

A Pilot Study: To Evaluate the Efficacy of *Nimbadi Yoga* Ointment in Post-operative Wound Healing Following Excision of Sentinel Pile.

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ABSTRACT

Background: Sentinel pile is commonly associated with chronic fissure-in-Ano and often requires surgical excision. Post-operative wound healing in the anorectal region is frequently delayed due to pain, inflammation, moisture, and faecal contamination with repeated trauma. Ayurveda describes several formulations possessing *Vrana-shodhana* and *Vrana-ropana* properties for effective wound management. *Nimbadi Yoga* is a classical formulation traditionally indicated for wound healing.

Objective: To evaluate the efficacy of *Nimbadi Yoga* ointment in post-operative wound healing following excision of the sentinel pile.

Materials and Methods: An open-label, single-arm pilot clinical study was conducted on 10 patients who underwent surgical excision of the sentinel pile. *Nimbadi Yoga* ointment was applied locally once daily for 28 days after proper wound cleansing. Assessment parameters included pain (Visual Analogue Scale), wound size and wound colour. Observations were recorded during treatment every 7 days for 1 month, then after treatment every 15 days for the next 1 month (day 0, 7, 14, 21, 28, 43 and 58)

Results: The study showed marked improvement in all wound-healing parameters. Pain was significantly reduced by day 7. Progressive wound contraction and healthy granulation tissue formation were observed by day 14. No adverse drug reactions were reported.

Conclusion: *Nimbadi Yoga* ointment demonstrated promising efficacy in enhancing post-operative wound healing following excision of the sentinel pile. The findings support its use as a safe and effective adjunct in post-surgical wound care. Larger randomised controlled trials are required to confirm these results.

Keywords: Sentinel pile; *Nimbadi Yoga*; Post-operative wound; *Vrana Ropana*; Pilot study

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INTRODUCTION

A sentinel pile is a fibrotic skin tag commonly found at the distal end of a chronic anal fissure and is considered a marker of long-standing disease¹. Surgical excision is indicated in symptomatic cases where conservative treatment fails. However, postoperative wound healing in the anorectal region remains a clinical challenge due to constant movement, moisture, local inflammation, and faecal contamination with repeated trauma.

Delayed wound healing not only prolongs patient discomfort but also increases the risk of secondary infection and recurrence. Traditional wound care emphasises pain relief, proper hygiene, and infection prevention; however, the need for safe, effective topical agents to promote healing remains significant.

In Ayurveda, surgical wounds are classified under *Agantuja Vrana*. Classical texts emphasise that proper

wound management involves two sequential principles—*Vrana shodhana* followed by *Vrana ropana*². *Acharya Sushruta* described 60 *Upkramas*³, and *Acharya Charaka* described 36 *Upkramas*⁴ for the treatment of surgical and non-surgical wound care. One of them is *lepan karma*.

Nimbadi Yoga is a traditional formulation described in *Yogratnakar* as a *lepan yoga* in *Vrana chikitsa*⁵, which is highly effective in preventing infection and promoting wound healing. I prepared *Nimbadi yoga* as an ointment to be used as a *lepan* for wound healing. The ingredients present in this ointment are well known for their antimicrobial, anti-inflammatory, analgesic and wound-healing properties⁶⁻⁷.

Despite extensive traditional use, there is limited clinical evidence evaluating the role of *Nimbadi Yoga*

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ointment in post-operative wound healing, particularly in anorectal surgeries.

Hence, the present pilot study was undertaken to evaluate the efficacy of *Nimbadi Yoga* ointment in post-operative wound healing following excision of the sentinel pile.

AIM AND OBJECTIVES

Aim: To evaluate the efficacy of *Nimbadi Yoga* ointment in post-operative wound healing following excision of the Sentinel Pile.

Objectives:

- To assess the effect of *Nimbadi Yoga* ointment on post-operative pain.
- To evaluate wound healing based on wound size.
- To observe changes in wound colour and signs of local infection.

MATERIALS AND METHODS

Study Design

Open-label, single-arm pilot clinical study.

Study Centre: -

The research work will be done in OPD and IPD of the Department of *Shalya Tantra* in Shri Khudadad Doonga Ji Government Ayurveda College and Hospital, Raipur (C.G.).

Sample Size

10 patients (pilot study).

Ethical Considerations

The study was conducted after approval from the Institutional Ethical Committee. Written informed consent was obtained from all patients before enrolment.

Selection Criteria

Inclusion Criteria

- Patients without any severe systemic disease in the age group of 18 to 50 years of both sexes were selected.
- Clinically diagnosed cases of sentinel pile undergoing excision.
- Willingness to participate in the study.

Exclusion Criteria

- Diabetes mellitus or immunocompromised states
- Associated anorectal disorders such as fistula-in-ano, abscess, or malignancy
- Patients on long-term steroid or immunosuppressive therapy
- Patients below 18 years and above 50 years.
- Patients suffering from varicose ulcers, lepromatous ulcers, syphilitic ulcers, skin malignancies, and HIV were excluded.

INVESTIGATIONS

- CBC, ESR, BT & CT
- Blood sugar (PP/F)
- HIV, VDRL, HbsAg
- RFT & LFT (if required), Urine R / M
- ECG (If required), Chest X-RAY (if required)
- Mantoux test, PCR test for T.B. (If required)
- Wound biopsy (if necessary)

INTERVENTION

After excision of the sentinel pile under aseptic precautions, the wound was cleansed with sterile normal saline. *Nimbadi Yoga* ointment was applied locally once daily from the 1st postoperative day to the 28th day or till wound heals.

Use of *Nimbadi Yoga* on wounds is assumed to be effective because the drug ingredients present in these preparations have *Vranashodhaka*, *Vranaropaka*, *Vedanasthapaka*, *Varnya*, *Shothahara*, *Jantughna*, and *Krimighna* properties⁸ and keep the wound clean and facilitate the healing process. It is self-applicable, non-invasive and easy to implement.



A



B



C

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Fig. 1. Therapeutic interventions (A) Before excision, sentinel pile present at 12' o clock position. (B) After excision of sentinel pile mass wound was formed. (C) *Nimbadi Yoga* Ointment. (D) Application of *Nimbadi Yoga* Ointment. (E) Wound at day 0. (F) At day 7 (G) At day 14. (H) At day 21. (I) At day 28 wound was healed.

Contents of *Nimbadi Yoga* (Ointment): -⁸

S. N	DRUG	BOTANICAL NAME	RAS	GUNA	VIRYA	VIPAKA	KARMA
1.	<i>Nimba</i>	<i>Azadirachata indica</i>	<i>Kashaya, Tikta</i>	<i>Laghu, Tikshna</i>	<i>Shita</i>	<i>Katu</i>	<i>Jantughna, Vranashodhak, Putihara</i>
2.	<i>Yastimadhu</i>	<i>Glycyrrhiza glabra</i>	<i>Madhur</i>	<i>Guru, Snigdha</i>	<i>Shita</i>	<i>Madhur</i>	<i>Vedanasthapan, Shonitsthapan</i>
3.	<i>Daruharidra</i>	<i>Berberis aristate</i>	<i>Tikta, Kashaya</i>	<i>Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Shoth-har, Vranaropan</i>

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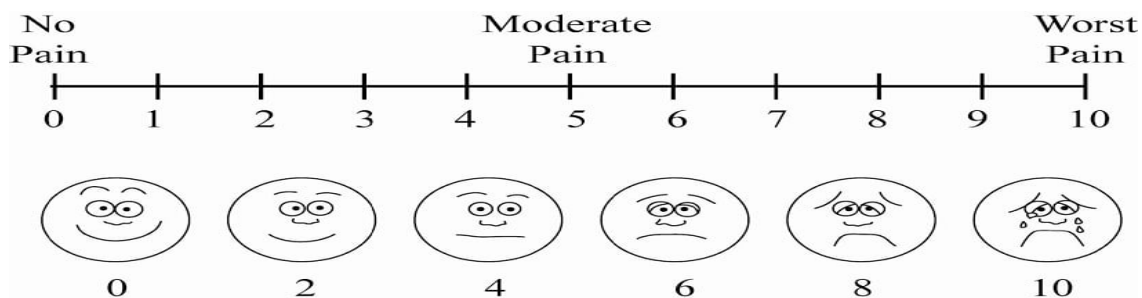
4.	<i>Krishna Tila</i>	<i>Sesamum indicum</i>	<i>Madhur, Kashaya, Tikta</i>	<i>Guru, Snigdha</i>	<i>Ushna</i>	<i>Madhur</i>	<i>Vranashodhan, Vedanasthapan, Sandhaniya</i>
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Key Medicinal Herbs, Bioactive Constituents, and Their Wound-Healing Actions⁹⁻¹⁴

Herb	Major Bioactive Agents	Anti-microbial	Anti Inflammatory	collagen synthesis wound contraction	Anti-oxidant
Azadirachta indica (Neem)	Nimbidin Nimbin Gedunin Tannins	✓ ✓ ✓	✓ ✓	 ✓	 ✓ ✓
Berberis aristata (Daruharidra)	Berberine Palmatine Tannins & Phenolic Compounds	✓ ✓	✓	 ✓ ✓	✓ ✓
Glycyrrhiza glabra (Yashtimadh)	Glycyrrhizin Glabridin & Liquiritin Isoliquiritin	✓ ✓ ✓		✓	✓
Krishna Tila (Sesamum indicum)	Sesamin & Sesamolin Vitamin E Phytosterols	✓	 ✓	 ✓ ✓	✓ ✓

CRITERIA FOR CLINICAL ASSESSMENT

1. **PAIN** – As the sufferer himself expressed the pain in his own term, so this was graded, starting from mild to severe as per with the Visual Analogue Scale (VAS).



Grade	Symptoms
0	Absence of pain
1	Mild pain-between 1-3 mark on scale (pain that can be easily ignored)
2	Moderate pain-between 4-6 mark on scale (pain that can't be ignored)
3	Severe pain-between 7-10 mark on scale (pain that cannot be ignored, needs treatment)

2. COLOUR OF WOUND: -

Grade -0	<i>Twak savarna</i>	Healed wound / equivalent to skin colour
Grade-1	<i>Kapota varna</i>	Healing wound
Grade-2	<i>Shyavoshta & Jihva-talabho (Shweta- rakta)</i>	Cleaned wound/ equivalent to reddish- white with dust
Grade-3	<i>Krishna-rakta, Peeta, Shweta varna</i>	Necrosed Tissue / Dead Tissue/Slough Infected Wound / equivalent to congested reddish- black

3. SIZE OF WOUND: -

The size of the wound will be directly recorded. The sterile blotting paper will be placed over the wound and pressed with uniform pressure. The impression will be directly measured: -

Grade 0	Healed
Grade 1	Upto 0 to 1 sq. cm
Grade 2	1 to 2 sq. cm
Grade 3	2 to 3 sq. cm

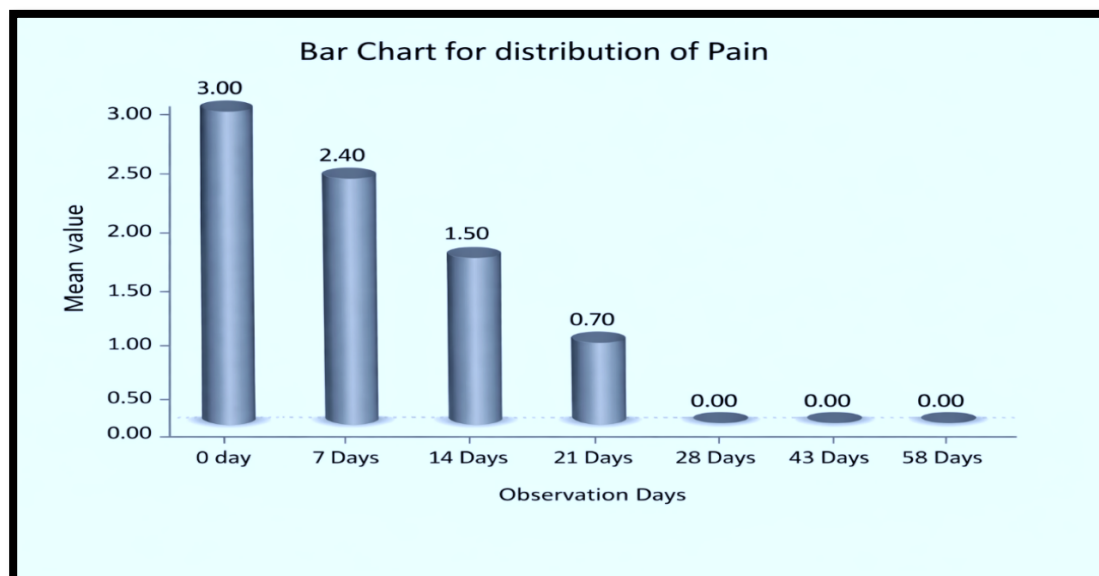
4. UNIT HEALING TIME: -

Wound healing was assessed by UHT (Unit Healing Time) and scoring of signs and symptoms. The UHT means the number of days required for healing of the per sq. cm area of the wound. UHT was calculated by the formula: $UHT = \frac{TDRH}{IAW}$ sq.cm.

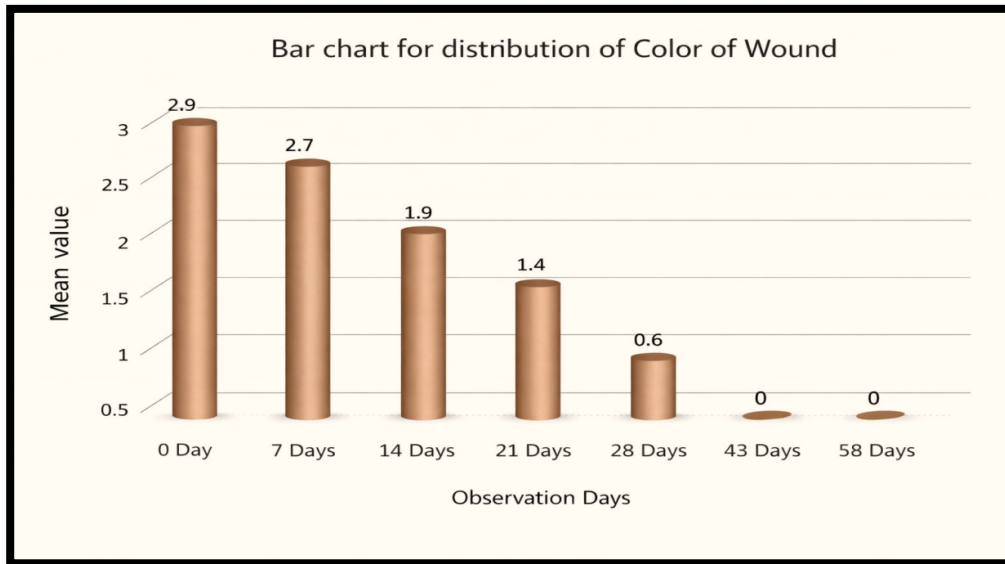
Where, TDRH = Total number of Days Required for Healing and IAW = Initial Area of Wound in square centimetres

OBSERVATIONS: -

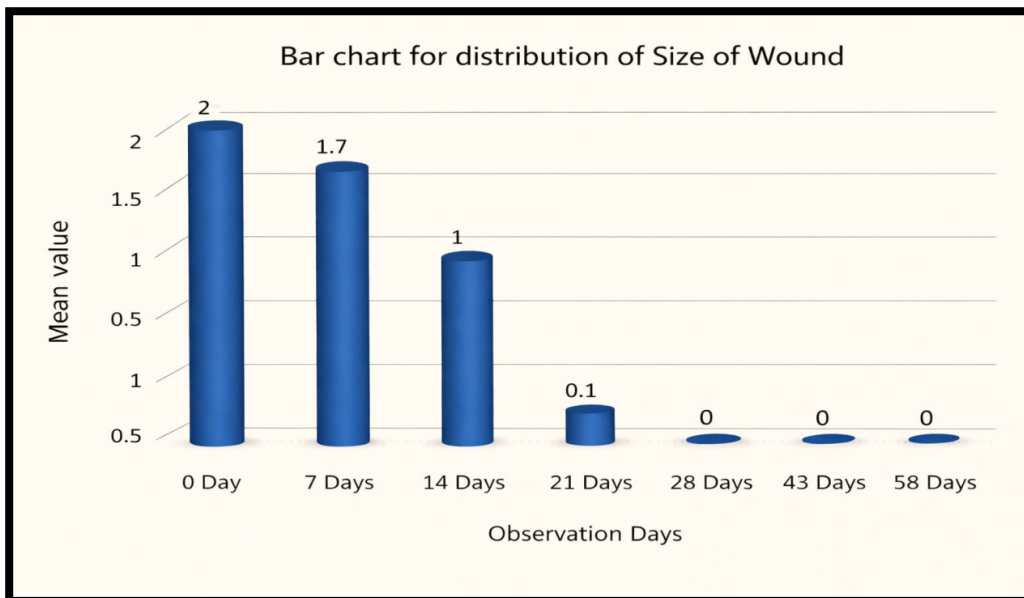
Assessment of pain



Assessment of the colour of the wound



Assessment of the size of the wound



Assessment of Unit Healing Time

Statistics		
UHT		
N	Valid	10

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	Missing	0
Mean		19.640
Std. Error of Mean		.7557

RESULT:

All of the patients who signed up for the trial completed it. All measured metrics indicated consistent improvement, and there were no adverse effects from the medications. The mean UHT was observed to be 19.64 ± 0.76 days (SEM), indicating a consistent and predictable healing trend in the study population.

Effect on Pain: -

The pain score was 3.00 on the first day, but it improved over time. After 7 days, pain decreased by 20% ($p=0.034$), and after 14 days, it went down by 50% ($p=0.004$). Full alleviation was achieved at 28 days and maintained for 58 days ($p=0.002$).

Effect on the Colour of Wound: -

The first score for the colour of the wound was 2.90, and it decreased over time. At seven days, there was no major difference ($p=0.157$). Significant improvement started at 14 days, with complete relief by 43 days, continuing until 58 days ($p=0.002$).

Effect on Wound Healing: -

The score at the start was 2.00. Significant improvement from 14 days (50%), and full healing at 28 days, sustained afterwards ($p=0.002$).

Discussion

The anorectal region is particularly susceptible to delayed wound healing due to anatomical and physiological factors. Ayurveda emphasises the importance of *Vrana shodhana* and *Vrana ropana* for successful wound management³. *Nimbadi Yoga* possesses *Tikta* and *Kashaya rasa*, *Laghu* and *Ruksha guna*, and *Vedanasthapaka*, *Varnya*, *Shothahara*, *Jantughna*, and *Krimighna* properties, which facilitate wound cleansing and healing. From a modern pharmacological perspective, *Azadirachta indica* exhibits antimicrobial, anti-inflammatory, antioxidant, and collagen-modulating activities, which support wound contraction and epithelialization⁹⁻¹⁰. The clinical outcomes observed in this pilot study align with these properties.

Conclusion

Nimbadi Yoga ointment was found to be effective and safe in enhancing post-operative wound healing following excision of the sentinel pile. The formulation significantly reduced pain while promoting healthy granulation tissue formation. The results of this pilot study provide preliminary clinical evidence supporting the role of *Nimbadi Yoga* in post-operative wound care. Further randomised controlled trials with a larger sample size are recommended.

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