

TO EVALUATE THE POTENTIAL OF YAVA PANEeya KSHARA (ALKALI PREPARATION OF BARLEY) ON NEPHROLITHIASIS – A PILOT STUDY

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ABSTRACT

Objective:-Renal calculi are one among such diseases which is associated with recurrence even after removal by surgery in most of the cases. In this study, *Yava Kshara* (Alkali preparation of Barley) is used to explore the supportive evidence of Litholytic activity in the management of existing and recurrent Nephrolithiasis. **Method:** - A comparative study was conducted on 20 patients. 10 patients of Group I received *Yava Kshara* and remaining 10 patients were given an indigenous drug called GCP Compound for a period of 60 days. The size of renal calculi was studied by periodic ultrasonographic assessment in both groups. Mechanistic and clinical studies evaluating the use of these agents were identified using the Medline data base. The articles were then critically reviewed and summarized. **Results:** - Statistical analysis showed that P - value of less than 0.05 was seen in Group I from 0 to 60 days course. There was no significant difference observed in the stone size in Group II when the actual value and calculated value were compared. **Conclusion:** - *Yava Kshara* can be used to reduce the recurrence of calcium oxalate stone (*Vataja Ashmari*) and it is shown to have better result than the use of indigenous GCP Compound in such cases.

Keywords: *Ashmari*, GCP Compound, *Paneeeya kshara* , Renal calculi, *Yava kshara*

INTRODUCTION

A number of people suffer from problems due to urinary stones (calculi). As much as 10.0% of men and 3.0% of women have stone at least once, during their adult life^[1]. Areas of high incidence of urinary calculi worldwide include the British Isles, Scandinavian countries, northern Australia, central Europe, northern India, Pakistan and Mediterranean Countries^[2]^[3]. Saurashtra region of Gujarat has higher prevalence of urinary stones. According to an estimate every year, 6, 00,000 Americans suffer from urinary stones^[4]. In India, 12% of the population is expected to have urinary stones, out of which 50% may end up with loss of kidneys or renal damage. Also, nearly 15% of the population of northern India suffers from kidney stones^[5]. Calcium stones are most common, comprising 75% of all urinary calculi^[6]. Although, development of modern

techniques such as Extracorporeal shock wave lithotripsy (ESWL)^[7] and Percutaneous nephrolithotomy (PCNL) have revolutionized surgical management of the problem, yet not much progress has been made towards the medical management of kidney stone problem. Patients may experience discomfort, soreness or pain at the treatment site. A prescription for pain relieving medication or extra strength of acetaminophen is recommended. Some patients also show discomfort or pain as particles pass through the ureter. A large number of Indian medicinal plants are being routinely used by practitioners of Ayurvedic system of medicine in the treatment of urinary stone disease^[6]^[7]. Many plants have also been reported all over the world which is able to inhibit kidney stones^[7]^[8]^[9]^[10]^[11]. Size of the stone is also a very important disposing factor. It was found that the stone 5 mm in size sponta-

neously passes through the urine, whereas the size more than it is to be treated properly. Most of the time, greater than 10 mm size of stone has been treated surgically. Location of the stone is also an important factor^[12] from treatment point of view. Acute renal colic has symptoms like intermittent colic pain radiating toward lower abdomen, backache, etc. and often associated with symptoms like nausea, vomiting, etc.; lower urinary symptoms like urgency in micturition, dysuria and frequency may also be present^[13]. Management of renal calculi is dependent upon size and location of the stone; unbearable pain for the calculi more than 10 mm requires strong analgesics and surgical measures as drugs dissolving such stones have so far been unsuccessful. However, the stones less than this size have been treated successfully using herbal medicines which have possess diuretic, anti-inflammatory, antimicrobial^{[2][3]} and antispasmodic activities^{[14][15]}. An alarming rise in the incidence of urolithiasis coupled with a motivation provided by W.H.O. (World Health Organization) to explore the possibility of discovering cure on traditional line has created an impetus for further research in the light of Ayurvedic knowledge. So, here an attempt has been made to evaluate the potential of Yava Paneeya Kshara on nephrolithiasis.

AIMS AND OBJECTIVES

1. To study the Litholytic activity of Yava Kshara (Alkali preparation of Barley).
2. To study the disease Renal Calculi in terms of its etiopathogenesis, clinical manifestations with possible correlation to the description available in modern and Ayurveda medicine for Urolithiasis.
3. To evaluate the safety and efficacy of Ayurvedic formulation in patients with urolithiasis by assessing the symptomatic relief, reduction/expulsion of renal stones, urinary biochemical parameters.

Grouping:

All the patients in the present study have been divided into two groups, containing 10 patients in each group.

Group I: 10 patients (Yava Paneeya Kshara) –EXPERIMENTAL GROUP

Group II: 10 patients (GCP Compound) – CONTROL GROUP

MATERIALS AND METHODS

Total 20 patients were taken up for study from P.G. Department of Shalya, considering selection criteria based on inclusion and exclusion criteria. 10 patients were given Yava Kshara (Alkali preparation of Barley) 400mg twice in a week internally mixed with 200 ml of sterile water, before meal in the morning for a period of 6 weeks. Remaining 10 patients were given GCP Compound (An indigenous compound prepared out of Gokshuradi guggulu, Chandraprabha Vati, Punarnavadi mandoora in equal quantities) internally with dosage of 500 mg BID schedule for a period of 6 weeks. Renal stones were diagnosed by X-ray kidney, ureter and bladder (KUB) and ultrasonography. Both the groups were subjected for a subjective parameters (Pain, Burning micturition, Dysuria, Tenderness at renal angle) and Objective parameters (X-ray KUB, USG KUB) following a standard proforma^[13]. USG for KUB determines size, consistency and location of calculus and it play an important role in assessing objective criteria. In both the groups all the patients were instructed to follow their normal dietetics and to maintain regular intervals in between the two meals. All the patients were advised to resist from all the diets which are directly or indirectly contributory to the formation of stone. Further all the patients were instructed to take plenty of water^[14].

4.2. Drug Study:

Kshara (alkali) preparation of Barley (Yava Kshara Nirma a Vidhi): This is an alkali substance, which is being prepared from the breads of Barley by adopting procedure of Kshara Nirmana Vidhi as per text. Dry Yava Panchanga should be divided into

small pieces, ignited by sesamum stalks (*Tila*) with pebbles of limestone. When the fire has burnt out, the ash and the slake lime was collected separately. Then one *Dro a* (10.24KGs) of the ash should be dissolved in six *Dro s* of water and filtered 21 times and should be treated on fire in a big pan, while it is slowly stirred by a ladle. When it becomes clear, red, sharp and slimy, it should be filtered through a wide piece of fine cloth and the filtrate should be placed again on fire after removing the separated residue^[16].

4.3. GCP Compound: A compound prepared out of *Gokshuradi guggulu* - 50gms, *Chandraprabha Vati* - 50 gms, *Punarnavadi mandoora* - 50gms in equal quantities.

Both the test drugs were prepared at the Pharmacy of S.V. Ayurveda Pharmacy, Tirupati.

5. Parameters

5.1.1. Subjective Parameters: Assessment of the therapy is done according to the relief observed in the signs and symptoms with the help of scoring pattern which is prepared according to classical Ayurveda and modern texts.

5.1.2 Objective Parameters: Based on various investigations like urine, blood, biochemical examination, X-Ray (KUB), USG (KUB) are carried before and after treatment.^[17]

6. Inclusion Criteria

6.1. Age: Between 15 to 60 years

6.2. Sex: Either sex

6.3. Radiological evidence of stone (up to 10 mm) in Kidney, Ureter and Urinary Bladder.

7. Exclusion Criteria

7.1. Patients with age below 15 years and above 60 years.

7.2. Stone size more than 10 mm.

7.3. Impacted stone.

7.4. Gross Hydronephrosis.

7.5. Pyelonephritis.

7.6. Uncontrolled Diabetic Mellitus and Hypertension

7.7. Malignancy.

7.8. Impaired Renal Function.

7.9. Poorly Functioning Kidney.

7.10. Patients with obstruction in urinary passage.

7.11. Patients with known metabolic abnormality for calculus formation.

7.12. Any other complication of calculus.

7.13. Patients undergoing treatment for any other serious illness.

8. Follow Up:

All the patients who were studied under this clinical trial after completion of treatment for prescribed period were instructed to have regular check up at the interval of 7 to 15 days for the period of 3 months (90 days). During this follow up study period patients were examined thoroughly for the recurrence of either signs and symptoms of stones.

Statistical Analysis: Urinary parameters and calculi size were analyzed by Wilcoxon signed-rank test, biochemical parameters by paired-test and complete expulsion of calculi by Fisher's exact test. Values were expressed as mean \pm SD for calculi size, relief of clinical symptoms, urine, and biochemical parameters. Complete expulsion of renal stones was expressed as the incidence of occurrences in *Ayurvedic* formulation treated groups. The minimum level of significance was fixed at $p < 0.05$.

Statistical analysis showed that P-value of less than 0.05 was seen in the first group from 0 to 3 month. There was no significant difference in the stone size within group II when the 1st month and 3rd month visit was compared with initial visit.

RESULTS

- Out of 28 patients, 10 in each group were completed the therapy & follow up period. So, in this study, general observations were made on 20 patients as mentioned in Table 1. Analytical study of both the drugs is mentioned in Table 2 and Results were made on 20 patients as shown in Tables 3 to 4.

- **Patient satisfaction:** At 4 weeks of follow-up, all patients were asked to ex-

press their degree of satisfaction about treatment outcome in terms of 'cured' / 'markedly improved' / 'improved' / 'unchanged' / 'worsened'. In group I (Yava Paneeya Kshara Group), 83.33% patients reported as 'Cured' and 16.67% as 'markedly improved' while in group II (GCP Compound Group), 66.67% patients reported as 'improved' and 33.37% as 'unchanged'. This difference of patient satisfaction was significant statistically at $P < 0.05$ using Chi-square test, with Group I patients reporting a higher degree of satisfaction at 04 weeks.

- In group I, Statistically highly significance ($P < 0.001$) is noted in the result outcome of Nabhi vedana, Mutradharasanga and Atiavilamutratha while in group II, Statistically highly significance ($P < 0.001$) is noted in the result outcome of Basti Vedana (Bladder pain).

DISCUSSION

Urolithiasis is a complex process that results from a succession of several physicochemical events including super saturation, nucleation, growth, aggregation and retention within the kidneys. Treatment of urolithiasis involves either conservative therapy or interventional procedures. The primary agents in medical management for urolithiasis, has been investigated with calcium channel blockers, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), and α_1 -adrenergic receptor antagonists [18]. Although calcium channel blockers with or without steroids and/or NSAIDs have shown to be successful in the treatment, α_1 -blockers, with their high success rates have become the leading candidate in medical therapy [19]. However, these treatment regimens are not free from side effects. The endoscopic stone management have allowed kidney stones to be treated using minimally invasive techniques, which have increased success rates and decreased treatment-related morbidity. These advances include shock wave lithotripsy (SWL), ureteroscopy, and percuta-

neous nephrostolithotomy [6]. Although these approaches are less invasive than the traditional open surgical approaches, they are expensive and have inherent risks. Due to the high cost and adverse effects of minimally invasive techniques and recurrence, alternative treatment modalities with phytotherapeutic agents have become the mainstay of medical therapy. In the present study, an Ayurvedic formulation containing principal herbs useful in the treatment of urinary calculi was evaluated for its safety and efficacy. Levels of urinary super-saturation correlate with the type of stone formed, and lowering of super saturation is effective for preventing stone recurrence and reduces the relapse risk [3]. In vitro crystallization systems are widely used to study the processes of crystal nucleation growth and agglomeration, which in turn helps in exploring the patho-physiology of renal stone disease. In vitro and in vivo studies on crystallization showed an inhibition of the matrix bound mineral phase formation and its subsequent growth with the *Yava Paneeya Kshara* [20][21]. The findings of the study showed beneficial effects of Ayurvedic formulation (*Yava Paneeya Kshara*) as revealed by the improvement of various clinical symptoms, increased stone expulsion rate and the time required for expulsion as well as urine microscopy (WBC and RBC), which correlated well with the experimental findings. The observed beneficial effects in the management of urolithiasis following an Ayurvedic formulation treatment in this trial could be due to the prevention of urinary supersaturation, inhibition of mineralization of stone-forming constituents, normalization of cellular function in renal oxidative stress, correction of crystalloid-colloid balance as well as the beneficial effects such as anti-inflammatory, antimicrobial, diuretic, antispasmodic, litholytic, and anticalcifying activities of individual ingredients.

Study involving larger population of patients will be necessary to confirm the findings of this study. Urolithiasis (*Mutrashmari*) in

Ayurveda is described as a painful disease which needs to be addressed early. In the beginning stages, disease can be effectively managed with medical intervention, while in the later stages with enlarged stones, the only successful measure would be lithotripsy. The medical management would include the administration of lithotriptic herbs and substances besides the measures to manage the bio-energies that control the disease manifestations. With this line of treatment, Ayurveda envisages that the stone forming substances are controlled, which prevents recurrence of the stone.

Role of Yava Kshara

YAVA KSHARA -Alkali preparation of Barley

Latin name: *Hordeum vulgare*

Family: Gramineae

Properties:

- *Rasa: Ka u*
- *Gu a: Laghu, Snigdha*
- *Virya: U a*
- *Vip ka: Ka u*
- *Do aghnat : Kapha V ta maka*

Pharmacological Action: This drug is useful in the pathogenesis like *Amlapitta, A mari, M trak ccra, Udara la, Gulma, Ar a*.

Chemical Constituents: The substance contains potassium chloride, potassium sulphate, potassium bicarbonate and potassium carbonate.

Yava Kshara (Alkali preparation of Barley) is having pH 11.73. Thus it helps to neutralize the acidic media and prevents stone formation. As the *Yava Kshara* is alkaline in nature which changes the pH of the urine, this helps in preventing the hyper-concentration of the urine. As it changes the pH of the urine by its alkali nature, it helps in the dissolution of the calculi. *Yava Kshara* has

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undergone clinical trials that support its impact on Calcium Oxalate crystallisation. Preliminary clinical trials have evaluated the role of GCP Compound in the prevention of Urolithiasis and as a method of stone expulsion, yet the treatment effect and mechanism of action remains to be elucidated.

CONCLUSION

Haematological and biochemical investigations reveal that both groups having statistically non-significant effect on all the parameters. However, it was noticed that the variation in all the parameters were observed within normal range. Both the drugs were found more effective on *Vataja Ashmari* (Calcium Oxalate Stones), moderately effective on *Pittaja Ashmari* and least effective on *Kaphaja Ashmari* in the present Clinical Study. Overall effect of therapy shows that *Yava Paneeya kshara* group (Experimental Group) --- 40% of patients were cured, 20% markedly improved, 20% improved and 20% remained unchanged. In GCP Compound (Control Group), 10% patients were cured, 10% were markedly improved, 40% improved and 40% remained unchanged. The results of the present study indicated that the Ayurvedic formulation (*Yava Paneeya Kshara*) is safe and effective in the treatment of urolithiasis, with significant improvement in symptoms associated with renal stones. This Ayurvedic formulation has also shown to facilitate stone expulsion rate. It has significantly reduced concomitant symptomatic treatment with pain killers. Hence, this Ayurvedic formulation appears to be an effective and safe phytotherapeutic agent and could be useful in the alternative management of urolithiasis.

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Table 1:

No. of Patients	Group I	Group II	Total
Registered	15	13	28
Completed	10	10	20
LAMA*	05	03	08

*LAMA – Left Against Medical Advice

Table 2: Analytical Study of the Drugs

	Yava Paneeya Kshara	GCP Compound
Specific Gravity	1.019	1.016
pH	11.73	6.38

Table –3: Effect of therapy on clinical features (Acc. to Ayurveda) in 10 patients of Renal calculi by using Yava Paneeya Kshara (Group – I: Experimental group):

Clinical features	Mean B.T.	Mean A.T.	%	SD	SE	't'	P
Nabhivedana	2.20	1.00	54.55	0.78	0.25	4.80	< 0.001
Bastivedana	1.30	0.60	53.85	0.82	0.26	2.69	< 0.01
Sevanivedana	1.10	0.60	45.45	0.53	0.17	2.94	< 0.01
Mehanvedana	0.80	0.40	50.00	0.70	0.22	1.81	< 0.05
Mutraddharasanga	2.10	1.10	47.62	0.66	0.21	4.76	< 0.001
Sarudhiramutrata	0.70	0.30	57.14	0.52	0.16	2.50	< 0.01
Gomedaprakasa	0.70	0.10	85.71	0.84	0.27	2.22	< 0.05
Atiavilamutrata	2.00	0.90	55.00	0.99	0.31	3.55	<0.001

Table –4: Effect of therapy on clinical features (Acc. to Ayurveda) of 10 patients of Renal calculi by using GCP COMPOUND (Group – II: Control Group)

Clinical features	Mean B.T.	Mean A.T.	%	S.D.	S.E.	't'	P
Nabhivedana	2.20	1.70	22.73	0.53	0.17	2.94	< 0.01
Bastivedana	1.70	0.70	58.82	0.82	0.25	4.00	<0.001
Mehanvedana	0.40	0.10	75.00	0.67	0.21	1.43	<0.05
Mutraddharasang	1.10	0.40	63.64	0.82	0.26	2.69	< 0.01
Sarudhiramutrata	0.80	0.30	62.50	0.71	0.22	2.27	< 0.01
Gomedaprakasha	0.50	0.10	80.00	0.84	0.27	1.48	< 0.05
Atiavilamutrata	1.60	1.00	37.50	0.70	0.22	2.73	< 0.01

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