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A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF ROPANA TAILA AND JATYADI TAILA ON EPISIOTOMY WOUND

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ABSTRACT

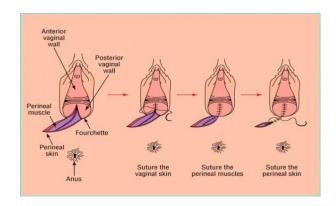
Ensuring healthy and safe motherhood with utmost care rendered to every women is the outright responsibility of an Obstetrician. Episiotomy is performed almost as routine in cases of vaginal delivery to cut short the 2nd stage of labour and to prevent irregular tears. Yoniprasarana^[1] explained in our classics can be achieved through medicaments or surgical procedures like Utkartana Karma^[2] are beneficial in this regard. The wound thus formed after an Episiotomy^[3] is associated with immense pain and discomfort and seeks appropriate medical care and attention. If ignored it may lead to various Puerperal infections that are costly in terms of delayed mother infant interaction, lactation difficulties and prolonged hospital stay. Hence the present study was conducted to ensure faster and healthy healing of the Episiotomy wound by utilizing Ropana Taila^[4] as trial drug. The efficacy of the drug was compared with Jatyadi Taila^[5] which is a very well-known formulation advised for vrana.

KEYWORDS: Utkartana, Episiotomy Wound, RopanaTaila, JatyadiTaila, Vrana.

INTRODUCTION

Pregnancy and puerperium are the two events that prove to be boon and bane in any woman's life. The most beautiful facet of life is reproduction and continuation of the cycle and thereby the mother attains unique capacities and true nobility through childbirth. Our Acharyas have elaborated many measures to ensure Sukhaprasava. One such measure is Yoni Prasarana mentioned in cases of perineal insufficiency during prasava by Acharya Vagbhata. Yoni prasarana can be achieved either by dilating with the fingers or by making an incision on the perineum. In Mudhagarbhachikitsa, Utkartana karma is mentioned as one of the shalyachikitsa. This can be taken as the Episiotomy, a surgically planned incision on the perineum and posterior vaginal wall, done during second stage of labour. In India the overall rate of episiotomy was 40.6% in 2003. [6] The episiotomy rate in Karnataka is very high. It is about 88% in women who are undergoing difficult labour. In Bangalore, rates of episiotomy for vaginal birth ranges from 31% to 75%. [7] A current medical literature documented that 60% of women with episiotomies reported severe postpartum pain, 25% experienced infection at the site and 20% had problems during intercourse for up to 3 months after child birth. [8] Hence it is evident that special care must be taken to prevent infection, hasten healing and reduce scar. Although relatively small in size, an episiotomy wound can cause considerable discomfort because the perineum is an extremely tender area owing to rich nerve supply.

The muscles of the perineum are involved in many activities like (sitting, walking, squatting, bending, urinating, and defecating), which are affected by the complications of the Episiotomy wound. The Episiotomy wound can pose a problem in healing, being present nearer to all the flushing outlets of the body, it threatens for infections and further complications like wound dehiscence and healing by secondary intension causes fibrosis. Healing by fibrosis causes rigidity of perineum predisposing to dyspareunia, subsequent difficult deliveries in women. Puerperal infections are costly in terms of delayed mother infant interaction, lactation difficulties, prolonged hospital stay or readmission to hospital and increased expenses. Thus, in the present study, a sincere attempt was made to hasten the rate of Episiotomy wound healing, by the application of Ropanataila in Group A and JatyadiTaila in Group B.



AIMS AND OBJECTIVES

- To evaluate the effect of RopanaTaila on Episiotomy wound.
- To evaluate the effect of JatyadiTaila on Episiotomy wound.
- To compare the efficacy of both the groups.

MATERIALS AND METHODS

• 40 patients with sutured Episiotomy wound following normal vaginal delivery, were randomly selected form IPD of Prasooti Tantra Evam StreeRoga Department of SKAMCH and RC, Bangalore.

METHOD OF COLLECTION OF DATA

- A case proforma specially designed with all points of history taking, physical signs and lab investigations as mentioned in text.
- The parameters of signs and symptoms were scored as mentioned in the proforma.

INCLUSION CRITERIA

- All Primi and Multi Gravida who undergo normal vaginal delivery with Episiotomy
- Forceps delivery, ventose delivery

EXCLUSION CRITERIA

- 3rd or 4th degree perineal tear.
- Perineal lacerations.
- Delivery complications like PPH and cervical tear.

Any systemic diseases that interfere normal wound healing

Table 1: Showing laboratory investigations included for the study.

Blood for Hemoglobin %
Random Blood Sugar
Bleeding time
Clotting time
VDRL
HIV
HBsAg
Blood grouping& Rh typing

INTERVENTION

- **Group A:** Application of RopanaTaila twice daily for 7 days taking all aseptic precautionary measures.
- Time of application- applied once in the morning and once in the evening.
- **Group B:** Application of JatyadiTaila twice daily for 7 days taking all aseptic precautionary measures.
- Time of application- applied once in the morning and once in the evening.

Method of Drug preparation

Table 2: Showing ingredients of Ropanataila.

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Tagara	Valerianawallichii
Agaru	Aquilaria agallocha
Devadaru	Cedrus deodara
Haridra	Curcuma longa
Daruharidra	Berberis aristata
Lodhra	Symplocos racemose
Priyangu	Agalaiaelaeagnoidea
Taila	Sesame (Sesamum indicum) oil
Jala	Water

Table 3: Showing ingredients of Jatyaditaila.

Jati	Myristica fragrans
Nimba	Azadirachta indica
Patola	Stereospermumsauveolens
Naktamala	Leaves of Pongamia pinnata
Sikta	Bee wax
Madhuka	Glycyrrhiza glabra
Kushta	Saussurealappa
Haridra	Curcuma longa
Daruharidra	Berberis aristata
Manjishta	Rubia cordifolia
Katurohini	Picrorizhakurroa
Padmaka	Prunus puddum
Lodhra	Symplocos racemose
Abhaya	Terminalia chebula
Nilotphala	Nymphaea stellata
Tuttha	Copper sulphate
Sariva	Hemidesmus indicus
Naktamalabeeja	Seeds of Pongamia pinnata
Taila	Sesame (Sesamum indicum) oil
Jala	Water

ROPANA TAILA is an unique formulation of Ayurveda explained by Acharya Sushruta in vranaropana& JATYADI TAILA is a formulation best described in vranaropana by Acharya Sharangadhara in Madhyama

khanda, both were prepared by authentic tailapakavidhi of Ayurveda.

Method of drug application

- ♣ Group A: RopanaTaila application –about 5ml of Taila was taken on a sterile cotton gauze and applied over the wound area.
- Group B: JatyadiTaila application –about 5ml of Taila was taken on a sterile cotton gauze and applied over the wound area.
- Post-test was done on 7th day.

• **Follow- Up**: was done on the 14th and the 21st day.

Total duration of study: 21days

Assessment was done during the treatment and after the treatment considering the following subjective and objective parameters:

SUBJECTIVE PARAMETERS

Table 4: Showing Assessment criteria.

1.PAIN	
No pain	0
Localized pain during movement but tolerable	1
Localized pain during movement which effects the movement	2
Localized pain during rest but not disturbing the sleep	3
2.PRICKING SENSATION	YES/NO
3. TENDERNESS	
No pain	0
Tenderness on applying pressure	1
tenderness when touched along with finger	2
Tenderness on touching soft area	3
4. INFLAMMATION	
No swelling	0
Slight without discoloration	1
Slight red, tender and pain during movements	2
More red, having painful movements along with local temperature	3
5.ODOUR	
No odour	0
Mild odour	1
Offensive odour	2
Foul	3
6.DISCHARGE	
None	0
Scanty	1
Less	2
Moderate	3

OBJECTIVE PARAMETERS

Size of the Vrana was measured in cm with a special graduated scale designed for the study



Table 5: Showing REEDA SCALE parameters. [9]

Parameter	Finding	Score				
	None	0				
1. Redness	within 0.25 cm of the incision bilaterally					
	within 0.50 cm of the incision bilaterally	2				
	beyond 0.50 cm of the incision bilaterally	3				
	None	0				
2 Edomo	perineal, < 1 cm from the incision	1				
2. Edema	perineal and/or vulvar, 1-2 cm from the incision	2				
	perineal and/or vulvar, > 2 cm from the incision	3				
	None	0				
2 Fachymagia	Serum	1				
3. Ecchymosis	Serosanguinous	2				
	bloody, purulent	3				
	Closed	0				
4. Approximation	skin separation <= 3 mm	1				
	skin and subcutaneous fat separated	2				
	skin, subcutaneous fat and fascial layer separation	3				
Total Score						

Minimum score: 0 Maximum score: 15

Higher the score, more severe the perineal trauma

STATISTICAL ANALYSIS

- For the statistical analysis, the data obtained was recorded, presented in tabulations and drawings.
- The Statistic Mean, Standard Deviation (SD), Standard Error of Mean (SEM) were employed for descriptive statistics.
- To infer the clinical study and draw conclusion, unpaired 't' test was applied for between the group analysis
- Contingency table analysis and Repeated measure ANOVA using SPSS for Windows Software for objective parameters.
- The corresponding p value was noted and the obtained results were interpreted as:

Table 6: Showing Interpretation of statistical results.

Interpretation	P value
Not Significant	>0.05
Significant	< 0.05
Highly Significant	<0.01, <0.001

Table 7: Showing results on observations.

Parameter	Observation	%
Age	21-25years	47.5%
Socio Economic Status	Poor class	55 %
Diet	mixed diet	82.5 %
Prakruti	Vata-Pitta Prakruti	45 %
Saara	MadhyamaSaara	87.5 %
Satwa	MadhyamaSatwa	65 %
Samhanana	MadhyamaSamhanana	82.5%
Satmya	PravaraSatmya	87.5%
Aahara shakti	PravaraAharaShakti	82.5 %
Vyayama Shakti	MadhyamaVyayama Shakti	80%
Parity	Primi para	67.5 %
Gapping of wound	Absent	95 %
Size of wound	3.1-4cm	45%

Table 8: Showing The Effect Of Treatment On Pain.

Comparison of effect of Treatment on Pain between the Group A and Group B

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PARAMETER	Unpaired- t test									
	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks	
Pain	DAY 1(BT)	Group A	2.30	±0.57	0.128	0.1860	1.344	0.187	N.S.	
		Group B	2.55	±0.61	0.135					
	DAY 7(AT)	Group A	0.20	±0.41	.092	0.1232	0.406	0.687	N.S.	
		Group B	0.15	±0.37	.082					
		Group B	0	0	0					

Table 9: Showing The Effect Of Treatment On Tenderness.

Comparison of the effect of treatment on Tenderness between Group A and Group B

DADAMETED	Unpaired t test									
PARAMETER	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks	
	DAV 1/DT)	Group A	2.00	±0.459	0.103	0.1604	1.561	0.127	NS	
	DAY 1(BT)	Group B	2.25	±0.550	0.123	0.1004	1.301	0.127		
	DAY 7(AT)	Group A	0.05	±0.224	0.05	0.05	1.000	0.324	NS	
TENDERNESS		Group B	0.00	±0.000	0.00					
TENDERNESS	DAY14(FU1)	Group A	0.05	±0.224	0.05	0.05	1.000	0.324	NS	
		Group B	0.00	±0.000	0.00					
	DAV 21(EH2)	Group A	0.05	±0.224	0.05	0.05	1.000	0.324	NS	
	DAY 21(FU2)	Group B	0.00	±0.000	0.00	0.05	1.000			

Table 10: Showing The Effect Of Treatment On Inflammation.

Comparison of the effect of treatment on Inflammation between Group A and Group B

PARAMETER	Unpaired t –Test										
	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks		
INFLAMMATION	DAY 1(BT)	Group A	1.10	±0.31	0.69	0.1554	4.549	13.07	VH.S		
		Group B	1.80	±0.62	0.138						

Table 11: Showing The Effect Of Treatment On Odour.

Comparison of the effect of treatment Odour between Group A and Group B

PARAMETER	Unpaired t –Test										
	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks		
ODOUR	DAY 1(BT)	Group A	1.10	±0.31	0.069	0.08521	0.588	0.553	N.S		
		Group B	1.05	±0.0.24	0.050						

Table 12: Showing The Effect Of Treatment On Discharge.

Comparison of The Effect of Treatment Discharge Between Group A And Group B

PARAMETER	Unpaired t-Test									
PARAMETER	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks	
DISCHARCE	DAY	Group A	1.10	±0.31	0.069	0.08521	1.763	0.086	N.S	
DISCHARGE	1(BT)	Group B	0.95	±0.0.22	0.050					

Table 13: Showing The Effect Of Treatment W.R.T. Reeda Scale.

Comparison of The Effect of Treatment W.R.T. Reeda Scale Between Group A and Group B.

Parameter	Unpaired t- Test								
	Treatment	Group	Mean	SD	SE	PSE	t value	p value	Remarks
REEDA Scores	DAY 1(BT)	Group A	4.65	±1.14	0.254	0.39537	0.253	0.802	NS
		Group B	4.55	±1.36	0.303				
	DAY 7(AT)	Group A	0.05	±0.22	0.050	0.5237	0.065	0.365	NS
		Group B	0.20	±0.69	0.156				
	DAY14(FU1)	Group A	0.00	±0.00	0.00	0.3162	1.000	0.324	NS
		Group B	0.10	±0.447	0.100				
	DAY 21(FU 2)	Group A	0.00	±0.00	0.00	0.3162	1.000	0.324	NS
		Group B	0.10	±0.447	0.100				

DISCUSSION

The process of labour is so unpredictable and obstetrician needs to have keen observation and act according to the need of the situation. Hence a planned incision i.e., Episiotomy, prevents irregular tears of the perineum and vagina.

Yonikshata, yoni vibhinna are some of the Sootikavyadhis having explanations of irregular perineal tears that occur during prasava. Very limited references regarding utility of shastra karma during prasava are available in our classics. In the MudhagarbhaChikitsa,

where a surgical procedure –Utkartana is mentioned, very well suits the present-day description of an Episiotomy.

Utkartana

"urdwasyakasyachidangasyachedhanam" — meaning cutting of the organ which is obstructing and that organ which impedes the rate and process of delivery is the perineum. Thus, chedhana is necessary to facilitate and quicken the process of labour.

Effect of Treatment in Healing of The Wound: The healing process of this vrana is good as it is done in young women and it located in prajanana (genital area)

which is a site for sukhasadhyavrana. Along with this Aahara and Vihara also play a great role. The rich vascularity to the region also favors the wound healing. This sukha sadyavrana may turn to krichrasadya or asadhyavrana if proper care is not given. Sadhyovrana is devoid of the doshas and only after a span of 7 days they become doshajavrana. Explaining the tender condition of Sutika, it is said that, it is just like taking care of an old and dirty cloth which cannot be washed vigorously. Any roga occurring in sutika are krichrasaadya as the women would have become emaciated due to pravahanavedhana and nisrithi of kleda and rakta leading to Dhatu Shaithilva. VataPrakopa, Agnimaandya ShunyaSharira-avasta.

Proper care of the Episiotomy wound, which is already associated with a lot of pain, is of utmost importance as the perineal area is highly contaminated with lochia, feces and urine. Improper care would lead to immediate complications like infection, hematoma, dehiscence and remote complications like incontinence of urine, incontinence of flatus, rectovaginal fistula and many more may occur

Effect of Treatment on Pain: JatyadiTaila had better effect on Pain when compared to RopanaTaila as t value in Group B is higher than t value in Group A.

Reduction in pain was observed in both groups as Taila is best Vatashamaka. Tagara, Devadaru and Priyangu in RopanaTaila and in JatyadiTaila drugs like Abhaya, Tuttha, Sariva have vedanastapana and shoolaprashamana action.

In both Tailas, the drugs having Vranashodhana and Ropana karma are present, all these drugs have Ushnaveerya. Due to Ushnaveerya of these drugs pachana karma is seen, as quoted by Dalhana 'PachanamVranadinam'.This helps in proper blood supply to the wound area and thus relieves pain.

JatyadiTaila may have a better effect on pain as the ushnaveerya drugs are more compared to RopanaTaila.

Effect of Treatment on Tenderness: Both RopanaTaila and JatyadiTaila had same effect on tenderness

JatyadiTaila has better effect on Tenderness when compared to RopanaTaila as t value in Group B is higher than t value in Group A. In Group A, one patient a small of the sutured area the suture material had not fallen off which caused tenderness on touch. Once the suture material was removed the wound healed well.

Reduction in Tenderness is observed in both groups as Taila is best Vatashamaka and yoni vishodhaka.

Vranashodhana and Ropana action are mainly seen in all drugs of both the Taila.

Twakdoshahara, Dahaprashamana, krimighna drugs are more in JatyadiTaila

Sikta is Bhutagna, Tuttha is has very good Lekhana property. All these helps in checking the infection though, the wound is situated in the perineum which is prone to contamination. Hence, JatyadiTaila has better effect on Tenderness.

Effect of Treatment on Inflammation: RopanaTaila had better effect on Inflammation when compared to JatyadiTaila.

All the drugs i.e., Tagara, Agaru, Devadaru, Haridra, Daruharidra, Lodhra and Priyangu in RopanaTaila and in JatyadiTailaDaruharidra, Abhaya, Manjishta, Naktamalabeeja have shothahara property.

Priyangu and Lodhra in RopanaTaila and Yashtimadhu in JatyadiTaila haveDahaprashamana property. This subsides the raised temperature due to inflammation at the wound site.

Daruharidra and Devadaru are specifically mentioned in SutikaVranaRopana. This must have led to better results with RopanaTaila

Effect of Treatment on Odour of Wound: Both RopanaTaila and JatyadiTaila had same effect on odour JatyadiTaila has better effect on odour when compared to RopanaTaila as t value in Group B is higher than t value in Group A.

Odour at the wound site was evident as the wound is situated in the perenium which is prone to contamination. It was bit difficult to differentiate the odour between the Lochialodour, fecal odour and odour of the urine.

Still the wound area had a distinct odour which was mild. Drugs like Jati, Agaru, Devadaru, Naktamala, Haridra, Kushta have properties like Twakdosha hara.

Priyangu-dourgandhyanashaka property.

Haridra and Lodhra have Yoni doshahara property.

Drugs like Nimba, Devadaru, Haridra, Daruharidra have krimihara property which helps is combating the infection and thus maintain the area aseptic

Katukarohini-Raktashodhaka property.

All the drugs have VranaShodhaka and Ropana property hence eliminates the odour at the wound site.

Effect of Treatment on Discharge From Wound: RopanaTaila and JatyadiTaila had same effect on odour

Hence JatyadiTaila has better effect on Discharge when compared to RopanaTaila as t value in Group B is higher than t value in Group A.

Discharge from a sutured wound is minimum, but is an important indicator of the healing process and also of infection at wound site.

Drugs like Tagara, Agaru, Haridra, Daruharidra and Devadaru in RopanaTaila and Jati,Patola, Naktamala, Kushta, Katukarohini, Manjishta, Abhaya and Tuttha in JatyadiTaila and TilaTaila, the base drug in both the Tailas have ushnaveerya and have Kashaya, Katu as pradhana rasa. This helps in reducing the amount of discharge

In JatyadiTaila the number of drugs having Ushnaveerya, Kashaya Rasa are more, hence it is proved to better.

Effect of Treatment on Assessment Through Reeda Scale: RopanaTaila was better than JatyadiTaila.

TilaTaila is Yonivishodhaka. and most of the drugs in both the Tailas are VranaShodhaka and Ropaka, hence in

both the groups the wounds have healed well on time and have a healthy scar.

Drugs like Tagara, Agaru, Devadaru and Priyangu are the drugs that are exclusively present in RopanaTaila.

Tagara and Priyangu are vishagna

Agaru is Dushtavrananashaka

Devadaru is specifically mentioned as a drug used in Sutikaroga.

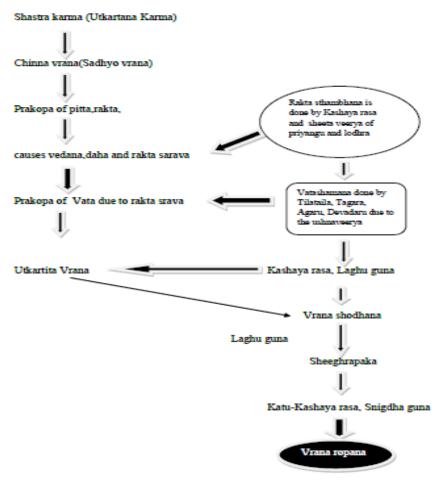
Priyangu is Dourgandhyanashaka

Apart from the above mentioned actions these drugs also possess the following pharmacological actions

 Tagara, Agaru, Devadaru, Haridra, Daruharidra, Priyangu and Lodhra have Anti inflammatory action.

- Agaru, Devadaru and Haridra have Antiseptic activity.
- Lodhra, Daruharidra and Priyangu have Anticoagulant and Haemostatic action.
- Haridra, Agaru, Tagara, Haridra and Devadaru have Analgesic activity.
- Devadaru, Tagara, Daruharidra and Haridra have Antibacterial action.
- Haridra has Anti histaminic and Antiprotozoal activity.
- Haridra and Devadaru have Antifungal action.
- All these factors have helped to show that Ropanataila had better effect on Episiotomy wound healing compared to JatyadiTaila when assessed with REEDA Scale.

Schematic representation of Probable Mode of action



CONCLUSION

In the present study 40 patients who underwent normal vaginal delivery with sutured episiotomy wound were taken for the study. Based on the clinical observations of the Episiotomy wound healing, following conclusions can be drawn.

- 1. The trial drug RopanaTaila was more effective on the patients in the age group of 21-25 (47.5%), on patients with Hb% of at least 10g%.
- 2. The clinical study was conducted using the REEDA Scale (Redness, Edema, Echymosis, Discharge, Approximation) which is an internationally accepted scale to assess episiotomy wound healing. Both the drugs showed statistically Highly Significant results with P value 0.000 when assessed with this scale but in comparisionRopanaTaila proved to be more effective with cc value 0.795 and that of JatyadiTaila is 0.789.

- 3. Other subjective parameters like Pain, Odour both the drugs had equal effect.
 - On Tenderness, ability to sit in squatting position RopanaTaila had better effect with cc values 0.767,0.662respectively.
- 4. RopanaTaila was also used for application in post operative wound, anal fissures,
 - Vaginal dryness in the form of yoni pichu and encouraging results were seen.
 - The method of preparation is simple, it is cost effective, less no of drugs with good patient compliance, as the Taila does not contain any rasoushadhi, the possibility of any hypersensitive reactions are avoided.
- 5. It can be concluded JatyadiTaila -a drug of choice in various wounds and RopanaTaila have scientific validation and are equally effective in hastening the healing of Episiotomy wound without any undue complications.

Scope for future studies

- The present research work was aimed to find out the effect of RopanaTaila keeping JatyadiTaila as reference drug. Though the results were good and encouraging, further study on large number of patients is expected to provide a definite conclusion.
- The other formulation for Ropana mentioned by Acharya Sushruta like Ropanagrutha, kashaya, kalka, varti, rasakriya can be tried in further studies.
- Application of RopanaTaila coupled with Kegels's exercise for better wound healing.
- Application of RopanaTaila after Sitz Bath in RopanaKashayas.

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