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Research Article

A COMPARATIVE CLINICAL STUDY OF *NIMBADI* AND *YASTYADI* OINTMENT ON EPISIOTOMY WOUND W.S.R. TO WOUND HEALING

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ABSTRACT

Episiotomy procedure is introduced in obstetrical practice more than 200 years ago but is put in frequent practice in the 20th century. Postnatal complications were more common among women who had episiotomy compared to those who did not have episiotomy; hence postpartum care of episiotomy wound should begin as soon as possible. So the present study has been done on episiotomy wound healing. Basically two things *Shodhana* (cleaning) and *Ropana* (healing) are desirable for proper healing. Many single drugs and compound formulations have been described in the classics for wound healing. The present study is taken up with the aim of comparison of clinical evaluation of wound healing property of *Nimbadi* and *Yastyadi* ointment, topical application on episiotomy wound. Study carried out on total 30 patients, under group A 15 patients treated with *Nimbadi* ointment, and 15 patients in group B treated with *Yastyadi* ointment. Both Groups were given local application of ointment on episiotomy wound as per requirement twice a day for a period of 14 days. On observation Group A therapy shows 66.62 % relief in signs and symptoms of wound along with good status of healing (cured) i.e. 53.33%. Group B therapy shows 49.50% relief in signs and symptoms of wound along with average status of healing (Partially cured) i.e. 46.66%. Better result was observed in group A in comparison to group B. No adverse effect was observed in any patient during the trial.

INTRODUCTION

Episiotomy is a surgically planned incision on the perineum and posterior vaginal wall during second stage of labour with the aim of increasing soft tissue outlet dimensions to help with easier childbirth and prevent perineal lacerations.[1] In India, the overall rate of episiotomy was 67% during 2014-2015 years[2]. The wound formed after an episiotomy is associated with immense pain and discomfort. A current medical literature documented that 60% of women with episiotomy reported severe post-partum pain, 25% experienced infection at the site and 20% had problems during intercourse for up to 3 months after childbirth. Hence it is evident that special care must be taken to prevent infection and fasten the healing. Healing of wounds, whether internal or external involves a series of overlapping events viz. inflammation, cell migration, angio-genesis, matrix synthesis, collagen deposition and re-epithelialization.

Although in Ayurvedic samhita, description of episiotomy wound has not been given directly but *Vrana* (wound) is described very well and hence it can be considered as *Shuddha Agantujavrana* or *Vaidyakritvrana* or *Sadhyovrana*. According to *Sushruta Alepa* (application of paste) is the first line of treatment for wounds and inflammations. *Sushruta* said "just as fire of a burning house is immediately controlled by spraying of water, similarly the pain (of the wound) is removed by the application of the *Alepa"*[3]. The application of *Alepa* on wound is soothing; it cleanses the wound, reduces the swelling, fills up the wound and heals it. Episiotomy wound can be treated on the lines of *Sadhyovrana.*[4]

Keeping all in mind, present study is taken up to evaluate the local application of trial drug

Nimbadi ointment and *Yastyadi* ointment as an effective treatment with higher acceptability. The present clinical study was carried out to compare the efficacy of *Nimbadi* and *Yastyadi* ointment to establish the effective Ayurvedic medicine in healing of episiotomy wound and to reduced the complications of the wound healing.

Materials and methods

Nimbadi (*Sarangdhara Samhita Uttara-khanda* -11/89)[5] and *Yastyadi* (*Vangasena Vrana-shotharogaadhikar* 78/82)[6] are the selected trial drugs, both are selected for present research work due to their authentic references, easy availability, cost effectiveness, wound healing properties, anti-inflammatory, anti-microbial, analgesic and anti-oxidant properties etc. The wound included in this study were fresh wounds of episiotomy and management of these wounds done by local application of *Nimbadi* ointment and *Yastyadi* ointment. Because of easy administration *Alepa* converted into Malhar form i.e. ointment as per instructions mentioned in our classics.

All the subjects are recruited from IPD of *Prasutitantra* and *Striroga,* Department of *NIA*, Jaipur (Rajasthan) as per criteria of inclusion and written informed consent were obtained from each patient before starting trial.

Inclusion criteria

- Patient aged between 20-35 years.
- Patients who underwent normal vaginal delivery with episiotomy.
- Patient with 1st and 2nd degree perineal tear.
- Patients who had regular antenatal checkups and previously routine investigations performed regularly.

Exclusion criteria

- Patient with severe anaemia.
- Patient with third degree perineal tear.
- Any skin disease, patient with known case of allergic reaction.
- Patients having positive VDRL, HIV, HbsAg.
- Patients suffering with any systemic diseases like Diabetes, Tuberculosis, Thyroid dysfunction, Hypertension etc.

Grouping and drug schedule

Total 30 patients with episiotomy and perineal tear wound included in the study and are randomly allocated into two equal groups(15 patients in each group). Group A was given local application of *Nimbadi* ointment on episiotomy wound as per requirement twice a day for a period of 14 days. Group B was given local application of *Yastyadi* ointment on episiotomy wound as per requirement twice a day for 14 days.

Criteria for assessment

Parameters and its Gradation

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	:	3

2.Pricking sensation at the region of wound

No	:	0
Mild	:	1
Moderate	:	2
Severe	:	3

3.Tenderness

No tenderness	:	0
Tenderness on applying pressure	:	1
Tenderness when touching with one finger	:	2
Tenderness on just touching the soft area	:	3

4.Reeda Scale

4.1. Redness

None	:	0
within 0.25 cm of the incision bilaterally	:	1
within 0.50 cm of the incision bilaterally	:	2
beyond 0.50 cm of the incision bilaterally	:	3

4.2. Edema

None	:	0
Perineal, < 1 cm from the incision	:	1
Perineal and/or vulvar, 1-2 cm from the incision	:	2
Perineal and/or vulvar, > 2 cm from the incision	:	3

4.3. Ecchymosis

None	:	0
Within 0.25 cm bilaterally or 0.5 cm unilaterally	:	1
Within 1.0 cm bilaterally or 0.5-2.0 cm unilaterally	:	2
> 1 cm bilaterally or > 2 cm unilaterally	:	3

4.4. Discharge

None	:	0
Serum	:	1
Sero-sanguinous	:	2
Bloody, Purulent	:	3

4.5. Approximation

Close	:	0
Skin separation <= 3 mm	:	1
Skin and subcutaneous fat separated	:	2
Skin, subcutaneous fat and fascial layer separation	:	3

Overall effect of treatment

The score of individual symptoms were obtained before and after treatment and the total effect of therapy was assessed accordingly in term of relief in signs and symptoms of wound along with healing of wound.

Status of Healing	**Criteria**
Completely cured (very good status of healing)	>75% relief in sign & symptoms of wound along with complete healing.
Cured (good status of healing)	>50 upto75% relief in sign & symptoms of wound along with healing of wound.
Partially cured (average status of healing)	>25% up to 50 % relief in sign & symptoms of wound along with healing of wound.
Uncured (Poor status of healing)	No relief or up to 25 % relief in sign & symptoms of wound without healing.

Follow up study

The wound was examined initially (with in 24 hr), the improvement in parameters observed during the patients stay in hospital and in the follow up period after discharge. The patient's first follow up on seventh day and second follow up on fifteenth day.

Statistical Analysis

Various observations made and results obtained were computed statistically using Wilcoxon matched-pairs signed-ranks test, Mann-Whitney test to find out the significance of the values obtained and various conclusions were drawn accordingly.

Observation

The observations procured on the assessment parameters of 30 patients before treatment and after treatment in Group A (n=15) and Group B (n=15) each were statistically analyzed to determine the effect of the treatment.

Most of the cases i.e. 56.67% were between the age group 20-25 years. Maximum number of patients i.e.50% were primigravidae and about 53.33% patients were primipara. In primiparous women perineum is comparatively rigid than multiparous women and more chances of perineal tear hence to avoid this complication episiotomy is usually done in primiparous women. The data of present study shows that 70 % of patients were having episiotomy wound, 16.66 % were having wound related to first degree perineal tear and 10 % of patients were having wound related to episiotomy with tear and 3.33 % patients having second degree perineal tear wound. Both group had normal bleeding with usage of 3-4 pads/day. There was normal colour of the bleeding in both the groups and there was no foul smell in any of the patients. This owed that the lochia was maintained clean which did not hinder the process of healing. Majority of the patients had maintained hygiene. Suturing material: The suturing material that was used is chromic catgut 1-0 which fell off on the 3rd or 4th Day.

Type and length of the incision: Medio lateral incision was done in all selected patients in trial group. The length of the incision varied from 2.5 cm to 4cm.

Results:

Table : Clinical recovery in various parameters of episiotomy wound treated with *Nimbadi* ointment in Group A (Wilcoxon matched-pairs signed-ranks test) (n=15)[7]

S.No.	Symptoms	Mean		Dif.	% of Change	SD	SE	W	P	Results
		BT	AT							
1.	Pain	1.53	.666	.866	56	.833	.215	55	0.002	HS
2.	Pricking sensation	0.53	0.13	0.40	75.47	0.50	0.13	21	0.031	S
3.	Tenderness	1.13	.533	.60	53	.632	.163	36	0.07	HS
4.	Redness	.896	.466	.4138	46	0.56	0.10	90	0.002	HS
5.	Edema	0.6	0.06	0.53	88.33	0.83	0.21	21	0.031	S
6.	Ecchymosis	0.93	0.33	0.60	64	0.50	0.13	45	0.003	HS
7.	Discharge	0.46	0.06	0.4	86.95	0.56	0.14	3.00	0.5	NS
8.	Approximation	0.20	0.06	0.13	65	0.35	0.09	3.00	0.50	NS

Table 2: Clinical recovery in various parameters of episiotomy wound treated *with Yastyadi* ointment in 'Group B (Wilcoxon matched-pairs signed-ranks test) (n=15)

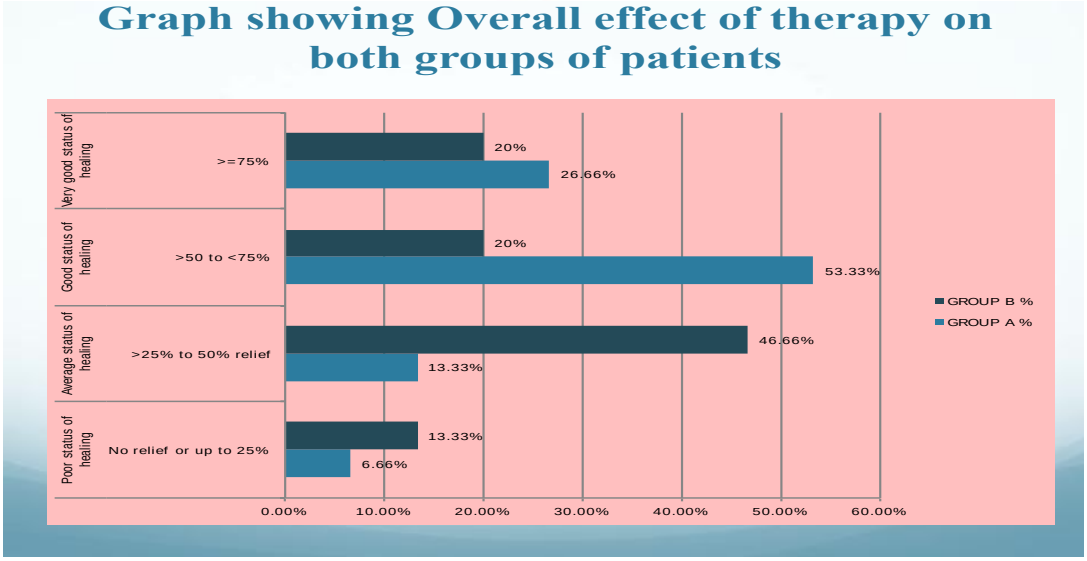
S No.	Symptoms	Mean		Dif.	% of Change	SD	SE	W	P	Results
		BT	AT							
1.	Pain	1.46	1.00	.466	32	0.51	0.13	28	0.15	S
2.	Pricking sensation	0.73	0.26	0.46	63	0.51	0.13	28	.15	S
3.	Tenderness	1.4	1.0	.40	28	.507	.130	21	.0313	S
4.	Redness	1.26	.733	.533	42	0.51	0.13	36	0.007	HS
5.	Edema	0.6	0.2	0.4	66	0.63	0.16	15	0.062	NQS
6.	Ecchymosis	1.26	0.80	0.466	36	0.51	0.13	28	0.01	S
7.	Discharge	0.33	0.066	0.266	80.81	0.70	0.18	3.00	0.05	NS
8.	Approximation	0.26	0.13	0.13	50	0.35	0.09	3.0	0.50	NS

Table 3: Percentage of improvement in parameter in both groups

S.No	Parameters	Result in percentage	
		Group A(n=15)	Group B (n=15)
1	Pain	56 %	32%
2	Pricking sensation	75%	63%
3	Tenderness	53%	28%
4	Redness	46%	42%
5	Edema	88%	66%
6	Ecchymosis	64%	36%
7	Discharge	86%	81%
8	Approximation	65%	50%
Average percentage of relief		**66.62 %**	**49.75%**

Table No -4 Episiotomy wound healing result

S.No.	Effect of therapy	Result	Group A		Group B	
			No.	%	No.	%
1	Poor status of healing	No relief or up to 25%	1	6.66%	2	13.33%
2	Average status of healing	>25% upto 50% relief	2	13.33%	7	**46.66%**
3	Good status of healing	>50 upto75%	8	**53.33%**	3	20%
4	Very good status of healing	>75%	4	26.66%	3	20%



DISCUSSION

The study carried out on total 30 patients in two groups viz., group-A (n=15) and group-B (n=15). In Group-A highly significant results are found in the relief of pain, tenderness, redness, ecchymosis; significant results obtained on pricking sensation and edema; but discharge and approximation were insignificant (Ref: Table- 1). In Group-B, highly significant results are seen only in reduction of redness; significant results obtained on pain, pricking sensation, tenderness, ecchymosis. Results on Discharge and Approximation were insignificant and edema was not quite significant. (Ref: Table- 2). Average percentage of improvement in all parameters along with healing of wound in Group A was 66.62% (under the category of Good state of healing) and in Group B it was 49.75 %(under the category of Average state of healing). In Inter Group comparison there is statistically no significant changes observed in parameters (Table - 3).

In Group A 53.33% of patients had good status of healing while in Group B 46.66% patient had average status of healing. (Ref: Table- 4)

For the trial subjects of Group-A, *Nimbadi* ointment was administered as trial drug, where as in Group-B, *Yashtyadi* ointment was given. *Nimbadi* ointment contains *Nimba, Daruharidra, Yastimadhu, Tila* and the base is honey and ghee. *Yastyadi* ointment contains *Yastimadhu*, *Tila* and the base of

ointment is ghee.

Nimba (*Azadirecta indica*) is having *Tikta, Kashaya* tastes as well as *Katu* (hot) in post digestive effect (*Vipaka)* and *Sheeta* in potency *(Veerya)*. According to Ayurveda pharmacological actions of *Tikta* (bitter) taste are *Vranaropana* (wound healing), *Krimihara* (wormicidal/ bactericidal), *Dahaprasamana* and *Kanduhara* (anti-pruritic). Due to *Krimihara* action *Nimba* might have helped to remove microbes and there by helps in cleansing of the wound, and through its *Dahaprasamana* property it helps to bring about cool effect to the burning sensation and checks it. *Kashaya* (astringent) acts as *Sandhanakara, Ropaka, Tvachya* and *Sthambana*, with the help of these properties it checks bleeding and discharge from wounds and exerts haemostatic action due to *Stambhana* property.

Neem is well known for its wound healing properties. *Neem* leaf extract showed significant anti-inflammation effect. A study result has suggested that Nimbidin suppresses the function of macrophages and neutrophils relevant to inflammation. *Neem* is also an excellent wound healer that helps the body to rapidly create collagen fibres to close the wound. *Neem* contains an excellent amount of amino acid, vitamin and minerals which are very important in wound healing process in proliferation phases. *Neem* leaves extract speeds up the proliferation phases in the entire wound healing process.[8] Nimbidin a crude bitter principle extracted from the oil seed of kernels has possess significant anti-inflammatory activity against carrageenin induced acute paw oedema in rats.[9,10]

Neem oil has been shown to have antimicrobial effect to inhibit many species of pathogenic bacteria, including S. aureus and Salmonella typhora, it has not been considered as antibiotic due to some limitations.[11] Recently the antibacterial activity of *Neem* seed oil was assessed in vitro against 14 strains of pathogenic bacteria.[12] Oil from the leaves, seeds and bark possesses a wide spectrum of antibacterial action against Gram-negative and Gram-positive microorganisms, including M. tuberculosis and streptomycin resistant strains.[13]

Daruharidra (*Berberis aristata*) acts on wound by its *Ushnaveerya* property and alleviate *Vata*and *Kapha*; also alleviates *Pitta* through its *Tikta Rasa*. Due to *Vata* pacifying action it reduces pain (*Vednastapaka*) at the site of wound. Its *Tikta Rasa, Ushnaveerya* and *Katuvipaka* reduces *Shotha*. Healing always takes place in a *shuddhavrana*, *Shodhana* in this context refers to irrigation of the local debris, and here this drug irrigates the wound by the *Lekhana*, *Ruksha* and *Laghu* properties. *Daruharidra* through all the above said properties helps in *Vranashodhana* and *Vranaropana*.

The root bark of *Berberis aristata* contains berberin, quaternary ammonium salts of isoquinoline alkaloid. Berberin has antibacterial, antifungal, antiviral, anti- inflammatory and anti oxidant properties. *Berberis aristata* contains alkaloids which are berbamine, Berberine, oxycanthine, epiberberine, palmatine, dehydrocaroline, jatrorhizine and columbamine, karachine etc. Aqueous, alcoholic and powdered root in distilled water extracts also shows wide antibacterial activity against Gram-positive bacteria. The extract was also tested for antibacterial activity against Gramnegative bacteria; the antibacterial activity was limited against E. coli, S. typhimurium, S. dysenteriae type 1 and V. cholerae, the best activity being against V. cholerae. The Gram-negative bacteria reported here as susceptible to the extracts of *B. aristata* are important human pathogens responsible for causing diarrhoea and dysentery.[14]

The antimicrobial activity of hydroalcholic extracts of *Berberis aristata* was tested against eleven bacterial and eight fungal strains. *B. aristata* root extract gave low MIC values against Bacillus cereus, Escherichia coli, Staphylococcus aureus and Aspergillus flavus while stem extract against B. cereus and Streptococcus pneumoniae.[15]

Yastyadi ointment was given for the trial subjects of group-B, and *Yashtimadhu* is the main ingredient in this trial drug. *Yastimadhu* (*Glycyrrhiza glabra*) is having *Madhura Rasa* and *Sheeta Veerya*. Due to the presence of *Madhura* taste and its property of *Rasayana* it provides *Dathuposhana* to skin and thus helpful for healing of wound. Through its *Sheetaveerya* it alleviates *Pitta* and thereby pacifies burning sensation and checks *Vranashotha* (anti-inflammatory). By its *Snigdha* and *Guru* properties it smears the wound and prevents it from external pathogens. It acts as *Sandhanakara* of the tissues, and also brings about *Varnya* effect over the scar, gives it natural colour. It also acts as *Kandughna* and indicated in *Vranakshata*.

Glycyrrhizin is an established anti-inflammatory drug, anti-exudative, anti- microbial and anti-ulcer property. Primary active ingredient of *Yashtimadhu* is Glycyrrhizin, which is considered as the quenching agent of free radicals and also as blocking agent of lipid peroxidation chain reactions.It has showed chemopreventive, antioxidant, and antiproliferative activity when

tested on animal model.[16] On in vitro studies, glycyrrhizic acid found to inhibit all factors responsible for inflammation. It inhibits cyclo-oxygenase activity and prostaglandin formation (specifically prostaglandin E2). It is also responsible for indirectly inhibiting platelet aggregation.[17,18] Secondary metabolites such as saponins, alkaloids, flavonoids are present in hydro-methanolic root extract of *Glycyrrhiza glabra*, the extract exhibited potent antibacterial activity[19]. In vitro studies have proved that aqueous and ethanolic extracts of liquorice show inhibitory activity on cultures of Staphylococcus aureus and Streptococcus pyogenes.[20]

Tila (*Sesamum indicum*) is having *Madhura* (sweet), *Kashaya* (astringent), *Tikta* (bitter) and G*uru* and S*nigdha*, *Vatashamaka* properties and ithas got *Tridosha* pacifying action. It has got *Varnya*, *Snehana*, *Vedanasthapana*, *Sandhaniya*, *Krimighna*, *Shothahara* properties which help in *Vranashodhana* and *Ropana* process. According to pharmacological studies it has Haemostatic effects due to *Kashaya Rasa*.[21] *Tila* contains mineral matters 4.1-7.4, calcium 1.06-1.45 and phosphorous 0.47-0.62. *Tila* Seeds contain various vitamins, particularly vitamin A, B and C. In wound healing, for maturation of collagen, Vitamin C is important. Vitamins A, B, C are also responsible for supporting epithelialization and collagen formation; also important for the inflammatory phases of wound healing. Thus it helps in different phases of wound healing.

In Ayurveda Ghee is used as a carrier in the medicinal preparations to carry the essence of herbs because of its supreme penetrating qualities into deeper tissues and hence in the present study also this was used as a base to carry the active principles of drugs deep into the *Dhatus* (tissues). *Ghrita* also has *Samskara-anuvartanum* property, through which it carries active principles of the drug to increase the potency of the compound drug.[22]

Madhu (Honey) is another drug used in the above preparations due to its well known actions. The effect of honey in prompting *Vranaropana* is attributed to its *Madhura, Kashaya rasa* and *Pichhila, Sheeta, Laghuguna*. *Madhura rasa* of honey exerts direct nutrient effect on regeneration of tissue because it contains a wide range of amino acids, vitamins, and trace elements in addition to large quantities of readily assimilable sugars. *Kashaya rasa* cleans the wound surface and removes foul smell from wounds by destroying the bacteria which produce ammonia. *Sheeta Guna* is correlated as anti inflammatory action of honey which soothes and promotes healing by reducing pain and inflammation. *Picchila Guna*-acts as moisture retentive as wound environment is less painful require fewer dressing changes, and produces better cosmetic result.

Honey when comes in contact with wound, the glucose oxidase enzyme introduced to the honey by the bee slowly releases the antiseptic H_2O_2.This H_2O_2 Released at sufficient levels is effective against bacteria but does not cause tissue damaging and fibroblast growth is stimulated by H_2O_2. Acidic nature of honey releases oxygen as new growing cells need oxygen and stimulates the white blood cells. Osmotic effect of the honey keeps the wound moist and clean. It prevents the dressing sticking to the wound, as it belongs to moist retentive dressing material which promotes formation of clean healthy granulation tissues, and accelerates epithelialization of wound without producing any adverse effects. Honey promotes rapid healing as it stimulates tissues regeneration, angiogenesis and fibroblast growth. Anti-inflammatory action of honey soothes and promotes healing by reducing pain and swelling.[23]

Highly significant results in Group-A was found in the relief of pain, tenderness, redness, Ecchymosis and significant results in pricking sensation and edema, where as in highly significant results were seen only in reduction of redness and significant results obtained on pain, pricking sensation, tenderness, ecchymosis. On comparison of healing status of wound, average status of wound healing was found in 02 (13.33%) cases in group-A, in 07 (46.66%) cases in Group-B. Good status of healing was found in 08 (53.33%) cases in Group-A, and in 03 (20.00%) cases in Group-B. When both the groups are compared Group-A is found superior. This superior action can be attributed to the synergistic action of *Nimba, Daruharidra, Yastimadhu, Tila*.

CONCLUSION

- It can be safely concluded that all the drugs taken in the present study, have the capability to act at all the levels of wound healing.
- This justifies that episiotomy wound can be treated on the lines of *Sadhyovrana.*
- Group A therapy shows 66.62 % relief in signs and symptoms of wound along with Good status of healing(cured) i.e. 53.33%.
- Group B therapy shows 49.50% relief in signs and symptoms of wound along with Average status of healing (Partially cured) i.e. 46.66%.
- On comparison of improvement in both groups it was found that overall relief was higher in

group A followed by group B.

- Overall effect of therapy is 58%.
- The result obtained from the above study is encouraging. The drug is inexpensive, easily available and easy to prepare and apply. There is no unwanted effect found during the course of treatment.

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