incipient lesion and ultimately be held responsible in the pathogenesis of Mutrashmari³. Clinical features are typically characterized by Colicky pain, haematuria, difficulty in Micturition. The methods of management of urinary calculi are chiefly surgical in the

contemporary science. However, Acharya Sushruta says that it is Aushadhasadya in Tarunavastha and Shastrakarma has been explained in Pravruddha Avastha. Under Bhesaja, oral medicines like Ghrutha, Kshara, Kashaya, Ksheeraand Uttharabasthi has been told for the management of Mutrashmari.

The treatment principle of urinary calculus in contemporary science varies depending upon size, position of calculi etc. Nonsurgical management includes flush therapy, diuretics, medical expulsive therapy using alpha-antagonists or calciumchannel blockers, ESWL & Dormia basket procedure.

Surgical line of management includes advanced techniques like PCNL, Ureteroscopy, Pyelolithotomy, Nephrolithotomy, Partial Nephrectomy, Nephrectomy, Nephrostomy. However, these therapies aim at expulsion of the existing urinary calculi, but do not break the vicious cycle in the recurrence of calculi. Non surgical and surgical management has their own advantage and disadvantages. Even though they are useful & provide immediate relief, they involve considerable amount of risk and the rate of recurrence is also high as much as 50%.

Although surgical management has become increasingly tolerable, medical management and prevention is always desirable, advisable, easily obtainable and feasible. Hence constant efforts are been made to evolve an effective, economical and safe conservative management. In light of the above situation, The drugs with lithotriptic action are given in the form of snehapana, it will add up the effect. Using Ghrita is best in such condition as it is having samskarasya anuvartana property. So that, even the stone with size more than 5mm can be managed without surgical intervention. Hence present study was undertaken to compare the efficacy of Traikantaka Ghrita⁴ which is having lithotriptic drugs like Gokshura, Shilajatu, Pashanabheda and Tilanala Kshara in the management of Mutrashmari

OBJECTIVES OF STUDY

- 1)To evaluate the efficacy of Traikantaka Ghrita in the management of Mutraashmari.
- 2)To evaluate the efficacy of Tilanala Kshara in the management of Mutraashmari.
- 3)To compare the efficacy of Traikantaka Ghrita and Tilanala Kshara in the management of Mutraashmari

HYPOTHESIS:

NULL HYPOTHESIS

- 1)Traikantaka ghrita is not effective in the management of Mutraashmari.
- 2)Tilanala kshara is not effective in the management of Mutraashmari.
- 3)There is no significant difference between Traikantaka ghrita and Tilanala kshara in the management of Mutraashmari.

ALTERNATE HYPOTHESIS

- 1)Traikantaka ghrita is effective in the management of Mutraashmari.
- 2)Tilanala kshara is effective in the management of Mutraashmari.
- 3)There is significant difference between Traikantaka ghrita and Tilanala kshara in the management of Mutraashmari .

METHODOLOGY

SOURCE OF DATA:

Patients with the Classical features of Mutrashmari, will be randomly selected irrespective of gender and socio-economic status from OPD, IPD and special camps organized at SJIIM Hospital, Bangalore.

METHOD OF COLLECTION OF DATA:

Patient suffering from Mutrashmari and willing to undergo the trial study, presenting with the features like: Pain in the renal angle, pain in the hypochondrium, pain in the lumbar region, pain radiating from Loin to groin, pain in the Scrotum & inner aspect of thigh, haematuria, dysuria & presence of Calculi confirmed by Ultra sonogram of abdomen and pelvis will be selected for the study.

INCLUSION CRITERIA :

- 1) Patients complaining of any of the following features a. unilateral or bilateral pain in the renal angle b. pain in hypochondrium, c. pain in the lumbar region, d. pain radiating from Loin to groin & inner aspect of thigh , with or without pain in any of these above sites.
- 2)With or without dysuria
- 3)With or without Haematuria
- 4)With solitary or multiple calculi
- 5) Age – 18 to 60yrs
- 6)Presence of calculi upto 9mm size confirmed by USG of abdomen and pelvis either unilaterally or bilaterally
- 7)Accidentally diagnosed urinary calculi by ultra sonogram of abdomen and pelvis

EXCLUSION CRITERIA:

- 1)Patients with retention of urine due to any pathology like BPH, Urethral stricture.

- 2) Patient with other systemic disorder like Hyperparathyroidism, HTN, Diabetes mellitus.
- 3) Patients with Stag horn Calculi
- 4) Patients with Moderate to Severe Hydronephrosis
- 5) Pregnant & Lactating women

Note: The Pathological conditions mentioned in exclusive criteria were ruled out after considering the clinical features and conducting required investigations.

SAMPLING PROCEDURE :

A total of 40 cases with classical features of Mutrashmari / Urolithiasis will be selected and they will be distributed randomly into two groups namely, Group-A and Group-B of 20 patients each.

STUDY DESIGN

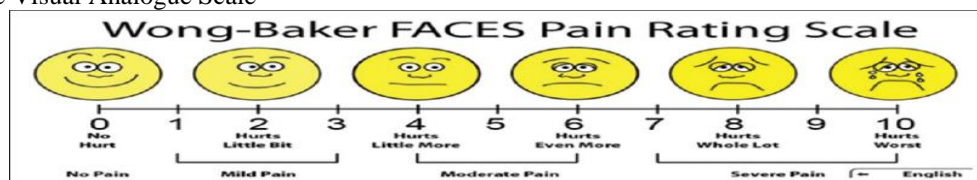
GROUP-A

In this group 20 patients will be treated with Traikantaka ghrita. It will be orally administered in the dose of 25 ml, twice daily before food with warm water for 28 days. Observation with respect to changes in the subjective Parameters was assessed before treatment on 7th day, 14th day, 21st day, 28th day and Objective parameters was assessed on before and after the treatment, the same will be recorded in the Performa of case sheet specially prepared for the study.

GROUP-B

In this group 20 patients will be treated with Tilanala kshara. It will be orally administered in the dose of 250 mg twice daily with water for 28 days. Observation with respect to changes in the subjective Parameters was assessed before treatment on 7th day, 14th day, 21st day, 28th day and Objective parameters was assessed on before and after the treatment, the same will be recorded in the Performa of case sheet specially prepared for the study.

As per the Visual Analogue Scale



- 2) Burning micturition
 - Grade (0)- Absence of burning micturition.
 - Grade (1)- Burning micturition and tolerable.
 - Grade (2)- Severe burning micturition and intolerable.
- 3) Dysuria
 - Grade (0)- Absence of pain during micturition.
 - Grade (1)- Pain during micturition and tolerable.

Duration: Duration of study will be 28 days.

OBSERVATION FOR RECURRENCES: Duration of 3 months will be fixed for observing possible recurrences in cases where total cure would be obtained with the treatment & the patients will be advised to report immediately in case of recurrences of symptoms. Confirmation of recurrence will be made by specific investigations & same shall be recorded in the case sheet.

Suitable Pathya & Apathya will be advised to the patient during and after the treatment.

Pathya:

Ahahara: Shashtikashali, Rakthashali, Yava, Kulatta, Purana Kushmanda Phala, Ardraka, Gokshura, Pashanabheda, Yavashooka, Renuka, Shyamaka, Varuna, Krounchamamsa Rasa and Vari. Vihara: Langana, Avagaha sweda.

Apathya:

Ahara: Shushka, Rooksha Pistanna Sevana, Viruddha Bhojana, Karjura, Shaluka, Kapitta, Jambu, etc., Vihara: Divaswapna, Vegadharana, Ativyayama and Atimithuna. All the Ahara Viharas which aggravates Kapha and Vata can be considered as Apathya.

Note: In cases where the patients during the period of treatment shall go for complications will be referred to the higher medical centers for needful and such cases will be dropped out from the study.

ASSESSMENT CRITERIA: Assessment will be made with the following parameters.

Subjective parameters:

- 1) Pain
 - Grade (0) – VAS Score 0 : No pain.
 - Grade (1) - VAS Score 1-3 : Mild pain.
 - Grade (2) - VAS Score 4-6 : Moderate Pain.
 - Grade (3)- VAS Score 7-10: Severe pain.

Grade (2)- Severe pain during micturition and intolerable.

Objective parameters:

- 1) Size of calculi: Change in the original size of calculi as assessed by USG abdomen and pelvis.
- Grade (4) - No reduction in the original size of calculi.

Grade (3) - Reduction in the original size of calculi up to 25% and below.

Grade (2) - Reduction in the original size of calculi up to 26-50%.

Grade (1) - Reduction in the original size of calculi above 51-75%.

Grade (0) - Reduction in the original size of calculi above 76%.

2) Haematuria (with microscopic examination of urine)

Grade (0) - Absence of RBCs in urine.

Grade (1) - Presence of RBCs in urine.

INVESTIGATIONS:

1)USG of Abdomen and Pelvis.

2) Microscopic examination of urine (haematuria)

II. Observation and Results

Statistical analysis

The data were represented in mean ± SD or Median (Interquartile), distribution of the data was done by Shapiro-Wilk test for normality, based on the distribution Wilcoxon signed rank test was done for within-group comparison and the Mann-Whitney U test was done to compare between Group-A and Group-B. Categorical variables were analyzed using Fischer exact test. The jamovi project (2022). jamovi. (Version 2.3) software for statistical analysis was used for statistical analysis.

Observation

Statistical analysis of trial drug Traikantaka ghrita administered in group A and standard drug Tilanala kshara administered in group B, those suffering from Mutrashmari before and after treatment are described below.

Out of 40 Renal calculi subjects that were screened, 40 consented subjects who fulfilled the criteria were enrolled in the study. These the 40 subjects were randomly divided into 2 groups Group-A (n = 20) and Group-B (n = 20). No subjects were dropped out from the study, whereas all the subjects were adhered to the study protocol and no adverse events were noticed. The trial was conducted between August 2022 and August 2023 involved subject recruitment, randomization, evaluations, and intervention. The study was completed after the expected samples reached

Results

1) Pain

DISTRIBUTION OF PATIENTS BASED ON PAIN

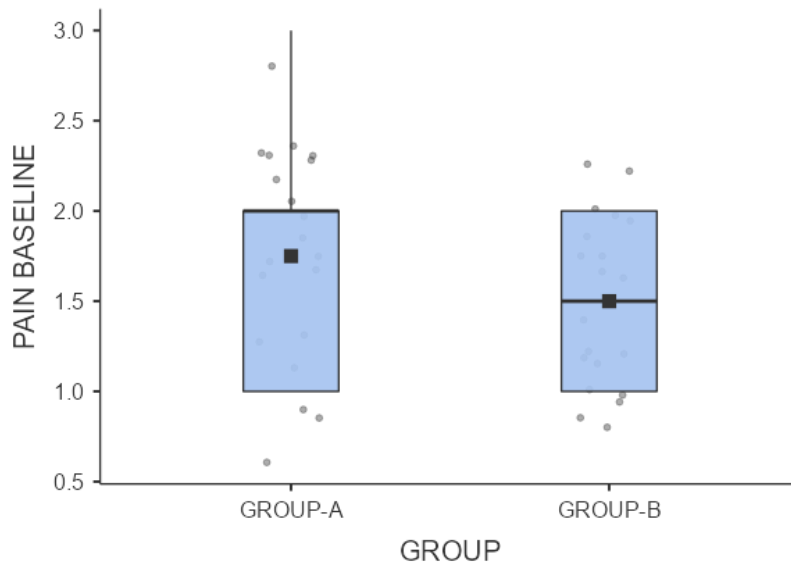
1) In Group A out of 20 patients, 1 Patient had Severe pain, 13 Patients had moderate pain, 6 Patients had mild pain.

2) In Group A out of 20 patients, 1 patient had G-2 dysuria, 11 patients had G-1 dysuria, 8 patients had G-0 dysuria.

PAIN		Mean difference	SE	df	t	Pbonferroni
BASE LINE	- 7 TH DAY	0.100	0.0688	19.0	1.45	1.000
	- 14 TH DAY	0.350	0.1094	19.0	3.20	0.071
	- 21 ST DAY	0.750	0.0993	19.0	7.55	<.001
	- 28 TH DAY	1.100	0.1000	19.0	11.00	<.001
	- POST INTERVENTION	1.200	0.0918	19.0	13.08	<.001
7 TH DAY	- 14 TH DAY	0.250	0.0993	19.0	2.52	0.315
	- 21 ST DAY	0.650	0.1094	19.0	5.94	<.001
	- 28 TH DAY	1.000	0.0725	19.0	13.78	<.001
	- POST INTERVENTION	1.100	0.0688	19.0	15.98	<.001
14 TH DAY	- 21 ST DAY	0.400	0.1124	19.0	3.56	0.031
	- 28 TH DAY	0.750	0.1230	19.0	6.10	<.001
	- POST INTERVENTION	0.850	0.1313	19.0	6.47	<.001
21 ST DAY	- 28 TH DAY	0.350	0.1094	19.0	3.20	0.071
	- POST	0.450	0.1352	19.0	3.33	0.053

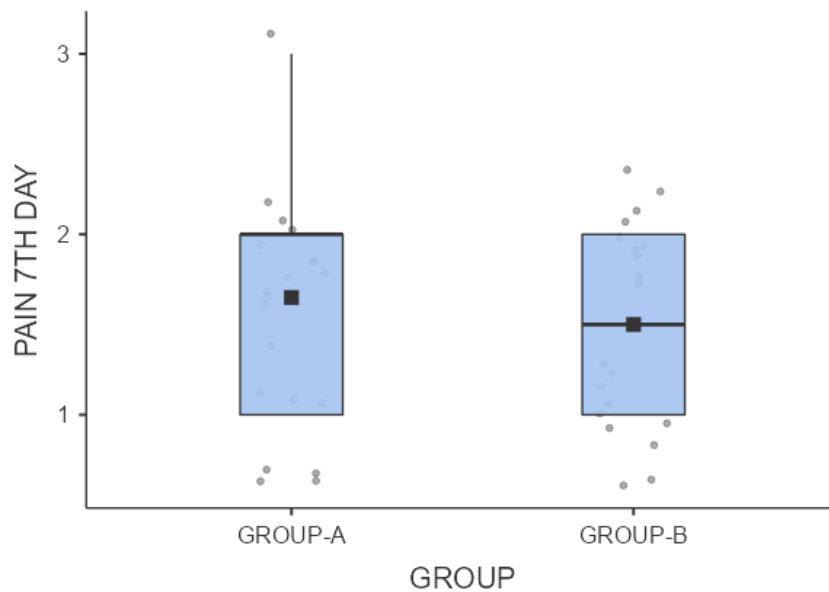
	INTERVENTION					
28 TH DAY	- POST INTERVENTION	0.100	0.0688	19.0	1.45	1.000

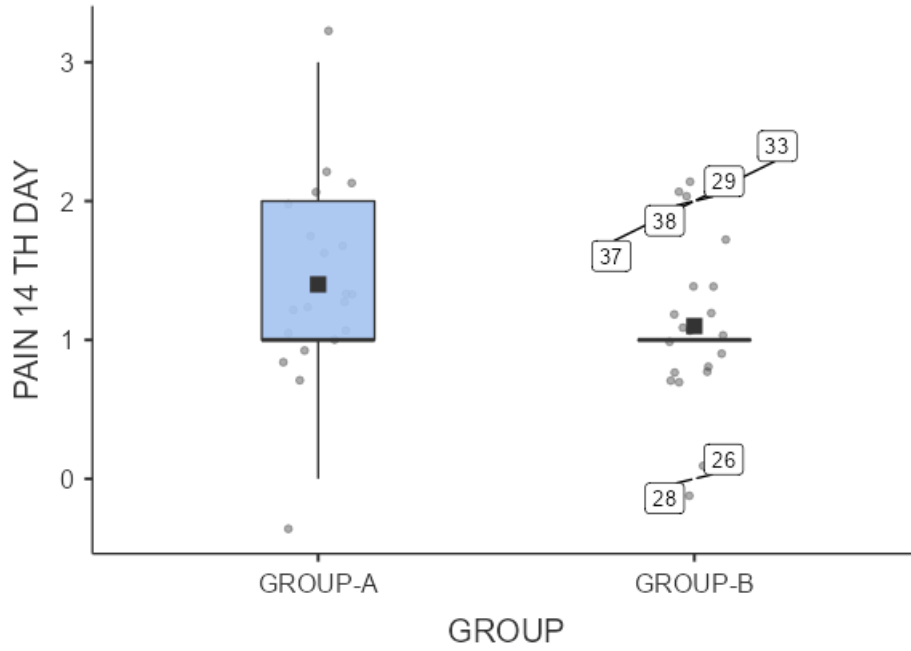
Graph 7: Shows Pain descriptive at baseline



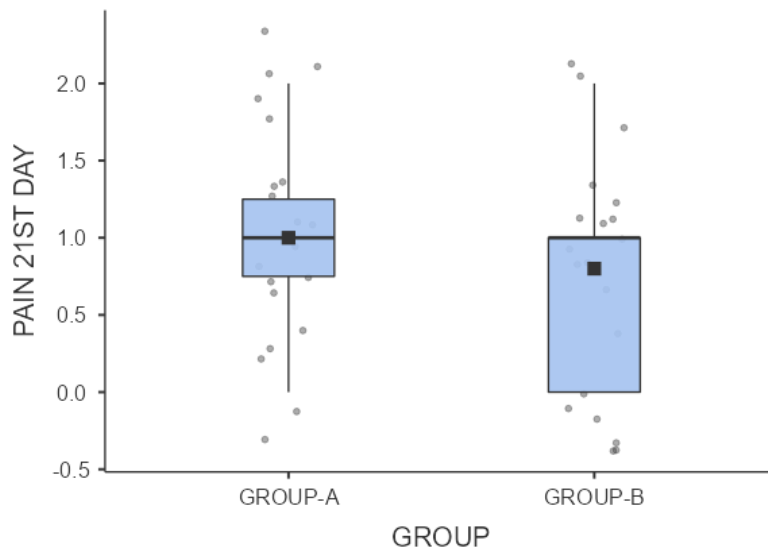
Graph 8: Shows Pain descriptive at 7th day

Graph 9: Shows Pain Descriptive at 14th day

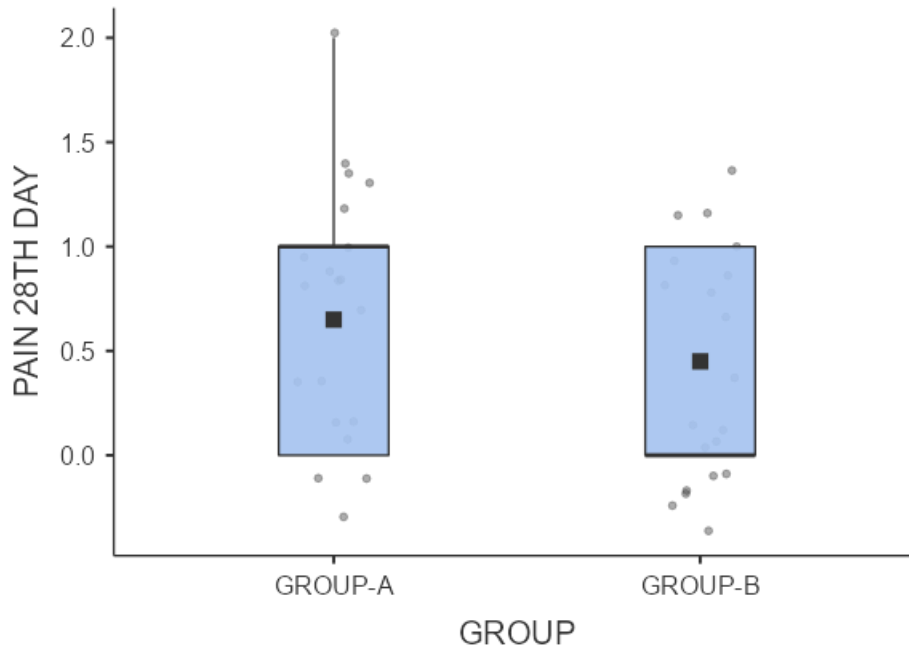




Graph 10 :Shows Pain descriptive at 21st da



Graph 11 :Shows Pain descriptive at 28th day



Size of Calculi

EFFECT ON SIZE OF LEFT RENAL CALCULI IN GROUP A

After 28 days of intervention there was a significant difference was noted with ‘p’ value < 0.001 with effect size of 1.38. Which shows that the size of left Renal calculi was reduced with an average of 67.5% in group-A.

Shows pre and post comparison of size of left renal calculi in group

Table 17: Tests of Normality				
Time point	Time point	Test	statistic	P
SIZE OF CALCULI LEFT PRE	SIZE OF CALCULI LEFT POST	Shapiro-Wilk	0.912	0.145
		Kolmogorov-Smirnov	0.191	0.642
		Anderson-Darling	0.501	0.175

EFFECT ON SIZE OF RIGHT RENAL CALCULI IN GROUP A

After 28 days of intervention there was a significant difference was noted with p < 0.001 with effect size of 2.26. Which shows that the size of right Renal calculi was reduced with an average of 67.1% in group-A.

Shows pre and post comparison of right renal calculi in group A

Table 19:Shows Tests of Normality				
Time point	Time point	Tests	statistic	P
SIZE OF CALCULI RT PRE TREATEMENT	SIZE OF CALCULI RT POST TREATEMENT	Shapiro-Wilk	0.907	0.089
		Kolmogorov-Smirnov	0.191	0.567
		Anderson-Darling	0.658	0.071

DYSURIA

EFFECT ON DYSURIA IN GROUP A

In Group A out of 20 patients, 10 patients had G-2 dysuria , 8 patients had G-1 dysuria and 2 patients had G-0 dysuria.

When the dysuria characters were compared between baseline and post-intervention showed a significant difference with $p = 0.002$. Which concludes that the average decrease of dysuria characteristics was 92% when compared to baseline.

Shows Test of normality of dysuria in group A

DYSURIA	DYSURIA	Mean Difference	SE	df	t	pbonferroni
BASE LINE	-7 TH DAY	0.0500	0.0500	19.0	1.000	1.000
	-14 TH DAY	0.3000	0.1051	19.0	2.854	0.152
	-21 ST DAY	0.4500	0.1141	19.0	3.943	0.013
	-28 TH DAY	0.5500	0.1141	19.0	4.819	0.002
	-POST TREATMENT	0.6000	0.1338	19.0	4.485	0.004
7 TH DAY	-14 TH DAY	0.2500	0.0993	19.0	2.517	0.315
	-21 ST DAY	0.4000	0.1124	19.0	3.559	0.031
	-28 TH DAY	0.5000	0.1147	19.0	4.359	0.005
	-POST TREATMENT	0.5500	0.1141	19.0	4.819	0.002
14 TH DAY	-21 ST DAY	0.1500	0.0819	19.0	1.831	1.000
	-28 TH DAY	0.2500	0.0993	19.0	2.517	0.315
	-POST TREATMENT	0.3000	0.1051	19.0	2.854	0.152
21 ST DAY	-28 TH DAY	0.1000	0.0688	19.0	1.453	1.000
	-POST TREATMENT	0.1500	0.0819	19.0	1.831	1.000
28 TH DAY	-POST TREATMENT	0.0500	0.0500	19.0	1.000	1.000

BURNING MICTURATION

In Group A out of 20 patients, 11 patients are having G-1 burning micturation and 9 patients are having G-0 burning micturation.

When the burning micturation was compared from baseline and post-intervention shows a significant difference with $p = 0.001$. Which concludes that average improvement in burning micturation was 100% in group-A.

Shows Pre and post comparison of burning micturation in group A

BURNING MICTURATION	BURNING MICTURATION	Mean Difference	SE	df	t	Pbon ferroni
BASE LINE	-7 TH DAY	0.0000	0.0000	19.0	NaN	NaN
	-14 TH DAY	0.2000	0.0918	19.0	2.179	0.631
	-21 ST DAY	0.5000	0.1147	19.0	4.359	0.005
	-28 TH DAY	0.5500	0.1141	19.0	4.819	0.002

	-POST INTERVENTION	0.5500	0.1141	19.0	4.819	0.002
7 TH DAY	-14 TH DAY	0.2000	0.0918	19.0	2.179	0.631
	-21 ST DAY	0.5000	0.1147	19.0	4.359	0.005
	-28 TH DAY	0.5500	0.1141	19.0	4.819	0.002
	-POST INTERVENTION	0.5500	0.1141	19.0	4.819	0.002
14 TH DAY	-21 ST DAY	0.3000	0.1051	19.0	2.854	0.152
	-28 TH DAY	0.3500	0.1094	19.0	3.199	0.071
	-POST INTERVENTION	0.3500	0.1094	19.0	3.199	0.071
21 ST DAY	-28 TH DAY	0.0500	0.0500	19.0	1.000	1.000
	-POST INTERVENTION	0.0500	0.0500	19.0	1.000	1.000
28 TH DAY	-POST INTERVENTION	0.0000	0.0000	19.0	NaN	NaN

EFFECT ON HEMATURIA IN GROUP A

There was no change in hematuria because at the baseline no body has hematuria and no subject developed hematuria over the period in group-A.

EFFECT ON PAIN IN GROUP B

When the pain was analyzed using RM-ANOVA comparing between baseline, on 7th day, 14th day, 21st day, 28th day and post-intervention, shows a significant difference with $p < 0.001$, $F = 55.5$ and $\eta^2p = 0.745$.

Due to $p < 0.05$ in maulchis test the Bonferroni correction was used to do post- hoc analysis which

shows that compared to baseline there was a significant difference was noted compared between 14th day ($p = 0.03$), 21st day ($p < 0.001$), 28th day ($p < 0.001$) and post-intervention ($p < 0.001$) but no difference was noted while comparing baseline with 7th day ($p=0.07$).

After comparing these results it concludes that after giving the intervention in group-B the pain was decreased only after 14 days which was maintained on 21st, 28th day and post intervention. With average improvement of 27% on 14th day, 47% on 21st day, 70% on 28th day and 80% on post intervention.

Pain	Pain	MeanDifferen ce	SE	df	t	Pbonferroni
BASE LINE	-7 TH DAY	0.000	0.0000	19.0	NaN	NaN
	-14 TH DAY	0.400	0.1124	19.0	3.56	0.031
	-21 ST DAY	0.700	0.1051	19.0	6.66	<.001
	-28 TH DAY	1.050	0.0881	19.0	11.92	<.001
	-POST INTERVENTION	1.200	0.0918	19.0	13.08	<.001
7 TH DAY	-14 TH DAY	0.400	0.1124	19.0	3.56	0.031
	-21 ST DAY	0.700	0.1051	19.0	6.66	<.001
	-28 TH DAY	1.050	0.0881	19.0	11.92	<.001
	-POST INTERVENTION	1.200	0.0918	19.0	13.08	<.001
14 TH	-21 ST DAY	0.300	0.1051	19.0	2.85	0.152

DAY	-28 TH DAY	0.650	0.1094	19.0	5.94	<.001
	-POST INTERVENTION	0.800	0.0918	19.0	8.72	<.001
21 ST DAY	-28 TH DAY	0.350	0.1094	19.0	3.20	0.071
	-POST INTERVENTION	0.500	0.1147	19.0	4.36	0.005
28 TH DAY	-POST INTERVENTION	0.150	0.0819	19.0	1.83	1.000

EFFECT ON SIZE OF LEFT RENAL CALCULI IN GROUP B

When the size of Renal calculi was compared between baseline and post-intervention there was a significant difference with $p < 0.001$. It concludes that there was an average decrease of 54.8% in size of left Renal calculi among group-B.

Shows Pre and post comparison of left renal calculi in group B

Time point	Time point	Test	statistic	df	p	Effect size
Size of calculi left Pre Treatment	Size of calculi left Post Treatment	Student's t	7.34	15.0	< .001	1.84

EFFECT ON SIZE OF RIGHT RENAL CALCULI IN GROUP B

When the size of Renal calculi was compared between baseline and post-intervention there was a significant difference with $p < 0.001$. It concludes that there was an average decrease of 52% in size of right Renal calculi among group-B.

Shows Pre and post comparison of right renal calculi in group B

Time point	Time point	Test	statistic	p	Correlation	Effect size
Size of calculi RT Pre Treatment	Size of calculi RT Post Treatment	Wilcoxon w	136	< .001	Rank biserial correlation	1.00

EFFECT ON DYSURIA IN GROUP B

In Group B out of patients, 2 patients are having G-2 dysuria, 7 patients are having G-1 dysuria, 11 patients are having G-0 dysuria.

When the dysuria characters were compared between baseline and post-intervention showed a significant difference with $p = 0.005$. Which concludes that the average decrease of dysuria characteristics was 90% when compared to baseline.

Shows Pre and post comparison of dysuria in group B

DYSURIA	DYSURIA	Mean Difference	SE	df	t	Pbonferroni
BASE LINE	-7 TH DAY	0.000	0.0000	19.0	NaN	NaN
	-14 TH DAY	0.200	0.0918	19.0	2.18	0.631
	-21 ST DAY	0.350	0.1094	19.0	3.20	0.071
	-28 TH DAY	0.500	0.1357	19.0	3.68	0.024
	-POST INTERVENTION	0.500	0.1357	19.0	3.68	0.024
7 TH DAY	-14 TH DAY	0.200	0.0918	19.0	2.18	0.631
	-21 ST DAY	0.350	0.1094	19.0	3.20	0.071
	-28 TH DAY	0.500	0.1357	19.0	3.68	0.024

	-POST INTERVENTION	0.500	0.1357	19.0	3.68	0.024
14 TH DAY	-21 ST DAY	0.150	0.0819	19.0	1.83	1.000
	-28 TH DAY	0.300	0.1051	19.0	2.85	0.152
	-POST INTERVENTION	0.300	0.1051	19.0	2.85	0.152
21 ST DAY	-28 TH DAY	0.150	0.0819	19.0	1.83	1.000
	-POST INTERVENTION	0.150	0.0819	19.0	1.83	1.000
28 TH DAY	-POST INTERVENTION	0.000	0.0000	19.0	NaN	NaN

EFFECT ON BURNING MICTURITION IN GROUP B

In Group B out of 20 patients, 9 patients are having G-1 burning micturation and 11 patients are having G-0 burning micturation.

When the burning micturation was compared between baseline and post intervention shows a significant difference with $p = 0.003$. It concludes the after giving intervention in group-B the average improvement was 100%.

BURNING MICTURATI ON	BURNING MICTURATION	Mean Difference	SE	df	t	Pbon ferroni
BASELINE	-7THDAY	0.0000	0.0000	19.0	NaN	NaN
	-14THDAY	0.1000	0.0688	19.0	1.45	1.000
	-21STDAY	0.4000	0.1124	19.0	3.56	0.031
	-28THDAY	0.4500	0.1141	19.0	3.94	0.013
	-POST INTERVENTION	0.4500	0.1141	19.0	3.94	0.013
7THDAY	-14THDAY	0.1000	0.0688	19.0	1.45	1.000
	-21STDAY	0.4000	0.1124	19.0	3.56	0.031
	-28THDAY	0.4500	0.1141	19.0	3.94	0.013
	-POST INTERVENTION	0.4500	0.1141	19.0	3.94	0.013
14THDAY	-21STDAY	0.3000	0.1051	19.0	2.85	0.152
	-28THDAY	0.3500	0.1094	19.0	3.20	0.071
	-POST INTERVENTION	0.3500	0.1094	19.0	3.20	0.071
21STDAY	-28THDAY	0.0500	0.0500	19.0	1.00	1.000
	-POST INTERVENTION	0.0500	0.0500	19.0	1.00	1.000
28THDAY	-POST INTERVENTION	0.0000	0.0000	19.0	NaN	NaN

BETWEEN GROUP COMPARISON

EFFECT ON PAIN IN BETWEEN GROUPS

When the pain was compared between group-A and group-B there was no much difference was noted with $p = 0.1$. Which concludes that the pain decreased more in group-B than group-A over 21st day, 28th day and post-intervention with 47%, 70% and 80% respectively but in group-A shows only 43%, 63% and 69% respectively.

Shows Independent Samples T-Test in Between groups

Time point	Test	Statistic	p	Correlation	Effect Size
POST TREATMENT	Mann-Whitney U	150	0.118	Rank Biserial correlation	0.250

EFFECT ON DYSURIA IN BETWEEN GROUPS

When the dysuria was compared between group-A and group-B there was no much difference was noted with p = 1. Which concludes that the dysuria decreased more in group-B than group-A over 28th day and post-intervention with 91% and 91% respectively but in group-A shows only 85% and 91% respectively. But in group-A the decrease trend was started from 21st day but in group-B it started from 28th day.

Table 41: Shows Independent Samples T-Test in Between groups

Time point	Test	Statistic	P	Correlation	Effect size
DYSURIA POST TREATMENT	Mann-Whitney U	200	1.000	Rank biserial correlation	0.00

EFFECT ON SIZE OF LEFT RENAL CALCULI IN BETWEEN GROUPS

when the size of left Renal calculi was compared between group-A and group-B shows no no much significant difference with p = 0.08. but in group-A shows 67% reduction in size of calculi but in group-B only 54.8% of size was reduced.

Table 42:Shows Independent Samples T-Test in Between groups

Time point	Test	Statistic	p	Correlation	Effect Size
SIZE OF CALCULI LEFT POST	Mann-Whitney U	77.0	0.085	Rank biserial correlation	0.358

EFFECT ON SIZE OF RIGHT RENAL CALCULI IN BETWEEN GROUPS

when the size of Right Renal calculi was compared between group-A and group-B shows no much significant difference with p = 0.007. but in group-A shows 67.1% reduction in size calculi but in group-B only 52% of size was reduced.

Table 43:Shows Independent Samples T-Test in Between groups

Time point	Test	Statistic	p	Correlation	Effect Size
SIZE OF CALCULI RT POST	Mann-Whitney U	62.5	0.007	Rank biserial correlation	0.540

BURNING MICTURATION

When group-A and group-B was compared for burning micturition it shows in both the groups the burning micturition was completely absent after interventions.

DISCUSSION ON DRUGS

Traikantaka ghrita

The yoga (formulation) selected for the present study contains 15 drugs. They are, Traikantaka, Ela, Girijatu, Girijabheda, Yastimadhu, Shatavari, Darba, Draksha, Musta, Pippalimoola, Vasuka, Vasira, Kasha, Ikshu, Matsyakshi these ingredients helps to disintegrate Ashmari and also to reduce the infection, this ingredients possess properties like Mutrala, Basti-shodaka, Ashmarigna, Mutrajanana,

Dahashamaka, Anulomaka and Agnideepaka. According to previous research studies, these drugs have properties like lithotriptic and diuretic actions. Pachaka pitta and samana vayu plays an important role in the formation of urine whereas Apana Vayu regulates the excretion of urine. So, any dysfunction in Pachaka pitta and samana vayu leads to initiate pathogenesis of Ashmari. Ashmari is Kapha Pradhana roga which later get associated with vata and other dushyas which leads to formation of Ashmari in mutravaha srotas. Treatment of Ashmari will be in two stages, initially correction of agni is to be done by correcting pachaka pitta and samana vayu and anulomana of apana vayu to be done.

In second stage, treatment is aimed at bhedana and lekhanana of Ashmari. The Trikantaka Ghrita contains drugs like Ela, Apamarga, Mustaka, Pippali, Arka which are have properties like katutiktika rasa and ushna veerya which helps in correction of pachaka pitta and samana vayu. The ingredients like Girijatu, Girijabheda, Apamarga and Kasha have bhedana property which helps in lithotriptic action and disintegration of stone. Ingredients like Gokshura, Draksha, Ela, Kasha and Ikshu have Mutrала and Bastishodaka properties which helps in Diuretic action. Ingredients like Kasha, Darba have properties like Antispasmodic and Muscle Relaxant actions to overcome the nauseating and painful symptoms of Ureteric colic. Tilanala kshara

Acharya Sushruta has dedicated entire 11th chapter of Sutra Sthana to describe Kshara. Tilanala kshara is one among them. Mutrashmari is formed due to vata and kapha dosha samurcchana. Kshara has properties like Shodana, Lekhana, Bhedana, Pachana, and Tridoshagna Properties.

Bhedana property of kshara helps to disintegrate urinary stones, as it is Tridoshaja vyadhi. The tridoshagnata effect of kshara helps to break dosha samprapti of disease, Shodana and ropana are beneficial properties of kshara helps in healing the lacerated mucosal surface of urogenital tract due to friction of spiky and nodular type of ashmari (Oxalate stones) and Kshara is 100% Soluble in water, so it can actively precipitate to counteract the pathogenesis of stone formation and it neutralize acidic media of urine as it behaves as alkaline substance.

Tila is having properties like Madhura tikta rasa, Guru snigdha guna, Usna veerya, Vatakapha shamaka and Agni janana properties. These Properties helps in pacifying vata and kapha dosha. Hence Tilanala in the form of kshara is selected as a the standard drug, which was proven efficacious with 90% results in the previous works.

III. DISCUSSION ON RESULTS

Subjective parameters

Effect of Treatment on Pain

In **Group A**, the treatment had a highly significant effect on Pain ($p < 0.001$) with an average improvement of 69%. In **Group B**, the treatment had a highly significant effect on Pain ($p < 0.001$) with an average improvement of 80%. The comparative analysis of the treatment's effect on Pain between Group A and Group B resulted in a p -value = 0.1 suggesting a statistically insignificant difference. Hence the result in the effect of

treatment on Pain in group B was comparatively better than group A.

The pain present in *ashmari vyadhi* due to *prakopa* of *vata* dosha so, In Group A, The drug Traikantaka ghrita consist of Ingredients like *Gokshura*, *Shatavari*, *Draksha*, *Yastimadhu* which are have properties like *Guru*, *snigdha guna* and *Madhura vipaka* which helps in *vata shamana* and ingredients like *kasha*, *darba* which are having properties like antispasmodic action which helps in reduction of pain. In Group B, The drug *Tilanala kshara* which are having the properties like *Guru snigdha guna*, *usna veerya* along with *kshara*, which are having properties like *Shodana*, *Lekhana*, *Bhedana*, *Pachana*, And *Tridoshagna* Properties. Which helps in *vata* and *kapha dosha shamana* and reduction of pain.

Effect of Treatment on Dysuria

Both the groups have shown significant response in dysuria. Group A has shown Significant difference with $P = 0.002$, reduction in by 92 %. Group B has shown significant difference with $P = 0.005$, reduction in pain by 90 %. So, Group A has comparatively good outcome in the management of Dysuria. In Group A, the drug *Traikantaka Ghrita* contains *gokshura*, *draksha*, *ela*, *kasha* which are having the properties like *mutrала*. so, the drug *Traikantaka Ghrita* which may helps in the reduction of dysuria.

Effect of Treatment on Burning Micturition

Group A has shown Significant difference with $P = 0.001$, reduction in by 100 %. Group B has shown significant difference with $P = 0.003$, reduction in pain by 100%. So, both Group A and Group B have shown similar effect on Burning micturition. The Burning micturition in ashmari vyadhi due to pitta dosha prakopa. so, In Group A - the drug *Traikantaka ghrita* consist of Ingredients like *Gokshura*, *Shatavari*, *Draksha*, *Yastimadhu* which are having properties like *Guru*, *snigdha guna* and *Madhura vipaka* and Ingredients like *Draksha*, *Shatavari*, *Ikshu*, *Darba*, *Mustaka* and *Matsyakshi* which are having properties like *sita veerya* which helps in *pitta shamana* and the drug *yastimadhu* having *daha shamaka guna*. By these properties the drug *Traikantaka Ghrita* which may reduces the Burning micturition. In Group B, the drug *Tilanala Kshara* which is having properties like *Guru snigdha guna*, *Madhura vipaka* and alkaline properties of *Kshara* which helps in reduction of acidic nature of urine. By these

properties of Drug *Tilanala kshara* which may reduces the burning micturition.

Objective parameters

Response on size of the calculi

In terms of reduction in size of calculi Group A has shown a significant difference was noted with $p < 0.001$ with effect size of 2.26. Which shows that the size of right renal calculi was reduced with an average of 67.1% in group-A. and in Left renal calculi has shown a significant difference was noted with $p < 0.001$ with effect size of 1.38. Which shows that the size of left renal calculi was reduced with an average of 67.5% in group-A.

In terms of reduction in size of calculi Group B has shown has shown a significant difference with $p < 0.001$. It concludes that there was an average decrease of 52% in size of right renal calculi among group-B. and in Left renal calculi has shown a significant difference with $p < 0.001$. It concludes that there was an average decrease of 54.8% in size of left renal calculi among group-B.

By considering these results, In terms of reduction in size of calculi Group A has shown 67.5% reduction in size of calculi and Group B has shown 54.8% reduction in size of calculi. Comparatively Group A has shown good results. In Group A, The drug *Traikantaka ghrita* consist of ingredients like *Girijatu*, *Girijabheda*, *Apamarga*, *Kasha* which are have properties like *Ashmari bhedana* which helps in disintegration of stone. So, Group A has shown comparatively good results in reduction of size of calculi over the Group B.

Effect of Treatment on Hematuria

There was no change in hematuria because at the baseline no subjects has hematuria and no subjects developed hematuria over the period in group-A and Group B.

Overall effect of *Traikantaka Ghrita* (GroupA)

Out of 20 patients of Group A 43% of patients got marked improvement, 63% of patients got moderate improvement and 69% of patients got complete improvement.

Overall effect of *Tilanala kshara* (GroupB)

Out of 20 patients of Group B 27% of patients got marked improvement, 47% of patients got moderate improvement and 70% of patients got complete improvement.

IV. CONCLUSION

Following conclusions were drawn from the present clinical study with treatment and observations.

- Out of the 40 patients of Mutrashmari included in this study, 20 patients were treated with Traikantaka Ghrita under group A and 20 patients were treated with Tilanala Kshara in group B.

- In the present study it was observed that Mutrashmari was common in the age group of 30-50 years, Males were more affected than females, Occupation wise it was more common in Students, Farmers and housewives, more in lower class and middle class and was more in people with mixed dietary habits who had a habit of less water intake, irregular dietary habits with much intake of Diery products more roughage and proteins foods.

- Urinary calculi is a disease which give rise to various symptoms like pain abdomen, burning micturition, dysuria and more common symptom is pain and it is expressed in various manner like dull, colicky and radiating in different sites.

- Traikantaka Ghrita shown significant result in all subjective and objective criteria. But reduction in pain is less when compared to Tilanala Kshara. Both Traikantaka ghrita and Tilanala kshara are having same effective in dysuria, burning micturition and Haematuria. But, Traikantaka Ghrita is more effective in reduction in size of calculi compared to Tilanala kshara.

- During the observational period no recurrence of calculi was observed.

- During the Study and Follow up period no adverse effects were seen in both the Groups.

- The preparation of Traikantaka ghrita is simple, slightly palatable, easy for administration, free from side effects and therapeutic efficacy is good. So, it can be adopted as a remedy for treatment of Mutrashmari.

LIMITATIONS AND FURTHER SCOPE OF THE STUDY

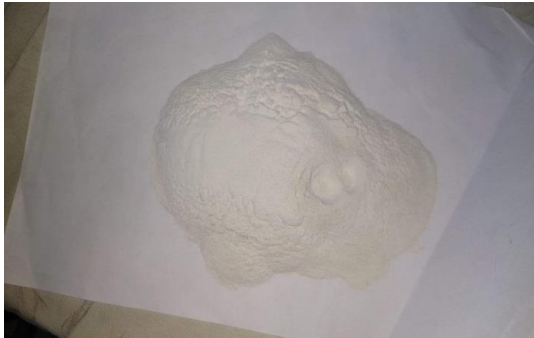
- In this study as the size of calculi was limited to 9mm, calculi greater than 9mm were excluded.

- As the medicine given in opd basis, proper monitoring of patients Pathyapathya was difficult.

- Further studies can be conducted to find the efficacy of Traikantaka ghrita and Tilanala kshara in specific types of Mutraashmari like Vataja, Pittaja and Kaphaja



TRAIKANTAKA GHRITA



TILANALA KSHARA

REFERNCES:

- [1]. Prof.K.R.Srikantha murthy, Susruta Samhita of Maharshi Sushruta, Vol-1, Varanasi; Chaukhamba Orientalia; 2012, pp-Su. 233.
- [2]. Sushruta samhita by Dr.Ambika data shastri, Chaukambha Sanskrit samsthana,chikitsasthana, 7th chapter. Sloka no.3, 52pp.
- [3]. Prof.K.R.Srikantha murthy, Susruta Samhita of Maharshi Sushruta, Vol-1, Varanasi; Chaukhamba Orientalia; 2012, pp-Su. 483.
- [4]. Sahasrayogam by Dr.K.Nishteswar and Dr.R.Vidyanath, Chaukamba Sanskrit samsthana,Ghritha prakarana,No.22,pp77.