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A Randomized Clinical Controlled Trial to Evaluate Post Episiotomy Analgesic Effect by Application of Nirgundi Taila and Yashtimadhu Taila

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Abstract

Background: Episiotomy is a surgically planned incision on the perineum and posterior vaginal wall during second stage of labour. The wound thus formed is associated with immense pain and discomfort and can affect maternal quality of life and mental health along with the mother and baby relationship. This wound can be compared to *Chinna vrana* (a type of S*adyovrana*) wherein Taila is one among the *Shashti upakrama* of management. Nirgundi does *Vatashamana* with its *ushna virya* and ultimately it does *vedananashana*. Hence present study was conducted to evaluate analgesic effect of *Nirgundi taila* in post-episiotomy period. *Objectives:* To evaluate analgesic effect of nirgundi taila in post-episiotomy period. *Methods:* 40 primigravida or multigravida who underwent episiotomy during normal vaginal delivery, admitted at KLEU's Ayurveda Hospital and Research centre, Shahapur, Belagavi were enrolled after informed consent and were randomly categorized into study group (*Nirgundi Taila* Application) and control group (*Yashtimadhu Taila* application). Pain was assessed in terms of Visual Analogue Scale (VAS) over a period of two-and-half hours at half hourly intervals. Collected data was analyzed using repeated measures ANOVA test and Tukey's Post hoc test. *Results:* Both the groups treated showed reduction in pain with the control group giving lasting effects. Statistical insignificant reduction in pain score was observed at 0, 30, 60 and 90 minute post application between the groups. However at 120 and 150 minutes post application, control group showed better result with t values 2.8($p<0.05$). Comparatively Yashtimadhu taila proved to decrease the quantum of pain more efficiently (67.56%). *Conclusion: Nirgundi taila* showed analgesic property in post-episiotomy period. But in comparison *Yashtimadhu taila* acted more effectively.

Keywords: Episiotomy; *Sadhyovrana*; *Nirgundi Taila*; *Yashtimadhu Taila*.

Introduction

Episiotomy is a surgically planned incision on the perineum and posterior vaginal wall during second stage of labour. The wound thus formed is associated with immense pain and discomfort and can affect maternal quality of life and mental health along with the mother and baby relationship. This wound can be compared to *Chinnavrana*(a type of S*adyovrana*) wherein Taila is one among the *Shashti upakrama* of management. Nirgundi does *Vatashamana* with its *ushnavirya* and ultimately it does *vedananashana*. Hence present study was conducted to evaluate analgesic effect of *Nirgunditaila* in post-episiotomy period.

Aims and Objectives

To evaluate analgesic effect of nirgunditaila in post-episiotomy period.

Materials and Methods

Source of Data

The subjects undergone normal vaginal delivery followed by episiotomy irrespective of their socio-economic status and religion were selected from IPD department of Shriroga & Prasootitantra of KLEU's Shri B.M.K. Ayurveda Hospital and Research Centre, Belagavi. The subjects were examined in detail as per proforma prepared for this study. Patients were

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further subjected to the following criteria of inclusion, exclusion.

Criteria for Selection of Patients

Inclusion Criteria of Clinical Trial

- Well informed consent
- All primi and multi gravida who underwent normal vaginal delivery with episiotomy
- Preterm labor
- IUGR.

Exclusion Criteria of Clinical Trial

- 3rd or 4th degree perineal tear.
- Perineal lacerations.
- Subject undergoing forcep and ventose delivery
- Delivery complications like Post Partum Hemorrhage and cervical tear.
- Subjects with eclampsia, bleeding disorders
- Subjects suffering from severe systemic diseases such as Bronchial asthma, Cardiac diseases, renal diseases, hormonal disorders etc.
- Subjects on Anti-depressant and Anti-psychotic drugs.
- K/C/O diabetes and hypertension
- Mentally retarded subjects.
- Subjects receiving regular medication containing any analgesic drug.

Research Design

Sample Size

40 subjects fulfilling the inclusion criteria were registered with the help of research proforma prepared for this study. They were randomly assigned into two groups i.e. Group 1 (Nirgunditaila pichu application) and Group 2 (Yashtimadhutaila pichu application) consisting of 20 subjects each.

Type of Randomization

Computerized block randomization

Study Design

Randomized Controlled Trial

Table 1: Study design groups

Group	Treatment	Duration
Trial	Nirgunditaila application	3 hrs
Control	Yashtimadhutaila application	3 hrs

Duration of Treatment

Pichu application was done once on post-operative period when subject starts complaining of pain.

Drugs

Nirgundipatra and moola were collected from natural habitat and swaras was prepared in GMP certified KLEU's Ayurveda Pharmacy, Khasbhag, Belagavi.Yashtimadhubharad and churna were procured fromGMP certified KLEU's Ayurveda Pharmacy, Khasbhag, Belagavi. The drugs were authenticated at Central Research Facility of K.L.E'S Shri. B. M. K. Ayurveda Mahavidyalaya, Belagavi.

Preparation of Taila

NirgundiTaila and Yashtimadhutaila were prepared as per classics in the ratio of 1:4:16 parts.

Nirgunditaila Contents [1,2]

Ingredients	Quantity
Nirgundimula and *patra (Kalka dravya)*	500gm
MurchitaTilaTaila (Snehadravya)	2 liter
Nirgundipatraswarasa (Drava dravya)	8 liter

Yashtimadhutaila Contents [3]

Ingredients	Quantity
Yashtimadhuchurna (Kalka dravya)	500gm
MurchitaTilaTaila (Snehadravya)	2 liters
Yashtimadhubharadakashaya (Drava dravya)	8 liters

Application of Pichu

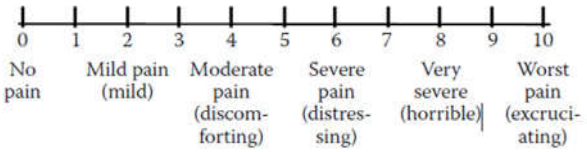
Patient was asked to lie in a Lithotomy position over lithotomy table. Painting was done with Povidone iodine solution around anal verge followed by draping with surgical hole towel. Application of pichu over the wound - Gauze (8×10 cms) soaked into the autoclaved taila is applied over the episiotomy wound. And gauze is kept over it.

The pichu was left in situ for 3 hrs which provides a sealing effect. Micro-pore plastering is done to keep gauze in situ. Then the patient is asked to sleep in supine position for 10 minutes.

Assessment Criteria

Post analgesia, pain was assessed by subjective

parameter - VAS (0-10) when subject complained of pain for first time.



Pain was assessed at 0th hour and subsequently for next 150 minutes of interval 30 minutes:

TIME	VAS
0thhr	
30 min	
60 min	
90 min	
120 min	
150 min	

Observations and Results

Table 2: Reduction in pain at different time

Time	Group 1 (in percentage)	Group 2 (in percentage)
0 thhr	00	00
30 min	18.75%	20.27%
60 min	27.50%	31.08%
90 min	47.50%	48.64%
120 min	47.50%	62.16%
150 min	52.50%	67.56%

Table 3: Showing the effect of therapy on pain

Treatment	Nirgunditaila application	Yashtimadhutaila application	Difference	Standard Deviation A	Standard Deviation B	95% CI of diff.	t	P value	Summary
0	8.0	7.4	0.60	3.0983	1.2806	-0.74 to 1.9	1.2	P > 0.05	ns
30	6.5	5.9	0.60	1.5329	1.6093	-0.74 to 1.9	1.2	P > 0.05	ns
60	5.8	5.1	0.70	1.7776	1.4798	-0.64 to 2.0	1.4	P > 0.05	ns
90	4.2	3.8	0.40	1.7776	1.4	-0.94 to 1.7	0.79	P > 0.05	ns
120	4.2	2.8	1.4	1.53623	1.3266	0.058 to 2.7	2.8	P < 0.05	*
150	3.8	2.4	1.4	1.6613	1.6248	0.058 to 2.7	2.8	P < 0.05	*

Table 4: Effect of therapy on pain within the groups

	0-30	0-60	0-90	0-120	0-150	30-60	30-90	30-120	30-150	60-90	60-120	60-150	90-120	90-150	120-150
NirgundiTaila	***	***	***	***	***	NS	***	***	***	***	***	***	NS	NS	NS
YashtimadhuTaila	***	***	***	***	***	NS	***	***	***	**	***	***	*	***	NS

This table shows statistical comparison of difference in mean of VAS Scale between & within the groups by applying RM Two Way Anova test, p-values.

Discussion

Effect of Therapy on Pain

It can be concluded that the reduction in the pain between the groups was statistically insignificant at 0, 30, 60 and 90 minutes of post application in both groups.

However at 120 and 150 minutes post application, significant reduction in the pain was observed in the control group (YashtimadhuTaila) with t values 2.8($p<0.05$).Thus, proving *Yashtimadhutaila* as a better formulation in post-operative pain management.

As episiotomy is a *sadyovrana* there is involvement of *Pitta dosha* along with *Vata* and *Rakta*. *Yashtimadhutaila* does *Pitta-Vatashamana* with its *sheetaveerya* and *snigdhaguna*.

Glycyrrhizin a glycoside obtained from G. glabra has proven anti-inflammatory and anti-arthritic properties which can be awarded the above said results. Though Nirgunditaila application has also shown some improvement in the pain reduction but it is statistically insignificant. Therefore it can also be concluded that the active principles in G. glabra are more potent than the control drug.

Discusion on Action

Taila as a base probably extracts or hold lipid soluble active fractions from the ingredients used and because of its vyavayi, vikasi & sukshmaguna, it might help in reaching the minute channels by means of its sukshma, vyavayi, vikasiguna and show it's action.

Prostaglandins (PGs) play significant role in different phases of inflammatory reactions. PGs elicit pain by direct stimulation of sensory nerve endings and also sensitize sensory nerve endings to other pain provoking stimuli [4].

Yashtimadhutaila exhibited decrease in pain which may be attributed due to presence of phenolic

constituents like flavonoids and other bioactive compounds like saponins. Literature review reveals that *glycyrrhizaglabra*contains several flavonoids, isoflavonoids and triterpinesaponins which have analgesic activity [5,6,7].

Presence of various flavonoid compounds were reported in the leaves of V. Negundo [8]. Flavonoids are known to inhibit the enzyme prostaglandin synthetase, more specifically the endoperoxidase [9] and reported to produce significant anti-inflammatory effect [10]. Alcaraz MJ, Jimenez MI. Flavonoids as anti-inflammatory agents. Fitoterapia. 1988; 59:2 5-38.

Photographs

Fig. 1: Tray for pichu application

Fig. 1: Pichu application over episiotomy wound

Fig. 3: Painting and draping of episiotomy wound

Since prostaglandins are involved in the pain perception and are inhibited by flavonoids, it could be suggested that reduced availability of prostaglandins caused by flavonoids of V.negundo might be responsible for its analgesic effect.

Conclusion

- Nirgunditaila have shown analgesic effect.
- Both the drugs have shown significant effect in post episiotomy pain management; however the trial drug (Nirgunditaila) is comparatively less efficient than the control drug (Yashtimadhu Taila).

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