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A Clinical Study to Evaluate The Healing Effect of Karanjadi Ghritha Topically in Ksharadagdha Vrana of Low Anal Fistula

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Abstract

Introduction:

Fistula-in-ano is an inflammatory track lined by unhealthy granulation tissue that connects the perianal skin to the anal canal, anorectum, or rectum. Commonly treated through fistulectomy or fistulotomy, it is correlated with *Bhagandhara* in Ayurveda. Acharya Susrutha recommends excision followed by *ksharakarma* or *agnikarma*, with *karanjadighritha*, described in *Susrutha Samhitha Vidradhichikitsadhyaya*, specifically indicated for managing *ksharadagdhavrana*.

Methods:

This pre-and-post interventional study included 25 participants aged 20–70 years diagnosed with low anal fistulas. *Karanjadighritha* was applied topically as a *varti* (wick) over the *ksharadagdhavrana* daily for 42 days. Outcomes, including pain, burning sensation, granulation tissue formation, and tract length, were assessed at seven time points: Days 0, 7, 14, 21, 28, 35, and 42.

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Results:

Significant improvements were observed across all parameters, with $p < 0.001$. Pain and burning sensation decreased substantially, healthy granulation tissue developed by Day 7, and the tract length showed progressive reduction throughout the study.

Discussion and Conclusion:

The results suggest that topical application of *karanjadighritha* is highly effective in managing *ksharadagdhavrana* in low anal fistulas, promoting rapid wound healing and symptom resolution. This study highlights its potential as a safe and effective therapeutic intervention in *Bhagandhara*.

Keywords: Low anal fistula, *Bhagandhara*, *Ksharadagdhavrana*, *Karanjadighritha*, Wound Healing

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Introduction

Fistula-in-ano is a common anorectal condition characterized by an inflammatory track lined with unhealthy granulation tissue, connecting an external opening in the perianal skin to an internal opening in the anal canal or rectum [1]. It is more prevalent in men than women, with incidence rates of 12.3 and 5.6 cases per 100,000, respectively [2]. Fistula-in-ano is classified as low-level and high-level, based on the location of the internal opening relative to the anorectal ring. Low-level fistulas are more common in young adult males, with a male-to-female ratio of 2:1 [3]. Surgical interventions such as fistulectomy, fistulotomy, and techniques like LIFT and seton placement are commonly employed [4].

In Ayurveda, this condition is correlated with *Bhagandhara*, one of the *Ashtamahagada vyadhis*. Classical Ayurvedic texts describe *Bhagandhara* as tearing (*dharana*) the *bhaga*, *guda*, and *vasthi pradesha* [5]. The treatment often involves excision followed by *ksharakarma* or *agnikarma*, with wound-healing agents applied post-procedure. *Karanjadighritha*, mentioned in *Susrutha Samhitha Vidradhichikitsadhyaya*, is noted for its healing properties, specifically for *ksharadagdhavrana*. This study evaluates the topical application of *Karanjadighritha* in the healing of low-level anal fistulas post-*ksharakarma*.

Aim and Objectives:

Aim:

To evaluate the topical application of *Karanjadighritha* in the management of *ksharadagdhavrana* in low anal fistulas.

Objectives:

1. To assess the healing effect of *Karanjadighritha* on clinical parameters such as pain, granulation tissue formation, and tract length reduction.
2. To evaluate its efficacy in promoting wound healing in *ksharadagdhavrana*.

Materials and Methods:

Study Design:

This single-group, pre-and-post interventional study evaluated the healing effect of *Karanjadighritha* on low anal fistulas.

Study Setting:

The study was conducted in the OPD and IPD of the Department of *Salyatantra*, Govt. Ayurveda College Hospital, Thiruvananthapuram.

Study Population:

Participants aged 20–70 years with low anal fistulas meeting inclusion criteria were recruited.

Inclusion Criteria:

1. Diagnosed low anal fistula confirmed by MRI with a tract length <5 cm.
2. *Ksharadagdhabhagandharavrana* (wounds caused by *ksharakarma*).

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Exclusion Criteria:

1. Congenital anal fistulas.
2. Patients with systemic diseases like uncontrolled diabetes, Crohn's disease, and CA rectum.

Intervention:

Post-*ksharakarma, Karanjadighritha* was applied topically over the wound daily for 42 days. Participants were evaluated at 7-day intervals.

Outcome Measures:

1. Pain and burning sensation (assessed using visual analog scales).
2. Granulation tissue formation (clinical examination).
3. Tract length reduction (measured using a malleable copper probe).

Sample Size:

A total of 25 participants were recruited using consecutive sampling.

Statistical Analysis:

Results were analyzed using paired t-tests, with significance set at $p<0.05$.

DETAILS OF INTERVENTIONAL DRUG

Name of the Drug: *Karanjadighritha*

Table 1: Ingredients of *Karanjadighritha*

Drug	***Rasa***	***Guna***	***Virya***	***Vipaka***	***Karma***
Nakthamala (*Pongamia pinnata*) [6]	*Tikta, Katu, Kashaya*	*Tiksna*	*Usna*	*Katu*	*Kaphavatahara, Kandughna, Krimighna, Shothahara, Bhedhana*
Sumana (*Jasminum officinale*) [7]	*Tikta, Kashaya*	*Laghu, Snigdha, Mridu*	*Usna*	*Katu*	*Tridoshahara, Vrana sodhana-ropana*
Patola (*Tricosanthus dioica*) [8]	*Tikta, Kashaya*	*Laghu, Snigdha, Mridu*	*Usna*	*Katu*	*Tridoshahara, Vrana sodhana-ropana*
Arishta (*Azadirachta indica*) [9]	*Tikta*	*Ruksha*	*Sheeta*	*Katu*	*Kaphapittahara, Grahi*
Haridra (*Curcuma longa*) [10]	*Tikta, Katu*	*Ruksha*	*Usna*	*Katu*	*Kaphapittahara, Krimighna, Kushtaghna, Varnya*
Daruharidra (*Berberis aristata*) [11]	*Tikta*	*Laghu, Ruksha*	*Usna*	*Katu*	*Kaphapittahara*
Madhucchishta (*Cera alba*)	*Kashaya, Madhura*	*Guru, Snigdha, Mridu*	*Sheeta*	*Katu*	*Pittahara, Vranaropana, Sandhaniya*
Madhuka (*Glycyrrhiza glabra*)[12]	*Madhura*	*Guru, Snigdha*	*Sheeta*	*Madhura*	*Vatapittahara, Rakthaprasadana, Varnya*
Tiktharohini (*Pichororhiza kurroa*) [13]	*Tikta*	*Laghu, Ruksha*	*Sheeta*	*Katu*	*Kaphapittahara*
Priyangu (*Callicarpa macrophylla*) [14]	*Tikta, Kashaya*	*Ruksha*	*Sheeta*	*Katu*	*Pittavatahara, Sandhaniya, Rakthaprasadana, Vrana ropana*

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Kusa (*Desmostachya bipinnata*)	*Madhura, Kashaya*	*Laghu*	*Sheeta*	*Madhura*	*Kaphapittahara, Mutrala*
Nichula (*Salix tetrasperma*)	*Kashaya*	*Ruksha*	*Sheeta*	*Katu*	*Kaphapittahara, Vrana sodhana*
Manjishta (*Rubia cordifolia*) [15]	*Kashaya, Madhura, Tikta*	*Guru*	*Usna*	*Katu*	*Kaphapittahara, Varnya, Vranaropana, Shothaghna, Sonithasthapana*
Chandhana (*Santalum album*) [16]	*Tikta, Madhura*	*Laghu, Ruksha*	*Sheeta*	*Katu*	*Kaphapittahara, Dahaprasamana, Durgandhahara, Krimighna, Varnya*
Useera (*Vetiveria zizanoides*) [17]	*Madhura, Tikta*	*Laghu, Snigdha*	*Sheeta*	*Madhura*	*Kaphapittahara, Dahaklanthihara*
Utpala (*Nymphaea stellata*) [18]	*Madhura, Kashaya*	*Picchila , Snigdha*	*Sheeta*	*Madhura*	*Pittahara, Rakthaprasadaka, Dahaghna*
Sariva (*Hemidesmus indicus*) [19]	*Madhura, Tikta*	*Guru, Snigdha*	*Sheeta*	*Madhura*	*Tridoshahara, Rakthasodhaka*
Trivrit (*Operculina turpethum*) [20]	*Madhura, Katu, Tikta, Kashaya*	*Laghu, Ruksha, Tikshna*	*Usna*	*Katu*	*Kaphapittahara, Rechana, Jwarahara*
Goghritha [21]	*Madhura*	*Guru*	*Sheeta*	*Madhura*	*Tridoshahara, Vrana sodhana-ropana*

Preparation of the Drug

Karanjadighritha is prepared as per classical Ayurveda texts by a GMP-certified manufacturer.

Intervention

Purvakarma

- Informed consent was obtained.
- Under aseptic conditions, the fistulous tract was laid open, and *Apamarga prathisaraneeya kshara* was applied using a spatula.
- Upon achieving *samyak ksharadagdha lakshanas*, the wound was washed with *nimbu swarasa*.
- The wound was cleaned thoroughly using sterile cotton.

Pradhana Karma

- *Karanjadighritha* was taken according to the size of the wound.
- The *ghrita* was applied over the *ksharadagdhavrana* as a *varthi*.
- Dressing was done using a sterile pad and adhesive plaster.

Paschath Karma

- The participant was advised to rest until stable.
- Dressing was changed the next morning.

Assessment Period

- The assessment period lasted 42 days.

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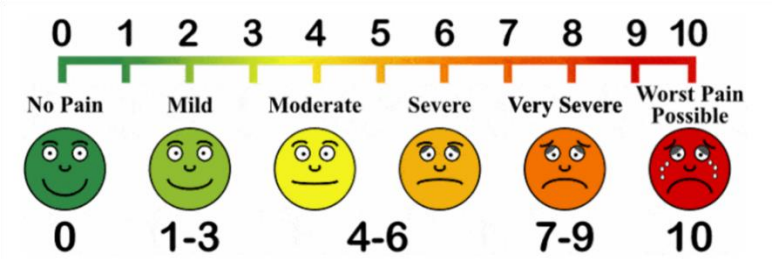
- Dressing was repeated daily, and assessments were conducted on the 0th, 7th, 14th, 21st, 28th, 35th, and 42nd days.
- Participants were advised daily sitz baths with lukewarm saline water until complete wound healing.
- *Brihat Triphala Churnam* (10 g) with hot water at bedtime was given until the wound healed.

Outcome Measures

The treatment's efficacy was assessed using subjective and objective parameters based on clinical observations.

Subjective Parameters

1. **Pain** (assessed using Visual Analogue Scale):



   - 0: Absent
   - 1–3: Mild
   - 4–6: Moderate
   - >7: Severe
2. **Burning Sensation**:
   - 0: Absent
   - 1: Mild
   - 2: Moderate
   - 3: Severe

Objective Parameters

1. **Granulation Tissue**:
   - 0: Healthy
   - 1: Moderate
   - 2: Unhealthy
   - 3: Absent

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2. **Length of the Tract**:
    - Length was measured along the long axis using a malleable copper probe.

Average Healing Rate per Week = Initial length of the tract ÷ Number of weeks to heal

Data Analysis

The data related to both subjective and objective parameters of 25 participants were analyzed statistically. The results were evaluated using the Wilcoxon Signed-Rank Test.

Observation and Results

Pain (VAS Scale)

The Pain VAS Scale statistics indicate a significant reduction in pain over a 42-day period. Initially, on Day 0, the mean pain score was 9.00 (SD = 1.00) with a median of 9, reflecting high pain levels among participants. By Day 7, the mean score decreased to 5.52, and by Day 42, it further reduced to 0.08. The Wilcoxon Signed-Rank Test showed statistically significant reductions in pain, with all p-values being <0.001. These results strongly support a substantial and statistically significant decrease in pain levels over the study period.

Burning Sensation

The Burning Sensation Scores showed a significant reduction from Day 0 to Day 42. On Day 0, the mean score was 3 (SD = 0), indicating all participants reported the highest burning sensation score. By Day 7, the mean score dropped to 1.88 and progressively decreased to 0.04 by Day 42, indicating almost complete resolution. The Wilcoxon Signed-Rank Test yielded z-scores ranging from 4.444 to 4.914, with all p-values <0.001, highlighting a consistent decrease in burning sensation throughout the study period.

Granulation Tissue Formation

Initially, on Day 0, there was no granulation tissue. From Day 7 onward, healthy granulation tissue was observed across all participants, and this improvement was sustained through Day 42. The Wilcoxon Signed-Rank Test results (z-score = 5.000, p-value <0.001) confirm a rapid and significant improvement in tissue health within one week, maintained throughout the study.

Length of the Tract

The tract length showed a significant reduction over the 42-day study period. By Day 7, the mean tract length decreased to 2.12, with further reductions observed weekly, reaching 0.02 by Day 42. The Wilcoxon Signed-Rank Test results demonstrated highly significant reductions in tract length across all time points (p-values <0.001), reflecting the effectiveness of the intervention.

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Table 2: Incidence of Demographic Factors

Distribution	Category	Number	%
Age	21-30	5	20
	31-40	7	28
	41-50	8	32
	51-60	4	16
	61-70	1	4
Gender	Male	21	84
	Female	4	16
Domicile	Urban	15	60
	Rural	10	40
Occupation	Sedentary work	17	68
	Active worker	8	32
Diet	Vegetarian	1	4
	Non-vegetarian	24	96
Bowel	Constipated	21	84
	Regular	4	16
Appetite	Good	7	28
	Reduced	18	72
Addiction	Smoking	12	43
	Alcohol	15	53
	Betel chewing	1	4

Table 3: Effectiveness of Treatment on Clinical Responses

Parameters	Mean							z-score	p-value	Remarks
	Day 0	Day7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0 vs Day 42	Day 0 vs Day 42	
Pain	9.00	5.52	2.68	1.08	0.52	0.28	0.08	4.431	<0.001	Significant
Burning sensation	3	1.88	0.92	0.4	0.2	0.2	0.04	4.914	<0.001	Significant
Granulation tissue formation	3	0	0	0	0	0	0	5.000	<0.001	Significant
Length of the tract	2.92	2.12	1.19	0.57	0.26	0.15	0.02	4.381	<0.001	Significant

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Figures

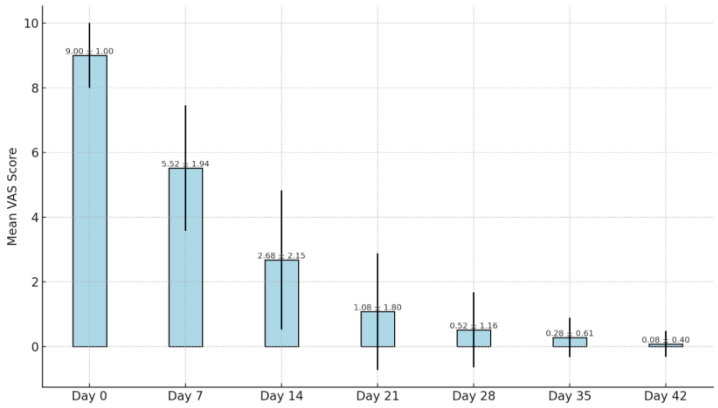

Figure 1: Mean change in pain

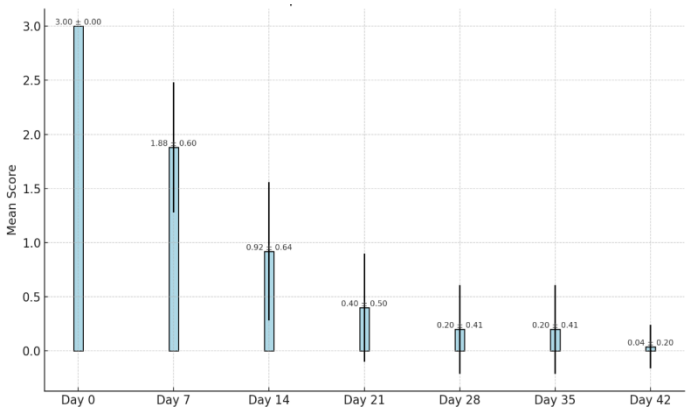

Figure 2: Mean change in burning sensation

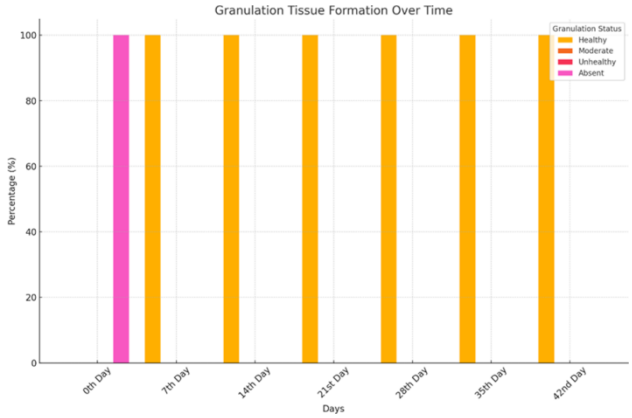

Figure 3: Mean change in granulation tissue formation

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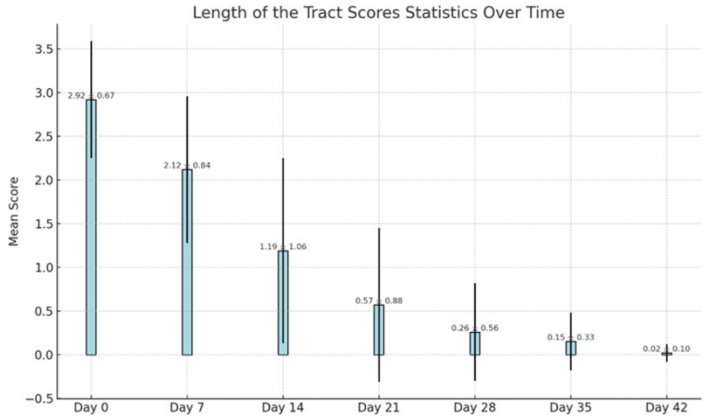

Figure 4: Mean change in length of the tract

Discussion

In the present study, 25 patients with low anal fistula were selected based on the inclusion criteria, and their outcomes were evaluated after treatment with *karanjadighritha*.

Demographic Insights

The age distribution indicates that most participants (60%) were within the 31–50 age range, with 28% in the 31–40 group and 32% in the 41–50 group. This finding suggests that middle-aged individuals are more susceptible to anal fistulas. Younger participants (21–30 years) had faster wound healing, consistent with the established understanding that wound healing is more efficient in younger individuals due to better cellular activity [22]. Gender analysis revealed a significant male predominance (84%), aligning with previous studies highlighting the higher prevalence of fistulas in men.

Domicile data showed that 60% of participants resided in urban areas, while 40% were from rural regions. Urban residents are more likely to have dietary habits contributing to constipation, a risk factor for anal fistulas. Non-vegetarian diets were prevalent among 96% of participants, with only 4% following a vegetarian diet. A low-fiber, non-vegetarian diet can impair *jadaragni* and lead to *agnimandhya*, a known *nidana* for *bhagandhara*. Additionally, 84% of participants reported constipation, emphasizing the strong correlation between bowel habits and the development of anal fistulas.

Occupational analysis revealed that 68% of participants engaged in sedentary work, such as prolonged sitting, which is a contributing factor to fistula formation. Appetite patterns further supported the role of *agnimandhya*, as 72% of participants had reduced appetite, indicating poor *jadaragni*. Addictions such as alcohol consumption

and smoking, reported by the majority, are known to impair wound healing by suppressing immune responses and delaying inflammatory and proliferative phases of healing [23].

Probable Mode of Action of Karanjadighritha

Effective wound healing requires the removal of *dushti* and maintaining a *shuddha vrana*. During *ksharakarma*, the *ksharana* property of *kshara* eliminates unhealthy granulation tissue and fibrous tissue from the fistula tract. The *laghu* and *tikshna guna* of *karanjadighritha* aid in cleansing the wound, while the *tikta* and *kashaya rasa* of its ingredients, combined with the *visada guna*, help remove slough.

The *pittahara* properties of *karanjadighritha* reduce inflammation, addressing symptoms like redness, pain, and burning sensation. Active compounds such as curcumin in *haridra*, alkaloids in *karanja* and *nimba*, and flavonoids in *jati* contribute to antimicrobial and anti-inflammatory effects. Additionally, tannins and phytosterols in *haridra*, *yashti*, *utpala*, and *sariva* enhance capillary formation, fibroblast proliferation, and epithelialization. The *yogavahi guna* of *ghrita* improves drug penetration, expediting wound healing [24].

Outcome Variables

Effect on Pain

Pain levels significantly decreased throughout the study. The *vatanashaka* properties of *madhuka*, *sariva*, and *goghrita* alleviated pain, while the *chedana* and *lekhana* properties of *karanja*, *jati*, *patola*, *manjishta*, and *daruharidra* ensured the removal of unhealthy granulation tissue, preventing pus formation. The *visada guna* of *kashaya rasa* helped clear wound slough and reduce infection, further contributing to pain relief.

Effect on Burning Sensation

All participants reported severe burning sensations immediately after *ksharakarma*, which progressively reduced with the application of *karanjadighritha*. This effect is attributed to the *pittahara* properties of the formulation, along with the *sheeta virya*, *soumya guna*, and *madhura vipaka* of ingredients such as *madhuka*, *chandana*, *ushira*, *sariva*, and *utpala*. These properties collectively facilitated the *dahaprasamana* of the wound.

Effect on Granulation Tissue Formation

Healthy granulation tissue formation was observed within the first week of treatment and was sustained throughout the study. This rapid transition highlights the effectiveness of *karanjadighritha* in promoting tissue healing. The *laghu guna* of *jati*, *nimba*, *patola*, *haridra*, *daruharidra*, *chandana*, and *ushira* supported wound cleansing. Additionally, the *tikta-kashaya rasa* and *lekhana* and *chedana* properties of *kashaya rasa* removed slough, while

the *ushna virya* of certain ingredients improved circulation, facilitating healthy granulation tissue development.

Effect on Length of the Tract

The study demonstrated a significant reduction in the length of the fistula tract, with healing nearly complete for most participants by Day 42. The *kashaya-tikta rasa* of the formulation's ingredients facilitated *ropanakarma* through their *sandhaniya* properties. Constituents like tannins and phytosterols enhanced capillary formation and fibroblast proliferation, promoting epithelialization and wound contraction. Notably, one participant's wound remained unhealed due to anemia (Hb 10.8 g%), indicating the influence of systemic factors on wound healing.

Conclusion

The findings of this study demonstrate that *karanjadighritha* is highly effective in managing *ksharadagdhavrana* in low anal fistulas. The topical application of *karanjadighritha* significantly reduced pain and burning sensation, shortened the length of the wound, and promoted the formation of healthy granulation tissue, thereby accelerating the wound healing process. This highlights its therapeutic potential as a supportive intervention in fistula management.

The study's results are statistically highly significant, providing strong evidence that *karanjadighritha* plays a vital role in enhancing the natural wound healing process. Furthermore, no adverse events were reported during the study period, indicating the safety of the formulation for clinical use.

Thus it can be said that, while wound healing is an inherent biological process, the application of *karanjadighritha* provides a valuable enhancement to this process. This study reinforces the efficacy and safety of *karanjadighritha* in promoting wound healing and supports its integration into the management of *bhagandhara* and similar conditions.

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