



# A STUDY TO SEE THE POTENTIALITY OF HOMOEOPATHIC MEDICINE IN ENHANCING THE WOUND HEALING OF DIABETIC FOOT ULCER IN PATIENTS OF GRADE I/II/III OF WAGNER'S CLASSIFICATION

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**Abstract:** Diabetic foot ulcer a serious and major complication of diabetes mellitus is a severe public health issue with global prevalence of 6.3%, with 100000 leg amputation per year due to DFU. Mechanism of wound healing is an innate process which does not work with certain disorders and physiological insults. Diabetes mellitus (glycemic levels, peripheral ischemia, peripheral neuropathy, infection) is one such cause hampering healing along with social and economic causes. Present study is undertaken with aim of seeing potentiality of homeopathy in enhancing wound healing of DFU, by stimulating the process of wound healing in return reducing the global burden of amputations by giving cost effective treatment and also making patients aware that it can be prevented and managed adequately. **Material and Methods:** A study with patients of diabetic foot ulcer of Wagner's grade I, II, III in phase 1 and grade III, IV, V along with I, II In phase 2 were enrolled based on inclusion and exclusion criteria, out of which 35 completed the follow ups. Patients were assigned to pre-decided homeopathic remedy (Arsenic album 0/1) and regular dressing. Detailed standard foot examination and required investigation (HbA1C, FBS, PP2BS, Culture, and venous Doppler) were done. Outcome was assessed by Saint Elian Score System before and after and photographs. **Results:** The study showed positive outcomes with test statistic value 11.01 and P (0.000) which is highly significant. Saint Ellen score before treatment was  $15.257 \pm 4.693$ , after treatment score reduced to  $6.6 \pm 7.78$ . **Conclusion:** The study proved that homeopathic treatment helps in enhancing the healing of DFU, but it is difficult to attribute positive results in such small sample study, further corroboration of RCT is recommended.

**Index Terms - :-** Diabetic foot ulcer, Ischemia, Neuropathy, Wagner's grading

## I.INTRODUCTION

Diabetic foot ulcer is a serious significant complication of diabetes mellitus, and probably the prime component of the diabetic foot<sup>1</sup> Wound healing is a natural mechanism of action that works reliably most of the time. A key feature of wound healing is gradual repair of the lost extracellular matrix that forms the maximum component of the dermal skin layer.<sup>2</sup> But in some patients, certain pathological conditions or physiological insults disturb the process of wound healing<sup>2</sup> Diabetes mellitus being one such metabolic disorder that hinders the normal mechanism of the wound healing<sup>3</sup> Extended inflammatory phase in diabetic wounds, causes a retardation in the formation of mature granulation tissue and a parallel decrease in wound tensile strength.<sup>5</sup>

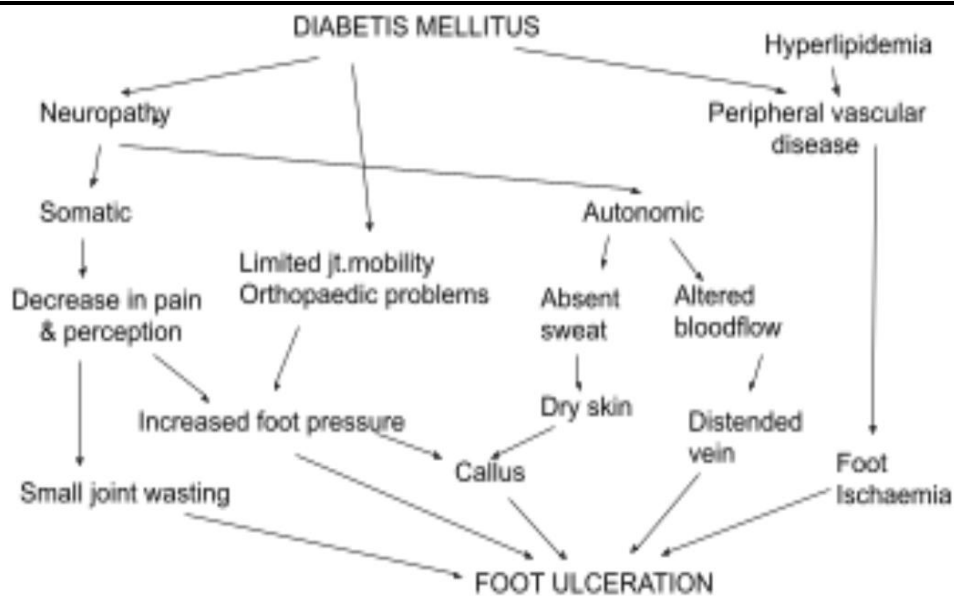


Figure 1 : Aetiological presentation of DFU

In diabetes, elevated glycaemic levels increase the risk of Atherosclerosis (peripheral vascular disease) and peripheral neuropathy

- (a) micro vascular: coronary heart disease, cerebrovascular disease, peripheral vascular disease  
 (b) macro vascular: nephropathy, retinopathy, and neuropathy

Atherosclerosis (peripheral vascular disease) and peripheral neuropathy occur with increased frequency in persons with diabetes mellitus (DM).

#### Diabetes-related atherosclerosis:

Generally, people with diabetes mellitus (DM) have an increased risk of atherosclerosis, thickening of capillary basement membranes, arteriolar hyalinosis, and endothelial proliferation. Calcification and thickening of the arterial media (Mönckeberg sclerosis) are also seen with increased prevalence in the diabetic people, while whether these factors have any effect on the circulatory condition is not clear<sup>4</sup>

The notable atherosclerotic condition of the infrapopliteal segments is distinctly common in the diabetic people. Rudimentary digital artery disease, when exacerbated by an infected ulcer in close accessibility, may result in complete loss of digital collaterals and give rise to gangrene

The grounds for the predominance of this form of arterial conditions in diabetic patients is believe to as an outcome from a numerous metabolic abnormality, including high low-density lipoprotein (LDL) and very-low-density lipoprotein (VLDL) levels, elevated plasma von Willebrand factor, inhibition of prostacyclin synthesis, elevated plasma fibrinogen levels, and increased platelet adhesiveness

#### Diabetic peripheral neuropathy:

The pathophysiology of diabetic peripheral neuropathy is multifactorial and is believe as an outcome from vascular disease occluding the vasa nervorum; endothelial dysfunction; deficiency of myoinositol-altering myelin synthesis and decreasing sodium-potassium adenosine triphosphatase (ATPase) activity; chronic hyperosmolarity, leading to edema of nerve trunks; and insults of increased sorbitol and fructose

The outcome of decreased sensation in the foot is repetitive stress; unnoticed injuries and fractures; structural foot deformity, such as hammertoes, bunions, metatarsal deformities, or Charcot foot; further stress; and gradual tissue breakdown. Unnoticed excessive heat or cold, pressure from a poorly fitting shoe, or damage from a blunt or sharp object inadvertently left in the shoe may cause blistering and ulceration. These factors, combined with poor arterial inflow, confer a high risk of limb loss on the patient with diabetes<sup>4</sup>

## II. AIM AND OBJECTIVE

To look for potentiality of homoeopathic medication in enhancing the process of wound healing of diabetic foot ulcers in grade I, II, III of Wagner's classification by stimulating the process of healing.

## III. SUBJECTS AND METHODS:

**3.1 Study settings:** study was conducted at homoeopathic hospital and research Centre, from January 2020 to January 2021.

### 3.2 inclusion and exclusion criteria

#### *Inclusion criteria:*

- Age over 30 years
- with diagnosed type 2 DM
- Both sexes (male and female)
- PHASE I: Grade I & II (Wagner's classification) & mild and moderate of saint Elian score chart.
- PHASE II: grade I, II, III & IV of (Wagner's classification) & mild and moderate of saint Elian score chart.
- Written informed consent.

#### *Exclusion criteria:*

- PHASE I: Patient with grade III, IV and V (Wagner's classification) & severe of saint Elian score chart.
- Development of typical Charcot joints, Fractures of particularly the feet.
- 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 hypoglycaemia, ketoacidosis, polyneuropathy, etc.
- 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

**3.3 Study design:** This is Experimental informal before and after pragmatic, snowball.

Sample size: 40 cases were enrolled after screening considering inclusion and exclusion criteria,

**3.4 Method:** The study was done in two phases, in the first {phase I}: 1st 6 months of the study patients with mild degree (grade I, II of WAGNER'S classification)<sup>6</sup> were treated and after seeing improvement in them {phase II}: 2nd 6 months of the study advanced degree (grade III, IV, V along with I, II of WAGNER'S classification)<sup>6</sup> were taken.

After Detailed foot examination (to look for peripheral ischaemia, neuropathy, infection) were done by the investigator & the surgeon involved in the study, also required investigation (HbA1C, FBS, PP2BS, Culture, venous doppler) were done.

**3.5 Intervention:** Homoeopathic remedy "Arsenic Album 0/1"<sup>7</sup> was prescribed along with local dressing<sup>9</sup> according to the severity. The Arsenic Album was prescribed in 0/1M liquid potency as per the Hahnemann guidelines given in the organon of medicine in frequent doses or Arsenic album 200/1M (Five cup method)<sup>8</sup>

Repetitions in the follow ups were made according to the requirement of the patient.

Parameters like Ischaemia, neuropathy, infection, were also checked to look for cause, along with healing which was appreciated by pictorial difference in every follow up along with foot examination. Saint Ellen's score system was used before and after treatment for outcome assessment.<sup>10</sup>

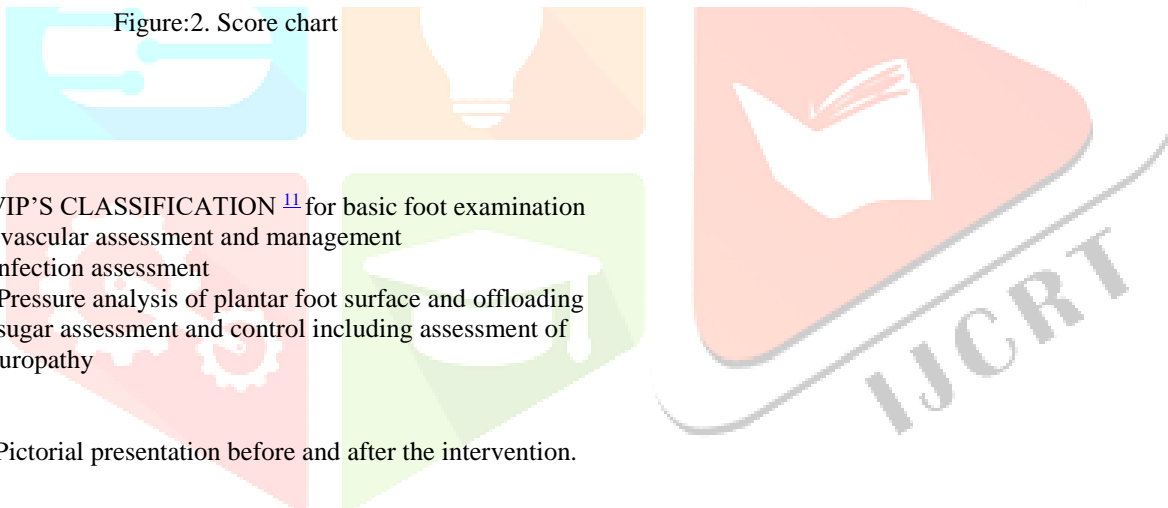
### 3.6 Outcome assessment:

3.6.1. it will according to the "Saint Elian Score System for 10 subcategorized wound severity factors and III Grades "<sup>10</sup>

Saint Elian Score System for 10 subcategorized wound severity factors and III Grades for prognosis

FACTORS	1 (MILD)	2 (MODERATE)	3 (SEVERE)	SCORE
Primary zone(location)	phalanges	metatarsal	tarsal	
Topographic aspects(location)	Dorsal or plantar	Lateral or medial	Two or more	
Zone no	one	two	three	
ischaemia	Palpable pulses, slightly diminished ABI(0.89-0.7) TBI(0.74-0.60)	Pulse scarcely palpable ABI(0.69-0.5) TBI(0.59-0.30)	Pulse not palpable ABI(<0.5) TBI(>0.30)	
infection	Erythema <2cm Purulent discharge warmth,tenderness	Erythema >2cm muscle ,tendon,joint infected	Systemic inflammatory response Secondary hypo or hyperglycemia	
oedema	periwound	One foot or leg	Bilateral secondary comorbidities	
neuropathy	Protective sensation decreased	Protective sensation absent	Diabetic neuropathic,osteoa rthropathy,DNOA-c harcot's	
area	Small <10cms2	Medium 11-40cm2	Big >40cm2	
depth	superficial	Tendon fascia,muscle.	Deep joints and muscles	
Wound healing	epithelialization	granulation	inflammatory	

Figure:2. Score chart



3.6.2. VIP'S CLASSIFICATION <sup>11</sup> for basic foot examination

- V: vascular assessment and management
- I: infection assessment
- P: Pressure analysis of plantar foot surface and offloading
- S: sugar assessment and control including assessment of neuropathy

3.6.3. Pictorial presentation before and after the intervention.

**Wagner's grade classification:**

- GRADE 0: No ulceration in high risk
- GRADE 1: Superficial ulcer
- GRADE 2: Deep ulceration
- GRADE 3: Osteomyelitis
- GRADE 4: localized gangrene
- GRADE 5: Extensive gangrene required amputation.

IV.RESULTS:

Analysis was done using paired t-test.

The graph shows that before treatment SESS score was  $15.257 \pm 4.693$ , after treatment SESS score reduced to  $6.6 \pm 7.78$ . To check the effectiveness of treatment, a paired t-test was used. Test statistic value is 11.01 and p-value (0.000) is very small, it suggests that we reject  $H_0$  and accept  $H_1$  that is, Homoeopathic treatment is helpful in the process of healing of diabetic foot ulcers.

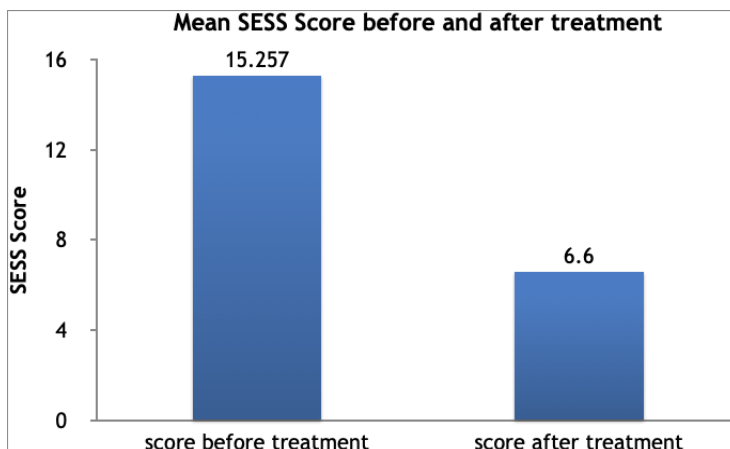


Figure 3: graph shows that There is a significant difference of reduction in scoring before and after the treatment suggestive of Effectiveness of intervention.

Table 1: Distribution of patients according to SESS score of patients before and after treatment

SESS Score	Before treatment	After treatment
	%	%
Mild	14.29%	74.29%
Moderate	68.57%	17.14%
Severe	17.14%	8.57%

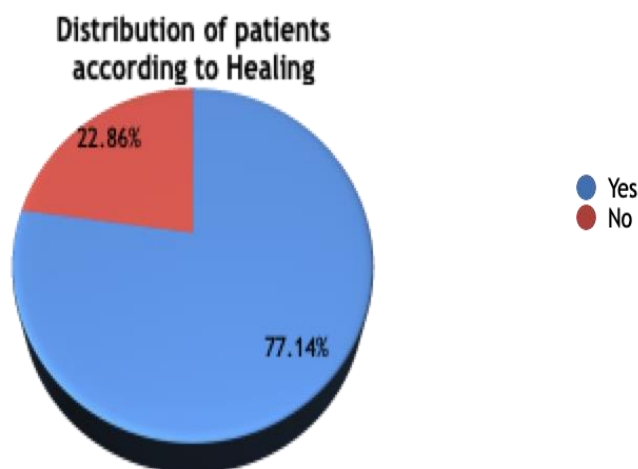


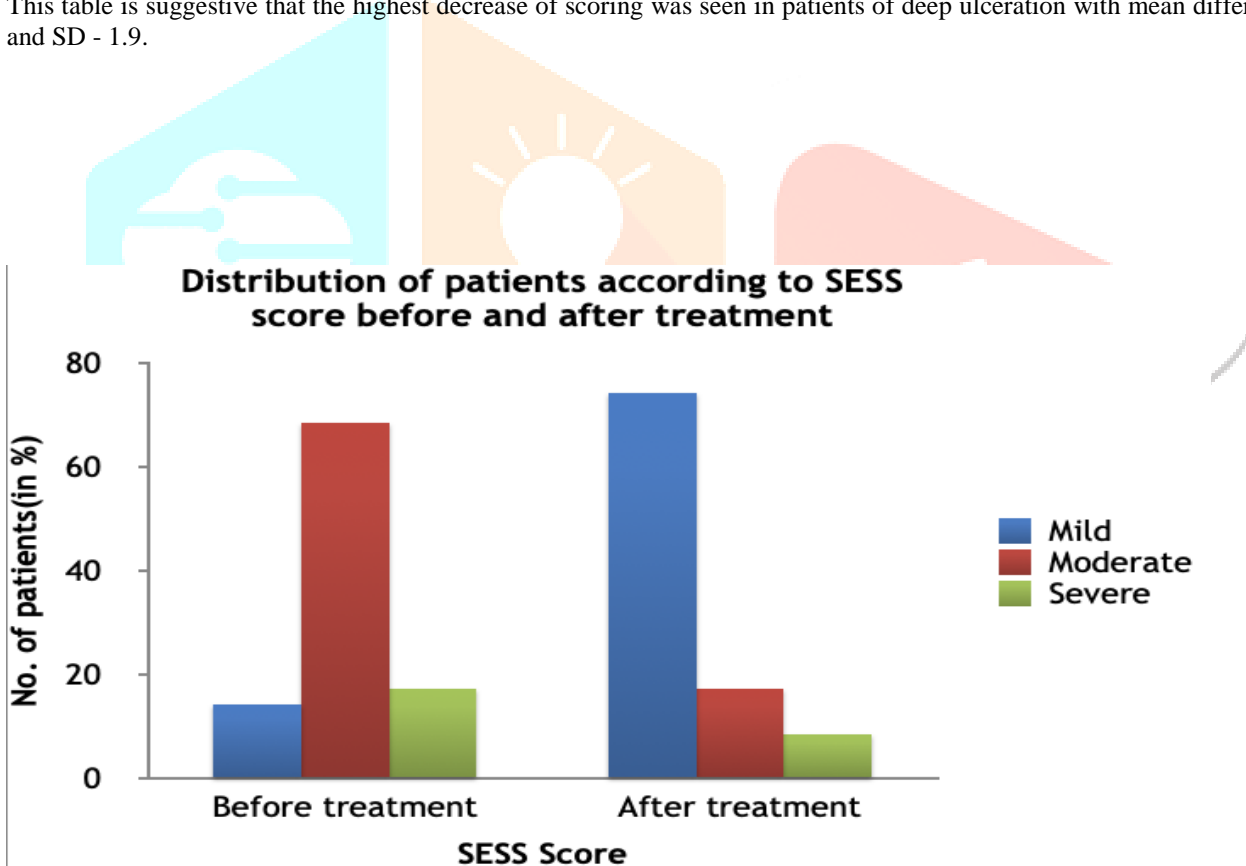
Figure 4: says that a maximum 77.14% of patients were helped with healing of diabetic foot ulcers, while 22.86% did not heal

**Table 2: Wagner's grade wise descriptive statistics of change in SESS score after intervention**

Wagner's grade	Mean	SD
GRADE 0: No ulceration in high risk	12	*
GRADE 1: Superficial ulcer	9.333	2.27
GRADE 2: Deep ulceration	12.111	1.9
GRADE 3: Osteomyelitis	7	6.98
GRADE 4: localised gangrene	6.33	5.85
GRADE 5: Extensive gangrene required amputation	1.333	1.528

Above table shows distribution of patients according to Wagner's classification, 12 patients presented with superficial ulcer who showed mean 9.33 of decrease in scoring after intervention, 9 patients presented with deep ulceration showed mean decrease of 12.11 after intervention, 4 patients presented with osteomyelitis showed decrease mean of 7 after intervention, 6 patients presented with localized gangrene showed mean decrease of 6.33 after intervention, while 3 patients presented with extensive gangrene who showed mean decrease of 1.33 after intervention.

This table is suggestive that the highest decrease of scoring was seen in patients of deep ulceration with mean difference of 12.11 and SD - 1.9.



**Figure 5:** The above graph shows before treatment maximum patients were under moderate scoring while after treatment maximum were under mild, s/o effectiveness of remedy after intervention

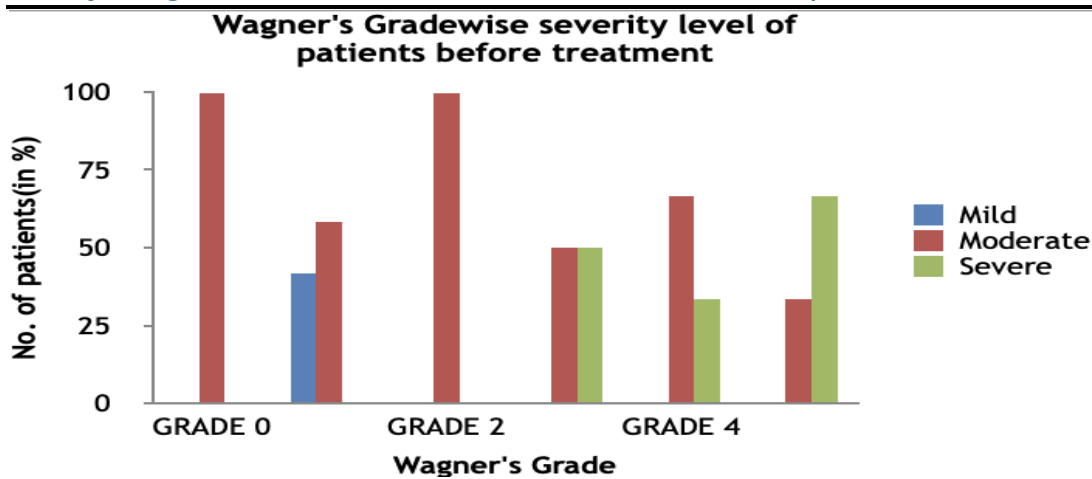


Figure: 6

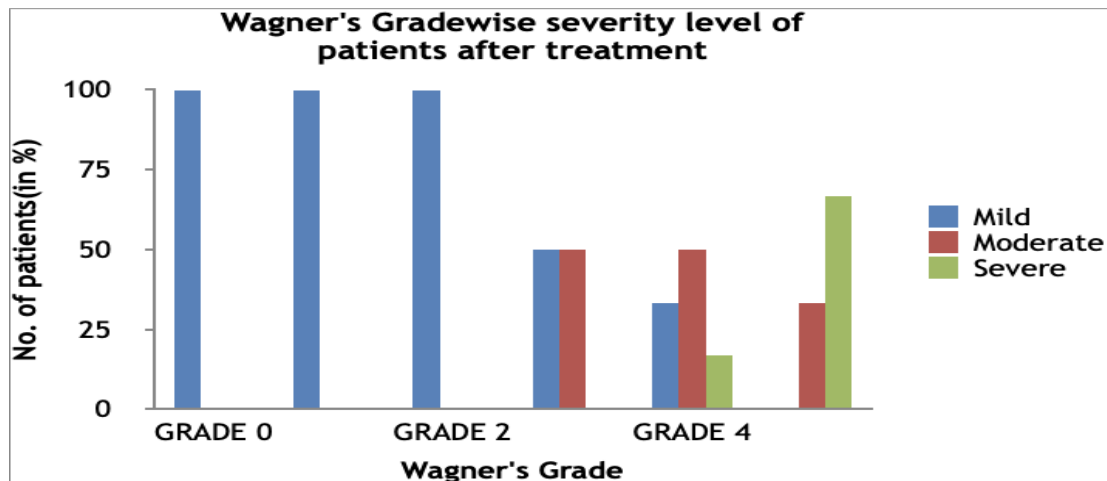


Figure: 7

Above graph 6 and 7 shows that maximums were found in moderate severity before the treatment in all the grades, while maximums changed to mild post treatment in Grade 0/I/II/III WHILE Grade IV/V showed less improvement, maximum remained in severe

Table 3: Distribution of patients according to debridement and amputation

Debridement and amputation	%
No	65.71%
Debridement	14.29%
Amputation	8.57%

Above table shows that maximum 65.71% did not have to undergo any surgical intervention while 14.29% underwent debridement, 8.57% underwent amputation, and 11.43 had to undergo both debridement and amputation.

There was 77.14% healing while 22.86% did not show improvement and had to undergo surgical intervention. It was seen that patients with DM more than 10 years were more prevalent (65.71%), with HbA1C ratio of  $7.36 \pm 1.399$ (SD). 65.71% showed some degree of ischemia, while 77.14% showed neuropathy. Maximum lesion site was ankle with prevalence of 22.86%, 37.14% showed history of injury, & 28.57% showed history recurrence.

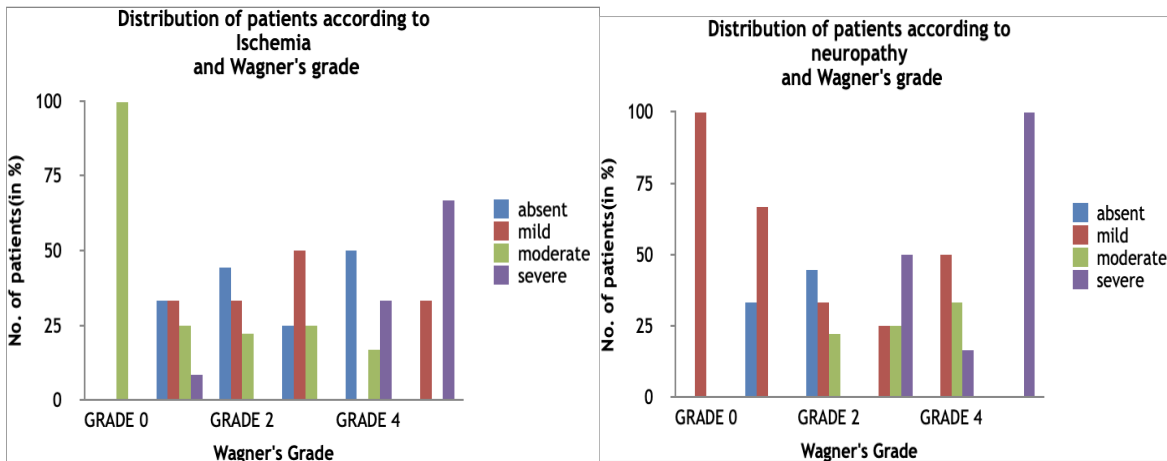
## V.DISCUSSION:

Diabetic foot ulcer a serious and major complication of diabetes mellitus is a severe public health issue with global prevalence of 6.3%, with 100000 leg amputation per year due to DFU<sup>12</sup> with a serious global threat.

Present study was undertaken to reduce the burden of amputation by using homeopathic remedy in enhancing the healing of diabetic foot ulcers.

With significant effect of homoeopathic remedy Arsenic Album in enhancing the wound healing it can be helpful in reducing the social burden of amputation and also to aware that it can be preventable and treated adequately.

Along with healing other factors like ischemia and neuropathy contributing in DFU were also studied which showed mild improvement with the limitation of predefined remedy we could not use other remedies in combinations to give a better outcome



**Figure 8**

Below Diagram depicts that ischemia and neuropathy is one of the main causes of DFU as it found in maximum of patients. Severity increases with increasing grade causing hindrance in healing

Also, ill managed patients with HbA1C >10 also hindered the process of healing so maintaining the glycemic control is of major importance.

Advanced therapy like oxygen therapy can be of utmost benefit along with the intervention.

**Table 4: Distribution of patients according to duration of diabetes**

Duration of Diabetes	%
Up to 5 years	11.43%
5 to 10 years	22.86%
Above 10 years	65.71%

Above table shows that most of the patients (65.71%) had diabetes for 10 years and more. 22.86% of the patients had diabetes since the last 5 to 10 years and 11.43% of the patients had diabetes for 5 years and less. Suggesting that patients with uncontrolled DM over 10 years are prone to DFU

**Table 5: Distribution of patients according to HbA1c percentage and Descriptive statistics of HbA1c percentage**

HbA1c	%	Mean ± SD
4 to 5.6%	2.86%	7.36 ± 1.399
5.7 to 6.4%	28.57%	
Above 6.5%	68.57%	

Above table and graph shows that 2.86% of the patients had HbA1C between 4 to 5.7% (normal range) while 28.57% of the patients had a higher HbA1C (5.7 to 6.4%) and most (68.57%) of the patients had HbA1C more than 6.5%.

Glycaemic control is an important factor in the process of healing. Patients having uncontrolled sugars are presented with DFU so controlling sugar is of utmost importance in these patients.



**Table 6: Distribution of patients according to duration of ulcer**

Duration of ulcer	%
Less than 2 Months	28.57%
2 Months – 5 Months	45.71%
More than 5 Months	25.71%

Above table shows that most of the patients (45.71%) had ulcer between 2-5 months. 25.71% of the patients had ulcer for more than 5 months and 28.57% of the patients had ulcer with duration less than 2 months.

**Table 7: Distribution of patients according to history of injury**

History of injury	%
Yes	37.14%
No	62.86%

Above table shows 62.86% of patients having DFU with no history of injury, while 37.14 with history of injury.

## VI.CONCLUSIONS:

Diabetic foot ulcers are a serious burden to mankind with the increasing cases of amputation. DFU is a major complication of DM. Other microvascular complications of DM like peripheral vascular disease(atherosclerosis) and peripheral neuropathy increases the risk of DFU, forming the prime cause of DFU other than glycaemic control.

In this study 35 completed the study rest got dropped in the middle of the study. The results showed improvement in the healing process of DFU, indicating effectiveness of homeopathic remedy. Therefore, Arsenic Album has shown positive results and proved to be specific, safe, effective, preventive and affordable treatment for DFU.

The remedy showed significant improvement in Wagner's grade I, II, II in comparison of grade IV, V which had negative outcomes. As the current study is a small sample study it is difficult to provide positive results, further large sample RCT are recommended extending the duration of the study.

Also advanced equipment like oxygen therapy, doppler study, can be helpful.

Hence there is a significant effect of homoeopathic remedy Arsenic Album in enhancing the wound healing of grade I, II, III of Wagner's classification reducing the social burden of amputation.

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