"A Comparative Study between the Effect of Topical Insulin Application and Normal Saline Dressing in Healing Of Diabetic Foot"

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Abstract
BACKGROUND
Around 15% of diabetic patients have diabetic foot ulcers. An estimated 80,000 amputations are made each year in the United States. The lifetime risk of diabetic foot ulcer among diabetics is 68/1000 persons. The risk of amputation increases with the size of the ulcer. In patients who had undergone amputation for diabetes, around 84% of them had foot ulcers.

AIM AND OBJECTIVE
The study aimed to compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers. It also aimed to study the clinical profile of patients getting admitted with diabetic foot.

MATERIAL And METHODS
A Prospective Comparative study was done from October 2018 to October 2020 among 100patients with clinical diagnosis of diabetic foot ulcers. They were divided into two groups; Group A: 50 patients subjected to topical insulin application and Group B: 50 patients subjected to normal saline dressing. The day of appearance of granulation tissue was observed and Size of the ulcer was measured on; Day 0, Day 7 and Day 14. One sample t-test was used to compare the results.

RESULTS
In the Topical insulin group, the mean age of the participants is 58.6 years. In the saline dressing group, the mean age of the participants is 53.3 years. In both the groups, there were equal number of males and females. Comparison of two groups based on percentage reduction: The percentage reduction in two groups is; Topical Insulin on Day 7: 4.95%, Saline Dressing on Day 7: 3.15% ; Topical Insulin on Day 14: 11.07% and Saline Dressing on Day 14: 7.27%. Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05. The size of the ulcer reduces considerably reduces in 14 days following application of topical insulin and saline dressing. The percentage reduction in topical insulin group is 11.07% in two weeks. The percentage reduction in saline dressing group is 7.27% in two weeks.

Conclusion
There is around 3.5% more reduction in the size of the ulcer following application of topical insulin in comparison to saline dressing.

I. Introduction

Diabetes mellitus is a worldwide epidemic resulting in significant morbidity and mortality[1]. It starts as a disorder of glucose metabolism and ends up as a multisystem disease. The main underlying mechanism is the abnormal insulin production or impaired insulin utilisation or both. It affects the kidneys, eyes, heart, cardiovascular system, limbs, etc. One of the main manifestations of increased morbidity related to uncontrolled diabetes mellitus is diabetic foot.

Diabetic foot is common throughout the globe with serious effects on quality of life, livelihood and has economic consequences for the families and the society as a whole[2]. The majority of diabetic foot ulcers is neuropathic in origin which suggests that it can be prevented if there are adequate measures in place. It is estimated that in the coming days, diabetic foot will cause serious problems to the developing countries[3].

This can be avoided by early screening and identification of people who are at high risk of developing diabetic foot ulcers, educate them and follow-up to avoid incidence. The lifestyle modifications are absolutely

necessary. The recurrence rate is 50% in a period of three years. The lifetime risk of acquiring diabetic foot ulcer is 25%[4]. A lower limb is lost every 30 seconds due to diabetes worldwide[5]. Therefore, it is essential to prevent the long term complications of diabetic foot to avoid

AIM OF THE STUDY
To compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers
OBJECTIVES OF THE STUDY
Primary Objective
To compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers
Secondary Objective
To study the clinical profile of patients getting admitted with diabetic foot
To compare the strategies for their effectiveness

Relevant studies
A study by Kamat and Sunil in 2019 among 74 patients compared the use of topical insulin and saline dressing. They were divided into two groups of 37 each. The wound was measured on; Day 0, Day 7 and Day 15. There was a statistically significant reduction in the size of the ulcer in the group that used topical insulin[33].
Another study by Ramarao and Ramu in 2017 among 60 patients in two groups of 30 each compared topical insulin and normal saline[34]. The study had the following findings;
In topical insulin group; the mean ulcer area reduction=35.19 ± 19.00 percent
In saline dressing groups; the mean ulcer area reduction=18.82 ± 4.06 percent
The overall size of the wound reduction was higher in the topical insulin group which is statistically significant. The study aimed to compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers. It also aimed to study the clinical profile of patients getting admitted with diabetic foot, the effect of various topical treatment strategies on diabetic foot ulcers and to compare the strategies for their effectiveness.

II. Materials And Methods

STUDY DESIGN
A Prospective Comparative study
STUDY POPULATION
This study includes patients with clinical diagnosis of diabetic foot ulcers
STUDY PERIOD
From OCTOBER 2018 TO OCTOBER 2020
SAMPLE SIZE
This study includes 100 patients with clinical diagnosis of diabetic foot ulcers
INCLUSION CRITERIA
All the cases of diabetic foot ulcers
EXCLUSION CRITERIA
1. Those patients with non-diabetic foot ulcers
2. Patients with severe anemia
3. Patients with collagen vascular disorders.
4. Patients with immunocompromised states.

METHODOLOGY
The material for the study is taken from the cases admitted to department of General Surgery in GMK Medical College & Hospital Salem, who are clinically diagnosed to have diabetic foot ulcers.
a)   A detailed history is taken and examination is done to diagnosed diabetic foot ulcers
b)   Other causes of ulcer was ruled out
c)   Clinical evaluation was done
d)   Laboratory investigations were done
They were divided into two groups.
Group A: 50 patients subjected to topical insulin application
Group B: 50 patients subjected to normal saline dressing.

Patients were followed up till their discharge and at periodic intervals.
e)   The day of appearance of granulation tissue was observed
f)   Size of the ulcer was measured from maximum width and maximum breadth and it is measured on Day 0

Day 7
Day 14

PRIVACY/CONFIDENTIALITY OF STUDY SUBJECTS:
Privacy of the subjects shall be maintained.

STATISTICAL ANALYSIS
All data were recorded in structured questionnaires, coded and entered in Microsoft Excel. The data was then cleaned, checked for inconsistencies, missing values and prepared for analysis using SPSS v23. The data was then analyzed for descriptive statistics and inferential statistics. The tests for significance were run to statistically validate the data. One sample t-test was used. The results were then tabulated and visualized in Microsoft word.

III.   Results

The study aimed to compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers. It also aimed to study the clinical profile of patients getting admitted with diabetic foot, the effect of various topical treatment strategies on diabetic foot ulcers and to compare the strategies for their effectiveness. The analysis revealed the following findings;

In the Topical insulin group, the mean age of the participants is 58.6 years with a standard deviation of 8.14 years. It ranges between 42-75 years. The median age of the sample is 60 years. In the saline dressing group, the mean age of the participants is 53.3 years with a standard deviation of 8.4 years. It ranges between 32-75 years. The median age of the sample is 54 years.

Independent samples t-test shows that the two groups do not differ significantly in age distribution. Hence, the two groups are comparable. This comparability is important to establish in comparative studies like this in order to avoid bias in patient selection and categorisation.

In both the groups, there were equal number of males and females.
In the topical insulin group, there were 25 males (50%) and 25 females (50%)
In the saline dressing group, there were 25 males (50%) and 25 females (50%)

The gender distribution is comparable in both the groups. Since, there are equal numbers of males and females, the risk of age based confounding factor are minimal. The bias is also reduced. Globally, there is a male preponderance for diabetic foot, however, in this study, equal number of males and females were selected to show the effect of the treatment options on two groups that are comparable on the sociodemographic factors.

In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out.

On Day 0, the mean size of the ulcer for topical insulin is 186.74 cm^2
On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm^2
Though the size of the ulcer is slightly lesser in the topical insulin group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.
Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.
On Day 7, the mean size of the ulcer for topical insulin is 177.48 cm^2
On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm^2
On Day 14, the mean size of the ulcer for topical insulin is 166.06 cm^2
On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm^2
Comparison of two groups based on percentage reduction
The percentage reduction in two groups is;
Topical Insulin on Day 7: 4.95%
Saline Dressing on Day 7: 3.15%
Topical Insulin on Day 14: 11.07%
Saline Dressing on Day 14: 7.27%
Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.
a)   The size of the ulcer reduces considerably reduces in 14 days following application of topical insulin and saline dressing
b)   The percentage reduction in topical insulin group is 11.07% in two weeks
c)   The percentage reduction in saline dressing group is 7.27% in two weeks
d)   There is around 3.5% more reduction in the size of the ulcer following application of topical insulin in comparison to saline dressing

STUDY PICTURES

Age distribution

In the Topical insulin group, the mean age of the participants is 58.6 years with a standard deviation of 8.14 years. It ranges between 42-75 years. The median age of the sample is 60 years. The following table and figure shows the age distribution of the participants of the topical insulin group.

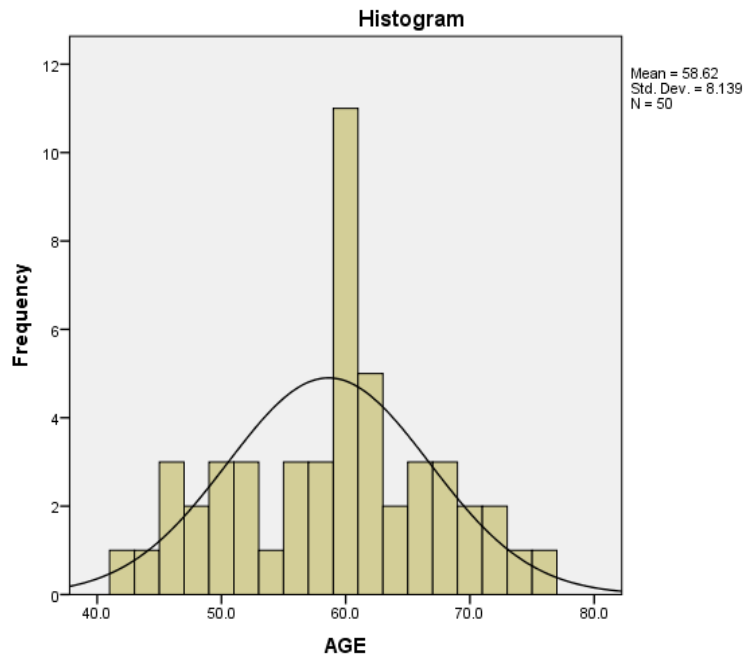| S.No	Parameters for Topical Insulin Group	Age (in years)
1	Mean	58.620
2	Median	60.000
3	Mode	60.0
4	Std. Deviation	8.1388
5	Minimum	42.0
6	Maximum	75.0

Table 1: Age Distribution for Topical Insulin

Figure 1: Age Distribution for Topical Insulin

In the saline dressing group, the mean age of the participants is 53.3 years with a standard deviation of 8.4 years. It ranges between 32-75 years. The median age of the sample is 54 years. The following table and figure shows the age distribution of the participants of the saline dressing group.

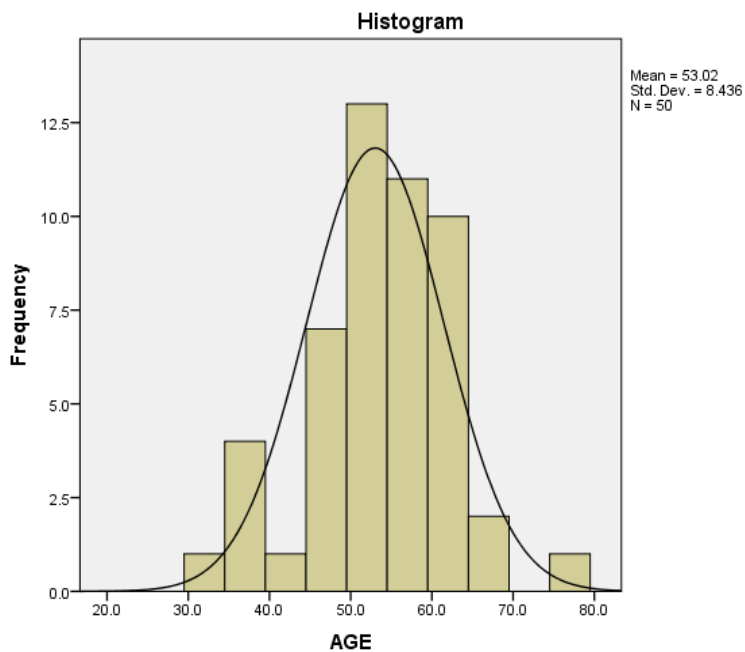| S.No	Parameters for Saline Dressing Group	Age (in years)
1	Mean	53.020
2	Median	54.000
3	Mode	60.0
4	Std. Deviation	8.4358
5	Minimum	32.0
6	Maximum	75.0

Table 2: Age Distribution for Saline Dressing

Figure 2: Age Distribution for Saline Dressing

The following table and figure shows the comparison of age between the two groups

S.No	Parameters (Age in years)	Topical Insulin Group	Saline Dressing Group
1	Mean	58.620	53.020
2	Median	60.000	54.000
3	Mode	60.0	60.0
4	Std. Deviation	8.1388	8.4358
5	Minimum	42.0	32.0
6	Maximum	75.0	75.0

Table 3: Age comparison between two groups
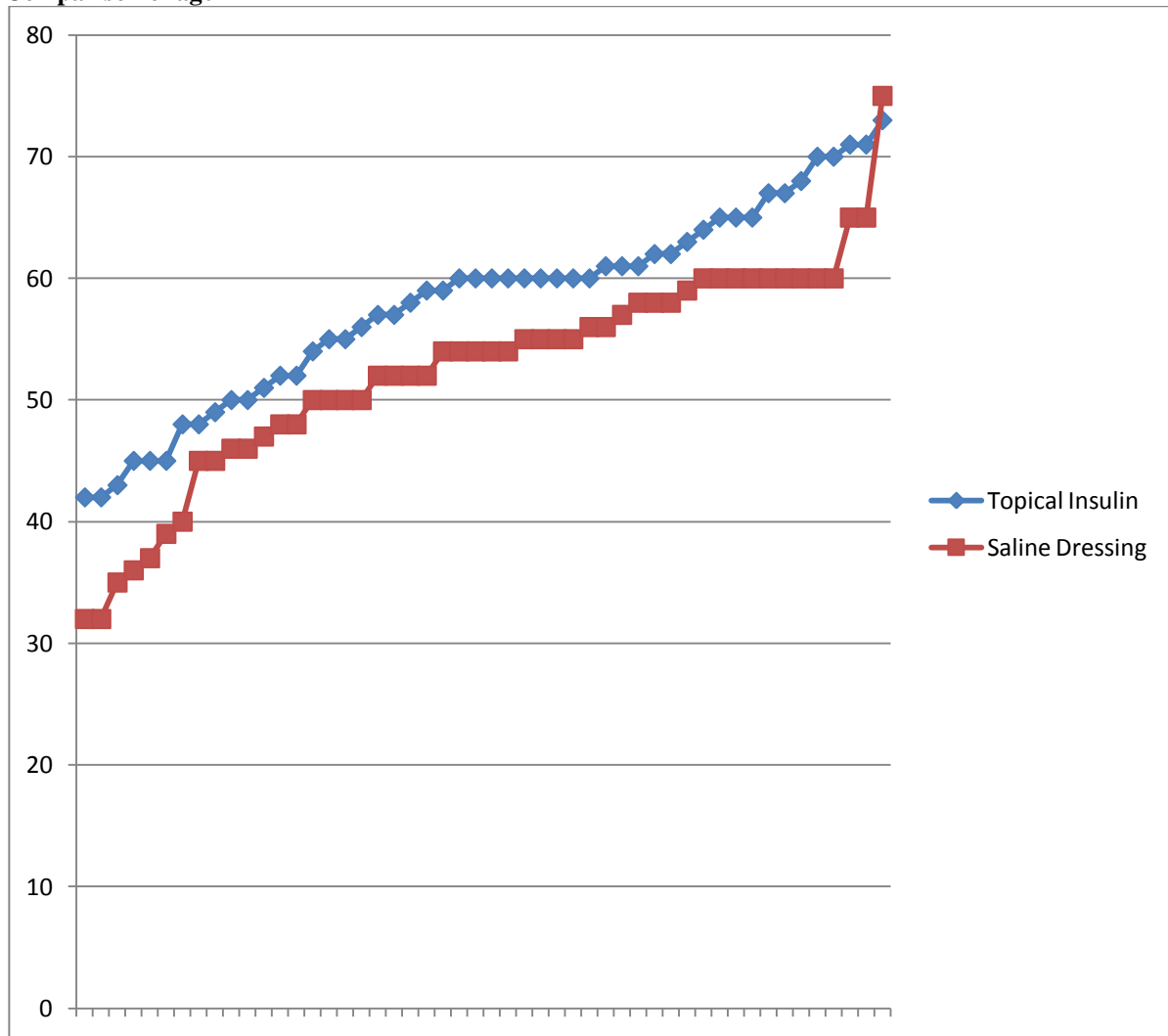
Comparison of age

Figure 3: Age comparison between two groups

Independent samples t-test

Independent samples t-test shows that the two groups do not differ significantly in age distribution. Hence, the two groups are comparable. This comparability is important to establish in comparative studies like this in order to avoid bias in patient selection and categorisation.

Group Statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean
AGE	Topical Insulin	50	58.420	8.2266	1.1634
	Saline Dressing	50	53.020	8.4358	1.1930

Table 4: Independent Sample t-test for age comparison between two groups

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AGE	Equal variances assumed	.018	.894	3.241	98	.002	5.4000	1.6664	2.0931	8.7069
	Equal variances not assumed			3.241	97.938	.002	5.4000	1.6664	2.0931	8.7069

Table 5: Independent Sample t-test for age comparison between two groups

Gender distribution
In both the groups, there were equal number of males and females.
In the topical insulin group, there were 25 males (50%) and 25 females (50%)
In the saline dressing group, there were 25 males (50%) and 25 females (50%)
The gender distribution is comparable in both the groups. Since, there are equal numbers of males and females, the risk of age based confounding factor are minimal. The bias is also reduced. Globally, there is a male preponderance for diabetic foot, however, in this study, equal number of males and females were selected to show the effect of the treatment options on two groups that are comparable on the sociodemographic factors.
The following tables and figure shows the gender distribution
In the topical insulin group, there were 25 males (50%) and 25 females (50%)

S.No	Gender (Topical Insulin)	Frequency	Percentage
1	Male	25	50
2	Female	25	50
	Total	50	100

Table 6: Gender distribution in Topical Insulin Group

In the topical insulin group, there were 25 males (50%) and 25 females (50%)
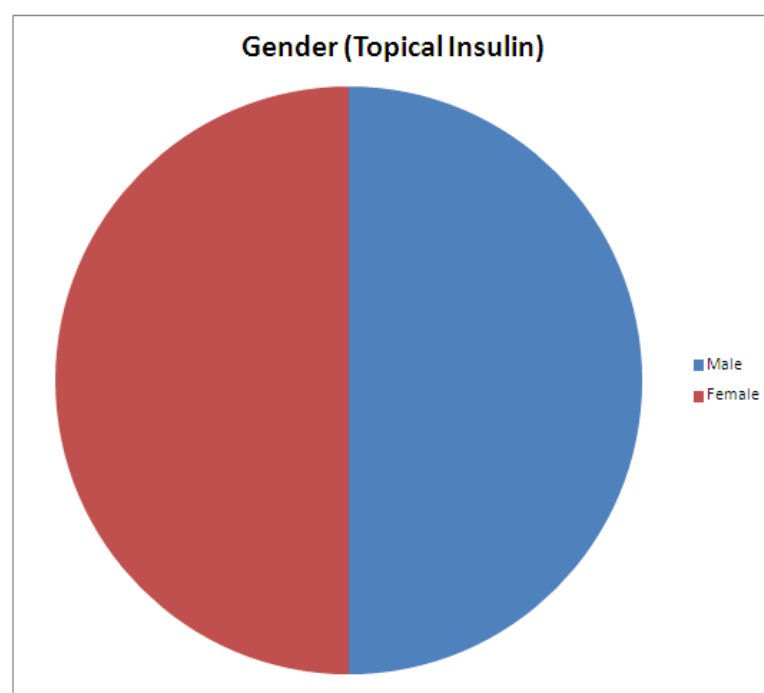

Figure 4: Gender distribution in Topical Insulin Group

In the saline dressing group, there were 25 males (50%) and 25 females (50%)

S.No	Gender (Saline dressing)	Frequency	Percentage
1	Male	25	50
2	Female	25	50
	Total	50	100

Table 7: Gender distribution in Saline Dressing Group

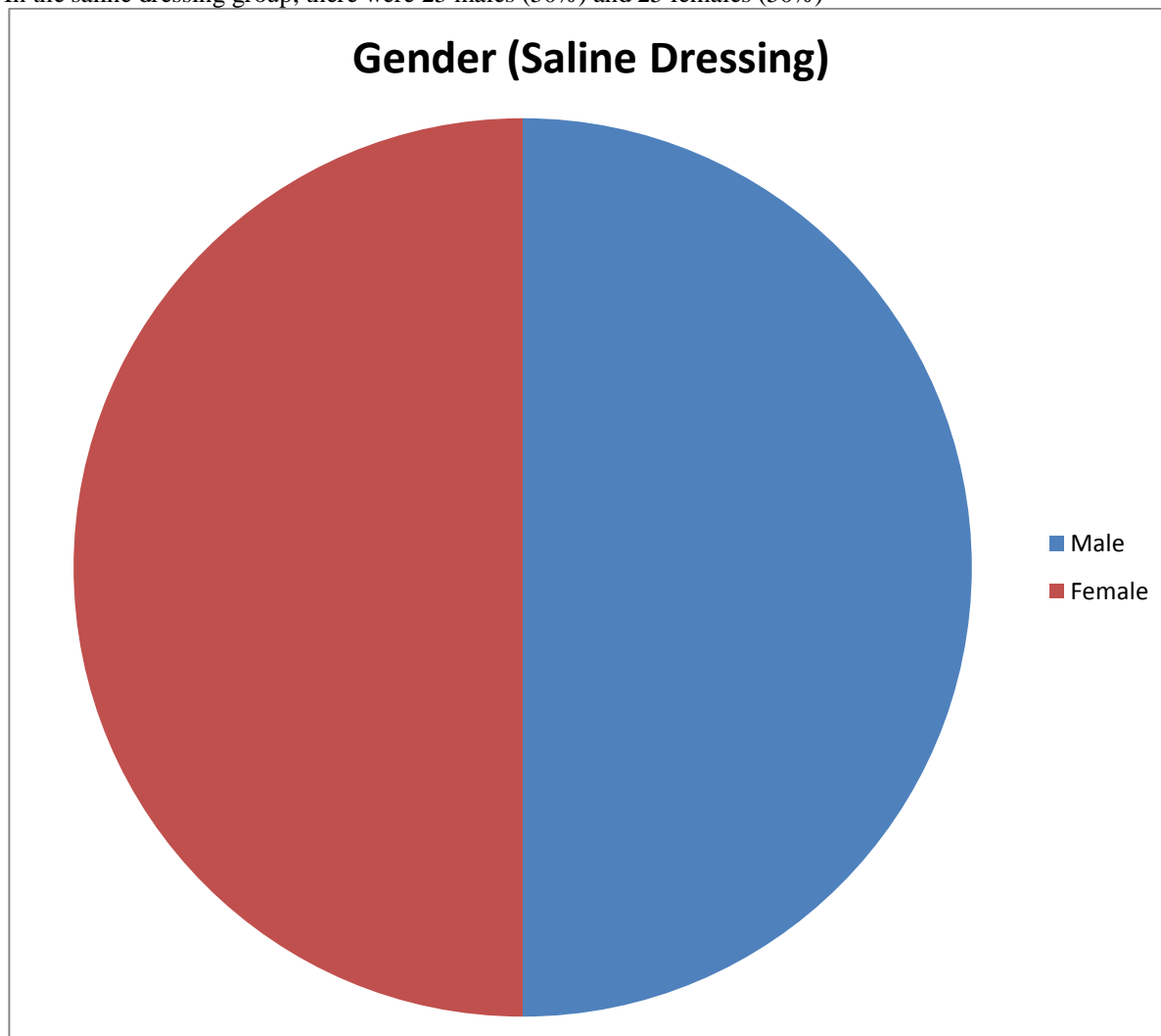In the saline dressing group, there were 25 males (50%) and 25 females (50%)

Gender (Saline Dressing)

■ Male
■ Female

Figure 5: Gender distribution in Saline Dressing Group

Descriptive Statistics
Size of the ulcer
The important outcome of the study is the appearance of granulation tissue and the reduction in the size of the ulcer.
The mean size of the ulcer for topical insulin on
Day 0 is 186.74 cm^2
Day 7 is 177.48 cm^2
Day 14 is 166.06 cm^2

Topical Insulin (size of the ulcer in cm^2)	Day0	Day7	Day14
Mean	186.74	177.48	166.06
Median	186.00	174.00	164.00
Mode	164	158	142[a]
Std. Deviation	25.892	26.664	28.547
Minimum	136	128	112
Maximum	240	235	228

Table 8: Size of ulcer in Topical Insulin Group
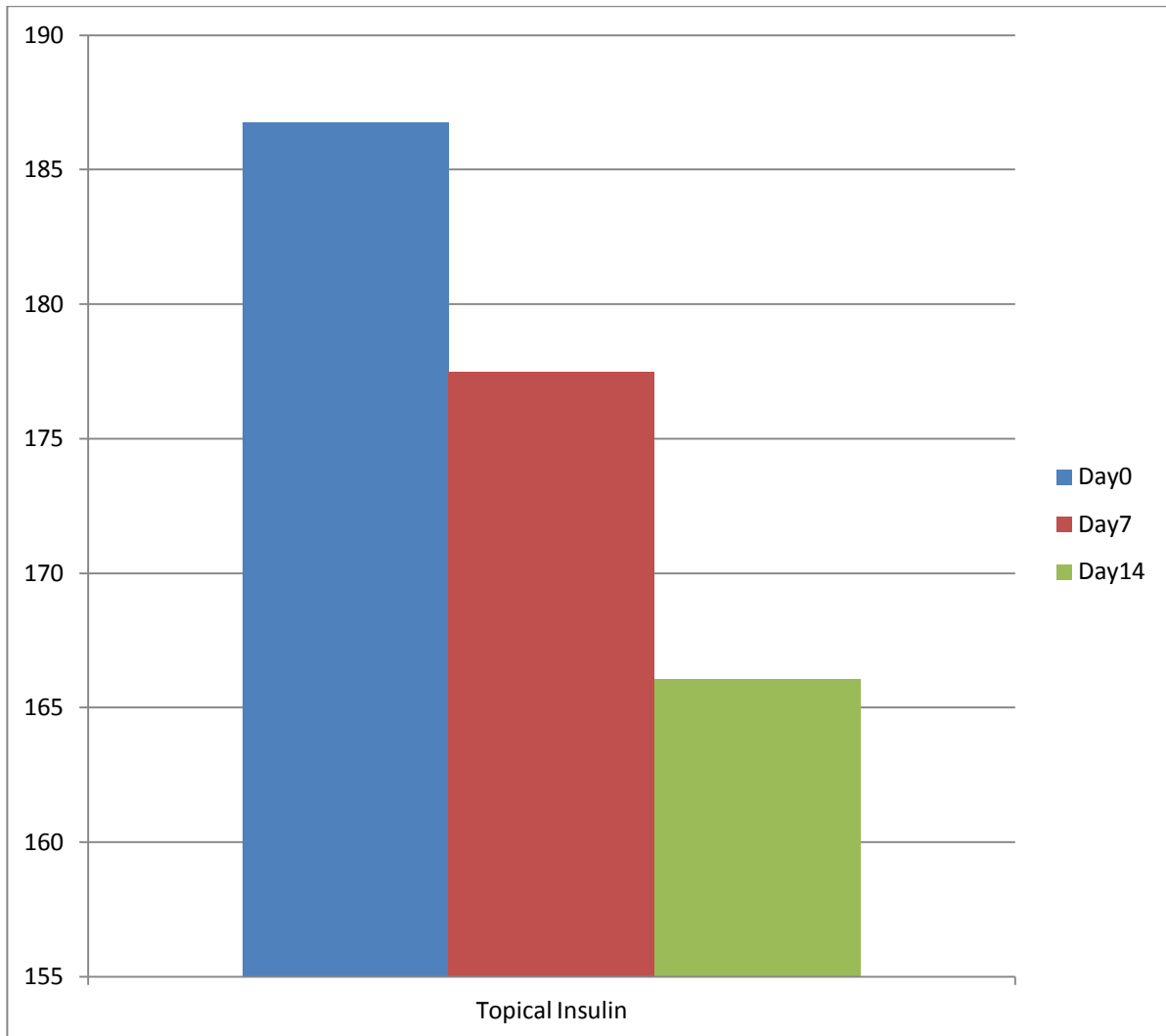
Figure 6: Size of ulcer in Topical Insulin Group

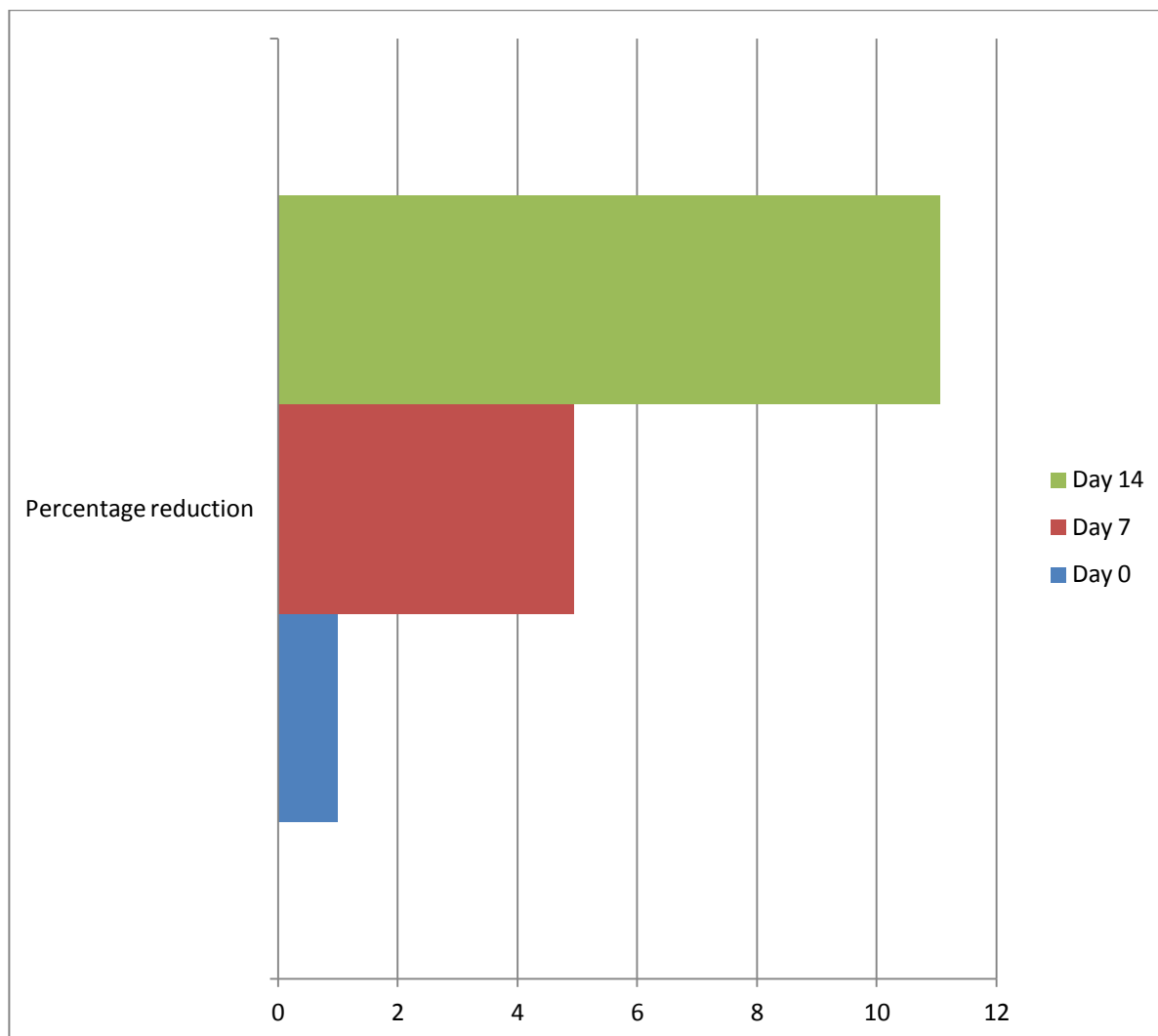|	Topical Insulin (Mean size in cm^2)	% reduction
Day0	186.74	-
Day7	177.48	4.95%
Day14	166.06	11.07%

Table 9: Percentage reduction in Topical Insulin Group

Figure 7: Percentage reduction in Topical Insulin Group

The mean size of the ulcer for saline dressing on
Day 0 is 187.56 cm^2
Day 7 is 181.64 cm^2
Day 14 is 173.92 cm^2

Saline Dressing size of the ulcer in cm^2)	Day0	Day7	Day14
Mean	187.56	181.64	173.92
Median	186.00	180.00	172.00
Mode	186	180	170[a]
Std. Deviation	15.319	15.850	16.061
Minimum	158	152	144
Maximum	220	214	208

Table 10: Size of ulcer in Saline Dressing Group
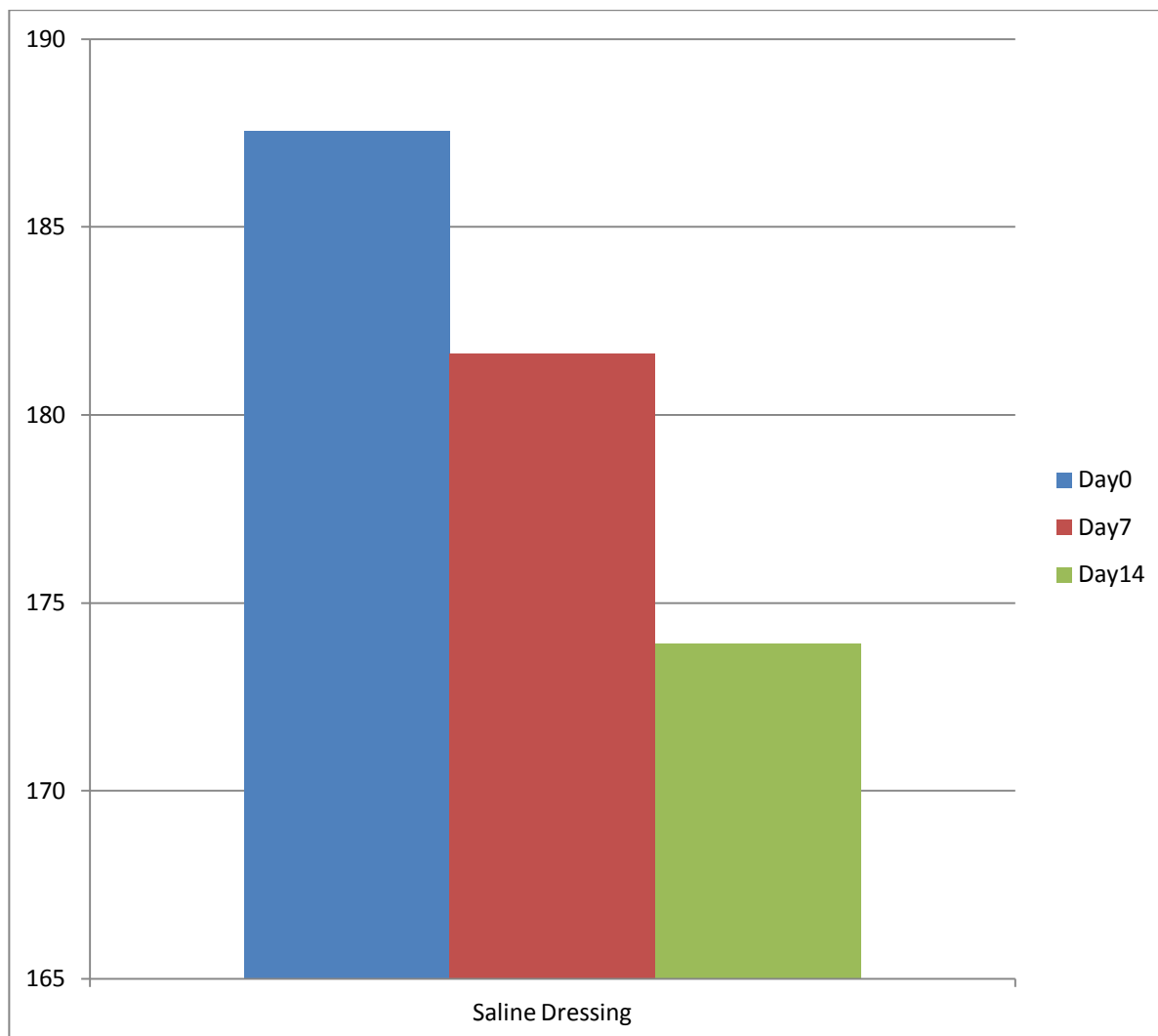
Figure 8: Size of ulcer in Saline Dressing Group

	Saline Dressing (Mean size in cm^2)	% reduction
Day0	187.56	-
Day7	181.64	3.15%
Day14	173.92	7.27%

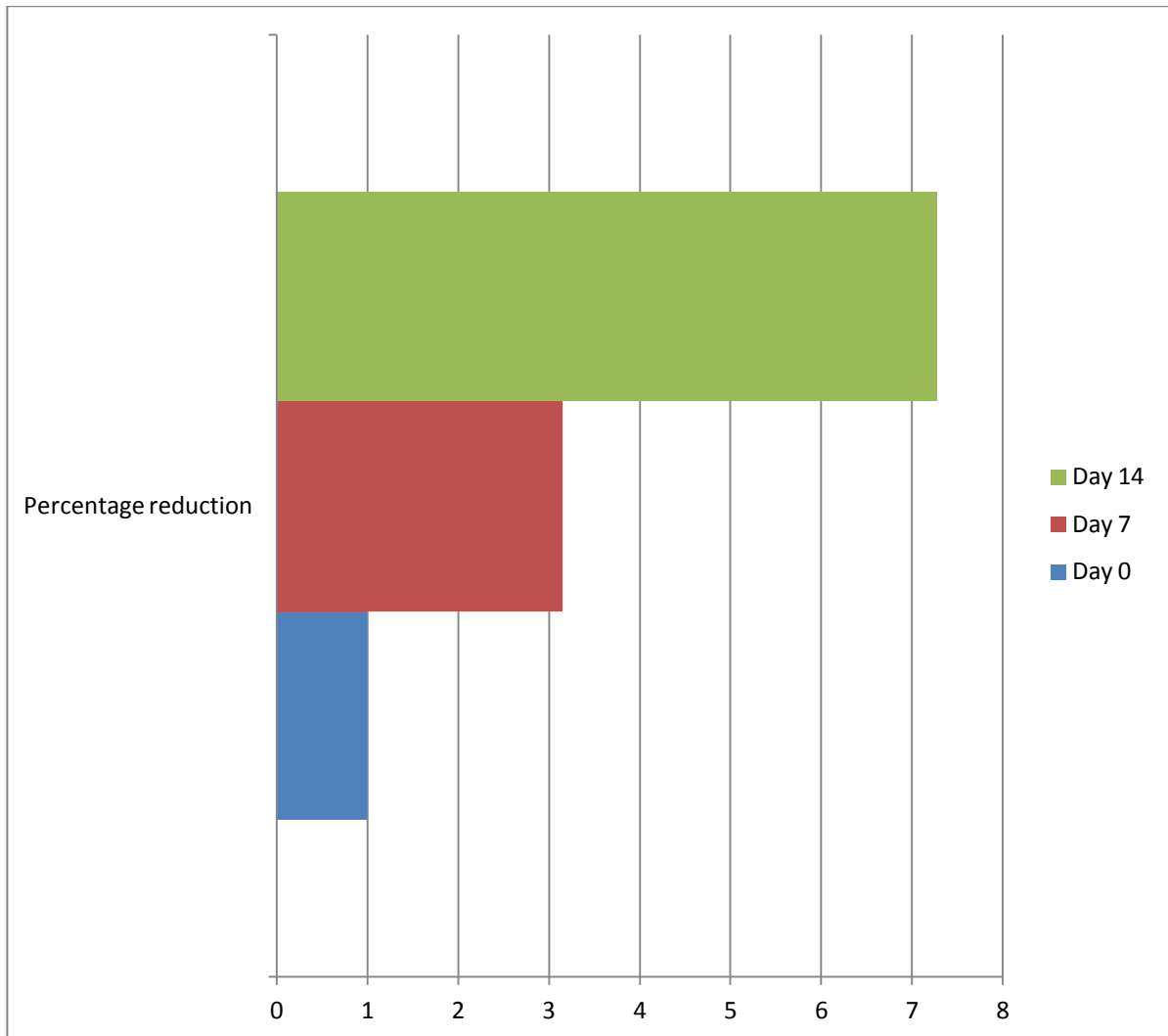Table 11: Percentage reduction in Saline Dressing Group

Figure 9: Percentage reduction in Saline Dressing Group

Comparison of ulcer size between the two groups
In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out.
On Day 0, the mean size of the ulcer for topical insulin is 186.74 cm^2
On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm^2
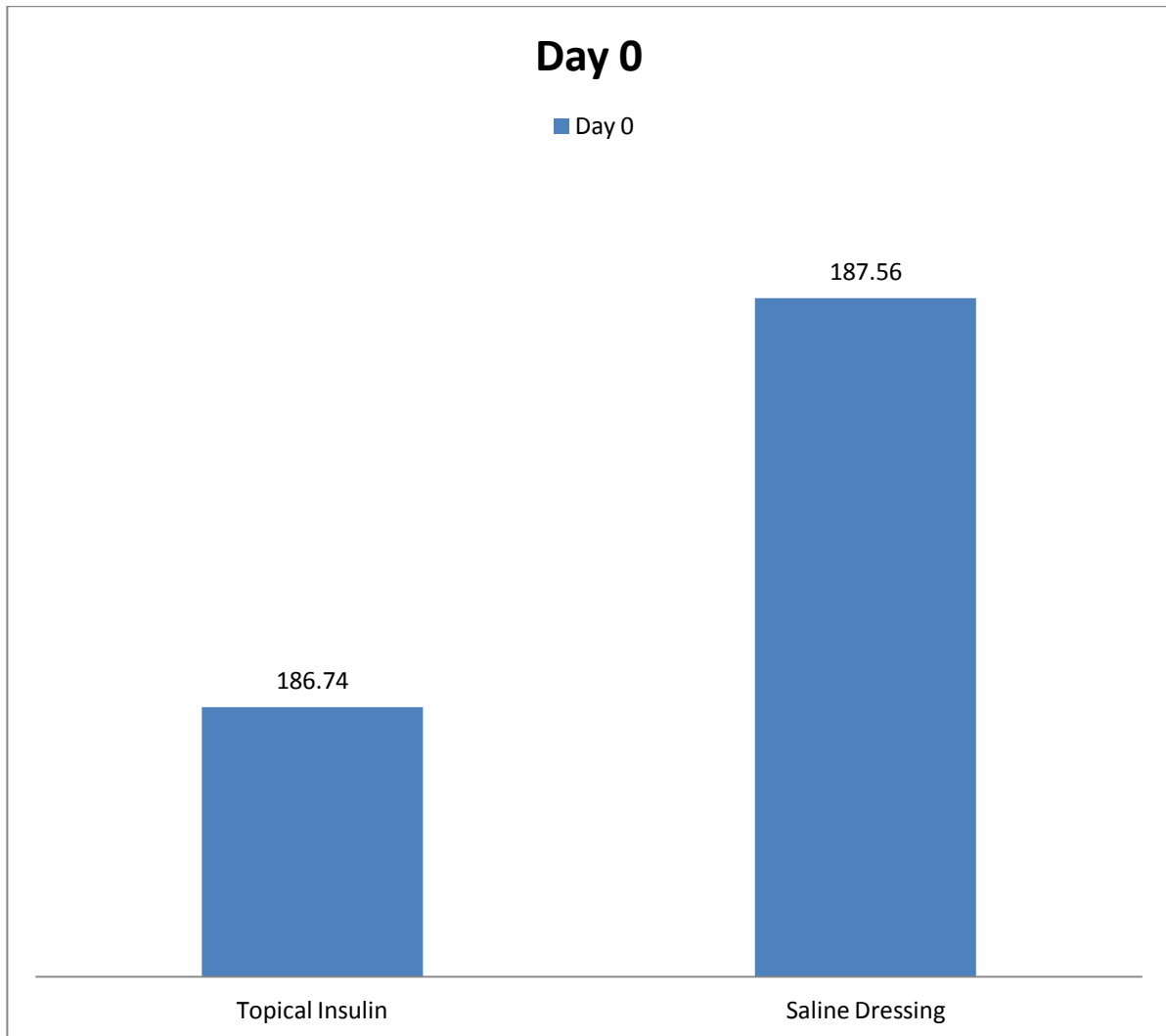
Day 0

■ Day 0

Figure 10: Comparison of ulcer on Day 0

Though the size of the ulcer is slightly lesser in the topical insulin group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.

Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.

On Day 7, the mean size of the ulcer for topical insulin is 177.48 cm^2

On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm^2
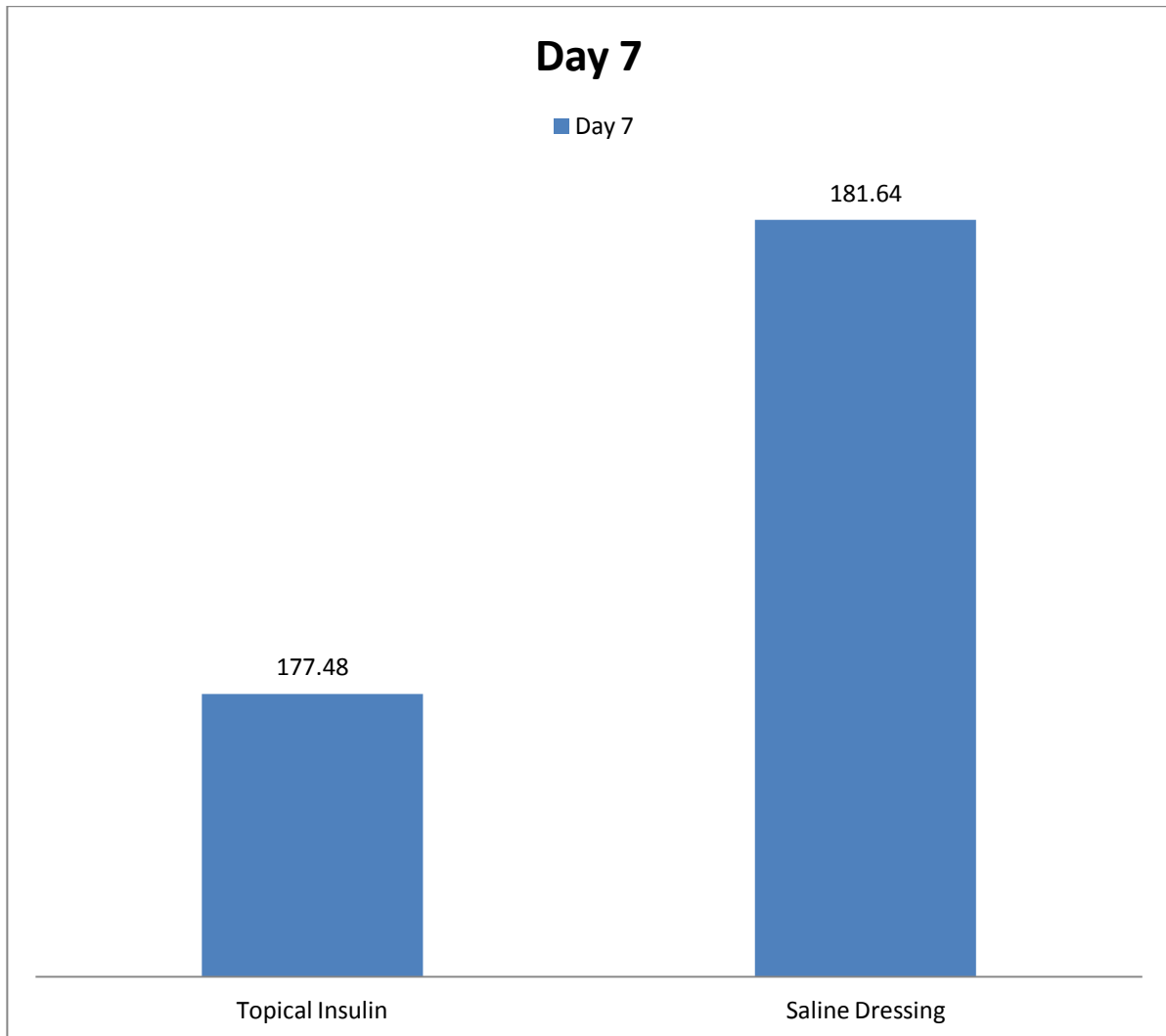
Day 7

■ Day 7

Figure 11: Comparison of ulcer on Day 7

On Day 14, the mean size of the ulcer for topical insulin is 166.06 cm^2
On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm^2
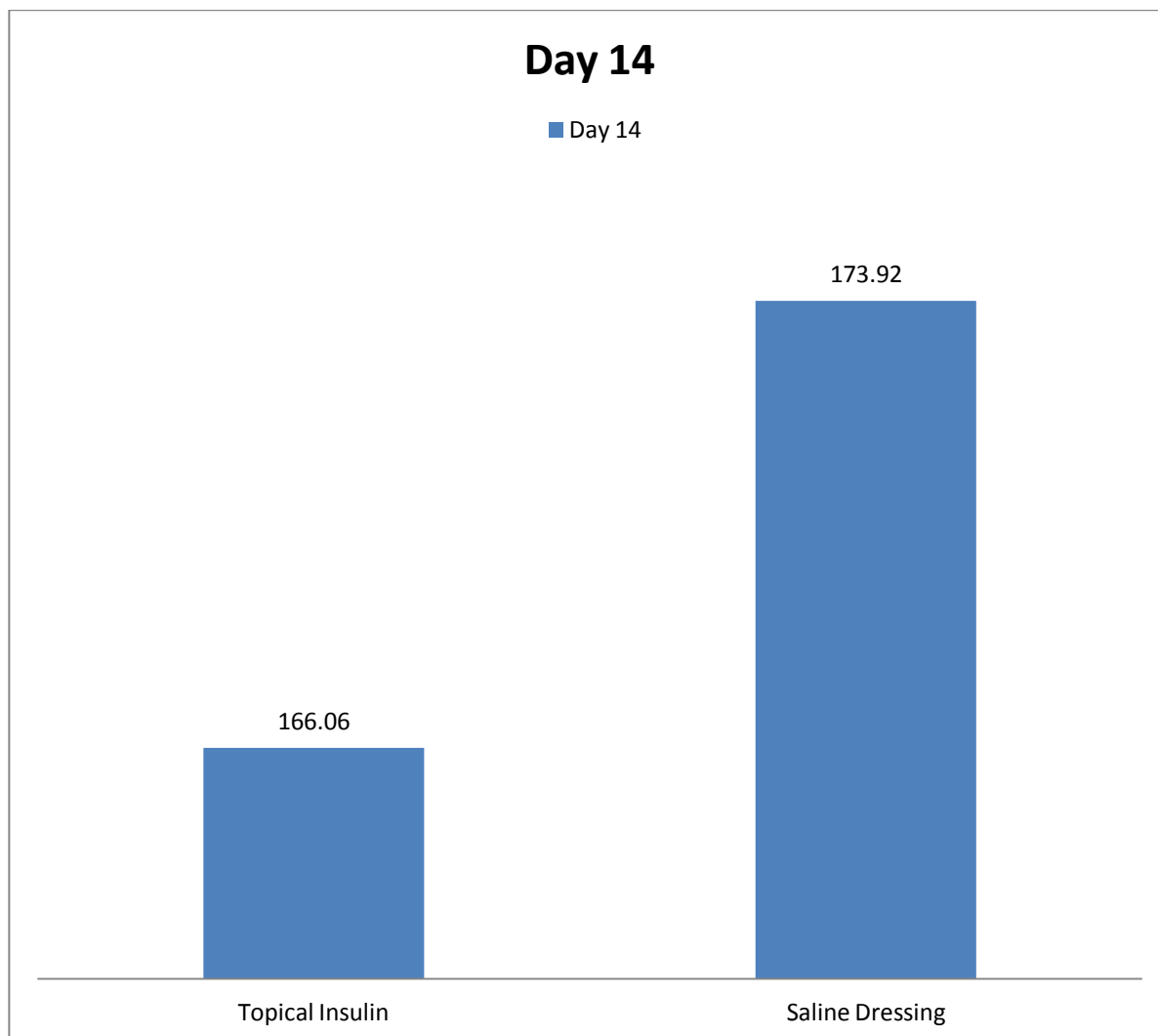
Day 14

■ Day 14

Figure 12: Comparison of ulcer on Day 14

On Day 0, the mean size of the ulcer for topical insulin is 186.74 cm^2
On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm^2
On Day 7, the mean size of the ulcer for topical insulin is 177.48 cm^2
On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm^2
On Day 14, the mean size of the ulcer for topical insulin is 166.06 cm^2
On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm^2

	Saline Dressing (Mean size in cm)	Topical Insulin (Mean size in cm)
Day0	187.56	186.74
Day7	181.64	177.48
Day14	173.92	166.06

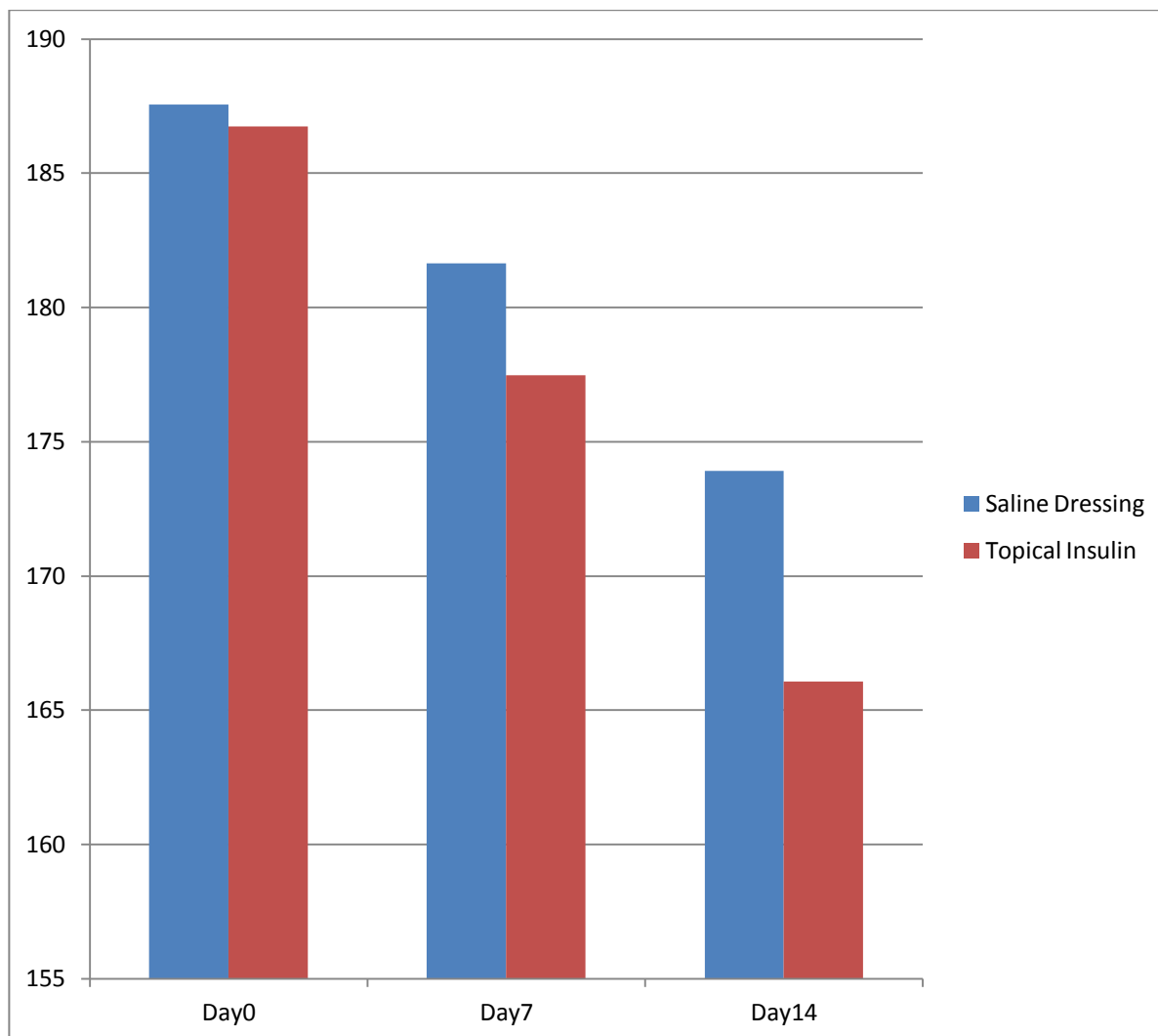Table 12: Comparison of mean ulcer sizes

Figure 13: Comparison of mean ulcer sizes

Comparison of two groups based on percentage reduction
The percentage reduction in two groups is;
Topical Insulin on Day 7: 4.95%
Saline Dressing on Day 7: 3.15%
Topical Insulin on Day 14: 11.07%
Saline Dressing on Day 14: 7.27%

	Topical Insulin (Mean size in cm^2)	% reduction	Saline Dressing (Mean size in cm^2)	% reduction
Day0	186.74	-	187.56	-
Day7	177.48	4.95%	181.64	3.15%
Day14	166.06	11.07%	173.92	7.27%

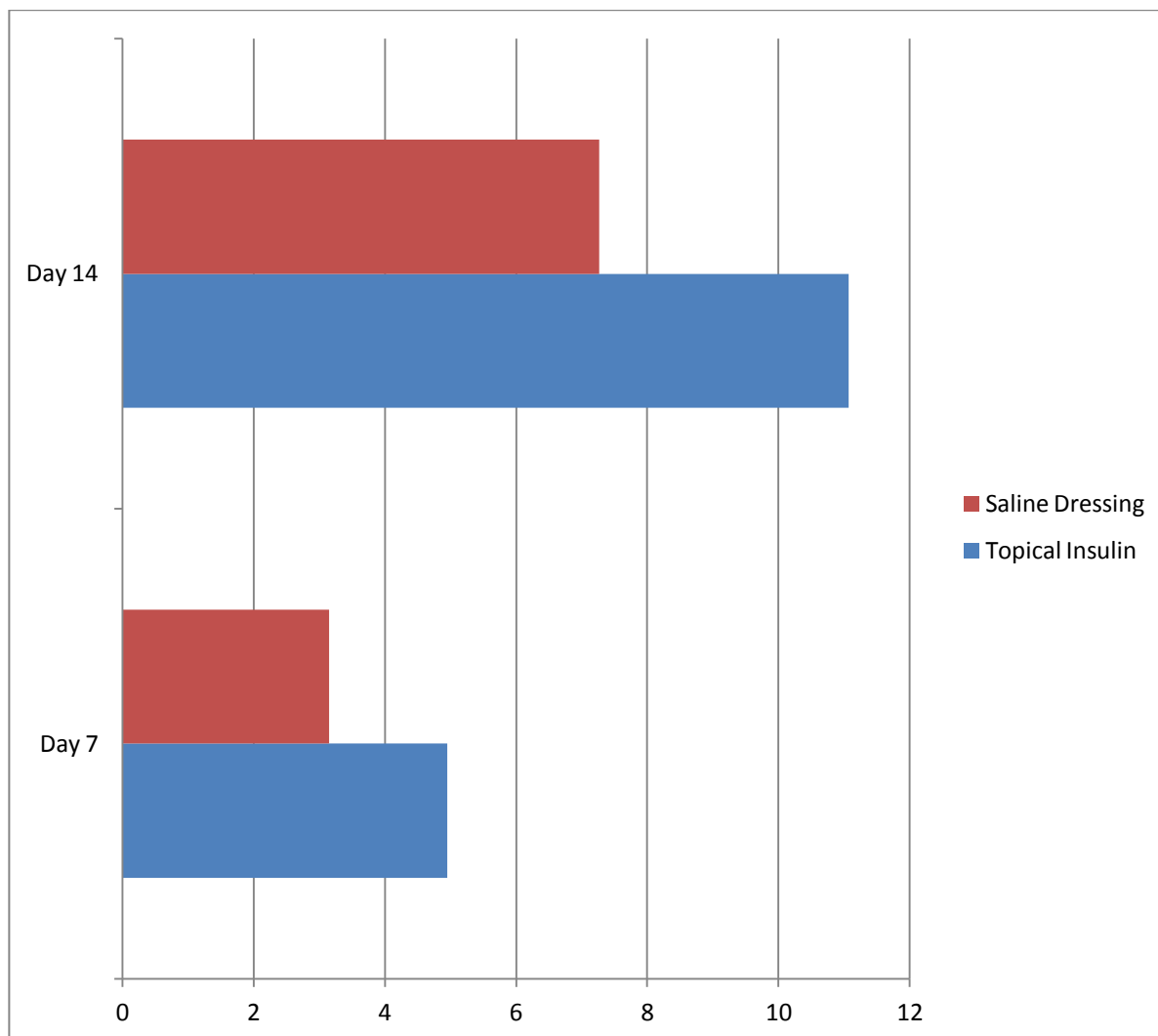Table 13: Comparison of reduction percentages

Figure 14: Comparison of reduction percentages

Independent sample t-test for comparison of size of ulcer
Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.

	Group	N	Mean	Std. Deviation	Std. Error Mean
DAY 0	Topical Insulin	50	186.740	25.8921	3.6617
	Saline Dressing	50	187.560	15.3186	2.1664
DAY 7	Topical Insulin	50	177.480	26.6644	3.7709
	Saline Dressing	50	181.640	15.8498	2.2415
DAY 14	Topical Insulin	50	166.060	28.5474	4.0372
	Saline Dressing	50	173.920	16.0609	2.2714

Table 14: Independent sample t-test for comparison of ulcer sizes

From the findings of the study,
e)   The size of the ulcer reduces considerably reduces in 14 days following application of topical insulin and saline dressing
f)   The percentage reduction in topical insulin group is 11.07% in two weeks
g)   The percentage reduction in saline dressing group is 7.27% in two weeks
h)   There is around 3.5% more reduction in the size of the ulcer following application of topical insulin in comparison to saline dressing

IV. Discussion

Diabetes mellitus is a worldwide epidemic resulting in significant morbidity and mortality[1]. It starts as a disorder of glucose metabolism and ends up as a multisystem disease. The main underlying mechanism is the abnormal insulin production or impaired insulin utilisation or both. It affects the kidneys, eyes, heart, cardiovascular system, limbs, etc. One of the main manifestations of increased morbidity related to uncontrolled diabetes mellitus is diabetic foot.

Diabetic foot is common throughout the globe with serious effects on quality of life, livelihood and has economic consequences for the families and the society as a whole[2]. The majority of diabetic foot ulcers is neuropathic in origin which suggests that it can be prevented if there are adequate measures in place. It is estimated that in the coming days, diabetic foot will cause serious problems to the developing countries[3].

This can be avoided by early screening and identification of people who are at high risk of developing diabetic foot ulcers, educate them and follow-up to avoid incidence. The lifestyle modifications are absolutely necessary. The recurrence rate is 50% in a period of three years. The lifetime risk of acquiring diabetic foot ulcer is 25%[4]. A lower limb is lost every 30 seconds due to diabetes worldwide[5]. Therefore, it is essential to prevent the long term complications of diabetic foot to avoid social, economic, personal and medical costs[6,7].

Estimates show that the burden of diabetic foot ulcers will increase in future due to the increase in other comorbid factors like vascular disease and peripheral neuropathy[8]. This is increasing in the first year after diagnosis of type-II diabetes[9]. Most of the cases of diabetic foot ulcers are neuropathic in origin[10]. Therefore, it is highly preventable if there are adequate measures in place[11]. Foot-care service programmes are known to reduce lower limb amputations in diabetic patients[12]. A collaborative group formed a decade ago helps in documenting the amputations in different communities in the world[13]. This group reported differences in the amputation rates across the world where diabetes was associated with 25-90% of all amputations[14]. Developing countries show higher incidence than developed countries due to better care in the developed countries[15].

Diabetic foot ulcers are caused by the following[16-19];
- Loss of glycemic control
- Peripheral neuropathy
- Peripheral vascular disease
- Immunosuppression

Around 15% of diabetic patients have diabetic foot ulcers. An estimated 80,000 amputations are made each year in the United States[20,21]. The lifetime risk of diabetic foot ulcer among diabetics is 68/1000 persons[22]. The risk of amputation increases with the size of the ulcer. In patients who had undergone amputation for diabetes, around 84% of them had foot ulcers[23]. Peripheral neuropathy due to type-II diabetes is known to affect around 5.5 million in USA[24]. Thus, diabetic foot ulcers cause serious economic consequences, reduction in quality of life and serious disabilities[25].

Diabetic foot ulcers can be prevented and treated through;
- Increased screening on risk assessment
- Early diagnosis
- Management of diabetic foot ulcers
- Educate the patients and care givers

All these will help in improving the patient outcomes and reduce the costs.

The study aimed to compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers.The analysis revealed the following findings;

In the Topical insulin group, the mean age of the participants is 58.6 years with a standard deviation of 8.14 years. It ranges between 42-75 years. The median age of the sample is 60 years. In the saline dressing group, the mean age of the participants is 53.3 years with a standard deviation of 8.4 years. It ranges between 32-75 years. The median age of the sample is 54 years.

Independent samples t-test shows that the two groups do not differ significantly in age distribution. Hence, the two groups are comparable. This comparability is important to establish in comparative studies like this in order to avoid bias in patient selection and categorisation.

In both the groups, there were equal number of males and females.

In the topical insulin group, there were 25 males (50%) and 25 females (50%)

In the saline dressing group, there were 25 males (50%) and 25 females (50%)

The gender distribution is comparable in both the groups. Since, there are equal numbers of males and females, the risk of age based confounding factor are minimal. The bias is also reduced. Globally, there is a male preponderance for diabetic foot, however, in this study, equal number of males and females were selected to show the effect of the treatment options on two groups that are comparable on the sociodemographic factors.

In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out.

On Day 0, the mean size of the ulcer for topical insulin is 186.74 cm^2

On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm^2

Though the size of the ulcer is slightly lesser in the topical insulin group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.

Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.

On Day 7, the mean size of the ulcer for topical insulin is 177.48 cm^2

On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm^2

On Day 14, the mean size of the ulcer for topical insulin is 166.06 cm^2

On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm^2

Comparison of two groups based on percentage reduction

The percentage reduction in two groups is;

Topical Insulin on Day 7: 4.95%

Saline Dressing on Day 7: 3.15%

Topical Insulin on Day 14: 11.07%

Saline Dressing on Day 14: 7.27%

Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.

i)   The size of the ulcer reduces considerably reduces in 14 days following application of topical insulin and saline dressing

j)   The percentage reduction in topical insulin group is 11.07% in two weeks

k)   The percentage reduction in saline dressing group is 7.27% in two weeks

l)   There is around 3.5% more reduction in the size of the ulcer following application of topical insulin in comparison to saline dressing

The present study is similar to the studies done by other authors

A study by Kamat and Sunil in 2019 among 74 patients compared the use of topical insulin and saline dressing. They were divided into two groups of 37 each. The wound was measured on; Day 0, Day 7 and Day 15. There was a statistically significant reduction in the size of the ulcer in the group that used topical insulin[33].

Another study by Ramarao and Ramu in 2017 among 60 patients in two groups of 30 each compared topical insulin and normal saline[34]. The study had the following findings;

In topical insulin group; the mean ulcer area reduction=35.19 ± 19.00 percent

In saline dressing groups; the mean ulcer area reduction=18.82 ± 4.06 percent

The overall size of the wound reduction was higher in the topical insulin group which is statistically significant.

V.   Summary And Conclusions

The study aimed to compare the effect of topical insulin application and normal saline dressing in healing of diabetic foot ulcers.The analysis revealed the following findings;

In the Topical insulin group, the mean age of the participants is 58.6 years with a standard deviation of 8.14 years. It ranges between 42-75 years. The median age of the sample is 60 years. In the saline dressing group, the mean age of the participants is 53.3 years with a standard deviation of 8.4 years. It ranges between 32-75 years. The median age of the sample is 54 years.

Independent samples t-test shows that the two groups do not differ significantly in age distribution. Hence, the two groups are comparable. This comparability is important to establish in comparative studies like this in order to avoid bias in patient selection and categorisation.

In both the groups, there were equal number of males and females.

In the topical insulin group, there were 25 males (50%) and 25 females (50%)

In the saline dressing group, there were 25 males (50%) and 25 females (50%)

The gender distribution is comparable in both the groups. Since, there are equal numbers of males and females, the risk of age based confounding factor are minimal. The bias is also reduced. Globally, there is a male preponderance for diabetic foot, however, in this study, equal number of males and females were selected to show the effect of the treatment options on two groups that are comparable on the sociodemographic factors.

In order to establish the comparability of the two groups, the mean size of the ulcer between the two groups was found out.

On Day 0, the mean size of the ulcer for topical insulin is 186.74 cm^2

On Day 0, the mean size of the ulcer for saline dressing is 187.56 cm^2

Though the size of the ulcer is slightly lesser in the topical insulin group, yet the difference is not statistically significant, hence the two groups are comparable and there is no bias in the selection of cases.

Then these cases were followed up for two weeks and the ulcer was measured on Day 7 and Day 14.

On Day 7, the mean size of the ulcer for topical insulin is 177.48 cm^2

On Day 7, the mean size of the ulcer for saline dressing is 181.64 cm^2

On Day 14, the mean size of the ulcer for topical insulin is 166.06 cm^2

On Day 14, the mean size of the ulcer for saline dressing is 173.92 cm^2

Comparison of two groups based on percentage reduction
The percentage reduction in two groups is;
Topical Insulin on Day 7: 4.95%
Saline Dressing on Day 7: 3.15%
Topical Insulin on Day 14: 11.07%
Saline Dressing on Day 14: 7.27%
Independent sample t-test for comparison of size of ulcer shows that the two groups differ significantly in the results. Statistically p-value is <0.05.
a)   The size of the ulcer reduces considerably reduces in 14 days following application of topical insulin and saline dressing
b)   The percentage reduction in topical insulin group is 11.07% in two weeks
c)   The percentage reduction in saline dressing group is 7.27% in two weeks
d)   There is around 3.5% more reduction in the size of the ulcer following application of topical insulin in comparison to saline dressing

LIMITATIONS
Following are the limitations of the study;
a)   The study is a single centric study
b)   Findings may be biased due to non-random sampling
C)   Smaller   sample   size   affects   the   generalizability   of   the   findings

FUTURE RECOMMENDATIONS
Following are the future directions;
a)   Multicentric studies must be conducted
b)   Larger sample size to be used
c)   Use random sampling to avoid bias

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