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Clinical trial to evaluate the addon effect of *Vimlapana Karma* in *Dushta Vrana* w.s.r. to Varicose Ulcer: A Randomised Controlled Trial

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ABSTRACT

Dushta Vrana, associated with delayed healing and correlated with varicose ulcers, arises from venous insufficiency. According to *Sushrut Samhita*, Ayurvedic treatments like *Vimlapana Karma* and *Jalaukavacharana* are emphasized for their wound-healing and anti-inflammatory properties, while *Saptopakrama* and *Shasti Upakrama* address *Vrana Shopha* and *Vrana*. This study explores the additive effect of *Vimlapana Karma* on the standard treatment of *Jalaukavacharana* for *Dushta Vrana*. Forty patients with *Dushta Vrana* were randomly assigned to two groups: Group A received wound dressing and *Jalaukavacharana*, while Group B received *Vimlapana Karma* and *Jalaukavacharana,* both over 21 days. Both Group A (*Jalaukavacharana*) and Group B (*Vimlapana Karma* with *Jalaukavacharana*) showed statistically significant improvements ($p < 0.001$) in ulcer size, edges, exudate, surrounding skin color, and granulation tissue formation. Combining *Jalaukavacharana with Vimlapana Karma* significantly enhanced wound healing and accelerated recovery in *Dushta Vrana* (varicose ulcers).

Key words: *Dushta Vrana, Vimlapana Karma, Jalaukavacharana, Saptopakrama, Chronic wounds, Non-healing ulcer.*

INTRODUCTION

Varicose ulcers are the most prevalent complication of varicose veins, likely to affect many patients during their lifetime. Varicose ulcers, also referred to as venous insufficiency ulcers, venous leg ulcers, or gravitational ulcers, are a severe and debilitating consequence of chronic venous insufficiency. A chronic venous ulcer can be defined as an area of discontinuity of epidermis, persisting for four weeks or more and occurring as a result of venous hypertension and calf muscle pump insufficiency.[1]

Venous leg ulcers (VLUs) are open lesions of the lower limb and represent between 60 to 80% of all leg ulcer.[2] It is the commonest painful condition that every patient inflicted with varicose veins and occurs by Ambulatory venous hypertension is the prime cause of venous ulcer formation. The prevalence of chronic venous ulcers in the leg is 70%-80% (2022) and Overall Incidence rate was 0.76% for males and 1.42%in females (2018).[3]

In Varicose ulcer various growth factors and inflammatory cells, which get trapped in the fibrin cuff promote severe uncontrolled inflammation in surrounding tissue preventing proper regeneration of wounds. Leukocytes get trapped in capillaries, releasing proteolytic enzymes and reactive oxygen metabolites, which cause endothelial damage. These injured capillaries become increasingly permeable to various macromolecules, accentuating fibrin deposition.[4] Occlusion by leukocytes also causes local

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ischemia thereby increasing tissue hypoxia and reperfusion damage. So, it is the responsibility of surgeon that it should be cured within short period with less pain and less cost.

Conservative management of varicose ulcer includes compression, stocking, elevation of limb, antibiotics usage and regular dressing of the wound. Surgical treatments like skin grafting, sclerotherapy, laser ablation or surgical correction of superficial venous reflux practice are in use. However, recurrence of venous ulcer about 75% develop within a 3weeks and on average 60% Healed by12 weeks. Untreated ulcers have complications like infection, loss of mobility, cellulites, gangrene and eventually lead to amputation of a limb.[5]

Varicose ulcer is correlated to *Dushtavrana* having classical features[6] such as *Ativivruta* (too wide), *Atikhatina* (too hard), *Atiutsanna* (extremely elevated), *Atyushna* (too hot), *Pootipuyasrav* (Purulent discharge), *Dheergha Kalanubandi* (long duration). In Sushruta Samhita (17th chapter of Sutrasthana: *Aamapakveshaneeya Adhyaya*[7] and 1st chapter of *Chikitsa Sthana*: *Dwivraniya Chikitsitam* Adhyaya),[8] *Vimlapana Karma*[9] (gentle massage) is recommended for managing *Vrana Shotha* (wound inflammation) and *Vrana* (wound). This preliminary treatment relieves *Vata-Kapha dosha* obstruction, promoting wound healing by increasing local temperature, relaxing vasoconstriction, enhancing oxygenation and nutrient delivery to the wound site, removing accumulated toxins, and accelerating wound healing.

To relieve such obstruction, sensitize the cells in and around the wound, and enhance the rate of wound healing, *Vimlapana Karma* was selected. *Vimlapana Karma* resolved inflammation around the wound and improved blood circulation, thereby aiding in early wound healing.

After, *Vimlapana Karma Jalaukaavacharana*(leech therapy) was performed. *Jalaukavacharanaha*[10] has its own benefits viz.-*Jalauka* (Leech) is anti-phlogistic, i.e. used for relief of local inflammation in tissue and has capability of improving microcirculation. *Jalaukavacharana* being a bio-purificatory method removes deep seated toxins by letting out blood, clearing *Srotasa* and pacifying vitiated *Doṣha*. It is indicated in *Pittaja* and *Raktaja Dosha* conditions and act on improving the microcirculation and vasodilatation by decreasing the venous pressure hence improves tissue perfusion and help in wound healing.

Aims and Objectives

1. To evaluate the effect of *Jalaukavacharana* in *Dushtavrana* w.s.r to Varicose ulcer.
2. To evaluate the combined effect of *Vimlapana Karma* and *Jalaukavacharana* in *Dushtavrana* w.s.r to Varicose ulcer.
3. To compare the combined effect of *Vimlapana Karma* followed by *Jalaukavacharana* with *Jalaukavacharana* in *Dushtavrana* w.s.r to Varicose ulcer.

Hypothesis

Null Hypothesis

- There is no significant effect of *Vimlpana Karma* followed by *Jalaukavacharan* in *Dushta Vrana* w.s.r. to Varicose ulcer.
- There is no significant effect of *Jalaukavacharan* in *Dushta Vrana* w.s.r. to Varicose ulcer.
- There is both group *Vimlapana Karma* followed by *Jalaukavacharana* and *Jalaukavacharana* in *Dushta Vrana* w.s.r. to Varicose ulcer is comparable.

Alternate Hypothesis

- There is significant effect of *Vimlpana Karma* followed by *Jalaukavacharana* in *Dushta Vrana* w.s.r. to Varicose ulcer.
- There is significant effect of *Jalaukavacharana* in *Dushta Vrana* w.s.r. to Varicose ulcer.
- There is both group *Vimlapana Karma* followed by *Jalaukavacharana* and *Jalaukavacharana* in *Dushta Vrana* w.s.r. to Varicose ulcer is not comparable.

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METHODOLOGY

This study was conducted between September 2023 to August 2024

Source of Data

Subjects with clinical features of *Dushtavrana* fulfilling the inclusion criteria approaching the OPD and IPD of Shalya tantra, Government Ayurveda and Unani Hospital, Bengaluru were selected for the study. The sample collection was initiated after post approval from the institutional ethics committee.

Sampling Design

The subjects who fulfil the inclusion criteria and complying with the informed consent (IC) were selected using method of simple random sampling.

Inclusion Criteria

- Selection of patients is done irrespective of religion, occupation, economic and educational status.
- Age (20 to 80year)
- Patient presented with classical features of *Dushtavrana*
- Patient presented with clinical features of varicose ulcer.

Exclusion Criteria

- Patients with conditions like Systemic disorders, HIV, HBsAg, Burn wounds, Osteomyelitis, Gangrene, Diabetic foot ulcer, Bleeding Disorder.

Study Design

Groups	Topical Treatment	Duration
Group A	*Jalaukavacharana*	21 days
Group B	*Vimlpana Karma f/b Jalukavacharana*	21 days

Procedure

Group A: *Jalaukavacharana*

- All required investigations were done.
- Under all aseptic precautions. *Vranaprakshalana* done with *Panchavalkala Kashaya.*
- *Jatyadi Taila* was applied; the wound was closed with dressing and bandage (1st to 6th day).

7th day *Jalaukavacharan* procedure was done.

Purvakarma

- *Jalauka* was placed in a kidney tray containing *Haridra Jala*. Once *Jalauka* get activated it was considered fit for procedure.
- Subject made to sit comfortably with extended leg and back rest. Part intended for *Jalauka* application was cleaned and made rough by Rubbing (*Vigharshana*) with dry Gauze.

Pradhan Karma

- The *Jalauka* was brought into contact with the intended site. When the *Jalauka* was attached firmly to the intended site, it was covered with wet gauze and was moistened at intervals until the end of the procedure.
- The *Jalauka* detached voluntarily; in cases where the *Jalauka* did not detach by itself, it was removed after 45 minutes.

Paschat Karma

- Haemostasis was achieved by applying a pressure bandage.
- The *Jalauka Vamana* procedure was carried out.
- The patient was advised to come for daily dressing. In case of a reduction in wound size within the time period of 21 days, the patient was advised to stop further treatment.

Group B: Treated with *Vimlapana Karma* followed by *Jalaukavacharana*

Vimlapana Karma followed by *Jalaukavacharana*.

Vimlapana Karma

Purvakarma

- The procedure was performed under aseptic precautions, during which gloves were worn.
- *Vranaprakshalana* was performed using *Panchavalkala Kashaya*. The area was then wiped clean with gauze.

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Pradhan Karma

- *Jatyadi Taila* was applied around the edge of the wound.
- According to the size of the ulcer, the palm, thumb, or pulp of fingers were used to massage around the ulcer area in a circular fashion, for a duration of 15-20 minutes.

Paschat Karma

- After applying *Jatyadi Taila,* the wound was dressed and bandaged.

7th day *Jalaukavacharana* was done

- *Jalaukavaacharana* was performed, followed by *Vranaprakshalana* with *Panchavalkala Kashaya. Jatyadi Taila* was applied, and the wound was dressed and bandaged.
- The patient received daily dressing instructions.

In case of reduction in wound size within the time period of 21 days, then patient was advised to stop further treatment.

Duration of Treatment

Duration of treatment was 21days. Subjective and Objective parameters was assessed on before treatment (0^{th} day), 7^{th} day, 14^{th} day, and 21^{st} day

Statistical design

Statistical test for within the groups Wilcoxon signed rank test –for all parameters. Statistical test for between the groups Mann Whitney 'U' test –for all parameters.The differences in the mean values were considered, the corresponding p value was noted, and the results obtained were interpreted as Highly significant at $p<0.001$ and $p<0.01$, significant at $p<0.05$

Assessment Criteria

Assessment of the study was done before treatment, during and after treatment and at follow-up on the basis of assessment parameters as per case proforma

Bates-Jensen Criteria for Wound Assessment

Gradation of Parameters

Size

Grade 1 - Length X Width < 4sq.cm

Grade 2 - Length X Width 4 -< 16sq.cm

Grade 3 - Length X Width 16.1 -< 36sq.cm

Grade 4 - Length X Width 36.1 -< 80sq.cm

Grade 5 - Length X Width > 80sq.cm.

Edge

Grade 1 - Indistinct, diffuse, none clearly visible.

Grade 2 - Distinct, outline clearly visible, attached, even with wound base.

Grade 3 - Well defined, not attached to wound base.

Grade 4 - Well defined, not attached to base, rolled under, thickened.

Grade 5 - Well defined, fibrotic, scarred or hyperkeratosis.

Exudate Type

Grade 1 - None.

Grade 2 - Bloody

Grade 3 - Serosanguineous, thin, watery, pale, red /pink.

Grade 4 - Serous, thin, watery, clear.

Grade 5 - Purulent, thin or thick, opaque, tan/yellow, with or without odor.

Skin Colour Surrounding Area

Grade 1 - Pink or normal for an ethnic group.

Grade 2 - Bright red &/or blanches to touch.

Grade 3 - White or grey pallor or hypo pigmented.

Grade 4 - Dark red or purple &/or non-bleachable

Grade 5 - Black or hyper pigmented.

Granulation Tissue

Grade1 - Skin intact or partial thickness wound.

Grade 2 - Bright, beefy red; 75% to 100% of wound filled &/or tissue over growth.

Grade 3 - Bright, beefy red; 75%to>25%0f wound.

Grade 4 - Pink, &/or dull, dusky red &/or fills<25% of wound.

Grade 5 - No granulation tissue present.

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Observation and Results

Clinically diagnosed 40 subjects of *Dushta Vrana* w.s.r. to Varicose ulcer were randomly selected and assigned in two groups of 20 subjects each for study. Group-A was treated with *Jalaukavacharana* followed by daily dressing for a period of 21 days and Group-B was treated with *Vimlapana Karama* followed by *Jalaukavacharana* and daily dressing for 21 days.

Observation of Patients profile

The study found that both groups had a similar distribution in terms of gender (p=1.000), socioeconomic status (p=0.33), occupation (p=0.07), diet (p=0.05), and a family history of Varicose vein or ulcer (p=1.00). There were significant differences in the age distribution (p=0.77), mean ulcer chronicity (p=0.82), Affected limb(p=0.32), and position of ulcer (p=0.28).

Results

1. Effect on Size

Table 1: Effect of treatment on Size (between the group)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Size	Group A	20	13.60	272.00	62.000	0.00004	Sig
	Group B	20	27.40	548.00			
	Total	40					

The study data indicates that, effect of therapy on size of the ulcer before and after the intervention between the group showed significant difference(p<0.001) favouring towards group B (with higher mean change of 27.40).

Table 2: Effect of treatment on Size (within the group)

Size		Mean	Median	SD	SE	Wilcoxon Z	P-Value	% Effect	Result
Group A	BT	2.85	3.00	0.88	0.20	-	-	-	-
	Day 7	2.85	3.00	0.88	0.20	.000[b]	1.000000	0.00	NS
	Day 14	2.70	2.00	0.92	0.21	-1.732[c]	0.083265	5.26	NS
	Day 21	2.45	2.00	0.83	0.18	-2.530[c]	0.011412	14.04	Sig
Group B	BT	3.05	3.00	0.76	0.17	-	-	-	-
	Day 7	3.00	3.00	0.73	0.16	-1.000[b]	0.317311	1.64	NS
	Day 14	2.35	2.00	0.67	0.15	-3.500[b]	0.000465	22.95	Sig
	Day 21	1.75	2.00	0.55	0.12	-4.130[b]	0.000036	42.62	Sig

Effect of therapy on size within the group analysis on size of the ulcer different time interval showed that, group A had shown significant changes on 21st day of intervention(p=0.01), whereas group B showed significant changes on 14th(p<0.001) and 21st(p<0.001) day of intervention.

2. Effect on Edge

Table 3: Effect of treatment on Edge (between the group)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Edge	Group A	20	13.20	264.00	54.000	0.00001	Sig
	Group B	20	27.80	556.00			
	Total	40					

Based on the trial results, group B (with a larger mean change of 27.80) prevailed in the significant difference (p<0.001) between the intervention effect on the ulcer's edge preceding and following the intervention.

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Table 4: Effect of treatment on Edge (within the group)

Edge		Mean	Median	SD	SE	Wilcoxon Z	P-Value	% Effect	Result
Group A	BT	3.35	3.00	0.59	0.13	-	-	-	-
	Day 7	3.35	3.00	0.59	0.13	.000[b]	1.000000	0.00	NS
	Day 14	2.65	3.00	0.67	0.15	-3.742[c]	0.000183	20.90	Sig
	Day 21	2.45	2.50	0.60	0.14	-4.243[c]	0.000022	26.87	Sig
Group B	BT	3.60	4.00	0.60	0.13	-	-	-	-
	Day 7	3.20	3.00	0.52	0.12	-2.828[b]	0.004678	11.11	Sig
	Day 14	2.50	2.50	0.51	0.11	-3.947[b]	0.000079	30.56	Sig
	Day 21	1.80	2.00	0.52	0.12	-4.035[b]	0.000055	50.00	Sig

The edge of the ulcer statistical analysis revealed that group A had significant changes on the 14th day of the intervention ($p<0.01$), while group B showed significant changes on the 7th, 14th, and 21st days of the intervention ($p<0.001$), respectively.

3. Effect on the Exudate Type

Table 5: Effect of treatment on Exudate type (between the group)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Exudate type	Group A	20	16.75	335.00	125.000	0.01418	Sig
	Group B	20	24.25	485.00			
	Total	40					

The research findings demonstrate that the treatment impact on ulcer exudate type from before to after the intervention differed significantly ($p<0.05$), preferring group B (whose mean change increased at 24.25).

Table 6: Effect of treatment on Exudate type (within the group)

Exudate type		Mean	Median	SD	SE	Wilcoxon Z	P-Value	% Effect	Result
Group A	BT	3.55	3.00	0.69	0.15	-	-	-	-
	Day 7	2.90	3.00	0.85	0.19	-3.606[c]	0.000311	18.31	Sig
	Day 14	2.30	2.00	0.98	0.22	-3.852[c]	0.000117	35.21	Sig
	Day 21	1.75	1.00	0.91	0.20	-4.035[c]	0.000055	50.70	Sig
Group B	BT	3.25	3.00	0.44	0.10	-	-	-	-
	Day 7	2.40	2.00	0.50	0.11	-4.123[b]	0.000037	26.15	Sig

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	Day 14	1.35	1.00	0.49	0.11	-4.177[b]	0.000030	58.46	Sig
	Day 21	1.00	1.00	0.00	0.00	-4.134[b]	0.000036	69.23	Sig

According to the data analysis of the ulcer exudate, group B revealed substantial changes on day 7th of the intervention ($p<0.001$), whereas group A exhibited significant changes on day 7th ($p<0.001$).

4. Effect on the Skin Colour Surrounding Area

Table 7: Effect of treatment on Skin colour surrounding area (between the group)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Skin colour surrounding area	Group A	20	17.55	351.00	141.000	0.02218	Sig
	Group B	20	23.45	469.00			
	Total	40					

The effect of the intervention on the skin colour surrounding the ulcer area before and after treatment was shown to differ significantly ($p<0.05$) between Group B mean rank of 23.45 and the trial results. This indicates that Group B skin colour changes in the healing of the surrounding area improved more noticeably than Group A.

Table 8: Effect of treatment on Skin colour surrounding area (within the group)

Skin colour surrounding area		Mean	Median	SD	SE	Wilcoxon Z	P-Value	% Effect	Result
Group A	BT	4.65	5.00	0.75	0.17	-	-	-	-
	Day 7	4.60	5.00	0.82	0.18	-1.000[c]	0.317311	1.08	NS
	Day 14	4.60	5.00	0.82	0.18	-1.000[c]	0.317311	1.08	NS
	Day 21	4.55	5.00	0.94	0.21	-1.000[c]	0.317311	2.15	NS
Group B	BT	4.55	5.00	0.89	0.20	-	-	-	-
	Day 7	4.30	5.00	1.03	0.23	-1.890[b]	0.058782	5.49	NS
	Day 14	4.15	5.00	1.27	0.28	-2.271[b]	0.023141	8.79	Sig
	Day 21	3.95	5.00	1.57	0.35	-2.401[b]	0.016351	13.19	Sig

The group analysis pertaining to the changes of skin colour surrounding the ulcer at different time intervals revealed that group B exhibited substantial changes on the 14th ($p<0.05$) and 21st ($p<0.05$) day of intervention, while group A showed no significant changes on the 21st day of intervention ($p>0.05$).

5. Effect on Granulation Tissue

Table 9: Effect of treatment on Granulation tissue (between the group)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Granulation tissue	Group A	20	14.43	288.50	78.500	0.00009	Sig
	Group B	20	26.58	531.50			
	Total	40					

The study findings indicate that group B had a greater mean change of 26.58 and was superior in terms of a significant difference ($p<0.001$) between the intervention effect on the granulation tissue of the ulcer before and after the intervention.

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Table 10: Effect of treatment on Granulation tissue (within the group)

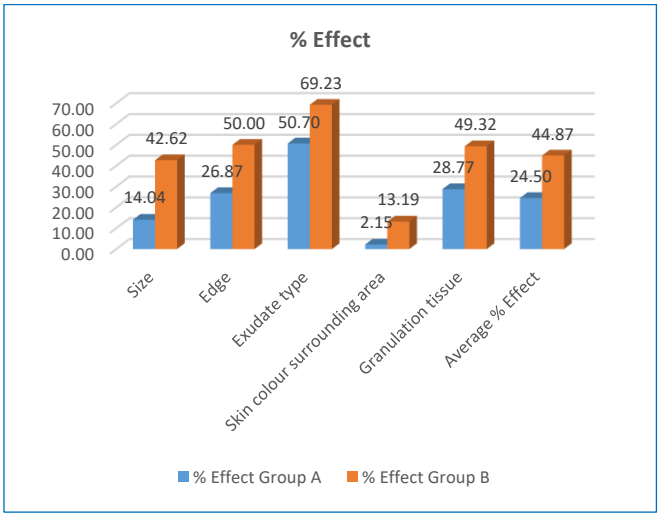
Granulation tissue		Mean	Median	SD	SE	Wilcoxon Z	P-Value	% Effect	Result
Group A	BT	3.65	4.00	0.49	0.11	-	-	-	-
	Day 7	3.60	4.00	0.50	0.11	-1.000 c	0.317311	1.37	NS
	Day 14	2.95	3.00	0.51	0.11	-3.742 c	0.000183	19.18	Sig
	Day 21	2.60	3.00	0.60	0.13	-4.379 c	0.000012	28.77	Sig
Group B	BT	3.65	4.00	0.49	0.11	-	-	-	-
	Day 7	3.40	3.00	0.50	0.11	-2.236 b	0.025347	6.85	Sig
	Day 14	2.45	2.00	0.51	0.11	-4.179 b	0.000029	32.88	Sig
	Day 21	1.85	2.00	0.49	0.11	-3.999 b	0.000064	49.32	Sig

In the group analysis, substantial changes were observed in the granulation tissue of the ulcer on day 14 ($p=0.001$), while group B showed significant changes on day 7 ($p<0.05$), day 14, and day 21 ($p<0.001$) of the intervention.

Table 11: Total Percentage of Improvement observed in Group A and Group B

Parameter	% Effect	
	Group A	Group B
Size	14.04	42.62
Edge	26.87	50.00
Exudate type	50.70	69.23
Skin colour surrounding area	2.15	13.19
Granulation tissue	28.77	49.32
Average % Effect	24.50	44.87

Group B outperformed Group A in ulcer healing, with a 42.62% reduction in ulcer size compared to 14.04%. Group B also showed greater improvements in ulcer edge (50% vs 26.87%), exudate type (69.23% vs 50.70%), skin color (13.19% vs 2.15%), and granulation tissue (49.32% vs 28.77%). Overall, Group B had a 44.87% improvement, while Group A had 24.50%, indicating more effective treatment in Group B.



Graph 1: Overall Effect of treatment on the Group A and Group B

DISCUSSION

Discussion of demographic data

This study found that varicose veins and ulcers commonly begin after age 20, with a peak in the fourth decade. Among participants, 97.05% were male, though historical data suggests women may also be predisposed due to pregnancy and hormones. Most participants were middle-class (50%) or lower-middle-class (45%), with 75% engaged in occupations involving prolonged standing or sedentary work, contributing to poor circulation and delayed healing. Mixed diets were prevalent (80%), with vegetarian diets potentially aiding wound healing. Family history was absent in 85%

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of cases, highlighting lifestyle as a major factor. The right limb was most affected (45%), followed by the left (30%) and bilateral cases (25%), with chronicity ranging from less than a year (42.07%) to over five years (7.05%). Ulcers were common at the medial malleolus (50%), and both solitary and multiple ulcers were equally distributed, reflecting the need for timely, personalized management to prevent complications.

Discussion on Results

Effect on Size: According to the study, Group B (*Jalaukavacharana* and *Vimlapana Karma*) significantly performed Group A (*Jalaukavacharana*) with a 42.62% reduction in ulcer size. A comparison for the groups showed $p<0.05$, signifying more effective results, while Group B showed a highly significant effect ($p<0.001$). Although it affects slower, *Jalaukavacharana* alone minimises toxins and inflammation. By minimising vasoconstriction, enhancing neovascularisation, and accelerating up recovery, the combination treatment in Group B, on the opposite hand, enhanced healing and was more successful in decreasing ulcer size.

Effect on Edge: In the study, Group A *(Jalaukavacharana*) showed a 26.87% improvement in wound edge healing, while Group B (*Vimlapana Karma and Jalaukavacharana)* showed 50% improvement. Both therapies promote wound contraction through fibroblasts and collagen. *Jalaukavacharana* enhances tissue penetration and toxin removal. In Group B, the combination therapy boosts circulation and reduces inflammation, while *Jalaukavacharana* accelerates microcirculation, promoting faster wound edge healing in chronic varicose ulcers.

Effect on Edge: Significant improvements in exudate type were shown by Group A (*Jalaukavacharana)* and Group B (*Vimlapana Karma and Jalaukavacharana*), with Group A demonstrating a 50.70% improvement and Group B a 69.23% improvement. While *Vimlapana Karma* cures the underlying cause by purifying blood and minimising inflammation, *Jalaukavacharana* decreases exudates by harmonising doshas and improving venous function. The combination accelerates wound healing effectively decreases exudate.

Effect on Skin colour of Surrounding area: Skin colour did not change significantly in Group A (*Jalaukavacharana*) (2.15%, $p > 0.05$), but it did significantly improve in Group B *(Vimlapana Karma and Jalaukavacharana*) (13.19%, $p < 0.05$). While Group B's healing might be the result of *Vimlapana Karma's* improvement of circulation, re-epithelialization, and blood purification, which encouraged healing and decreased inflammation, Group A's lack of change may be explained by the gradual effect of leech therapy.

Effect on Granulation tissues: Granulation tissue in Group A (*Jalaukavacharana)* and Group B (*Vimlapana Karma and Jalaukavacharana)* improved significantly; Group A's improvement was 28.77%, while Group B's was 49.32%. By increasing the effectiveness of its components, *Jalaukavacharana* improves granulation and lowers inflammation in Group A. *Vimlapana Karma* from Group B enhances tissue healing and circulation by stimulating the growth of healthy granulation tissue.

Probable mode of action of *Vimlapana Karma*:

Vimlapana Karma in *Dushta Vrana* facilitates wound healing by relieving local vasoconstriction, improving circulation at the wound site, and enhancing oxygen supply. This is where mechanotransduction—a key process—comes into play. Mechanotransduction is the conversion of a mechanical stimulus into a biochemical response within cells. In the context of wound healing, mechanical forces from actions like massage stimulate cells, prompting signalling pathways that enhance tissue repair and regeneration[11]. Studies show that massage acts as an immune modulator, influencing neutrophils' apoptotic signalling, reducing the release of proinflammatory cytokines[12], and promoting tissue repair.

Additionally, the mechanical pressure during massage increases local temperature, improving blood flow by relieving vasoconstriction and carrying essential nutrients, oxygen, and insulin to the wound site. This improved circulation aids in alleviating the anoxic condition of the wound. Mechanotransduction also promotes the release of beta-endorphins, which

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provide pain relief[13]. With improved blood flow and nutrient delivery, epithelial cell regeneration is accelerated, leading to faster healing of the extracellular matrix (ECM)—a critical component in dermal repair, particularly for varicose ulcers.

CONCLUSION

The study found that most participants were male, aged 41-50, predominantly, followed a mixed diet, and had varicose ulcers with a chronicity of 1 to 5 years. Group B (*Vimlapana Karma* followed by *Jalaukavacharana*) was more effective in managing varicose ulcers, showing significant improvements in ulcer size, edge, exudate type, skin color, and granulation tissue compared to Group A (*Jalaukavacharana*). Group B consistently outperformed Group A, with an average improvement of 44.87% in Group B versus 24.50% in Group A. Statistically significant differences were observed at all time points (BT, Day 7, Day 14, and Day 21), with Group B demonstrating superior results. No adverse effects were reported in either group. The study supports the hypothesis that *Vimlapana Karma* provides a significant added benefit to *Jalaukavacharana. Vimlapana Karma* is a cost-effective, feasible, and simple procedure with minimal equipment requirements and no complications, confirming its significant role in enhancing the treatment of varicose ulcers.

Before and After treatment in Group-A

Before treatment

During treatment *Vimlapana Karma*

During *Jalaukavacharana*

After treatment

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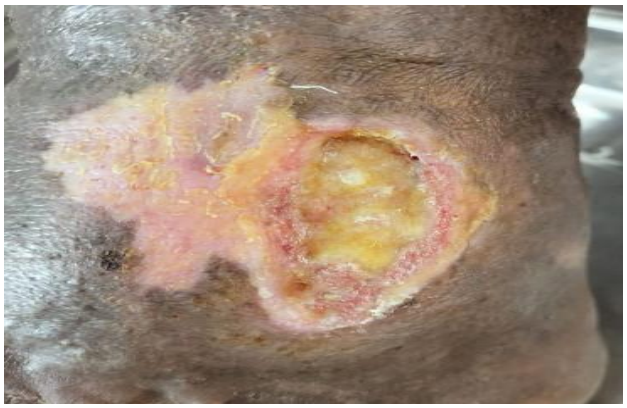
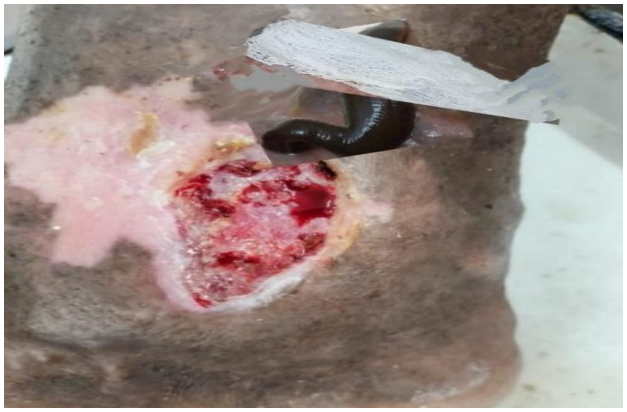
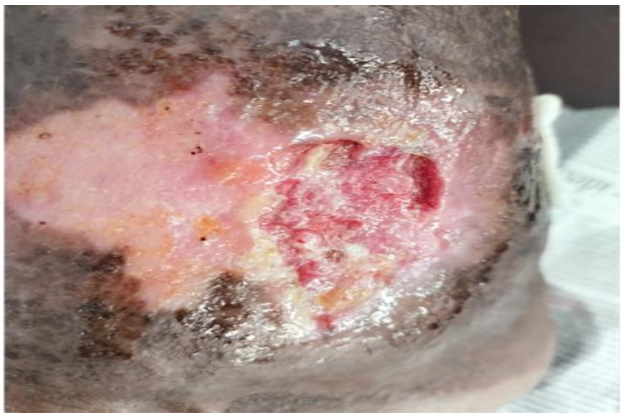
Before and After treatment in Group-B



Before treatment



7th day Jalaukavacharana



After treatment

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