

A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF JALOUKAVACHARANA FOLLOWED BY JATYADI GHRITA VIKESHIKA DRESSING AND PRP THERAPY FOLLOWED BY SOFRA TULLE DRESSING IN THE MANAGEMENT OF DUSHTA VRANA W.S.R TO CHRONIC NON-HEALING ULCERS

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ABSTRACT

Dushta Vrana, as described in classics, represents a wound associated with vitiated Doshas and impaired healing. Acharya Sushruta has defined Vrana as condition wherein tissue undergoes destruction, which even after complete healing leaves a scar (Vrana Vastu) over the area which stays as long as person is alive.^[1] Ulcer is a break in the continuity of the covering epithelium, skin or mucous membrane. In India occurrence of chronic wounds is estimated at 4.5 per 1000 population. Chronic non-healing ulcers are wounds that fail to progress through the normal phases of healing within the expected period. The causes may include poor blood supply, venous insufficiency, nerve damage, infection, trauma, or excessive pressure. Effective wound healing requires removal of necrotic tissue through dressings or surgical debridement. If untreated, infections can extend from superficial to deeper tissues, increasing the risk of systemic infection. Therefore, timely and appropriate management of chronic wounds is

crucial. **Materials and Methods:** A total number of 40 patients diagnosed with Dushta vrana of either sex was selected from OPD and IPD of Taranath Government. Ayurvedic medical college and hospital, Ballari and was randomly allotted into 2 groups namely Group-A and Group-B with 20 patients each. **Results:** In the present study, the effect of treatment in both the groups showed statistically significant in all parameters and the overall changes are higher in Group A (71.74 %) as compared to Group B (60.12 %). **Conclusion:** Jaloukavacharana f/b Jatyadi Ghrita Vikeshika is more effect when compared to PRP Therapy f/b Sofratulle.

KEYWORDS: Vrana, Jaloukavacharana, Jatyadi Ghrita, Jatyadi Ghrita, Sofratulle.

INTRODUCTION

Acharya Sushruta while defining Shalya Tantra explains Vrana Vinischayartham as its prime aspect by which we can understand the importance given to Vrana amongst many other diseases. Also, Acharya Dalhana in Agropaharaneeya chapter explains Trividha karma for Vrana which again indicates its importance in Shalya Tantra.^[2] He also beautifully explains the stages of wound healing as Dushta vrana, Shuddha, Ruhyamana and Rudha Vrana.^[3] Acharya Sushruta has elaborately explained Saptaupakramas, Ekadasha Upakramas and Shashti upakramas and this huge variety of treatments cannot be found in any other diseases. The features of Dushtavrana mentioned can be compared with chronic non-healing ulcers in modern science.^[4] In modern science, ulcer refers to discontinuity in the covering epithelium, skin or mucous membrane and may either follow molecular death of surface epithelium or its traumatic removal. While most wounds heal in an orderly and timely manner, some fails to progress through the normal stages of healing and become chronic. Chronic non healing ulcers commonly arises due to conditions like diabetes melitus, vascular insufficiencies, trauma, pressure ulcers and infections. The underlying pathophysiology involves impaired microcirculation, persistent inflammation, microbial colonization and reduced cellular regeneration. The conventional treatment for non-healing ulcers includes wound cleansing, necrotic tissue debridement, infection management etc. Application of Autologous Platelet Rich Plasma (PRP)^[5] has emerged as promising modality for the treatment of non-healing ulcer, as it is easy and effective method and provides necessary growth factors that enhance tissue healing. But on the other hand, it has complications like bleeding, tissue damage, infection, nerve injuries at the injected site. Sofratulle containing 1% Framycetin sulphate, soft paraffin, anhydrous lanolin is used as dressing material. They reduce adherence in the

wound bed and allow exudates to pass into secondary dressing, thus maintains moist environment to wound.^[6] The properties of chronic non healing ulcers come under the umbrella of Dushtavrana explained by Acharya Sushruta. Hence among Shashtiupakramas an apt choice of treatment serves the purpose. Jaloukavacharana vidhi is one of the important treatments mentioned in vrana chikitsa.^[7] Dushta vrana which is Katina, Vivarna, Vedananvita, Vishayukta dushta rakta are drained by leeches.^[8] Leech saliva contains anticoagulants, vasodilator, anti-inflammatory agents, thus promotes wound healing. Acharya Sushruta also mentions Bandha for healing purpose^[9] in different forms like vikeshika, kavalika, plota, pichu.^[10] Among these Vikeshika is the cloth which contains tila kalka, madhu and ghrita. The application of Jatyadi Ghrita^[11] vikeshika serves as an ideal wound dressing due to its vrana shodhana and ropana properties. Keeping these into consideration, the study has been conducted to assess the combined effect of Jaloukavacharana followed by Jatyadi Ghrita Vikeshika dressing in comparison with standard PRP Therapy followed by Sofratulle dressing in the management of Dushta vrana w.s.r to Chronic non healing ulcers.

AIMS AND OBJECTIVES

- To evaluate the effect of Jaloukavacharana followed by Jatyadi Ghrita Vikeshika dressing in the management of Dusta vrana w.s.r to Chronic non-healing ulcers.
- To evaluate the effect of PRP Therapy followed by Sofratulle dressing in the management of Dusta vrana w.s.r to Chronic non-healing ulcers.
- To compare the combined effect of Jaloukavacharana followed by Jatyadi Ghrita Vikeshika dressing and PRP Therapy followed by Sofratulle dressing in the management of Dusta vrana w.s.r to Chronic non-healing ulcers.

MATERIALS AND METHODS

A. Study Design

A randomized, open-labelled, comparative clinical study was conducted in patients diagnosed with Dushta Vrana correlating with chronic non-healing ulcers. A total of **40 patients** fulfilling the predetermined inclusion criteria were randomly allocated into two groups of 20 patients each. **Group A** received Jaloukavacharana followed by Jatyadi Ghrita Vikeshika dressing, whereas **Group B** received PRP therapy followed by Sofra Tulle dressing.

B. Source of Patients

A total number of 40 patients diagnosed with Dushta vrana of either sex was selected from OPD and IPD of Taranath Government. Ayurvedic medical college and hospital, Ballari.

DIAGNOSTIC CRITERIA

Inclusion Criteria

1. Patients will be selected between 20-70 years of age, irrespective of sex religion, occupation.
2. Specific signs and symptoms of dusta vrana (durgandha yukta, puti puya, vedana, raga, kandu, dusta shonita srava, dhirkakalanubandhi)
3. Size of ulcer within 7×7 cm
4. Diabetes mellitus (under control)
5. Hypertension (under control)

Exclusion criteria

1. If Hb% less than 10gm%, Thrombocytopenia
2. Malignant ulcer, Burns
3. Multiple ulcers
4. Ulcer associated with, HIV I &II, Hepatitis-B, Tuberculosis, Osteomyelitis

INVESTIGATIONS

- CBC
- ESR
- RBS
- CT
- BT
- HIV I & II
- HBsAg

MATERIALS REQUIRED



SL NO.	Material Required	Quantity
1	Dressing Trolley	01
2	Dressing Table	01
3	Surgical Gloves 6.5	01
4	Sterile Gauze Piece	q.s
5	Sterile Pads	q.s
6	Sterile Artery Forceps	01
7	Normal Saline	q.s
8	Roller Bandage	q.s
9	Kidney trays	02
10	Nirvisha jalouka	02
11	Haridra choorna	q.s
12	Insulin syringe	01
13	Dispo van syringe	01
14	Fresh PRP	q.s
15	Jatyadi ghrita vikeshika	q.s
16	Sofratulle	q.s

PROCEDURE

1 JALOUKAVACHARANA

Purva Karma

- Patient consent is taken
- All the materials required for procedure are arranged and later the subject was made to lie down.
- Jalouka have been anointed with paste of Sarshap and Haridra choorna and placed in a water to make it active.

Pradhana Karma

- Jaloukas applied over the wound after cleaning its mouth. If Jalouka doesn't bite the site then sterile needle prick is done on the area. When Jalouka starts sucking blood cover it with wet piece of cotton.

Paschat Karma

- After Jalouka falls off, the Jalouka should be dusted with Haridra and Saindhava, then gently rub their backs to make them vomit the blood.
- Wound dressing is done with Jatyadi Ghrita Vikeshika.
- The same procedures done once in 7days for 4 sittings

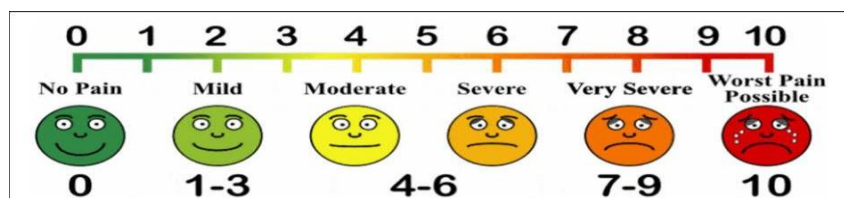
2 PRP THERAPY

- Depend upon the Size of the Wound, the required quantity of blood is drawn from

Median cubital vein of the patient (Approximately 10ml blood is drawn).

- Withdrawn blood is collected in a tube and then subjected to Centrifugation for around 15-20 min.
- After centrifugation, there will be solid particles sedimentation at the bottom of tube and upper plasma layer is collected which is rich in platelets. To get more concentration, the tube is centrifuged again for 4-5 minutes.
- After double centrifuge, a small platelet rich pellet was obtained at bottom of the tube. The upper 2/3rd of plasma discarded and lower 1/3rd was resuspended with pellet to prepare platelet rich plasma with platelets counts 3 to 4 folds of baseline.
- Then platelet rich plasma is collected and used within 20 minutes of its collection.
- Wound is cleaned with normal saline.
- PRP loaded in Insulin syringe and slowly injected up to 2-3mm depth into the edges of wound and then into the floor of the wound with 0.3ml of PRP every centimetre.
- After injecting PRP, the wound dressing is done with Sofratulle.

ASSESSMENT CRITERIA



SUBJECTIVE PARAMETERS

1. Vedana (VAS)

GRADE	VAS SCALE
0	No pain
1 (1-3)	Mild pain
2 (4-6)	Moderate pain
3 (7-9)	Severe pain
4 (10)	Worst pain

2. Kandu (Itching)

GRADE	KANDU (ITCHING)
0	No Itching
1	Mild (occasionally)
2	Moderate (persist all the day)
3	Severe (Itching with scratch marks)
4	Continuous severe (Itching disturbs routine activities and sleep)

3. Gandha (Odour)

GRADE	GANDHA (FOUL SMELL)
0	No Odor
1	Weak odor
2	strong odor
3	Very strong odor

OBJECTIVE PARAMETERS

1. Parimana (Size of Wound)

GRADE	SIZE
0	Healed
1	1 - 3 cm
2	3.1 - 5 cm
3	5.1 - 7 cm

2. Margins

GRADE	MARGINS
0	Well-defined
1	With advanced border of epithelium
2	No advancing border of epithelium
3	Not well-defined

3. Srava (Discharge)

GRADE	SRAVA (DISCHARGE)
0	No discharge
1	Wets 2×2 cm gauze
2	Wets 4×4 cm gauze
3	Wets >6×6 cm gauze

4. Floor (Granulation Tissue)

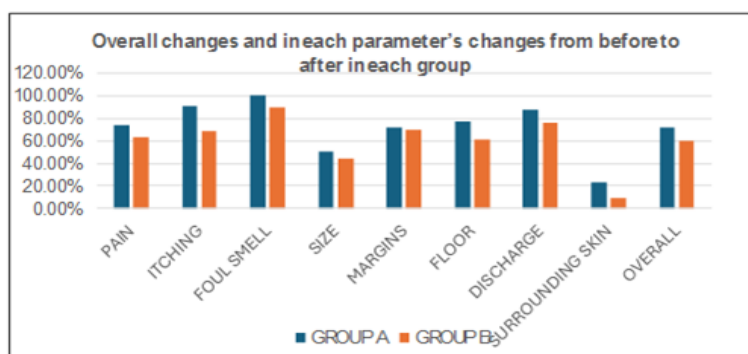
GRADE	FLOOR (GRANULATION TISSUE)
0	Complete epithelialization, well-defined granulation Tissue
1	Complete epithelialization, poor granulation Tissue
2	No epithelialization, granulation Tissue poorly formed
3	No epithelialization, no granulation Tissue formed

5. Surrounding Skin

GRADE	SURROUNDING SKIN
0	Twaka sama varna
1	Kapota varna
2	Shweta Rakta varna
3	Krishna varna

RESULTS

Parameters	Group	Mean change	Median change	% of change
Pain	Group A	1.8	2.0	73.47
	Group B	1.4	1.0	63.64
Itching	Group A	1.4	1.0	90.32
	Group B	1.1	1.0	68.75
Foul smell	Group A	1.1	1.0	100.00
	Group B	1.3	1.0	89.29
Size	Group A	1.2	1.0	51.06
	Group B	0.9	1.0	43.90
Margins	Group A	1.8	2.0	71.43
	Group B	2.0	2.0	69.64
Floor	Group A	1.9	2.0	77.08
	Group B	1.4	1.0	60.87
Discharge	Group A	1.4	1.0	87.50
	Group B	1.3	1.0	75.76
Surrounding skin	Group A	0.6	1.0	23.08
	Group B	0.2	0.0	9.09
Overall	Group A	1.4	1.4	71.74
	Group B	1.2	1.0	60.12



OBSERVATIONS

Group A: Jaloukavacharana Followed By Jatyadi Ghrita Vikeshika Dressing



BEFORE TREATMENT



DURING TREATMENT



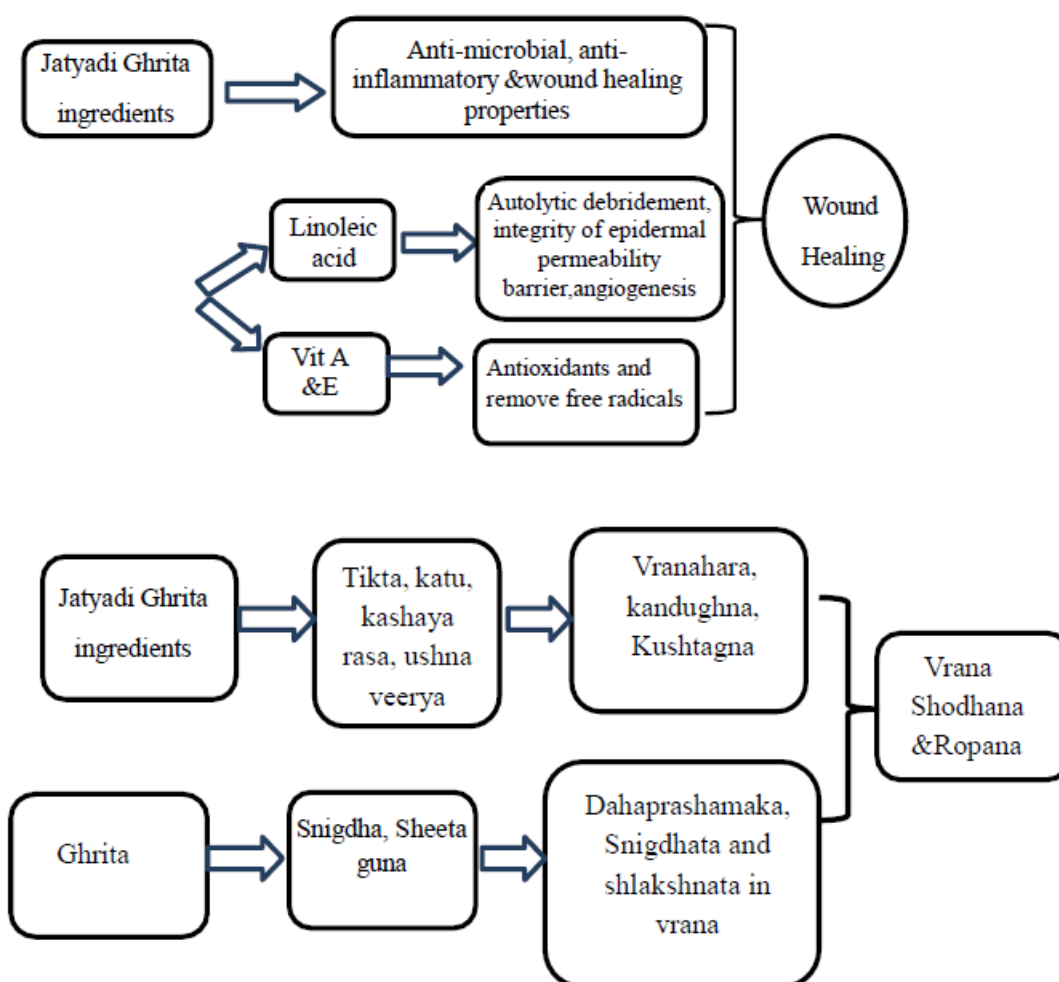
AFTER TREATMENT

**BEFORE TREATMENT****DURING TREATMENT****AFTER TREATMENT****GROUP B - PRP THERAPY FOLLOWED BY SOFRATULLE DRESSING****BEFORE TREATMENT****DURING TREATMENT****AFTER TREATMENT****BEFORE TREATMENT****DURING TREATMENT****AFTER TREATMENT**

DISCUSSION

MODE OF ACTION OF JALOUKAVACHARANA and its observed effects in the present study can be summarized as follows:

- **Pain:** Significant reduction may be attributed to its **Vedanasthapana and Shothahara** effects, along with the analgesic and anti-inflammatory actions of bioactive substances in leech saliva.
- **Itching and foul smell:** Marked improvement seen which may be due to the **Raktashodhana effect** and reduction of local inflammatory factors.
- **Wound healing:** Improvement in the wound floor and margins indicates healthy granulation and progression towards healing, possibly aided by enhanced local microcirculation and tissue oxygenation.
- **Patient acceptability:** Jaloukavacharana is a **minimally invasive, well-tolerated and patient-friendly** procedure.



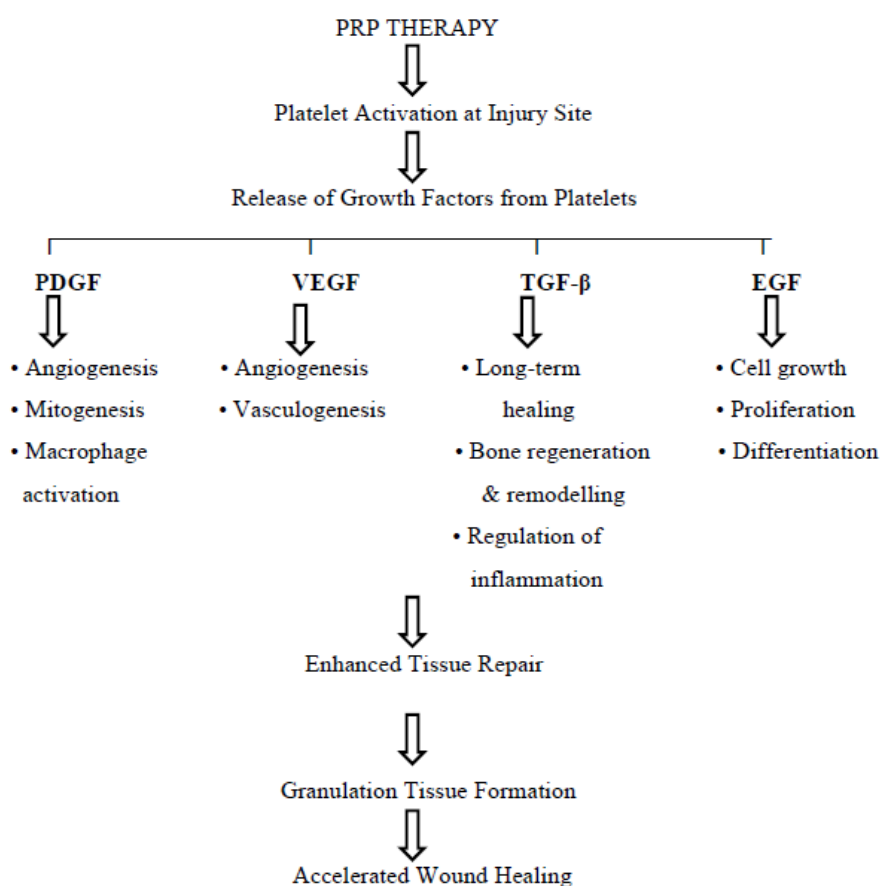
MODE OF ACTION OF JATYADI GHRITA VIKESHIKA

VIKESHIKA

Vikeshika acts as a medicated gauze dressing that helps in maintaining cleanliness, adequate moisture, and protection of the wound from external contamination. The sustained local action of Jatyadi Ghrita through Vikeshika may have enhanced its Vrana Shodhana and Vrana Ropana properties.

MODE OF ACTION OF PRP THERAPY

PRP THERAPY



The observations on effect of PRP Therapy in the present study are as follows:

- Reduction in pain and inflammation observed in the study may be due to the anti-inflammatory action of growth factors and improved tissue repair.
- Marked improvement observed in ulcer floor and margins suggests healthy granulation tissue formation and enhanced vascularity at the wound site.
- PRP therapy was found to be relatively more invasive, painful procedure and comparatively less effective in certain clinical parameters like itching, surrounding skin discoloration.

Overall, the observations of the study suggest that PRP therapy is an effective modality in promoting wound healing in chronic non-healing ulcers through enhanced tissue regeneration and growth factor-mediated repair mechanisms.

MODE OF ACTION OF SOFRATULLE

- Sofratulle dressing was used as a secondary dressing following PRP therapy which helped in maintaining a moist wound environment and prevents adherence of the dressing to the wound surface.
- Its non-adherent nature minimized pain and tissue damage while removing the dressing, thereby improving patient comfort.

CONCLUSION

- The present study was conducted to evaluate the efficacy of *Jaloukavacharana* followed by *Jatyadi Ghrita Vikeshika* dressing (Group A) and PRP therapy followed by Sofratulle dressing (Group B) in the management of *Dushta Vrana* w.s.r. to Chronic Non-Healing Ulcers. A total of 40 patients were randomly selected and divided equally into two groups.
- *Jaloukavacharana* followed by *Jatyadi Ghrita Vikeshika* dressing possesses significant *Vrana Shodhana*, *Raktashodhana*, *Shothahara*, *Vedanasthapana*, and *Vrana Ropana* properties, which contribute to effective healing of chronic non-healing ulcers.
- PRP therapy followed by Sofratulle dressing is also effective in promoting wound healing through growth factor-mediated tissue regeneration and angiogenesis.
- On the basis of overall clinical improvement and percentage relief in various parameters, *Jaloukavacharana* followed by *Jatyadi Ghrita Vikeshika* dressing showed better results than PRP therapy followed by Sofratulle dressing in the management of *Dushta Vrana* (Chronic Non-Healing Ulcer).

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