A STUDY ON MANAGEMENT OF DIABETIC FOOT AT TERTIARY CARE HOSPITAL

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INTRODUCTION

Diabetes is fast gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. In 2000, India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) with the United States (17.7 million) in second and third place respectively (1).

According to Wild et al. the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see significant increases in those affected by the disease (2,3).

With the advent of twenty first century where advances in medical technology and literature has reached its pinnacle, where mankind has succeeded in deciphering the human genetic code, the issue of chronic wound management is still an enigmatic challenge. Diabetic foot ulcers is the most common cause of chronic wounds. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25%.

It is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes. Diabetic foot ulcers are the single biggest risk factor for non-traumatic foot amputations in persons with diabetes (6). The peculiar characteristic is the refusal of the diabetic foot ulcer to heal despite the best wound care management given. The false notion the wounds heal better if kept dry has given way to the newer concept of wound healing which allows chronic wounds to re- epithelialize much faster or develop granulation tissue much faster when treated with moist wound dressings.

There are different treatment modalities for diabetic foot ulcers like advanced moist wound dressing, bioengineered tissue or skin substitutes, growth factors, electric stimulation, low potential laser therapy and vacuum assisted closure or vacuum therapy or topical negative therapy or vacuum sealing. The traditional moist dressings were initially supplemented with hydrocolloid dressings, gels, foams, and other measures like hyperbaric oxygen, growth factors, and various offloading therapies.

METHODOLOGY

Study Design: A prospective randomized comparative study.

Inclusion criteria
• Patients with diabetes mellitus
• Aged 20 to 70 years.
• Stage 2 or 3 diabetic foot ulcers as defined by Wagner's classification.
• Male and female

Exclusion criteria
• Patients with osteomyelitis of underlying bone.
• Peripheral vascular disease
• Co-morbid conditions of respiratory, cardiovascular or renal system
• Patients receiving radiotherapy, chemotherapy, corticosteroids, immunosuppressants.

A foam-based dressing was applied over the wound of group A patients involving use of topical negative pressure therapy or to group B involving conventional moist dressing using saline soaked gauze dressing. Equal number of patients were allotted randomly to group A involving use of topical negative pressure therapy or to group B involving conventional moist dressing using saline soaked gauze dressing.

A foam-based dressing was applied over the wound of group A patients involving use of topical negative pressure therapy or to group B involving conventional moist dressing using saline soaked gauze dressing. A foam-based dressing was applied over the wound of group A patients under all aseptic conditions. The dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube embedded in the foam was connected to wall suction apparatus or surgical vacuum bottles on a continuous basis for 3-4 days.

Group B patients received daily saline soaked gauze dressing.

All patients were observed for appearance of granulation tissue, its covering of the floor (in percentage), change in the size and depth of the ulcer on days 3, 7, 14, 28 and 42 respectively. Results: At the end of 42nd day 72.5% of patients showed complete response in group Whereas only 40% of patients showed complete response in group B 25% showed partial response in group A when compared to 42.5% of patients in group B at the end of 42 days. 12.5% patients showed no response in group B where as only 2.5% of patients in group A showed no response. Conclusion: Inter group comparison of size of the ulcer in group A and group B on different assessment days reduction in size of the ulcer was more in group A when compared to group B and the difference was statistically significant except for 42nd day.

KEYWORDS
Diabetic Foot, Wound Management, Topical Negative Pressure Therapy

RESULTS

29 patients out of 40 patients in group A underwent split skin grafting

ABSTRACT

Introduction: With the advent of twenty first century where advances in medical technology and literature has reached its pinnacle, where mankind has succeeded in deciphering the human genetic code, the issue of chronic wound management is still an enigmatic challenge. Diabetic foot ulcers is the most common cause of chronic wounds. The false notion the wounds heal better if kept dry has given way to the newer concept of wound healing which allows chronic wounds to re- epithelialize much faster or develop granulation tissue much faster when treated with moist wound dressings.

All patients received appropriate medical treatment to control diabetic foot ulcers surgically, spontaneous and until completion of 42 days. Patients received daily saline soaked gauze dressing. A foam-based dressing was applied over the wound of group A patients involving use of topical negative pressure therapy or to group B involving conventional moist dressing using saline soaked gauze dressing. Group B patients received daily saline soaked gauze dressing.

All patients were observed for appearance of granulation tissue, its covering of the floor (in percentage), change in the size and depth of the ulcer on days 3, 7, 14, 28 and 42 respectively. Ulcers were treated until the wound closure surgically, spontaneous and until completion of 42 days (6 weeks) of assessment whichever was earlier. Additional surgical procedures like amputation were carried out in required cases and noted down.

All patients received appropriate medical treatment to control diabetic status by diet restriction and insulin therapy and antibiotics based on culture and sensitivity report after initial broad spectrum antibiotics.

A foam-based dressing was applied over the wound of group A patients involving use of topical negative pressure therapy or to group B involving conventional moist dressing using saline soaked gauze dressing.

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A foam-based dressing was applied over the wound of group A patients under all aseptic conditions. The dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube embedded in the foam was connected to wall suction apparatus or surgical vacuum bottles on a continuous basis for 3-4 days.

Group B patients received daily saline soaked gauze dressing.

All patients were observed for appearance of granulation tissue, its covering of the floor (in percentage), change in the size and depth of the ulcer on days 3, 7, 14, 28 and 42 respectively. Ulcers were treated until the wound closure surgically, spontaneous and until completion of 42 days (6 weeks) of assessment whichever was earlier. Additional surgical procedures like amputation were carried out in required cases and noted down.

All patients received appropriate medical treatment to control diabetic status by diet restriction and insulin therapy and antibiotics based on culture and sensitivity report after initial broad spectrum antibiotics.

RESULTS

29 patients out of 40 patients in group A underwent split skin grafting
when compared 18 patients in group B underwent split skin grafting.

5 patients out of 40 patients underwent below knee amputation in group B when compared to 1 patient from group A underwent below knee amputation.

### TABLE 1: PROCEDURE

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Group-A (N=40)</th>
<th>Group-B (N=40)</th>
<th>Chi Square test</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSG</td>
<td>29</td>
<td>18</td>
<td>7.056, p&lt;0.02, S</td>
</tr>
<tr>
<td>BKA</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>10</td>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

At the end of 42rd day 72.5% of patients showed complete response in group A whereas only 40% of patients showed complete response in group B.

25% showed partial response in group A when compared to 42.5% of patients in group B at the end of 42 days.

12.5% patients showed no response in group B as where as only 2.5% of patients in group A showed no response.

### TABLE 2: END RESULT

<table>
<thead>
<tr>
<th>End result</th>
<th>Group-A (N=40)</th>
<th>Group-B (N=40)</th>
<th>Chi Square test</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>29</td>
<td>18</td>
<td>7.056, p&lt;0.02, S</td>
</tr>
<tr>
<td>PR</td>
<td>10</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>NR</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Inter group comparison of granulation tissue of group A and group B on different assessment days shows group A showed better results and this difference was statistically significant on day 3, 7, 14, 28, except for day 42 which was not statistically significant.

### TABLE 3: INTER GROUP COMPARISON OF SIZE OF ULCER (cm²)(days)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Size of ulcer (cm²)</th>
<th>Mann Witney U Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 days</td>
<td>99.1 ± 38.9</td>
<td>P=0.000</td>
</tr>
<tr>
<td>7 days</td>
<td>79.7 ± 28.7</td>
<td>P=0.000</td>
</tr>
<tr>
<td>14 days</td>
<td>57.5 ± 25.3</td>
<td>P=0.000</td>
</tr>
<tr>
<td>28 days</td>
<td>48.0 ± 27.5</td>
<td>P=0.000</td>
</tr>
<tr>
<td>42 days</td>
<td>41.61 ± 46.8</td>
<td>P=0.763</td>
</tr>
</tbody>
</table>

Inter group comparison of size of ulcer in group A and group B on different assessment days reduction in size of the ulcer was more in group A when compared to group B and the difference was statistically significant except for 42nd day. There was no statistical significant difference between groups on day 42.

### TABLE 4: INTER GROUP COMPARISON OF DEPTH OF ULCER IN MM (days)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Depth of ulcer in mm (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 days</td>
<td>10.07 ± 1.12</td>
</tr>
<tr>
<td>7 days</td>
<td>8.0 ± 1.38</td>
</tr>
<tr>
<td>14 days</td>
<td>5.27 ± 1.85</td>
</tr>
<tr>
<td>28 days</td>
<td>2.92 ± 2.08</td>
</tr>
<tr>
<td>42 days</td>
<td>2.30 ± 1.72</td>
</tr>
</tbody>
</table>

Intergroup comparison of depth of the ulcer in both the groups there was statistical significant difference on days 3, 14 and 28. The difference on day 7 and day 42 was not statistically significant.

The difference on day 7 and day 42 was not statistically significant.

In terms of reduction in depth of the ulcer group A is better than group B.

### DISCUSSION

In our present study depth of the ulcer was assessed on day 3, 7, 14, 28 and 42. Depth of the ulcer on day 3 in NPWT group (group A) was 10.07 ± 1.12 mm and 8.42 ± 0.98 mm in conventional saline soaked gauze dressing (group B) which was statistically significant (p<0.000). Depth of ulcer on day 28 in NPWT group was 2.92 ± 2.08 mm and 4.57 ± 2.23 mm in conventional saline soaked gauze dressing group which was statistically significant (p<0.001). Inter group comparison of depth of the ulcer in both the groups showed statistically significant difference on days 3, 14, 28. The difference on day 7 and day 42 was not statistically significant. In terms of reduction in depth of the ulcer, group A is better than group B.

Similar results were seen in study conducted by Hassan Ravari et al. Depth of ulcer before (17 ± 6 mm) and after (20 ± 8 mm) the moist dressing was not statistically significant (p = 0.5), whereas this difference was significant for VAC dressing (p = 0.007; 19 ± 7 mm before versus 12 ± 4 mm after treatment). The difference in the depth of ulcers in the VAC group versus moist dressing was significant (p = 0.02).

In our present study, average duration of hospital stay in group A was 46.58 days (Standard deviation 9.88) versus 53.05 days in group B (Standard deviation 12.31). Mean days of stay in the hospital was less in group A than group B.

In our present study, 29 patients out of 40 patients in group A underwent split skin grafting when compared 18 patients in group B underwent split skin grafting (p<0.02).

In our present study, 17 patients of group A showed complete healing of ulcer in < 40days when compared to group B only 5 patients showed complete healing of the ulcer. The difference was statistically significant (p<0.000) when compared with Peter A Blume et al. 66.6 days in the group and 78.1 days in the control group.

1 patient out of 40 patients underwent below knee amputation in group A when compared to 5 patients from group B underwent below knee amputation (p<0.02).

At the end of 42rd day, 72.5% of patients showed complete response in group A whereas only 40% of patients showed complete response in group B which was statistically significant (p<0.02). 25% showed partial response in group A when compared to 42.5% of patients in group B which was statistically significant (p<0.02).

### CONCLUSION

72.5% of patients showed complete response in group A whereas only 40% of patients showed complete response in group B. 25% showed partial response in group A when compared to 42.5% of patients in group B.

### REFERENCES