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Comparison of the outcome of amnion versus conventional (Vaseline-impregnated gauze) dressing in superficial partial thickness burn patients in terms of healing time and mean pain.

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ABSTRACT... Objectives: To compare the healing time and mean pain score of Amnion versus Conventional (Vaseline-impregnated gauze) dressing in superficial partial thickness burn patients. Study Design: Randomized controlled study. Settings: Plastic & Reconstructive Surgery Department, Jinnah Hospital & Burn Center, Lahore. Period: January 2018 to January 2019. Material & Methods: A total of 60 patients with superficial second degree burns full filling the inclusion criteria were recruited for the study. Subjects were divided into two groups randomly. All patients were followed up regularly and dressing was changed on alternate days in Group B (Vaseline-impregnated gauze) and only secondary dressing was changed in Group A (amnion) until the auto sloughage (self-removal) of amnion. Outcome variables i.e. pain during first dressing change and healing time were noted. Statistical analysis of data was done using SPSS version 22. Quantitative variables i.e. age, duration of burn, total body surface area, pain during dressing and healing time were presented as mean and standard deviation. Frequency and percentage was calculated for qualitative variables like gender. The pain during dressing change and healing time of both groups were compared for difference. Student't' test was applied to compare the outcome and p-value ≤ 0.05 was considered as significant. **Results:** Out of sixty cases, 18 (30.0%) were females and 42 (70.0%) were males, with female to male ratio of 1:2.3. Mean age of patients in group A was 33.0 ± 10.19 years and in group B was 33.73 \pm 9.55 years. The mean pain score in group A (amnion group) was 1.93 \pm 0.91 and in group B (Vaseline-impregnated gauze) was 3.33 ± 1.56 with p-value of 0.0001. The mean healing time in group A (amnion group) was 15.73 ± 2.79 days and in group B (Vaseline-impregnated gauze) was 22.80 ± 4.44 days with p-value of 0.0001. Conclusion: Amnion dressing in superficial partial thickness burn patients is more effective in terms of mean pain score and healing time as compared to conventional (Vaseline-impregnated gauze) dressing.

Key words:	Amnion Dressing, Healing Time, Pain Score, Vaseline Impregnated Gauze, Superficial Partial Thickness Burn.		
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INTRODUCTION

Cutaneous burn is a notable medical problem worldwide. Burn is considered as the 4th frequent out of all injuries, globally. Acute cases that require treatment and admission affect nearly five hundred thousand peoples each year in USA, with about 3,400 deaths and forty thousand hospital admissions on average annually. Over the past few decades, survival rates for admitted patients has improved significantly due to advancements in burn wound care, improvement in critical care and treatment modalities and approaches about >90 % for admitted patients . Since, over 50 years ago after conference in Burns research, progress has been made with vital improvements in resuscitation, control of infection, fluid management, excision and coverage of burn wound that resulted in reduction of mortality.¹

Pathophysiologically, as burn is susceptible to infection due to loosening of epidermal integrity and necrosis of vascular tissue, it is considered as one of the most serious types of wound. Wounds healing is a dynamic process that involves various overlapping stages. First of all is inflammatory phase that destroys necrotic tissue,

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Article received on: 28/09/2020 Accepted for publication: 04/01/2021 inhibits infection during healing and stimulates signals necessary for wound repair. Proliferative phase helps to restore vascular network and wound closure and finally scar maturation phase occurs.² However, healing is often interrupted by excessive inflammation that may lead to increased pain and delayed wound healing.

Early and aggressive treatment of burnt skin is important to fasten wound closure and proper healing. The current surgical modality entails early tangential excision of burn wounds and coverage with STSG. In large burns there may be paucity of autologous tissue necessitating the other modalities of wound dressings and coverage. However, early after injury, it may be difficult to determine the depth of burn wounds accurately and burn wounds can be of mixed depths, thus requiring more than one local wound care regimen. The application of dressings began in ancient times with goals of keeping the wound moist, avoiding water and heat loss, promoting re-epithelialization, preventing infection and decreasing the pain. A variety of dressings are available for this purpose. Biological dressings that are used to cover the wound while reepithelialization occurs and include xenograft, allograft skin and human amnion. The ease of application and reduced frequency of dressing changes make these dressings practical in burn care, however these can be associated with problems, including availability, storage, tissue collection, high costs and risk of infection transmission.3

Since 1910⁴, Amnion is used as biological dressing for burn wounds with variable success. It is one of the widely used and medically accepted biological dressing in burn wound treatment. Presence of different factors such as, nidogen, fibronectin, elastin, multiple collagen types and hyaluronic acid in amniotic membrane, help in proliferation and differentiation of epithelial cells.^{5,2} It also possesses an anti-inflammatory effect due to lack of HLA-A, B and DR antigens and maintain a moist environment to fasten the healing, relief from pain, adherence to wounds and prevention of infection.

Amnion is a readily available biological dressing material used to treat acute burns. It have been used as temporary dressing for freshly excised burn wounds, donor sites and to cover clean partial-thickness burns. Advantages of amnion include non-reactiveness, easily availability and reduction of 15% water loss. Finally histological structure is same as of skin and morphologically BM of amnion shares majority of its components with human skin BM.6 It synthesizes different growth factors such as keratinocyte, fibroblast, epithelial and tissue growth factors that help to accelerate re-epithelialization by the activation of keratinocytes. In a study, the mean ± SD of pain score was 1.6 ± 0.79 in the amnion group compared with 2.93 ± 0.71 in the Vaselineimpregnated gauze group (P < 0.05). Healing time was also shorter in the amnion group $(17.61 \pm 2.56 \text{ days})$ with (P < 0.05) compared with the Vaseline-impregnated gauze dressing (21.16 ± 3.45 davs).7

This study is conducted with rationale to compare the outcome of amnion versus conventional (Vaseline-impregnated gauze) dressing in terms of mean pain and healing time in superficial partial thickness burn patients in local population. This study results will provide the clinicians with a method of dressing in burn patients which will not only reduce the morbidity of these particular patients but will also be cost effective in resource poor countries.

MATERIAL & METHODS

This research study was conducted at the Plastic & Reconstructive Surgery Department, Jinnah Hospital & Burn Center Lahore, from 15^{th} January 2018 to 14^{th} January 2019. Sample size of 60 patients was calculated i.e. 30 in each group with 5% margin of error, 90% power of study, taking number of days for wound healing in the amnion group as 17.61 ± 2.56 days and in the Vaseline-impregnated gauze group as 21.16 ± 3.45 days. Patients full filling the inclusion criteria (All patients with superficial second degree burns determined by clinical examination, Duration of burn <72 hours, 15-50 years of age, both gender) were selected through Non-probability, consecutive sampling. Patients with deep burns as assessed

clinically, already applied dressing before presentation, diabetic, hypertensive patients and with bleeding disorders were excluded from study.

Informed consent was obtained after approval from hospital ethical committee. Subjects were randomly divided into two groups. All patients were followed up regularly and dressing was changed on alternate days in Group B and only secondary dressing was changed in Group A (amnion) until the auto sloughage of amnion. Amnion was harvested from elective C section after screening of mother for Hepatitis B & C, HIV and syphilis done in Gynae Department of Jinnah Hospital. Then amnion was washed in 2 liters of normal saline after separation from chorion. It was then treated with antibiotics (Augmentin and gentamicin) and washed again with normal saline. Amnion was then placed in 30% glycerol for 8 hours and then it was preserved in 70% glycerol for usage up to 7 days. Dressing was done by a consultant plastic surgeon having ten year post fellowship experience. Outcome variables i.e. pain during first dressing change and healing time were noted. Statistical analysis of data was performed by using SPSS version 22. Quantitative variables i.e. age, duration of burn, total body surface area, pain during dressing and healing time were presented as mean and standard deviation. For qualitative variables Frequency and percentages were calculated. The pain during dressing and healing time in both study groups

were compared for difference. Student t-test was applied to compare the outcome and p-value ≤ 0.05 was considered as significant.

RESULTS

Mean age in this study was 33.37 ± 9.80 years with range of 15-50 years. Group A had mean age of 33.0 ± 10.19 years and group B 33.73 ± 9.55 years. Majority of the patients 36 (60.0%) were between 15 to 35 years of age. There were 42 (70.0%) males and 18 (30.0%) females with male to female ratio of 2.3:1. Mean total body surface area was 24.43 \pm 11.27%. The mean total body surface area in group A was 23.73 \pm 10.51% and in group B was 25.13 \pm 12.11%. Mean duration of burn was 30.97 \pm 17.39 hours. The mean duration of burn in group A was 32.40 \pm 17.18 hours and in group B was 29.53 \pm 17.77 hours as shown in Table-I.

The mean pain score in group A (amnion group) was 1.93 ± 0.91 and in group B (vaselineimpregnated gauze) was 3.33 ± 1.56 with p-value of 0.0001. The mean healing time in group A (amnion group) was 15.73 ± 2.79 days and in group B (Vaseline-impregnated gauze) was 22.80 ± 4.44 days with p-value of 0.0001 Table-II. Stratification of pain score with respect to age, gender, TBSA and duration of burn (hours) for both groups is presented in Table-III. Stratification of healing time with respect to age, gender, TBSA duration of burns in both groups is presented in Table-IV.

	Group A (n=30)		Group B (n=30)		Total (n=60)		
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	
Age Mean ± SD	33.0 ± 10.19		33.73	33.73 ± 9.55		33.37 ± 9.80	
15-35	19	63.33	17	56.67	36	60.0	
36-50	11	36.67	13	43.33	24	40.0	
Gender							
Male	21	50.0	21	50.0	42	70.0	
Female	9	50.0	9	50.0	18	30.0	
TBSA Mean ± SD	23.73 ± 10.51		25.13 ± 12.11		24.43 ± 11.27		
≤25%	18	60.0	18	60.0	36	60.0	
>25%	12	40.0	12	40.0	24	40.0	
Duration of Burn (hours)Mean ± SD	32.40 ± 17.18		29.53 ± 17.77		30.97 ± 17.39		
≤36 hours	18	73.33	22	66.67	40	70.0	
>36 hours	12	26.67	08	33.33	20	30.0	

Table-I. Demographic and clinical comparison among groups (n=50).

Amnion Dressing

Variable	Group A (n=30)	Group B (n=30)	P-Value		
Pain score	1.93 ± 0.91	3.33 ± 1.56	0.0001		
Hospital stay (days)	15.73 ± 2.89	22.8 ± 4.44	0.0001		
Table-II Pain score and hospital stay among groups					

	Group A (n=30) Pain Score		Group B (n=30) Pain Score		P-Value
Age of Patients (Years)					
	Mean	SD	Mean	SD	
15-35	1.84	0.69	3.47	1.46	0.0004
36-50	2.09	1.22	3.15	1.72	0.0927
Gender					
Male	2.00	1.02	3.25	1.71	0.0079
Female	1.50	0.46	3.50	1.27	0.0006
TBSA					
≤25%	2.00	1.03	3.50	1.58	0.0021
>25%	1.83	0.72	3.08	1.56	0.0231
Duration (hours)					
≤36 hours	1.78	0.94	3.36	1.59	0.0004
>36 hours	2.17	0.83	3.25	1.58	0.1072

Table-III. Pain score, demographic and clinical variable cross tabulation.

	Group A (n=30)		Group B (n=30)		P-Value
Age of Patients (Years)	Healing Time		Healing Time		
(Teals)	Mean	SD	Mean	SD	
15-35	15.79	3.19	23.53	4.99	0.0001
36-50	15.64	2.42	21.85	3.56	0.0001
Gender					
Male	15.95	3.15	23.40	4.60	0.0001
Female	15.13	2.03	21.60	4.03	0.0001
TBSA					
≤25%	15.11	2.35	23.00	3.14	0.0001
>25%	16.67	3.45	22.50	6.04	0.0001
Duration (hours)					
≤36 hours	16.06	2.96	23.55	4.79	0.0001
>36 hours	15.85	2.83	20.75	2.49	0.0008
Table-IV. Duration of hospital stay, demographic and clinical variable cross tabulation.					

DISCUSSION

Burn is still a devastating emergency with many physical and psychological disabilities Annually many individuals in both developing and developed countries suffer from burn injuries. Different methods are in practice for dressing and care of the burns donor and recipient site due to the facilitation in the improvement and reduction of wound symptoms.8 An ideal dressing for burns maintains a moist environment, protects the wound from secondary infection and provides relief from pain. Moreover it should be nonallergenic, economical, easily available and promote healing. In recent years, occlusive

dressings or skin substitutes are introduced with qualities of almost an ideal dressings.9 Other agents like cultured epithelial autograft, xenograft and allograft has been used as biological dressing to promote healing with improved aesthetic outcome but they are quite expensive and somewhat difficult to apply on crevices of face. Skin substitutes such as alloderm and Integra are also practiced as dressing with good results but their cost and availability are major problems.

Biological dressing was introduced as a gold standard for temporary covering of wounds. All biologic dressings are susceptible to early

reaction and the only exception is the amniotic membrane. The use of amnion in the treatment of extensive burn wounds has been described in order to facilitate early recovery of patient, improvement of wound healing and its quality. Studies demonstrated that use of amnion in burn wounds can lead to reduction of pain intensity and prevent water and electrolyte disturbances and also can help for early preparation of the wound bed for grafting. Application of amnion in the first few days adheres tightly to wound surface and has positive modulation for wound healing process either in quality or in rapidity.⁸

Donor site morbidity with non-healing and delayed healing of burns and hypertrophy are major concerns in burn patients. Human amnion accelerates epithelialization and reduces postoperative dressing changes thereby, reducing the risk of complications at skin graft donor sites.10 Overall amnion is composed of extracellular matrix, biologically active cells, structural collagen and regenerative molecules. Regenerative biomolecules that are abundant in amniotic membrane, include fibroblast, epidermal, platelet derived, transforming growth factor and metalloproteinase and are involved in growth process and healing. In addition there is lack of different HLA (A, B, C) types, making amnion a non-immunogenic dressing material. All of these characteristics, make amnion itself a near ideal dressing for all kinds of wounds and burns⁹

Regular epithelialization that play an important role in the functionality and integrity of skin requires complete regeneration of the basement membrane along with wound closure. The basement membrane is primarily composed of laminin and type IV collagen and is pivotal for coherence between dermal and epithelial layers. In a study by Andree et al. formation of the BM was observed during wound-healing covered with various epidermal dressings. They studied the correlation between the rate of basement membrane formation and transplant materials and found improved formation of the BM in amnion treated group with complete epithelization on tenth post-operative day.¹¹

Branski et.al did a study of amnion as biological dressing on face in pediatric age group¹² and found it to be more effective than other antibacterial dressings, in terms of duration of wound healing. This study was conducted to compare the mean pain score and healing time of amnion versus conventional (Vaselineimpregnated gauze) dressing in superficial partial thickness burn patients. Mean age in this study was 33.37 \pm 9.80 years. The mean healing time in group A (amnion group) was 15.73 ± 2.79 days and in group B (Vaseline-impregnated gauze) was 22.80 \pm 4.44 days with p-value of 0.0001 which are comparable with study mentioned below. In this study in 2015, the mean \pm SD of pain score was 1.6 ± 0.79 in the amnion group compared with 2.93 ± 0.71 in the Vaseline-impregnated gauze group, revealing a statistically significant difference (P < 0.05). Total days of wound healing was significantly shorter (P < 0.05) in the amnion group $(17.61 \pm 2.56 \text{ days})$ compared with the Vaseline-impregnated gauze group (21.16 \pm 3.45 days).7

Adly and colleagues¹³ in their study have reported that use of amnion has resulted in fewer needs of dressing change that could probably decrease the pain. Wound healing time was also less in the amnion group. Branski et al12 proved that the dressing with amnion had a short duration of healing compared with other dressing modalities. Similarly, amniotic membrane dressing results in faster epithelialization rate in partial burn wounds.¹⁴ Maral et al¹⁵, in their study also demonstrated that the amniotic membrane facilitates donor sites wound healing. In a clinical trial study, two hundred and 11 cases were divided in group A &B. The group A patients were dressed with amnion dressing with average burn of 11.90 ± 3.80% TBSA. The group B patients were treated with silver sulfadiazine dressing with average burn of $12.30 \pm 4.14\%$ body surface area. Acceleration in wound healing and less pain was observed with amniotic membrane dressing. The mean healing time was also shorter in the amnion group than control group (9.50±2.13 v 14.30±2.60 days; P value < 0.01).16

CONCLUSION

This study concluded that mean pain score and healing time after amnion dressing in superficial partial thickness burn patients is less as compared to conventional (Vaseline-impregnated gauze) dressing. Considering that amnion dressing can be routinely used in our practice for superficial partial thickness burn patients especially in resource poor countries.

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3	Usman Ishhaque	Writing of manuscript, results analysis.	Irmi
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