

# Study of Efficacy of Topical Insulin Application in Wound Healing in Diabetic Foot Ulcers

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**Abstract:** ***Aim:** To study the effectiveness of Topical Insulin on healing of Diabetic Ulcer **Objective:** 1. To find out the advantages of Topical Insulin in management of Diabetic Foot Ulcer. 2. To assess the wound healing of diabetic foot ulcer after applying topical insulin. **Material and Methods:** This is a Hospital - based prospective observational study involving 100 patients presenting with diabetic foot ulcers in Department of General Surgery in Muzaffarnagar Medical College during a period of 1 year from January 2021 to January 2022. **Results:** In our study, there was no significant difference in mean age between case (50.14±8.22 years) and control groups (49.44±8.46 years). Majority of the study population belonged to 46 - 55 years (60.0%) followed by 35 - 45 years (14.0%) and above 55 years (26.0%). The mean Wound size Post - treatment and Change from pre to post treatment was significantly more among Topical Insulin group compared to control group. The mean Percent reduction in size of ulcer was significantly more among Topical Insulin group compared to control group. In present study, the mean Hospital stay (in days) was significantly more among control group compared to Topical Insulin group. **Conclusion:** Insulin has a favorable impact on wound healing and is widely acknowledged as a critical factor in wound healing.*

**Keywords:** Topical Insulin, Diabetic Foot, IGF

## 1. Introduction

In this time where mankind has succeeded in decoding the human genetic code, wound management still remains an ambiguous challenge. The history of wound healing is as old as the history of mankind. 1 Chronic wounds, especially non - healing types, are one of the most common surgical conditions that a surgeon comes across. From ancient time, doctors have been trying many methods to treat such wounds. 2

A wound by true definition is a breakdown in the protective function of the skin; the loss of continuity of epithelium, with or without loss of underlying connective tissue (i. e. muscle, bone, nerves) 3 following injury to the skin or underlying tissues/ organs caused by surgery, a blow, a cut, chemicals, heat/ cold, friction/ shear force, pressure or as a result of disease, such as leg ulcers or carcinomas 4

Wounds can be the results of trauma or surgical incisions. Further, pressure ulcers are a type of skin ulcer and can be regarded as wound. Chronic wounds or ulcers are the wounds that have failed to progress through the orderly process that produces satisfactory anatomic and functional integrity or that have proceeded through the repair process without producing an adequate anatomic and functional result. The majority of wounds that usually don't heal in 3 months are considered as chronic 5

Current estimates indicate that nearly 600, 000 people suffer from chronic wounds worldwide. The prevalence of chronic wounds in India has been reported as 4.5 per 1000 population, whereas that of acute wounds is nearly double, at 10.5 per 1000 population. The poor hygienic condition in some third world countries has been attributed as the main cause. 3 - 5

Diabetes mellitus is one of the most common metabolic disorders affecting a large part of our population. Hyperglycaemia is the main reason behind the complications of diabetes mellitus. Most common complications of

diabetes are retinopathy, nephropathy, neuropathy and cardiovascular diseases. Hyperglycaemia also affects wound healing and foot ulcers are a well - known complication of diabetes. Diabetes affects wound healing due to reduced collagen deposition and delaying the healing process. Diabetic wounds are difficult to treat with conventional treatments. Delayed wound healing has led to increased morbidity and mortality in the population. Increased blood glucose leads to ineffective angiogenesis and less collagen deposition.

Diabetic foot ulcer is one of the commonest sequelae following trauma or infection mainly around the distal ends of limbs where the vascularity is relatively decreased due to effects of diabetes. Important step in managing diabetic ulcer is offloading the wound by using appropriate therapeutic footwear [6, 7] daily saline or similar dressings to provide a moist wound environment, 8 debridement when necessary, antibiotic therapy if cellulitis is present [8, 9] optimal control of blood glucose, evaluation and correction of peripheral vascular insufficiency. Numerous topical medication and gels are promoted for ulcer care and healing. Relatively few have proved to be more efficacious than saline wet to dry dressings. 8, 9 Insulin stimulates the growth and development of keratinocytes, endothelial cells and fibroblasts and help proliferation, and tissue healing.

Insulin also causes rapid re - epithelization of the wound by promoting protein synthesis. Wounds unresponsive to conventional foot ulcer treatments have been shown to benefit by local insulin application but the accurate dose and concentration of insulin to be used is still under observation.

The aim of this study is to assess the effectiveness of topical insulin therapy in the healing of diabetic foot ulcers.

### Aim

- 1) To study the effectiveness of Topical Insulin on healing of Diabetic Ulcer

**Objective:**

- 2) To find out the advantages of Topical Insulin in management of Diabetic Foot Ulcer.
- 3) To assess the wound healing of diabetic foot ulcer after applying topical insulin.

**2. Material and Methods**

This is a Hospital - based prospective observational study involving 100 patients presenting with diabetic foot ulcers in Department of General Surgery in Muzaffarnagar Medical College during a period of 1 year from January 2021 to January 2022.

**Inclusion Criteria:**

- Diabetic Patients between the age groups of 25 - 70 Years
- Patients having ulcers on the foot
- Patients with blood glucose level more than 126 mg/dl

**Exclusion Criteria:**

- Patient not giving consent
- Patients who were not on regular followup

**3. Methodology**

**Methods of Data Collection/ Procedure**

The present prospective study was conducted in General Surgery Department of Muzaffarnagar Medical College among 100 patients selected consecutively from January 2021 - January 2022. All the relevant patients coming to OPD and casualty were included in the study based on

exclusion and inclusion criteria. Relevant details, history and clinical examinations were observed. Informed consent was taken from all the subjects. Detailed case history along with physical and local examination was recorded for every patient. Before enrolling the patients for study culture and sensitivity swab of all the ulcers were taken and ulcers were cleaned with normal saline & All routine investigations were done.

The patients were divided into 2 groups –

**Group A:** The ulcers will be cleaned with normal saline and then will be irrigated with 4 units of human soluble insulin in 1 ml normal saline for each 10 cm of wound. The solution prepared will be sprayed on ulcer surface with an insulin syringe and the ulcer will be left to dry and then will be covered with sterile cotton gauze.

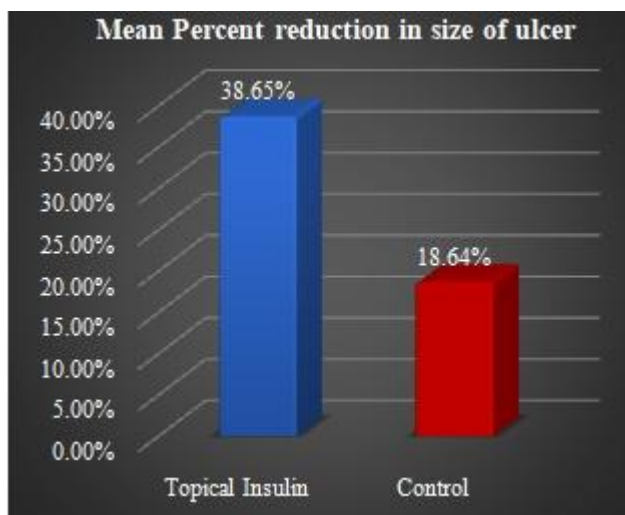
**Group B:** Dressing with normal saline and betadine 10 %. Antibiotics will be given and later on will be changed according to the pus culture report.

**4. Results**

	Variable	Topical Insulin	Control
Age Group	35 - 45 years	8	6
	46 - 55 years	32	28
	Above 55 Years	10	16
Gender	Male	29	32
	Female	21	17
Random Blood Sugar	Controlled	20	30
	Uncontrolled	30	20
HbA1c	>6.5	50	50

Wound size	Topical Insulin		Control		Mean Difference	t - test value	p - value
	Mean	Std. Deviation	Mean	Std. Deviation			
Pre - treatment	4.74	0.08	4.71	0.08	0.03	1.846	0.168
Post - treatment	2.91	0.10	3.83	0.11	- 0.92	- 44.032	0.001*
Change from pre to post treatment	1.83	0.05	0.88	0.08	0.95	70.487	0.001*

	Percent reduction in size of ulcer				
	Mean	Std. Deviation	Mean Difference	t - test value	p - value
Topical Insulin	38.65%	1.28%	20.01%	16.086	0.001*
Control	18.64%	1.71%			



**5. Discussion**

Healing a wound is a complicated biological process that requires chemotaxis and neovascularization, as well as the creation of extracellular matrix protein, components, and remodeling of tissues. This process takes place after an injury has been sustained. Chronic skin wounds, such as diabetic foot ulcers, are more prone to bacterial contamination, which further increases the risk of unfavorable complications. As a result, many studies have reported on efforts and products to improve healing rates in the management of these types of wounds, which may, in turn, reduce the risk of complications.

Numerous studies have shown that insulin has a favorable impact on wound healing and is widely acknowledged as a critical factor in wound healing.<sup>[108]</sup> Through in vivo studies, it was discovered that insulin - like growth factor (IGF), which shares a high degree of sequence homology with the hormone insulin, stimulates keratinocyte, endothelial, and fibroblast proliferation, migration, and

excretion of extracellular matrix and even aids in the reformation of granulation tissue.<sup>[109]</sup>

In addition to increasing reepithelialization, collagen content, granulation tissue, wound tensile strength, and local fibroblast production of insulin-like growth factors, insulin works on human growth hormone receptors found throughout the skin.<sup>[16]</sup> Human keratinocytes' migration and proliferation are also induced by insulin, which promotes cell development and improves wound healing.<sup>[110]</sup>

In the 20th century, topical insulin formulations were used to try to manage localized peripheral tissue hyperglycemia. Later studies, however, have focused on topical insulin administrations in relation to IGF.<sup>[111]</sup>

In our study, there was no significant difference in mean age between case (50.14±8.22 years) and control groups (49.44±8.46 years). Majority of the study population belonged to 46 - 55 years (60.0%) followed by 35 - 45 years (14.0%) and above 55 years (26.0%). The mean Wound size Post-treatment and Change from pre to post treatment was significantly more among Topical Insulin group compared to control group. The mean Percent reduction in size of ulcer was significantly more among Topical Insulin group compared to control group. In present study, the mean Hospital stay (in days) was significantly more among control group compared to Topical Insulin group.

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