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Research Article

CLINICAL STUDY ON THE EFFICACY OF DUSHTA VRANA PRASHAMAN LEPA AS AN EXTERNAL APPLICATION IN THE MANAGEMENT OF DUSHTA VRANA

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ABSTRACT:

Acharya Sushruta is one among the few to recognize different stages of healing in precision and has advocated appropriate management. Sixty treatment (Shasti-upakramas) modalities are mentioned in vrana roga. No other disease has such large number of treatment modalities. This reveals the importance of vrana as roga. Wound management is emerging as a specialty branch. Vrana is the condition associated with Dhatu nasha (Destruction of tissue) and characterized by Vedana (Pain), Srava (Discharge) and Vikruti (deformity). It is interesting to note that the management of deformities after Vrana Ropana is also being dealt with equal importance. With the changing scenario, Ayurveda has an opportunity to contribute by its wide range of medicaments available in the pharmacopeia. Therefore in the present study all efforts are first aimed at keeping the wound clean during the various stages of its healing. An appropriate measure to control blood sugar level is also taken in to consideration. The present study is planned to evaluate the role of local application of Dushta vrana prashaman lepa in dushta vrana, mentioned in sharangadhar samhita.

KEY WORDS: *Shushruta, vrana, Dhatu Nasha, Ropana,l epa*

INTRODUCTION:

Vrana is one of them which have been managed by human being from starting of civilization. Vrana is seen as debilitating and scaring disorder usually seen affecting the human being at any age. Vrana is the most important and widely described chapter of Shalya Tantra, because Vran is most commanly occurs, every technic of surgical and parasurgical process deals with vran, any kind of war's, any natural calamities, any bites leads to vran, shothadi samprapti leads to vran, these all may leads further to Dushta vrana, Acharya Sushruta – The father of surgery has scientifically classified it in a systemic manner whose wealth of clinical material and the principles of management are valid even today. A wound which refuses to heal or heals very slowly in spite of best efforts by Chikitsa Chatushpada (Bhishak, Dravya, Upsathata and Rogi) is known as Dushta Vrana. According to Acharya Sushruta, wound healing is quite evident if the patient is self-controlled and treated by good surgeon, on the contrary, if the patient is impatient and treated by quacks they become Dushta or vitiated further due to increase of Doshas. After that they become chronic and non-healing ulcers. In Ayurveda, such chronic, non-healing ulcers are treated as Dushta vranas. Sushruta has elaborately explained 16 types of Vrana, depending on the vatadi doshic involvement and also including shuddha-vrana. There is no doubt, that art of surgery revolves around the Vrana and its essence is uncomplicated healing. The society believes "Times is a Great Healer" but surgeons are dissidents in this respect, they needs early and uncomplicated healing. The present study is planned to evaluate the role of local application of Dushta vrana prashaman lepa in dushta vrana, mentioned in sharangadhar samhita.

AIM:

To study the efficacy of dushta vrana prashaman lepa as an external application in the mamagement of dushta vrana.

OBJECTIVES:

1. To compile the information on dushta vrana according to Ayurveda literature and modern science.

2. To evaluate information on dushta vrana prashaman lepa prayog according to ayurvedic literature in the management of dushta vrana.
3. To conduct the clinical study to find out the efficacy of dushta vrana prashakman lepa and povidone iodine in the management of dushta vrana.

MATERIAL AND METHODS:

Nimbapatradi Dravya (In Dushta Vran Prashaman Lepa)–Standardized.
Povidone Iodine –Standardized.
Gelatin Graph Paper.
Convex Lens.
All sterile dressing material & Surgical Instrument.

Source of data: - Patients attending the O.P.D & I.P.D. of our hospital.

DRUG: - Dushta Vran Prashaman lepa

निम्बपत्रं तिलं दन्ती त्रिवृत्सैन्धवमाक्षिकम् ।
दुष्टव्रणप्रशमनो लेपः शोधनरोपनः ॥ शा.स.अ. 11 श्लो. 91.

APPARATUS:-
Khalwa yantra, Cylindrical vessel, Stirrer, Mortar, Pestle, Trang.

Ingredients:

Nimba Patra	-	01 part
Tila	-	01 part
Danti	-	01 part
Trivrutta	-	01 part
Saindhava	-	01 part
Makshika	-	01 part

Method of Preparation -
The drugs mentioned above are to be taken 50gm each make into churna in the khalwa yantra. The churna is to be collected and by mixing with honey the paste is to be made and applied to the patient in a lepa form.

Method of Application –
The procedure adopted was:-

1. Vrana was properly exposed.
2. It was thoroughly washed with normal saline.
3. It was dried with sterile gauze.
4. Application Dushta vrana prashaman lepa.

METHOD OF WORK
Design -
It is Randomized Open Controlled Study.

Sample size -
Total 60 patients (subjects) who have clinically diagnosed with Dushta-Vrana will be randomly classified into 2 groups.

Statistical Analysis –
The collected data analyzed using 't' Test.

Group A (Trial Group) :- Dressing by using Dushta Vrana Prashaman Lepa under all aseptic precautions for 20 Days & applied to all parameters for 30 patients.

Group B (Control Group):- Dressing of Povidone Iodine under all aseptic precautions for 20 Days & applied to all parameters for 30 patients.Debridement in both groups will be done by Surgical Instruments, if Slough is present.Both the group will follow pathyakar Ahar-vihar.

PARAMETERS OF ASSESSMENT:
The patients were assessed on the basis of subjective and objective parameters before and after treatment.

SELECTION CRITERIA
A. INCLUSION CRITERIA
1. Age 18 – 50 yrs – either sex.
2. Clinically diagnosed patients of Dushta Vrana.
3. Wound – Maximum area Not exceeding than 3×3 cm (900sq.mm.) with depth ≤0.5cm
4. Written concent will be taken from selected patient.

B. EXCLUSION CRITERIA
1. Dushta vrana associated with other predignosed desease like-
   - Diabetes mellitus
   - Tuberculosis.
   - Leprosy.
   - Ischemic Ulcer.
   - Neurogenic Ulcer
   - Malignant ulcers.
   - Gangrene.
   - Presence of magets.
2. Subjects with K/c/o positive HIV & HBV.
3. Agantuj Vrana/Sadyovrana (Shudhavasta).

SUBJECTIVES
1.Pain:
- No Pain (0)
- Tolerable occasional localised Pain / mild pain (1)
- Localised pain during movement is not tolerable/ moderate pain (2)
- Localized pain even during rest, disturbing sleep / severe pain (3).

OBJECTIVE:
1. Size of Wound:
- Sterile transparent sheet with printed graph lines of size 1mm × 1mm was used for this procedure.

2. Discharge:
- No Discharge/ dry dressing (0)
- Scanty occasional Discharge (1)
- Little wet dressing with slight discharge (2)
- Profuse Discharge (3)

3. Swelling of the surrounding of wound:
- No swelling (0)
- Slight red, tender swelling / mild (1)
- Red with painful movements / moderate (2)
- Hot, resist on touch / Severe (3)

4. Granulation tissue:
- Healthy granulation tissue (0)
- Presence of unhealthy granulation tissue less than 25% (1)
- Presence of unhealthy granulation tissue between 25-50% (2)
- Presence of unhealthy granulation tissue more than 50% (3)

INVESTIGATIONS If required
- CBC
- BSL (R)
- Urine (R & M)
- ELISA for HIV

Observation Table:

Sr. No.	**Symptoms**	Day 0	Day 5th	Day 10th	Day 15th	Day 20th
1.	Size of Wound					
2.	Pain					
3.	Discharge					
4.	Swelling					
5.	Granulation Tissue					

OBSERVATIONS AND RESULTS:

Incidence of Wound site:-

Sr. No.	Wound site	Group A		Group B		Total	
		Count	%	Count	%	Count	%
1.	Ankle	04	13.33%	05	16.67%	09	15.00%
2.	Buttock	03	10.00%	01	03.33%	04	06.67%
3.	Elbow	02	06.67%	03	10.00%	05	08.33%
4.	Foot	09	30.00%	06	20.00%	15	25.00%
5.	Forearm	04	13.33%	04	13.33%	08	13.33%
6.	Knee	02	06.67%	02	06.67%	04	06.67%
7.	Leg	00	00.00%	01	03.33%	01	01.67%
8.	Palm	01	03.33%	01	03.33%	02	03.33%
9.	Shoulder	02	06.67%	03	10.00%	05	08.33%
10.	Thigh	02	06.67%	02	06.67%	04	06.67%
11.	Toe	01	03.33%	02	06.67%	03	05.00%

Pain:

Pain	Median score			IQR of diff. ($Q_3 - Q_1$)	Sample size	Wilcoxon signed rank test (T+)	P – Value
	Bef	Aft	Median (Bef- Aft)				
Group A	2	0	2	0.75 (2 – 1.25)	30	465	< 0.001
Group B	2	0	2	0.75 (2 – 1.25)	30	465	< 0.001

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H_0 : Reduction in Pain scores for group A and group B are equal (equally distributed)

H_1 : Reduction in Pain scores for group A and group B are not equal(not equally distributed)

Group	Median of difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2	1.77	0.504	439	0.849
Group B	2	1.80	0.551		

Distribution of "reduction in Pain" for group A and group B is not significantly different. (p –value = 0.849) Thus **both drug A and drug B can be considered as equally effective in reducing Pain.**

1. **Discharge**

Discharge	Median score			IQR of diff. ($Q_3 - Q_1$)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	Bef	Aft	Median (Bef- Aft)				
Group A	2	0	2	0.75 (2 – 1.25)	30	465	< 0.001
Group B	2	0	2	1 (2 – 1)	30	465	< 0.001

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H_0 : Reduction in Discharge scores for group A and group B are equal (equally distributed)

H_1 : Reduction in Discharge scores for group A and group B are not equal(not equally distributed)

Group	Median of difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2	1.77	0.504	453.5	0.957
Group B	2	1.77	0.568		

Swelling

Swelling	Median score			IQR of diff. ($Q_3 - Q_1$)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	Bef	Aft	Median (Bef-Aft)				
Group A	1	0	1	0 (1 – 1)	30	465	< 0.001
Group B	1	0	1	0 (1 – 1)	30	406	< 0.001

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H_0 : Reduction in Swelling scores for group A and group B are equal (equally distributed)

H_1 : Reduction in Swelling scores for group A and group B are not equal(not equally distributed)

Group	Median of difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	1	1.03	0.183	464	0.677
Group B	1	1.00	0.371		

Distribution of "reduction in Swelling" for group A and group B is not significantly different. (p –value = 0.667)

Thus, **both drug A and drug B can be considered as equally effective in reducing swelling**.

Unhealthy granulation tissue

Unhealthy granulation tissue	Median score			IQR of diff. ($Q_3 - Q_1$)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	Bef	Aft	Median (Bef - Aft)				
Group A	2	0	2	0 (2 – 2)	30	465	< 0.001
Group B	2	0	2	1 (2 – 1)	30	435	< 0.001

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H_0 : Reduction in Unhealthy granulation tissue scores for group A and group B are equal (equally distributed)

H_1 : Reduction in Unhealthy granulation tissue scores for group A and group B are not equal (not equally distributed)

Group	Median of difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2	1.83	0.461	525.5	0.173
Group B	2	1.63	0.615		

Distribution of "reduction in Unhealthy granulation tissue" for group A and group B is not significantly different. (p –value = 0.173)

Thus, **both drug A and drug B can be considered as equally effective in reducing unhealthy granulation tissue.**

Wound size (cm^2)

Decrease in Wound size (Group A)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Wound size	4.72	1.21	3.51	30	0.646	0.118	29.773	< 0.001

Decrease in Wound size (Group B)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Wound size	4.51	1.43	3.08	30	0.803	0.147	21.015	< 0.001

Comparative analysis of groups:

Group	Mean difference	S.D. of difference	n	d.f.	Two sample "t"	P- value
Group A	3.51	0.646	30	58	2.303	0.025
Group B	3.08	0.803	30			

Distribution of patients according to relief:

Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Unchanged	00	00.00%	00	00.00%
Mild improvement	00	00.00%	03	10.00%
Moderate improvement	07	23.33%	04	13.33%
Marked improvement	23	76.67%	23	76.67%

For group A, Out of 30 patients, 23 patients (76.67%) showed marked improvement and 7 patients (23.33%) were moderately improved.
Whereas, for group B, 23 patients (76.67%) were markedly improved, 4 patients (13.33%) were moderately improved and 3 patients (10%) showed mild improvement.

DISCUSSION:

DISCUSSION ON LITERARY REVIEW: Vrana implies rupture of the tissues leading to discolorations and scar, hence it is termed as Vrana. It is better understood in terms of discontinuity of skin, muscles, mucus membrane etc. According to onset of wound, pathogenesis and characters; it can be established in the form of Agantuja (Traumatic wound) & Nija (Ulcers) Vrana. Though no specific Samprapti regarding Vrana exists in any Ayurvedic text an attempt is made here to checkout a specific etiopathogenesis of the disease Vrana

Discussion On probable action of Drug: The drug used for the trial group was Dushta vrana prashaman lepa. Dushta vrana prashaman lepa contains Nimbapatra(Azadiracta indica), Tila(Sesamum indicum), Danti-mool(Baliospermum montanum), Trivritta(Operculina turpethum), Saindhava-lavana (Sodium chloride), and Madhu(Honey). After studying their properties, an innovative compound drug had been prepared by classical Lepa preparation method and named "Dushta vran prashaman Lepa" the word itself suggest its importance in wound healing. It on the basis of shodhana and ropanakarma, used as a prime healing drug described in ayurvedic literatures. An attempt was made to explore the shodhana and ropana properties of the trial drug scientifically. In the process of management of dushta vrana, shodhana followed by ropana two stages happen practically, that is, subsiding local shopha by removal of dhatu dushti, followed by initiation of ropana process, that is, contraction and covering of wound by epithelial layers. *Removal of local Dhatu dushti*: The grading of shuddha vrana depends on the amount of dushti present in local dhatu, that is, twaka and mamsa with rakta dhatu. The containts of trial drug have shothahar (anti-inflammatory), vedanasthapan (analgesic), stambhana (coagulation/contraction), shoshana (absorptive) and rakta shodhaka (blood purifier), krumighna(bactericidal), lekhaniya (debriding), properties, along with samshodhana-sandhana (detoxifying, cleansing-repairing) properties, as explained in the drug review, which provides the desired effect. The ropan of vrana could have been possible after shodhana (medical & surgical debridement) due to removal of dhatu dushti with the help of Dushta vrana prashaman lepa's contents and Yogavahi (catalytic) properties of Tila and madhu, which removes and cleans the dhatu dushti as well as saindhav also carried out the shodhan karma at the site of wound, have been acted and promoted the ropan of vrana.

Drug effect on Pain: Pain is always associated due to the accumulation of Vaata Dosha, as "वातादृते नास्ति रुजा।".Most of the drugs of Dushta vrana prashaman lepa like Danti, trivrutta, tila have ushna veerya and guru, snigdha guna it supresses the sheeta-veerya, laghu, ruksha guna of vaata, madhu also helps in vatashaman and subsides the pain.

Drug effect on Discharge: Discharge is always associated with kaph and pitta dosha. Most of the drugs of this lepa have ruksha, laghu guna, katu vipaaka and ushna veerya, thus reduces the dushta kapha dosha and kleda associated with it. Pitta dosha supresed due to Madhura, Tikta and Kashaaya rasa, sheeta veerya and madhura vipaaka. Thus as kapha-pittaghna action of Nimbapatra, trivrutta, danti etc.) is there, it reduces the discharge.

Drug effect on Inflammation: it is always associated due to dushta Vaata- Kapha dosha. Ingredients of lepa have ruksha, laghu guna, katu vipaaka and ushna veerya, thus reduces the dushta kapha dosha and kleda associated with it. Also, most of the drugs of this lepa have Shothahar and raktashodhak property, due to which the local inflammation reduces. (Nimbapatra, saindhav, danti, tila, madhu etc.)

Drug effect on granulation tissue: Formation of healthy granulation tissue may be due to Madhura Rasa, sandhaniya sneegdha guna of Tila, trivrutta, madhu etc. and Vipaka as well as. It provides nourishment to the skin and all dhatus, thereby influencing the formation of healthy granulation tissue. Also, Katu, Tikta Rasa and Ushna Veerya absorbs the kleda and discharge from unhealthy granulation tissue. Tila and madhu having good vrana ropan properties thereby helps in the formation of healthy granulation tissue.

Drug effect on size of wound: As healthy granulation tissue forms it reduces the size of wound. Also kashaay rasa of nimba, trivrutta and tila plays an important role in contraction of wound edges, thereby reducing the size of wound. The reduction in the size of wound may be due to the shodhan (wound cleaning and healing) property of Nimbapatradi dravyam, which helps for vrana ropan. Madhura ras, sheeta veerya and Madhura vipaka, increases the nourishment to it and helps in healthy granulation tissue formation. As healthy granulation tissue forms it reduces the size of wound. Further the vrana was healed due to the sanghatakar, Ropan propery of nimbapatra, tila and madhu.All the drug included in trial group are having Katu, tikta, kashaya ras, ushnaveerya, and laghu, tikshna guna, katuvipaka, they acts as pachana on kleda in vrana which results into Shodhana and Ropana karma of vrana, and helps to reduce all the symptoms.

Overall response of therapy in both groups : Results shows healthier action on all the subjective and objective symptoms of patients in both the groups. Some symptoms were persisting in some patients and rest of all had reduced their symptoms within stipulated period. Overall analysis shows overall effect of therapy by patients that,For group A, Out of 30 patients, 23 patients (76.67%) showed marked improvement and 7 patients (23.33%) were moderately improved.

Whereas, for group B, 23 patients (76.67%) were markedly improved, 4 patients (13.33%) were moderately improved and 3 patients (10%) showed mild improvement.

CONCLUSION:

The present data of series revels that, For group A, Out of 30 patients, 23 patients (76.67%) showed marked improvement and 7 patients (23.33%) were moderately improved. Whereas, for group B, 23 patients (76.67%) were markedly improved, 4 patients (13.33%) were moderately improved and 3 patients (10%) showed mild improvement. No side effects were observed in this study. To achieve more significant results, we can increase the duration of treatment. In short, the parameters of pain, discharge, swelling, healthy granulation tissue formation, and size of wound showed significant reduction in gradation trial study as compare to control, so we can state that - **After all the above discussions, it can be inferred that the Trial drug – Dushtavrana prashaman Lepa is clinically and Statistically proven to be an effective drug in the management of Dushtavrana.** Hence the hypothesis behind the study found to be correct. Present study limits with only 30 patients, Further study is needed with larger sample size to establish more authentically the efficacy of Dushta vrana prashaman Lepa.

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