# Evaluation of Wound healing activity of *Jatyadi* Ointment and *Jatyadi taila* in the management of clean wound (*ShuddhaVrana*)- A Randomised Controlled Trial

Pradeep Shahjirao Shindhe, Ramesh Shivappa Killedar, Laxmikant S D, Santosh Y M, Manjula Madiwalar

Department of Shalyatantra KAHER Shri BM Kankanwadi Ayurveda Mahavidyalaya, Belagavi, Karnataka, India Corresponding Author's Email: drramesh39@gmail.com

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#### ABSTRACT

**Background**: *Vrana* (Wound) is a one which does the *gatravichurnan*(disruption of tissues) and does the *vivarnata* (discolouration) of body part. These wounds are frequently encountered in our day today life and they are produced mainly due to the trauma or pathological insult to the body and may cause long term agony to the patient. Retrospective analysis of Medicare beneficiaries reveals that 8.2 million people had wounds with or without infections in 2018.

Objective: To evaluate wound healing efficacy of Jatyadi ointment in shuddhavrana(clean wound)

**Materials and Method**: A total number of 30 patients were included in the study and were randomly divided into two groups using random number generator software. The patients of Groups A were treated with *Jatyadi* ointment application and Group B treated with *Jatyadi taila* local application for a period of 7 days, assessment of changes in wound were recorded before treatment and on 8<sup>th</sup> day. Bates Jensen wound assessment tool containing eight parameters indicating the features of healing wound were assessed. Wilcoxon matched pair test was used to assess within group results and Mann-Whitney U test to assess in between group results.

**Results**: Significant improvements were seen in within group results and in between group results were comparable in all the selected parameters of Bates Jensen wound assessment tool.

**Conclusion**: Jatyadi ointment and Jatyadi taila, both are effective and results are comparable.

Key words: Wound healing, Jatyadi ointment, Jatyadi taila, Clean wound

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#### Introduction

The *vrana* is one which causes *gatravichurnana* and does the *vivarnata* of the *shareera* which is described as 'a break in the continuity of tissue, from violence or trauma' and is regarded as healed if there is a restoration of the wounded or inflamed tissue to normal condition.<sup>1,2</sup> Wound healing is an important biological process involving tissue repair and regeneration and various stages.<sup>3</sup> Worldwide prevalence of wounds is 1%, estimated that 1.5 million cases of traumatic wounds (13%) found every year.<sup>4</sup>

The reference of *vrana* in regards to its definition, classification and management are available in the classics. Its effective management for a surgeon is the basic skill required on which the outcome of surgery revolves. Wound healing is a dynamic and complex process which requires suitable environment to promote healing process. It is era of evidence based medicine which requires aid of modern equipment's, various drug delivery system, dosage form for global acceptance of any drug or therapy. Ayurveda is accepted as alternative and traditional system of medicine which requires modernisation, scientific approach towards drug preparation, drug delivery and patient care. JT is a

medicated oil formulation popularly used in the treatment of various topical wounds (AFI, 2003). Tis known for *vranashodhana*, *ropana* and *raktastambhana* properties. *Malahara kalpana* is considered as ointment preparation as per modern pharmaceutical science which comprises *sikthataila* (bees wax and oil mixture) or *ghrita*, as basic ingredient. It possess properties like *snehana* (oelation), *shodhana* (cleansing), *ropana* (healing) and *varnya* (beautifying) which depends on the composition of drugs used. The *malahara* form has advantages like, it is easy to apply, to store and also possess good shelf life period. Hence the study was undertaken to pharmaceutically modify *Jatyadi taila* into an ointment form and to evaluate its wound healing efficacy in *shuddhavrana*.

#### Materials and method

The patients attending the OPD and IPD of KAHER'S B.M.K Ayurvedic Hospital, Belagavi were enrolled for the study. The CONSORT Statement guidelines were followed in reporting the study outcome. The study was approved by Institutional ethical committee with Ethical clearance number - BMK/17/SL/PS/1.

#### **Raw drugs and Finished Products**

Drugs were collected from KAHER's GMP Certified Ayurved Pharmacy, Khasbag, Belagavi and natural sources. Control drug (*Jatyadi Taila*) was procured from GMP certified Pharmacy. *Jatyadi* ointment was prepared with collaboration of GMP certified KAHER Ayurveda pharmacy, Khasbag.

## **Hypothesis**

H0-There is no significant effect of *Jatyadi* ointment over *Jataydi Taila* in the management of *shuddhavrana* 

H1 - There is significant effect of *Jatyadi* ointment over *Jataydi Taila* in the management of *shuddhavrana* 

**Subjects-** Total 30 patients of *shuddhavrana* were recruited for the study from the OPD and IPD of

KAHER'S BMK Ayurveda Hospital and Medical research centre, Belagavi.

**Source of Subjects** – Patients exhibiting *shuddhavrana* features in cases of traumatic injuries of upper and lower limb, post-operative wounds like pilonidal sinus, fistulectomy wounds, abscess (post drainage) were selected for the study.

**Inclusion criteria** - Patients of either sex between 20-70 years of age and having the sign and symptoms of *shuddhavrana* were included in the study.

**Exclusion criteria** - Patients suffering from *dustavrana* (non healing wounds), wounds associated with systemic diseases like diabetes mellitus, tuberculosis, malignant wounds, arterial, varicose ulcer, pressure ulcer, HbsAg, HIV I &II positive were excluded from the study.

**Screening methods** - Patients included in the study were thoroughly examined for the wound and all data collected was systematically recorded. Wound was assessed by selected parameters of Bates-Jensen Wound Assessment Tool i.e. 1,2,3,7,9,10,11,12and13 indicating the features of healing wound.

**Study design** - The study was prospective randomised controlled trial and patients were randomly allotted to both the groups by computer generated random numbers. The patients were allocated to control and trial groups in 1:1 ratio.

**Intervention** - All the 30 patients were randomly divided into two groups, Group A (intervention) was treated with *Jatyadi* ointment and Group B (control group) was treated with *Jatyadi taila*. In both groups method of application was external, duration of application was once in a day and duration of treatment was 7 days. Assessment was done on baseline and 8th day for changes and recorded systematically. The nature and study design was explained to every patient and informed consent was taken. Institutional Ethics Committee approval was obtained for the study. Patients were instructed to report any adverse events to the investigator during the study period.

Table 1: Ingredients of Jatyadi Ointment.8

Sl.No.	Name of the Ingredients	Parts use	Quantity of Ingredients Batch 15 kg	10 gm of Jatyadi Ointment contains	
1.	Jati (Jasmine officinale Linn.)	Leaves	208.33gm	0.138gm	
2.	Nimba (Azadiracta indica A. Juss)	Leaves	208.33gm	0.138gm	
3.	Patola(Trichosanthus dioica Roxb.)	Leaves/Plant	208.33gm	0.138gm	
4.	Naktamala (Pongamia pinnata Linn.)	Leaves	208.33gm	0.138gm	
5.	Madhuka (Glycyrrhiza glabra Linn.)	Root	208.33gm	0.138gm	
6.	Kushta (Saussure alappa C.B.Clarke.)	Root	208.33gm	0.138gm	
7.	Haridra (Curcuma longa Linn.)	Rhizome	208.33gm	0.138gm	
8.	Daruharidra (Berberis aristata DC.)	Stem	208.33gm	0.138gm	
9.	Manjishta (Rubia cordifolia Linn.)	Stem	208.33gm	0.138gm	
10.	Katurohini (Picrorhiza kurroa Royle ex Benth.)	Rhizome	208.33gm	0.138gm	
11.	Padmaka (Prunus cerasoides D.don)	Heart wood	208.33gm	0.138gm	
12.	Lodhra (Symplocos racemose Roxb.)	Stem bark	208.33gm	0.138gm	
13.	Abhaya (Terminalia chebula Retz.)	Pulp	208.33gm	0.138gm	
14.	Nilotpala (Nelumbo nucifera Gaertn. )	Flower	208.33gm	0.138gm	
15.	Tutthaka (Copper sulphate)	Mineral	208.33gm	0.138gm	
16.	Sariva (Hemidisums indicus Linn)	Root	208.33gm	0.138gm	
17.	Naktamala (Pongamia pinnata Linn.)	Seed	208.33gm	0.138gm	
18.	Siktha( Yellow Honey bee wax)	Wax	208.33gm	0.276 gm	
19.	TilaTaila (Sesame indicum Linn.)	Oil	15kg	10gm	
20.	Water		60liter	40ml	
21.	Siktha for ointment form		208.33gm	0.138gm	

# Method of Malahara (ointment) preparation<sup>7</sup>

Appropriate quantity of honey beeswax was taken and gently heated in a suitable vessel until it melts completely. In another vessel appropriate volume of *Jatyadi taila* was taken and it was added slowly in to the vessel containing

melted bees wax. Gentle stirring was done until homogeneous mixture was obtained and was allowed to cool at room temperature. The appropriate amount of homogeneous mixture was taken on ointment tile and it was mixed properly to get consistency of ointment and it

was stored in a wide mouth container, at room temperature.

## Criteria for Assessment

**Primary Outcome** - Wound was assessed by selected parameters of Bates-Jensen Wound Assessment Tool i.e.1,2,3,7,9,10,11,12 and 13 (Size, Depth, Edge, Exudates Type, Skin Colour Surrounding Wound, Peripheral Tissue Oedema, Peripheral Tissue Induration, Granulation Tissue, Epithelialization).

Statistical Methods - SPSS version 20.0 was used for the statistical analysis. Chi Square test was used to evaluate the homogeneity of data across the groups. Comparison of two study groups (A and B) before and after treatment was carried out by using Mann-Whitney U test. Comparison of within the groups was carried out by using Wilcoxon matched pair test. Dependent T test was used to assess before and after treatment total scores in two study groups (Table 4). All tests were considered statistically significant at p<0.05.

Total patients screened were 31 and enrolled were 30. No adverse effect was reported during the study. There was one drop out in the study as patient did not come for dressing properly.

**Subject characteristics** - The mean age (p = 0.3182) and gender (p=1.0000) were comparable between the groups (Table 2).

**Primary Outcome** - The study showed that in between group results were comparable in all the assessed wound parameters (Table 3). However in within group, significant results wereobserved in all the parameters of wound i.e. Size (p=0.007), Depth (p=0.007), Edge (p=0.007), Exudates Type (p=0.0010), Exudate Amount (p=0.001), Skin Colour Surrounding Wound (p=0.0051), Peripheral Tissue Oedema (p=0.0180), Peripheral Tissue Induration (p=0.0180), Granulation Tissue (p<0.007), and Epithelialization (p=0.007) at baseline and on 8th day.

Table 2:- Percentage of Sex wise distribution of male and female in Group A and B.

Gender	Group A % Group		Group B	%	Total	
Male	11	78.57	13	86.67	25	
Female	3	21.43	2	13.33	5	
Total	14	100.00	15	100.00	30	
Chi-square with Yates's	correction = 0.0001 P =	1.0000		1		
Comparison of two stud	dy groups (A and B) by a	age groups				
Age groups	Group A	%	Group B	%	Total	
20-29yrs	3	21.43	3	20.00	7	
30-39yrs	7	50	4	26.67	11	
40-50yrs	4	28.57	8	53.33	12	
50 – 70yrs	0		0		0	
Total	14	100.00	15	100.00	30	
Mean age	37.87	42.40	40.13			
SD age	13.53	14.83	14.13			

Table 3: Comparison of two study groups (A and B) with status of wound parameters before and after treatment in between groups (Mann-Whitney U test) and within groups (Wilcoxon matched pair test)

SI No.	Paramete r	Treatmen t	Group	Sample size (n= 30)	Mean	SD	S.E	Z value	P Value
1.	A	BT	Trial (A)	14	2.214	0.699	0.1869	-	0.835
	Size		Control (B)	15	2.250	0.577	0.1443	0.207 4	7
	,		Trial (A)	14	1.143	0.363	0.0970	-	0.787
		AT	Control (B)	15	1.063	0.442	0.1106	0.269 6	5
2.		BT	Trial (A)	14	2.571	0.513	0.1373	-	0.982
	Depth		Control (B)	15	2.563	0.512	0.1281	0.162	7
			Trial (A)	14	1.214	0.425	0.1138	-	0.843
		AT	Control (B)	15	1.438	0.512	0.1281	0.311 1	2
3.		BT	Trial (A)	14	2.714	0.468	0.1253	-	0.933
	Edge		Control (B)	15	2.750	0.577	0.1443	0.083	9
	Andrea	100.000000	Trial (A)	14	1.143	0.363	0.0970	-	0.119
		AT	Control (B)	15	1.500	0.516	0.1291	1.555 4	9
			Control (B)	15	1.000	0.000	0.000		
4.		BT	Trial (A)	14	2.429	0.937	0.2506	-	0.081
	Exudate		Control (B)	15	2.813	0.655	0.1638	1.742 1	4
	type		Trial (A)	14	1.071	0.2673	0.07143	-	0.119
		AT	Control (B)	15	1.375	0.500	0.1250	1.555 4	9
5.		BT	Trial (A)	14	2.286	0.726	0.1941	-	0.072
	Exudate amount		Control (B)	15	2.500	0.730	0.1826	1.632 4	3
			Trial (A)	14	1.357	0.497	0.1329	=	0.107
		AT	Control (B)	15	1.375	0.500	0.1250	1.432 5	2
6.		BT	Trial (A)	14	2.071	1.207	0.3225	=	0.648
	Skin colour		Control (B)	15	2.125	0.957	0.2394	0456 3	2
	surroundin		Trial (A)	14	1.000	0.000	0.000	0.000	1.000
	g wound	AT	Control (B)	15	1.125	0.500	0.1250		
7.	Danim!!	BT	Trial (A)	14	1.500	0.650	0.1738	- 200	0.771
	Peripheral tissue		Control (B)	15	1.500	0.632	0.1581	0.290	6
	edema		Trial (A)	14	1.000	0.000	0.000	0.000	1.000
		AT	Control (B)	15	1.000	0.000	0.000	0	

Shindhe PS et.al.: Evaluation of Wound healing activity of Jatyadi Ointment...

8.	Induration	BT	Trial (A)	14 15	1.643	0.744 0.750	0.1991 0.1875	- 0.684 4	0.493 7
			Control (B)		1.813				
			Trial (A)	14	1.000	0.000	0.000	0.000	1.000
		AT	Control (B)	15	1.000	0.000	0.000	0	
9.	Granulatio n Tissue	BT	Trial (A)	14	2.857	0.663	0.1772	-	0.851
			Control (B)	ontrol (B) 15 2.875 0.718	0.718	0.1797	0.186 7	9	
			Trial (A)	14	1.286	0.468	0.1253	-	0.755
		AT	Control (B)	15	1.313	0.478	0.1197	0.311	7
10.	Epitheliali	BT	Trial (A)	14	3.143	1.167	0.3120	-	0.604
			Control (B)	15	3.250	0.930	0.2327	0.518 5	1
	zation	AT	Trial (A)	14	1.429	0.513	0.1373	- 0.622 2	0.533 8

Table 4: Comparison of Before and After treatment total scores in two study groups (A and B) by

Dependent T Test

Groups	Treatment	Mean	Std. Dv.	Mean Diff.	SD Diff.	% of change	Paired t	p-value
Group A	Before treatment	18.60	3.04					
	After treatment	8.93	1.44	9.67	2.61	51.97	14.3471	0.0001*
Group B	Before treatment	19.40	2.85					
	After treatment	9.67	1.84	9.73	3.28	50.17	11.4810	0.0001*

<sup>\*</sup>p<0.05

#### Discussion

Wound treatment is given prime importance by *Acharya Sushruta*, which involves two major components i.e. *shodhana* and *ropana*. When the wound attains *shudhha laxana* (features of clean wound), *ropana* is adopted which is important phase of healing, where wound is more prone for trauma and infection. Wound healing is a complex process and involves three phase's viz., inflammation (0–3 days), cellular proliferation (3–12 days) and remodelling (3–6 months). During healing process wound requires adequate tissue perfusion/oxygenation, proper nutrition and moist environment. Healing is complete by firm knitting of wound edges with collagen. <sup>10</sup>

Dressings are broadly divided into two types i.e. Irritant and Emollient. In the presence of slough it requires mechanical measures and chemical agents which are irritant agent and does desloughing (Hydrogen peroxide, Povidone iodine solution. etc). Emollient dressing constitutes application of lubricating agents when wound is not having any slough (Hydrogels, Hydrocolloids, and Ointment etc.). Ointment form of drug is essential for wound healing because of its Biocompatibility, it maintains moist environment thus preventing dehydration, it provides protection against dust and microorganisms, it allows gas permeability, promotes epithelisation, painless dressing due to non-adherent property. 12,13 Dressing with ointment are considered as occlusive, which blocks transcutaneous

water loss and natural essential fatty acids easily penetrate into cell membranes, to enhance drug penetration and hastens wound healing.<sup>14</sup>

#### **Wound parameters**

**Size, Depth and Edge**: A significant reduction in wound size (Table 3)(Fig. 1 and 2)was observed within the groups because of phytochemicals presents in *Jatyadi* ointment (Table 1) such as flavonoids, essential oils (terpenoids), tannins (phenolics), glycosides, steroids and alkaloids which helps in wound contraction and thus promotes wound healing. Is Ingredients of *Jatyadi* ointment possess *tikta*, *kashaya rasa*, *laghu*, *ruksha gunas*. These *rasa* and *guna* possess properties like *vrana ropana*, *twak -mamsa sthireekarana* (Strengthening the tissue). If

Exudate type and amount: There was significant reduction in exudate (Table 3) was observed within the groups. Decrease in the quantity of exudate is due the *shodhana* effect of *ointment* as it contents *Jati*, *Kushta*, *Padmaka*, *DaruHaridra*, *Lodra* having *kashaya* (astringent), *tikta* (bitter) *rasa* (taste), *lekhana* (scraping), *kleda shoshana* (drying of exudates) properties.<sup>17</sup> Recent animal study proved the Beeswax is effective in reducing wound exudates.<sup>18</sup>

Peripheral Tissue Oedema and Induration: Significant reduction in peripheral odema (Table 3) and induration was observed within the groups. *Patola, Jati, Katuki, Lodra, Sariva* has *shothahara* (anti-inflammatory) properties and thereby reduces the peripheral tissue oedema. <sup>19</sup> Curcumin present in *Haridra* has anti-inflammatory, antiseptic, antibacterial and antimicrobial property, Salicylic acid present in *Jati* is antibacterial, antifungal and anti-inflammatory property, *Kushta* has Anti-inflammatory action. <sup>19</sup> Beeswax has the qualities like *mridu* (soft), *snigdha* (unctuous) and having the properties *vrana shodhana* (cleansing the wound), *vranaropana* (healing the wound). <sup>20</sup>

**Granulation Tissue**: Promotion of collagen synthesis by fibroblast, neoangiogenesis increases amount of

granulation tissue which speeds up the regeneration process. *Jatyadi* ointment helps in knitting of tissue matrix (Fig. 3 and 4), soothes the mucosa. It does the *snehana* of tissue, provides adequate nourishment. *Rakta prasadak dravya* like *Manjishta* and *Sariva* enhances the *raktadhatu* which helps in improving tissue perfusion and strengthening local venous structure as *sira* is the *upadhatu* of *rakta*. <sup>21</sup> *Katuka* present in the *Jatyadi* ointment improves re-epithelialization, neovascularization and migration of endothelial cells, dermal myofibroblasts and fibroblasts into the wound bed. <sup>22</sup> Recent studies proved that *Tuttha* (CuSO4) promotes angiogenic responses in vitro, in vivo wound models, thus helps in rapid filling of wound area with granulation tissue in turn helps in closure of wound area. <sup>23</sup>

**Epithelization**: Decrease in the epithelization time was observed within the groups (Table 3) (Fig. 5 and 6). This was due to the presence of Tannins and phytosterols which promote the wound healing process with increased capillary formation and fibroblast proliferation enhancing the rate of epithelization.<sup>24</sup>

#### Conclusion

The present study showed that both the formulations (*Jatyadi* ointment and *Jatyadi taila*) are effective within group results and comparable in between group results. Ointment form of application was easier and has showed its efficacy in all the selected parameters of the Bates Jensen wound assessment tool.

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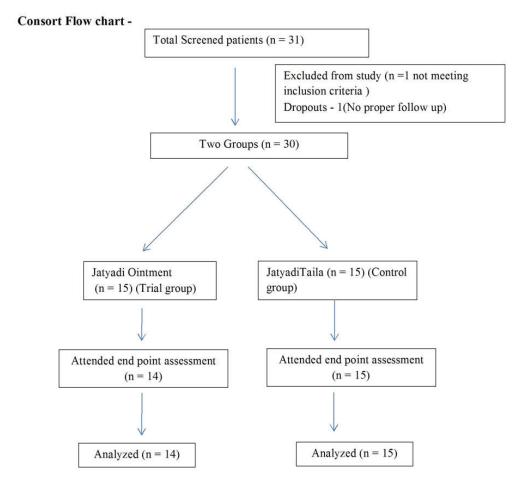




Fig. 1 Before treatment of Excised pilonidal sinus wound



Fig. 2 After treatment of Excised pilonidal sinus wound



Fig. 3 Before treatment of Fistulectomy wound



Fig. 4 After treatment of Fistulectomy wound



Fig. 5 Before treatment of Lacerated wound



Fig. 6 After treatment of Lacerated wound