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CLINICAL EVALUATION OF WOUND HEALING ACTIVITY OF ARKA PATRA EXTRACTED OINTMENT IN AGANTUJA VRANA - A RANDOMIZED CONTROLLED CLINICAL TRIAL

Dr. Harishankar P V*[1], Dr. Laxmikant S D[2], Dr. Ajit Chandrashekhar Lingayat[3], Dr Athira Mohan K[4]

[1]Assistant Professor, Department of Shalya Tantra, KLE Ayurveda Medical College and Hospital, Chikodi, Karnataka, India. 628harishankarpv@gmail.com
[2]Professor, Department of Shalya Tantra, KLE's Shri BMK Ayurveda Mahavidyalaya Belagavi, Karnataka, India. shalyalsd@gmail.com
ORCID: https://orcid.org/0009-0006-0516-7960
[3]Associate Professor, Department of Dravyaguna, Kaher Shri B M K Ayurved Mahavidyalaya Belagavi, Karnataka, India. ajitlingayat26@gmail.com
[4]Assistant Professor, Department of Rasa Sastra Evum Bhaishajya Kalpana, KLE Ayurveda Medical College and Hospital, Chikodi, Karnataka, India. drkadathanadan5588@gmail.com
Corresponding Author: Dr. Laxmikant S D
Professor, Department of Shalya Tantra, KLE's Shri BMK Ayurveda Mahavidyalaya, Belagavi
ORCID: https://orcid.org/0009-0006-0516-7960 | Email: shalyalsd@gmail.com

ABSTRACT

This case study examines the clinical course, therapeutic interventions, and structured wound-healing assessments documented in two treatment groups participating in an Ayurvedic wound-care programme. The primary intervention evaluated was a topical ointment prepared from Arka Patra (Calotropis procera leaves), while Jatyadi ointment served as the comparator. The clinical protocol involved routine wound cleansing, topical application of the respective ointments, regular dressing, and systematic assessment of wound-healing parameters over a 14-day observation period. Particular attention was given to changes in wound size, wound margins, surface characteristics, colour, granulation tissue formation, and epithelialization as indicators of healing progression. The analysis draws on documented clinical observations and statistical findings to describe the treatment approach, patient characteristics, wound assessment procedures, observed outcomes, and limitations of the available evidence [1–3].

The statistical records comprise 110 participants, equally distributed between Group A (n = 55) and Group B (n = 55). The documented observations provide a basis for examining wound-healing patterns and comparing the clinical responses recorded during treatment. However, the available information consists predominantly of group-level findings rather than a complete longitudinal account of an individual patient. Consequently, this report is presented as a structured clinical case-study analysis rather than an individual case report conforming to CARE guidelines, which require a clearly documented patient history, clinical timeline, investigations, treatment details, follow-up, and relevant consent [4]. The findings contribute to the clinical documentation of traditional topical wound-care interventions while highlighting the importance of standardized assessment, careful interpretation of treatment outcomes, and further well-designed clinical investigations to establish the effectiveness and safety of Arka Patra ointment in the management of Agantuja Vrana.

KEYWORDS: Arka Patra; Calotropis procera; Agantuja Vrana; Jatyadi ointment; Ayurvedic wound management; wound healing; topical formulation; clinical case study.

1. Clinical background

A wound is a disruption of normal tissue continuity. Its evolution depends on tissue injury, vascular supply, microbial burden, nutrition, local moisture balance, systemic illness, and the quality of wound management. Healing moves through interacting phases of hemostasis, inflammation, proliferation and remodeling; an orderly reduction in wound burden is therefore a useful observation, but the full biological process cannot be established from a single visible finding [5–8].

In classical Ayurvedic surgical literature, Vrana is described with an emphasis on local examination, cleansing, protection and tissue restoration. Agantuja Vrana refers to a wound originating from an external cause. The present comparison uses that category as the study diagnosis, not as a substitute for conventional evaluation of wound depth, contamination, neurovascular integrity or infection [9,10].

Arka is identified in the study materials as Calotropis procera. Traditionally reported properties of this plant motivate formulation research, but its latex and other constituents may be biologically active or irritating. A standardized finished formulation must not be assumed safe or effective merely because the raw botanical is used in traditional medicine [11–13].

2. Setting, participants and study design

The institutional synopsis describes a randomized controlled clinical trial examining wound-healing activity of Arka Patra extracted ointment against Jatyadi ointment. Group A was the trial arm and Group B was the standard-treatment arm; 55 participants appear in each group in the final statistical compilation.

The planned treatment duration was 14 days, with assessments at enrollment, day 7 and day 14. The protocol anticipated cleaning and dressing in both groups. The available documents describe computerized simple randomization, but do not provide an auditable allocation sequence, concealment records, blinding documentation or a trial registration identifier. These omissions limit independently verifiable claims about trial conduct [14].

The protocol excludes a range of potentially confounding or high-risk wound conditions, including uncontrolled diabetes, specified infectious diseases, varicose or malignant ulcers, and wounds intended for primary-intention healing. Those restrictions should be kept in mind when interpreting whether results could apply to other wound populations.

3. Clinical presentation and entry assessment

Enrolled cases were described in the clinical documents by wound dimensions, margin and surface, colour, granulation tissue and epithelialization. These domains address different visible aspects of healing: reduction in size, healthy wound-edge progression, wound-bed appearance, granulation, and the development of new epithelial cover [15].

The aggregate sample contained 74 males and 36 females. The groups comprised 39 males and 16 females in Group A, and 35 males and 20 females in Group B. The mean age was 40.36 years (standard deviation 11.95) in Group A and 44.56 years (standard deviation 14.43) in Group B. The supplied age comparison had a reported two-sided p value of 0.099; sex comparison p=0.416. Neither comparison established a statistically significant demographic difference at a 0.05 threshold.

In the demographic worksheet, 100 participants were married and 10 unmarried. Both groups had 18 vegetarians and 37 with mixed diets. Such details describe the enrolled cohort but cannot, by themselves, establish prognostic equivalence.

Table 1. Age distribution recorded in the statistical report

Age	Group A	Group B	Total	Total	
18 to 20	2	1	3	3	
%	3.64	1.82	2.73	2.73	
21 to 30	12	8	20	20	
%	21.82	14.55	18.18	18.18	
31 to 40	12	16	28	28	
%	21.82	29.09	25.45	25.45	
41 to 50	20	13	33	33	
%	36.36	23.64	30.00	30.00	
51 to 60	6	7	13	13	
%	10.91	12.73	11.82	11.82	
61 to 70	3	7	10	10	
%	5.45	12.73	9.09	9.09	
71 to 75	0	3	3	3	
%	0.00	5.45	2.73	2.73	

4. Study timeline and course of observation

The clinical observation schedule documented the following sequence. These are protocol-defined study milestones, not reconstructed dates for a particular patient.

Visit	Planned action	Recorded domains
Baseline	Eligibility; wound cleaning and dressing; first application	Size, margin/surface, colour, granulation, epithelialization
Day 7	Continued treatment and clinical review	Repeated grades for the five wound characteristics
Day 14	End-of-treatment clinical assessment	Repeated grades and reported effect categories

No reliable description of a longer-term follow-up, recurrence surveillance, independently adjudicated infection, complete epithelial closure after day 14, or quality-of-life outcomes was available in the available statistical summary. Therefore, this report discusses short-term wound assessment only.

Assessment scales and grade coding were recorded as ordinal outcome measures. A lower grade should be interpreted according to the original coding document; a reported percentage improvement in a composite score is not equivalent to a percentage of patients achieving full clinical healing.

5. Investigational product and preparation context

The synopsis specifies an ointment derived from an ethanol extract of Arka Patra mixed with a pharmacopoeial ointment base. The available photographs illustrate the botanical source and preparation activities. They are process documentation, not chemical identity testing or batch-release certificates. The exact extraction yield, constituent profile, batch concentration, stability, sterility and microbial quality cannot be established from photographs alone [11–13].



Figure. Original photograph of Arka plant at the collection location (photograph supplied with study materials).

Botanical identity should be confirmed by an authenticated voucher specimen and documented extraction records before the formulation is described as chemically standardized. Calotropis-containing materials require attention to irritation, sensitization and possible exposure to latex during handling [11–13].

6. Original product photographs



Figure. Original photograph showing ointment-like semisolid preparation.

7. Additional preparation documentation

Figure. Original preparation photograph showing the finished-appearance semisolid material in a container.



Photographs may demonstrate the practical sequence of preparation, but they cannot replace written standard operating procedures, quantitative formulation composition, extract assay, contamination testing, or batch reconciliation.

8. Clinical evaluation: wound size

At baseline all 55 members of each group were recorded in wound-size grade 3. By day 7, Group A had 20 patients in grade 1 and 35 in grade 2, whereas Group B had 8 in grade 1, 41 in grade 2 and 6 remaining in grade 3. The statistical report describes improvement through day 14, with 34 Group A participants (61.82%) in its "excellent >75% effect" category and none in that category in Group B.

Table 2. Wound-size effect classification (source values)

% Effect on Size	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	21	21
%	0.00	38.18	19.09
Better (50 to 75%)	21	34	55
%	38.18	61.82	50.00
Excellent (> 75%)	34	0	34
%	61.82	0.00	30.91
Total	55	55	110

The grades are ordinal, and the provided effect labels are analysis-derived categories. They do not demonstrate a measured percentage wound-area reduction for any single patient. Nor is grade zero necessarily equivalent to documented complete closure without the original item-level scoring specification.

9. Clinical evaluation: wound margin and surface

Changes in the wound margin and surface were also tabulated for baseline, day 7 and day 14. At baseline, 54 participants in Group A and all 55 in Group B were recorded in grade 3; one Group A participant was in grade 2. On day 7, Group A contained 25 grade-1 and 30 grade-2 records compared with 9 grade-1, 42 grade-2 and 4 grade-3 observations in Group B.

Table 3. Margin/surface effect classification (source values)

% Effect on Margin and Surface	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	17	17
%	0.00	30.91	15.45

Better (50 to 75%)	34	38	72
%	61.82	69.09	65.45
Excellent (> 75%)	21	0	21
%	38.18	0.00	19.09
Total	55	55	110

The study report records 21 (38.18%) Group A participants classified as "excellent >75% effect" for margin/surface versus none in Group B. These data indicate a favorable short-term distribution in the trial arm; the underlying wound images and subject-level score calculations would be needed for an independent analysis.

10. Clinical evaluation: wound colour

Wound colour, although clinically informative, is affected by granulation, fibrin, exudate, tissue viability, illumination and observer judgment. The cohort began with all participants graded 3 for this variable. At day 7, 24 Group A participants were graded 1 and 31 graded 2, compared with 11, 38 and 6 in grades 1, 2 and 3 respectively in Group B [15].

Table 4. Wound-colour effect classification (source values)

% Effect on Colour	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	18	18
%	0.00	32.73	16.36
Better (50 to 75%)	25	37	62
%	45.45	67.27	56.36
Excellent (> 75%)	30	0	30
%	54.55	0.00	27.27
Total	55	55	110

Thirty participants in Group A (54.55%) were classified in the excellent effect category for colour; no Group B patients were assigned that category. The assessment is susceptible to observer differences unless photo conditions, color references and blinded rating are standardized.

11. Clinical evaluation: granulation tissue

Granulation tissue is a visible sign of tissue repair, but its presence is not a complete healing endpoint. On day 7 the recorded distribution for Group A was grade 0 in 1 participant, grade 1 in 33 and grade 2 in 21; Group B had 8 participants in grade 1, 40 in grade 2 and 7 in grade 3 [5–8].

Table 5. Granulation-tissue effect classification (source values)

% Effect on Granulation tissue	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	24	24
%	0.00	43.64	21.82
Better (50 to 75%)	23	31	54
%	41.82	56.36	49.09
Excellent (> 75%)	32	0	32
%	58.18	0.00	29.09
Total	55	55	110

Thirty-two Group A participants (58.18%) were reported in the excellent category for the granulation parameter versus none in Group B. The distinct clinical meanings of granulation quantity, tissue quality and proportion of healthy wound bed should not be collapsed into an unsupported mechanistic conclusion.

12. Clinical evaluation: epithelialization

Epithelialization is an important component of wound closure. On day 7, Group A was recorded as 1 participant in grade 0, 26 in grade 1 and 28 in grade 2; Group B had 6 in grade 1, 42 in grade 2 and 7 in grade 3. The day-14 effect table categorized 25 Group A patients (45.45%) as excellent and no Group B patients as excellent.

Table 6. Epithelialization effect classification (source values)

% Effect on Epithelialization	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	25	25
%	0.00	45.45	22.73

Better (50 to 75%)	30	30	60
%	54.55	54.55	54.55
Excellent (> 75%)	25	0	25
%	45.45	0.00	22.73
Total	55	55	110

Because a complete closure definition, time-to-healing analysis, independent assessment and sustained follow-up are not documented in the aggregate material, the above distribution supports only a short-term comparison of the recorded epithelialization grades.

13. Summary of group outcomes

The reported statistical analysis used Friedman tests for repeated ordinal observations within arms and Mann–Whitney-type group comparisons in the report. Across the wound characteristics, the analyst described improvement in both treatment groups and more favorable day-7/day-14 rank distributions for Group A. Several comparisons were reported at $p<0.05$.

However, a p value alone does not quantify clinical importance. The available compilation does not independently establish protocol adherence, allocation concealment, measurement reliability, a prespecified primary outcome, intention-to-treat handling, confidence intervals or adverse-event rates. The observed differences should consequently be reported as the statistical report's findings, not as definitive proof that one preparation is superior in every type of wound [14–16].

For a case-study account, the most useful finding is the sequence: a defined wound-care problem; a proposed botanical topical preparation; documented comparator treatment; repeated objective/ordinal examinations; and a measurable, though methodologically constrained, difference over 14 days.

Table 7. Overall effect categories from the statistical compilation

Overall Effect	Group A	Group B	Total
Mild (< 25%)	0	0	0
%	0.00	0.00	0.00
Moderate (25 to 50%)	0	18	18
%	0.00	32.73	16.36
Better (50 to 75%)	9	37	46
%	16.36	67.27	41.82
Excellent (> 75%)	46	0	46
%	83.64	0.00	41.82
Total	55	55	110

14. Clinical interpretation and mechanisms

The findings are compatible with improvement in several visible wound parameters under the trial-arm dressing regimen. They do not establish that the plant extract itself caused the entire change: cleansing, wound coverage, starting wound condition, dressing frequency, natural healing, assessor expectation and any concurrent care may contribute [5–8,14].

Traditional Ayurvedic descriptions of Vrana management provide the clinical rationale for exploring cleansing and ropana-oriented topical medicines. The terms should be interpreted within their textual context; they do not prove antibacterial action, collagen induction, angiogenesis or direct cytokine modulation in the participants of this study [9–11].

Calotropis species can contain compounds with strong biological activity. Some reports examine their pharmacology in preclinical systems, but species, plant part, extraction solvent and dosage form matter. Effects of fresh latex or crude extracts must not be indiscriminately extrapolated to a controlled human ointment [11–13].

15. Safety, limitations and ethics

Skin irritation, allergy, contact reactions and unexpected infection should be actively monitored during topical use. Clinical photographs containing patients or practitioners must not be published without documented permission and adequate removal of identifying information. Only plant and product images without identifiable patients have been selected here.

The uploaded synopsis includes a record of an institutional ethics committee query and an application for human ethical clearance. These materials should not be represented as a verified final ethics approval certificate. An approval number, final determination, trial registration (if applicable), patient publication permissions, and authorship declarations need confirmation from the investigator before submission [4,14].

The case analysis has several limitations: no verified patient-level narrative suitable for an individual case report; source statistics rather than access to the complete auditable dataset; no independent examination of randomization and missing data; short 14-day observation; uncertainty about formulation standardization; and insufficient adverse-event and recurrence data. Findings are therefore preliminary and restricted to the studied clinical setting.

16. CONCLUSION AND CLINICAL LESSONS

In the documented clinical case series, Arka Patra extracted ointment was assessed alongside Jatyadi ointment in 110 participants over 14 days. The statistical report describes favorable short-term distributions of wound size, margin/surface, colour, granulation and epithelialization grades in the investigational arm. Such results justify careful further evaluation, not an unrestricted therapeutic claim.

The principal clinical lesson is that botanical wound formulations should be studied as reproducible products within documented wound-care protocols, using transparent randomization, validated assessments, safety surveillance and clinically important healing endpoints. Further work should emphasize standardized extraction, batch testing, reliable wound photography, complete healing, recurrence, and patient-reported outcomes [5–16].

Publication requirements: establish the exact author list; confirm final ethics permission, trial registration if applicable, permission to publish source images and sponsor/contributor roles. The document is intentionally designated a clinical study case analysis, not an individual-patient CARE case report [4].

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