



Comparative Wound-Healing Outcomes of Trivritadi and Jatyadi Ointments after Partial Fistulectomy for Bhagandara: A Pilot Study

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Abstract

Background: Partial fistulectomy wounds heal by secondary intention and require repeated dressing. Comparative evidence for Trivritadi and Jatyadi ointments in this setting is limited.

Objective: To compare wound-status trajectories after Trivritadi or Jatyadi ointment dressing in adults undergoing partial fistulectomy for Bhagandara.

Methods: In this randomized two-arm pilot study, 24 participants were allocated 1:1 to Trivritadi or Jatyadi ointment. Vranatal, Gandha, Varna, and Srava were graded 0-3 at baseline and on Days 7, 14, and 30, and summed (0-12; lower scores are better). Analyses included paired and Welch t-tests, ANCOVA, rank-based sensitivity tests, Friedman tests, and a participant-fixed-effects repeated-measures model with cluster-robust inference.

Results: Complete four-domain scores were available for all 24 participants. Mean Day-30 scores were 0.58 ± 0.51 with Trivritadi and 1.42 ± 0.51 with Jatyadi. The unadjusted mean difference was -0.83 points (95% CI -1.27 to -0.40; Welch $p < 0.001$). Baseline-to-Day-30 improvement was 7.25 ± 0.87 versus 6.08 ± 0.90 points (difference 1.17, 95% CI 0.42 to 1.91; $p = .004$; Hedges $g = 1.28$). The baseline-adjusted Day-30 difference was -0.95 points (95% CI -1.19 to -0.71; $p < 0.001$).

Conclusion: Both groups improved substantially. At the final scheduled assessment, Trivritadi was associated with lower composite scores and greater improvement than Jatyadi; however, the small exploratory sample, ordinal composite, floor effects and unavailable safety/feasibility variables preclude a definitive efficacy claim.

Keywords: Bhagandara, fistula-in-ano, partial fistulectomy, wound healing, Trivritadi, Jatyadi, Ayurveda, randomized pilot study

Introduction

Fistula-in-ano (Bhagandara) is a chronic anorectal condition characterised by an abnormal tract connecting the anal canal to the perianal skin. After partial fistulectomy, the open wound heals by secondary intention and may require repeated dressing changes, assessment of granulation tissue and exudate, and surveillance for infection. An ointment specifically formulated for Bhagandara may serve as a practical adjunct to postoperative wound care, but comparative clinical evidence remains limited. Jatyadi preparations have been evaluated in clean wounds and other wound settings, whereas Trivritadi has been studied less after fistulectomy. A protocol comparing these formulations has been published. The present 24-participant analysis should be interpreted as exploratory, as the sample size is too small to establish definitive comparative effectiveness or to detect uncommon harms.

The study objective was to compare longitudinal change in a four-domain wound-status composite after Trivritadi or Jatyadi ointment dressing. The final scheduled Day-30 assessment was emphasised, with Day-7 and Day-14 results presented to show the trajectory rather than selected in isolation.

Materials and Methods

Study Design and Reporting

This was a prospective, two-arm, parallel-group, randomized pilot clinical study with 1:1 allocation.

Setting and Study Period

The study was conducted at MGACHRC, Salod Wardha, Maharashtra, India, between July 2022 and October 2022. Participants were assessed postoperatively at baseline, before the first study dressing, on Day 7, Day 14, and Day 30. Dressing continued for 14 days at twice-daily frequency.

Ethics, Registration and Consent

The protocol was approved by the Institutional Ethical Committee of MGACHRC (approval number MGACHRC/IEC/May-2022/486) on 30 June 2022. Written informed consent was obtained in English, Hindi, or Marathi, as preferred by the patient.

Participants

The analytic dataset contained adults aged 27-58 years with Bhagandara who underwent partial fistulectomy. The earlier manuscript draft stated an eligibility range of 20-45 years, but nine of the analysed participants were older than 45. The approved eligibility range, screening decision and any protocol deviations must therefore be verified and reported before submission. Participants had to provide written informed consent and be able to attend scheduled assessments.

Exclusion criteria were diabetes mellitus, leprosy, chronic renal failure, Crohn's disease, ulcerative colitis, extrapulmonary tuberculosis, syphilis, previous radiotherapy, anorectal carcinoma, or another condition judged likely to materially impair wound healing.

Sample-Size Rationale

Twelve participants per group (total n=24) were selected as a conventional pilot rule of thumb when prior information is insufficient to estimate outcome variability. This choice is intended to assess logistics and obtain preliminary estimates of variance; it does not provide sufficient power for a definitive conclusion on efficacy or superiority.

Randomisation, Allocation Concealment and Blinding

The patient was assigned to groups using a computer-generated randomization table, and double blinding was implemented.

Interventions

All raw materials were obtained from an authenticated Ayurvedic pharmacy and verified by Department of Dravyaguna. Manufacturing took place in Dattatray Rasashala, MGACHRC, Salod Wardha. Finished products were packed in identical sterile containers.

Preparation of Trivritadi Ointment

The cleaned, shade-dried ingredients *Trivrit* (*Operculina turpethum*), *Danti* (*Baliospermum montanum*), *Haridra* (*Curcuma longa*), *Arka* (*Calotropis procera*), *Aguru* (*Aquilaria agallocha*), *Ashmantaka* (*Ficus rumphii*), *Vidanga* (*Embelia ribes*), *Haritaki* (*Terminalia chebula*), *Vibhitaki* (*Terminalia bellirica*), *Amalaki* (*Embolica officinalis*) and *Snuhi* (*Euphorbia neriifolia*) were powdered separately, combined in equal proportions and made into Kalka with water.

Tila Taila was used as Sneha Dravya. Kalka, Taila, and water were combined in the classical 1:4:16 proportion and heated gently with continuous stirring until Madhyama Paka Taila Siddhi was achieved, as judged by the cessation of crackling and frothing and the specified Kalka characteristics. The warm Siddha Taila was filtered through clean muslin. Sikhthaka (beeswax) was added to the lukewarm filtrate and mixed until uniform. After cooling to near room temperature, Madhu (honey) was incorporated, and the ointment was homogenised and filled into airtight containers.



Fig 1: Ingredients of Trivritadi ointment



Fig 2: Procedure of Preparation of Trivritadi ointment

Preparation of Jatyadi Ointment

The authenticated ingredients *Jati* (*Jasminum officinale*), *Nimba* (*Azadirachta indica*), *Patola* (*Trichosanthes dioica*), *Naktamala* (*Pongamia pinnata*), *Madhuka* (*Glycyrrhiza glabra*), *Kushtha* (*Saussurea lappa*), *Haridra* (*Curcuma longa*), *Daruharidra* (*Berberis aristata*), *Manjistha* (*Rubia cordifolia*), *Katuruhini* (*Picrorhiza kurroa*), *Padmaka* (*Prunus cerasoides*), *Lodhra* (*Symplocos racemosa*), *Abhaya* (*Terminalia chebula*), *Nilotpala* (*Nelumbo nucifera*) and

Sariva (*Hemidesmus indicus*) were processed into Kalka.

Kalka, Tila Taila, and water were combined in a 1:4:16 ratio and heated with continuous stirring until Taila Siddhi. The warm medicated oil was filtered and allowed to cool to a defined temperature range. Sikhthaka was incorporated to obtain the ointment consistency. Finely powdered, quality-tested Tūttha (copper sulphate) was dispersed uniformly at the validated post-heating temperature. The product was homogenised, filled and stored.



Fig 3: Ingredients of Jatyadi Ointment



Fig 4: Procedure of Preparation of Jatyadi ointment

Dressing Procedure and Concomitant Care

After cleansing with betadine solution, a sufficient quantity of coded ointment was applied to the sterile gauze, which was then placed in the wound by trained staff. Dressings were changed twice a day for 14 days. Analgesia, antibiotics, sitz

baths, irrigation, diet advice and rescue procedures were standardised and recorded. Adherence was calculated from completed prescribed dressings divided by planned dressings.



Fig 5: Case Treated By Trivritaadi Ointment



Fig 6: Case Treated By Jatyadi Ointment



Fig 7: Before and after treatment image of the post-fistulectomy wound site of patient

Outcome Measures

Feasibility outcomes were numbers screened and eligible, consent rate, recruitment rate per month, randomisation completion, treatment adherence, retention at each visit, completeness of each outcome domain, protocol deviations,

success of blinding and time required per assessment. Safety outcomes included local irritation, allergic reaction, bleeding, clinically suspected infection, need for antibiotics or re-intervention, serious adverse events, and withdrawals due to harm.

The clinical outcome was the wound-status composite: Vranatal (wound bed), Gandha (odour), Varna (granulation tissue colour), and Srava (discharge), each scored 0-3. The total ranges from 0 to 12, with lower scores indicating a healthier wound. Scores at Day 7, Day 14 and the final scheduled Day 30 assessment were analysed. Day-30 findings were emphasised in this report.

Percentage improvement was a descriptive statistic only and was calculated as $100 \times (\text{baseline total score} - \text{followup total score}) / \text{baseline total score}$.

Statistical Analysis

Analyses were conducted using the investigator-confirmed Master_Chart in Python 3 with NumPy, pandas, and SciPy. Feasibility outcomes were summarised as counts, proportions and 95% confidence intervals. All randomised participants were analysed in their assigned group, where data were available. Because the pilot was not powered for efficacy, clinical p-values were interpreted as exploratory rather than as proof of equivalence, non-inferiority, or superiority.

Within-group baseline-to-Day-14 and baseline-to-Day-30 changes were examined using paired t-tests and Wilcoxon signed-rank tests. Between-group changes were compared with a two-sided Welch independent-samples t test. Results were reported as mean change, between-group mean difference, 95% confidence interval, p value and Hedges g.

Baseline Characteristics

Table 1

Characteristic	Trivritadi (n=12)	Jatyadi (n=12)
Age, years	42.2 ± 8.7	41.5 ± 9.5
Male sex, n (%)	8 (66.7)	8 (66.7)
Baseline total, mean ± SD	7.83 ± 1.27	7.50 ± 1.31
Baseline total, median (IQR)	8.0 (7.0-9.0)	7.0 (6.8-8.2)
Wound area, cm ²	7.15 ± 1.48	6.79 ± 1.35
Antibiotic use, n (%)	6 (50.0)	5 (41.7)
Intersphincteric fistula, n (%)	4 (33.3)	4 (33.3)
Low trans-sphincteric, n (%)	5 (41.7)	5 (41.7)
High trans-sphincteric, n (%)	2 (16.7)	1 (8.3)
Subcutaneous/low anal, n (%)	1 (8.3)	2 (16.7)

Baseline age, wound area and composite score did not show marked differences (Welch $p=.859$, $p=.542$ and $p=.534$, respectively). Sex was identical between groups (Fisher $p=1.000$); antibiotic use and fistula-type distributions were also similar (Fisher $p=1.000$ and 100,000-permutation

Supportive ANCOVA models estimated Day-14 and Day-30 differences adjusted for baseline total using HC3 heteroskedasticity-robust standard errors, because baseline-adjusted analysis is generally more efficient and less vulnerable to chance baseline imbalance than percentage change.

The composite is bounded and assembled from ordinal items. Distributional shape, floor effects and residual diagnostics were therefore inspected. Mann-Whitney comparisons of change scores and within-group Wilcoxon signed-rank analyses were used as rank-based sensitivity analyses. Within each group, the four scheduled totals were assessed by Friedman tests with Kendall W. A participant-fixed-effects model with cluster-robust standard errors tested time-by-group interaction. Visit-wise and domain-wise families were adjusted by the Holm method. Individual ordinal domains were summarised by grade as counts/percentages. Statistical significance, where shown, used a two-sided alpha of 0.05, but estimation and uncertainty were emphasised.

Results

Participant Data Completeness

The study contains 12 participants assigned to Trivritadi and 12 assigned to Jatyadi. Complete composite and domain-level measurements were available at baseline, Day 7, Day 14 and Day 30 for all 24 participants.

$p=1.000$). These baseline tests are descriptive and do not prove equivalence. Ages ranged from 27 to 58 years; nine participants were older than the 20-45-year range stated in the earlier draft, requiring protocol reconciliation.

Composite Wound-Status Trajectory

Table 2

Visit	Trivritadi	Jatyadi	Mean difference (95% CI)	Welch p	M-W p
Day 0	7.83 ± 1.27	7.50 ± 1.31	0.33 (-0.76 to 1.43)	.534	.514
Day 7	5.25 ± 1.54	4.50 ± 1.31	0.75 (-0.47 to 1.97)	.214	.236
Day 14	3.25 ± 1.06	2.75 ± 1.22	0.50 (-0.46 to 1.46)	.294	.379
Day 30	0.58 ± 0.51	1.42 ± 0.51	-0.83 (-1.27 to -0.40)	<0.001	.002

At Day 30, Trivritadi had a lower mean total than Jatyadi by 0.83 points (95% CI -1.27 to -0.40; $t=-3.96$, $df=22.00$, $p<0.001$; Hedges $g=-1.56$). The rank-based comparison was concordant (Mann-Whitney $U=24.5$, $p=.002$). After Holm

adjustment across the four visits, the Day-30 results remained statistically significant (Welch $p=.003$; Mann-Whitney $p=.009$); earlier visit comparisons did not.

Within-Group and Between-Group Improvement

Table 3

Change (positive=better)	Trivritadi	Jatyadi	Difference (95% CI)	Welch p	M-W p
Baseline to Day 14	4.58 ± 0.51	4.75 ± 0.62	-0.17 (-0.65 to 0.32)	.482	.549
Baseline to Day 30	7.25 ± 0.87	6.08 ± 0.90	1.17 (0.42 to 1.91)	.004	.006

Both groups improved from baseline to Day 30 (paired t tests $p < 0.001$; Wilcoxon $p = .0019$ in each group). Mean improvement was 7.25 points with Trivritadi and 6.08 with Jatyadi; the between-group difference was 1.17 points (95% CI 0.42 to 1.91; $t = 3.24$, $df = 21.97$, $p = .004$; Hedges $g = 1.28$). Mann-Whitney sensitivity analysis was concordant ($U = 118.5$, $p = .006$; rank-biserial correlation = 0.65). Group-mean score reductions were 92.6% and 81.1%, respectively. At Day 14, between-group change was not distinguishable (difference -0.17, 95% CI -0.65 to 0.32; $p = .482$).

Baseline-Adjusted and Repeated-Measures Analyses

Baseline-adjusted ANCOVA showed no clear Day-14

difference (Trivritadi minus Jatyadi 0.24, 95% CI -0.25 to 0.73; $p = .327$). At Day 30, the adjusted difference was -0.95 points (95% CI -1.19 to -0.71; HC3 $p < 0.001$), favouring Trivritadi.

The cluster-robust participant-fixed-effects model identified an overall time-by-group interaction ($F = 4.57$, $df = 3, 23$; $p = .012$). The additional Trivritadi change relative to Jatyadi was -1.17 points at Day 30 (95% CI -2.04 to -0.29; $p = .011$; negative denotes a lower score), while the Day-14 interaction was not significant ($p = .548$). Within-group Friedman tests confirmed strong change across visits (Trivritadi $\chi^2 = 36.00$, Kendall $W = 1.00$; Jatyadi $\chi^2 = 35.31$, $W = 0.98$; both $p < 0.001$).

Individual Wound Domains and Zero Composite

Table 4

Domain	Trivritadi: Day 0 → 30	Jatyadi: Day 0 → 30	Change U	Holm p
Vranatal	2.00 ± 0.60 → 0.17 ± 0.39	1.83 ± 0.58 → 0.17 ± 0.39	82.0	1.000
Gandha	1.75 ± 0.45 → 0.08 ± 0.29	1.50 ± 0.52 → 0.33 ± 0.49	104.0	.158
Varna	1.83 ± 0.39 → 0.33 ± 0.49	1.92 ± 0.29 → 0.50 ± 0.52	75.0	1.000
Slava	2.25 ± 0.45 → 0.00 ± 0.00	2.25 ± 0.45 → 0.42 ± 0.51	94.5	.480

Each domain improved within both groups after Holm adjustment (all adjusted Wilcoxon $p \leq 0.006$). No individual domain showed a Holm-adjusted between-group change difference; the lowest unadjusted value was for Gandha ($p = .039$; adjusted $p = .158$). At Day 30, all four grades were zero in 5/12 (41.7%) Trivritadi participants and 0/12 Jatyadi participants (risk difference 41.7 percentage points, 95% CI 8.7 to 68.0; Fisher $p = .037$). This threshold analysis was exploratory.

Discussion

Principal Findings

Both ointment groups showed pronounced improvement across the 30-day observation period. Scores and changes were similar through Day 14. By Day 30, the Trivritadi group had a lower composite score and a greater baseline-to-follow-up improvement than the Jatyadi group. The finding was consistent across unadjusted Welch testing, Mann-Whitney sensitivity analysis, baseline-adjusted ANCOVA and the repeated-measures interaction model. Thus, the conclusion is driven by the between-group trajectory and final assessment, not by significant paired tests within each arm.

The composite decrease, based on group means, was 92.6% for Trivritadi and 81.1% for Jatyadi. Percentage reduction is descriptive; the more interpretable comparative result is the 1.17-point difference in mean improvement (95% CI 0.42 to 1.91). Five Trivritadi participants and no Jatyadi participants reached a total score of zero at Day 30, but this threshold analysis was exploratory and based on very small counts.

Interpretation of The Time Course

The absence of a clear Day-14 difference and emergence of separation at Day 30 suggest a time-dependent pattern. This

may reflect delayed differences in granulation, exudate resolution or epithelial maturation, but the study did not measure mechanisms. Because dressings were reportedly administered for 14 days, the later separation should be replicated and interpreted alongside co-interventions, wound area and time to complete epithelialisation.

Relation to Existing Evidence

Prior research supports the feasibility of evaluating Ayurvedic wound dressings, including Jatyadi-based preparations, in clean wounds. Those data are indirect for post-partial fistulectomy wounds. The present results provide preliminary comparative estimates for planning and replication but do not replace the adequately powered trial described in the published protocol.

Strengths and Limitations

Strengths included complete, repeated observations; internally reconciled composite totals; a defined four-domain rubric; agreement between parametric and rank-based analyses; baseline adjustment; and explicit control of multiplicity for visit-wise and domain-wise families. Important limitations were the sample of only 12 participants per arm, an unvalidated bounded composite assembled from ordinal grades, marked floor effects at Day 30, very regular score trajectories, the unresolved discrepancy between the earlier 20-45-year eligibility statement and nine participants older than 45, and the absence of adverse-event, adherence, blinding, rescue-treatment and followup wound-area variables from the analytic file. The small sample produces unstable effect-size estimates and limited protection against confounding by co-interventions. The findings should therefore be considered exploratory rather than definitive.

evidence of superiority.

Implications for A Definitive Trial

A definitive trial should prespecify the primary time point, clinically meaningful difference, and estimand; capture wound area and time to epithelialisation; and use a repeated-measures model suited to bounded or ordinal outcomes.

Conclusion

In this 24-participant randomized exploratory study, both Trivritadi and Jatyadi ointments were associated with substantial improvement after partial fistulectomy. At Day 30, Trivritadi showed lower wound-status scores and greater

improvement than Jatyadi across complementary analyses, whereas no clear between-group difference was present at Day 14. The result supports further investigation but is not sufficient for a definitive efficacy or safety claim.

Declarations

Ethics Approval and Consent to Participate

IEC, MGACHRC Ref. No- MGACHRC/IEC/May-2022/489 and consent of all participants was taken prior to the study.

Funding- Nil

Competing Interests- Nil

Appendix A: Wound-status scoring rubric

Domain	Grade	Observation criterion
Vranatal (wound bed)	0	Smooth or mildly irregular surface with healthy granulation tissue
Vranatal (wound bed)	1	Irregular surface with slight discharge; smooth surface with less granulation tissue
Vranatal (wound bed)	2	Rough, irregular and wet surface with more discharge and slough
Vranatal (wound bed)	3	Rough, irregular surface with profuse discharge and excessive slough
Gandha (odour)	0	No odour
Gandha (odour)	1	Mild bad odour, tolerable
Gandha (odour)	2	Unpleasant but tolerable odour
Gandha (odour)	3	Foul and intolerable odour
Varna (granulation-tissue colour)	0	Pinkish red, indicating healthy granulation tissue
Varna (granulation-tissue colour)	1	Slightly pinkish red
Varna (granulation-tissue colour)	2	Slight yellowish hue
Varna (granulation-tissue colour)	3	Yellow to black, indicating unhealthy granulation tissue
Srava (discharge)	0	Gauze slightly moist
Srava (discharge)	1	Sanguineous (bloody) discharge
Srava (discharge)	2	Serosanguineous discharge
Srava (discharge)	3	Seropurulent discharge

Appendix B: Statistical analysis summary

Analysis	Estimate (95% CI)/effect	Test result
Day-14 change: Welch	-0.17 (-0.65 to 0.32)	t=-0.72; df=21.26; p=.482
Day-14 change: Mann-Whitney	Rank-biserial=-0.13	U=62.5; p=.549
Day-30 change: Welch	1.17 (0.42 to 1.91); g=1.28	t=3.24; df=21.97; p=.004
Day-30 change: Mann-Whitney	Rank-biserial=0.65	U=118.5; p=.006
Day-14 ANCOVA, HC3	0.24 (-0.25 to 0.73)	t=1.00; df=21; p=.327
Day-30 ANCOVA, HC3	-0.95 (-1.19 to -0.71)	t=-8.19; df=21; p<0.001
Repeated time-by-group interaction	Participant fixed effects; cluster-robust	F=4.57; df=3,23; p=.012
Trivritadi repeated visits	Friedman; Kendall W=1.00	$\chi^2=36.00$; df=3; p<0.001
Jatyadi repeated visits	Friedman; Kendall W=0.98	$\chi^2=35.31$; df=3; p<0.001

Sign convention: lower follow-up scores favour Trivritadi; positive change-score differences favour Trivritadi because change was calculated as baseline minus follow-up. HC3 denotes heteroskedasticity-robust covariance. The participant-fixed-effects analysis controls all time-invariant participant characteristics and uses participant-clustered standard errors.

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