

# A Controlled Clinical Trial to Evaluate the Efficacy of Gandharvahastadi Kalka in the Management of Mutrashmari vis-à-vis Urolithiasis

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**Abstract:** In Ayurvedic literatures Mutrashmari is considered as one among the Ashta Mahagada. The disease Mutrashmari resembles with that of Urolithiasis with respect to its signs and symptoms. Urolithiasis is the third most common affliction of the urinary tract with increased rate of recurrence. In Urolithiasis surgery will be the choice many a times, but those surgical procedures have limitations in various aspects. They are expensive and many a times leads to complications. Considering all these the present study was undertaken to evaluate the added effect of Gandharvahastadi kalka an Ayurveda formulation with good safety and efficacy profile. In the study, a result obtained in between the groups is statistically non-significant. However, Group A showed better result in reduction of number of calculi and symptoms such as basti shoola and mutra dharasanga. Whereas Group B showed better result in symptoms such as mutra daha and mutra krichra.

**Keywords:** Mutrashmari, Urolithiasis, Gandharvahastadi kalka.

## 1. Introduction

The formation of stone like substance within the *mutravaha srotas* is called as *Mutrashmari*<sup>1</sup>. In *Ayurveda* literature *Mutrashmari* is considered as one among the *Ashta Mahagada*<sup>2</sup>. This shows that the *Mutrashmari* disease prevailed since the inception of medicine in India.

Majority of signs and symptoms of the disease *Mutrashmari* resembles that of Urolithiasis. It is the third most common affliction of the urinary tract. The annual incidence is about 1-2 cases per 1000 people. Men are more commonly affected than female with a male to female ratio of 3:1. The peak age for developing calculi is between 30-50yrs, and recurrence is common<sup>3</sup>. Without treatment, the typical patient has a 10% risk of recurrence at 1year, 35% at 5year and nearly 50% at 10years<sup>4</sup>.

The epidemiology of Urolithiasis differs according to geographical area in terms of prevalence and incidence, age and sex distribution, stone composition and stone location. Such differences have been explained in terms of race, diet and climate factors. Furthermore, changing socio-economic conditions have generated changes in the prevalence, incidence and distribution for age, sex and type of lithiasis in terms of both the site and the chemico-physical composition of the calculi<sup>5</sup>.

Nephrolithiasis is common worldwide. Globally, its incidence is increasing. An analysis from India shows an increase from 0.9% to 9.0% over 20 years. There is geographical variation in stone composition. The analysis from north India shows calcium oxalate is 93.4% (monohydrate is 80%, dehydrate is 20%), mixed is 2.76%, struvite is 1.42%, uric acid is 0.95%, cystine is 0.05%. In India, maximum prevalence occurs in Jammu and Kashmir,

Punjab, Haryana, Delhi, Rajasthan, Madhya Pradesh and Gujarat (stonebelt of India).<sup>6</sup>

The treatment principle of Urolithiasis in contemporary science is flush therapy in case of stones up to 5mm, in larger stones the advanced procedures like ESWL (Extracorporeal shock wave lithotripsy) and operative procedures like PCNL (Percutaneous nephrolithotomy), Pyelolithotomy, Nephrolithotomy, Extended pyelolithotomy, Pyelo nephrolithotomy, Partial nephrectomy, Nephrectomy are done<sup>7</sup>. But these procedures have limitations in various aspects. They are expensive and many a times leads to complications such as injury to colon, injury to blood vessels and sepsis<sup>8</sup>.

On the other hand, many medicinal formulations mentioned in *Ayurvedic* literature for the management of *Mutrashmari*, are cost effective, devoid of complications and provide wide scope for the successful treatment of Urolithiasis. The *Ayurvedic* formulations *Nagaradi kashaya* mentioned in *Chakradatta*<sup>9</sup>, *Badarashma pishti* (*hajarul yahud pishti*) mentioned in *Rasamritam*<sup>10</sup> and *Gandharvahastadi kalka* mentioned in *Astanga Hridaya*<sup>11</sup> are specifically indicated in *Mutrashmari* and the drugs of these *yogas* possess *ashmaribhedana* and *mutrala* properties. In addition to this it has *kapha-vata pradhana tridosahara* action.

Hence the current study was undertaken as an attempt to evaluate the added effect of *Gandharvahastadi kalka* in the management of *Mutrashmari*.

In the present study, total of 70 subjects with each group consisting of 35 subjects of *Mutrashmari* via-a-vis Urolithiasis were incidentally selected.

**Objective of the Study**

To evaluate the efficacy of *Gandharvahastadi Kalka* in the management of *Mutrashmari* vis-a-vis Urolithiasis.

**2. Materials and Methods****Materials**

The materials used in the study were:

- 1) Nagaradi kashaya- Shunthi, Varuna, Gokshura, Pashanabheda, Bhrami, Yavakshara, Guda
- 2) Badarashma pishti - Badarashma
- 3) Gandharvahastadi kalka – Eranda, Vyagri, Gokshura, Brahati, Ikshuraka

**Source of Drugs and Method of preparation**

*Nagaradi kashaya*, *Badarashma pishti*, *Gandharvahastadi kalka* were specifically prepared for the purpose of study and procured from S.N. Pandit Ayurvedic Co. Pvt. Ltd, Mysuru, (a GMP certified pharmacy).

**Methods****Source of data**

Subjects were selected from the OPD & IPD of Government Ayurveda Medical College & Hospital and Government Hi-tech Panchakarma Hospital, a teaching hospital of Government Ayurveda Medical College, Mysuru.

**Study Design**

A controlled clinical study with pre – post test design. Purposive sampling technique was employed.

**Grouping**

Subjects were assigned into two groups i.e., Group A (Control Group) and Group B (Trial Group).

**Sample size**

The study was completed in 70 subjects and the numbers of registered volunteers were 74 with 4 dropouts.

**Duration of the intervention:** 30 days

**Inclusion criteria**

- 1) All individuals irrespective of gender, between the age group of 18 to 60 years were included for the study.
- 2) The individual with or without the clinical features of *Mutrashmari*, diagnosed to be suffering from urinary calculi confirmed by Ultrasonography (USG) of Kidney, Ureter, Bladder (KUB) were included for the study.
- 3) The individuals with solitary or multiple urinary calculi irrespective of number, location were included in the study.
- 4) Urinary calculi within the size of 8mm were only included in the study.
- 5) The individuals of Urolithiasis with mild to moderate Hydronephrosis were included for the study.
- 6) Both fresh and treated cases were taken for the study.

**Exclusion criteria**

- 1) Subjects suffering from renal pathologies such as renal failure, severe hydronephrosis, pyonephrosis and renal tumors were excluded.
- 2) Individuals suffering from severe Haematuria.
- 3) Volunteers with other obstructive diseases of urinary tract system like urethral stricture, CA ureter, CA prostate, meatal stenosis, bladder neck contracture were excluded.
- 4) The subjects with uncontrolled diabetes and with other major systemic disorders which interfere with the intervention were excluded.
- 5) Pregnant and lactating women were excluded.

**Diagnostic criteria****Objective criteria**

Ultrasonography (USG) of Kidney, Ureter, Bladder (KUB) region.

**Signs and symptoms**

*Basti Shoola* (pain in abdomen or loin)

Sarakta Mutra (haematuria)

*Mutradaha* (burning micturition)

*Mutra dhara Sangha* (obstruction in the flow of urine)

*Mutrakrichra* (difficulty in micturition).

**Assessment criteria****Grading for the signs and symptoms is detailed below**

Complete absence of signs and symptoms 0

Occasionally presence of signs and symptoms 1

Mild degree of the signs and symptoms 2

Moderate degree of the signs and symptoms 3

Severe degree of the signs and symptoms 4

Assessment was done before and after the interventions based on scoring of symptoms were as follows:

S. No.	Subjective parameter	Grading
1.	<i>Basti shoola</i> None Occasionally Mild Moderate Severe	BS0 BS1 BS2 BS3 BS4
2.	<i>Mutra daha</i> None Occasionally Mild Moderate Severe	Md0 Md1 Md2 Md3 Md4
3.	<i>Mutradhara sanga</i> None Occasionally Mild Moderate Severe	Mds0 Mds1 Mds2 Mds3 Mds4
4.	<i>Sarakta mutrata</i> None Occasionally Mild	Srm0 Srm1 Srm2

	Moderate Severe	Srm3 Srm4
5.	Mutrakrichrata None Occasionally Mild Moderate Severe	Mkr0 Mkr1 Mkr2 Mkr3 Mkr4

- 1) *Nagaradi Kashaya*: 100ml in two equally divided dose and *Yavakshara* 350mg in each dose with *Guda*.
- 2) *Badarashma Pishti*: 1gm in two equally divided dose with honey as *Anupana*.

**Group B**

Trial group, following intervention were done -

- 1) *Gandharvahastadi Kalka*: 12gm in two equally divided dose with *Madhura Dadhi* as *Anupana*.
- 2) *Nagaradi Kashaya*: 100ml in two equally divided dose and *Yavakshara*. 350mg in each dose with *Guda*.
- 3) *Badarashma Pishti*: 1gm in two equally divided dose with honey as *Anupana*.

**Duration of intervention:** 30 days before food.

**Investigations**

- 1) Subjects were diagnosed on the basis of Ultrasonography (USG) of the Kidney, Ureter, Bladder (KUB) region.
- 2) However investigations were conducted to rule out other systemic disorders, investigations such as Hb%, TC, DC, ESR, Urine – sugar, albumin and microscopic examination.

**Statistical methods**

The results were analyzed statistically by using Chi square test and descriptive statistics using service for statistical solution (SPSS) for windows software.

**Intervention**

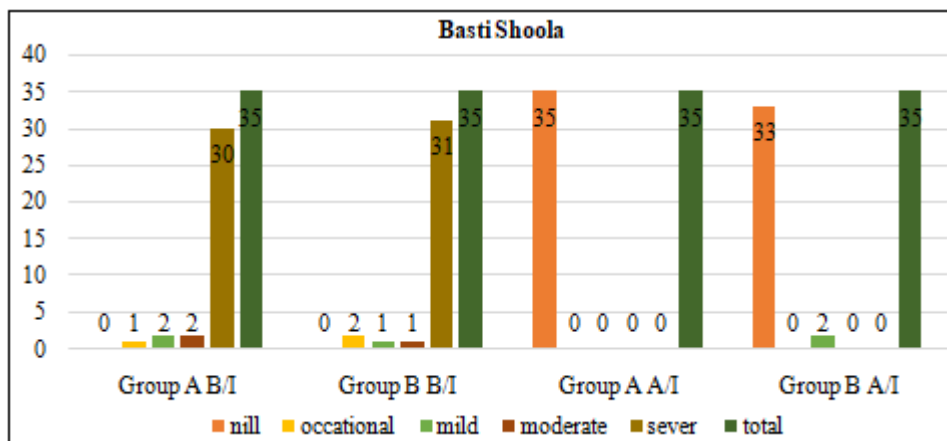
**Group A**

Control group, following intervention were done -

**3. Observations and Results**

The data regarding the samples were collected based on the diagnostic criteria and scoring given to each of the symptoms. The symptoms were assessed using the parameters and ultrasonography of KUB region was done, before intervention on 0 day and after the intervention on 31<sup>st</sup> day.

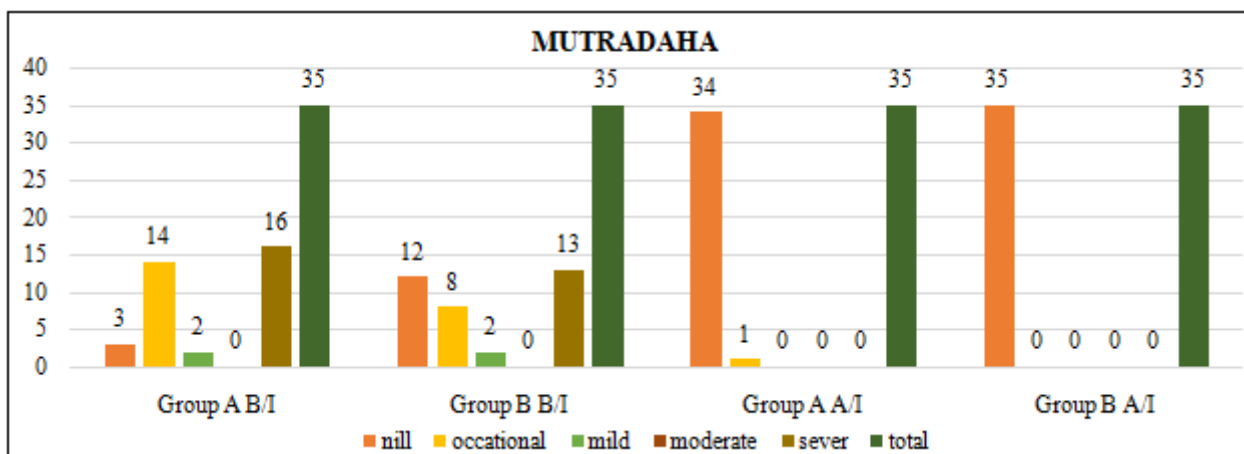
**Results of Basti shoola**



Among 70 subjects, 30 individuals in group A and 31 in group B had severe *basti shoola* before intervention. After intervention 35 volunteers in group A and 33 in group B were completely relieved from *basti shoola* whereas 2 clients in group B had mild symptom. Group A showed

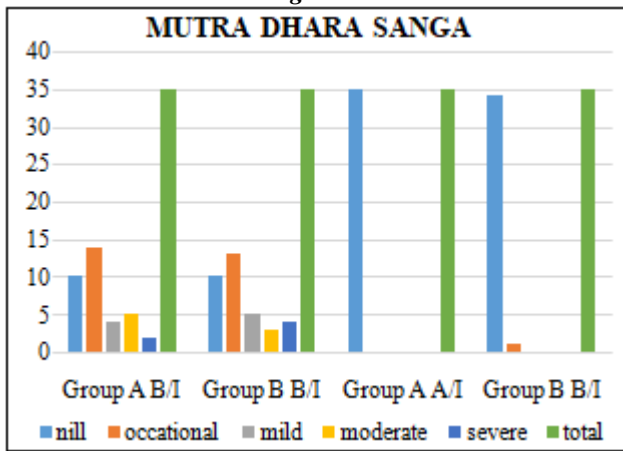
100% remission in *basti shoola* and Group B showed 94.3% remission.

**Results on Mutradaha**



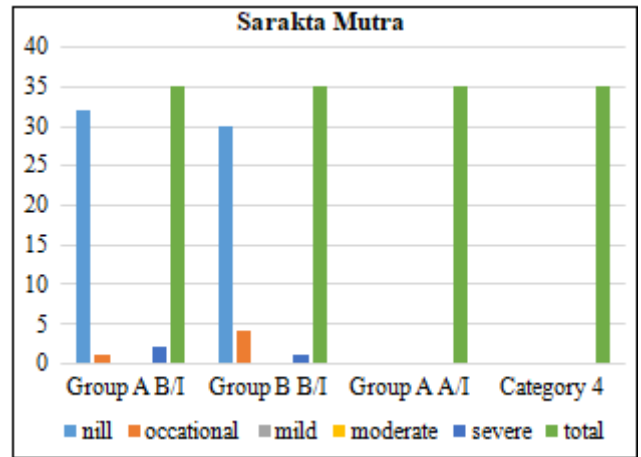
Before intervention in Group A 16 volunteers and 13 in Group B had severe *mutradaha* whereas 14 individuals in Group A and 8 in Group B had occasional symptom. After intervention in Group A, 1 individual had *mutradaha*. Group B showed 100% remission whereas Group A with 97.1%.

**Result on *Mutra dhara sanga***



Before intervention in both the groups 13-14 subjects had occasional *mutra dhara sanga* whereas 3-4 individuals had severe symptom. After intervention in Group A 100% remission was seen in the subjects and 97.1% in Group B.

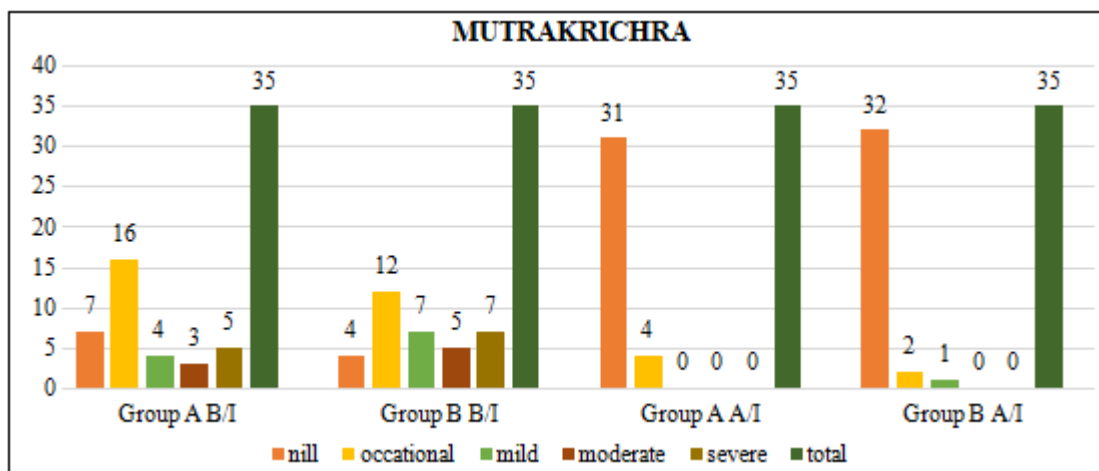
**Results on *Sarakta Mutra***



Out of 70 subjects before intervention, in Group A , 2 (5.7%) subjects had severe *sarakta mutra* and 1 (2.9%) with occasional *sarakta mutra*, where as in Group B, 1 (2.9%) subject had severe *sarakta mutra* and 4 (11.4%) with occasional *sarakta mutra*. After the intervention all the individuals were relieved from the symptom *sarakta mutra*.

There was no statistically significant result in between the groups, however according to percentage, both the group showed 100% remission.

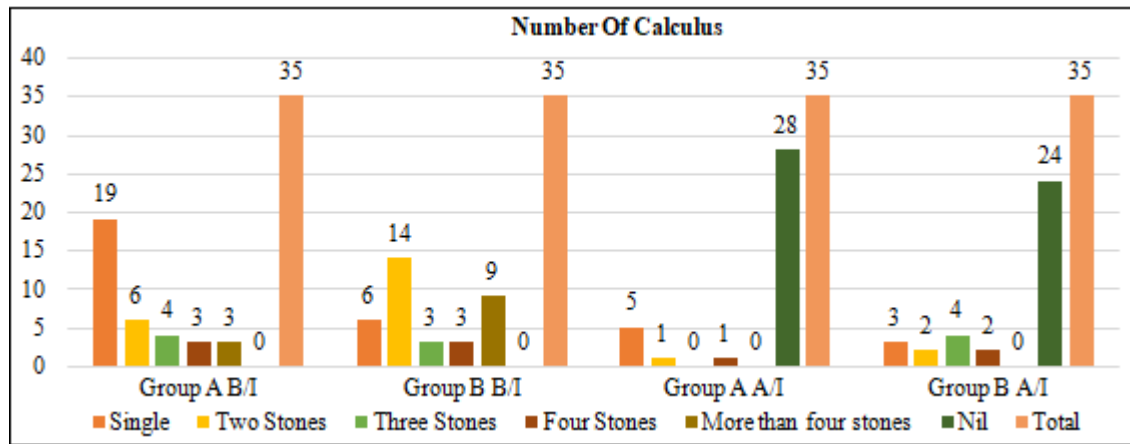
**Result on *Mutrakrichra***



Among 70 subjects, 16 in Group A and 12 in Group B had occasional *mutrakrichra*, 5 – 7 subjects in both groups had severe symptom, 3-5 individuals had moderate symptom in both the group and 4 – 7 clients had mild *mutrakrichra*

before intervention. After intervention 88.6% in Group A and 91.4% in Group B got complete remission of symptom.

**Result on number of calculus in subjects of *Mutrashmari***



Out of 70 subjects 19 in Group A and 6 in Group B had single calculus, 6 in Group A and 14 in Group B had two calculi, 4 clients in Group A and 3 in Group B had three calculi, 3 individuals in both the Groups had four stones and more than four stones was seen in 3 subjects in Group A and 9 individuals in Group B was seen before intervention. After intervention

#### 4. Results

In the present study, a result obtained in between the groups is non-significant. However, Group A showed better result in reduction of number of calculi and symptoms such as *basti shoola* and *mutra dhara sanga*. Whereas Group B showed better result in symptoms such as *mutra daha* and *mutra krichra*.

#### 5. Conclusion

The combination of these drugs acts as *mutrala*, *ashmarihara* and *tridosahara*. With the obtained results it can be concluded that the *Nagaradi kashaya*, *Badarashma pishti* and *Gandharvahastadi kalka* can be safely and effectively carried out in subjects of *Mutrashmari* with better results.

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