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Original Article

Clinical Study Of Ksharaplota In The Management Of Pramehajanya Dushtavrana (Diabetic Foot Ulcer)

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ABSTRACT:
Pramehajanya Dushta Vrana, correlated with Diabetic Foot Ulcer (DFU), is one of the most challenging chronic wound conditions due to microangiopathy, neuropathy, and reduced immune response. Ayurveda describes several treatment modalities for Dushta Vrana, among which Ksharaplota—a specialized caustic alkali-based wound application—holds significant therapeutic value. This review explores the Ayurvedic principles, mode of action, pharmacological properties, clinical relevance, and contemporary evidence supporting the use of Ksharaplota in the management of diabetic foot ulcers.

Keywords: Ksharaplota, Apamarga Kshara, Pramehajanya Dushta Vrana, Diabetic Foot Ulcer, Ayurveda

INTRODUCTION

The ultimate goal of every medical discipline is to ensure the longevity and quality of life for all individuals, best summarized by the ancient maxim: "A healthy mind in a healthy body[i]. Achieving this state of complete well-being has driven scholars across various civilizations for millennia. In this pursuit, Ayurveda, the traditional science of life and an Upaveda of the Atharvaveda, plays a pivotal role. Ayurveda's core objective is two-fold: to maintain the health of a healthy person (Swasthasya Swasthya Rakshanam) and to cure the ailments of the diseased person (Aturasya Vikara Prashamanam)[ii]. Health, as defined by Acharya Sushruta, is not merely the absence of disease but a balanced state of mind, body, and soul (Su. Su. 15/47). Ayurveda is categorized into eight branches (Ashtangas), with Shalya Tantra (the branch of surgery) being one of the most predominant. Acharya Sushruta, revered as the "Father of Surgery," systematically organized this branch, emphasizing the need for swift action (Aashu Kriya Karanaad) and the proficient use of sharp instruments (Shastra), caustic alkalis (Kshara), and thermal cautery (Agni) in therapeutic applications (Su.Su. 1/18)[iii].

Diabetes mellitus is a global health burden, and its chronic complication, Diabetic Foot Ulcer (DFU), affects nearly 15–25% of diabetics. In Ayurveda, DFU can be correlated with Pramehajanya Dushta Vrana caused by vitiation of Kapha, Meda, Rakta, and Pitta. Sushruta describes measures like Kshara, Agnikarma, Lepa, and Ropana for non-healing wounds. Among them, Ksharaplota is effective for debridement, infection control, slough removal, and promoting granulation.

AIMS

To evaluate the efficacy of *Ksharaplota* in the management of *Pramehajanya dushtavrana* with (Diabetic Foot Ulcers).

OBJECTIVES

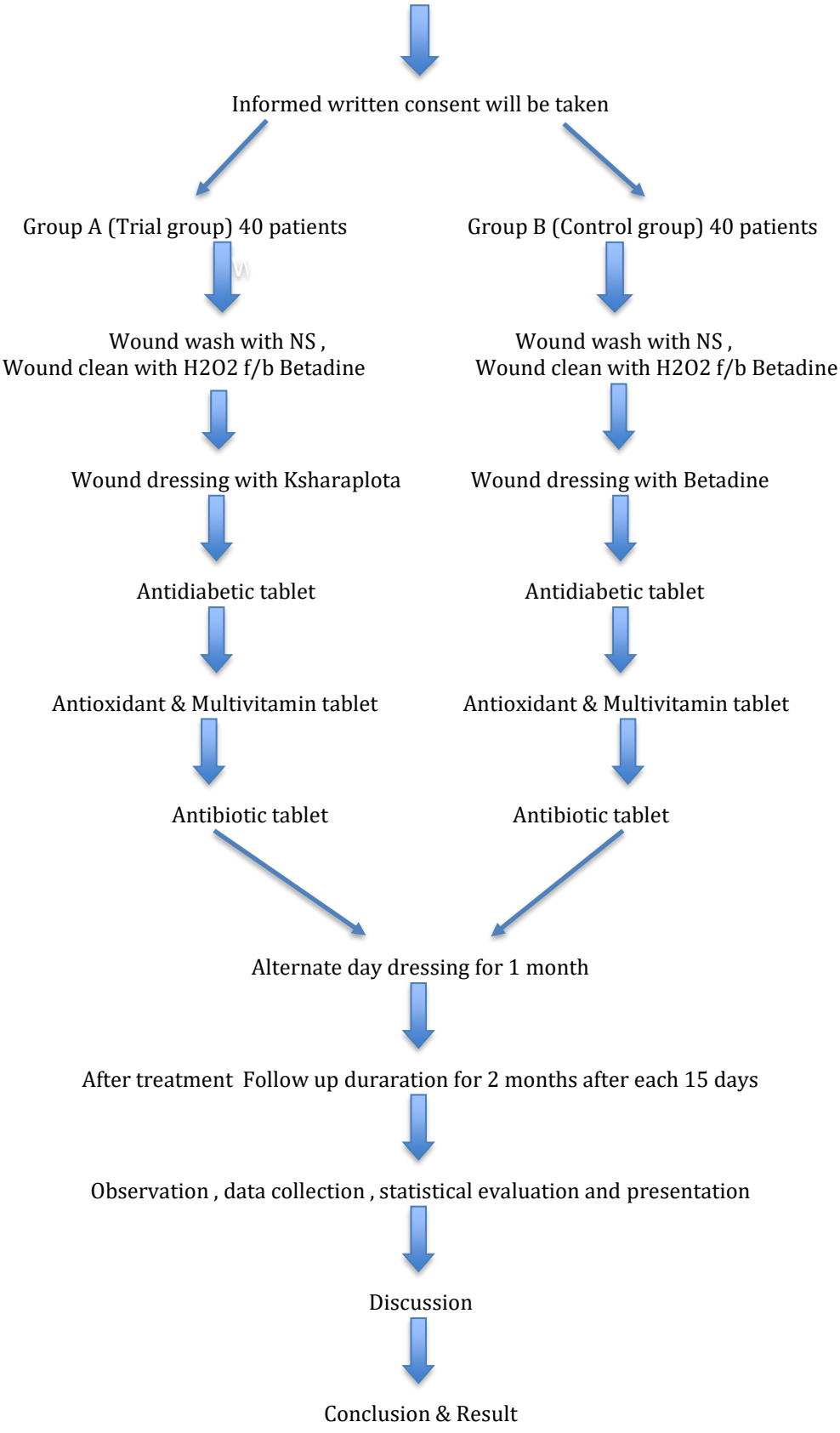
To Study the Vrana Shodhan (wound cleansing) and Vrana Ropan (wound healing) effect of Ksharaplota in the management of Diabetic Foot Ulcers.

MATERIALS & METHODS

STUDY DESIGN

Prospective randomized clinical trial

Selection of patient as per inclusive & exclusive criteria


Informed written consent will be taken
Group A (Trial group) 40 patients
Group B (Control group) 40 patients
Wound wash with NS ,
Wound clean with H2O2 f/b Betadine
Wound wash with NS ,
Wound clean with H2O2 f/b Betadine
Wound dressing with Ksharaplota
Wound dressing with Betadine
Antidiabetic tablet
Antidiabetic tablet
Antioxidant & Multivitamin tablet
Antioxidant & Multivitamin tablet
Antibiotic tablet
Antibiotic tablet
Alternate day dressing for 1 month
After treatment Follow up duraration for 2 months after each 15 days
Observation , data collection , statistical evaluation and presentation
Discussion
Conclusion & Result

Concept of Ksharaplota
Ksharaplota refers to applying Kshara-soaked gauze over the ulcer for controlled chemical debridement.

PREPARATION OF KSHARAPLOTA
The Ksharaplota was prepared in the Institute's Department of Shalyatantra over a three-day period, involving sequential coating and drying.

Step 1: A 23 cm diameter, spherical, single-layer gauze piece was fixed uniformly and tightly within the wooden embroidery ring.

Step 2 (Day 1): Using gloved hands to prevent contact and a sterile cotton swab to ensure even application, 50 ml of Snuhi Ksheera was applied as a single, uniform coating over the entire circumference of the gauze. The wet coated gauze, still in its wooden ring, was placed in the air-tight cabinet for 24 hours to dry.

Step 3 (Day 2): A second application of 50 ml of Snuhi Ksheera was smeared uniformly with a cotton swab. Immediately following this, 20 gm of Apamarga Kshara powder was dusted uniformly over the wet surface. The ring was then returned to the cabinet to dry for another 24 hours.

Step 4 (Day 3): A final coating of 50 ml of Snuhi Ksheera was applied with a cotton swab. Immediately after, 20 gm of Haridra Churna was dusted uniformly over the surface. The preparation was then allowed to dry in the cabinet for a final 24 hours.

Step 5 (Packaging and Sterilization): After the final drying, the prepared Ksharaplota (containing a total of 150 ml of Snuhi Ksheera) was cut into 6 cm x 6 cm pieces. These pieces were packed in sealed polythene packs. The final packaged Ksharaplota was stored and sterilized in the cabinet using Ultra-Violet (UV) rays until use.

Pharmacological Properties
1. Lekhana – removes slough, necrosis
2. Shodhana – purifies and reduces infection
3. Ropana – promotes granulation
4. Krimighna action – inhibits Staphylococcus, Pseudomonas, E. coli

INCLUSION CRITERIA
1. Patients 40 to 70 yrs. of age.
2. Patients with normal bleeding and clotting time.
3. Patients with h/o Diabetes Mellitus.
4. Patients having diabetic foot ulcer.
5. Sex- both male & female.
6. Patient belonging to all socioeconomic group.
7. HB- more than 10 gm/dl. Wound size less than 6 × 4 ×2 cm.
8. Randam Blood Sugas (RBS)below 200 mg/dl.

Patient under treatment of Antidiabetic tablet

EXCLUSION CRITERIA
1. Patients with below age group of 40 and above 70 years.
2. Patients suffering from uncontrolled hypertension, IHD, TB, Hep.B, HIV, Malignancy, Chronic renal failure.
3. Patients with congenital & acquired urogenital anomalies like Cancer.
4. Patient's with Diabetic Ketoacidosis.
5. Bleeding Disorder (Increase BT, CT).
6. RBS greater than 200 mg/dl.
7. Patient under treatment of Insulin/ Insulin dependent diabetes mellitus

ASSESSMENT PARAMETER

Subjective Parameters

1. Pain (0-10 VAS Numeric Pain Distress Scale)

Grade	Description
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

2. Itching

Grade	Description
0	Absent
1	Present but Not Annoying or troublesome.
2	Troublesome but not interfere with Normal daily activities or sleep.
3	Severe itching which is sufficiently troublesome to interfere with normal daily activities or sleep.

3. Tenderness

Grade	Description
0	No Tenderness
1	Mild Tenderness-Subjective experience of Tenderness
2	Moderate Tenderness- Wincing of face on pressure
3	Severe Tenderness- Wincing of face and withdrawal of the affected part on pressure

4. Inflammation

Grade	Description
0	No Inflammation.
1	Mild Inflammation- Ulcer present at superficial layer
2	Moderate Inflammation- Ulcer involve the tendon, ligament, muscle
3	Severe Inflammation- Ulcer affect underlying bone

Objective Parameters

1. Discharge

Grade	Description
0	No discharge
1	Gauze is slight moist
2	After opening the bandage gauze is completely wet.
3	Bandage is moist within 24 hr but no need to change the dressing.
4	Bandage is moist within 24 hr and need to change the dressing.

2. Length of Wound

Grade	Description
0	0-1 cm
1	1.1-2 cm
2	2.1-3 cm
3	3.1-4 cm
4	4.1-5 cm

3. Breadth of Wound

Grade	Description
0	0-1 cm
1	1.1-2 cm
2	2.1-3 cm

4. Depth of Wound

Grade	Description
0	0-1 cm
1	1.1-2 cm
2	2.1-3 cm

DISCUSSION

The present study, titled "To evaluate the efficacy of Ksharaplota in the management of Pramehajanya dushtavrana with special reference to Diabetic Foot Ulcers," was conducted as a prospective, open-label, randomized controlled clinical trial. The primary objective was to critically assess and compare the *Vrana Shodhana* (wound cleansing/debridement) and *Vrana Ropana* (wound healing) efficacy of a classical Ayurvedic formulation, *Ksharaplota* (Group A), against a contemporary standard of care, Betadine (Povidone-Iodine) dressing (Group B).

A total of 80 patients diagnosed with Diabetic Foot Ulcers, fulfilling the stringent inclusion and exclusion criteria, were randomly allocated into two equal groups of 40 patients. The demographic data and baseline assessment of all parameters showed no statistically significant difference between the two groups. This homogeneity is a critical strength of the study, as it confirms that the patient populations were comparable at the onset, ensuring that any subsequent differences in outcomes can be confidently attributed to the interventions themselves.

The results of this study accept the alternate hypothesis and demonstrate that *Ksharaplota* are highly effective treatments for Diabetic Foot Ulcers. However, the comparative analysis reveals that they function through different mechanisms and have distinct clinical strengths. *Ksharaplota* excelled in reducing inflammatory
parameters like Tenderness and Inflammation, while Betadine excelled in reducing surface symptoms like Itching and Edema.

CONCLUSION

This prospective, randomized controlled clinical study was designed to critically evaluate the efficacy of *Ksharaplota* in the management of *Pramehajanya Dushtavrana* (Diabetic Foot Ulcers). The results obtained provide a clear and definitive answer to the research question.

The study conclusively demonstrates that Ksharaplota (Group A) is a highly effective treatment, showing comparable overall efficacy to the standard contemporary control, Betadine 10 solution (Group B). The overall assessment revealed that 83% of patients in the Ksharaplota group and 85% in the Betadine group achieved "Marked Improvement".

While the total therapeutic effect was similar, the trial group (Group A) exhibited specific superiority in managing the inflammatory pathology of the wounds. *Ksharaplota* achieved a 82% reduction in Tenderness (vs 63% in control) and an 85% reduction in Inflammation (vs 76% in control). Conversely, the control group showed superior results in reducing Edema (89%) and Itching (90%). These outcomes validate the classical Ayurvedic principles upon which the trial drug was formulated, proving that *Ksharaplota* acts as a multi-modal wound management system addressing the complex pathophysiology of a *Dushta Vrana*:

- **Vrana Shodhana (Active Debridement):** The *Kshara* components (*Apamarga Kshara* and *Snuhi Ksheera*) performed effective chemical debridement through their *Tikshna* (sharp) and *Lekhana* (scraping) properties. This was proven by the 86% improvement in the Wound Floor, transforming it from a slough-covered bed to healthy granulation tissue—an effect identical to the control group.
- **Shothahara (Anti-inflammatory Action):** The *Haridra Churna* component successfully broke the chronic inflammatory cycle. This was evidenced by the statistically superior reduction in deep-seated Tenderness and Inflammation. This action directly contributed to the 88% relief in Pain.
- **Krimighna (Antimicrobial Action):** Both groups achieved an ~86% reduction in Discharge . This strongly suggests that *Ksharaplota* possesses potent antimicrobial properties comparable to the gold-standard antiseptic (Betadine), effectively controlling the bio-burden and inflammatory exudate (*Kleda*).
- **Vrana Ropana (Complete Healing):** Because the *Ksharaplota* successfully debrided and controlled inflammation, the wounds progressed to the proliferative phase. This was proven by the 83% reduction in Breadth and 61% reduction in Length, facilitating significant wound closure .

In conclusion, this study confirms that *Ksharaplota* is a scientifically validated, effective, and safe alternative to Betadine for Diabetic Foot Ulcers. While Betadine remains effective for surface symptoms (itching/edema), *Ksharaplota* demonstrates distinct advantages in relieving deep tissue tenderness and inflammation, making it a viable frontline treatment, particularly for painful, inflamed, and necrotic ulcers.

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