

“Effectiveness of Radiation Sterilized Amniotic Membrane in Reducing Patient’s Morbidity In Comparison To Non Biological Dressing Like Medicated Tulle (Sofra Tulle)”

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Abstract: This study was performed to observe whether local burn wound coverage with radiation sterilized amniotic membrane provides a better outcome than conventional dressings with non biological medicated tulle (sofratulle). This interventional randomized control trial study was conducted during the period of 15 months from 01, July, 2006 to 30, September, 2007 in Burn Unit of Dhaka Shishu(Children) Hospital. 50 burned patients with 10- 20% of total body surface area and suffering from second degree superficial burn(scald) were allocated randomly into two groups, the first receiving classical dressings with sofratulle, and the second had the burn areas covered with radiation sterilized amniotic membrane dressing. Each patient in both groups received a same standard schedule of general management. Patients were followed up on daily basis for number of dressing changes, development of pyrexia, wound infection, and wound healing time, duration of hospital stay and requirement of further surgical procedures like skin grafting. After recovery, the patients were followed up on weekly basis for up to 4 weeks and on monthly basis for up to two months thereafter. Any signs of abnormal scar formation, wound contracture and cosmetic disfiguration were recorded. In present study wounds of 7(28%) patient healed up in 14 days and 18(72%) patients required 15 days or more to heal up their wounds in group A (sofratulle). On the other hand wound healed up in 22 (88%) patient in 14 days and in 3(12%) patients required 15 days or more to heal up their wounds in group B (amniotic membrane). So amniotic membrane group demonstrated a clear early wound healing rate. Hospital stay was also significantly short in amniotic membrane group. Present study revealed that only 1 patient in medicated tulle (sofratulle) group required single dressing and rest 24 patients required multiple dressings. While 17 patients in amniotic membrane group required single dressing and rest 8 patients required multiple dressings. Out of 25 patients in medicated tulle (sofratulle) group 8 showed positive culture of pathogenic organisms with pyrexia and neutrophilia with an infection rate of 32%. In amniotic membrane group one patient had positive culture of pathogenic organisms with pyrexia and neutrophilia, making an infection rate of 4%. In the present study 100% patients of amniotic membrane group required no further procedure for wound healing but 2(8%) patients in medicated tulle (sofratulle) group required skin grafting. The present study demonstrated that amniotic membrane is a suitable and effective biological dressing in reducing patient’s morbidity when compared with non-biological medicated tulle (sofratulle).

Key words: Effectiveness, Radiation sterilized amniotic membrane, Medicated tulle (Sofra tulle)

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I. Introduction

Burn injuries are one of the most devastating physical and psychological injuries that a person can suffer (Demling 2003). Burn includes, tissue injury caused by dry heat, moist heat, chemicals, electricity, friction and radiant and electromagnetic energy (Rosin 1992). As the second leading cause of accidental death in children younger than 5 years in United States, burns result in 532 pediatric deaths in 2001, in 2002 an estimated 92,500 children younger than 14 years were treated in hospital emergency rooms for burn related injuries (Chung et al. 2006). The burn problems in the third world is almost certainly both greater and different in many respects, where Children comprise 45% of the total burns unit workload (Lawrence 1996). From 1981 to 1990

it was the second most common surgical problem in pediatric age group in the department of pediatric surgery, Dhaka Shishu Hospital (Masood et al. 1991). The Burn wound is the same, whether it occurs in adult or a child but the management of a Paediatric burn differs considerably from that of an adult in many aspects. Once the child is injured and requires treatment, this care and the responsibility for his/her wellbeing becomes split between hospital staff and parents. From a practical point of view the burn wound is best treated with dressings. Small children tend to prefer injured sites to be covered with dressing; perhaps they find a change in body image difficult to cope with. (Carolyn 1996). Survival of burn patient is largely dependent upon prompt and efficient wound healing. This not only limits wound contracture but also reduces the incidence of wound infection. (Ghalambor et al. 2000). Early coverage of a burn wound may be life saving. The search for an ideal wound cover as a substitute for patient’s skin began more than a century ago and continues today (Gruss and Jirsch 1978). It is not surprising that man has dressed his wounds for thousands of years and to speculate that he may have a natural tendency to dress his wounds (Lawrence 1996). Various dressing materials have been recommended for the treatment of burn wounds. Synthetic dressings such as Duoderm, Tegaderm, Omniderm; Biosynthetic material such as Biobrane, Transcyte and collagen products, (gel, sponges) and Biological allograft, xenograft, Amniotic membrane are being used in burn wound management (Dioguardi et al. 1990). Tulle either medicated or plain is a popular dressing for burns. These materials are easy to use, convenient and cheaper than many alternatives (Lawrence 1996). A comparative study between Nitrofurazone embedded gauze (NEG), Silver Nitrate incorporated Amniotic Membrane (SNIAM), Water jel and Omniderm in Baskent University Hospital, Ankara, Turkey showed SNIAM had less infection rate, more cost effective & had relatively shorter hospital stay in Burn wound management (Ugar and Haberal 1999). Islam et al. (1989) reported that use of Radiation sterilized Amniotic membrane in burn wound care was helpful in quick healing, change of dressings were less painful. Average hospital stay of the patients was 8 days. Ghalambor et al. (2000) in their study demonstrated the effectiveness of amniotic membrane in comparison to the classical method of treatment in thermal burn patients in reducing wound sepsis. Though superficial second degree burn wounds are managed by regular application of dressings (Chung and Herndon 2005). Comparative studies to find out more effective dressing material is few in Paediatric patients in our country. The present study compared the effectiveness of amniotic membrane to non biological medicated tulle dressing in treatment of burned children.

Epidemiology of burn in children

Thermal injuries are common both in highly sophisticated societies and in less developed communities (Raine and Azmy 1994). Chung and Herndon (2005) reported that approximately 2 million burn injuries occur every year in the United States. Although most cases are minor 50,000 patients have moderate to severe burns requiring hospitalization for treatment. Of these cases two thirds are young males and 40% are children younger than 15 years. Of the children age 4 years and younger who are hospitalized for burn related injuries, 65% had scald burns, 20% contact burns and remainder flame burns. The majority of scalds of infants and children were from hot foods and liquids. A total number of 45010 children under the age of 14 were admitted to hospitals in 1981 in England and Wales following burns and 98% patients were under the age of 4. In this age group the majority (76%) of the heat injuries occurred by scalding (Carolyn 1996). The burn problems in the third world is almost certainly both greater and different in many respects (Lawrence 1996). Prevalence of burn is very high in Bangladesh though exact statistics is not available. (Rahman and Shakoor 2007). Socioeconomic and cultural influence in the causation of burns in the urban children of Bangladesh was studied by Daisy et al. (2001). There were highly significant associations between burns and lack of alertness to burns among parents, clothing of manmade fabrics, and cooking equipment in the kitchen within reach of children. There was also significant association between burns and illiteracy of the mother, housing located in slums and congested areas and low economic status of the parents. The bimodal distribution of burn injuries with the peak incidence being in children < 5 years and people aged 26- 35 years was observed by Lal et al. (2006) in the study of burn injuries in slum community of Delhi. Masood, Khan and Islam (1991) reported that from 1981 to 1990 a total of 12109 patients were admitted in the department of pediatric surgery, Dhaka Shishu Hospital, of which 1131 (9.29%) cases were burn.

II. Objectives

General objectives:

- To study the effectiveness of radiation sterilized amniotic membrane in reducing patient’s morbidity in comparison to non biological dressing like, medicated tulle (Sofra tulle).

Specific objectives:

- To assess the role of amniotic membrane and medicated tulle in reducing burn wound infection rate.
- To estimate wound healing rate and duration of hospital stay by amniotic membrane and medicated tulle.
- To estimate number of dressing changes by amniotic membrane in comparison to medicated tulle.

III. Materials And Methods

We conducted an interventional study with a model of randomized control trial and the study was carried out in Dhaka Shishu (Children) Hospital (DSH) during the period from period from 01 July, 2006 to 30 September, 2007. Burn patients admitted in Burn Unit of Dhaka Shishu Hospital during the study period were taken as study population. A total number of 2910 patients were admitted into the dept. of Surgery of Dhaka Shishu Hospital during the study period of 15 months from July 2006 to September 2007. Out of them 195 Patients were due to Burn. From the admitted patients 50 cases of second degree superficial burn (scald) patients were selected as sample for the study. Simple Random sampling technique was followed to select groups for each sample by means of lottery. Medicated tulle (sofra-tulle) was grouped as group A and Amniotic membrane was grouped as group B. Prior to commencement of this study thesis was approved by Ethical committee of BICH and Dhaka Shishu (Children) Hospital. Information about the patient was collected in a prescribed questionnaire after getting written consent from the parents or legal guardian in a preformed consent form (translated into Bangla). Data were collected by: Set questionnaire, Clinical examination, and Daily follow up studies. Investigations, ex. Culture sensitivity tests, Operative procedures, follow up studies. Collected data were arranged in systematic manner, presented in various tables and figures and statistical analysis was made to evaluate the objectives of this study. P value <0.05 was taken as significant. After recovery, the patients were followed up on weekly basis for up to 4 weeks and on monthly basis for up to two months thereafter. Any signs of infection or abnormal scar formation, wound contracture and cosmetic disfiguration were recorded. There was no **drop out** of cases in the study.

Inclusion criteria:

Second degree superficial thermal Burn patients with moist heat (scald) of 10% to 20% body surface area burn were included in the study.

Exclusion criteria: Infected burn, Delayed arrival into the hospital (more than 24 hours), Burn in perineum & External genitalia, face& scalp, Burn patients with associated other illness and weight less than standard according to growth chart.

IV. Observation And Results

We conducted an interventional study with a model of randomized control trial and the study was carried out in Dhaka Shishu (Children) Hospital (DSH) during the period from period from 01 July, 2006 to 30 September, 2007. Burn patients admitted in Burn Unit of Dhaka Shishu Hospital during the study period were taken as study population. A total number of 2910 patients were admitted into the dept. of Surgery of Dhaka Shishu Hospital during the study period of 15 months from July 2006 to September 2007. Out of them 195 Patients were due to Burn. From the admitted patients 50 cases of second degree superficial burn (scald) patients were selected as sample for the study. Hot water was the main causes of burn in both groups. Representing 52% and 44% in Group-A and in Group-B respectively. A significant difference of hospital stay was observed between the two groups. Mean duration of hospital stay for group A was 17.24 days and for group B 12.32 days. On the other hand, wound healed up in 22 (88%) patient in 14 days and in 3 (12%) patients required 15 days or more to heal up their wounds in group B (amniotic membrane). Wound healing time compared between group A (sofratulle) and group B (amniotic membrane). λ^2 value was 16.09 and $p < 0.001$, which is highly significant. Mean duration of hospital stay was compared between group A (sofratulle) and group B (amniotic membrane), t-test was performed. P value was $p < 0.001$, which is highly significant. In the group A only 1 (4%) required single dressing and the rest 24 (96%) patients required 2 or more dressing changes. On the other hand, 17 (68%) patients of amniotic membrane group were healed by single dressing and 8 (32%) patients required 2 or more dressings. Number of dressing changes was compared in group A (sofratulle) and group B (amniotic membrane) groups. λ^2 value was 19.53 and $p < 0.001$, which is highly significant. All the patients in group B (amniotic membrane) were healed by epithelization without any scarring and required no skin grafting. Most (23) of the patients in group A (sofratulle) also healed by epithelization without any scarring but 2 patients required skin grafting. Out of 25 patients in group A, 8 patients showed positive culture of pathogenic organisms with pyrexia and neutrophilia with an infection rate of 32%. In group B one patient had positive culture of pathogenic organisms with pyrexia and neutrophilia, making an infection rate of 4%. λ^2 value was 4.88 . P value was 0.02, which is significant. The types of organisms isolated by positive culture are mentioned in the following table 8. Culture sensitivity reports revealed that Staphylococcus aureus was sensitive to flucloxacillin, Cephradine and ciprofloxacin groups of antibiotics. Pseudomonus was sensitive to Gentamycin, Ceftazidime and Escherechia coli was sensitive to Gentamycin and Imipenum group of antibiotics. Infection was controlled by using sensitive antibiotics. Duration of pyrexia and presence of neutrophilia also had a varied presentation. In the amniotic membrane treated patient onset of pyrexia was detected on 5th day of burn and persisted for 7 days. On the other hand in medicated tulle treated group onset of pyrexia was on 4th day for one patient on 5th day for one patient, on 6th day for three patients and on 7th day for two patients respectively.

Figure 1: Distribution of causes of burn injury (n=50)

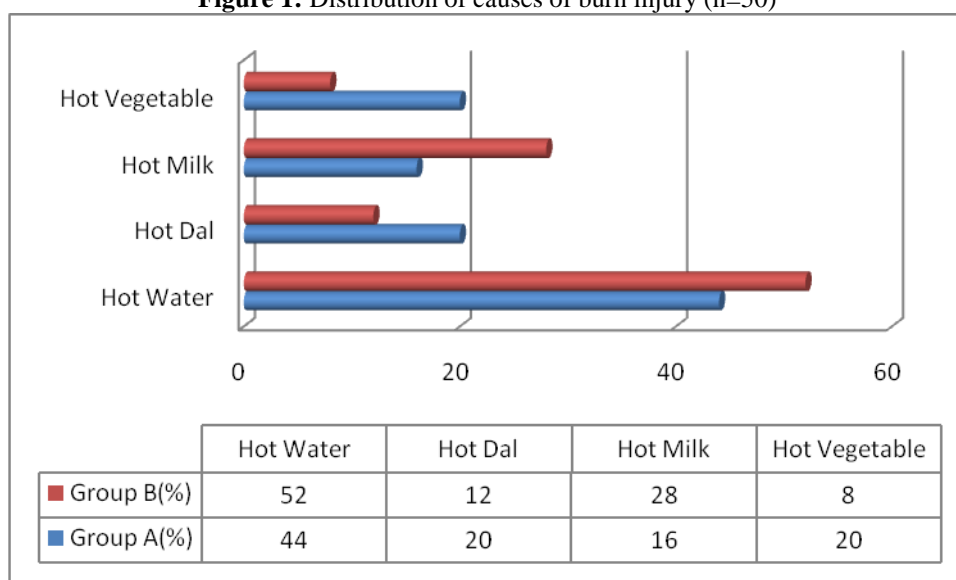


Table 1: Distribution of body surface area of burn of the study participants (n=50)

Percentage of area burn	Group-A	Group-B
Up to 10 %	7 (28.0)	9 (36.0)
11-15 %	15 (60.0)	12 (48.0)
> 15 %	3(12.0)	4 (16.0)
Total	25 (100)	25 (100)

Table 2: Healing time according to burning agents between two groups of the study participants (n=50)

Causes of injury	Healing time up to 14 days		Healing time 15 + days (Number of patients)	
	Group-A	Group-B	Group-A	Group-B
Hot water	1 (9.1)	11 (84.6)	10 (90.9)	2 (15.4)
Hot dal	2 (40.0)	2 (66.7)	3 (60.0)	1 (33.3)
Hot milk/tea/oil	2 (50.0)	7 (100.0)	2 (50.0)	0 (0.0)
Hot vegetables	2 (40.0)	2 (100.0)	3 (60.0)	0 (0.0)
Total	7 (28.0)	22 (88.0)	18 (72.0)	3 (12.0)

Table 3: Comparison of duration of hospital stay (days) of the study participants (n=50)

Type of dressing	Mean duration of stay (days)	Std. deviation
Sofra tulle	17.24	6.44
Amniotic membrane	12.32	1.73

Table 4: Comparison of total number of dressing changes (n=50)

Type of dressing	Single time	2 times	3 times	4 times	5 times	6 times	7 times	8 times	9 times and more
Sofra tulle	1		8	6	7		2	1	
Amniotic membrane	17	5	2	1					

Table 5: Requirement of skin grafting for wound coverage, Type of organism, Duration of pyrexia of the study participants (n=50)

	Group-A	Group-B
Skin grafting	Type of surgery	
	2 (8.0)	0 (0.0)
	23 (92.0)	25 (100)
Total	25 (100)	25 (100)
Skin grafting	Type of organism	
	3	1
	2	0
	2	0

Pseudomonas auroginosa + E.coli	1	0
Total	8	1
	Duration of pyrexia	
3 days	4	0
5 days	2	0
7 days	2	1
Total	8	1

V. Discussion

The main goal in the management of an open wound is to obtain a clean and closed wound in the shortest time. The search for an ideal wound cover as a substitute for patient’s skin began more than a century ago and continues today. In present study wound healing time was significantly shorter in amniotic membrane treated group in comparison to control sofratulle group. Quicker healing of burn wounds was also reported by Islam et al. (1989). Similar findings were found in the study of Ugar and Haberal (1999). Even wounds unresponsive to usual therapeutic measures responded to membrane application in the study of Gruss and Jirsch (1978). They also reported that ease of availability, negligible cost and facilitated wound healing made this temporary biologic dressing generally superior to either cadaver skin allograft or pigskin xenograft. Quicker wound healing by amniotic membrane in all the studies is due to its inherent antibacterial and anti-inflammatory properties as postulated by Ghalambor et al. (2000). The mechanism underlying the effectiveness of amniotic membrane as an aid in the treatment of burn wounds has been postulated by a number of researchers. In addition to its physical properties in reducing water and heat loss, the mechanism responsible for the rapid healing observed is due to the inhibition of the proteinase activity, thus reducing the inflammatory responses by reducing the infiltration of polymorphonuclear leukocytes. Hospital stay was significantly shorter in amniotic membrane treated group in the present study. Similar results were found by Islam et al. (1989), in which average hospital stay was 8 days. The decreased number of days of hospitalization of burn patients by use of amniotic membrane has also been reported by Ley Chavez et al. (2003). Shorter hospital stay in these studies was due to inclusion of small surface area (up to 4%) and superficial burn patients. In the study of Pischerchia and Akenzua (1981) amniotic membrane treated children spent an average of 31 days in hospital, as compared with 56 days for the control group treated with non biological dressing. In this non randomized study a small number of samples were taken belonging to a wide age range of seven months to eleven years. Prolonged hospital stay in this study was due to inclusion of deep burn patients and development of infection. Present study revealed that amniotic membrane treated group required less frequent dressing changes. This was also noted by Islam et al. (1989) and Ghalambor et al. (2000). As amniotic membrane has a good adherent property to remain attached with wound for a longer time and it strikethrough and falls of when wound is about to healed up, so numbers of dressing changes are less frequent. Furthermore, it has been reported that human amniotic epithelial cells do not express on their surfaces HLA-A, B, C, and DR antigens, or beta2 micro globulin, which could further contribute to the lower inflammatory responses and relatively delayed rejection of this type of biological dressing (Ghalambor et al. 2000). In the present study wound infection rate was significantly lower in amniotic membrane treated group. Infection rate was much lower as reported by Mostaque (1998), due to inclusion of superficial and smaller surface area burn patients. Similar findings has also been reported by Ghalambor et al. (2000) and Ugar and Haberal (1999). Lower wound infection rate in amniotic membrane treated patients in all the series is due to inherent antibacterial properties of amniotic membrane. The intimate adherent property of this biological dressing to an open wound suppresses bacterial proliferation and helps to eliminate existing bacteria. In a clean surgical wound, the collagen of the graft or biological dressing, via its haemostatic properties, helps to stop bleeding and thus prevent subsequent haematomas, which would provide opportunities for bacterial proliferation. In addition, the very close bonding between graft and wound eliminates dead space; Bacteria are trapped in the thin fibrin matrix linking the collagen fibers of the graft with the collagen of the wound bed. The fibrin matrix provides an ideal substratum for migration of phagocytes and ensures that all the bacteria are within reach of the phagocytes (Islam et al.1989).

VI. Limitations Of The Study

This was a single centre study with small sample size. So, the study results can’t reflect the scenarios of the whole country.

VII. Conclusion And Recommendations

The present study demonstrated that amniotic membrane was a suitable and effective biological dressing in reducing burn wound sepsis in the treatment of second degree superficial burns among all age groups under investigation. This dressing not only lowered the hospital’s and patients’ costs, but also significantly reduced the rate of infection. The patients in the amniotic membrane treatment regimen required less frequent dressing change. The ease of availability of this dressing is a further advantage. It is recommended that amniotic

membrane dressing is to be preferred in the treatment of burns because of its ready availability, ease of preparation, cheapness of storage and higher effectiveness.

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