Assessment of Kukubhadi Malahar as a Prophylactic Antiseptic in Episiotomy Wounds: A Randomized Controlled Trial

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Abstract- Background: Episiotomy is a commonly performed surgical incision during the second stage of labor to facilitate childbirth and prevent severe perineal tears. However, episiotomy wounds are prone to infection, delayed healing, and maternal discomfort. In Ayurveda, Prasutaa Yoni Kshata is comparable to episiotomy wound and requires proper wound management. Kukubhadi Malahar is a classical Ayurvedic formulation indicated for wound care due to its Krimighna, Vrana Shodhana, and Vrana Ropana properties.

Aim: To evaluate the prophylactic antiseptic effect of Kukubhadi Malahar in comparison with Betadine ointment in the management of episiotomy wounds.

Materials and Methods: A randomized controlled clinical study was conducted on 40 postnatal women with episiotomy wounds following normal vaginal delivery at Govankop Nursing Home, Koppal. Patients were randomly divided into two groups of 20 each. Group A received Kukubhadi Malahar and Group B received Betadine ointment. Wound healing was assessed using the REEDA scale (Redness, Edema, Ecchymosis, Discharge, Approximation) and associated clinical parameters.

Results: Both groups showed statistically significant improvement in wound healing parameters. Intergroup comparison revealed no statistically significant difference ($p > 0.05$), indicating comparable efficacy.

Conclusion: Kukubhadi Malahar is equally effective as Betadine ointment in providing prophylactic antiseptic action and promoting healthy episiotomy wound healing without complications.

Keywords: Prasutaa Yoni Kshata, Episiotomy, Kukubhadi Malahar, Betadine Ointment, REEDA Scale.

I.INTRODUCTION

Women are blessed with producing progeny. The process of delivering a child is associated with prolonged pain and discomfort. To facilitate easy delivery, a surgical incision called episiotomy is given on the perineum, for the comfort of mother and fetus with an easy outcome 2nd stage of labour. This not only facilitates easy and safe delivery of the fetus, but also minimizes the chances of bleeding, laceration, and various degree of tears[1].

Ayurveda is the science of the general quality of health. It helps to balance all the 3 *doshas* and increases the body's ability to resist and recover from disease. *Ayurveda* views pregnancy as a very important time in a woman's life(2). Among the *Sutika rog* there is a reference of *yoni kshata, yoni shopha, yoni Shoola, and yonidosha*. In the case of *Prasuta yoni kshata,* it is *shastra kshata*, It is considered as *Shuddha Vrana* and to overcome this pain and promote good wound healing drugs that possess *Vranaropan* and *vedanasthapan* properties were selected.

Episiotomy is one of the most commonly performed procedures in obstetrics. It 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 so as to facilitate easy and safe delivery of the fetus spontaneously or manipulative and to minimize overstretching and rupture of the perineal muscle and fascia to reduce the stress and strain on the fetal head[3]. The rate of episiotomy was found to be 93.3% in primipara women and 30.2% in multipara women[4]

As the perineum is highly susceptible to infection due to different secretions like vaginal discharges, faeces, and urine. Episiotomy wound requires a proper intervention which could otherwise be self–limiting due to high vascularity of the perineal area. If not taken proper care of, episiotomy wound may lead to immediate complications like bleeding, infection, or

remote complications like dyspareunia, scar endometriosis or chances of perineal laceration in subsequent labour[5].

Episiotomy wound care should be started immediately after suturing the wound to reduce pain and inflammation. The surgical wound of episiotomy can be considered as *Sadyo Vrana*[6]. Different treatment modalities have been told in *Ayurveda* for *Vrana Chikitsa*. Drugs having *Shodhana, Ropana, and Vranasthapana* qualities are essential for healing[7].

A majority of normal deliveries are conducted at RHs or PHCs, with only a limited segment of the population receiving complete pre- and post-natal care. In this context, *Kukubhadi Malahara* has been selected for the present study. Since an episiotomy wound closely resembles *Prasuta Yoni Kshata*, its management can be considered under the principles of *Prasuta Yoni Kshata Chikitsa*.

To overcome this problem, I have selected this topic as the properties of this *Kukubhadi Malahar* is *Vranaropak, Vedanasthapak, Shothaghna, kledashoshak, krumighna* etc. and the contents are easily available and also easy to prepare, effective and cost-effective to patient.

"Hence, the present study was undertaken to evaluate the efficacy of Kukubhadi Malahar in the management of *Prasutaa Yoni Kshata* (Sadyovrana). The effect of Kukubhadi Malahar was also compared with Betadine ointment."

II.METHODOLGY

Trial design:

This study was an open-label randomized, comparative clinical trial designed to evaluate the prophylactic antiseptic effect of kukubhadi malhar with betadine ointment in the management of prasuta yonikshata.

The trial was conducted in the Govankop nursing home, Koppal

Participants:

A total of 40 patients presenting with episiotomy wound were recruited for the study with allocation ratio 1:1. The current study was approved by Shree Jagadguru Gavisiddeshwara ayurvedic medical college Institutional ethical committee (Ref.No/2023/448/15). Informed consent was obtained from each participant prior to recruitment. The trial was registered with the Central Trial Registry of India (CTRI/2025/06/).

Eligibility criteria for participants

Inclusion Criteria:

The patients of age group between 20-35 years. All primi and multi gravida. Women who underwent normal vaginal delivery with Episiotomy.

Exclusion Criteria:

Systemic disorder like Diabetes Mellitus, Hypertension, Pulmonary tuberculosis, Impaired thyroid Functions. Patients with serology positive for HIV, VDRL, HBsAg. Patients with perineal tear. Patients having perineal abscess. Patient with coagulopathies. Hb having less than 8 gm%.

Outcome measures:

Primary outcome: the primary outcome of *kukubhadi Malhar* was prophylactic antiseptic effect in episiotomy wound.

Intervention:

Sufficient quantity of kukubhadi malhar and betadine was applied over the episiotomy wound in Group A and Group B respectively and observed for the wound healing.

Method of drug preparation:

1 Part of *Kalka Dravya*, 4 parts of *Murchita Tila Taila* and 16 parts of *Kwatha Dravya* are to be mixed together and boiled on *Mandagni* till *Sneha Siddhi Lakshana.* Then it is filtered and stored. Then *Malahar* was prepared by adding *Sikhta* as a base in the *Taila* in the ratio of 1:6.

Randomization and Allocation:

Participants were randomly allocated into two groups using a simple randomization method. Group A (n = 20), received Kukubhadi Malhar and Group B (n = 20), Received Betadine ointment. Alteration of patients was done under supervision of guide. The estimated duration of the trial was 1year and trial ended by 3months prior to the estimated date with efficient procurement of required sources.

Statistical Analysis

Data were analyzed using appropriate statistical tests. The Wilcoxon sign rank test was applied within the group and the man whitney test was applied for intergroup comparision. A p-value of <0.05 was considered statistically significant.

III.ASSESSMENT AND ANALYSIS

1. Pain- Mankoski pain scale[8]

Pain free	0
Very minor occasional annoyance	1
Minor occasional, strong annoyance	2
Annoying enough to be distracting	3
Distracting but can be ignored if doing work	4
Can't be ignored for more than 30 minutes	5
Can't be ignored for any length of time but still can do daily activities	6
Makes it difficult to concentrate, interferes with sleep but can do daily activities with efforts	7
Physical activities severely limited, can read and talk with effortfully	8
Crying and moaning uncontrollably like delirium.	9
Unconcious	10

Objective Assessment:

2. REEDA Scale (An international scale to measure episiotomy wound)[9]

REDNESS	GRADE
None	0
Within 0.25 cm of incision	1
Within 0.5cm of incision bilaterally	2
Beyond 0.5cm of incision bilaterally	3
EDEMA	
None	0
Less than 1 cm	1
1-2 cm from incision	2
More than 2 cm from incision	3
ECCHYMOSIS	GRADE
None	0
Within 0.25 cm B/L or 0.5 cm U/L	1
Within 0.25 cm -1 cm B/L or 0.5 – 2 cm U/L	2
More than 1 cm bilaterally or more than 2 cm unilaterally	3
DISCHARGE	GRADE
None	0
Serous	1
Sero sanguineous	2
Bloody, purulent	3
APPROXIMATION	GRADE
Close	0
Skin separation< = 3mm	1
Skin and subcutaneous fat separated	2
Skin, subcutaneous fat and fascial layer separation	3

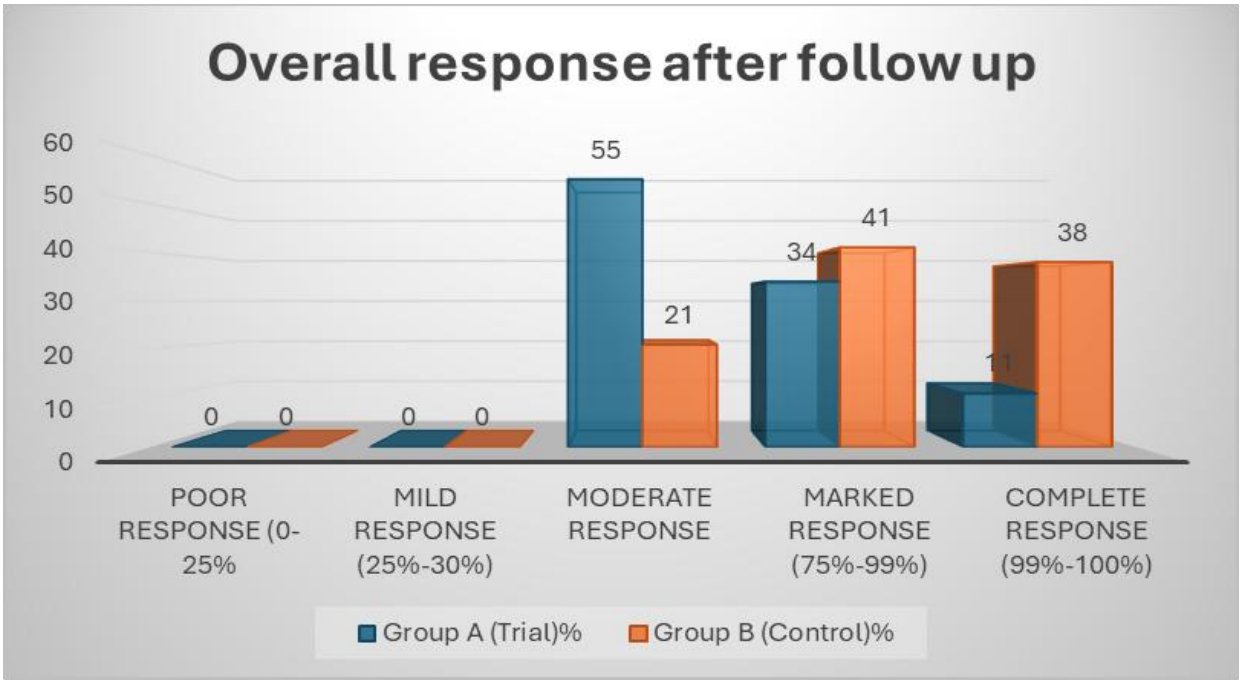
Observations:

Out of 40 patients included in the study, the majority belonged to the age group of 21–25 years (45%), followed by 26–30 years (32.5%). Most participants were Hindu (75%), housewives (42.5%), from middle socioeconomic class (57.5%), and urban residents (75%). A mixed diet was observed in 72.5% of patients. Regarding Prakruti, Vata-Kapha and Pitta-Kapha were predominant (37.5% each). Most patients had Madhyama Sara (62.5%), Madhyama Satwa (82.5%), Madhyama Samhanana (67.5%), and Madhyama Satmya (70%). Clinically, the majority were primigravida (around 60–70%) with regular bowel habits (77.5%). All patients (100%) had left

mediolateral episiotomy wounds, most commonly measuring 3.1–4 cm (57.5%). Pain, redness, edema, discharge, and proper wound approximation were present in all patients on Day 1, with gradual reduction in symptoms by Day 15, where pain was completely relieved in both groups. Ecchymosis was observed in 42.5% of patients initially. Overall, the baseline characteristics of both groups were comparable.

IV.RESULT & INTERPRETATION

Response Rates	Response	GROUP-A (Kukubhadi Malahar)		GROUP-B (Betadine ointment)		Mann-Whitney U Test
		Frequency	%	Frequency	%	Test Statistic Value
(0%-25%)	Poor Response	0	0%	0	0%	U 396
(25%-50%)	Mild Response	0	0%	0	0%	Effect Size 0.14
(50%-75%)	Moderate Response	16	55%	6	21%	Z 1.21
(75%-99%)	Marked Response	10	34%	12	41%	P 0.23 (>0.05)
(99%-100%)	Complete Response	3	11%	11	38%	Remarks NS
Total		29	100%	29	100%	NS - Non-Significant



In Group A (Kukubhadi Malahar), none of the patients exhibited poor or mild response to treatment. A majority of participants (55%) demonstrated a moderate response, while 34% showed a marked response and 11% achieved complete response. Thus, the majority of patients in this group fell within the moderate healing category, with relatively fewer attaining complete recovery.

In Group B (Betadine ointment), no patients exhibited poor or mild response. Moderate response was observed in 21% of patients, while 41% showed marked response and 38% achieved complete response. Hence, Betadine ointment was associated with a greater proportion of patients progressing to complete recovery when compared to Group A.

The comparison between the two groups using the Mann–Whitney U test (U = 396, Z = 1.21, p = 0.23) revealed that the difference in treatment response was not statistically significant. The calculated effect size (r = 0.14) indicated a small effect. Although Kukubhadi Malahar showed a higher proportion of moderate responses, Betadine ointment demonstrated a trend towards more complete responses; however, this difference was not significant.

V.DISCUSSION

Episiotomy wounds require effective antiseptic care to prevent infection and promote timely healing. In the present study, both Kukubhadi Malahar and Betadine ointment showed significant improvement in pain, redness, edema, ecchymosis, discharge, and wound approximation as assessed by the REEDA scale. The reduction in inflammatory signs and complete relief of pain by Day 15 in both groups indicate satisfactory wound healing. Intergroup comparison revealed no statistically significant difference, suggesting comparable efficacy of Kukubhadi Malahar with Betadine ointment. The observed effects of Kukubhadi Malahar may be attributed to its Krimighna, Vrana Shodhana, and Vrana Ropana properties, which help in preventing infection and enhancing tissue repair. Overall, the study supports the use of Kukubhadi Malahar as a safe and effective alternative for the management of Prasutaa Yoni Kshata (episiotomy wound).

VI.CONCLUSION

The present study concludes that Kukubhadi Malahar is as effective as Betadine ointment in the management of episiotomy wounds (Prasutaa Yoni Kshata). Both treatments produced statistically significant improvement in pain, redness, edema, ecchymosis, discharge, and wound healing parameters, with no significant difference between the groups in overall outcomes. Kukubhadi Malahar demonstrated effective antiseptic, anti-inflammatory, and wound healing properties, and was found to be safe and well tolerated. Therefore, Kukubhadi Malahar can be considered a reliable and effective alternative to conventional antiseptic therapy in episiotomy wound care.

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