



Clinical Study On Gokshuradi Kashaya In The Management Of Urolithiasis (Mutrashmari)

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Urolithiasis is one of the most common diseases found globally. It is described under the term Mutrashmari in Ayurvedic texts. In the present study an effort was made to evaluate the efficacy of Gokshuradi Kashaya (decoction of Tribulus terrestris, Ricinus cummunis, Zingiber officinalis, Creataeva nurvala). The main aim of this particular study was inclined towards the disintegration, dissolution, dislodgement and expulsion of renal stones. These drugs are easily available, economical and are easy to administer, which are having anti-inflammatory, diuretic and Antilithic properties. Total 30 patients were selected randomly and were divided into two groups i.e. Group-I and Group-II each group contains 15 patients. Group-I: This group was treated with Gokshuradi Kashaya in a dose of 45 ml, twice daily, after food for a period of 45 days. Group-II: This group was treated with hydro therapy. After completion of the study with Gokshuradi Kashaya for 45 days, the results were encouraging. The efficacy of Gokshuradi Kashaya in relief of Pain (82%), Haematuria(86%), Dysuria(78.1%), Size of calculi(88%) and Number of calculi(71.7%) was highly significant. Hence it was concluded that ayurvedic management is effective and have no adverse effects on the patients of Urolithiasis.

Key Words: Mutrashmari, Urolithiasis, Gokshuradi Kashaya.

Introduction:

urolithiasis is considered as one among the eight most deadly diseases¹, which has been described elaborately in Ayurvedic classic. Urinary stone constitute one of the commonest diseases in our country and pain due to kidney stones is known as worse than that of labour pain. Acharya sushruta has delt separate chapter for this disease². The information regarding Ashmari is available in almost all samhitha. This infers the prevalence of Ashmari since the inception of medicine in India. Anthropological history provides evidence of urinary calculi existed as long as 7000 years ago and perhaps more. Nephrolithiaosis is a common ecological disease accounting for approximately 2, 00,000 hospitalizations per year in USA alone. In India every 5 out of 1000 persons suffers from an episode of attack of renal colic. The ratio of man to women is 2:1. The disease usually peaks between the ages of 30-40 years³.

Now in this era, there are many treatment modalities like Hydro therapy and Surgical procedure are develop in this regard but failed in treating the root cause and recurrence of disease, as these procedures cannot avoid the pathogenesis behind the formation of stone results in recurrence of stone which is becoming a great problem and constant efforts are being made to evolve an effective treatment as well as prevention and recurrence of disease. It is the time for the medical science to give it's best to treat the condition effectively.

In *Ayurveda* numbers of drugs are mentioned to treat *mutrashmari*⁴. Among them the '*Gokshuradi Kashaya*' was selected for the study. This is a compound preparation of 4 drugs which are commonly and vigorously used in Urinary system disorders individually and also with other drugs⁵. This compound drug is advised in decoction form. This drug can be given on O.P.D basis and is administered without requiring

hospitalization. These drugs are easily available, economical and are easy to administer. These are also using since ancient period traditionally. These are having Analgesic¹⁸, anti-inflammatory⁶, diuretic⁷ and Antilithic⁸ properties combindly. Hence the clinical study has been undertaken to evaluate the efficacy of 'Gokshuradi Kashaya' in the management of Urolithiasis.

Aims and objectives of the study were:

- To assess the efficacy of Gokshuradi Kashaya in the management of urinary tract calculi.
- To relieve the patients from pain and mental tension associated with surgical procedures.
- To find out a simple, harmless, conservative and cost-effective method to treat Mutrashmari.

Materials and methods:

The present clinical study was a single blind clinical study where 30 patients were selected by random sampling procedure, attending the OPD of National Institute of Ayurveda and Hospital, Jaipur, Rajasthan. The selection of cases was done on the bases of clinical presentation and the diagnosis was established accordingly. The selected patients were divided into two groups, 15 in each.

Group-A (Trail group): This group was treated with *Gokshuradi Kashaya* in a dose of 45 ml, twice daily, after food for a period of 45 days.

Group-B (Control group): This group was treated with Hydro therapy.

Patients of both the group were advised for a follow up of every week for 3 weeks, during treatment. The patient was advised to drink 3-4 liters of water and to consume suitable diet with proper sleep & excretion of natural urges. Patients were advised to avoid milk, tomato, cauliflower, spinach, fish and meat (incompatible diets & regimen)⁹ during the period of treatment.

Inclusion Criteria: Patients were selected between 20 to 50yrs age group, irrespective of sex, having calculi size less than 8mm anywhere on KUB. Patient's those who were ready to give written consent.

Exclusion Criteria: Patients with size of calculi greater than 8mm, Patients with systemic pathology and any acute urinary obstructive condition.

Diagnostic Phase: The patients complaining of pain abdomen and other related symptoms like Dysuria, Haematuria and burning micturition were selected and all these patients were subjected to through general and systemic examination i.e. microscopic examination of urine, X-Ray KUB and USG. After the diagnosis was confirmed the patients were registered for the clinical study.

Gokshuradi Kashaya :

This is the drug used in the study. The ingredients of this yoga are *Tribules terrestris* fruits + *Ricinus cummunis* fruits + *Zingiber officinalis* roots + *Creataeva nurvala* bark + Water.

Preparation of Gokshuradi Kashaya¹⁴: It is a compound preparation contains 4 ayurvedic drugs (decoction of *Tribules terrestris*¹⁰, *Ricinus cummunis*¹¹, *Zingiber officinalis*¹², *Creataeva nurvala*¹³) which are having therapeutic effect on Urinary system individually. Here an effort was made to evaluate the efficacy of these drugs in combined form. In this preparation first coarse powder of all the 4 drugs is taken. 32parts of water is added to this powder. This mixture is boiled under low flame till it reduced to 1/4th part¹³. This decoction is filtered and used for trail.(Ref-Sarangadhar Samhita)¹⁴

Dosage: 45ml of *kwatha*(decoction) both the times is advice after meals for 45 days.

Hydro therapy:

The procedure in which intravenous fluids are administered to the patient (in an attempt to flush them out). Intravenous fluid administration is a standard therapy for stones.

Materials: IV stand, IV set, scalp vein needle, spirit swab, adhesive plaster strips and IV Fluid bottle-NS 0.9%.

Procedure: Compress the distal limb with hand in pumping motion to press the blood into the vein then palpate the vein & clean the site with spirit swab then puncture the vein. with the scalp vein needle then release the compressing hand then connect the IV set to the Scalp vein needle then open the regulating clamp & adjust the flow to 20drops/minute, fix the scalp vein needle securely with 3 to 4 adhesive strips .

Dosage: 2 L 0.9% saline over 4 hours.

Assessment Phase:

The patients were assessed on the basis of subjective and objective parameters before and after treatment.

A. Subjective criteria

- Pain abdomen
- Haematuria
- Dysuria

B. Objective Criteria

- Size of stone
- Site of stone
- Number of the stone

Assessment Criteria¹⁵:

Subjective criteria: Pain Abdomen¹⁶: - Pain was assessed by VAS: In term of sufferer it is Grade 0: Absence of pain/No pain; Grade I: 1 to 3 mark on scale (mild pain); Grade II: 4 to 6 mark on scale (moderate pain cannot be ignored, interferes with function, and needs treatment from time to time); Grade III: 7 to 10 mark on scale (severe-requires constant attention).

Haematuria: was assessed by routine urine examination and presence and absence of RBC. Grade 0 : Absence of RBC's in urine; Grade I: Presence of RBC's in urine; Grade II: More than 3-5 RBCs in urine; Grade III: Plenty of RBC's in urine.

Dysuria: - was assessed by history of pain and radiation during Micturition .Grade 0-Absence of pain during micturition; Grade 1-Mild pain during micturition; Grade 2-Moderate pain during micturition; Grade 3-Severe pain during micturition

Objective criteria: Size of stone: was assessed by USG every week in mm. Grade 0(good): More than 50% of decrease in size; Grade 1(fair): In between 25% to 50% of decrease size; Grade 2(poor): Less than 25% of decrease in size; Grade 3 (no response): No change in size

Site of stone: was assessed under USG guidance and graded as follows. Grade 0: Expelled; Grade 1: Stone in bladder; Grade 2: Stone in ureter; Grade 3: Stone in renal pelvis.

PH of urine: was assessed by biochemical examination of urine. **Blood Urea:** was assessed by routine urine examination. **Serum Creatinine:** was assessed by routine urine examination.

X- Ray KUB: was assessed before treatment and after treatment and was presented with Present (1) and Absent (0).

USG: was assessed before treatment and after treatment and was presented with Present (1) and Absent (o).

Assessment of result: For the purpose of the assessment of result we have used some grade points considering the severity of different sign and symptoms and clinical assessment of result of result was done as:- cure: 100% free from cardinal sign and symptoms (pain abdomen, haematuria, dysuria, site of stone & dislodgement). Maximum improvement: 75% to 99% improvement of the above mentioned cardinal sign and symptom. Moderate improvement: 50% to 75% improvement of the above mentioned cardinal sign and symptom. Mild improvement: 25% to 50% improvement of the above mentioned cardinal sign and symptom. No improvement: less than 25% improvement of the above mentioned cardinal sign and symptom.

All the patients were advised to take similar dietary regimen. The duration of treatment was 45 days in maximum. The clinical assessment was done in every 15th day's interval. The initial finding through clinical, pathological and radiological statements were compared with the result of progressive 15th day, 30th day and 45th day & so on of investigations. Grading & grouping according to the assessment criteria concerned to each item categorically differentiated the findings among the patients in the clinical study. And finally the assessment as a whole was presented in percent value. In order to present the study in a scientific manner the statistical assessment of the result were assessed of result mean \pm S.D of each sign and symptom before treatment was compared with mean \pm S.D value of after treatment, t-test was used for the purpose of the test of significance the effectiveness *Gokshuradi Kashaya* and was assessed through p-value.

Observations and Results:

Table no.1: Demographic observations of total registered patients.

Observations	Predominance	Percentage
Age	31-40	43.33%
Sex	Male	66.66%
Religion	Hindu individuals	70%
Habitat	Urban area	63.33%
Marital status	Married	76.66%
Educational status	Higher secondary	53.33%
Socio-economic status	Lower Middle class	56.66%
Occupation	Service	53.33%
Dietary habits	Mixed	73.33%
Site of the Stone	Ureteric	56.66%

Table no.2: Showing effectiveness of Drug in GROUP-A

Sign / symptom	Mean \pm S.D			Df	p-value	t-value	Effectiveness %	Remark
	BT	AT1	AT2					
Pain	2.18 \pm 0.71	AT1	1.38 \pm 0.41	14	<0.01	4.15	38%	HS
		AT2	0.78 \pm 0.46		<0.01	5.8	63%	HS
		AT3	0.6 \pm 0.68		<0.01	9.8	82%	HS
Haematuria	0.81 \pm 0.30	AT1	0.39 \pm 0.29	14	>0.01	2.9	52%	NS
		AT2	0.38 \pm 0.56		>0.01	3.6	69%	S
		AT3	0.18 \pm 0.28		<0.05	5.8	86%	HS
Dysuria	1.4 \pm 0.55	AT1	0.72 \pm 0.80	14	<0.01	5.6	45.6%	HS
		AT2	0.78 \pm 0.62		<0.01	5.1	53.3%	HS
		AT3	0.45 \pm 0.45		<0.01	6.6	78.1%	HS
Size of stone	4.88 \pm 0.28	AT1	2.6 \pm 1.4	14	<0.01	3.8	43%	HS
		AT2	1.68 \pm 1.6		<0.01	5.8	65%	HS
		AT3	0.4 \pm 0.6		<0.01	8.8	88%	HS
Site of stone	22.3 \pm 0.6	AT1	1.5 \pm 0.8	14	<0.05	2.2	31%	S
		AT2	1.07 \pm 0.7		<0.05	3.6	55%	S
		AT3	0.5 \pm 0.7		<0.01	5.7	76%	HS
Number	BT	AT1	0.73 \pm 0.46	14	>0.01	2.78	38.5%	NS

	1.24±0.34	AT2	0.73±0.4		>0.01	2.68	47.5%	NS
		AT3	0.37±0.4		<0.01	5.1	71.7%	HS
X-ray	BT	AT1	0.64±0.49		<0.01	2.4	35.7%	HS
		AT2	0.42±0.51		<0.01	4.2	57.1%	HS
	1.2±0.5	AT3	0.28±0.46		<0.01	5.7	74.5%	HS
USG	BT	AT1	0.86±0.22		<0.01	1.4	14.2%	HS
		AT2	0.5±0.51		<0.01	3.5	50%	HS
	1±0	AT3	0.28±0.46		<0.01	5.7	73.4%	HS

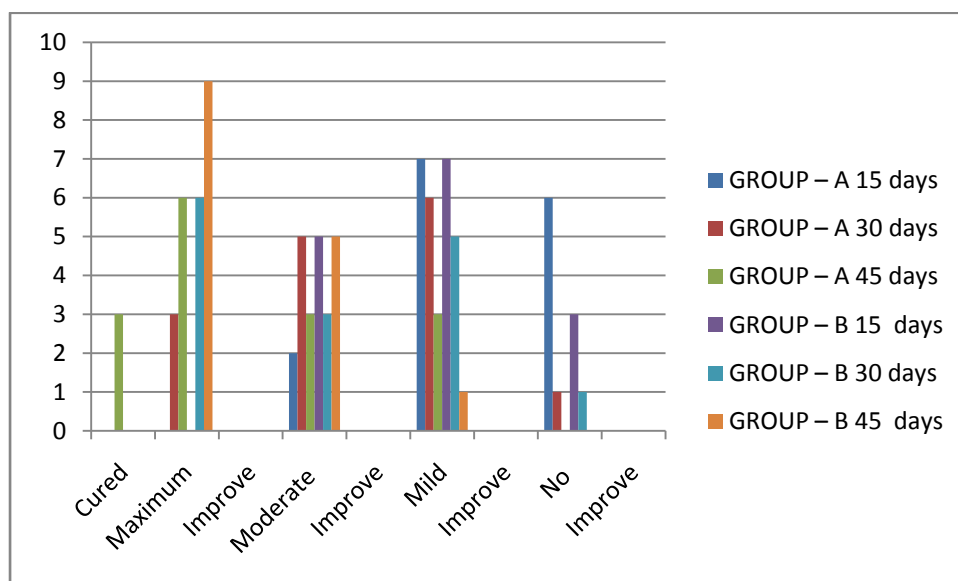
S.D–Standard deviation, B.T–Before treatment, A.T–After treatment, df– Degree of freedom, t–Test of significant, p–Probability, H.S- Highly significant N.S.- Non significant.

Table no.3: Showing effectiveness of Drug in GROUP-B

Sign /symptom	Mean ± S.D			Df	p-value	t-value	Effective ness %	Remark
Pain	BT	AT1	1.46±0.51	14	<0.01	5.29	31.20%	HS
		AT2	1.2±0.56		<0.01	5.13	43.75%	HS
	2.13±0.83	AT3	0.8±0.67		<0.01	4.93	62.50%	HS
Haematuria	BT	AT1	0.6±0.5		<0.05	1	18.10%	HS
		AT2	0.4±0.5		<0.05	2	45.40%	HS
	0.73±0.45	AT3	0.2±0.41		<0.01	4	72.20%	HS
Dysuria	BT	AT1	1.06±0.88		<0.05	6.5	44.80%	S
		AT2	0.46±0.51		<0.01	8.87	75.80%	HS
	1.93±0.79	AT3	0.33±0.48		<0.01	6.8	82%	HS
Size of stone	BT	AT1	3.7±0.9	<0.05	3.7	11	S	
		AT2	2.4±1.9	<0.01	4.4	43.30%	HS	
	4.2±0.7	AT3	1.2±1.7	<0.01	7.5	70%	HS	
Site of stone	BT	AT1	1.7±0.5	<0.05	2.6	16.10%	S	
		AT2	1.06±1.7	<0.01	3.8	48.30%	HS	
	2.06±0.70	AT3	0.7±0.45	<0.01	5.7	64.50%	HS	
Number	BT	AT1	0.9±0.25	<0.05	2.25	22.20%	S	
		AT2	0.53±0.51	<0.01	5.29	55.50%	HS	
	1.2±0.41	AT3	0.33±0.48	<0.01	9.53	72.20%	HS	
X-ray	BT	AT1	0.53±0.51	<0.01	3.5	46.60%	HS	
		AT2	0.4±0.50	<0.01	4.58	60%	HS	
	1±0	AT3	0.2±0.4	<0.01	7.4	80%	HS	
USG	BT	AT1	0.53±0.51	<0.01	3.5	46.6%	HS	
		AT2	0.4±0.50	<0.01	4.58	60%	HS	
	1±0	AT3	0.13±0.35	<0.01	9.5	86.60%	HS	

Table no.4: OVERALL CLINICAL ASSESSMENT OF RESULT

RESULT	GROUP – A			GROUP – B		
	15 days	30 days	45 days	15 days	30 days	45 days
Cured	0	0	3	0	0	0
Maximum Improve	0	3	6	0	6	9
Moderate Improve	2	5	3	5	3	5
Mild Improve	7	6	3	7	5	1
No Improve	6	1	0	3	1	0

Graph No.1: Overall Clinical Assessment of Result

Group –A: Overall Clinical assessment on 45th day showed that 0 patient had no improvement, 6 patients had maximum improvement, 3 patients had moderate improvement; whereas 3 patients had mild improvement and 3 patients had completely cured.

Group –B: Overall Clinical assessment on 45th day showed that 9 patients had maximum improvement, whereas 5 patients had moderate improvement, and 1 patient had mild improvement.

Discussion:

From the present study it becomes evident that the urological problems form an important part of medical deliberations. Perhaps, this can be the reason for detailed description of the urinary system related disease i.e. *Mutrashmari* (Urolithiasis) in our Ayurvedic texts. Old literature gives a clear idea of the disease that it has come into existence from the very beginning. In *Ayurveda madhura*(sweets) and *guru*(heavy for digestion) diets and hot climate are the main cause for the formation of *Ashmari*(stones)¹⁷.As this can be understood hypothetically with the present contemporary science that these types of food may reduce the solubility crystals in the urine, which may lead into precipitations and formation of the stone. Where as in Modern Science they have considered many causative factors for the stone formation, but stone has been seen even in those patients also, where these factors are absent. So in total, the etiology of the disease is still unknown.

Discussion upon the observation:

All cases were analyzed for the incidence of *Mutrashmari* in relation to age, sex, socio-economic status etc.

In the present series of observation it was found that 43.33%of patients were in the age group 31-40years. This indicates that the incidence is higher in 4th decade of life. Excessive work and by the excessive sweating leads to decrease in urine output in turn helps for the formation of stone. The incidence of *Mootrashmari* was relatively more in males (66.66%) than in females (33.33%) in the present study and the

ratio was almost 2:1. The incidence of calculogenesis will be same in female compared to men after menopausal age, as citrates are not secreted during menstrual cycle and after menopause (Table no.1).

On observing the distribution of incidence among Hindu, Muslim and Christian, the prevalence was seen more in Hindu (70%), in Muslim (25%) and then Christian (5%). This does not indicate the incidence as higher in Hindus. This percentage is synchronous with their general percentage in the population. People of any community appear to be equally susceptible to the disease. Incidence of socio-economic status shows predominance of Lower middle class (56.66%). It will indicate that there is no any particular socio-economic status for stone formation.

Discussion on Mode of Action of Drugs: The *Gokshuradi Kashaya* contains *Tribulus terrestris*, *Ricinus cummunis*, *Zingiber officinalis* & *Creataeva nurvala* drugs. All these drugs are having antipyretic¹⁹, analgesic¹⁸, anti-lithic⁸ and anti-inflammatory⁹ properties combindly. The major component isolated from *Creataeva nurvala* and *Ricinus cummunis* plants is lupeol, which is used to treat hypercrystalluria, hyperoxaluria and hypercalciuria. The compound is also widely used to treat urinary disorders like urolithiasis, and it decreases elevated concentration of oxalate, phosphorous and magnesium in renal tissue. Lupeol also possesses antipyretic, analgesic, anti-inflammatory activity²¹.

Discussion on Result's of Subjective criteria:

The effectiveness of the treatment adopted in both the groups in respect to each parameter is tabulated on the basis of the difference between the scores before treatment and after treatment (Table no.3&4).

Pain: The effectiveness of *Gokshuradi Kashaya* is 82% with t-value 9.8 and the level of significance of p-value is <0.01, which is highly significant. The effectiveness of group-B is 62.5% with t-value 4.93 and the level of significance of p-value is <0.01. It shows that *Gokshuradi Kashaya* having the analgesic¹⁸ and anti-inflammatory⁹ properties.

Haematuria: The effectiveness of group-A is 86% with t-value 5.8 and the level of significance of p-value is <0.01, which is highly significant. The effectiveness of group-B is 72.7% with t-value 4 and the level of significance of p-value is <0.01. The effectiveness of *Gokshuradi Kashaya* over the group-A patients are showing good response to the treatment, because of the effectiveness of the intended drugs over the *mutrashmari* showing anti-inflammatory properties.

Dysuria: The effectiveness of group-A is 78.1% with t-value 6.6 and the level of significance of p-value is <0.01. The effectiveness of group-B is 82.7% with t-value 6.80 and the level of significance of p-value is <0.01, which is highly significant. Administration of fluids causes the increase urine output by this dysuria is subsided so Hydro therapy is highly significant then *Gokshuradi Kashaya*.

Obejective criteria:

Size of stone: The effectiveness of group-A is 88% with t-value 8.8 and the level of significance of p-value is <0.01, which is highly significant. The effectiveness of group-B is 71.42% with t-value 6.99 and the level of significance of p-value is <0.01, which is highly significant. It indicates that *Gokshuradi Kashaya* having the *Ashmaribhedana* (Anti-lithic)²⁰ property.

Site of stone: The effectiveness of group-A is 76% with t-value 5.7 and the level of significance of p-value is <0.01, which is highly significant. The effectiveness of group-B is 64.5% with t-value 5.7 and the level of significance of p-value is <0.01, which is highly significant. It is due to stagnation of the urine in the specific area causes the precipitation of crystals by which stone is formed.

Number of stone: The effectiveness of group-A is 71.7% with t-value 5.1 and the level of significance of p-value is <0.01, which is highly significant. The effectiveness of group-B is 72.2% with t-value 9.53 and the level of significance of p-value is <0.01, which is highly significant.

Overall clinical assessment of result:

Finally the clinical assessment was carried out on overall results of the effect of *Gokshuradi Kashaya* on each individual sign and symptoms and collectively presented in the form of cured, maximum improvement, moderate improvement, mild improvement and no improvement (Table no.4). However it was evident that in group-A after 45 days 3(100%) patients were cured, 6 (75%-99%) had maximum improvement, 3 (50%-75%) had moderate improvement, 3(25%-50%) had mild improvement and 0(<25%) patient with no improvement. In group-B 9(75%-99%) had maximum improvement, 5(50%-75%) had moderate improvement, 1 (25%-50%) had mild improvement. *Gokshuradi Kashaya* has a significant role in the management of *Mutrashmari* as majority of patients showed highly significant response.

Conclusion:

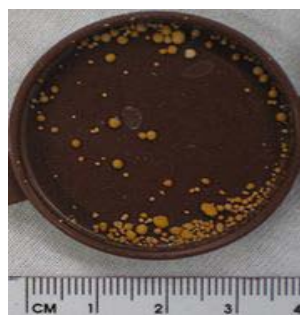
Following conclusion were drawn after analysis of review (Ayurvedic, Modern and Drug), clinical observation and interpretations on the parameters.

- In the observation it was found that, the lithotryptic(Ashmaribhedan)²⁰ action of the *Gokshuradi Kashaya* was showing significant effect.
- *Gokshuradi Kashaya* was capable of reducing Pain intensity (82%) than Hydro therapy (62.5%).
- *Gokshuradi Kashaya* was capable of reducing Haematuria (86%) than flush out therapy (70%).
- *Gokshuradi Kashaya* was capable of reducing Dysuria (78.1%) and flush out therapy (82.7%).
- *Gokshuradi Kashaya* was capable of reducing Size of stone (88%) than flush out therapy (71.42%).
- *Gokshuradi Kashaya* was capable of reducing Site of stone (76%) than flush out therapy (61.6%).
- *Gokshuradi Kashaya* was capable of reducing number of stone 71.7%) and flush out therapy (72.2%).

• TYPES OF STONES



Pic-1: Calcium oxalate stone



Pic-2: Uric acid stone



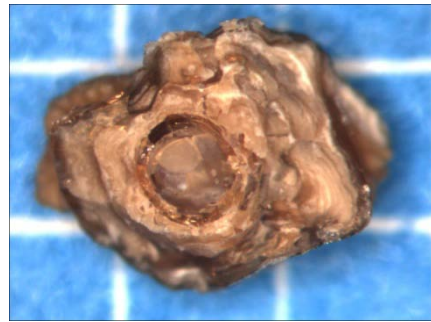
Pic-3: Cystine stone



Pic-4: Xanthine stone



• Pic-5: Phosphate stone



Pic-6: Mixed stone

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