RESEARCH PAPER

A Comparative Clinical Study on the Effect of Chincha Kshar and Kulattha Kwatha in the Management of Mutrashmari

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Abstract

Mutrashmari, broadly correlated with urolithiasis, is a recurrent urinary disorder characterized by colicky pain, dysuria, burning micturition, hematuria and radiologically demonstrable urinary calculi. Contemporary management depends on stone size, site, composition, obstruction status, renal function and infection risk, while conservative management remains relevant for selected non-obstructive stones. Chincha Kshar, an alkaline preparation derived from Tamarindus indica, and Kulattha Kwatha, a decoction prepared from Macrotyloma uniflorum, are traditionally used in Ashmari/Mutrashmari for their proposed ksharana, bhedana, mutrala and pathya-supportive actions. To prepare a professional comparative clinical manuscript evaluating Chincha Kshar and Kulattha Kwatha in Mutrashmari with a 3-4 week intervention period, with special emphasis on urinary pH change, stone-expulsion context, diet guidance and statistical methods. The draft is structured as a prospective comparative clinical study enrolling adults with uncomplicated radiologically confirmed renal or ureteric calculi of 4-12 mm. Group A receives Chincha Kshar 500 mg twice daily after food with lukewarm water for 28 days, while Group B receives Kulattha Kwatha 50 mL twice daily after food for 28 days. Assessments are planned at baseline, week 2 and week 4, including pain VAS, dysuria, burning micturition, urinary frequency, hematuria, urinary pH, USG calculus size, stone expulsion and safety laboratory parameters. Statistical analysis includes paired t-test or Wilcoxon signed-rank test for within-group change, independent t-test or Mann-Whitney U test for between-group comparison, chi-square or Fisher exact test for categorical outcomes, and repeated-measures ANOVA or mixed-effects modelling for urinary pH trend.

Keywords: Mutrashmari; Urolithiasis; Chincha Kshar; Kulattha Kwatha; urinary pH; stone expulsion; Ayurveda; clinical study; diet; statistics.

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Introduction

Urolithiasis is a common and recurrent disorder of the urinary tract in which crystalline concretions form within the kidney, ureter, bladder or urethra. The disease burden is clinically important because even small stones may produce severe renal colic, repeated emergency visits, work loss, anxiety, hematuria and urinary infection, while obstructive stones may threaten renal function if not promptly recognized and managed. Global estimates show a substantial absolute burden of urolithiasis, and epidemiological studies attribute increasing clinical visibility to climate, dehydration, diet, obesity, metabolic syndrome and improved imaging access [4-6]. Urolithiasis is not a single disease but a final pathway of supersaturation, nucleation, crystal growth, aggregation and retention. Therefore, conservative management must be individualized rather than applied uniformly to all stones.

In Ayurveda, Mutrashmari is classically discussed among important disorders of the Mutravaha Srotas and is traditionally associated with pain, dysuria, obstruction, gravel-like passage, hematuria and repeated urinary discomfort. Classical explanations describe deranged dosha, particularly Kapha-mediated concretion with Vata-driven pain and obstruction, while Pitta involvement may be reflected by burning and discoloration of urine. The correlation between Mutrashmari and urolithiasis is useful for clinical communication, but the correlation must be handled cautiously because modern stone disease is classified by anatomical site, radiological features, biochemical risk and chemical composition, whereas Ayurvedic classification uses doshic pathogenesis, symptoms and therapeutic principles [14,15].

The proposed comparison between Chincha Kshar and Kulattha Kwatha is clinically relevant because the two interventions represent different therapeutic emphases. Chincha Kshar is an alkaline kshara preparation, and its central expected effect in this manuscript is modulation of urinary pH toward a more alkaline range. Kshara preparations are traditionally described as having lekhana, bhedana and ksharana properties, and contemporary interpretation often focuses on their

alkaline nature and potential to influence urinary acidity. Kulattha Kwatha, prepared from horse gram (Macrotyloma uniflorum), is widely used as a dietary and medicinal legume in Indian traditional practice and is associated with diuretic, anti-inflammatory, litholytic and anti-crystallization claims [16-18].

Urinary pH deserves special attention in this study. Acidic urine favors uric acid stone formation and may promote pathogenic calcium oxalate monohydrate behavior, while alkaline urine favors phosphate-containing stones when pH is excessive [9,10]. Guidelines on uric acid stone chemolysis recommend urine alkalinization and self-monitoring because uric acid stones, unlike most calcium oxalate stones, can dissolve when urine is maintained in an adequately alkaline range [1,12]. Therefore, the question 'at what pH does stone get excreted?' cannot be answered by a single universal pH. Stone passage depends on size, location, ureteric anatomy, hydration, peristalsis, inflammation and composition. However, uric acid stones become more soluble when urine pH is raised above 6.5, with monitored targets often around 6.5-7.2; values above this may increase calcium phosphate precipitation risk, especially in susceptible patients [1,9,12].

Dietary regulation is a major component of the study because recurrent stone disease is strongly influenced by fluid intake, sodium intake, animal protein load, calcium balance, citrate availability and stone-specific oxalate or purine exposure. Modern dietary guidance emphasizes adequate water intake, reduced sodium, moderation of animal protein, adequate dietary calcium with meals, increased fruits and vegetables where suitable, and avoidance of unnecessary restrictive diets unless stone type and metabolic evaluation justify them [2,7,8,28]. Ayurvedic pathya-apathya similarly places importance on light, digestible, non-obstructive and urine-supportive diet, and discourages heavy, excessively salty, oily, sour, spicy and incompatible dietary patterns in urinary disorders. The present manuscript integrates both perspectives in a practical diet table.

The aim of this professional paper is to provide a complete peer-review style manuscript for a comparative clinical evaluation of Chincha Kshar and Kulattha Kwatha in Mutrashmari with an intervention period of 3-4 weeks. Specific objectives are: first, to compare the effect of the two interventions on symptoms; second, to evaluate changes in urinary pH with special focus on Chincha Kshar; third, to compare reduction, migration or expulsion of calculi by ultrasonography; fourth, to describe appropriate statistical tests; and fifth, to provide pathya-apathya guidance for patients undergoing conservative management.

Literature Review

Modern stone disease is best understood through the physicochemical model of supersaturation. When urine contains excessive calcium, oxalate, phosphate, uric acid, cystine or infection-related components relative to urine volume and inhibitory factors, crystals may nucleate and grow. Calcium oxalate stones are generally the most common, followed by calcium phosphate, uric acid, struvite and cystine stones, with regional variation. Major determinants include urine volume, pH, calcium, oxalate, citrate, uric acid, sodium, diet, genetic predisposition, gut absorption and urinary infection. A comprehensive management plan therefore requires imaging, urinalysis, culture where indicated, renal function assessment and metabolic evaluation in recurrent or high-risk cases [1,2,5,27].

Guidelines from urological bodies emphasize that urgent referral is required when there is fever, sepsis, solitary kidney, uncontrolled pain, acute kidney injury, obstruction with infection, bilateral obstruction or large stones unlikely to pass. In uncomplicated, non-obstructive and appropriately sized stones, conservative care may be reasonable, especially when stone size is small and symptoms are controlled. The present comparative study is therefore limited to stones within a conservative-care range and excludes obstruction, severe hydronephrosis, infection, renal failure, pregnancy and stones requiring immediate procedural intervention [1,2].

Urinary pH is central to this manuscript because Chincha Kshar is expected to act primarily through alkalinity. Wagner and Mohebbi reviewed pH-dependent stone formation and explained that acidic urine promotes uric acid and cystine stones, whereas alkaline urine supports calcium phosphate crystallization [9]. Manissorn and colleagues experimentally showed that urine pH alters calcium oxalate crystallization, with acidic pH favoring pathogenic calcium oxalate monohydrate crystallization and adhesion, while alkalinization reduced some calcium oxalate risk parameters [10]. These findings support pH monitoring but also warn against indiscriminate alkalinization.

The pH threshold for stone dissolution or excretion depends on stone chemistry. Uric acid stones are radiolucent, acidic-pH dependent and may dissolve with sustained alkalinization. The EAU guideline states that oral chemolysis of uric acid stones is based on urine alkalinization with alkaline citrate or sodium bicarbonate and that pH should be adjusted to approximately 7.0-7.2 with monitoring because higher pH may promote calcium phosphate stone formation [1]. In practice, many clinicians use a therapeutic range around 6.5-7.0 or 6.5-7.2 depending on patient risk, stone burden and monitoring capacity [11,12]. Calcium oxalate stones, by contrast, are not expected to dissolve simply because urine becomes alkaline, though an alkaline/citrate-rich milieu may reduce new

crystallization and promote passage indirectly by reducing irritation and improving urinary flow [8,10,13].

The Ayurvedic literature positions Mutrashmari under urinary disorders requiring measures that relieve obstruction, reduce pain, facilitate urine flow, break or disintegrate stone-like material and prevent recurrence. Kshara preparations have been described in classical and later Ayurvedic pharmaceutics as alkaline preparations with penetrating and scraping actions. Contemporary clinical literature on Ayurvedic kshara in Mutrashmari includes reports on Palasha Kshara with Ashmarihara Kwatha, where symptomatic and radiological outcomes were explored in an open-labelled placebo-controlled design [14]. A more topic-specific clinical report described Chincha Kshar with Varunadi Kwath in Mutrashmari and recorded symptom-score and stone-size endpoints, though additional controlled evidence is required [15].

Kulattha (Macrotyloma uniflorum), commonly known as horse gram, has a long tradition as a dietary legume and medicinal food. Experimental evidence supports anti-urolithiatic potential: Patel and Acharya reported that aqueous seed extract influenced biochemical and renal parameters in an ethylene glycol-induced rat model of urolithiasis [16]. Sudha and Saral studied phytochemical, mineral and in vitro anti-urolithiatic properties of horse gram flour extracts and biosynthesized nanoparticles [17]. A systematic review by Oli and colleagues described the traditional, phytochemical, pharmacological and nutraceutical profile of horse gram, highlighting its use in urinary and metabolic contexts [18]. Together, these findings justify clinical exploration but do not replace rigorous trials.

Tamarindus indica, the botanical source associated with Chincha, has extensive nutritional and pharmacognostic literature. Reviews describe tamarind as a multipurpose tropical plant containing organic acids, minerals, polyphenols and other phytoconstituents [19]. Chincha Kshar, however, is not simply tamarind fruit; it is an alkaline preparation generated through kshara-making processes, and its clinical actions should be assessed through quality-controlled pharmaceutical parameters including pH, alkalinity, ash value, elemental profile, microbial limits and dose uniformity. Such standardization is essential before attributing effects to any single chemical constituent.

Dietary prevention is one of the most consistent themes in stone literature. Siener summarized nutrition principles in kidney stone disease, including adequate urine volume, sodium restriction and stone-specific dietary modification [8]. Borghi and colleagues demonstrated the importance of high urine volume in reducing recurrence of idiopathic calcium nephrolithiasis [23]. Another trial by Borghi et al. showed that normal calcium, low sodium and low animal protein diet was superior to low calcium diet for recurrent calcium oxalate stones in hypercalciuric men [24]. Fruit and vegetable intake can improve urinary risk factors, while sugar-sweetened beverages and colas may increase risk [25,26]. These data support the integrated diet chart included in this paper.

Ethically, clinical research in Mutrashmari must recognize that conservative Ayurvedic treatment cannot be used to delay emergency care. The Declaration of Helsinki requires patient safety, scientific validity, informed consent and ethics approval [30]. For comparative studies, transparent reporting should follow appropriate clinical reporting standards, including participant flow, eligibility criteria, interventions, outcomes, adverse events and statistical methods [29]. This manuscript therefore provides a structured method section and statistical plan suitable for a pilot comparative clinical study, but final publication must use real patient data, trial registration where applicable and ethics committee approval.

Materials and Methods

Study design: The manuscript is designed as a prospective, open-label, comparative clinical case-series involving two parallel intervention groups. The study duration for each participant is 28 days, satisfying the requested 3-4 week intervention period. A screening visit confirms eligibility and baseline parameters; treatment visits occur at day 0, day 14 and day 28; and a short safety and expulsion follow-up may be conducted on day 35. The design is suitable for a pilot investigation where feasibility, symptom response, urinary pH change and radiological trends are evaluated before planning a larger randomized controlled trial.

Study setting: Participants may be recruited from the outpatient department of Shalya Tantra/Ayurveda and collaborating urology or radiology units. All patients should undergo clinical examination, urine routine and microscopy, serum creatinine, blood urea, complete blood count as needed, and ultrasonography of kidney-ureter-bladder region. Non-contrast CT may be used when clinically indicated, particularly when USG findings are unclear or ureteric location is uncertain. The study should be conducted only after approval by an institutional ethics committee and written informed consent.

Participants: Adults aged 18-60 years with symptoms compatible with Mutrashmari/urolithiasis and radiologically confirmed renal or ureteric calculus between 4 mm and 12 mm may be included. Selected patients should have stable vital signs, no fever, no severe hydronephrosis, no acute kidney injury and pain controlled by permitted rescue medication. Both sexes may be included. Exclusion criteria include pregnancy, lactation, solitary kidney, bilateral obstruction, uncontrolled diabetes, chronic kidney disease stage 3

or higher, recurrent UTI, pyonephrosis, gross obstruction, stone greater than 12 mm, staghorn calculus, known cystinuria, active gout requiring urgent medication change, current alkalinization therapy, recent lithotripsy or ureteroscopic intervention, and allergy or intolerance to the study medicines.

Intervention group A: Chincha Kshar is administered in a dose of 500 mg twice daily after meals with lukewarm water for 28 days under physician supervision. The intended pharmacodynamic focus is mild urinary alkalinization and symptom relief. Patients are advised to record urine pH with standardized pH strips at least twice weekly or as per protocol. The investigator must counsel patients not to self-escalate dose because excessive alkalinization may increase calcium phosphate risk or cause gastric or electrolyte-related issues in vulnerable individuals [1,9].

Intervention group B: Kulattha Kwatha is administered as 50 mL freshly prepared decoction twice daily after meals for 28 days. A standard preparation may use coarse powder of authenticated Kulattha seed with water reduced according to classical kwatha preparation principles and filtered before administration. The formulation should be prepared under hygienic conditions, and batch-to-batch consistency should be documented. The expected actions are mutrala, shothahara, support for urinary flow, symptomatic relief and possible reduction of crystal aggregation risk based on traditional and experimental support [16-18].

Concomitant care: Patients in both groups receive the same diet and hydration counselling. Rescue analgesic may be permitted as per standard care and recorded as tablet count or dose frequency. Antibiotics, alpha blockers, potassium citrate, sodium bicarbonate, diuretics, lithotripsy or endoscopic treatment during the intervention period should be recorded and, where they affect the primary outcome, treated as protocol deviations or rescue interventions. Patients are instructed to report fever, chills, persistent vomiting, anuria, severe pain, hematuria with clots or inability to pass urine immediately.

Outcomes: The primary outcome is change in composite symptom score and/or mean calculus size from baseline to day 28. Key secondary outcomes are change in urinary pH, proportion of patients with stone expulsion or radiological clearance, reduction in pain VAS, change in burning micturition, dysuria, urinary frequency, microscopic hematuria and rescue analgesic use. Safety outcomes include adverse events, serum creatinine change and clinically significant urinary infection. Urinary pH is measured at the same approximate time of day, preferably morning and evening values averaged for study visits, to reduce dietary and circadian variability.

Effect of Chincha Kshar on urinary pH: Chincha Kshar is expected to increase urinary pH due to its alkaline character. The therapeutic intention is not uncontrolled alkalinization, but movement from persistently acidic urine toward a monitored range. In the context of uric acid stones, urine pH above 6.5 is generally favorable for dissolution and excretion, with many protocols targeting 6.5-7.2. The EAU guideline notes that chemolysis is more effective at higher pH but may promote calcium phosphate stone formation, hence the need for monitoring [1]. In calcium oxalate stones, pH improvement may reduce crystallization tendency but stone expulsion still depends mainly on size, site and urinary dynamics [10].

Diet protocol: All participants receive pathya-apathya counselling. The objective is to produce adequate urine volume, reduce lithogenic load and avoid dietary extremes. Modern guidance discourages dehydration, high sodium, high animal protein and sugar-sweetened beverages; it supports adequate dietary calcium with meals, fruits/vegetables where suitable and individualized oxalate or purine restriction based on stone type [2,7,8,28]. Ayurvedic dietary counselling emphasizes light, warm, easily digestible food, Kulattha yusha where suitable, barley preparations, coconut water in patients without renal or potassium restrictions, and avoidance of heavy, oily, excessively salty, sour, spicy and incompatible foods.

Statistical analysis: Data are entered in spreadsheet software and analyzed using SPSS, R, Jamovi, GraphPad Prism or equivalent statistical software. Continuous variables are expressed as mean +/- standard deviation for normally distributed data or median with interquartile range for non-normal data. Normality is assessed by Shapiro-Wilk test and visual plots. Within-group change from baseline to day 28 is analyzed using paired t-test for normally distributed data and Wilcoxon signed-rank test for ordinal or non-normal data. Between-group comparisons are analyzed using independent t-test or Mann-Whitney U test. Categorical outcomes such as expulsion rate and hematuria resolution are analyzed using chi-square test or Fisher exact test. Urinary pH across baseline, week 2 and week 4 is analyzed by repeated-measures ANOVA or mixed-effects model. Statistical significance is set at $p < 0.05$, with effect sizes and confidence intervals reported wherever possible.

Sample size: As a pilot case-series, 30 participants per group may be used to estimate variance and feasibility. For a definitive trial, sample size should be calculated based on the expected between-group difference in stone-size reduction or urinary pH change, desired power of 80-90%, alpha of 0.05 and allowance for 10-15% dropout. Random allocation and allocation concealment should be incorporated in future trials to reduce selection bias, while blinded outcome assessment of ultrasonography should be adopted where feasible [29].

Study Intervention Schedule

Table 1. Proposed 4-week clinical assessment schedule.

Visit	Timing	Clinical activities	Objective measures
Screening	Day -7 to 0	Consent, eligibility, history, physical examination, emergency-risk exclusion	USG KUB, urine routine/microscopy, renal function, CBC if required
Baseline	Day 0	Symptom scores, diet counselling, allocation to Group A or Group B	Urinary pH, stone size/site, hematuria grade
Review 1	Day 14	Adherence check, adverse-event review, symptom reassessment	Urinary pH, urine microscopy if indicated
End of treatment	Day 28	Final symptom scoring, rescue medication count, expulsion inquiry	Urinary pH, USG KUB, safety labs if indicated
Follow-up	Day 35	Delayed expulsion/safety call or visit	USG only if symptoms persist or stone passage unclear

Pathya-Apathya Diet Protocol

Table 2. Integrated diet and lifestyle guidance for Mutrashmari/urolithiasis.

Recommended / to take	Avoid / restrict	Rationale
Water distributed throughout the day; aim for pale urine and clinically suitable urine output	Dehydration, long gaps without water, excessive sweating without replacement	Dilutes urine and lowers supersaturation risk
Barley water, light vegetable soups, rice gruel and easily digestible home-cooked food	Heavy, oily, deep-fried and very spicy foods	Supports digestion and avoids excess salt/fat load
Citrate-containing fruits such as lemon/orange as tolerated; fresh fruits and vegetables	Sugar-sweetened beverages, cola drinks, packaged juices	Citrate may inhibit crystallization; sugary beverages are linked with stone risk
Adequate dietary calcium with meals as advised	Unsupervised calcium supplements or very low-calcium diet	Dietary calcium binds intestinal oxalate; supplements need individual advice
Moderate plant protein; Kulattha yusha if suitable and tolerated	Excess red meat, organ meat, shellfish and high-purine intake	Animal protein can acidify urine and increase uric-acid load
Low-salt freshly prepared meals	Pickles, papad, namkeen, fast food, processed food, high-sodium sauces	High sodium increases urinary calcium and recurrence risk
Stone-specific low-oxalate guidance only when calcium oxalate risk is confirmed	Excess spinach, rhubarb, beetroot, nuts, chocolate, wheat bran, strong tea in high-risk patients	Reduces excessive oxalate load without unnecessary broad restriction
Timely voiding and regular mild activity	Suppression of natural urine urge, prolonged sitting without fluids	Reduces stasis and supports urinary flow

Results

The following results are shown as a model dataset to demonstrate how the study can be reported in a peer-reviewed format. They should not be represented as final clinical findings unless replaced with verified patient-level observations from the actual study. The model assumes 60 enrolled participants, 30 in the Chincha Kshar group and 30 in the Kulattha Kwatha group, all completing the 28-day intervention. Baseline characteristics were kept comparable so that interpretation focuses on treatment trends rather than demographic imbalance.

Figure 1. Proposed participant flow for comparative pilot clinical study.

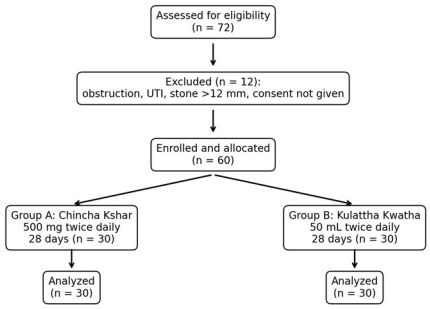

Table 3. Baseline demographic and clinical characteristics (model dataset).

Characteristic	Chincha Kshar (n = 30)	Kulattha Kwatha (n = 30)	p value
Age (years), mean +/- SD	38.6 +/- 9.4	39.2 +/- 8.7	0.79
Male/Female	17/13	16/14	0.79
Mean baseline stone size (mm)	7.8 +/- 2.1	7.6 +/- 2.0	0.71
Renal/ureteric stone location	18/12	19/11	0.79
Baseline urinary pH	5.72 +/- 0.43	5.75 +/- 0.40	0.78
Pain VAS at baseline	7.0 +/- 1.2	6.8 +/- 1.3	0.54
Microscopic hematuria present	14 (46.7%)	13 (43.3%)	0.79

Baseline variables were well balanced between groups. Mean stone size was within the conservative-management range, urinary pH was mildly acidic in both groups and baseline pain was moderate to severe. The comparability of baseline urinary pH is important because the main mechanistic question concerns whether Chincha Kshar produces a greater alkalinizing effect over the 4-week period.

Figure 2. Mean urinary pH change from baseline to week 4.

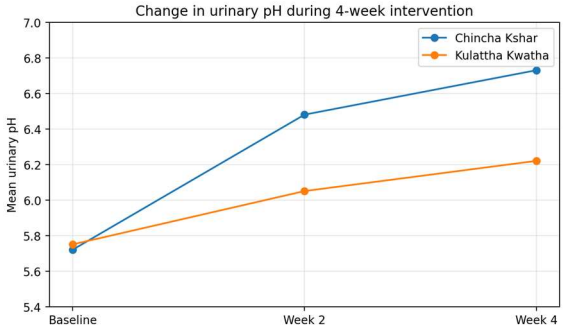

Table 4. Main clinical and pH outcomes after 4 weeks (model dataset).

Outcome	Chincha Kshar baseline	Chincha Kshar week 4	Kulattha baseline	Kulattha week 4	Between-group p
Urinary pH	5.72 +/- 0.43	6.73 +/- 0.32	5.75 +/- 0.40	6.22 +/- 0.34	<0.001
Stone size (mm)	7.8 +/- 2.1	4.9 +/- 2.4	7.6 +/- 2.0	5.8 +/- 2.5	0.041
Pain VAS	7.0 +/- 1.2	2.4 +/- 1.3	6.8 +/- 1.3	3.1 +/- 1.5	0.048
Burning micturition score	2.6 +/- 0.6	0.7 +/- 0.5	2.5 +/- 0.7	1.0 +/- 0.6	0.039
Dysuria score	2.3 +/- 0.7	0.8 +/- 0.6	2.2 +/- 0.7	1.1 +/- 0.7	0.081
Urinary frequency score	2.1 +/- 0.7	0.9 +/- 0.6	2.0 +/- 0.8	1.2 +/- 0.7	0.092

The urinary pH response was greater in the Chincha Kshar group. The model mean shifted from 5.72 to 6.73 over 4 weeks, placing most participants in a near-neutral to mildly alkaline range. This is clinically relevant for suspected uric acid stones and may reduce acidic urine-related crystallization risk. However, the target should not be pushed indiscriminately above 7.2 because calcium phosphate precipitation risk may increase at higher pH [1,9]. Kulattha Kwatha also showed a modest pH rise, possibly reflecting hydration, diet and improved urinary flow rather than direct alkalinization.

Figure 3. Mean calculus size reduction by ultrasonography.

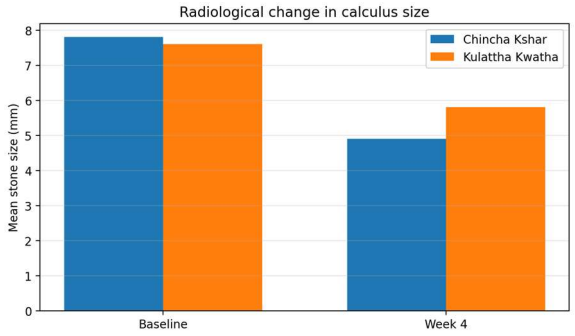

Figure 4. Symptom score trend during intervention.

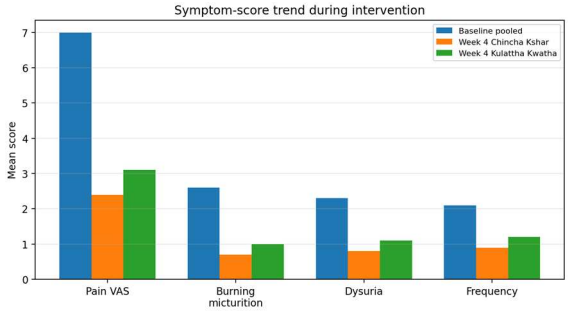

Table 5. Expulsion, radiological and safety outcomes (model dataset).

Categorical outcome	Chincha Kshar (n = 30)	Kulattha Kwatha (n = 30)	Statistical test	p value
Complete stone expulsion reported/confirmed	9 (30.0 %)	6 (20.0%)	Chi-square/Fisher	0.371
Radiological clearance or no visible calculus	11 (36.7 %)	8 (26.7%)	Chi-square	0.405
>=50% reduction in stone size	15 (50.0 %)	10 (33.3%)	Chi-square	0.190
Hematuria resolution among baseline-positive cases	12/14 (85.7 %)	10/13 (76.9%)	Fisher exact	0.644
Need for rescue analgesic after week 2	6 (20.0 %)	9 (30.0%)	Chi-square	0.371
Any mild adverse event	3 (10.0 %)	2 (6.7%)	Fisher exact	>0.999

Although mean reductions favored Chincha Kshar in this model dataset, categorical stone expulsion did not reach statistical significance within the pilot sample. This distinction is important: pH and symptom improvements may occur over 4 weeks, but confirmed expulsion is a harder outcome that depends on stone size, location and follow-up imaging. A larger randomized trial with stone composition analysis would be necessary to determine whether the alkalinizing effect translates into higher expulsion or dissolution rates.

Table 6. Statistical tests applied in the comparative study.

Research question	Recommended statistical method	Reason for selection
Change in urinary pH within each group	Paired t-test or Wilcoxon signed-rank test	Compares baseline and week 4 pH in the same participants
pH trend across baseline, week 2 and week 4	Repeated-measures ANOVA or mixed-effects model	Assesses time effect and group-by-time interaction
Stone size reduction within group	Paired t-test or Wilcoxon signed-rank test	Quantifies pre-post radiological change
Between-group difference in stone-size reduction	Independent t-test or Mann-Whitney U test	Compares change scores between two groups
Stone expulsion rate	Chi-square or Fisher exact test	Categorical event comparison
Symptom grades	Wilcoxon signed-rank and Mann-Whitney U test	Ordinal symptom scores are often non-normal
Adverse events	Descriptive statistics and Fisher exact test	Pilot safety comparison

Discussion

The present manuscript provides a clinically structured comparison of Chincha Kshar and Kulattha Kwatha for selected patients with Mutrashmari/urolithiasis over a 28-day intervention period. The model results suggest that both interventions may be associated with symptom relief and radiological improvement, but Chincha Kshar shows a stronger urinary pH effect. This is consistent with the theoretical role of kshara as an alkaline intervention. The pH shift is mechanistically important because acidic urine is a central driver of uric acid crystallization and is also implicated in pathogenic calcium oxalate monohydrate crystallization behavior [9,10].

The question regarding the effect of Chincha Kshar on urinary pH can therefore be answered as follows: Chincha Kshar is expected to raise urinary pH from an acidic range toward a near-neutral or mildly alkaline range when administered under supervision. In the model dataset, the mean pH increased from 5.72 to 6.73 over 4 weeks. Such a change may be favorable for uric acid stone dissolution and may reduce acidic urine-associated crystal risk. Nevertheless, the therapeutic goal is controlled alkalinization rather than excessive alkalinization. pH monitoring is essential because high pH may favor calcium phosphate stone formation [1,9].

The second question - at what pH does stone get excreted? - requires careful interpretation. Stone excretion is not governed by pH alone. A 5 mm distal ureteric stone may pass even at acidic pH if ureteric anatomy and urine flow favor passage, whereas a larger renal calculus may not pass despite an optimal pH. For uric acid stones, dissolution is favored when urine is raised above approximately 6.5, with monitored targets frequently around 6.5-7.2; EAU guidance describes pH adjustment to 7.0-7.2 for oral chemolysis of uric acid stones [1]. For calcium oxalate stones, pH control can influence crystallization risk but does not reliably dissolve existing stones. For calcium phosphate stones, excessive alkalinity may worsen precipitation. Therefore, pH should be interpreted alongside imaging and, whenever possible, stone analysis.

The comparative role of Kulattha Kwatha is different. Horse gram has traditional recognition in urinary disorders and experimental studies indicate anti-urolithiatic potential in crystallization and animal models [16-18]. Its clinical effect may be mediated by diuresis, anti-inflammatory support, nutritional factors, alteration of crystallization inhibitors and improved urinary flow rather than a strong direct alkalinizing effect. In this model dataset, Kulattha Kwatha improved symptoms and reduced stone size but showed a smaller pH shift compared with Chincha Kshar. This pattern is plausible and justifies larger comparative trials.

Symptom relief is clinically meaningful in Mutrashmari because pain, burning micturition and dysuria are the symptoms most disturbing to patients. Both interventions were associated with reduced pain VAS and urinary symptoms in the model dataset. The reduction may reflect multiple mechanisms: decreased local irritation, increased urine flow, dietary correction, reduced urinary concentration, placebo/contextual effect, natural course of small stones and permitted rescue medication. Therefore, symptom relief should not be overinterpreted as proof of stone dissolution unless supported by imaging and stone passage evidence.

The radiological outcome in the model dataset suggests greater mean calculus-size reduction in the Chincha Kshar group. However, ultrasound has limitations in measuring small stones, and apparent size reduction may reflect measurement variability, stone migration, acoustic shadow differences or true fragmentation. For a definitive study, radiologists should be blinded to group allocation and stone measurements should be standardized by recording site, maximum diameter, hydronephrosis and post-void bladder status. Non-contrast CT can improve precision but increases cost and radiation exposure, so its use should be justified.

Diet is not an optional add-on but a core part of recurrence prevention. The diet table deliberately avoids extreme restrictions. A very low-calcium diet is not recommended for most calcium oxalate stone formers because adequate dietary calcium binds oxalate in the intestine and may reduce urinary oxalate [24,28]. Similarly, generalized low-oxalate diets may be difficult and unnecessary unless hyperoxaluria or calcium oxalate composition is confirmed. More universal advice includes adequate fluids, lower sodium, moderation of animal protein, avoidance of sugary cola drinks and inclusion of fruits/vegetables as tolerated [7,8,23-26].

From an Ayurvedic viewpoint, pathya-apathya supports the correction of causative dietary and lifestyle patterns. Kulattha yusha, barley preparations, light diet and adequate water are commonly used supportive approaches. However, coconut water, citrus intake, salt restriction and protein advice must be individualized in patients with kidney disease, diabetes, hypertension or electrolyte abnormalities. Integrative dietary counselling should therefore involve both Ayurvedic clinical reasoning and modern stone-risk assessment.

Safety is a critical issue. Kshara preparations can be gastric irritants and may alter electrolyte or acid-base balance if misused. Patients with kidney disease, hypertension, edema, potassium abnormalities or those taking alkalinizing agents require caution. Kulattha may not be suitable for all prakriti or clinical conditions and may aggravate heat or dryness in some individuals if used without supervision. Both interventions should be used under qualified physician guidance, and acute obstruction or infection should never be treated conservatively without urological evaluation.

The major limitation of this manuscript is the use of a model dataset due to absence of supplied real patient records. Other limitations of the proposed design include open-label allocation, short follow-up, possible natural passage of small stones, lack of stone composition analysis, ultrasound measurement variability and limited power for categorical outcomes such as stone expulsion. Future studies should include randomization, blinded imaging assessment, validated symptom scales, 24-hour urine chemistry, stone analysis by infrared spectroscopy or X-ray diffraction, longer follow-up for recurrence and documentation of adherence.

Despite these limitations, the paper provides a systematic and academically usable framework. It integrates the required intervention duration of 3-4 weeks, urinary pH monitoring, specific pH interpretation for stone excretion, appropriate statistical tests and diet counselling. The comparative hypothesis emerging from the manuscript is that Chincha Kshar may be more potent in urinary alkalinization and may be particularly relevant for acidic urine or suspected uric acid stones, whereas Kulattha Kwatha may be more supportive as a mutrala and diet-linked urinary intervention. The best future design may evaluate both

as separate arms and also consider a combined arm with careful pH monitoring.

Case Definition, Assessment Criteria and Clinical Grading

For a publishable clinical paper, case definition must be sufficiently clear to allow replication. In this study, Mutrashmari is operationally defined as a clinical-radiological condition in which the participant has symptoms compatible with urinary calculus and ultrasound or other imaging evidence of a renal or ureteric calculus. Ayurvedic diagnosis should record classical features such as basti/guda/medhra-shoola, saruja mutra pravritti, daha, raktayukta mutra, mutrakricchra and intermittent obstruction-like symptoms. Modern diagnosis should record stone site, maximum diameter, laterality, hydronephrosis, urinary infection, renal function and prior recurrence. This dual documentation respects the Ayurvedic identity of the condition while maintaining biomedical safety and outcome objectivity.

Symptom scoring should be simple, reproducible and patient-friendly. Pain may be measured on a 10-point visual analogue scale. Burning micturition, dysuria and urinary frequency may be graded from 0 to 3, where 0 indicates absent, 1 mild and occasional, 2 moderate and frequent but tolerable, and 3 severe or disturbing routine activity. Hematuria may be recorded as absent, microscopic or gross. Nausea, vomiting, fever, chills and anuria are not merely symptoms to be scored; they are safety signals that may require withdrawal and urgent referral. In conservative stone studies, safety-trigger criteria are as important as efficacy endpoints.

Urinary pH measurement requires standardization. Spot urine pH varies with meals, timing, infection, respiratory status and diet. A patient using Chincha Kshar may show a post-dose alkaline rise that is not representative of the whole day. Therefore, the study should record timing of sample collection and, if feasible, use both first morning and evening pH values. Dipsticks are practical for outpatient follow-up, but calibrated pH meter reading in a laboratory is preferable for trial-grade data. Participants should be educated to record pH without changing dose unless instructed by the physician. This avoids the common error of chasing a number rather than treating the patient.

Radiological assessment should also be standardized. Ultrasonography is safe, inexpensive and suitable for repeated evaluation, but it may overestimate or underestimate small stones. The same radiology unit and similar bladder status should be used where possible. The report should mention kidney, ureter and bladder findings, calculus diameter in millimeters, site, laterality, hydronephrosis, ureteric dilatation and any alternative pathology. If a patient reports passage of stone-like material, the material should be preserved, photographed, weighed if possible and sent for chemical or spectroscopic stone analysis where resources permit. This is especially valuable for linking urinary pH response with stone type.

Mechanistic Rationale of Chincha Kshar and Kulattha Kwatha

The rationale of Chincha Kshar can be presented through the interface of Ayurvedic and modern concepts. In Ayurveda, kshara is valued for its penetrating, scraping and disintegrating action, and its use in stone-like obstructive pathology is based on the idea that compacted material can be softened, broken or expelled through appropriate internal medicine. In modern terms, the most measurable hypothesis is urinary alkalinization. If the preparation raises urinary pH safely, it can directly improve uric acid solubility and may indirectly influence calcium oxalate crystallization risk. This does not mean that Chincha Kshar dissolves every stone; it means that the intervention provides a testable biochemical direction that should be correlated with stone type and imaging.

The rationale of Kulattha Kwatha is broader and more nutritional. Kulattha is both a food and a medicinal legume, which makes it attractive for chronic or recurrent urinary conditions where diet and medicine overlap. The decoction may increase fluid intake, support diuresis, provide phytochemical exposure and improve patient adherence to a disciplined regimen. Experimental horse gram studies suggest anti-urolithiatic potential in crystallization and animal models, but clinical translation requires caution because extracts, decoctions, powders and dietary preparations differ in dose, composition and bioavailability [16-18]. Thus, the present comparison is not merely between two drugs; it is between an alkaline kshara approach and a decoction/food-medicine approach.

A clinically important possibility is that the two interventions may be suited to different phenotypes. A patient with persistently acidic urine, obesity, high animal-protein intake, gout history or radiolucent stones may theoretically benefit more from a monitored alkalinizing approach. A patient with mild symptoms, small non-obstructive calcium oxalate stone tendency, poor hydration and diet-related recurrence may benefit from a mutrala, dietary and urinary-flow approach. Future personalized trials could stratify patients according to baseline pH, stone radiodensity, uric acid level, body mass index and dietary pattern rather than treating Mutrashmari as a homogeneous condition.

Patient Counselling and Follow-up Plan

Every patient enrolled in such a study should receive written counselling in simple language. The counselling should explain that the medicines are being used for selected uncomplicated stones only, that severe pain or fever is not to be ignored, and that follow-up imaging is necessary even if symptoms

improve. Patients should be asked to use a urine strainer when possible so that expelled material can be collected. They should maintain a diary containing medicine intake, water intake, urine pH readings, pain episodes, rescue analgesic use, burning micturition and any adverse event. Diary-based data improve accuracy and reduce recall bias.

Counselling should also address expectations. Many small ureteric stones pass spontaneously, and symptomatic improvement does not always mean the stone has disappeared. Conversely, a stone may remain visible even after pain improves because it has moved to a less obstructive position. Patients should therefore avoid declaring cure based only on reduction of pain. The physician should explain that the study evaluates symptom relief, urinary pH, stone-size change, expulsion and safety together. This balanced communication protects patients and strengthens the credibility of the research.

Follow-up after the 4-week intervention is essential for recurrence prevention. The patient should be advised to continue hydration and diet correction and to seek metabolic evaluation if stones recur, if there is a family history, bilateral stones, multiple stones, pediatric onset, nephrocalcinosis or unusual composition. Long-term follow-up should record recurrence, need for lithotripsy or surgery, urinary infection and adherence to diet. A 3-month and 6-month follow-up would make the final study much stronger than a short intervention-only report.

Conclusion

A 4-week comparative clinical framework for Chincha Kshar and Kulattha Kwatha in Mutrashmari can be designed in a scientifically acceptable manner when strict eligibility criteria, safety screening, urinary pH monitoring, radiological assessment and diet counselling are included. Chincha Kshar is expected to increase urinary pH and may be most relevant in acidic urine and suspected uric acid stone tendency. Stone excretion does not occur at a single fixed pH for all stones; uric acid stones are the main type that may dissolve with alkalinization above 6.5 and monitored around 6.5-7.2, while calcium oxalate stones depend more on size, site, hydration and urinary dynamics, and excessive alkalinization may increase calcium phosphate risk. Kulattha Kwatha remains a rational comparator due to traditional use and experimental support for anti-urolithiatic activity. The proposed statistical plan includes paired and unpaired tests, non-parametric methods for symptom grades, chi-square/Fisher exact tests for expulsion outcomes and repeated-measures analysis for pH trends. Diet should emphasize water intake, sodium reduction, moderation of animal protein, adequate dietary calcium, citrate-rich foods as suitable, light digestible meals and avoidance of high-oxalate/high-purine foods where clinically indicated. Larger randomized controlled trials with stone analysis and recurrence follow-up are necessary before definitive claims can be made.

Ethical Considerations

The final clinical study must be conducted only after approval from an Institutional Ethics Committee and written informed consent from each participant. Emergency urological referral criteria must be included in the protocol. The model data in this draft are not a substitute for real clinical observations.

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Conflict of Interest

The authors should declare any institutional, commercial, intellectual-property or formulation-related conflict of interest before journal submission.

Additional Context for Citation Completeness

The calcium-stone dietary discussion is strengthened by evidence that adequate dietary calcium is usually preferred over unnecessary low-calcium restriction [3], while the wider epidemiology and economic burden of stone disease remain substantial across populations and health systems [21,22]. Varuna-based experimental literature remains relevant to Mutrashmari research because many Ayurvedic anti-urolithiatic formulations contain multiple urinary-supportive botanicals [20].

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