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# Therapeutic efficacy of *Itrifal e shahatra*, *Irsal e* Alaq (Hirudo therapy) and a herbal paste in the management of Qurooh-e-Aseerat-ul-Indamaal (Non- healing ulcer) - A Case study

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#### **Abstract:**

Background: Ourooh-e-Aseeerat-ul-Indamaal are described as ulcers which are associated with more damage and destruction of the surrounding tissues and show no tendency towards healing. This condition corresponds with Non-healing ulcers in modern medicine and is defined as ulcers which do not heal by conservative treatment within six weeks. The Chronic non-healing ulcer is a major health problem and its prevalence in the world ranges from 1.9 to 13.1%. The incidence is expected to increase as the population ages and due to increased risk factors for atherosclerotic occlusion such as smoking, obesity and diabetes mellitus. It badly affects the patient's quality of life and also increases the risk of prolonged hospitalization and the cost of health care.

Objective: To evaluate the effectiveness of oral use of Itrifal e shahatra along with Irsal e Alaq (Hirudotherapy) and a specially prepared herbal paste in the management of non healing ulcer.

Methodology: A 76-year-old female patient visited to Asma Herbals, Kalpitiya, Sri Lanka with the complaint of wound in right leg for 3 years. She was treated by Itrifal e shahatra internally for 3 months with external applications of Irsal e Alaq daily(Hirudotherapy) until healthy granulation tissue forms on wound and then applied the herbal paste over the wound every other day.

Results: At the end of 90th day, 96.5% of wound area healed with normal epithelialisation and the size of the wound reduced. The remaining area of wound became superficial and covered with healthy granulation tissues.

**Conclusion:** The combination therapy *Irsal e Alaq* (Hirudotherapy), herbal paste and *Itrifal e shahatra* were effective in the management of non-healing ulcer and can be a relied alternative to the conventional treatment.

Keywords: Non-healing ulcers, Qurooh-e-Aseeerat-ul-Indamaal, Irsal e Alaq, Itrifal e shahatara

#### 1. INTRODUCTION

Chronic ulcers or non-healing ulcers are defined as spontaneous or traumatic lesions, typically in lower extremities that are unresponsive to initial therapy or that persist despite appropriate care and do not proceed towards healing in a defined time period with an underlying etiology that may be related to systemic disease or local disorders. There are many types of non-healing ulcers that may include venous, arterial, diabetic, pressure and traumatic ulcers (Manish Suthar .2017). According to Unani classical texts non-healing ulcers (Qurooh-e-Aseerat-ul-Indamaal) are those ulcers which do not heal by conservative treatment within six weeks. In Unani system of medicine Qaraha (ulcer) is defined as jarahat (wound) which contains pus and wound, and is caused by Tafarruq-e-ittesal (discontinuity) of the lahem (muscles). There are three types of Qurooh. First type being Qurooh-e-baseet (Simple ulcer), such ulcers are free from the factors which delay its healing. Second type is Qurooh-e-murakkab (Compound ulcer), such ulcers associated with blackening of tissues, suppuration and pain. Third type is Qurooh-e-Aseerat-ul-Indamaa (Non-healing ulcers) are those ulcers which are associated with more damage and destruction of the surrounding tissues and show no tendency towards healing (Saiyad Shah Alam. 2018).

Chronic non-healing ulcer is a major health problem and is estimated to affect approximately 2–6 million people in the United States alone, while its prevalence in the world ranges from 1.9 to 13.1%. The incidence of chronic ulcers is expected to increase as the population ages and due to increased risk factors for atherosclerotic occlusion such as smoking, obesity and diabetes mellitus (Manish Suthar .2017). It badly affects the patient's quality of life and also increases the risk of prolonged hospitalization and the cost of health care.

Non-healing ulcer is a leading cause of amputation and wound related morbidity. In view of its common prevalence and non-availability of affordable treatment it is worthwhile to look towards Unani system of medicine where non-healing ulcer can be treated efficiently with local application of drugs having *mujaffif* (desiccant), *khatim* (siccative), *daaf-e-taaffun* (antimicrobial), *muhallil* (anti inflammatory) *and mundammil-e-qurooh* (wound healing) actions (Saiyad Shah Alam. 2018) and with *Irsal e Alaq/Taleeq* (Hirudotherapy) (Hamdani SKDH. 1980).

# 2.RESEARCH METHODOLOGY 2.1 CASE STUDY

A 76-year-old female patient visited to Asma Herbals, Kalpitiya, Sri Lanka with the chief complain of difficulty in walking due to the wound on the right leg for 3 years.

#### 2.2 MEDICAL PRESENTATION

According to the statement of the patient, she had suddenly developed a blister at the right leg, which was filled with watery material and was associated with no pain. After 2–3 days, the blister got rupture on its own giving rise to the watery discharge from it. So she paid no attention to it. In very few days she noticed a

small wound at the site of previous blister. The size of this wound increased gradually over the period of last 3 years and has acquired the present size. She also complained of no pain, no foul smell and no itching in and around the wound. The patient is a hypertensive for 4 years and non-diabetic.

#### 2.3 LOCAL EXAMINATION

 Table 1: Local Examination of right lower limb before commencement of treatment

Characteristics		Findings
Inspection	Site	Medial aspect of the right leg in, above and below the
		ankle joint
	Number of wounds	One
	Size of wounds	Approximately 17x6 cm <sup>2</sup>
	Edges	Punched out
	Margin	Irregular
	Floor	Filled with unhealthy granulation tissue
	Discharge	Watery discharge presented
	Surroundings	Dry eczematous and dark pigmented
	Smell	No foul smell present
	Visible veins	No visible, dilated and tortuous veins
	Sign of ischemia	Present
Palpation	Local temperature	Normal
5	Tenderness	Not present over the edge or base or surrounding area
	Margins	Indurated
	Length	Approximately 17x 6 cm <sup>2</sup>
	Depth	Approximately 1.5 cm
	Bleeding on touch	Absent
	Other findings	Scar of previously healed wound presented at the lateral aspect
		of the right leg 1cm above the ankle joint.

# 2.4: INVESTIGATIONS

The patient was routinely investigated after admission. His haematological values were Hb 10.3%, TLC 12590 cells/mm3. Differential counts (neutrophils 79%, lymphocytes 17%, eosinophils 01%, monocytes 03%, basophils 0.0%) and ESR 110 mm/1 h. Biochemistry values were normal, i.e., random blood sugar 102 mg/dl.

#### 2.5: METHODOLOGY

After all investigations Ta'leeq (Hirudotherapy) was planned as a  $1^{st}$  line of treatment along with wound cleaning with normal saline water. Then the local application of research herbal paste over the wound was

planned as a 2<sup>nd</sup> line of treatment after the formation of granulation tissue. Internally, 5 grams of *Itrifal-e-shahatra* with hot water morning and evening was given as a supportive treatment.

#### 2.6: Method of preparation and administration of Ta'leeg

5 leeches of moderate size were kept in a cleaned jar containing *Haldi* (*Curcuma longa*) water. The wound was cleaned with normal saline to remove any discharge or slough. Those 5 leeches were kept over wound site. They all started sucking blood well. Wet cotton kept over them. The leeches fall itself after sucking of impure blood. For haemostasis *Safoof Haldi* (powder *of Curcuma longa*) was applied over sucked site. Pressure bandage was applied. Then the leeches were kept in *Haldi* water for proper expulsion of sucked blood. When leeches become active they then kept in the container filled with water. This procedure was done daily until the healthy granulation tissue formed over the wound for next 15 days.

## 2.7: Method of preparation and administration of the herbal paste

The herbal paste consists of *Post e gulnar* (dried peel of *Punica granatum*), rhizomes of *Amba haldi* (*Curcuma aromatica*), bark of *Terminalia catappa* and *Barg e amaltas*(*Cassia fistula*) in equal amounts. These ingredients were taken freshly, cleaned, washed thoroughly and then ground them to make a fine paste. After healthy granulation tissue noticed on the wound on 15<sup>th</sup> day the paste was locally applied every other day for next 75 days.

# 3. RESULTS

In this case healing response could be seen by the  $2^{nd}$  day of the dressing. The discharge from the wound gradually reduced by  $6^{th}$  day of the dressing, healthy granulation tissue appeared by  $15^{th}$  day of dressing. At the start of the treatment the size of the wound was approximately  $17x6 \text{ cm}^2$  and depth approximately 1.5 cm. By the end of  $90^{th}$  day of the dressing, 96.5 % of wound area healed with normal epithelialisation. The size of the wound reduced to approximately  $3.5x2 \text{ cm}^2$ . The remaining area of wound became superficial and covered with healthy granulation tissues.

# 4. DISCUSSION

Medicinal plants play a key role in preventing various diseases (Fazeenah, AHA. Quamri, MA.2017). Our study demonstrated a marked reduction in the size of the wound by the formation of healthy granulation tissue and completely reduced watery discharge. The effect of *Itrifal e Shahatra* and herbal paste is due to chemical constituents of their ingredients. *Itrifal e Shahatra* is a Unani compound preparation which contains *Shahatra* (*Fumaria officinalis L.*), *Post-e Halela Zard* (*Terminalia chebula*), *Post-e Halela Kabuli*, (*Terminalia chebula*), *Sana makki* (*Cassia angustifolia*), *Gul-e Surkh* (*Rosa damascene Mill.*) and *Maweez Munaqqa* (*Vitis vinifera*). It has *Musaffi e Dam* (Blood purifier), *Munzij wa Mus'hil-e-Sauda* (Concoctive and Purgative Melancholic humor), *Murattib-e-Umoomi* (General moisturizer) properties (Mohammad Shamim Khan. 2018).

Shahatra (Fumaria officinalis L.): Fumitory or earth smoke-is a medicinal plant which has long had a role to play in empirical medicine in numerous countries. (Hentschel C, 1995.) The juice or syrup or seed have been traditionally used in cutaneous irruptions such as eczema and psoriasis, in scabies, syphilis, leprosy, tatters and itches (Heidari H, 1993.) (Baker RC, 1993). It is a blood purifier (Mohammad Shamim Khan. 2018). According to Preininger V, Shahatra (Fumaria officinalis L.) has bactericidal activity against the Gram-positive organisms Bacillus anthracis and Staphylococcus and according to Sengul M et al the antimicrobial activity of aqueous and methanolic extract of aerial parts of Fumaria officinalis was carried out by disc diffusion test against several bacteria.

and Post-e Halela Kabuli (Terminalia chebula): Terminalia chebula Post-e Halela Zard Retz. (Combretaceae) is called the "King of Medicines" in the Tibet and is always listed first in the Avurvedic materia medica because of its extraordinary powers of healing with a wide spectrum of biological activity (Chattopadhyay RR, 2007). It is a blood purifier (Mohammad Shamim Khan. 2018). Terminalia chebula exhibited antibacterial activity against a number of bacterial species (Ahmad Z .1998). Antibacterial activity of Terminalia chebula against both Gram positive and Gram negative human pathogenic bacteria has also been reported (Phadke SA .1989). An aqueous extract of Terminalia chebula exhibits antifungal activity against a number of dermatophytes and yeasts (Dutta BK. 1998). It is effective against the pathogenic yeast Candida albicans and dermatophytes Epidermophyton, Floccosum, Microsporum gypseum and Trichophyton rubrum (Vonshak O .2003).

Senna (Cassia angustifolia): Cassia angustifolia (senna), a native plant of Yemen, Somalia and Arabia and now cultivated in other parts of the world, has a variety of medicinal uses in Unani as well as other traditional systems of medicine. The laxative principles sennoside A and sennoside B, isolated from leaves and pods of senna, constitute important ingredients in purgative medicines(TRIPATHI YC .1998). A researcher concluded that Cassia angustifolia has been used as laxative agent because it contains hydroxyanthracene glycosides which increase the peristaltic movement of colon and also alters its absorption and resulting in fluid accumulation and expulsion of excreta (Silva CR .2008).

#### Gul-e Surkh (Rosa damascena Mill.) is commonly known as Damask rose

Rosa damascene Mill, is flower's king (Kaul. 2000). It is an ornamental and a precious herb with modern pharmacological importance which are used in medicine (Cai Y-Z. 2005) (Nikbakht A. 2005). Iranian people used the rose hips with bread because it is an approved blood purifier. Rose water was also used for mouth disinfectant (Akhmadieva A. 1993). The efficacy of Rosa damascene in aphthous ulcer has been reported in a randomized, double blind, placebo-controlled study (Hoseinpour H. 2011). The anti microbial effect of essential oil is proved by Well diffusion, Disc and microdilution methods. Multiple studies published in the literature reported antimicrobial activity of R. damascena Mill (Tofighi Z. 2015). Rosa damascena has anti-inflammatory activity. Anti-inflammatory activity of essential oil and hydroalcoholic extract of R. damascena was investigated by administering the extract orally at dose concentrations of 250, 500 and 1000 mg/kg bw in rats with carrageenan-induced paw oedema. Essential oil was used at dose of 100, 200 and 400 μl/kg bw (Hajhashemi V. 2010)

*Maweez Munaqqa* (*Vitis vinifera*) is known as the grapevine. Its seed extract in particular has been reported to possess a broad spectrum of pharmacological and therapeutic effects such as antioxidative, anti-inflammatory, and antimicrobial activities.( Marjan Nassiri-Asl . 2009).

Ta'leeq (Hirudotherapy): Hirudotherapy has remained the part of various systems of medicine including Unani system through the centuries. It is one of the most important and widely practiced methods used for local evacuation of morbid (invalidated and waste) matter with the use of medicinal leech (Azad Hussain Lone .2011). It is known from the time of extreme antiquity and is still alive (Swaid Abdullah .2012). Its major therapeutic benefits are not only due to blood sucked during the biting, but also from the various bioactive substances, such as Hirudin, calin, Hyaluronidase, and Histamine-like substances, to name a few (Swaid Abdullah .2012).

Ibn-e-Sina (Avicenna) and Indian Unani physicians have suggested that *Ta'leeq* (Leeching) is very effective and beneficial in chronic inflammatory skin diseases and unhealed ulcer (Hamdani SKDH. 1980). It eliminates microcirculation disorders, eliminates hypoxia, restores damaged vascular permeability of tissue and organs (Glyova O. 2005). Use of leeches is useful in non-healing ulcers as the secretions enhance the microcirculation of the blood in wound site and from surrounding thus flushing out all metabolic waste, impure blood and toxins. This process enables to increase in perfusion of fresh oxygenated and pure blood at wound and it triggers wound healing by proliferation and formation of healthy granulation tissue (Samata Semaskar. 2020).

#### The research herbal paste:

The effect of the herbal paste is due to its chemical constituents.

Gulnar (Punica

granatum): The pomegranate(Punica granatum L) is an ancient, mystical, unique fruit borne on a small, long-living tree (Jurenka. 2008). Gallic acid and catechin in Punica granatum are the major components which are responsible for the healing activity( Neelam Arun .2012). The methanolic extract of dried pomegranate peels was formulated as a 10% (w/w) water-soluble gel and it showed wound healing property against an excision wound on the skin of wistar rats. The group of rats that received 5.0% gel showed complete healing after 10 days, whereas in rats treated with 2.5% gel, healing was observed on day 12, in contrast to the positive control animals receiving the blank gel, which took 16-18 days for complete healing due to the presence of a high content of phenolic compounds (44.0%) along with other constituents (Murthy KN. 2004). The pomegranate peel extract (rind), seed extract, juice and whole fruit showed antibacterial and antifungal activities on the selected bacteria and fungi. The peel extract showed the highest antimicrobial activity compared to other extracts (Dahham SS.2010). It is reported that pomegranate fruit peel compound punicalagin has antimicrobial activity against S. aureus and P. Aeruginosa (Perez C .1994).

Curcuma aromatica Salisb: It is commonly known as wild turmeric (vana haridra) or yellow zedoary is a species that stands second among the widely used curcumin species next to common turmeric (Curcuma longa Linn.) (Shamim A. 2011). According to Ayurveda the drug is used in various kinds of diseases related to skin, cardiovascular and respiratory system. It is used in cosmetic formulations and traditional medicinal applications as an anti-inflammatory agent, to promote blood circulation, to enhance complexion, to remove blood stasis and also for the treatment of cancer (Revathy S. 2013). The powdered rhizome of CA exhibited wound healing activity in rabbits. Studies also showed significant wound healing activity in excision wound models, conducted to assess the wound healing activity of topical application of CA rhizome extracts and its cream formulations (Kumar A. 2009). Aqueous and alcoholic extracts showed anti -inflammatory activity in mice. The ethanol extracts and formulations exhibited significant anti- inflammatory activity in arachidonic acid -induced ear inflammations. The resulting anti inflammatory activity was suggested to be due to effects on several mediators and arachidonic acid metabolism involving cyclo-oxygenase pathway (Kumar. 2009). A study conducted by Revathi and Malathy (2013) revealed that crude hexane extract of C. aromatica was effective against Gram-positive bacteria and ineffective against the tested Gram-negative bacteria .On the other hand, the essential oil extracted from the fresh rhizomes of C. aromatica has been shown to inhibit the growth of both Gram-positive and Gram-negative bacteria (Ahmed et al., 2008). Apart from germacrone and curcumin, C. aromatica is also composed of other bioactive compounds, such as ar-turmerone (Dhingra et al., 2007; Lee, 2006), camphor (Kordali et al., 2005; Kotan et al., 2008; Viljoen et al., 2003; Zafar et al., 2019), curdione (Naz et al., 2010), linalool (Queiroga et al., 2007; Van Zyl et al., 2006), and xanthorrhizol (Hwang et al., 2000; Rukayadi and Hwang, 2007; Rukayadi et al., 2006), that are reported elsewhere to have an antimicrobial effect against both fungi (Aspergillus flavus, Fusarium semitectum, Colletotrichum gloeosporioides, Colletotrichum musae, Candida albicans, Candida glabrata, Candida guilliermondii, Candida krusei, Candida parapsilosis, and Candida tropicalis) and bacteria (Escherichia coli, S. aureus, and Bacillus cereus) (Thaigarajan Parumasiyam. 2020).

Terminalia catappa: Tropical almond (Terminalia catappa) is a large tree distributed throughout the tropics in coastal environments (Khan AA. 2014). It is considered one of the important medicinal plants in the world. According to Ayurveda and Siddha, T. catappa is useful in the treatment of inflammation diseases, wound healing, allergies, skin related problems, asthma, ulcer, cardiovascular diseases, diarrhea, etc (Pranjali Chole. 2020).

The ointment prepared by bark extract of *Terminalia catappa* on excision wound in wistar albino rats (200– 250 gm) showed wound healing properties by exchibiting 97% reduction in wound area as compared to the control animals (81%). The wound healing activity of ethanolic and aqueous extracts of *T.catappa* leaves and bark showed moderate to good antibacterial activity when compared to that of the standard antibiotic Ciprofloxacin (10 µg/ml) (NEELAVATHI P. 2013). It is studied that the bark extract shows effective activity against wound healing as it is antimicrobial as well as antioxidant in nature. It induces the growth of epithelial tissue faster (Anand AV. 2015). From the study of Oyindamola O. Abiodun. (2016) the beneficial effect of ETCB in the TNBS induced colitis in rats could be related to its antioxidant, *Terminalia catappa*'s immunomodulatory and anti-inflammatory activities, which could be attributed to the phenolic compounds identified.

Cassia fistula Linn. (Cassia) commonly known as Amulthus in english popularly called "Indian Laburnum" has been extensively used in Ayurvedic system of medicine for various ailments. The leaves posses anti periodic and laxative properties, the leaves are used in jaundice, piles, rheumatism, ulcers and also externally skin eruptions, ring worms, eczema. The leaves and bark mixed with oil are applied to pustules, insect bites (Kirtikar K.R. 2006) From the study of Muthusamy Senthil Kumar(2006) C. fistula treated rats showed, better wound closure, improved tissue regeneration at the wound site, and supporting histopathological parameters pertaining to wound healing. Biochemical analysis and matrix metalloproteinases expression correlated well with the results thus confirming efficacy of C. fistula in the treatment of the infected wound. Methonolic extract of Cassia fistula leaves were examined for its wound healing property in the form of an ointment in excision and incision wound models. The ointment of two different concentrations of (5% and 10% w/w ointment of leave extract in simple ointment base) responded significantly in both models of wounds tested. The results were also comparable to the standard drug, Nitrofurazone, in terms of wound contraction ability, epithelisation period, tensile strength and regeneration of tissue at wound area (Bhakta T. 1998).

#### 5.CONCLUSION

A 3 months treatment of non healing ulcer with 5 grams of *Itrifal-e-shahatra* with hot water morning and evening as a supportive treatment for internal use with *Ta'leeq* (Hirudotherapy) as a 1<sup>st</sup> line of treatment along with wound cleaning with normal saline water till the healthy granulation tissue appears on the wound and then the local application of herbal paste contains equal amount of dried peels of *Punica granatum*, rhizomes of *Curcuma aromatica*, bark of *Terminalia catappa and* leaves of *Cassia fistula* over the wound every other day have markedly reduced continuous watery discharge from the wound, size and depth of the wound and promoted formation of healthy granulation tissue by blood purification, anti inflammatory, anti microbial, anti oxidant, wound healing, blood circulation promoting properties of various drugs and evacuation of morbid humours from the blood and injecting of various bio active substances having lots of biological properties at the site of biting.

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