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EFFECT OF *SHWETA PARPATI* AND *NAGARADI KASHAYA* IN THE MANAGEMENT OF UROLITHIASIS

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ABSTRACT

Background: Urolithiasis is the formation of urinary calculi at any level of the urinary tract. Urinary calculi are worldwide in distribution but are particularly common in some geographic locations such as in part of United States, South Africa, India and Southeast Asia. The problem of stone formation is considered as a medical challenge due to multifactorial aetiology involving intrinsic factors (e.g., age, sex, heredity) and extrinsic factors (e.g., geography, climate, diet, mineral composition and water intake). Current treatment modalities like ESWL & PCNL are costly and recurrence chance is also more. In Ayurveda classics, Acharyas have given a detailed description regarding urinary stones which is known as *Mutrashmari*. Many formulations with *Ashmari Bhedhaka* property mentioned in ayurvedic literatures are cost effective, devoid of complications and provide wide scope for the successful treatment of *Mutrashmari*. **Aim:** To evaluate the efficacy of internal administration of *Nagaradi Kashaya* and *Shweta Parpati* in the management of Urolithiasis. **Settings and Design:** The study was an interventional pre-post study with sample size of 21. Participants were selected according to inclusion and exclusion criteria defined in study methodology. A detailed history of participant along with urinalysis and abdominal / Pelvic USG was used for diagnosis. **Materials and Methods:** Participant were administered with the trial drug for 45 Days. Follow up of the patients were performed every 15 days. Results of urinalysis and abdominal / Pelvic USG reports on 46th day, along with clinical assessment of Subjective parameters (Pain, Renal Angle Tenderness, Burning Micturition and Dysuria), and Objective parameters (Haematuria, Epithelial cells and Pus cells in urine) were reviewed and summarized to confirm the effectiveness of the trial drug.

Result: Outcome variables were size and number of stones, changes in urinalysis, score of signs and symptoms which was analysed before and after the treatment. Further statistical analysis was performed using Wilcoxon signed-rank test and Paired t-Test as applicable. Number of stones and the size of stones among the participants shown a remarkable change with $p \leq 0.001$. The change in signs and symptoms like Pain, Burning Micturition, Dysuria and Renal Angle Tenderness also shown a $p < 0.001$ on statistical analysis. Statistical analysis results of Haematuria ($p = 0.01$), Epithelial cells ($p = 0.001$), Pus cells ($p < 0.001$) indicate a remarkable change with a significant $p < 0.05$. **Conclusion:** The study result shows that the combination trial drug of Nagaradi kashaya and Shweta parpati is effective in management of Urolithiasis.

KEYWORDS: *Mutrashmari; Urolithiasis; Shweta Parpati; Nagaradi Kashaya; Kidney stone; Urinary Calculus.*

INTRODUCTION

The most prevalent and unpleasant condition affecting the urinary system is urolithiasis, which affects around 12 percent of the global population. Urolithiasis refers to calculi or stones which are formed within the urinary tract. Calcifications could be in any part of the urinary system which includes kidneys, ureters, bladder and/or urethra. End stage renal failure, chronic kidney disease, cardio-vascular disease, diabetes mellitus, and hypertension are all associated with a higher incidence of kidney stones.[1] Kidney stones have multiple etiologies. Other complications of urolithiasis include hydronephrosis, Sepsis, urine extravasation, urethral stricture, pyelonephritis, renal scarring and renal failure.

The most prevalent kind of kidney stone is calcium oxalate. This develops at the Randall's plaque on renal papillary surfaces. Numerous physicochemical processes, such as supersaturation, nucleation, development, aggregation, and retention of the constituents of urinary stones within tubular cells, contribute to the intricate process of stone formation. An imbalance between the variables that encourage or prevent urine crystallization affects these stages.

Recent research indicates that during the past few decades, urolithiasis has increased in frequency in both developed and developing countries. This increasing tendency is linked to food and lifestyle changes, including less physical activity, as well as global warming. One in eleven Americans get kidney stones, and an estimated 600,000 Americans experience urinary

stones annually.[2] Approximately five to seven million people suffer from disease of stone in India. Also at least 1/10th of Indian population needs hospitalization due to diseases related to Urolithiasis.[3]

The stone prevalence rate in Kerala is 2,643 per 100,000 adult inhabitants older than 14 years.[4]

All ages, genders, and races are affected by kidney stones; however, males are more likely than women to experience them between the ages of 20 and 49. The predicted relapse rate for secondary stone is 10–23 percent annually, 50 percent in 5 to10 years, and 75 percent in 20 years.[5] Though the incidence of urolithiasis is rising in females, the lifetime recurrence rate is higher in males.[6] Therefore, the main goal of this study is to find an affordable, efficient antilithiatic medication that does not have any adverse effects to control urolithiasis.

In general, depending upon the patient's presentation, management of urolithiasis includes both medical therapies and surgical interventions. Oral anti-inflammatory and pain-relieving medication being the first line of management to tackle the pain related to calculi. Related symptoms of Nausea and vomiting shall be managed with antiemetics. For calculi in the range of 5-10 mm, Medical Expulsive Therapy (MET) which includes the usage of Alpha blockers to facilitate the expulsion of the calculi is useful.

Individuals who exhibit bigger stones, oliguria/anuria, solitary kidney, systemic inflammatory response syndrome (SIRS) criteria, acute renal failure, or an associated infection, may need urgent or emergent urologic intervention.

Acute urological intervention includes well-advanced techniques in the field of surgery to remove the stones. ESWL, PCNL, URS etc. However, these expensive treatment modalities are not affordable or viable in many situations due to patient conditions like, pregnancy, malignant kidney tumors, untreated UTI, hypertension, coagulopathy, aortic aneurisms etc. Hence medical management through Ayurveda becomes inevitable.

Conventional system of medicine advocates many drugs to prevent the stone formation in urinary system. However, the side effects related to these drugs prevents the regular use of such medicines. Although surgical and invasive treatments have taken great strides in recent pasts, yet the common man in developing countries may not find it affordable. Further kidney

stones, the surgery to remove the stones and the conventional techniques of management affect the Health-Related Quality of Life (HRQL) of the patient.[7]

In classical Ayurvedic texts, Urinary Calculi is referred to as *Mutrashmari*. It is considered as one among the *Ashta Mahagadas*, since the condition is difficult to cure and can disturb the anatomy and physiology of the urinary system. It has been mentioned in all ayurvedic texts, but *Acharya Susrutha* has described it elaborately along with medical and surgical management.[8] But *Acharya Charaka* mentioned only medical management. In ayurvedic classics various formulations are mentioned in this context but only a few of them are scientifically validated.

The present study aims to utilize a combination of *Shweta Parpati* and *Nagaradi Kashaya* in specific proportion for the management of Urolithiasis. The study is expected to contribute valuable information regarding therapeutic use of these drugs in the management of Urolithiasis. It is easy to prepare, administer and cost effective. The ingredients are easily available and are without any known side effects.

Nagaradi Kashaya is referred in *Chakradatta.*[9] The main ingredients of which is *Nagara, Varuna, Kallurvanchi, Gokshura* and *Brahmi* which possesses *Kaphavata shamana, Ashmari Bhedana, Mutrala, Deepana and Pachana* properties. It has been used by local traditional *Vaidya's* in urinary calculi with promising results. But proper documented scientific evidence of this formulation is not available till now. Physicochemical analysis of this combination also is not done.

Shweta Parpati is referred in *Siddhayogasangrah*[10] and has direct indications in *Mutrashmari.* The main ingredients *Suryakshara* and *Sphatika* in *Shweta Parpati have Ashmari Bhedana, Mutrala, Vastishodhana and Rasayana* properties.

Hence the present study, which involves a sizable group of participants with controlled monitoring, follow ups and feedbacks, is effective in documenting the results and further performing a scientific proof-based evaluation of the efficacy of the drug combination in the management of Urolithiasis.

AIM

To find out the effect of *Shweta Parpati* and *Nagaradi Kashaya* in the Management of Urolithiasis.

OBJECTIVE

- To evaluate the effect of *Shweta Parpati* and *Nagaradi Kashaya* in reducing the size of the stone.
- To evaluate the effect of *Shweta Parpati* and *Nagaradi Kashaya* in reducing the signs and symptoms of Urolithiasis.

MATERIALS AND METHODS

Research study to evaluate the effect of *Shweta Parpati* and *Nagaradi Kashaya* in the management of Urolithiasis was performed following a mixed research methodology which included both qualitative and quantitative methodologies. Qualitative methodology was utilized for patient assessment through clinical consultation and assessment of the symptoms. Quantitative method was followed for analysing the effect of the administered combination by obtaining numerical data, through USG and urinalysis before and after treatment and further statistical evaluation of the data.

STUDY SETTING

Participants attending OPD *Kayachikitsa* Department Government Ayurveda College Hospital, Thiruvananthapuram.

STUDY DESIGN

Interventional Study – Single group Pre-post clinical study.

STUDY POPULATION

Participants aged 20 - 60 years of both sexes diagnosed as Urolithiasis and confirmed by USG with stone size < 10 mm from the OPD of *Kayachikitsa* Government Ayurveda College, Thiruvananthapuram.

SAMPLING METHOD - Consecutive Sampling.

SAMPLE SIZE – 23.

SELECTION CRITERIA

Inclusion Criteria

- Participants of both sexes between the age group of 20 - 60 years diagnosed as Urolithiasis and confirmed by USG.
- The size of calculi is less than 10 mm.

Exclusion Criteria

- Participants with known cases of renal insufficiency.
- Participants suffering from known cases of Cardiac Illness.
- Participants with uncontrolled Diabetes and Hypertension.
- Pregnant & Lactating Women.
- Participants with Malignancy.

INTERVENTION

Name and Details of the drug

- *Shweta Parpati* mentioned in *Siddhayogasangraham Ashmari Mutrakrichradhikaram.*

Ingredients of *Shweta Parpati* is tabulated below*:*

Table 1: Shweta Parpati – Ingredients.

DRUG	IUPAC NAME	FORMULA
SHWETA PARPATI		
Surya Kshara	*Potassium Nitrate*	KNO_3
Sphatika	*Potash Alum*	$K_2SO_4.Al_2(SO_4)_3.24H_2O$
Navasadara	*Ammonium Chloride*	NH_4Cl

- *Nagaradi Kashaya* with Y*avakshara* and *Guda* as *anupana* mentioned in *Chakradattam Asmaryadhikaram*. Ingredients of *Nagaradi kashaya* as below:

Table 2: Nagaradi Kashayam – Ingredients.

DRUG	BOTANICAL NAME	FAMILY	PARTS USED
NAGARADI KASHAYA			
Nagaram	*Zingiber officinale*	*Zingiberaceae*	Tuberous root
Varuna	*Crataeva nurvala*	*Capparaceae*	Bark
Kallurvanchi	*Bergenia ligulata*	*Saxifragaceae*	Rhizome
Gokshura	*Tribulus terrestris*	*Zygophyllaceae*	Fruits
Brahmi	*Bacopa monnieri*	*Scrophulariacea*	Whole plant

Trial Drug Preparation – Shweta Parpati

There are 3 stages in the preparation of Shweta Parpati as per *Siddhayogasangraham*:

➢ *Poorva karma* includes grinding and mixing of *Asudhha Surya Kshara, Sphatika and Navasadara* in the ratio of 16:2:1. Then collected powder is taken in the Mud *Sharava.*

➢ *Pradhana karma* includes heating of this mixture in mud *sharava* over fire till the complete melting to liquid stage. Then it is quickly spread over the flat non-reactive surface for cooling.

➢ *Paschat karma* includes collection of these white flakes like *Shweta Parpati* and storage in the airtight container after grinding into fine powder.

Further the powdered drug was capsulated (Hard Gelatine) and given to participants in capsule form.

Trial Drug Preparation – Nagaradi Kashayam

Nagaradi Kashaya Choornam is prepared as per the references in *Chakradattom*

Nagara, Varuna, Kallurvanchi, Gokshura, Brahmi, drugs which satisfy standard parameters will be collected from genuine source. These drugs were washed, dried in shade, chipped and dispensed in airtight packet of 48 gm (9.6 gm each drug). Given printed direction to the patient in regional language to make *Kashaya* each day by using 48 gm of drug. (*Kashaya* preparing direction for one day: -Take one packet of Kashaya Choorna (48 gm Coarse Powder), add 768ml of water and reduce to 96ml in mild fire and drink while bearable hot).

Details regarding the study drug was explained to the participants. They were advised to take 48ml of *Nagaradi Kashaya* twice daily, one hour before food with 500 mg *Yavakshara* and 6gm *Guda* as *anupana* along with 500mg of *Shweta Parpati* in capsule form twice daily one hour after food with water for 45 Days. Participants were advised for regular visits at an interval of 15 days for uninterrupted feedback. Evaluation was done on 0th and 46th days. The results were statistically analysed.

ASSESMENT CRITERIA

Clinical assessments based on subjective and objective parameters were made on 0th day and 46th day. USG (abdomen & pelvis) was taken on 0th and 46th day.

The outcome measures assessed were pain and tenderness over renal angle, dysuria, burning micturition, hematuria, pus cells in urine and size of the calculi on USG (Abdomen & pelvis).

Below scoring table was used for the subjective parameter evaluation:

Table: 3 Scoring Criteria.

	PAIN
0	No pain
1	Occasional pain, did not require treatment
2	Occasional pain, but require treatment
3	Constant dull ache pain

4	Severe constant pain but did not show relief after treatment
GRADE	**BURNING MICTURITION**
0	No burning micturition
1	Occasional burning micturition, did not require treatment
2	Occasional burning micturition, but require treatment
3	Constant burning micturition
4	Constant severe burning micturition but did not show relief after treatment
GRADE	**DYSURIA**
0	No dysuria
1	Occasional dysuria, did not require treatment
2	Occasional dysuria, but require treatment
3	Constant dysuria
4	Constant severe dysuria but did not show relief after treatment
GRADE	**RENAL ANGLE TENDERNESS**
0	No Tenderness
1	Mild Tenderness
2	Moderate Tenderness
3	Severe Tenderness
4	Acute severe Tenderness
GRADE	**HAEMATURIA (ON MICROSCOPIC EXAMINATION OF URINE)**
0	No RBC / hpf
1	0 – 5 RBC / hpf
2	6 – 10 RBC / hpf
3	11 – 15 RBC / hpf
4	> 15 RBC / hpf
GRADE	**PUS CELLS (ON MICROSCOPIC EXAMINATION OF URINE)**
0	No pus cells / hpf
1	0 – 5 pus cells / hpf
2	6 – 10 pus cells / hpf
3	11 – 15 pus cells / hpf 4 - > 15 pus cells / hpf
4	No pus cells / hpf
GRADE	**CRYSTALS (ON MICROSCOPIC EXAMINATION OF URINE)**
0	0 – Absent
1	1 - Present

DATA ANALYSIS

The Clinical study to evaluate the effect of *Shweta Parpati* and *Nagaradi Kashaya* in the management of Urolithiasis was conducted on a group of 23 participants. Out of the 23 participants, two participants we not able to continue the medication due to personal reasons, one being discontinued due to fever and the other due to lack of improvement of symptoms. Hence was considered as dropped out from the studies.

Remaining 21 participants were consistently involved in the study and were evaluated on a regular basis of 15 days to analyse the effect of the medication. Lifestyle improvement advices and guidance about the importance of taking medicine regularly were provided to

each participant on every visit and feedback taken on the same during subsequent visits to ensure that the participant has taken the medication properly.

Study started with collecting preliminary data and data based on symptoms from each participant. Blood reports and USG report of Abdomen and Pelvis presented were evaluated to record the condition of each patient before treatment. Further the data related to prevailing symptoms were also captured during the first visit.

Data collected were categorized into data related to:

- Socio-demographic data
- Family history
- Treatment history
- Personal history
- Disease
- Response to treatment with respect to Signs and Symptoms
- Urinalysis
- Ultrasonography (USG) – Abdomen and Pelvis reports

Final data related to the status of the disease post treatment was collected through personal consultations and respective USG scan reports at the end of 46 days.

Data collected and categorized over the duration of 46 days of treatment period were analysed statistically to find the result of the treatment. Friedman test's Chi square value and Wilcoxon Signed Rank test were used and a p value of less that 0.001 was obtained which is considered as a significant result comparing pre and post treatment.

Below table summarizes the socio-demographic incidence of the participants

Table 4: Socio-Demographic incidence of participants.

Factor	Category	Frequency	Percentage
GENDER	Male	10	48
	Female	11	52
AGE IN YEARS	20-30	1	15
	31-40	4	19
	41-50	9	43
	51-60	7	33
DIET	Vegetarian	2	10
	Mixed	19	90

DOMICILE	Urban	12	57
	Rural	9	43
OCCUPATION	Labourer/ Manual work	5	24
	Office work	7	33
	Field work	1	5
	Housewife	7	33
	Student	1	5

DISCUSSION

Discussion on selection of Trial drug

The formulations used for the trial were referred in *Chakradattam*[9] *and Siddhayogasangraham*.[10] 48ml of *Nagaradi Kashaya* twice daily, one hour before food with 500mg *Yavakshara* and 6gm *Guda* as *anupana* along with 500mg of *Shweta Parpati* in capsule form twice daily one hour after food with water for 45 Days was the dosage proposed for the trial.

The main ingredient of *Shweta Parpati*, *Suryakshara*, having *Theekshna*, *Athyushna* and *Deepana* properties will act as *Ashmari bhedana* and *patana*. *Shweta Parpati* being a *rasa yoga* and easy to prepare, are very effective in low doses to produce good results in urolithiasis. The ingredients in *Shweta Parpati* are easily available as well.

Nagaradi Kashaya having *Tridoshagna, Mutrala, Deepanapachana* and *Ashmari bhedana* properties, also gets an improved alkalizer property when it is combined with *Yavakshara* as *anupana*, thereby increasing the Anti-urolithiatic property of the same.

Discussion on the Sociodemographic background of participants

Socio-demographic data collected from the participants includes age, gender, domicile, religion, social status, educational status and occupation.

Age is an important factor having implication on the calculus formation. As age advances, many changes in body results in favourable conditions for the formation of calculus. In present study, most of the participants belonged to the age group 41-50. Out of 23 participants, 43% belong to the above age group. 33% of the participants belonged to the age group 51-60, which shows that prevalence of urolithiasis among the participants peaked in 4th to 5th decade of age.

Among the participants, 52 % were females and 48% were males. As compared to females, in general, males have higher prevalence of stones considering the difference in waist size, presence of increased Testosterone, food intake and hence difference in the urine composition. In females, hormonal changes at menopause influences the stone formation, as age advances. Out of 11 female participants in the present study 8 were of the menopausal age who have higher risk of calculi formation.

Area of domicile is a factor which can influence the stone formation, since the area of domicile influences the diet and lifestyle of the person. People in urban area probably have a busy lifestyle, irregular and untimely food habits, stressed and fast paced life, exposure to higher urban environmental temperatures as compared to rural areas, all of which are favourable factors for urinary calculi formation. In the present study 57% of the participants were from urban areas and 43% from rural areas.

Sedentary lifestyle professionals are more prone to have problems related to urinary calculi. Further the *mutra vegadharana* is a general cause of urinary calculi, which can be attributed to long working hours or lack of adequate toilet facilities. Among the participants, 29% were labourers, field workers who are more prone to above.

Discussion on the effectiveness of treatment

Effectiveness of treatment with the formulations of study was assessed based on the observations on the changes in scoring of each sign and symptom before and after treatment. The data collected before and after treatment through urinalysis and USG reports were analysed statistically as well, which showed consistent results that substantiated the effectiveness of the formulations used for the study.

Response to treatment was analysed by evaluating Subjective and Objective parameters.

Effectiveness of Treatment on Subjective Parameters

Subjective parameters evaluated as part of the study includes symptoms like pain, Burning micturition, Renal angle tenderness and Dysuria.

Pain: Before treatment 86% had occasional pain but required treatment, 14% had constant pain. After treatment only 14% had occasional pain that does not require any treatment, and remaining others were presented without any symptoms of pain. Statistical analysis also

indicates a significant difference between the data before and after treatment with a significant level of 1% (P<0.001).

Reason for pain in urolithiasis is mainly due to blockage of urine due to calculi there by resulting in swelling of kidney and spasm in ureter, which causes severe pain. Ureteral calculi are mainly responsible for the pain in urolithiasis. *Vatanulomana*, *Sothahara*, *shoolanirmulana* and *mutrala* properties of the major ingredients like *Pashanabheda*, *Varuna*, *Gokshura* in *Nagaradi Kashaya* might have resulted in reduction of pain.

Burning Micturition: Prior to receiving treatment, 33% of patients experienced occasional burning micturition that required treatment, and 10% occasionally experienced burning micturition which did not required any treatment. Only 14% of patients experienced occasional burning micturition after treatment; the other patients did not exhibit any burning micturition symptoms. A substantial change between the data before and after therapy is also shown by statistical analysis, with a significant level of 1% (P<0.001).

Burning micturition while urinating is associated with the inflammation and / or infection of the urinary tract due to the uneven edges of the passing stones. Diuretic property of *Gokshura*, Anti-inflammatory, Anti-Bacterial and diuretic activity of *Varuna* in *Nagaradi Kashaya* might have reduced the associated burning micturition. *Vranaropana* properties of *Sphatika* in *Shweta Parpati* might have helped in healing injuries which results in reduction in burning sensation. Furthermore, *Yavakshara*, which is a diuretic and alkalizer, as anupana, should have augmented the action of the drug in burning micturition.

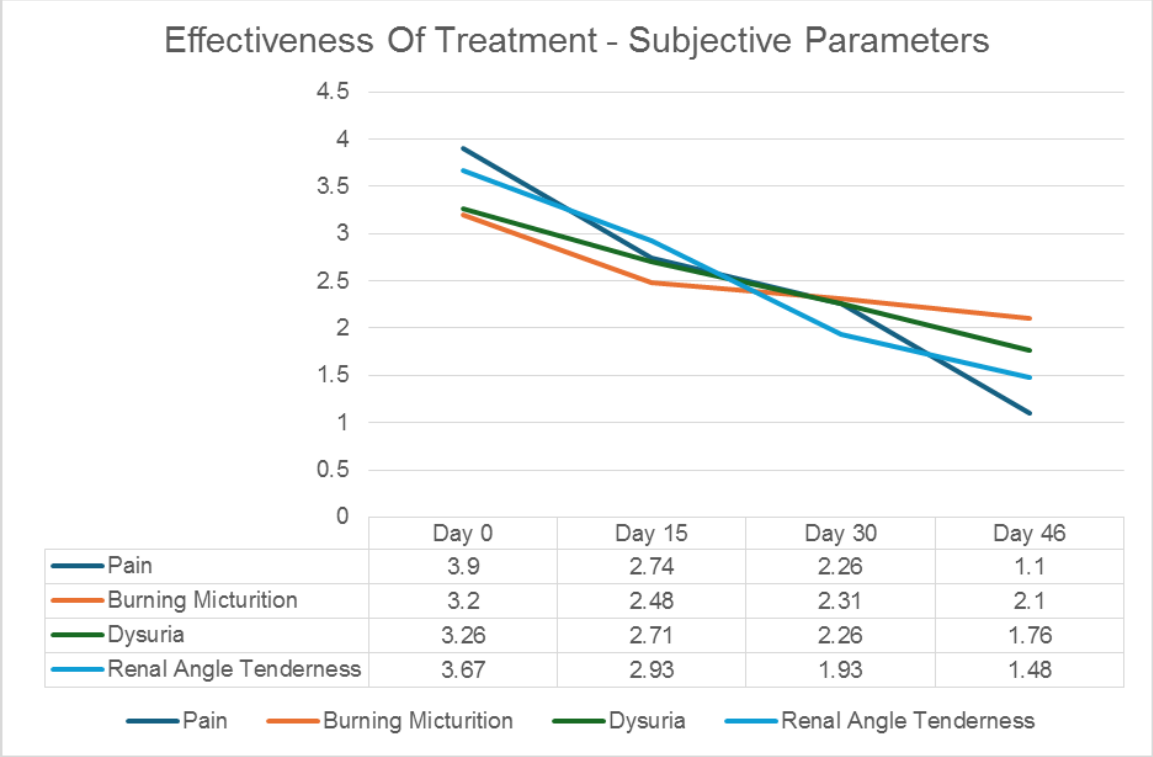
Dysuria: Dysuria refers to the pain, stinging, or itching of the urethra or urethral meatus that occurs during urination. It is a prevalent urinary symptom encountered by most people having calculus passed through the urinary tract. Urine encountering the irritated or inflamed urethral mucosal lining due to uneven edges of calculus results in dysuria. Usually this is made worse and is linked to urethral peristalsis and detrusor muscle contraction, which activates submucosal pain receptors and causes pain during urination. Present study shows that at first time presentation 5% had Grade 1, whereas 43% had Grade 2 and 10% had Grade 1 dysuria. After treatment, only 5% had Grade 1 and rest all had no Dysuria. A substantial change between the data before and after treatment also shown by statistical analysis, with a significant level of 1% (P<0.001). Anti-inflammatory and Antioxidant property of *Shweta Parpati* might have helped in reducing dysuria.

Renal Angle Tenderness: Renal tenderness or costovertebral angle tenderness associated with urolithiasis was observed in 14 participants on moderate level and in 7 participants at mild level, which constitutes 67% and 33% respectively on first time presentation. After treatment 38% of participants were presented with mild tenderness, while all others recovered. The reason for the above shall be attributed to the presence of calculus with few participants. However, on statistical analysis, the p value obtained is less than 0.001 which means the effect of treatment on renal angle tenderness is significant at 1% level.

Shoolahara, sothanischotana and *ashmari bhedana* properties of Pashanabheda and varuna might have reduced the size of calculi and pain related to the same which in turn reduces the renal angle tenderness.

Table 5: Effectiveness of Treatment – Subjective Parameters.

Subjective Parameters	Mean Rank				'p' Value	Remark
	Day 0	Day 15	Day 30	Day 46		
Pain	3.90	2.74	2.26	1.10	<0.001	Significant
Burning Micturition	3.20	2.48	2.31	2.10	<0.001	Significant
Dysuria	3.26	2.71	2.26	1.76	<0.001	Significant
Renal Angle tenderness	3.67	2.93	1.93	1.48	<0.001	Significant



Graph 1: Effectiveness of Treatment – Subjective Parameters.

Effectiveness of Treatment on Objective Parameters

Objective parameters include analyzing Urinalysis and USG before and after treatment. The presence of Hematuria, Pus cells, Crystals and Epithelial cells in urine were analyzed using urinalysis reports and the number and size of stones were analyzed using USG reports presented by the participants.

Based on Urinalysis

Hematuria: Hematuria is an indication of stones in the urinary tract. There was a significant difference between the mean value before and after treatment. The p value resulted from statistical analysis is less than 0.05 which rejects the null hypothesis and confirms a significant change before and after treatment, indicating the effectiveness of trial drugs.

Urolithiatic stones are initiated through crystallization of minerals and further hardening to form stone. In the process, the stones acquire irregular shapes and sharp edges which when passing through the urinary tract can create bruises which result in Hematuria or presence of RBC in urine. Lithotriptic activity of the main ingredient, *pashanabheda*, *varuna* and anti-inflammatory action of *Gokshura* and *Sunthi* might have resulted in reducing the stone size and reducing the inflammation thereby relieving hematuria.

Pus Cells: Pus cells in urine are indicative of physical irritation and subsequent inflammation and infection, which results from the passing of kidney stones along the urinary tract. The present study reveals a result with a mean difference of 0.91 before and after treatment and with a p value less than 0.001 which indicates a significant difference between the data collected before and after treatment, which substantiates the effectiveness of the formulations used for the treatment in the study.

Suryakshara and *Sphatika* in *Shweta parpati* has *tridoshagna*, *shodhana*, *ropana* properties. Similarly, *Suryakshara* and *Navasadara* in *Shweta parpati* has *kaphavatahara* properties. These ingredients help in maintaining an atmosphere which prevents the advancement of infection (*prakritivighata*) thereby preventing the multiplication of bacteria.

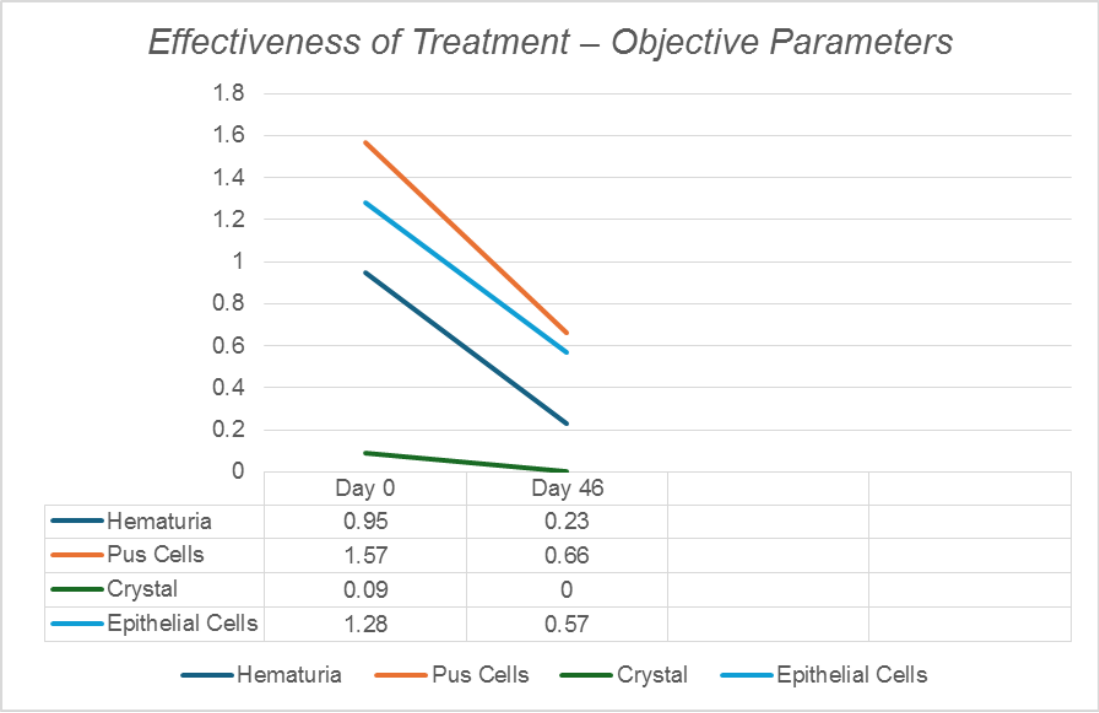
Crystal: Crystal in urine was detected in urinalysis for 2 out of the 21 participants. After treatment, the reports indicate no crystals for any of the participants. However, the statistical analysis shows a p value of 0.157 which is greater than 0.05 and results in accepting the null hypothesis. However, considering that all the participants who had crystals in urine before

treatment showed no crystal after the treatment, indicates the effectiveness of the treatment irrespective of the statistical analysis, which may be due to the lower mean difference between the pre and post treatment data.

Epithelial Cells: The presence of epithelial cells in urine indicates underlying conditions that result in shedding epithelial cells of urinary tract. Reason for the same can vary including infections in the system or calculi in the urinary system. The present study statistical analysis indicates a p value of 0.001 which indicates a significant change in the related values before and after treatment, which further substantiates the effectiveness of the treatment followed in the study.

Table 6: Effectiveness of Treatment – Objective Parameters.

Subjective Parameters	Mean Rank				'p' Value	Remark
	Day 0	Day 15	Day 30	Day 46		
Hematuria	0.95	-	-	0.23	0.010	Significant
Pus Cells	1.57	-	-	0.66	<0.001	Significant
Crystal	0.09	-	-	0.00	0.157	Significant
Epithelial Cells	1.28	-	-	0.57	0.001	Significant



Graph 2: Effectiveness of Treatment – Objective Parameters.

Based on USG (Abdomen / Pelvic)

Number of Stones: The number of stones of the participants were reviewed based on the USG report provided before and after the treatment. The distribution of the number of stones among the participants is summarized in the table below:

Table: 7 Response to Treatment – Distribution of Number of Stones.

No. Of Stones	No. of Participants			
	Before Treatment		After Treatment	
	Number	Percentage	Number	Percentage
0	0	0%	13	62%
1	12	57%	5	24%
2	6	29%	1	5%
3	0	0%	2	10%
4	1	5%	0	0%
5	2	10%	0	0%

The above table indicates the significance and effectiveness of the study formulation. Further the statistical analysis resulted in a p value 0.001 which shows that the result is statistically significant when comparing the data before and after treatment.

Below table indicates the location of stone among the participants in urinary system

Table 8: Response to Treatment – Based on location of calculi.

Position of Stone	No. of Participants			
	Before Treatment		After Treatment	
	Number	Percentage	Number	Percentage
Kidney	18	86%	6	29%
Ureter	2	10%	1	5%
Urinary Bladder	1	5%	1	5%
Urethra	0	0	0	0

From the above table it is evident that the percentage of participants with renal stone after treatment has reduced drastically by 57% as compared to the status before treatment This indicates the effectiveness of the trial drug combination in renal stones.

For Ureteric stones only 5% difference was observed which represents 50% of the participants with ureteric stones, which in turn represents the effectiveness of the trial drug combination, though the sample size with ureteric stone was less.

For Bladder stones no difference was observed before and after treatment. However, the number of participants with bladder stone was only one.

Size of Stones: Evaluation of the size of stone was performed based on the USG reports of participants. The overall mean stone size before treatment was 7.48mm which reduced to a mean size of 2.20mm after treatment. On statistical analysis, the resulted p value of less than 0.001indicates that the effect of treatment with the trial drug on the size of stones is significant.

PROBABLE MODE OF ACTION OF THE TRIAL DRUGS

The combination consists of two drugs:

a. Shweta Parpati

b. *Nagaradi Kashaya* with *Yavakshara* and *Guda* as *anupana*.

Mutrashmari being one among the A*shtamahagadas*, is a disease of *Madhyama rogamarga*. According to *Acharya Susrutha*, in persons who doesn't undergo timely *sodhana* procedures, and using unwholesome diet, *Kaphapradhana Tridosha* occurs and mixes with *mutra*, enters *basthi* and take the shape of *Ashmari.*[11] The vitiated *apana vayu* is responsible for T*heevra vedana* (Excruciating pain over region where calculi are located), *Krichra mutra nissara* (Dysuria), Vitiated pitta dosha causes S*adaha* (Burning Micturition) and *Saraktamutrata* (Haematuria).[12]

Chira sanchita doshatva, uttarothara dhatu vahagatwa, deerkha kala anubandhitwa and dursodhanatwa are the reasons for *maharogas* being *asadhya*. So, treatment for *Ashmari* must be started in the initial stage itself.

By analysing the *rasadipanchaka* and proportions of ingredients, *Shweta parpati* processes, *Katu-Lavana Rasa, Theekshna, Snigdha, Laghu guna, Ushna veerya and Katu vipaka.* Thus, the combination acts as V*asthi sodhana, Mutrala, Ashmari bhedana and Rasayana.*

Katu rasa, ushna veerya and teekshna guna of the *yoga* helps in *kapha samana*. Its *Sgnidha guna* pacifies *vata* and *pitta doshas*. *Ushna veerya* pacifies both *vata* and *kapha doshas*. Thus, the *yoga* acts as *tridosha samana*.

Katu rasa disintegrates *bandha*, dilate *srotasas* and act as *kapha samana*. *Lavana rasa* relieves *sanghata* and *bandha* and it possesses *chedana karma*. Hence the yoga disintegrates *kapha dosha*, clear *srotasas* and promotes *ashmari bhedana*. *Lekhana* property helps in reduction of size of stones. *Vranaropaka* and *raktasthambana* property of the *yoga* helps in healing the injury caused by *ashmari. Rasayana* property helps to prevent the recurrence of

stone formation and increase the overall health of the patient. For the impairment of *mutravaha srotas*, the root cause is *agnimandya*. *Deepana* property of the *yoga* improves *agni*.

Suryakshara the main ingredient in *Shweta Parpati*, acts as a good diuretic and doesn't cause any hypokalaemia unlike the other diuretics. Also, the potassium ions in it raise the pH of urine by reducing urine sodium level and will make less conducive for crystallization. Further increased pH will reduce the microbial activity in urinary tract.

Nagaradi Kashaya, contains *pashanabheda*, which has *ashmarighna, mutravirechaniya, vasthisodhana* and *bhedana* properties. Lithotriptic properties of *Pashanabheda* aids in breaking down the calculi and helps expelling the same easily and its anti-inflammatory effect reduces the inflammation and pain associated with urolithiasis.

Gokshura in *Nagaradi Kashaya* have *vatapitta samana, ashmarihara, mutrala* properties act as diuretic and relieves burning micturition.

Varuna possessing *tiktha Kashaya rasa* and *ushna veerya* has *vatashleshmahara, Deepana* and *bhedana* properties.

Yavakshara which is used as *anupana* augment the action of the drug. It possesses *Chetana* and *bhedana* properties by virtue of its *Prabhava* and anti-urolithiatic property due to its alkalinity.

The above properties of the trial drug combination were responsible for the positive results obtained in the study outcome. Statistical results also indicate a significant difference between the conditions before and after treatment for the participants. The drug combination was successful in relieving the signs and symptoms of urolithiasis during the treatment period of 45 days. Size and number of stones reduced in majority of the participants which indicate the effectiveness of the combination.

CONCLUSION

Urolithiasis with a correlation of *Mutrashmari* is one of the most common diseases affecting urinary system.

The trial drugs utilized for the study, *Shweta Parpati* and *Nagaradi Kashaya* with *Yavakshara* and *Guda* as *Anupana* is found to be effective in treating urolithiasis among the participants. The drug combination had a consistent result among participants on relieving the signs and symptoms of urolithiasis as well.

Number of stones and the size of stones among the participants of the study shown a remarkable change with p value less than or equal to 0.001.

The change in signs and symptoms like Pain, Burning Micturition, Dysuria and Renal Angle Tenderness also shown a p value of less than 0.001 on statistical analysis. Further clinical significance of the same is confirmed based on the feedback from the participants, substantiating the effectiveness of the combination in relieving the signs and symptoms of urolithiasis.

Statistical analysis results of Haematuria (p value 0.01), Epithelial cells (p value 0.001), Pus cells (p value less than 0.001) indicate a remarkable change with a significant p value of less than 0.05.

Presence of crystals in urine before and after treatment shows a p value of 0.157 in statistical analysis. However, only two participants had crystals in urine before treatment and the same was cured after treatment and no participants had crystals after treatment, thereby making the result clinically significant and hence the statistical result is ignored.

Shweta Parpati has *Ashmarihara, Mutrala, Vasthisodhana, Rasayana* properties, whereas *Nagaradi Kashaya* has *Ashmari bhedana, Kaphavata samana, Deepana* and *pachana* properties along with *Anupana Yavakshara* and *Guda,* which has resulted in reducing the number and size of stones and relieving the signs and symptoms of Urolithiasis. No adverse effect was reported on any of the participants during the treatment period.

Hence it can be concluded that the trial drug combination is effective in treating Urolithiasis.

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