

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

Hima Bindu Ponnam^{1*}, Chetna Deep Lamba^{2*}, Praveen Oberai², Syed Viqar Masood³, Suryanarayana Yandamuri¹, M. Narsing Rao¹, Raj Kumar Manchanda²

¹Extension Clinical Research Unit, Hyderabad, Central Council for Research in Homoeopathy, Princess Durru Shehvar Children's and General Hospital, ³Department of Surgery, Princess Durru Shehvar Children's and General Hospital, Telangana, ²Central Council for Research in Homoeopathy, New Delhi, India

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%.

***Address for correspondence:** Dr. Chetna Deep Lamba, Central Council for Research in Homoeopathy, New Delhi, India.

E-mail: drchetnalamba@gmail.com

Dr. Hima Bindu Ponnam,

Extension Clinical Research Unit, Princess Durru Shehvar Children's and General Hospital, CCRH, Hyderabad, Telangana, India.

E-mail: drbindu_hima@yahoo.com

Received: 22.11.2019; **Accepted:** 20.10.2020; **Published:** 29.12.2020

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

How to cite this article: Ponnam HB, Lamba CD, Oberai P, Masood SV, Yandamuri S, Rao MN, *et al.* 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. *Indian J Res Homoeopathy* 2020;14:233-41.

Access this article online

Quick Response Code:



Website:
www.ijrh.org

DOI:
10.4103/ijrh.ijrh_87_19

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.^[1,4,5] 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.^[8] 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*^[17] Q to that of dressing using normal saline, along with IHI and conventional diabetic management.

MATERIALS AND METHODS

Study design

The study was a unicentric, 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; uncontrolled 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.^[18]

Table 1: Baseline characteristics of the diabetic foot ulcer patients of both the groups

Parameter	Mean \pm SD	
	Group A (IHI + <i>Calendula</i> dressing) (n=30)	Group B (IHI + <i>saline</i> dressing) (n=30)
Age (years)	53.4 \pm 13.0	56.1 \pm 5.9
Duration of diabetes (years)	10.5 \pm 7.9	9.6 \pm 6.8
Sex		
Male	22 (73.3)	27 (90.0)
Female	8 (26.7)	3 (10.0)
Ulcer size: At entry	4.04 \pm 0.58	3.67 \pm 0.48
BMI: ([height in metres] ² /[weight in g]/M ²)	26.5 \pm 5.3	28.3 \pm 5.0

BMI: Body mass index; SD: Standard deviation; IHI: Individualized homoeopathic intervention

The prescriptions were repeated and/or modified based on the changes in the prescribing totality in accordance with the principles of Homoeopathy.^[19] 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^[20] 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 \pm 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^[21] declaration on human experimentation and Good Clinical Practices India.^[22] Necessary clearance of the Institutional Ethical Committee of CCRH was obtained (1-172/2011-12/CCRH/CR/CTRI/769,

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.^[1] 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.^[23] 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

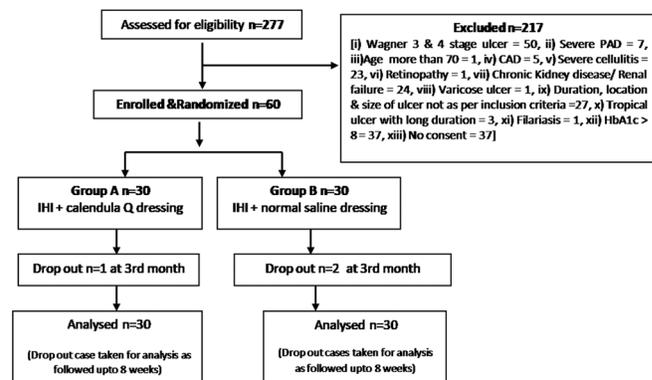


Figure 1: Study flowchart

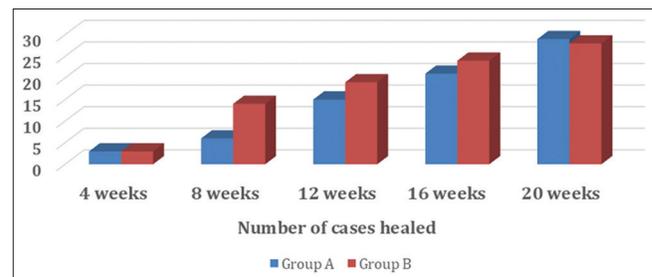


Figure 2: Healing of the ulcer as per timeline in both groups

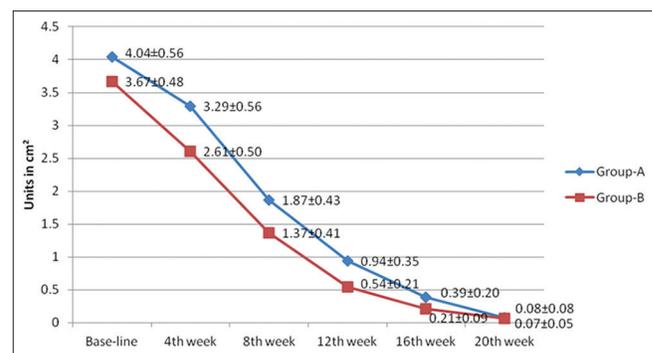


Figure 3: Remission of ulcer size at baseline and different follow-ups

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.

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)

Parameter	Groups Group A (IHI + <i>Calendula</i> dressing) (n=30) versus Group B (IHI + saline dressing) (n=30)	Mean±SD			P
		Baseline	12 weeks	After treatment at 20 weeks	
Ulcer size	Group A	4.04±0.58	0.89±0.36	0.00±0.00	0.00001
	Group B	3.67±0.48	0.54±0.21	0.07±0.05	0.00001
Leisure	Group-A	14.52±0.78	10.14±0.91	7.21±0.58	<0.00001
	Group-B	15.82±0.60	11.07±0.78	8.96±0.66	<0.00001
Physical health	Group-A	13.07±0.74	8.52±0.67	6.45±0.39	<0.00001
	Group-B	12.96±0.68	9.00±0.70	6.75±0.55	<0.00001
Dependence and daily life	Group-A	12.45±1.01	9.07±0.86	6.86±0.46	<0.00001
	Group-B	13.21±1.01	10.11±0.67	8.89±0.58	<0.00001
Emotions	Group-A	25.93±1.35	17.52±1.22	14.14±0.79	<0.00001
	Group-B	26.75±1.49	20.25±1.64	17.29±1.05	0.000012
Healthy behaviour and medical compliance	Group-A	10.52±0.55	6.90±0.48	5.48±0.34	<0.00001
	Group-B	10.64±0.43	7.29±0.48	6.32±0.40	<0.00001

SD: Standard deviation, IHI: Individualized homoeopathic intervention

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

Group	Weeks	
	Mean±SD	Range
Group-A (IHI+ <i>Calendula</i> dressing) (n=29)*	12.38±1.0	4-20
Group-B (IHI+saline dressing) (n=28)*	11.8±1.2	4-20
t-test	1.985	Not significant
P	0.0521	

*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

Medicine prescribed	Number of cases			
	IHI + <i>Calendula</i> Q		IHI + NS	
	Prescribed	Effective	Prescribed	Effective
<i>Arsenic album</i>	8	8	6	6
<i>Calcarea carb</i>	3	3	2	2
<i>Carbo veg</i>	-	-	1	1
<i>Causticum</i>	1	1	-	-
<i>Conium</i>	-	-	1	1
<i>Lycopodium</i>	2	2	6	6
<i>Natrum mur</i>	1	1	1	1
<i>Nitric acid</i>	1	-	-	-
<i>Nux vomica</i>	1	1	-	-
<i>Opium</i>	-	-	1	1
<i>Phosphorus</i>	5	5	1	1
<i>Pulsatilla</i>	1	1	-	-
<i>Sepia</i>	3	3	2	2
<i>Silicea</i>	2	2	5	5
<i>Sulphur</i>	2	2	4	4

In this prospective study, after enrolling the cases in the study and the administration of IHI, the signs of healing



Figure 4: A case of Group A

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 *Calendula* 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 5: Characteristic indications of the efficacious medicines prescribed

Medicine	Symptoms		
	Mental	Physical General	Particular/Common
<i>Arsenic album</i>	Despair of recovery with anxiety and restlessness, Oversensitive, lack of courage, fearful dreams	Chilly patient, great thirst, food nauseates, craves coffee/milk, extreme weakness, dyspepsia from watery fruits, right side complaints, worse cold	Diabetes, ulcer with offensive discharge and burning pain, ulcers on sole, burning pains lower limbs, peripheral neuritis
<i>Lycopodium</i>	Fear to be alone, Loss of self-confidence, Hurried tendency, Fear of undertaking new things, weak memory, confused thoughts, sensitive	Right sided complaints, weakness, thin withered, excess flatulence, excess hunger with easy satiety, likes hot food and drinks, hot patient, constipation, polyuria at night, worse warmth	Numbness in lower limbs esp. night, profuse offensive foot sweat, ulcers on sole, bleeding ulcers, indurated base of ulcer
<i>Silicea</i>	Sensitive, yielding, obstinate, refined personality, stage fear	Extremely chilly patient, worse cold weather, draft of air, disgust of warm food, diminished appetite, thirsty	Suppurations lead to ulcers, ulcers on sole of foot, profuse offensive perspiration palms and soles, every injury suppurates, pus offensive from ulcer, hardened base of ulcer, soreness in the ulcer
<i>Sulphur</i>	Irritable and domineering, selfish, cleanliness aversion to	Bathing aversion, eats little, drinks a lot, weak digestion, burning eructations, cannot tolerate hunger, morning diarrhoea, frequent excess urine must hurry, worse warmth, night, tall lean with stooped shoulders	Burning ulcers in soles of feet, every little injury suppurates, burning severe at night, diabetes mellitus
<i>Phosphorus</i>	Irritable, hypersensitive to noise and odour, well behaved	Desires cold water, thirsty, aversion salty food, chilly patient, great drowsiness, worse cold exposure, tall thin individuals	Burning of soles of feet, ulcer sole of feet with burning, diabetes mellitus, ulcer bleeds easily, ulcer heal and break up again, ulcer burning pain better washing with cold water
<i>Sepia</i>	Short tempered, Indifference to family members, aversion to work	Chilly patient, Dislikes salty food, desires sour things esp. pickles, intolerance to milk causes flatulence, women in menopausal age with hot flashes	Ulcer on sole of feet, sweating more on feet with offensive pungent odour, burning sensation of feet with coldness of feet



Figure 5: A case of Group B

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.

Acknowledgements

Dr. Anil Khurana, Director General is acknowledged for providing technical co-operation and administrative support from time to time. The authors are thankful to Mr Sheik Afsar Ali, Statistician, CCRUM, Hyderabad for the valuable inputs in statistical analysis. Authors acknowledge Dr. Abdul Wajid, Deputy Superintendent and all the staff of Princess Durru Shehvar Children’s & General Hospital, Hyderabad, for their constant support & encouragement during the project. The co-operation of the patients enrolled in the study is appreciated that gave an opportunity to intrude the scope of homoeopathic medicines.

Financial support and sponsorship

The study was funded by the Central Council for Research in Homoeopathy, under the Ministry of AYUSH, Government of India.

Conflicts of interest

None declared.

REFERENCES

1. Khanolkar MP, Bain SC, Stephens JW. The diabetic foot. *QJM* 2008;101:685-95.
2. Rastogi A, Bhansali A. Diabetic foot infection: An Indian scenario. *J Foot Ankle Surg (Asia-Pacific)* 2016;3:71-9.
3. International Diabetes Federation. *IDF Diabetes. 7th ed.* Belgium: International Diabetes Federation; 2015. Available from: <http://www.diabetesatlas.org>. [Last accessed on 2018 May 24].
4. Armstrong DG, Wrobel J, Robbins JM. Are-diabetes-related wounds and amputation worse than cancer? Guest editorial. *Int Wound J* 2007;4:286-7.
5. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005;293:217-28.
6. Cavanagh PR, Lipsky BA, Bradbury AW, Botek G. Treatment for diabetic foot ulcers. *Lancet* 2005;366:1725-35.
7. Papanas N, Maltezos E. Polyherbal formulation as a therapeutic option to improve wound healing in the diabetic foot. *Indian J Med Res* 2011;134:146-7.
8. Registered Nurses' Association of Ontario. *Assessment and Management of Foot Ulcers for People with Diabetes.* Toronto, Canada: Registered Nurses' Association of Ontario; 2015. Available from: <https://www.rnao.org/bestpractices>. [Last accessed on 2020 May 26].
9. Margolis DJ, Kantor J, Berlin JA. Healing of diabetic neuropathic foot ulcers receiving standard treatment. A meta-analysis. *Diabetes Care* 1999;22:692-5.
10. Chellan G, Srikumar S, Varma AK, Mangalanandan TS, Sundaram KR, Jayakumar RV, *et al.* Foot care practice – The key to prevent diabetic foot ulcers in India. *Foot* 2012;22:298-302. Available from: <http://www.sciencedirect.com/science/article/pii/S0958259212001022>. [Last accessed on 2018 May 25]
11. Ribu L, Rustøen T, Birkeland K, Hanestad BR, Paul SM, Miaszkowski C. The prevalence and occurrence of diabetic foot ulcer pain and its impact on health-related quality of life. *J Pain* 2006;7:290-9.
12. Yazdanpanah L, Nasiri M, Adarvishi S. Literature review on the management of diabetic foot ulcer. *World J Diabetes* 2015;6:37-53.
13. Mahesh S, Mallappa M, Vithoulkas G. Gangrene: Five case studies of gangrene, preventing amputation through Homoeopathic therapy. *Indian J Res Homoeopathy* 2015;9:114-22.
14. Harsh N, Raveena J. Role of homoeopathic intervention in diabetic foot ulcer. *Homoeopath Herit* 2017;ISSN: 9070-6038.
15. Ali MS, Bindu HP. A case of diabetic foot gangrene. *Indian J Res Homoeopathy* 2007;1:42-51.
16. Ali MS, Bindu HP. A case of diabetic foot ulcer: Homoeopathic treatment could avoid amputation. *Homoeopath Herit* 2009;34:35-8.
17. Hadfield RA, Vlahovic TC, Khan MT. The use of marigold therapy for podiatric skin conditions. *Foot Ankle J* 2008;1:7. Available from: <http://faoj.org/2008/07/01/the-use-of-marigold-therapy-for-podiatric-skin-conditions/>. [Last accessed on 2018 May 25]. [doi: 10.3827/faoj.2008.0107.0001].
18. Boericke W. *Pocket Manual of Homoeopathic Materia Medica & Repertory.* 9th ed. New Delhi: B. Jain Publishers (P) Ltd.; 2001. p. 399-463.
19. Hahnemann S. *Organon of Medicine.* 5th & 6th ed. New Delhi: B Jain Publishers (P) Ltd.; 1994.
20. Abetz L, Sutton M, Brady L, McNulty P, Dennis GD. The Diabetic Foot Ulcer Scale (DFS): A quality of life instrument for use in clinical trials. *Pract Diabetes Int* 2002;19:167-75 Available from: <http://onlinelibrary.wiley.com/doi/10.1002/pdi.356/full>. [Last accessed on 2018 May 25].
21. WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. Available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>. [Last accessed on 2020 May 26].
22. *Good Clinical Practices for Clinical Research in India.* New Delhi: CDSCO; 2001. Central Drugs Standard Control Organization, Directorate General of Health Services, India. *Good Clinical Practices for Clinical Research in India.* Available from: <http://www.sggpi.ac.in/sop/GCP-%20Indian.pdf>. [Last accessed on 2012 Jul 04].
23. Nayak C, Singh V, Singh K, Singh H, Gupta J, Ali S, *et al.* A prospective observational study to ascertain the role of homeopathic therapy in the management of diabetic foot ulcer. *AJHM* 2011;104:166-76.
24. Ndosi M, Wright-Hughes A, Brown S, Backhouse M, Lipsky BA, Bhogal M, *et al.* Prognosis of the infected diabetic foot ulcer: A 12-month prospective observational study. *Diabet Med* 2018;35:78-88.

मधुमेह सम्बन्धित पैरों के नासूर (अल्सर) के प्रबंधन में व्यक्तिगत होम्योपैथी के हस्तक्षेप के साथ एक सहायक औषधि के रूप में नासूर की ड्रेसिंग के लिए कैलेंडुला मटर टिंचर बनाम सामान्य सैलाइन: एक यादृच्छिक नियंत्रित मार्गदर्शी अध्ययन

पृष्ठभूमि: मानक प्रबंधन के बाद भी, मधुमेह संबंधित पैरों के नासूर का उपचारात्मक दर कम रहता है जो निचले अंग विच्छेदन का संकट उत्पन्न करता है। **उद्देश्य:** इस अध्ययन को यह मूल्यांकन करने के लिए किया गया था कि क्या कैलेंडुला-Q ने व्यक्तिगत होम्योपैथिक हस्तक्षेप (आईएचआई) के साथ से अतिरिक्त लाभ प्रदान किया है। इसका प्राथमिक उद्देश्य था, 20 सप्ताहों के अंदर नासूर का सम्पूर्ण उपवर्तनीकरण (एपिथेलियालाइजेशन) करना और माध्यमिक उद्देश्य था, डीएफयू स्केल-शॉर्ट फॉर्म (डीएफयू-एसएफ) प्रश्नोत्तरी का प्रयोग करके जीवन की गुणवत्ता में परिवर्तन का आकलन करना। **पदार्थ और पद्धतियाँ:** 20 सप्ताहों के हस्तक्षेप के साथ, 2014 से 2017 के बीच एक यादृच्छिक नियंत्रित मार्गदर्शी अध्ययन का निष्पादन किया गया। 277 प्रकरणों की जांच की गई एवं 60 प्रकरणों का नामांकन किया गया और ग्लाइसेमिक नियंत्रण के लिए मानक पारंपरिक औषधि के साथ, समूह 1: आईएचआई + कैलेंडुला-Q ड्रेसिंग (एन = 30) और समूह 2: आईएचआई + सामान्य सैलाइन (एनएस) ड्रेसिंग (एन = 30) के लिए यादृच्छिक किया गया। **परिणाम:** दोनों समूहों में नासूर के ठीक होने के औसत समय (समूह 1 = 12 सप्ताह, समूह 2 = 11 सप्ताह) ने सांख्यिकीय रूप से कोई महत्वपूर्ण अंतर नहीं दर्शाया, इस प्रकार से ड्रेसिंग के लिए प्रयुक्त कैलेंडुला से कोई अतिरिक्त लाभ (पी = 0.0521) नहीं प्राप्त हुआ। आर्सेनिकम एल्बम (एन = 14, 23.3 प्रतिशत), लाइकोपोडियम (एन = 8, 13.3 प्रतिशत), सिलिशिया (एन = 7, 11.7 प्रतिशत), सल्फर (एन = 6, 10 प्रतिशत), फॉस्फोरस (एन = 5, 10 प्रतिशत) और सेपिया (एन = 5, 10 प्रतिशत) को प्रभावशाली औषधियों के रूप में पाया गया। **निष्कर्ष:** घाव की स्वच्छता और पारंपरिक मधुमेह प्रबंधन के साथ, आईएचआई प्रभावशाली सिद्ध हुआ, चाहे कैलेंडुला-Q या सामान्य सैलाइन का उपयोग घाव की स्वच्छता के लिए किया गया हो, इस प्रकार से डीएफयूस के वैग्नर के प्रथम एवं द्वितीय चरणों का शीघ्र एवं सम्पूर्ण उपवर्तनीकरण का मार्ग प्रशस्त हुआ। मानक देखभाल के साथ, आईएचआई की तुलना करते हुए अध्ययन करने की सलाह दी जाती है।

Teinture mère de calendula vs solution saline normale pour pansement ulcéreux 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). **Matériel 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 contrôlée. **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%), Soufre (n = 6, 10%), Phosphore (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 salina normal para el apósito de úlceras como complemento a la intervención homoeopática 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 calendula 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 licopodio (n= 8, 13.3%), la sílice (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 salina 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 comparen IHI con la atención estándar.

Ringelblume Urtinktur vs normal Kochsalzlösung für Ulkus-dressing als ein add-on für individualisierte Homöopathische intervention im management des diabetischen Fußes Geschwür: eine randomisierte kontrollierte Pilotstudie

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 es, 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 Fällen 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 Stufen von DFUs. Weitere Studien zum Vergleich der IHI mit standard-Pflege gewährleistet ist.

金盞花母酊vs生理盐水用于溃疡敷料作为个体化顺势疗法干预糖尿病足溃疡管理的附加作用：随机对照试点研究

背景: 尽管有标准管理, 糖尿病足部溃疡 (D充分) 的愈合率仍然很低, 造成下肢截肢的风险。目标: 本研究是评估金盞花 Q 是否比个性化同源性干预 (IHI) 具有额外的益处。主要目标是在20周内实现完整的上皮化, 次要目标是使用DFU规模短表 (DFU SF) 问卷评估生活质量的变化。材料和方法: 2014-2017年进行了一项随机对照试验研究, 为期20周。对277例进行了筛查, 60例被登记并随机登记到第一组: IHI + 金盞花 Q敷料 (n= 30) 和第二组: IHI = 正常盐水 (NS) 敷料 (n= 30), 以及用于血糖控制的标准常规药物。结果: 两组溃疡愈合的均时 (I组=12周, 第II组=11周) 均无统计学显著差异, 因此用于敷料的金盞花Q没有任何附加益处 (p= 0.0521)。砷 (n= 14, 23.3%), 利科波迪姆 (n= 8, 13.3%), 西里萨 (n= 7, 11.7%), 硫 (n= 6, 10%), 磷 (n= 5, 10%) 和棕褐色 (n= 5, 10%) 被发现是有效的药物。结论: IHI, 连同伤口卫生和常规糖尿病管理, 被证明是有效的, 无论卡伦杜拉Q或正常的盐水是否用于伤口卫生, 从而导致瓦格纳的第一和第二阶段的DDF的早期, 完全上皮化。需要进一步研究将 IHI 与标准护理进行比较。