

Effectiveness of Various Modalities of and Protocol for Optimal Management of Chronic Leg Ulcers

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Abstract

Context: Based on the cause and type of wound, numerous products are available in the market, making the selection a very difficult task.

Aims: To study the Effectiveness of various modalities of and protocol for optimal management of chronic leg ulcers

Settings and design: The present study was a hospital based observational descriptive study carried out in Government Medical College, Latur

Methods: The study population was all patients with leg ulcers with complaint duration of more than 6 weeks. The patients were subjected to appropriate investigations like complete blood counts (Hb gm%, total leucocyte count and platelets), blood sugar (random blood sugar). Colour Doppler study of lower limb vessels was done in patients with suspected vascular disease of lower extremity, X ray of affected leg to rule out any bone involvement in clinically suspicious cases.

Statistical Analyzis: Chi-square for proportions and ANOVA for continuous variables was applied.

Results: Healthy granulation formation and mean follow-up period was significantly less in VAC method. Healthy granulation formation and mean

follow-up period was significantly lesser when silver nitrate was used. Mechanical debridement was required in only one case when silver nitrate was used.

Conclusion: Out of all the available dressing methods for conservative management of ulcer in this setup, vacuum assisted closure/negative pressure wound therapy is superior followed by conventional dressing method. Placental extract is better for ulcers with no or minimal slough for accelerated formation of granulation tissue. Any ulcer with any etiology of size more than 5 cm² mostly requires surgical intervention.

Keywords: Management; Therapy; Dressing; Placental extract; Tissue.

Introduction

Ulcer on the legs of duration of more than six weeks and non-healing nature even three months or more in spite of treatment is called the chronic leg ulcer. Among all the types of ulcers of the legs, venous ulcer seems to be the most common type. Arterial ulcer and neuropathic ulcer are other two common types seen in daily clinical practice. 70% of the cases of leg ulcers are venous type and others like diabetic, traumatic, malignant, vascular etc constitute remaining 30% of the cases. There is pain, improper healing of the wound, foul odour is some of the common clinical characteristics of the chronic leg ulcers. It affects the quality of life of the person.¹

It has been estimated that the prevalence of chronic leg ulcers in the age group of sixty years

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and more ranges from 0.6–3% and then it increases as the age increases.²

There is lack of data on chronic leg ulcers in countries like India. One study has reported that the prevalence of chronic leg ulcers was 0.45%.³

There are many factors, which govern the rate at which a wound heals. These factors can be divided into three groups like focal in which depending upon the site, mechanism of wounding, local factors like blood supply and systemic factors like malnutrition, diabetes.⁴

To protect the wound from contaminations, various methods can be tried like bandages etc.⁵

The objective of the modern dressing is rapid healing apart from covering it. They promote healing. The method of adoption of the modern dressing depends upon the type of chronic leg ulcer. Hence it is not easy to select the one method for one type in one patient. The products differ for different types.⁶

Present study was carried out to study the Effectiveness of various modalities of and protocol for optimal management of chronic leg ulcers

Materials and Methods

The present study was carried out in Government Medical College, Latur from December 2017 to November 2019 department of General Surgery. The present study was a hospital based observational descriptive study. The study population was all patients with leg ulcers with complaint duration of more than 6 weeks. Patients were recruited as cases using the below mentioned inclusion and exclusion criteria. All patients age more than 12 years with chronic leg or footulcers for more than 6 weeks and are willing to participate in the study were included in the present study. Patients with Burns, Immunocompromised patients, Patients less than 12 years of age and Malignant ulcers were excluded. The study was granted by the institutional ethical committee of the tertiary care institute and the concerned university authorities. The patients were subjected to appropriate investigations like complete blood counts (Hb gm%, total leucocyte count and platelets), blood sugar (random blood sugar).

Pus/Discharge from ulcers were sent for culture and sensitivity and gram staining at the time of presentation to the tertiary care institute. Colour Doppler study of lower limb vessels was done in patients with suspected vascular disease of lower extremity, X ray of affected leg to rule out any bone

involvement in clinically suspicious cases.

Liver function test, kidney function test and seropositive status, (HIV/HBsAg) as a part of routine pre Anesthetic work up. Electrocardiograph (ECG), X-ray chest and echocardiography (ifrequired) was done to assess the cardiorespiratory status of selected old age patients with history of cardiorespiratory diseases. Appropriate advice was taken from physician for cardiorespiratory diseases and diabetes when ever indicated. Patients with chronic leg ulcer were treated depending on the cause of ulcer and they were followed up for healing of the ulcer, reduction in size of ulcer, or flaring up of the ulcer.

Plan of management of ulcer was based on aetiology of ulcer, presence of infection and viability of tissue and size of ulcer. Patients with small ulcer with pale or healthy granulation tissue and minimal slough or infection were treated by conservative management and patients having spreading ulcer were treated with surgical debridement on the day of admission to remove necrotic tissue, slough and eschar from the ulcer.

Patients were given one of the following methods of regular dressings in the wards. These included:

Conventional dressing

Modern dressing: Collagen dressing (due to non-availability of other types of modern dressing methods in our set up and financial constraints of the patients only collagen dressing could be done whenever possible.)

Vacuum assisted closure: Also, regular bedside mechanical debridement was done when ever needed and this was recorded in the case proforma.

Conventional dressing

Patients receiving conventional dressing were treated with one of the following 4 available solutions in this study-

1. Hydrogen peroxide betadine
2. EUSOL
3. Silver nitrate
4. Placental extract

All patients were given empirical IV antibiotics, and were later shifted to specific antibiotic after pus culture sensitivity report. Regular dressing with respective solution was done in wards till appearance of healthy granulation tissue. Following this, the patients were either discharged if the ulcer is small or was surgically treated. The ulcers of size

more than 5 cm² were surgically managed either by split skin grafting or flap surgery in cases where bone or tendon was exposed.

Modern dressing/collagen dressing

The patients in this group were treated with either collagen sheets or collagen granules after mechanically debriding the wound. These patients were also given IV antibiotics, initially empirical and later specific.

Vacuum assisted closure

The ulcers of patients in this group were mechanically debrided and vacuum dressing was applied under all aseptic precautions. The dressing was changed every 3rd day and findings were recorded.

The procedure done for VAC in our study is as follows

1. Wound was debrided and thorough wash was given
2. Autoclaved sponge was kept over the wound.
3. Ryle's tube was kept over the sponge and it was covered with another sponge taking care that all holes of Ryle's tube are covered in the sponge.
4. This was covered with sterile pads.
5. This was covered with Steridrape taking care that it is air tight.
6. Dressing was done and Ryle's tube was connected to suction machine intermittently.

IV antibiotics were given to the patients in a similar method as the other groups.

The co morbidities were controlled and treated in all patients. Depending upon the etiology of the ulcer, further treatment was decided. Diabetic ulcer and infective ulcer were treated with dressing of one of the above-mentioned methods till appearance of granulation tissue and later depending on the size either discharged and followed up for complete healing or were treated with split skin grafting.

All venous ulcers found in study were due to involvement of superficial venous system and incompetence of perforator. Deep venous system was normal in all participants. Multiple perforator

ligation, ligation of saphenofemoral junction and stripping of veins were performed accordingly in patients with venous ulcers with no signs of healing by conservative management. A study of recurrences of venous ulcers could not be made due to inadequate time for follow-up. Traumatic ulcers were debrided and regular dressing was done till appearance of healthy granulation tissue. Later flap surgery or split skin grafting was done as a part of surgical intervention if the ulcer size was big and if bone or tendon exposed.

Ulcers due to vascular insufficiency were treated conservatively in cases where collateral circulation was established. In cases with gangrenous changes with secondary bacterial infection or clear line of demarcation and on doppler showing poor collaterals were amputated at appropriate level.

General treatment given to all cases of chronic leg ulcers were-

- Rest to the affected limb
- Elevation of limb above heart level
- Dressing with magnesium sulphate to reduce oedema
- NSAIDs and opiate analgesics were given to alleviate pain
- Nutritional supplementation with high protein diet, vitamins, iron tablets.
- Systemic antibiotic for control of infection.
- Strict control of diabetes, correction of anaemia.

Statistical Analysis

Data obtained was compiled on a MS Office Excel Sheet. Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted.

Results

Table 1 shows inter group comparison of Healthy granulation formed in vs dressing method. There was a statistically significant/highly significant difference seen for the values between the groups ($p < 0.01, 0.05$) with higher values in Collagen group and least in VAC.

Table 1: Inter group comparison of Healthy granulation formed in vs dressing method

Dressing method	N	Mean \pm SD	F-value	p-value
Conventional	93	16.9 \pm 8.6	9.516	0.000
Collagen	2	30 \pm 14.14		
Vacuum assisted closure	9	6.22 \pm 1.39		

Table 2 shows inter group comparison of follow-up in weeks vs dressing method. There was a statistically significant/highly significant difference

seen for the values between the groups ($p < 0.01, 0.05$) with higher values in Collagen group and least in VAC

Table 2: Inter group comparison of follow-up in weeks vs dressing method

Dressing method	N	Mean \pm SD	F-value	p-value
Conventional	95	4.09 \pm 1.67	5.935	0.004
Collagen	2	7.5 \pm 2.12		
Vacuum assisted closure	7	3 \pm 0.57		

Table 3 shows inter group comparison of healthy granulation formed in vs solution used. There was a statistically significant/highly significant

difference seen for the values between the groups ($p < 0.01, 0.05$) with higher values in HPB and least in SN

Table 3: Inter group comparison of healthy granulation formed in vs solution used

Solution used	N	Mean \pm SD	F-value	p-value
Eusol	26	18.88 \pm 9.026	12.774	0.000
Hydrogen peroxide	27	22.3 \pm 9.09		
Placental extract	11	18.73 \pm 5.38		
Silver nitrate	30	10.4 \pm 4.768		

Table 4 shows inter group comparison of follow-up in weeks vs solution used. There was a statistically significant/highly significant difference

seen for the values between the groups ($p < 0.01, 0.05$) with higher values in HPB and least in SN

Table 4: Inter group comparison of follow-up in weeks vs solution used

Solution used	N	Mean \pm SD	F-value	p - value
Eusol	27	4.22 \pm 1.783	8.327	0.000
Hydrogen peroxide	29	5.07 \pm 1.71		
Placental extract	10	4.5 \pm 1.269		
Silver nitrate	30	3.07 \pm 1.258		

Table 5 shows comparison of frequency of solution used vs mechanical debridement. There was a statistically significant/highly significant

difference seen for the frequencies between the groups ($p < 0.01, 0.05$) with higher free for SN with not done

Table 5: Comparison of frequency of solution used vs mechanical debridement

Solution used	Mechanical debridement			Chi-square	p-value
	Done	Not done	Total		
Nil	10	0	10	76.050	0.000
Eusol	24	3	27		
Hydrogen peroxide	26	4	30		
Placental extract	11	0	11		
Silver nitrate	1	29	30		

Table 6 shows comparison of frequency of solution used vs slough. There was a statistically significant/highly significant difference seen for

the frequencies between the groups ($p < 0.01, 0.05$) with higher frequency for slough 1 with EUS and SN while 1, 2 with HPB

Table 6: Comparison of frequency of solution used vs slough

Solution used	Slough				Chi-square	p-value
	0	1	2	3		
Nil	0	10	0	0	46.396	0.000
Eusol	0	16	8	3		
Hydrogen peroxide	0	14	14	2		
Placental extract	3	7	1	0		
Silver nitrate	0	25	5	0		

Table 6 shows comparison of frequency of solution used vs slough. There was a statistically significant/highly significant difference seen for

the frequencies between the groups ($p < 0.01, 0.05$) with higher frequency for slough 1 with EUS and SN while 1, 2 with HPB.

Table 7: Comparison of surgery vs size of ulcer

Surgery	Size of ulcer			Total	Chi-square	p-value
	< 5	5-7	> 7			
Amputation	8	1	0	9		
Conservative	39	9	9	57		
Flap	0	0	14	14	97.45	0.000
Split skin grafting	0	0	22	22		
Trendelenburg Procedure	6	0	0	6		

Table 7 shows comparison of surgery vs size of ulcer. There was a statistically significant / highly significant difference seen for the frequencies

between the groups ($p < 0.01, 0.05$) with higher frequency for <5 with conserve, >7 with SSG and Flap.

Table 8: Comparison of frequency of etiology vs surgery

Etiology	Surgery					Total	Chi-square	p-value
	Amputation	Conservative	Flap	Split skin grafting	Trendelenburg Procedure			
Diabete 3s	0	22	0	3	0	25		
Infection	0	27	0	15	0	42		
PVD	7	0	0	0	0	7		
Trauma	2	7	14	4	0	27	230.603	0.000
Varicose	0	1	0	0	6	7		

Table 8 shows comparison of frequency of etiology vs surgery. There was a statistically significant/highly significant difference seen for the frequencies between the groups ($p < 0.01, 0.05$) with higher frequency for trauma with flap and inf & DM with conserve

comprised 27.4%, amputation comprised 17.6%, Trendelenburg's procedure comprised 11.7%.

A study done by Rahman GA et al.⁷ reported that 43.3% of their patients had wound debridement only, 28.3% had debridement with dressing and split skin graft placement and 2 patients needed cross flap leg after the debridement was done. Kahle B et al.⁸ summarised the evidence-based treatment for treatment of chronic leg ulcers in their study.

Discussion

About 52.7% were managed conservatively i.e. wound dressing only and 47.3% managed by surgical intervention of surgical intervention, split skin grafting comprised 43.1%, flap surgery

The average days required for formation of granulation tissue in the conservative method in our study was found to be 16.89 days with std deviation of 8.5 days. The mean time required for healing of

ulcer was found to be 4.09 weeks. This comprised of daily dressing either with hydrogen peroxide betadine, EUSOL, silver nitrate or placental extract. The ulcers were debrided mechanically in all cases except for patients being treated with silver nitrate. In case of hydrogen peroxide-betadine solution, the average days required for formation of granulation tissue was 22.30 days. For EUSOL, 18.88, For silver nitrate, the average days for granulation tissue formation was 10.40 days

In a study conducted by Khandelwal S et al., dressings with antiseptics like betadine, hydrogen peroxide and EUSOL, mean ulcer healing time is not significantly different in the three groups.⁹

About 8.3% patients were treated with vacuum assisted closure. Granulation tissue was formed in these ulcers with mean of 6.22 ± 1.3 days. The ulcer healed in about 3 weeks in our study. McCallon et al. observed an average decrease of 28.4% (924.3) in wound size in the VAC group as compared to 9.5% (916.9) average increase in wound size in the control group (treated by saline-moistened gauze dressings).¹⁰

In our study, collagen sheets were used in about 2% of the patients due to non-availability of the same in our hospital setup and financial constraints of the patients. In our study it was found that the complete healing of ulcer took 7.5 weeks with collagen dressing.

A comparative study by KM Rai et al. (1986) with collagen granules showed that ulcers took a mean of 39 days to heal. All ulcers treated with collagen healed whereas 8% in control failed to heal after 9 months of treatment. Thus, there is similarity with our results where 70% ulcers healed after six weeks treatment.¹¹

Majority of participants with venous leg ulcer (85.7%) needed surgical intervention and rest were managed conservatively. Trendelenburg operation was done as surgical intervention in cases of chronic venous ulcers. 14.28% of the ulcers were found to be not healed on follow-up in which surgical intervention could not be done.

A study conducted by Gokhale Y et al.¹² inferred that 10 out of 40 cases were of venous origin. Among them 1 completely healed, 5 had reduction in size, 3 cases did not show signs of healing and one case was lost to follow-up.

Study participants were followed at 4 weeks, 6 and 8 weeks after treatment. 2.7% patients were lost in follow-up, while 1% patient showed no signs of healing, while 96.3% patients showed complete healing of ulcer.

Conclusion

Out of all the available dressing methods for conservative management of ulcer in this setup, vacuum assisted closure/negative pressure wound therapy is superior followed by conventional dressing method. In conventional dressing methods, silver nitrate solution gives better results with respect to granulation tissue formation and wound healing. However, its action on ulcers with dense slough and necrotic tissue is limited without mechanical debridement. EUSOL showed better results than hydrogen peroxide betadine combination with respect to removal of slough and formation of granulation tissue. Placental extract is better for ulcers with no or minimal slough for accelerated formation of granulation tissue. Conservative line of management of ulcer can be done for infective ulcer, traumatic ulcer and ulcer with co morbidities like diabetes mellitus provided the ulcer size is less than 5 cm. However, ulcer with peripheral vascular disease or varicose veins usually require operative intervention for complete healing of ulcer. Traumatic ulcers with bone or tendon exposed or of size more than 5 cm² require flap surgery or split skin grafting respectively. Any ulcer with any etiology of size more than 5 cm² mostly requires surgical intervention.

Key messages: Conservative line of management of ulcer can be done for infective ulcer, traumatic ulcer and ulcer with co morbidities like diabetes mellitus provided the ulcer size is less than 5 cm. However, ulcer with peripheral vascular disease or varicose veins usually require operative intervention for complete healing of ulcer.

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