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ORIGINAL ARTICLE

Comparison of amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers

Anurag Dikshit

Associate Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences, India

ABSTRACT:

Background: Because of their high prevalence, refractory nature, impact on patients' quality of life, and financial implications for the healthcare system, non-healing leg ulcers provide significant clinical challenges for therapy. The present study was conducted to compare amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers. **Materials & Methods:**80 patients of non-healing lower limb ulcers were divided into 2 groups of 40 each. Group I patients were treated with AM dressing and group II with saline dressing. At the end of the 1st, 2nd and 3rd weeks wound were compared in both groups in terms of epithelialization, pain, exudation, infection and granulation etc. **Results:**Group I had 19 males and 21 females and group II had 18 males and 22 females. The mean duration of ulcer was 5.1 months in group I and 4.5 months in group II. Types of ulcers were neuropathic ulcers in 12 and 10, ischemic ulcer in 6 and 7, venous ulcers in 2 and 4, post-traumatic ulcer in 18 and 16 and others in 1 and 3 patients in group I and II respectively. Co-morbidities were cardiac diseases in 17 and 14, diabetes mellitus in 36 and 32 and others in 5 and 9 patients in group I and II respectively. Epithelialisation at 1st week was seen in 7 and 2, at 2nd week in 15 and 9, at 3rd week in 11 and 13 and no epithelialisation was seen in 7 and 16 patients in group I and II respectively. Exudation was absent in 28 and 17 and present in 12 and 23 in group I and II respectively. Wound infection was absent in 35 and 29 and present in 5 and 11 in group I and II respectively. Pain relief at day 0 was seen in 4 and 2, at day 7 in 19 and 8, at day 14 in 26 and 10 and at day 21 in 37 and 15 patients in group I and II patients respectively. **Conclusion:** For non-healing leg ulcers, the amniotic membrane dressing offers a safe, affordable, and efficient substitute technique, especially in developing nations where the primary issue is dressing material cost.

Keywords: amniotic membrane, diabetes mellitus, normal saline

Corresponding author: Anurag Dikshit, Associate Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences, India

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INTRODUCTION

Because of their high prevalence, refractory nature, impact on patients' quality of life, and financial implications for the healthcare system, non-healing leg ulcers provide significant clinical challenges for therapy.[1] Autologous skin grafting is currently the preferred treatment for these resistant lesions. However, this typically results in a donor wound and several days of hospitalization.[2] Allogeneic skin replacements that are sold commercially are too costly for regular clinical use.[3]

One tissue of special importance is the amniotic membrane (AM). It is the perfect biological dressing because of its stimulating, anti-inflammatory, antifibrotic, and antibacterial qualities as well as its lack of immunogenicity, ability to control fluid loss, pain relief, re-epithelialization, and granulation.[4] It has the benefit of being readily available and costing the patient nothing more. The amnion is the inner most lining of the foetal membranes. It is made up of two membranes, the inner amniotic membrane and the outer chorion. The AM can be easily separated from the chorion.[5] The AM is a thin but tough, smooth and transparent membrane. As a biological dressing, it provides secure coverage to the wound site, which reduces exudation from the wound.It has been in use in ophthalmology for a long time. Based on its success which was observed in ophthalmology, we wished to evaluate AM as a wound dressing in chronic leg ulcers.[6]The present study was conducted to compare amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers.

MATERIALS & METHODS

The study was carried out on 80 patients of non-healing lower limb ulcers of both genders. All gave their written consent to participate in the study.

Data such as name, age, etc. was recorded. Patients were divided into 2 groups of 40 each. Group I patients were treated with AM dressing and group II with saline dressing. At the end of the 1st, 2nd and 3rd weeks wound were compared in both groups in terms of epithelialisation, pain, exudation, infection and granulation etc. Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Method	AM dressing	saline dressing
M:F	19:21	18:22

Table I shows that group I had 19 males and 21 females and group II had 18 males and 22 females.

Table II Clinical details

Parameters	Variables	Group I	Group II	P value
Mean duration of ulcer in months		5.1	4.5	0.14
Types	Neuropathic ulcers	12	10	0.65
	Ischemic ulcer	6	7	
	Venous ulcers	2	4	
	Post-traumatic ulcer	18	16	
	Others	1	3	
Co-morbidity	Cardiac diseases	17	14	0.81
	Diabetes mellitus	36	32	
	Others	5	9	

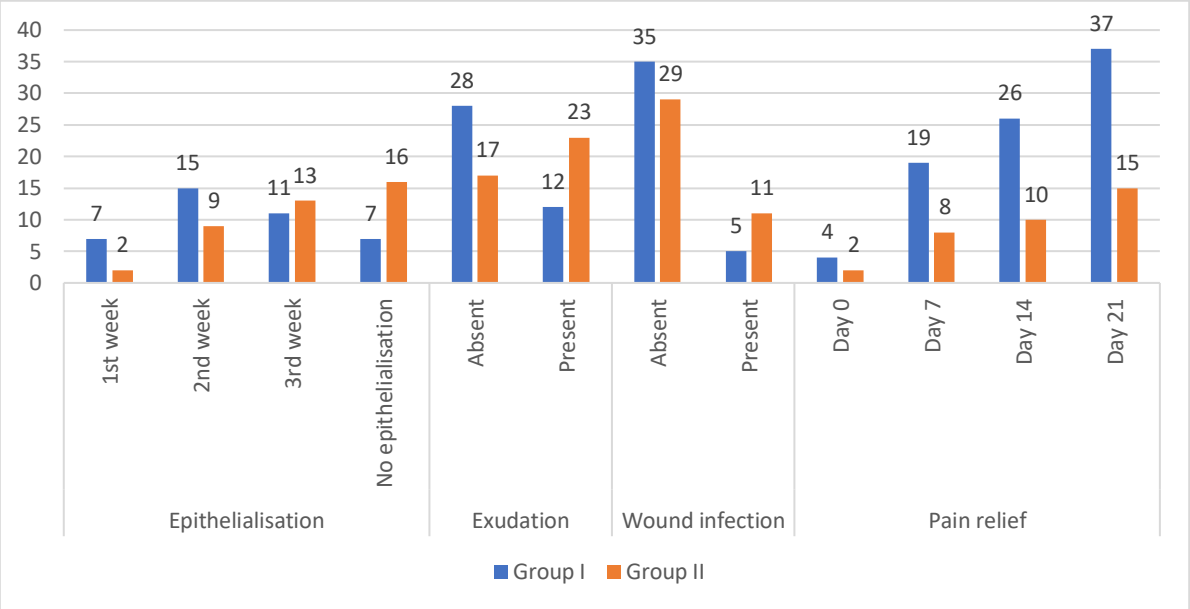
Table II shows that mean duration of ulcer was 5.1 months in group I and 4.5 months in group II. Types of ulcers were neuropathic ulcers in 12 and 10, ischemic ulcer in 6 and 7, venous ulcers in 2 and 4, post-traumatic ulcer in 18 and 16 and others in 1 and 3 patients in group I and II respectively. Co-morbidities were cardiac diseases in 17 and 14, diabetes mellitus in 36 and 32 and others in 5 and 9 patients in group I and II respectively. The difference was non- significant (P> 0.05).

Table III Assessment of parameters

Parameters	Variables	Group I	Group II	P value
Epithelialisation	1st week	7	2	0.02
	2nd week	15	9	
	3rd week	11	13	
	No epithelialisation	7	16	
Exudation	Absent	28	17	0.01
	Present	12	23	
Wound infection	Absent	35	29	0.04
	Present	5	11	
Pain relief	Day 0	4	2	0.05
	Day 7	19	8	
	Day 14	26	10	
	Day 21	37	15	

Table III, graph I shows that epithelialisation at 1st week was seen in 7 and 2, at 2nd week in 15 and 9, at 3rd week in 11 and 13 and no epithelialisation was seen in 7 and 16 patients in group I and II respectively. Exudation was absent in 28 and 17 and present in 12 and 23 in group I and II respectively. Wound infection was absent in 35 and 29 and present in 5 and 11 in group I and II respectively. Pain relief at day 0 was seen in 4 and 2, at day 7 in 19 and 8, at day 14 in 26 and 10 and at day 21 in 37 and 15 patients in group I and II patients respectively. The difference was significant (P< 0.05).

Graph I Assessment of parameters



DISCUSSION

Aamniotic membrane (AM) decreases exudation from the wound by securely covering the site of the wound.[7] The presence of antibodies in the AM and its imperviousness to microorganisms are thought to be the causes of this antibacterial ability. The AM can connect to the granulating surface extremely quickly and effectively due to its strong thrombin activity.[8] This tight adherence prevents the wound from becoming exposed, which counts microorganisms and restores lymphatic integrity, protecting circulating phagocytes from exposure and enabling the clearance of bacteria and surface detritus.[9,10]The present study was conducted to compare amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers.

We found that group I had 19 males and 21 females and group II had 18 males and 22 females. Hanumanthappa MB et al[11]evaluated the effects and the safety of the AM dressing. They studied 200 cases with chronic leg ulcers which were divided equally and randomly into the test group (which underwent the AM dressing) and the control group (which underwent the saline dressing). Epithelialization was observed in 88% of the cases in the study group (in the control group, it was 52%), the percentage of the granulation tissue increased significantly from 20% to 80%, the infection rate was 13 % in the test group (it was 59% in the control group), absence of exudation was noted in 69% cases of the test group (it was noted in 29% cases in the control group) and the pain score dropped from 70 to 10. No adverse effects were observed.

We found that mean duration of ulcer was 5.1 months in group I and 4.5 months in group II. Types of ulcers were neuropathic ulcers in 12 and 10, ischemic ulcer in 6 and 7, venous ulcers in 2 and 4, post-traumatic ulcer in 18 and 16 and others in 1 and 3 patients in group I and II respectively. Co-morbidities were cardiac diseases in 17 and 14, diabetes mellitus in 36 and 32 and others in 5 and 9 patients in group I and II respectively. We found that epithelialisation at 1st week was seen in 7 and 2, at 2nd week in 15 and 9, at 3rd week in 11 and 13 and no epithelialisation was seen in 7 and 16 patients in group I and II respectively. Exudation was absent in 28 and 17 and present in 12 and 23 in group I and II respectively. Wound infection was absent in 35 and 29 and present in 5 and 11 in group I and II respectively. Pain relief at day 0 was seen in 4 and 2, at day 7 in 19 and 8, at day 14 in 26 and 10 and at day 21 in 37 and 15 patients in group I and II patients respectively. Mermet et al[12] evaluated the safety, feasibility, and the effects on healing of AM graft in 15 patients with chronic venous leg ulcers. AM grafts were prepared from placentas harvested during cesarean section. All grafted AM had adhered to the wound bed 7 days after being applied with a 100% engraftment rate. The percentage of granulation tissue increased significantly (from 17% on day 0 to 69% on day 14, $p<0.0001$), along with a significant decrease of fibrinous slough (from 36% at day 0 to 16% at day 14, $p<0.001$). A significant clinical response occurred in 12 patients (80%) including complete healing (20%) in three during the 3-month follow-up period. The ulcer surface area decreased significantly from a mean value (+/- standard deviation) of 4.59 +/- 2.49 cm (2) at baseline to 2.91+/-2.01 cm (2) on day 30 ($p<0.001$). All patients experienced a significant reduction of ulcer-related pain rapidly after AM transplantation. No adverse events were recorded. AM transplantation seems to function as a safe substrate, promoting proper epithelialization while suppressing excessive fibrosis.

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that for non-healing leg ulcers, the amniotic membrane dressing offers a safe, affordable, and efficient substitute technique, especially in developing nations where the primary issue is dressing material cost.

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