

# ASHMARI: A CLINICAL TRIAL WITH SOME INDIGENOUS DRUGS

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## Abstract

Urolithiasis has been and still is being the most common problem of developing countries. Also in recent times, it has come up to be a pandemic disease. It is recurrent in nature which makes it more and more difficult for treatment. It produces pain and inconvenience in routine life. urolithiasis means the aggregation of urinary crystalloids in urinary system'. Calculus (Stone) is a polycrystalline aggregate composed of varying amounts of crystalloid and organic matrix. urolithiasis is a pathological condition of urinary system where aggregation of urinary crystalloids takes place anywhere in urinary tract i.e. from kidney to urinary bladder. Now a days, surgical management of *calculus* is very common in modern science but it is invasive in nature, So the world needs to have a non invasive procedure i.e. *Ayurvedic* therapy, it has gained popularity due to its Non invasive approach and complete cure of the disease. In the present research work *Shwandanshtradi* Yoga and *Varunadi Kwath* have been prepared for the management of *Mootrashmari*. 30 diagnosed case of *ashmari* were selected from OPD and IPD of P.G Department of *Shalya Tantra*. All the patients were divided in two groups. The results showed marked relief in subjective and objective parameters. Moreover, this therapy was well accepted by all patients and did not cause any hindrance in their daily routine work during period of management.

**KEYWORDS:** *ashmari, urolithiasis. Mootrashmari, calculus*

## INTRODUCTION

Now a day, Innumerable patients are reporting to the hospitals regularly being afflicted with different urinary disorder. *Mutrashmari* has peculiar tendency of recurrence. *Ashmari* description is the specific contribution of *Acharya Sushruta* the father of surgery & he has included it in the '*Ashta- Mahagada*'<sup>1</sup> the eight most troublesome diseases may be owing to its potentiality to disturb the anatomy and physiology of urinary system. The reason is because of the disease is:

- *Tridoshaja* in origin
- *Marmashrayee*<sup>2</sup>
- *Bastiisvyakthasthana* of *ashmari*<sup>3</sup>

- This *basti* comes under *dashavidha pranayathana*<sup>4</sup>

The patients of this disease will have the symptoms like pain abdomen, dysuria, burning micturition, retention of urine etc, but the investigations have become a routine practice. both the plain X-Ray and intravenous pyelography are not considered as a full proof diagnostic methodologies in cases of urinary calculi like cysteine and uric acid stones which are least opaque as well as radiolucent. As a result of invention of USG, it is now possible to cope up with these drawbacks. However these assumptions need to be supported by modern practical clinical reviews. Several theoretical classical data has been obtained which are proof of fact that the kind of indigenous operative surgeries that Acharya Sushruta had practised were even unknown to Greeks and Europeans. This is indicative of the fact that surgery in India was at its pinnacle in the past also. Now in this era, there are many treatment modalities like Hydro therapy and various surgical procedures but most of the time they fail in eradicating the root cause and therefore recurrence of disease occurs commonly. This is because these procedures have no effect on the pathogenesis behind the formation of stone. Unfortunately urolithiasis occurs during the most productive years of one's life which prohibits him from his normal daily routine task. Thus we have enough reasons to look out for something which may be a radicle treatment of the disease treating it by its root cause.

## Material & methods

### Aims and objectives:

- To compare the Effect of *Shwandanshtradi* Yoga and *Varunadi kwath* in management of *Mutrashmari*.
- To evaluate the efficacy of *Shwandanshtradi* Yoga in management of *Mutrashmari*.
- To evaluate the efficacy of *Varunadi kwath* in management of *Mutrashmari*.

### Selection of the patients:

Patients with *Mutrashmari* were selected randomly from the O.P.D. / I.P.D. P.G Department of Shalya Tantra,. The study was conducted upon single group of 30 patients.

### Criteria for selection of patients:

#### (A) Inclusion criteria

Patients with stones present in any part of urinary system, Age between 15 - 65 yrs, Size of calculus - 1 to 10 mm.

#### (B) Exclusion criteria

Patients with impaired Renal function or other severe complications, Patients with immediate surgical requirement, Stone impacted in renal parenchyma.

### Criteria for diagnosis of *mutrashmari*

Patients were diagnosed on the basis of clinical features, physical examination, lab investigation findings and radiological evidences.

### Laboratory investigation

Routine hematological investigations like Hb%, CBC, ESR etc.

Biochemical investigation – Blood Urea, Serum Creatinine, Serum uric acid, Serum Calcium

Urine examination – Routine & Microscopic.

Plain X-ray abdomen for Kidney, Ureter and Bladder (KUB) region.

USG (Abdomen & Pelvis)

**Research Design** – Open randomized clinical trial. Total 30 patients were selected randomly and divided into 2 groups for a period of 90 days.

### Follow up:

After the completion of the therapy, patients were advised to visit O.P.D. at 15 days interval with follow up period of 1 month.

### Criteria for examination and assessment:

Assessment was done on the basis of relief in signs and symptoms of urolithiasis. Other investigation findings (laboratory as well as radiological) on the basis of specially designed research proforma through scoring pattern.

### Subjective criteria:

Assessment of therapy was done according to the relief observed in the Signs and symptoms with the help of following scoring pattern.

### General Symptoms Score :

- Complete absence of the sign and symptoms - 0
- Mild degree of the signs and symptoms - 1
- Moderate degree of the signs and symptoms - 2
- Severe degree of the signs and symptoms - 3

The details of the scores adopted for the chief signs & symptoms (before & after treatment) in the present study as follows -

1. Pain

2. Tenderness at Renal Angle
3. Burning micturition
4. Hematuria: On the basis of microscopic urine analysis
5. Pus Cells: On the basis of microscopic urine analysis

**Objective parameters:**

1. Size of stone
2. Number of stone

**Criteria for overall assessment of therapy :**

- Cured – 76% to 100%
- Complete relief in subjective parameters.
- Removal of stone in urinary tract with radiological evidence.
- Markedly Improved – 51% to 75%
- Mild Improvement – 26% to 50%
- No Improvement – Up to 25%

**Observations:**

In this study 30 patients were registered and completed the treatment, divided into 2 group. Following observations were made during the study.

1. Clinical study showed that age group of 26- 35years (40%) were more prone to *Ashmari*.
2. Males (60%) were more prone to *Ashmari* than females.
3. Marital status, religion and educational status showed no relation with *Ashmari*
4. Regarding occupation, majority of patients were in service and labour class (33.33%) and house wives (26.66%).
5. Middle class people were more prone to *Ashmari*, may be due to stressful life style and irregular dietary habits.
6. Peoples of *sadharan Desha* were more prone to *Ashmari*, probably due to climatic condition and more mineral content present in the water of this region.

7. Mixed diet patients (76.66%) were more prone to *Ashmari*, may be due to production of *ama* which vitiates the *doshas*.

8. Pain (80%), tenderness (86.66%), burning micturition (73.33%), were important symptoms of *Ashmari* found in this study.

## Discussion

*Sushruta* gives importance to *Shleshma* in all the three types of *doshaj Ashmari*; similarly modern medicine also mentioned that the urinary calculi consist of aggregates of crystals which are bounded by small amount of proteins and glycoproteins (*shleshma*) to make the stone indissoluble. So the basic cause of *Ashmari* is aggregation of *kapha- pradhanadoshas* in *mutravaha srotasa* due to *agnimandya* and *ama* formation, which is caused by different *nidana sevana*. The ingredients of the trial formulations are easily available and cost effective.

### Effect of therapy on stones at different site and size:

Statistically overall effect of *Shwandanshtradi* Yoga and *Varunadi kwath* in stone is highly significant ( $p < .001$ ). Effect on size 0-5mm is highly significant, 6-10 mm was not significant.

When comparison was drawn between Group A and Group B, Group B was found to be more effective in symptoms of *Hematuria*, *Size of Stone* respectively. But these differences were found to be insignificant. Both groups were equally effective on providing relief from burning Micturition,. Group A intervention was more effective in relieving Pain.

In the present study, in Group-A stones of less than 5 mm size were 52.17% expelled, 30.44% stone were decreased in size, no change was observed in 17.39%. whereas none of the stone were increased in size.

In the present study, in Group-B stones of less than 5 mm size were 62.17% expelled, 23.83% stone were decreased in size, no change was observed in 14% stone whereas none of the stone were increased in size.

Hence after the result we can say that Group-B *Varunadi Kwath* is having good effect on stones of size less than 5mm because of its *Vata- anuloman*, *Mutral*, *Ashmari bhedak* properties than *Shwandanshtradi* Yoga. While on Stone size >6mm Result of both group was insignificant.

**Presentation of data:**

The data gathered and compiled from this clinical trial was sorted and processed further by subsection to varied statistical methods and presented in following sequence.

- Results of therapy evaluated on the basis of improvement in sign and symptoms along using paired' test.
- Comparative effect of two drugs evaluated by applying statistical techniques via unpaired' test.

**Effect on of Subjective and Objective Criteria Group A- :****Table no. 1**

Subjective and Objective Criteria	Mean Score		$\bar{X}$	%	SD	SE	T	P
	BT	AT						
Pain	2.33	0.083	2.25	96.42	0.753	0.217	10.34	<0.001
Burning Micturition	2.25	0.25	2	88.88	0.852	0.246	8.124	<0.001
Hematuria	1.833	0.5	1.33	72.27	0.816	0.333	4	<0.02
Size of Stone	1.714	0.714	1	58.33	0.8165	0.3086	3.240	<0.02

As shown by the table, 96.42% relief was observed in Pain followed by 88.88% relief in *Burning Sensation*. 72.27% change was observed in *Hematuria*. There was 58.33% relief in *Size of Stone*.

**Effect on Subjective and Objective Criteria of Group B- :****Table no 2**

Subjective and Objective Criteria	Mean Score		$\bar{X}$	%	SD	SE	T	P
	BT	AT						
Pain	2.2308	0.4615	1.7692	79.31	0.725	0.2011	8.798	<0.001

Burning Micturition	1.833	0.25	1.5833	86.36	0.793	0.2289	6.917	<0.001
Hematuria	1.6666	0.333	1.333	80	0.866	0.288	4.618	<0.01
Size of Stone	1.7778	0.6667	1.111	62.5	0.6009	0.2003	5.547	<0.001

As shown by the table, 79.31% relief was observed in Pain followed by 86.36% relief in *Burning Sensation*. 80% change was observed in *Hematuria*. There was 62.5 % relief in *Size of Stone*.

### Comparison between group A and group B

Table: 3

Subjective and Objective Criteria	Mean ± SD		% RELIEF		Df =N1 + N2- 2	Unpaired t test	p value	Pvalue
	Group A	Group B	Gr. A	Gr. B				
Pain	2.25±0.753	1.7692±0.725	96.42	79.31	23	1.596	0.1241	>0.05
Burning Micturition	2±0.852	1.58±0.793	88.88	86.36	22	1.250	0.2244	>0.05
Hematuria	1.33±0.816	1.333±0.866	72.27	80	13	0.6036	0.5565	>0.05
Size of Stone	1±0.8165	1.11±0.6009	58.33	62.5	14	0.7819	0.4473	>0.05

When comparison was drawn between Group A and Group B, Group B was found to be more effective in symptoms of hematuria, size of stone respectively. But these differences were found to be insignificant. Both groups were equally effective on providing relief from burning micturition, Group A intervention was more effective in relieving Pain.

**Table NO. 4 Effect of therapy on number and size of stone in group -A**

Stone size	Expelled out	Decrease in size	No change	Increase in size
1-5 mm	52.17%	30.44%	17.39%	00
6-10mm	27.27%	31.81%	18.18%	22.72%

Table indicate that expulsion of stones was found better 52.17% in small sized stone and expulsion rate was not good where stone size more than 6 mm.

**Table no. 5 Effect of therapy on number and size of stone in group -b**

Stone size	Expelled out	Decrease in size	No change	Increase in size
1-5 mm	62.17%	23.83%	14%	00
6-10mm	29.02%	36.38%	24%	10.60%

Table indicate that expulsion of stones was found better in small sized stone 62.17% and expulsion rate was not good where stone size more than 6 mm.

### Summary and conclusion

Conclusions & Summary have been drawn on the basis of discussion.

Highly significant ( $p < 0.01$  or  $< 0.001$ ) results were observed in pain, burning micturition.

Statistically overall effect of *Shwandanshtradi Yoga* and *Varunadi kwath* in stone is highly significant ( $p < .001$ ). Effect on size 0-5mm is highly significant; 6-10 mm was not significant.



When comparison was drawn between Group A and Group B, Group B was found to be more effective in symptoms of hematuria, size of stone respectively. But these differences were found to be insignificant. Both groups were equally effective on providing relief from burning Micturition, Group A intervention was more effective in relieving Pain.

In the present study, in Group-A stones of less than 5 mm size were 52.17% expelled, 30.44% stone were decreased in size, no change was observed in 17.39%. whereas none of the stone were increased in size.

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Hence after the result we can say that Group-B *Varunadi Kwath* is having good effect on stones of size less than 5mm because of its *vata-anuloman, mutral, ashmari bhedak* properties than *Shwandanshtradi Yoga*. While on Stone size >6mm Result was insignificant.

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