World Journal of Pharmaceutical Sciences ISSN (Print): 2321-3310; ISSN (Online): 2321-3086 Published by Atom and Cell Publishers © All Rights Reserved Available online at: http://www.wjpsonline.org/ Original Article



A Clinical Comparative Study of Vrikkashoolantaka Vati and Pashanbheda Kwatha Churna W.S.R to Mutrashamri

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Received: 31-08-2015 / Revised: 19-09-2015 / Accepted: 25-09-2015

ABSTRACT

In Ayurveda Ashmari is mainly considered as Mutrashmari (Urolithiasis) which is emerging as a sequel to deranged mutra pravritti leading to deterioration in urine excretion and micturition. The urinary stones have peculiar tendency of recurrence despite of their surgical removal which prove that surgery only cannot become effective part of treatment. To avoid the incidence of recurrence after surgical removal of stone and in search of an effective conservative treatment comparative work on Vrikkashoolantaka Vati and pashanbheda kwatha churna has been taken. The project has been designed for study by open labeled clinical comparative trial. The effect of therapy was observed by improvement in the clinical and laboratory features selected under criteria for assessment. The effects of the trial drugs Vrikkashoolantaka Vati and Pashanbheda Kwatha churna in was evaluated and compared. Study shows vrikkashoolantaka vati has more significant result over Pashanbheda kwatha churna in Mutrashmari.

Key Words- Mutrashmari, Urolithiasis, Vrikkashoolantaka vati, Pashanbheda kwatha churna

INTRODUCTION

Mutrashmari is known to mankind since ancient. Clinical features of the disease are described even in Vedas. Acharya Sushruta explained urinary calculus under the heading of Ashmari in details including etiological factors, classification, symptomatology, pathology, complications and its management in a most scientific manner. Acharya Sushruta included it in the "AshtaMahagada" i.e. one of the grave diseases ^[1] may be owing to its potentiality to disturb the anatomy and physiology of urinary system. Acharya Charaka has advised medical management and Acharya Sushruta advised both conservative and surgical removal of stone.

अक्रियायां ध्रुवों मृत्यु क्रियायां संशयो भवेत।^[2]

The urinary stone have peculiar tendency of recurrence despite of their surgical removal. To avoid the incidence of recurrence after surgical removal of stone and in search of an effective conservative treatment the present work has been chosen. **Selection of Problem:** The urolithiasis is considered as one of the leading problem of urology^[3]. The cause of stone formation is not yet fully understood, but in majority of the cases multiple factors are involved. Further exploration and extensive research in the field of urolithiasis is the need of hour. *Mutrashmari* leads to urinary tract infection and other complications like hydronephrosis, hydroureter, pyonephrosis, renal failure etc. and subsequent damage to the renal architecture which is often irreversible. Even after surgery, the recurrence rate is as high as 60% to 80% (Williams 1963).

AIMS AND OBJECTIVES

- 1) To conduct a conceptual and clinical study on *Mutrashmari w.s.r. to* Urolithiasis.
- 2) To study the effect of *Vrikkashoolantaka vati* in the management of *Mutrashmari*.
- 3) To study the effect of *Pashanbheda Kwatha Churna* in the management of *Mutrashmari*.

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To compare the effect of *Vrikkashoolantaka* 4) vati and Pashanbheda Kwatha Churna on Mutrashmari.

MATERIALS AND METHODS

A special history proforma was prepared on the basis of signs and symptoms of Mutrashmari and urolithiasis described in Ayurvedic and modern text respectively.

Inclusion criteria

- i. Patients of either sex, age 18-70 years.
- ii. Single or Multiple calculi having size ≤ 15 mm each in any part of urinary system.
- iii. Patients who are not interested to undergo for surgery and those who are unfit for surgical intervention.

Exclusion criteria

Pain

No pain

- i. Patients with known metabolic/endocrinal disorder favoring calculus formation.
- ii. Patients with impaired renal function or any severe complication.
- iii. Patients with evidence of malignancy.
- iv. Patients with poorly controlled diabetes mellitus.
- v. Patients with known serious hepatic disorders, severe pulmonary dysfunction.

Study design- Randomized, single center, open label, clinical trial Sampling Technique:

Total 60 patients with signs and symptoms of Mutrashmari were registered and randomly (by lottery method) divided into two groups viz.

- Group A: Vrikkashoolantaka vati-30 patients
- Group B: Pashanbheda Kwatha Churna –

30 patients **Drug Administrations:**

Group A: In this group patients were treated with

Vrikkashoolantaka vati Vrikkashoolantaka Vati^[4]-:

Dose- Two tablet (500mg) twice daily orally with water, for 1 month

Group B: In this group patients were treated with Pashanbheda Kwatha Churna

Pashanbheda Kwatha Churna^[5] -: Dose: 40 ml (25 gm) twice daily Orally, for 1 month

In both the groups all the patients were instructed to follow their normal dietetics and to maintain regular intervals in between the two meals. All the patients were advised to give up all the diets which are directly or indirectly contributory to the formation of stone. All the patients were instructed to take plenty of water.

CRITERIA FOR ASSESSMENT SUBJECTIVE CRITERIA:

- 0

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

*	Occasional pain did not require treatment	- 1	
*	Occasional pain but, required treatment	- 2	
*	Constant dull ache pain, required treatment	- 3	
*	Severe constant pain, but did not show relief even after treatment	- 4	
Burnin	g Micturition:		
*	No burning micturition		- 0
*	Occasional burning micturition		- 1
*	Occasional burning micturition, required treatment		- 2
*	Constant burning micturition required treatment		- 3
*	Constant severe burning micturition did'nt show relief even after treat	ment	-4
Dysuria	a:		
*	No dysuria	- 0	
*	Occasional dysuria	- 1	
*	Occasional dysuria which require treatment	- 2	
*	Constant dysuria which require treatment	- 3	
*	Constant severe dysuria but did not show relief even after treatment	- 4	
Tender	ness in Renal Angle:		
*	No tenderness	- 0	
*	Mild tenderness	- 1	
*	Moderate tenderness	- 2	
*	Severe tenderness	- 3	
*	Acute tenderness	- 4	

Hematuria: On the basis of microscopic urine analysis

- ✤ No RBC/Hpf
- 0-5 RBC/Hpf
- ✤ 6 10 RBC/Hpf
- ✤ 11 15 RBC/Hpf
- ✤ >16 RBC/Hpf

Pus cells: On the basis of microscopic urine analysis

- No pus cells/Hpf
- 0-5 pus cells/Hpf
- 6 10 pus cells/Hpf
- 11 15 pus cells/Hpf
- ✤ >16 pus cells/Hpf

Objective Criteria: Based on various investigations like urine, biochemical examination, x-ray (KUB), USG (KUB), done before and after treatment. The statistical analysis was done of these score before starting the treatment and after completion of 30 days course.

CRITERIA FOR TOTAL EFFECT OF THERAPY

For the assessment of the total effect of the therapy following four categories were taken into considerations.

Cured – 76% to 100%

- Complete relief in subjective signs and symptoms.
- Absence of any calculus in urinary tract with radiological evidence.

Markedly Improved – 51% to 75%

- 0

- 1

- 2

- 3

- 4

- Relief in subjective signs and symptoms
- Downward movement or partial disintegration of *Mutrashmari* with radiological evidence.

Improved – 26% to 50%

- 0

- 1

- 2

- 3

- 4

- Relief in signs and symptoms
- Without any change in size of stone confirmed with radiological evidence.

Unchanged – Up to 25%

- Relief in subjective sign and symptoms.
- Without any change in size of stone confirmed with radiological evidence.

General Observations: In the present clinical study total 60 patients were registered which were divided into two groups.

	No. of patients		Total	
	Group A	Group B		
Registered	30	30	60	
Completed	26	28	54	
LAMA	04	02	06	

Nidana Sevana wise distribution of 60 pts. of Mutrashmari: On considering the data of Nidana in the present series, it was observed that 98.33% were Asamshodhanasheela, followed by 96.66% having Apathya Sevana, 80.00% having Divaswapna 73.33% had Guru Ahara, 71.66% had Madhura Ahara, 56.66% had Snigdha Ahara, 53.33% had Sheeta Ahara, 48.66% each had Adhyashana and Tikshnaushna Ahara, 45.00% had Mamsa Sevana, 38.33% had Madya Sevana and Mutra Avarodhana 35.00% had Ajirna Sevana, , 30.00% of patients were found having Samashana, 28.33% had Ati Vyayama Nidana Sevana and 08.33% had Matsya Sevana.

Chief complaints wise distribution of 60 pts. of Mutrashmari: On considering the clinical presentation of the patients 91.66% were with Pain (Nabhi & Basti Vedana) 80.00% patients were having burning micturition, 66.66%, 35.00% 31.66%, and 30.00% patients were having dysuria, pyuria, Haematuria, and tenderness at renal angel respectively. This manifestation of symptoms indicates the stage at which the patients approached for treatment. Pain, burning micturition, dysuria being a common symptom manifesting early in the course of illness and Sarudhiramutrata (Haematuria) and pyuria etc. indicate the more advanced stage.

Size of stone wise distribution of 82 stones in the 54 patients of *Mutrashmari:* It is evident from the above table that maximum i.e. 63.41 % stones of 5 to 10 mm in size while 21.95 stones were less than 5 mm stone in size and only 14.63% stones of above 10 mm.

Site of stone wise distribution of 82 stones in the 54 patients of *Mutrashmari:* On considering the site of stone, it was found that maximum i.e. 81.66% patients were having stone in kidney, 11.66% patients had stones at VU junction, 06.66% patients had ureteric stones, while not a single patient had stone in bladder

Number of stone wise distribution of 54 patients of *Mutrashmari:* It is clear from table that maximum number of patients i.e. 79.62% had single stone while remaining 20.37% patients had multiple stone.

Radiological appearance of stones: In the present study radiological character of stone showed 80.48% were opaque followed by 14.63% were

very opaque and remaining were dull appearance in character.

Variety of stone wise distribution of 82 stones in 54 patients of *Mutrashmari:* It is evident from the above table that maximum 71.66% patients had *Vataja* type of *Ashmari*, while 20.00% each patients were found having *Kaphaja* and only 08.33% *Pittaja* type of *Ashmari*.

Effect of therapy in subjective Parameters: In the present study, 60 patients were registered in two groups each having 30 patients out of which 26 patients in first group and 28 patients in second group completed the full course of the treatment. They were categorized into two groups and studied as follows.

 Table No. OR- 1: Showing effect of Therapy in Subjective Parameters.

 (Wilcoxon matched paired single ranked test)

(whether parted single ranked test)									
	~	Mean		MeanD	%				~
Variable	Gr.	BT	AT	iff.	Relief	SD±	SE±	Р	S
Pain (Nabhi &	Gr. A	1.84	0.57	1.26	68.47	0.7776	0.1525	< 0.0001	ES
Basti Vedana)	Gr.B	1.70	1.04	0.66	38.82	0.5647	0.1153	< 0.0001	ES
Burning	Gr.A	1.76	0.76	1.0	56.81	0.8367	0.1826	< 0.0001	ES
Micturation	Gr.B	1.63	0.86	0.77	47.23	0.6119	0.1305	< 0.0001	ES
Dysuria (Mutradhara	Gr.A	1.66	1.02	0.61	36.74	0.5016	0.1182	0.0010	ES
Sanga)	Gr.B	1.81	1.18	0.625	34.53	0.6191	0.1548	0.0039	VS
Tenderness at renal angle	Gr.A	1.63	0.50	1.12	68.71	0.6409	0.2266	0.0156	S
renal angle (Sevani Vedana)	Gr.B	1.70	0.7	1.00	58.82	0.8165	0.2582	0.0156	S
Haematuria	Gr.A	1.72	0.36	1.36	79.06	0.8090	0.2439	0.0020	VS
(Sarudhira Mutrata)	Gr.B	2.00	0.42	1.57	78.5	0.7868	0.2974	0.0313	S
Pyuria (Ati	Gr.A	1.83	0.41	1.41	77.04	0.6686	0.1930	0.0010	ES
avilamutrata & gomed Prakash)	Gr.B	1.77	0.66	1.11	62.71	0.6009	0.2003	0.0078	VS

(Gr.:Group, BT:Before treatment, AT: After treatment, Diff.: Difference, SD : Standard Deviation, SE: Standard Error, P: P value, S :Significance level, VS: Very Significant ES: Extremely Significant)

In Group A, extremely significant results regarding subjective parameters - Pain (Nabhi & Basti Micturation, Vedana), Burning Dysuria (Mutradhara Sanga), Pyuria (Ati avilamutrata & gomed Prakash) with % relief of 68.47%, 56.81%, 36.74%, 77.04% respectively. In case of other subjective parameters i.e. Haematuria (SarudhiraMutrata) there was very significant result with % relief of 79.06% and Tenderness at renal angle (SevaniVedana) there significant results with % relief of 68.71%.

In Group B, extremely significant results regarding subjective parameters – Pain (Nabhi & Basti Vedana), Burning Micturition, with % relief of 38.82%, 47.23% respectively. In case of other subjective parameters i.e. Dysuria (Mutradhara Sanga), Pyuria (Ati avilamutrata & gomed Prakash) there were very significant result with % relief of 34.53% 62.71% and Tenderness at renal angle (SevaniVedana), Haematuria (SarudhiraMutrata) there were significant results with % relief of 58.82% 78.5% respectively.

Variable	Groups	(AT) Mean	SD±	SE±	Р	S
Pain (Nabhi & Basti Vedana)	А	1.231	0.8152	0.1599	0.0102	S
	В	0.6667	0.5647	0.1153	0.0103	
Burning Micturation	А	1.095	0.8309	0.6396	0.3772	NS
-	В	0.863	0.6396	0.1364		
Dysuria (Mutradhara Sanga)	А	0.6111	0.6077	0.1432	0.0101	NS
	В	0.6875	0.7042	0.1760	0.8181	
Tenderness at renal angle	А	1.125	0.6409	0.2266	0.7710	NS
(SevaniVedana)	В	1.000	0.8165	0.2582	0.7719	
Haematuria	А	1.273	0.9045	0.2727	0.2209	NG
(SarudhiraMutrata)	В	1.714	0.4880	0.1844	0.2208	NS
Pyuria (Ati avilamutrata &	А	1.500	0.5222	0.1508	0 1527	NG
gomed prakash	В	1.111	0.6009	0.2003	0.1537	NS

Deshmukh *et al.*, World J Pharm Sci 2015; 3(10): 2035-2041 Table No OR- 2: Intergroup Comparison of Group A & Group B for Subjective Parameters: (Mann-Whitney Test)

(AT: After treatment, SD: Standard deviation, SE: Standard Error, P: P Value, S: Significance level, S: Significant, NS: Non Significant)

Intergroup comparison shows that there is no major difference in efficacy of trial drug of Group A & B. But, in Pain (*Nabhi & Basti Vedana*) The P < 0.05 which is statistically significant which shows that

vrikkashoolantaka vati has statistically better result than pashanbheda kwatha churna on Pain (*Nabhi & Basti Vedana*).

Table-3: Effect of therapy on stone	es at different site and size in both groups
ruble of Energy on Stone	b ut uniter ent site una size in both groups

Size	Site	No. of patients					
(diameter)		Group A	Effect	Group B	Effect		
	Kidney	03	Exp2, DS1	09	Exp.3, DS5 No.change-1		
<0.5 cm	Ureter	01	Exp 1	2	Exp-2		
	Bladder		—	—			
	VUJ	2	Exp 1	01	Exp1		
. 0.5	Kidney	32	Exp12, DS-17 No change-03	28	Exp6, DS- 14 No change- 8		
>0.5 cm.	Ureter	-	-	-	-		
	Bladder	-	-	-	-		
	VUJ	03	Exp3	03	Exp3		

Key of observations -

Exp.: Expelled **DS:** Decrease in size

It has been observed in Group A (*Vrikkashoolantaka Vati*) that total 41 stones (three <0.5 cm. & thirty two >0.5 cm.) were found in kidney, out of them 14 expelled out, 18 decreased in size and size of three stones remains unchanged after the completion of the therapy. However in 1 ureteric stones (<0.5 cm.), was expelled out. Out of 5 stones (2 of <5mm and 3 of >5mm) found at VUJ, all are expelled out.

In Group B (*Pashanbheda kwatha churna*), it has been observed that total 43 stones were found (9 stones of < 5mm. & 28 stones of >5 mm in size) in the kidney, out of them 9 kidney stones were expelled out, 19 got decrease in size and 9 remains unchanged. It has been observed 3 out of 3 stones found at VUJ were expelled out.

Table – 50. Over an Effect of therapy on 54 patients of Mutrushhurt							
Results	Group A		Group B				
Ксбинб	No. of pts.	% relief	No. of pts.	% relief			
Cured	16	61.53	13	46.42			
Markedly Improved	07	26.92	10	35.71			
Unchanged	03	11.53	05	17.85			

Deshmukh *et al.*, World J Pharm Sci 2015; 3(10): 2035-2041 Table – 36 : Overall Effect of therapy on 54 patients of *Mutrashmari*

The data of the present series reveals that in Group A (*Vrikkashoolantaka vati*) out of 26 patients, 16 patients (61.53%) were cured, 07 patients (26.92%) were markedly improved and 03 patients (11.53%) were observed unchanged.

In Group B (*Pashanbheda Kwatha churna*), out of 28 patient, 13 patients (46.42%) were cured, 10 patients (35.71%) markedly improved and 05 patients (17.85%) were found unchanged.

DISCUSSION

This trial has shown very good effect on every subjective criteria of mutrashamri.

In Group A, extremely significant results regarding subjective parameters – Pain (*Nabhi & Basti Vedana*), Burning Micturation, Dysuria (*Mutradhara Sanga*), Pyuria (*Ati avilamutrata & gomed Prakash*). In case of other subjective parameters i.e. Haematuria (*SarudhiraMutrata*) there was very significant result and Tenderness at renal angle (*SevaniVedana*) there significant results.

In Group B, extremely significant results regarding subjective parameters - Pain (Nabhi & Basti Vedana), Burning Micturition. In case of other subjective parameters i.e. Dysuria (Mutradhara Sanga), Pyuria (Ati avilamutrata & gomed *Prakash*) there were very significant and Tenderness at renal angle (SevaniVedana), Haematuria (SarudhiraMutrata) there were significant results.

Discussion on Probable Mode of Action of Vrikkashoolantaka vati: Ingredients in the Vrikkashoolantaka vati are Hingu, Akarkarkara, Tankana, Yavakshar, Sajjikshar, Nausadar, Saindhav Lavan, Piprament and ghritkumari swaras in Saman matra^[6]. In this combination, many of the drugs possesses Katu, Tikta dominant Rasa and Laghu, Ruksha Guna which having the property of deepana and pachan thus help in digestion of Ama. This vati has Kaphaghna property which is the main *dosha* in pathogenesis of Ashmari. This formulation is also dominantly has Ushna virya which also helps to pacify the Vata-kapha Dosha. Hingu^[7] and Akarkara^[8] has shoolaghna property and thus overall formulation Vedana Sthapana, has Vatanulomana, Shoolaprashamana, Bhedana, Mutrala, Mutra

Virecaniya Deepana, Pachana property. The Vatanulomana, Shothahara and Mutrala properties of ingredients helps to relieve pain and Sthanika Sotha, Deepana property of drugs helps to increase the Agni, which further check the formation of Ama at Jatharagni level itself. Pachana property of ingredients helps in assimilation of drugs in the body in case of Jatharagnimandya. Stone might be dissolved due to the Ashmari Bhedana or Ashmarihara property of ingredients present in both the drugs. 4 types of kshara is having Lekhana, Bhedana, Pachana, Shodhana and Tridoshaghna properties.^[9] Intergroup comparison shows that there is no major difference in efficacy of trial drug of Group A & B. But, in Pain (Nabhi & Basti Vedana) it is statistically significant difference in group A and B which shows that vrikkashoolantaka vati has statistically better result than pashanbheda kwatha churna on Pain (Nabhi & Basti Vedana).

Discussion on Probable Mode of Action of *Pashanbheda Kwatha Churna*: *Pashanbheda* is having *Kashaya tikta rasa, laghu, snigdha, tikshna guna, katu vipaka, shita virya* and *ashmarighna, bhedana, bastishodhan* and *mutra-virechaniya* properties and Chemical composition is Tannic acid, gallic acid, starch, Co-oxalate, glucose which has Antiprotozoal, anti-cancer, lithotryptic, cardiotoxic, CNS depressant, anti-inflammatory, diuretic properties. Due to all these functions *pashanbheda* is very good *ashmarighna* drug^[10].

Conclusion

Mutrashmari is Tridoshaja Vyadhi of mutravaha strotas in which there is predominance of Kapha dosha. It can be concluded that indicated hypofunctioning of Agni otherwise termed as Mandagni is largely responsible for the formation of Ama, which vitiate the Kapha dosha which is the chief pathogenic factor of the disease. Majority of the stone were found in kidney, so it can be said kidney is more prone to Ashmari formation. Majority of patients were having single stone. Maximum no of patients were having Vataja Ashmari. Finally, comparing the effect of two therapies it can be concluded that Group A (Vrikkashoolantaka Vati) provided better relief cure rate than Group B (Pashanbheda Kwatha Churna) in most of the sign, symptom of the disease as well as in expulsion of stone at significant level. It also considerably prevents the relapse.

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