



A CLINICAL STUDY TO EVALUATE THE EFFICACY OF DARVI TAILA AND TRIPHALA GUGGULU IN THE MANAGEMENT OF EPISIOTOMY WOUND

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ABSTRACT

Women have the property of creation. The existence of human race depends on women. During the process of childbirth women has to go through severe mental and physical trauma. Episiotomy is the purposeful incision given on the thin perineum at the time of crowning which cut short the 2nd stage of labour. Various treatment procedures explained in Mudhagarbha, vaidyakrit vrana, sadyovarana can be taken as reference of episiotomy. Here, in this present trial a comparative study was done to evaluate the efficacy of Darvi taila and Triphala Guggulu in the management of episiotomy. 60 numbers of patients were registered for this research, treated in 2 groups, group A with Darvi taila and Triphala guggulu and group B with cap Amoxicillin 500mg and povidone iodine. Both the groups were found to have equal efficacy and proved that Ayurvedic healing agents are equally effective in the management of episiotomy wound.

KEYWORDS : Mudhagarbha, Vaidyakrita vrana, Sadyovrana , Darvi taila , Triphala guggulu , Episiotomy

INTRODUCTION:

Ensuring healthy and safe motherhood with utmost care render to every woman is the outright responsibility of an obstetrician. Episiotomy is performed in cases of vaginal delivery to cut short the 2nd stage of labour and to prevent irregular tears. Direct reference of episiotomy is not available in Ayurvedic classics, but Sadyovrana¹ and Vaidyakrita vrana² explained by Acharya Sushruta can be correlated with it. In Mudhagarbha chikitsa³, while explaining the management for difficulties during extractions of fetus , Utkartana karma is mentioned as one of the procedure, this can be considered as episiotomy.

The wound that formed after episiotomy is associated with pain, discomfort and needs appropriate care and attention; otherwise it may lead to various puerperal infections which are costly in terms of delayed mother-infant interaction, lactation difficulty and prolonged hospital stay. In modern practice, the post-operative care of episiotomy wound is done by swabbing with cotton soaked in antiseptic and antibiotic solution and followed by local applications of antiseptic and antibiotic ointment, along with oral antibiotics. Ayurveda also have lots of preparations having good quality property along with antiseptic and antibacterial actions. In this study, a comparative study was done to evaluate the efficacy of Ayurvedic healing agents in comparison to modern.

Local application of Darvi taila and Triphala guggulu was selected for the present study.⁴

AIM AND OBJECTIVES

- Literary study (Ayurvedic and modern point of view) regarding Episiotomy.
- To study the Ayurvedic and modern concept of wound healing.
- To compare the effectiveness of Darvi Taila and Triphala Guggulu with antibiotics in the management of episiotomy.

MATERIALS AND METHODS

Selection of patient and study design:

- 1) All the patients were randomly selected from IPD of Prasuti tantra and Stree Roga dept., Govt. Ayurvedic College and Hospital, Guwahati.
- 2) Total 60 numbers of patients were registered for the study.
- 3) All 60 patients were divided into 2 groups.

Group A- 30 patients were given trial drug Darvi taila and Triphala Guggulu.

Group B- 30 patients were given control drug (Cap Amoxicillin 500mg and povidone iodine ointment)

- 5) All the 60 patients were studied with the help of objective parameters before and after treatment.

Duration of study:

Total duration of the study was 2 years.

Inclusion Criteria:

All primi and multi gravida those who have normal vaginal delivery with episiotomy,

Exclusion Criteria:

- 3rd and 4th degree perineal tear.
- Any systemic diseases that interfere normal wound healing like severe anaemia (less than 7 gm%) , hyperglycemia, tuberculosis.

Criteria for withdrawal:

- Development of any complications.
- Aggravation of any morbid symptoms in terms of sign of inflammation within 72 hrs.
- Discontinuation of treatment during the trial by the patient.

Ethical clearance and consent

Institutional ethical committee clearance and signed informed consent from subjects was obtained prior to the commencement of study.

Criteria for selection of drugs^{7,9}

Darvi taila: It contains Daruharidra and Tila taila

Daruharidra, due to its tikta rasa, katuvipaka helps in relieving pain, increases granulation and reduces shrava, also it has got antibacterial and anti inflammatory property. Tila taila, has lekhanika and krimighna action and does reducing oedema and infection at local vrana site, also due to lekhanika guna it helps to remove cell debris at local vrana site hence improves granulation i.e, vranaropana. It is vatashamak due to ushna veerya and snigdha guna, hence reduces shola.

Triphala Guggulu: It contains Amalaki, Haritaki, Bibhitaki, Pippali churna, shodhita guggulu. All the ingredients are having vranaropaka, shothahara, krimighna and rasayana properties.

Preparation of trial drugs:

1) Darvi taila:

For the preparation of Darvi taila murchita tila taila was taken and davi kalka and water added to it. Heating on mild fire is continued till only oil part remains. This part is filtered properly and final product is Darvi taila.

2) Triphala Guggulu:

Fine powder of Haritaki ,Amalaki, Vibhitaki and Pippali is mixed with the 5 part of shodhita Guggulu choorna and grind it. It should be made into paste by adding appropriate amount of ghee and grinded well. Then it is rolled into pills of 500 mg size.

Statistical analysis:

- 1) Unpaired t-test: Objective parameters between the groups.
- 2) Paired t-test: Objective parameters within the group.

Interpretation of the tool:

1. It is comprised of 6 items seeking information on demographic data of the postnatal mothers like age, religion, locality, parity, occupation and socioeconomic status.
2. Clinical profile includes the number of patients comprising individual symptoms with percentage.
3. The scale used was a standardized REEDA scale (Davidson 1974)¹² which has five components namely Redness, Edema, Ecchymosis, Discharge, Approximation of wound edges.
4. Criteria for assessment of wound:

Grade	Redness	Edema	Ecchymosis	Discharge	Approximation
0	None	None	None	None	None
1	Within 0.25 cm of the incision bilaterally	Perineal, less than 1cm from incision	Within 0.25 cm bilaterally or 0.5 cm unilaterally	Serum	Skin separation 3mm or less
2	Within 0.5 cm of the incision bilaterally	Perineal and/or between 1-2 cm from the incision	Between 0.25 cm to 1cm bilaterally or between 0.5 to 2 cm unilaterally	Sero-sanguinous	Skin and subcutaneous fat separation
3	Beyond 0.5 cm of the incision bilaterally	Perineal and/or vulvar, greater than 2 cm from incision	Greater than 1 cm bilaterally or 2cm unilaterally	Bloody, purulent	Skin, subcutaneous fat and fascial layer separation

Final assessment

The four categories are-

- 1) Grade 0: Healed
 - 2) Grade 1-5: moderately healed
 - 3) Grade 6-10: mildly healed
 - 4) Grade 10-15: not healed
- Total score is 15. Higher the score, more severe the infection.

Table 1: Final assessment:

Total no. of patients	Completely healed (Grade0)	%	Moderately healed Grade(1-5)	%

Group A	30	14	46.66	16	53.33
Group B	30	15	50	15	50
Total	60	29	-	31	-

STATISTICAL REVIEW:

Table2: Comparative study of trial and control drug on all the symptoms:

Sl. no.	Symptoms	Mean A±SD	Mean B±SD	t ₅₈	P	Remarks
1	Redness	1.56±0.61	1.7±0.58	0.84	>0.05	N.S.
2	Edema	1.5±0.76	1.3±0.52	1.16	>0.05	N.S.
3	Ecchymosis	1.41±0.48	1.24±0.51	1.29	<0.05	S
4	Discharge	0	0.03±0.17	1	>0.05	N.S.
5	Approximation	1.33±0.74	1.16±0.45	1.02	>0.05	N.S.

DISCUSSIONS

Discussion on trial drug:

Darvi taila: It contains daru haridra and tila taila

Daru haridra:¹⁰

- It includes in kandughna, kushtaghna, arshoghna mahakashaya, Haridradi gana and Lakshadi gana.
- Due to tikta and kashaya rasa it acts as pachak and shoshak at vranasrava.
- Due to vatakapha shamak property it reduces shool and kandu.
- As per the action of Lakshadi gana it acts as dushta vrana shodhak and kriminashak.
- Daru haridra helps in Lekhan hence vrana heals uniformly.
- Daru haridra helps granulation at vrana site and reduces swelling by ushnavirya, kashaya, tikta rasa and acts as local anaesthetic.
- Daru haridra due to its tikta rasa, katu vipaka helps relieving pain.

Tila taila:

- Tila is the main ingredient in taila. It has lekhaniya and krimighna action and thus reducing oedema and infection at local vrana site. Also due to lekhaniya guna they help to remove cell debris at local vrana site hence improves granulation i.e, vranaropana.
- Tila taila is Vatashamak due to its ushna virya and snigdha guna. It reduces shool.
- Tila taila is having vranaropana property, thereby helps in the formation of healthy granulation tissue And reduces the size of wound.
- Kashaya rasa plays an important role in contraction of wound edges, thereby reducing the size of wound.
- Tila seeds yield taila rich in Lignan, Lignan glycosides and Sterols, Phenyl ethanoid glycosides from the whole plant and Phenolic acid from the leaves and seeds. A petroleum ether fraction of an alcoholic extract yielded sesamin, sesamol, stigmasterol, β-sitosterol and stigmasterol-3-0-β-Dglucoside. A butanol fraction yielded ferulic acid, rhamnrtin, verbascoside and mequelianin has known effect in different traumatic conditions, promotes body strength.

Triphala Guggulu:⁸

This combination is used internally. Triphala Guggulu has Dahasamana, Vedanahara, Vrana Sodhana and Ropana properties. It is tridoshagnam. It is indicated in Arshas, Gulma, Shotha and Bhagandara. Acharya Vagbhatta has mentioned Triphala Guggulu as Agryaushadha for Vrana.

As the content contains Guggulu due to its Sukshma, Laghu, Sara gunas it will provide fast absorption in body

through Sukshma srotas and because of Snighdha, Picchila gunas it will provide prolonged drug action too.

The Vati prepared out of Triphala & Guggulu when taken internally Cures Vibandha and it acts as Vrana Shodhaka & Vrana Ropaka.

The Triphala along with Guggulu taken internally relieves dushta Vrana, which is associated with pain, swelling, moisture, discharge & smell.

Triphala guggulu contains phenols, alkaloids, glycosides, flavonoids fats and oils, tannins and terpenoid which promote wound healing.

Discussion on clinical profile

After the clinical trial it was found that out of 60 patients in both Group A and Group B, 59(98.3%) patients were having Redness and ecchymosis, 57(95%) were having edema, 7(11.6%) having Discharge and all 60(100%) patients were having Approximation problem.

1) Assessment of wound after 7 days:

Group A: In 14(46.66%) number of patients out of 30, wound healed completely (graded as 0) and in 16(53.33%) numbers of patients moderate healing of wound found (graded in between 1-5).

Group B: In 15(50%) numbers of patients wound healed completely (graded as 0) and in 15 (50%) number of patients moderate healing found (graded in between 1-5).

2) Assessment on clinical symptoms:

a) Redness: In Group A, 29(96.6%) number of patients were having Redness on 1st day and after 7 days of treatment 27(93.10%) number of patients got complete relief. 2(6.89%) patients not got complete relief but symptom improved.

In Group B All the 30 (100%) number of patients were having Redness on Day1 and after 7 days of treatment 21(70%) number of patients got complete relief and rest 9 patients were having redness on Day7 also, but grade wise severity of symptom decreased.

b) Edema: In Group A, 28(93.3%) number of patients were having Edema on Day 1 and after 7 days of treatment 24(85.71%) patients got complete relief, 4 patients were not completely cured but improvement of symptom is seen. In Group B, 29(96.6%) number of patients were having Edema on Day1, after 7 days of treatment 26(89.6%) number of patients got complete relief.

c) Ecchymosis: In Group A, 30(100%) number of patients were having Ecchymosis on Day 1 and after treatment for 7 days all the 29(96.6%) patients got complete relief. In Group B, 29(96.6%) number of patients were having Ecchymosis on Day1, and all 29(100%) patients got complete relief after 7 days of treatment.

d) Discharge: In Group A, 3(10%) number of patients developed Discharge as complaint on Day2 and Day3 but all 3(100%) got complete relief by 7th day. In Group B, 4(13.3%) number of patients were developed discharge as a complaint on Day2 and complete relief on Day7.

e) Approximation: In Group A, All 30(100%) patients were having Approximation problem on Day 1 and 18(60%) got complete relief after 7 days of treatment, rest 12(40%) number of patients were not get complete approximation but grade wise it showed improvement.

In Group B, All 30 (100%) patients were having approximation as a problem and 19(63.3%) number of patients got complete relief on 7th day of treatment, rest 11(36.6%) number of patients showed improvement but not got complete relief.

C) Discussion on statistical significance:

a) Redness: In Group A t_{29} is 13.7, in Group B t_{29} is 15.62 and in both the groups P value is <0.05 , hence both trial and control drugs are highly significant in control of redness.

In unpaired t-test, t_{58} is 0.84 and P value is >0.05 , hence no difference of significance is found in between Group A and Group B.

b) Edema: In Group A t_{29} is 10.57, in Group B t_{29} is 13.30 and in both the groups P value is <0.05 , hence both trial and control drugs are highly significant in control of redness.

In unpaired t-test, t_{58} is 1.16 and P value is >0.05 , hence no difference of significance is found in between Group A and Group B.

c) Ecchymosis: In Group A t_{29} is 15.38, in Group B t_{29} is 13.32 and in both the groups P value is <0.05 , hence both trial and control drugs are highly significant in control of ecchymosis.

In unpaired t-test, t_{58} is 1.29 and P value is <0.05 , hence the trial drug is more effective in ecchymosis.

d) Discharge: In Group A t_{29} is 0.34, in Group B t_{29} is 0.24 and in both the groups P value is <0.05 , hence both trial and control drugs are highly significant in control of discharge.

In unpaired t-test, t_{58} is 1 and P value is >0.05 , hence no difference of significance is found in between Group A and Group B.

e) Approximation: In Group A t_{29} is 9.63, in Group B t_{29} is 1.53 and in both the groups P value is <0.05 , hence both trial and control drugs are highly significant in control of approximation..

In unpaired t-test, t_{58} is 1.02 and P value is >0.05 , hence no difference of significance is found in between Group A and Group B.

Finally discussion can be concluded with the findings that both the groups i.e, trial and control group are highly significant in the management of episiotomy wound and no difference of significance is found in between trial group and control group in redness, edema, discharge and approximation. But in ecchymosis the trial drug is found more effective than control drug.

In this present study observation was done for 7 days. But all patients were examined after the end of puerperium i.e, after 6 weeks and complete healing of wound found in all cases.

CONCLUSION:

Parturition is an important event of women's life. The wound that formed after episiotomy is associated with pain, discomfort and needs appropriate attention; otherwise it may lead to various puerperal infections which are costly in terms of delayed mother-infant interaction, lactation difficulties and prolonged hospital stay.

Limitations:

- This study can be conducted in large population.
- This study can be conducted for longer duration for its effectiveness.

Recommendations:

The study recommends the following for further research:

- The similar study can be replicated with larger samples in different setting to strengthen the findings.

- A study can be conducted for assessing the effectiveness of Darvi taila on wound healing after caesarean section.
- A study can be done including pain as a parameter along with REEDA scale.

The present study assessed the effectiveness of Darvi taila and Triphala Guggulu in the management of Episiotomy wound. The results revealed that Darvi taila and triphala guggulu are equally effective in wound healing in comparison to Antibiotics. Moreover it is easy to apply and not harmful.

It prevented some most commonly observed side effects of antibiotics like nausea, loss of appetite, fullness of abdomen, stomach cramping etc.

It can equally prevent development of antibiotic resistant bacteria due to improper intake of antibiotics.

Women health is much important to have family integrity.

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