



CLINICAL STUDY OF TRAYAKSHEERA GAUZE IN THE MANAGEMENT OF PRAMEHAJANYA DUSHTAVRANA (DIABETIC FOOT ULCER)

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ABSTRACT

In Ayurveda, the clinical presentation of diabetic foot ulcer can be correlated with Pramehajanya Dushta Vrana, where chronicity of Prameha and derangement of Dosha, Dushya and Strotas contribute to delayed healing and recurrent infection. Local wound management plays an important role in achieving Vrana Shodhana and Vrana Ropana. Trayaksheera Gauze, prepared using the Snuhiksheera (Latex of Euphorbia neriifolia), Arkaksheera (Latex of Calotropis procera) and Papayaksheera (Latex of Carica papaya) may provide beneficial wound cleansing and healing effects.

Keywords: Trayaksheera Gauze, Snuhiksheera, Arkaksheera, Papayaksheera, Pramehajanya Dushta Vrana, Diabetic Foot Ulcer, Ayurveda.

INTRODUCTION

Meconium-stained amniotic fluid (MSAF) is a common obstetric finding, observed in 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(1) . 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)(2).

Health, as defined by Acharya Sushruta, is not merely the absence of disease but a balanced state of mind, body and soul. 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 (Shashtra), caustic alkalis (Kshara) and thermal cautery (Agni) in therapeutic applications.(3)

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.(4)

The incidence of diabetes mellitus is rapidly increasing and this condition often results in significant metabolic disease and severe complications. Diabetic foot ulcers (DFUs) are estimated to occur in 30% of all patients with diabetes and precede 84% of all diabetes related lower-leg amputations. The triad of peripheral neuropathy, peripheral arterial disease and infection is responsible for foot problem.

Infected wounds requires surgical debridement to maintain good healing process. Such procedure is very painful & patient gets afraid of surgical debridement. In this way patient keeps away himself from proper treatment. In such cases non surgical procedure should be used which are similarly effective to surgical procedure hence this attempt is tried to make by Trayaksheera gauze in the present study.

Ayurveda offers numerous plant-derived medicinal substances possessing Shodhana, Ropana, Krimighna, Shothahara, Vedanasthapana and Raktashodhaka properties. Among these, Trayaksheera Gauze was prepared with the help of Snuhiksheera (latex of *Euphorbia neriifolia*), Arka Ksheera (latex of *Calotropis procera*) and Papaya Ksheera (*Carica papaya*) has attracted considerable attention because of its potent debriding and woundhealing potential. These latex-containing plants have been described in Ayurvedic classics for their ability to remove unhealthy tissue and promote healing. Modern pharmacological studies have also demonstrated that these plants possess proteolytic, antimicrobial, antiinflammatory, antioxidant and wound-healing activities, which may facilitate faster removal of slough, reduction in microbial load, stimulation of granulation tissue formation and epithelialisation. Papaya latex contains proteolytic enzymes such as papain and chymopapain which facilitate enzymatic debridement by digesting necrotic tissue without significantly damaging viable tissue(5).

Snuhi Ksheera possesses Lekhana, Shodhana, Krimighna and wound healing properties,(6) whereas Arka Ksheera exhibits Shothahara, Vedanasthapana, antimicrobial and tissue regenerative effects(7). The synergistic combination of these three latex drugs in the form of Trayaksheera Gauze may provide an effective, economical and minimally invasive method for active wound debridement and healing in diabetic foot ulcers.

Aims

To evaluate the efficacy of Trayaksheera Gauze 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 Trayaksheera Gauze in the management of Diabetic Foot Ulcers.

Ayurvedic Review

Nidan(8)

Day-sleep (Divasvapna), is averse to physical exertion (Vyayamalasyapursaktam) and is consuming foods and drinks that are cold (Sita), unctuous (Snigdha), sweet (Madhura) and fatpromoting (Medhotvana)—that person will likely develop Prameha (Pramehi bhavisyatiti).

Purvaroop(9)

- 1.Karpadyo Suptata/Daha (Numbness & burning sensation in hands and feet).
- 2.Snigdha- Pichhila- Guru Gatra (stickiness, slimy and heaviness in body).
- 3.Madhura-Sukla Mutra (Sweet, turbid urine).
- 4.Tandra, Sada (Malaise)
- 5.Pipasa/ Sheeta Priyta (Thirst).
- 6.Vishra Sareera Gandha (Bad body odour)..
- 7.Hridya, Netra, Jiwha, Danta Updeha (Accumulation of dirt in palate, throat, tongue and teeth).
- 8.Jatilibhava Kesha (Matting of hairs).
- 9.Kesha-Nakha Ativridhi (excessive growth of nails and hairs).

Samprapti(10)

When the aggravated Dosas (Vata, Pitta, Kapha) together with the increased but improperly processed Meda enter and travel through the urinary channels (Mutravaha Srotas), descend to the urinary bladder and localize there they produce disease known as Prameha.

Modern Medical History Of Diabetes Mellitus

Madhumeha is directly translated as Diabetes Mellitus, both conveying the concept of "honey discharge" or "honey urine." The modern understanding began in 1670 AD when Thomas Willis first described the sweet aroma of diabetic urine, followed by Mathew Dobson demonstrating the presence of sugar in the urine in 1776 AD. Early theories included Johan Conard's belief (1682) that polyuria was induced by the pancreas, verified through experiments on canines.

A major milestone was reached by Claude Bernad (1813–1878), who successfully induced glycosuria by puncturing the fourth ventricle of a dog's brain. In 1869, Paul Langherhans identified the specialized cells in the pancreas, named the Islets of Langherhans after him.

Finally, the identification of antidiabetic hormones was achieved by Kunhana and Lea in 1893, solidifying the understanding of the disease's underlying mechanism(11).

Upadrava of Madhumeha (Diabetic Boils)

Due to the neglect (Upekshaya) of Madhumeha, seven severe boils (Pidakah Sapta Darunah) develop on the body, with Vidradhi (abscess) being the seventh type.

All Acharyas recognize Pramehapidaka (Diabetic Boils/Carbuncles) as a major complication of Prameha. Charaka, however, specifically described them as a complication of Madhumeha resulting from ignorance of the disease(12).

Materials & Methods

Study Design

This study was designed as a prospective randomized controlled clinical trial. Patients fulfilling the predetermined inclusion and exclusion criteria were selected for the study. After explaining the nature and purpose of the study, written informed consent was obtained from all participants. The selected patients were then randomly allocated into two groups: Group A (Trial Group) and Group B (Control Group). In both groups, the ulcer was initially cleaned with Normal Saline (NS) and Hydrogen Peroxide (H₂O₂), followed by an Eusol foot bath. In Group A, daily ulcer dressing was performed using Trayaksheera Gauze and the wound was subsequently covered with a sterile bandage. In Group B, daily sterile dressing was performed using Betadine (Povidone-Iodine) and the ulcer was covered with a sterile bandage. The patients were followed up regularly, and the clinical outcomes were assessed according to the predetermined study parameters.

Following the dressing procedure, both groups received the same systemic supportive treatment to maintain uniformity and minimize bias. Patients in both Group A (Trial Group) and Group B (Control Group) were prescribed appropriate antidiabetic medication for the control of blood glucose levels. In addition, multivitamin tablets were given and continued until complete ulcer healing. Where indicated, an antibiotic regimen of Tablet Clavum 625 mg twice daily (BD) for 7 days was prescribed.

All patients were observed and assessed daily for 28 days and the clinical findings and changes in the ulcer were recorded regularly according to the predetermined assessment parameters.

After completion of the treatment period, the patients were kept under follow-up for 3 months, with follow-up assessments conducted at 7-day intervals. The collected data were subsequently analyzed statistically and the findings were evaluated to determine the therapeutic efficacy of Trayaksheera Gauze dressing in comparison with Betadine dressing. Finally, the results were interpreted and presented in the form of Results, Discussion and Conclusion.

Method Of Trayaksheera Gauze Preparation :-

The gauze piece of size used is 23cm in circumference which is fixed in the single layered circular Wooden ring. Gauze piece is made so tight that the coating is made uniformly.

Under aseptic condition on 1st day Snuhiksheera (15gm) was applied over the gauze on its whole area with the help of small cotton swab. The wet medicated gauze, affixed to the ring, is stored in the designated Ksharsutra cabinet for 24 hours to allow for thorough drying. Repeat the same procedure on 2nd and 3rd day.

On the 4th day dried gauze was smear with Arkksheer (15gm) with cotton swab, it was stored in the designated Ksharsutra cabinet for 24 hours to allow for thorough drying.

Repeat the same procedure on 5th and 6th day.

On the 7th day dried gauze was smear with Papayaksheer (15gm) with cotton swab, it was also stored in the designated Ksharsutra cabinet for 24 hours to allow for thorough drying. Repeat the same procedure on 8th and 9th day.

In this way coating of Snuhiksheera, Arkksheera and papayaksheera are completed and sealed in polythene packs. Trayaksheer Gauze should be placed in Ksharsutra cabinet for safety storage as well as for sterilization.

Sample Size :-

A total of 80 patients diagnosed with Pramehajanya Dushta Vrana/Diabetic Foot Ulcer were included in the study.

The patients were randomly divided into two groups:

- Group A – 40 patients: Trayaksheera Gauze dressing
- Group B – 40 patients: Betadine dressing

Inclusion Criteria

1. Patients from age group of 18 to 70 year irrespective of gender, religion, occupation, socioeconomical status having sign and symptoms of diabetic foot ulcer.
2. Presence of a diabetic foot ulcer corresponding to Wagner classification Grade 1 – 2(3)
3. Patient with fasting blood sugar level less than 200mg/dl.
4. Patients with normal bleeding and clotting time.
5. Patients with history of Diabetes Mellitus.
6. Patient having diabetic foot ulcer.
7. HB-more than 10 gm /dl.
8. Wound size less than 6x4x2 cm.

Exclusion Criteria :-

1. Patients below 18 year age group and above 70 year age.
2. Patients with known case of T.A.O., HIV, TB, HBsAg, HTN, D.V.T., Malignant Ulcer, Ketoacidosis, Under malnutrition.
3. Pregenancy
4. Patients not willing for trial.
5. Patients having HB less than 10 gm/dl.
6. wound size more than 6x4x2 cm.
7. Patients who need surgical and other intervention.

8. Patients on Insulin.

Withdrawal Criteria :-

1. Non co-operative patients
2. Patient not willing to continue the treatment.
3. Patients who did not take follow up regularly will be excluded.
4. During treatment if patient develop any complication will be dropped out from trial and receive appropriate treatment.

Assessment Criteria

The following parameters were assessed before and after treatment.

Subjective Parameters

Pain (Shool)	Itching (Kandu)
Burning sensation (Daha)	Colour of wound (Varna)
Foul smell (Gandha)	Tenderness (Sparshaasahatva)
Edges Margins	Wound floor
Edema (Shotha)	Local Temperature of ulcer

Objective Parameters

Wound discharge (Strava)	Length of ulcer
Breadth of ulcer	Depth of ulcer

Results

The clinical assessment demonstrated improvement in both groups after treatment. However, the degree and pattern of improvement differed according to the parameters assessed.

Effect on Pain (Vedana)

Both groups showed a reduction in pain after treatment. The improvement observed in the Trayaksheera Gauze group may be attributed to the reduction of local inflammation and irritation. The Shothahara and Vedanasthapana effects of the ingredients may help reduce inflammatory mediators and provide symptomatic relief.

Reduction in inflammation and improvement in the wound environment can decrease stimulation of peripheral nerve endings, thereby reducing pain.

Effect on Edema

Reduction in edema was observed following treatment. The improvement may be explained by the reduction of local inflammation and improvement in tissue condition.

The Shothahara properties of the Trayaksheera ingredients may contribute to decreased inflammatory swelling and improved local wound healing.

Effect on Tenderness

Tenderness decreased after treatment in both groups. In Group A, the reduction may be associated with decreased inflammation, reduced discharge and improvement in the wound bed. As the local inflammatory process subsides, irritation of sensory nerve endings decreases, resulting in reduced tenderness.

Effect on Itching (Kandu)

Improvement in itching may be attributed to the cleansing effect of the medicated dressing and improvement in the local wound environment. Reduction in exudate, microbial contamination and inflammatory irritation may help relieve itching.

Effect on Burning Sensation (Daha)

This improvement may be related to the reduction of inflammation and local irritation.

The therapeutic action of the formulation in controlling the unhealthy wound environment may help reduce Daha associated with chronic inflammatory wounds.

Effect on Wound Discharge

Trayaksheera Gauze may assist in Vrana Shodhana by helping remove unhealthy discharge and

improving the condition of the wound bed. Reduction of microbial contamination and inflammatory exudation may also contribute to decreased discharge.

Effect on Foul Smell

Improvement in foul smell following treatment suggests better wound cleansing and reduction in unhealthy tissue and discharge.

The Shodhana and Krimighna actions of the ingredients may contribute to improvement in wound hygiene.

Effect on Wound Colour

A change from unhealthy wound colour toward healthy granulation tissue indicates progression toward wound healing. Trayaksheera Gauze may help improve the wound environment by facilitating removal of unhealthy tissue and supporting the development of healthy granulation tissue.

Effect on Wound Floor

Improvement in the wound floor was observed with treatment. Removal of slough and unhealthy tissue is an essential part of preparing a chronic wound for healing.

The local Shodhana action of Trayaksheera Gauze may support the formation of a cleaner and healthier wound bed.

Effect on Wound Edges

Healthy wound edges are important for epithelial migration and wound closure.

Improvement in wound edges following treatment indicates progression toward the healing phase. Reduction of inflammation and improvement in the wound bed may facilitate epithelialization.

Effect on Length, Breadth and Depth of Ulcer

Reduction in ulcer dimensions represents an objective indicator of wound healing. The decrease in length, breadth and depth may indicate:

Formation of healthy granulation tissue, Contraction of the wound, Improvement in epithelialization, Reduction in tissue destruction

The combined Vrana Shodhana and Vrana Ropana effects of Trayaksheera Gauze may contribute to progressive reduction in ulcer size.

Discussion

Meaningful scientific discussion and critical analysis are essential for the advancement of any branch of medicine. The discussion section is considered the cornerstone of a scientific study because it interprets the findings, explains their clinical significance, compares them with existing literature and provides direction for future research.

The primary objective was to evaluate and compare the Vrana Shodhana (wound cleansing and debridement) and Vrana Ropana (wound healing) efficacy of Trayaksheera Gauze (Group A) a classical Ayurvedic intervention with Betadine (Povidone-Iodine) dressing (Group B) a widely accepted conventional wound care modality.

A total of 80 patients diagnosed with diabetic foot ulcers and fulfilling the predefined inclusion and exclusion criteria were enrolled in the study. The participants were randomly allocated into two equal groups of 40 patients each. Baseline demographic characteristics and clinical parameters showed no statistically significant differences between the groups, confirming their comparability before initiation of treatment. This baseline homogeneity strengthens the internal validity of the study by minimizing selection bias and ensuring that the observed therapeutic outcomes are attributable to the respective interventions rather than pre-existing differences between the study populations.

The overall findings support the alternative hypothesis, indicating that both Trayaksheera Gauze and Betadine dressing are effective modalities in the management of diabetic foot ulcers. However, the comparative analysis demonstrates that the two interventions exhibit distinct therapeutic profiles and mechanisms of action.

Trayaksheera Gauze showed superior efficacy in reducing inflammatory manifestations such as tenderness and local inflammation suggesting a pronounced anti-inflammatory and wound-healing effect. These observations may be attributed to the pharmacological properties of the ingredients of Trayaksheera Gauze which are described in Ayurvedic literature as possessing Shodhana (cleansing),

Ropana (healing), Krimighna (antimicrobial), Shothahara (anti-inflammatory) and Vedanasthapana (analgesic) properties. The sustained reduction in these parameters indicates that Trayaksheera Gauze promotes a favorable wound environment by controlling inflammation and facilitating healthy granulation tissue formation.

In contrast Betadine dressing demonstrated comparatively greater effectiveness in reducing itching and edema, reflecting its established antiseptic action and its ability to reduce superficial wound irritation and microbial colonization. These findings are consistent with the conventional role of Betadine in wound management where it primarily acts by decreasing microbial load and preventing wound infection. Although both treatment modalities resulted in significant clinical improvement, the differential pattern of response highlights their respective clinical strengths. Trayaksheera Gauze appears to exert a more comprehensive therapeutic effect on the underlying inflammatory process and tissue repair whereas Betadine dressing provides effective control of surface-related symptoms and local wound hygiene.

Overall, the findings suggest that Trayaksheera Gauze is a safe and effective Ayurvedic wound dressing for the management of Pramehajanya Dushta Vrana (Diabetic Foot Ulcer). Its significant anti-inflammatory and wound-healing properties make it a promising alternative or complementary dressing material in diabetic wound care. Nevertheless, further multicentric studies with larger sample sizes, longer follow-up periods and objective wound assessment techniques are recommended to validate these findings and establish the broader clinical applicability of Trayaksheera Gauze.

Vrana Shodhana (Debridement): The Tikshna (sharp) and Lekhana (scraping) properties of Arka Ksheera and Snuhiksheera chemically debrided the necrotic tissue. This was evidenced by the significant reduction in the Wound Floor score.

Shothahara (Anti-inflammatory): Arka Ksheera and Snuhiksheera acts as a potent antiinflammatory agent. This explains why Group A showed superior results in reducing deepseated Tenderness compared to the control group.

Ropana (Healing): The combined effect of inflammation control and debridement allowed for healthy granulation.

Conclusion

The present clinical study suggests that Trayaksheera Gauze is an effective local dressing modality in the management of Pramehajanya Dushta Vrana with special reference to Diabetic Foot Ulcer.

The treatment showed beneficial effects on various subjective and objective parameters including pain, inflammation, edema, tenderness, discharge, foul smell, wound colour, wound floor, wound edges and wound dimensions.

The probable therapeutic action of Trayaksheera Gauze can be explained through its combined Vrana Shodhana, Shothahara, Krimighna and Vrana Ropana properties.

The formulation may help create a favorable wound environment by reducing unhealthy tissue and inflammatory changes while supporting the development of healthy granulation tissue and wound healing. Therefore, Trayaksheera Gauze may be considered a promising

Ayurvedic dressing for the local management of Pramehajanya Dushta Vrana/Diabetic Foot Ulcer. However, larger multicentric clinical trials with advanced microbiological and biochemical investigations are required to further establish its efficacy and mechanism of action.

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