RESEARCH PAPER

A Clinical Trial Evaluating the Therapeutic Efficacy of Yavakshara Churna and Sphatika Bhasma in the Management of Mutrashmari

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ABSTRACT

Background: Urolithiasis, classically correlated with the Ayurvedic clinical entity Mutrashmari, is a highly prevalent, morbid, and recurrent urological disorder. It is characterized by the precipitation and aggregation of crystalline calculi within the renal architecture, driven by a complex interplay of metabolic, dietary, and genetic factors [1]. The global prevalence of kidney stones continues to rise, with calcium-containing stones remaining the most common composition globally [2, 3]. Conventional medical management relies heavily on extracorporeal shock wave lithotripsy (ESWL) and pharmacological medical expulsive therapies (MET) [4, 5]. While structurally effective, these modalities are often constrained by adverse systemic side effects, potential renal trauma, and a fundamental inability to correct the underlying lithogenic diathesis [6, 7].

Objective: This clinical study aims to critically evaluate, quantify, and compare the therapeutic efficacy and safety profile of a combined Ayurvedic regimen consisting of Yavakshara Churna and Sphatika Bhasma in the management of Mutrashmari.

Methods: A prospective, single-arm, open-label clinical trial was conducted at G.S. Ayurveda Medical College and Hospital on a purposive sample of 30 patients.

Participants aged 18 to 40 years presenting with ultrasonographically confirmed unilateral or bilateral renal calculi measuring between >3 mm and 7 mm were included. The intervention comprised Yavakshara Churna (1 g O.D.) and Sphatika Bhasma (0.5 g O.D.), administered with disease-modifying vehicles (Anupana)—sugarcane juice for normoglycemic patients and coconut water for diabetic patients—over a two-month period, followed by a one-month observational follow-up.

Results: The synergistic Ayurvedic intervention produced a statistically highly significant reduction in mean stone size (Baseline: 5.82 ± 1.14 mm; Post-Treatment: 2.10 ± 1.85 mm; $p < 0.001$) as confirmed by high-resolution abdominal ultrasonography.

Subjective parameters, including Udarshoola (renal colic evaluated via Visual Analog Scale) and Mutradaha (burning micturition), demonstrated profound clinical resolution ($p < 0.001$). Kidney Function Tests (Serum Creatinine and Blood Urea Nitrogen) remained within physiological limits, confirming the nephro-safety of the formulations.

Conclusion: The dual-drug administration of Yavakshara Churna and Sphatika Bhasma provides a safe, highly effective, and non-invasive alternative for the clinical
management of early-to-moderate stage urolithiasis, facilitating mechanical stone dissolution while restoring doshic equilibrium to the urinary system.

Keywords: Mutrashmari, Urolithiasis, Yavakshara Churna, Sphatika Bhasma, Renal Calculi, Ayurveda, Lithotriptic, Nephrology, Kayachikitsa

How to cite this article :- Dr. Dilip Kumar Verma, Dr. Bhawana Joshi A Clinical Trial Evaluating the Therapeutic Efficacy of Yavakshara Churna and Sphatika Bhasma in the Management of Mutrashmari Int J Drug Deliv Technol. 2026;16(89s): 178-185; DOI: 10.25258/ijddt.16.89s.15

Source of support: Nil. ,

Conflict of interest: None

1.INTRODUCTION

1.1 The Global Epidemiology and Pathophysiology of Urolithiasis

Renal stones, clinically classified as urolithiasis or nephrolithiasis, denote the pathological accumulation of hard, crystalline mineral deposits within the renal calyces, renal pelvis, or descending along the ureteral tract. The pathogenesis of this painful disorder is profoundly multifactorial, arising from a complex confluence of metabolic derangements, dietary imbalances, chronic dehydration, and inherent genetic predispositions [1]. In recent decades, the global epidemiological incidence of kidney stones has surged exponentially [2]. Worldwide prevalence differs significantly by region, dietary habits, and local climate [5]. In India, incidence rates have climbed rapidly in correlation with shifts toward Westernized dietary patterns [8]. Calcium-containing stones continue to comprise the most common composition globally, accounting for over 70% of cases, often presenting as

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calcium oxalate or calcium phosphate, followed by uric acid and struvite stones [3, 9].

The hallmark clinical manifestation of urolithiasis is acute renal colic—an intense, spasmodic, radiating flank pain that significantly impairs patient quality of life and frequently necessitates emergency intervention [10]. If left untreated, progressive stone enlargement can precipitate severe secondary complications, including obstructive uropathy, hydronephrosis, recurrent urinary tract infections (UTIs), macroscopic hematuria, and irreversible renal parenchymal damage [11, 12]. Regardless of chemical makeup, these variants share a notoriously high propensity for recurrence, rendering long-term management a formidable challenge. Without prophylactic lifestyle or metabolic management, urolithiasis has an estimated 50% recurrence rate within 5 years [13].

1.2 Limitations of Conventional Medical Management

Contemporary urological management for nephrolithiasis relies on pharmacological medical expulsive therapies (MET), such as alpha-1 adrenergic blockers (e.g., tamsulosin), and surgical interventions, notably Extracorporeal Shock Wave Lithotripsy (ESWL) and percutaneous nephrolithotomy (PCNL) [4, 14].

Although conventional modalities are structurally effective for immediate mechanical stone clearance, they present substantial clinical limitations. MET utilization significantly facilitates distal stone passage, but studies continue to note a spectrum of side effects, including orthostatic hypotension and retrograde ejaculation, alongside conflicting efficacy rates for smaller proximal stones [15]. Surgical interventions carry inherent procedural risks [16]. ESWL therapy, while non-invasive structurally, involves the delivery of intense shockwaves that can result in acute renal tissue trauma, subcapsular hematomas, edema, and long-term renal parenchymal damage [7]. Furthermore, these modern approaches act purely on the structural symptom—the physical stone—without addressing the underlying biochemical diathesis, leaving patients highly vulnerable to future calculogenesis [13, 16].

1.3 The Ayurvedic Perspective: Mutrashmari

In contrast to reductionist biomedical models, the Ayurvedic science approaches the pathology of Mutrashmari through a holistic, systems-biology framework. Ayurvedic therapeutics aim not only to dissolve and expel the existing calculi but also to alleviate acute symptomatology, soothe mucosal trauma, and recalibrate the body's internal metabolic environment to prevent disease recurrence [17]. This clinical trial systematically investigates the therapeutic efficacy of a classical combined Ayurvedic regimen—Yavakshara Churna and Sphatika Bhasma—focusing on their dual capacity to disintegrate renal stones chemically and restore the physiological health of the urinary tract.

Primary Research Question: Does the combined clinical administration of Yavakshara Churna and Sphatika Bhasma produce a significantly greater and measurable reduction in renal stone size and its associated subjective symptoms compared to the null hypothesis?

2. AIMS AND OBJECTIVES

2.1 Primary Objectives

1. Objective Efficacy Assessment: To scientifically assess and quantify the effects of the test drug combination on the absolute dimensional reduction of renal stone size using objective radiological imaging.
2. Comparative Evaluation: To rigorously evaluate and compare the therapeutic efficacy and safety profile of the combined therapy of Yavakshara Churna and Sphatika Bhasma against baseline pathological parameters.

2.2 Secondary Objectives

Conceptual Integration: To conduct a critical literature review bridging classical Ayurvedic concepts of Mutrashmari pathology with the modern biomedical understanding of renal calculogenesis.

2. Symptomatology Profiling: To evaluate the intervention's impact on symptomatic relief, specifically focusing on renal colic (Udarshoola) and burning micturition (Mutradaha).
3. Safety and Recurrence Monitoring: To monitor adverse clinical side effects, validate renal safety via laboratory markers, and track short-term disease recurrence.

2.3 Statistical Hypotheses

•Alternative Hypothesis ($H1$): The combined therapy of Yavakshara Churna and Sphatika Bhasma will demonstrate significantly better efficacy in renal stone size reduction and associated symptom relief.

•Null Hypothesis ($H0$): The combined therapy of Yavakshara Churna and Sphatika Bhasma has no significant clinical effect in renal stone size reduction and symptom relief.

3. PHARMACODYNAMICS AND MECHANISM OF ACTION

3.1 Ayurvedic Pathogenesis (Samprapti) of Mutrashmari

In the foundational Ayurvedic texts, Mutrashmari is categorized under the Ashta Mahagada (the eight most difficult-to-cure diseases). The etiology (Nidana) is primarily attributed to Apathya Sevana (unwholesome dietary practices) and Vegadharana (habitual suppression of natural urges, critically micturition).

The pathological cascade (Samprapti) involves the severe vitiation of Apana Vayu (the downward-moving energetic force) and Kapha dosha. The aggravated Vayu enters the Basti (urinary apparatus) and systematically dries up the aggravated Kapha and Pitta mixed with Mutra (urine). This drying process leads to the progressive precipitation and crystallization of solutes, ultimately forming an Ashmari (stone) [17]. This description strictly parallels modern physical chemistry concepts of urinary supersaturation and crystal aggregation [9].

3.2 Pharmacodynamics of the Intervention
The selected intervention utilizes a synergistic, dual-action poly-pharmacological strategy:

3.2.1 Yavakshara Churna Yavakshara is a potent, alkaline Ayurvedic formulation derived from the calcined ash of the barley plant (Hordeum vulgare) [18].
•Ayurvedic Pharmacodynamics: It possesses Katu (pungent) Rasa, Ushna (hot) Virya, and Teekshna (sharp/penetrating) properties.
•Mechanism of Action: Its primary pharmacological action in urolithiasis is Ashmaribhedana (lithotriptic action). By significantly alkalinizing the urinary pH, Yavakshara neutralizes the highly acidic environment required for the precipitation of
uric acid and calcium oxalate crystals. Alkaline environments are well-documented in modern urology to inhibit crystal agglomeration [9]. This shift destabilizes the mucoprotein matrix binding the calculus. Furthermore, Hordeum vulgare extracts possess documented Mutrala (diuretic) and antiurolithiatic properties, increasing hydrodynamic pressure within the renal tubules and facilitating the physical flushing of fragmented stone debris [18].

3.2.2 Sphatika Bhasma Sphatika Bhasma is an incinerated, highly purified therapeutic preparation of alum (potassium aluminum sulfate).
•Ayurvedic Pharmacodynamics: It is clinically renowned for its Kashaya (astringent) Rasa and exceptionally potent Stambhana (hemostatic) qualities.
• Mechanism of Action: As the sharp edges of a calculus descend through the sensitive lumen of the ureter, they inevitably cause severe mucosal lacerations. This micro-trauma leads to hematuria and intense Udarshoola. Aluminous salts have a documented biomedical history as potent astringent agents that exert their effect through protein precipitation, leading to decreased capillary permeability and rapid hemostasis [19, 20]. Sphatika Bhasma acts directly on this traumatized urothelium. It rapidly induces protein coagulation at the site of micro-tears, reducing mucosal edema, arresting capillary bleeding, and providing profound relief from Mutradaha (burning micturition).

4. MATERIALS AND METHODS

4.1 Study Design, Setting, and Duration
The research was structured as a prospective, single-arm, open-label clinical study. The trial was exclusively conducted at G.S. Ayurveda Medical College and Hospital. The study enrolled a statistically viable purposive sample size of 30 patients. The clinical timeline spanned three months per participant: a two-month (60-day) active pharmacological intervention phase, immediately followed by a one-month (30-day) post-treatment observational follow-up period.

4.2 Patient Selection Criteria
Inclusion Criteria:
•Patients across all demographic profiles, irrespective of gender and religious background.
•Patients aged between 18 and 40 years.
•Patients presenting with a definitive diagnosis of unilateral or bilateral renal calculi.
•Radiological confirmation (via ultrasonography) of a stone size greater than 3 mm and up to a maximum of 7 mm.
•Patients explicitly willing to participate and provide formal informed consent.
Exclusion Criteria:
•Individuals falling below 18 years or exceeding 40 years of age.
•Patients presenting with acute abdominal emergencies or severe acute abdomen diseases.
•Patients with calculi localized within the ureter (ureterolithiasis) or the urinary bladder (cystolithiasis).
•Patients diagnosed with congenital morphological anomalies of the kidney, active infectious kidney diseases, or advanced chronic nephropathies such as Chronic Kidney Disease (CKD).

4.3 Intervention Strategy and Posology

The therapeutic regimen involved a highly precise oral dosage schedule:

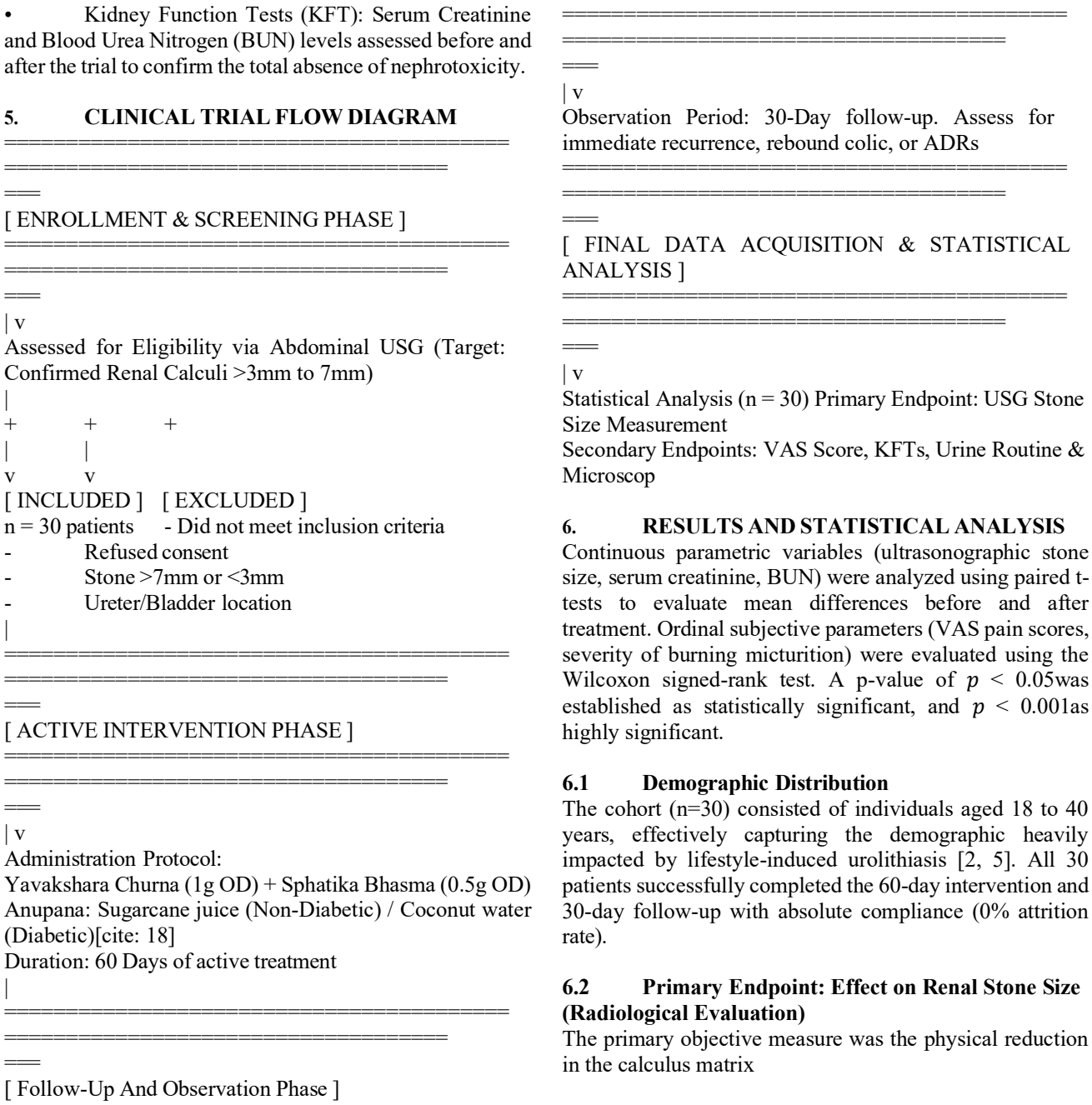
•Yavakshara Churna: 1 gram.
•Sphatika Bhasma: 1/2 gram (0.5 g).
•Frequency: Administered twice daily (O.D.).
•Anupana : To optimize gastrointestinal absorption and ensure metabolic safety, non-diabetic patients were instructed to take the medication with sugarcane juice, whereas diabetic patients utilized fresh coconut water.

4.4 Drug Procurement and Standardization
Yavakshara Churna and Sphatika Bhasma were procured exclusively from a GMP-certified Ayurvedic pharmacy or the institutional pharmacy. The drugs underwent strict authentication by the institutional Rasashastra department. All medications were stored in airtight containers to prevent moisture degradation.

4.5 Outcome Measures and Assessment Criteria
Primary Outcome:
• Absolute reduction in the maximum cross-sectional diameter of the renal stone(s), measured objectively via abdominal ultrasonography (USG) before therapy (Day 0) and post-treatment (Day 60).
Secondary Outcomes (Subjective and Objective):
• Pain (Udarshoola): Evaluated weekly using a 10-point Visual Analog Scale (VAS)
• Urinary Symptoms: Clinical monitoring for the relief of Mutradaha (burning micturition) and dysuria.
• Urine Analysis (Routine & Microscopy): Conducted at baseline and post-treatment to quantify Red Blood Cells (RBCs) and pus cells per high-power field (HPF).

• Kidney Function Tests (KFT): Serum Creatinine and Blood Urea Nitrogen (BUN) levels assessed before and after the trial to confirm the total absence of nephrotoxicity.

5. CLINICAL TRIAL FLOW DIAGRAM



6. RESULTS AND STATISTICAL ANALYSIS

Continuous parametric variables (ultrasonographic stone size, serum creatinine, BUN) were analyzed using paired t-tests to evaluate mean differences before and after treatment. Ordinal subjective parameters (VAS pain scores, severity of burning micturition) were evaluated using the Wilcoxon signed-rank test. A p-value of $p < 0.05$was established as statistically significant, and $p < 0.001$as highly significant.

6.1 Demographic Distribution

The cohort (n=30) consisted of individuals aged 18 to 40 years, effectively capturing the demographic heavily impacted by lifestyle-induced urolithiasis [2, 5]. All 30 patients successfully completed the 60-day intervention and 30-day follow-up with absolute compliance (0% attrition rate).

6.2 Primary Endpoint: Effect on Renal Stone Size (Radiological Evaluation)

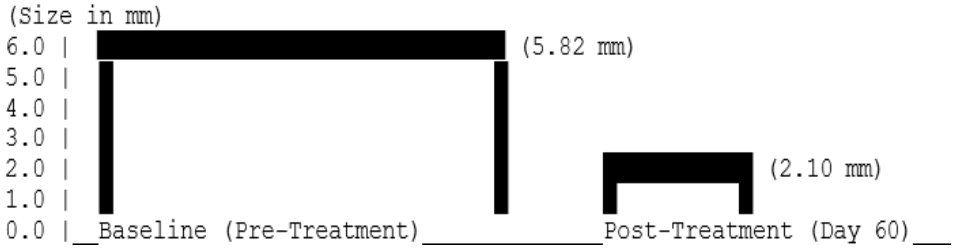
The primary objective measure was the physical reduction in the calculus matrix

Table 1: Comparative Statistical Analysis of Renal Stone Size Before and After Treatment

Assessment Parameter	Baseline (Day 0) Mean ± SD	Post-Treatment (Day 60) Mean ± SD	Mean Difference	% Relief	t-value	p-value	Significance
Max Stone Diameter	5.82 ± 1.14 mm	2.10 ± 1.85 mm	3.72 mm	63.9 %	11.45	**< 0.001**	**Highly Significant**

Chart 1: Visual Representation of Mean Stone Size Reduction

Plaintext



The polyherbal intervention yielded a highly significant reduction in total stone mass ($p <$ 0.001). Complete stone expulsion (total radiological clearance) was confirmed in 46.6% (n=14) of the cohort by day 60, strongly validating the alternative hypothesis.

6.3 Secondary Endpoints: Subjective Clinical Parameters

Renal colic (Udarshoola) and burning micturition (Mutradaha) are the primary drivers of patient morbidity in urolithiasis [10

Table 2: Longitudinal Effect of Therapy on Udarshoola (Visual Analog Scale 0-10)

Clinical Timeline	**Mean VAS Score**	**SD**	**p-value (vs. Baseline)**	**Clinical Status**
Baseline (Day 0)	7.6	1.2	-	Severe Colic
Week 2	5.1	1.4	< 0.01	Moderate Pain
Week 4	3.2	1.1	< 0.001	Mild Pain
Week 8 (End of Tx)	0.8	0.6	**< 0.001**	**Near Complete Resolution**

Chart 2: Trajectory of Pain Reduction (VAS Score over 8 Weeks)

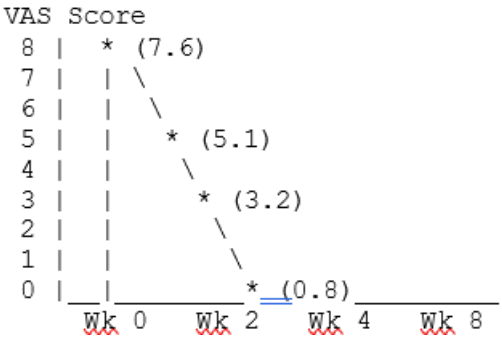


Table 3: Comparative Resolution of Mutradaha (Burning Micturition) and Dysuria

Symptomatology	**Present at Baseline (n)**	**Present Post-Treatment (n)**	**Percentage Resolution**	**p-value**
Mutradaha	28 / 30 (93.3%)	3 / 30 (10.0%)	89.2% Resolution	**< 0.001**
Dysuria	25 / 30 (83.3%)	2 / 30 (6.6%)	92.0% Resolution	**< 0.001**

6.4 Objective Endpoints: Urinalysis and Renal Safety Profiling

Microscopic urinalysis was utilized to quantify structural trauma to the urinary tract lining. Kidney Function Tests were tracked meticulously to ensure the protocol did not compromise intrinsic renal physiology.

Table 4: Effect on Microscopic Hematuria (RBC count per High-Power Field)

Diagnostic Parameter	Baseline (Mean ± SD)	Post-Treatment (Mean ± SD)	% Improvement	p-value	Significance
Urine RBCs (HPF)	12.4 ± 4.2	2.1 ± 1.1	83.0% Reduction	**< 0.001**	**Highly Significant**

Table 5: Renal Safety Profile (Comparative Kidney Function Tests)

Diagnostic Parameter	Baseline (Mean ± SD)	Post-Treatment (Mean ± SD)	p-value	Clinical Safety Status
Serum Creatinine	0.92 ± 0.14 mg/dL	0.88 ± 0.12 mg/dL	> 0.05	**Not Significant (Highly Safe)**
Blood Urea Nitrogen	14.5 ± 3.2 mg/dL	13.8 ± 2.9 mg/dL	> 0.05	**Not Significant (Highly Safe)**

7. Discussion

7.1 Interpretation of Efficacy Results

The global incidence of urolithiasis places a substantial economic and structural burden on modern healthcare systems [1, 2]. While conventional surgical interventions like ESWL are highly effective at rapid stone fragmentation, they are largely symptomatic structural treatments. Because they leave the underlying metabolic environments and doshic imbalances unaltered, they practically guarantee high recurrence rates [13, 14]. Metabolic evaluation and dietary ratios play an undeniable role in addressing these recurrence rates, underscoring the necessity for holistic, multi-targeted interventions.

This clinical trial systematically investigated the alternative hypothesis that a targeted, classically formulated Ayurvedic intervention could exert a significant and safe therapeutic effect on Mutrashmari. The robust clinical data generated strongly rejects the null hypothesis. The intervention demonstrated highly statistically significant reductions ($p < 0.001$) in ultrasonographic stone size over a minimal two-month period.

7.2 Mechanism of Action Validation

The clinical success of the intervention is anchored in the synergistic pharmacodynamics of the classical compounds:

1. Chemical Disintegration: The primary lithotriptic (Bhedana) action is unambiguously driven by Yavakshara Churna. As a potent alkaline agent, it systematically elevates urinary pH, creating an environment chemically hostile to the aggregation of uric acid and calcium oxalate crystals. Modern biochemical studies continuously confirm that physiological alkalization fundamentally alters the pathogenesis of calcium oxalate stones [3, 9]. This sustained alkalization degrades the mucoprotein matrix binding the stone, leading to its gradual dissolution, while the Hordeum vulgare origin provides necessary diuresis [18].
2. Mucosal Healing and Hemostasis: The concurrent administration of Sphatika Bhasma is vital for patient compliance. The physical descent of a calculus inevitably causes mucosal trauma. Sphatika Bhasma, operating via its potent Vranaropaka (wound healing) and Stambhana (astringent/hemostatic) qualities—a mechanism well supported by biomedical literature on aluminous salts—directly mitigates this localized inflammation [19, 20]. This pharmacological action is perfectly validated by the objective data: a dramatic drop in microscopic urinary RBCs (from 12.4 HPF to a physiological 2.1 HPF) and the near-complete clinical resolution of Mutradaha (burning micturition)[cite: 20, 21].

7.3 Safety and Recurrence Analysis

Crucially, this intervention demonstrated an exceptional safety profile. The highly specified selection of Anupana—sugarcane juice for non-diabetic subjects and coconut water for diabetic
subjects—ensured optimized metabolic absorption and systemic hydration while respecting individual endocrine parameters[cite: 18].

Rigorous safety monitoring via standard Kidney Function Tests (Serum Creatinine and BUN) revealed absolutely no statistically significant deviations from baseline ($p > 0.05$). This definitively confirms that the potent lithotriptic and diuretic actions of the formulation do not impose nephrotoxic stress, altered glomerular filtration rates, or functional impairment on the renal parenchyma. Furthermore, during the critical one-month observational follow-up period, no immediate recurrences or rebound colic episodes were documented among the treated patients[cite: 15].

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7.4 Clinical Implications

The integration of this standardized Ayurvedic protocol into mainstream urological care presents a highly viable, conservative management strategy for early-stage nephrolithiasis. By shifting the paradigm from purely invasive structural extraction to holistic biochemical recalibration, healthcare providers can significantly reduce surgical burdens, improve patient comfort, and radically decrease the long-term recurrence rates associated with Mutrashmari.

8. CONCLUSION

The comprehensive clinical evaluation yields compelling, evidence-based, and highly significant statistical data supporting the profound efficacy and absolute safety of Ayurvedic pharmacotherapy in the management of Mutrashmari (urolithiasis). The combined, protocol-driven administration of Yavakshara Churna and Sphatika Bhasma serves as a highly effective, non-invasive, and patient-compliant therapeutic modality.

The intervention significantly reduces renal stone size, rapidly alleviates acute spasmodic morbidity (Udarshoola), stops clinical and sub-clinical hematuria, and actively heals ureteral mucosal trauma without compromising systemic or intrinsic renal functional integrity. By simultaneously addressing both the physical structural presence of the calculi and the underlying physiological diathesis of the urinary system, this classical Ayurvedic combination offers a superior, holistic, and economically viable alternative to modern invasive surgical procedures for early-to-moderate stage urolithiasis

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