

EVALUATION OF CLINICAL EFFICACY OF EPIDERMAL GROWTH FACTOR COMBINED WITH NANO SILVER DRESSINGS ON DIABETIC FOOT INFECTION: A PROSPECTIVE STUDY

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Abstract

Background: Diabetic foot is a serious infection of the limbs. This is also one of the major cause for disability and death in diabetic patients. Prompt treatment is essential to reduce the progression of disease. Combination of epidermal growth factor and nano silver dressings can be considered ass effective treatment in diabetic foot patients. With this background the present study aimed to evaluate the efficacy of epidermal growth factor combined with nano silver dressings on diabetic foot infection.

Materials and Methods: The study was done in the department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari (Dist), Tamil Nadu. Based on inclusion and exclusion criteria 120 patients were included in the study. They were divided in to 4 groups each of 30 patients. Group-I (Normal Saline), Group-II (Epidermal growth factor), Group-III (Nano silver dressingss) and Group-IV (Epidermal growth factor and nano silver dressings). All groups were treated with respective drugs every alternative day. All the patients demographic, clinical and wound progression data were recorded and analyzed. Statistical Package for Social Sciences (SPSS 20.0) version used for analysis.

Results: Comparison of demographic data between the groups not showed any significant difference. It was observed that there is no significant difference between the groups reaching the level 1 effective stage. Group-II and Group-III showed significant difference compared to group-I achieving the wound repairing stages 2 and 3. Comparison of bacterial load between the group-I and II, III and IV showed significant difference with p value less than 0.05.

Conclusion: This study results concluded that combination of epidermal growth factor with nano silver dressings have a significant effect in wound healing and preventing the infection.

Keywords: Diabetes mellitus, Epidermal growth factor, Foot, Microbial infection, Nano silver, Wound,

Introduction

The incidence of diabetes mellitus world wise will increase by 55% over the next 20 years. Diabetes mellitus is a metabolic disorder which is characterized by increased glucose

levels.¹ Based on insulin levels diabetes mellitus divided into type-1 and type-2. Type-1 also known as insulin dependent diabetes mellitus and type-2 is non insulin dependent diabetes mellitus.^{2,3} In diabetic patients, if the glucose levels are not maintained properly will lead to development of diabetic complications. The most common complication is nephropathy, neuropathy and optic neuritis.⁴ In diabetic patients development of foot ulcer is more common. According to previous studies development of diabetic foot ulcer is 7 times more common and mortality increased from 13% to 28% when compared to normal.⁵⁻⁷ The major cause for diabetic foot infection is the reduction of blood supply which can lead to micro and macro vascular disease. Mortality due to diabetic foot can be reduced by proper wound care and medication. Daily cleaning of diabetic foot can prevent the infection and progression of diseases.^{8,9} There are so many materials are used to reduce the infection and halt the progression of the diabetic foot ulcer. Epidermal growth factor and nano silver particles are being tried for the same. Epidermal growth factor promotes the wound healing and nano silver dressing prevents the infection.¹⁰ The present study aimed to evaluate the efficacy of combination of epidermal growth factor with nano silver dressing in the treatment of diabetic foot ulcer.

Materials and Methods

Study design: A prospective observational study

Study settings: This study was done in the department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari (Dist), Tamil Nadu.

Study period: This study was conducted for a period of 1 year from February 2023-2024.

Inclusion criteria

- Age between 30-80 years
- Both male and female sex
- Full fill the WHO and ADA criteria
- Wound present in the foot
- Patients acceptance and sign the informed consent form

Exclusion criteria

- Severe vascular dysfunction
- Allergic to silver and drugs
- Hypertension
- Liver disease
- Kidney disease
- Psychiatric diseases

Groups

Group-I: Control

Group-II: Epidermal Growth factor

Group-III: Nano silver

Group-IV: Epidermal Growth factor with Nano silver

Procedure

The study included 120 patients based on inclusion and exclusion criteria. They were divided in to four groups each of 30 patients. Study procedure was explained to all the patients and informed consent was obtained. Group-I patients considered as control group, group-II treated with epidermal growth factor, group-III with nano silver and group-IV with combination of epidermal growth factor with nano silver. All the patients demographic and clinical data was recorded. Before and after treatment wound area size and bacterial infection load was analyzed.

Statistical analysis

The data was expressed in number, percentage, mean and standard deviation. Statistical Package for Social Sciences (SPSS 20.0) version used for analysis. One way ANOVA post hoc followed by Dunnet t test applied to find the statistical significant between the groups. p value less than 0.05 considered statistically significant at 95% confidence interval.

Results

This study included 120 patients each group had 30 patients. Comparison of mean age between the groups not showed any significant difference. The mean age of study groups between 53-57 years. Gender distribution between the groups and within the groups not showed any significant difference. The mean history of diabetic foot is 3 years, the difference between the groups not showed any significant difference. All the groups showed wound formation time (week) between 12-13 weeks. The mean wound formation time was compared between the groups not showed any significant difference (Table-1). Comparison of mean 40% wound healing time between the groups not showed any significant difference. There is significant difference compared group-I with other groups and group-III with other groups of 70% wound healing time. Comparison of complete wound healing time between the group-I and III not showed any significant difference. There is significant difference compared group-I with III and Group-III with group-IV of complete wound healing time (Table-2). Positive bacterial culture was measured at 2 and 4 weeks. Comparison of number of positive bacterial culture growth between the group-I, II with group-III and IV showed significant difference. There was no significant difference compared Group-I with II. (Table-3).

Discussion

Diabetic foot ulcer can develop due to neuropathy, ischemia, nutritional dysfunction and infection. A well perfused foot is more resistant to infection and ulcer formation. In these patients tendons undergo glycosylation which can lead to claw, hammer toes and Achille's tendons.^{11,12} Complications of diabetic foot can be reduced by proper care and proper maintenance of glycemic control. Various studies suggested that appropriate foot wear is also essential to reduce the disease progression. Treatment approach of diabetic foot are moist environment, treating infection, offloading wound area, clean the wound area, improve the blood supply and oxygen delivery.¹³ Commonly these infections treated with topical antibiotics. Resistance and adverse drug reactions are major limitations to use antibiotics for long term.^{14,15} These drugs can prevent infection but cannot promote the wound healing.

Epidermal growth factor is commonly used to treat refractory wounds and rebuild the blood vessels. Nano Silver particles has showed antimicrobial effect.^{16,17} The combination of epidermal growth factor with nano silver dressing can prevent infection and promote the wound healing. In the present study a total of 120 patients included and divided into 4 groups each of 30. Group-IV was treated with combination of epidermal growth factor with silver nano dressing. Yu Hsiang Lee et.al study proved that combination of epidermal growth factor with silver nano dressing showed reepithelization, collagen deposition and increased the wound healing.¹⁸ Juanzi Z et.al study suggested that epidermal growth factor accelerate the healing of diabetic foot by upregulation of mRNA which can increase the formation of new tissue.¹⁹ Huijing Lin et.al study proved that nano silver dressing is a novel method to prevent infection, safe and long spectrum for the treatment of diabetic foot.²⁰ It reduces the infection and improve the healing. This present study showed patients treated with nano silver dressing and epidermal growth factor showed significant difference compared to control group. It was observed that combination of nano silver dressing with epidermal growth factor treatment showed faster healing and less infection. This study showed combination therapy is better than mono therapy in the management of diabetic foot.

Limitations

The major limitation of study is sample size is less.

Conclusion

This study results concluded that treatment with epidermal growth factor or nano silver dressing showed less effect than combination therapy. Use of epidermal growth factor with nano silver dressing improve the healing and prevent the infection.

Conflict of interest: Nil

Funding: Self

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Table-1: Comparison of demographic and wound parameters between the groups

Groups		Gender		
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	Age (Years) (MEAN±SD)	Male	Female	History of diabetic foot (Year) (MEAN±SD)	Wound formation time (Week) (MEAN±SD)
Group-I	53.45±1.89	12	18	3.89±1.67	13.45±0.89
Group-II	57.19±2.93	10	10	3.18±1.34	12.89±0.34
Group-III	55.81±1.45	18	12	3.92±1.56	13.32±0.84
Group-IV	57.31±2.84	14	16	3.27±1.89	12.89±0.36

Table-2: Comparison of wound repair between the groups

Observations	Group-I (MEAN±SD)	Group-II (MEAN±SD)	Group-III (MEAN±SD)	Group-IV (MEAN±SD)
40% wound healing time/day	7.89±1.56	6.83±0.63	7.14±0.78	6.21±0.39
70% wound healing time/day	31.78±0.43	23.89±1.80*	26.34±1.32*	18.37±1.04*,\$
Complete wound healing time/day	40.89±1.45	34.89±0.56*	38.04±0.84	29.67±0.967*,\$
Grade 1/day	6.42±0.89	5.89±0.45	6.20±0.98	5.45±0.98
Grade 2/day	28.45±0.92	21.89±0.35*	24.85±1.45	16.34±0.54*,\$
Grade 3/day	39.45±0.56	32.89±0.84*	36.94±0.56	25.34±1.98*,\$

(*p<0.05 significant compared with group-I, \$p<0.05 significant compared with group-III)

Table-3: Comparison of positive bacterial culture and count between the groups

Observations	Group-I (MEAN±SD)	Group-II (MEAN±SD)	Group-III (MEAN±SD)	Group-IV (MEAN±SD)
Positive bacterial culture (2 weeks)	9	10	5*	2*,\$
Positive bacterial culture (4 weeks)	14	11	6*	3*,\$
Bacterial count (Grade 0)	4.28	4.82	4.19	4.38
Bacterial count (Grade 1)	4.34	4.77	3.87	3.04
Bacterial count (Grade 2)	4.37	4.63	2.18*,\$	2.19*,\$
Bacterial count (Grade 3)	4.21	4.39	2.06*,\$	2.06*,\$

(*p<0.05 significant compared group-I with others, #p<0.05 significant compared group-II with other groups)