VOLUME-9, ISSUE-3, MARCH-2020 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

General Surgery

EFFICACY OF LOCAL USE OF INSULIN IN DIABETIC ULCER HEALING, A RANDOMISED CONTROL STUDY.

Dr. Suhas V. Taralekar	Professor, Dept. of General Surgery Bharati Vidyapeeth (Deemed to be University) Medical college, Pune.
Dr. Abhay Kumar	Asst. Professor, Dept. of General Surgery Bharati Vidyapeeth (Deemed to be University) Medical college, Pune.
Dr. Kshitij Kakade*	Resident, Dept. of General Surgery. Bharati Vidyapeeth (Deemed to be University) Medical college, Pune. *Corresponding Author

ABSTRACT

Introduction:- Diabetic Foot Ulcer remains a major challenge to general surgeons irrespective of the advanced dressing techniques. This comparative study assesses the efficacy of the use of topical insulin in diabetic ulcer healing.

Materials and methods:- Diabetic foot patients were segregated in 2 groups randomly. Cases were treated with topical insulin on ulcers while controls were treated with traditional wound dressing i.e. betadine. Ulcer contracture rate were calculated of both groups and statistically compared.

Results:- Patients in Cases group had effective size reduction of diabetic ulcer by 38.87% compared to 21.37% in control group. That shows that Cases group treatment is more effective than control group treatment.

Conclusions:- Topical insulin is an effective therapy in treating diabetic ulcer in the terms of reduction in size of the wound.

KEYWORDS : Diabetic foot ulcer, Topical insulin, wound healing

INTRODUCTION

Diabetes is a major cause of kidney failure, heart failure and lower limb amputation (1). Hyperglycemia reduces collagen deposits and delays wound remodeling. This delay in wound healing has been associated with increased morbidity and mortality rates in patient population (3) (2). Previous preclinical studies have successfully used intralesional insulin administration to restore collagen synthesis and formation of granulation tissue (4). Insulin has many benefits beyond the regulation of blood sugar levels. Preclinical and clinical studies shows positive impacts of insulin on wound improvement, but unfortunately no appropriate method for daily use of topical application of insulin has been developed. Hence, the present study was conducted to know the effect of local insulin on healing on diabetic foot and to develop an appropriate method for topical application of insulin.

METHODOLOGY

The present study was a randomized control trial (block randomisation) undertaken from October 2016 to October 2018 at Department of Surgery, Bharati Vidyapeeth (Deemed to be University) Medical college. Total number of 60 patients with diabetic foot ulcer were enrolled after informed consent and were segregated equally and randomly in Group A which was treated with local use of insulin and Group which was treated with conventional dressing i.e. Betadine.

Inclusion criteria:

- Patients above 18 years of age who are diagnosed to have diabetic foot ulcer.

Exclusion criteria:

- Patients with bone deformities like osteomyelitis
- Patients with gangrene
- Other clinically significant medical conditions that would impair wound healing including renal, hepatic, hematological, neurological and immunological diseases.
- Patients receiving corticosteroids, immune-suppressive agents, radiation or chemotherapy within one month prior to entry into study

Dressing Technique

- Area of a diabetic ulcer wound was segregated into 5cm x 5cm.
- 4 unit of Regular human insulin with 1 cc of NS was directly sprayed on the ulcer using sterile syringes after cleaning/debriding the wound.(5)
- Wound was then covered with sterile gauze and dressing material.
- BSL levels were checked 1 hr. prior and after the insulin dressing using glucometer.
- Dressing frequency was once a day.
- In the control group dressings was done with traditional techniques such as Betadine dressings etc. with the same frequency.

All patients were administered systemic antibiotics as per culture sensitivity and other systemic management of any associated symptoms were continued. Strict systemic glycemic control was achieved. Healing of the wound was recorded using measuring tape and transparent tracing paper. Maximum length of the ulcer was recorded once a week. Depth of the ulcer was recorded using millimeter scale, once a week. Photographs were taken to assess the contraction rate of the wound. The end point of the study was complete closure of wound or wound ready for grafting i.e. healthy granulation tissue formation, no slough, no discharge (this was for wounds bigger than $5cm^2$).

The rate of contraction of ulcer area was calculated using = (initial area of wound – n'th day area of wound) / initial area of wound x 10

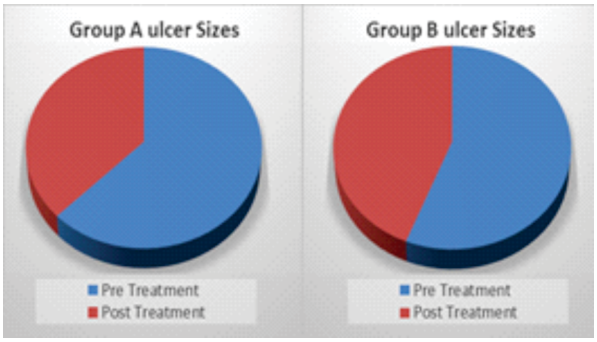
The obtained data was statistically analysed contraction rates of ulcers from both groups were calculated.

Comparison of ulcer size pre & post treatment among two groups:

Ulcer area (cm2)	Group A (Insulin)	Group B (Control)	Mean difference from baseline (95% CI)	P value
Pre-treatment	16.93 ± 3.76	18.20 ±4.26	39.87%	>0.05
Post treatment	10.18 ±2.43	14.31 ±4.19	21.37%	<0.0001

The mean ulcer area pre-treatment of group A and group B

patients was 16.93 ± 3.76 and 18.20 ± 4.26 cm^2 respectively with no statistical significance. The mean ulcer area post-treatment of group A and group B patients was 10.18 ±2.43 and 14.31 ±4.19 cm^2 respectively with statistical significance. (P<0.0001). Patients in Group A had effective size reduction of diabetic ulcer by 39.87% compared to 21.37% in Group B.



DISCUSSION:

The study was conducted after taking ethical clearance from the institute and informed consent from the patients. The data was collected from patients regarding demographic profile, clinical spectrum and outcome.

In the present study, the mean age of group A and group B was 51.13 ±10.92 and 52.06 ±9.58 years respectively. Hence maximum number of patients belongs to age group 51-60 years in both study groups. There was no statistical difference among both groups with respect to age. (P>0.05), as DM T-II is seen in elderly age group.

In a study by Amrita Prasad et al (6) on efficacy of topical insulin vs conventional dressing on wound healing in diabetic foot ulcers observed majority of the patients 65.8% are less than 60 years in insulin group and in control it is 64.2%. There is no significant difference between Insulin group and saline group patients' age distribution. With majority of the patients were males in insulin group (73%) and in control (80%) with no characteristic deficit was seen between Insulin and saline group patients gender distribution.

R. Swaminathan (7) in management of chronic foot ulcers in diabetic patients investigated the efficacy of topical insulin with its safety, observed no statistical difference among both groups with respect to age.

In this study the total numbers of males were 36 (60%) and females were 24 (40%). There was no statistical difference among both groups with respect to sex. (P>0.05). The mean duration of DM of group A was 9.40 ± 3.99 and group B was 8.70 ±3.73 years. Duration of illness statistically was similar between both groups with p value >0.05. In the study, 16 patients (53.33%) in Group A had diabetic ulcer <6 months compared to 18 patients (60%) in Group B. There was no statistical difference among both groups with respect to duration of diabetic ulcer. (P>0.05)

The mean fasting blood sugar of group A and group B patients was 95.36 ±12.77and 97.40 ±10.29 mg/dl respectively. The mean post prandial blood sugar of group A and group B patients was 163.40 ±16.04 and 158.26 ±15.02 mg/dl respectively. The mean HbA1c of group A and group B patients was 7.51 ±0.87 and 7.74 ±0.84 % respectively. The blood sugar levels were statistically similar between both groups with p value >0.05.

In the study, 19 patients (63.33%) in Group A had diabetic ulcer of Grade II compared to 21 patients (70%) in Group B. There was no statistical difference among both groups with respect to grade of diabetic ulcer. (P>0.05)

In a study by Amrita Prasad et al [6] observed 80.0% of the patients have grade 2 ulcer in insulin group and 85.7% in saline group with no statistical difference.

The mean length of ulcer of group A and group B patients was 4.39 ±0.53 and 4.48 ±0.59 cm respectively. The mean width of ulcer of group A and group B patients was 3.99 ±0.51 and 4.02 ±0.48 cm respectively. The mean depth of ulcer of group A and group B patients was 8.13 ±1.71 and 8.23 ±1.92 mm respectively.

The ulcer depth was noted to be significantly improved in group receiving insulin therapy before than after treatment. The average ulcer size of 4.1 cm2 and 3.9 cm2 was reported in patients undergoing treatment with insulin and saline respectively, with significant ulcer size improvement in ulcer size after treatment. The mean ulcer area pretreatment of group A and group B patients was 16.93 ± 3.76 and 18.20 ±4.26 cm^2respectively with no statistical significance.
In a study by Amrita Prasad et al (6) before treatment, 13 cm^2 was the mean ulcer size in insulin group and 14.51 cm^2 in control group, the difference of mean between the two groups is 1.51 cm^2 and this difference was small with no statistically significant difference.

In a study by Gaurav Goenka et al[8] observed the mean ulcer size on day 1 was 670 ± 215 mm^2 in Group A (Insulin group) and 629 ± 257 mm^2 in Group B (Saline group) which was comparable and statistically not significant.

The mean ulcer area post-treatment of group A and group B patients was 10.18 ±2.43 and 14.31 ±4.19 cm^2 respectively with statistical significance. (P<0.0001)

In the study, 23 patients (76.67%) in Group A had size reduction of diabetic ulcer by 26-50% compared to 8 patients (26.67%) in Group B. There was statistical difference among both groups with respect to ulcer size reduction of diabetic ulcer. (P<0.05)

In the study, patients in Group A had effective size reduction of diabetic ulcer by 38.87% compared to 21.37% in Group B. There was statistical difference among both groups with respect to effectiveness of ulcer size reduction of diabetic ulcer. (P<0.05) This shows that Group A treatment is more effective than Group B treatment.

CONCLUSION:

The present study to evaluate the efficacy of topical use of human regular short acting insulin on wound healing of diabetic ulcer, we conclude that topical insulin is an effective therapy in treating diabetic ulcer in the terms of reduction in size of the wound, ulcer contraction, granulation tissue formation.

Limitation of The Study:

Study on larger group of subjects would give better statistical analysis and understating.

REFERENCES:-

1. World Health Organization. Diabetes Fact Sheet. 2008; Available at: http://www.who.int/mediacentre/factsheets/fs312/en (Accessed at 9/05/2019)
2. Pendsey S.P. Insulin in Diabetic Foot. JAPI .July 2007: 55:66.
3. Martinez M, Garcia J.A., Jesus Martinez J.M., Gonzales F.Z. Local Use of Insulin in Wounds of Diabetic Patients: Higher Temperature, Fibrosis, and Angiogenesis PRS journal, American Society of Plastic Surgeons, 2013; 132 (6): 1015-19.
4. Goodson WH 3rd, Hung TK. Studies of wound healing in experimental diabetes mellitus. J Surg Res. 1977;22:221–227.
5. Juutilainen, V., & Hietanen, H. In Principles of wound care. 1st ed. Helsinki: SanomaPro. 2012:712.
6. Dr. Amrita Prasad, Dr. Ashwin Aby Thomas, Dr. D.S.A.Mahadevan. To Study The Efficacy of Topical Insulin Vs Conventional Dressing on Wound Healing In Diabetic Foot Ulcers. IOSR Journal of Dental and Medical Sciences (IOSR-JDMS). 2018; 17 (4): 33-38.
7. R. Swaminathan. Effectiveness of topical insulin in management of chronic

diabetic foot Ulcers. Indian Journal of Basic and Applied Medical Research. June 2014; 3 (3): 455-459.
8. Goenka G, Athavale VS, Nirhale DS, Deshpande N, Agrawal K, Calcuttawala M. Role of topical use of insulin in healing of chronic ulcer. Med J DY Patil Univ 2014;7:579-83.