ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4

Journal of Coastal Life Medicine

Using of Amniotic Membrane Derivatives for the Treatment of Chronic Wounds

Received: 19 October 2022, **Revised:** 18 November 2022, **Accepted:** 22 December 2022

Dr. Mrs.Patange Aparna P.
Associate Prof, Department of Medicine, Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth, ""Deemed To Be University"", Karad, Malkapur, Karad (Dist. Satara), Maharashtra, India. PIN – 415539"

Dr. Shilpa C. Patil,
Associate Professor, Department of Medicine, Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth, ""Deemed To Be University"", Karad, Malkapur, Karad (Dist. Satara), Maharashtra, India. PIN – 415539"

Dr. Patil Dilip P.
Associate Professor, Department of Medicine, Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth, ""Deemed To Be University"", Karad, Malkapur, Karad (Dist. Satara), Maharashtra, India. PIN – 415539"

Keywords
Amniotic membrane, ulcer, wounds, chronic

Abstract
Background - Amniotic membrane (AM) can reset chronic wound healing, including re-epithelialization. Cell models have examined many AM effects on wound healing.
Materials and methods - This 18-month prospective observational study was conducted in the Surgery wards of Krishna Institute of Medical Sciences and Research Hospital, Karad. The study examined 100 patients.
Results - In this study, amniotic membrane dressings dramatically increased epithelialization and infection control on the 7th, 14th, and 21st days of follow-up. Amniotic membrane dressings considerably reduced exudation. Visual analogue scale pain scores were considerably lower in amniotic membrane dressing group. Thus, amniotic membrane is a low-bacterial biological skin replacement for diverse wounds. It also reduces fluid loss, infection, discomfort, wound healing, and handling.
Conclusion - This study concludes that amniotic membrane is one of the effective biological skin substitutes used in lesions of different etiologies, with minimal bacterial counts. In addition, it reduces the risk of infection, reduces pain, accelerates wound healing, and has excellent management properties.

1. Introduction –

Amniotic membrane is the placenta's embryo-facing layer. This layer forms an amniotic sac surrounding the embryo. This thick, transparent, and robust membrane lines the chorionic layer. It's collagen-rich. The amniotic membrane protects the growing fetus from outside threats during intrauterine development (Hilmy et al, 2017).

The amniotic membrane (amnion) forms during fetal development. It appears quite early, on the seventh day after the embryoblast creates the egg. Early development. The embryonic cell mass is divided into the epiblast and hypoblast. The epiblast develops in the amniotic cavity, surrounded by amnioblasts.

The amnion wraps around practically the whole embryo in the fourth week, and the amniotic wall begins to enter the embryo at the umbilical chord location. (Peterka et al., 2007).

The fetus is closest to the epithelial cells in the innermost layer of the amnion, a flexible and semi-permeable tissue with five layers (Figure 1B). These cells can be an important stem cell source (Fernandes et al., 2005).

The thick basal membrane, composed largely of laminins, type IV and type VII collagen, and fibronectin, is the next layer. The stroma, which has three layers—compact, fibroblast, and spongy—follows that (Fukuda et al., 1999). Along with the spongy layer, the outer fibroblast layer of amnion tissue contains mesenchymal cells and makes up most of its

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

thickness (Zhang et al., 2016). Layers safeguard several functions, including growth factor and cytokine production. It regulates pH, transports water, and partly blocks amniotic chemicals (Kang et al., 2012).

The mesodermal embryonic plate's fibroblast-like outer mesenchymal layer has a membrane. A non-fibrillar type III collagen meshwork surrounds the chorionic laeve (Mamede et al., 2012). Therapeutic mechanisms are unclear. The native human amniotic membrane includes EGF, bFGF, keratinocyte growth factor, TGFa and TGFp, nerve growth factor, and hepatocyte growth factor (Rahman & Parvin, 2014, Sheridan et al., 2007). Growth factors aid wound healing and tissue regeneration. It scaffolds cell growth and differentiation. Amniotic membrane scaffolds promote healing (Zelen et al., 2013).

The amniotic membrane is used therapeutically due of these qualities. Autotransplants of tissue from amniotic membranes and chorionic villi have been used successfully to treat chronic neuropathic wounds, corneal surface injuries, pterygium, conjunctivochalasis, and dental and neurological surgery for the past 50 years (Fénelon et al., 2021).

Due to their anti-inflammatory, bacterio-static, wound preservation, reduced scarring, pain reduction, and epithelial stimulating capabilities, grafting wounds is recommended. Amniotic membrane is easily accessible. Germany performed 2008 ophthalmological reconstructions using human amniotic membrane. Due to its strength, the amniotic membrane is important in ophthalmology (Dhall et al., 2018).

Anti-inflammatory proteins and reduced production of transforming growth factor B and pro-inflammatory cytokines like interleukin 10 are considered to cause the amniotic membrane's anti-inflammatory effects. B defensins, elastase blockers, elastin, and lactoferrin also help the amniotic membrane fight inflammation (Hortensius et al., 2016, Navas et al., 2018).

We currently know more about heat injury pathogenesis and therapies than ever before. Burn bite therapy is the best indicator of pain (Lari et al., 2005).

Infection is the most common wound treatment problem. Aggressive topical antibacterial treatments, early dead skin removal, and strict burn unit environmental protection standards can resolve most difficulties. Active evaporative air, or heat loss, aids burn healing. Burn depth and area determine loss rate. Allograft and xenografting can fast-close the wound and avoid heat and fluid evaporation (Singer & Boyce et al., 2017).

Human amniotic membrane is ideal for this. The amniotic membrane has been used to prevent burn injuries since 1910, with mixed results. It may be freely compiled. Preparation is easy. Non-reactive, it reduces water loss 15%. Finally, the body's histology is identical (Mohan et al., 2017, Malhotra & Jain, 2014, Gupta, 2015).

In order to investigate the benefits of using human amniotic membrane dressing on ulcer healing in the General Surgery department of a tertiary healthcare facility in Maharashtra, as related studies are few in the Indian setting.

2. Materials and Methodology -

This was a prospective and comparative study of surgery OPD and ward patients at the Krishna hospital in Karad. Patients diagnosed with ulcers at the Department of General Surgery at the Krishna Hospital in Karad were recruited for this study with their written consent. The time period for the study was 18 months.

Daily follow up for the in patients and alternate day follow up for the out patients for three months or until the lesion heals needs to be carried out for every patient. The sample size was 100 patients with 50 patients each in the study group and control group respectively. The confidence level is 95% and power of the study is 95%, based on the following inclusion & exclusion criteria.

In order to meet the requirements for participation in the study as a patient, a patient must be at least 18 years old, have an ulcer confirmed by a clinical examination in the Surgery Outpatient Department (OPD), be able and willing, in the opinion of the investigator, to comply with all study procedure, provide written informed consent before any treatment is begun, and have an ulcer that is between one centimetre and twenty-five centimetres in size.

Patients who are immune-compromised, have a suspicion that they have cancer, have tuberculous ulcer bed sores, and patients who are already getting

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

chemotherapy or radiation are not eligible to participate in the research.

Prerequisites for the methodology of the study: Placental extracts, normal saline, and 85% glycerol were the necessary materials for the goal of this investigation in order to determine the serological status of the donor (HIV, HBsAg, and HCV).

PROCEDURE –

Patients received ulcer treatment, including diabetes control, antibiotics, and surgical debridement. Patients were randomly allocated to the study or control group. The amniotic membrane grafts were harvested from caesarean sections of serologically negative women. After being separated from the placenta, the amniotic membrane grafts were isolated in a sterile environment. Washing the amniotic membrane grafts in large amounts of normal saline removed soft tissue attachments and blood clots. In case of a delay, the membranes were stored in large bottles of 85% glycerol at room temperature for 24 hours before being refrigerated at 4 degrees Celsius.

Amniotic membrane grafts were defrosted by soaking in normal saline for five minutes before use. They were then equally dispersed and covered with a non-occlusive covering.

After cleaning and irrigating the ulcer with normal saline, the amniotic membrane grafts were placed with their rough (chorionic) surfaces facing the ulcers and covered with a three-layered gauze covering. The dressing was left on for four days to monitor exudation. After then, redressing occurred every three days.

Figure 1: Peeling of amniotic membrane from placenta

The ulcers were cleansed and treated with normal dressing once or twice daily, depending on the exudates. This was the method used for applying the dressing to the ulcers in the control group.

Evaluation of the wound using the following method:

Both the test group and the control group were assessed and compared after the first, second, and third weeks had passed. Epithelialization, the percentage of granulation, the local pain score, exudation, and infection prevention were the parameters that were recorded at each evaluation.

Each participant in the study was given a thorough explanation of the goal of the investigation, as well as the potential benefits and drawbacks of taking part in the research project, before they gave their "Informed Written Consent." Participants were given the assurance that their identities would not be made public. The institutional ethical committee gave its stamp of approval after conducting an ethics review.

TRAUMATIC ULCER

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Figure 2: Traumtic ulcer over foot on day 1

Figure 3: Traumatic ulcer over foot on day 7

Figure 4: Traumatic ulcer over foot on day 14

Figure 5: Traumatic ulcer over foot on day 2

DIABETIC ULCER

Figure 6: Diabetic ulcer on day 1 without amniotic dressing

Figure 7: Diabetic ulcer on day 1 after amniotic dressing

Figure 8: Diabetic ulcer on day 21 after amniotic dressing

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

GLUTEAL ULCER

Figure 9: Ulcer over gluteal region in a burns patient on day 1

Figure 10: Ulcer over gluteal region in a burns patient on day 21

TRAUMATIC ULCER

Figure 11: Traumatic ulcer on leg on day 1

Figure 12: Traumatic ulcer on leg –Granulation tissue seen on day 14

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Figure 13: Traumatic ulcer on leg Granulation tissue seen on day 21

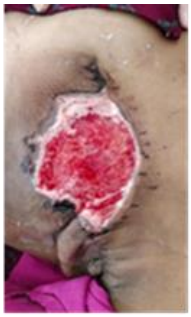

Figure 14: Post Mastectomy Ulcer

Figure 15: Post mastectomy ulcer on day 14 of amniotic dressing

Tables and graphs were used to analyze frequency, central tendency, and dispersion. Statisticians utilize IBM SPSS 22.0. Parametric significance tests (the students test) assessed normal distribution variables.

Using non-parametric analyses (Chi-square test), the association between categorical and nominal variables was examined. The desired outcome was calculated within 95% confidence intervals. If the calculated P-value was less than 0.05, the differences between the two observations were considered statistically significant.

3. Results –

The current research was conducted on 50 patients with diverse etiologies of ulcers admitted to the Department of General Surgery at Karad Institute of Medical Sciences (KIMS). In this study, we included patients with diabetic, pressure, traumatic, and venous ulcers ranging in size from 1 cm2 to 25 cm2. The subjects of the study were divided into two groups: In group A, patients were treated with amniotic membrane dressings, while in group B, other forms of dressings were used.

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

DEMOGRAPHIC FEATURES

In this research, we evaluated the demographic characteristics of both categories of the study population. We observed that the preponderance of cases in both categories were male (76% in group A and 68% in group B).

Table 1: Distribution of study population according to their gender

Gender	Group A		Group B	
	Number	Percentage	Number	Percentage
Male	38	76	34	68
Female	12	24	16	32
Total	50	100%	50	100%
M:F ratio	1:0.31		1:0.47	

Age distribution

This study examined subject age distribution. The bulk of research participants were aged 56–65 (30% in group A and 28% in group B), followed by 46–55 (20% in each group). Group A averaged 52.72 18.89 years, whereas group B averaged 50.34 19.08 years

Table 2: Distribution of study population according to their age

Age distribution (years)	Group A		Group B	
	Number	Percentage	Number	Percentage
18-25	6	12	7	14
26-35	3	6	6	12
36-45	7	14	5	10
46-55	10	20	10	20
56-65	15	30	14	28
>66	9	18	8	16
Total	50	100%	50	100%
Mean age ±SD	52.72 ± 18.89 years		50.34 ± 19.08 years	

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Body mass index distribution

BMI determined case distribution in this study. In group A, 31–40 (n=16, 32%) and 25–30 (n=13, 26%) were the most common BMIs. Malnourished patients comprised 10%. In group B, the majority (n=17, 34%) had a BMI between 31 and 40, followed by 25 to 30 (28%) and underweight (6%). The Chi-square test showed no statistical significance. BMI or body weight did not confuse the two weight-matched groups.

Table 3: Distribution of study population according to their BMI

BMI (kg/m^2)	Group A		Group B	
	Number	Percentage	Number	Percentage
<17.5	5	10	3	6
17.6-25	10	20	12	24
26-30	13	26	14	28
31-40	16	32	17	34
>40	6	12	4	8
Total	20	100%	20	100%
Significance	The chi-square statistic is 1.1492. The p-value is 0.886396.The result is **not significant** at p >0.05.			

DISTRIBUTION OF STUDY SUBJECTS ACCORDING TO COMORBIDITIES PRESENT

Both groups had co-morbidities in this research. Hypertension (34% in group A and 24% in group B) and diabetes mellitus (22% in group A and 20% in group B) were the most prevalent co-morbidities in both groups. The Chi-square test showed no significance (0.2). p-value 0.904859. p > 0.05).

Table 4: Distribution of study subjects according to co-morbidities present

Co-morbidities	Group A		Group B	
	Number	Percentage	Number	Percentage
Diabetes Mellitus	11	22	10	20
Hypertension	17	34	12	24

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Other CVDs	6	12	5	10
Significance	The chi-square statistic is 0.2. The p-value is **0.904859**.The result is **not significant** at p > 0.05.			

DISTRIBUTION OF CASES ACCORDING TO LOCATION OF ULCERS

Both groups had co-morbidities in this research. Hypertension (34% in group A and 24% in group B) and diabetes mellitus (22% in group A and 20% in group B) were the most prevalent co-morbidities in both groups. The Chi-square test showed no significance (0.2). p-value 0.904859. p > 0.05).

Table 5: Distribution of study subjects according to location of ulcers

Location of ulcers	**Group A**		**Group B**	
	Number	**Percentage**	**Number**	**Percentage**
Gluteal region	8	16	6	12
Leg	13	26	14	28
Foot	29	58	30	60
Total	50	100	50	100
Significance	The chi-square statistic is 0.3397. The p-value is 0.843791. The result is **not significant** at p >0.05.			

DISTRIBUTION OF CASES ACCORDING TO THEIR WOUND AREA

In group A, the majority of patients had a wound area of 16-20 cm2 (36%), followed by 11-15 cm2 (28%). In group B, the majority had 11-15 cm2 (34%), followed by 16-20 cm2 (22%). The chi-square statistic was 4.9983. p-value 0.287473. The result is insignificant if p > 0.05.

Table 6: Distribution of study population according to the wound area

Wound area category	**Wound area (incm^2)**	**Group A**		**Group B**	
		Number	**Percentage**	**Number**	**Percentage**
A	**1-5**	2	4	4	8
B	**6-10**	4	8	9	18

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

C	**11-15**	14	28	17	34
D	**16-20**	18	36	11	22
E	**21-25**	12	24	9	18
Total		50	100%	50	100%
Significance		The chi-square statistic is 4.9983. The p-value is 0.287473. The result is **not significant** at p > 0.05.			

DISTRIBUTION OF CASES ACCORDING TO TYPE OF ULCER

We compared study ulcer categories. Traumatic ulcers (44% in group A and 50% in group B) were the most common, followed by diabetic (26% and 28% in both groups) and surgical (20% and 16% in both groups). The chi-square statistic was 0.95. p = 0.81. Insignificant result is seen here.

Table 7: Distribution of study population according to type of ulcer

	Group A		**Group B**	
	Number	**Percentage**	**Number**	**Percentage**
Traumatic	22	44	25	50
Varicose	5	10	3	6
Diabetic	13	26	14	28
Surgical Wounds	10	20	8	16
Total	50	100	50	100
Significance	The chi-square statistic is 0.9507. The p-value is 0.813167. The result is **not significant** at p >0.05.			

EPITHELIALIZATION

Groups A and B showed lesion epithelization after dressings. Participants were contacted on the seventh, fourteenth, and twenty-first days. Epithelialization was most common on the 14th, 21st, and 7th days of follow-up in group A, which used amniotic membrane dressings. 16% of follow-ups showed no epithelialization. Epithelialization was absent in 52% of group B dressings. 26% had maximum epithelialization 14 days later. Group A had considerably more epithelialization than group B (chi-square statistic 16.9451). P-value: 0.000725. p 0.05 indicates statistical significance.

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Table 8: Epithelialization seen on various days of follow up:

EPITHELIALIZATION	Group A		Group B	
	Number of cases	**Percentage**	**Number of cases**	**Percentage**
7th day	10	20	2	4
14th day	21	42	13	26
21st day	11	22	9	18
No epithelisation	8	16	26	52
Total	50	100	50	100
Significance	The chi-square statistic is 16.9451. The **p-value is0.000725**. The result is **significant** at p <0.05.			

EFFECT ON INFECTION CONTROL

In this study, we compared amniotic membrane dressing to other types for infection management. Group A had 22% wound infections, whereas group B had 74%. The chi-square test showed that group A had a far lower infection rate than group B (27.0833, 0.00001).

Table 9: Effect on infection control seen on various days of follow up

PRESENCE OF INFECTION	Group A		Group B	
	Number of cases	**Percentage**	**Number of cases**	**Percentage**
PRESENT	11	22	37	74
ABSENT	39	78	13	26
Total	50	100	50	100
Significance	The chi-square statistic is 27.0833. The **p-value is <0.00001**. The result is **significant** at p < .05.			

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

PRESENCE OF EXUDATION

In the current study, we evaluated the efficacy of the amniotic membrane dressing relative to other types by comparing the presence of exudation following its application. In 36% of cases in group A, exudation was observed, while it was observed in 70% of cases in group B.Using the chi-square test, we compared the observations of the two groups and found that the proportion of study subjects with infection in group A was significantly lower than in group B (The chi-square statistic is 11.6018. The p-value has a value of 0.000659. (When p 0.05, the result is statistically significant.)

Table 10: Presence of exudation seen on various days of follow up

Presence of exudation	Group A		Group B	
	Number of cases	Percentage	Number of cases	Percentage
PRESENT	18	36	35	70
ABSENT	32	64	15	30
Total	50	100	50	100
Significance	The chi-square statistic is 11.6018. The **p-value is 0.000659**. The result is **significant** at $p < 0.05$.			

PAIN RELIEF

In the present study, we evaluated the efficacy of the amniotic membrane dressing relative to other forms of dressing by comparing the pain relief experienced by study participants following its application. We measured it using ratings on a Visual analogue scale. In group A, we observed that nearly 50% of the subjects had moderate pain (4-7 score), while 46% had minimal pain (0-3 score). In group B, the majority of cases (74%) had moderate pain (4-7 score). In group A, the mean score for pain alleviation was 3.48 1.76, while in group B, the mean score was 5.26 2.06. The incidence of severe pain was statistically higher in group B than in group A. (The statistic for Chi-square is 12.8559. p-value equals 0.0016. The result is statistically significant (p 0.05)

Table 11: Pain relief achieved at the end of procedures during follow up

VISUAL ANALOGUE PAIN SCORE	Group A		Group B	
	Number of cases	Percentage	Number of cases	Percentage
0-3 (Mild)	23	46	7	14
4-7 (Moderate)	25	50	37	74

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

8-10 (Severe)	2	4	6	12
Total	50	100	50	100
Mean score ±SD	3.48 ± 1.76		5.26 ± 2.06	
SIGNIFICANCE	Chi-square statistic is 12.8559. The p-value is **0.0016**. Theresult is **significant** at p < 0.05.			

4. Discussion -

The study included 50 cases and 50 controls with varied ulcer etiologies admitted to KIMS, Karad's general surgery department. This study includes diabetic, pressure, traumatic, and venous ulcers ranging from 1 cm2 to 25 cm2. Group A used amniotic membrane dressings, whereas Group B used various dressings. Ulcer healing was monitored on the 7th, 14th, and 21st days for patients and controls.

DEMOGRAPHIC FEATURES

This study examined demographics of both groups. 76% of patients in group A and 68% in group B were male. Case M:F ratio was 1:0.31. We examined the research participants' ages. The bulk of research volunteers were aged 56-65 (30% in group A and 28% in group B), followed by 46-55 (20% each group). Group A had a mean age of 52.72 ± 18.89 years, whereas group B had 50.34 ± 19.08 years.

Hanumanthappa M B, et al (Hanumanthappa et al., 2012) did a similar investigation. To assess the safety and efficacy of amniotic membrane dressing for varicose ulcers in 100 patients and 100 controls. Both cases and controls were male (78% and 80%). Hossam ElHeneidy et al (Omran et al., 2016) explored whether AM scaffold may affect wound healing by favoring tissue rebuilding rather than scar tissue development. They found that all patients were men aged 26–43. The mean age was 34.45±7.03. Ali Akbar Mohammadi et al. (Mohammadi et al., 2009) compared daily dressing with human amniotic membrane to topical antibiotics in outpatient therapy of limited burns to find the most successful and cost-efficient strategy. The case and control groups had 61/43 and 62/45 male-female ratios. Hanumanthappa M B, et al (Hanumanthappa et al., 2012) found that patients had a mean age of 46.5 (18-75) years and controls 45.5 (18-73) years. Ali Akbar Mohammadi et al. (Mohammadi et al., 2009) found that patients had a mean age of 17.30±12.42 and controls 19.10±11.56.

BODY MASS INDEX DISTRIBUTION

The study dispersed patients by body mass index. In group A, most patients had BMI between 31-40 (n=16, 32%) and 25-30 (n=13, 26%). 10% were underweight. In group B, most patients had BMIs between 31-40 (n=17, 34%), 25-30 (28%), and underweight (6%).

DISTRIBUTION OF STUDY SUBJECTS ACCORDING TO COMORBIDITIES PRESENT

Both groups had co-morbidities in this research. The most prevalent co-morbidity in both groups was hypertension (34% in group A and 24% in group B), followed by diabetes (22% in group A and 20% in group B). The Chi-square test showed no significance (0.2). p-value 0.904859. p > 0.05). Hanumanthappa M B, et al (Hanumanthappa et al., 2012) discovered that 32% of cases and 27% of controls were known diabetics. The prevalence of diabetes mellitus in their study is comparable to our findings.

DISTRIBUTION OF CASES ACCORDING TO LOCATION OF ULCERS

We examined ulcer location in this study. Most ulcers occurred on the feet (58% in group A and 60% in group

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

B), followed by legs (26% in group A and 28% in group B) and gluteal area (16% in group A and 12% in group B). The chi-square value for both groups was 0.3397. p =.843791. p > 0.05).

WOUND AREA DISTRIBUTION

In this study, most patients in group A had wound areas of 16-20 cm2 (36%), followed by 11-15 cm2 (28%), while most cases in group B had wound areas of 11-15 cm2 (34%), followed by 16-20 cm2 (22%). The chi-square statistic was 4.9983. p-value 0.287473. p > 0.05). Hossam ElHeneidy et al. (Omran et al., 2016) found that the ulcer area at the start of the trial was 4.8±0.65 cm2.

DISTRIBUTION OF CASES ACCORDING TO TYPE OF ULCER

We compared study patients by ulcer type. Traumatic ulcers (44% in group A and 50% in group B) were the most prevalent ulcers in both groups, followed by diabetic (26% and 28%, respectively) and surgical wound (20% and 16%, respectively). The chi-square value was 0.9507. P-value: 0.813167. p > 0.05). In their study, Hossam ElHeneidy et al. (Omran et al., 2016) found 81.8% venous ulcers and 18.2% traumatic ulcers.

OUTCOME INDICATORS

1. EPITHELIALIZATION

We detected wound epithelialization in group A and B after varied dressings. The research patients were checked on days 7, 14, and 21. In group A, when amniotic membrane dressings were provided, most incidences of epithelialization occurred on the 14th, 21st, and 7th days of follow-up. Epithelialization was absent in 16% of follow-up instances. In group B, alternative dressings prevented epithelialization in 52% of instances. The remaining (26%), however, reached maximal epithelialization after 14 days. Group A had higher epithelialization than group B (chi-square statistic 16.9451). P = 0.000725. (p < 0.05). Hanumanthappa M B, et al (Hanumanthappa et al., 2012) found that 81% of test group patients had epithelialized by week 3, compared to 40% of control group cases.Significant (P<0.005).

In 1973, Robson, Krizek, Koss, and Samburg (Robson et al., 1973) found that AM accelerated epithelium development from wound margins in full-thickness defects and partial-thickness burns. AM growth factors and progenitor cells stimulate epithelialization.

2. INFECTION CONTROL

Antibodies and lysozyme, a bacteriolytic protein, provide AM its antibacterial properties. AM attaches to granulating tissue quickly due to its strong thrombin activity. Close adherence restores lymphatic integrity, protecting circulating phagocytes and removing surface debris and germs. Adherence reduces bacterial count by covering the wound surface.

In this study, we compared amniotic membrane dressing to other forms for infection management. Group A had 22% wound infection, whereas group B had 74%. The presence of infection in group A was substantially lower than in group B (chi-square statistic 27.0833, p-value <.00001). p <.05.

Hanumanthappa M B, et al (Hanumanthappa et al., 2012) found that 81 (81%) patients in the test group had epithelialized by the third week, compared to 40 (40%) in the control group.

3. EXUDATION

Amniotic membrane minimizes wound exudation by covering it. Burn wound care requires this characteristic due to tissue fluid loss. We compared amniotic membrane dressing to other kinds by comparing exudation after application. Group A had 36% exudation, whereas group B had 70%.

Hanumanthappa M B, et al (Hanumanthappa et al., 2012) found that 63% of test group dressings were dry by the end of the first week, compared to 25% in control group (P<0.034). According to KMN Ferdous et al. (Ullah et al., 2015), amniotic membrane wound covering reduces wound exudates more than traditional wound dressing and without clothing wound17. Our investigation found amniotic membrane grafts to be sticky. 24-hour adhesion. All wounds dried faster by avoiding plasma leakage.

PAIN RELIEF

We compared pain alleviation after applying amniotic membrane dressing to different dressings in this study.

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

Visual analogue scale scores measured it. Group A experienced roughly 50% moderate pain (4-7 score) and 46% mild pain (0-3 score). Group B had 74% moderate pain (4-7 score). Group A had a mean pain alleviation score of 3.48 ± 1.76, whereas group B had 5.26 ± 2.06. Group B reported more severe discomfort than group A.

Mohammadi AA et al (Mohammadi et al., 2009) observed that the amniotic membrane group had a mean pain score of 3.90±2.38, similar to the current study. VAS scores averaged 7.40±1.85 in the control group. Mermet et al.'s prospective pilot investigation on AM graft safety, feasibility, and healing in 15 chronic venous leg ulcer patients supported the current study. Granulation tissue grew from 17% on day 0 to 69% on day 14, while fibrinous slough decreased from 36% to 16%. Ulcer size and pain decreased significantly.

Alsina, Gibert, and Pedregosa-Fauste (Weinhandl et al., 2016) transplanted AM for four refractory vascular ulcers. One ulcer re-epithelialized by week 8, while the other three had a 50% size decrease. The four ulcers reduced by 81.93% at week 16. 86.6% less pain.

5. Conclusion

Within the limitations of the study, this study found that amniotic membrane is a low-bacterial biological skin replacement for diverse wounds. It reduces infection, discomfort, fluid loss, wound healing, and handling. Amniotic membrane dressing promotes epithelialization and granulation tissue growth, preventing wound infection and exudation. The membrane may be purchased cheaply and utilized for ambulatory therapy without immobilization. It's readily available and allergy-free. It manages burns well in underdeveloped nations

References

[1] Dhall, S., Sathyamoorthy, M., Kuang, J. Q., Hoffman, T., Moorman, M., Lerch, A., Jacob, V., Sinclair, S. M., & Danilkovitch, A. (2018). Properties of viable lyopreserved amnion are equivalent to viable cryopreserved amnion with the convenience of ambient storage. PLOS ONE, 13(10), e0204060.

[2] Fénelon, M., Catros, S., Meyer, C., Fricain, J. C., Obert, L., Auber, F., Louvrier, A., & Gindraux, F. (2021). Applications of Human Amniotic Membrane for Tissue Engineering. Membranes, 11(6), 387.

[3] Fernandes, M., Sridhar, M. S., Sangwan, V. S., & Rao, G. N. (2005). Amniotic Membrane Transplantation for Ocular Surface Reconstruction. Cornea, 24(6), 643–653.

[4] Fukuda, K., Chikama, T. I., Nakamura, M., & Nishida, T. (1999). Differential Distribution of Subchains of the Basement Membrane Components Type IV Collagen and Laminin Among the Amniotic Membrane, Cornea, and Conjunctiva. Cornea, 18(1), 73–79.

[5] Gupta, A., Kedige, S. D., & Jain, K. (2015). Amnion and Chorion Membranes: Potential Stem Cell Reservoir with Wide Applications in Periodontics. International Journal of Biomaterials, 2015, 1–9.

[6] Hanumanthappa, M. B., Gopinathan, S., Suvarna, R., Guruprasad, R. D., Shetty, G., Shetty, K., ... & Nazar, Z. (2012). Amniotic membrane dressing versus normal saline dressing in non-healing lower limb ulcers: A prospective comparative study at a Teaching Hospital. Journal of Clinical and Diagnostic Research, 6(3), 423-427.

[7] Haugh, A. M., Witt, J. G., Hauch, A., Darden, M., Parker, G., Ellsworth, W. A., & Buell, J. F. (2017). Amnion Membrane in Diabetic Foot Wounds. Plastic and Reconstructive Surgery - Global Open, 5(4), e1302.

[8] Hilmy, N., Yusof, N., & Nather, A. A. (Eds.). (2017). Human amniotic membrane: basic science and clinical application. World Scientific.

[9] Hortensius, R. A., Ebens, J. H., & Harley, B. A. C. (2016). Immunomodulatory effects of amniotic membrane matrix incorporated into collagen scaffolds. Journal of Biomedical Materials Research Part A, 104(6), 1332–1342.

[10] Kang, N. H., Hwang, K. A., Kim, S. U., Kim, Y. B., Hyun, S. H., Jeung, E. B., & Choi, K. C. (2012). Potential antitumor therapeutic strategies of human amniotic membrane and amniotic fluid-derived stem cells. Cancer Gene Therapy, 19(8), 517–522.

[11] Lari, A. R., Alaghehbandan, R., & Akhlaghi, L. (2005). Burn wound infections and antimicrobial

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

resistance in Tehran, Iran: an increasing problem. Annals of burns and fire disasters, 18(2), 68. (Lari et al., 2005)

[12] Maan, Z. N., Rennert, R. C., Koob, T. J., Januszyk, M., Li, W. W., & Gurtner, G. C. (2015). Cell recruitment by amnion chorion grafts promotes neovascularization. Journal of Surgical Research, 193(2), 953–962.

[13] Malhotra, C., & Jain, A. K. (2014). Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World Journal of Transplantation, 4(2), 111.

[14] Mamede, A. C., Carvalho, M. J., Abrantes, A. M., Laranjo, M., Maia, C. J., & Botelho, M. F. (2012). Amniotic membrane: from structure and functions to clinical applications. Cell and Tissue Research, 349(2), 447–458.

[15] Mohammadi, A. A., Bakhshaeekia, A., Alibeigi, P., Hasheminasab, M. J., Tolide-ei, H. R., Tavakkolian, A. R., & Mohammadi, M. K. (2009). Efficacy of Propranolol in Wound Healing for Hospitalized Burn Patients. Journal of Burn Care & Research, PAP.

[16] Mohan, R., Bajaj, A., & Gundappa, M. (2017). Human amnion membrane: Potential applications in oral and periodontal field. Journal of International Society of Preventive and Community Dentistry, 7(1), 15.

[17] Navas, A., Magaña-Guerrero, F. S., Domínguez-López, A., Chávez-García, C., Partido, G., Graue-Hernández, E. O., Sánchez-García, F. J., & Garfias, Y. (2018). Anti-Inflammatory and Anti-Fibrotic Effects of Human Amniotic Membrane Mesenchymal Stem Cells and Their Potential in Corneal Repair. Stem Cells Translational Medicine, 7(12), 906–917.

[18] Omran, E., Hieneedy, H., Halwagy, A., Al-Inany, H., Al-Ansary, M., & Gad, A. (2016). Amniotic membrane can be a valid source for wound healing. International Journal of Women's Health, Volume 8, 225–231.

[19] Peterka, M., Peterková, R., & Likovský, Z. (2007). Chernobyl: Relationship between the Number of Missing Newborn Boys and the Level of Radiation in the Czech Regions. Environmental Health Perspectives, 115(12), 1801–1806.

[20] Rahman, S., & Parvin, R. (2014). Therapeutic potential of Aegle marmelos (L.)-An overview. Asian Pacific Journal of Tropical Disease, 4(1), 71–77.

[21] Robson, M. C., & krizek, T. J. (1973). The Effect of Human Amniotic Membranes on the Bacterial Population of Infected Rat Burns. Annals of Surgery, 177(2), 144–149.

[22] Sheridan, R. L., & Thompkins, R. G. (2007). Alternative wound coverings. Total Burn Care, 239-245.

[23] Singer, A. J., & Boyce, S. T. (2017). Burn Wound Healing and Tissue Engineering. Journal of Burn Care & Research, 38(3), e605–e613.

[24] Ullah, M. S., Ferdous, K., Mullick, M. M. H., Alam, M. R., Rahman, M. S., & Khan, A. (2015). Amnion Membrane Graft Dressing in Superficial Partial Thickness Burn in Pediatric Patients. Chattagram Maa-O-Shishu Hospital Medical College Journal, 14(1), 22–25.

[25] Weinhandl, E. D., Gilbertson, D. T., & Collins, A. J. (2016). Mortality, Hospitalization, and Technique Failure in Daily Home Hemodialysis and Matched Peritoneal Dialysis Patients: A Matched Cohort Study. American Journal of Kidney Diseases, 67(1), 98–110.

[26] Zelen, C. M., Serena, T. E., Denoziere, G., & Fetterolf, D. E. (2013). A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. International Wound Journal, 10(5), 502–507.

[27] Zhang, L., Zou, D., Li, S., Wang, J., Qu, Y., Ou, S., Jia, C., Li, J., He, H., Liu, T., Yang, J., Chen, Y., Liu, Z., & Li, W. (2016). An Ultra-thin Amniotic Membrane as Carrier in Corneal Epithelium Tissue-Engineering. Scientific Reports, 6(1).