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# "A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *NIMBAADI LEPA* IN THE MANAGEMENT OF *PRASUTAA YONI KSHATA* WITH SPECIAL REFERENCE TO EPISIOTOMY WOUND."

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## ABSTRACT

*Prasutaa Yoni Kshata* comes under the category of *Sadyovrana*, subcategorized as *Chinna / Kshta Vrana* (cut wound). Despite the rich blood supply of the perineum, which facilitates easy wound healing, there is still a risk of contamination by lochia, faeces, urine, etc., so there is a need for proper care of episiotomy wounds to avoid complications. **Study design:** An open-labelled randomised control clinical trial with pre-and post-test designs. **Materials and methods:** 40 Females who underwent normal vaginal delivery with episiotomy were selected and randomly divided into two groups of 20 each. In Group A, *Nimbaadi Lepa* was applied on the surface of a sutured episiotomy wound with 1/4th Angula (0.44cms approx.) thickness, and in Group B (control) *Kumari Majja* with *Haridra Lepa* was applied two times a day for seven days. Follow-ups: on the 7th and 15th day. **Results** obtained were tabulated and statistically analysed using the Friedman, Wilcoxon signed rank, and Mann- Whitney U tests. Both groups showed statistically significant results within the group. Comparison between 2 groups shows

*Nimbaadi Lepa* is slightly more effective than *Kumari Majja* with *Haridra Lepa*. **Conclusion:** Both the formulations proved effective on statistical value in terms of *Vrana shodhana*, *Vrana ropana*, *Vedanasthapana*, and *Shothahara* properties for episiotomy wound healing.

**Keywords:** Wound healing, Episiotomy, *Nimbaadi lepa*, *Kumari majja*, *Haridra*.

## INTRODUCTION

Labour is a strenuous event, painful but essential for standard delivery. Episiotomy is a surgically planned incision on the perineum and the posterior vaginal wall during the second stage of labour. It is performed to enlarge the vaginal introitus to facilitate easy and safe delivery of the fetus spontaneously or manipulative and to minimise overstretching and rupture of the perineal muscle and fascia.[1]

In developing countries, the episiotomy rates continue to be high.[2] Worldwide episiotomy rate is 27%. Among them, 54% are nulliparous, and 6% are multiparous women (WHO 2003). In India, the birth rate is very high 56% of women had episiotomy.[3] Vaginal secretions, lochia, faeces and urine can cause episiotomy wounds more susceptible to infections; However, the perineum has high vascularity, which promotes healing, but still proper care of episiotomy wounds must be taken. Post-natal complications were more common among women who had episiotomy compared to those who did not have episiotomy.[4] *Prasutaa yoni kshata chikitsa* has been explained in *Yogaratnakar*[5] and *Bhaavaprakash*[6]. *Prasutaa yoni kshata* can be co-related with episiotomy wounds, which is *China*/ *Kshata vrana*, a type of *Sadhyovrana*. Classics mention that Sadhyovrana should be treated with *Kashaya*, *madhura rasa*, *sheeta veerya*, and *snigdha Gunayukta dravyas* for one week.[7] *Acharya Vagbhata* mentioned *Lepana* and *Sadhana karma* with *Kashaya*, *madhura rasa*, *sheeta veerya*, and *snigdha guna dravyas*. For traumatic wounds, *Madhu* and *Sarpi* specially made use of and other treatment which mitigates *Pitta* and *Sheeta kriya* to promote healing.[8] *Aacharya Sharangadhara* mentioned the *Doshaghna* type of *Lepa* for *Vaata-Pittadi dosha prakopa janya Shothadi roga*, which should be applied in the 1/4$^{th}$ *Angula* thickness.[9] *Lepa* helps for better wound healing with minimal scar formation and controls pain.

**Objectives:**

To evaluate the efficacy of *Nimbaadi lepa* in *Shodhana* and *Ropana* of *Prasutaa yoni kshata* (*Sadyovrana*). The effect of *Nimbaadi lepa* will be compared with *Kumari majja* and *Haridra lepa.*

**Source of data:** Subjects fulfilling the inclusion criteria were selected from our hospital's IPD.

**Study design:**

It is a randomised control clinical trial with pre and post-test design. Women, irrespective of socio-economic status, religion and place, who underwent normal vaginal delivery with episiotomy were selected. In both groups, topical antibiotic ointment was replaced with *Lepa*.

**Sample size: 40**

**Selection criteria:**

**A) Inclusion criteria:**

- Women of the age group between 18-40 years.
- All Primi and multi gravida.
- Women who underwent normal vaginal delivery with episiotomy.

**B) Exclusion criteria:**

- Women with 3$^{rd}$ and 4th-degree perineal tears.
- Women suffering from any complications like a cervical tear or post-partum haemorrhage.
- Women suffering from any other systemic illness like Diabetes mellitus, Hypertension, etc.
- Women who have impaired wound healing due to altered coagulation mechanism.
- Women having hematoma or abscess in the vagina.
- Assisted labor like forceps delivery, Ventouse etc.

**C) Investigations:** CBC, CT, BT.

**D) Assessment criteria:**

**Subjective criteria:**

1. Perineal pain.

2. Pricking sensation at the region of wound.

**Objective criteria:**

1. The standard REEDA scale[10] (Redness, Edema, Ecchymosis, Discharge, Approximation).
2. Tenderness.

**Method of preparation:** For group A - All the ingredients of *Nimbaadi lepa* were taken in equal quantity in *churna* form and then mixed with honey and ghee to make a paste form. For group B - *Kumari majja* paste was sprinkled with *Haridra churna* made lukewarm by indirect heat of hot water and applied.

***Poorva karma*:** Under all aseptic precautions sutured episiotomy wound was washed with *sukhoshna jala* and dried up completely.

***Pradhaan karma:*** Patient was asked to lie down in lithotomic position and *Lepa* was applied on the wound in 1/4$^{th}$ *Angula* (0.44cm approx.) thickness and covered with gauze pad.

***Paschat karma:*** *Lepa* was removed slowly before it dries up completely with the help of wet gauze piece. Patient was advised to maintain local hygiene.

**Intervention**

| | GROUP – A | GROUP – B |
|---|---|---|
| Sample size | 20 Patients | 20 Patients |
| Medicine | External application of *Nimbaadi lepa* | External application of *Kumari majja* with *Haridra* |
| Dosage | 1/4$^{th}$ *Angula* thickness | 1/4$^{th}$ *Angula* thickness |
| Frequency | Two times a day | Two times a day |
| Duration of application | 7 Days | 7days |
| Total duration of the study trial | 15 Days | 15 Days |
| Follow-ups | 7$^{th}$ And 15$^{th}$ day | 7$^{th}$ And 15$^{th}$ day |

**Observation and results:**

**Statistical methods:**

**The Friedman test** and **Wilcoxon Signed Rank test** were applied to analyse the significance of parameters within the groups.

**The Mann- Whitney U test** was used to analyse the significance of parameters between the groups.

The obtained results were interpreted as:

- Non-significant (NS): if the p-value is > 0.05.
- Important (S): if the p-value is < 0.05.

Most patients, i.e., 24 (60%) included in this study, were primigravida, and 16 (40%) patients were multigravida. 8 (20%) patients were having *Mrudu kostha*, 30 (75%) patients were having *Madhyama kostha* and 2 (5%) patients were having *Krura kostha*.

**Showing the final status of wound healing**

| Parameters | Healing status | Group A (Total 20 Patients) | | Group B (Total 20 Patients) | |
|---|---|---|---|---|---|
| | | No. of patients | Percentage | No. of patients | Percentage |
| **Perineal pain** | Absent | 18 | 90% | 17 | 85% |
| | Present | 2 | 10% | 3 | 15% |
| **Pricking sensation** | Absent | 19 | 95% | 17 | 85% |
| | Present | 1 | 5% | 3 | 15% |
| **Redness** | Absent | 18 | 90% | 16 | 80% |
| | Present | 2 | 10% | 4 | 20% |
| **Edema** | Absent | 20 | 100% | 17 | 85% |
| | Present | 0 | 0% | 3 | 15% |
| **Ecchymosis** | Absent | 20 | 100% | 19 | 95% |
| | Present | 0 | 0% | 1 | 5% |

| | | | | | |
|---|---|---|---|---|---|
| **Discharge** | Absent | 19 | 95% | 17 | 85% |
| | Present | 1 | 5% | 3 | 15% |
| **Approximation** | Absent | 16 | 80% | 15 | 75% |
| | Present | 4 | 20% | 5 | 25% |
| **Tenderness** | Absent | 17 | 85% | 15 | 75% |
| | Present | 3 | 15% | 5 | 25% |

## DISCUSSION

Probable mode of action of *Lepa* for wound healing: After the application of *Lepa* over the sutured surface of wound the active principles of the ingredients of *Lepa* are released into the skin, further it enters *Romakupa* and gets absorbed through *Swedavaha srotas* and *Siramukha*. This leads to increase in the local blood circulation which removes *Sthanika Doshavruddhi* and acts as *Vrana shodhaka* and *Ropaka*. Synergistic action of all the ingredients of *Lepa* helps to pacify provoked *Doshas* at the region of wound and also reduces *Vedana*, *Shopha*, *Daha* etc. prevents infections and promotes wound healing.

**Ingredients and *Rasapanchaka* of *Nimbadi lepa*[11]**

| SR.NO. | INGREDIENT | BOTANICAL NAME | *RASA* | *VIRYA* | *VIPAAK* | *GUNA* | *KARMA* | PARTS USED |
|---|---|---|---|---|---|---|---|---|
| 1. | *NIMBA* | Azadirachta indica | *Tikta, Kashaya* | *Sheeta* | *Katu* | *Laghu* | *Vrana-shodhana, paachana, dahaprasamana, kandughna, Putihara* | *Patra* (Leaves) |
| 2. | *TILA* | Sesamum indicum | *Madhura* | *Ushna* | *Madhura* | *Guru, Snigdha* | *Vedana sthapana, Vrana- shodhana, ropana, Sandhaniya* | *Beeja* (Seeds) |
| 3. | *DARUHARIDRA* | Berberis aristata | *Tikta* | *Ushna* | *Katu* | *Laghu, Ruksha* | *Shothahara, Vedanasthapana, Vrana-ropana, shodhana* | *Twak* (Stem bark) |
| 4. | *YASHTIMADHU* | Glycyrrhiza glabra | *Madhura* | *Sheeta* | *Madhura* | *Guru, Snigdha* | *Vedanasthapana, Daaha shaamaka, shothahara* | *Moola* (Root) |
| 5. | *GHRITA* | | *Madhura* | *Sheeta* | *Madhura* | *Snigdha* | *Samskarasyaanuvartanam, Tridoshaghna, balya* | |
| 6. | *MADHU* | | *Madhura, Kashaaya* | *Sheeta* | *Madhura* | *Picchila, Ruksha, Laghu, Sukshma* | *Vrana ropana, Yogavahi, Grahi, Vilekhana* | |

***Rasa panchaka* of *Kumari majja* and *Haridra*[12]**

| SR. NO. | INGREDIENT | BOTANICAL NAME | *RASA* | *VIRYA* | *VIPAAK* | *GUNA* | *KARMA* | Parts used |
|---|---|---|---|---|---|---|---|---|
| 1. | *Kumari* | Aloe vera | *Katu* | *Sheeta* | *Tikta* | *Guru, Snigdha, Picchila* | *Shothahara, Vedanaasthaapan, Vranaropan* | *Majja* (Pulp) |
| 2. | *Haridra* | Curcuma longa | *Tikta, Katu* | *Ushna* | *Katu* | *Ruksha, Laghu* | *Shothahara, Vedanaasthaapan, Varnya, Vrana-Shodhana, Ropana.* | *Kaanda* (Rhizome) |

## CONCLUSION

In the present study, both the groups, i.e. Group A Nimbaadi lepa and Group B Kumari majja with Haridra lepa, proved effective in terms of wound healing within the group with statistically significant p value < 0.05. On comparing in between two groups the study has shown statistically non-significant results with p value > 0.05 but on overall assessment between the groups *Nimbaadi Lepa* was little more effective than *Kumari majja* with *Haridra lepa* with difference in mean rank on both subjective and objective parameters. Hence, it is concluded by rejecting the null hypothesis H0 and accepting the alternate hypothesis H3 – Nimbaadi lepa has a more significant effect than Kumari Majja with Haridra lepa in managing episiotomy wounds.

**Probable causes for delayed wound healing in the study:** Vigorous and straining activity. Constipation may lead to weakening and can cause wound gapping and delayed wound healing, so mild laxatives are preferred.

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