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Research Article

EFFICACY OF UNANI FORMULATION IN THE MANAGEMENT OF NON-HEALING ULCER: A CASE SERIES

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ABSTRACT

Non-healing ulcers are defined as ulcers that do not heal in 6-9 weeks. Non-healing ulcers are a serious health issue that impacts people all over the world. They have a significant influence on people's lives on a personal, professional, and social level. They come at a high cost in terms of human and material resources. There is a direct impact on quality of life and individual impacts too (poor work capacity and lack of morale), physical (restricted activity and disability due to amputation), psychological (depression or anxiety), social (disconnection from family and associates), and economic effects (costly treatment). In view of the common prevalence and non-availability of affordable treatment of non-healing ulcers, Unani pharmacopeial formulation (*Marham-e-Khal*), with easy affordability and availability, was used on the non-healing ulcer to find out its effect in two patients.

Keywords: Non-healing ulcer, Unani formulation, *Marham-e-Khal*.

INTRODUCTION

Non-healing ulcers are those that do not heal after 6 weeks of conservative therapy. These ulcers are difficult to treat because of resistance to treatment due to superadded infection, nutrition, age factors, and severe systemic illnesses. There are several strategies to treat these ulcers in conventional medicine like wound cleansing, proper debridement, diagnosis, use of local healing agents and antibiotics if required, yet the effect of which is not satisfactory. It often leads to physical handicap for a lifetime due to amputation of the affected part, which affects the patient's quality of life.

There are several formulations in the Unani system of medicine for non-healing ulcers. A detailed procedure of cleaning and dressing of which has been recommended in the old Unani literature. Henceforth *Marham-e-Khal* was selected for the present case series.

MATERIALS AND METHOD

Selection of cases: Two diagnosed patients with non-healing ulcers were taken for the study on an OPD basis. The treatment was started after obtaining ethical clearance from Biomedical Institutional Ethics Committee (NIUM/IEC/2019-20/023/Jar/03).

***Marham-e-Khal*:** The ointment was prepared in NIUM in-house pharmacy according to guidelines of Unani reference Pharmacopoea[1,2]. *Mom zard* (bee wax) was dissolved in *Roghan-e-gul* (Oil of *Rosa damascena*), then finely powdered *Mardarsang* was mixed in the same solution. finally, *Sirka* (vinegar) was added according to the requirement to prepare ointment and was stored in a glass jar.

Procedure: The wound was cleaned with Normal Saline and debridement was done under aseptic precautions, followed by dressing with *Marham-e-Khal*. The dressing was done on every alternate day. wound healing was assessed on every 15th day by measuring objective and subjective parameters like Number of wounds, Discharge, Pain (VAS scoring), Area of the wound in a square centimeter, Appearance of healthy granulation tissues, Epithelialization in percentage, Depth of wound in centimeter. No other antiseptic solutions / oral medications were used during the treatment for the healing of the wound.

Duration of the study: 45 days.

Case Presentation

Case 1: A 70-year-old male patient presented to our NIUM, Surgery OPD with complaints of post-amputation (above-knee) wound on a left lower limb at the operated site, pain at the wound site, yellowish discharge from wound site for three months.

According to the statement of the patient he was apparently well about 3 months ago, then he had to undergo above-knee amputation of left lower limb due to severe arterial disease and the stitches were removed on 3rd day elsewhere and hence the wound was opened up, which is gradually increasing in size day by day. The patient also complained of severe throbbing pain at the site of the wound radiating to the rest of the limb, the intensity of pain increases especially at night and relieves after taking oral pain killer, he also had a c/o thick, yellowish, scanty, foul-smelling discharge from the wound for 3 months. There were no other associated complaints. The patient had no comorbidities and there was no history of smoking/ alcohol/drug/ tobacco chewing.

Case 2: A male patient of 64 years old presented to NIUM, surgery OPD with c/o wound on the plantar aspect of the left foot for 7 months, pain at the site of the wound for 6 months, and discharge from the wound for 4 months.

According to the statement of the patient he was apparently well about 7 months ago, during his routine work at his own farm accidentally he had a stone prick at his left foot which was removed immediately and taken to a nearby clinic where tight bandaging was done to hold bleeding since then the wound is not healing, its constant in size and depth, there was also severe pricking and burning pain at the site of wound radiating to the whole foot due to which patient had to use supporting stand for walking. The pain was aggravating while walking and standing for long and relieved on taking oral pain killers. The patient also had c/o minimal, serous, non-foul-smelling discharge from the wound.

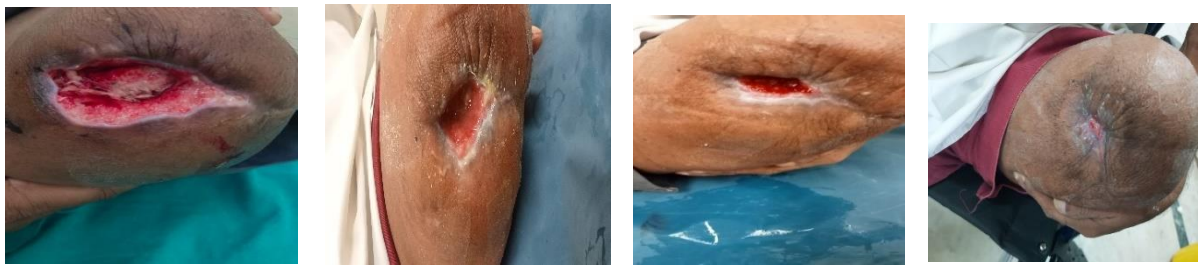
He was a known patient of Diabetes Mellitus Type II for 21 years on Tab. Metformin 500mg + Glimepiride 2 mg twice a day, k/c/o Hypertension for 7 years on Tab. Amlodipine 10 mg once a day. And there was no history of smoking/ alcohol/drug/ tobacco chewing.

Result and Observation

Case 1: On the first day when the patient presented to OPD the wound size was 30 sq. cm and depth was 1.8 cm, the floor was filled with slough and pale granulation, edges were punched out, pain according to VAS score was 10 and there was foul-smelling discharge. On 45th day there was a significant reduction in size (0.77 sq. cm), depth (0.2 cm), pain (VAS score - 2), and the floor filled with healthy granulation tissues. Observations are summarized in Table 1 and Fig 1.

Table no. 1. Wound healing assessment of cases during treatment

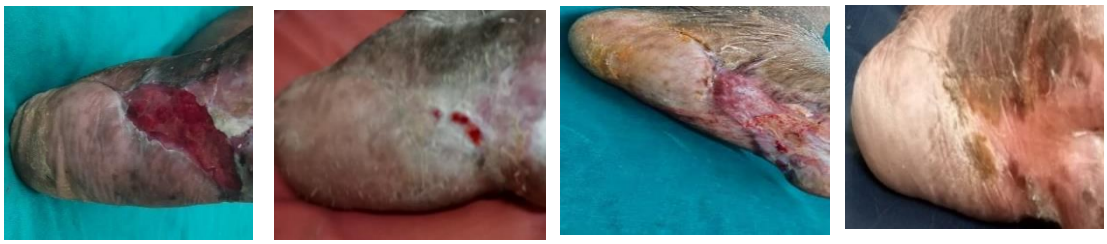
	Case 1	Case 2	Case 1	Case 2	Case 1	Case 2	Case 1	Case 2
Assessment Parameters	Day 0		Day 15		Day 30		Day 45	
Size in sq. cm	30	21.76	25.2	7.02	2.52	0.48	0.77	0
No. of wound	1	1	1	1	1	1	1	0
Edges	Punched out	Sloping	Punched out	Sloping	Punched out	Sloping	Sloping	0
Granulation tissues in %	16	36.8	4.3	100	100	100	100	0
Epithelialization in %	0	0	16	67.7	90	93.1	69.4	100
Depth in cm	1.8	0.2	1.2	0.1	0.8	0.1	0.2	0
Pain (VAS)	10	6	8	0	4	0	2	0
Surroundings	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal



Day 0 Day 15 Day 30 Day 45

Fig. 1: Photograph showing wound healing of case 1

Case2: On day first wound size was 21.76, depth 0.2 cm, the floor filled with pale granulation and very few healthy granulation tissues, pain according to VAS score was 6. By 45th day the wound was healed completely. Observations are summarized in Table 1 and Fig. 2



Day 0 Day 15 Day 30 Day 45

Fig. 2: Photograph showing wound healing of case 2

DISCUSSION

An ulcer is described as a breach in the integrity of covering epithelium, skin, or mucus membrane. It may occur because of the surface epithelium's molecular death or its traumatic removal[3]. Non-healing ulcers are those that do not heal after 6 weeks of conservative therapy[4] and have not progressed through a timely repair sequence or those that go through the recovery process without restoring structural and functional results. Wound healing is typically slowed or prevented due to a physiologic deficit[5]. Most common types of chronic wounds are venous leg ulcers, ischemic wounds, diabetic foot ulcers, and pressure wounds[6]. The probable causes of non-healing ulcers are compromised venous flow, atherosclerosis, age, diabetes, renal impairment, lymphedema, rheumatological disease, poor nutritional status, local pressure over prominent bone, and ischemic injury[6]. Normally, the wound healing process is classified into four structural and temporal sequences which occur in some strict regulated modes: (a) Hemostasis following a structural damage, b) Inflammation, (c) Proliferation, (d) Tissue Remodeling[6]. Non-healing wound complications are many, which include severe pain, septicemia, hospitalization, and amputations in some cases[6]. The estimation of non-healing ulcers is approximately 2–6 million people in the United States alone, and its prevalence in the world ranges from 1.9 to 13.1%. The incidence of which is expected to rise as the population ages[7]. Among all non-healing ulcers, Diabetic and vascular ulcers affect 98% of total lower extremity wound[1] and Approximately 15–25% of diabetic patients develop a foot ulcer, of which at least 12% require amputation of affected part. India is in first place with approximately 42 million cases in the list of the ten nations most affected with diabetes[8]. About 0.6-3% of patients above 60 years are expected to get affected by non-healing ulcers and 5% above 80 years[9], pressure ulcer incidence ranges from 2.7% to 9% in the acute case in comparison to 2.4% to 23% in chronic cases[10]. Venous ulcers constitute 70% of cases, Arterial ulcers comprise 10% of total cases, 15% of ulcers are Due to mixed etiology and 5% of leg ulcers are due to lesser-known pathophysiology causes[9].

Tafarruq-e-Ittesal (damage) *of Lehem* (muscles) is called *Jaraha* and if *Jaraha* contains pus, it is termed as *Qarha* (ulcer). The cause of *Jaraha* may be external and internal[16]. The ulcer can be classified into three types according to Unani concept: (1) *Qurooh-e-Baseet* (Simple Ulcers) - Ulcer which is free from factors that delay healing[16], (2) *Qurroh-e-Murakkab* (Compound Ulcer) - Ulcer which is associated with suppuration, pain and blackening of surrounding tissue[16], and (3) *Qurooh-e-Asir-ul-Indam*aal (Non-healing ulcer) - Ulcer which do not show a tendency towards healing and is associated with more damage and destruction[16].

According to the Unani literature, *Marham-e-Khal* is used for non-healing ulcers to gain intensive and Quick response. It cleanses wounds, removes dead tissue/ slough, and helps in the growth of healthy tissue at the site of ulcer[1,2]. The ingredients of the formulation have actions that aid in wound healing like Mom (Bee wax) is an important content of the Marham (ointment), which improves the action of other contents. It helps in penetration of the other contents of a *Marham* into the tissues of ulcer, without mom (bee wax) other contents fail to penetrate, as they are desiccant and astringent[11]. It also acts as *mulayyan* & *mohallil-e-warm*[12]. *Mardarsang* acts as *Akkal* (It cleanses wound, removes slough or dead tissues), *Mudammil-e-Quruh* (growth of healthy granulation tissue), *Mohallil-e-Auram* (Anti-inflammatory), and *Mujaffif-e-Quruh* (produces dryness)[11,13,14,15].

Roghan-e-Gul (*Rosa Damascena* Oil) acts as *Murakkabul Quwa* (multifunctional), *Mohallil-e-Waram* (anti-inflammatory) and *Mujaffif-e-Quruh* (produces dryness)[12,13]. *Sirka* (Vinegar) acts as catalyst which enhances action of other drugs[11]. Hence this formula was chosen to demonstrate its effect. No other oral drugs were used during treatment for wound healing.

CONCLUSION

The Unani formulation (*Marham-e-Khal*) as a local application has shown excellent results in the above-discussed cases, it has got good cleansing and healing property. It is easily available in the market at an affordable price. Further research may be taken up to evaluate its efficacy in healing nonhealing ulcers in a greater number of patients and compared with a control group.

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