



EFFICACY OF UNANI FORMULATION MARHAM- EJAZ IN THE MANAGEMENT OF NON-HEALING ULCER: A CASE REPORT

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ABSTRACT

Background and Aim: A Non-healing ulcer is defined as an ulcer that does not heal after 6 weeks of conservative therapy. It is estimated that 1-2% of the people of the world experience a chronic wound during their lifetime. There is a direct impact on the physical (amputation), psychological (depression) and social life of an individual. The present study was carried out to assess the acclaimed effect of Unani formulation *Marham-e-Ejaz* in a patient. **Material and Method:** A Female patient with a non-healing ulcer presented in the surgery OPD of our institute hospital. She presented with the chief complaint of the wound at the plantar aspect of her left foot for the last one year associated with Maggots in the wound for 10 days. She is a known case of diabetes mellitus. The case was treated with an Unani topical formulation, *Marham-e-Ejaz* for 45 days. The formulation was applied to the wound after cleaning it with turpentine oil and the dressing was changed on every alternate day. The wound was assessed for pain, discharge, size and depth on the wound at 0th, 15th, 30th and 45th days. **Result:** On the first day the wound size was 49 square cm and the depth was 2 cm, the floor was filled with slough, maggots, and pale granulation tissue. On the 45th day, there was a significant reduction in the size of 1 square cm, depth of 0.2 cm and 88.2% epithelization and 100% granulation. **Conclusion:** It was observed that there was significant healing of the ulcer. So, *Marham-e-Ejaz* has potential efficacy in healing non-healing ulcers.

Keywords: Non-healing ulcer, *Qurūh*, *Mujaffif*, Unani formulation, *Marham-e-Ejaz*

INTRODUCTION

A Non-healing ulcer is defined as an ulcer that does not heal even after 6 weeks of conservative treatment. It is estimated that 1-2% of the people of the world experience a chronic wound during their lifetime in developed countries. In the USA Chronic wound are reported to affect 6.5 million patients. Based on causative aetiologies the wound healing society classifies chronic wounds into 4 categories Pressure ulcer, Diabetic ulcer, Venous ulcer, and Arterial ulcer¹. Globally 463 million people are living with diabetes. India reported 77 million adult diabetic patients and contributing the second-highest number of patients after China. The lifetime risk of a diabetic patient having a foot ulcer has been reported to be as 25%. In India, the number of diabetic foot patients is increasing in both urban and rural areas with 85% of amputations preceded by a foot ulcer. In India, approximately one million legs are amputated every year. Diabetic prevalence is increasing in developed and developing countries all over the world. Among diabetic patients, the Diabetic foot is one of the major complications in the health care system. Diabetes is the main cause of more than half of non-traumatic lower-limb amputations. Every 30 seconds in the world a lower limb is amputated due to diabetes and about 15-25% of patients may develop a foot ulcer during their lifetime. The annual risk of developing diabetic foot ulcers in patients with diabetes is estimated to be about 2% but this risk in patients with a previous history of foot ulcerations is expected to increase to 17-60% over the next 3 years². Avicenna was the first to describe diabetic gangrene Hippocrates the father of medicine had a leg ulcer. He was managing the wound by using various kinds of boiled herbs mixed with wine used as a cleansing agent. He also used various kinds of salts, oxides of copper, and lead was also used to dry and soothe the wound³. *Jarāhat* (wound) is described as the *Tafarruq-*

e- ittişāl of laham (wear and tear of muscle) free from pus. It is a severe *Tafarruq-e- ittişāl* in any part of the body, especially in those structures which are soft and delicate. *Qurūh* (ulcer) according to the Unani system of medicine are *Tafarruq-e- ittişāl of leham* (wear and tear of muscle) is associated with pus formation in it. *Qurūh* (ulcer) can be classified into 3 categories. *Qurūh-e-Baseet* (simple ulcer)- The ulcer is free from those factors which may delay the healing process. *Qurūh -e- Murakkab* (compound ulcer)- The ulcer which is associated with pain, suppuration, and blackening of surrounding tissue. *Qurūh-e-Aseer-ul-Indimal* (Non-healing ulcer) – Ulcer that does not show any tendency towards healing and is associated with more damage and destruction of tissues^{4,8}. There are several formulations in the Unani system of medicine for non-healing ulcers. *Marham-e-Ejaz* was selected for the present case series.

MATERIALS AND METHODS

Selection of case: A diagnosed patient with non-healing ulcers was taken for the study from Surgery OPD Unani hospital. The treatment was started after taking written informed consent from the patients.

Marham-E-Ejaz- The Ointment was prepared in the pharmacy of the Institute according to procedure guidelines of the National Formulary of Unani medicine ⁴. It has got *Kath Safaid* (white catechu/ Acacia Catechu) 4 parts, *Raal Safaid* (Shorea robusta/Sal tree) 4 parts, *Shibbe Yamani* (sulphate of alumina/alum) 1 Part, *Tutiya sabz* (copper sulphate) one part, water 4 parts, and *Roghan -e-kunjad* (sesame oil) 4 parts as ingredients. First *Kath Safaid*, *Raal Safaid*, *Shibbe Yamani* and *Tutiya sabz* were finely ground and sieved to make *safoof* (Powder), then Oil and water were mixed in a vessel and sieved. Fine powder of all the above

ingredients was added in the oil and water mixture in a vessel and stirred to make *Marham* (Ointment) ⁹.

Procedure: The initial step of the treatment of a case was to remove maggots from the wound for this purpose, the wound is cleaned with turpentine oil. After that, the wound was cleaned with normal saline and dressed in *Marham-e-Ejaz* on alternate days under all aseptic precautions. Debridement of the wound was done as per the need, to remove dead tissues. No oral or topical antibiotics were used during the of study. Wound healing was assessed on 0, 15th, 30th and 45th days based on pain (VAS scoring), discharge, number of wounds, and area of the wound in a square centimeter, the appearance of healthy granulation tissues, epithelization in percentage and depth of wound in centimetres.

Duration Of Study: 45 days

Case Presentation: A 70-year-old female was admitted on 15/01/22 to NIUM Unani Hospital, Bengaluru - 560091 Karnataka State, India. with a Chief complaint of Wound at the plantar aspect of her left foot from the last 1year associated with Pain and discharge from the wound from last 3 months and Maggots in the wound from 10 days.

According to the statement of the patient she was well one year back after that she developed a wound at the plantar aspect of the

left foot from one year, and she got injured by falling off on a wooden stick at the upper portion of the left foot below the ankle joint. Bleeding occurred at the site of injury after 3 days, a small blister was formed at the site of injury. After 4-5 Days the blister was burst spontaneously to form an ulcer associated with foul-smelling discharge. The ulcer gradually increases in size over one year and acquired the present size as shown in the image of the wound of 0 Day. The patient also complained of pain at the wound site, the pain was insidious in onset and dull aching in nature and mild to moderate according to VAS scoring, pain was localized and was not aggravate on walking. She was also complaining of discharge from the wound for 6 months which was foul in smell moderate in quantity and yellow in colour. She was also complaining of maggots in the wound for 10 days. The patient is a known case of DM type 2 from 8 years and on tablet Metformin 500mg + Glimepiride 2mg twice a day. There was no history of hypertension and other comorbidities.

RESULT

On the first day the wound size was 49 sq. cm and depth was 2cm, the floor was filled with slough, maggots, and pale granulation tissue, pain according to VAS score was 8 and there was foul-smelling discharge. On 30th day completely granulation tissue was developed. On the 45th day, there was a significant reduction in the size of 1 sq. cm, depth of 0.2 cm, and the floor filled with red granulation tissue and the pain was completely relieved.

Table 1: On examination, the following observation was noted findings of a local examination of a non-healing ulcer of diabetic foot

Examination	Findings
Inspection	
Site	On the dorsal aspect of the left ball of the foot
Size	7x7 square cm
No. of wound	One
Shape	Irregular
Margins	Edematous
Floor	Filled with pale granulation tissue, slough and full of maggots
Discharge	Yellow
Smell	Foul
Maggots	Creeping out in the wound
Other findings	Brittleness of nails
Palpation	
Local temperature	Raised
Tenderness	Present
Depth	1.5cm
Margins	Indurated
Base	Mobile
Bleeding on touch	Absent

Table 2: Assessment of healing in non-healing Diabetic foot using unani formulation, Marham-e-Ejaz

Assessment parameters	Day 0	Day 15	Day 30	Day 45
Size in sq.cm	49	25	9	1
Number of wounds	1	1	1	0
Granulation tissue in %	32.6	100	100	100
Epithelization in percentage	0	48.9%	64%	88.2%
Depth in cm	2	1.5	0.5	0.2
Pain (VAS)	8	4	2	0
Discharge	Profuse	Scanty	Absent	Absent

Investigation: On first day swab culture report shows aerobic bacteria *Klebsiella pneumoniae* (heavy growth) and *Morganella morganii* (moderate growth). Hb-11.3gm%, TLC-10600/cumm, Neutrophils-70%, Lymphocyte-21.4%, Eosinophils-1%, Basophills-0.5%, Random blood sugar-159mg/dl, HbA1c-9.9%, Blood urea-17mg/dl, serum creatinine-0.54mg/dl, Serum sodium-136.7meq/L, Serum potassium- 4.5meq/L, Serum chloride-

100.3meq/L. Arterial doppler- diffuse atherosclerotic changes in aorta and iliac vessel. popliteal artery, posterior tibial artery, anterior tibial artery and dorsalis pedis have diffuse atherosclerotic change with biphasic flow. No evidence of significant stenosis and occlusion. At 45th-day swab, the culture report has no significant growth.



Figure 1: Healing in Diabetic foot Non- healing ulcer by *Marham-e-Ejaz*, an Unani formulation

DISCUSSION

A Non-healing ulcer is defined as an ulcer that does not heal after 6 weeks of conservative therapy. Repair of damaged tissue occurs by 2 processes first one is regeneration which restores normal cells and the second is scarring, and deposition of connective tissue. In regeneration, tissues are able to replace the damaged components and return to normal state. Example is epithelial organ, characterised histologically by the presence and proliferation of fibroblasts, keratinocytes, endothelial cells migration. fibroblast is a cell type and is responsible for the formation of granulation tissue and extracellular matrix (ECM)¹². The term granulation tissue derives from the pink, soft, granular, gross appearance seen in the wound. Granular tissue progressively fills the site of injury. Granulation tissue is progressively replaced by the deposition of collagen. Transforming growth factor beta (TGF- β) is most important cytokine for the synthesis and deposition of connective tissue protein. It is produced by most of cells in the granulation tissue. TGF- β stimulate fibroblast migration and proliferation increase synthesis of collagen and fibronectin and decrease degradation of ECM by inhibiting metalloproteinase. The ECM consists of type III collagen it is a weaker form of collagen it is replaced by stronger type I collagen. Connective tissue in the scar continues to be modified and remodelled. The degradation of collagen is accomplished by family of matrix metalloproteinase (MMP). MMP include interstitial collagenase MMP1, MMP2, MMP3 which cleave fibrillar collagen. Healing by first intention occurs when the injury involves the epithelial layer the principal mechanism of repair is Epithelial regeneration. Healing by second intention occurs when a wound causes large tissue deficits. So, the fibrin clot is larger, there is more exudate and necrotic debris in the wound area. At First type type III collagen is formed but in about 2 weeks this is replaced by type 1 collagen ultimately

original granulation tissue scaffold is converted into pale avascular scar. Studies have shown that chronic wounds have elevated levels of inflammatory cytokines and matrix metalloproteinases. The increased concentration of matrix metalloproteinases is enhanced by the associated decrease in protease inhibitors^{10,11}. A chronic wound is difficult to treat and take time and patience. Debridement of the wound, careful cleaning and dressing change has been the only hope of advancing healing. Negative pressure devices, recombinant growth factors, hyperbaric oxygen are some methods that have been used to assist in wound healing. Chronic wound develops when normal healing mechanism are not capable of repairing the tissue injury, they include both systemic and local factors. Malnutrition, uraemia hyperglycaemia, are example of systemic factors that retard healing, oedema, Infection, Arterial insufficiency and pressure on the wound are example of local factors can impair healing¹². According to Unani literature, *Marham-e-Ejaz* is used for non-healing ulcers to gain quick healing. It cleanses the dead tissues (slough) and helps in growth of healthy tissue. It also possesses antiseptic action.

Sesame Oil is obtained from the seeds of *Sesamum indicum*. It contains glycerides of oleic 43%, linoleic acid 43%, palmitic 9% stearic 4%, lignan sesamin 1% and myristic acid. Externally it is act as an emollient and soothing agent for the inflamed surface. It is used to soften skin and crusts. It is claimed to have *Muħallil waram* (anti-inflammatory) and antiseptic action. Sesame Oil active ingredients sesamin and sesamol have antioxidants, antimicrobial and anticancer activity¹³. Mom (Bees Wax) is an important content of the *Marham*. It improves the action of other content in the *Muħallil Marham*. It is used as a preservative in *Marham*. It also acts as *Mulayyin and Muħallil-e-waram* (Anti-inflammatory)¹³⁻²². It is reported for wound healing action¹³. *Shibbe Yamani* (sulphate of alumina/alum)—acts as a *Mujaffif-e-ratubat* (Desiccative), *Hābis-i-Dam* (hemostatic), *musakkin-i-alam* (analgesic), *Dāf '-e-Ta 'affun* (antiseptic), *Jālī* (detergent)¹⁷⁻²². *Tutiya Sabz* (copper sulphate)-*akkāl* (removes dead tissue and

slough) *Mujaffife-e-Qurūh*, *Dāf ‘-e-Ta ‘affun* (antiseptic) *Muṣaffī-e-Dam*¹⁷⁻²². The body of a 70-kg healthy individual has about 110 mg of copper, 50% of which is found in the bones and muscles, 15% in the skin, 15% in the bone marrow in the skin, copper a) stimulates dermal fibroblasts proliferation upregulates collagen (types I, II, and V) and elastin fibre components (elastin, fibrillin) production by fibroblasts¹⁵. *Raal Safaid* (*Shorea robusta*/Sal tree)- *Daḥī ‘-i-Ta ‘affun* (antiseptic) *Mujaffif-e-Qurūh Mudammil-e-Qurūh* (wound healing)¹⁷⁻²². *Kath Safaid* (white catechu/ Acacia Catechu)- contain flavonoids (catechin, rocatechin, epicatechin, quercetin), alkaloids (taxifolin), tannins (gallic acid) glycosides (poriferasterol) active constituents responsible for antimicrobial activity for both gram negative and gram-positive bacteria such as *Escherichia coli*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Salmonella typhi*, *Shigella flexneri*, *Pseudomonas aeruginosa* and *Salmonella typhi*¹⁶. *Qabiz*, *Hābis-i-Dam* (hemostatic) *Dāf ‘-e-Ta ‘affun* (antiseptic) *Mujaffif-e-Qurūh*, *Muṣaffī-e-Dam* (blood purifier)¹⁷⁻²².

According to the Unani system of medicine, the action of the drug ingredients present in *Marham-e-Ejaz* are favorable for the treatment of non-healing ulcers. Complications of VAC therapy include failure of the VAC system, wound infection, pain, bleeding, allergies to the adhesive drape, excoriation of the skin, restricted mobility, adherence of the tissues to the foam, lack of patient compliance and skin necrosis Hyperbaric oxygen therapy, ultrasound and electromagnetic therapy, negative pressure wound therapy (VAC), topical application of platelet derived growth factors (PDGF), skin grafting all common measure used for healing of the ulcer²³. Side effects of hyperbaric oxygen therapy is middle ear barotrauma, rupture of the tympanic membrane, paranasal barotrauma, pulmonary barotrauma, claustrophobia and CNS toxicity²⁴. It is too costly and has certain limitations. *Marham-e-Ejaz* applied to the non-healing ulcer in the patient healed the ulcer within 45-day treatment with adequate granulation and epithelization. So, treatment through the local application of *Marham-e-Ejaz* is very simple, cheap and convenient.

CONCLUSION

The Unani formulation *Marham-e-Ejaz* as a local application shown good result in the healing ulcer. It is easily available, cheap and very effective in non-healing ulcers. It removes dead tissue slough and helps in the growth of healthy granulation tissue and epithelization. This case report strategy Recommends for taking it up for further studies to dealing *Marham-e-Ejaz* as an effective drug for non-healing ulcer.

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