

A PRE & POST-TEST CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF YOGA BASTI & SHAMANA YOGA CHIKITSA IN ASHMARI (RENAL STONE) BASED ON SUSHRUT PROTOCOL

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ABSTRACT

Background: *Ayurveda* is a life science that is a comprehensive system of healthcare based mainly on experiential knowledge. It also considers Ahitahara-vihara to be the cause of the majority of diseases. *Ashmari* (renal stone) is one of the most common diseases of *Mutravaha srotas* (urinary system). Presenting *Ashmari* (urolithiasis) is classified as an *Ashtamahagada* (major disease) in *Ayurveda* due to its high recurrence and the limitations of conventional medical management. This study evaluates the combined efficacy of *Shodhana* (purification) and *Shamana* (palliative) therapies in managing renal calculi based on Sushrut's protocols. **Aims:** To assess the combined effect of *Yoga Basti* and *Shamana Yoga* on the subjective and objective parameters of *Ashmari*. **Method:** Patients with USG-confirmed renal stones were randomly selected from MIAER, Mandsaur. The treatment protocol included an 8-day *Yoga Basti* (Anuvasan with *Sahacharadi Tail* and Asthapan with *Varunadi Kwatha*)

followed by 60 days of *Shamana* therapy (*Varunadi Kwatha*, *Chandraprabha Vati*, and *Gokshuradi Guggulu*). Outcomes were measured using Wilcoxon signed-rank and paired

t-tests to analyze changes in pain, dysuria, hematuria, and stone size via USG and urine analysis. **Results:** The combined therapy showed statistically significant improvement ($P < 0.05$) across all criteria. Results included a 63% reduction in renal colic, 94% relief in burning micturition, and 86% relief in dysuria. Objective parameters showed an 89% reduction in RBCs, 91% reduction in pus cells, and a 47.67% mean reduction in stone size. Post-treatment USG confirmed reduced stone dimensions in all patients. **Conclusion:** The combined protocol of *Yoga Basti* and *Shamana Yoga* is an effective non-surgical approach for the management of Ashmari, significantly reducing both clinical symptoms and stone size.

KEYWORD: *Ashmari, Renal stone, Varunadi Kwath, Gokshuradi Guggul, ChandraprabhaVati, Yoga Basti.*

INTRODUCTION

Ashmari is one of the most common diseases of *Mutravaha srotas*. In classics *Ashmari* is considered as one among the *Ashtamahagada* by *Acharya Sushrut*.^[1] Presenting the **symptoms** like *Nabhi-Basti-Sevani-Mehna vedna, Shopha, Mutradaha, Sarudhir mutrata, Mutravikirana, Vishirnadhara, Mutrarodha, Sasiktamutrata, Atiyavilam, Bastiagandhitva, Gomedaparakasham, Dhavan-langhana-plavana-prashthayanogamane vedana* etc.^[2] The sign and symptoms of *Ashmari* lies very close to Renal Stone with synonym Urolithiasis, Nephrolithiasis, Calculus of kidney, kidney stone, Staghorn calculus, Uric acid nephrolithiasis, Uric acid renal calculus.^[3] **It is a disease** found in the urinary tract **of the genitourinary system** according to **ICD-10-CM Diagnosis Code N20.0 to N23.0** **characterized** by the formation or deposition of solid piece of mineral, acid, salts present in urine in **kidney, bladder, ureter**.

Significance of Study, *Basti chikitsa* (enema therapy) is known as *Ardha chikitsa*, which controls and regulates *Vata dosha*. As kidney, ureter, and bladder are the site of the disease and are named *Basti Pradesh* in *Ayurved*, the leading site of *Vata Dosha*.^[4] So, *Basti* (medicated enema) treatment directly acts on the site of renal stone. It is clinically practiced, which is a safe and effective mode of administration without complication and surgical interventions. As per the line of treatment (*Chikitsasutra*) mentioned in *Susruta Samhita*^[5], *Yoga Basti with Varunadi kwatha*^[6] (Mishra S.,2016) and *Sahacharadi tail*.^[7] (Moreshwar Kunte et al., 2012) and *Shaman yoga chikitsa with Varunadi kwath, Chandraprabhavati*.^[8] (Mishra S.,2016) and *Gokshuradi Guggulu*^[9] (Tripathi.B,2017) selected for the study to break

down the pathogenesis. So, the study aims to evaluate the efficacy of the combined effect of *Yoga Basti* and *Shamana Yoga chikitsa* in the management of *Ashmari* (renal stone).

Aims & objectives of the study

Aim: Evaluate the combine efficacy of *Yoga Basti* and *Shamana yoga Chikitsa* in the subjective and objective parameters of *Ashmari* (renal stone).

Objective: To determine the effect of above therapy on the size of *Ashmari* (renal stone) to determine the effect of above therapy on Renal colic, Burning micturition, Dysuria, Tenderness, Pus cell, and Haematuria due to *Ashmari* (renal stone)

Research methodology

► **Research Question:** Is the combined effect of *Yoga Basti* and *Shaman Yoga Chikitsa* effective in *Ashmari* (Renal Stone).

Hypotheses to be tested

► **Alternate Hypothesis (H_1)** - The combined treatment of *Yoga Basti* & *Shaman Yoga Chikitsa* in *Ashmari* (Renal stone) is very effective.

► **Null hypothesis (H_0)** -The combined treatment of *Yoga Basti* & *Shaman Yoga Chikitsa* in *Ashmari* (Renal stone) is not effective.

MATERIAL AND METHOD

► **Study Design:** It was a single arm, A Pre and post-test clinical study.

► **Sample size:** A Minimum of 60 patients diagnosed as *Ashmari* (renal stone) were selected and incidentally categorized in a single group.

► **Source & Selection of patients:** Patients fulfilling the inclusion criteria of *Ashmari* (renal stone) were selected from patients attending the O.P.D. and I.P.D. of Mandsaur Institute of Ayurvedic Education and Research, Mandsaur (M.P.)

Selections of Drugs: The following Drugs were used in the Clinical Trial

► *Varunadi kwatha* (for both Oral and internal use as a *Kashaya Basti*), *Chandraprabha vati*, *Gokshuradi guggulu* (orally), *Sahacharadi oil* (internal use as *Anuvasana Basti*).

Method of preparation of medicines

► All the medicines were collected and manufactured in pharmacy of Mandsaur institute of Ayurveda education and research, Mandsaur.

Varunadi Kwatha, *Chandraprabha Vati*, and *Gokshuradi guggulu* preparation is a Herbo-mineral formulation mentioned in *Sharangadhara Samhita* and *Bhaishajyaratnawali* for the *Chikitsa* of *Muthravahastroto Vikaras*. Authentication was done before the pharmacological analytical study of this drug.

Pharmaceutico analytical study of *Varunadi Kwatha*, *Chandraprabha Vati* and *Gokshuradi guggulu* preparation

► All the raw materials used for the preparation were identified and authenticated by the experts.


► ***Varunadi kwatha***- *Crataeva nurvala* Buch. - Ham, *Tribulus terrestris* Linn, *Zingiber officinale* Rosc, (1 part each) with 16-part water, *Hordeum vulgare* Linn (2 part). All raw materials were collected from market and through *Yavakut* method it converted into cores powder.


► ***Gokshuradi guggul*** – *Terminalia chebula*, *Terminalia bellerica*, *Terminalia officinalis*, *Cyperus rotundus* (4 part) *Zinziber officinalis*, *Piper nigrum*, *Piper longum* (1 part each). *Gokshura* (*Tribulus terrestris*) was taken in 6 parts of water and decoction was subjected to heat until half of it remain. *Guggulu* (*Commiphora mukul*) 30 part was added to the filtered *Kashaya* which was boiled again to *rasakriya Paka*. Fine powder of remaining drugs was added and mixed well. **Vati of uniform size and weight were prepared, dried in a shade and later it was stored in air tight container.**


► ***Chandraprabhavati***- The ingredients like *Cinnamomun camphora*, *Asphaltum*, *Cinnamomum camphora*, *Aconitum heterophyllum*, *Curcuma longa*, *Corus calamu*, *Cyprus rotundus*, *Emblica officinalis*, *Terminalia bellirica* (fruit rind), *Piper chaba*, *Terminalia chebula* (fruit rind), *Andrographis paniculata*, *Embelia ribes*, *Cedrus deodara*, *Coriander sativum*, *Tinospora cordifolia*, *Plumbago zeylanica* (lead wort), *Zingiber officinalis*, *Berberis aristata* (32 parts each) *Piper nigrum* (16 part), *Sodium carbonate*, *Potassium carbonate*, *Copper pyritis*, *Sodium sulphate*, *Black and Rock salt* (1 part of each), *Bambusa arundinacea* (4 part), *Loha bhasma* (8 part) *Commiphora mukul* (32 parts) etc. Fine powder of remaining drugs is added and mixed well. *Vati* of uniform size and weight were prepared, dried in a shade and later it was stored in air tight container.



► The finished product was subjected for necessary analytical parameters. Present work was carried out to **standardize the finished product** of *Varunadi kwath*, *Chandraprabha vati* and *Gokshuradi guggulu* preparation in terms of its identity, quality and purity. Pharmacognostical and Physico-chemical observations revealed all the specific characters of active constituents in the preparation. The data obtained could be useful in deciding the standards for this potential ayurvedic drug and can contribute in the uses and preparation of quality ayurvedic drugs.

 QUALITY CONTROL LABORATORIES ALN RAO MEMORIAL AYURVEDIC MEDICAL COLLEGE AND PG CENTRE KOPPA, DISTRICT: CHIKMAGALUR, KARNATAKA, 577116	
Reference Number: QC/ST/21/2020	Date: 24 th November 2020
Purpose: Analysis for Chandraprabha Vati	
Result:	
A. Organoleptic Characters:	
Colour	Brown
Odour	Characteristic
Taste	Bitter, salty
Texture	Vat (gills)
B. Physico-chemical parameters:	
Foreign matter	0.00%
Loss on Drying at 105°C	7.34%
Total ash	21.34%
Acid insoluble ash	8.73%
Water insoluble ash	12.81%
Water soluble extractives	37.66%
Alcohol soluble extractives	12.78%
pH (10% aqueous solution)	5.86 ± 0.10
Tablet Parameters:	
Diameter in mm (Mean ± St. Dev.)	7 ± 0.15
Weight (Mean ± St. Dev.)	550 ± 12.41mg
Friability (Loss percentage)	0.11%
Hardness (Kg/cm ²)	9.01 ± 0.07
Dissolution time	10.55 minutes
Patron: Honourable Shri Aroor Ramesh Rao Laboratory is not liable to bear any legal action or dispute based on this report	

 QUALITY CONTROL LABORATORIES ALN RAO MEMORIAL AYURVEDIC MEDICAL COLLEGE AND PG CENTRE KOPPA, DISTRICT: CHIKMAGALUR, KARNATAKA, 577116	
Reference Number: QC/ST/20/2020	Date: 23 rd November 2020
Purpose: Analysis for Gokshuradi Guggulu	
Result:	
A. Organoleptic Characters:	
Colour	Greyish black
Odour	Characteristic
Taste	Astringent, bitter, pungent
Texture	Vat (gills)
B. Physico-chemical parameters:	
Foreign matter	0.00%
Loss on Drying at 105°C	7.53%
Total ash	9.34%
Acid insoluble ash	3.82%
Water insoluble ash	5.85%
Water soluble extractives	42.67%
Alcohol soluble extractives	18.66%
pH (10% aqueous solution)	4.92 ± 0.10
Tablet Parameters:	
Diameter in mm (Mean ± St. Dev.)	6 ± 0.25
Weight (Mean ± St. Dev.)	450 ± 11.33mg
Friability (Loss percentage)	0.79%
Hardness (Kg/cm ²)	10.11 ± 0.09
Dissolution time	11.58 minutes
Patron: Honourable Shri Aroor Ramesh Rao Laboratory is not liable to bear any legal action or dispute based on this report	

 QUALITY CONTROL LABORATORIES ALN RAO MEMORIAL AYURVEDIC MEDICAL COLLEGE AND PG CENTRE KOPPA, DISTRICT: CHIKMAGALUR, KARNATAKA, 577116	
Reference Number: QC/ST/22/2020	Date: 28 th November 2020
Purpose: Analysis for Varunadi Kwath	
Result:	
A. Organoleptic Characters:	
Colour	Green
Odour	Characteristic
Taste	Astringent, bitter
Texture	Coarse powder
B. Physico-chemical parameters:	
Foreign matter	0.05%
Loss on Drying at 105°C	4.08%
Total ash	11.32%
Acid insoluble ash	1.73%
Water insoluble ash	7.57%
Water soluble extractives	31.71%
Alcohol soluble extractives	23.38%
pH (10% aqueous solution)	5.42 ± 0.10
C. Preliminary Phytochemical Tests (Qualitative Tests)	
Carbohydrate	Present
Protein	Present
Alkaloid	Present
Glycoside	Present
Flavonoid	Present
Tannin	Present
Terpenoids	Present
Saponin	Present
Phytosteroid	Present
Patron: Honourable Shri Aroor Ramesh Rao Laboratory is not liable to bear any legal action or dispute based on this report	

The drug selected were identified. Later the decision was made to genuinely prepare these medicines and also for clinical use in OPD practice instead of using market available

pharmaceutical product. Hence effort was made for *Chandraprabha Vati*, *Gokshuradi Guggulu* and *Varunadi Kwath(kashaya)*, was prepared by ideal pharmaceutical preparations to ensure the genuinely by examining all necessary analytical parameters. **The results and analytical values were confirmed by pharmaceutical experts. All the parameters were within the range and there is nil microbial (aerobic and fungal) contamination.**

An effort was made towards manufacturing of these three medicines in order to use in OPD or clinically practices. This was ensuring the potency and efficacy of the product hence effort was made for their pharmaceutical study.

► Ethics committee clearance and consent

As this was a clinical research, Institutional Ethics Committee (IEC) approval was taken prior to initiation of research work & Present clinical study was registered in Clinical Trial Registry India (CTRI). The CTRI registration number of present study is **CTRI/2019/08/020891** [Registered on: 26/08/2019] - Trial Registered Prospectively.

INCLUSION CRITERIA

- ❖ Patients between 20 to 60 years of age irrespective of sex and occupation.
- ❖ Size of the urinary calculi from 2 mm to 15 mm, without any complications.
- ❖ Calculus present in urinary tract Kidney, ureter, lower part of urinary tract etc.
- ❖ Patients having signs and symptoms of *Ashmari* (renal stone) **viz.**

***RuknabhisevaniBastimoordhashu* (Urination)**

- ❖ Pain in the region of umbilicus, perineum and dome of bladder; experience of severe pain on movement of the urine were be include.
- ❖ Patient having Refer pain lower back to abdomen, in external genitalia and groin get burning sensation during urination or blood in urine and increase urge and frequency of urination. On- specific symptoms of stones in the kidney include Fever, Haematuria, Nausea, vomiting, burning micturition.

EXCLUSION CRITERIA

- ❖ Congenital obstructive defects of renal, pelvis and ureter.
- ❖ Patient of *Ashmari* having systemic diseases like **IHD, RHD, AIDS&** other **chronic** diseases like **TB** and **acute & chronic renal failures**.
- ❖ Pregnant women and lactating mother & patients below **20** years.

DIAGNOSTIC CRITERIA

Diagnosis was done based on classical signs and symptoms of *Ashmari* (renal stone). Laboratory investigations were performed for differential diagnosis as well as for the exclusion.

Assessment Criteria

Parameters of assessment were based on subjective and objective parameters of *Ashmari* (renal stone).

Subjective Parameters

Renal colic (Pain in lumber region), Burning micturition, Dysuria, Tenderness.

Objective Parameters (on the basis of Laboratory Investigations)

Size of renal stone through USG Findings, Urine routine and microscopic- Haematuria, Pus cells.

INTERVENTIONS

After thorough examination of the patient, the treatment starts with *Yoga Basti* as *Shodhana chikitsa* for eight days. In *Yoga Basti*- *Sahacharadi oil* 140 ml(12Tola) after meal in morning is use under *Anuvasan basti* and *Varunadi kwath* is use under *Asthapan basti* 750 ml (64Tola) before meal in morning and *Shaman yoga chikitsa* is continue for 60 days. Combination of the drug in *Shaman yoga chikitsa* is *Varunadi kwatha* 90 ml in divided dose a day before meal, *chandraprabha vati* 250 mg twice a day with honey before meal and *gokshuradi guggul* 500 mg twice a day after meal with warm water for 60 days was given.

CRITERIA FOR ASSESSMENT

Overall assessment of the therapy was made based on the subjective and objective parameters improvement in Signs and symptoms were assessed before and after the treatment according to the **grade score**. Total duration of treatment was 60 days. Signs and symptoms were assessed before and after treatment. Investigations was done on the Initially and at the end of the treatment of the patient.

TableNo.1: Gradation of symptoms for assessment of Subjective Criteria

<i>Nabhi-Basti-Sevani-Mehna vedna (Renal colic/Pain in lumber region)</i>	No pain	0
	Mild pain	1
	Moderate pain	2
	Sever pain	3

Mutra Daha (Burning Micturition)	No burning micturition	0
	Occasional burning micturition	1
	Occasional burning micturition, required treatment	2
	Constant burning micturition required treatment	3
Mutrakrichhrata (Dysuria)	No dysuria	0
	Occasional dysuria relives without alkalizer or medicament, associated urethral pain after 1 hour of urination	1
	Occasional dysuria which requires treatment, associated urethral pain more then 1hrs after urination.	2
	Constant dysuria doesn't relive by treatment and continue associated urethral pain for 24 hrs.	3
Atiyavilam (Tenderness at Renal Angle)	No tenderness	0
	Mild tenderness	1
	Moderate tenderness	2
	Severe tenderness	3

TableNo.2: Gradation of symptoms for assessment of Objective Criteria

Sarudhir mutrata (Haematuria)	On the basis of microscopic urine analysis	
	No RBC/Hpf	0
	0 – 5 RBC/Hpf	1
	6 – 10 RBC/Hpf	2
	11 – 15 RBC/Hpf	3
	>16 RBC/Hpf	4
Atiyavilam (Pus Cells)	On the basis: On the basis of microscopic urine analysis	
	No pus cells/Hpf	0
	0 – 5 pus cells/Hpf	1
	6 – 10 pus cells/Hpf	2
	11 – 15 pus cells/Hpf	3
	>16 pus cells/Hpf	4
Size of renal stone	No stone	0
	0-5 mm	1
	6-10 mm	2
	11- 15 mm	3

Assessment criteria: Statistical Method applied for Assessment: Mean, percentage, \pm S.D., \pm S.E., 't' and P value were calculated. All the values in following tables are calculated by using **Wilcoxon sign rank test** for **subjective criteria** and **Paired t-test** applied for **objective criteria**. Statistical analysis of every symptom is described separately. The information gathered based on above observations was subjected to statistical analysis in terms of mean (X), standard deviation (S.D.) and standard error (S.E.). **Paired test was carried out at P<0.01, P<0.05 and P<0.001 levels.** The obtained results were interpreted as:

Overall Assessment: Insignificant - $P > 0.05$, Significant - $P < 0.05$, < 0.01 , Highly Significant - $P < 0.001$.

Observation/ data interpretation

Table 3: Nidana sevana wise distributions of 60 patients of Ashmari

Nidana	No of patients	Percentage
Asamshodhana sheela	44	73.33%
Apathya sevana	53	88.33%
Alpa jalapana	45	75%
Atilanghana	28	46.66%
Aniyamita dincharya	44	73.33%
Adhyasana	13	21.66%
Sheeta ahara	20	33.33%
Snigdh Ahara	22	36.66%
Madhura Ahara	21	35%
Guru Ahara	28	46.66%
Teektaausna sewana	13	21.66%
Madhya sevana	13	21.66%
Samish (nonvegetarian)	28	46.66%
Vegadharana	54	90%
Atapsevana	15	25%
Atichankramana	23	38.33%
Deewaswapna	25	41.60%

TableNo.4: Kala wise distributions of 60 patients of Ashmari.

Kala	No of patients	Percentage
Varsha ritu	6	10 %
Grishma ritu	40	66.7 %
Shita ritu	14	23.3 %

Table 5: Size, Number of stone wise distributions of 60 patients of Ashmari.

Size of stone	No. of patients	Percentage
2 – 5 mm	27	45%
6 – 10 mm	29	48.33%
11 – 15 mm	10	16.66%

Number of stone	No. of patients	Percent
Single stone	37	61.7 %
Multiple stone	23	38.3 %

Table No.6: Clinical features wise distributions of 60 patients of Ashmari

Clinical features	No of patients	Percentage
Nabhi-Basti-Sevani-Mehna Vedna (Renal colic/Pain in lumber region)	58	96.6%

<i>Mutradaha</i> (Burning micturition)	48	80%
<i>Mutrakruchhra</i> (Dysuria)	46	76.6%
<i>Shoph</i> (Tenderness at renal angle)	49	81.6%
<i>Sarudhir Mutrata</i> (Haematuria)	24	40%
<i>Atiavil Mutrata</i> (Pus cells present in urine)	19	31.6%

RESULTS

Table 7: Effect of Treatment on Subjective Criteria.

Symptoms	Mean score		% Of Relief Symptom	S.D (±)		S.E. (±)		P	Results
	BT	AT		BT	AT	BT	AT		
Renal Colic	2.083	0.667	63.1%	0.696	0.542	0.089	0.069	P<0.05	Significant
Burning Micturition	1.483	0.083	94.4%	0.747	0.278	0.096	0.035	P<0.001	Highly Significant
Dysuria	1.250	0.167	86.6%	1.035	0.492	0.133	0.063	P<0.05	Significant
Tenderness	1.7	0.467	72.5%	0.829	0.535	0.107	0.069	<0.05	Significant

Table No.8: Effect of Treatment on Objective Criteria.

Symptoms	Mean score		% Of Relief	S.D (±)	S.E. (±)	T	P	Results
	BT	AT						
Haematuria	2.08	0.214	89.7 %	1.84	0.26	7.13	<0.05	Significant
Pus Cells	2.34	0.208	91.1 %	2.031	0.262	8.10	P<0.001	Highly Significant
Size of Stone	7.891	4.129	47.6 %	1.317	0.186	20.2	<0.05	Significant

TableNo.9: Number of Stone.

BT		AT	
Size of Stone	No. of Stone	Size of Stone	No. of Stone
0 to 5 mm	39	Expelled out	26
		0 to 5 mm	13
5 to 10 mm	60	Expelled out	21
		0 to 5 mm	14
		5 to 10 mm	25
10 to 15 mm	20	Expelled out	1
		0 to 5 mm	0
		5 to 10 mm	8
		10 to 15 mm	11

RESULT AND DISCUSSION/ FINDINGS, CONCLUSIONS AND SUGGESTIONS OF THE STUDY

► Discussion on Disease and Drugs

► According to *Acharya Susruta*, indulging of *apathya ahara vihar* (unwholesome diet and regimen), not follow proper *Samshodhan* therapy gets their *Kapha dosha* aggravated, that aggravate *Kapha dosha* carried through circulation and reached to *Mutravaha srotas* mixed with *Mutra* (urine) and the *Mutra* gets *Prakupita*. With the help of *Mutravahaknadies* (urinary tract) and the help of *vata dosha*, *Prakupita Mutra* enter into the *Basti*.

► Discussion on probable mode of action of medicines

The action of every drug is determined by the dominant pharmacodynamics factors.

1. Yoga Basti - Basti Maintain the Vata dosha & eliminates *Purish-Kapha-Pitta-Vayu* & *Mutra* from the body, facilitating the absorption of endotoxin and producing detoxification during elimination helps inhibit the formation of stone and decrease the recurrence rate of disease

2. Varunadi kwath - Varunadi kwath Kapha- Vata Shamaka by ushna guna, kaphghna by katu & snigdha guna. which is directly act on *Mutravaha srotas*, **inhibits the binding of Kapha dosha. Results reduces the growth of the calculus and prevents hyper-concentration of urine**

3. Gokshuradi guggul - The Madhura Rasa, Snigdha guna and Madhura vipaka decrease the aggreivated Vata Dosha where as sheeta veerya act as Mootral & Pittahara. **It stimulates the urinary system results increase urine volume and Stone is excrete through urine from the body.**

4. Chandraprabha Vati - The ingredients of *chandraprabha vati* possess *Karchura / Chandraprbha (curcuma zedoaria)*, *Vacha (acorus calamus)*, *kiratikta/chirayata (swertia chirayita)* & *Haridra (curcuma longa)* has laghu- tikshna guna, katu-tikta rasa, vipaka katu and ushna virya act as kapha-vata shamaka properties. **its katu-tikta-ushna guna works as deepana, anulomana, rochana, krimighna, ushna virya** maintain body temperature act as *jwaraghna*. its *Mutrajanana* property helps in reduce increase frequency of micturition by frequent flow of urine with increase in urine volume. *lekhaniya guna* of *Vacha* directly act on *ashmari* which can be helps in decreases the size of stone. Its *tikta-kashaya rasa* increases *agni* acts as *deepana*, *lekhaniya- ruksha guna* rapidly decrease the stone and *sara guna* increase the mobility of vitiated *doshas* and remove from the body & act as best alkalizer which is alkaline in nature having ph. 11.73. thus, it helps to neutralize the acidic media &

prevent calculus formation as well as change in pH of urine with prevents the hyper-concentration of the urine. its *sheeta veerya* coolant in nature decrease *pitta* with decrease heat of the body and control blood pressure, good for heart as *hridya*, *katu vipaka* helps in *kapha viliyana* and *chedan. anulomaka- vata* to move downwards.

► all the drug combinedly act as dominance with *katu-tikta-kashaya rasa*, *ruksha-laghu guna*, *ushna virya*, *madhura vipaka* act as *tridoshashamaka*, *deepana- pachana*, *mutrala*, *jwarghna*, *kaphaghna*. *shothahara*, *vednashama*, *lekhaniya*, *anulomaka*, *raktaprasadaka*, *rasayana*.

► As this protocol explain by *acharya sushrut* can help in *samprapti vighatan* of *mutravaha srotas vyadhi*.

► Discussion on the observation and results

► In this clinical study, as we observed about the factors that promotes in pathogenesis of formation of stone has found in 60 patients as described below.

► **Age** - This might be due to the stressed work, irregular dietetics habits, lack of improper daily routines life, late night awaking etc. there by reducing the quantity of urine output in turn prompted in pathogenesis of formation of stone.

► **Diet:** According to classical text *Nidana sevan* has responsible factor in aggravation of disease *Ashmari*, *Ashmari* mainly occurs in those who does not take proper fluid intake with proper diet, dehydrated body is main etiological factors in create pathogenesis. These conditions found maximum in Students i.e., 17(28.3%).

► **Socio-economic status:** As shown in pathogenesis, it starts from disturbance in digestion, where already patients were suffering from *Agnimandhya* and etiological factors make it more prone. Dietary habits were one another main etiological factors which occurs *Agnimandhy*.

► **Kala:** One another factor were observed that **excessive heat and sun stroke gets dehydrated to the body due to it increased perspiration leading to more concentrated urine thereby leading to formation of *Ashmari***. Aggravation's period of *Ashmari* disease observed in *Grishma ritu* i.e., 40 (66.7%) and 14 (23.3%) were aggravated in *Shita ritu* while 6 (10%) in *Varsha ritu*.

► Discussion on the results

EFFECT OF THERAPIES

- **The null hypothesis, H_0 :** The effect of treatment on all symptoms in combined effect of *Yoga Basti & Shamana Yoga chikitsa* is not significant.
- **The alternate hypothesis, H_1 :** The effect of treatment on all symptoms in combined effect of *Yoga Basti & Shamana Yoga chikitsa* is significant.
- **Effect on Renal colic:** This relief has due to the *Basti* therapy that control the *Vata* which has the main responsible factor of Pain. with that *ushnavirya* of Medicine act as *Vednasthapana & Shothahara* like Anti-inflammatory and analgesic drugs like Guggulu (*Commiphoramukul* Hook. Ex Stocks), *Gokshura*, also uphold to maintain pain.
- **Effect on *Mutradaha* (Burning Micturition):** This relief is due to the properties of contains the drugs like *lavana*, *Shilajeeta*, *Lohabhasm*, *Chandana*, *Ushir*, *Dhanyak* etc. has decreases pitta with their *shita guna* with maintain in ph of Urine.
- **Effect on *Mutrakricchrata* (Dysuria):** This relief is due to the properties of contains the drugs like *Gokshura*, *Varuna* etc which are having properties like *Laghu*, *Snigdha guna*, *Madhura vipaka*, *Sheeta virya* with *Mutra virechaniya* properties and *Vata-pittahara Doshaghnata* this helps in reducing the *Daha* produced due to the *Ashmari*.
- **Effect on *Basti Shopha* (Tenderness):** It is due to the *vatahara* and *shopha* hara properties of drugs.
- **Effect on size of stone:** effect of treatment **47.67%** approx. relief provided. The results were statistically significant with p value ($p < 0.001$). On the basis of **Ultrasonographic reports the size of stone is decrease in all the patients reduced after treatment.**
- **Follow up of the period can be extended to know the efficacy of the therapy.**

CONCLUSION

Based on the observations made in the clinical study the alternate hypothesis is accepted and null hypothesis is rejected.

Alternate Hypothesis (H_1) - The combined treatment of *yoga Basti & shaman yoga chikitsa* in *ashmari* (Renal stone) is effective.

Incidence in male is more prone. Relief in both subjective and objective parameters was highly significant. The combined effect of *Yoga Basti & Shamana Yoga Chikitsa* is significant at for subjective criteria such as Renal Colic, Burning Micturation, Dysuria, and Tenderness of *Ashmari* (Renal Stone). The combined effect of *Yoga Basti & Shamana Yoga Chikitsa* is

significant for objective criteria such as Haematuria, Pus Cells and Size of Stone of *Ashmari* (Renal Stone). Haematuria, Pus Cells are not present in 100% patients found. All the classical medicines were prepared by necessary pharmaceutical parameters. The resultant outcome for patients was satisfactory. The *Guna & Karma* of medications enlisted in the classics was actually achieved and confirmed. This gives further motivation to prepare the medications by our own to achieve desired therapeutic efficacy with hundred percent genuine qualities. It was proven that *Basti chikitsa* control the *vata* and helps in detoxification and eliminations of morbid doshas as well as *ashmari*. It was proven that *Chikitsa Sutra* explain by *Acharya sushrut* described in classics was help in breakdown the *Samprapti vighatan* (pathogenesis) of renal stone comes under *Mutravaha srotas vyadhies* (Urinary system).

- Over all conclusion was found that treatment was effective. As this protocol explain by *Acharya sushrut* it helps in breakdown the *Samprapti vighatan* (pathogenesis) of renal stone disease occurs in *Mutravaha srotas vyadhies* (Urinary system) as *Mutravirechaniya* (diuretics), *Chhedana* (Cutting & breaking), *Bhedana* (Splitting), *lekhana* (Sacrificing), increases the *Deepan* (digestive fires), *pachana* (Increase digestion), *Jwaragna* (Anti-Pyretics), *Vednashamak* (Analgesics), *Shothahara* (Anti-Inflammatory). *Sankramaka pratishedhatmaka* (Antibiotics), *Dahashamak* (coolant the Burning sensation), *Rasayan* (Immunomodulators), *Kshariya* (Alkalizers), *Shodhak* (Detoxifications), *Anulomak* (remove obstruction and gets move in down direction).

► By virtue of these medicinal properties, the administered drugs have effectively disintegrated the pathogenesis of *Ashmari* and lead to expulsion of the *Ashmari* from the urinary tract. However, based on the clinical outcome of this clinical study, it has a well-designed study for managing and cure the disease.

Clinical Outcomes

► As this protocol are effective, easily available and inexpensive, they can be used in the management of *Ashmari* (renal stone) in the initial stage when there are mild symptoms, small size of calculus with no high-grade obstruction in the urinary tract.

► Hence as per *Chikitsa Sutra* in this clinical study, *Yoga Basti* (Internal medicated enema) & *Shaman Yoga Chikitsa* (Oral Ayurvedic medication) has selected for the management of *Ashmari*. It combinely serves the purpose of *Srtoto shodhana* (open micro channels) and helps in *Samprapti bhanga/ Vighatan*. Through this we were proved that this clinical study has evaluated with authenticity through pharmacognostical procedures and developed the

pharmacognostical and phyto-chemical profile of classical medicines made by us and has proven that these *Chikitsasutra* works better which described classically as in text.

RECOMMENDATIONS

- ❖ As it is Clinical Study Invitro-Invivo Study of the drugs can be performed. So, that the proper mode of action on the aetiopathogenesis of *Ashmari* (Renal Stone) can be established.
- ❖ Follow up of the Study can be Extended up to 6 Month at least or 1 Year by giving some placebos.

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