



To Evaluate The Efficacy of Tila Kalka Along With Madhusarpi And Jatyadi Tail Application on Dushta Vrana W.S.R To Diabetic Foot Ulcer- A Study Protocol

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ABSTRACT

BACKGROUND: Diabetes mellitus is one of the trouble in health system and threat to health. Patient with Diabetes mellitus are more vulnerable to many complication such as diabetic foot ulcer, neuropathies, nephropathies, retinopathies etc.. Diabetic ulcer occur due to increased glucose in the tissue precipitates the infection. Increased glycosylated haemoglobin decrease the oxygen dissociation, increased glycosylated tissue protein decrease the oxygen utilization. Common site of diabetic ulcer is foot- planter aspect and leg.

Aim and Objectives: The purpose of the study to evaluate the efficacy of tila kalka along with madhusarpi and jatyadi tail application on dushta vrana (diabetic foot ulcer).

Methodology : for the duration of study, 60 patients are being given dressing of tila kalka along with madhusarpi and jatyadi tail, follow up is being taken on 7th, 14th, 30th day.

Results : changes are to be ascertained on the basis of subjective and objective parameters.

Keywords : Dushtavrana, diabetic foot ulcer, jatyadi tail, tila kalka .

INTRODUCTION

An ulcer is a break in the continuity of the covering epithelium- skin or mucous membrane.^[1] Vrana those are not healed for a long time are called *dushtavrana*. In *Sushruta samhita* description of *suddhavrana*, *rohitavrana* and *samyakrudhavrana* are present. *Vrana* is derived from the verbal root “vrana”.^[2] After injury healing is a natural phenomenon and continuous in sequential manner till the formation of *vrana vastu*. *Dushta vrana* is a *vrana* that is getting vitiated by *dosha*. *Vrana* which has intense pain, take long time to heal and profuse discharge of abnormal color is a *dushta vrana*. Similar disease is parallel in contemporary system of medicine is Diabetic foot ulcer. *Acharya Sushruta* has described the *pramehaj pidika* in *nidansthan*.^[3] Greatly covered or greatly exposed, very hard or very soft, greatly elevated or greatly depressed, very cold or very warm, having color of any black, yellow and white terrifying filled with putrefying pus, blood, vein, ligaments etc. wound raised up having unpleasant look and smell, accompanied with severe pain, burningsuppuraton, redness, itching, such as complication greatly, exuding vitiated blood and persisting for long time- are the symptoms of *dushta vrana*.^[4]

Diabetes mellitus is one of the trouble in health system and threat to health. Patient with Diabetes mellitus are more vulnerable to many complication such as diabetic foot ulcer, neuropathies, nephropathies etc. it is the result of poor glycemic control. It is the common cause of the amputation of the lower extremities. The development of diabetic ulcer is usually in 3 stages. The initial stage is the development of the callus. The callus result from neuropathy. The motor neuropathy cause physical deformity of foot and sensory neuropathy causes sensory loss which lead to ongoing trauma drying of skin because of autonomic neuropathy is another contributing factor. Frequent trauma of the callus result in subcutaneous haemorrhage and eventually it erode and becomes a ulcer.^[5]

Diabetic ulcer occur due to increased glucose in the tissue precipitates the infection. Increased glycosylated haemoglobin decrease the oxygen dissociation, increased glycosylated tissue protein decrease the oxygen utilization. Common site of diabetic ulcer is foot- planter aspect and leg.^[6] the prognosis of these ulcer is good if identified early and optimal treatment initiated. Unfortunately delay in care can have detrimental effect which can lead to amputation of the foot.

Diabetes mellitus is a disease that not be cured completely. But diabetic foot ulcer and *pakva pramehaj pidika* may be cured by application of *Krishna Tila kalka* along with *Madhusarpi* and *Jatyadi Tail* and change of the life style of the patient. Many scholars worked on application of paste and tail banding, so in continuation of the *Krishna Tila kalka* along with *Madhusarpi*^[7] and *Jatyadi Tail*^[8] are applied to see their effects in case of diabetic foot ulcer to build more evidence based data. Along with this application is harmless and hopefully beneficial and cost effective.

AIM AND OBJECTIVE:

To study the efficacy of *Krishna Tila kalka* along with *Madhusarpi* in the management of *Dushta Vrana* (Diabetic Foot Ulcer).

To study the efficacy of *Jatyadi Tail* application in the management of *Dushta Vrana* (Diabetic Foot Ulcer).

RESEARCH QUESTION:

Is there any difference in the efficacy of *Krishna Tila kalka* along with *Madhusarpi* and *Jatyadi Tail* in the management of *Dushta Vrana* (Diabetic Foot Ulcer)?

HYPOTHESIS:

NULL HYPOTHESIS(H0)

There is no significant difference between the efficacy of *Krishna Tila kalka* along with *Madhusarpi* and *Jatyadi Tail* in the management of *Dushta Vrana* (Diabetic Foot Ulcer).

ALTERNATE HYPOTHESIS(H1)

There is significant difference between the efficacy of *Krishna Tila kalka* along with *Madhusarpi* and *Jatyadi Tail* in the management of *Dushta Vrana* (DiabeticFoot Ulcer).

MATERIAL AND METHODS

Study type: interventional

Masking: open trial

Study Setting : this will be conducted in SKGAC&H, Kurukshetra, Haryana.

INCLUSION CRITERIA:

Patient of either sex.

Diabetic foot ulcer.

Pakav Pramehaj Pidika.

Patients of age group 20-70yrs

EXCLUSION CRITERIA:

Patient suffering of any systemic diseases like tuberculosis etc.

Uncontrolled hypertension

Gangrene

Ischemic heart diseases

Malignant ulcer

Grade 4 and 5 of diabetic foot ulcer.

Patient suffering from grave condition like HIV, HbsAg, VDRL, HCV will be excluded.

INTERVENTION :

Patient is made to sit on examination table. Wound is cleaned with normal saline and after possible manual debridement of the wound, gauze is dipped into the mixture of *Krishna Tila kalka* along with *madhusarpi* and applied on the wound and bandaging is done. Gauze is dipped into the *jatyadi tail* and applied on the wound and bandaging is done.

GROUPING & INTERVENTION

Group A: Dressing with *Krishna Tila kalka* along with *madhusarpi* and bandaging is done.

Group B: Dressing with *jatyadi tail* and bandaging is done.

Group A

The procedure was performed in three stages as Purva Karma (preoperative), Pradhana Karma (operative), Paschata Karma (post operative) mentioned by Acharya Sushruta.

POORVA KARMA:

Written informed consent will be taken as it is an important part of surgical or para surgical

procedure. Patient is make to sit on examination table. Ulcer area is cleaned with normal saline and manual debridement of the wound will be done in both group patients.

PRADHAN KARMA:

Gauze is dipped into the mixture of *Krishna Tila kalka* along with *madhusarpi* and applied on wound and bandaging is done in group A patients.

PASCHAT KARMA:

Patient is advised not to wet the wound and not to do vigorous exercise. Rest is advised and diet management should be done.

Group B

The procedure was performed in three stages as Purva Karma (preoperative), Pradhana Karma (operative), Paschata Karma (post operative) mentioned by Acharya Sushruta.

POORVA KARMA:

Written informed consent will be taken as it is an important part of surgical or para surgical procedure. Patient is make to sit on examination table. Ulcer area is cleaned with normal saline and manual debridement of the wound will be done in both group patients.

PRADHAN KARMA:

Jatyadi tail gauze is applied on wound and bandaging is done in group B patients.

PASCHAT KARMA:

Patient is advised not to wet the wound and not to do vigorous exercise. Rest is advised and diet management should be done.

Criteria for Discontinuing intervention:

If any acute illness and complication develops, patient will be treated accordingly.

STATISTICAL ANALYSIS-

Data will be analyzed using appropriate statistics.

TIME DURATION OF THE STUDY –

Total – 30 days

FOLLOW UP

3 times on 7th, 14th, 30th day.

METHODS :













Data collection , management and analysis.

DATA COLLECTION METHODS-**ASSESSMENT CRITERIA**

PARAMETERS	NIL-0	MILD-1	MODERATE-2	SEVERE-3
Size of ulcer	Healed	Upto 4x4 cm	Upto 6x6cm	More than 8x8cm
Granulation tissue	>50% wound surface covered with granulation tissue	25-50% wound surface covered with granulation tissue	Upto 25% wound surface covered with granulation tissue	No granulation tissue
Slough tissue	No slough tissue	Upto 25% wound surface covered with slough tissue	25-50% wound surface covered with slough tissue	>50% wound surface covered with slough tissue
Pain	No pain	Localized pain during movement & not during rest	Localized pain during rest but not disturbed sleep	Continuous Pain
Discharge	No discharge	Scanty discharge	Often discharge with blood on dressing	Profuse continuous
Smell	No smell	Bad smell	Tolerate unpleasant smell	Foul smell which is intolerable
Burning sensation	No burning	Little localized and sometimes feeling of burning sensation	More localized and often burning sensation not disturbed the sleep	Continuous burning disturbed sleep

Table 1

COMPARATIVE PAIN SCALE CHART (Pain Assessment Tool)

											
0 Pain Free	1 Very Mild	2 Discomforting	3 Tolerable	4 Distressing	5 Very Distressing	6 Intense	7 Very Intense	8 Utterly Horrible	9 Excruciating Unbearable	10 Unimaginable Unbearable	
No Pain	Minor Pain			Moderate Pain			Severe Pain				
Feeling perfectly normal	Nagging, annoying, but doesn't interfere with most daily living activities. Patient able to adapt to pain psychologically and with medication or devices such as cushions.			Interferes significantly with daily living activities. Requires lifestyle changes but patient remains independent. Patient unable to adapt pain.			Disabling; unable to perform daily living activities. Unable to engage in normal activities. Patient is disabled and unable to function independently.				

Wagner's classification of Diabetic foot ulcer^[9]

ULCER GRADING	DESCRIPTION
Grade 0	No ulcer
Grade 1	Superficial ulcer
Grade 2	Deep ulcer, no bony involvement or abscess
Grade 3	Abscess with bony involvement
Grade 4	Localized gangrene e.g. toe, heel etc.
Grade 5	Extensive gangrene involving the whole foot

Table 2

Floor

Grade	
0	Smooth, regular & with healthy granulation tissue
1	Smooth, irregular & slight discharge, less granulation tissue, need dressing & soft scar
2	Rough, regular wet with more discharge, needs dressing & having firm scar
3	Rough, irregular with profuse discharge, needs frequent dressing & having hard scar

Table 3

INVESTIGATION:

The patients who fulfill the inclusion criteria will be subjected for routine Blood Investigations like Hb

ESR

TLC

DLC

BLOOD SUGAR

Urine test .

DATA MANAGEMENT-

Data coding will be done by Principle investigators.

ETHICS AND DISSEMINATION –

Research ethical approval, after critical evaluation and presentation to the ethical committee, has taken on the research topic No. CTRI / 2023/ 02 / 049757.

Consent and assessment

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

DISSEMINATION POLICY-

Will be in the form of paper publication, presentation and monograph.

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