Calendula mother tincture vs normal saline for ulcer dressing as an add-on to Individualized Homoeopathic Intervention in the management of Diabetic Foot Ulcer: A Randomized Controlled Pilot Study

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Abstract

Background: Despite standard management, healing rate of Diabetic Foot Ulcers (DFUs) remains low, posing risk of lower extremity amputation. Objectives: This study was undertaken to evaluate if Calendula Q has added benefit over individualized homoeopathic intervention (IHI). The primary objective was to achieve complete epithelialisation within 20 weeks and secondary objective was to assess the changes in quality of life using DFU Scale-short form (DFU-SF) questionnaire. Materials and Methods: A randomised controlled pilot study with a 20-week intervention was conducted from 2014-2017. 277 cases were screened and 60 cases were enrolled and randomised to Group I: IHI + Calendula Q dressing (n= 30) and Group II: IHI + normal saline (NS) dressing (n = 30), along with standard conventional medication for glycaemic control. Results: The mean time (Group I= 12 weeks, Group II= 11 weeks) of ulcer healing in both groups showed no statistically significant difference, thus calendula Q used for dressing did not have any added benefits (p= 0.0521). Arsenicum album (n= 14, 23.3%), Lycopodium (n= 8, 13.3%), Silicea (n= 7, 11.7%), Sulphur (n= 6, 10%), Phosphorus (n= 5, 10%) and Sepia (n=5, 10%) were found to be effective medicines. Conclusion: IHI, along with wound hygiene and conventional diabetic management, proved to be effective, irrespective of whether Calendula Q or normal saline was used for wound hygiene, thus leading to early, complete epithelialisation of Wagner’s first and second stages of DFUs. Further studies comparing IHI with standard care are warranted.

Keywords: Calendula, Diabetic foot ulcer Short Form questionnaire, Diabetic foot ulcer, Homoeopathy, India, Lower extremity amputation, Randomised controlled pilot study

INTRODUCTION

Diabetic Foot Ulcer (DFU) is the most devastating complication in diabetic patients, causing permanent disability due to lower extremity amputation (LEA), thus posing a major public health concern of the present day. The major leading cause in 80% of the non-traumatic LEA is diabetes and is preceded by foot ulcer (DFU) in 85% cases.[1] India shows an overall prevalence rate of 9.3% with 69.1 million patients of diabetes mellitus.[2] The International Diabetes Federation (IDF) envisages that 80% of people with diabetes come from low- to middle-income group countries including India, a country with the second largest number of patients with diabetes after China.[3] The increase in the global burden of diabetes in turn is leading to the raise in the incidence of DFUs. The annual incidence of DFU in population-based studies is 1.0%- 4.1% and prevalence of 4.5%-10%, with an overall lifetime incidence of up to 25%.


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Ponnam, et al.: Homoeopathic intervention in the management of diabetic foot ulcer

The LEA is seen 10–30 times more often in diabetic population compared to the rest of the population. The age-adjusted annual incidence for non-traumatic LEA in persons with diabetes ranges from 2.1 to 13.7/1000 persons. It is believed that in every 30 s, a lower limb is lost somewhere in the world as a consequence of diabetes.[11,14,5] Foot ulcers cause substantial morbidity, impair quality of life, engender high treatment costs and are the most important risk factor for LEA. Especially in India, the diabetic foot represents a considerable health problem, aggravated by the high frequency of infection and the ever-rising prevalence of diabetes.[6,7] Toes are the most common site for ulcer, followed by the plantar metatarsal heads, and the heels, with ill-fitted footwear being the most common cause in diabetes.[9] The DFUs result from peripheral neuropathy (most common cause) and/or large vessel disease. Vascular insufficiency, infection and failure to implement effective treatment of DFUs are linked to secondary medical complications, such as osteomyelitis and amputation.[9] An inverse relationship between DFU and foot care knowledge as well as practice was observed. Apart from tight glycaemic control, diabetic patients must be educated and motivated on proper foot care practice and lifestyle modifications for preventing DFUs.[10] Despite the use of standard management strategies, healing rates of DFUs remain low, and rapid, complete healing of DFUs remains a challenge.[9] The economic burden of DFUs and the complications arising from them are enormous. Nearly 70% of the healed ulcers are estimated to recur within 5 years.[8] The meta-analysis of ten control groups from clinical trials, using good standard wound care (including debridement and off-loading, and either saline moistened gauze or placebo gel and gauze), demonstrated that the weighted mean rates of neuropathic ulcer healing were 24.2% (95% confidence interval [CI] 19.5%–28.8%) over 12-weeks and 30.9% (95% CI 26.6%–35.1%) over 20 weeks.[9] DFU pain affects the health-related quality of life (HRQL). Additional research is warranted to further characterise the pain associated with DFU and its impact on patient outcomes and HRQL.[11] In view of the multiple risk factors involved in the healing of DFU, a multidisciplinary approach is always suggested comprising of regular wound care and patient education (lifestyle modifications) apart from the oral appropriate medications, and timely monitoring by integrated therapists is suggested which would greatly reduce, delay or prevent further progression into devastating complications as gangrene and amputation.[12]

The homoeopathic literature suggests many medicines for the healing of ulcers. Previous studies, although not systematically done with specified sample size and design, reveal a positive effect of individualized homoeopathic medicines in the treatment of DFUs.[13–16] One observational study on ninety patients with individualised Homoeopathy (IH) and regular Calendula Q dressings indicated that the mean time for complete healing of ulcers was 75 days, with superficial ulcers healing in 30 days and those with penetration to the depth of the musculature healed within 90 days or 12 weeks.

The present randomised controlled pilot study was conducted to further compare the added effect of Calendula Q to that of dressing using normal saline, along with IH and conventional diabetic management.

**Materials and Methods**

**Study design**

The study was a unicusentric, single-blind, randomised controlled pilot study with a 20-week intervention including follow-up period.

**Participants**

The inclusion criteria for the study participants was: men and women aged 18–70 years, (extremes included) with Type 1 or Type 2 diabetes mellitus on standard conventional treatment; single DFU at or below the malleoli; DFU Wagner 1–2 stage; chronic ulcer of at least 4 weeks’ duration but not more than 3 months; ulcer size (greatest length by greatest width) at randomisation between 1.0 cm² and 10 cm², both inclusive; adequate blood supply, to be measured by (colour) Doppler ultrasonography, ankle brachial pressure index 0.60, or ankle systolic pressure 70 mmHg or toe pressure 30 mmHg; peripheral neuropathy as assessed by Semmes–Weinstein monofilament test, HbA1c ≤8%; women surgically sterile, post-menopausal, or agree to practice adequate contraception and written informed consent from the patient.

The exclusion criteria included: Wagner grade 0, 3, 4 and 5, cases presenting with long-term complication of diabetes such as severe retinopathy, severe renal involvement or with history of recurrent acute complications such as hypoglycaemia, ketoacidosis and polyneuropathy; alcohol addiction or dependence; uncontrollable hypertension; cases with severe coronary, cerebral, renal vascular, liver diseases as well as malignant neoplasms and cases taking conventional medicines which interfere with the ulcer healing as antibiotics, ulcer healing agents and circulation-enhancing drugs.

**Settings**

The patients presenting with DFU in the outpatient department (OPD) of Princess Durru Shehvar Children’s and General Hospital, Hyderabad, were screened for eligibility and underwent baseline investigations. The research personnel involved in the study were a homoeopathic physician experienced in the treatment of DFU and a consultant general surgeon for screening, assessing at baseline, monitoring concurrent allopathic treatment if taken for sugar control and evaluating the healing of the ulcer at the end of the study.

**Intervention**

Patients fulfilling the eligibility criteria were enrolled and randomized as per computer-generated randomization chart to receive either individualised homoeopathic intervention (IHI) with Calendula Q dressing (Group I) or IHI with NS dressing (Group II). Homoeopathic medicines were given in 6c, 30c, 200c or 1M potency as per the prescribing totality after repertorising and in consultation with the Materia Medica.[14]
The prescriptions were repeated and/or modified based on the changes in the prescribing totality in accordance with the principles of Homoeopathy. All the study participants were asked to follow regular ulcer dressings as advised with Calendula Q and NS dressings as assigned in respective groups. The patients were asked to continue their routine standard conventional diabetic management.

**Criteria for baseline assessment and follow-up**

All the enrolled participants underwent complete case taking along with clinical examination, baseline investigations: fasting and postprandial sugar levels, glycosylated haemoglobin, lipid profile, complete blood count, erythrocyte sedimentation rate, lipid profile, renal function tests, Vitamin B12, folate levels, Semmes–Weinstein monofilament test, ankle brachial pressure index and Doppler study of lower limb. Further, DFU-SF questionnaire was filled.

Patients were assessed at 4-week interval (or earlier, as per the need) for 20 weeks. However, comprehensive assessment using DFU-SFQ was done at baseline, 12th and then at the 20th week to evaluate the mental and physical domains of the patients in relation to the disease, along with compliance to medicine and health-related behaviour. The investigations which were out of range at baseline were repeated at the end of treatment and sugar levels were especially monitored on monthly basis.

The ulcer dressings were scheduled daily or on alternate day, basing on the intensity of the ulcer, as per the suggestions of the consultant surgeon.

**Outcomes**

The primary outcome was to compare the effect of IHI with ulcer dressing using Calendula Q vs IHI with ulcer dressing using NS in the complete closure or epithelialisation of DFU within 20 weeks of treatment. The secondary outcomes were to assess the change in size of wound area from baseline at 4, 8, 12, 16 and 20 weeks in the two groups and to assess the impact of foot ulcers and their treatment on quality of life in diabetic patients using DFU-SF scale at baseline, 12 and 20 weeks in the two groups. Data were analysed for all the cases considering intention to treat (ITT) as the dropout cases were very few (Group A n = 1 and Group B n = 2), the cases followed for minimum two follow-ups and even in these cases there was an initiation of epithelialisation of ulcer observed.

**Sample size**

Sixty cases of DFU as it was a pilot study as advised by the expert/committee.

**Randomization and allocation**

The sixty patients fulfilling the eligibility criteria were randomised as per computer-generated randomisation chart, and allocated in 1:1 ratio in the two groups: thirty patients received either oral IHI + Calendula Q dressing and another thirty patients received oral IHI + NS dressing.

**Blinding**

This was a single-blind study wherein only patients were blinded regarding the identity of the treatment group.

**Study duration**

The study was conducted from May 2014 to June 2017.

**Data collection**

Each case was followed up for 20 weeks to assess the outcome results of the treatment. The study data were collected at baseline, every follow-up (4 weekly or early if required) and at final/termination visit. The patients were evaluated for symptoms, clinical assessment and laboratory parameters as per the study protocol.

**Statistical methods**

Data obtained during the study were verified and analysed using Statistical Package for Social Sciences (SPSS) version 20 IBM Corporation, India. Data were recorded in a pre-designed pro forma and excel sheet. Accordingly, the demographic details, baseline characteristics, ulcer size and the DFU-SF of both the groups were compared by using paired t-test. Data were expressed in n (%), mean ± standard deviation. Statistical significance was considered at P < 0.05.

**Regulatory and ethical approval**

The study protocol was in accordance with the latest revision of the Helsinki declaration on human experimentation and Good Clinical Practices India. Necessary clearance of the Institutional Ethical Committee of CCRH was obtained (1-172/2011-12/CCRHC/CR/CTRI/769,
Ponnam, et al.: Homoeopathic intervention in the management of diabetic foot ulcer
dated 04/09/2013) and CTRI registration was done as CTRI/2013/11/004139 (November 12, 2013).

RESULTS
Out of 277 cases of DFU screened from the OPD of the study site, only 60 were enrolled according to the inclusion criteria and followed for 20 weeks, with 30 cases being allocated to each of the two groups. The other 217 cases were excluded due to various reasons as mentioned in Figure 1. Among the thirty cases of Group I, one case dropped out and from the thirty cases of Group II, two cases were dropped out as they did not comply with the protocol. Hence, a total of 57 cases completed their 20-week follow-up, as per protocol [Figure 1]. The baseline characteristics of these cases were comparable in both the groups, as shown in Table 1. The ulcer healing size from baseline to 20 weeks, with monthly follow-up in both groups, was significant individually, but showed no statistically significant difference between the groups, as depicted in Tables 2 and 3. The mean DFU healing time was an average of 12 weeks in Group I and 11 weeks in Group II, as shown in Figure 2.

The DFU-SF has been analysed under five domains as leisure, physical health, dependence and daily life, emotions and healthy behaviour and medical compliance, all of which showed a significant improvement in both groups but showed no significant difference between groups, as shown in Table 2. The frequently indicated individualized homoeopathic remedies found effective were Arsenic album (n = 14, 23.3%), Lycopodium (n = 8, 13.3%), Silicea (n = 7, 11.7%), Sulphur (n = 6, 10%) and Phosphorus (n = 6, 10%), as shown in Table 4, and their characteristic indications used for prescribing are given in Table 5. The ulcer remission in both the groups in the 4 weekly follow ups up to 20 weeks from baseline was found to be almost in the same pace, as depicted in Figure 3. The ulcer recurrences were not found in the cases within the study period of 20 weeks.

DISCUSSION
Homoeopathy has proved to be safe and effective in healing Grade I and II DFUs within short time as compared with the standard conventional treatment, in a previous study.[9] The fast pace of healing at an early stage would further help in not only preventing the limb from amputation risk but also reducing the treatment costs, thus, in turn, reducing the burden on the healthcare economy of the country. To prevent LEA is the need of the hour, as every 30 seconds, a limb is being amputated as a consequence of diabetes.[10] The results of this study with 95% ulcer healing over a period of 11–12 weeks are in consonance with a previous observational study wherein the mean healing rate was 90.5% over a period of 12 weeks.[12] Ulcer dressing with Calendula Q or normal saline did not make any significant difference as shown in Figures 4 and 5 (each sample case from the groups), reaffirming the fact that regular ulcer dressings are important to control infection and create a healthy base for healing. But the overall healing was initiated and completed by the IHI given orally, which has also been found in the previous studies,[13–16,23] has been confirmed by this randomised controlled trial.

The quality of life assessed by DFU-SFQ[20] in various domains such as emotional, physical health, behavioural, dependency, leisure and daily activities aspects in both the groups before and after treatment showed statistically significant values, thus indicating improvement in the overall quality of life in patients along with the ulcer healing. The homoeopathic remedies found frequently prescribed and efficacious were Arsenic album, Lycopodium, Silicea, Sulphur and Phosphorus, which also corroborates with the previous studies, [12-16] and thus again affirms the positive role of IHI in ulcer healing. The ulcer recurrences were not found in the cases within the study period.
In this prospective study, after enrolling the cases in the study and the administration of IHI, the signs of healing were progressive and showed early epithelialisation, that is 96.7% in Group A and 93.3% in Group B over a period of 11–12 weeks in comparison to previous studies of conventional treatment where the weighted mean rates of healing was 24.2% over 12 weeks and 30.9% over 20 weeks.\(^{[9]}\)

The study did not show any significant benefit of \textit{Calendula} \textit{Q} dressing over oral IHI as both the groups showed equal time with marginal difference of healing between the groups. Further, the healing time does not seem to be much influenced by factors such as ulcer duration, ulcer size and the degree of peripheral arterial disease as seen in the findings of a previous study\(^{[24]}\) because the criteria of inclusion (Wagner 1 and 2 stages)

### Table 2: Foot ulcer size and diabetic foot ulcers - Short Form scores in both the groups at baseline, 12 weeks and after treatment (20 weeks)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Groups</th>
<th>Mean±SD</th>
<th>After treatment at 20 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A (IHI + \textit{Calendula} dressing) (n=30) vs Group B (IHI + saline dressing) (n=30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Ulcer size</td>
<td>Group A</td>
<td>4.04±0.58</td>
<td>0.89±0.36</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>3.67±0.48</td>
<td>0.54±0.21</td>
</tr>
<tr>
<td>Leisure</td>
<td>Group A</td>
<td>14.52±0.78</td>
<td>10.14±0.91</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>15.82±0.60</td>
<td>11.07±0.78</td>
</tr>
<tr>
<td>Physical health</td>
<td>Group A</td>
<td>13.07±0.74</td>
<td>8.52±0.67</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>12.96±0.68</td>
<td>9.00±0.70</td>
</tr>
<tr>
<td>Dependence and daily life</td>
<td>Group A</td>
<td>12.45±1.01</td>
<td>9.07±0.86</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>13.21±1.01</td>
<td>10.11±0.67</td>
</tr>
<tr>
<td>Emotions</td>
<td>Group A</td>
<td>25.93±1.35</td>
<td>17.52±1.22</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>26.75±1.49</td>
<td>20.25±1.64</td>
</tr>
<tr>
<td>Healthy behaviour and medical compliance</td>
<td>Group A</td>
<td>10.52±0.55</td>
<td>6.90±0.48</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>10.64±0.43</td>
<td>7.29±0.48</td>
</tr>
</tbody>
</table>

Table 2: Foot ulcer size and diabetic foot ulcers - Short Form scores in both the groups at baseline, 12 weeks and after treatment (20 weeks)

| SD: Standard deviation, IHI: Individualized homoeopathic intervention

### Table 3: Mean foot ulcer healing period in both the groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Weeks</th>
<th>Mean±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group-A (IHI+\textit{Calendula} dressing) (n=29)*</td>
<td>12.38±1.0</td>
<td>4-20</td>
<td></td>
</tr>
<tr>
<td>Group-B (IHI+saline dressing) (n=28)*</td>
<td>11.8±1.2</td>
<td>4-20</td>
<td></td>
</tr>
<tr>
<td>\textit{t}-test</td>
<td>1.985</td>
<td>Not significant</td>
<td></td>
</tr>
</tbody>
</table>
| *Total analysis has been taken up by ITT (ITT as mentioned in outcome part) method. The mean healing time when considered only those cases which completed 20 weeks with complete epithelialisation are taken and dropouts are left. SD: Standard deviation, ITT: Intention to treat, IHI: Individualized homoeopathic intervention

### Table 4: Medicines prescribed and found effective in both groups

<table>
<thead>
<tr>
<th>Medicine prescribed</th>
<th>Number of cases</th>
<th>IHI + \textit{Calendula} Q</th>
<th>IHI + NS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prescribed</td>
<td>Effective</td>
<td>Prescribed</td>
</tr>
<tr>
<td>\textit{Arsenic album}</td>
<td>8</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>\textit{Calcarea carb}</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>\textit{Carbo veg}</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>\textit{Causticum}</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>\textit{Conium}</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>\textit{Lycopodium}</td>
<td>2</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>\textit{Natrum mur}</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>\textit{Nitric acid}</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>\textit{Nux vomica}</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>\textit{Opium}</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>\textit{Phosphorus}</td>
<td>5</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>\textit{Pulsatilla}</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>\textit{Sepia}</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>\textit{Silicea}</td>
<td>2</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>\textit{Salphur}</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

In this prospective study, after enrolling the cases in the study and the administration of IHI, the signs of healing were progressive and showed early epithelialisation, that is 96.7% in Group A and 93.3% in Group B over a period of 11–12 weeks in comparison to previous studies of conventional treatment where the weighted mean rates of healing was 24.2% over 12 weeks and 30.9% over 20 weeks.\(^{[9]}\) The study did not show any significant benefit of \textit{Calendula} \textit{Q} dressing over oral IHI as both the groups showed equal time with marginal difference of healing between the groups. Further, the healing time does not seem to be much influenced by factors such as ulcer duration, ulcer size and the degree of peripheral arterial disease as seen in the findings of a previous study\(^{[24]}\) because the criteria of inclusion (Wagner 1 and 2 stages)
included) were kept very specific and uniform for all the cases enrolled in the study to prevent this type of bias. Apart from standard diabetic management, wound hygiene, necessary debridement and patient education, no other medication which interferes with the healing of the ulcer has been used such as neither biological agents – growth factors, any offloading procedures (total contact cast) – nor any antibiotics, which further emphasises the positive effect of IHI in the ulcer epithelialisation. However, such multifactorial approach in DFU is always necessary to greatly reduce, delay or prevent complications, such as gangrene and amputation.[12]

**Conclusion**

This randomised controlled pilot study affirms that IHI along with proper wound hygiene (irrespective of Calendula Q or normal saline) and standard conventional diabetic management can effectively lead to early, complete epithelialisation of Wagner’s first and second stage of DFUs. Further studies comparing the role of IHI with standard care alone are warranted.

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**Financial support and sponsorship**

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Conflicts of interest
None declared.

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Materiaux et méthodes: Une étude pilote contrôlée randomisée avec une intervention de 20 semaines a été menée de 2014 à 2017. 277 cas ont été dépistés et 60 cas ont été recrutés et randomisés dans le groupe I: pansement IHI + Calendula Q (n = 30) et groupe II: pansement IHI + solution saline normale (NS) (n = 30), ainsi que les médicaments conventionnels standard pour la glycémie contrôle. **Résultats:** Le temps moyen (groupe I = 12 semaines, groupe II = 11 semaines) de cicatrisation de l’ulcère dans les deux groupes n’a montré aucune différence statistiquement significative, ainsi le calendula Q utilisé pour le pansement n’a pas eu d’avantages supplémentaires (p = 0.0521). Arsenicum album (n = 14, 23,3%) Lycopodium (n = 8, 13,3%), Silicea (n = 7, 11,7%), Sulphur (n = 6, 10,%), Phosphoricum (n = 5, 10,%) et Sepia (n = 5, 10%) se sont avérés être des médicaments efficaces. **Conclusion:** L’IHI, ainsi que l’hygiène des plaies et la prise en charge conventionnelle du diabète, se sont révélés efficaces, que le Calendula Q ou une solution saline normale aient été utilisés pour l’hygiène des plaies, conduisant ainsi à une épithélialisation précoce et complète des premier et deuxième stades des UPD de Wagner. D’autres études comparant l’IHI aux soins standard sont justifiées.

Tintura madre de Calendula vs solución saline normal para pansement ulceréux en complément d’une intervention homéopathique individualisée dans la prise en charge de l’ulcère du pied diabétique: une étude pilote randomisée contrôlée

**Contexte:** Malgré une prise en charge standard, le taux de cicatrisation des Ulcères du Pied Diabétique (UPD) reste faible, ce qui pose un risque d’amputation des membres inférieurs. Objectifs: Cette étude a été entreprise pour évaluer si Calendula Q a un avantage supplémentaire par rapport à l’Intervention Homéopathique Individualisée (IHI). L’objectif principal était d’obtenir une épithélialisation complète dans les 20 semaines et l’objectif secondaire était d’évaluer les changements de qualité de vie à l’aide du questionnaire UPD Scale short form (UPD-SF).

**Materiaux et méthodes:** Une étude pilote contrôlée randomisée avec une intervention de 20 semaines a été menée de 2014 à 2017. 277 cas ont été dépistés et 60 cas ont été recrutés et randomisés dans le groupe I: pansement IHI + Calendula Q (n = 30) et groupe II: pansement IHI + solution saline normale (NS) (n = 30), ainsi que les médicaments conventionnels standard pour la glycémie contrôle. **Résultats:** Le temps moyen (groupe I = 12 semaines, groupe II = 11 semaines) de cicatrisation de l’ulcère dans les deux groupes n’a montré aucune différence statistiquement significative, ainsi le calendula Q utilisé pour le pansement n’a pas eu d’avantages supplémentaires (p = 0.0521). Arsenicum album (n = 14, 23,3%), Lycopodium (n = 8, 13,3%), Silicea (n = 7, 11,7%), Sulphur (n = 6, 10,%), Phosphoricum (n = 5, 10,%) et Sepia (n = 5, 10%) se sont avérés être des médicaments efficaces. **Conclusion:** L’IHI, ainsi que l’hygiène des plaies et la prise en charge conventionnelle du diabète, se sont révélés efficaces, que le Calendula Q ou une solution saline normale aient été utilisés pour l’hygiène des plaies, conduisant ainsi à une épithélialisation précoce et complète des premier et deuxième stades des UPD de Wagner. D’autres études comparant l’IHI aux soins standard sont justifiées.

Tintura madre de Calendula vs solución saline normal para pansement ulceréux en complément d’une intervention homéopathique individualizada en el manejo de la úlcera de pie diabético: un estudio piloto controlado aleatorizado

**Antecedentes:** A pesar de la gestión estándar, la tasa de curación de las úlceras de pie diabético (DDU) sigue siendo baja, lo que representa el riesgo de amputación de las extremidades más bajas. **Objetivos:** Este estudio se llevó a cabo para evaluar si Calendula Q ha añadido beneficio sobre la intervención homoeopática individualizada (IHI). El objetivo principal era lograr una epitelización completa en un plazo de 20 semanas Y el objetivo secundario fue evaluar los cambios en la calidad de vida mediante el cuestionario de la escala de DFU de forma corta (DFU SF).

**Materiales y métodos:** Se realizó un estudio piloto aleatorizado controlado con una intervención de 20 semanas entre 2014 y 2017. Se seleccionaron 277 casos y se inscribieron 60 casos y se aleatorizaron al grupo I: Vendaje IHI Calendula Q (n=30) y grupo II: Vendaje IHI normal (NS) (n = 30), junto con medicación convencional estándar para el control glucémico. **Resultados:** El tiempo medio (Grupo I- 12 semanas, Grupo II a 11 semanas) de la curación de la úlcera en ambos grupos no mostró ninguna diferencia estadísticamente significativa, por lo tanto, la caléndula Q utilizada para el apósito no tenía ningún beneficio adicional (p. 0.0521). Se encontró que el album de Arsenicum (n=14, 23,3%), el lycopodium (n=8, 13,3%), la silice (n=7, 11,7%), el azufre (n=6, 10,%), el fósforo (n=5, 10,%) y la sepia (n=5, 10%) eran medicamentos efectivos. **Conclusión:** El IHI, junto con la higiene de la herida y el tratamiento diabético convencional, demostró ser eficaz, independientemente de si se utilizó Calendula Q o solución saline normal para la higiene de la herida. De esta manera, se conduce a una epitelización temprana y completa de la primera y segunda etapa de Wagner de las DFU. Se justifican estudios adicionales que comparan IHI con la atención estándar.
Hintergrund: Trotz standard-management-, Heilungs-rate von Diabetic Foot Ulcers (DFUs) bleibt niedrig ist, posiert das Risiko der unteren Extremität amputation. Ziel: Diese Studie wurde durchgeführt, um zu prüfen, ob RingelblumeQ hat den zusätzlichen Vorteil, über individualisierte Homöopathische intervention (IHI). Das primäre Ziel war um die vollständige epithelialisation innerhalb von 20 Wochen und secondary Ziel war es, zu beurteilen, die änderungen in der Lebensqualität mit Hilfe DFU-Skala Kurzform (DFU - SF) - Fragebogen. Materialien und Methoden: Eine randomisierte kontrollierte Pilotstudie mit 20 Woche intervention wurde durchgeführt von 2014-2017. 277 Fälle wurden überprüft und 60 Fälle wurden in die Studie aufgenommen und randomisiert auf Gruppe I: IHI + Ringelblume Q-dressing (n= 30) und Gruppe II: IHI + normaler Kochsalzlösung (NS) Verband (n = 30), zusammen mit standard-konventionelle Medikamente zur glykämischen Kontrolle. Ergebnisse: Die mittlere Zeit (Gruppe I= 12 Wochen, Gruppe II= 11 Wochen), die Heilung von Geschwüren in beiden Gruppen zeigte sich kein statistisch signifikanter Unterschied, somit Ringelblume Q verwendet für das dressing habe keine zusätzlichen Vorteile (p= 0.0521). Arsenicum album (n= 14, 23.3%), Lycopodium (n= 8, 13.3%), Silicea (n= 7, 11.7%), Sulphur (n= 6, 10%), Phosphorous - (n= 5, 10%) und Sepia (n=5, 10%)wurden gefunden, um wirksame Medikamente. Fazit: IHI, zusammen mit wundhygiene und konventionellen diabetische management, erwies sich als wirksam, unabhängig davon, ob RingelblumeQ oder normaler Kochsalzlösung wurde verwendet für die wundhygiene, so was zu früh, komplette epithelialisation von Wagners erste undzweite Stufes von DFUs. Weitere Studien zum Vergleich der IHI mit standard-Pflege gewährleistet ist.