Xenoderm Versus 'Conventional' Treatment in Pediatrics Burns

1Seyed Nejat Hosseini, 2Seyed Nouraddin Mousavinasab, 3Haleh Rahmanpour and 4Alireza Shoghi
1Department of Surgery, Shafiee Hospital,
2Department of Social Medicine, 3Vali-Asr Hospital, School of Medicine,
Zanjan University of Medical Sciences, Zanjan, Iran

Abstract: The aim of this study was to compare the outcome of Xenoderm (biologic dressing) and 'conventional' treatments (Silver sulfadiazine) in pediatrics' burns in our burn center, which is the only burn center in Zanjan province. In this non-randomized clinical trial, 86 burned pediatrics were investigated. The patients were divided into two groups. Those in the 'conventional' group (n = 35) did not accepted to enter in Xenoderm group and the second group (n = 51) accepted to enter in to Xenoderm group. Mortality rates in the 'conventional' group were 5 (14.3%) and no death were in the Xenoderm group. The median of number of dressing in the 'conventional' group and Xenoderm group were 10 and 3 (p = 0.0005), respectively. In 20 to 39% Total Body Surface Area (TBSA), the median of first admission hospital stay in the 'conventional' group and Xenoderm group were 20 and 7.5 (p = 0.001), respectively. In conclusion, the results indicate that Xenoderm dressings offer a lower mortality, hospital stay and dressing exchange in pediatrics burns. A randomized clinical trial that compares the number of operations, albumin intake and scar formation in pediatrics burns is warranted.

Key words: Biological dressing, xenoderm, pediatrics, burns

INTRODUCTION

Pediatric burn injuries are always a tragedy, most are preventable, all are treatable. The World Health Organization (WHO) amongst others has recognised that children's trauma is the major cause for surgical admissions in developing countries and burns account for the most morbidity and mortality in this group (Erickson et al., 1991; Potokar, 2005; Maghsoudi and Samnia, 2005), burns have ranked second among the causes of accidental death in children under age 4 and third for older children (Maghsoudi and Samnia, 2005).

The superficial partial-thickness (2nd degree) burns healed in three weeks and the deep partial thickness burns and 3rd degree burns treat with early excision and graft, but in traditional method healed in several weeks (Brunicardi et al., 2005). Partial-thickness burns in children have been treated for many years by daily, painful tubing, washing and cleaning of the burn wound, followed by topical application of antimicrobial creams. Pain and impaired wound healing are the main problems (Barret et al., 2000). In other hand, the parents were not let for early excision and graft in pediatrics with 2nd deep degree burn. It depended with culture and regional traditional methods (Albertyn et al., 2006). In the past, many study compare the effectiveness of burns dressings in partial-thickness burns (Barret et al., 2000; Kumar et al., 2004; Costagliola and Agrosi, 2005). Synthetic (Opsite, Biobrane, transcyte) and biological dressings (xenograft, xenoderm (pig skin), allograft (homograft & cadaver skin)) are an integral part of modern burn care and an alternative for anti-microbial dressings (Chiu and Burd, 2005). Porcine skin has gained acceptance as a temporary dressing, three types are common, living, fresh and lyophilized (Xenoderm, Xenograft) (Becker, 1998). Experimental trials studies showed that these three types had the same results (Chiu and Burd, 2005). Porcine skin (Xenoderm) has the desirable properties of being able to:

Adhere to clean wounds and decrease pain, evaporative water, heat, protein, electrolyte loss and costs (Elliot and Hoehn, 1973; Kiene et al., 1976; Pruitt and Levine, 1984; Becker, 1998). Skin heals faster, with less scar formation and infection (Burleson and Eiseman, 1972; Schmitt, 1973). Biological dressing has become an integral part of modern burns care (Brunicardi et al., 2005; Chiu and Burd, 2005). Disadvantages are theoretical risk of zoo noses and ethnic/religious groups (Becker, 1998).

We hypothesized that the treatment of second-degree burns with xenoderm is superior to topical treatment in treating children with partial-thickness burns. The aim of this study was to compare the outcome of Xenoderm and 'conventional' treatments in pediatrics' burns in our burn center, which is the only burn center in Zanjan province.

Corresponding Author: Dr. Seyed Nejat Hosseini, Shafiee Hospital, Zanjan University of Medical Sciences, Zanjan, Iran
Tel: +98-241-4260815 Fax: +98-241-4249553
MATERIALS AND METHODS

In this non-randomized prospectively clinical trial, 86 burns pediatrics were investigated in the Shafeieh Hospital (Zanjan, Iran), between October 2004 and March 2007. The pediatrics entered the study whose had burned due to scalds or flames. They had second degree and second degree with third degree burns less than 5% TBSA. The pediatrics had only third degree burns (contact burn and others), infection (wound infection, 72 h after burn), dirty (chemical material, fecal and soil) excluded from the study. This study was approved by the Ethics Committee of Zanjan University of Medical Sciences. All patients gave informed consent before entering into the study.

The patients were divided into two groups. Those in the first group ('conventional' treatment) were treated by daily washing followed by topical application of silver sulfadiazine dressing. The second degree burn healed with scarring but, third degree burn treated with early excision and graft usually after 2-6 weeks.

The second group was treated by Xenoderm. In Iran usage of lyophilized Xenoderm is legalized by authorities in Ministry of Health and religious authorities. The import of these types of products is allowed to one Iranian company. Xenoderm is lyophilized pig skin, manufactured by MBP (Medical Biomaterial Products, Germany). First, Xenoderm was prepared in normal saline solution. After debridement of the burnt area and rinsing of the wound with normal saline, Xenoderm was placed on to the wound by the surgeon and fixed using a suture, dressing or bandage (Fig. 1). The region was immobilized by a splint if necessary. Twenty four hours after surgery, the dressing was removed. After 2 to 6 weeks, Xenoderm removed spontaneously. In patients with full thickness areas after 2 to 4 weeks, Xenoderm was removed (Fig. 2) and Split Thickness Skin Graft (STSG) was performed. All patients received Cefazolin prophylaxis.

Data, including demographics, mechanism of injury, dept of the burns, TBSA, location of burns, total hospital stay, number of oral or injectable analgesics, the number of dressings was recordable similarly, inhalation injury and mortality measured by staff nursing, burn's department physician and general surgeon.

Significant differences were evaluated using the unpaired Student t-test, the Mann-Whitney U-test and the χ²-test. A p-value less than 0.05 were significant. All analyses were performed using SPSS 11.5.

RESULTS

A total of 86 pediatrics were divided into two groups (35 pediatrics in the group for 'conventional' treatment and 51 pediatrics in Xenoderm group, using Xenoderm).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Conventional treatment N = 35</th>
<th>Xenoderm N = 51</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>21 (60%)</td>
<td>25 (49%)</td>
</tr>
<tr>
<td>Female</td>
<td>14 (40%)</td>
<td>26 (51%)</td>
</tr>
<tr>
<td>Median age (year)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Range age</td>
<td>(0.1-15)</td>
<td>(0.1-15)</td>
</tr>
<tr>
<td>Mechanism of injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scalds</td>
<td>22 (62.9%)</td>
<td>37 (72.5%)</td>
</tr>
<tr>
<td>Flamm</td>
<td>13 (37.1%)</td>
<td>14 (27.5%)</td>
</tr>
<tr>
<td>Inhalation injury</td>
<td>2 (5.7%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>Mean TBSA</td>
<td>(28.8%)</td>
<td>(28.2%)</td>
</tr>
<tr>
<td>Range</td>
<td>(10%-50%)</td>
<td>(10%-54%)</td>
</tr>
<tr>
<td>Depth of burn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I, II degree</td>
<td>3 (8.6%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>I, II, III degree</td>
<td>14 (40%)</td>
<td>18 (35.3%)</td>
</tr>
<tr>
<td>I, II, III degree</td>
<td>18 (51.4%)</td>
<td>28 (54.9%)</td>
</tr>
<tr>
<td>Location of burn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face</td>
<td>9 (25.7%)</td>
<td>19 (37.2%)</td>
</tr>
<tr>
<td>Neck</td>
<td>24 (68.5%)</td>
<td>33 (64.7%)</td>
</tr>
<tr>
<td>Body</td>
<td>15 (42.8%)</td>
<td>25 (49%)</td>
</tr>
<tr>
<td>Upper limb</td>
<td>25 (74.1%)</td>
<td>33 (64.7%)</td>
</tr>
<tr>
<td>Lower limb</td>
<td>13 (37.1%)</td>
<td>23 (45.1%)</td>
</tr>
<tr>
<td>Genital</td>
<td>1 (2.8%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>5 (14.3%)</td>
<td></td>
</tr>
</tbody>
</table>

N = Number, TBSA = Total Body Surface Area
Table 2: Effect of treatment on various clinical parameters in pediatrics after excluding mortality

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Mean (SD)</th>
<th>Median</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burn skin area (%)</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>25.5(11.5)</td>
<td>29</td>
<td>0.51</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>28.3 (10.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of dressings</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>12.9 (9.3)</td>
<td>10</td>
<td>0.0005</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>6.62 (8.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of analgesics (IV)</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>0.77 (1.2)</td>
<td>0</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>1.75 (3.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of analgesics (oral)</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>12.8 (17.5)</td>
<td>5.5</td>
<td>0.81</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>13.3 (14.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First admission hospital stay (days)</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>17 (14.4)</td>
<td>16</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>10 (10.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV-serum before oral intake</td>
<td>Conventional 30</td>
<td>Xenoderm 51</td>
<td>3.69 (2.1)</td>
<td>2.2</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Xenoderm 51</td>
<td></td>
<td>2.46 (1.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N = Number, SD = Standard Deviation, FFP = Fresh Frozen Plasma, IV = Intra Venous

Table 3: The results of treatment in different TBSA

<table>
<thead>
<tr>
<th>TBSA%</th>
<th>Conventional</th>
<th>Xenoderm</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>median</td>
<td>median</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(range)</td>
<td>(range)</td>
<td></td>
</tr>
<tr>
<td>10-19%</td>
<td>11</td>
<td>11</td>
<td>NS*</td>
</tr>
<tr>
<td>N</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>3 (1-16)</td>
<td>1 (1-15)</td>
<td>NS*</td>
</tr>
<tr>
<td>No. of dressings</td>
<td>5.5 (1-10)</td>
<td>2 (1-4)</td>
<td>0.01</td>
</tr>
<tr>
<td>No. of analgesics (IV)</td>
<td>0 (0-2)</td>
<td>2 (1-4)</td>
<td>NS</td>
</tr>
<tr>
<td>No. of analgesics (oral)</td>
<td>3 (1-12)</td>
<td>3 (1-12)</td>
<td>NS</td>
</tr>
<tr>
<td>IV-serum before oral intake</td>
<td>2 (1-4)</td>
<td>2 (1-4)</td>
<td>NS</td>
</tr>
<tr>
<td>First admission hospital stay (days)</td>
<td>4 (1-6)</td>
<td>4 (2-10)</td>
<td>NS</td>
</tr>
<tr>
<td>N</td>
<td>16</td>
<td>16</td>
<td>34</td>
</tr>
<tr>
<td>Age</td>
<td>5.5 (2-16)</td>
<td>5 (1-15)</td>
<td>NS</td>
</tr>
<tr>
<td>No. of dressings</td>
<td>14 (5-31)</td>
<td>3 (1-33)</td>
<td>0.0005</td>
</tr>
<tr>
<td>No. of analgesics (IV)</td>
<td>0.5 (0-3)</td>
<td>0.5 (0-8)</td>
<td>NS</td>
</tr>
<tr>
<td>No. of analgesics (oral)</td>
<td>15 (5-64)</td>
<td>13 (1-41)</td>
<td>NS</td>
</tr>
<tr>
<td>IV-serum before oral intake</td>
<td>2.5 (1-8)</td>
<td>2 (1-5)</td>
<td>NS</td>
</tr>
<tr>
<td>First admission hospital stay (days)</td>
<td>20 (4-55)</td>
<td>7.5 (3-36)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*NS = Non Significant, TBSA = Total Body Surface Area

The most common burned areas were the upper limb and neck in two groups (Table 1). Detachment of Xenoderm from burn sites started from the third week and continued until the fifth week.

DISCUSSION

The results of the present study have shown suggest that application of Xenoderm led to a reduction in dressings time, hospital stay and mortality compared to 'conventional' treatment.

The mortality in the 'conventional' treatment group was 14.3% pediatrics in mean TBSA 28.8%. Maghsoodi and Samnia (2005) reported 6.2% mortality in mean TBSA 19%. The mortality rate was (ages 0-10) 7.4% in India (Kumar et al., 2000) and 6.4% mortality in mean TBSA 19% (Allberty et al., 2006). There was no death in the Xenoderm group. Xenoderm dressing is particularly well suited to use with massive partial thickness injury (Townsend et al., 2004). Application of these dressings provides the opportunity for the surgeon to reconstruct the wounds step by step. It may help to increase the chance of survival in critical cases (Kiene et al., 1976).

The hospital stay in the 'conventional' group was more than Xenoderm dressings group, in which the pediatrics with a 20 to 39% burn area was significant (20 versus 7.5 days, p = 0.001), because Xenoderm cause of treatment II degree burns and reminder burned area (degree III) closed with STSG, but in pediatrics with 10% to 19% TBSA, the hospital stay was not different in two groups (4 versus 4 days) due to usage of Xenoderm or learning how to wash and dressing in the 'conventional' group and hospital stay were the same. Pediatrics more than 40% TBSA needs special care for treatment, therefore were not different in hospital stay in two groups. The average hospital stay was 16.1±12.2 days in the 'conventional' treatment (Xin et al., 2006). Becker suggests the application of pig skin affects the occupancy at the hospital (Becker, 1998). Hosseini et al. (2007) reported the mean first admission hospital stay of
second degree burns with xenoderm dressing were 6.45±5.51 days with mean TBSA 16.8%. Other studies reported the usage of biological or Synthetic dressing reduce the hospital stay in second degree pediatrics burns (Barret et al., 2000; Lukish et al., 2001; Paddock et al., 2007).

In this study, the number of dressings was very small and less in the Xenoderm group when compared to the ‘conventional’ group. Daily exchange of dressing is very painful (Kiene et al., 1976; Barret et al., 2000; Chiu and Shah, 2002). Therefore, with decreasing number of dressing on the burned site, patients were more satisfied and more comfortable. This is very important in facilitating the mobility of patients or the burned area. This characteristic of treatment was most useful in children’s burns (Klein et al., 1995).

Replacement of the dressing, reduction of bed time can be justified. Kuner et al. (2004) suggested the application Synthetic dressing When used in partial-thickness burns in children, TransCyte promotes fastest re-epithelialization and required less overall dressings than Biobrane or Silvazine.

The results showed that there were no significant difference in the number of analgesics used and IV serum therapy between two groups. But, the reduction of pain is documented in previous studies. Regarding the effect of pig skin dressings in reduction of heat, liquids, protein and electrolyte loss and its role as a physical barrier against excessive bacterial growth and no requirement to rinsing the wound and replacement of the dressing, reduction of bed time can be justified (May, 1991; Barret et al., 2000; Chiu and Shah, 2002).

The most common burn sites were the neck, upper limb and the anterior trunk. Similar reports appeared in other studies (Davy, 1999; Ho and Ying, 2001; Xin et al., 2006). The median age for burnt children was 4 years. Similar reports appeared in other studies (Xin et al., 2006; Goldman et al., 2006; Rawlins et al., 2007).

The study shows that xenoderm can be applied as temporary coverage in pediatrics burned. Xenoderm leads to reconstruction of wound and reduction of scar by prevention of infection and maintenance of remaining epithelial tissue. Application of this coverage provides the opportunity for the surgeon to reconstruct the wounds step by step. It may help to increase the chance of survival in critical cases and reduce hospital stay, dressing exchange and cost. The limitation of this study including a non randomized design and evaluation total healing time should be taken in to account and suggest future investigation.

In conclusion, the results of this study indicate that Xenoderm give lower mortality and we suggest using Xenoderm in massive pediatric partial thickness burns. However, a randomized clinical trial that compares the number of operations, albumin intake, scar formation re-epithelialization time and decreasing need for STSG in pediatric partial thickness burns is warranted.

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