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EFFICACY OF USING TOPICAL L-LYSINE WITH DEBRIDEMENT IN CHRONIC NON HEALING ULCERS

General Surgery

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ABSTRACT

Chronic non healing ulceration is a frequent condition and wide in distribution . they may be associated with a number of surgical & also some medical & dermatological conditions .Nonhealing or slow healing wounds represent a major health burden and drain on resources , contributing to substantial disability , morbidity , and costs1.The incidence of ulceration is more in ageing population & increased risk factor for atherosclerotic occlusion such as smoking , obesity and diabetics.

AIMS AND OBJECTIVES

- To study the efficacy of application of L-lysine in management of chronic non healing ulcers
- efficacy of topical L-Lysine in promoting healthy granulation tissue and wound healing
- efficacy was studied in terms of

1. Rate of granulation tissue formation
2. Percentage of graft take up
3. Duration of hospital

CONCLUSION: topical L-Lysine can be considered as a better option in the management of chronic wounds compared to conventional dressing

KEYWORDS

L-Lysine hydrochloride , chronic non healing ulcers , ulcer healing

INTRODUCTION

Chronic wounds are defined as wounds , which have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity .

The problems of chronic ulcers represent a wide spectrum of etiology , pathology, severity and morbidity. Multiple factors have been identified as contributors to impaired wound healing, such as, ischemia , infection , advanced age , malnutrition , diabetics , venous insufficiency and renal disease . Other conditions , such as cardiac and lung disease , decreased cognitive function , endocrine disease , disease , hematologic disorders , vasculitis , musculoskeletal problems , neurological disease , alcohol / drug abuse , immunosuppressives , chemotherapy , steroids , smoking , as well as inadequate wound care have been implicated For a long time there has existed a grey area so far as management of wound therapy and wound healing is concerned . Antibiotic ointments were used empirically to ward off any infections of the wound site . Yet not all wounds are necessarily infected , hence routine use of anti-microbial topical preparations are questionable

AIM

The aim of this study was to efficacy of topical application of L-Lysine in management of chronic non healing ulcers

MATERIALS AND METHODS

A prospective study has been conducted at Department of surgery , Adichunchungiri institute of medical sciences,mandya, India, between September 2019 and April 2020 comprising of 112 cases.Subjects of this study include all individuals with chronic non healing non malingnant ulcers . Randomization was done (by allotting random number 1 to 112 to all patients coming with complaints of non healing non malignant ulcers) followed by which alternate subjects were treated with treatment A (topical L-Lysine with mechanical debridement)and the others were treated by treatment B (betadine with debridement)

INCLUSION CRITERIA : All patients with chronic non healing , non malignant , ulcers irrespective of the age , sex and socioeconomic status .

EXCLUSION CRETERIA :

1. Patients with malignant ulcers , ischemic ulcers and osteomyelitis
2. Patients with malnutrition
3. Patients on corticosteroids , immunosuppressants and chemotherapy .
4. Patients with fistula to organs or body cavities

All patients who presented to hospital with complaints of chronic non healing non malignant ulcers were taken into study . A detailed history and clinical examination was done and the size of the ulcer was measured with a standard measuring tape in centimetres , and patients were randomly put into test and control groups . Relevant investigations were done . Patients in test group were subjected to topical L-lysine with mechanical debridement , while the cases under control group were subjected to betadine dressing and mechanical debridement .

At the end of ten days , the wounds in the both the groups were inspected after removal of dressing from the test group . The wounds were compared based on the following parameters . They are ,

- Rate of granulation tissue formation as percentage of the ulcer surface area .
- Quality of ulcer bed
- Resulting dimensions & surface area of the ulcer .

Once the wound was adequately covered by granulation tissue and once bacterial growth was ruled out by wound swabs , both the groups were subjected to split thickness skin grafting . both groups were given the same systemic antibiotics during the post – operative period . The wounds were reassessed at the end of fifth post operative day and the following parameters were accounted for . They were ,

- Skin graft take up as percentage of ulcer surface area
- Number of days of hospitalization
- After discharge , patients were followed up in the out patient department after one month to assess .
- Post skin graft complications like contractures , itching , pain and infection
- Wound dimensions
- The results obtained were statistically evaluated and the main parameters , which were analysed , were ,
- Rate of granulation tissue formation
- Graft survival and uptake
- Duration of hospital stay .

The mean rate of granulation tissue formation , graft survival and hospital stay was calculated and compared for both groups . The

variables were compared using the unpaired student's t-test. A P-vale <0.05 was considered significant .

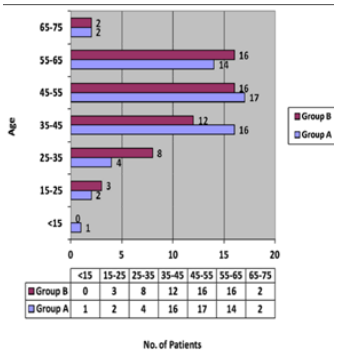
OBSERVATIONS

The 112 patients admitted for the study were divided into two groups . GroupA with treatment (topical L-Lysine with mechanical debridement) and group B with treatment (betadine with debridement). The patients characteristics of the two groups were well matched as given in the table below (Table 1)

Table 1 . Comparison of patient characteristics

	GROUP A	GROUP B
No. of patients	56	56
Range of age (Years)	4-75	15-75
Male – Female ratio (M:F)	31:25	34:22
Range of ulcer surface area (cm2)	6-200	4-160

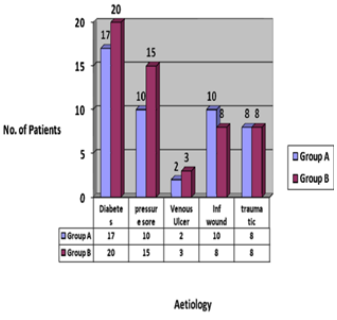
The age wise distribution of the patients in this study is as given below . The mean age in group A was 47.59 years and in group B was 47.42 years .



GRAPH 1 . Age wise distribution of patients

Table 3 . Age wise distribution of patients

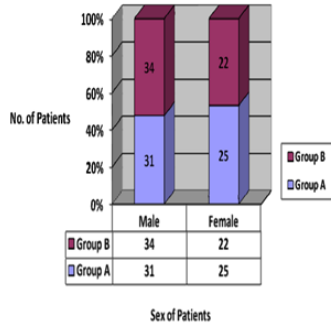
All the patients included in the study were suffering from chronic ulcers of varied aetiology . The underlying aetiologies of the ulcers were largely comparable in both groups . The aetiology wise distribution of the ulcers in both groups is shown in the graph below . The main aetiology in both groups was diabetic mellitus followed by pressure ulcers .



GRAPH 2 . Aetiology wise distribution of patients

Table 4 . Aetiology wise distribution of patients

The sex wise distribution of the two groups is as follows



Graph 3. Sex wise distribution of patient

Table 5 . Sex wise distribution of patients

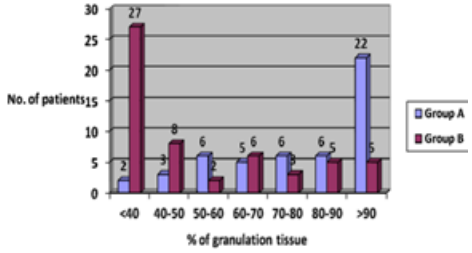
The male : female ratio in Group A was 1.24 :1 and that in Group B was 1.54:1. In both groups higher incidence of ulcers were seen among men .

All patients belonged to the middle and low socio-economic groups .

The efficacy of the dressing was assessed as the percentage of ulcer surface area covered by healthy granulation tissue after 10 days (Graph 4) . The mean rate of granulation tissue formation in Group A was 79.9% +or – 18.45 (SD) of total ulcer area and in Group B was 52.85 %+ or – 21.37(SD) of total ulcer area .

Table 6. Distribution of patients based on rate of granulation tissue formation

GROUP	>90%	80-90	70-80	60-70	50-60	40-50	<40%
A	22	6	6	5	6	3	2
B	5	5	3	6	2	8	27

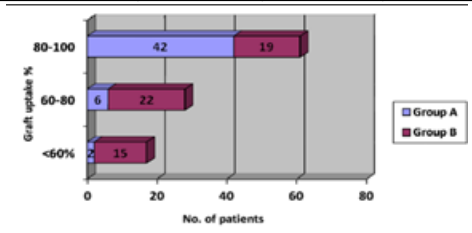


GRAPH 4 . rate of granulation tissue formation as percentage of ulcer surface area

The patients in both groups were subjected to split skin grafting as the final treatment modality . The graft take up was then assessed at the end of fifth post operative day as the percentage of ulcer surface area is given below .

Table 7 . Distribution of patients based on graft take up

GROUP	80-100	60-80	<60%
A	42	6	2
B	19	22	15



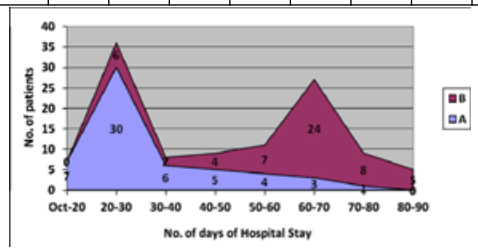
Graph 5 . Graft take up as % of ulcer surface area

The mean graft take up in Group A was 80.6%+ or -15.14 (SD) and in Group B was 60.45 % + or – 19.34 (SD)

The quality of life of the patients in both the groups was assessed by the assessment of total hospital stay as number of days of admission in the hospital as follows ,

Table 8 . Distribution of patients based on no.of days of hospital stay

GROUP	10-20	20-30	30-40	40-50	50-60	60-70	70-80	80-90
A	7	30	6	5	4	3	1	0
B	0	6	2	4	7	24	8	5



Graph 6 . Duration of hospital stay (as number of days of admission)

The mean hospital stay in Group A was 32.64+or – 13.81 (SD) days and that in Group B was 60.32+ or – 16.48 (SD) days .

In both the groups , no complications occurred during the application of dressing , skin grafting or in the post operative period . The patients were followed were followed up after 1 month of discharge . The main post operative parameters noted in both the groups during follow up were ,

- Wound size
- Contractures
- Pain
- Infections

All the parametes were less in Group A as compared to Group B .

Figure 6 : Wounds Treated With L -lysine With Debridement

Figure 7 : Wounds Treated With Conventional Dressings With Debridement

RESULTS AND DISCUSSION

Wound dressings have evolved from the status of proviing physical protection to the raw surface , absorbing exduates and controlling local infections by local medictions to level of providing adequate environment promoting wound healing . This has been achieved by modern wound dressing agents which promote granulation tissue formation .

As the concept of 'outcome based medicine' evolved , the need for a better wound dressing modality has become more acute . Now wound dressing systems are compared not only on the basis of the rate of granulation tissue formed or the rate of wound healing , but also on the duration of hospital stay of the patient which is considered as a measure of chronic wounds .

This study was done as a prospective randomized controlled comparative study to compare the efficacy of using topical L-Lysine to conventional wound care with debridement in management of chronic wounds

The average age in this study was 47.50years , with 61 patients falling in the 21-50years age group . This being the most active and economically productive period of life , the impact of a chronic non healing ulcer on the quality of life is imaginable . The loss of man - hours at work is significant , causing financial losses to the patients and to the society in general .

Males being more physically active and leading more outdoor life , especially in the Indian society , are prone to injury and accidents . This fact has been reflected well in this study also , where overall sex ratio is 7 males : 5 females .

The ulcers included in this in study in both the groups had diverse aetiologies but the diabetic ulcers formed the major component of each group . Both groups had comparable age and sex distribution as seen in depicted graphs . The mean rate of granulation tissue formation in both the groups were 79.9% (SD =1118.45) for Group A and 52.85% (SD=21.37) for Group B . The results were analysed by unpaired student's t-test which showed highly significant diiference in rate of granulation tissue formation ($p<0.00000001$).

The mean graft take up in both the groups were 80.6% (SD=15.14) for Group A and 60.45%(SD=19.34) for Group B . Analysis of the data by unpaired student's t-test revealed highly significant difference in graft take up ($p=0.0000001$).

The total days of hospital stay for the patients was also compared . The mean number of days of hospital stay was 32.64 days (SD =13.81) for Group A and 60.32 days (SD =16.48) for Group B . Analysis of the data showed highly significant difference in the hospital stay in both groups with a negligibly low p value obtained in the Unpaired student's t-test .

Comparison With Similar Study In Which Collagen Dressings Were Compared With Conventional Dressing

	Collagen	Conventional	Lysine	Conventional
No. of Patients	25	25	56	56
Avg Age in Yrs	42	43	47.59	47.42
M:F	4:1	3.2:1	1.2:1	1.5:1
Diabetic foot	16%	16%	30%	35%
Venous	28%	32%	3%	5%
Trauma	0%	0%	14%	14%
Inf. Wound	0%	0%	17%	14%
PVD	20%	16%	0%	0%
Avg Duration of Hosp Stay	39	41	32.6	60.3

The study by Rai.K.M et al from department of surgery , AFMC , Pune compares collgen dressing to conventional dressings .

The present study contains more patients per group than the above one . The etiologies of ulcers in the two studies are quite different reflecting the diverse nature of the cases encountered in individual setup .

Average duration of hospital stay was 39 days for collagen dressings as

against 41 days for conventional dressings in Rai.K.M et al study this gives collagen dressings an advantage of 9% reduction in average duration of hospital stay.In the present study using L-Lysine hydrochloride the reduction in average duration of hospital stay is nearly 50%

This comparative study which shows a reduction in reduction in average duration of hospital stay by nearly 50% in cases treated by topical L-lysine hydrochloride is achieved obviously by its efficacy in drastically promoting granulation tissue formation and higher percentage of successful skin grafts .

SUMMARY

- Increased rate of granulation tissue formation was seen in topical L-Lysine group when compared to the conventional group .
- Better graft take up was seen in the topical L-Lysine group as compared to the conventional group .
- Shorter duration of hospital stay was observed in the topical L-Lysine group .
- Follow up observations revealec that topical L-Lysine group suffered lesser post skin graft complications like wound contractures , residual raw area and pain compared to the conventional group .

CONCLUSION

In our study it was concluded that the rate of granulation tissue formation , overall graft up and survival was better in topical L-Lysine group as compared to povidone iodide group . It was also seen that the overall hospital stay and post operative complications were less in the topical L-Lysine group . Thus , topical L-Lysine can be considered as a better option in the management of chronic wounds probably because of its properties of angiogenesis and tissue regeneration . Further studies with larger population will help in even better understanding of this novel topical agent in the management of chronic wounds .

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