

A CLINICAL STUDY ON THE EFFICACY OF NIMBAPATRAADI LEPA IN THE MANAGEMENT OF DUSHTA VRANA

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ABSTRACT

The science *Ayurveda* is one of the most promising branches of health care system. *Sushruta Samhita* is the pioneer textbook of ancient Indian surgery, which is also known as *Vranapradhana Tantra*² (Textbook of traumatology). According to *Acharya Sushruta Vrana* is a condition which causes break in the continuity of epithelium, consumes the tissue and exposes the underlining structures resulting in a lifelong scar of the affected part even after healing. *Ayurveda* has a vast scope of research in this field to revalidate the efficacy of *Ayurvedic* management for chronic non-healing wound for the benefit of mankind. Chronic wound or non-healing ulcers are the most common problem in surgery which leads to considerable disability and are associated with increased mortality and morbidity. An ulcer is breaking in the continuity of the covering epithelium, either following molecular death of the surface epithelium or its traumatic removal. Therefore, a clinical study on the efficacy of *Nimbapatradi Lepa* in the management of *Dushta Vrana* is an approach to re-evaluate an effective, cost effective and minimally invasive *Ayurvedic* dressing material.

Keywords: *Dushta Vrana*, Wound, *Nimbapatradi Lepa*

INTRODUCTION

Ayurveda is one of the oldest health care systems now existing in the world. Among the eight branches of *Ayurveda* (*Astanga Ayurveda*) as described in *Sushruta Samhita*, *Shalya Tantra* was mentioned in the top considering its usefulness and popularity.¹ In *Sushruta Samhita* different kinds of surgical and para-surgical modalities of treatment described along with medical management. The basic aim of the surgery is to cure the diseases completely without any chances of recurrence. The wounds and their management are fundamental practice of *Shalya Tantra*. Basic idea of cleansing of wound, closure as well as splinting has been mentioned in various medical systems. *Ayurveda* is a science of life and there is very vivid description of *Vrana* (wound), its etiological factors, pathophysiology, clinical features, classification and management including various local and systemic measures. *Acharya Charaka*, *Sushruta* and *Vagbhata* have described the types of wound in two categories mainly *Nija* and *Agantuja*. Based on the pathophysiology and clinical presentation of wound, *Acharya Sushruta* has also mentioned the four stages of wound like *Dushta Vrana*, *Suddha Vrana*, *Ruhyamana Vrana* and *Samyaga Rudha Vrana*. The classics of *Ayurveda* have mentioned *Atisanvrita*, *Ativivrita*, *Atikathina*, *Atimridu*, *Utsanna*, *Avasanna*, *Atishita*, *Atiushna*, *Krishna*, *Rakta*, *Pita*, *Shukla Varna*, *Vedana*, *Daha*, *Paka*, *Raga*, *Kandu*, *Shopha*, *Pidaka*, *Dushta-Shonitsravi*, *Dirgha-kalanubandhi*, *Putipuyasravi*, *Atigandhadyukta* etc. as the symptoms of *Dushta Vrana*.³ Treatment of non-healing wound (*Dushta Vrana*) is one of the most challenging problems in the field of surgery that is why *Acharya Sushruta* has given utmost importance for the management of *Dushta Vrana*. The non-healing wounds significantly impair the quality of life of people and they have a significant impact on public health and the expenditure of healthcare resources. Therefore, proper treatment is required to overcome the enormous burden on society. Although wounds and ulcer are many times misunderstood with each other, but the etiology of each condition is different. The contamination of the wound due to various micro-organisms delayed the process of wound healing. Bleeding, pain, infection & cicatrization are the main

complications of a wound which require immediate treatment. It is observed that a number of scientists and wound surgeon are working on various national and state level institutes for revalidation of the efficacy of *Vrana Shodhana* and *Ropana* formulation. *Acharya Sharangadhara* has mentioned *Nimbapatradi Lepa*⁴ containing *Nimbapatra* (*Azadirachta indica* A. Juss.), *Daruharidra* (*Berberis aristata* DC), *Madhuka* (*Glycyrrhiza glabra* L.), *Krishna Tila* (*Sesamum indicum* Linn.), *Madhu* (Honey), *Ghrita* (Ghee) having both *Vrana Shodhana* and *Ropana* property. It is also found that the ingredients of *Nimbapatradi Lepa* possess *Shodhana* (cleansing), *Ropana* (healing), *Vedanahara* (analgesic) and *Krimighna* (antimicrobial) properties.

Aim: To revalidate the efficacy of *Nimbapatradi Lepa* in the management of *Dushta Vrana*.

Materials and Methods: This is a randomized open controlled study on 80 numbers of patients suffering from *Dushta Vrana*. The patients were registered from OPD, IPD and casualty of Government Ayurvedic College, Guwahati and divided into two groups; randomly selected 40 patients in each group.

- **Group A (Trial Group):** 40 patients treated with *Nimbapatradi Lepa*.
- **Group B (Control Group):** 40 patients treated with Povidone Iodine 5% w/w ointment.

For both group A and B, *Dushta Vrana* covered with slough, necrosed tissue, thick discharge; unhealthy granulations etc. were cleaned by adopting the suitable debridement technique. Followed by cleaning of the wound with normal saline and the respective drug were applied externally. Daily cleaning and dressing were done and assessed and recorded on every 7th day in the proforma specially designed for this study.

Duration of treatment: The patients were treated for a period of maximum 42 days or complete healing, whichever is earlier.

Inclusion criteria

- Age group: 5 years to 80 years.
- Patients of either sex selected for the study.
- Both new and referred cases considered for the study.
- *Doshadushtjannya* (*Nija Vrana*) *Dushta Vrana*.

- *Saddya Vrana* [*Chinna, Bhinna, Kshata and Ghrista*] which failed to heal after 7 days was considered for the study.
- *Shastra Karma Uttara Dushta Vrana* (post-surgical infected wound)

Exclusion criteria

- Patient with malignant, tubercular, venous, ischemic, tropical, neurogenic ulcers and uncon-

trolled diabetes, underlying bony lesion were excluded.

- Any wound with involvement of vital organs.
- HIV, HbsAg, HCV positive cases.
- Patient with pregnancy and medico-legal case

Outcome parameters: Assessment was done on the basis of subjective and objective parameters planned for the study.

Subjective parameters

Ruja (Pain): Visual analogue scale (VAS), with numerical rating scale (NRS) that allow patient to rate pain intensity on numbered scale, such as the 0 to 10.

0 =	No pain
1 – 3 =	Mild pain
4 – 7 =	Moderate pain
8 – 10 =	Severe pain

Kandu (Itching): Visual analogue scale (VAS), with numerical rating scale (NRS) that allow patient to rate itching intensity on numbered scale, such as the 0 to 10.

0 =	No itching
1 – 3 =	Mild itching
4 – 7 =	Moderate itching
8 – 10 =	Severe itching

Objective Parameters

• *Srava (Discharge)*

No discharge/ dry dressing	0
The gauze is slightly moist	1
The gauze is completely wet in 24 hours	2
The gauze is completely wet in 12 hours	3

Akriti (Size): The wound sizes have been measured by multiplying the maximum length (head to foot), maximum width (left to right) and maximum depth in cm.

No discontinuity of epithelium	-0 0
Size of wound	= 0.1 – 5 cm ³
Size of wound	= 5.1 – 10 cm ³
Size of wound	> 10 cm ³

Statistical methods: The data collected from study was compiled, tabulated and analyzed and comparison of data of both the group was done following standard statistical methods.

Observation and Results: All the patients were treated upto a period of 42 days or till complete healing of wound. Each patient was observed thoroughly and noted neatly. As per the prepared proforma, observa-

tions were made regarding incidence of *Dushta Vrana* with regard to age, sex, occupation, religion, socioeconomic status, marital status, habitat, chronicity, site and cause of the wound etc. For assessments of results from outcome parameters, observations were made before treatment, during the follow up and after treatment and shown in table.

Table 1: Comparison of healing time in both the groups

Group	Mean	SD	SE	Z value	P value	Remark
A	20.13	13.05	3	2.05	<0.05	Statistically significant
B	26.28	13.68				

Table 2: Efficacy of treatment in Group A

Sl. No.	Parameters	BT	AT	SE	t value	p value
		Mean ± SD	Mean ± SD			
1.	<i>Ruja</i> (Pain)	6.88 ± 0.65	0.10 ± 0.30	0.12	58.428	p <0.01
2.	<i>Kandu</i> (Itching)	7.35 ± 1.05	0.20 ± 0.41	0.14	52.351	p <0.01
3.	<i>Srava</i> (Discharge)	2.5 ± 0.55	0.18 ± 0.38	0.08	27.975	p <0.01
4.	<i>Akriti</i> (Size)	1.88 ± 0.82	0.33 ± 0.66	0.09	16.421	p <0.01

Table 3: Efficacy of treatment in Group B

Sl. No.	Parameters	BT	AT	SE	t value	p value
		Mean ± SD	Mean ± SD			
1.	<i>Ruja</i> (Pain)	6.78 ± 0.95	0.38 ± 0.67	0.15	43.609	p <0.01
2.	<i>Kandu</i> (Itching)	7.00 ± 1.04	0.33 ± 0.62	0.12	57.842	p <0.01
3.	<i>Srava</i> (Discharge)	2.35 ± 0.53	0.25 ± 0.49	0.07	30.087	p <0.01
4.	<i>Akriti</i> (Size)	1.83 ± 0.84	0.45 ± 0.71	0.09	16.102	p <0.01

Table 4: Comparison of efficacy of treatment between Group A & Group B

Sl. No.	Parameters	Mean ± SD		SE	Z value	p value
		Group A	Group B			
1.	<i>Ruja</i> (Pain)	6.78 ± 0.73	6.40 ± 0.93	0.19	2.005	p <0.05
2.	<i>Kandu</i> (Itching)	7.15 ± 0.86	6.63 ± 0.77	0.18	2.862	p <0.05
3.	<i>Srava</i> (Discharge)	2.33 ± 0.53	2.1 ± 0.44	0.11	2.073	p <0.05
4.	<i>Akriti</i> (Size)	1.55 ± 0.60	1.38 ± 0.54	0.13	1.375	p >0.05

DISCUSSION

Both the groups have shown highly significant effect in controlling the symptoms of *Dushta Vrana* such as pain (*Ruja*), itching (*Kandu*), discharge (*Srava*) and wound size (*Akriti*) as a local wound care agent. When the differences observed between the groups, the trial drug i.e. *Nimbapatradi Lepa* is found to be more effective in controlling pain (*Ruja*), itching (*Kandu*) and discharge (*Srava*) than povidone iodine. But the differences were not significant in reducing wound size (*Akriti*) and suggest that the trial drug has similar property with control drug. It was found that the healing time was significantly lower in trial group A compared to group B. The mean healing time was 20.13 days in trial group whereas 26.28 days in control group and the difference was found to be statistically significant, indicates that the trial drug has significant *Vrana Ropana* effect.

Probable Mode of Action To achieve the proper healing of chronic wound, removal of the debris or debridement is very much necessary. In *Sushruta Samhita* various drugs for *Shodhana* and *Ropana* of *Vrana* along with different kinds of medical, para-surgical and surgical methods of debridement are mentioned. In this study, the prepared trial drug i.e. *Nimbapatradi Lepa* contains phytochemical constituents like alkaloids, glycosides, foam, tannins, terpenoid, molecules which reduces sugar etc. In various phytochemical studies, reducing sugar found to be helpful in promoting granulation tissue formation. Alkaloids of neem possess antimicrobial property and maintain the healing process by reducing the bacterial population. Glycosides and foams are known to have angiogenic effect and decreases wound exudates respectively. Terpenoid helps in proliferation phase of wound healing whereas tannins decrease the scar tis-

sue formation by inhibiting the formation and removal of reactive oxygen substances. Tannins improved the wound healing process by wound contraction with increased capillary formation and collagen synthesis. Based on the *Ayurvedic* properties of the used drugs in this study, it is observed that most of the drugs are of *Tikta*, *Kashaya* and *Madhura Rasa*. Combinedly these three acts as *Pittashamaka*, *Avidahi*, *Sravasoshaka*, etc. thus decrease inflammation, exudates and promote proper healing process. *Madhura Rasa* has *Dhatuvaradhaka* (promote granulation, epithelialization), *Dahaprashamaka* (relieves burning sensation), *Twachya* (helps in epithelialization), *Balya* (increase tensile strength) properties. *Kandughna* (reduces itching), *Lekhana* (debridement), *Swedaghna* (reduces secretion), *Sthirakara* (helps in healthy and stable granulation) etc. are the actions of *Tikta Rasa*. *Kashaya Rasa* has *Ropana* (improves healing), *Lekhana* (debridement), *Swavarnikara* (bring back the normal colour after healing) etc. properties. Again most of the components of the formulation are *Shita Virya* which causes *Vishyandana* (reduces exudates), *Sothahara* (reduces the swelling), *Pitashamaka* (decreases inflammation), *Vedanasthapana* (subsides pain), *Sandhaniya* (helps in tissue union), *Varnya* (prevents discolouration), *Krimighna* (antimicrobial), *Kandughna* (reduces itching) *Vrana Shodhana*, *Pachana* (cleansing), and *Ropana* (improves wound healing) etc. The *Madhu* (honey) helps in remove the debris and reduces discharge due its *Lekhana*, *Samgrahi* property. *Ghrita* and *Tila* imparts *Snigdghata* to the preparation, which alleviates the aggravated *Vata Dosha* and helps to minimize the inflammation as well as it increases the moisture to protect the healing surface.

CONCLUSION

Various medicinal formulations have been described in *Ayurvedic* classics for the treatment of *Dushta Vrana*. With proper research they can add an extra dimension in the field of wound care. In this study, it was observed that the wound healing was significantly faster in group A (trial group) with no complications and less pain during dressing change. Both the drugs

have shown significant effect on controlling symptomatology such as pain, itching, discharge and wound contraction. When the effect was compared between both the groups, the trial drug was found to be more effective in reducing pain, itching and discharge than control drug. But an insignificant difference was observed in reducing wound size and it suggests that both the drug have similar effect in reducing wound size. Thus, it can be concluded that the *Nimbapatradi Lepa* has significant efficacy in the management of *Dushta Vrana* (chronic infected wound).

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