Topical insulin versus normal saline in healing of diabetic ulcers

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Abstract

Introduction: Diabetic ulcers are a common complication encountered in a significant number of diabetic patients. This study aims to compare topical insulin and normal saline in healing of diabetic ulcers.

Materials and Methods: A prospective case-control study was performed in the Department of General Surgery, Medical College, Baroda. In a period of one year, a total of 100 patients were enrolled and divided into two groups, normal saline and topical insulin and their effects were

Results: Males outnumbered females in both the study groups in a ratio of approximately 4:1. The mean age in topical insulin and normal saline group was 41.3±16.4 and 40.0±15.84 years respectively. In patients who received topical insulin, the healing rate was 18.36 cm^2/week on 21st day as compared to 13.71 cm^2/week in normal saline group. Topical insulin was found to be superior as compared to normal saline in clearance of bacteriological burden as evidenced by higher rates of negative pus culture and sensitivity on day 14 and day 21.

Conclusion: Topical insulin is marginally more efficacious than normal saline in terms of ulcer healing rate and reduction in burden of wound infection but comparable to normal saline in other aspects of wound healing.

Keywords: diabetic ulcers, normal saline, topical insulin, wound healing

Introduction

Skin is a complex tissue, which comprises multiple layers. An injury to this stratified structure is considered to be the beginning of a sequence of events designed to restore skin integrity. Depending on the diameter and severity of a wound, deleterious physiological and metabolic changes can occur, leading to impaired wound

healing and increased morbidity and mortality. While wound dressings provide some form of protection and remedy, the main challenge is to restore local metabolic pathways to normality, especially in the comprised patient suffering from chronic illness, such as diabetes. The implications of this disease in particular have prompted investigations into topical insulin as a potential and promising therapeutic intervention.

The economic cost of wound management has been estimated to be measured in billions of dollars. Current financial projections indicate that the cost of managing wounds accounts for almost 4% of total health care expenditure, and that this spiraling burden shows no sign of slowing down. Recalcitrant, non-healing wounds constitute a major problem that plagues those patients with chronic illness, such as diabetes. Despite systemic insulin treatment and a carefully regulated life style, approximately 15% of all diabetic patients will have some form of non-healing wound and be particularly susceptible to amputation of the lower extremities [1,2].

Besides regulating glucose levels, insulin has been reported to participate actively in many other functions, including modulating inflammatory reactions [3]. Insulin not only acts as a glucose-regulating hormone but also as a growth-like factor and cytokine regulator that could accelerate wound healing [4]. In this study we investigated how topical insulin application would affect the diabetic wound healing process compared to the time-tested normal saline.

Aims and objectives

To study the efficacy of topical insulin v/s normal saline dressing on wound healing in diabetic ulcers in terms of

1. Appearance of granulation tissue
2. Presence or absence of slough.
3. Percentage reduction in wound surface area. Wound covered with granulation tissue.
4. Duration of hospital stay.
5. Ucer healing rate.

Inclusion criteria

- The patients aged above 20 years of age
- Patients of either sex
- With diabetic ulcers with controlled diabetes (random blood glucose levels between 110 mg/dl and 130mg /dl)
- Visiting opd or getting admitted or getting operated
- With wound area upto 100 sq. Cm
- Falling under wagner grade 1 and grade 2 categories will be included in the study

Exclusion Criteria

- X-rays showing features of osteomyelitis.
- Doppler showing gross atherosclerotic changes and venous abnormalities like varicosities.
- Uncontrolled diabetes (random blood glucose levels more than 130 mg/dl)
- Other clinically significant medical conditions that would impair
- Wound healing including renal, hepatic, hematological, immunological, neurological diseases and malignancies
- Patients receiving corticosteroids other immunosuppressive agents, radiation or chemotherapy one month prior to entry into the study.
- Wound area more than 100 sq. Cm
- Wagner grade 3,4,5

Materials and methods

This is a prospective randomized case-controlled study conducted in the department of general surgery, ssg hospital, vadodara. Study was started from the time of

approval of the study by institute ethics committee till June 2022.

Duration of study - June 2021 till June 2022.

Sample Size

As the concerned population was more than 10,000, initial sample size was calculated on the basis of n= z^2pq/l^2 , where p was taken as 23% and allowable error of 5%, with a confidence interval of 95% (z=1.96) which came to 240 . But due to restrictions in non- emergency admissions and less number of patients coming to OPD due to COVID-19 pandemic, final sample size of patients was taken as 100 out of which 50 were allocated in normal saline group and 50 in topical insulin group

Total – 100

Test – 50

Control – 50

Study Setting

Dept. Of General Surgery, SSG Hospital, Vadodara Randomisation

Patients were allocated into Insulin group (Test) and Normal Saline

Group (control) alternately.

Statistical analysis

Statistical analysis was done using unpaired t test, student t test Chi-square

Test using Medcalc software and conclusion was drawn based on the results of statistical analysis.

Methodology

Patients visiting OPD or admitted in ward from completion of IECBHRC review in June 2021 to June 2022 matching the above inclusion and exclusion criteria were explained about the study and on willingness were enrolled after written informed consent was obtained.

History data was collected on printed Performa and detailed clinical examination was done.

All the patients underwent standard preoperative workup.

Initial assessment of the wound in terms of surface area (sq.cm) was done   and then allocated into Insulin group (Test) and Normal Saline group (control) alternately. Ulcers of both groups were thoroughly debrided mechanically or surgically and antibiotic Inj. Augmentin 1.2g IV 12 Hourly was started empirically for all patient initially and then based on pus culture and sensitivity report, antibiotics were changed to a different injectable antibiotic, or changed to oral antibiotic if wound was improving and pus culture showed no organism.

Technique of dressing

The test group ulcers were thoroughly cleaned then cotton soaked with insulin (amount decided based of surface area) was applied on the wound and allowed to dry then the test group wounds were dressed with sterile dressings. The saline group ulcers were cleaned with normal saline and covered with sterile dressing.

The study participants will not be aware of the type of dressing/ treatment (insulin or saline) that is being received by them.

The ulcers in both groups were inspected after removal of dressing and analyzed for the following-

For the presence of granulation tissue in percentage.

Presence or absence of slough in percentage.

Percentage reduction in wound surface area.

Signs of wound infection: redness or discharge.

Both groups were dressed as per need depending on wound exudate from 1st day

-Twice if dressing gets soaked

-Once if dressing doesn 't gets soaked

Once healthy granulation has been obtained and when culture comes back negative for growth, dressings will be continued as once per day.

Wound C/S were taken on day 1, in all patients on inclusion to study if negative on day 4 then next wound CS was taken when either discharge or signs of inflammation was present or before planning for definitive surgery. If positive, definitive antibiotics were given and wound C/S was repeated after completion of therapy until it turns negative. Review assessment was done every 7 days with photograph to monitor progress along with wound measurements, wound C/S. hotograph were taken of the wound with camera 15 cm away and perpendicular to wound surface. Dressing materials and ointments were made available free of cost to the participants of the study.

Patients undergoing STSG or Secondary Suturing were followed up for any complications such as graft loss and wound dehiscence. Patients who had comorbidities such as hypertension were controlled by appropriate medications in both groups during the study. Patients who had low hemoglobin of less than 10 gm/dl were transfused red cell concentrates and Hemoglobin count was brought up to more than 10 gm/dl.

- Preparation of insulin – 0.1 m of soluble human insulin (Act rapid) diluted in 0.9 ml normal saline for every 10 sq. Cm ulcer area

Method of measurement of ulcer = Maximum length × maximum breadth

Results and Analysis

The present study was a prospective randomized case control study in which a total of 100 patients were enrolled and conducted in the Department of General Surgery, SSG Hospital, Baroda, Gujarat. In this study, 50 patients had been given dressing with topical insulin(n=50) and remaining 50 patients had been given dressing with normal saline (n=50) and various parameters were compared among both the groups which are discussed below.

Table 1: Age group wise distribution of the patients

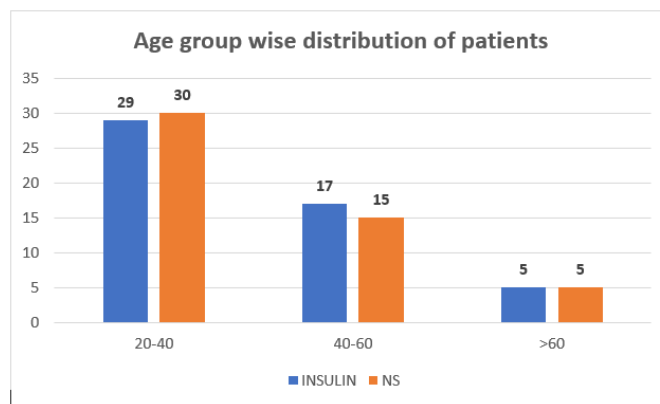| Variable	Medication				Chi-square/t-test (p-value)
AGE in years	INSULIN group (n=50)	%	Normalsaline group (n=50)	%	
20-40	29	58	30	60	Chi-square value=1.32
40-60	17	34	15	30	p-value = 0.51
More than 60	04	08	05	10	
TOTAL	50		50		
Mean ± SD	41.3±16.4		40.0±15.84		t-test value=0.36(p value-0.71)
Median	38				
Mode	40				

Figure 1: Age group wise distribution of patients

Above table and figure shows age group wise distribution of patients. The majority of patients belong to the age group of 20-30 years of age group in both the groups. Association of age group with dressing was calculated through chi-square and it was statistically not significant(p value-0.51). Mean(sd) of patients who had been given topical insulin dressing was 41.3±16.4 years. Mean (sd) among patients who had been given dressing with normal saline was 40.0±15.84. Difference between mean age among both the group was calculated through un-paired t-test and it was statistically not significant.

Table 2: Gender wise distribution of patient

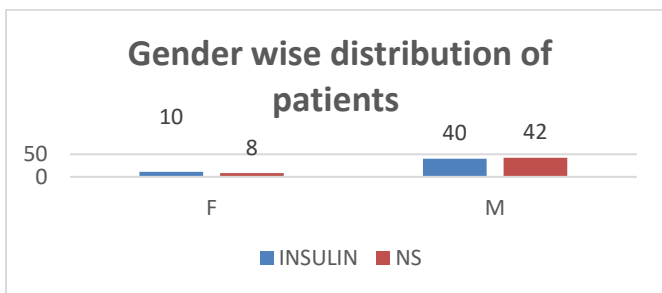| SEX	Medication				Chi-square(p-value)
	INSULIN (n=50)	%	NS(n=50)	%	
F	10	21.57	8	16	Chi-square value=0.51
M	40	78.43	42	84	p-value = 0.47
TOTAL	50		50		

Figure 2: Gender wise distribution of patients

The above table and figure show gender wise distribution of patients. There were 78% male in the group who had been given topical insulin and there were 84% male in the group who had been given normal saline dressing. Association of dressing with gender was carried out through chi-square test and it was statistically not significant.

Table 3: Comorbidities among patients

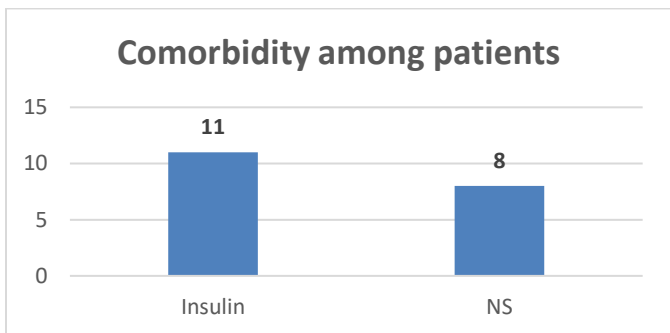| Associated Comorbidities	Medication			Chi-square test
	INSULIN (n=50)	NS (n=50)	Total	Pvalue
Hypertension	11	08	19	0.47

Figure 3: Associated co-morbidities among patients

Above table shows associated comorbidities among patients. All the patients included in the study were diabetics. Out of total there were 19 patients who had hypertension. There was no statistical difference observed among distribution of hypertensive patients in both the group.

Table 4: Mean ulcer length among both the groups

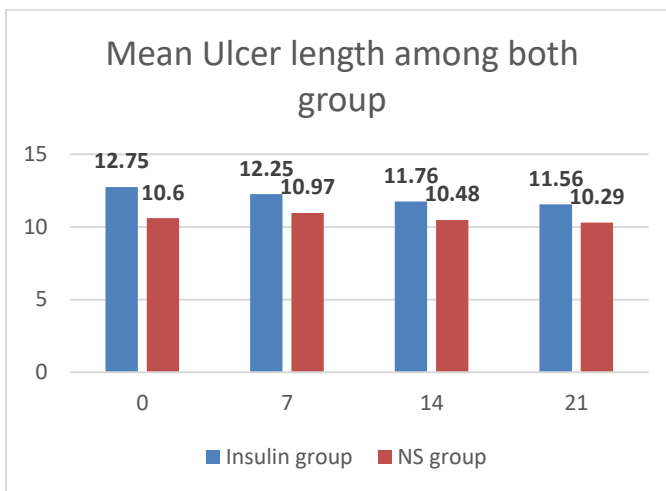| Day	Insulin group n=50	NS group (n=50)	Unpairedt-test / P-value
	Mean length of anulcer (cm) (mean ± SD)	Mean length of anulcer (cm) (mean ± SD)	
0	12.75 ± 5.54	10.60 ± 3.34	0.01
7	12.25 ± 5.53	10.97 ± 3.81	0.17
14	11.76 ± 5.34	10.48± 3.70	0.16
21	11.56 ± 4.43	10.29 ± 3.91	0.17

Figure 4: Comparison of mean ulcer length among both groups

The above table and figure show mean length of ulcer in both the group. The mean length among topical insulin group was 12.75 ± 5.54 cm and 10.60 ± 3.34 cm among patients who had been given normal saline at the day of admission.

The mean on 21st day was 11.56 ± 4.43 cm in the group who had been given dressing with topical insulin , and 10.29 ± 3.91 cm in the group who had been given normal saline dressing.

Table 5: Mean Surface area of ulcer among both groups

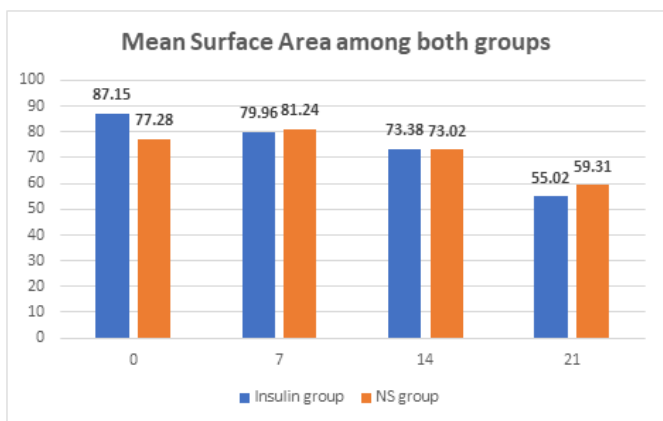| Day	INSULINgroup (n=50)		NSgroup (n=50)		Un-pairedt-test
	Mean surface area of an ulcer (cm²) (mean ± SD)	Healing Rate (cm²/week)	Mean surface area of an ulcer (cm²) (mean ± SD)	Healing Rate (cm²/week)	p-value
0	87.15±38.27	--	77.28 ± 33.79	--	0.17
7	79.96 ±36.76	7.19	81.24 ± 42.36	-3.96	0.87
14	73.38 ± 36.43	6.58	73.02 ± 37.33	8.26	0.96
21	55.02 ± 39.93	18.36	59.31 ± 43.24	13.71	0.67

Figure 5: Comparison of mean surface area among both the groups

The mean surface area among insulin group was 87.15±38.27 sq. Cm at the day of admission. On the other hand, mean surface area among normal saline was 77.28 ± 33.79 sq. Cm . On the 21st day mean surface area among insulin group and normal saline group were 55.02 ± 39.93 sq.cm and 59.31 ± 43.24 sq.cm respectively. The healing rate was 18.36 cm^2/week on 21st day in the patients who had been given topical insulin dressing. On the contrary, healing rate was 13.71 cm^2/week in the patients who had been given normal saline dressing.
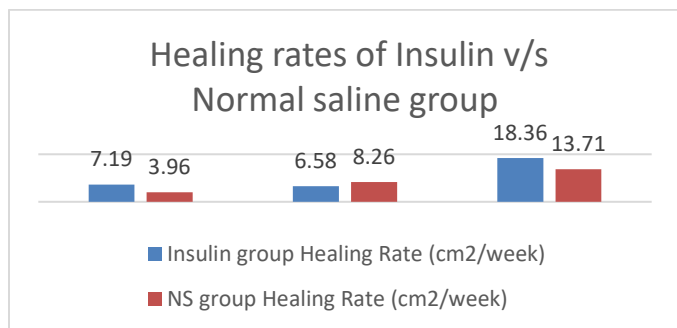

Figure 6: comparison of healing rates among insulin v/s normal saline group

Table 6: Pus culture and sensitivity in both groups

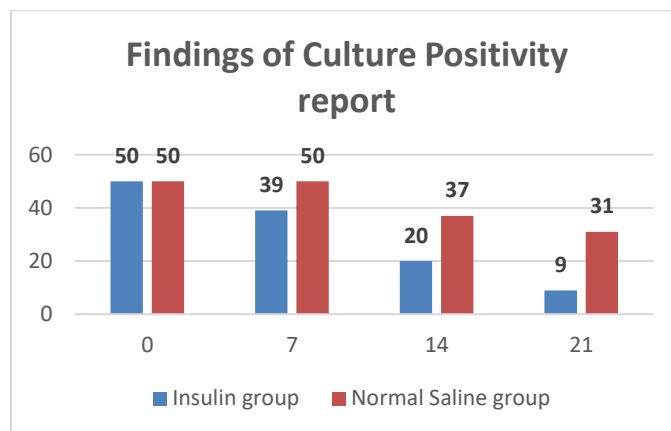| Day	INSULIN group (n=50)		NS group (n=50)		Chi-square test /P value
	Number of patients with pus CS positive (n=50)	%	Number of patients with pus CS positive (n=50)	%	
0	50	100	50	100	1
7	39	78	50	100	0.12
14	20	40	37	74	0.06
21	9	18	31	62	0.03

Figure 7: Findings from Culture Sensitivity reports

The above table and figure show day wise culture sensitivity report among patients in both groups. In the group who had been given topical insulin dressing only 18 % of patients had been culture positive at the end of 21 days, while 62 % of patients were showing positive culture report at the end of 21 days in normal saline group. Difference among both group for culture sensitivity was calculated through chi-square test and it was statistically significant on 21st day.

Table 7: Days taken for appearance of granulation tissue among both groups

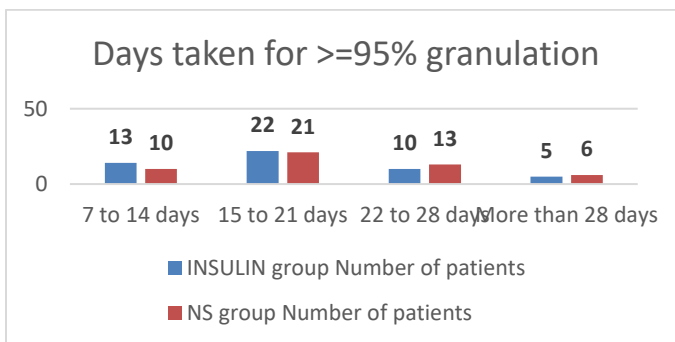| Days taken for granulation tissue	INSULIN group (n=50)		NS group (n=50)		P value (Chi-square test)
	Number of patients	%	Number of patients	%	
7 to 14 days	13	27.45	10	20	0.76
15 to 21 days	22	43.41	21	42	
22 to 28 days	10	19.61	13	26	
More than 28 days	05	09.80	06	12	

Figure 8: Days taken for appearance of granulation tissue among both groups

Above table and figure shows days taken for appearance of more than 95% of granulation tissue. Majority of patients had developed granulation tissue in the time period of 15-21 days in both the groups. Their association with each medication was calculated through chi-square test and it was statistically not significant.

Table 8: Outcome among both the groups

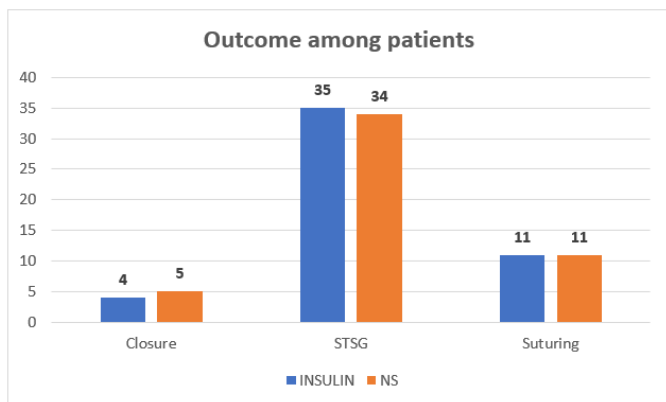| Outcome	INSULIN group (n=50)	NS group (n=50)	P value (Chi-square test)
STSG	35	34	0.67
Spontaneous healing	04	05	
Suturing	11	11	
Non-healing	0	0	

Figure 9: Outcome among patients

The above table and figure show the outcome among patients in both the group. Majority of the patients among both the group had STSG. Their association with medication was statistically not significant. Significance was calculated through chi-square test.

Table 9: Number of days to STSG/suturing/closure in both the groups

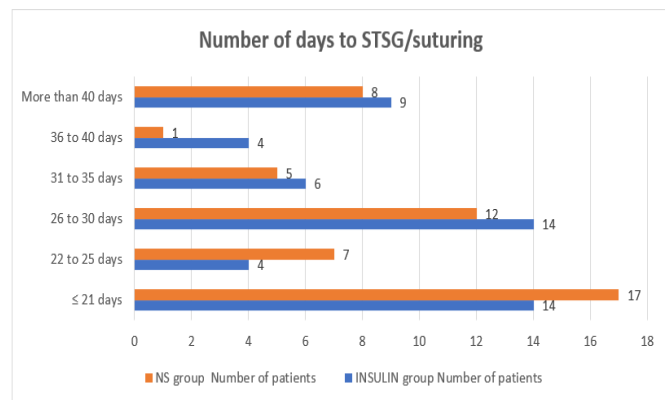| STSG/ Suturing/Closure	INSULIN group (n=50)		NS group (n=50)		P value (Chi-square test)
Days	Number of patients	%	Number of patients	%	
≤ 21 days	14	27.45	17	34.00	0.66
22 to 25 days	04	07.84	07	14.00	
26 to 30 days	14	27.45	12	24.00	
31 to 35 days	06	11.76	05	10.00	
36 to 40 days	04	7.81	01	02.00	
More than 40 days	09	17.65	08	16.00	

Figure 10: Number of days to STSG/suturing

Above table and figure shows number of days to STSG. Majority of patients in both the group belongs to the category of 26 to 30 days and there was no statistically significant difference observed among both the groups.

Table 10: Mean hospital stay among both the group

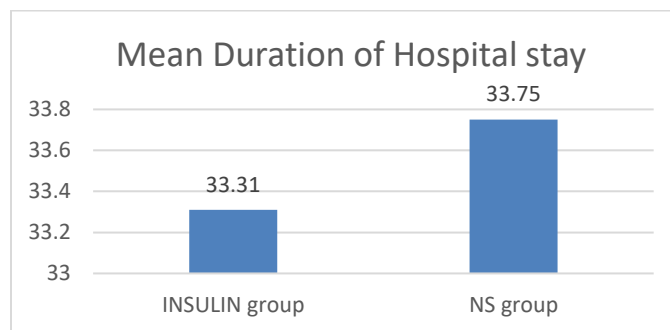| Hospital stay in days	INSULIN group (days)	NS group (days)	P value
Mean ± SD	33.31 ± 10.93	33.75 ± 11.53	0.76

Figure 11: Mean hospital stay among both the group

Mean hospital duration among insulin group was 33.31 ± 10.93 days and among normal saline group it was 33.75 ± 11.53 days. There was no statistically significant difference was observed among both the group.

Discussion

Diabetes can result from defective insulin production or defective action of insulin to peripheral tissue. Presentation of diabetes varies from asymptomatic to systemic involvement like retinopathy, neuropathy and nephropathy. Diabetes decreases the immunity of the body and make easily susceptible to the infections. Diabetic ulcer is most common sequelae observed in diabetic patients. Prevalence of diabetic ulcer in india is 15% to 51% in india[5,6]. Important steps in managing the ulcers are daily dressings, debridement, if necessary, antibiotics and good sugar control. For dressing numerous topical medications are used for ulcer healing. Most commonly used is normal saline and many less had been proved effective than normal saline. Insulin stimulates the growth and development of keratinocytes, endothelial cells and fibroblasts and help proliferation, and tissue healing. Hence present study had been carried out to compare the effect of topical insulin and normal saline in healing diabetic ulcer.

Socio-demo graphic details of patients

A study was done by Uddin a et aimed at effect of topical insulin and normal saline in healing diabetic ulcer. The study had found out that majority of

Patients belong to 46-60 years of age group in both the groups[7] . In our study the main age group was patients coming in the age group of 20-40 years of age group. The possible reason could be diabetes type ii usually occurs after the age of 40 years as increased age is an independent risk factor for diabetes.

Table 11: comparison of this study with study performed by Uddin a et al in terms of age group of patients

Study	Age-group
Our study	20-40 years
Uddin A et al	46-60 years

Table 12: comparison of this study with study performed by dinh t et al and navarro-peternella fm et al in terms of gender distribution

Study	Gender
Our study	78% in Insulin group and 84 % in Normal saline group
Dinh T et al	80% male
Navarro-Peternella FM et al	77% male

More than two third of patients in both the group were males. Studies done by Dinh T et al and Navarro-Peternella FM et al had found out that male gender was a risk factor for developing the diabetic ulcer. The same findings are reflected in our study results and explains more number of male participants in the study[8,9].

Comparison in reduction of ulcer surface area

A comparative study had been carried out by k Ramarao et al aimed at comparing the effect of topical insulin and normal saline dressing in healing diabetic foot. They had found out that there was significant reduction in ulcer surface area who had been given topical insulin (p value<0.001)[10] .

A was study done by Uddin a et al aiming at effect of topical insulin and normal saline in healing diabetic ulcer. This study had revealed there was 15%

Reduction in wound surface area as compared to 6% reduction in the group of normal saline area[49] . But the difference was not statistically significant.

Findings from this study were also same as mentioned in above two studies. In this study mean surface area reduction was faster in patients who had been

Given topical insulin dressing as compared to other group and the difference was not statistically significant. As above mentioned, study and our study have

Lesser number of patients to compare, it might be possible that statistical test did not come significant. Therefore, it could be recommended that study with increased sample size should be carried out in the future.

Table 13: comparison of this study with study performed by k Ramarao et al and Uddin a et al in terms of reduction of surface area

Study	Area reduction in Insulin group	Area reduction in normal saline
Our study	18.36 cm2	33.37 cm2
K Ramarao et al	18.82 cm2	38 cm2
Uddin A et al	15 % reduction	6% reduction

Role of topic al insulin vs normal saline in reducing the bacterial organism

In a study by k Ramarao et al wound culture was reduced in 73% of patients in a group who had been given topical insulin group. On the other hand, only 56% of patients had been free from infection in the group who had been given normal saline[10] . In our study et the end of 21st day only 18% of patients had shown positive culture report in patients who had been given topical insulin dressing. On the contrary, 62% of the patients had shown positive culture report who had been given normal saline dressing. Hence there was statistically significant difference in reducing organism positivity in the unsul in group as compared to normal saline group in our study.

Table 14: comparison of this study with study performed by k ramarao et al in terms of reducing bacterial load

Study	Bacterial growth reduction in Insulin group	Bacterial growth reduction in normal saline
Our study	82%	38%
K Ramarao	73%	56%

Organism found in ulcer area

In a study done by Uddin a et al had identified *E.coli* followed by klebsiella in both the group (topical insulin vs normal saline)[7] . Studies had identified diabetic ulcers are commonly associated with gram-positive organisms such as staphylococcus aureus, enterococcus, and gram-negative organisms like aeruginosa, Escherichia coli, klebsiella species, proteus species, etc., and pseudomonas anaerobes[53] . These organisms also show multi-drug resistance. In our study main organism found was staphylococcus aureus and pseudomonas.

Table 15: comparison of major organism found in our study compared to study performed by Uddin et al

Study	Major organism found
Our study	Staphylococcus aureus >Pseudomonas
Uddin A et al	A. Coli > Klebsiella

Comparison of both groups on the basis of appearance of granulation tissue

In a study done by biradar d et al it was revealed that average time required for appearance of granulation tissue was 6.08 ± 2.15 days & 9.48 ± 4.21 days in patients with topical insulin draining and normal saline dressing respectively[12] . In our study majority of patients had taken 26 to 30 days for appearance of 95% of granulation tissue and there was no difference observed in appearance of granulation tissue among both the group. Therefore, it is difficult to comment on the appearance of granulation tissue among both groups. Therefore, we were not able to compare the efficacy of topical insulin and normal saline on the basis of this group.

Table 16: comparison of time taken for appearance of granulation tissue

Study	Time taken for appearance of granulation tissue (in days) in insulin group	Time taken for appearance of granulation tissue (in days) in normal saline group
Our study	26 to 30 days	26 to 30 days
Biradar et al	6.08 ± 2.15	9.48 ± 4.21

Comparison of both group so the basis of hospital stays

In a study done by Sanjay Pandey et al, they found out Mean hospital duration among patients who had been Given topical insulin was lesser as compare to patients who had been given normal saline dressing[13]. On the contrary there was no statistically significant difference was observed for mean duration of hospital stay was

observed among both groups. Therefore, role of topical insulin in reducing the hospital stays unclear in this study the main limitation of the study was study had lower sample size, thus the comparison was not able to give a comparative difference for the efficacy of the topical insulin and normal saline dressing.

Conclusion

In this study it was observed that topical insulin was marginally superior to normal saline in terms of healing rate of ulcer. Percentage reduction in wound surface area was approximately 29.98% in case of topical insulin which was slightly better compared to normal saline group where it was 23.25 %. Topical insulin and normal saline were found to be comparable in terms of appearance of >95% granulation tissue and resolution of slough in wound. Topical insulin and normal saline were also comparable when it came to duration of hospital stay.

Therefore, topical insulin is an effective method of diabetic wound dressing compared to normal saline in some aspects but comparable to normal saline in other aspects.

Therefore, topical insulin is an effective method of diabetic wound dressing compared to normal saline in some aspects but comparable to normal saline in other aspects.

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Abbreviations

IECBHR – Institutional Ethics Committee for Biomedical And Health Research

INJ - Injection

PUS C/S – Pus Culture And Sensitivity

PT – Patient

STSG – Split Thickness Skin Graft

DFU – Diabetic Foot Ulcer

P - Prevalence/Proportion

Q- (100-p)

L – Allowable Error

Z- Standard Normal Distribution