

A Randomised Controlled Clinical Study to Evaluate the Efficacy of *Gunavati Varti* in The Management of *Dushta Vrana* Vis-À-Vis Chronic Non-Healing Ulcer

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Abstract—Background: Chronic non-healing ulcers (*Dushta vrana*) present significant therapeutic barriers due to persistent inflammation, necrosis, and deep cavity formation. *Varti Kalpana* (medicated wick therapy) provides localized, sustained drug delivery to facilitate debridement (*Shodhana*) and healing (*Ropana*).

Objectives: To evaluate the difference in the efficacy of *Gunavati varti* and *Jatyadi taila* gauze dressings in reducing Bates-Jensen Wound Assessment Tool (BWAT) scores and healing *Dushta vrana*. **Trial Design:** Single-centre, open-label, two-arm, parallel-group, randomized controlled (1:1 allocation ratio; 28-day study period).

Participants: Forty-five enrolled patients aged 18–60 years presenting with *Dushta vrana* (venous, diabetic [HbA1c < 8.0%], and neurogenic ulcers with cavity/sinus formation) at a tertiary Ayurvedic hospital.

Interventions: Intervention Group (Group A, n=20 completed): Daily wound debridement/cleansing with normal saline followed by placement of *Gunavati varti* wicks (or flakes) into the ulcer base/cavity for 14 days, followed by standard sterile dry dressings through Day 28.

➤ Control Group (Group B, n=20 completed): Daily wound cleansing with normal saline followed by application of *Jatyadi taila*-soaked sterile gauze for 14 days, followed by standard dry dressings through Day 28.

Primary & Secondary Outcomes: The primary outcome was the change in Total BWAT score at Day 14 and Day 28. Secondary outcomes included individual BWAT sub-scores (ulcer dimensions, depth, undermining, necrotic tissue amount/type, granulation, and epithelialization) and subjective symptoms (VAS pain, itching, and malodor).

Randomization & Blinding: Participants were randomly allocated using simple randomization. The study was open-label (unblinded to participants and investigators due to physical differences in formulations).

Results: Out of 45 randomized participants, 40 completed the 28-day protocol (Group A: n = 20; Group B: n = 20; 5 dropouts due to loss to follow-up). Group A demonstrated statistically significant superiority over Group B in reducing total BWAT scores at Day 14 (mean rank 29.75 vs. 11.25, $p = 0.0001$) and Day 28 (mean rank 29.85 vs. 11.15, $p = 0.00001$). Group A achieved significantly greater improvements in healthy granulation tissue formation ($p < 0.0001$), epithelialization ($p < 0.0001$), slough type clearance ($p = 0.013$), and peripheral tissue induration ($p = 0.001$) at Day 28, as well as early cavity debridement and reduction in undermining at Day 14 ($p = 0.006$). Necrotic slough amount showed a favorable trend in Group A, but did not reach two-tailed statistical significance ($p = 0.055$). Subjective parameters (pain, pruritus, malodor) resolved equally in both groups ($p > 0.05$). No adverse events or device-related reactions were observed.

Conclusions: *Gunavati varti* showed superior therapeutic efficacy over *Jatyadi taila* gauze in debriding deep necrotic cavities and promoting structural tissue regeneration in chronic *Dushta vrana*.

Trial Registration & Open Science: Registered with Institutional Ethics Committee; Clinical trial registration number: CTRI/2025/06/088303.

Index Terms—*Dushta vrana*, Chronic non-healing ulcers, *Gunavati Varti*, *Jatyadi taila*.

I. INTRODUCTION

Scientific Background & Rationale

Chronic non-healing ulcers (*Dushta vrana*) affect approximately 1–2% of the global population, leading to major risks of secondary sepsis, amputation, and substantial socio-economic burdens.¹ In Ayurvedic surgery (*Shalya Tantra*), impaired physiological wound healing cascades—arising from *doshic* vitiation, microangiopathy, or local bioburden—require sequenced *Shashti Upakramas* (sixty wound care modalities),² specifically transitioning a contaminated, stagnant wound (*Dushta vrana*) to a clean, granulating bed (*Shuddha Vrana*) through *Vrana Shodhana* (cleansing/debridement) and *Vrana Ropana* (healing/re-epithelialization).³

While classical oil dressings such as *Jatyadi taila*⁴ offer topical nourishment, their liquid consistency often fails to maintain sustained physical contact at the base of deep, undermining cavity wounds or sinus tracts. *Varti Kalpana* (medicated wicks) addresses this limitation by facilitating capillary drainage, mechanical debridement of slough, and prolonged release of active phytoconstituents directly into deep tissue crevices.

II. OBJECTIVES & HYPOTHESES

- Primary Objective: To find out the difference in the efficacy of *Gunavati varti* and *Jatyadi taila* in structural wound healing and tissue debridement in patients suffering from *Dushta vrana*.
- Hypothesis (H1): There is a significant difference in the efficacy of *Gunavati varti* and *Jatyadi taila* in the management of *Dushta vrana*.
- Null Hypothesis (H0): There is no significant difference in the efficacy of *Gunavati varti* and *Jatyadi taila* in the management of *Dushta vrana*.

III. METHODS

Trial Design & Open Science Commitments

Design: Parallel-group, two-arm, randomized controlled clinical trial conducted over a 28-day observational timeline (after days active drug administration + 14 days dry dressing follow-up).

Open Science & Data Availability: Complete raw datasets, scoring sheets and analytical codes

Eligibility Criteria

Inclusion Criteria:

1. Clinically diagnosed *Dushta vrana* (exhibiting slough, discharge, chronicity, sinus tract, or cavity formation).
2. Venous ulcers, diabetic wounds, or neurogenic ulcers open for ≥ 4 weeks.
3. Patients aged 18 to 60 years of either gender.
4. Diabetic patients with controlled glycaemic status ($\text{HbA1c} < 8.0\%$).

Exclusion Criteria:

1. Ulcers associated with active gangrene, osteomyelitis, active spreading cellulitis, or malignant degeneration (Marjolin's ulcer).
2. Diagnosed systemic comorbidities (HIV, HBsAg positivity, leprosy, renal failure).
3. Uncontrolled systemic illnesses.

Settings & Locations

Conducted at the Department of Shalya Tantra (Inpatient and Outpatient services), Tertiary Ayurvedic Hospital, Karnataka, India.

Patient & Public Involvement (PPI)

Patients contributed to feedback regarding dressing comfort, pain during varti insertion/removal, and tolerance of the malleable varti matrix versus standard taila-soaked gauze during preliminary formulation trials.

Interventions

Trial Drug Preparation (*Gunavati varti*): Classical *Gunavati varti* (*Rasaratnakara*)⁵ incorporates *Sikthaka* (beeswax, 10 parts) and 1 part each of *Sarja Rasa* (*Shorea robusta*), *Lodhra* (*Symplocos racemosa*), *Ativisha* (*Aconitum heterophyllum*), *Haridra* (*Curcuma longa*), *Vibhitaki* (*Terminalia bellirica*), *Kampillaka* (*Mallotus philippensis*), *Guggulu* (*Commiphora mukul*), *Sindura* (red oxide of lead), *Ghrita* (clarified butter), and *Tila Taila* (sesame oil). To eliminate excessive physical rigidity and improve clinical conformability, the formulation was modified: *Sikthaka* (4 parts) was melted over *Manda Agni* (low flame), blended with *Tila Taila* (5 parts) and *Ghrita*, and thoroughly mixed with micro-fine herbal *Churna* (1 part) to yield a pliable, viscoelastic wick.

Scope of Formulation Standardization:

While the modified ratio of *Gunavati Varti* (utilizing 4 parts *Sikthaka* and 5 parts *Tila Taila*) successfully enhanced physical conformability and viscoelastic performance compared to classical proportions, comprehensive analytical standardization—such as high-performance thin-layer chromatography (HPTLC) fingerprinting, advanced thermal profiling, and formal shelf-life stability testing of this specific matrix variant—is currently undergoing independent development in ongoing pharmaceutical research. Because establishing full industrial standardization falls outside the primary clinical objectives and purview of the present therapeutic trial, future dedicated pharmaceutical studies will focus entirely on standardizing the physicochemical parameters of this modified ratio.

Administration:

Group A (Study Group, n=20): Ulcer irrigated with sterile 0.9% normal saline. *Gunavati varti* sized to the depth/contour was inserted into the cavity/sinus (or applied as flat malleable flakes over shallow ulcer beds), covered with sterile gauze, and secured daily for 14 days.

Group B (Control Group, n=20): Ulcer irrigated with sterile 0.9% normal saline, dressed daily with *Jatyadi taila*-soaked sterile gauze for 14 days.

Common Phase (Days 15–28): Both groups received daily standard sterile dry dressings.

Outcomes & Measurement

Primary Outcome Measure:

Total Bates-Jensen Wound Assessment Tool (BWAT) score evaluated at Baseline (Day 0), Post-Treatment (Day 14), and Follow-Up (Day 28).

Secondary Outcome Measures:

Objective BWAT individual items: Ulcer size, depth, edges, undermining, necrotic tissue type/amount, exudate type/amount, periwound color, peripheral edema, induration, granulation tissue development, and epithelialization.⁶

Subjective Parameters: Visual Analogue Scale (VAS 0–10) for Pain⁷, Itching (4-point ordinal scale)⁸, and Malodor (2-point ordinal scale)⁹.

Sample Size Determination & Statistical Power

The sample size was calculated based on the primary outcome measure. Based on historical data from published topical Ayurvedic wound trials and standard validation literature for BWAT in chronic wounds, a minimum clinically meaningful difference between groups of 7.0 points on the Total BWAT scale, with an anticipated pooled standard deviation of 7.5 points, was hypothesized (corresponding to an effect size Cohen's $d = 0.93$). Assuming a two-sided significance level of 0.05 and a statistical power of 80%, a minimum of 18 completed participants per treatment arm ($n = 36$ total) was required. Anticipating a potential attrition rate of approximately 20% due to loss to follow-up over the 28-day study timeline, the target recruitment was rounded up to 45 enrolled participants (Group A: $n = 22$; Group B: $n = 23$). The final analyzed cohort of 40 completers ($n = 20$ per arm) preserved >80% post-hoc statistical power for the primary outcome.

Randomization & Sequence Generation

Participants were assigned (1:1) to either Group A or Group B using a simple computer-generated random allocation sequence.

Allocation Concealment & Implementation

Allocation sequence was implemented using sequentially numbered, opaque, sealed envelopes (SNOSE) opened only upon signed informed consent and baseline confirmation.

Blinding

Because the physical forms of the interventions were inherently distinct (a solid, viscoelastic molded herbal-wax wick versus an oil-soaked liquid gauze dressing), double-blinding of patients and treating clinicians was not feasible. To mitigate observer and detection bias, standard clinical evaluation guidelines for the Bates-Jensen Wound Assessment Tool (BWAT) were applied strictly. Ulcer surface dimensions and cavity depths were measured using sterile metric calipers and calibrated depth probes rather than visual estimation alone. Serial digital clinical photographs were taken under standardized lighting, framing, and distance at Baseline (Day 0), Post-Treatment (Day 14), and Follow-Up (Day 28) to provide verifiable records of tissue morphological changes. Nonetheless, because direct bed-side BWAT scoring was conducted in an

unblinded clinical setting, the potential for observer expectancy bias is acknowledged as a methodological limitation.

Harms & Adverse Event Protocol

Standardized monitoring for adverse device reactions, localized allergic contact dermatitis, excessive burning, or secondary infection spread was executed at every daily dressing change.

Statistical Methods & Missing Data Handling

Non-parametric variables and inter-group comparisons across time intervals (Baseline, Day 14 and Day 28) were analyzed using the Wilcoxon Signed-Rank Test / Mann-Whitney U Test where applicable. A two-tailed $p < 0.05$ was considered statistically significant. Analysis was conducted on a complete-case protocol adhering to per-protocol parameters after accounting for loss to follow-up. Mann-Whitney U analysis was performed on change-from-baseline scores (Δ Day 0–Day X), where higher rank values indicate greater clinical reduction in score and superior wound healing.

IV. RESULTS

Participant Flow

Assessed for Eligibility: N = 50

Excluded: N = 5 (did not meet inclusion criteria or declined).

Drop out- N=5 (due to no follow-up-unknown reasons)

Randomized (N = 45):

➤ Allocated to Group A (*Gunavati varti*): n = 22

- Received allocated intervention: n = 22
- Lost to follow-up (Day 10–18): n = 2
- Completed study & analyzed: n = 20

➤ Allocated to Group B (*Jatyadi taila*): n = 23

- Received allocated intervention: n = 23
- Lost to follow-up (Day 7–14): n = 3
- Completed study & analysed: n = 20

Baseline Data

A total of 40 completed participants (20 in Group A and 20 in Group B) were evaluated for baseline homogeneity. In both cohorts, participants aged 51–60 years predominated (Group A: 50.0%, Group B:

40.0%), and the difference in mean age was not statistically significant ($t = 1.21$, $p > 0.05$).

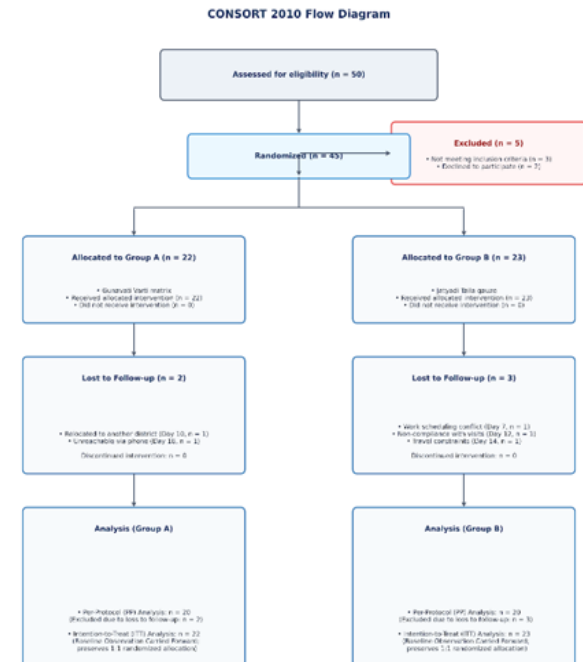


Figure I- CONSORT Flow chart

Males represented 60.0% of Group A (n = 12) and 65.0% of Group B (n = 13), showing no significant difference ($p > 0.05$). The etiology of chronic ulcers was evenly balanced across groups without statistically significant differences ($p = 0.345$), comprising venous ulcers (n = 14, 35.0), diabetic ulcers (n = 11, 27.5%), chronic traumatic wounds (n = 12, 30.0%), and arterial wounds (n = 3, 7.5%). Ulcer duration ranged from 7 days to over 5 years, with the majority falling between 1 and 2 years (37.5%), showing comparable distribution between cohorts ($p = 0.362$). Baseline wound severity measured via the Total BWAT score was comparable between Group A and Group B with no significant difference ($t = 1.53$, $p = 0.134$), confirming adequate baseline randomization. (Refer to table-VI)

Numbers Analysed

Forty participants (n = 20 in Group A; n = 20 in Group B) who completed the full 28-day evaluation protocol were included in the primary and secondary statistical syntheses.

Outcomes & Estimation

Pre-Treatment Baseline Homogeneity of Clinical Parameters:

Prior to the initiation of trial interventions, baseline evaluations were conducted across all 12 individual Bates-Jensen Wound Assessment Tool (BWAT) sub-scores, total BWAT score, and subjective symptom parameters (Pain VAS, Itching, and Odour). Between-group analysis using the Mann-Whitney U test confirmed that there were no statistically significant differences ($p > 0.05$) between Group A (*Gunavati Varti*) and Group B (*Jatyadi Taila*) for any clinical parameter at Day 0. Both cohorts presented with comparable baseline wound severity, tissue chronicity, and subjective complaints, verifying that randomization successfully established uniform baseline conditions prior to active treatment.

Note for Granulation Tissue:

All enrolled chronic ulcers presented with completely absent/ ungranulated beds (maximum baseline score of 5.0) prior to treatment, meaning both groups started at an identical pathological baseline.

Primary & Objective Wound Parameters (Inter-Group Analysis):

Inter-group analysis revealed that the change in Total BWAT score was highly significant in favor of Group A at both Day 14 (mean ranks 29.75 vs. 11.25; $p < 0.0001$) and Day 28 (mean ranks 29.85 vs. 11.15; $p < 0.0001$). Among the individual sub-scores, Granulation Tissue, Epithelialization, and Necrotic Slough Type maintained statistically significant superiority throughout the intervention and follow-up periods. Refer Table: II

Ulcer Undermining demonstrated statistically significant resolution during the active wick phase at Day 14 (mean rank 25.55 vs. 15.45, $p = 0.006$), while leveling to a non-significant difference at Day 28 follow-up ($p = 0.176$).

Ulcer Size, Ulcer Depth, Ulcer Edge, Peripheral Induration, and Surrounding Skin Color were comparable between groups at Day 14 ($p > 0.05$) but demonstrated statistically significant structural improvement in Group A over Group B by Day 28 (Table II).

Necrotic Slough Amount showed marked reduction in both arms with greater improvement in Group A, but between-group difference remained borderline non-

significant on two-tailed testing (Day 14: $p = 0.056$; Day 28: $p = 0.055$).

Equipotent Parameters (Non-Significant Between-Group Differences)

- Exudate Amount & Type: Resolved similarly across groups by Day 28 (Amount: $p = 0.171$; Type: $p = 0.232$).
- Necrotic Slough Amount: Reductions were clinically evident in both cohorts, with between-group analysis yielding two-tailed $p = 0.056$ at Day 14 and $p = 0.055$ at Day 28.
- Periwound Oedema: Decreased in both groups by Day 28 ($p = 0.079$).
- Pain (VAS): Reduced consistently from baseline with no inter-group difference at Day 14 ($p = 0.322$) or Day 28 ($p = 0.232$).
- Pruritus & Malodor: Normalized across both groups by Day 28 (Itching: $p = 0.114$; Odor: $p = 0.088$).

The improvement in the parameters of study using from day 0 to day 14 is graphically depicted in FIGURE: II and improvement in the same parameters from day 0 to day 28 is graphically depicted in FIGURE: III.

Note: for Odour at Day 28: Both groups achieved resolution of clinical malodor from baseline (Group A mean score 0.05, Group B mean score 0.30; $p = 0.176$ between groups), reflecting negligible residual odor scores across both cohorts.

Categorical Clinical Efficacy:

The study showed that the participants of group A (managed by *Gunavati varti*) showed majority in marked as well as moderate improvement category.

The participants of group B (managed by *Jatyadi taila* dipped gauze) showed moderate to mild improvement as we can see in TABLE: V.

Refer to FIGURE: IV and FIGURE: VI for pictorial improvement in two different cases of *Dushta vrana* undertaken in this study.

Harms & Adverse Reactions

No patient developed contact dermatitis, local toxicity, foreign-body granulomatous reactions, or secondary spreading infection. Both topical modalities showed clinical safety and local tolerability.

TABLE I- PRE-TREATMENT (DAY 0 / BT) BASELINE COMPARISON OF ALL CLINICAL PARAMETERS

Assessment Parameter	Group A Mean $\pm$ SD (<i>Gunavati Varti</i>)	Group B Mean $\pm$ SD (<i>Jatyadi Taila</i>)	Z Value	p-value	Inference
Total BWAT Score	44.40 $\pm$ 5.21	46.85 $\pm$ 4.88	-2.529	0.057	Comparable (N.S.)
Ulcer Size	3.00 $\pm$ 0.00	3.45 $\pm$ 0.51	-0.393	0.694	Comparable (N.S.)
Ulcer Depth	3.25 $\pm$ 0.44	3.55 $\pm$ 0.60	-1.352	0.176	Comparable (N.S.)
Ulcer Edge	3.75 $\pm$ 0.55	3.80 $\pm$ 0.41	-0.154	0.878	Comparable (N.S.)
Ulcer Undermining	3.00 $\pm$ 0.00	2.70 $\pm$ 0.66	-1.623	0.104	Comparable (N.S.)
Necrotic Tissue Type	3.25 $\pm$ 0.44	3.45 $\pm$ 0.51	-0.811	0.417	Comparable (N.S.)
Necrotic Tissue Amount	3.20 $\pm$ 0.41	3.65 $\pm$ 0.49	-0.649	0.516	Comparable (N.S.)
Exudate Type	2.95 $\pm$ 0.22	3.35 $\pm$ 0.49	-0.811	0.417	Comparable (N.S.)
Exudate Amount	2.80 $\pm$ 0.41	2.90 $\pm$ 0.31	-0.662	0.508	Comparable (N.S.)
Peri wound Skin Color	3.45 $\pm$ 0.51	3.75 $\pm$ 0.44	0.000	1.000	Comparable (N.S.)
Peripheral Edema	3.05 $\pm$ 0.22	3.50 $\pm$ 0.51	-0.270	0.787	Comparable (N.S.)
Peripheral Induration	3.15 $\pm$ 0.37	3.20 $\pm$ 0.41	-1.163	0.245	Comparable (N.S.)
Granulation Tissue	5.00 $\pm$ 0.00	5.00 $\pm$ 0.00	4.273	0.00001	Comparable (Constant)
Epithelialization	4.80 $\pm$ 0.41	4.90 $\pm$ 0.31	-1.920	0.055	Comparable (N.S.)
Pain (VAS Score)	4.00 $\pm$ 0.79	5.10 $\pm$ 0.85	-0.054	0.957	Comparable (N.S.)
Itching Score	1.45 $\pm$ 0.51	1.10 $\pm$ 0.72	0.202	0.840	Comparable (N.S.)
Ulcer Odour Score	0.60 $\pm$ 0.50	0.60 $\pm$ 0.50	-0.270	0.787	Comparable (N.S.)

TABLE II- PARAMETERS DEMONSTRATING STATISTICALLY SIGNIFICANT DIFFERENCES BETWEEN GROUPS.

Parameter	Interval	Group A Mean Rank	Group B Mean Rank	Mann-Whitney U	Two tailed p-value	Significance
Total BWAT Score	Post-Tx (Day 14) Follow-Up (Day 28)	29.75	11.25	15.0	<0.0001	Highly Significant
		29.85	11.15	13.0	<0.00001	Highly Significant
Granulation Tissue	Post-Tx (Day 14) Follow-Up (Day 28)	27.60	13.40	58.0	<0.0001	Highly Significant
		29.68	11.33	16.5	<0.0001	Highly Significant
Epithelialization	Post-Tx (Day 14) Follow-Up (Day 28)	25.83	15.17	93.5	0.0040	Significant
		29.03	11.98	29.5	<0.0001	Highly Significant
Necrotic Slough Type	Post-Tx (Day 14) Follow-Up (Day 28)	24.28	16.73	124.5	0.0410	Significant
		25.08	15.93	108.5	0.0130	Significant
Undermining	Post-Tx (Day 14)	25.55	15.45	99.0	0.0060	Significant

TABLE: III- PARAMETERS NON-SIGNIFICANT AT DAY 14 THAT ACHIEVED SIGNIFICANCE AT FOLLOW-UP (DAY 28)

Parameter	Interval	Group A Mean Rank	Group B Mean Rank	Mann- Whitney U	Two tailed p-value	Significance
Ulcer Size	Post-Tx (Day 14)	22.50	18.75	165.00	0.3440	Non-Significant
	Follow-Up (Day 28)	24.68	16.33	116.5	0.0240	Significant
Ulcer Depth	Post-Tx (Day 14)	21.70	19.30	176.00	0.5160	Non-Significant
	Follow-Up (Day 28)	24.98	16.03	110.5	0.0150	Significant
Ulcer Edge	Post-Tx (Day 14)	22.65	18.35	157.00	0.2450	Non-Significant
	Follow-Up (Day 28)	25.70	15.30	96.00	0.0050	Significant
Peripheral Induration	Post-Tx (Day 14)	23.40	17.60	142.00	0.1170	Non-Significant
	Follow-Up (Day 28)	26.55	14.45	79.00	0.0010	Highly Significant
Surrounding Skin Color	Post-Tx (Day 14)	22.60	18.40	158.00	0.2560	Non-Significant
	Follow-Up (Day 28)	25.48	16.53	120.5	0.0310	Significant

TABLE IV- QUIPOTENT & BORDERLINE PARAMETERS BETWEEN GROUPS (NON-SIGNIFICANT ACROSS ALL INTERVALS)

Parameter	Interval	Group A Mean Rank	Group B Mean Rank	Mann- Whitney U	Two tailed p-value	Significance
Necrotic Slough Amount	Post-Tx (Day 14)	24.03	16.98	129.5	0.0560	Non-Significant
	Follow-Up (Day 28)	24.05	16.95	129.0	0.0550	Non-Significant
Undermining	Follow-Up (Day 28)	23.00	18.00	150.0	0.1760	Not Significant
Exudate Amount	Post-Tx (Day 14)	21.70	19.30	176.0	0.5160	Non-Significant
	Follow-Up (Day 28)	22.25	18.75	165.0	0.3440	Non-Significant
Exudate Type	Post-Tx (Day 14)	21.20 18.70	19.80	186.0	0.7050	Non-Significant
	Follow-Up (Day 28)		20.30	164.0	0.4650	Non-Significant
Peripheral Edema	Post-Tx (Day 14)	20.83	20.28	193.5	0.8610	Non-Significant
	Follow-Up (Day 28)	23.10	17.90	148.0	0.1600	Non-Significant
Pain (VAS)	Post-Tx (Day 14)	19.65	21.25	183.0	0.6460	Non-Significant
	Follow-Up (Day 28)	21.85	19.15	173.0	0.4650	Non-Significant
Itching	Post-Tx (Day 14)	22.18	18.83	166.5	0.3650	Non-Significant
	Follow-Up (Day 28)	22.73	18.28	155.5	0.2290	Non-Significant
Ulcer Odour	Post-Tx (Day 14)	22.50	18.50	160.0	0.2790	Non-Significant
	Follow-Up (Day 28)	23.00	18.00	150.0	0.1760	Non-Significant

TABLE: V- Showing Categorical Clinical Efficacy (Fisher's Exact test)

Overall Response Category	Group A (<i>Gunavati Varti</i>) [n=20]	Group B (<i>Jatyadi Taila</i>) [n=20]
Marked Improvement ($\geq 75\%$ reduction)	4 (20.0%)	1 (5.0%)
Moderate Improvement (50% to 74.9% reduction)	12 (60.0%)	4 (20.0%)
Mild Improvement (25% to 49.9% reduction)	3 (15.0%)	9 (45.0%)
No Improvement ($< 25\%$ reduction)	1 (5.0%)	6 (30.0%)

TABLE VI- Baseline Demographic and Clinical Characteristics of Participants (N = 40)

Baseline Characteristic	Group A (Gunavati Varti) [n = 20]	Group B (Jatyadi Taila) [n = 20]	Total Cohort [N = 40]	Test Statistic	p-value	Inference
Age (Years)						
≤ 40 years	2 (10.0%)	5 (25.0%)	7 (17.5%)	t = 1.21	> 0.05	Comparable (N.S.)
41–50 years	8 (40.0%)	7 (35.0%)	15 (37.5%)			
51–60 years	10 (50.0%)	8 (40.0%)	18 (45.0%)			
Gender						
Male	12 (60.0%)	13 (65.0%)	25 (62.5%)	$\chi^2 = 0.10$	> 0.05	Comparable (N.S.)
Female	8 (40.0%)	7 (35.0%)	15 (37.5%)			
Ulcer Etiology / Type						
Venous Ulcer	6 (30.0%)	8 (40.0%)	14 (35.0%)	$\chi^2 = 3.32$	0.345	Comparable (N.S.)
Diabetic Ulcer (HbA1c < 8.0)	6 (30.0%)	5 (25.0%)	11 (27.5%)			
Traumatic Ulcer	5 (25.0%)	7 (35.0%)	12 (30.0%)			
Arterial Ulcer	3 (15.0%)	0 (0.0%)	3 (7.5%)			
Ulcer Chronicity / Duration						
7 days to 1 year	7 (35.0%)	5 (25.0%)	12 (30.0%)	$\chi^2 = 3.20$	0.362	Comparable (N.S.)
1 to 2 years	5 (25.0%)	10 (50.0%)	15 (37.5%)			
3 to 5 years	5 (25.0%)	4 (20.0%)	9 (22.5%)			
> 5 years	3 (15.0%)	1 (5.0%)	4 (10.0%)			
Baseline BWAT Score (Mean ± SD)	44.40 ± 5.21	46.85 ± 4.88	45.63 ± 5.12	t = 1.53	0.134	Co

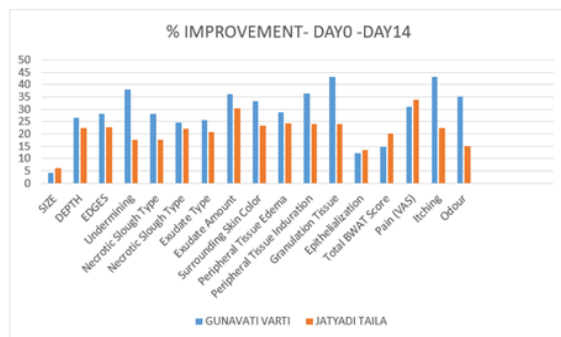


Figure II- Improvement of parameter from day-0 to day-14 between different groups

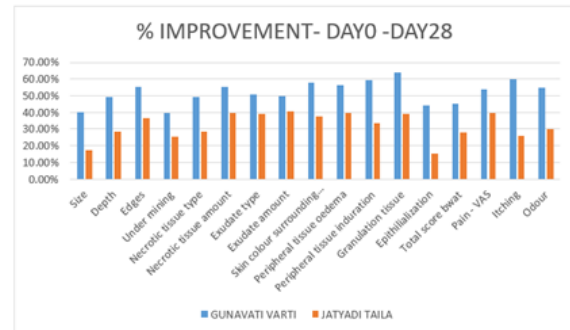


Figure III- Improvement of parameter from day-0 to day-28 between different groups



Figure IV- Improvement of Trophic Ulcer in a patient from day-0 to day-28



Figure V- Improvement of a diabetic ulcer in a patient from day-0 to day-28

V. DISCUSSION

Key Findings & Mechanistic Synthesis

This trial establishes that *Gunavati varti* is therapeutically superior to standard *Jatyadi taila* gauze in debriding necrotic cavities, clearing wound undermining, and accelerating healthy granulation in *Dushta vrana*.

The pharmacological actions reflect the synergistic properties of its ingredients:

➤ Mechanical & Rheological Matrix:

Modifying the classical formula with 5 parts *Tila Taila* and 4 parts *Sikthaka* acts as a viscoelastic plasticizer, allowing the wick to mold to irregular deep tracts and provide prolonged drug release.

➤ Debridement & Cavity Resolution

(*Vrana Shodhana*): *Sarjarasa* (*Ushna Guna*), *Kampillaka* (*Teekshna-Katu*), and *Giri-Sindura* (*Tikta-Rooksha*) break down non-viable slough, halt tissue putrefaction (*Putihara*), and eliminate overhanging margins.

➤ Granulation & Re-Epithelialization

(*Vrana Ropana*): *Ghritha* (*Madhura, Snigdha*) and *Vibhitaki* (*Kashaya*) stimulate tissue matrix consolidation (*Mamsa Dhatu Vardhana*), while *Guggulu* clears microcirculatory obstruction (*Sira-rodha*) to soften indurated margins and accelerate wound closure (*Sankochana*).

Toxicological Rationale and Local Safety of Sindura (Red Lead Oxide):

Classical *Gunavati Varti* utilizes *Sindura* (red lead oxide) processed with mineral and vegetable binders (*Sarja Rasa, Sikthaka, and Taila*). When blended into a lipophilic matrix of *Tila Taila* and unbleached beeswax (*Sikthaka*), lead oxide forms insoluble fatty acid soaps (lead oleate/plumbous esters) that remain localized on the ulcer surface, facilitating protein coagulation and necrotic slough liquefaction without systemic transmucosal or systemic dermal absorption. Throughout the 14-day active application period and subsequent follow-up through Day 28, patients were assessed daily for localized dermatitis, ulcer bed contact hypersensitivity, or excessive burning sensation, as well as systemic clinical indicators of heavy metal burden (including peripheral neuropathy, gastrointestinal colic, fatigue, or gingival Burtonian blue lines).

No patient exhibited local hypersensitivity, mucosal pigmentation, systemic toxicity, or device-related adverse reactions during the trial.

Limitations & Risk of Bias

Sample Size & Setting: Single-centre cohort (n=40 completers), which limits generalization across broader multimorbid populations.

Risk of Observer Bias: Due to unmistakable physical differences between the solid *Gunavati Varti* matrix and fluid *Jatyadi Taila* gauze, blinding the bedside investigators was unachievable. Although BWAT provides operationalized ordinal scales and wound dimensions were measured with metric probes, scoring of tissue characteristics (such as granulation quality, slough coverage, and edge appearance) retains subjective elements. The lack of an independent, masked photographic endpoint review panel introduces a potential risk of detection bias. Future trials should implement independent blinded evaluation of blinded, high-resolution serial wound

photographs to eliminate practitioner scoring subjectivity.

Generalizability & Clinical Interpretation

Varti Kalpana is an effective local delivery approach for cavity-forming and undermining chronic wounds, providing structural debridement where surface liquid dressings have physical limitations.

OTHER INFORMATION

Registration: Clinical trial registration number: CTRI/2025/06/088303. (Prospective study)

Protocol Access: Full manufacturing monographs and clinical trial protocols are available from the institutional repository.

Funding & Support: CCRAS PGSTAR-03 and Institutional departmental support; no commercial conflicts of interest.

Competing Interests: Authors declare no competing financial or non-financial interests.

Data Availability: De-identified participant datasets are accessible for meta-analyses upon institutional review.

Ethics Approval: Obtained from the Institutional Ethics Committee prior to study commencement; written informed consent obtained from all participants.

IEC Certificate number- IEC/MIAMS/ST/01/24. Issued on 20/05/2024.

Photo Publication Consent- Taken from both the participants. Will be shared on request.

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