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Research Article

# AN OPEN RANDOMISED CONTROL TRAIL TO EVALUATE THE LITHOTRIPTIC ACTION OF *SHIGRU MULA KWATH* ON UROLITHIASIS

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**ABSTRACT**

Urolithiasis is a multifactorial disease that remains a significant health problem. It carries significant morbidity and imposes tremendous financial burden on healthcare system. A variety of intrinsic and extrinsic factors influence the incidence of disease. Management of urolithiasis depends on size and location of stone. Stone larger than 5 mm, which fails to pass through urinary system, should be treated by some interventional procedure such as Extracorporeal Shock Wave Lithotripsy (ESWL), Ureteroscopy, Percutaneous Nephrolithotomy.

Unfortunately the propensity for stone recurrence is not altered by removal of stone by these procedures and recurrence is still about 50% within 10 years. In addition these interventional procedures show some significant side effects. For prevention or recurrence of stone many herbal medicines have been traditionally used to treat kidney stones and have been shown to be effective. Acharya *Vagbhatta* has explained in *Ashmari Chikitsa adhyaya* that intake of lukewarm decoction of root of *Moringa oleifera (Shigru*) have lithotriptic action. Considering the above reference the present study was carried out to evaluate lithotriptic action of *Moringa oleifera* as it is cheap, easily available and palatable.

**Result & Conclusion:** This study shows that *Shigru Mula Kwath* is as effective as compared to *Varunadi Kwath*, also *Shigru Mula Kwath* significantly helped to reduce the signs, symptoms and help to disintegrate the calculus. The prospective aspect of this study reveals that *Shigru Mula Kwath* can be used as lithotriptic, diuretic, alkalizer and analgesic to treat the *Ashmari* effectively.

**KEYWORDS:** *Mutrashmari*, RCT, *Ashmaribhedana*, *Shigru mula Kwath, Varunadi Kwath.*

## INTRODUCTION

Ayurveda, the system of Indian medicine and science of life deals with the well being of mankind. The three great authors namely Charaka, Sushruta and Vagbhata followed the scientific methods of study to enhance the perception of Ayurveda towards humanity. *Mutrashmari* is known to mankind since times immemorial. Clinical features of the disease are described even in Vedas, the oldest repositories of human knowledge. Sushruta the "Father of Surgery" explained urinary calculus under the heading of *Ashmari* in details including etiological factors[1], classification,[2] symptomatology,[3] pathology,[4] complications[5] and its management[6] in a most scientific manner. This disease is dreadful and hence considered one of the *'Mahagadas'[7]* by Sushruta, may be owing to its potentiality to disturb the anatomy and physiology of urinary system.

While going through the Ayurvedic Classics, a vivid description is available on the obstructive uropathy since ancient time. Their means of management include different treatment modalities; medicinal and surgical.[9],[10],[11] As surgical modalities have certain limitations, risk, complications and high recurrence rate. Various drugs are in a trial to prove their efficacy.

The efficacy of various indigenous drugs referred from various classical texts of Ayurveda has also proven; by various researches from Ayurvedic Institute and Modern Medical Institutions. But the demand for New Scientific evidence for the efficacy, safety and quality of its medications is gaining momentum; such demands has motivated me to launch ambitious research and strengthen the principles of Ayurveda.

Hence from the various available references a *Shigru Mula* (*Moringa oleifera*) *Kwath* described by Vagbhata was selected for study.[8]

### Objectives

1. To evaluate the lithotriptic actions of *Shigru Mula Kwath* (*Moringa oleifera*) in Urolithiasis.
2. To compare the lithotriptic action of *Shigru* with *Varunadi Kwath*.
3. Comprehensive compilation of action of various herbs and compounds acting on *Mutravaha Srotas* as mentioned in various Ayurvedic texts.

## MATERIALS AND METHODS

### Study population

The patients were selected from the outpatient unit of Govt. Ayurveda College and Hospital Nagpur according to inclusion and exclusion criteria. A special proforma was prepared in which detail examinations of Urolithiasis patients recorded.( as per the ethical guideline with informed consent of each and every patient from Yr.

2012-2014). They were divided in to two equal groups by Lottery method.

**Plan of Work:** Patients selected for study, screened into two groups-Trial and Control group.

1) Group A: Trial Group- The patients were treated with *Shigru Mula Kwath.*
2) Group B: Control Group- The patients were treated with *Varunadi Kwath.*

**Sample size**

The present study was an Open Randomized control trial. Total 60 patients were selected on the basis of selection criteria mentioned above and divided in two groups i.e. Trial Group and Control Group, each containing 30 patients.

**Criteria of selection of patients**

- Patients suffering from urinary calculus measuring size 6-15 mm were selected randomly.
- Patients of age between 15-60 yrs were selected for study, and Dose of Medicine was same for the age group in trial group A as well as control group B.
- The patients without any major complication like obstructive uropathy renal failure, renal hypertension, diabetes mellitus etc. were selected on the basis of clinical sign, symptom & pathological as well as radiological Investigation.
- The patient who had either positive radiological diagnosis of calculus or significant evidence of crystal in urine was selected for the present clinical study.

**Criteria for the rejection of the patient**

The following patients of calculus were excluded from the present clinical study.

- Patient suffering from calculus size more than 15mm, 6 mm for ureteric calculi.
- The Patient having major complication like-
  - Renal Failure
  - Renal hypertension
  - Severe hydronephrosis
  - Uraemia
  - Diabetic mellitus
  - Acute retention of urine
- Patient having severe obstructive uropathy.
- Patient in critical condition having severe signs & symptoms, requiring immediate surgery or intensive care.

The patient with no symptomatic relief within 7 day of trial treatment were terminated from the study and advised for the surgical removal of calculus.

**Treatment plan**

For the evaluation of efficacy of *Ashmaribhedan* compound study was divided into two groups Group A **(**Trial Group) and Group B (Control Group).

Each group contains 30 patients selected on the basis of selection criteria.

**Trial group – Group –A**

Group A was called TRIAL GROUP, for this group the special drug i.e. *Shigru Mula Kwath* containing. *Kwath* of root of *Shigru* (*Moringa oleifera*).

*Kwath* prepared according to method mentioned in Sharangdhar Samhita[12] *Madhyam Khand* Cha. 2/1-2.

**Drug:** *Shigrumula kwath*

**Dosage form:** Luke warm *Kwath*

**Dose:** 20 ml

**Route of administration:** Oral

**Time of administration:** Twice a day, before meal

**Duration of therapy:** 30 days

**Control group –Group B**

Group B was control group, in this group, the patients were treated with *Varunadi kwath* taken from reputed pharmacy. *Kwath* prepared according to method mentioned in Bhaisajya Ratnavali 36/19.

**Drug:** *Varunadi Kwath*

**Dose:** 20 ml

**Route of administration:** Oral

**Time of administration:** Twice a day, before meal.

***Anupana*:** Luke warm water

**Duration of therapy**: 30 days

**Criteria of assessment**

The main criteria of assessment in present clinical study was based on the symptomatic relief of associated symptoms. Apart from above; passing out of *Ashmari* was also taken into consideration.

**Subjective Criteria**

Gradations of symptoms for the assessment were as follows:

**Pain**

Grade 0 - Absent

Grade 1 – Present but does not disturb daily routine.

Grade 2 – Present and disturbs daily routine.

Grade 3 - Severe colicky pain due to which patient rolls on bed.

**Hematuria**

Grade 0 - Below 4 RBC'S/HPF

Grade 1 - 5-10 RBC'S/HPF

Grade 2 - Above 10 RBC'S/HPF

Grade 3 - Visible by naked eye (pink or red colour urine)

**Dysuria**

Grade 0 - Absent

Grade 1 - Mild pain during Micturation

Grade 2 – Moderate pain during Micturation

Grade 3 - Severe pain during Micturition

**Objective Criteria**

**Ultrasonography**

Grade 0 -Negative Finding

Grade 1 -Positive Finding

**Criteria for assessment of total effect of therapy**

| | |
|---|---|
| Complete relief | 75%-100% relief |
| Markedly relieved | 50%-75% relief |
| Relieved | 25%-50% relief |
| Unchanged | <25% relief |

Two follow ups were carried out on 30th and 60th day after completion of treatment. Patient was assessed by their symptomatic relief, USG guidance.

## RESULT AND DISCUSSION

### Assessment of parameter Pain

The evaluation of effect of therapy by Wilcoxon-Signed-Rank Test in the above table is suggestive of Extremely significant results for the assessment parameter PAIN in Group A and Group B as p value (p<0.0001) and (p<0.0001) respectively.

**Table 1: Showing Observations on the Basis of Wilcoxon-Signed-Rank Test for the Assessment Parameter Pain in Group A (Trial Group) and Group B (Control Group)**

| | Trial Group | | Control Group | |
|---|---|---|---|---|
| | BT | AT | BT | AT |
| Mean | 1.86 | 0.53 | 1.86 | 0.33 |
| Median | 2 | 1 | 2 | 0 |
| SD | 0.43 | 0.50 | 0.62 | 0.47 |
| Range | 1-3 | 0-1 | 1-3 | 0-1 |
| Z-statistic | 4.983 | | 4.932 | |
| p-value | <0.0001 | | <0.0001 | |

### Comparison of Mean change in PAIN

For examining the significance of intergroup differences, further the data is treated by Mann-Whitney test. From the table shown below, the Mean difference ±S.D of assessment parameter Pain in group A and B is1.33±0.47and 1.53±0.50 respectively and the p value is0.1211, which shows no significant result in both the groups. That mean therapies show similar changes in respective Groups after the treatment.

**Table 2: Table Showing Comparison of Mean Change in PAIN Between Group A (Trial Group) and Group B (Control Group) by Mann-Whitney Test.**

| | Trial Group | Control Group |
|---|---|---|
| Mean change | 1.33 | 1.53 |
| SD | 0.47 | 0.50 |
| Z-statistic | 1.550 | |
| p-value | 0.1211 | |

### Assessment of Parameter Dysuria

The evaluation of effect of therapy by Wilcoxon-Signed-Rank Test in the table below is suggestive of extremely significant results for the assessment parameter dysuria in Group A and Group B as p value is less than 0.0001 in both groups.

**Table 3: Showing Observations Based on Wilcoxon-Signed-Rank Test for the Assessment Parameter Dysuriaof Group A (Trial Group) and Group B (Control Group)**

| | Trial Group | | Control Group | |
|---|---|---|---|---|
| | BT | AT | BT | AT |
| Mean | 1.5 | 0.5 | 1.53 | 0.36 |
| Median | 1.5 | 0.5 | 2 | 0 |
| SD | 0.50 | 0.50 | 0.68 | 0.49 |
| Range | 1-2 | 0-1 | 0-2 | 0-1 |
| Z-statistic | 5.170 | | 4.808 | |
| p-value | <0.0001, HS | | <0.0001, HS | |

### Comparison of Mean Change in Dysuria

From the table below, the Mean difference ±S.D of assessment parameter Dysuria in group A and B is1±0.37and 1.16±0.64 respectively and the p value is0.1905, which shows not significant result in both the groups. That mean therapies show similar changes in respective Groups after the treatment.

**Table 4: Showing Comparison of Mean Change in Dysuria in between Group A (Trial Group) and Group B (Control Group) by Mann-Whitney test.**

| | Trial Group | Control Group |
|---|---|---|
| Mean change | 1 | 1.16 |
| SD | 0.37 | 0.64 |
| Z-statistic | 1.309 | |
| p-value | 0.1905 | |

### Assessment parameter HAEMATURIA

The evaluation of effect of therapy by Wilcoxon-Signed-Rank Test in the table shown below is suggestive of extremely significant results for the assessment parameter haematuria in Group A and Group B as p value (p<0.0001) in both groups.

**Table 5: Showing Observations of Wilcoxon-Signed-Rank Test for the Assessment Parameter Haematuria of Group A (Trial Group) and Group B (Control Group)**

| | Trial Group | | Control Group | |
|---|---|---|---|---|
| | BT | AT | BT | AT |
| Mean | 1.03 | 0.13 | 0.86 | 0 |
| Median | 1 | 0 | 1 | 0 |
| SD | 0.76 | 0.34 | 0.77 | 0 |
| Range | 0-2 | 0-1 | 0-2 | 0 |
| Z-statistic | 4.459 | | 4.259 | |
| p-value | <0.0001, HS | | <0.0001, HS | |

### Comparison of Mean change in Haematuria

From the table below, the Mean difference ±S.D of assessment parameter haematuria in group A and B is0.90±0.71and 0.86±0.77 respectively and the p value is0.1905, which shows not significant result in both the groups. That mean therapies show similar changes in respective Groups after the treatment.

**Table 6: Showing Comparison of Mean Change in Haematuria in Between Group A (Trial Group) and Group B (Control Group) by Mann-Whitney test.**

| | Trial Group | Control Group |
|---|---|---|
| Mean change | 0.90 | 0.86 |
| SD | 0.71 | 0.77 |
| Z-statistic | 0.215 | |
| p-value | 0.8298,NS | |

### Assessment of U.S.G. findings

1. **Assessment of Parameter Positive/Negative U.S.G. Finding Related with Lithotriptic Action**

In Group A of 30 patients 27 (90%) patients are having Positive U.S.G. finding i.e. cured by therapy. While 03(10%) patients are having no change in U.S.G. finding. Hence percentage of relief is 90%. In Group B of 30 patients 12 (40%) patients are having Positive U.S.G. finding i.e. cured by therapy. While 18(60%) patients are having no change, hence percentage of relief is only 40%. For examining the significance of intergroup differences,

the data is treated by Chai-square test. From the table below, at 1 degree of freedom chai-square value 16.48, is highly significant (P<0.001). That mean therapy in Group A is having better lithotriptic action as compare to the therapy in Group B.

**Table 7: Showing Observations on the Basis of CHAI-SQUARE TEST for the Assessment Parameter Positive/Negative U.S.G. Finding Related with Lithotriptic Action in Group A (Trial Group) and Group B (Control Group)**

| Change | Trial Group | Control Group |
|---|---|---|
| Positive | 27 (90) | 12 (40) |
| No change | 3 (10) | 18 (60) |
| Chi2 value | 16.48 | |
| p-value | <0.001, HS | |

**2. Assessment of Parameter Size of Calculus**

The evaluation of effect of therapy by Pair t test in the above table is suggestive of Extremely significant results for the assessment parameter Size of calculus in Group A and Group B as p value (p<0.0001) in both groups.

**Table 8: Table Showing Observations on the Basis of Pair-t Test for the Assessment Parameter Size of Calculus in Group A (Trial Group) and Group B (Control Group)**

| | Trial Group | | Control Group | |
|---|---|---|---|---|
| | BT | AT | BT | AT |
| Mean | 7.44 | 1.91 | 7.62 | 3.01 |
| Median | 7 | 2 | 7.55 | 3 |
| SD | 1.24 | 1.75 | 1.33 | 1.31 |
| Range | 6-10 | 0-5 | 6-10 | 0-5.5 |
| Z-statistic | 4.796 | | 4.788 | |
| p-value | <0.0001 | | <0.0001, HS | |

**Comparison of Mean change in size of calculus**

From the table below, the Mean difference ±S.D of assessment parameter size of calculus in group A and B is5.52±0.95and 4.61±1.05 respectively and the p value is0.0008, which shows highly significant result. That means therapy in Group A show better effect on reducing the size of stone as compare to therapy in Group B.

**Table 9: Table Showing Comparison of Mean change in Size of Calculus in Between Group A (Trial Group) and Group B (Control Group) by Unpair-t test**

| | Trial Group | Control Group |
|---|---|---|
| Mean change | 5.52 | 4.61 |
| SD | 0.95 | 1.05 |
| Z-statistic | 3.339 | |
| p-value | 0.0008 | |

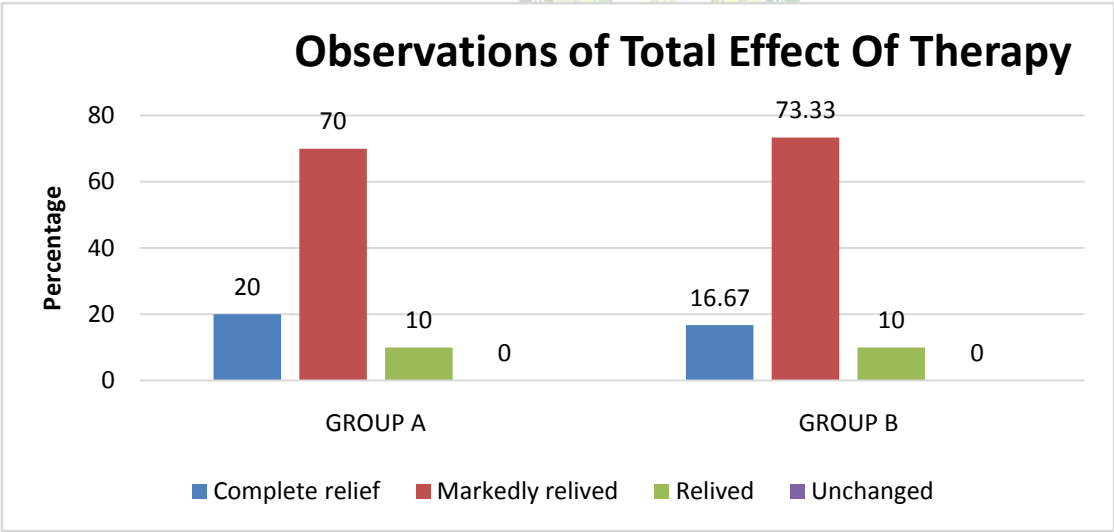
**Total effect of therapy**

In Group-A, out of 30 patient suffering from urolithiasis of 06 (20%) patients got complete relief, 21 (70%) patients were Markedly Relieved, 3 (10%) patient was Relieved and no patient is recorded as Unchanged.

In Group–B of 30 patients. 5 (16.67%) got Complete relief, 22 (73.33%) patient were Markedly Relieved, 03 (10%) patients Relieved and no patient was recorded as Unchanged.

This shows that Group–A and Group-B had almost similar overall effect of therapy but therapy in Group A had better lithotropic action as compare to therapy in Group B.

**Graph-1 showing observations of Total Effect Of Therapy**




Thus from all discussion regarding the research work and mode of action of drug it can be concluded, that the Shigru Mula Kwath possesses stone dissolving *(Ashmarichedanam),* anti-infective, antiseptic *(Mutrarakta-shodhana)*, diuretic *(Mutral)* and antispasmodic properties *(Mutrakrichapranashan).*

The present clinical study reveals that *Shigru Mula Kwath* is useful in urinary symptoms and has a lithotriptic action.

**CONCLUSION**

From overall study and statistical analysis, it is obvious that *Shigru Mula Kwath* is as effective as *Varunadi Kwath* in relieving symptoms of Urolithiasis like pain, Heamaturia and Dysuria but the effect of *Shigru mula Kwath* on reduction in size of calculus and on U.S.G. finding related *Ashmari bhedana* (lithotriptic action) were found to be more effective as compare to *Varunadi Kwath. Shigru mula Kwath* is effective in relieving *Pain, Heamaturia and Dysuria* due to its *Mutrakrichapranashan, Mutral, Mutra-*

*raktashodhana* and *Mutraghathar* property. No significant complications or side effect of *Shigru Mula Kwath* is observed during the treatment. Pain was the first symptom which reduced very fast during the treatment by administration of *Shigru Mula Kwath*.

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