



Short Communication

Management of *Madhumehajanya Vrana* (diabetic wound) with *Katupila* (*Securinega leucopyrus* [Willd] Muell.) *Kalka*

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Abstract

Introduction: Prevalence of diabetes and its complications have been a burden to the society from the ancient times, in the present and also will be in the future unless proper measures are taken to prevent its manifestation. There have been an increasing number of death associated-amputation cases which are mainly caused by nonhealing wounds. These facts urge researchers to develop new, more effective wound treatments for diabetic patients. **Aim:** To evaluate and compare the effect of *Katupila Kalka* (*Securinega leucopyrus* [Willd.] Muell. leaf paste) and *Tila Taila* (*Sesamum indicum* oil) in *Madhumehajanya Vrana* (diabetic wounds/ulcers) with Betadine ointment. **Materials and Methods:** A total of 23 patients of *Madhumehajanya Vrana* were chosen and randomly divided into two groups (Group A and B). Patients of Group A were treated with local application of *Katupila Kalka* with *Tila Taila*, whereas, in Group B, Betadine ointment was applied on the affected parts, once a day in the morning for 30 days. The relief in signs and symptoms were assessed on scoring pattern. **Results:** In Group A, diabetic wounds treated with *Katupila* paste got healed within 28 days with minimal scar formation without any complications, whereas in Group B, wound was healed completely only in two patients within 28 days. In both the groups, no patients reported any adverse drug reaction during the entire course of treatment as well as in follow-up period. **Conclusion:** Study concluded that the drug *Katupila Kalka* possesses *Vrana Ropana* (wound healing) activity with fine scarring.

Key words: Betadine, diabetic foot ulcer, *Katupila Kalka*, *Madhumehajanya Vrana*, *Ropana*, *Securinega leucopyrus*, *Tila Taila*, wound healing

Introduction

In 2011, it was estimated that 366 million people worldwide had diabetes, representing roughly 8.3% of the adult population (20–79 years of age group). The number is expected to reach 552 million by 2030, representing 9.9% of the adult population. Diabetes is associated with various short and long-term complications, many of which, if left untreated, can be fatal. All these also have the potential to reduce the quality of life of people with diabetes and their families. The most common long-term complications affect the heart, eyes, kidneys, and feet.^[1] Foot infections in persons with diabetes are a common and complex.^[2,3] In addition to causing severe morbidities, they now account for the largest number of diabetes-related hospital

bed-days^[4] and are the most common proximate, nontraumatic cause of amputations.^[5,6] Diabetic foot infections require careful attention and coordinated management, preferably by a multidisciplinary foot-care team.^[7]

Ayurveda has its own principles, but it is incorporating new theories and drugs in it and is presenting them according to its principles. Number of drugs known to Ayurveda since Vedic era is increasing with the time. *Acharya Charaka* says that a physician can add new drugs to these *Mahakashayas* by his own

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intelligence that will help him to treat the patients.^[8] He also states that one should get the knowledge about plants from tribal people or cowherds as they know and use the plants in a better way.^[9] However, after *Acharya Bhavamishra*, the process of addition of new drugs to science has diminished or somewhat ceased. It is said that the wounds/ulcers of the diabetic patient are cured with difficulty.^[10] Even with the latest technology and modern medicine in hand, highly trained medical team around, yet the majority of the diabetic ulcers end up with more or less amputation of the concerned major or minor part of the lower limb.

Securinega leucopyrus (Willd.) Muell. is known as *Humari* in India, *Katupila* in Sri Lanka and Spinous *Fluggea* in English. It is a desert climatic plant used typically in paste form for the healing of chronic and nonhealing wounds.

Hence, in the light of the above references from classics, *Katupila Kalka* (paste) was selected for this study with an aim to assess its effect in the management of *Madhumehajanya Vrana* (diabetic ulcer).

Materials and Methods

Diagnosed patients of diabetic wounds were selected from outpatient and inpatient departments of Shalya Tantra irrespective of the age, sex, religion, caste, occupation, etc. The study was started after obtaining approval from the Institutional Ethics Committee (PGT/7-A/2012-2013/1964 dated 21/09/2012) and study has been registered under Clinical Trial Registry of India (No.: CTRI/2013/09/004020). Informed written consent from each patient was obtained before starting treatment course.

Inclusion criteria

Diagnosed cases of *Madhumehajanya Vrana* with Type I and Type II diabetes mellitus of 18–70 years age of either sex.

Exclusion criteria

The patients with a history of tuberculosis, wounds other than diabetic wounds, uncontrolled hypertension, cardiac diseases, such as myocardial infarction, coronary artery disease, and ischemic heart disease were excluded in this study. Patients with human immune virus (HIV), venereal disease research laboratory (VDRL) and hepatitis-B test positive were also excluded from the study.

Laboratory investigations

Routine hematological parameters such as hemoglobin percentage, total leukocyte count, differential leucocyte count, bleeding time, clotting time, erythrocyte sedimentation rate; blood biochemical parameters such as fasting blood sugar, postprandial blood sugar, hepatitis B surface antigen, VDRL, and HIV; urine examination (routine and microscopic) was done to find out any other pathological condition.

Radiological examination

X-ray of the affected foot (dorsoventral and lateral view) was done to rule out the osteomyelitis of bone.

Grouping and posology

Totally 23 patients of the diabetic wound were allocated randomly into two groups (Group A and B).

- Group A ($n = 13$): In this group, *Katupila Kalka* (paste of *S. leucopyrus* leaves) with *Tila Taila* (sesame oil) was applied locally on the affected part. The dressing was done once in the morning up to 1 month or healing of wound which is earlier
- Group B ($n = 10$): In this group, patients were treated with dressing of Betadine ointment once daily in the morning and treated as the standard control group.

The leaves of *Katupila* were obtained from Sri Lanka and authenticated^[11] at Pharmacognosy Laboratory, IPGT and RA, Jamnagar.

Patients were advised to continue their anti-diabetic and anti-hypertensive medications (Allopathic/Ayurvedic) during treatment.

Assessment of therapy

The assessment of results was carried out mainly on the basis of relief in the signs and symptoms of the ulcers that are odor (*Gandha*), peri-wound skin (*Varna*), exudates level (*Srava*), type of exudates, pain (*Vedana*), wound measurement in cm (*Akruti*), and signs of infection [Table 1].

Effect of therapy was statistically analysed by using student 't' test.

Overall effect of therapy

- Cured: 100% improvement in subjective and objective parameters
- Marked improvement: 70–99%

Table 1: Gradation for assessment of results

Signs and symptoms	Score			
	0	1	2	3
Gandha (odor)	None	Present when dressing removed	Present when patient approached	Patient distressed by odor
<i>Varna</i> (peri-wound skin)	Healthy	Erythema (red)	Macerated (white)	Excoriated (red and wet)
<i>Srava</i> (exudates levels)	None	Dressing marked	Dressing wet	Dressing soaked
<i>Srava</i> (type of exudates)	None	Serous (yellow/clear)	Hemoserous (pink/clear/yellow)	Purulent (yellow/green/brown)
<i>Vedana</i> (pain)	No pain	Pain on dressing change	Intermittent pain	Continuous pain
<i>Akruti</i> (wound measurements in cm ²)	<5 cm ²	>5 cm ² but <10 cm ²	>10 cm ² but <20 cm ²	>20 cm ²
Signs of infection	No infection	Increased odor	Increased exudates	Heat/cellulitis

- Moderate improvement: 50–69%
- Mild improvement: 30–49%
- Unchanged: <30%.

Observations

The demographic data reveal that maximum patients were from the age group of 46 to 65 years (57%). Male patients were more that is 78.3% may be due to their irregular eating habits, addiction, excess standing work, and less care. Maximum patients were following Hindu religion (78%) and married (87%). Socioeconomically middle-class patients were in the majority (78.2%). The 78.27% of patients were having a history of diabetes and 21.73% of patients found with a history of both diabetes and hypertension. The 69.5% of patients had family history of diabetes. For the management of diabetic wound, 39.1% of patients had received medical treatment in past and 52.1% of patients had undergone surgery, whereas 8.6% of patients had both medical and surgical treatment. The majority of the patients that is 56.5% were suffering from wounds since 1 to 6 months, 34.7% of patients noted traumatic onset and maximum 73.9% were found with single wound. The 82.6% of patients were having *Puya Srava* (purulent exudates) and 95.6% of patients had *Ghana Srava* with 43.4% were having moderate *Srava* (discharge). Maximum numbers of patients presented without pain whereas only 34.9% of patients were found with pain. Bad odor was noted in all wounds and fever was found in maximum 73.91% of patients. In maximum 47.81% of patients the location of wound was at foot, as this part of the body more often gets trauma.

Results

In this study, infection was controlled within 3–4 days and foul smell was controlled after 3 days in patients of Group A. In Group B, foul smell from ulcer continues until the wound was healed. The surrounded skin color became normal skin color within 7 days in maximum patients (76%) of Group A, whereas only 32% patients showed normal peri-wound skin color in Group B. In Group A, 55% of patients showed a complete cessation of discharge within 7 days whereas in Group B, exudation found reduced in 34% of patients at the end of 28th day. In all patients, pain sensation at wound site regained by 7th day in Group A, due to neo-vascularization and restored pain sensation in nerve fibers. In Group A, 12 patients wound size was reduced completely within 28 days, whereas in Group B, only 29% of patients wound size was reduced completely within 28 days. In Group A, signs of infections relieved 61% by the 7th day and totally relieved at the end of 28th day, whereas in Group B, patients infection was relieved 41% by the end of 28th day [Tables 2 and 3].

In Group A, 92.3% of patients were completely cured, whereas in Group B, 20% of patients were completely cured [Figure 1]. Wound healing effect of *Katupila* in four cases is depicted in Figure 2.

Discussion

In this study, foul smell was controlled after 3 days in Group A patients, which was found statistically significant ($P < 0.001$). In Group B, foul smell from ulcer continues until the wound was

Table 2: Effect of therapy on signs and symptoms of wound in Group A

Signs and symptoms	Before treatment	7 th day	Percentage of relief	14 th day	Percentage of relief	21 th day	Percentage of relief	28 th day	Percentage of relief
<i>Gandha</i> (odor)	2.38	0.00***	100↓	0.00***	100↓	0.00***	100↓	0.00***	100↓
<i>Varna</i> (peri wound skin)	2.23	0.54***	76↓	0.00***	100↓	0.00***	100↓	0.00***	100↓
<i>Srava</i> (exudates level)	2.92	1.31***	55↓	0.69***	76↓	0.23***	92↓	0.00***	100↓
<i>Srava Varga</i> (type of exudates)	2.69	1.00***	63↓	0.62***	77↓	0.15***	94↓	0.00***	100↓
<i>Vedana</i> (pain)	0.23	1.38***	500↑	0.77	233↑	0.15	33↓	0.00	100↓
<i>Akruti</i> (wound measurement)	2.15	1.62*	25↓	1.00***	54↓	0.46***	79↓	0.08***	96↓
Sign of infection	2.77	1.08***	61↓	0.31***	89↓	0.15***	94↓	0.00***	100↓

*** $P > 0.001$, * $P > 0.05$; ↓: Decrease; ↑: Increase

Table 3: Effect of therapy on signs and symptoms of wound in Group B

Signs and symptoms	Before treatment	7 th day	Percentage of relief	14 th day	Percentage of relief	21 th day	Percentage of relief	28 th day	Percentage of relief
<i>Gandha</i> (odor)	2.70	2.10**	22↓	1.90**	30↓	1.50***	44↓	1.30***	52↓
<i>Varna</i> (peri wound skin)	1.90	1.90	00	1.90	00	1.60	16↓	1.30	32↓
<i>Srava</i> (exudates level)	2.90	2.5*	14↓	2.40*	17↓	2.20*	24↓	1.90*	34↓
<i>Srava Varga</i> (type of exudates)	2.80	2.20*	21↓	1.80*	36↓	1.50***	46↓	1.30***	54↓
<i>Vedana</i> (pain)	1.20	1.20	00	1.20	00	1.10	08↓	0.90	25↓
<i>Akruti</i> (wound measurement)	2.40	2.30	04↓	2.10	13↓	2.00*	17↓	1.70**	29↓
Sign of infection	2.70	2.30*	15↓	2.10*	22↓	2.00***	26↓	1.60***	41↓

*** $P > 0.001$, ** $P > 0.01$, * $P > 0.05$, ↓: Decrease

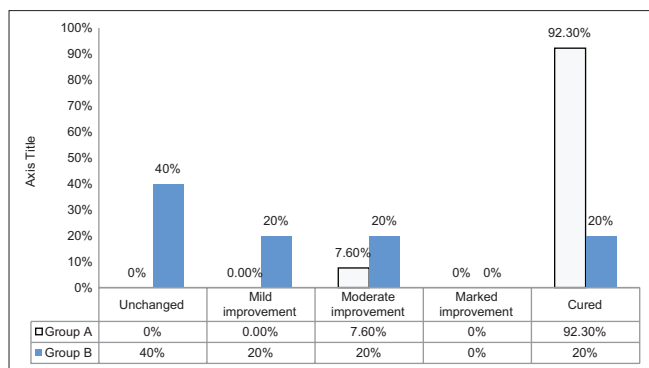


Figure 1: Overall effect of therapy

healed. The *Krimighna*, *Vishaghna*, *Rakshoghna* (antimicrobial) properties of the *Katupila* helped to control the local infection and ultimately the bad odor.^[12]

In Group A, 100% normal skin coloration was achieved which was found statistically significant ($P < 0.001$). In 32% of patients of Group B, peri-wound skin color became normal which was found statistically significant ($P > 0.05$). *Katupila* may have *Rakta Shodhana*, *Pittashamana*, *Varnya*, *Twaka Prasadana* properties which helped to improve the surrounding wound skin color.

Complete cessation of discharge within 7 days was observed in 55% of patients of Group A, while in remaining patients discharge was reduced by 28th day which was statistically significant ($P < 0.001$). *Krimighna* property of drug helped to control the infection. Hence, it can be said that *Katupila* paste had a better role than Betadine to reduce exudates level.

In Group A, 77% of patients presented without pain while the pain was reported in 23% of patients due to diabetic neuropathy. After treating with *Katupila*, pain sensation regained by 7th day due to neo-vascularization and restored pain sensation in nerve fibers. The statistically insignificant result in pain relief was seen due to the restoration of pain sensation by correcting neuropathy. The *Snigdha Guna* of *Tila Taila* helped in control the vitiation of *Vata* and helped to relief in pain.^[13] In Group B, there was minimal neovascularization, but the pain was relieved in 25% of patients due to the healed wounds which were statistically significant ($P > 0.05$). Hence, it can be inferred that *Katupila* is better than Betadine ointment to regain pain sensation (initial stage) as well as to relieve pain (in later stage).

Complete wound healing was observed within 28 days in 92% cases so wound size reduction was found statistically highly significant ($P < 0.001$) which may be due to *Katupila* which may have *Lekhana* (scraping), *Shodhana* (cleaning) and *Ropana* (healing) properties. *Madhura Rasa*, *Prinana* (nourishment), *Dhatuwardhana* (tissue strength) and *Dhatuposhana* (nutrition) actions of *Katupila* helped to reduce the wound size by promoting healing and the rate of contraction. The infection at the wound site was assessed on the basis of odor, exudate level, local temperature, and swelling in both the groups. In Group A, signs of infections relieved 61% by the 7th day and totally relieved at the end of 28th day. Local application of *Katupila* reduces the discharge, swelling, pain by controlling the bacterial load, so wound became *Shuddha* (clean or healthy). Whereas in Group B, infection was relieved in 41% by the



Figure 2: Before and after treatment wound status of *Katupila* treated cases

end of 28th day. Both drugs have shown statistically highly significant ($P < 0.001$) result in controlling infection. However, on the comparison, the duration of infection control by *Katupila* paste (that is 1st week) was found earlier than Betadine which took longer duration in controlling infections. The strength and positive finding of this study is *Katupila Kalka* had the potential to cure the diabetic wounds early than Betadine ointment. Findings in previously published case reports also showed the good potential in wound healing by *Katupila*.^[14,15] None of the adverse drug reaction noted during the treatment period.

A reverse pharmacological study in the suitable animal model is a further scope of this work. As this drug is being used by traditional people and of herbal origin, there is a need to generate safety and toxicity profile of *Katupila*. The limitation of this research work is less number of patients due to the limited time of the postgraduate study.

Conclusion

The study concluded that *Katupila Kalka* (paste) possesses highly qualitative efficacy in "*Vrana Ropana*" with fine scarring. Therefore, it may be recommended that this low cost, easily preparable application may be prescribed for continuous use for the healing purposes.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

कटुपिला द्वारा मधुमेहजन्य व्रण की चिकित्सा

अहमद शाह अजमीर, तुकाराम एस. दुधमल, संजयकुमार गुप्ता

प्राचीन काल से ही मधुमेह का प्रसार एवं उपद्रव समाज के लिए कष्टदायक है। वर्तमान एवं भविष्य में उचित साधनों के उपयोग से इसका बचाव संभव है। आचार्य सुश्रुत ने मधुमेह के वर्गीकरण निदान, सम्प्राप्ति, लक्षण, चिकित्सा एवं उपद्रवों के संदर्भ में वर्णन किया है। मधुमेहजन्य अरुह्यमान व्रणों में अंगविच्छेदित रुग्णों में मृत्यु की संख्या में वृद्धि हो रही है। यही तथ्य अनुसंधान कर्मियों को अधिक प्रभावकारी व्रणचिकित्सा को विकसित करने की प्रेरणा देती है। इस अध्ययन में मधुमेह जन्य व्रणों में कटुपिला/हुमरी कल्क+तिल तैल का बिटाडीन ऑइन्टमेट (मानक दवा) के साथ तुलनात्मक मूल्यांकन किया गया है। इस अध्ययन में मधुमेहजन्य व्रण के कुल २३ रुग्णों को चयनकर, दो वर्गों में विभाजित किया गया। वर्ग-अ (१३ रुग्ण) की चिकित्सा में कटुपिला कल्क+तिल तैल का स्थानिक प्रयोग एवं वर्ग-ब (१० रोगी) में बिटाडीन ऑइन्टमेट का स्थानिक प्रयोग लगातार ३० दिनों तक किया गया। तत्पश्चात रुग्णों के स्थानिक लक्षणों में सुधार का निरीक्षण एवं मूल्यांकन सांख्यिकी दृष्टि से किया गया। वर्ग-अ में कटुपिला कल्क से उपचारित व्रण २८ दिनों में घाव पूर्ण रूप से भर गये। लेकिन वर्ग-ब में केवल २ रोगियों में २८ दिनों में व्रण का रोपण हो गया। अंततः यह निष्कर्ष निकलता है की कटुपिला कल्क मधुमेहजन्य व्रण में अत्यंत गुणकारी है।