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Effectiveness of homoeopathic medicines in reducing the size of non-specific chronic leg ulcers - A single-arm, prospective observational study

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Abstract

Background: A chronic leg ulcer (CLU) is a chronic wound of the leg that does not tend to heal easily. Venous, arterial insufficiency, diabetes mellitus, or a combination of these factors may cause pain, restricted mobility, impaired social activities, and increased personal expenses, all of which can adversely affect the quality of life. **Objectives:** To determine the effectiveness of homoeopathic medicines in reducing the size of non-specific chronic leg ulcers using the Leg Ulcer Measurement Tool (LUMT) and changes in the quality of life by the Euro QoL (EQ-5D-3L) score. **Materials and methods:** A prospective clinical study was conducted at the National Homoeopathy Research Institute in Mental Health, Kottayam, India, from February 2021 to August 2022, and was registered in CTRI/2021/02/030951. Out of 35 cases, 34 completed the treatment for six months and were analyzed by evaluating the size of the ulcer, LUMT score, and Euro QoL score at baseline, as well as at the 3rd and 6th months. **Results:** Of 52 screened patients, 35 were enrolled and prescribed individualized homoeopathic medicine. Statistically significant reduction was observed in the size of the ulcer, from 5.6 cm² to 0 and in the LUMT score from 31 to 7 ($p < 0.001$). *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum*, and *Pulsatilla nigricans* were frequently indicated, and no serious adverse events were recorded during the study. **Conclusion:** The study determined that individualised Homoeopathy effectively reduces the size of non-specific chronic leg ulcers and improves patients' QoL. Well-designed pragmatic trials are warranted.

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ORIGINAL ARTICLE

Effectiveness of homoeopathic medicines in reducing the size of non-specific chronic leg ulcers - A single-arm, prospective observational study

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ABSTRACT

Background: A chronic leg ulcer (CLU) is a chronic wound of the leg that does not tend to heal easily. Venous, arterial insufficiency, diabetes mellitus, or a combination of these factors may cause pain, restricted mobility, impaired social activities, and increased personal expenses, all of which can adversely affect the quality of life. **Objectives:** To determine the effectiveness of homoeopathic medicines in reducing the size of non-specific chronic leg ulcers using the Leg Ulcer Measurement Tool (LUMT) and changes in the quality of life by the Euro QoL (EQ-5D-3L) score. **Materials and methods:** A prospective clinical study was conducted at the National Homoeopathy Research Institute in Mental Health, Kottayam, India, from February 2021 to August 2022, and was registered in CTRI/2021/02/030951. Out of 35 cases, 34 completed the treatment for six months and were analyzed by evaluating the size of the ulcer, LUMT score, and Euro QoL score at baseline, as well as at the 3rd and 6th months. **Results:** Of 52 screened patients, 35 were enrolled and prescribed individualized homoeopathic medicine. Statistically significant reduction was observed in the size of the ulcer, from 5.6 cm² to 0 and in the LUMT score from 31 to 7 ($p < 0.001$). Furthermore, Euro QoL was also measured at baseline, and the results at 3rd and 6th months were compared and analyzed using Friedman's test, with a significant reduction from 13 to 5 ($p < 0.001$). *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum*, and *Pulsatilla nigricans* were frequently indicated, and no serious adverse events were recorded during the study. **Conclusion:** The study determined that individualised Homoeopathy effectively reduces the size of non-specific chronic leg ulcers and improves patients' QoL. Well-designed pragmatic trials are warranted.

Keywords: Arterial ulcer, Chronic leg ulcer, Euro QOL score, Homoeopathy, LUMT score, Traumatic ulcer, Varicose ulcer

Introduction

Chronic leg ulcer (CLU), [ICD-10-L97.909], also known as chronic lower limb ulcer, is a chronic wound of the leg that fails to heal despite appropriate treatment for three months to even a year.¹ However, an ulcer is “a break in the continuity of the overlying epithelium of the skin or mucosa.” It results in complete loss of the epidermis and often a portion of the dermis and subcutaneous fat.² The prevalence of chronic leg ulcers ranges from 1.9% to

13.1%, a common cause of morbidity.³ Worldwide, chronic wounds manifest in 60% of patients with leg ulcers, and 2.5% is the wound-related mortality rate, particularly in India, where its prevalence is 4.5 per 1000 population.^{4,5}

However, the CLU affects 0.6% to 3% of those over 60 years old and increases to more than 5% of those over 80 years old.⁶ This incidence of ulceration is rising due to the ageing population and increased risk

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of factors for atherosclerotic occlusion, like smoking, obesity, and diabetes mellitus.⁷

The leading causes of these CLUs are venous, arterial insufficiency, neuropathy, diabetes mellitus (DM), or a combination of these factors.⁵ Of these 81% of ulcers have been reported due to venous disease, 16.3% are arterial ulcers, and 15% are reported as diabetic foot ulcers.⁶

A study in India shows that the causes of chronic wounds include systemic conditions such as DM, atherosclerosis, tuberculosis, and leprosy. Other major causes are venous ulcers, pressure ulcers, vasculitis and trauma. Old age, malnutrition, obesity, poor hygiene, varicose veins, intravenous drug abuse, and deep vein thrombosis are the other factors that coexists.⁸ Diseases like diabetes mellitus, peripheral arterial disease, rheumatoid arthritis, and systemic vasculitis, also adversely affect the treatment and prognosis of these CLU.⁹

CLU impacts the quality of life with pain, impaired sleep, restricted mobility, work capacity, and increased personal expenses. Also, social activities are restricted due to fear of injury and negative body image.^{6,10}

Conventional medicine usually treats CLU with pentoxifylline, flavonoids, nutritional supplements, aspirin, and antibiotics.¹¹ Besides, surgical management includes debridement and skin grafting, and further possibilities comprise saphenous vein ablation, subfascial endoscopic surgery, stenting, phlebectomy, stripping, sclerotherapy, or laser therapy.¹² The economic burden of managing patients with leg ulcers, especially varicose leg ulcers, in the UK's National Health Service (NHS) and the US is around £2 billion and \$14.9 billion, respectively.¹³

These classical surgical procedures, such as endovascular thermal procedures and sclerotherapy, offer less benefit in the healing of venous stasis ulcers and in preventing their recurrence.¹⁴

Homoeopathy, a personalised medicine, is based on the totality of the patient's symptoms, encompassing mental and physical makeup, apart from the particular (disease-related) symptoms, to determine the similimum.¹⁵ *Manchanda* and *Kulhashreshtha*, in their study, emphasized that Homoeopathy is quite popular, very cost-effective, and used extensively for common diseases and other chronic diseases such as atopic dermatitis, asthma, migraine, and depression.^{16,17}

A case report¹⁸ of a long-standing venous ulcer was treated with homoeopathic medicine *Graphites*, and another case report¹⁹ with a recurring venous ulcer was treated with *Lycopodium Clavatum*, *Arsenicum album*, and *Natrum muriaticum*,

based on the symptomatology. Further, a case report²⁰ of Diabetic Foot Ulcer was treated with *Lycopodium clavatum*, *Natrum muriaticum*, *Arnica montana*, *Arsenicum album*, *Ipecac*, *Natrum sulph* and *Silicea* in different potencies at different intervals. Another DFU²¹ was managed with *Hepar sulphuris calcareum* and standard care management.

However, a five-case series of venous stasis and dermatitis was treated with individual homoeopathic treatment.²² A study on a novel wound healing powder, *MittiHeal*, a homoeopathic and natural powder composed of a mixture of *Calendula officinalis*, *Arnica montana*, *Mentha arvensis*, and *Santalum album*; reported the product to have potential antimicrobial and healing effects on venous leg ulcers.²³

An observational study found that *Silicea*, *Sulphur*, *Lycopodium*, *Arsenicum album* and *Phosphorus* had positive results in DFU.²⁴

A Randomised Controlled Trial (RCT) on leg ulcers found that the Homoeopathic medicine combination of *Sulphur*, *Silicea* and *Carbo vegetabilis* 6c potency was very effective.²⁵

Another randomized, placebo-controlled, double-blind trial on varicose veins results indicate that a combined homoeopathic medicine (*Poikiven*®) (the composition of medicine: *Aesculus Hippocastanum* D1, *Arnica Montana* Q, *Silbyum marianum* D1, *Hamamelis Virginiana* D1, *Lachesis mutus*D6, *Lycopodium clavatum* D4, *Melilotus officinalis* D3), reduces the subjective complaints of cramps, itching, heaviness in the limbs, and pain during standing without any side effects.²⁶

Moreover, another RCT was conducted on DFU using individualized Homoeopathy with wound hygiene, and it was found that *Arsenicum album*, *Lycopodium*, *Silicea*, *Phosphorus*, and *Sepia* proved effective in promoting early and complete epithelialization at different stages of ulcers.²⁷

However, the increasing incidence, prevalence, and economic burden of chronic leg ulcers increase the scope of Homoeopathy in the field. This observational study aimed to determine the effectiveness of individualized homoeopathic management in reducing the size of Non-specific chronic leg ulcers using the Leg Ulcer Measurement Tool (LUMT)²⁸ and changes in the quality of life by using the Euro QOL (EQ-5D-3L) Health Questionnaire.²⁹

Materials and methods

Study design

This study was a single-arm, prospective observational study.

Study settings

National Homoeopathy Research Institute in Mental Health, Kottayam, India, from February 2021 to August 2022. The total duration of the study was 18 months (6 months for enrollment and 12 months of follow-up, due to the COVID-19 pandemic, the follow-up was reduced to six months with the approval of the IEC.

Study participants

Inclusion criteria

The study group consisted of individuals aged 18–75 years who presented with a leg ulcer older than three months that was not healing despite appropriate treatment. All individuals, regardless of gender, who were willing to participate in the study were included.

Exclusion criteria

Participants with diabetic foot ulcers, diabetic gangrene, trophic ulcers, thrombophlebitis, leprosy, tuberculous ulcers, and pregnant and lactating mothers were excluded.

Method of selection of the participants

Participants who were pre-diagnosed or reported a non-healing ulcer on a leg, as defined, and with specific clinical presentations,¹ underwent verbal screening. After the detailed screening, participants who met the inclusion criteria were informed about the trial, and written consent was obtained. All cases were subjected to a detailed case taking in a Case Recording Format (CRF) formulated for the purpose, including the Clinical assessment of the ulcer, which is done by considering the Site (medial, lateral, anterior, posterior, or combination), size (measure two maximum perpendicular axes, tracing margin), depth, edge, margin, floor, base and condition of the surrounding skin followed by advised the baseline investigations, including a complete blood count, ESR, blood glucose level, fasting lipid profile, and renal function test, were performed.

A Doppler study of the lower extremity was also performed in cases with an appropriate indication to assess thrombophlebitis, venous, and arterial ulcers.

Variables

Outcomes

The primary outcome measure was the assessment of the healing ulcer, measured by the LUMT score. The LUMT consists of both clinician-rated and patient domains. The clinician-rated domain consists of 14 sub-items, including exudate type, exudate amount, size of the ulcer, depth, undermining, necrotic tissue

type, necrotic tissue amount, granulation tissue type, granulation tissue amount, edges, periauricular skin viability, leg oedema type, leg oedema location and assessment of bioburden scores in the Likert scale. The patient's (Proxy) rated domains consist of 3 sub-items: pain amount (measured on a numerical rating scale), pain frequency, and quality of life. Adding to the total domains score is the total LUMT score. The score ranges from 0 (healed) to 68 (worst).

The secondary outcome measure was the quality of life, as assessed by the EuroQoL, a widely used tool that describes a patient's quality of life. This questionnaire has five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, as well as a Visual Analogue Scale (VAS) for self-rated health. Each dimension uses a 5-level Likert scale (1 = no problems, 5 = extreme problems), ensuring nuanced data collection. The VAS ranges from 0 (the worst imaginable health) to 100 (the best imaginable health). Sum the scores from each dimension (1–5), yielding a total of 5–25. Higher scores indicate worse health status.

The LUMT & EuroQoL scales were used to assess at baseline, and follow-up was performed periodically every month. Photographs of the ulcer of each participant were maintained separately at the beginning of the study, at each follow-up, and at the end of the study to analyse the changes.

Thus, the distinct values of the participants at the baseline, third month, and sixth month were used for statistical analysis, and values before and after the treatment were used to analyse the results.

The percentage of improvement was calculated using the formula. $(\text{Baseline value} - \text{End value} / \text{Baseline value}) \times 100$ and values interpreted as Marked Improvement if the score is >75%, Moderate improvement if the score is between 50–75%, Mild Improvement if 25–50% and No significant improvement, if the score turned out to be <25%. The status quo was mentioned if the score was 0%.

Confounders

In the present study, several potential confounders were identified that could influence the healing outcomes. These included patient-related factors such as age, sex, nutritional status, smoking or alcohol use, and the presence of comorbidities like diabetes mellitus, peripheral vascular disease, hypertension, or obesity. Ulcer-specific characteristics, such as duration, size, depth, aetiology, infection status, and history of recurrence, may also affect the response to treatment. Additionally, treatment-related variables such as individualization of homoeopathic prescriptions, concurrent conventional medications, adherence to

therapy, and local wound care practices could modify the results. Lifestyle and environmental factors, including physical activity, occupation, socioeconomic status, and hygiene, as well as psychological aspects such as stress or treatment expectations, may also act as confounders. These variables were considered during data analysis to minimize bias and to ensure a more accurate assessment of treatment outcomes.

Bias

In this study, potential sources of bias included selection bias from enrolling motivated or compliant participants, information and measurement bias due to subjective assessment of ulcer healing, and confounding bias from comorbidities such as diabetes, vascular disease, and nutritional factors that may influence outcomes. Observer and recall bias may also affect clinical evaluation and patient history. Efforts were made to minimize these through standardized assessment methods, such as measuring the ulcer by the first author under the supervision of the second author, as well as photographic evidence, consistent documentation, and regular follow-up; however, some residual bias cannot be completely ruled out.

Ethical statements

This study protocol was prepared in accordance with the Declaration of Helsinki³⁰ and the ethical guidelines for Biomedical Research on human experimentation in India.³¹

The necessary ethics clearance was obtained from the NHRIMH Institutional Ethical Committee held on 24.07.2020 (Reference No: 4-59/2020-21/NHRIMH/Ktm /IEC/2401). This study was registered under the Clinical Trials Registry – India (CTRI/2021/01/040257).

Sample size

A formal sample size calculation was not performed because no previous published studies on this clinical condition were available. This study is one of its kind, and considering the availability of such subjects in the population standard, a sample size of 30 was selected. Expecting a 15% dropout rate, 35 participants were enrolled, and one participant dropped out; therefore, the final analysis was conducted with 34 participants.

Intervention

All cases were subjected to a detailed case taking in a standardized CRF formulated for the purpose, including the Clinical assessment of the ulcer, which

is done by considering the Site (medial, lateral, anterior, posterior, or combination), size (measure two maximum perpendicular axes, tracing margin), depth, edge, margin, floor, base and condition of the surrounding skin, after which the totality is elicited and repertorised by using HOMPATH³¹ or RADAR OPUS.³² The reportorial result was analysed according to the prevailing standardized *Materia Medica*, and individualized homoeopathic medicine was prescribed in adherence to the principles of the *Organon of Medicine*.³³ The medicines were dispensed from the institute's Pharmacy unit, which sources medicines from a Good Manufacturing Practices (GMP)-certified firm. With adherence to the protocol, 6C potency was administered initially, and the doses and potency were repeated as indicated. After the first prescription, participants were assessed according to the design outlined in the follow-up form of the study. The ulcer was cleaned and dressed with normal saline during follow-up, and the patient was also advised to do so as needed. Each case was reviewed at one-month intervals.

Participants who were unable to attend the OPD during the COVID-19 pandemic were provided with their prescribed medicine from nearby Kerala state government homoeopathic dispensaries by communicating with the relevant medical officers or pharmacies. A telephone assessment was conducted using LUMT and EuroQol Health Questionnaire scores, and a photograph was taken via WhatsApp. Acute cases were reviewed as needed and treated according to the totality of the indicated medicine. Changes in follow-up medicine were made according to the homoeopathic principles.³⁴

Auxiliary measures

Every participant was advised to follow a nutritious diet, in addition to ceasing smoking and alcohol consumption, where applicable. The ulcer was cleaned and dressed regularly with normal saline solution, accompanied by debridement as needed. Furthermore, elevating the legs at bedtime was recommended to help reduce oedema in venous ulcers.^{8,9} The participants were educated about the self-care of these ulcers, and prevention was advised to patients with any history of accessory illnesses, such as diabetes mellitus, hypertension, or hyperlipidemia, for which a specific diet was recommended.

Adverse events (AE)

AEs were not observed throughout the study period. No formal distinction could be made between true AEs and homoeopathic aggravation.

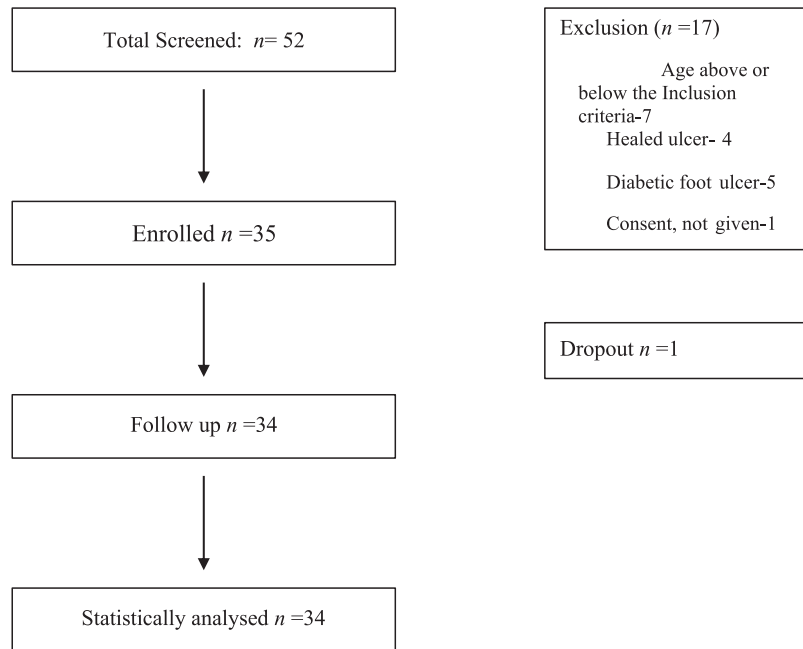


Fig. 1. Flow chart of the study.

Results

Out of 52 participants screened, only 35 could be enrolled as per the inclusion criteria, while 17 were excluded due to age, diabetic foot, and healed ulcer. One participant dropped out, and 34 participants were treated. The flow chart of patients in this study is shown in Fig. 1.

Baseline characteristics

The mean age of enrolled participants was 53.1 ± 10.67 years, with a minimum age of 26 and a maximum age of 73. It was observed that the maximum number of participants fell within the 46–55 age group. The demographic details of enrolled participants are presented in Table 1. Out of 34 cases, venous leg ulcers had the highest incidence, accounting for 88.23%; traumatic ulcers had an incidence of 5.88%. Arterial and mixed aetiology ulcers (arterial and venous) had 2.94%. Out of 34 cases, the right leg was affected in 16 cases (47.05%), the left leg was also involved in 16 cases (47.05%), and both legs were involved in 2 cases (5.9%).

Size of the ulcers

For the primary outcome measurement, the size of the ulcers was significantly reduced over the six-month treatment period. The size of the ulcers (cm^2) decreased significantly from 5.6 (2, 28.9) at

baseline to 1.0 (0, 15.25) at the third month and further decreased to zero (0, 9.5) at the end of the six-month study.

The Friedman test revealed a statistically significant difference across the three time points ($\chi^2_{(2)} = 53.294$, $p < 0.001$) in the size of the ulcer (measured in cm^2), with the median score decreasing from 5.6 to 0 over the six months. Post hoc analysis revealed a statistically significant reduction in ulcer size from baseline to the 3rd month ($p < 0.001$), whereas the reduction from the 3rd month to the 6th month was not statistically significant. However, the overall change from baseline to the 6th month remained statistically significant ($p < 0.001$) (Table 2).

Leg ulcer measurement tool (LUMT)

Among the 34 cases, the LUMT score was 31 (26, 37.25) at baseline, decreased to 18.5 (7, 29.25) at the third month, and further reduced to 7 (3, 20) at the sixth month, marking the end of the study. The Friedman test revealed a significant difference in LUMT scores across the study period ($\chi^2_{(2)} = 56.709$, $p < 0.001$), with the median score decreasing from 31 at baseline to 7 at the sixth month. Post hoc analysis revealed statistically significant differences between all pairs of time points: from baseline to the 3rd month, from baseline to the 6th month, and from the 3rd month to the 6th month (all $p < 0.001$) (Table 2).

In the LUMT score of 34 cases, 17 cases (50%) showed marked improvement (15 varicose ulcers and

Table 1. Sociodemographic of participants.

Sociodemographic profile	Total number of participants (including %)
Age in years	
18–25	0
26–35	2 (5.8%)
36–45	5 (14.7%)
46–55	13 (38.2%)
56–65	10 (29.4%)
66–75	4 (11.7%)
Gender	
Male	19 (55.9%)
Female	15 (44.1%)
Occupation	
Homemaker	9 (26.4%)
Farmer	6 (17.6%)
Manual Labour	5 (14.7%)
Salesman	5 (14.7%)
Health care profession	2 (5.8%)
Govt.Employee	2 (5.8%)
Teacher	1 (2.9%)
Homemaid	1 (2.9%)
Karate master	1 (2.9%)
Tailor	1 (2.9%)
Pastor	1 (2.9%)
Domicile	
Urban	11 (32%)
Rural	23 (68%)
Socioeconomic status	
Upper class	6 (18%)
Middle class	20 (59%)
Lower class	8 (23%)
Side affinity of the leg ulcers	
Right	16 (47.05%)
Left	16 (47.05%)
Both	2 (5.9%)
Type of ulcers	
Varicose ulcer	30 (88.24%)
Traumatic ulcer	2 (5.88%)
Arterial ulcer	1 (2.9%)
Mixed (arterial and venous)	1 (2.9%)

two traumatic ulcers), 7 cases (20.6%) showed moderate improvement (5 varicose ulcers, one arterial and one mixed aetiology ulcer), 9 showed (26.5%) mild improvement (9 varicose ulcers) and one case of varicose ulcer (2.9%) showed insignificant change.

European quality of life (Euro QoL)

The quality of life was assessed using the EuroQoL scale, which showed a reduction in score from baseline [13(12,15)] to the third month [10(6,10.25)] and further decreased to [5(5,9)] at the end of the six-month study, indicating an improvement in the quality of life. The EuroQoL scores measured at baseline, third, and sixth months showed a statistically significant difference over time, as indicated by the Friedman test ($\chi^2(2) = 60.016, p < 0.001$). In the post-hoc analysis, statistically significant differences

were observed in all pairwise comparisons ($p < 0.001$) (Table 2).

In the Euro QOL score, of 34 cases, 21 cases (61.8%) showed moderate improvement (18 varicose ulcers, one each case of arterial, mixed aetiology and traumatic ulcer), 11 cases (32.4%) showed mild improvement (10 varicose ulcers and one traumatic ulcer), and 2 cases (5.8%) showed no significance after the intervention (2 varicose ulcers).

Out of 34 cases, 30 (88.24%) had a varicose ulcer, 2(5.88%) had a traumatic ulcer, and 1 (2.94%) each had an arterial ulcer and a mixed arterial and venous ulcer. Sixteen patients (47.06%) had an ulcer on the right side, 16 patients (47.06%) had an ulcer on the left leg, and two patients (5.88%) had ulcers on both sides.

Twenty-four out of 34 cases (70.59%) completed six months of follow-up, three cases (8.82%) completed four months of follow-up, and seven patients (20.59%) completed three months of follow-up. Of those, 10 cases (29.41%) did not complete six follow-ups, but the ulcer was completely healed in 5 patients.

In 21 cases (61.76%), the ulcer healed completely. One case (2.94%) ulcer completely healed in the first month, 6 cases (17.65%) in the second month, 5 cases (14.71%) in the third month, 2 cases (5.88%) in the fourth month, 2 cases (5.88%) in the fifth month, and 5 cases (14.71%) in the sixth month.

The ulcer was partially healed in 13 cases (38.24%). Among these cases, 4 cases (30.8%) showed marked improvement, 4 cases (30.8%) experienced moderate improvement, 3 cases (23.1%) had mild improvement, and 2 cases (15.3%) demonstrated a reduction in ulcer size that was not significant. No cases showed the status quo of the ulcer.

Homoeopathic medicines prescribed

The medicines were prescribed as per the principles of individualized homoeopathy. Medicines frequently indicated were *Lycopodium clavatum* ($n = 8$), *Sulphur* ($n = 6$), *Lachesis mutus* ($n = 4$), *Phosphorus* ($n = 3$), *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum* and *Pulsatilla nigricans* ($n = 2$) and further *Calcarea carbonica*, *Causticum*, *Graphites*, *Petroleum*, and *Silicea* ($n = 1$) (Table 3).

In this study, the potency began with 6C potency and gradually increased to 12C, 30C, and 200C potencies based on the participant's condition. Of the 34 cases, 15 cases (44.11%, comprising 12 varicose ulcers, two traumatic ulcers, and one arterial ulcer) received treatment. In 13 cases (38.24%, 12 varicose ulcers and one mixed aetiology ulcer), the potency rose from 6C to 30C, and in one varicose ulcer (2.94%), the potency rose to 12C. In 5 cases (14.7%,

Table 2. Outcome of the variables.

Variables No of participants (n = 34)	Baseline	3 rd month	6 th month	Friedman's Chi-square	p-Value	Post hoc Comparisons (p-value)
Size of the ulcer (Cm ²)	5.6 (2,28.9)	1 (0,15.25)	0 (0,9.5)	53.294	<.001	Baseline vs 3M: (p < 0.001), 3M vs 6M: (p > 0.05), Baseline vs 6M: (p < 0.001).
LUMT Score	31 (26,37.25)	18.5 (7,29.25)	7 (3,20)	56.709	<.001	Baseline vs 3M: (p < 0.001), Baseline vs 6M: (p < 0.001), 3M vs 6M: (p < 0.001).
Euro QOL	13 (12,15)	10 (6,10.25)	5 (5,9)	60.016	<.001	Baseline vs 3M: (p < 0.001), Baseline vs 6M: (p < 0.001), 3M vs 6M: (p < 0.001).

Values are represented as median (Q1, Q3), Friedman test is used. $p < 0.05$ is considered statistically significant.

Abbreviations:

LUMT Score- Leg Ulcer Measurement Tool.

Euro QOL- European Quality of Life.

Table 3. Prescribed medicines in the study (n = 34).

No	Medicine	No of cases (type of ulcers- VU, AU, MU and TU)	Percentage
1.	<i>Lycopodium clavatum</i>	8 (VU-6,AU-1,MU-1)	23.52
2.	<i>Sulphur</i>	6 (VU-5,TU-1)	17.64
3.	<i>Lachesis mutus</i>	4 (VU)	11.76
4.	<i>Phosphorus</i>	3 (VU-2, TU-1)	8.82
5.	<i>Arsenicum album</i>	2 (VU)	5.88
6.	<i>Mercurius soubilis</i>	2 (VU)	5.88
7.	<i>Natrum muriaticum</i>	2 (VU)	5.88
8.	<i>Pulsatilla nigricans</i>	2 (VU)	5.88
9.	<i>Calcarea carbonica</i>	1 (VU)	2.94
10.	<i>Causticum</i>	1 (VU)	2.94
11.	<i>Graphites</i>	1 (VU)	2.94
12.	<i>Petroleum</i>	1 (VU)	2.94
13.	<i>Silicea</i>	1 (VU)	2.94

VU: Varicose ulcer.

AU: Arterial ulcer.

MU: Mixed Ulcer.

TU: Traumatic ulcer.

varicose ulcers), the potency was raised to 200C, and further observation revealed that the 6C potency, with frequent repetition, has resulted in good improvement both subjectively and objectively.

In two cases, the medicine was changed due to a change in the complaints. One case began with *Pulsatilla* 6C; after four months, the complaints were changed to *Graphites* 6C and *Lycopodium* 6C, followed by *Lachesis* 30C in another case. After changing the medication, these cases showed significant improvement.

Discussion

This study sheds light on the role that homoeopathic medicines can play in the treatment of non-specific chronic leg ulcers. In a similar study, *Mukherjee et al.*³⁶ observed that non-diabetic leg ulcers were predominantly found in individuals aged 30-50 years. *Strandness et al.*³⁷ found non-diabetic

ulcers to be more prevalent in individuals aged 63 years. According to *Tassiopoulos et al.*³⁸ the mean age of patients was 59 years, based on a study of 1,249 limbs. In the present study, the mean age group was 53 years in nearly all the studies.

The gender distribution was 55.88% male and 44.12% female. In their study, *Mukherjee et al.*³⁶ reported that males predominated over females, with a male-to-female ratio of 1.9:1. The incidence of gender varies, and *Margolis et al.*³⁹ showed that women have an increased rate, in contrast to the present study.

The maximum incidence in this study was observed among middle-class individuals, constituting 58.82% of the total, followed by lower-class individuals at 23.53% and upper-class individuals at 17.65%. A study conducted by *Mukherjee et al.*³⁶ showed that 56% of patients with chronic, non-healing, non-diabetic ulcers belonged to the lower socioeconomic class, which differs from the findings of the present study.

The rural population accounted for a significantly larger proportion of patients, at approximately 68%, while the urban population comprised 32% of the total. A study by *Mukherjee et al.*³⁶ found that a higher proportion of patients with chronic leg ulcers belong to the rural population than to the urban population, with a ratio of 2.57:1, which corroborates the results of the present study.

In general, venous leg ulcers have the highest incidence rate of all chronic leg ulcers. In a study, *O'Brien JF et al.*⁴⁰ concluded that 81% of ulcers are venous ulcers, followed by arterial ulcers at 16.3%, and ulceration due to diabetic neuropathy and rheumatoid arthritis was uncommon. In their study, *Andreas Korber et al.*⁴¹ found that the primary reasons for chronic leg ulceration are venous insufficiency in 47.6% and arterial insufficiency in 14.5%. Combined arterial and venous insufficiency causes the remaining 17.6%. All the results support the findings of the present study.

Garrett *et al.*²⁵ in their RCT on leg ulcers found that a combination of homoeopathic medicines, including *Sulphur*, *Silicea*, and *Carbo vegetabilis* in 6C centesimal potency, is effective in treating leg ulcers. However, in this study, individualized homoeopathic medicine in 6C potency was used, emphasizing that 15 ulcers were healed with frequent repetition.

In previous publications,^{22,42–45} the duration of the ulcer's healing ranged from two months to one and a half years. Similarly, in this study, 21 (61.76%) cases showed complete healing of the ulcer from one to six months, reinforcing the effectiveness of homoeopathic management in chronic leg ulcers.

Most commonly, *Aurum metallicum*, *Flouric acid*, *Graphites*, *Lachesis*, *Lycopodium clavatum*, *Nux vomica*, *Pusatilla nigricans*, *Silicea*, *Sulphur*, and *Syphillinum* were prescribed in the previous publications in treating chronic venous ulcers. Similarly, in this study, *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum*, *Pulsatilla nigricans*, *Calcarea carbonica*, *Causticum*, *Graphites*, *Petroleum*, and *Silicea* were commonly indicated. Among these remedies, *Lycopodium clavatum* was the only remedy indicated in both arterial and venous ulcers, which require further research to establish these findings.

In his 6th edition of the *Organon of Medicine*,³⁴ aphorisms 185–203, Dr Samuel Hahnemann emphasized that either local or internal causes can cause ulcers. According to this literature, it is understood that after excluding surgical and injury-related ulcers, the remaining ulcers are of psoric origin. If treated externally, we may not be able to accurately assess the prognosis of the external ulcer and its underlying internal disease. He cautioned us to treat these cases judiciously with internal medication only. In this study, adherence to these instructions resulted in the prescription of a single individualized medicine, and both subjective and objective improvements were assessed using scientifically validated scales, such as LUMT and Euro QoL.

The study was conducted on a small sample size, which is a limitation, since the chances of bias were comparatively higher with purposive sampling. Due to the lack of a control group, the degree of improvement after treatment with homoeopathic medicine cannot be comprehended exactly. The study's duration was only six months. The study would have yielded more if the study period had been extended to consider the chances of recurrence of ulcers. Additionally, a duplex ultrasonography investigation is necessary at the conclusion of the study to assess any significant changes in the vascular system that may result from the intervention. Due to the COVID-19

pandemic and the lack of inpatient facilities, patients were treated on an outpatient basis, with follow-ups conducted monthly. Most of the time, patients cleaned and dressed their own ulcers. Therefore, a lack of proper cleaning and dressing of the ulcer may hinder its healing in cases of large leg ulcers.

Conclusion

This prospective study demonstrates the effect of homoeopathic medicines in reducing the size of non-specific, non-healing chronic leg ulcers, improving the quality of life according to scientifically validated scales and homoeopathic principles. Further pragmatic studies are warranted to validate the findings.

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Conflict of interest

None.

Author contribution

GIK and **DP** developed the concept and drafted the protocol. **GIK** has done the data acquisition, analysis, and evaluation. Both authors drafted the final manuscript and approved the final submission.

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Efficacité des médicaments homéopathiques dans la réduction de la taille des ulcères chroniques non spécifiques de la jambe: étude observationnelle prospective à un seul bras

Contexte: Un ulcère chronique de la jambe (UCJ) est une plaie chronique de la jambe qui cicatrise difficilement. L'insuffisance veineuse ou artérielle, le diabète, ou une combinaison de ces facteurs, peuvent entraîner des douleurs, une mobilité réduite, une altération des activités sociales et une augmentation des dépenses personnelles, autant d'éléments susceptibles de nuire à la qualité de vie.

Objectifs: Déterminer l'efficacité des médicaments homéopathiques dans la réduction de la taille des ulcères chroniques non spécifiques de la jambe à l'aide de l'outil de mesure des ulcères de la jambe (LUMT) et évaluer les changements de la qualité de vie grâce au score EuroQoL (EQ-5D-3L). **Matériel et méthodes:** Une étude clinique prospective a été menée à l'Institut national de recherche en homéopathie et santé mentale de Kottayam, en Inde, de février 2021 à août 2022 (enregistrée sous le numéro CTRI/2021/02/030951). Sur 35 patients, 34 ont terminé le traitement de six mois et ont été analysés en évaluant la taille de l'ulcère, le score LUMT et le score EuroQoL à l'inclusion, ainsi qu'aux 3e et 6e mois.

Résultats: Sur 52 patients examinés, 35 ont été inclus dans l'étude et ont reçu une prescription de traitement homéopathique individualisé. Une réduction statistiquement significative a été observée pour la taille de l'ulcère (de 5,6 cm² à 0) et pour le score LUMT (de 31 à 7) ($p < 0,001$). De plus, l'EuroQoL a été mesuré à l'inclusion, et les résultats à 3 et 6 mois ont été comparés et analysés par le test de Friedman, révélant une réduction significative de 13 à 5 ($p < 0,001$). Les remèdes suivants ont été fréquemment indiqués : *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum* et *Pulsatilla nigricans*. Aucun événement indésirable grave n'a été observé au cours de l'étude. **Conclusion:** Cette étude a démontré que l'homéopathie individualisée réduit efficacement la taille des ulcères de jambe chroniques non spécifiques et améliore la qualité de vie des patients. Des essais pragmatiques bien conçus sont nécessaires.

Wirksamkeit homöopathischer Arzneimittel bei der Verkleinerung unspezifischer chronischer Beingeschwüre – Eine einarmige, prospektive Beobachtungsstudie

Hintergrund: Ein chronisches Beingeschwür (CLU) ist eine chronische Wunde am Bein, die schlecht heilt. Venöse oder arterielle Insuffizienz, Diabetes mellitus oder eine Kombination dieser Faktoren können Schmerzen, eingeschränkte Mobilität, Beeinträchtigungen sozialer Aktivitäten und erhöhte Lebenshaltungskosten verursachen, was die Lebensqualität erheblich mindert. **Zielsetzung:** Bestimmung der Wirksamkeit homöopathischer Arzneimittel bei der Verkleinerung unspezifischer chronischer Beingeschwüre mithilfe des Leg Ulcer Measurement Tool (LUMT) und der Veränderungen der Lebensqualität anhand des EuroQoL-5D-3L-Scores. **Material und Methoden:** Eine prospektive klinische Studie wurde von Februar 2021 bis August 2022 am Nationalen Homöopathie-Forschungsinstitut für psychische Gesundheit in Kottayam, Indien, durchgeführt und unter CTRI/2021/02/030951 registriert. Von 35 Fällen schlossen 34 die sechsmonatige Behandlung ab und wurden hinsichtlich der Ulkusgröße, des LUMT-Scores und des EuroQoL-Scores zu Studienbeginn sowie nach drei und sechs Monaten analysiert. **Ergebnisse:** Von 52 gescreenten Patienten wurden 35 in die Studie aufgenommen und erhielten eine individualisierte homöopathische Therapie. Es zeigte sich eine statistisch signifikante Reduktion der Ulkusgröße von 5,6 cm² auf 0 cm² und des LUMT-Scores von 31 auf 7 ($p < 0,001$). Des Weiteren wurde der EuroQoL-Fragebogen zu Studienbeginn erhoben. Die Ergebnisse nach 3 und 6 Monaten wurden verglichen und mittels Friedman-Test analysiert, wobei eine signifikante Reduktion von

13 auf 5 ($p < 0,001$) festgestellt wurde. *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum* und *Pulsatilla nigricans* wurden häufig indiziert. Während der Studie traten keine schwerwiegenden unerwünschten Ereignisse auf. **Schlussfolgerung:** Die Studie ergab, dass individualisierte Homöopathie die Größe unspezifischer chronischer Beingschwüre effektiv reduziert und die Lebensqualität der Patienten verbessert. Gut konzipierte, praxisnahe Studien sind erforderlich

गैर-विशिष्ट दीर्घकालिक टांग के अल्सर का आकार कम करने में होम्योपैथिक दवाओं का असर - एक सिंगल-आर्म, प्रॉस्पेक्टिव ऑब्ज़र्वेशनल अध्ययन

पृष्ठभूमि: क्रोनिक लेग अल्सर (CLU) पैर का एक पुराना घाव होता है जो आसानी से ठीक नहीं होता। वेनस या आर्टरी में खून की कमी, डायबिटीज मेलिटस, या इन सभी वजहों से दर्द, चलने-फिरने में दिक्कत, सामाजिक गतिविधियों में रुकावट और इलाज के खर्च से परेशानी, ये सभी ज़िंदगी की क्वालिटी पर बुरा असर डाल सकते हैं। **उद्देश्य:** लेग अल्सर मेज़रमेंट टूल (LUMT) का इस्तेमाल करके इस अल्सर के आकार को कम करने में होम्योपैथिक दवाएँ कितनी असरदार हैं, यह पता लगाना और यूरो QoL (EQ-5D-3L) स्कोर से जीवन की क्वालिटी में बदलाव करना। **विधि:** फरवरी 2021 से अगस्त 2022 तक कोट्टायम, भारत में नेशनल होम्योपैथी रिसर्च इंस्टीट्यूट इन मेंटल हेल्थ में एक प्रॉस्पेक्टिव क्लिनिकल अध्ययन किया गया, और इसे CTRI/2021/02/030951 में पंजीकृत किया गया। 35 केस में से, 34 ने छह महीने तक इलाज पूरा किया और बेसलाइन पर अल्सर के साइज़, LUMT स्कोर और यूरो QoL स्कोर के साथ-साथ तीसरे और छठे महीने में भी उनका एनालिसिस किया गया। **परिणाम:** स्क्रीन किए गए 52 मरीजों में से, 35 को भर्ती किया गया और उन्हें व्यक्तिगत होम्योपैथिक दवा दी गई। अल्सर के आकार में 5.6 cm^2 से 0 तक और LUMT स्कोर में 31 से 7 तक ($p < 0.001$) आंकड़ों के हिसाब से बड़ी कमी देखी गई। इसके अलावा, बेसलाइन पर यूरो QoL भी मापा गया, और तीसरे और छठे महीने के नतीजों की तुलना की गई और फ्रीडमैन टेस्ट का इस्तेमाल करके उनका एनालिसिस किया गया, जिसमें 13 से 5 तक ($p < 0.001$) की बड़ी कमी देखी गई। *लाइकोपोडियम क्लैवाटम*, *सल्फर*, *लैकेसिस म्यूटस*, *फॉस्फोरस*, *आर्सेनिकम एल्बम*, *मरक्यूरियस सॉल्युबिलिस*, *नेट्रम म्यूरिएटिकम*, और *पल्सेटिला निग्रिकेंस* का असरदार संकेत देखा गया। इस अध्ययन के दौरान कोई गंभीर साइड इफ़ेक्ट रिकॉर्ड नहीं किया गया। **निष्कर्ष:** स्टडी से पता चला कि इंडिविजुअलाइज़्ड होम्योपैथी नॉन-स्पेसिफिक क्रोनिक लेग अल्सर के साइज़ को असरदार तरीके से कम करती है और मरीजों के QoL में सुधार करती है। अच्छी तरह से डिज़ाइन किए गए प्रैक्टिकल ट्रायल ज़रूरी हैं।

Eficacia de los medicamentos homeopáticos para reducir el tamaño de las úlceras crónicas inespecíficas de pierna: estudio observacional prospectivo de un solo brazo.

Antecedentes: Una úlcera crónica de pierna (UCP) es una herida crónica en la pierna que no cicatriza fácilmente. La insuficiencia venosa o arterial, la diabetes mellitus o una combinación de estos factores

pueden causar dolor, movilidad reducida, disminución de las actividades sociales y aumento de los gastos personales, todo lo cual puede afectar negativamente la calidad de vida. **Objetivos:** Determinar la eficacia de los medicamentos homeopáticos para reducir el tamaño de las úlceras crónicas inespecíficas de pierna mediante la Herramienta de Medición de Úlceras de Pierna (LUMT) y los cambios en la calidad de vida según la escala Euro QoL (EQ - 5D - 3L). **Materiales y métodos:** Se realizó un estudio clínico prospectivo en el Instituto Nacional de Investigación en Homeopatía en Salud Mental, Kottayam, India, de febrero de 2021 a agosto de 2022, registrado en el CTRI/2021/02/030951. De 35 casos, 34 completaron el tratamiento durante seis meses y se analizaron evaluando el tamaño de la úlcera, la puntuación LUMT y la puntuación Euro QoL al inicio, así como al tercer y sexto mes. **Resultados:** De los 52 pacientes examinados, 35 fueron incluidos y se les prescribió un medicamento homeopático individualizado. Se observó una reducción estadísticamente significativa en el tamaño de la úlcera, de 5,6 cm² a 0, y en la puntuación LUMT, de 31 a 7 ($p < 0,001$). Además, se midió la calidad de vida europea al inicio del estudio, y los resultados a los 3.er y 6.º meses se compararon y analizaron mediante la prueba de Friedman, con una reducción significativa de 13 a 5 ($p < 0,001$). *Lycopodium clavatum*, *Sulphur*, *Lachesis mutus*, *Phosphorus*, *Arsenicum album*, *Mercurius solubilis*, *Natrum muriaticum* y *Pulsatilla nigricans* se indicaron con frecuencia, y no se registraron eventos adversos graves durante el estudio. **Conclusión:** El estudio determinó que la homeopatía individualizada reduce eficazmente el tamaño de las úlceras crónicas inespecíficas de las piernas y mejora la calidad de vida de los pacientes. Se justifica la realización de ensayos pragmáticos bien diseñados.

顺势疗法药物缩小非特异性慢性腿部溃疡面积的疗效——一项单组前瞻性观察研究

背景: 慢性腿部溃疡 (CLU) 是指腿部难以愈合的慢性伤口。静脉或动脉功能不全、糖尿病或这些因素的组合可能导致疼痛、活动受限、社交活动受损以及个人开支增加, 所有这些都对生活产生不利影响。**目的:** 使用腿部溃疡测量工具 (LUMT) 评估顺势疗法药物缩小非特异性慢性腿部溃疡面积的疗效, 并通过欧洲生活质量量表 (EQ-5D-3L) 评分评估其对生活的影响。**材料与方**法: 本前瞻性临床研究于2021年2月至2022年8月在印度科塔亚姆国家顺势疗法精神健康研究所进行, 并已在CTRI/2021/02/030951注册。35例患者中, 34例完成了为期6个月的治疗, 并在基线、治疗后第3个月和第6个月评估了溃疡面积、LUMT评分和EuroQoL评分。**结果:** 在52例筛查患者中, 35例符合入组条件并接受了个体化的顺势疗法药物治疗。溃疡面积从5.6 cm²显著缩小至0 cm², LUMT评分从31分显著降低至7分 ($p < 0.001$)。此外, 基线时还测量了欧洲生活质量评分 (Euro QoL), 并使用弗里德曼检验对第3个月和第6个月的结果进行了比较和分析, 结果显示评分从13显著降低至5 ($p < 0.001$)。石松 (*Lycopodium clavatum*)、硫磺 (*Sulphur*)、蛇毒 (*Lachesis mutus*)、磷 (*Phosphorus*)、白砷 (*Arsenicum album*)、可溶性汞 (*Mercurius solubilis*)、氯化钠 (*Natrum muriaticum*) 和黑头白头翁 (*Pulsatilla nigricans*) 是常用的药物, 研究期间未记录到严重不良事件。**结论:** 本研究表明, 个体化顺势疗法能有效缩小非特异性慢性腿部溃疡的面积并改善患者的生活质量。有必要开展设计严谨的实用性试验。