



Research Article

A RANDOMISED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF ARAGWADHADI KASHAYA PRAKSHALANA FOLLOWED BY SWARJIKADHYA TAILA PICHU AND JATYADI TAILA PICHU APPLICATION IN THE MANAGEMENT OF DUSHTA VRANA W.S.R. TO NON-HEALING ULCERS

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ABSTRACT

Dushta Vrana is a type of *Vrana* which presents with delayed healing. The management of *Dushta Vrana* has been described in various Ayurvedic texts. Many formulations are in use for centuries out of those formulations. Present Study is to manage it with *Shodhana Kashaya* and *Ropana Taila* and treat *Dushta Vrana*. **Aims and Objectives:** 1. To evaluate the efficacy of *Aragwadhadi Kashaya Prakshalana* followed by *Swarjikadhya Taila* application in the management of *Dushta Vrana*. 2. To evaluate the efficacy of *Aragwadhadi Kashaya Prakshalana* followed by *Jatyadi Taila* application in the management of *Dushta Vrana*. 3. To compare the efficacy of both the groups in the management of *Dushta Vrana*. **Methodology:** It is a comparative clinical study with pre-test and post-test design where in 60 patients diagnosed with *Dushta Vrana* of either sex was randomly assigned into two groups of 30 members each in Group A and Group B. **Intervention: Group A:** *Aragwadhadi Kashaya Prakshalana* followed by *Swarjikadhya Taila Pichu* for 30 days. **Group B:** *Aragwadhadi Kashaya Prakshalana* followed by *Jatyadi Taila Pichu* for 30 days. **Observations and Results:** The effect of the treatment in both the groups were assessed by applying Wilcoxon rank sum test within the groups and Mann-Whitney U test between the groups, it showed that Group B is slightly better than Group A but both the groups showed equally good results. **Discussion and Conclusion:** It can be concluded from the study that in the management of *Dushta Vrana* - *Aragwadhadi Kashaya Prakshalana* followed by *Swarjikadhya Taila Pichu* and *Jatyadi Taila Pichu Chikitsa* both the drugs were highly effective in wound healing.

INTRODUCTION

Shalya Tantra, an essential segment of *Ayurveda*, encompasses surgical and para-surgical approaches delineating the treatment of diverse ailments. Within this realm, *Vrana* (ulcer/wound), a distressing condition, tends to afflict individuals across all age groups, leaving behind both physical and emotional scars. The challenge of managing persistent, non-healing wounds has persistently posed

difficulties throughout the progression of medical methodologies. In the general population, the occurrence of chronic wounds stemming from various causes is documented at a rate of 2.21 cases per 1000 individuals. Specifically, for chronic leg ulcers, the prevalence is noted to be 1.51 cases per 1000 individuals [1].

Dushta Vrana can be correlated to chronic non-healing ulcers, pose a significant challenge in medical management. These wounds are characterized by a disruption in the normal progression of wound healing, often remaining stuck in one of the typical healing phases- haemostatic, inflammatory, proliferative, or remodelling [2] for an extended duration, sometimes never healing at all.

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Vrana Shodhana plays an important role in *Dushta Vrana*. *Aragwadhadi Gana Kashaya* is described as '*Dushta Vrana Vishodhana*' in *Sushruta Saamhitha* and *Astanga Hrudaya*. One among the medicated *Taila* mentioned directly for *Dushta Vrana* is *Swarjikadhya Taila*, described as '*Dushta Vrana Prashamana*' in *Chakradatta* and *Bhaishajya Ratnavali*. It does the *Vrana Ropana*.

Methodology

Source of Data

- Literary Source:** Available Ayurvedic literatures, contemporary text books, journals, E-books and imprint resources in library about disease, procedure and drugs were reviewed and documented for the present intended clinical study.
- Sample Source:** 60 patients with *Lakshanas* of *Dushta Vrana* coming under inclusion criteria approaching Out-patient department and In-patient department of *Shalya Tantra* of Shri Shivayogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal, were selected for the study.
- Drug Source:** *Swarjikadhya Taila* and *Aragwadhadi Kashaya* were prepared in the Rasa Shala- Pharmacy of our college- Shri Shivayogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal. *Jatyadi Taila* was purchased from the S.D.M. Ayurveda Pharmacy, Udupi.

Method of Collection of Data

Study Design

- Study Type: Interventional
 - Allocation: Randomized
 - Endpoint Classification: Efficacy study
 - Intervention Model: Double group assignment
 - Primary Purpose: Treatment
 - Masking: Open label
 - Total duration of study: 30 days
- Sampling Technique:** The subjects who fulfilled the inclusion criteria and complied with the Informed Consent (IC) were selected for the study using Random Sampling Techniques.
 - Sample Size:** This is a randomised comparative clinical study where in 60 Subjects of either gender diagnosed as *Dushta Vrana* were selected through randomised sampling method and assigned into two groups comprising of 30 patients in each group.

Diagnostic Criteria

The patients presenting with *Lakshanas* of *Dushta Vrana* [3] as mentioned in the classics was diagnosed and selected for the study.

Inclusion Criteria

- Patients of age group between 30-70 years.
- Patients were selected irrespective of sex, religion and occupation status.
- Patients presenting with the *Lakshanas* of *Dushta Vrana*.
- Patients who are fit for procedures like *Kashaya Prakshalana* and *Taila* application.
- Patients with known case of diabetes mellitus and hypertension under control.
- All types of specific and non – specific ulcers will be Included.

Exclusion Criteria

- Patients who are aged below 30 years and above 70 years.
- Patients with severe systemic disorders like uncontrolled diabetes mellitus, uncontrolled hypertension that interfere with the course of treatment.
- Patients with complications like malignancy, gangrene, tuberculosis wounds, etc.
- Known case of HIV, HBsAg, tuberculosis, etc.

Investigations: Blood examination- C.B.C.- Complete Blood Count, R.B.S.- Random Blood Sugar, E.S.R.- Erythrocyte Sedimentation Rate, Other relevant investigation as and when required.

Interventions: 60 patients who fulfilled the Inclusion Criteria were selected and randomly assigned into 2 groups as Group-A and Group-B comprising of 30 patients each.

Group-A: The patients of Group A were subjected to *Aragwadhadi Kashaya Prakshalana* followed by *Swarjikadhya Taila Pichu* application for 30 days.

Group-B: The patients of Group B were subjected to *Aragwadhadi Kashaya Prakshalana* followed by *Jatyadi Taila Pichu* application for 30 days.

Procedure – For both Group A and Group B

1. *Poorva karma*

- Preparation of the Medicine**
 - Collection of all necessary equipment's needed for the procedure.
 - Collection of drugs needed for the procedure.
- Preparation of the Patient**
 - Procedure was explained to the patient and consent was taken.

2. *Pradana karma*

Method of *Chikitsa*

- Under all aseptic measures wound toileting was done.
- Wound debridement was carried out with the instruments.

- *Vrana Prakshalana* was done by rubbing sterile gauze dipped in *Aragwadhadi Kashaya* [4,5].
 - Then *Vrana* was dried with sterile gauze.
 - For Group A: Surface of the *Vrana* was covered with *Swarjikadhya Taila Pichu* [6, 7].
 - For Group B: Surface of the *Vrana* was covered with *Jatyadi Taila Pichu* [8].
 - Sterile pad was placed over the *Vrana* and bandaging was done.
- Nirikshana:*
- Daily/alternative bandaging is continued based on the *Vrana* conditions.
- Patients of both the groups were given oral medicines for entire study duration: *Gandhaka Rasayana Vati* [9,10] - 1-0-1, *Triphala Guggulu* [11] - 1-0-1.
 - Patient is advised to take *Laghu, Ushna, Anabhishtyandi bhojana*.

Assessment done on

1st day, 8th day, 15th day, 22nd day, 30th day

Assessment Criteria

Assessment of the clinical study was done on the Subjective and objective parameters based on the Bates-Jenson’s Wound Assessment Scale proforma-

3. Paschat karma

Chart for Gradings of Objective Criteria

Table 1: Gradings of Objective Criteria for Group A and Group B

S.No.	Wound Criteria	Assessment Grading
1.	Wound Size in Centimeter (cm)	1 = Length x width <4 sq cm 2 = Length x width 4 to <8 sq cm 3 = Length x width 8.1 to <16 sq cm 4 = Length x width 16.1--<32 sq cm 5 = Length x width >32.1 sq cm
2.	Wound Edges	1 = Indistinct, diffuse, none clearly visible. 2 = Distinct, outline clearly visible, attached with wound base. 3 = Well-defined, not attached to wound base. 4 = Well-defined, not attached to base, rolled under, thickened. 5 = Well-defined, fibrotic, scarred or hyperkeratotic.
3.	Necrotic Tissue Type	1 = None visible 2 = White non-viable tissue and/or non-adherent yellow slough. 3 = Loosely adherent yellow slough. 4 = Adherent, soft, black eschar. 5 = Firmly adherent, hard, black eschar.
4.	Exudate Type	1 = None 2 = Bloody 3 = Serosanguinous: Thin, watery, pale red/pink 4 = Serous: Thin, watery, clear 5 = Purulent: Thin or thick, opaque, yellow
5.	Exudate Amount	1 = None, dry wound 2 = Scanty, wound moist but no observable exudate. 3 = Small 4 = Moderate 5 = Large
6.	Peripheral Tissue Edema	1 = No swelling or edema 2 = Non-pitting edema extends <4cm around wound 3 = Non-pitting edema extends >4 cm around wound. 4 = Pitting edema extends < 4 cm around wound. 5 = Pitting edema extends >4 cm around wound.
7.	Granulation Tissue	1 = Skin intact or partial thickness wound. 2 = Bright red; 75% to 100% of wound filled or tissue growth. 3 = Red; <75% & >25% of wound filled.

4 = Pink, and/or dull, dusky red and/or fills < 25% of wound.
5 = No granulation tissue present.

S. No. = Serial Number, Sq. cm. = Square centimetre, cm - centimetre

Chart for grading of subjective criteria

Table 2: Grading of Subjective Criteria for Group A and Group B

S.No.	Wound Criteria	Assessment Grading
1.	Vrana Vedana (Pain)	1 = No pain 2 = Pain on dressing change. 3 = Intermittent pain. 4 = Continuous pain.
2.	Vrana Daha (Burning Sensation)	1 = No burning sensation 2 = Intermittent burning sensation 3 = Frequent burning sensation 4 = Continuous burning sensation
3.	Vrana Kandua (Itching)	1 = No itching 2 = Occasional itching episode 3 = Frequent itching episode 4 = Continuous itching episode
4.	Vrana Durgandha (Foul Smell)	1 = No foul smell 2 = Mild foul smell present 3 = Moderate foul smell present 4 = Severe foul smell present

OBSERVATIONS AND RESULTS

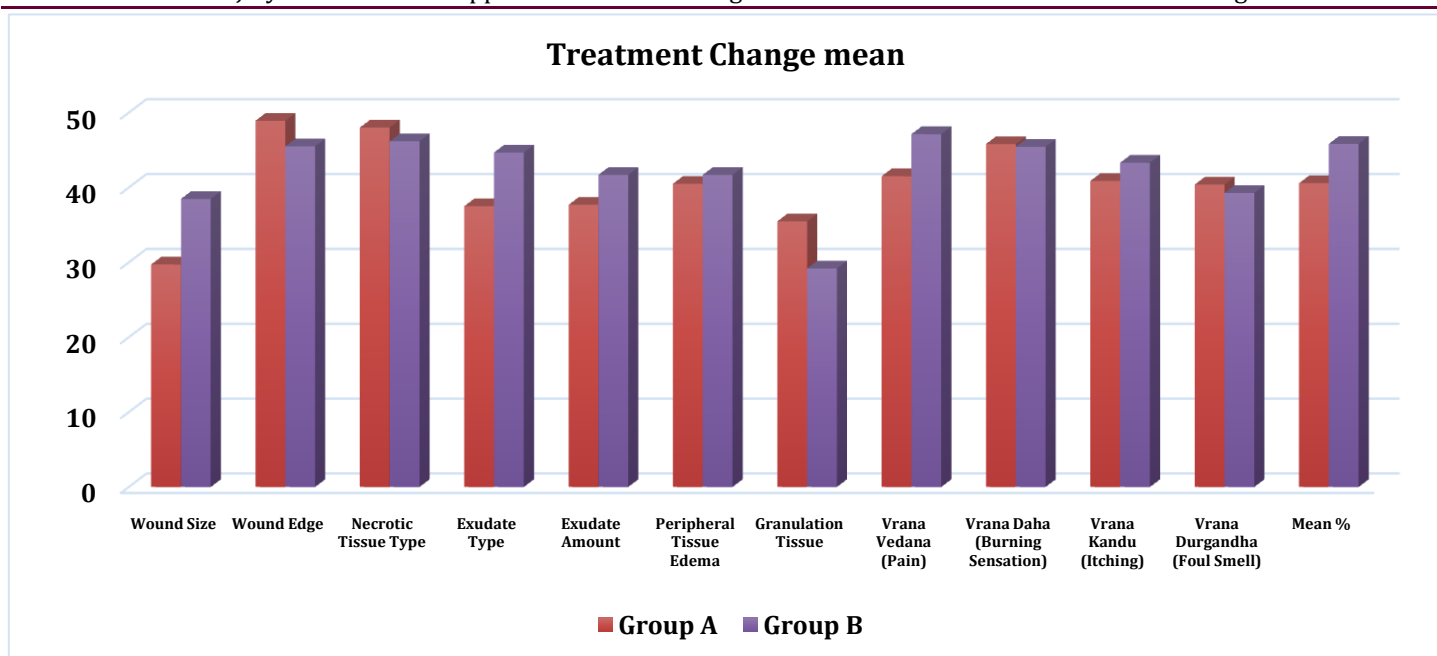
Overall Assessment

- Overall improvement assessment within Group A: 41%
- Overall improvement assessment within Group B: 42%
- On comparing total improvement in between Group-A and Group-B = 49%:51%

Table 3: Overall Assessment of Pre-Post Treatment Percentage Mean all criteria

S.No.	Parameters	Mean Change Treatment %			
		Group A		Group B	
		AT	AF	AT	AF
Objective parameters					
1.	Wound size in cm	24.76%	29.72 %	25.15%	38.48 %
2.	Wound edges	31.80%	48.92 %	27.24%	45.50 %
3.	Necrotic tissue type	38.83%	48.01 %	26.47%	46.17%
4.	Exudate type	25.75%	37.5 %	27.24%	44.68%
5.	Exudate amount	23.07%	37.69 %	25.07%	41.69%
6.	Peripheral tissue edema	25.49%	40.50 %	24.19%	41.69%
7.	Granulation tissue	21.33%	35.48%	17.35%	29.20%
Subjective parameters					
8.	<i>Vrana Vedana</i> (Pain)	28.18%	41.51%	26.93%	47.13%
9.	<i>Vrana Daha</i> (Burning sensation)	30.80%	45.81%	30.45%	45.45%
10.	<i>Vrana Kandua</i> (Itching)	27.58%	40.88%	26.26%	43.31%
11.	<i>Vrana Durgandha</i> (Foul smell)	22.80%	40.39%	15.35%	39.28%
Total Mean %		27%	41%	25%	42%

AT = After Treatment, AF = After Followup



Graph 1: Overall Assessment of Pre-Post Treatment % Mean of all Criteria

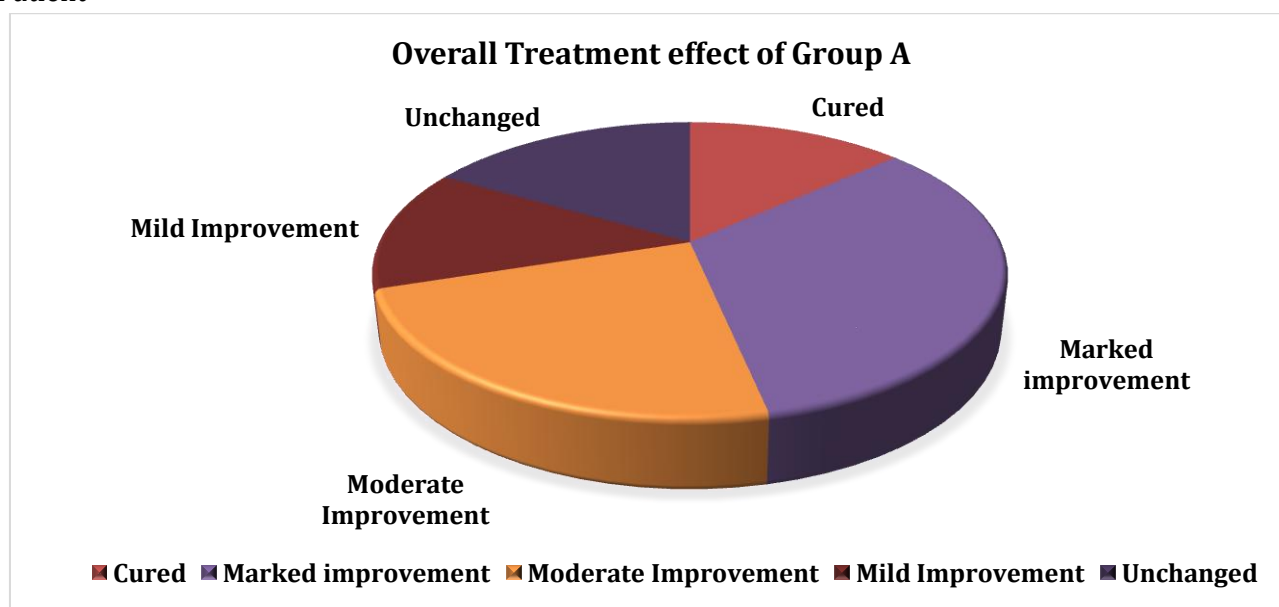
Overall Treatment Result

Group A: Patients had good results in the initial stages till the end.

Table 4: Overall Assessment of Post Treatment Effect in Group A

S. No.	Criteria	% Gradings	Pt. in Group A	% of Results
1.	Cured	91% - 100%	4	13.33%
2.	Marked Improvement	71% - 90%	10	33.33%
3.	Moderate Improvement	51% - 70%	7	23.33%
4.	Mild Improvement	31% - 50%	4	13.33%
5.	Unchanged	0% - 30%	5	16.66%
Total			30	100%

Pt. = Patient

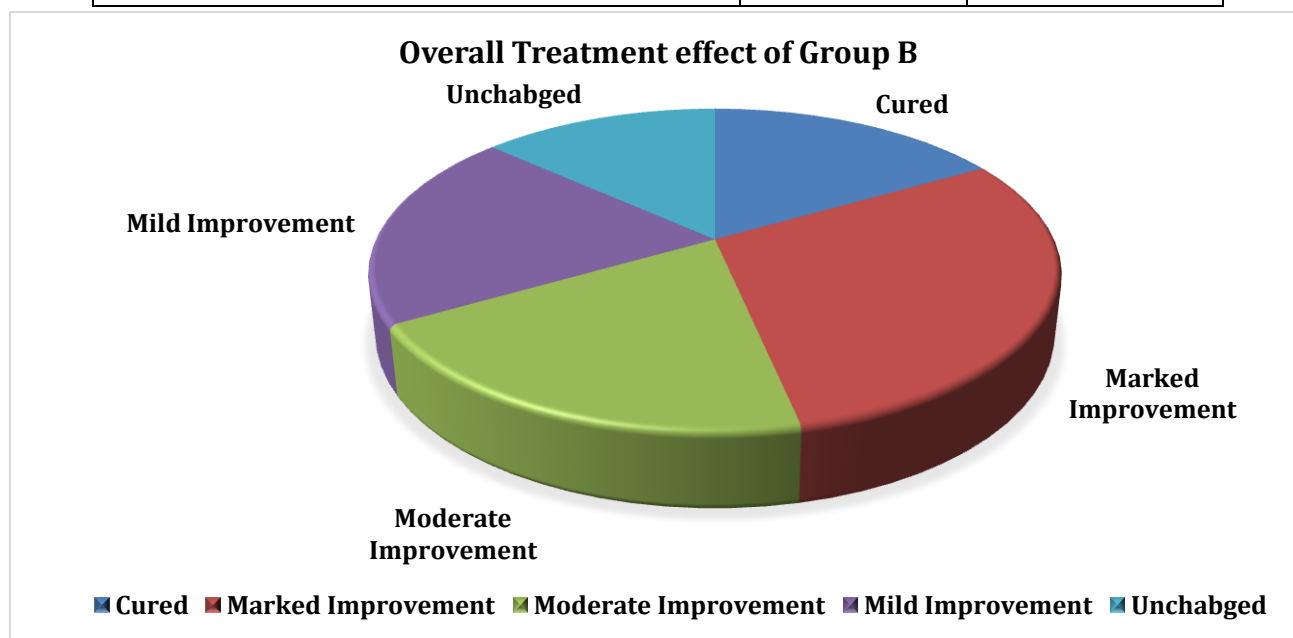


Graph 2: Overall Assessment of Post Treatment Effect in Group A

Group B: Patients had persistent better results showed ascending improvements.

Table No. 5: Overall Assessment of Post Treatment Effect in Group B:

Sl.No.	Criteria	% Gradings	Pt. in Group B	% of Results
1.	Cured	91% - 100%	5	16.66%
2.	Marked Improvement	71% - 90%	9	30%
3.	Moderate Improvement	51% - 70%	6	20%
4.	Mild Improvement	31% - 50%	6	20%
5.	Unchanged	0% - 30%	4	13.33%
Total			30	100%

**Graph 3: Overall Assessment of Post Treatment Effect in Group B****DISCUSSION****Probable Mode of Action of Swarjikadhya Taila**

The ingredients of Swarjikadhya Taila are Swarjika kshara, Saindhava Lavana, Danti Moola, Chitraka Moola, Shwetha Arka, Bhallataka Beeja, Neelika, Apamarga Beeja, Tila Taila and Gomutra. Most of these drugs have Katu, Kshara, Tikta, kashaya Rasa, Laghu, Rooksha, Teekshna, Ushna Gunas, Ushna Veerya, Katu Vipaka, Vrana Ropana, Shothahara, Rakta Shodhaka, Rakta Prasadaka, Vedana Sthapaka, Krimighna, Srotovishodhakara and Kapha-Vatahara properties. By the virtue of these properties Swarjikadhya Taila does Vrana Shodhana, increases blood circulation and also helps in reduction of infection (bacterial growth) and toxicity. Most of the drugs are Ushna veerya, Kapha shamaka dravyas and hence help in reducing the symptoms like Shotha, Kandu and Vedana at the site of Vrana. Ingredients of Swarjikadhya Taila have good antibacterial activity, anti-inflammatory, and antioxidant properties.

Probable Mode of Action of Aragwadhadi Kashaya:

The ingredients of Aragwadhadi Kashaya are Aragwadha, Twak, Kutaja Beeja, Patala Moola, Kakatiktika Panchanga, Nimba Twak, Amruta Moola,

Madhuras Moola, Snuhikshara Kanda, Patala Kanda, Bhunimba Panchanga, Saireyaka Kanda, Patola Panchanga, Pootikaranaja Twak, Karanja Beeja, Saptachaddha Twak, Chitraka Moola, Kaaravelaka Phala, Madanaphala, Neela sahadahara Kanda, Pooga Phala. Most of these drugs have Katu, Tikta, Kashaya Rasa, Laghu, Rooksha, Teekshna Gunas, Ushna Veerya, Katu Vipaka, Vrana Shodhana, Vrana Pachana, Vrana Ropana, Vranahara, Lekhana, Rakta Shodhaka, Shothahara, Shoolahara, Vedana Sthapana, Kandughna, Krimighna, Kusthghna, Twakdoshahara, Pootihara, Trushna Shamaka, Daha Prashamana and Kapha-Vatahara properties. Aragwadhadi Kashaya enhances the formation of granulation tissue by removing the slough. Due to its Laghu, Rooksha, Teekshna Guna and Ushna Veerya it reduces Slough. It has Kashaya Rasa which does Shoshana and Shodhana of Vrana. It has chemical constituents like tannins which are anti-inflammatory, anti-microbial, increased collagen content, phytosterols and beta sitosteryl-d-glucosides have analgesic property. Flavonoids are anti-inflammatory, vitamin A & K helps in epithelialization and maturation.

Probable Mode of Action of Jatyadi Taila

The ingredients of Jatyadi Taila are Jati Patra, Nimba Panchanga, Patola Patra, Katuki Patra, Sikta, Madhuaka Moola, Kusta Moola, Haridra Kanda, Daruharidra Khanda, Katurohini Kanda, Manjishta Khanda, Padmaka Khanda, Lodhra Twak, Haritaki Phala, Neela Utpala Pushpa, Tuttha, Sariva Moola, Naktamala Beeja. Most of these drugs have Tikta, Katu, Kashaya Rasa, Ushna Veerya, Katu Vipaka and Vrana Shodhana, Vrana Ropana, Vedana Sthapana properties. Ingredients like Tuttha have Lekhana, Bhedana, Shoolagna property, which helps in removal of slough effectively. The ingredients like Nimba, Patola, Karanja, Katuki have Tikta, Kashaya Rasa helps in Vrana Shodhana, Krimighna. Katuki, Nisha and Daruharidra have Lekhana, Chedana, Kanduhara, Vishagna, Varnya and Twakdoshahara properties. Sariva and Manjishta have Rakta Prasadana, Vedana Sthapana property. Tila Taila is Twachya and SrotoShodaka. Usheera, Manjishta, Sariva are Kapha-Pitta hara hence, help in reducing the symptoms like Daaha, Paaka and Vedana at the site of Vrana. Anti-inflammatory action of Nimba, Patola, Haridra, Daruharidra, Katuki and Jati helps in reduction of local inflammation. Jati Patra Swarasa shows antibacterial activity against Staphylococcus aureus. Other drugs like Nimba, Patola, Darvi, Nisha, Sariva, Karanja have anti-inflammatory and immunostimulant properties.

Wound Debridement

To achieve the main goal of healing, it is necessary to remove the local Dosha dushti and carry out debridement of the non-viable tissue and slough at the site of Vrana. Wound debridement promotes healthy granulations tissue.

Kashaya Prakshalana

Dushta Vrana with Durgandha, Kleda and Picchilata, Shodhana Kashaya Prakshalana has to be done for Vrana Shodhana. Later Vrana which has obtained Shuddha Lakshana, Ropana Kashaya Prakshalana has to be done for the purpose of Vrana Ropana. Aragwadhadi Kashaya has both Vrana Shodhana and Ropana Properties. Hence Prakshalana is done with Kashaya during entire study.

Vrana Picchu

It enhances local drug delivery time and Increases absorption rate of drug used in Pichu. Taila being in Drava form retains longer with Pichu.

Vrana Bandana

Bandana with sterile gauze aids in wound healing with protection from dust, infection and local injury. Bandha acts as protection and prompts healing by body natural mechanism. It provides cushion for wound and maintains wound integrity.

Overall Observations

The overall observations in the study revealed that the maximum numbers of subjects were males, age were males, age between 51-70 Years, maximum numbers of subjects belonged to Hindu community, married, having mixed diet and with chronicity of more than 6 weeks. In the present study, the effect of the treatment has shown statistically highly significant results in both the groups in all the assessment parameters like objective criteria and subjective parameters (BT-AF). The effect of treatment was statistically non-significant between the Groups – Group A and Group B with respect to all 11 assessment criteria.

On Statistically Comparison

Group A was comparatively better than Group B in 5 parameters like wound edge, necrotic tissue type, granulation tissue, Vrana Daha and Vrana Durgandha. Statistically: Group B was comparatively better than Group A in 6 Parameters like wound size, exudate type, exudate amount, peripheral tissue edema, Vrana Vedana and Vrana Kandu. Both the groups were best in healing wound, statistically group B had slightly better results than group A. However, Swarjikadhya Taila has an edge over Jatyadi Taila. Clinically: Group A patients showed fast and overwhelming response in the initial stage – during Kapha Avasta of Vrana Chikitsa. Slough, necrotic tissue, dead tissue i.e., Dushtata of Vrana were all removed by Swarjikadhya Taila and Aragwadhadi Kashaya Dravya action.

CONCLUSION

This dissertation work is entitled as “A Randomised Comparative Clinical Study to Evaluate the Efficacy of Aragwadhadi Kashaya Prakshalana Followed by Swarjikadhya Taila Pichu and Jatyadi Taila Pichu Application in the Management of Dushta Vrana w.s.r. to Non-Healing Ulcers.” Dushta Vrana can be compared to chronic non-healing ulcers. Among Shasti Upakramas mentioned by Acharya Sushruta: Kashaya Prakshalana Upakrama and Taila Pichu Upakrama were taken for the study. All the drugs selected for the study had direct references for Dushta Vrana. Aragwadhadi Kashaya: Mentioned in Astanga Hrudaya. Swarjikadhya Taila: Mentioned in Bhaishajya Ratnavali and Chakradatta. Jatyadi Taila: Mentioned in Sharangadhara Samhitha. No adverse effects were observed in both the groups during the Course of the study.

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Procedure Steps for Both Group A and B

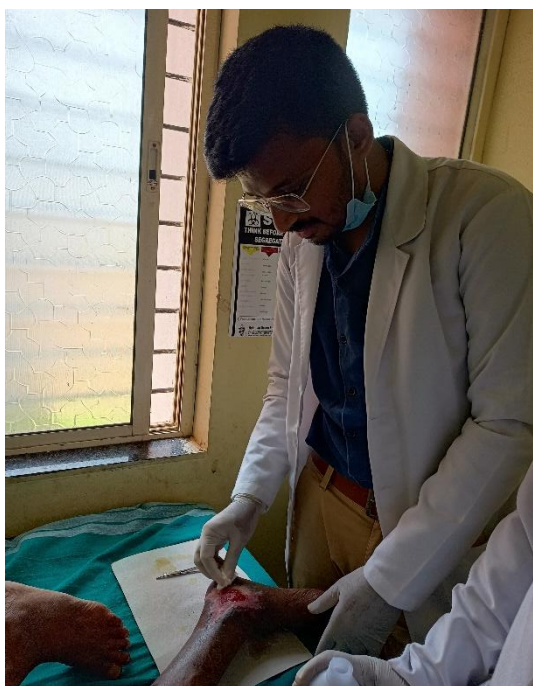


Figure 1: Wound Debridement



Figure 2: Aragwadhadi Kashaya Prakshalana



Figure 3: Swarjikadhya Taila Pichu for Group A and Jatyadi Taila Pichu for Group B



Figure 4: Vrana Bandhana

Group A: Patient No. - 1



Figure 5: Before Treatment Day 1



Figure 6: After Treatment Day 21

Group A: Patient no. - 2



Figure 7: Before Treatment Day 1

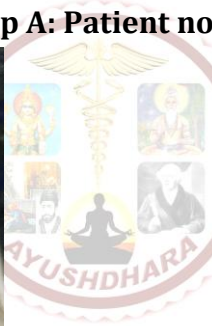


Figure 8: After Treatment Day 30

Group B: Patient No.1



Figure 9: Before Treatment Day 1



Figure 10: After Treatment Day 30

Group B: Patient no. 2



Figure 11: Before Treatment Day 1



Figure 12: After Treatment Day 21