

## REPRINT ARTICLE

### A prospective observational study to ascertain the role of homeopathic therapy in the management of diabetic foot ulcer\*\*

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**Background:** The risk for lower extremity amputation (LEA) in patients with diabetic foot ulcer is high, and high recurrence rates of foot ulcers pose a risk that the amputations will be repeated. While the incidence rates of diabetic foot ulcers are often poorly documented, such as is the case in India, the heavy strain of the disease on health care budgets can easily be felt the world over. The high cost of the treatment of foot ulcers causes many patients to neglect needed care, resulting in amputations. The present observational study of diabetic foot ulcer was undertaken for the purpose of deriving a group of useful homeopathic medicines for the treatment of this condition, hopefully revealing a cost effective means of reducing the incidence of foot amputations.

**Method:** A prospective observational study was conducted by the Central Council for Research in Homoeopathy at its Drug Standardization Extension Unit, Hyderabad, from October 2005 to September 2009. One hundred and fifty-six (156) patients with diabetic foot ulcer in the age group of above thirty years from both sexes were screened and eighty-one patients were enrolled as per the pre-set inclusion and exclusion criteria. Out of eighty-one cases enrolled only sixty-three cases completed the follow up. The remainder of the cases were excluded. Homeopathic medicines prescribed to the enrolled patients were limited to a group of fifteen pre-defined trial medicines. The improvement of the cases was assessed basing upon the diabetic foot ulcer assessment score, before and after treatment, on a prescribed format devised by the council (Table 1) and by periodic photographs.

**Results:** The difference in the mean of the ulcer assessment score was found to be statistically significant ( $P=0.000, <0.05$ ) after the treatment with trial medicines. In only one case, the ulcer assessment score showed no significant improvement from the baseline. *Silicea* ( $n=22$ ), *Sulphur* ( $n=11$ ), *Lycopodium* ( $n=10$ ), *Arsenicum album* ( $n=8$ ), *Phosphorus* ( $n=8$ ) were found to be the most useful among the fifteen pre-identified trial medicines.

**Conclusion:** This was an observational study with positive results; however, it is difficult to attribute the positive results to homeopathic therapy alone as the dressing of the ulcer and ancillary measures of themselves often eventuate in ulcer resolution. Further RCT corroboration is recommended for validation of the results.

**Keywords:** observational study; diabetic foot ulcers; homeopathic treatment of; *Silicea*; *Sulphur*; *Lycopodium*; *Arsenicum album*; *Phosphorus*; ulcer assessment score

## INTRODUCTION

Many diabetic patients over time develop the chronic complications of diabetes: retinopathy, nephropathy,

peripheral neuropathy, and atherosclerotic vascular disease. From a patient's perspective, one of the most dreaded complications is loss of a leg as a consequence of peripheral neuropathy or ischemia. Diabetes is the most common disease process associated with lower limb amputation, accounting for approximately half of non-traumatic amputations in North America and Europe.<sup>1,2</sup> Up to eighty-five percent of lower limb amputations in diabetic patients are preceded by foot ulcers that fail to heal.<sup>3</sup> About two to three percent of all diabetic patients will develop a foot ulcer every year, and many of these will require prolonged hospitalization

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for treatment of complications of ensuing infection or gangrene.<sup>4,5</sup> These foot problems affect the health care system considerably. A recent report estimated that direct annual costs of diabetic foot care in the United States were approximately \$5 billion (US).<sup>6</sup>

India has the highest number of people with diabetes in the world. Diabetic foot care is one of the most ignored aspects of diabetes care in India. Due to social, religious, and economic compulsions, many people walk barefoot. Poverty and illiteracy lead to usage of inappropriate foot wear and late presentation of foot lesions. India has about 42 million people with diabetes, putting it first on the list of the ten nations most affected by this disease. The present projection indicates that India will continue to hold the same position till 2025. A study of 18,000 people in India has revealed that up to seventy percent of people may have undiagnosed diabetes, which is much higher than expected. Up to twenty-five percent of those with diabetes will develop a foot ulcer. Worldwide, more than one million amputations are performed each year as a consequence of diabetes, which means that a lower limb is lost (amputated) due to diabetes somewhere in the world every thirty seconds. Up to eighty-five percent of all amputations in people with diabetes are preceded by foot ulcers. In ninety percent of foot ulcer cases with diabetes, sensory neuropathy is part of the problem.<sup>7</sup>

From April 1997 to March 2003, the Central Council for Research in Homoeopathy conducted a study in which one hundred cases (53 males and 47 females) of diabetes mellitus were studied to clinically evaluate the usefulness of a mother tincture of *Cephalandra indica* in the management of diabetes mellitus. Evaluation of clinical and laboratory data showed improvement in varying degrees in ninety-two cases. The study demonstrated that *Cephalandra indica* Q could maintain glycemic control and thus might prevent long-term complications of diabetes mellitus.<sup>8</sup>

With the background of the above study, a prospective observational open clinical study was conducted by the Central Council for Research in Homoeopathy at its Drug Standardization Extension Unit, functioning on the premises of Princess Durru Shehvar Children's and General Hospital, Hyderabad from October 2005 to September 2009.

**Primary Objective:** To ascertain the usefulness of a group of fifteen pre-defined homeopathic medicines in treating patients suffering from diabetic foot ulcer.

#### **Secondary Objectives:**

- To verify the characteristic symptoms of the medicines used.

- To ascertain the additional clinical symptoms, if any, of the homeopathic medicine(s) used during the study.

## **METHODS**

### *Study Design*

The patients were screened from the general out-patient department of the unit and those who met our inclusion criteria were assessed for baseline symptom score. At entry an objective assessment by using a "diabetic foot ulcer assessment score," developed by the Council (Table 1) was conducted. Photographs were also taken from the same angle and same distance of ulcers at entry, the third month, and at sixth month. Each patient was examined thoroughly by the consultant surgeon at different stages of the study, including at entry level and after completion of the study.

The study protocol was in accordance with the Helsinki declaration on Human Experimentation.<sup>9</sup> Clearance by the Ethics Committee was obtained before initiation of the study. The study was verbally explained to each patient with the help of a patient information sheet printed in regional language, and thereafter a written informed consent was obtained from the patient. However, the patient was free to withdraw from the study at any time. As previously mentioned, the severity of diabetic foot ulcer symptoms was measured by means of a diabetic foot ulcer assessment score developed by the Council. One hundred-and-fifty-six patients above thirty years of age from both sexes with diabetic foot ulcer were screened and eighty-one patients were enrolled as per the pre-set inclusion and exclusion criteria. Seventy-five cases were excluded as the patients had either glycosylated hemoglobin levels greater than eight percent or were suffering from foot gangrene, systemic complications, or some other severe known disease as per the pre-set exclusion criteria in the protocol of the study.

Statistical analysis was done with the help of t-test, ANOVA & Wilcoxon Sign Rank Test using SPSS (Statistical Package for Social Science) Version 16 and System Stats Version 10.

### *Inclusion criteria*

Both male and female patients over thirty years of age, diagnosed insulin-dependent or non-insulin-dependent diabetes mellitus (IDDM and NIDDM), presenting with ulcer on the lower extremity for more than one week were included. During the study the patients were allowed to take allopathic medication on which they were dependent (in consultation with an endocrinologist). Gradually, the allopathic medication

was tapered or withdrawn in consultation with an endocrinologist depending on the level of the blood sugar. Patients taking antihypertensive and/or lipid lowering drugs were allowed to continue such drugs.

#### Exclusion criteria

- Subjects with ill-managed diabetes; i.e., glycosylated hemoglobin (HbA1c) greater than eight percent;
- Cases presenting with gangrene or impending gangrene (manifesting sudden black discoloration of skin);
- Ulcers with underlying osteomyelitis;
- Venous ulcers or ulcers due to any other cause;
- Cases presenting with a long-term complication of diabetes, such as severe retinopathy, severe renal involvement or with a history of recurrent acute complications like hypoglycemia, ketoacidosis, polyneuropathy, etc;
- Patients requiring intravenous antibiotics, emergency management or surgical intervention;
- Patients suffering from life-threatening or chronic diseases like ischemic heart disease of less than six months duration, unstable angina, hypertension, malignancy, or HIV/AIDS, etc.
- History of diabetic coma.

#### Data Collection

Demographic details and duration of diabetes were recorded for all the patients. HbA1c percentage was estimated by immunoturbidimetric method. Fasting and postprandial blood sugar levels, urea, creatinine and lipid profile were measured by using standard enzymatic procedures. Doppler study of blood vessels of the affected limb was also done to evaluate any underlying vascular pathology. All the subjects were educated regarding diabetic foot disease and its complications and the need for regular foot examination. Education on diabetic foot care was given to all the patients and their attendants during their first visit. They were individually shown how to check any minor foot injuries using a mirror. Handouts in the regional language emphasizing the need for foot care were also provided.

#### Selection of Medicine

Fifteen pre-defined trial medicines were selected by repertorizing the diagnostic symptoms of diabetic foot ulcer. The repertorization was performed using the Complete Repertory in Cara Professional.<sup>10</sup> Fifteen medicines mentioned in either first grade (three points),

followed by those in second grade (two points), in the rubrics 'Diabetes mellitus' and 'Non-healing Ulcer' in the Complete Repertory were considered. These were: *Sulphur, Silicea, Lycopodium, Arsenium album, Lachesis, Phosphorus, Sepia, Phosphoricum acidum, Opium, Mercurius solubilis, Pulsatilla, Secale cornutum, Calcarea carbonicum, Plumbum metallicum and Rhus toxicodendron*. Medicines were prescribed to the enrolled patients from these fifteen pre-defined trial medicines. The simillimum was selected from this short list of medicines on the basis of the totality of symptoms of each patient. Nine out of these fifteen medicines were prescribed in the centesimal potency (30c). Besides repertorization, the materia medica<sup>11</sup> was also referred to in determining the simillimum. The cases requiring a homeopathic medicine other than one of the trial medicines were excluded from the study and treated separately in the out-patient department.

#### Treatment Plan

All the enrolled patients were given the indicated homeopathic medicine in 30c potency in single dose. Each dose consisted of four pills, size number 30; followed by placebo three times a day for two weeks. Follow-ups were conducted weekly for the first month, fortnightly for the next two, months and monthly thereafter until the sixth month. The intensity of the symptoms determined whether the medicine was repeated. Medicines in the 200c and 1M potencies were subsequently prescribed when the 30c acted but did not relieve symptoms completely. All subsequent prescriptions were made as per the guidelines given by Kent.<sup>12</sup> If improvement was not forthcoming even after adequate repetition of the medicine in higher potencies; investigators were allowed to change the prescription up to two times, again limiting their selections to the trial medicines. As a part of non-medical management all the patients were advised to go for periodic dressing of the ulcer with the external application of *Calendula* tincture to prevent secondary infection.

#### Outcome Assessment

Primary outcome was reduction in diabetic foot ulcer symptom score. Improvement was calculated by using the following formula:

$$\% \text{ of improvement} = \frac{\text{Symptom score at base line} - \text{Symptom score at completion of the study}}{\text{Symptom score at base line}} \times 100.$$

Changes occurring during the study were graded as: cure (100 percent improvement), marked improvement (75 to less than 100 percent improvement), moderate (50 to less than 75 percent improvement), mild (25 to less than 50 percent improvement), not significant (less than 25 percent improvement), static (no change), worse (increase in baseline score).

The patient was assessed at the third month and sixth month with the help of the ulcer assessment score (Table 1) for a maximum period of six months. The final assessment was done subjectively through the ulcer assessment score as shown in Table 2 and objectively by periodic photographs.

**Table 1:** Diabetic Foot Ulcer Assessment Score

S.No.	Symptoms	0	1	2	3	4
1.	Numbness of lower limbs	Absent	Occasional	Frequent	Persistent	-
2.	Ulcer on lower extremity					
i)	Duration	-	1 Less than 2 weeks	2 More than 2 weeks	3 More than 1 month	-
ii)	Pain	0 Absent	1 Infrequent	2 Frequent	3 Persistent	-
iii)	Edges	-	1	- Shelving	3	- Sharply cut
iv)	Depth	0 No ulcer (healed)	1 Superficial	2 Up to Muscles	3 Up to Bones	-
v)	Discharge	0	1 Absent	2 Serous	3 Purulent	- Blood stained
vi)	Odor	0 Odorless	1 Foul	2 Offensive	3 Putrid	-
vii)	Floor	0 Healed	1 Granular	2 Dry	3 With exudates	4 Necrotic
3.	Regional lymph nodes	0 No Palpable	-	2 Palpable	-	-
4.	Blood Sugar					
i)	Fasting	0 80-120	1 120-140	2 140-160	3 160-180	-
ii)	P.P.	0 120-180	1 180-240	2 240-300	3 300 & above	-
5.	History of taking Allopathic Medications					
i)	Insulin	0 No/ Withdrawn	1 Lower than at entry	2 Same as at entry	-	-
ii)	Dosage of Allopathic Medications	0 Withdrawn	1 Lower than at entry	2 Same as at entry	-	-
<b>Total symptom score</b>						
MILD (2-12)		MODERATE (13-23)	SEVERE (24-37)			

**Table 2:** Parameters Adopted for Assessment of Response to Treatment

<b>1. Improvement:</b>	<b>Marked</b>	75% and above improvement in symptom score from baseline score
	<b>Moderate</b>	50% to less than 75% improvement in symptom score from baseline score
	<b>Mild</b>	25% to less than 50% improvement in symptom score from baseline score
<b>2. Not significant</b>		Less than 25% improvement in symptom score from baseline score
<b>3. Not improved</b>		No change in symptom score from baseline score even after administration of best indicated medicines.
<b>4. Worsened</b>		Increase in score from baseline
<b>5. Static</b>		No change of score from baseline
<b>6. Referred</b>		Referred to other therapy in the eventuality of any adverse event
<b>7. Drop out</b>		Does not fulfill the conditions as per protocol

### Statistical Analysis

Statistical analysis was carried out using SPSS 16.0 for Windows (Statistical Package for Social Sciences). The data was examined for normality of distribution. For normally distributed data, comparisons of score at entry and at end of study were done by using paired t test, ANOVA and Wilcoxon Sign Rank Test.  $P < 0.05$  was considered as significant.

### RESULTS

In the study period, 156 cases with diabetic foot ulcer were screened, out of whom eighty-one were enrolled, as per the protocol. Among the eighty-one cases enrolled, sixty-three cases (forty-five males; eighteen females) were followed up and studied; the others were excluded as they deviated from the protocol norms. The incidence of diabetic foot ulcer was found to be maximal in the age group of 50-59 years ( $n=29$ ) and minimal in the age group of 70-79 years ( $n=1$ ) as shown in Table 3. The intensity of the disease in patients at baseline and after treatment, as per the ulcer assessment score, is given in Table 7.

The predisposing factors observed in the enrolled diabetic foot ulcer cases are shown in Table 5. The difference in the symptoms and signs at baseline and at the end was found to be statistically significant with their respective  $P$  values. The ulcer assessment score at entry and at the end with its varied range is shown in Table 7.

The fasting blood sugar and postprandial blood sugar values were analyzed by using ANOVA and multiple comparisons of baseline values with the values at the end of the study, as shown in Table 8. The result of this analysis showed statistical significance. ( $P = 0.001$ ,  $< 0.05$ ).

An analysis of the trial medicines (Table 9) showed that out of fifteen, nine medicines were used in this study, out of which five were frequently used ( $n=59, 93.7\%$ ), which were *Sulphur* ( $n=11, 17.5\%$ ), *Silicea* ( $n=22, 34.9\%$ ), *Lycopodium* ( $n=10, 15.9\%$ ), *Arsenic album* ( $n=8, 12.7\%$ ), and *Phosphorus* ( $n=8, 12.7\%$ ). In rest of the cases ( $n=4, 6.3\%$ ), the four trial medicines used were *Sepia* ( $n=1$ ), *Calcarea carbonica* ( $n=1$ ), *Secale cornutum* ( $n=1$ ) and *Plumbum metallicum* ( $n=1$ ). The cases which were given *Silicea* showed 95.5% improvement, *Sulphur* showed 90.9% improvement, *Lycopodium* showed 100% improvement, *Arsenicum album* showed 100% improvement and *Phosphorus* showed 75% improvement. The characteristic indications of the five frequently used medicines are described in Table 11.

90.6% of diabetic foot ulcer patients ( $n=57$ ) were cured at various stages of their treatment during the study period of six months (Table 10 and Figures 1,2). Most of the cases were cured within three months, and a few at the end of the study. Among sixty-three cases which have completed follow up, fifty-seven cases showed marked improvement where the ulcer completely healed, four cases showed moderate improvement, one case showed mild improvement and one case did not show any significant improvement.

**Table 3:** Age & Sex Distribution of Cases

Age (yrs.)			Sex			
	Total	%	Male	%	Female	%
30 – 39	9	14.3	7	77.8	2	22.2
40 – 49	24	38.1	10	41.7	14	58.3
50 – 59	29	46.0	23	79.3	6	20.7
60-69	10	15.9	4	40	6	60
70-79	1	1.6	1	100	0	-
TOTAL	63	100	45	71.4	18	28.6

**Table 4:** Data of the Diabetic Foot Ulcer Cases at Baseline

	Study group (n)	Mean ±SD	%
Sex			
• Male	45		71.4
• Female	18		28.6
Duration of ulcer			
• Less than 2 weeks	5		7.9
• More than 2 weeks	26		41.3
• More than 1 weeks	32		50.8
Ulcer index score (range)			
• Mild (2-12 )	56	8±2.5	88.9
• Moderate (13-23)	7	13.1±0.4	11.1

**Table 5:** Predisposing Factors Observed in Diabetic Foot Ulcer Cases

Predisposing Factors	No. of cases	(n=63) %
Duration of Diabetes		
Up to 5 Yrs / 5-10 Yrs / Above 10 Yrs	17 / 16 / 30	27/25.4 / 47.6
Family History of Diabetes		
Present / Absent	48 / 15	76.2 / 23.8
Body Mass Index		
Below 24.9 / 25-29.9 / 30-39.9	31 / 24 / 8	49.2 / 38.1 / 12.7

**Table 6:** Symptoms & Signs of the Diabetic Foot Ulcer Cases at Baseline and at the End of the Study

Symptoms/Signs (N = 63)	At Baseline		At end		P value*
	No. of cases	%	No. of cases	%	
Numbness of lower limbs					
Absent/Occasional/Frequent/Persistent	17/16/12/18	27/25.4/19.1/28.6	52/11/0/0	82.5/17.5/0/0	0.0001
Ulcer foot – Pain					
Absent/Infrequent/Frequent/Persistent	19/19/7/18	30.2/30.2/11.1/28.6	61/0/0/2	96.8/0/0/3.2	0.0001
Ulcer foot – Edges					
Healed/Shelved/Sharply cut	0/39/24	0/61.9/38.1	54/8/1	85.7/12.7/ 1.6	0.0001
Ulcer foot – Depth					
Healed/Superficial/Muscles/Bones	0/51/12/0	0/81/19.0/0	57/5/1/0	90.5/7.9/1.6/0	0.0001
Ulcer foot – Discharge					
Absent/Serous/Purulent/Blood stained	47/9/6/1	74.6/14.3/9.5/1.6	63/0/0/0	100/0/0/0	0.0001
Ulcer foot – Odor					
No/Foul/Offensive/Putrid	52/7/4/0	82.5/11.1/6.3/0	63/0/0/0	100/0/0/0	0.002
Ulcer foot – Floor					
Healed/Granular/Dry/Exudates/Necrotic	0/17/24/21/1	0/27/38.1/33.3/1.6	56/7/0/0/0	88.9/11.1/0/0/0	0.0001
Ulcer foot – Regional Lymph Nodes					
Palpable/ Not palpable	62/1	98.4/1.6	63/0	100/0	0.317

\* Statistically significant, P value<0.05

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**Table 7:** Diabetic Foot Ulcer Assessment Score at Entry and at End

	Mean score at entry ± SD (n)	Mean score at end ± SD (n)	P value*
Ulcer score assessment	8.5±2.8 (63)	0.7±1.7 (63)*	0.0001
Range in ulcer index score			
• Mild (2-12)	8±2.5 (56)	0.6±1.3 (56)*	0.0001
• Moderate (13-23)	13.1±0.4 (7)	1.6±3.7 (7)*	0.0001

\* Statistically significant, P value <0.05

**Table 8:** Investigation in Diabetic Foot Ulcer cases at Entry and at End

Investigations	Mean score at entry ± SD (n)	Mean score at end ± SD (n)	P value*
Fasting Blood Sugar	107.2±18.5 (63)	94.9±6.6 (63)*	0.002
Post Prandial Blood Sugar	174.7±38.6 (63)	152.1±18.3 (63)*	0.0001
HbA1c	7.7±0.5 (63)	7.6±0.3 (63)*	0.001

\* Statistically significant, P value <0.05

**Table 9:** Date of Trial Frequently Used and Improvement Assessment

Trial Medicine	Prescribed cases	%	Improvement assessment			
			Marked >	Moderate >	Mild >	Not Significant
<i>Sulphur</i>	11	17.5	10	01	-	-
<i>Silicea</i>	22	34.9	21	01	-	-
<i>Lycopodium</i>	10	15.9	10	-	-	-
<i>Arsenic album</i>	08	12.7	08	-	-	-
<i>Phosphorus</i>	08	12.7	06	-	01	01
<i>Sepia</i>	01	1.6	01	-	-	-
<i>Secale cor.</i>	01	1.6	-	01	-	-
<i>Calc. carb.</i>	01	1.6	01	-	-	-
<i>Plumbum met.</i>	01	1.6	-	01	-	-

**Table 10:** Distribution of Patients According to Improvement Status

Improvement Status	No. of Patients	Percentage
Marked	57	90.5%
Moderate	4	6.3%
Mild	1	1.6%
Not Significant	1	1.6%
Total	63	100.0%

**Table 11:** Characteristic Indications of Frequently Used Medicines

Name of trial medicine	Indications
<i>Silicea</i>	Obstinate personality; chilly patient; right sided complaints; tendency to suppuration; constipation; sweat -profuse, offensive specially palms & soles; ulcer foot; diabetes mellitus; skin dry; burning soles.
<i>Sulphur</i>	Domineering and angry; hot patient; complaints relapse; offensivedischarges; Ulcer foot; diabetes mellitus; numbness of feet; burning soles; chronic; obstinate ulcers.
<i>Lycopodium</i>	Lack of confidence; irritable; intellectually keen but physically weak; right sided complaints; hot patient; easy satiety; desires sweets; Ulcer foot; diabetes mellitus; numbness of feet; burning soles.
<i>Arsenic album</i>	Fastidious; anxiety about health; restlessness; chilly patient; right sided complaints; Ulcer foot; diabetes mellitus; burning soles; burning pains ameliorated by warmth.
<i>Phosphorus</i>	Extrovert; communicative; friendly; desires company; chilly patient; desires cold food & drinks; Ulcer foot; diabetes mellitus; burning soles; burning pains.

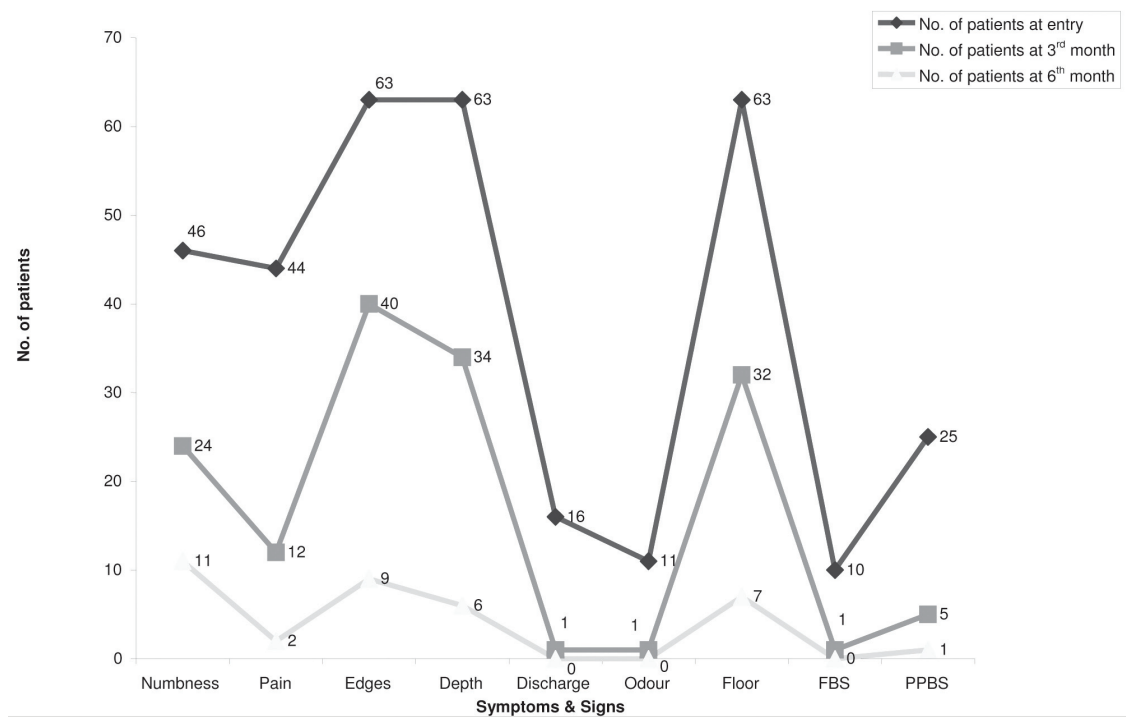


Figure 1 : Improvement of Symptoms & Signs in Diabetic Foot Ulcer Cases

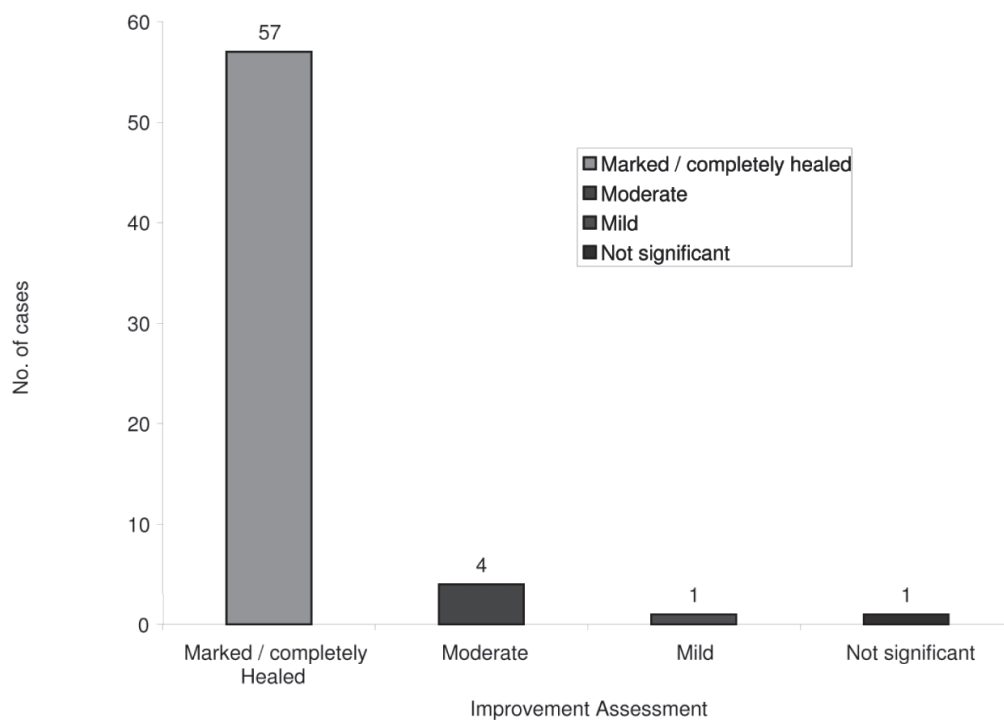


Figure 2 : Improvement status of Diabetic foot ulcer cases



## DISCUSSION

The present study, conducted by the Central Council for Research in Homoeopathy, is a prospective observational evaluation of the efficacy of the homeopathic treatment of diabetic foot ulcer.

Diabetic foot care is one of the most ignored aspects of diabetes care in India. India is a country with diverse social, religious, and economic incentives eventuating in the common practice of barefoot walking, and, as stated previously, poverty and illiteracy often lead to usage of inappropriate footwear, which in turn gives rise to foot lesions. Although precise statistical figures are not available in India to indicate the exact preponderance and economic cost of this problem, it is readily apparent that the toll diabetic foot ulcer exacts on the populace's welfare and the country's economy is considerable. For these reasons this study was undertaken.

Patients with diabetic foot ulcer of variable duration unresponsive to regular conventional treatment were enrolled in this study. Most of the patients (50.8%) enrolled had their ulcer for more than one month; 41.3% of patients for more than two weeks, and only five cases (7.9%) for less than two weeks. Most of the enrolled patients presented with diabetes of greater than ten years duration ( $n=30$ , 47.6%) as well as a family history of diabetes ( $n=48$ , 76.2%); no specific correlation could be made to the body mass index in that fifty percent of patients ( $n=31$ , 49.2%) had a normal BMI.

In this study it was observed that the mean ulcer assessment scores at entry and at end were  $-8.5 \pm 2.8$  and  $0.7 \pm 1.7$  respectively. The reduction in the score of the symptoms and signs of diabetic foot ulcer was statistically significant ( $P=0.000$ ). More than ninety percent of the cases remained ulcer free at the end of the study and no amputations were required. This observation is similar to one study which was reported from the United Kingdom.<sup>13</sup> In the present study, the mean time for complete healing of ulcers was found to be seventy-five days, with superficial ulcers healing within thirty days and those which penetrated to the depth of the musculature healing within ninety days, which conforms to the results of another prospective study of this condition.<sup>14</sup> In one particular case the healing process was very fast but not completed within the study period, a result attributed to the depth and location of the ulcer in a pressure-bearing area on the thickest part of the sole.

The incidence in males was greater than in females in this study; however, other studies show that both sexes are equally vulnerable. Most of the patients in

this study were fifty to fifty-nine years of age. The above findings corroborate those of a previous study which showed that the risk of foot ulceration increases with the duration of diabetes, male gender, and advanced age.<sup>15, 16, 17</sup>

The five medicines found most useful in this study were *Silicea*, *Sulphur*, *Lycopodium*, *Arsenicum album*, and *Phosphorus*. The authors consider the results encouraging. *Silicea* showed improvement in 95.5% of the cases in which it was administered, *Sulphur* in 90.9% of cases, *Lycopodium* and *Arsenicum album* in one hundred percent, and *Phosphorus* in seventy-five percent.

Among the eighty-one enrolled cases, sixty-three have completed the follow-up. Out of these sixty-three cases, fifty-seven demonstrated complete healing, four showed moderate improvement, one mild improvement, and one case no significant improvement.

Glucose levels (fasting and postprandial) were measured on all patients at one month, three months and at the end of the study (sixth month). The glycosylated hemoglobin levels of all the patients were measured at entry, at the third month and the sixth month. There was a significant reduction in these measurements at the end of the study, indicating a positive role of homeopathic medicines in reducing glucose levels in diabetics. (Table 8) This finding echoes the findings of a previous study conducted by the Central Council.<sup>8</sup>

Doppler studies of the vessels of the affected lower limbs were conducted on almost all patients at the screening stage; however, they were not repeated at the end of the study. The absence of this data precludes analysis of the effect of homeopathic medicines on specific blood vessel pathology associated with diabetic foot ulcer.

One of the secondary objectives of the study was to identify previously undiscovered clinical symptoms of the homeopathic medicines employed; however, no such symptoms were elicited in this study.

## CONCLUSION

This prospective observational study of the homeopathic treatment of diabetic foot ulcer demonstrated positive results. It is difficult, however, to attribute the positive results to homeopathic therapy alone as diabetic wound care (cleansing, dressing, etc.) of such ulcers alone has often proven quite adequate to heal diabetic foot ulcers. Consequently, it is recommended that further RCTs be conducted at multiple centers, preferably with comparison to a

group of patients undergoing ulcer hygiene alone, for validation and elaboration of these results.

### CONFLICT OF INTEREST

We declare no conflict of interest.

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