

A Single-Arm Clinical Trial to Evaluate the Efficacy of Palash Kshara in the Management of Dushta Vrana w.s.t. Infected Wound

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Abstract: *Background & Objective:* Infected and non-healing wounds pose a significant therapeutic challenge in surgical practice, often characterized by persistent pain, excessive purulent or seropurulent discharge, foul odor, thick slough, unhealthy pale/exuberant granulation tissue, and stalled wound contraction. In Ayurvedic surgical literature, this pathological entity is comprehensively described as Dushta Vrana (vitiated/unhealthy wound), which mandates active debridement (Vrana Shodhana) followed by restorative healing (Vrana Ropana). Among the sixty classical therapeutic measures (Shashti Upakrama), Kshara Karma holds prime prominence owing to its Chedana (excision), Bhedana (incision), and Lekhana (scraping/debriding) properties.

Materials & Methods: The study was conducted as an open-label, single-arm clinical trial comprising 20 patients presenting with signs and symptoms of Dushta Vrana (infected wound). Standardized Palash Kshara (alkaline preparation derived from the water-soluble ash of Butea monosperma) was applied topically over the prepared wound bed under aseptic precautions. Follow-up evaluations were conducted periodically to monitor changes in clinical parameters, including pain (VAS), wound discharge, foul smell, slough percentage, wound-bed floor condition, granulation tissue health, and wound surface area reduction.

Results: Out of 20 enrolled patients, 18 patients (90.0%) demonstrated marked to complete clinical recovery (positive response) with statistically significant reduction in pain (mean score decreased from 2.65 to 0.45; 83.0% relief, $p < 0.001$), clearance of slough (decreased from 2.50 to 0.35; 86.0% reduction, $p < 0.001$), cessation of discharge (decreased from 2.30 to 0.40; 82.6% reduction, $p < 0.001$), and elimination of foul odor (decreased from 2.05 to 0.20; 90.2% relief, $p < 0.001$). Furthermore, healthy red, velvety granulation tissue was successfully established in 85.0% of cases, and significant wound surface area contraction (mean reduction of 71.4%) was achieved. Only 2 patients (10.0%) exhibited an unsatisfactory response.

Conclusion: Palash Kshara represents a potent, cost-effective, and safe Ayurvedic topical modality for chemical debridement (Lekhana) and bio-cleansing (Shodhana) of Dushta Vrana, facilitating the conversion of chronic non-healing infected wounds into healthy granulating bed (Shuddha Vrana).

Keywords: Palash Kshara, Butea monosperma, Dushta Vrana, Infected Wound, Wound Debridement, Vrana Shodhana, Vrana Ropana, Kshara Karma, Ayurveda.



I. INTRODUCTION

A wound is defined anatomically as a disruption of the normal cellular, anatomical, and functional continuity of living tissue. Under physiological circumstances, the human body initiates an orchestrated cascade of biological events—comprising hemostasis, inflammation, proliferation, and tissue remodeling—aimed at restoring anatomical integrity and barrier function. However, this physiological continuum is frequently impeded by local and systemic impediments such as high bioburden, necrotic devitalized tissue, excessive inflammatory exudate, foreign debris, tissue hypoxia, and persistent microbial colonization, culminating in a chronic, stalled, non-healing state known clinically as an infected wound.

The clinical burden of chronic infected wounds is substantial for both patients and healthcare infrastructure. Manifestations such as relentless pain, offensive malodor, heavy purulent exudation, adherence of tenacious yellow slough, perilesional erythema, and absence of healthy vascularized tissue significantly impair patient quality of life and escalate hospital admissions. Modern wound-bed preparation paradigms, notably the TIME framework (Tissue debridement, Infection/inflammation control, Moisture balance, and Epithelial edge advancement), underscore that comprehensive cleansing and removal of devitalized tissue are non-negotiable precursors to cellular proliferation and tissue repair.

In classical Ayurvedic surgical literature, Acharya Sushruta—acknowledged as the father of surgery—extensively expounded upon wound etiology, classification, and management under the doctrine of Vrana Chikitsa. A wound that deviates from the normal healing trajectory due to local vitiation of Tridoshas and Rakta Dhatu, characterized by abnormal discharge (Atisrava), putrid odor (Poothigandha), excruciating pain (Teevra Vedana), extensive slough (Mamsa Kotha), and stalled chronicity, is designated as Dushta Vrana. For managing Dushta Vrana, Acharya Sushruta formulated the Shashti Upakrama (sixty clinical procedures), with primary therapeutic emphasis placed upon Vrana Shodhana (wound purification/debridement) followed by Vrana Ropana (wound healing/epithelialization).

Among all Shodhana modalities, Kshara Karma occupies the foremost rank among Anu-Shastras (para-surgical instruments) because of its exceptional capability to perform excision (Chedana), incision (Bhedana), and bio-cleansing/scraping (Lekhana) without inciting excessive mechanical hemorrhage. Classical treatises identify Palasha (*Butea monosperma* (Lam.) Taub., Family: Fabaceae) as one of the preeminent botanical sources for preparing Kshara, grouped specifically under Madhyama and Tikshna categories. Palash Kshara possesses Tikshna (sharp/penetrating), Ushna (hot potency), Laghu, and Lekhana (scraping) attributes, alongside an intensely alkaline pH, conferring superior capabilities to digest necrotic debris, eliminate bacterial biofilm, and stimulate the microvascular base.

Although classical texts document the broad efficacy of Kshara, systematic clinical documentation with structured assessment criteria evaluating Palash Kshara specifically in Dushta Vrana (infected wounds) remains sparse. Therefore, the present single-arm clinical trial was designed and conducted to evaluate the therapeutic efficacy, wound-bed preparation dynamics, and safety profile of Palash Kshara application in patients suffering from Dushta Vrana.

II. AIMS AND OBJECTIVES

2.1 Aim

To clinically evaluate the therapeutic efficacy and safety of topical Palash Kshara application in the management of Dushta Vrana with special reference to infected wounds.

2.2 Specific Objectives

1. To clinically evaluate and record the baseline characteristics of Dushta Vrana correlating with the pathophysiological profile of infected chronic wounds.
2. To objectively assess the therapeutic effect of topical Palash Kshara on individual clinical cardinal parameters: pain, wound exudate/discharge, foul odor, slough adherence, wound-bed condition, healthy granulation tissue formation, and wound surface area.



3. To compute and assess the overall clinical response rate (positive vs. unsatisfactory recovery) following the protocolized intervention period.
4. To monitor, document, and assess patient acceptability, tolerability, adverse local reactions, and procedural safety during and after the application of Palash Kshara.

III. MATERIALS AND METHODS

3.1 Study Design & Setting

The clinical study was conducted as an open-label, single-arm, prospective clinical trial carried out in the Department of Shalyatantra, Yashwant Ayurvedic College, Post Graduate Training & Research Centre, Kodoli, Kolhapur, Maharashtra, India. The institutional ethics guidelines were adhered to throughout the study, and written informed consent was procured from every participant prior to enrollment.

3.2 Sample Size and Selection Criteria

A total of 20 patients presenting with clinically established Dushta Vrana fulfilling predefined diagnostic criteria were recruited into the clinical trial.

- Inclusion Criteria: (1) Patients aged between 18 and 65 years of either gender; (2) Patients presenting with chronic wounds exhibiting cardinal features of Dushta Vrana / wound infection (purulent or seropurulent discharge, foul odor, slough/necrotic tissue, persistent pain, unhealthy pale or exuberant granulation tissue, and chronicity > 2 weeks); (3) Wounds situated on accessible anatomical sites amenable to topical dressing; (4) Patients willing to comply strictly with trial protocol and follow-up schedules.
- Exclusion Criteria: (1) Patients presenting with malignant ulcers, tubercular ulcers, or syphilitic lesions; (2) Wounds secondary to major uncontrolled systemic co-morbidities (e.g., uncontrolled diabetes mellitus with HbA1c > 9.0%, severe peripheral arterial occlusive disease, advanced renal failure, hepatic decompensation); (3) Patients with deep osteomyelitis or exposed major neurovascular bundles; (4) Pregnant or lactating women; (5) Patients on long-term systemic corticosteroids, immunosuppressive drugs, or chemotherapy.

3.3 Drug Preparation and Standard Operating Procedure

Palash Kshara was prepared strictly adhering to classical Ayurvedic pharmaceutical principles outlined in the Ayurvedic Formulary of India (AFI) and Sushruta Samhita Sutra Sthana Chapter 11 (Ksharapakavidhi). Mature, authenticated whole plants and stem bark of Palasha (*Butea monosperma*) were cleaned, thoroughly sun-dried, and incinerated into white ash (Kshara-bhasma). The ash was dissolved in four times (or six times) distilled water, stirred thoroughly, allowed to stand undisturbed for decantation, and filtered through four-folded muslin cloth twenty-one times. The pristine clear filtrate (Ksharodaka) was subjected to slow boiling over Mandagni until moisture was completely evaporated, yielding fine, dry Palash Kshara powder. The finished product was tested for physicochemical standards (pH 10.5–11.5, solubility, moisture content, loss on drying) and stored in airtight glass containers.

3.4 Clinical Intervention Protocol

Step 1: 1. Wound Bed Cleansing: The perilesional skin was cleaned with sterile normal saline. The ulcer was gently cleansed to remove superficial debris without aggressive mechanical scrubbing.

Step 2: 2. Barrier Protection: The surrounding healthy skin margin was carefully protected using a fine layer of sterile Yashtimadhu Ghrita or sterile petroleum jelly to avoid accidental chemical irritation of healthy epithelial edges.

Step 3: 3. Topical Kshara Application: A measured thin film of sterile Palash Kshara powder was evenly dusted/applied over the slough-covered, unhealthy wound bed using a sterile applicator, strictly ensuring uniform contact with devitalized tissue for a contact duration of 1 to 2 minutes.



Step 4: 4. Neutralization & Cleansing: The applied Kshara was gently neutralized/flushed with sterile normal saline or mildly acidic washing (as indicated classically with Nimbu Swarasa / Dhanyamla / sterile saline rinse) until the alkaline residue was completely lavaged.

Step 5: 5. Sterile Protective Dressing: A sterile secondary absorbent pad was secured over the lesion. Dressings were renewed daily or alternate-day based on exudate level for a period of up to 4 to 6 weeks, with periodic formal clinical evaluations on Day 0, Day 7, Day 14, Day 21, and Day 28.

3.5 Assessment Criteria and Scoring System

Clinical parameters were scored semi-quantitatively using a standardized 4-point ordinal grading scale (Grade 0 to Grade 3) alongside metric surface area measurements before and after treatment, as delineated in Table 1.

Clinical Parameter		Grade / Score	Operational Clinical Definition
Pain [VAS Score 0–10]	(Vedana)	Grade 0	No pain (VAS 0)
		Grade 1	Mild pain, does not disturb daily routine/sleep (VAS 1–3)
		Grade 2	Moderate pain, bothersome, requires occasional analgesia (VAS 4–6)
		Grade 3	Severe pain, interferes with sleep/activity, continuous (VAS 7–10)
Wound Discharge (Srava)		Grade 0	Nil / dry wound bed
		Grade 1	Mild / scanty discharge; dressing moist but no strike-through
		Grade 2	Moderate discharge; dressing wet, requires daily change
		Grade 3	Severe / copious discharge; frequent soakage, strike-through
Foul Smell (Poothigandha)		Grade 0	Completely absent
		Grade 1	Mild odor; perceptible only in close proximity during dressing
		Grade 2	Moderate odor; perceptible upon entering dressing area
		Grade 3	Severe foul / putrid malodor; strong, nauseating at a distance



Slough (Mamsa Kotha)		Grade	0	Completely absent; clean base (0% slough)
		Grade	1	Mild; thin, loose slough covering < 25% of wound bed
		Grade	2	Moderate; tenacious slough covering 25% to 50% of wound bed
		Grade 3		Severe; thick, necrotic adherent slough covering > 50% of wound bed
Granulation Tissue (Ropana / Dhatu Vriddhi)		Grade	0	Healthy, vascular, beefy-red velvety granulation (> 75% bed)
		Grade	1	Moderate pink/red granulation tissue covering 50% to 75% bed
		Grade	2	Poor / pale granulation tissue covering 25% to 50% bed
		Grade 3		Absent / necrotic / pale / glassy / unhealthy bed (< 25% bed)
Wound Floor / Bed Condition		Grade	0	Floor clean, healthy pink, even, ready for epithelial edge migration
		Grade	1	Floor partially clean (> 50% clear of debris), minimal exudate
		Grade	2	Floor covered with patchy slough, dull pale appearance
		Grade 3		Floor completely unhealthy, covered with thick slough and purulent pool
Wound Size / Surface Area (L × W in cm ²)		Quantitative Measurement		Traced using transparent metric grid film or sterile caliper; area calculated as Length × Width; percentage reduction calculated as: [(Baseline Area – Post-treatment Area) / Baseline Area] × 100

Table 1: Standardized Ordinal Grading System for Clinical Assessment Parameters in Dushta Vrana.

IV. RESULTS AND OBSERVATIONS

A total of 20 patients presenting with Dushta Vrana were treated with local application of Palash Kshara. Statistical analysis was performed using the Paired Student's t-test for quantitative data and Wilcoxon Signed-Rank Test for non-parametric ordinal graded variables. A p-value of < 0.05 was considered statistically significant, and p < 0.001 was considered highly significant.

4.1 Demographic and Baseline Characteristics of Patients

The demographic profile of the enrolled cohort revealed a higher incidence among males (65.0%) compared to females (35.0%), with the most frequent age distribution falling between 41 and 60 years. The mean duration of non-healing



wounds prior to intervention was 24.6 ± 8.4 days. The anatomical sites most commonly affected were the lower extremities (foot, ankle, and leg regions accounting for 70.0% of cases), reflecting classic clinical patterns of trauma, chronic venous congestion, and secondary bacterial infection.

Demographic / Baseline Parameter	Category	No. of Patients (n=20)	Percentage (%)
Age Distribution	18 – 30 years	3	15.0%
	31 – 45 years	6	30.0%
	46 – 60 years	8	40.0%
	> 60 years	3	15.0%
Gender	Male	13	65.0%
	Female	7	35.0%
Chronicity of Wound (Baseline)	< 2 weeks	0	0.0%
	2 – 4 weeks	12	60.0%
	> 4 weeks	8	40.0%
Anatomical Site of Lesion	Lower Limb (Foot/Leg/Ankle)	14	70.0%
	Upper Limb (Hand/Forearm)	4	20.0%
	Trunk / Back / Gluteal	2	10.0%
Etiological Subtype	Traumatic infected wound	9	45.0%
	Post-operative infected ulcer	4	20.0%
	Venous / Stasis ulcer	4	20.0%
	Infected carbuncle / abscess floor	3	15.0%

Table 2: Baseline Demographic and Clinical Profile of the Enrolled Study Population (N = 20).

4.2 Effect of Palash Kshara on Cardinal Clinical Parameters

Marked symptomatic and objective relief was observed across all cardinal parameters following topical application of Palash Kshara. Pain scores dropped from a baseline mean of 2.65 ± 0.49 to 0.45 ± 0.51 (83.0% relief, $p < 0.001$). Wound discharge was reduced by 82.6%, clearing purulent pooling within 7 to 10 days. Foul odor was eliminated in 90.2% of cases, and necrotic slough score decreased by 86.0%. Granulation score improved significantly (85.2% shift toward healthy vascular tissue), accompanied by a 71.4% mean reduction in total wound surface area.

Clinical Parameter	Pre-Tx (Mean $\pm$ SD)	Post-Tx (Mean $\pm$ SD)	Mean Diff.	% Relief	t-Value	p-Value
Pain (Vedana)	2.65 ± 0.49	0.45 ± 0.51	2.20	83.0%	15.68	< 0.001 (HS)



Discharge (Srava)	2.30 ± 0.57	0.40 ± 0.50	1.90	82.6%	13.42	< 0.001 (HS)
Foul Smell (Poothigandha)	2.05 ± 0.60	0.20 ± 0.41	1.85	90.2%	14.15	< 0.001 (HS)
Slough (Mamsa Kotha)	2.50 ± 0.51	0.35 ± 0.49	2.15	86.0%	16.89	< 0.001 (HS)
Unhealthy Bed Condition	2.40 ± 0.50	0.45 ± 0.51	1.95	81.3%	14.28	< 0.001 (HS)
Granulation Deficit Score*	2.70 ± 0.47	0.40 ± 0.50	2.30	85.2%	17.45	< 0.001 (HS)
Wound Size (Area in cm ²)	12.45 ± 4.82	3.56 ± 1.84	8.89	71.4%	11.92	< 0.001 (HS)

Table 3: Statistical Evaluation of Palash Kshara on Cardinal Clinical Parameters Before and After Treatment (N = 20). [HS = Highly Significant ($p < 0.001$); *Granulation scored as degree of unhealthy/absent granulation; paired t-test applied].

4.3 Weekly Interval-wise Healing Trajectory

Sequential assessment at weekly intervals revealed rapid debridement during the first two weeks (Days 0 to 14), with slough clearance dropping from 2.50 to 1.15, followed by vigorous granulation and peripheral re-epithelialization during Days 14 to 28.

Clinical Parameter (Mean)	Day 0 (Base)	Day 7	Day 14	Day 21	Day 28
Pain (Vedana Score)	2.65	1.90	1.25	0.75	0.45
Discharge (Srava Score)	2.30	1.65	1.05	0.60	0.40
Foul Smell (Poothigandha Score)	2.05	1.20	0.55	0.25	0.20
Slough (Mamsa Kotha Score)	2.50	1.80	1.15	0.65	0.35



Mean Wound Surface Area (cm ²)	12.45	11.10	8.95	6.20	3.56
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Table 4: Progressive Weekly Resolution of Wound Parameters Across Study Intervals (N = 20).

4.4 Overall Therapeutic Response

The overall clinical efficacy was categorized into Positive Response (marked healing, complete debridement, disappearance of foul smell and slough, > 60% wound area reduction) and Unsatisfactory Response (< 50% improvement, persistent exudation, or recalcitrant slough). In the present study, 18 patients (90.0%) achieved a positive clinical response, whereas only 2 patients (10.0%) showed an unsatisfactory response.

Clinical Outcome Category	Criteria for Response	Patient Count (n=20)	Percentage (%)
Marked / Complete Healing (Excellent Response)	> 75% surface area reduction, 100% slough debridement, no odor, healthy granulating bed / full re-epithelialization	12	60.0%
Moderate Improvement (Good Response)	50% – 75% surface area reduction, > 75% slough clearance, minimal serous discharge, good pink granulation	6	30.0%
Positive Clinical Response (Pooled Efficacy)	Composite of Marked and Moderate Clinical Improvements	18	90.0%
Unsatisfactory / Poor Response	< 50% wound reduction, persistent tenacious slough, ongoing discharge, or stalled healing edge	2	10.0%
Total Enrolled Cohort	Complete Study Protocol	20	100.0%

Table 5: Overall Clinical Response and Therapeutic Outcome Distribution (N = 20).

V. DISCUSSION

Chronic non-healing infected wounds (Dushta Vrana) present a challenging clinical dilemma, characterized by a complex pathological feedback loop involving bacterial bioburden, excessive matrix metalloproteinases, necrotic cellular debris, and compromised tissue perfusion. The present clinical trial demonstrates that local application of Palash Kshara effectively breaks this cycle, achieving a 90.0% favorable clinical response rate.



5.1 Ayurvedic Mode of Action (Samprapti Vighatana)

In classical Ayurveda, Acharya Sushruta described Kshara as the supreme entity among Shastra and Anu-Shastra: 'Shastra Anushastranam Ksharah Pradhanatamah...' due to its multifaceted actions including Chedana, Bhedana, Lekhana, and Tridoshaghna capability. Dushta Vrana is primarily driven by vitiated Kapha and Rakta Dhatu, leading to Mamsa Kotha (slough/putrefaction), Poothigandha (foul odor), and Bahu Srava (excessive exudate).

Palash Kshara is prepared from Butea monosperma, a drug classified classically as Katu-Tikta-Kashaya Rasa, Ushna Virya, and Kaphapittahara. The resulting alkaline Kshara possesses sharp (Tikshna), micro-channel entering (Sukshma), and scraping (Lekhana) attributes. Upon local application, the Lekhana Guna rapidly lyses and dissolves tenacious slough (Mamsa Kotha) and purges devitalized tissue without traumatic bleeding. The Ushna Virya and Katu Vipaka stimulate local Dhatvagni and promote micro-vascularization. As the necrotic burden and morbid Kapha are eliminated (Vrana Shodhana), the wound transforms into a Shuddha Vrana (clean, uninfected wound), enabling spontaneous Ropana (healing and epithelialization).

5.2 Modern Biomedical and Pathophysiological Interpretation

From a modern surgical and wound-bed preparation (TIME) perspective, the findings can be interpreted through established physiological mechanisms:

- 1. Chemical Debridement of Devitalized Tissue (T - Tissue Management): Slough consists of denatured collagen, fibrin, cellular debris, and trapped bacterial colonies. The strongly alkaline pH (approx. 10.5–11.5) of Palash Kshara saponifies fats, digests necrotic protein matrices, and loosens the dense fibrinous biofilm clinging to the wound bed. This non-surgical chemical debridement de-roofs protected microbial niches without injuring underlying capillary buds.
- 2. Antimicrobial & Malodor Abatement (I - Infection/Inflammation Control): Most pathogenic bacteria (Staphylococcus aureus, Pseudomonas aeruginosa, Proteus mirabilis) thrive within a slightly acidic to neutral micro-environment (pH 6.0–7.5). The transient hyper-alkaline shift induced by Palash Kshara disrupts bacterial transmembrane proton gradients and inhibits bacterial enzymatic function. Furthermore, the rapid dissolution of putrefying tissue directly abolishes volatile fatty acids and sulfur compounds responsible for foul odor (Poothigandha), resulting in a 90.2% relief in malodor.
- 3. Exudate Regulation (M - Moisture Imbalance): By debriding slough and eradicating bioburden, Palash Kshara terminates persistent neutrophil recruitment and down-regulates excessive inflammatory exudate (82.6% reduction in discharge), shifting the wound microenvironment from a destructive catabolic state into an anabolic restorative state.
- 4. Angiogenesis and Re-epithelialization (E - Epithelial Edge Advancement): Once necrotic tissue is cleared, clean mechanical irritation from mild alkaline exposure stimulates local hypoxia-inducible factor and vascular endothelial growth factors, recruiting fibroblasts and endothelial precursors. This explains the 85.2% improvement in beefy-red granulation tissue and 71.4% wound area contraction.

5.3 Safety, Tolerability, and Clinical Limitations

Local application of Palash Kshara was well tolerated by all patients. Minor transient burning sensation (mild Ushna sensation) lasting 2 to 5 minutes post-application was reported in 4 patients (20.0%), which was readily relieved by saline neutralization and barrier dressing. No serious adverse cutaneous reactions, secondary chemical burns, or systemic toxicities were observed.

Study Limitations: Although the results are highly encouraging, the present study is limited by its single-arm design, relatively modest sample size (n=20), and lack of a parallel active control group (e.g., modern enzymatic debriding ointments or povidone-iodine). Furthermore, qualitative microbiological profiling (pre- and post-swab culture colony counts) and histological biopsies were not incorporated.



VI. CONCLUSION

The findings of this clinical trial demonstrate that Palash Kshara is a clinically effective, expeditious, and safe Ayurvedic topical agent for the comprehensive management of Dushta Vrana (infected chronic wounds). The local application of Palash Kshara achieved an overall positive clinical response in 90.0% of patients, characterized by significant clearance of slough (86.0%), cessation of purulent discharge (82.6%), eradication of foul odor (90.2%), marked alleviation of pain (83.0%), vigorous induction of healthy vascular granulation bed (85.2%), and significant wound contraction (71.4%).

Palash Kshara functions as a potent bio-cleansing and debriding agent (Vrana Shodhana), successfully transiting a stalled Dushta Vrana into a healthy granulating Shuddha Vrana ready for re-epithelialization. It provides a simple, economically viable, and reproducible bedside surgical alternative for wound debridement in both hospital and outpatient settings.

Further large-scale, multicenter, randomized controlled clinical trials incorporating microbiological culture analysis, bio-film quantification, and standardized phytochemical profiling are strongly recommended to establish Palash Kshara as a mainstream evidence-based protocol in integrated wound care.

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