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MANAGEMENT OF DIABETIC FOOT ULCER WITH EXTERNAL APPLICATION OF AYURVEDIC POLYHERBAL PREPARATION – A CASE STUDY

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ABSTRACT

Diabetic foot is one of the most significant and devastating complications of diabetes, and is defined as a foot affected by ulceration that is associated with neuropathy and peripheral arterial disease of the lower limb in a patient with diabetes. The prevalence of diabetic foot ulceration in the diabetic population is 4–10%, the condition is more frequent in older patients. It is estimated that about 5% of all patients with diabetes present with a history of foot ulceration. The majority (60–80%) of foot ulcers will heal, while 10–15% of them will remain active, and 5–24% of them will finally lead to limb amputation after the first evaluation. But early diagnosis, following proper guidelines and timely intervention could save the limb. Treatment of diabetic foot ulcer is the standard therapeutic modalities include debridement, pressure offloading, dressing regimens (Film, foam dressing, hydrogel, hydrocolloid, Alignate dressing etc.) *Acharya Sushruta* was also aware of the facts infected wounds and describe its various characters as *Dushta Vrana*. The *Sushruta* described many number of drugs and formulations for management of *Dushtavrana* classified in two processes *Vranashodhana*(debridement of unhealthy necrosis tissue from wound) and *Vranaropana* (promote wound healing). Hence an attempt was done to assess the effect of *Tiktadighrita* in Wound Healing which is very cost effective. **Case Presentation:** This is case study of 52 years old female patient complain of wound present over planter aspect of right foot involving right great toe with foul smelling purulent

discharge for since last 04 month, with a past history of Diabetes mellitus & Hypertension since 05 yrs. She also had raised FBS & PPBS profile. Patient not given any previous history of amputation or ulceration. **Management:** Included controlling Diabetes and Hypertension following DFU guidelines and daily cleaning with Normal saline and dressing with application of *Tiktadighrita* for a period of 03 months. **Result:** There was a complete cure of the huge diabetic wound after 03 months of continuous care and treatment. Wound healing was assessed by Bates Jenson Wound assessment tool.

KEYWORDS: Diabetic Foot Ulcer (DFU), *Tiktadighrita, Dushtavrana***,** *Vranashodhana, Vranaropana.*

INTRODUCTION

Diabetes mellitus (DM) is a complex disease affecting almost all the vital organs in the body.[1] The classical triad of DFU is neuropathy, ischemia, and infection. It happens due to series of mechanisms which include decreased cell and growth factor response, diminished peripheral blood flow and decreased local angiogenesis. So, the feet are influenced by damage to peripheral nerves, the peripheral vascular disease, ulcerations, deformities, and gangrene.[2] Many of the people globally are dying from non-communicable diseases known as lifestyle diseases; one among which is diabetes according to a recent survey. Diabetes is a growing challenge in India with an estimated 8.7% diabetic population (National Health Profile 2018).[3] Diabetic Foot Ulcer (DFU) is one among the major complications of Diabetes. In India, DFU affects 15% of diabetics during their lifetime. Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected; requiring hospitalization while 20% needs amputation.[4] DFU contribute about 80% of all non-traumatic amputations in India annually. Diagnosis of diabetic foot by giving patient medical history, physical examination, blood test hemoglobin, total leukocyte count, protein, albumin, blood sugar fasting, random, HbA1c, etc. previous history of foot amputation or ulceration, duration of diabetes, peripheral vascular disease, Foot X-ray useful for rule out in case of osteomyelitis. Wound infection has been one of the major problems in process of wound healing and to manage it application of appropriate debridement, cleaning and dressing method is needed. Today in modern medicine various modification are available to treat non-healing chronic or infected wound include debridement, pressure offloading, dressing regimens (Film, foam dressing, hydrogel, hydrocolloid, Alignate dressing etc.) hyperbaric oxygen, antibiotics, gene therapy, and topical growth factors.[5] New treatment strategies in wound

healing, such as bioengineered dressings and cellular applications.[6] In *Sushruta Samhita* he not only elaborated the description of *Vrana*, its etiopathogenesis, types, principles of management, sixty procedures *Shastiupakrama*[7] but also described locally applied drugs as well as systemic application of drugs in wound management along with the cosmetic management of wound scar. *Dushta Vrana* is a broad phenomenon which not only includes non-healing wounds but it also includes some serious life-threatening conditions like diabetic foot, Fournier's gangrene, necrotizing fasciitis etc. *Sushruta* diagnosis was based on clinical observation of wound during those days. He mentioned six kind of examination that includes examination using all five senses and interrogation. *Acharya Sushruta* described *Vrana pariksha*[8] (local examination) on the basis of five important findings such as *Vedana* (Various kinds of pain according to vitiated *Doshas*-as feature of all type of pain), *Varna* (Colour of wound), *Gandha* (Smell of wound), *Aakriti* (Size and shape), and *Srava* (Discharge from wound). *Sushruta* described two types of drugs for wound management i.e. *Shodhan* (Converting tidy wound into clean wound) and *Ropan* (Promote healing). The main purpose of treatment of *Dushta Vrana* is mainly converting *Dushta Vrana* into *Shuddha Vrana.*

Diabetic foot classifications -The most accepted and used classification system in the world is the Wagner Meggitt Classification of Diabetic Foot which describes six grades overall as follows:

Table 1 : Wagner-Meggitt classification of diabetic foot

Grade 0	Foot symptoms like pain, only
Grade 1	Superficial ulcers
Grade 2	Deep ulcers
Grade 3	Ulcer with bone involvement
Grade 4	Forefoot gangrene
Grade 5	Full foot gangrene

In Ayurveda, type II DM may be compared to *Madhumeha* and as per *Acharya Sushruta*, '*madhumehinam adha kaye pidika pradurbhavanthi* '[9] that is lower extremity is the common site of occurrence of diabetic ulcers. Also it is mentioned that pakwa pidaka should be treated like a wound. So for DFU, treatment protocol could be taken from *Vrana chikitsa*. This case study drug *Tiktaadi ghrita*[10] is taken from *Chakradutta vranasotha chikitsa.* Ingredients are *katuki, Haridra, Yashtimadhu, Karanja phala & patra, Patola patra, Jati patra, Nimba patra & Beewax. Tiktaadi ghrita* is having both *sodhana* and *ropana* property. This paper contains a case report of DFU as follow-

Case report- A female patient 52 year of age, came to OPD of Shalya- Tantra, Institute of Medical Sciences Banaras Hindu University, Varanasi (UP) presented with chief complains Wound over planter aspect of right foot involving right great toe with foul smelling purulent discharge for 4 month, fever for last 10 days.

Present history- According to the patient she was asymptomatic well before 4 month, gradually she developed wound over planter aspect of right foot, and wound was progressively increasing in size to the involving right great toe of foot having complain of foul smelling purulent discharge. She consulted private practitioner doctor and taken treatment like antibiotic therapy and dressing but patient did not get properly relief and she was not satisfied for given treatment by the doctor. So she came to OPD, department of Shalya Tantra, IMS-BHU for better treatment.

Past history – Patient was suffering from diabetes type-2 for 5 years he was taking oral hypoglycemic drugs. The patient admitted in IPD and given insulin subcutaneous for control blood sugar level as advised by endocrinologist. Patient also had history of hypertension in the past 5 years and was taking anti hypertensive drugs as advised by cardiologist. Patient had no any previous history of amputation/ulceration/surgical intervention. Patient not given any history of drug allergy/tuberculosis/bronchial asthma/epilepsy/other systemic disease.

Family history –All family members are alive and healthy, no any relevant family history found.

Personal history

Diet- diet (vegetarian)**, Appetite**-Decrees **Bowel**-Regular (normal) ,**Maturation**-5-6 times per day/ 2-3 times per night **,Sleep**-6-8 hour in 24 hrs**, Addiction**-No any, **General examination -** General condition – fair, Weight- 61 kg , Blood pressure- 110/70mmHg,Pulse rate- 80/min Respiration rate -18/min ,Temperature- 99.6 F. **Physical examination-** Pallor – present, Icterus- absent, Cyanosis-absent, Clubbing-absent, Edema- mild present , Regional lymph node- not palpable. **Systemic examination- Central nervous system-** patient was conscious and well oriented to time, place and person. **Cardiovascular system-** No cardiac murmur heard, S1S2 sound normal heard**. Respiratory system-** trachea is centrally placed, bilateral equal air entry normal, bilateral chest expansion normal, Broncho-vesicular sound normal. **Per abdomen -Inspection-** Abdomen skin normal, No any scar mark present on abdomen, No visible vein, No abdomen distention. **Palpation-** Abdomen soft and non-tender,

No palpable swelling/mass, No palpable Organomegaly. **Auscultation**–Bowel sound heard normal pattern. **Percussion**- No shifting dullness, Fluid thrill absent.

Local examination of wound

Anatomical location- Planter aspect of right foot involving a single ulcer on medial aspect of big toes, **Size-** 09×05cm, **Margin-** well demarcated and irregular, **Edg**e-well defined, not attached to base, **floor/Base-** not visible covered with adherent slough and necrotic tissue, **Necrotic tissue-** firmly adherent black Eschar with slough, **Exudates-** purulent, thick yellowish discharge with odor, **Peripheral wound skin-** Mild edematous, **Granulation tissue**- Healthy granulation tissue not present**, Appearance of wound-** covered with slough and necrotic tissue and Surrounding wound skin mild edematous.

LAB INVESTIGATION – (Before Treatment)-

Hb-9.6gm/dl, **TLC**-16.1×10^3/µl, **DLC**-$N_{66.7}$,$L_{9.1}$, $M_{10.0}$, $E_{13.9}$,$B_{0.3}$, Platelet-302×10^3/µl, **SGPT/SGOT/ALP/T.BIL/D.BIL**-27.2 (IU/L)/24.8(IU/L)//288(IU/L)/0.7(mg/dl)/0.4 (mg/dl), **Totalprotein/Albumin**–6.8gm/dl/2.7gm/dl, **Na/K/Cl/urea/creatinine-** 133.2mmol/L/4.7mmol/L/99.4mmol/L/62.1mg/dl/2.6mg/dl, **FBS/PPBS-** (mg/dl)/- 202/379, **HbA1c-** 8.3%, **HIV –** Non- reactive, **HBsAg & Anti HCV –** Negative, Chest x-ray- Within normal limit, ECG- Within normal limit. **X-ray right foot-** No osteomyelitis changes seen and No any bone deformity.

(After Treatment)- Hb-10.6gm/dl**, TLC**-8.6×10^3/µl, **DLC-** N_{53}, $L_{27.3}$, $M_{6.8}$, $E_{12.5}$, $B_{0.4}$, **Platelet-** 318×10^3/µl, **SGPT/SGOT/ALP/T.BIL/D.BIL**-22.2 (IU/L)/20.8 (IU/L)/216(IU/L)/0.7(mg/dl)/0.4(mg/dl)/, **Total protein/Albumin** – 7.2gm/dl/3.2gm/dl, **Na/K/Cl/urea/creatinine**-135.2mmol/L/5.2mmol/L/98.1mmol/L/22.3mg/dl/0.9mg/dl, **FBS/PPBS** – 132/168 mg/dl

MANAGEMENT

After careful examination and clinical findings diagnosed as *Dushta Varna* patient admitted in hospital. A thorough counseling was done regarding severity of wound and future complications of diabetic foot ulcer. After consent of patient, the diabetic foot wound was treated under *Sushruta's Dushta Vrana* principle of management. At the outset relevant routine blood examination with viral marker were done before dressing. Appropriate surgical debridement of the wound was done and wound washed with normal saline. Daily dressing was done with *Tiktadighrita*[10] (*Katuki* (Picrorrhiza kurro), *Haridra* (Curcuma longa),

Karanja Phala & Patra (Pangamia pinnata), *Nimbapatra* (Azadirachta indica), *Patol Patra* (Trichosanthes dioica), *Maltipatra* (Jasminum officinale), *Yasthimadhu* (Glycyrrhiza glabra) & *Beewax* was applied to achieve V*ranashodhana* (Wound cleaning) and *Ropana* (wound healing process). Dressings were repeated for three months continuously. The wound completely healed in 03 months of continuous dressing & care. Wound was regularly assessed on 0^{th}, 15^{th}, 30^{th}, 45^{th}, 60^{th}, 75^{th} & 90^{th} days. Wound healing was assessed by Bates-Jenson wound assessment tool.[11] At initial level total leukocyte count was increased so a short course of broad antibiotics was given for five days to reduced septicemia. Anti-Diabetic medications and anti hypertensive medications were also given. Some oral ayurvedic medication - *Punarnava Mandur* 250mg + *Dhatri Loha* 250mg+ *Sanjivani Vati* 125 mg +*Shankh Bhasma* 250mg, *Madhumehari Churna*, BGR-34, *Ashwaghandha Churna*, *Aamalki Rasayan* were given.

OBSERVATIONS AND RESULTS

Assessment criteria -: Table No-2-As Bates-Jensen wound assessment tool (Score)[11]

Parameter	0 day	15 day	1 month	2 month	3month
Size	4	4	3	2	1
Depth	3	3	3	2	1
Necrotic tissue type	3	2	2	1	1
Exudates type	5	4	2	1	1
Granulation tissue	5	3	3	2	1
Epithelization	5	3	3	2	1

An assessment Criteria of Bates-Jensen for wound assessment was taken to observe the status of wound various parameters i.e. size, depth, necrotic tissue type, exudates type, granulation tissue, Epithelization was observed on different interval of treatment. Table No.2- shows that size of wound starting from 0 day score was found 4, On 1 month was found at the Score 3, however after 1 month this score decreasing and found score 2 at the end of 2 month, On 3 month, it was observed score 1. Same pattern of the depth score was observed that at initial day score was 3 which found reduced to score 3 month however, it was decreasing up to 1 score by the end of 3 month. The necrotic tissue was observed 3 score at the initial day, and it was decreasing up to score 2 within 15^{th} day, this pattern of decreasing got score 1 after end of 2 month. The same pattern of decreasing of granulation tissue, Epithelization were observed and found on decreasing pattern from initial day 0 to 1month to 3month. Overall wound Assessment Criteria of this score have been observed consequently on decreasing pattern and all the score were found 1 of the end of 3 month. All these finding

are suggesting that size of wound decreased, Depth also improved, type of tissue i.e. necrotic, exudates are also decreasing, it suggest that condition of wound significantly improved. At the same type Granulation tissue and Epithelization have been found filled with bright beefy healthy tissue and Wound was completely healed at the end of 3 month**.**

Follow up advices -Patient was admitted in hospital for 1 month during treatment, daily cleaning (debridement) and dressing was done carefully. After removed unhealthy necrotic tissue and slough, when wound started healing process the healthy granulation tissue appeared, patient was discharge from hospital. After discharge he was advice to review in shalya OPD every 7 days up to 2 months then review on every 15 days until the wound is completely healed.

Duration of wound healing time- Wound was healed completely period of 3 month.

0 day (initial)

15th days (After removal of necrotic tissue)

Application of drug

1 month (Healthy granulation tissue appear)

2 month (Wound healing)

3 month (completely healed wound)

DISCUSSION

Tiktadighrita on mild to moderate infected wound is having debriding and wound healing properties. This drugs have *Katu, Tikta and Kashaya rasa* (except *Yastimadhu* having *madhura rasa*), *ruksha, laghu and snigdha guna*. *Katu rasa* causes *sodhana* and *krimiprasamana.*[12] *Katu rasa* act as *Shonitasanghata* (decrease the wound discharge irritation act against bacteria and splits the hemorrhagic clots), *Mamsavilakhati* (removal of necrotic tissue), *Shvathu Upahanti (reduce inflammation). Tikta rasa* is *Vrana Shodhaka* (free from slough and necrotic tissue) *and Kledapooyaupasoshana.*[13] It dries up the exudates and promotes healing. *Tikta rasa* has good debridement property reduces excessive exudates and hyper granulation tissue thus helps to balance moisture of the wound. *Kashaya rasa* is *Vranashodhan, Lekhana karma* (expels out toxins and necrotic tissue), *Sandhankar* (help to check bleeding and *Ropana* (promote healthy granulation tissue). *Kashaya rasa* is also *Vrana Shodhaka, Ropana*, causes *lekhana* and k*ledopashoshana*[14] (reduce exudates). *Madhura rasa* is *Sonithaprasadana*[15] (promotes angiogenesis and granulation tissue formation). *Madhura ras* property is *Mamsavardhanam*[16] *(*formation of new blood capillaries and fibroblast), *Ksheenakshat Sandhankar*[16] (promote wound healing) has been helpful in *Shodhan* and *Ropan* of diabetic foot ulcer. The *ruksha guna* causes *Srotosodhana* and thus destroys the micro circulatory occlusion and helps in carrying the active principles of the medicine into the capillaries. Moisture maintenance is a major factor for promoting wound healing and the application of the medicine in a *ghrita* form serves this function.

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