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# A randomized controlled clinical study to evaluate the efficacy of Karanja Patra Arka in the management of Dusta Vrana vis-à-vis Chronic Non-Healing Ulcer

# Ravindra M Joshi<sup>1</sup>, Gururaja D<sup>2</sup>

<sup>1</sup>Post Graduate Scholar, Dept. of Shalya Tantra, Muniyal Institute of Ayurveda Medical College and Hospital, Manipal, Karnataka, India.

<sup>2</sup>Professor & HOD, Dept. of Shalya Tantra, Muniyal Institute of Ayurveda Medical College and Hospital, Manipal, Karnataka, India.

# ABSTRACT

Background: Dusta Vrana is a prevalent surgical issue that delays healing due to infection, slough, poor hygiene, and foreign bodies. A holistic approach is essential for chronic leg ulcer care, addressing underlying causes, accurate diagnosis, and peculiar treatment. Karanja patra is indicated for wound management in Arka Prakasha. Therefore, this study seeks to assess this aspect. Objectives: To evaluate the efficacy of Karanja Patra Arka in the management of Dushta Vrana and to compare the efficacy of Karanjapatra Arka and Gomutra Arka. Methodology: A single-blind study with a total number of 40 patients with selection criteria of Dushta Vrana were included in this study. In Group A Karanja Patra Arka wound dressing. In Control: Gomutra Arka dressing. Daily wound care for 30 days or granulation tissue formation. Weekly follow-ups and statistical analyses were done. Result: A significant improvement was noted in both subjective (Pain, Itching, and smell) and objective (Bates Jenson criteria) outcomes. Conclusion: Both Arkas shows improvement in subjective symptoms (smell, itching, pain), but differ in their objective outcomes. Karanjapatra Arka excelled in wound healing (Vrana Ropana), while Gomutra Arka showed stronger wound cleansing (Vrana Shodhana).

Key words: Karanjapatra Arka, Gomutra Arka, Dusta Vrana, Chronic non-healing ulcer

#### **INTRODUCTION**

The human body has a natural ability to heal through regeneration and repair after injury. This physiological process is triggered consistently in response to wounds. Globally, approximately 1% of the population suffers from wounds, with varying causes reported in different regions. For instance, a hospital-based study in India identified leprosy, diabetes, venous disease, and trauma as primary causes of lower extremity

#### Address for correspondence:

Dr. Ravindra M Joshi

Post Graduate Scholar, Dept. of Shalya Tantra, Muniyal Institute of Ayurveda Medical College and Hospital, Manipal, Karnataka, India. E-mail: ravindrajoshi1998@gmail.com

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wounds, accounting for 87% of cases, while 13% remained unexplained.<sup>[1]</sup> The growing incidence of wounds, particularly among the aging population and those with diabetes, underscores the need for a comprehensive understanding of wound healing and prevention strategies.

Ayurveda, the ancient science of life, emphasizes prevention and strives for holistic healing and minimal disease recurrence. Similarly, surgical interventions prioritize optimal wound healing, minimal scarring, and effective pain management. Vrana, a debilitating condition characterized by tissue damage, pain, discharge, and deformity, can affect individuals at any age. While wound healing is a natural bodily process, Ayurvedic practice recognizes the importance of protecting the affected area from Dosha Dushti and harmful microorganisms (Krimis) that can delay the healing process.

So, for the early and uncomplicated healing of Vrana, treatment is necessary Acharya Sushruta has described Shastiupakramas (60 procedures)<sup>[2]</sup> for management

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of Wound, to achieve good approximation, (*Dusta vrana*) early healing, without complications, and acceptable scar. Numerous drugs were used in various forms like *Kwatha* (Decoction), *Churna* (Powder), *Malahara* (Cream), *Kshara* (Plant alkali), *Rasakriya* (Concentrated extract), *Taila* (medicated oil), *Ghrita* (medicated ghee) in the management of *Dusta Vrana*.

The goal of wound management is to create an optimal healing environment by removing contaminated tissue, devitalized tissues, or necrosed tissues and foreign bodies, controlling bleeding, closing the wound, preventing infection, and minimizing complications.

Each substance (*Dravya*) has medicinal potential, but pharmaceutical processes enhance or modify its properties. The basic goal of administering medication is to better adapt it to the needs of the body. Numerous manufacturing processes, referred to as *Kalpanas*, were developed in order to accomplish this. Our classics provide comprehensive guidelines on the essential qualities of effective medicinal substances (*Bhaishaja/Ausadha*).

Ancient *Ayurvedic* texts elaborate on wound care, for optimal healing, a drug should possess two essential properties: *Vrana Shodhana* (Wound cleansing) and *Vrana Ropana* (Wound healing). According to various *Acharya, Karanja* is indicated in Wound care with different *Kalpanas*.<sup>[3]</sup>

These days, *Arka Kalpana* is one of the most wellknown *Ayurvedic* treatments. It was added to *Ayurvedic* pharmacy later in the system's development. Because of its unique preparation method, the finished product may contain all of the volatile active ingredients in an effective form. Compared to *Swarasa, Kalka, Kwath*, and other *Ayurvedic* dosage forms, it is a more palatable form.

Different types of procedures and heating methods are mentioned in *Arka Prakash*<sup>[4]</sup> for preparing *Arka* from different types of *Dravya*. In contemporary pharmaceutics, distillation and *Arka Kalpana* are related.

## **MATERIALS AND METHODS**

#### Source of data

Subjects of chronic non-healing ulcers were selected from the outpatient and inpatient departments of Muniyal Institute of Ayurveda Science Hospital, Manipal. Medicinal plants were collected *Arka* was prepared as mentioned in *Arkaprakasha*.

#### Method of collection of data

To participate in the study, patients with chronic nonhealing ulcers were thoroughly screened and selected based on predetermined diagnostic, inclusion, and exclusion criteria. Eligible patients provided detailed informed consent before being enrolled in the clinical trial. The study's randomized controlled design will involve comparing the outcomes of 40 selected patients with those of a control group. Patients will be randomized into two groups of 20 patients each: a) Study group and b) the Control group. The study will assess signs, symptoms, and specified parameters before and after treatment. The outcomes of both groups will be compared, subjected to statistical analysis, and interpreted.

**Design of the study:** An Open labelled, randomized, comparative, interventional clinical study

#### **Inclusion Criteria**

- Patients having the Lakshanas of Dushta Vrana occurring only in the lower extremities.
- Venous ulcers, diabetic ulcers, neurogenic ulcers of any duration.
- Patients of either sex will be taken.
- Patients aged between 20-75 years.
- Diabetic patients with controlled blood sugar levels (RBS<200mg/dl).</li>

#### **Exclusion Criteria**

- Patients with pre-diagnosed disorders like Malignancy, Leprosy, Osteomyelitis, Syphilitic ulcer, and Tubercular ulcer.
- Ulcers with signs of gangrene, cellulitis, and active infections.

 Immunocompromised patients with pre-diagnosed HIV and HBsAg positive.

#### Investigation

Hb%, DC, HBsAg, RBC, ESR, RBS, TC, HbA1C, HIV.

#### Assessment Criteria

#### **Subjective Parameters**

- Pain
- Itching
- Smell

**Objective Parameters:** Bates-Jensen Wound Assessment Tool<sup>[5]</sup>

#### Intervention

#### Study group

Treatment involved a comprehensive wound care process, consisting of:

- The wound was carefully examined, and any exudates, debris, or slough was gently removed.
- Karanja Patra Arka solution was irrigated over the wound for 5 minutes to promote healing.
- A gauze soaked in *Karanja Patra Arka* solution was applied to the wound, and secured with a dressing.
- Patients were educated to do the same for 30 days.

## **Control group**

Treatment involved a comprehensive wound care process, consisting of:

- The wound was carefully examined, and any exudates, debris, or slough was gently removed.
- Gomutra Arka solution was irrigated over the wound for 5 minutes to promote healing.
- A gauze soaked in *Gomutra Arka* solution was applied to the wound, and secured with a dressing.
- Patients were educated to do the same for 30 days.

#### **Duration of study**

Wound management will be done once a day and the duration of the study will be 30 days or till the wound heals whichever is earlier.

#### Follow-up

Patients were evaluated Weekly once for 4 weeks (7th, 14th, 21st, and 29th days) and Additional follow-up on the 45th day after treatment completion.

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#### **Statistical analysis**

Data analysis was done with the help of the statistical software GraphpadInStat v3.0. Quantitative data was presented with the help of Mean and Standard deviation. Qualitative data was presented as frequency and percentages. The BATES-JENSEN WOUND ASSESSMENT TOOL were assessed in the same group using repeated measures ANOVA, and intergroup at a particular time-point using unpaired t test

#### **OBSERVATION**

Among the 40 subjects of both group maximum (n=11) were from the age group of 41-50 years and the majority were males (n=25). 24 subjects were from the middle-class groups. The majority of them (n=22) had a history of ulcer between 7 days to 1year. Diet-wise distribution showed (n=34) had a vegetarian diet.

## RESULT

Group A (mean ± SD)	BT	AT	AF	P-value
Wound size	2.1 ± 0.7	1.55 ± 0.7	1.25 ± 0.4	<0.0001
Wound depth	2.25 ± 0.6	1.75 ± 0.8	1.55 ± 0.6	<0.0001
Wound edge	2.6 ± 1.1	1.85 ± 0.7	1.6 ± 0.5	<0.0001
Wound undermining	1.7 ± 0.4	1.35 ± 0.5	1.2 ± 0.4	<0.0001
Wound necrotic tissue type	2.65 ± 0.9	2.05 ± 0.7	1.9 ± 0.8	<0.0001
Wound necrotic tissue amount	2.95 ± 0.9	1.9 ± 0.6	1.45 ± 0.5	<0.0001

# Table 1: Group A: Within-group comparison fromBefore treatment to after follow-up:

Exudate type	2.65 ± 0.5	2.1 ± 0.6	1.85 ± 0.5	<0.0001
Exudate amount	3.3 ± 0.8	2.2 ± 0.7	1.85 ± 0.6	<0.0001
Skin color	2.45 ± 0.5	2 ± 0.7	1.6 ± 0.5	<0.0001
Peripheral tissue edema	2.6 ± 0.5	1.8 ± 0.7	1.3 ± 0.4	<0.0001
Peripheral tissue induration	2.25 ± 0.7	1.75 ± 0.7	1.5 ± 0.5	<0.0001
Granulation tissue	3.45 ± 0.5	2.65 ± 0.6	2.2 ± 0.7	<0.0001
Pain score	2.65 ± 0.5	1.75 ± 0.6	1.05 ± 0.8	<0.0001
Itching score	2.5 ± 0.5	1.3 ± 0.4	0.6 ± 0.6	<0.0001
Smell VAS score	2.3 ± 0.4	1.5 ± 0.6	1 ± 0.7	<0.0001

On analyzing the within group A comparison, there was a decreasing trend in the above mentions parameters over the timeframes seen during before, after and at follow-up (p<0.00001 on repeated measures ANOVA).

Table 2: Group B: Within group comparison fromBefore treatment to after follow up:

Group B (mean ± SD)	BT	AT	AF	P-value
Wound size	2.15 ± 0.7	1.75 ± 0.7	1.35 ± 0.5	<0.0001
Wound depth	2.75 ± 0.8	2.2 ± 0.6	1.9 ± 0.7	<0.0001
Wound edge	2.25 ± 0.5	1.85 ± 0.7	1.5 ± 0.6	<0.0001
Wound undermining	1.8 ± 0.7	1.35 ± 0.5	1.15 ± 0.3	<0.0001
Wound necrotic tissue type	2.9 ± 0.6	2.45 ± 0.5	1.5 ± 0.6	<0.0001
Wound necrotic tissue amount	2.5 ± 0.6	2.2 ± 0.7	1.5 ± 0.6	<0.0001
Exudate type	2.85 ± 0.6	2.05 ± 0.7	1.6 ± 0.7	<0.0001

Exudate amount	2.85 ± 0.8	2.45 ± 0.8	1.9 ± 0.8	<0.0001
Skin color	2.4 ± 0.5	1.95 ± 0.7	1.4 ± 0.5	<0.0001
Peripheral tissue edema	2.55 ± 0.5	1.65 ± 0.5	1.15 ± 0.3	<0.0001
Peripheral tissue induration	2.35 ± 0.5	2.15 ± 0.6	1.65 ± 0.6	<0.0001
Granulation tissue	2.2 ± 0.7	1.7 ± 0.8	1.45 ± 0.5	<0.0001
Pain score	2.65 ± 0.5	1.75 ± 0.6	0.5 ± 0.7	<0.0001
Itching score	2.4 ± 0.6	1.35 ± 0.5	0.3 ± 0.4	<0.0001
Smell score	2.2 ± 0.6	1.35 ± 0.6	0.5 ± 0.5	<0.0001

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On analyzing the within group B comparison, there was a decreasing trend in the above mentions parameters over the timeframes seen during before, after and at follow-up (p<0.00001 on repeated measures ANOVA).

# Table 3: Percentage change in treatment outcomesbetween before treatment and at after follow-up

	Group A			Group B		
Paramet ers	Before treatm ent	At follo w-up	% Chan ge	Before treatm ent	At follo w-up	% Chan ge
Wound size	2.1 ± 0.7	1.25 ± 0.4	40.5	2.15 ± 0.7	1.35 ± 0.5	37.2
Wound depth	2.25 ± 0.6	1.55 ± 0.6	50.8	2.75 ± 0.8	1.9 ± 0.7	30.9
Wound edge	2.6 ± 1.1	1.6 ± 0.5	38.5	2.25 ± 0.5	1.5 ± 0.6	33.3
Wound undermi ning	1.7 ± 0.4	1.2 ± 0.4	29.4	1.8 ± 0.7	1.15 ± 0.3	36.1
Wound necrotic tissue	2.65 ± 0.9	1.9 ± 0.8	28.3	2.9 ± 0.6	1.5 ± 0.6	48.3
Wound necrotic	2.95 ± 0.9	1.45 ± 0.5	50.8	2.5 ± 0.6	1.5 ± 0.6	40

tissue amount						
Exudate type	2.65 ± 0.5	1.85 ± 0.5	30.2	2.85 ± 0.6	1.6 ± 0.7	43.9
Exudate amount	3.3 ± 0.8	1.85 ± 0.6	43.8	2.85 ± 0.8	1.9 ± 0.8	33.3
Skin color	2.45 ± 0.6	1.6 ± 0.5	34.7	2.4 ± 0.5	1.4 ± 0.5	41.7
Peripher al tissue edema	2.6 ± 0.5	1.3 ± 0.4	50	2.55 ± 0.5	1.15 ± 0.3	54.9
Peripher al tissue induratio n	2.25 ± 0.7	1.5 ± 0.5	33.3	2.35 ± 0.5	1.65 ± 0.6	29.7
Granulat ion tissue	3.45 ± 0.5	2.2 ± 0.7	36.2	2.2 ± 0.7	1.45 ± 0.5	34.1
Pain score	2.65 ± 0.5	1.05 ± 0.8	60.4	2.65 ± 0.5	0.5 ± 0.7	81.1
Itching score	2.5 ± 0.5	0.6 ± 0.6	76	2.4 ± 0.6	0.3 ± 0.4	87.5
Smell score	2.3 ± 0.4	1 ± 0.7	56.5	2.2 ± 0.6	0.5 ± 0.5	77.3

The parameters was compared at three time-points: before treatment, after treatment and at follow-up. It was seen that there was no difference in the parameters at each time point between group A and B (p>0.05 on unpaired T-test).





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#### DISCUSSION

Karanja Patra Arka - Almost all the Acharya's have opined the properties of Karanja are Tikta (bitter), Katu (pungent) Kashaya (astringent) in Rasa (taste), Laghu (light) and Tikshna (sharpness) in Guna (properties), Ushna (hot) in Virya (potency) and Katu (pungent) in Vipaka (metabolism). Due to these properties, it alleviates Vata & Kapha Dosha.

The pharmacological effects of *Karanja* are *Kapha-Vathara, Shothahara* & *Bhedana*. It is indicated in wound healing.

Phytochemicals found in *Karanjapatra* are Alkaloids, Carbohydrates, Phytosterols, Saponins, Tannins, and Flavonoids.<sup>[6,7]</sup>

*Gomutra*<sup>[8]</sup> - *Gomutra* is proven to possess analgesic & *Krimighna* property.

- Parishekha is a Bahya Upakrama used especially for alleviating the pain and inflammation in Sopha and Vrana.
- Katu and Kashaya Rasa of Gomutra help in alleviating Kandu.
- *Tikta* and *Kashaya Rasa* of *Gomutra Arka* is responsible for alleviating *Vikrutha Gandha*.
- Kshara Guna, Lekhana, Chedana property of Gomutra helps in slough debridement in the ulcer facilitating granulation tissue formation.

**Effect on size of ulcer:** Observation was made in the 40 patients before and after treatment. Out of which, Reduction in the size of wound was observed in both the groups. In Group A reduction percentage was 40.5% while Group B reduction percentage was 37.2%. The likely reason for the reduction in size can be *Tikta*, *Kashaya Rasa* present in both drugs.

Based on *Kshalana* Karma (Cleansing and purification) treatment administered prior to wound dressing also helps in the reduction in the size of the ulcer.

**Effect on depth of ulcer:** Reduction in the depth of wound was observed in both the groups. In Group A reduction percentage was 50.8% while Group B reduction percentage was 30.9%. The *Kashaya rasa, of* 

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*drugs which is Raktashodhaka and Vrana Ropana in nature* along with *Laghu, Ruksha Guna* contributes to reduce depth of ulcer.

**Effect on edges of ulcer:** Reduction in the edge of wound was observed in both the groups. In Group A reduction percentage was 38.5% while Group B reduction percentage was 33.3%. According to the therapeutic properties of *Karanjapatra Arka* and *Gomutra Arka, Ropana Karma* yields significant results.

**Effect on undermining of ulcer:** Reduction in the undermining of wound was observed in both the groups. In Group A reduction percentage was 29.4% while Group B reduction percentage was 36.1%. *Gomutra Arka Pichu Bandhana's Shodhana* property likely accounts for its greater effectiveness compared to *Karanjapatra Arka*.

**Effect on Necrotic tissue type of ulcer:** Reduction in the Necrotic tissue type of wound was observed in both the groups. In Group A reduction percentage was 28.3% while Group B reduction percentage was 48.3%. When the effect of both the treatment was compared the patient in Group B showed better response in Necrotic tissue type of ulcer. Necrotic wounds can have numbers of underlying causes Infection, Vascular disorders etc. *Gomutra Arka's Vrana Shodhana Karma* likely caused the change due to its purifying properties.

Effect on Necrotic tissue amount of ulcer: Reduction in the Necrotic tissue amount of wound was observed in both the groups. In Group A reduction percentage was 50.8% while Group B reduction percentage was 40%. The probable reason for the improvement is that contaminated wounds (*Dusta Vrana*) require Krimghnadravya to promote healthy tissue growth and growth. Gomutra Arka reduce microbial recommended for this purpose, offering additional Lekhana and Ropana benefits. Alternatively, Karanjapatra Arka's Krimihara properties yield better outcomes.

**Effect on exudates type of ulcer:** Reduction in the exudates type of wound was observed in both the groups. In Group A reduction percentage was 30.2% while Group B reduction percentage was 43.9%. When the effect of both treatments compares patient of

Group B showed better response in exudates type of ulcer. The probable reason for reduction in exudates type is *Tikta, Katu Rasa* of *Gomutra Arka* which function of *Vrana Shodhana* and *Kleda Shoshana*.

**Effect on exudates amount of ulcer:** Reduction in the exudates amount of wound was observed in both the groups. In Group A reduction percentage was 43.9% while Group B reduction percentage was 33.3%. The probable reason for reduced exudate is the *Kapha-Vata* reducing properties of both drugs. However, *Karanja Patra* (Group A) showed superior results due to its additional *Bhedana* and *Shoth hara* properties.

**Effect on skin colour of ulcer:** Reduction in the skin colour of wound was observed in both the groups. In Group A reduction percentage was 34.7% while Group B reduction percentage was 41.7%. When both the group were compared, Group B showed better result in skin colour of ulcer, Because of *Aamapachan Guna* of *Gomutra Arka*.

Sthanik Aampachan lead to Twak Shuddhi of Body, which enhance quality of *Bharajak Pitta* present in *Twak*. Therefore, *Aampachan* does better result on Skin colour of ulcer.

**Effect on oedema of ulcer:** Reduction in the oedema of wound was observed in both the groups. In Group A reduction percentage was 50% while in Group B reduction percentage was 54.9%. There is not much differentiation between the before and after studies suggesting both the drugs having *Shothahara* properties play a role in the reduction of oedema of ulcers.

**Effect on induration of ulcer:** Reduction in the induration of wound was observed in both the groups. In Group A reduction percentage was 33. 3% while Group B reduction percentage was 29.7%. When the effect of both treatments compares there is not much difference between the results of groups.

**Effect on granulation tissue of ulcer:** Reduction in the granulation tissue of wound was observed in both the groups. In Group A reduction percentage was 40.5% while in Group B reduction percentage was 37.2%. While comparing both group patient of Group A

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showed better result in granulation tissue formation. The probable reason can be *Vrana Ropana Karma* of *Karanjapatra* showed in formation of granulation tissue. Whereas *Kshara Guna, Lekhan* and *Chedana Karma* of *Gomutra* have a role in the formation of granulation tissue.

**Effect on Pain of ulcer:** Reduction in the pain of wound was observed in both the groups. In Group A reduction percentage was 60.4% while Group B reduction percentage was 81.1%. When the effect of both drugs compare patient of Group B showed better response in pain.

The probable reason can be *Parisheka* is the procedure that is explained for alleviating pain. *Vata* is the main *dosha* causing pain. Further, *Ushna Veerya of Gomutra Arka* helps in the alleviation of *Vata* thereby reduces the pain. *Gomutra* is proved to have an Analgesic effect.

**Effect on itching of ulcer:** Reduction in the itching of wound was observed in both the groups. In Group A reduction percentage was 76% while Group B reduction percentage was 85.5%. Eventhogh both the group showed significant result but when the effect of both treatment compare patient of Group B showed better response in itching of ulcer.

The probable reason behind this can be *Katu, Kashaya Rasa* of *Gomutra Arka* and *Tikta, Kashaya Rasa* in *Karanja Arka* helps in attaining the *Niramaavastha* of *Kapha* thus reducing *Kandu*.

Effect on smell of ulcer: Reduction in the smell of wound was observed in both the groups. In Group A reduction percentage was 56.5% while Group B reduction percentage was 77.3%. Eventhogh Both the *Arka* having *Tikata, Kashay Rasa,* while comparing both the group, Group B showed significant result in smell of ulcer. The probable reason behind this *Tikata, Kashaya Rasa* of *Gomutra Arka* which alleviate smell by reducing infection in ulcer.

#### CONCLUSION

Both these treatments showed reduction in symptoms in different parameters. *Karanjapatra Arka* was having good result in reducing necrotic tissue amount, exudates amount, wound depth and wound edge. *Karanjapatra Arka* was having positive outcome in improving granulation tissue formation. *Gomutra Arka* was having good result in reducing wound undermining, necrotic tissue type, Exudate type and peripheral tissue edema. Both the group showed improvement in reduction of smell, itching, and pain. It can be concluded that even though having similar properties in the management of wound -*Karanjapatra Arka* has more *Vrana Ropana* property and *Gomutra Arka* having *Vrana Shodhana* property.



Photo 1: Before and after treatment in patient of group A



Photo 2: Before and after treatment in patient of group B

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