

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF NIMBADI YOGA IN THE MANAGEMENT OF VRANA W.S.R. TO POST-OPERATIVE WOUND OF THE SENTINEL PILE

Sahu Chanchal^{1*}, Nirmalkar Uttam Kumar², Nirmal Satrupa³, Chandravanshi Satish Kumar⁴, Singh Balendra⁵, Baghel Dheeraj Singh⁶

^{1*}MS Scholar, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: chanchalsahu0209@gmail.com

²Reader, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: druk01508@gmail.com

³Lecturer, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: rupanirmal1985@gmail.com

⁴Lecturer, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: satishkwd.123@gmail.com

⁵Professor and HOD, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: Drbalendrasingh@gmail.com

⁶Reader, Department of Shalya Tantra, GAC Raipur, C.G., India. Email: Dr.bagheldheeraj25@gmail.com.

ABSTRACT

Background: Sentinel pile is a common sequela of chronic fissure-in-ano and often requires surgical excision when conservative management fails. Although surgical excision effectively removes the lesion, the resulting post-operative wound remains vulnerable to pain, delayed healing, Repeated infection, if proper hygiene is not maintained after defecation. Ayurveda describes several Vrana Ropana (wound-healing) formulations, among which Nimbadi Yoga, mentioned in Yogaratnakara, possesses significant Vranashodhana (wound cleansing) and Vranaropana (wound healing) properties. However, clinical evidence regarding its efficacy in post-operative anorectal wounds is limited.

Aim: To evaluate the efficacy of Nimbadi Yoga Ointment in the management of postoperative wounds following sentinel pile excision and compare its effectiveness with Jatyadi Taila.

Materials and Methods: A non-randomised, prospective, open-label, double-arm interventional clinical study was conducted on 40 patients with postoperative wounds following sentinel pile excision. Patients were allocated into two groups comprising 20 patients each. Group A received topical application of Nimbadi Yoga Ointment, whereas Group B received Jatyadi Taila. Both groups were advised hot water sitz bath and Triphala Churna throughout the treatment period. Clinical assessment was performed on Days 0, 7, 14, 21, and 28 using pain (VAS), wound size, wound colour, Unit Healing Time (UHT), and Healing Index as outcome measures. Appropriate statistical tests were applied, and a p-value <0.05 was considered statistically significant.

Results: Both groups demonstrated statistically significant improvement in pain, wound size, and wound colour from baseline (p<0.001). Group A showed numerically greater improvement in pain relief (96.61%) and wound size reduction (91.11%), whereas Group B demonstrated slightly higher improvement in wound colour (86.67%). However, intergroup comparisons for pain, wound size, wound colour, Unit Healing Time, and Healing Index revealed no statistically significant difference (p>0.05), indicating comparable therapeutic efficacy.

Conclusion: Nimbadi Yoga Ointment was found to be safe, effective, and therapeutically comparable to Jatyadi Taila in the management of post-operative wounds following sentinel pile excision. Considering its wound-cleansing, antimicrobial, anti-inflammatory, and wound-healing properties, it may serve as a useful Ayurvedic alternative for post-operative wound care.

KEYWORDS: Nimbadi Yoga Ointment, Vrana, Sentinel Pile, Post-operative Wound, Wound Healing, Jatyadi Taila, Parikartika, Ayurveda.

1. INTRODUCTION

Wound healing is a dynamic and complex biological process involving haemostasis, inflammation, proliferation, and tissue remodelling. Successful post-operative wound management is essential for preventing infection, reducing pain, promoting early epithelialisation, and restoring normal tissue function. Delayed wound healing not only prolongs patient discomfort but also increases healthcare costs and the risk of postoperative complications.

A chronic anal fissure is frequently associated with the development of a sentinel pile, a hypertrophied skin tag located at the distal end of the fissure.¹ Although conservative treatment remains the first-line management, persistent symptomatic sentinel piles often require surgical excision. Following surgery, the resulting wound remains susceptible to pain, inflammation, delayed epithelialisation, secondary infection, and recurrence if not managed appropriately. Therefore, an effective, safe, economical, and patient-friendly postoperative dressing is essential for achieving optimal wound healing.

In Ayurveda, post-operative wounds are broadly described under the concept of Vrana, which has been extensively elaborated by Acharya Sushruta, the pioneer of Shalya Tantra. Acharya Sushruta emphasized that the primary objectives of wound management are Vrana Shodhana (wound cleansing) and Vrana Ropana² (promotion of wound healing), ultimately restoring the normal colour, texture, and integrity of the affected tissue (Vakritapaham). Acharya Sushruta described 60 Upkramas³, and Acharya Charaka described 36 Upkramas⁴ for the treatment of surgical and non-surgical wound care. Among the sixty measures (Shasti Upakrama) described for wound management, Lepana Karma plays a significant role in promoting healthy wound healing through topical application of medicinal formulations.

Nimbadi Yoga, described in Yogaratnakara as a Lepana Yoga for the management of Vrana⁵, consists of Nimbapatra (*Azadirachta indica*), Daruharidra (*Berberis aristata*), Yashtimadhu (*Glycyrrhiza glabra*), and Krishna Tila (*Sesamum indicum*). These ingredients possess well-documented Vranashodhana, Vranaropana, Vedanasthapana, Shothahara, Krimighna, Jantughna, and Varnya properties according to Ayurvedic literature. Modern pharmacological studies have also demonstrated that these medicinal plants exhibit antimicrobial, anti-inflammatory, antioxidant, collagen-promoting, angiogenic, and tissue-regenerative activities that are favourable for wound healing.

Jatyadi Taila is one of the most widely accepted Ayurvedic formulations for wound management and is routinely used in post-operative anorectal practice. However, few clinical studies have compared the efficacy of Nimbadi Yoga Ointment with Jatyadi Taila for post-operative wounds after sentinel pile excision. Generating such evidence may provide an effective and convenient alternative topical formulation for routine clinical practice.

Therefore, the present study was undertaken to evaluate the clinical efficacy of Nimbadi Yoga Ointment in the management of post-operative wounds following sentinel pile excision and to compare its therapeutic effectiveness with Jatyadi Taila using validated clinical parameters including pain, wound size, wound colour, Unit Healing Time, and Healing Index.

Aim And Objectives:

A clinical assessment of Nimbadi yoga in the management of Vrana with special reference to post-operative wound of the Sentinel Pile.

MATERIAL AND METHODS: -

Contents of Nimbadi Yoga Ointment⁶ : -

S.N.	DRUG	BOTANICAL NAME	RAS	GUNA	VIRYA	VIPAKA	KARMA
1.	Nimba	<i>Azadirachata indica</i>	Kashaya, Tikta	Laghu, Tikshna	Shita	Katu	Jantughna, Vranashodhaka, Putihara
2.	Yastimadhu	<i>Glycyrrhiza glabra</i>	Madhur	Guru, Snigdha	Shita	Madhur	Vedanasthapana, Shonitsthapana
3.	Daru haridra	<i>Berberis aristate</i>	Tikta, Kashaya	Ruksha	Ushna	Katu	Shotha-hara, Vranaropana
4.	Krishna Tila	<i>Sesamum indicum</i>	Madhur, Kashaya, Tikta	Guru, Snigdha	Ushna	Madhur	Vranashodhan, Vedanasthapana, Sandhaniya

Key Medicinal Herbs, Bioactive Constituents, and Their Wound-Healing Actions⁷⁻¹³ : -

Herb	Major Bioactive Agents	Anti microbial	Anti Inflammatory	collagen synthesis&wound contraction	Anti oxidant
<i>Azadirachta indica</i> (Neem)	Nimbidin Nimbin Gedunin Tannins	✓	✓		
		✓			✓
			✓		✓
		✓		✓	
<i>Berberis aristata</i> (Daruharidra)	Berberine Palmatine Tannins and Phenolic Compounds	✓	✓		✓
		✓		✓	✓
				✓	

Glycyrrhiza glabra (Yashtimadh)	Glycyrrhizin Glabridin Liquiritin & Isoliquiritin	✓		✓	
		✓			✓
		✓			
Krishna Tila (<i>Sesamum indicum</i>)	Sesamin & Sesamolin Vitamin E Phytosterols	✓			✓
				✓	✓
			✓	✓	

Clinical Study

Study Design

The present study was designed as a non-randomised, prospective, open-label, double-arm, comparative, interventional, clinical study to evaluate the clinical efficacy of Nimbadi Yoga Ointment in the management of postoperative wounds following sentinel pile excision and to compare its therapeutic effectiveness with the standard Ayurvedic wound-healing formulation, Jatyadi Taila.

Study Setting

The clinical trial was carried out in the OPD/IPD of Shalya Tantra Department of Shri Khudadad Dunga ji, Government Ayurved College & Hospital, Raipur (C.G). Institutional Ethics Committee Approval No.: 1/S.T./2023–2024

CTRI Registration No.: CTRI/2025/01/079677.

Study Population and Sample Size

A total of 40 patients with features of Vrana with special reference to post-operative wound of the sentinel pile were included in the study with 20 patients in each group. All enrolled participants completed the study protocol and follow-up, resulting in a 100% completion rate without any dropouts. Patients were enrolled after obtaining written informed consent and were allocated equally into two treatment groups,

Selection Criteria

Inclusion Criteria

- Patients fulfilling all of the following criteria were included.
- Patients of either sex between 18 and 60 years of age.
- Prakriti- all types of prakriti.
- Measurement of wound– approx 3 sq. cm in diameter or less.
- Post-operative wound with special reference to sentinel pile.
- Diabetes mellitus with controlled sugar level.
- Hypertensive patient with controlled blood pressure.
- Patients willing to provide written informed consent.

Exclusion Criteria

Patients with the following conditions were excluded:

- Patients Aged below 18 years and above 50 years were excluded.
- Immunological diseases like Crohn's disease and ulcerative colitis were excluded.
- HIV infection or other immunocompromised conditions.
- Severe systemic illness likely to interfere with wound healing.
- Pregnant and lactating women.
- Patients unwilling to participate or unable to complete follow-up.

Study Intervention

The enrolled patients were allocated into two treatment groups.

Group A (Intervention Group)

Patients received Nimbadi Yoga Ointment for topical application over the postoperative wound following wound cleansing. The ointment was applied once daily after hot water sitz bath under aseptic precautions for 28 consecutive days.

Group B (Control Group)

Patients received Jatyadi Taila, applied locally over the postoperative wound using the same dressing protocol and treatment duration as followed in Group A.

To eliminate treatment bias, both groups received identical postoperative care apart from the trial medication.

Duration of Treatment

The duration of active treatment was 28 days.

Follow-up

Clinical evaluation was carried out on: baseline (day 0), day 7, day 14, day 21, day 28. Following completion of treatment, all patients were followed for an additional one month to assess wound status, recurrence, and any delayed postoperative complications.

Criteria for assessment

Primary Outcome parameters included:

Pain intensity assessed using the Visual Analogue Scale (VAS), Wound size measured using a standard wound measurement technique assessed according to predefined grading criteria, and wound colour assessed according to predefined grading criteria.

Secondary outcome parameters included:

Unit Healing Time (UHT)

Healing Index

Observation And Results

Demographic result: -

A total of 40 patients with post-operative wounds of sentinel pile were enrolled in the study, and all completed the trial successfully. A total of 40 patients with post-operative sentinel pile wounds participated in the study, and all completed it successfully. Most patients were aged between 41 and 50 years (52.5%), Hindu (92.5%), female (77.5%), married (87.5%), urban residents (82.5%), and housewives (60%). The majority had primary education (37.5%), belonged to the lower-middle socio-economic class (50%), followed a mixed diet (60%), and experienced irregular bowel habits (82.5%), Madhyama Koshtha (67.5%), and Vishama Agni (72.5%).

Therapeutic Outcomes

Effect of therapy in Group A (Nimbadi Yoga Ointment)

a) Pain

Group A showed a progressive and highly significant reduction in pain. The mean pain score decreased from 2.95 (BT) to 0.1 (28th day), with percentage relief improving from 27.12% to 96.61% ($p < 0.001$ at all follow-ups). Grade-wise, 95% of patients were in Grade 3 at baseline (BT). By Day 28, 90% achieved complete pain relief (Grade 0) and 10% remained in Grade 1. This marked improvement may be due to the anti-inflammatory, antimicrobial, and wound-healing properties of Nimbadi Yoga Ointment.

b) Wound Colour

Mean wound colour score reduced from 3 (BT) to 0.5 (28th day), with percentage relief increasing from 16.67% to 83.33% ($p < 0.01$ at all intervals). Initially, 100% of patients were in Grade 3. By Day 28, 50% achieved Grade 0 and 50% were in Grade 1. This indicates progressive granulation, reduced inflammation, and improved wound healing.

c) Wound Size

Mean wound size reduced from 2.25 (Before Treatment) to 0.2 (28th day), with improvement from 17.78%(BT) to 91.11% ($p < 0.005$ at 7th day; $p < 0.001$ thereafter). At baseline, 75% were in Grade 2 and 25% in Grade 3. By Day 28, 80% achieved Grade 0 and 20% were in Grade 1. This suggests enhanced granulation, epithelialization, and wound contraction.

Effect of therapy in Group B (Jatyadi Taila)

a) Pain

Mean pain score reduced from 2.95 (BT) to 0.15 (28th day), with relief improving from 28.81% to 94.92% ($p < 0.001$ at all intervals). At baseline, 95% were in Grade 3 and 5% in Grade 2. By Day 28, 85% achieved Grade 0 and 15% were in Grade 1. This indicates strong analgesic and healing effects of Jatyadi Taila.

b) Wound Colour

Mean score reduced from 3 (BT) to 0.4 (28th day), with improvement from 13.33% to 86.67% ($p < 0.01$ at all intervals). At baseline, all were in Grade 3. By Day 28, 65% achieved Grade 0 and 35% were in Grade 1. This reflects progressive granulation and reduced inflammation.

c) Wound Size

Mean wound size reduced from 2.45 (BT) to 0.35 (28th day), with improvement from 22.45% to 85.71% ($p < 0.001$ at all intervals). At baseline, 55% were in Grade 2 and 45% in Grade 3. By Day 28, 65% achieved Grade 0 and 35% were in Grade 1. This indicates effective wound contraction and healing.

Table: - Effect of therapy in patients of group-A

Symptoms	Mean score		% relief	z value	p value	Remark
	BT	AT				
Pain	2.95	0.1	96.61	4.234	0.000	HS

Size of wound	2.25	0.2	91.11	4.056	0.000	HS
Colour of wound	3.00	0.5	83.33	4.038	0.000	HS

Table: - Effect of therapy in patients of group- B

Symptoms	Mean score		% relief	z value	p value	Remark
	BT	AT				
Pain	2.95	0.15	94.92	4.179	0.000	HS
Size of wound	2.45	0.35	85.71	4.089	0.000	HS
Colour of wound	3.00	0.4	86.67	4.053	0.000	HS

Comparative Discussion Between Groups

Assessment Of Pain

Pain	Mean		Z value	p value	Remark
	Nimbadi Ointment	Jatyadi taila			
At 7 days	0.80	0.85	0.477	0.634	NS
At 14 days	1.55	1.55	0.000	1.000	NS
At 21 days	2.25	2.15	0.629	0.539	NS
At 28 days	2.85	2.80	0.411	0.681	NS

Assessment Of Colour Of Wound

Colour of wound	Mean		Z value	p value	Remark
	Nimbadi Ointment	Jatyadi taila			
At 7 days	0.50	0.40	0.628	0.530	NS
At 14 days	1.20	1.30	0.576	0.564	NS
At 21 days	1.65	1.90	1.244	0.213	NS
At 28 days	2.50	2.60	0.628	0.530	NS

Assessment Of Size Of Wound

Size of Wound	Mean		Z value	p value	Remark
	Nimbadi Ointment	Jatyadi taila			
At 7 days	0.40	0.55	0.938	0.348	NS
At 14 days	1.20	1.15	0.298	0.766	NS
At 21 days	1.35	1.55	1.049	0.294	NS
At 28 days	2.05	2.10	0.262	0.793	NS

Pain:

Both groups showed progressive improvement with no statistically significant difference at any follow-up ($p > 0.05$ at all intervals).

Wound Colour:

Both groups showed steady improvement with non-significant differences at all time points ($p > 0.05$).

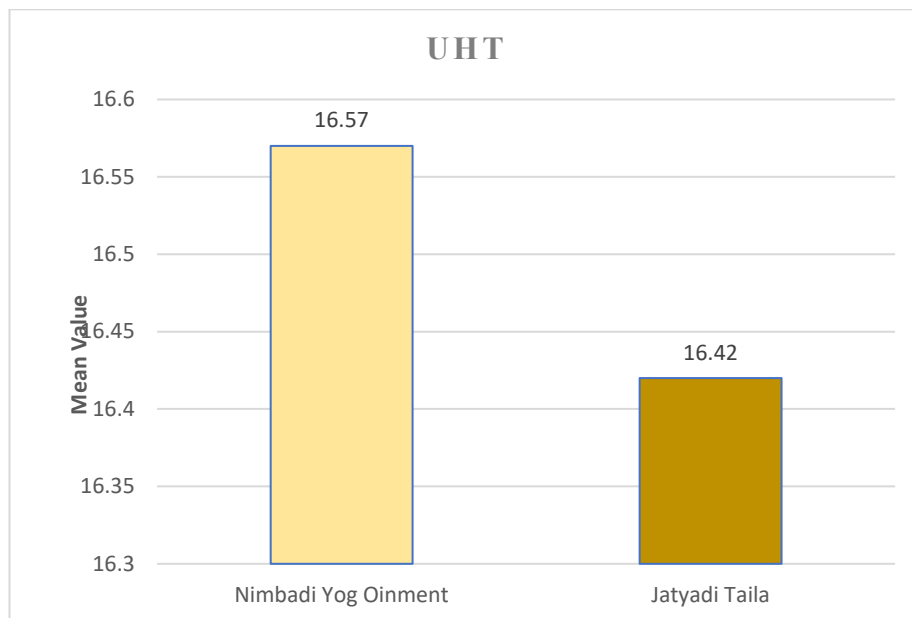
Wound Size:

Both groups demonstrated significant healing with no statistically significant intergroup difference ($p > 0.05$ at all intervals).

Overall, although Group A showed slightly better improvement in pain and wound size, differences were not significant, indicating comparable efficacy of both treatments in post-operative wound management following sentinel pile excision.

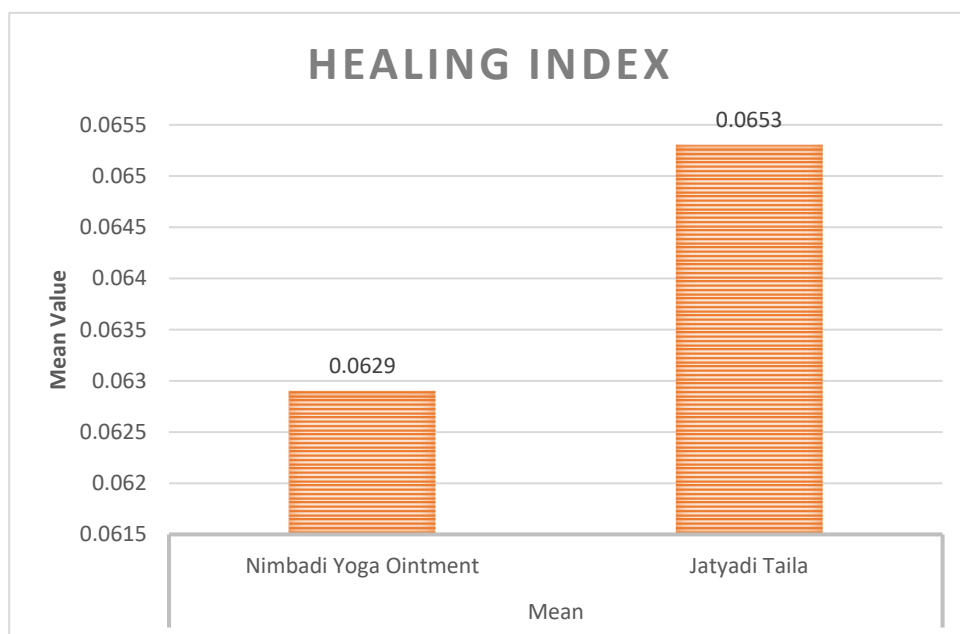
Unit Healing Time

Mean healing time was 16.57 days (Group A) and 16.42 days (Group B), with no significant difference ($p > 0.05$), indicating similar healing duration.



Healing Index

Mean Healing Index was 0.0629 (Group A) and 0.0653 (Group B), with no significant difference ($t = 0.483$, $p = 0.632$), indicating comparable healing efficiency.



Overall Effect of Therapy

Overall therapeutic response showed that in Group A, 50% achieved complete remission, 25% marked improvement, and 25% moderate improvement, with a mean improvement of 90.28%. In Group B, 60% achieved complete remission, 15% marked improvement, and 25% moderate improvement, with a mean improvement of 89.72%. No patient showed mild or no improvement in either group.

Result Classification	Group A (n%)	Group B (n%)
Complete Remission (100%)	10 (50%)	12 (60%)
Marked Improvement (75-99%)	5 (25%)	3 (15%)
Moderate Improvement (50-74%)	5 (25%)	5 (25%)
Mild Improvement (25-49%)	0 (00%)	0 (00%)
Unchanged ($\geq 25\%$)	0 (00%)	0 (00%)
Mean Overall Improvement	20 (90.28%)	20 (89.72%)

DISCUSSION

According to Yogratnakara, Nimbadi Yoga is indicated as a Lepana Yoga for Vrana. In the present study, its ointment form was used for postoperative wounds following sentinel pile excision. The formulation contains Nimba, Yashtimadhu, Daruharidra, and Krishna Tila, which collectively possess Vranashodhaka, Vranaropaka, Vedanasthapaka, Shothahara, Krimighna, Jantughna, and Varnya properties.

The predominant Tikta-Kashaya Rasa, Laghu-Ruksha-Tikshna Guna, Shita-Ushna Virya, and Katu-Madhura Vipaka contribute to wound cleansing, reduction of exudation, infection control and wound contraction. Madhura Rasa and Madhura Vipaka support Dhātu Poshana, granulation and epithelialization, while Shita Virya helps reduce pain and burning sensation. Thus, the formulation promotes Vrana Shodhana followed by Vrana Ropana and restoration of healthy skin.

Modern pharmacological correlation further supports these actions. Nimba contains nimbidin, nimbin, gedunin, quercetin and tannins with antimicrobial, anti-inflammatory, antioxidant and astringent effects. Daruharidra contains berberine and phenolic compounds that provide antimicrobial, anti-inflammatory and tissue-repair effects. Yashtimadhu contains glycyrrhizin, glabridin, liquiritin and flavonoids, which support anti-inflammatory, antioxidant, antimicrobial and epithelial-regenerative activities. Krishna Tila contains sesamin, sesamolin, tocopherols, linoleic acid, oleic acid and phytosterols, which support antioxidant protection, collagen formation, epithelialization and restoration of the skin barrier. Therefore, the synergistic Ayurvedic and pharmacological actions of Nimbadi Yoga may reduce pain, inflammation, exudation and microbial contamination, while promoting granulation, wound contraction, epithelialization and tissue regeneration, ultimately accelerating postoperative wound healing.

Inter-group comparison of pain, wound size, and wound colour also revealed non-significant differences ($p > 0.05$), indicating that both treatments were equally effective in promoting wound healing. However, Nimbadi Yoga Ointment showed slightly better improvement in pain relief and wound size reduction, while Jatyadi Taila demonstrated marginally better improvement in wound colour.

Overall, the study concludes that Nimbadi Yoga Ointment is as effective as Jatyadi Taila in the management of post-operative wounds of sentinel pile and can be considered a safe and effective wound-healing formulation.

CONCLUSION

Based on the observations and statistical analysis, both Nimbadi Yoga Ointment (Group A) and Jatyadi Taila (Group B) produced significant improvement in the clinical parameters of postoperative wound healing, particularly pain, wound size, and wound colour. The improvement observed within both groups was statistically highly significant.

Group A showed 96.61% improvement in pain and 91.11% reduction in wound size, whereas Group B showed 94.92% improvement in pain and 85.71% reduction in wound size. In wound colour, Group B showed slightly greater improvement (86.67%) compared with Group A (83.33%). However, the differences between the two groups were not statistically significant, indicating comparable efficacy of both treatment modalities.

The Unit Healing Time and Healing Index also demonstrated comparable results between the two groups, with no statistically significant intergroup difference.

From the Ayurvedic perspective, the efficacy of Nimbadi Yoga may be attributed to its Vranashodhana, Vranaropana, Shothahara, Vedanasthapana and Krimighna properties. The combined action of its ingredients—Nimba, Daruharidra, Yashtimadhu and Krishna Tila may contribute to wound cleansing, reduction of inflammation and microbial contamination, promotion of healthy granulation tissue and epithelialisation, and ultimately wound healing.

No adverse reactions or recurrence were observed during the treatment and follow-up period, suggesting that Nimbadi Yoga Ointment was safe and well tolerated.

Therefore, it can be concluded that Nimbadi Yoga Ointment is an effective and safe alternative to Jatyadi Taila for postoperative wound management after sentinel pile excision.

The favourable clinical response observed with Nimbadi Yoga Ointment supports its potential use as an alternative Ayurvedic topical formulation for postoperative wound management. Further studies with larger sample sizes, longer follow-up periods, randomized controlled designs, and objective wound-healing parameters are recommended to establish its efficacy more conclusively.

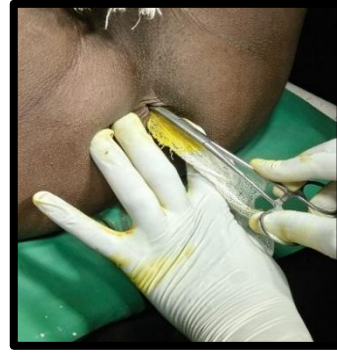
Case For Nimbadi Yoga Ointment



PRE-OPERATIVE



POST-OPERATIVE(DAY-0)



LOCAL APPLICATION OF
NIMBADI YOGA OINTMENT



DAY-7



DAY-14



DAY-21



DAY-28

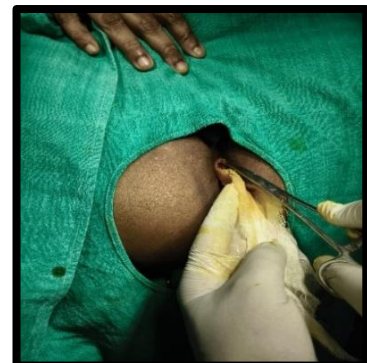
Case For Jatyadi Oil



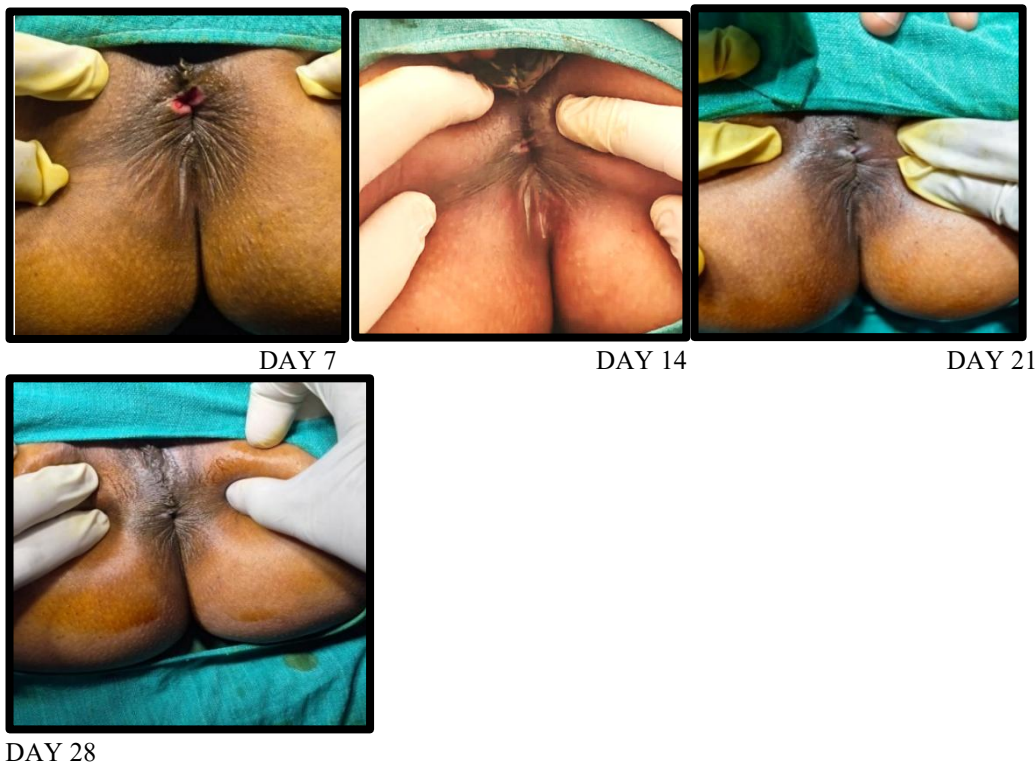
SENTINEL PILE AT 12' O CLOCK



EXCISION OF SENTINEL PILE
(DAY 0)



APPLICATION OF JATYADI OIL



DAY 7

DAY 14

DAY 21

DAY 28

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