

A Randomized Controlled Trial to Evaluate the Lithotriptic Action of Mutrala Kashaya in Mootraashmari W.S.R. Urinary Calculi

Salma H.*, Santosh Y.M.**

Abstract

Urinary calculi is one of the commonest diseases of urinary tract. The male- female ratio 3:1. 12% of population have renal calculi in their life time. *Mutrala kashaya* is propraetary formulation includes 8 drugs & has been pre clinically evaluated as a diuretic & lithotropic activity on wistar rats which showed diuretic activity by increasing urine output by restoring the electrolytes Evaluation of diuretic And lithotropic Activity of Mutrala Kashaya In Wistar Rats therefore a study was planned to evaluate the *mutrala kashaya* in comparison with *varunadi kashaya* was undertaken for clinical trial in *Mutraashmari*. The objective of the present study was to evaluate the efficacy of *mutrala kashaya* as lithotriptic action w.s.r. urinary calculi ingredients *Ushira, Gokshura, Kushmanda, Punarnava, Dhanyaka, Varuna, Kullatha, and Pashanabheda* 20-60 years Age group patients Total 30 patients were selected for the clinical study, were randomly divided in two equal and identical groups consisting of 15 patients in each group by using computerized block randomization table. The patients of group 'A' and 'B' were given *varunadi kashaya* and *Mutrala Kashaya* 25 ml BD for 45 days were given on 0th, 15th, 30th & 45th day each follow up assessment were done in both the groups. As per the pre and post test was showned significant relief in renal colicky pain, burning micturition, with in physiological range in urinary pH level and reduction in calculi size.

Keywords: *Varunadi Kashaya; Mutrala Kashaya; Mutraashmari; Urinary Calculi.*

Introduction

Urinary stone has become a burning problem in the era of the modern medicine because of its high recurrence rate even after best available treatment. In India approximately 5-7 million patients suffer from kidney stone disease [1,2] among 1/1000 of Indian population needs hospitalization due to kidney stone disease. Among them 12% of population have renal calculi in their life time [3]. The incidence of calculi varies as per geographical distribution, sex and age group. The recurrence rate is 50 to 80%. The incidence of Peak age is 3rd to 5th decade, majority of patients report regarding onset of disease in second decade of

life. [4] *Ashmari* one among the *Astamahagada* formed in the urinary system. *Basti* is the *Saddyā pranahara marma* So, *Marma* treatment is essential otherwise patient will die at last. [5]

The formation of urinary calculi at any level of urinary tract, clinically it is characterized by colicky pain as they pass down along the ureter and manifest by haematuria [6]. The method of management of urinary calculi are mainly surgical. Even though they are useful, they involve considerable amount of risk and are also expensive. The recurrence after surgery is also high up to 50% in the light of above situation, it is highly relevant to search for an alternative treatment which is both effective and inexpensive. So many single drugs among these ganas have been scientifically proved pre clinically and clinically as diuretic, lithotropic, anti-inflammatory, antispasmodic and antimicrobial [7] Among them the *Mutrala kashaya* is preparatory formulation which includes 8 drugs like *Punarnava (Boerhavia diffusa Linn)*, *gokshura (Tribulus terrestris Linn)*, *pashanabeda (Bergenia ligulata Wall)*, *varuna (Crateva nuroala Buch-Ham)*, *dhanyaka (Coriandrum sativum Linn)*, *ushira (Vetivera zizanoids Linn)*, *kushmanda (Benincasa hispida*

Author Affiliation: *PG Scholar **Reader, Dept. Of shalya Tantra, KLEU Shri B M Kankanwadi Ayurved Mahavidyalaya, PG Studies and Research Center, Belagavi, Karnataka 590005, India.

Reprint Request: Santosh Y.M., Shri B M Kankanwadi Ayurved Mahavidyalaya, PG Studies and Research Center, Belagavi, Karnataka 590005, India.
E-mail: drmysantosh@gmail.com

Received on 25.07.2017, Accepted on 30.08.2017

Thunb), *kulatha* (*Vigna unguiculata* Linn).

Aims and Objective

To evaluate the efficacy of Mutrala kashaya as lithotriptic action W.S.R. Urinary Calculi.

Materials and Methodology

In the present research work, an ayurvedic proprietary formulation Mutrala kashaya is used in management in Mutrashmari to assess the lithotriptic action. All ingredients were procured from GMP certified Ayurvedic pharmacy. KLEU'S BMK Ayurveda Mahavidyalaya with following reference number RefNo- KLE / AP/164/2016-1.

Collection and Authentication of Raw Drugs

Raw drugs required for the preparation of *Mutrala Kashaya* were procured from GMP certified KLE Ayurveda pharmacy, khasbag, Belagavi. All the raw drugs were authenticated from the Central Research Faculty of KLEU's Shri. B.M.K. Ayurveda mahavidhyalay, Shahapur, Belagavi.

Inclusion Criteria

- Patients with the chief complaints of pain (KUB-area).
- With a diagnosis of *moothrashmari* ultrasonographically calculi measuring 1- 10mm.
- With a normal renal profile (serum blood urea, serum creatinine).
- Calculi anywhere in KUB

Exclusion Criteria

- >10mm urinary calculi.
- Patient suffering from sever hydronephrosis

Assessment Criteria

The results were evaluated by subjective parameters, mainly based on clinical observation before and after treatment by grading.

Subjective Parameters

1. Pain (Assessed by VDS) [8]

Gradings for the Assesment Criteria

1. *Vedana (Pain)*: As the patient or the sufferer himself expresses the pain in his terms it was graded from mild to worst unbearable pain No pain, Mild pain, Modrate pain (discomfoting), Sever pain (Distressing), Very sever pain (Horrible) and Worst unbearable pain (Excruciating pain) 0 , 1-2, 3-4, 5-6, 7-8, 9 -10 Grading were given respectively.

2. Burning Micturation

No burning micturition -0, Occasional burning micturition-1, Occasional burning micturition, required treatment -2, Constant burning micturition required treatment-3. Constant severe burning micturition but did not show relief even after treatment-4.

Objective Criteria

1. Size of stone : Assessed in Millimetres

Investigations

1. Size of stone : Assessed in Millimetres USG- KUB.
2. Renal profile.
3. Urine pH

Duration: Treatment was given up to 45 days

Follow up Study: Follow up of patients was done upto i.e., 15th day, 30th day and 45th day. to assess the effect of treatment.

Statistics Analysis: Wilcoxon signed rank test , Man whitney U test Unpaired t test , paired t test.

Observations & Results

30 subjects of Mutrashmari were selected for this clinical trial. They were randomly divided into two groups i.e. Group A and Group B. Group A was treated with Varunadi kashaya and Group B was treated with Mutrala kashaya .

General & specific location wise calculi distribution in group A and B see Table 1

Number of Calculi: See Table 2.

Effect of therapy on expulsion, change in size, Change in location & No change in size: Group A wise calculi distribution 41.37% were changed in size, 27.58% were expulsion of calculi, 20.68% no change in size, remaining 10.34% were changed in location.

Group B wise calculi distribution 15(51.72%) were changed in size, 11(37.93 %)were expulsion of calculi, 3(10.33%) calculi were changed in location. See Table 3.

Table 1: General and specific location wise calculi distribution in group A and B

Location Group B	No of calculi BT	%	No of calculi AT	%
General location				
Rt kidney	13	44.82	8	44.44
Left kidney	15	51.72	8	44.44
UVJlf	1	3.44	2	11.11
Total	29		18	
Specific location				
Upper	12	41.37	3	16.66
Middle calyces	9	31.03	9	50
Lower calyces	7	24.13	4	22.22
UV J lf	1	3.44	2	11.11
Total	29		18	

Location Group A	No of calculi BT	%	No of calculi AT	%
General location				
Rt kidney	14	48.27	9	42.85
Left kidney	14	48.27	12	57.14
UVJlf	1	3.44	0	0
Total	0	0	0	0
Specific location				
Upper	12	41.37	3	14.28
Middle calyces	7	24.13	10	47.61
Lower calyces	9	31.03	8	38.09
UV J lf	1	3.44	0	0
Total	29		21	

Table 2: Showing the no. of calculi in Group A & B before & after treatment

	Group A			
	No of stones BT	%	No of stone AT	%
< 4mm	8	27.58	11	52.88
4-6mm	19	65.51	10	47.61
>6mm	2	6.89	0	0
Total	29		21	

	Group B			
	No of stones BT	%	No of stone AT	%
Below 4mm	6	20.68	4	22.22
4-6mm	20	68.96	13	72.22
>6mm	3	10.34	1	5.55
Total	29		18	

Table 3: Effect of therapy wise distribution on Calculi in group A & B

Effect of Therapy	No of Calculi Group B	%	No of Calculi Group A	%
Expulsion	11	37.93	8	27.58
Change in size	15	51.72	12	41.37
Change in location	3	10.33	3	10.344
No change in size	0	0	6	20.68

Table 4: Effect of mutrala kashaya and varunadi kashaya on pain Pain between the groups (Man whitney U test)

Variables (Pain)	Groups	Mean	SD	P Value	Significance
Baseline	Group A(BT-AT)	1.333	0.8997	0.5694	NS
	Group B(BT-AT)	1.2	0.7746		
30 days	Group A (BT-F1)	2.133	1.302	0.6480	NS
	Group B (BT-F1)	2.4	0.8281		
45 days	Group A (BT-F2)	2.133	1.302	0.2306	NS
	Group B(BT-F2)	2.733	0.7037		

Table 5: Burning Micturation between the Groups (Mann whitney U test)

Variables (BM)	Groups	Mean	SD	P Value	Significance
Baseline	Group A(BT-AT)	0.4	0.5071	0.2906	Ns
	Group B(BT-AT)	0.1333	0.5164		
30 days	Group A (BT-F1)	1.267	0.4577	0.0575	Ns
	Group B (BT-F1)	0.9333	0.2582		
45 days	Group A (BT-F2)	1.4	0.5071	0.0512	NS
	Group B(BT-F2)	1	0.378		

Effect on pain: see Table 4

Effect on Burning Micturation: see Table 5

Discussion

In this series of 30 patients of Mutrashmari. There will be more chances of vitiation of vata dosha plays important role for sthana samsraya of kapha in those persons leading to the formation of Ashmar. In this series maximum number of the patients i.e. 24 (80%) were *kati shoola* followed by *nabhi shoola* 5(16.66%) and remaining 1(3.33%) were *mutrakrichra*.

Atyavila mutrata, udara shoola, mutradhara sangha sarakta mutrata shows disease was having chroniy history. In this series maximum number of the patients i.e. 18(60%) was of single, followed by 4(13.33%) were number of three and four stones, 3(10%) two in number, and minimum was 1(3.33%) multiple i.e. > 4 stone were present. Calculi wise distribution 15(51.72%) were changed in size, 11(37.93%) were expulsion of calculi, 3(10.33%) calculi were changed in location. There is significant reduction of pain with in the group A and Group B. But in between the groups it is insignificant. It shows both the drugs are acting on the pain in same way. Pain is the *pratyatma lakshana* of *dushita vata*, on the contrary the most of the drugs in *mutrala kashaya* are having *snigdha guna* and *madhura vipaka*. Hence the pain reduction was seen.

Pain is also due to the obstruction of vata dosha by ashmari. The drugs and dosage form having *bastishodhaka* and *Mutra virajaneeya* property of subsides the vata and enhances the karma of Apana vata, hence relieves the pain with (p value 0.0009). There is significant reduction in both the groups, but non significant between the groups. By the action of Kshaya, Tikta and Madhura rasa of *mutrala kashaya* subsides the *kupita pitta*. Hence reduction of *mutradaha* seen with (p value of 0.0001). There were present of RBC in urine microscopy in group A & group B in 4 patient in each group. After the treatment there was no RBC's. It may be because of *kashaya*,

Tikta rasa which subsides *pitta*. With in the group A and Group B Significant reduction was shown but non significant between the groups. As the drugs of *Mutrala kashaya* is having *Kahsya* and *katu rasa* along with *madhura rasa*. To reduce the size of the stone, the *lekhana* property is required, it is taking care by *katu rasa* and *Kahsya rasa* by their *lekhana karma*, Hence reduction of calculi size with expulsion of calculi found significant with p value of 0.0003 which suggests its lithotriptic action.

5 patients i.e. 33.33% who had neutral pH of 7, followed by 7 patients 46.66% had pH of 6, 3 patients presented with pH which constituents acidic urine. Alkaline urine is more favorable for growing phosphate stone and acidic urine for uric acid stone. Hence maximum patients were of 7 i.e. 46.66% with pH of 6 which shows significant result with p value 0.0009.

Screening of Drugs on the basis of their Karma 70% of drugs are *Laghu*, *Ruksha guna* & *Medohara karma*. *Kapha vatahara dravya* 40% of *Madhura rasa* 40% of *kashaya rasa* does *Pitta hara* 40% of *Madhura rasa* 20% of *Laghu*, *snigdha guna* *Vata hara* 50% *Sheeta virya pitta hara* 50% *Ushna virya* *Kaphahara*. *Gokshura* -Alkaloid are proven to inhibit the nucleation and growth of calcium oxalate crystals but also has cyto protective role [9].

Aqueous extract of *Gokshura* showed that it has diuretic activity, which was slightly more than furosemide and showed the effect of potassium sparing. It has also showed to increase the tonicity of smooth muscles along with diuretic activity there by expels the stone from the urinary tract. Cardiac glycoside which is present in *kashaya*, will act on kidney and expel more urine.

Saponin glycoside will act as anti bacterial agent. Mannitol which is present in *dhanyaka* will act as an osmotic diuretic [10]. Many inorganic (e.g.: citrate magnesium) and organic (e.g. urinary prothrombin fragment 1, glycosaminoglycans, osteopontin) substance. So it may be by supporting these factors, *kashaya* might have reduced the size and symptoms of calculi.

Conclusion

Significant relief in Renal colicky pain, burning micturation, urinary pH level alteration and reduction in calculi size were similar in both the groups. Trial drug *Mutrala Kashaya* and control drug *Varunadi Kashaya* shown similar effect. However expulsion of calculi was more in *Mutrala Kashaya* group.

References

1. Norman S Williams. Bulstrode. Bailly & Love's short practice of Surgery. 71 Chapter 25th edition, Hodder Arnold publishers, London. 2010.
2. Townsend CM, Beauchamp D, Mattox KL. Sabiston Textbook of Surgery. 2010.
3. In editor. Sabiston Textbook of Surgery. Elsevier publications, Newdelhi. Indian journal of nephrology, 2009 July 19.p.107-111.
4. Dr. Gajanana Hegde – An observational study on the effect of narikela kusuma yoga in mutrashmari VIS urinary calculi 1999-2000.
5. Bera Pabitra Kumar et al Role of Varunadi Kvath along with Tab. Chandraprava and Tab. Gokshuradi Guggul in a case of Mutrashmari (Renal Stone).
6. Harshmohan, text book of pathology, 6th edition, jaypee publication New Delhi 2010.p.690.
7. Mukund sabins, chemistry & pharmacology of Ayurvedic medicinal plants, 1st edtn, Varanasi-chaukhamba amarabharati prakashan 2006.
8. Sushrutasamhita of Acharya sushruta, Nibandha-sangraha commentary by Sri Dalhanacharya Nyayachandrika panjika of sri Gayadasacharya on nidanasthana edited by Vaiyajadavji Trikamji Acharya, Chaukhambha orientalia Varanasi, Reprinted edition: 2009, Nidanasthana 3/7 Page no. 277.
9. Saurabh chatre et al, phytopharmacological overview of Tribulus terrestris
10. Dr. kishore K Evaluation of diuretic and lithotropic activity of mutrala kashaya in wistar rats in 2011

Special Note!

Please note that our all Customers, Advertisers, Authors, Editorial Board Members and Editor-in-chief are advised to pay any type of charges against Article Processing, Editorial Board Membership Fees, Postage & Handling Charges of author copy, Purchase of Subscription, Single issue Purchase and Advertisement in any Journal directly to Red Flower Publication Pvt. Ltd. Nobody is authorized to collect the payment on behalf of Red Flower Publication Pvt. Ltd. and company is not responsible of respective services ordered for.