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Randomized open control clinical study to assess the effectiveness of shunthyadi kashay in treating Mootrashmari w.s.r. to Urolithiasis.

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Introduction

The Indian medical system and living science known as ayurveda. Urinary calculi are discussed in Ashtamahagada1 under the subject of Ashmari by Acharya Shushruta, the father of surgery.

According to modern science, urolithiasis and the disease are correlated. mootrashmari, is result of changing lifestyles and fast food habits. The management of urolithiasis has been simplified by research and surgical procedure, however they are expensive and have a higher risk of

recurrence. there is a need to research the disease and its management.

There is a detailed account of the pathophysiology, causes, and treatments of calculi in AyurvedaHere, we can find a variety of lowcost therapies for all types of calculi, regardless of their chemical composition. Urolithiasis is third prevalent disorder after UTI& BPH2.

Calculi incidence varies according on age, sex, and geographic distribution. Up to 5% of the population is impacted3. Males experience more urinary stones than females do on average.

Most urologists and biochemists today consider that a crystalloid imbalance is the primary factor contributing to the production of stones. Stone formation is caused by concentrated urine, hypercalciuria carried on by hyperparathyroidism, a lack of substances that prevent the formation of stones, such as mucopolysaccharides and citrate, sarcoidosis, and idiopathic overabsorption4.

To prevent intrarenal or extrarenal causes of stone development, actions must be taken on a long-term or short-term basis. Untreated urolithiasis is a condition that can result in Infection, hydroureter, hydronephrosis, and other conditions all result in severe, colicky discomfort .in serious situations, can permanently harm the kidneys and their ability to function.

So, it is essential to understand the disease and find a practical, costeffective treatment for this common condition.

Aim and Objectives-

Aim:

To study the effect of Shunthyadi Kashay in Mootrashmari W. S.R to Urolithiasis.

Objectives-

1) to study the mootrashmari in terms of its atiopa thogenesis, clinical manifestation, and possible correlation to the description availabl e in both Ayurveda and modern medicine.
2) to find out a safe ,simple,effective and economical method of treating mootrashmari
3) to study the effects of both drugs on mootrash mari symptomatically or by verifying it with an ultrasound on the size and location of t he stone presence.

Material and Methods.-

Patient Selection:

The study was carried out by choosing particip ants from the OPD and Shalya's IPD, while during camp. To determine the type of urinary issues , the patients underwent regular laboratory testing and clinical screening.

Grouping:

A total of 60 samples were randomly selected a nd divided into two groups, the Trial and Control gro ups, each with 30 samples.

Pre-test and post-
test study designs are used in this clinical study.

Selection Criteria –

Inclusion-

1) The subject must show the signs and symptoms of mootrashmari, regardless of the nature of the calculus.
2) Any single or many calculi in the urinary syste m that are less than 10 mm in size.
3) People in the 20–60 age range, of either sexes.
4) The history of stones, both recurrent and nonre curring.

Exclusion-

1) Subjects requiring prompt attention, such as sep sis or extensive haematuria.
2) Patient has a history of BPH, hyperparathyroidi sm, gout, and other conditions.

3 Obstructive uropathy

4) Decreased renal functions.
5) Renal abnormalities that are congenital.
6) Impacted stones
7) Hydronephrosis that is severe.
8) Pyelonephritis
9) Malignancy.

Treatment scheme:

The study was divided into two groups (Trial Group) Group A and (Control Group) Group B to assess the efficacy of shunthyadi kashay.

शुण्ठ्यग्निमन्थपाषाणशिग्रुवरुणगोक्षुरैः।
अभयास्तबधफलैः क्वाथं कुर्य्याद्विचक्षणः॥५॥
गमठक्षारलवणंचुर्णदत्वा पिबेन्नरः।
अश्मरीमूत्रकृच्छ्रघ्नंपाचनंदीपनंपरम ।
हन्यातकोष्ठाश्रितंवातंकव्यरुगुदमेढ्रगम ॥६॥

चक्रदत्तः अश्मरी चिकित्सा ५/६

The duration of treatment for both groups was 28 days and effect recored on 0,7th,14th,21 th ,28th day

Mode of Administration of drug-

Groups	Trial Group-A	Control Group-B
Drug	Shunthyadi Kashay	Varunadi kwath
Form	Kashay(kwath)	Kashay(kwath)
Dose	40 ml	40ml
Frequency	Twice a day before meal	Twice a day before meal
Anupan	Koshna jala	Koshna jala
Duration	28 Days	28 Days
Diet	Pathyakar aahar &vihar adviced	Pathyakar aahar & vihar adviced

Shunthyadi kashay was prepared as per sharangdhar samhita ,madhyamkhand[6],

Assessment Criteria-

Subjective-

1) Pain-

No pain- 0
Occasional pain required no treatment- 1
Occasional pain required treatment - 2
Constant pain required treatment- 3

2) Burning micturition-

No burning micturition - 0
Occasional burning micturition not required treatment - 1
Occasional burning micturition required treatment - 2
Constant burning micturition required treatment- 3

3) Dysuria-

No dysuria- 0
Occasional dysuria not required any treatment - 1
Occasional dysuria required treatment - 2
Constant dysuria required treatment - 3

Objective criteria for assessment-

1.USG of KUB region

Site of the stone: Pelvis	Ureter	Vesicle	Urethra
Group A			
Before Treatment			
After Treatment			
Group B			

Before Treatment
After Treatment

2. Size of Stone:

	Before Treatment	After Treatment
Group A		
Group B		

3. Urine Analysis (M/R)

Haematuria:

- No RBC/Hpf – 0
- 0-5 RBC/Hpf – 1
- 6-10 RBC/Hpf – 2
- 11< RBC/Hpf – 3

Observation and Result-

Age-

Based on the observations, the age group represented the majority of patients
31 to50.Calculi may form as a result of physical activ ity, irregular food, insufficient water intake, heavy w orkload, and mental stress.

Sex-

Among the 60 patients who were chosen
43 cases (71.67%) were men.
17 patients (28.33%) were women.

Diet:

Of the 60 patients who were chosen,12 patients (abou t 20%) were vegetarians
The diets of 48 patients (80%) were mixed.

Occupation-

among the 60 patients who were chosen, 09 patients (15.00%) were students.
15 patients (about 25%) received care
13 patients (21.67%) worked as farmers.
15 patients (about 25%) were engaged in house work.
08 patients (13.33%) were conducting business.

Size of the stone-

Among the 60 individuals,20 patients (33.33%) had s izes ranging from 1mm to 5mm.
40 patients (66.67%) had sizes ranging from 5.1 mm t o 10 mm.

Statistical analysis-

All of the patients underwent indepth examinat ions and assessments using both quantitative and qual itative evaluation standards.The scores of the data bef ore and after treatment were compared using the Wilc oxon signed ranks test and the Mann- Whitney U Test
The real data between the two groups was analysed u sing paired and unpaired "t" tests.

Discussion-

It has been seen and reported that urolithiasis is a frequent condition among Indians. This disease's complex aetiology has a significant link to a nutritional way of life. Acharya Sushruta, known as the "Father of Surgery," includes "Ashmari" in "Ashtamahagad," a disease that is challenging to treat. Urolithiasis diagnosis and treatment are now made simpler and faster because to recent surgical advancements and instrument innovation. It is clear from the current study that urological issues play a significant role in medical discussions. Perhaps this explains why our Ayurvedic writings describe the ailment Mootrashmari (Urolithiasis), which is connected to the urinary system, in great detail. In Ayurveda, diets that include madhura (sweets), guru (heavy for digestion), and hot7.
The surgical procedure only provided temporary com fort and could not stop the stone from coming back. Hence, effective medical treatment is required for co ntrol over Ashmari.Manyherbal remedies recommend ed periodically by different Acharya for the treatment of urinary calculus were thoroughly detailed in Ayur veda books8.
In order to evaluate the effectiveness of the trial medi cine in Mootrashmari, one of the numerous reference s available, "Shunthyadi Kashay" from "Chakradatta" (inSarchandrikateeka), was chosen. A total of 60 Ash mari patients participated in the trial, which was divid ed into two groupwith a total of 30 patients each

Discussion on subjective Criteria:

Table 1=Showing Clinical symptoms wise Distribution

No of Ashmari	Group A	Group B	Total	Percentage %
Pain	30	30	60	100%
Burning	28	29	57	95.00%

Micturition				
Dysuria	24	30	54	90.00%
Haematuria	22	22	44	73.33%

Effect on Pain:

Following completion of treatment, 2 patients in the trial group experienced severe abdominal discomfort, 1 patient experienced moderate pain, and 4 patients experienced light pain.

23 patients experienced no abdominal pain following the end of treatment.

After completion of treatment, 0 patients in the control group experienced severe abdominal discomfort, 3 patients experienced moderate pain, and 12 patients experienced light pain.

After treatment was finished, 15 patients reported having no abdominal pain.

We find from statistical analysis that trial group A is more effective than control group B in termof pain criteria.

Table2 = Showing result on Pain

Pain	Day-0		Day-28		% Relief	Wilcoxon Signed Ranks Test (T+)	P
	Mean score	Sd	Mean score	Sd			
Group-A	2.63	0.490	0.40	0.855	86.6%	406	<0.0001 ES
Group-B	2.56	0.504	0.60	0.674	78.3%	465	<0.0001 ES

Effect on Burning Micturition:

After the completion of treatment, patient 01 in the trial group reported a moderate complaint.

10 individuals complained occasionally of burning mucus. 19 individuals reported no burning urination complaints.

In control Group ,after completion of the treatment ,One patient reported a mild complaint. 21 patients were free of the complaint of burning micturation, compared to 8 patients who had a slight complaint about ithere aren't many differences in the results of the two groups on burning urination after statistical analysis.

where the trial medicine fails and the control drug succeeds.

Table 3=Showing Results in Burning Micturation

Burning Micturation	Day-0		Day-28		% Relief	Wilcoxon Signed Ranks Test (T+)	P
	Mean score	Sd	Mean score	Sd			
Group-A	1.867	0.819	0.400	0.563	80.90%	378	<0.0001 ES
Group-B	2.000	0.643	0.333	0.546	86.2%	435	<0.0001 ES

Effect on Dysuria:

After completion of treatment, 0 patients in the trial group reported moderate complaints regarding their urination, whereas 05 individuals had mild complaints. Regarding dysuria, 25 patients had no complaints.

Under Control Group after the treatment is finished 25 patients reported no complaints at all, 05 patients had mild complaints, and 0 patients had moderate complaints.

There is no discernible difference between the results of the two groups on dysuria following statistical analysis.

Table4 = Showing Results in Dysuria

Dysuria	Day-0		Day-28		% Relief	Wilcoxon Signed Ranks Test (T+)	P
	Mean score	Sd	Mean score	Sd			
Group-A	1.733	0.980	0.167	0.379	90.9%	300	<0.0001 ES
Group-B	1.767	0.626	0.167	0.379	93.3%	465	<0.0001 ES

Effect on Haematuria:

In the Study Group, seven individuals experienced minor haematuria following the completion

of treatment, whereas 23 patients experienced total re lief from the condition.

In the control group, following completion of a moderate treatment 22 individuals had total relief fro m the haematuria, whereas 8 people still had it.

There is no statistically significant difference i n the outcomes of the two groups for haematuria.

Table5 = Showing Results in Haematuria

Haema-turia	Day-0		Day-28		% Relief	Wilcoxon Signed Ranks Test (T+)	P
	Mean score	Sd	Mean score	Sd			
Group-A	1.100	0.803	0.233	0.430	79.5 %	210	<0.001 ES
Group-B	0.900	0.661	0.267	0.449	77.2 %	190	<0.001 ES

Effect on size of stone:

Table 6= for Comparison of Results on size of stone of Both Groups.

Size of Stone (mm)	Day-0		Day-28		% Change	Paired t	P
	Mean	Sd	Mean	Sd			
Group-A	6.230	2.041	3.163	2.981	60.85 %	9.351	<0.0001 ES
Group-B	6.240	1.988	2.900	3.074	64.74 %	10.176	<0.0001 ES

The size of the stone changed by 60.85% in the Trial group. Before therapy, the study group's mean stone size score was 6.230; after treatment, it w as 3.163.

Following the use of Paired- 't . The result of the test, using the provided data, was determined to be statistically significant at the level of p0.05.

A 64.74% change in the size of the stone was s een in the control group. Before therapy, the control group's mean stone size score was 6.240; after treatm ent, it was 2.900.

Using the provided data and the Paired-T test, the result was determined to be statistically significan t at the level of p0.05. By comparing the outcomes of the trial and control groups' statistical an alyses of the stone's size using the unpaired t test;

Table7 = Showing Significance of Results on Size of Stone

Size of Stone (mm)	Mean difference	Sd	Unpaired T	P
Group-A	3.067	1.796	0.589	0.55 NS
Group-B	3.340	1.798		

Overall Response of Therapy in Both Groups:

Table 8s = Showing Overall effect of therapy in Assesement criterias

Symptoms	% Relief	
	Group-A	Group-B
Pain	86.66%	78.33%
Burning Micturation	80.95%	86.20%
Dysuria	90.95%	93.33%
Haematuria	79.54%	77.27%

Findings indicate that all of the patients' subjective an d objective symptoms in both groups are improving. Some individuals' symptoms persisted while others h ad decreased in severity.in a predetermined time fram e. According to statistical analysis, both groups' over all symptomshave improved, and with a pvalue of (0. 05),it can bedetermined that neither the trial medicine nor the control drug has a statistically significant effe ct on either group's symptoms.

After the investigation was finished,wediscove red that the trial drug has antiurolithiatic activityand i s effective in treating mootrashmari (urolithiasis).

Shunthi, Agnimanth, Shigru,Pashanbhed,Varu n,Gokshur,Abhaya, Aragvadha,Hingu,Lavan, and Ya vakshar are among the Shunthyadikashay members, which act similarly to VataKaphahara,

Ashmaribhedana,Lekhana, Mutral, and Vedanasthapana[9.]

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