# "A Clinical Observational Study of Assessment of *Doshaj Ashmari* With Special Reference To Urolithiasis: A Study Protocol"

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#### Abstract:

*Ashmari* is stated as *Mahagada* that means it is difficult to cure. It is correlated with urolithiasis. The thorough understanding of etiology, epidemiology and pathogenesis of urolithiasis is necessary so as to develop effective ayurvedic programme for diagnosis, treatment and prophylaxis of disease. Aim: To study and to assess *doshaj* types of *ashmari* on the basis of biochemical analysis with special reference to urolithiasis Objectives: 1.To Differentiate *doshaj ashmari* on the basis of signs and symptoms. 2.To carry-out biochemical analysis of samples of *ashmari* (Urinary stones). 3.To correlate *doshaj ashmari* with type of urinary calculi on the basis of laboratory investigations. **Methodology:** Patients will be screened and consent will be taken from willing subjects who fulfill the inclusion criteria. History taking and clinical examination will be carried out. Diagnosis and categorization according to the type of doshaj ashmari on the basis of history and clinical examination will be

done thereafter. Sample of the stones will be collected (From those who undergone surgery) and will be sent to lab for analysis. Data will be collected from the case record format, laboratory investigations, reports and then data will be analyzed with proper statistical test. Conclusion will be drawn on the basis of observations and data collected and analyzed. **Results:** Results will be drawn on the basis of observations and statistical analysis of data. **Conclusion:** Study will be concluded with the results drawn on the basis of observations and statistical analysis

Key words: *Mutrashmari*, Urinary Calculi, Biochemical Analysis, *Doshaj Ashmari*, Urolithiasis Introduction:

In ayurveda it is said that, every disease and diseased should be examined and diagnosed properly first and then physician should go ahead for treatment part.<sup>[1]</sup> *Rogapariksha* (Examination of the disease) is done with the help of *nidanpanchak* i.e. *Hetu* (etiological factors), *purvaroopa* ( premonitory symptoms), *Rupa* (Symptoms and signs), *Upashay-Anupashay* ( alleviating factors) and *Samprapti* (Pathogenesis).<sup>[2]</sup> Each and everything amongst these five has its own importance at its place and is essential for diagnosis and treatment of disease.

Ayurveda literature elaborates about various diseases; of them, some are difficult to treat hence called as '*mahagada*.' According to *sushruta*, *Ashmari* is one of those *mahagadas*.<sup>[3]</sup> There are four types of *ashmari* (Urolith) such as *vataja*, *pittaja*, *kaphaja* and *shukraj*.<sup>[4]</sup> Mostly the diagnosis is made on the basis of signs and symptoms observed in patient and differentiated accordingly.

*Mutrashmari* is correlated with urolithiasis.<sup>[5]</sup> Urolithiasis is a most common affliction now a days. About 15% to 25% population is suffering from urinary calculi.<sup>[6]</sup> The prevalence changes region to region and gender to gender. Various factors are responsible for this variation in prevalence rate. The incidence of urolithiasis is increasing day by day.

There are four main types of calculi; calcium stones, composed largely of calcium oxalate or calcium oxalate mixed with calcium phosphate; another are so called triple stones or struvite stones, composed of magnesium ammonium phosphate; some are uric acid stones; and least made up of cystine. An organic mucoprotein matrix. Although there are many causes for the initiation and propagation of stones, the most important determinant is an increased urinary concentration of the stones' constituents, such that it exceeds their solubility (supersaturation). A low urine volume in some metabolically normal patients may also favor supersaturation.<sup>[7]</sup>

The thorough understanding of etiology, epidemiology and pathogenesis of urolithiasis is necessary so as to develop effective ayurvedic programme for diagnosis, treatment and prophylaxis of disease.

This study is taken up to find out objective parameter for the diagnosis and treatment of *doshaj ashmari*.

## **RESEARCH QUESTION:**

Are there any differences in *doshaj ashmari* (*Doshaj* types of Urolith) on the basis of Biochemical Analysis?

#### HYPOTHESIS:

H0: There are no specific differences in *doshaj ashmari* on the basis of biochemical analysis

H1: There are significant differences between *doshaj ashmari* on the basis of biochemical analysis.

#### AIM :

To study and to assess *doshaj* types of *ashmari* on the basis of biochemical analysis with special reference to urolithiasis.

## **OBJECTIVES** :

- 1) To Differentiate *doshaj ashmari* on the basis of signs and symptoms.
- 2) To carry-out biochemical analysis of samples of *ashmari* (Urinary stones)
- To correlate *doshaj ashmari* with type of urinary calculi on the basis of laboratory investigations.

#### **REVIEW OF LITERATURE:**

Sushruta samhita classified the disease Ashmari into 4 types they are vatashmari, pittashmari, shleshmashmari and shukrashmari.<sup>[8]</sup> Ashtanga hrudaya, Ashtanga sangraha, Madhva nidana, Bhava prakasha, Sharangadhara samhita, Yogaratnakara, have classified the disease Ashmari similar to that of sushruta samhita.<sup>[9-14]</sup> *Charak samhita* has described the *Mutrashmari* under *Mutrakrichra* and on the basis of consistency, classified *shukraja*, *Pittaja* and *Kaphaja* varieties as *Mrudu Ashmari*, whereas *Vataja* variety of *Ashmari* as *Kathina Ashmari*.<sup>[15]</sup>

#### Types of ashmari

- i) *Vataja ashmari*: *Vataja ashmari* presents with the symptoms like severe pain due to obstruction to the flow of urine, due to excessive pain the patient clenches his teeth, squeezes the umbilical region, rubs the penis, touches the perineal region often and cries with agony, patient feels burning sensation and passess flatus, urine and stool with difficulty while straining for micturition. The *vataja ashmari* possess *Shyava varna* (Dark colour) and it will be *Parusha(Rough), Khara(Rough), Vishama(irregular)* and hard studded with thorns like *kadamba pushpa (flowers of Burflower tree)*.
- *Pittaja ashmari*: The symptoms of *pittaja ashmari* explained in *sushruta samhita* are; obstruction to the flow of urine causes warmth, sucking, burning or throbbing sensation in *basti* (Urinary bladder) and this result in *ushnavata* (Disease of urinary system in Ayurved) which are burning sensation in *basti*(*Urinary bladder*), *medhra* (Penis) & *guda* (Anus). The *Pittaja ashmari* posseses either *Rakta varna* (Red Colour), *peeta varna* (Yellow colour), *krishna varna* (Black Colour) or *madhu varna* (Honey like colour) and resembles *Bhallataka asthi*.

- iii) Kaphaja ashmari: According to Sushruta samhita symptoms of kaphaja ashmari are; obstruction to the flow of urine causes cutting, incising or pricking pain, heaviness and cold sensation in basti (Urinary bladder). The kaphaja ashmari possess shweta (white) or Madhuka pushpa (Flower of madhuka longifolia) varna and it will be Mahath (Large in size), Snigdha (smooth) & resembles Kukkutanda (hen egg)
- iv) Shukrashmari: The symptoms of shukrashmari explained in sushruta samhita are burning micturition, painful micturition, pain in the basti(Urinary bladder) and swelling in the vrushana (Scrotum). This type of ashmari disappears by just pressure in that region. The other Ayurvedic classics have mentioned similar lakshanas of shukrashmari, as mentioned in sushruta samhita.

#### **Classification of urinary calculi**

There are different types of urinary calculi mentioned in contemporary science based on pathogenesis, based on composition and based on location.

## **Based on pathogenesis**

- 1) Primary stones
- 2) Secondary stones<sup>[16]</sup>

Primary Stones are those which appear apparently in healthy urinary tract without any antecedent inflammation. These stones are usually formed

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in acid urine and usually consist of Calcium oxalate, Uric acid, Urates, Cystine, Xanthine or Calcium carbonate.

Secondary stones are usually formed as a result of inflammation. The urine is usually alkaline; urea splitting organisms are most often the causative factors. Secondary stones are mostly composed of calcium ammonium magnesium phosphate (Triple phosphate).

### **Based on composition**

**Calcium stone**: Calcium stones are Dirty white (Calcium Phosphate) or Dirty brown (Calcium oxalate) in colour. They are Composed of Calcium oxalate, Calcium oxalate monohydrate, Calcium oxalate dehydrate, Calcium Phosphate, Calcium hydroxy appetite and Brushite have Sharp projections, Rough surface and is usually single in number. Calcium oxalate stone presents with more symptoms, Calcium Phosphate stone presents with few symptom. These stones are usually radio opaque. The incidence of these calculi is 75-85% of total calculi.<sup>[17,18]</sup>

**Uric acid and urate stones**: Uric acid and urate stones are Red, Orange or from yellow to reddish brown. These are Composed of Uric acid, Ammonium or Sodium urate. The Incidence of these calculi is 5-8% of total renal calculi. These stones are usually Multiple hard and have smooth surface .these May be asymptomatic. Radiologically these stones are radiolucent. **Cystine:** Cystine stones are Lemon yellow in colour, composed of cystine. The incidence of it is 1% of total renal calculi. It is flat and hard, translucent, hexagonal plate. These stones may be asymptomatic many a times radiologically are radio opaque.

**Struvite**: Struvite stones have white colour and are composed of Calcium phosphate & Triple phosphate. The Incidence is 10/15% of total renal calculi. These stones have Rectangular prisms resembles with coffin lids and are dangerous. Radiologically these are radio opaque.

### **Based on location**

**Renal calculus**: The patient will have Extreme, sharp pain in the loin that will not subside, Blood in the urine, Nausea and vomiting, Cloudy or odorous urine, Frequent urination , A feeling of burning while patient urinates, Fever and chills.<sup>[19]</sup>

**Ureteric calculus**: Radiating, colicky, agonising pain, Rather constant ache in the costovertebral area and flank, Nausea and vomiting may be associated, Blood mixed urine, Urgency and frequency of urination, Chills.

**Vesical calculus** : Increased frequency, Pain and discomfort at the end of micturition, terminal haematuria, Dysuria, Acute retention of urine.

#### Urethral calculus:

In males: Patient may experience a sudden stoppage of urine while urinating and thereby unable to empty the bladder. Dribbling also occurs. Pain due to the stone in urethra may be rather severe and may radiate to the glans penis. In females : The symptoms of urethral diverticulum with or without calculus are those of infection of lower urinary tract including frequency, dysuria, nocturia, pyuria and in rare haematuria. Dyspaerunia is a prominent symptom. Occasional discharge of pus through urethra may occur.

Previous Work Done :

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## METHODOLOGY

Patients will be screened and consent will be taken from willing subjects who fulfill the inclusion criteria. History taking and clinical examination will be carried out. Diagnosis and categorization according to the type of doshaj ashmari on the basis of history and clinical examination will be done thereafter. Sample of the stones will be collected (From those who undergone surgery) and will be sent to lab for analysis. Data will be collected from the case record format, laboratory investigations, reports and then data will be analyzed with proper statistical test. Conclusion will be drawn on the basis of observations and data collected and analyzed.

- i) Setting : Research center and periphery
- ii) Duration of Study: Minimun 3 years.
- iii) Method of selection of study subject (Eligibility criteria)

Inclusion Criteria:

- a) Age : Between 12 to 60 years
- b) Genders : Both Males and females
- c) Patients having urolithiasis in USG and suffered from the symptoms of urolithiasis atleast once in last 1 year.
- d) Patients of urolithiasis having any type of calculus anywhere in urinary system.
- e) Patients of urolithiasis under treatment/ advised/undergone surgery/ Lithotripsy

Exclusion Criteria:

- a) Age : Below 12 years and above 60 years
- b) Patients had urolithiasis in past but symptomless from last 1 year and no USG is done since then.
- c) Patient had urolithiasis in past and no calculus is seen in USG at present.
- d) Patients with no symptoms of mutrashmari

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- e) Patients of shukrashmari.
- f) Seriously ill patients.
- iv) Methods of selection of comparison group

Comparison will be done within 3 groups of *doshaj ashmari* therefore same inclusion and exclusion criteria will be applied.

v) Matching criteria :

Matching will be done in all the groups.

- vi) Operational definitions :
  - *a) Mutrashmari* : Urolithiasis (Any type of one or more calculus anywhere in urinary system)
  - b) Doshaj Ashmari : vataja, pittaja and kaphaja ashmari
  - c) Hetu: Etiological Factors.
  - *d)* Lakshanas : Symptoms
- vii) Specifications of instruments and related measurements :
  - a) USG (Abdomen+Pelvis): Authorized report (done within last 1 year) of any USG center will be considered or USG Will be done at Authorized USG center.
  - b) Urine Routine Examination: Authorized report (done within last 1 Month) of any Pathology Laboratory will be considered or Urine routine Will be done at Authorized Pathology laboratory.
  - c) Chemical analysis of calculus will be done.
  - d) Weighing machine, Sphygmomanometer etc.

#### **RESEARCH METHODOLOGY SPECIFIED**

Sample size<sup>[20][21]</sup> : sample size will be: **289 ~ 300** (Table No. 01)

Sampling Technique: Simple Random Sampling.

Methods of Data collection relevant to subject: Through CRF, Investigation Reports

Data collection tool: Personal interview, History taking and Case record format,

Laboratory Reports, USG Reports.

Plan for statistical analysis:

Mean difference Z test

Mean difference T test

Chi Square test

**RESULTS:** Results will be drawn on the basis of observations and statistical analysis of data.

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## TABLE NO. 01: SAMPLE SIZE CALCULATION

## Sample Size for Frequency in a Population

Population size(for finite population correction factor or fpc)(N):	1000000
Hypothesized % frequency of outcome factor in the population (p):	25%+/-5
Confidence limits as % of 100(absolute +/- %)(d):	5%
Design effect (for cluster surveys-DEFF):	1

## Sample Size(*n*) for Various Confidence Levels

ConfidenceLe	vel(%) Sample S	ize
95%	289	
80%	124	
90%	203	
97%	354	
99%	498	
99.9%	812	
99.99%	1135	

## Equation

Sample size *n* = [DEFF\*Np(1-p)]/ [(d<sup>2</sup>/Z<sup>2</sup><sub>1-α/2</sub>\*(N-1)+p\*(1-p)]

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## Tables and figure titles and legend:

# TABLE 01: SAMPLE SIZE CALCULATION

Results from OpenEpi, Version 3, open source calculator--SSPropor