



COMPARISON OF VACUUM ASSISTED CLOSURE THERAPY AND CONVENTIONAL DRESSING ON WOUND HEALING IN PATIENTS WITH DIABETIC FOOT ULCER - A RANDOMIZED CONTROL TRIAL.

General Surgery

Dr A. K. Kalpana Devi M. S (General SURGERY), D.G.O, Associate Professor; Government Thiruvannamalai Medical College.

Dr. Shanmugam M.S (General Surgery), DA, Assistant Professor; Government Stanley Medical College.

Dr. Karthikeyan Sridevi M.S (general Surgery), Associate Professor, Government Thiruvannamalai Medical College.

ABSTRACT

Introduction: In a surgical ward acute and continual wounds have an effect on a minimal of 1% of the population. Vacuum assisted closure would possibly be a universally established approach for dressing. Vacuum-assisted wound closure (VAC) is a technique of lowering air pressure around a wound to improve the healing process.

Objectives :

1. To study the advantage of vacuum assisted closure over conventional dressing in the management of diabetic ulcer
2. To study the difference in rate of amputation, hospital stays in case and control groups

Methodology:

Study Design: Randomised controlled trial

Study Setting: Surgery department, Kilpauk Medical College

Sample Size: 36 in each group

Group 1 received –vacuum associated closure therapy

· Before and after procedure-culture taken

· Doppler taken after the procedure

· X ray-to find osteomyelitis

Group 2-Control group -conventional dressings

Study Population: Patients with Diabeticulcer

Study Period : 1 year

Results:

The present study is a Randomised controlled trial conducted among 72 Diabetic ulcer cases. Patients affected were most commonly in the age group of 41-60 years (64%). Majority of study population are males (58%) and females constitute 42%. About 64% of wounds occurred in foot followed by leg (28%), sole 1(4%) and forearm 1(4%). In cases group there were 22 split skin graft, 13 discharge and 1 amputation. In controls group there were 13 split skin graft, 14 discharge and 9 amputation. The cases group was better in the outcome compared to control group and the difference is statistically significant.

From the study results it is obvious that VAC dressing has many advantages in terms of

- Low no of amputation
- Earlier discharge
- Minimal infection
- Lesser complications
- Healing in a better way

It could be an appropriate new technology in treating variety of wounds

KEYWORDS

VAC(vacuum assisted compression therapy), split skin graft, amputation, diabetic ulcer

INTRODUCTION:

In surgical ward one of the most common cause for frequent admission is non-healing ulcer, among them diabetic foot ulcer is that the most common cause. In most of the cases, stay in medical institution for many weeks is required for. In many instances they in the end pick out amputation. Acute and continual wounds have an effect on a minimal of 1% of the population. No count number etiology, wounds are tough to deal with if coexisting elements like diabetes and different infections stop every day wound recovery.

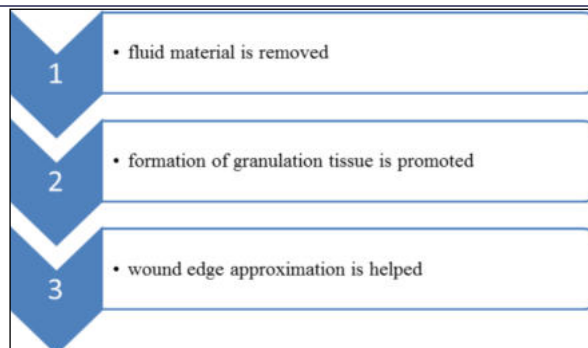
Vacuum assisted closure would possibly be a universally established approach for dressing. It is known by many pseudonyms:

- TNP (topical negative pressure)
- SPD (sub-atmospheric pressure)
- VST (vacuum sealing technique) and
- SSS (sealed surface wound suction).

Vacuum-assisted wound closure (VAC) is a technique of lowering air pressure around a wound to improve the healing process. During a VAC procedure,

- i. foam bandage –applied over an open wound,
- ii. A vacuum pump – to create negative pressure around the wound.
- iii. The pressure over the wound < the pressure in the atmosphere.
- iv. The negative pressure => pulls the edges of the wound together.

When applying negative pressure onto the bed of the wound,



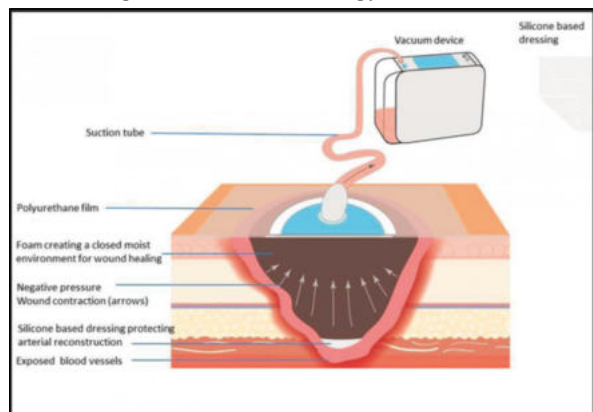
AIMS AND OBJECTIVES:

- To study the advantage of vacuum assisted closure over conventional dressing in the management of diabetic ulcers.
- To study the difference in rate of amputation, hospital stays in case and control groups

VAC Therapy:

NPWT applies subatmospheric pressure (continuous or intermittent, or suction, to the wound bed through a computerized vacuum pump attached to a foam sponge that is placed in the wound and secured with an adhesive semiocclusive dressing. Fluids from the wound are ev

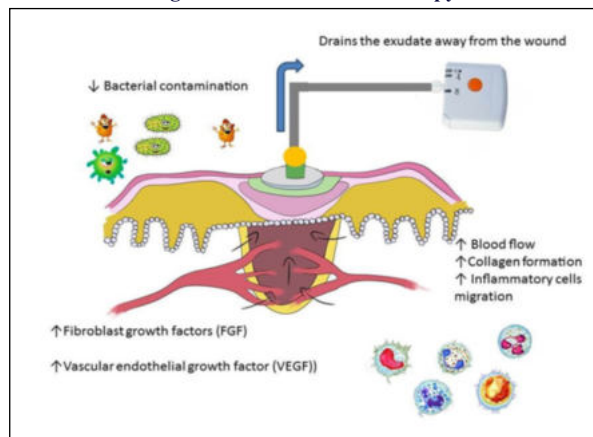
acuated by a tubing system placed on the foam at one end and connected to a disposable canister in the therapy unit on the other end.



It Consist Of Five Major Parts:

1. A canister containing therapy unit to hold the fluid- This function as 'CPU' of the VAC therapy system. The negative pressure system is managed and recorded by it. and if there is a problem it's alarms.
2. A Pad -It removes excess fluid and infectious materials from the wound in to the canister.
3. Foam dressing - The foam dressings convert open wound into closed wound to promote wound healing.
4. A contact layer is placed below the foam to protect the wound.
5. Adhesive drape - an adhesive layer spread over the foam dressing, ensuring a closed, moist wound healing environment.

Mechanism Of Negative Pressure Wound Therapy:



The major indications for the powered VAC Therapy:

- Acute wounds
- Traumatic wounds
- Full thickness surgical Wound
- Chronic Wounds
 - Stage 3 pressure ulcers
 - Stage 4 pressure ulcers
 - Diabetic ulcers
 - Venous stasis ulcers
- Flaps
- Meshed graft
- Dehisced Wound

Contraindications VAC:

- Malignancy in wound
- Necrotic tissue with eschar
- Untreated osteomyelitis
- Fistulas to organs or body cavities
- Do not place V.A.C. dressing over exposed arteries or veins

The Evolving Issue Of Defining The Appropriate Negative Pressure:

Practice parameters that outline strain intensity, period of treatment, and interval between remedies to supply the most environment friendly remedy are nonetheless lacking. Based on this result, poor stress of 125mmHg grew to be the most frequent putting when the use of this technique. However, preceding to that research, Russian

medical doctors have been refining NPWT. Aside from inconsistencies in stress levels, variations in stress intervals had been additionally Evident between the research of morykwas et al and the Russian research.

METHODOLOGY

Study Design

Randomized controlled trial

Study Setting: Kilpauk Medical college

Study Population:

Patients undergoing treatment with VAC therapy and conventional dressing for diabetic foot ulcer in Dept of General Surgery at KMC

Inclusion Criteria

- 18-70 years
- Ulcers of diabetic etiology

Exclusion Criteria:

- Complicated ulcer
- Bleeding disorders on treatment

Study Period- 1 year

METHODOLOGY

Procedure

Any dressings from the wound was removed and discarded. A culture swab for microbiology was taken before wound irrigation with normal saline. Surgical debridement was done and adequate haemostasis achieved. Application of negative pressure.

Two Groups

Group 1 Received - Vacuum Associated Closure Therapy

- Before and after procedure-culture taken
- Doppler taken after the procedure
- X ray to find osteomyelitis

Group 2-Control group -conventional dressings.

Outcome Variables

- 1) Mean duration of hospital stay
- 2) Organisms before and after VAC

The study is approved by Institutional ethical committee and written informed consent obtained from patients.

RESULTS

Table 1: Age Wise Distribution Of Wounds

Age in years	Frequency	Percentage
<40	12	16.7
41-60	46	63.9
>60	14	19.4
Total	72	100

In our study majority of the study population were in the age group of 41-60 years (64) about 17% were in the age group of less than 40 years. Nearly 19% were in the age group of more than 60 years.

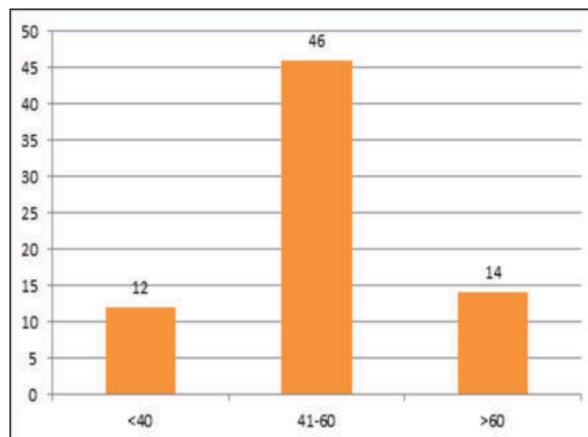
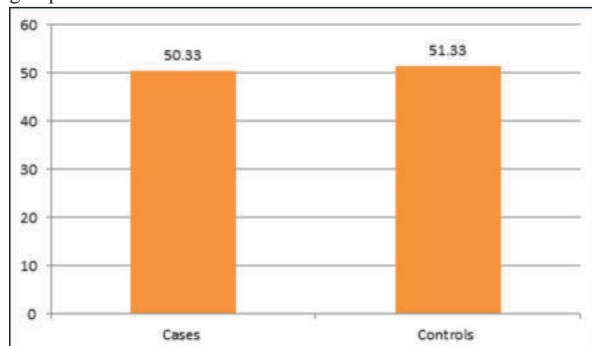


Figure 1: Age Wise Distribution Of Wounds

Table 2: Age Comparison Of Both The Groups

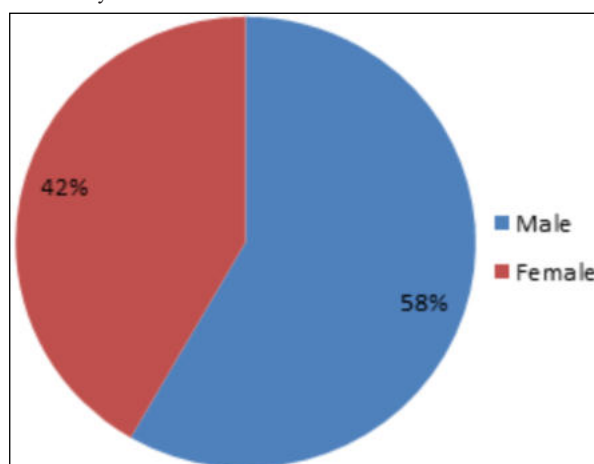
Group	Number	Mean	S.D	t	df	P value
Cases	36	50.33	10.38	0.406	70	0.6
Controls	36	51.33	10.51			

The two groups are comparable with respect to the age .There is statistically no significant association with respect to age in both the groups.

**Figure 2: Age Comparison Of Both The Groups****Table 3: Sex Wise Distribution Of Wounds**

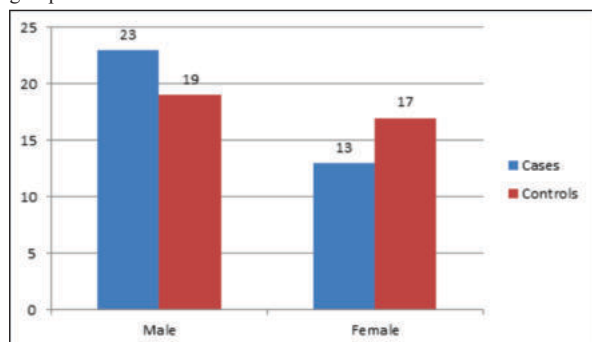
Sex	Frequency	Percentage
Male	42	58.33
Female	30	41.67
Total	72	100

In our study 58% were males and 42% were females

**Figure 3: Sex Wise Distribution Of Wounds****Table 4: Sex Comparison Of Both Groups**

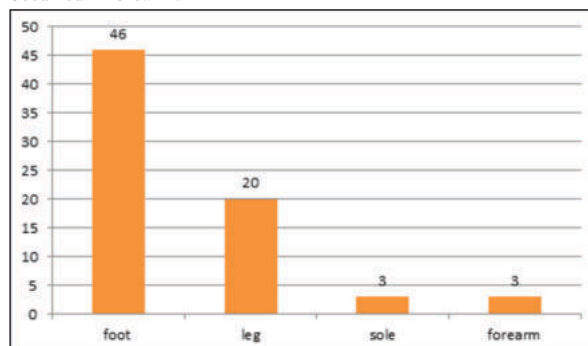
Group	Male	Female	Total	df	CHI Square	P value
Cases	23	13	36	1	0.914	0.33
Controls	19	17	36			
Total	42	30	72			

The two groups are comparable with respect to the sex .There is statistically no significant association with respect to sex in both the groups.

**Figure 4: Sex comparison of both groups****Table 5: Distribution Of Location Of Wound**

Location	Frequency	Percentage
foot	46	63.8
leg	20	27.8
sole	3	4.2
forearm	3	4.2
Total	72	100

Majority of the wounds occurred in foot(64%).About 28% of wound occurred in leg.Nearly 4% of wound occurred in sole and other 4% occurred in forearm.

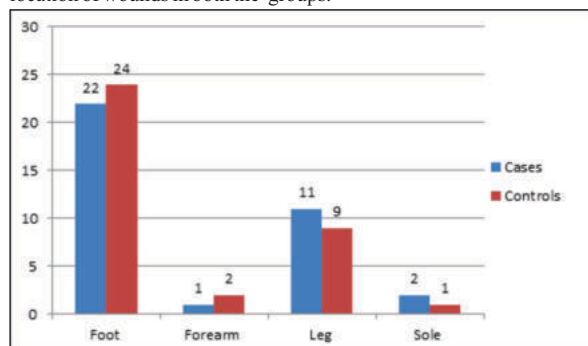
**Figure 5: Distribution Of Location Of Wounds****Table 6: Distribution Of Location Of Wounds Of Both The Groups**

Group	Foot	Forearm	Leg	Sole	Total
Cases	22	1	11	2	36
Controls	24	2	9	1	36
Total	46	3	20	3	72

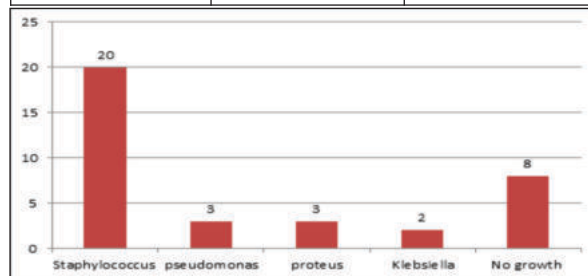
X²=0.954

P=0.812

The two groups are comparable with respect to the location of wounds .There is statistically no significant association with respect to the location of wounds in both the groups.

**Figure 6: Distribution Of Location Of Wounds Of Both The Groups****Table 7: Organisms Cultured From Wound (controls) Before Treatment**

Organism	Frequency	Percentage
Staphylococcus	20	55.55
pseudomonas	3	8.34
proteus	3	8.34
Klebsiella	2	5.55
No growth	8	22.22
Total	36	100

**Table 7: Organisms Cultured From Wound(controls) Before Treatment**

The most common bacteria cultured was staphylococcus(56%).No growth of organism was observed in 22% of patients.Next common bacteria is pseudomonas followed by proteus.

Table 8: Organisms Cultured From Wound(Controls) After Treatment

Organism	Frequency	Percentage
Staphylococcus	8	22.22
Pseudomonas	1	2.78
No growth	27	75
Total	36	100

After treatment 75% did not show any growth.About 22% showed staphylococcus and 3% showed pseudomonas.

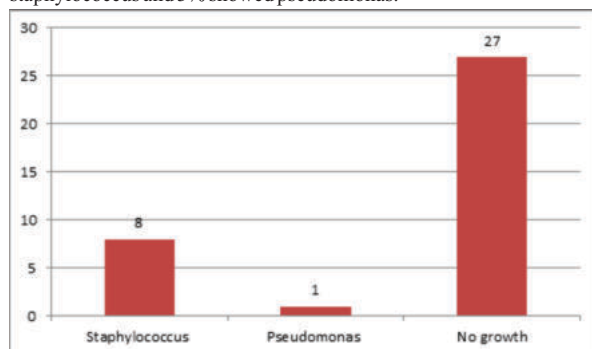


Figure 8: Organisms Cultured From Wound(controls) After Treatment

Table 9: Organisms Cultured From Wound(Cases) Before Treatment

Organism	Frequency	Percentage
Staphylococcus	20	55.55
pseudomonas	5	13.88
proteus	3	8.34
Klebsiella	2	5.56
No growth	6	16.67
Total	36	100

Before treatment 56% of culture tested positive for staphylococcus ,17% showed no growth,14% showed pseudomonas About 8% showed proteus and 6% showed Klebsiella

Table10: PRE Treatment And POST-VAC Treatment Culture And Sensitivity Comparison

Pre VAC	POST VAC		Total	Chisquare	P value
	Sterile	Nonsterile			
Sterile	6	0	6	0.71	0.39
Nonsterile	21	9	30		
Total	27	9	36		

There is no statistically significant association between pre and post vac treatment but in pre vac 6 patients showed sterile culture results and in post vac 27 patients showed sterile results.

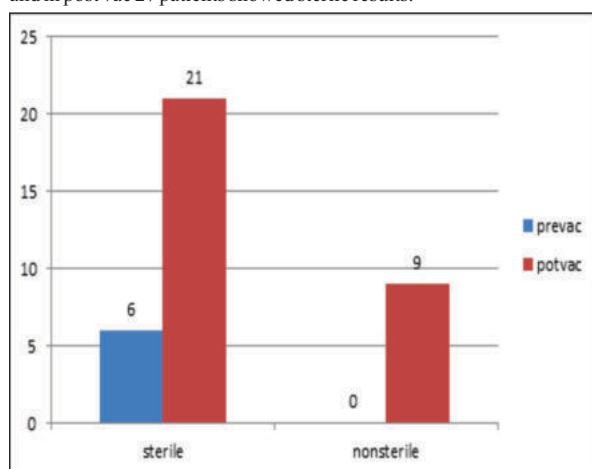


Figure11: PRE Treatment And POST-VAC Treatment Culture And Sensitivity Comparison

Table 12: Hospital Stay In Days

GROUP	N	Mean	Std. Deviation	t	df	P value
CONTROL	36	27.00	1.35	15.07	70	0.0001
CASES	36	21.58	1.68			
Total	72					

Mean duration of hospital stay in cases group is 21.58 and in controls group it is 27.00. There is statistically significant difference in between the two groups with respect to mean duration of hospital stay.

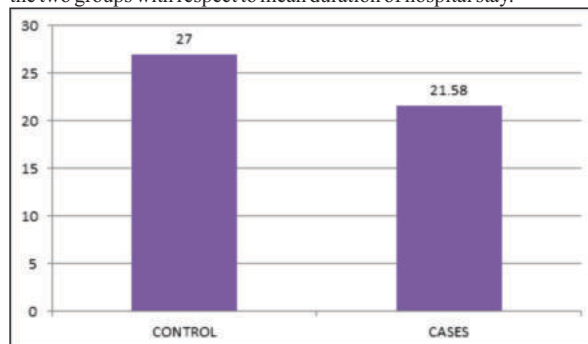


Figure12: Hospital Stay In Days

Table13: Outcome Comparison Of Both The Groups

GROUP	SSG	DISCHARGE	AMPUTATION	Chisquare	P value
Cases	22	13	1	8.75	0.013
Controls	13	14	9		

In cases group there were 22 split skin graft,13 discharge and 1 amputation. In controls group there were 13 split skin graft ,14 discharge and 9 amputation. The cases group was better in the outcome compared to control group and the difference is statistically significant.

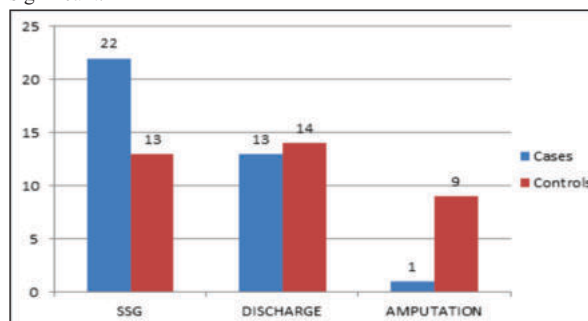


Figure13: Outcome Comparison Of Both The Groups

Table 14: Outcome Of Control Groups

Outcome	Frequency	Percentage
SSG	13	36.11
DISCHARGE	14	38.89
AMPUTATION	9	25
Total	36	100

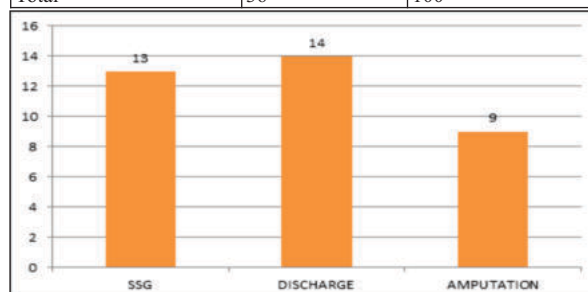


Figure 14: Outcome Of Control Groups

Table:15 Outcome Of Cases Group

Outcome	Frequency	Percentage
SSG	22	61.11
DISCHARGE	13	36.11

AMPUTATION	1	2.78
Total	36	100

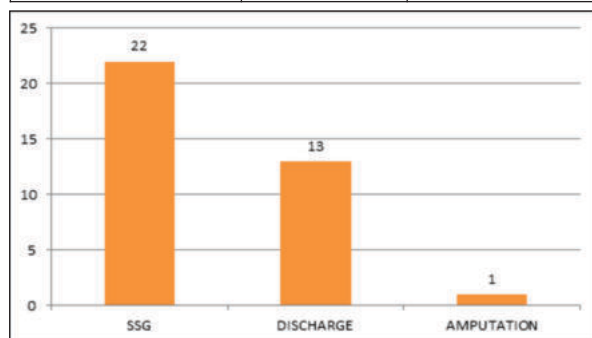


Figure :15 Outcome Of Cases Group

DISCUSSION:

The present study is a randomised controlled trial study conducted among 72 patients with diabetic foot ulcer of more than 18 years of age attending Department of General surgery for the treatment of diabetic ulcer. 72 patients were randomised in to two groups.

Cases group-received VAC therapy

Control group-Conventional dressing.

Demographic Characters

In our study majority of the study population were in the age group of 41-60 years (64%). About 17% were in the age group of less than 40 years. Nearly 19% were in the age group of more than 60 years. The two groups are comparable with respect to the age. There is statistically no significant association with respect to age in both the groups.

In our study 58% were males and 42% were females. The two groups are comparable with respect to the sex. There is statistically no significant association with respect to sex in both the groups.

Wounds Location:

Majority of the wounds occurred in foot (64%). About 28% of wound occurred in leg. Nearly 4% of wound occurred in sole and other 4% occurred in forearm. The two groups are comparable with respect to the location of wounds. There is statistically no significant association with respect to the location of wounds in both the groups ($P=0.81$).

Control Group

The most common bacteria cultured was staphylococcus (56%). No growth of organism was observed in 22% of patients. Next common bacteria is pseudomonas followed by proteus. After treatment 75% did not show any growth. About 22% showed staphylococcus and 3% showed pseudomonas.

Cases Group

Before treatment 56% of culture tested positive for staphylococcus, 17% showed no growth, 14% showed pseudomonas. About 8% showed proteus and 6% showed Klebsiella. After treatment 75% showed no growth in cases group and 22% showed staphylococcus growth and only one individual had proteus in the culture. There is no statistically significant association between pre and post vac treatment but in pre vac 6 patients showed sterile culture results and in post vac 27 patients showed sterile results.

Outcome

Mean duration of hospital stay in cases group is 21.58 and in controls group it is 27.00. There is statistically significant difference in between the two groups with respect to mean duration of hospital stay. In cases group there were 22 split skin graft, 13 discharge and 1 amputation. In controls group there were 13 split skin graft, 14 discharge and 9 amputation.

The cases group was better in the outcome compared to control group and the difference is statistically significant. In our study 47% had grade 3 ulcer, 42% had grade 2 ulcer and 11% had grade 1 ulcer. The two groups are comparable with respect to the grade of ulcer. There is statistically no significant association with respect to grade of ulcer in both the groups. In the present study 58% had vascular impairment and 42% had no vascular impairment. In controls group vascular impairment is more compared to cases group. The difference is statistically significant ($P=0.05$).

CONCLUSION:

The present study is a Randomised controlled trial conducted 72 Diabetic ulcer cases. Patients affected were most commonly in the age group of 41-60 years (64%). Majority of study population are males (58%) and females constitute 42%. About 64% of wounds occurred in foot followed by leg (28%), sole (4%) and forearm (4%). In cases group there were 22 split skin graft, 13 discharge and 1 amputation. In controls group there were 13 split skin graft, 14 discharge and 9 amputation. The cases group was better in the outcome compared to control group and the difference is statistically significant. From the study results it is obvious that VAC dressing has many advantages in terms of

- Low no of amputation
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- Healing in a better way

It could be an appropriate new technology in treating variety of wounds.

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