Original Article

Management of *Mutrashmari* (urolithiasis) with *Palasha Kshara* and *Ashmarihara Kwatha*: An open-labelled placebo-controlled clinical trial

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Abstract

Background: *Mutrashmari* (urolithiasis), a pathological condition of the urinary system where aggregation of urinary crystalloids takes place anywhere in the urinary tract, i.e., from the kidney to urinary bladder showing male preponderance (male:female = 2:1) and now becoming medico-surgical as well as economical challenge for all health-care systems. **Aims:** The aim of this study is to evaluate the effect of *Palasha Kshara* (alkali) with *Ashmarihara Kwatha* (decoction) in the management of *Mutrashmari* (urolithiasis). **Materials and method:** Thirty-nine patients of *Mutrashmari* were selected and randomly allocated with a computerized randomized method into two groups. In trial group A (n = 20), capsule *Palasha Kshara* (*Mridu*), 500 mg three times a day after meal, and *Ashmarihara Kwatha* (decoction) (40 ml twice daily) were given orally after meals for 2 months. In placebo control group B (n = 19), placebo capsule (granulated wheat), was given in a dosage of 500 mg along with 3–4 l of water for 2 months. **Results:** Patients of *Palasha Kshara* and *Ashmarihara Kwatha* group showed better relief in chief complaints, i.e., pain and increased frequency of micturition as compared to the placebo group. Complete remission of symptoms of *Mutrashmari* was more in patients treated with *Palasha Kshara* with *Ashmarihara* decoction. **Conclusion:** *Palasha Kshara* with *Ashmarihara Kwatha* is found more effective than placebo in the management of *Mutrashmari* (urolithiasis).

Keywords: *Ashmari, Ashmarihara* decoction, calculus, *Palasha Kshara*, urinary stone, urolithiasis

Introduction

Urolithiasis was recognized as a major health problem even way back in 12th century BC when Sushruta performed perineal lithotomy.[1] Urolithiasis is a pathological condition of the urinary system where aggregation of urinary crystalloids takes place anywhere in the urinary tract, i.e., from the kidney to urinary bladder,[2] and is a big challenge for all health-care systems. Because of changes in lifestyle, dietary habits, and treatment modalities, its incidence and prevalence have increased significantly over the past few decades. One can expect that the frequency of urolithiasis will rise even more (by 7%–10%) owing to global warming since stone disease is encountered more frequently in hot climate regions.[3] The main etiological factors for the formation of urolithiasis include dietary factors – Vitamin A deficiency, hot climate, decrease in citrate level, any kind of urinary stasis, infections in the kidney, prolonged immobilization, medullary sponge kidney, hyperparathyroidism, hyperoxaluria, cystinuria, and renal tubular acidosis. Other factors are sarcoidosis, myelomatosis, gout, idiopathic hypercalciuria, hypervitaminosis D, hypomagnesuria, neoplasms on treatment, etc.[4] Sushruta mentioned *Ashmari* under *Ashtomahagada* due to its recurrence and bad prognosis (eight major disorders).[5] Urologists claim that stones <15 mm can be expelled out with conservative treatment and lifestyle modifications (restriction of diet and drinking of plenty of water). Considering this fact, placebo control group has been included in this trial.

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Ashmarihara Kwatha is a *Anubhuta Yoga* of pharmacy Gujarat Ayurved University, Jamnagar, which is found effective in the management of *Ashmari.* As it is used by previous research scholars to treat *Mutrashmari*. Hence, in this trial, *Ashmarihara Kwatha* and *Palasha Kshara* have been selected as internal medication to manage the cases of *Ashmari*. Hence, to validate the role of Ayurvedic drugs (*Palasha Kshara* and *Ashmarihara Kwatha*) and to build up more evidence-based data, this study was planned.

Materials and methods

Selection of patients

Patients having signs and symptoms along with pragmatic diagnostic features of *Mutrashmari* were selected irrespective of gender, religion, occupation from the Outpatient department and Inpatient department of Shalya Tantra of IPGT and RA, hospital Jamnagar. The registered patients were randomly allocated into two groups by computer-generated randomization. This study was approved by the Institutional Ethical Committee vide letter no.-PGT/7/-A/Ethics/2017-18/2069, dated November 21, 2017, before starting the clinical trial, the study was also registered retrospectively in the Clinical Trial Register of India vide, registration number CTRI/2018/01/011199, registered on February 09, 2018. [Figure 1]

Diagnostic criteria

The diagnosis was made on the basis of clinical features like pain in the renal angle and loin region, radiating toward the groin, burning micturition, mild hematuria, and nausea and vomiting.

Inclusion criteria

Patients of age group from 18 to 70 years of either sex having renal and ureteric stones with size up to 10 mm were included in this trial.

Exclusion criteria

Patient having chronic renal failure, gross hydronephrosis (HN), acute abdominal pain, cases which requires surgical intervention, severe hematuria, and stone size more than 10 mm were excluded. Known cases of malignancy, tuberculosis, human immunodeficiency virus, venereal disease research laboratory, and hepatitis B-positive cases were excluded from the study. Uncontrolled hypertension, diabetes mellitus, and cardiac disorders were excluded. Urinary stone present in the urinary bladder and urethra were also excluded from this study.

Laboratory investigations

Routine hemogram, random blood sugar, liver function test, renal function test, urine analysis – routine and microscopic and urine culture, ultrasound (whole abdomen and pelvis), and X-ray abdomen (if needed) were done before and after treatment in all patients.

Materials

Among 43 registered patients, group A (n = 20) patients of *Mutrashmari* were treated with *Palasha Kshara* and *Ashmarihara Kwatha,* and group B (n = 19) patients of *Mutrashmari* were treated with placebo capsule and 3–4 l of water. *Pathya-Apathya* chart was provided to both groups of patients.

Preparation of trial drugs

Palasha Kshara and *Ashmarihara Kwatha* were procured from Pharmacy of Gujarat Ayurved University, Jamnagar, and authenticated by Pharmacognosy Laboratory, IPGT and RA, Jamnagar.

The trial drugs, i.e., *Palasha Kshara* and *Ashmarihara Kwatha* were subjected to a pharmaceutical study and results in all parameters meet to the standard value as per Ayurvedic Pharmacopeia of India (API).[6]

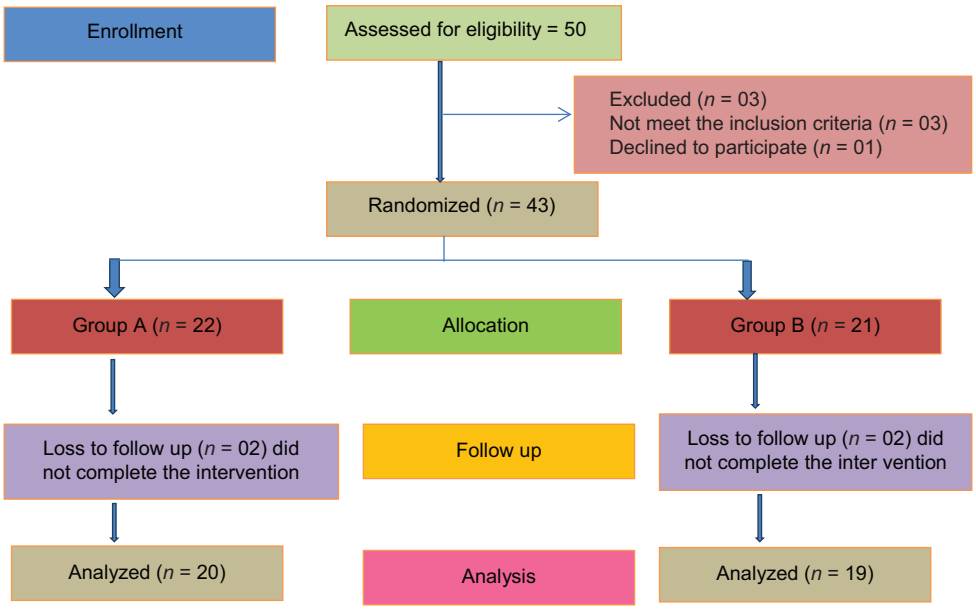

Figure 1: CONSORT chart

Preparation of *Palasha Kshara*

Kshara one part of ash of the whole *Palasha* plant (*Butea monosperma Kuntze*) was mixed with six parts of water, and kept stable for the whole night then above mixture was filtered and separated liquid part is boiled till the *Kshara* is formed.[7] The ingredients of *Ashmarihara Kwatha* are as shown in Table 1. *Kwatha* was prepared as per classical reference.[8]

Methodology

All the patients were randomly categorized into two groups in accordance with the computer-generated randomization method.

- Group A (trial group)
- Group B (placebo control group).

In patients of group A, 500 mg capsule of *Palasha Kshara* and *Ashmarihara Kwatha* (40 ml) thrice daily after meal for 60 days was given along with that the patients were also advised to take *Pathya Ahara* (wholesome diet) as prescribed diet chart in Table 2.

In patients of group B, 500 mg placebo (granulated wheat) capsule after the meal and *Pathya Ahara* was given along with 3–4 l of water over 24 h.

The gradation adopted for the assessment of results is depicted in Table 3. Patients were assessed on every 2 weeks interval up to 2 months and follow-up was done after 1 month of completion of the treatment to observe reoccurrence and any untoward effects of the treatment. SigmaStat software was used for statistical analysis. Wilcoxon signedrank test was used for intragroup statistical analysis of result. The Mann–Whitney rank sum test was used for intergroup comparison.

Observations

The maximum number of patients belonged to >25–40 years (48.84%) age and 67.44% of patients were male. The symptoms of *Mutrashmari* observed among 43 patients were pain (*Vedana* - 100%), burning micturition (*Sadaha Mutrata* - 69.78%), increased frequency of micturition (27.91%), and hematuria (*Sarakta Mutrata* - 13.95%).

About 88.37% of patients had renal stone, 2.33% of patients had ureteric stone, and 9.30% of patient had both ureteric as well as renal stone. About 60.47% of patients had renal stone size between 1 and 4 mm and 6.98% of patients had ureteric stone size between 8 and 10 mm. In 37.20% of patients, there was presence of bacterial infection and in 62.80% of patients no infection of bacteria was seen on urine culture (aerobic) in microbiology laboratory of institute.

Results

The assessment was made on the basis of relief in pain, hematuria, frequency of micturition, and burning micturition.

In group A (*Palasha Kshara* and *Ashmarihara Kwatha*), statistically significant results were observed in pain ($P < 0.0001$), increased frequency of micturition ($P < 0.001$) and burning

Table 1: Ingredients of *Ashmarihara Kwatha*

Drug	Botanical name	Part used	Quantity
Pashanbheda	*Bergenia ligulata* (Wall) Engl.	Root	1 part
Erandkarkatimool	*Carica papaya* Linn.	Root	1 part
Shatavari	*Asparagus racemosus* Linn.	Kanda	1 part
Gokshura	*Tribulus terrestris* Linn.	Fruit and root	1 part
Varun	*Crataeva nurvala* Buch.	Stem bark	1 part
Trapushabeeja	*Cucumis sativus* Linn.	Seeds	1 part
Kush mool	*Desmostachya bipinnata* Stp.	Root	1 part
Kashmool	*Saccharum spontaneum* Linn.	Root	1 part
Sagawana	*Tectona grandis* Linn.	Fruit	1 part
Dhana (rice) moola	*Oryza sativa* Linn.	Root	1 part
Punarnava	*Boerhavia diffusa* Linn.	Root	1 part
Amruta	*Tinospora cordifolia* Miersex Hook. F and Thomas	Root	1 part
Apamarga	*Achyranthes aspera* Linn.	Root	1 part
Jatamansi	*Nardostachys jatamansi* Dc.	Root	2 parts
Khurasaniyavani	*Hyoscyamus niger* Linn.	Leaves, flowers and seeds	2 parts

In place *Kasha Moola, Kusha Moola* has been used twice due to unavailability of *Kasha Moola. Yava Kshara* was used as *Prakshepa Dravya* during *Kwatha* preparation

Table 2: Diet chart (*Pathya-Apathya Ahara*)

Pathya Ahara	*Apathya Ahara*
Vegetables: Carrot, bitter guard, potatoes, radish, pumpkin seeds	Vegetables: Tomato, spinach, cauliflower, mushroom, brinjal, rajmah, beans, cucumber, capsicum, lady finger
Juice: Banana juice, pineapple juice, aloe vera juice, cranberry juice	Fruit and juice: Chikoo and grapes, pumpkin, cashew nuts, amla, strawberries
Fruits: Lemon, almond, bananas, apples, coconut water, papaya	Nonvegetarian foods: Mutton, chicken, fish, egg
Fibers: Barley, oats, horse gram, puffed rice	Chocolate, cocoa, other chocolate drink mixes, tea and coffee
Plenty of water (boiled water) or reverse osmosis water	Bore-well water

Table 3: Gradation for symptoms

Grade	None (0)	Mild (1)	Moderate (2)	Severe (3)
Pain (*Vedana*)	VAS 0	VAS 1–3	VAS 4–6	VAS 7–10
Burning micturition (*Mutradaaha*)	No burning micturition	Occasional burning micturition	Regular burning micturition	Burning micturition required medication
Dysuria (*Sashulamootrataa*)	No dysuria	Occasional dysuria	Regular dysuria	Regular dysuria required medication
Hematuria (*Sarudhira Mutrataa*)	No hematuria	Smoky color urine	Blackish color urine	Bright red urine color
Frequency of micturition (24 h)	Up to 6	7–9 times	10–12 times	>12 times

VAS: Visual Analogic Scale

Table 4: Effect of therapy in group A (*Palasha Kshara* and *Ashmarihara Kwatha*) on chief complaint (*n*=20)

Chief complaints	Mean			Percentage relief	SD	SE	*W*	*P** NS: >0.05 S: <0.05	Significance
	BT	AT	Difference						
Pain	2.500	0.45	2.050	82	0.69	0.150	210	<0.0001	S
Hematuria	0.20	0.00	0.20	100	0.00	0.00	10.00	>0.05	NS
Increased frequency	0.050	0.65	−0.6000	−120	0.503	0.112	78	<0.001	S
Burning micturition	0.70	0.10	0.6000	85.71	0.503	0.112	78	<0.001	S

*Wilcoxon signed rank-test. NS: Non-significant, S: Significant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment, **P*

Significance	*P*
Non-significant	*P*>0.05
Significant	*P*<0.05

micturition ($P < 0.001$) and statistically insignificant results were observed in hematuria ($P = 0.125$). [Table 4]

In group B (placebo), statistically significant results were observed in burning micturition) ($P = 0.007$) and insignificant results were observed in pain ([*Vedana*] [$P = 0.54$]), hematuria ([*Sarakta Mootrata*] [$P = 0.50$]), increased frequency of micturition ($P = 0.844$). [Table 5]

On comparison between the results of the groups by applying Mann–Whitney test significant difference was observed in pain ($P < 0.00001$), and increased frequency of micturition ($P = 0.0064$). Insignificant difference was observed in hematuria ([*Sarakta Mootrata*] [$P = 0.61$]) and burning micturition ([*Sadaha Mootrata*] [$P = 0.96$]) after comparison of treatment between both groups. [Table 6]

In group A, statistically significant results were obtained in all the objective parameters, i.e., size of stone, position of stone, number of stone, HN/hydroureter (HU). [Table 7] In group B (placebo), statistically significant result was obtained in only position of stone, rest of other objective parameters results were found statistically insignificant. [Table 8] On comparing the effect of therapy on objective parameters, significant difference in results was found in all objective parameters (number of stone, position of stone, size of stone, and HN/HU). [Table 9]

In group A, total 37 kidney stones and four ureteric stones of different sizes were found in 20 cases. About 29.73% of stones were expelled out, 51.35% of stones decreased in size and no change was observed in 10.81% of stones, whereas increment in stone size was observed in 8.11% of stones. With reference to ureteric stone, 75% of stones were expelled out, and 25% of stones were decreased in size.

In group B (placebo), a total of 35 kidney stones and five ureteric stones of different sizes were found in 19 cases. Twenty percent of stones were expelled out, 37.14% of stones decreased in size and no change was observed in 5.71% of stones, whereas increase in stone size was observed in 37.14% of stones. In relation to ureteric stone, all stones increased in size, i.e., 100%. [Table 10]

On comparing the effect of therapies on change in microbial load in urine after treatment, in group A, patients had 37.5% change than group B (placebo) in which there was no change in microbial load after treatment. [Table 11]

Discussion

Mutrashmari being a pathological condition of urinary system occurs due to aggregation of urinary crystalloids anywhere in urinary tract. Reason for which can be attributed to changes in lifestyle, dietary habits, and treatment modalities, its incidence and prevalence have increased significantly over the past few decades. The study showed that maximum patients belong to the age group of 25–40 years (reason for which could be the busy and stressful lifestyle at this age group as they are exposed to the etiological factors such as improper diet, continuous sitting, and excess work which leads to ignorance of their own health later on) and male:female ratio is 2:1 for urolithiasis the cause might be increased dietary protein intake, which increases urinary excretion of phosphates, magnesium, and reduces urinary citrate concentration. The lower risk of stone formation in women was attributed initially to increased urinary citrate concentrations due to the lower urinary saturation of stone-forming salts. Estrogen may also help to prevent the formation of calcium stones by keeping urine alkaline and raising protective citrate levels. Experiments in animals demonstrated that testosterone promoted crystal growth by suppressing osteopontin (OPN) expression in the kidney and increasing urinary oxalate excretion, whereas estrogen possibly inhibited stone formation by increasing OPN expression in the kidney and decreasing urinary oxalate excretion.[9] However, recent advances suggest that the difference in incidence between men and women is narrowing of urethra.

Patients treated with *Palasha Kshara* and *Ashmarihara Kwatha* have shown significant results in treating pain (*Vedana*), increased frequency, and burning micturition (*Sadaha Mutrata*). The mode of action of *Palasha Kshara* can be explained by its properties such as *Mootrala* (diuretics), *Lekhana* (scrapping), *Bhedana* (breaking up) and *Pachana* (digestion), *Basti Shodhana* (purgative of bladder), and *Tridosha Shamaka* (pacifying three bodily humors) properties,[10] by virtue of which it is not only helped in the treatment but also caused alleviation of symptoms through a major difference.

Table 5: Effect of in group B (placebo) on chief complaint (*n*=19)

Chief complaints	Mean			Percentage relief	SD	SE	*W*	*P** NS: >0.05 S: <0.05	Significance
	BT	AT	Difference						
Pain	2.263	2.105	0.1579	6.97	1.015	0.233	19	0.54	NS
Hematuria	0.11	0.00	0.11	100	0	0	−3	0.50	NS
Increased frequency	0.47	0.53	−0.05263	−11.2	0.71	0.162	3	0.844	NS
Burning micturition	0.95	0.37	0.5789	61.10	0.69	0.1589	66	0.007	S

*Wilcoxon signed rank-test. NS: Non-significant, S: Significant, SD: Standard deviation, SE: Standard error, BT: Before Treatment, AT: After Treatment

Table 6: Comparative effect of therapy on subjective parameters between group A (*Palasha Kshara* + *Ashmarihara Kwatha*) and group B (placebo)

Chief complaints	Mean difference	*U*	*P** NS: >0.05 S: <0.05	Significance
Pain (*Vedana*)	1.66	47	<0.00001	S
Hematuria (*Sarakta Mutrata*)	0.00	172	0.61	NS
Increased frequency of micturition	−0.65	300	0.0064	S
Burning micturition (*Sadaha Mutrata*)	0.021	192	0.96	NS

*Mann–Whitney test. NS: Non-significant, S: Significant

Table 7: Effect of therapy in group A (*Palasha Kshara* and *Ashmarihara Kwatha*) on objective parameters

Parameters	Mean difference	SD	Df	*t*	*P** NS: >0.05 S: <0.05	Significance
Stone size	0.950	0.2236	19	19.00	<0.0001	S
Position of stone	−0.6000	0.5026	19	5.339	<0.0001	S
Number of stone	0.4211	0.7685	18	2.388	0.0281	S
HN/HU	0.2500	0.4443	19	2.517	0.0210	S

SD: Standard deviation, HU: Hydroureter, HN: Hydronephrosis, S: Significant

Table 8: Effect of therapy in group B (placebo) on objective parameters (*n*=19)

Parameters	Mean difference	SD	Df	*t*	*P** NS: >0.05 S: <0.05	Significance
Stone size	−0.0500	1.026	18	0.2236	0.8256	NS
Position of stone	−0.2632	0.452	18	2.535	0.0207	S
Number of stone	−0.11	0.958	18	0.5669	0.5778	NS
HN/HU	−0.158	0.809	18	1.372	0.1868	NS

SD: Standard deviation, HU: Hydroureter, HN: Hydronephrosis, NS: Non-significant, S: Significant

Most of the ingredients of *Ashmarihara Kwatha* have *Tikta* (bitter)-*Kashaya* (astringent) *Pradhana Rasa, Laghu* (light) – *Ruksha* (dry), *Guna, Shita Virya* (cold potency), *Katu Vipaka* and *Vatakapha Shamaka* properties and have *Mutrala* (diuretic), *Vedanasthapana* (analgesic), *Anulomana* (laxative) and *Bastishodhana Karma, Rasayana* (immuno-modulator), *Ashmaribhedana* (anti-urolithiatic) and *Vrana Ropana* (healing especially desquamated epithelial cells) property too and by the virtue of this all properties it causes relief in symptoms of *Ashmari*.[11] *Pashana Bheda* (*Bergenia lingulate* (Wall) Engl.) possess antiurolithiatic, diuretic, anti-oxidant anti-inflammatory, and antimicrobial antipyretic activity.[12] *Gokshura* (*Tribulus terresteris* Linn): has anti-inflammatory, antiurolithiatic, analgesic, diuretic activity, anti-spasmodic activity, anti-hyperlipidemic, wound-healing, anti-microbial, and anti-hypertensive activity.[13,14] *Guduchi* (*Tinospora cordifolia* [*willd*] Miersex Hook. F and Thomas) showed anti-spasmodic, anti-inflammatory, diuretic, anti-oxidant, anti-stress, anti-bacterial, immune-modulatory, anti-diabetics, etc., properties.[15] *Varuna* (*Crataeva nurvalae* Buch.-Ham.) possess anti-lithogenic, diuretic, and anti-crystallization property.[16] *Parasika Yavani* (*Hyocyamus niger* Linn.) showed the anti-histaminic, anti-microbial, anti-spasmodic, analgesic, anti-inflammatory, anti-allergic, and sedative properties of the drug.[17] One study also showed the urinary bladder relaxant property of *Hyoscyamus niger* Linn.[18]

From the abovementioned properties of ingredients of *Ashmarihara Kwatha,* it can be hypothetically concluded that when used in combination this drug possesses the following activities such as:

1. Acetylcholinesterase inhibitory effects enhance the level of dopamine in the brain, thus inhibiting the expression of pro-inflammatory cytokines
2. Produce the diuretic effect due to the presence of potassium salts
3. Blocks the nucleation and growth of calcium oxalate crystals
4. Provide nourishment to the cells and prevent recurrent inflammation.

Furthermore, helps in natural cleansing of body by stimulating kidney function that flushes away the stones or crystals.

Patients treated with placebo capsule (granulated wheat) and plenty of water have shown in improvements in symptoms such as burning micturition and hematuria. Plenty of water intake itself is a diuretic, which helps in expulsion of small-sized stone

Table 9: Comparative effect of therapy on objective parameters between group A (*Palasha Kshara* + *Ashmarihara Kwatha*) and group B (placebo)

Parameters	Mean			Percentage change	SD	*t*	*P** NS: >0.05 S: <0.05	Significance
	BT	AT	Difference					
Stone size	0.950	0.0526	−0.897	94.42	−0.80	3.82	0.0005	S
Position of stone	−0.60	−0.26	0.337	56.13	−0.05	2.19	0.0345	S
Number of stone	0.45	−0.105	−0.55	1.22	−0.05	2.21	0.0333	S
HN/HU	0.25	−0.158	−0.41	1.64	0.057	2.69	0.0106	S

SD: Standard deviation, HU: Hydroureter, HN: Hydronephrosis, BT: Before treatment, AT: After treatment, S: Significant

Table 10: Comparison between number of stone expelled, increased, decreased, and no change between groups

Site	Group A		Group B		Total (%)
	Number of stone	Effect in percentage	Number of stone	Effect in percentage	
Kidney					
Expelled	11	29.73	7	20	18 (25)
Decrease	19	51.35	13	37.14	32 (44.44)
No change	4	10.81	2	5.71	6 (83.33)
Increase	3	8.11	13	37.14	16 (22.22)
Ureteric stone					
Expelled	3	75	0	0	3 (33.33)
Decrease	1	25	0	0	1 (11.11)
No change	0	0	0	0	0
Increase	0	0	5	100	5 (55.56)

Table 11: Comparative effect of therapies showing change in microbial load in urine after treatment

Group	Presence of urinary infection	After treatment result		Percentage change
		Change	No change	
Group A	8	3	5	37.5
Group B	15	0	15	0

due to forced diuresis, whereas big stones change their sites from kidney to ureter. Diet restriction advised to the patients might be helpful to prevent the further stone formation.

Conclusion

Palasha Kshara and *Ashmarihara Kwatha* showed effective in symptomatic management of *Mutrashmari* (urolithiasis) and also expel the small size stones, i.e., <10 mm.

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Conflicts of interest

There are no conflicts of interest.

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