INTRODUCTION

Diabetic foot is one of the most serious complications of diabetic wounds and is the leading cause of non-traumatic lower limb amputations.¹ If a standardized treatment approach is applied with a multidisciplinary foot care team, major amputations can be avoided in about 80-90% of patients with limb threatening ischemia and in 95% of patients with infection.²

Over the years, a variety of strategies have been evolved to address the issue of wound infection. One of such strategies is the use of superoxidized solutions. Most of these solutions or waters are electrochemically processed aqueous solutions manufactured from pure water and sodium chloride. In general, the concept of electrolysis is relatively simple: tap water is purified through reverse-osmosis and USP-grade sodium chloride is added before being submitted to an electric field. During the process of electrolysis, molecules are pulled apart in a chamber with positive and negative poles and hypochlorite/ous species and free radicals are formed. The final result is a blend of reactive species of chloride and oxygen with its numerous applications in medicine and disinfection. Superoxidized water (Microcyn™) is a pH-neutral, superoxidized solution with a longer shelf-life (> 12 months) than any other superoxidized solution tested to-date.³ It has proved its antimicrobial activity against a variety of microbes including bacteria, viruses, fungi and bacterial spores. It has been effective and safe when applied in different ways (e.g. sprays, immersion, irrigation, etc.) as well as in combination with other technologies. It can be applied 2-3 times daily according to the type and stage of the wound.³⁴

The aims of this study was to evaluate the effectiveness of superoxidized water in diabetic patients with different wounds.

PATIENTS AND METHODS

Between April 15, 2006 and June 14, 2006, this pilot clinical study (single-centre single blinded randomized controlled trial) was undertaken at the Departments of General Surgery, Orthopaedics and General Medicine. One hundred known diabetic patients were enrolled in the study. Informed consent for participation in the study was taken from all the study subjects to be randomized to either intervention or control.
Treating of infected diabetic wounds with superoxidized water

The use of antiseptic agents was found to be effective in the management of diabetic wounds. However, with the increasing emergence of MRSA and other bacteria, it is crucial to develop new antiseptic agents with improved efficacy and safety. This study aimed to evaluate the feasibility and operational efficiency of a new antiseptic agent in the management of diabetic wounds.

METHODS

A total of 100 diabetic patients were included in this study. Half of the patients were randomized to the intervention group (those whose wounds were managed with superoxidized water) and the other half to the control group (those whose wounds were treated with normal saline). A table of random numbers was employed to achieve simple random samples. The two groups were matched for age, gender, duration of diabetes and category of wound.

RESULTS

Each group included 50 patients of either gender. The male to female ratio was 43:7 respectively. The average age of the patients was 40 ± 11 years. Most of the wounds were infected diabetic foot ulcers (n = 29), while infected operative wounds were 09, carbuncles 07, and gangrenous wounds were 05. Arealwise, the wounds were located on foot (n=31), abdomen (n=9), back (n=7) and upper limb (n=3). At presentation, the majority of wounds were of grade IV (n=34), while grade III wounds were 10 and grade II wounds were 6 in each group. The Table I shows the wound downgrading observed after one week of treatment.

Table I: Wound downgrading observed with one week of treatment (n= 50 each group).

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Wound category on day 01</th>
<th>Wound category on day 08</th>
<th>No. of patients (study group)</th>
<th>No. of patients (control group)</th>
<th>p-value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IV</td>
<td>I</td>
<td>21 (61.76%)</td>
<td>15 (45.77%)</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>2</td>
<td>IV</td>
<td>II</td>
<td>8 (23.52%)</td>
<td>13 (38.23%)</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>3</td>
<td>IV</td>
<td>III</td>
<td>5 (14.7%)</td>
<td>16 (47%)</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>4</td>
<td>III</td>
<td>I</td>
<td>7 (30%)</td>
<td>2 (20%)</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>5</td>
<td>III</td>
<td>II</td>
<td>3 (30%)</td>
<td>0 (0%)</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>6</td>
<td>II</td>
<td>I</td>
<td>6 (100%)</td>
<td>3 (50%)</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>

The duration of hospitalization among the patients of the two groups (n = 50 each group) is depicted in Table II.

Table II: The duration of hospitalization among the patients of the two groups (n = 50 each group).

<table>
<thead>
<tr>
<th>S. No.</th>
<th>No. of patients (study group)</th>
<th>No. of patients (control group)</th>
<th>p-value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-7 DAYS</td>
<td>31 (62%)</td>
<td>10 (20%)</td>
</tr>
<tr>
<td>2</td>
<td>8-14 DAYS</td>
<td>9 (18%)</td>
<td>17 (34%)</td>
</tr>
<tr>
<td>3</td>
<td>15-21 DAYS</td>
<td>7 (14%)</td>
<td>15 (30%)</td>
</tr>
<tr>
<td>4</td>
<td>&gt; 21 DAYS</td>
<td>3 (6%)</td>
<td>8 (16%)</td>
</tr>
</tbody>
</table>

The Table I shows the wound downgrading observed after one week of treatment. The Table II shows the duration of hospitalization among the patients of the two groups. The data were analyzed through SPSS for Windows version 10 and various descriptive statistics were used to calculate frequencies, ratios, percentages, means and standard deviation. The nominal variables were reported as frequency and percentages. The numerical data were reported as mean ± standard deviation. The difference between mean was regarded as statistically significant if p-value was less than 0.05.

DISCUSSION

These preliminary results are promising indicating feasibility and operational efficiency of the new antiseptic agent in the management of diabetic wounds. These results are consistent with previous studies that have shown the effectiveness of superoxidized water in the management of diabetic wounds. This study is a part of a larger study that aims to investigate the effectiveness of superoxidized water in the management of diabetic wounds.

In conclusion, superoxidized water is a promising antiseptic agent in the management of diabetic wounds. Further studies are needed to investigate the long-term effectiveness and safety of superoxidized water in the management of diabetic wounds.

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including superoxidized water is one of such innovative approaches.\textsuperscript{3,4}\n
Superoxidized water is a relatively newer antiseptic agent and these initial results prove its superiority over normal saline in treating a broad spectrum of diabetic wound infections. The antiseptics can be employed to prevent and treat infection while preserving the healing process. They are preferable to topical antibiotics with regard to the development of bacterial resistance.\textsuperscript{8-10} Several studies have proved that antiseptic solutions are more effective than just saline alone when used as a wound cleanser to promote wound healing.\textsuperscript{11-13} Superoxidized solutions are well-validated disinfectants for various instruments and hard inanimate surfaces in hospitals.\textsuperscript{14-17} These solutions have also been used with success on humans for a variety of indications such as treatment of infectious skin defects, ulcers, mediastinal irrigation after open-heart surgery, treatment of peritonitis, intra-peritoneal abscess and hand washing etc.\textsuperscript{18-22} Superoxidized water has been enjoying worldwide approval and large-scale recognition in the recent years and our initial results are in conformity with the other reported studies.\textsuperscript{3,4}\n
Superoxidized water, owing to its low cost, can provide an economical alternative to the other available antiseptic agents. The economic implications of diabetic wound infections are devastating, particularly in poor societies. In the United States, over 5 million patients suffer from different chronic wounds annually at a total cost of greater than 20 billion US dollars a year.\textsuperscript{23-24} The yearly cost of treating pressure ulcers alone are greater than one billion US dollars and 1.5-3 million US adults require treatment in long-term care settings.\textsuperscript{25} In the US, the national daily hospital cost of Medicare patient averages 2,360 dollars and the overall yearly cost of infections worldwide are estimated to be greater than 100 billion US dollars. Diabetic wounds constitute a significant percentage of these. Any strategy aimed at rapidly sterilizing the wounds, decrease intravenous and oral antibiotics use, decrease hospitalization, and facilitate time to wound healing and have a significant clinical and economical impact.\textsuperscript{26} Such an impact would be a great welcome for nations of the developing world. These are the results of our preliminary study and the ongoing study still continues, its detailed results would be submitted for publication as soon as the study is completed.

\textbf{CONCLUSION}\n
Although the initial results of employing Super-oxidized water for the management of infected diabetic wounds are encouraging, further multicentre clinical trials are warranted before this antiseptic is recommended for general use in our population. Moreover, it must offer an economical alternative to other expensive antiseptics with positive impact on the prevailing infection rates, patient outcomes and patient satisfaction.

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\textbf{REFERENCES}\n


