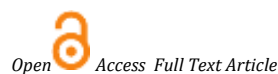


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Case Report

## Efficacy of *Irsal-i-Alaq* (Hirudotherapy) in the Management of Venous Ulcer: A Case Report

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### Abstract

**Background:** The most frequent and recurring type of leg ulcers seen in general practise is a venous ulcer (stasis ulcer). Its neglect has a considerable negative influence on quality of life, might result in gangrene, and may necessitate amputating the affected limb. The most serious and incapacitating complication of chronic venous insufficiency is venous ulcer. The conventional system of medicine offers limited clinical evidence for its effectiveness and usually needs amputation. Hence, it can be managed well by one of the Unani regimens, i.e., *Irsal-e-Alaq* (Hirudotherapy). **Objective:** The purpose of this case report is to provide insight into the effects of *Irsal-e-Alaq* (Hirudotherapy) in venous ulcer. **Intervention:** A 53-year-old male who has complaints of ulcer in left lower leg near lateral malleolus with swelling, pain, discharge and darkening of skin of left lower limb. Four leeches were applied once every 15 days for 45 days. Ulcer was assessed on 0<sup>th</sup> day, 15<sup>th</sup> day, 30<sup>th</sup> day and 45<sup>th</sup> day on the basis of area of the wound in a square centimetre, appearance of healthy granulation tissues, epithelization in percentage and depth of wound in centimetres, pain (VAS scoring), discharge, smell and number of wounds. **Results:** on the first day wound size was 4 cm long, 3 cm wide, 2 cm deep and the floor filled with dark granulation tissue with 0 % epithelization, discharge, pain and smell. On the 45<sup>th</sup> day ulcer was completely healed with 100% epithelization. **Conclusion:** *Irsal-e-Alaq* has been proven beneficial in treating venous ulcers and enhancing patients' quality of life. To determine the effectiveness of *Irsal-e-Alaq* in the management of venous ulcer, rigorous, controlled, randomised, blinded, and long-term follow-up studies on high sample sizes are required.

**Keywords:** Hirudotherapy, Unani Medicine, Leech Therapy, Varicose Ulcers

## INTRODUCTION

An ulcer is a discontinuity of the skin or mucous membrane that develops as a result of the tissue's microscopic death.<sup>1</sup> The most severe and disabling result of chronic venous insufficiency (inadequate functioning of venous valves) in the lower limbs is the venous ulcer (stasis ulcer), which accounts for 80% of ulcerations in the lower extremities.<sup>2</sup> Venous ulcers are caused by venous insufficiency, because of prolonged venous hypertension causes the valves of the perforator veins to become incompetent therefore allowing blood to back flow and pool. It is the fact that congested capillaries seep protein, fibrin and red blood cells through the capillary walls into the intercellular spaces. This in turn causes stasis and oedema that decreases tissue perfusion and leads to ulceration and cellulitis.<sup>1,3</sup> Various other causes for venous ulcerations could be arterial insufficiency, prolonged pressure, diabetic neuropathy and systemic illness such as rheumatoid arthritis, vasculitis, osteomyelitis, and skin malignancy.<sup>4</sup> Predisposing factors to the development of venous leg ulcers are: varicose veins, previous deep vein. Thrombosis (DVT), obesity, previous ulceration, pelvic occlusion, prolonged limb dependency.<sup>5,6,7</sup>

Venous ulcers are more prevalent in women and older persons. The overall incident rate in male is 0.76% and 1.42%

in the female population.<sup>5,8</sup> Venous ulcer is usually located on the medial side of lower one third (medial malleolus) of the leg in cases of long saphenous varicosity and on the lateral aspect (lateral malleolus) of the leg in short saphenous varicosity. It is shallow and superficial and never penetrates deep fascia. Usually painless and causes pain if it is infected or causes periostitis tibia. Usually associated with varicose veins. Typically, lower leg around the ulcer is pigmented.<sup>1</sup> They can be quite large but are usually shallow and flat with irregular borders and exudate. The affected limb can be oedematous and reddish brown in colour. The tissue surrounding the wound is thickened and it is common for dermatitis and the pain is dependent. Their Pulses can be palpable or absent and Ankle Brachial Index (ABI) may be >0.8. <sup>9</sup> Around 70 to 90% of chronic leg ulcer is of venous origin. They are often recurrent and may sometimes persist from weeks to years and if left untreated or not properly treated, giving rise to the complications like cellulitis, osteomyelitis, gangrene and even amputation of the affected limb and at times malignant change.<sup>5,8</sup> Recurrence is very common in 54 to 78% cases by the fifth year of healing. <sup>8</sup> In spite of low overall prevalence, the refractory nature of these ulcers causes an increased risk of morbidity, mortality and a significant impact on quality of life.

The father of medicine, Hippocrates, suffered from a leg ulcer. He was cleaning the wound with wine while treating it with various types of boiling herbs. To dry and comfort the wound, he also used different salts, copper oxides, and lead.<sup>10</sup> *Jarahat* (wound) is defined as the *Tafarruq-e-ittiṣal of laḥm* (wear and tear of muscle) free from pus. It is a severe *Tafarruq-e-ittiṣal* in any part of the body, especially in those structures which are soft and delicate. *Qurūḥ* (ulcers) according to the Unani system of medicine are *Tafarruq-e-ittiṣal of laḥm* (wear and tear of muscle) is associated with pus formation in it. *Qurūḥ* (ulcers) can be classified into 3 categories: <sup>10,11,12,13,14</sup>

**Qurūḥ-e-Baseet (simple ulcer):** The ulcer is free from those factors which may delay the healing process.

**Qurūḥ-e- Murakkab (compound ulcer):** The ulcer which is associated with pain, suppuration, and blackening of surrounding tissue.

**Qurūḥ-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.

In the Unani system of medicine, there are three methods of treatment viz; *Ilaj Bit Tadbeer wa Ghiza* (Regimenal therapy and Dietotherapy), *Ilaj Bil Dawa* (Pharmacotherapy) and *Ilaj Bil Yad* (Surgery).<sup>15,16</sup> Amongst these, *Ilaj Bit Tadbeer* is one of the most popular methods of treatment practiced by ancient Unani physicians for ages. *Ilaj Bit Tadbeer* means treatment through regimens, which is done by doing modification in *Asbabe Sitta Zarooriya* (six essential factors for life) in order to attain general health. It includes regimens like *Hijamat* (Cupping), *Dalk* (Massage), *Irsal-i-Alaq* (Leeching/Hirudotherapy), *Fasd* (Venesection), *Qai* (Emesis), *Idrar* (Diuresis), *Hammam* (Bathing), *Tareeq* (Diaphoresis), *Nutool* (pouring of medicated water slowly over an affected part from a distance).<sup>15</sup> These regimens are actually meant for the *Istefragh* (evacuation) of *Akhlate raddiya* (morbid humours), from the body or affected site. As soon as these morbid humors get evacuated, normal health gets restored, and vitality of the body gets increased.<sup>17</sup>

Ancient Egyptian, Indian, Greek-o-Arab physicians used leeches for a wide range of diseases starting from conventional use for bleeding to systemic ailments such as skin diseases, nervous system abnormalities, vascular diseases, inflammation, cardiovascular problems, cancer, and infectious diseases. Leech application has been used traditionally for the treatment of non-healing ulcers like venous ulcer. Leech saliva contains bioactive peptides and proteins involving

antithrombin (hirudin-prevents clotting, converts fibrinogen into fibrin and relieves ischaemic events, bufrudin), antiplatelet (calin-obstruct thrombi formation, saratin), factor Xa inhibitors (lefaxin), antibacterial (theromacin, theromyzin) and others, so it is used as a protective tool for venous congestion and prevents venous ulcer complications like gangrene, amputation and helps in ulcer healing.<sup>18</sup> It is also mentioned in *Jarahat-e-Zohrawia* that more often leeching can be done in those areas of the body where other procedures of bloodletting (viz., venesection, and wet cupping) are not possible.<sup>17</sup>

Present work is an attempt to highlight the role of *Irsal-e-Alaq* in alleviating venous ulcer.

## MATERIALS AND METHODS

**Selection of case-** A diagnosed patient with venous ulcer was taken for the study from Regimenal therapy OPD of National Institute of Unani Medicine.

### Case presentation

This patient was a 53-year-old male who attended our outpatient department of the National Institute of Unani Medicine on 13/03/2022 with three years history of varicose veins from last five years. He had complaints of ulcer in the left lower leg, pain, swelling in the left lower leg and darkening of skin over left lower leg. He was managing the condition with antiseptic dressings and oral antibiotics. He took treatment at multiple care centres but had no relief. The patient had no comorbidities and there was no history of smoking/alcohol/drug/ tobacco chewing.

The systemic examination of the patient was done, and all the vital parameters were found within normal limits. Sensory functions (pain, touch, pressure and temperature) were normal. The patient was hemodynamically stable. X-ray of the foot shows no bony involvement.

### Local Examination

In standing position long, tortuous, dilated veins were seen over bilateral lower limbs. Localized swelling also observed on the anterolateral aspect of the left lower leg along the course of the long saphenous vein. The skin of the lower left leg was hyperpigmented and thickened. There was no impulse on coughing at the saphenous opening. Also, the dorsalis pedis arterial pulsation was felt. Varicosity of the vein was confirmed by Trendelenburg's test and was found positive. No lymph node found palpable.

**Table 1: Findings of local examination of a venous ulcer**

| Examination       | Findings                                  | Examination       | Findings   |
|-------------------|-------------------------------------------|-------------------|------------|
| <b>Inspection</b> |                                           | <b>Palpation</b>  |            |
| Site              | Above lateral malleolus of left lower leg | Discharge         | Purulent   |
| Size              | 4 cm x 3 cm x 2 cm                        | Smell             | Foul       |
| No. of wounds     | one                                       | Local temperature | Not raised |
| Shape             | oval                                      | Local Tenderness  | Present    |
| Margins           | Hyperpigmented and irregular              | Margins           | Indurated  |
| Floor             | Dark granulation tissue present           | Base              | Mobile     |
|                   |                                           | Bleeding on touch | absent     |

**Informed consent:** Patient was willing for this study and informed consent was taken before the start of intervention.

**Intervention:** His vitals were stable (BP = 120/70 mmHg, Pulse rate = 76/min, Respiratory rate = 19/min, Temperature = 98.5°F). All routine blood tests were performed prior to

starting leech therapy on the patient and found to be within normal ranges for the following tests: complete haemogram, biochemical profile (fasting and postprandial blood sugar levels, blood urea, serum creatinine), bleeding and clotting time, and viral markers (HIV I and II, HbsAg). Following the evaluation, the patient's left lower leg was washed with sterile

distilled water and four leeches (*Hirudo medicinalis*) were applied around the ulcer for 30 to 40 minutes. The patient was kept under observation for any discomfort or allergic responses during this time. Upon leech auto-detachment, a small amount of blood was permitted to leak from the leech's attachment site. As soon as blood was sucked out, the site was immediately squeezed with a gauze pad and a tight cotton bandage was applied. This technique was done at each sitting. Based on the results of a capillary refilling test and the haemoglobin level (1.4 gm%), one sitting of Hirudotherapy (*Irsal-i-Alaq*) was administered once every 15 days for around 45 days. Telephonic follow up was done for five months and the patient was instructed that if he experienced any of the reoccurrences of symptoms in the future, he should immediately report to the hospital, but there was no re-occurrence of any of the signs and symptoms again. Following every procedure, the patient underwent four sessions of leech therapy, and the outcomes were quite satisfactory.

**Duration of Study:** 45 days

**Assessment:** ulcer was assessed on 0<sup>th</sup> day, 15<sup>th</sup> day, 30<sup>th</sup> day and 45<sup>th</sup> day on the basis of pain (VAS scoring), discharge, smell, number of wounds, and area of the wound in a square centimetre, appearance of healthy granulation tissues, epithelization in percentage and depth of wound in centimetres.

## RESULT

The patient's symptoms and signs significantly improved with leech therapy, as shown by the pictographic presentation in **Figs. 1-6** and **Table 2**. Other signs and symptoms like; Discolouration and swelling over the left lower leg also decrease with sittings of leech therapy.



Figure 1: BEFORE TREATMENT



Figure 2: 1<sup>st</sup> SITTING



Figure 3: 2<sup>nd</sup> SITTING



Figure 4: 3<sup>rd</sup> SITTING



Figure 5: 4<sup>th</sup> SITTING



Figure 6: AFTER TREATMENT

**Table 2: Assessment and prognosis of venous ulcer**

| Assessment Parameters        | Before Treatment | During Treatment    |                      |                        |                      |
|------------------------------|------------------|---------------------|----------------------|------------------------|----------------------|
|                              |                  | 0 <sup>th</sup> day | 15 <sup>th</sup> day | 30 <sup>th</sup> day   | 45 <sup>th</sup> day |
| Size in sq. cm               | 4cm x 4cm x 3cm  | 4cm x 3cm x 2cm     | 2 cm x 2 cm x 1.5 cm | 1 cm x 0.5 cm x 0.5 cm | 0                    |
| No. of wound                 | 1                | 1                   | 1                    | 1                      | 0                    |
| Granulation tissue in %      | 40 %             | 40 %                | 70 %                 | 90 %                   | 100 %                |
| Epithelization in percentage | 0 %              | 0 %                 | 40 %                 | 80 %                   | 100 %                |
| Discharge                    | Moderate         | Moderate            | Moderate             | Mild                   | Absent               |
| Smell                        | Moderate         | Moderate            | Mild                 | Absent                 | Absent               |
| Pain (VAS)                   | 5                | 5                   | 3                    | 2                      | 0                    |

## DISCUSSION

In this case report, 53 years old man who had venous ulcer in left lower leg just above lateral malleolus was studied for 45 days. The patient was given Leech therapy for local

application. In the conventional system of medicine, antiseptic dressings, certain medicines like oral antibiotics, local antibiotics and surgery can improve symptoms in some cases but not completely. So, it is the need of the hour to develop a treatment that can provide complete healing for venous ulcer



and reduce symptoms related to it, without any side effects. With the advances made in the medical sciences, leeches can work wonders in such circumstances. Considering the above-mentioned aspects, *Irsal-i-Alaq* (Leech Therapy) was selected to evacuate morbid humors from the blood vessels by its sucking property and hence found effective in this case. The reasons by which leech therapy has worked is that the presence of several pharmacologically active substances and enzymes in the leech's saliva, i.e., hirudin, hyaluronidase, Eglin, calin, bdellins, etc. Hirudin, calin are anticoagulant, as main cause of venous ulcer is venous insufficiency which cause stasis and these enzymes from leech's saliva helps in decreasing stasis and slowly cleansing the wound by maintaining secondary bleeding for approximately another 12 hours.<sup>19,20</sup> Histamine-like substances have a dilatation effect on the blood vessels and thereby causes an increase in the bloodstream to the bite site and helps in wound healing due to circulation.<sup>19,20</sup> The hyaluronidase increases the membrane permeability, reduces the viscosity, and promotes the diffusion of injected fluids and acts as antibiotic.<sup>19,20</sup> Bdelin and Eglin enzymes acts as an anti-inflammatory, antioxidant and a protease inhibitor and inhibits trypsin, plasmin, and acrocin and reduces the swelling due to venous congestion.<sup>19,20</sup> Eglin is well tolerated on the central nervous system and prevents neutrophil infiltration (adhesion, penetration, and migration) into inflamed vessels and neutrophil-mediated injury to the microvascular endothelium, thus helps in granulation.<sup>19,20</sup> Apyrase is a nonspecific inhibitor of platelet aggregation by its action on adenosine 5' diphosphate, arachidonic acid, platelet-activating factor (PAF), and epinephrine.<sup>19,20</sup> Destabilase: Dissolves fibrin and has thrombolytic effects which helps in healing.<sup>19,20</sup> Acetylcholine is a vasodilator which decreases stasis and increases blood circulation towards ulcer which promotes healing.<sup>19,20</sup> As per the Unani concept, impure blood is extracted from the body, thus releasing the body from toxins, and the circulation of fresh blood takes place at the site of the lesion, which makes the healing process easier. The patient was asked to follow up in OPD. However, no re-occurrence of any signs and symptoms were seen. *Irsal-i-Alaq* (Leech Therapy) proved very effective in this patient of venous ulcer. However, further evaluation with a large sample size is required to show its significance for venous ulcer.

## CONCLUSION

To conclude, *Irsal-i-Alaq* (Leech Therapy) has been used as a popular therapeutic practice throughout the ages for a wide range of diseases. It is a relatively simple and inexpensive treatment modality and very effective in venous ulcers. It removes dead tissue slough and helps in the growth of healthy granulation tissue and epithelization. On the basis of the results of the present case, it appears that such cases of venous ulcer can be managed with *Irsal-e-Alaq* and can improve the quality of life with a relative long-term clinical efficacy in such patients without any side effects, but the investment is urgently needed for advanced research of this therapy. The use of this therapy on a scientific basis is the need of the hour. Therefore, robust clinical trials using appropriate endpoints need to be conducted. Leech therapy will result in speedy and effective management in venous ulcer and will thus discourage the risk of amputation in venous ulcer patients. This case report strategy Recommends for taking it up for further studies to dealing *Irsal-i-Alaq* (Leech Therapy) as an effective drug for venous ulcer.

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## REFERENCES

- Shenoy RK. Manipal Manual of Surgery. New Delhi, India: CBS Publishers & Distributors; 2010.
- O'Meara S, Al-Kurdi D, Ologun Y, Ovington LG, Martyn-St James M, Richardson R. Antibiotics and antiseptics for venous leg ulcers. Cochrane Database Syst Rev. 2014 Jan 10; (1):CD003557. <https://doi.org/10.1002/14651858.CD003557>
- Pascarella L, Schönbein GW, Bergan JJ. Microcirculation and venous ulcers: a review. Ann Vasc Surg. 2005 Nov; 19(6):921-7. <https://doi.org/10.1007/s10016-005-7661-3>
- de Araujo T, Valencia I, Federman DG, Kirsner RS. Managing the patient with venous ulcers. Ann Intern Med. 2003 Feb 18; 138(4):326-34. <https://doi.org/10.7326/0003-4819-138-4-200302180-00012>
- Abbate LP, Lastória S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. Int J Dermatol. 2005 Jun; 44(6):449-56. <https://doi.org/10.1111/j.1365-4632.2004.02456.x>
- Das SA. A Concise Textbook of Surgery. 3rd edition. Calcutta:13, Old Mayor's Court. 2001:209-211.
- Smith PC. The causes of skin damage and leg ulceration in chronic venous disease. Int J Low Extrem Wounds. 2006 Sep; 5(3):160-8. <https://doi.org/10.1177/1534734606292429>
- Margolis DJ, Bilker W, Santanna J, Baumgarten M. Venous leg ulcer: incidence and prevalence in the elderly. J Am Acad Dermatol. 2002 Mar; 46(3):381-6. <https://doi.org/10.1067/mjd.2002.121739>
- Bergan JJ, Schmid-Schönbein GW, Smith PD, Nicolaidis AN, Boisseau MR, Eklof B. Chronic venous disease. N Engl J Med. 2006 Aug 3; 355(5):488-98. <https://doi.org/10.1056/NEJMra055289>
- Kabiruddin AM, kulliyat -e-Nafisi. New Delhi: Idara kitabus-shifa; p 176.
- Arzani HA, Mizan-ul-tib. (Kabirrudin HM translation). New Delhi: Idara kitab-us-shifa 2002; p 268
- Majoosi HA, Kamil-us-sana (kantoori GH translation). New Delhi: Idara kitab-us-shifa: 2010; p 438
- Razi A.M.B.Z, kitab-al-Mansoori.1st ed. New Delhi: CCRUM; 1991: p 262
- Arzani AH, Tibbe Akbar (Urdu translation by Mohammad Hussain). Deoband: Faisal publication YNM: p 772-773
- Tanzeel Ahmed, Mohd Anwar, Clinical Importance of Leech Therapy, Indian Journal of Traditional Knowledge, 2009; 8: 443-445.
- K. Jha, A. Garg, R. Narang, S. Das, Hirudotherapy in Medicine and Dentistry, Journal of Clinical and Diagnostic Research, 2015; 9: ZE05-ZE07. <https://doi.org/10.7860/JCDR/2015/16670.6918>
- M. Saqlain, F.Ali, A. Parveen, A. Riaz, Benefits of Leech Therapy in Unani System of Medicine: A Review, World Journal of Pharmacy and Pharmaceutical Sciences, 2016; 5: 559-569. DOI: <https://doi.org/10.20959/wjpps20164-6364>
- Abdulkader AM, Ghawi AM, Alaama M, Awang M, Merzouk A. Leech therapeutic applications. Indian J Pharm Sci. 2013; 75(2):127-137.
- Zaidi SM, Jameel SS, Zaman F, Jilani S, Sultana A, Khan SA. A systematic overview of the medicinal importance of sanguivorous leeches. Altern med rev, 2011 Mar 1; 16(1): 59-65.
- Kumar S, Dobos GJ, Rampp T. Clinical Significance of Leech Therapy in Indian Medicine. J Evid Based Complementary Altern Med. 2013 Apr; 18(2):152-158. <https://doi.org/10.1177/2156587212466675>