COMPARISON OF STANDARD NEGATIVE PRESSURE WOUND THERAPY ALONE WITH NEGATIVE PRESSURE WOUND THERAPY PLUS INSTILLATION OF NORMAL SALINE IN ACUTE TRAUMATIC WOUNDS

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ABSTRACT

Objective: To compare the efficacy of standard negative pressure wound therapy with combination of negative pressure wound therapy (NPWT) and instillation of normal saline (NS) in acute traumatic wounds.

Study Design: Randomized controlled trial.

Place and Duration of Study: CMH Rawalpindi from July to September 2017.

Material and Methods: Forty patients of both genders with acute traumatic wounds were included in the study after adequate debridement under appropriate anesthesia. They were divided into two groups by lottery method. In first group i.e. group A, standard negative pressure wound therapy was applied whereas in group B negative pressure wound therapy with instillation of NS was used. Mean number of days required for wound to be ready for the final surgical procedure was calculated for both the groups.

Results: Mean age of the patients who participated in the study was 37.98 ± 6.275. The mean time required for the final surgical procedure for conventional group A was 27.4 ± 2.2 days and for group B it was 21.92 ± 3.6 days (p-value <0.001).

Conclusion: NPWT with instillation of NS was a better treatment option as compared to NPWT alone in the initial management of acute traumatic wounds. No of days required to make the wound ready for the final surgical procedure were significantly reduced in the patients treated with the combination therapy.

Keywords: Negative-pressure wound therapy, Saline, Wounds and injuries.

INTRODUCTION

Management of acute traumatic wounds has always been a great challenge for the surgeons. All the traumatic wounds are categorized as dirty wounds with a lot of contamination predisposing them to various infections. Contamination and bacterial infections retard the natural healing process of the body. Highest mortality rate among surgical patients (77%) has been due to the wound infections highlighting the importance of early management to ensure that wounds remains healthy and uncontaminated.

Slow healing due to infection is a cause of great distress to the patients. This has warranted development of newer methods to treat the wounds. Negative pressure wound therapy (NPWT) is one of them. Proposed mechanisms of NPWT includes reduction in the wound size, removing infectious material and reducing edema and promoting the perfusion, thus creating tissue micro deformation. However still some wounds pose great challenge to the treating surgeons. For this reason a novel addition to conventional NPWT has been made i.e. instillation with various fluids and antiseptics including normal saline called negative pressure wound therapy with instillation (NPWTi).

The rationale for NPWT with saline is that it not only removes devitalized tissue but also removes dirt and bacteria. So combining an already widely accepted therapeutic modality i.e. NPWT with instillation seems a very effective option.

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instilled wound therapy system (KCL USA Inc. San Antonio, TX) and its commercial availability in 2003\(^5\). NPWTi is believed to be superior over conventional NPWT alone for enhancing autolytic and mechanical debridement and decreased microbial burden\(^6\). Negative pressure wound therapy has been shown to improve the healing process of infected wounds and to avoid infections associated with the bio-film, when applied as early as possible. Previous studies have attributed these benefits to the secondary effects of NPWT, including fluid removal, modulation of inflammation, and the stimulation of wound healing signaling pathways\(^4,8\).

A recent study compared NPWT with instillation to conventional NPWT. It was concluded that number of operative visits were significantly lower for 6 and 20 minute dwell time groups compared with no instillation group. Time to final surgical procedure was significantly shorter for the 6 and 20 minute dwell time groups compared with the no instillation group\(^9\). Dwell time is defined as the amount of time required for contact of a chemical agent with a surface.

Considering the immense workload and its expected repercussions in the form of financial burden, short hospital stay and quick turnover of patients are need of the hour. NPWT with instillation may have a role in earlier healing of the wounds. No study has been done in our part of the world to explore this phenomenon so this study was planned to compare the standard NPWT with NPWT with instillation in management of acute traumatic wounds on basis of time taken in definitive surgical closure of wounds.

**MATERIAL AND METHODS**

This randomized control trial was conducted at Plastic Surgery Department, Combined Military Hospital Rawalpindi from July to September 2017. After approval from hospital ethical committee, total of 40 patients were included in the study. Patients were selected by using the purposive sampling technique. Sample size was calculated by using the WHO calculator. Patients of both genders coming to accident and emergency department Combined Military Hospital Rawalpindi with acute traumatic wounds were included in the study. Acute traumatic wound was defined as wound 3-25 cm in length and less than 3 cm in depth. Wounds with exposed bone without periostium or exposed tendons without paratenon were excluded from the study as they required special surgical procedures for definitive closure and were liable to create the bias. Wound with exposed vital structures like nerves or vessels were also not included in the study as this is a contraindication for applying the negative pressure wound therapy. Patients less than 12 years and more than 80 years and with uncontrolled diabetes mellitus, osteomyelitis, any malignancy, or immuno-compromised status were also excluded from the study. Written informed consent was taken from each patient and necessary investigations including full blood count and required radiological investigations were carried out. Debridement of wound was done under anesthesia with removal of the entire slough, necrotic and devitalized tissue. After dividing the patients randomly into two groups i.e. A and B by lottery method, negative pressure wound therapy was applied to both the groups using sterilized roll gauze. Group A was treated with conventional negative pressure wound therapy applied at 125 mm Hg for 30 mins/hour, whereas in group B irrigation of normal saline was done through drain till the time roll gauze was visibly wet through transparent dressing indicated by change in color. A dwell time of 5 minutes was given and then negative pressure wound therapy applied at 125 mmHg for 30 mins/hour. This cycle was repeated every 8 hours. New dressing was changed every 3rd to 5th day in operation theatre in both the groups and swab for bacterial culture sensitivity was taken. Both groups were started with injectable antibiotics at the time of admission and antibiotic therapy was adjusted according to culture sensitivity report later. Length of hospital stay was defined as number of days from date of admission to the date of
discharge. In both study groups, time for preparation of wound for definitive surgical closure was calculated in days as decided by two consultant plastic surgeons independently. Final surgical procedure was defined as surgical closure with suturing or grafting. Total number of operative visits was also calculated for both the groups. A structured proforma was designed to collect the data from both the groups.

Data was analyzed by using the Statistical Package for Social Sciences (SPSS) 21.0. Descriptive statistics were used for the age, gender and site of the wound. Mean time to prepare the wound for the final surgical procedure was calculated for both the groups. Number of operative visits was also calculated for both the groups. Student t-test was applied to establish the difference in the number of days required for the final surgical procedure and number of operative visits of the two groups. A p-value <0.05 was considered significant.

RESULTS

A total of 50 patients were approached to participate in the study. Three refused participation and 04 were ineligible due to exclusion criteria (03 had bony exposure in the wounds and 01 had exposed vessels requiring immediate flap coverage). After being consented, an additional 03 did not provide complete data at baseline, leaving 40 patients. Mean age of the patients was 37.98 ± 6.275. Commonest site of the wound was the foot (65%) followed by thigh (20%) and the gluteal region (5%). General characteristics of study participants are given in table-I. In group-A (conventional negative pressure therapy) 14 patients were male and 06 were females. Mean age of the patients was 35.86 (± 4.185). Whereas in group B, 15 patients were male and 05 were female. Mean age of the patients was 39.658 ± 3.155 (p-value=0.002). Table-II shows that the mean time required for the final surgical procedure for conventional group A was 27.4 ± 2.2 days and for group B it was 21.92 ± 3.6 days (p-value<0.001). Number of operative visits was also significantly less in group B i.e. 3.8 ± 0.2 days as compared to group-A 5.7 ± 0.4 (p-value<0.001).

DISCUSSION

Surgical wounds pose a great burden on the budget of any health care system. Every year millions of people suffer from the traumatic wounds. Delayed healing or acquiring of the infection not only prolong the functional disability of the individual but also increases the

Table-I: Baseline characteristics of the study patients (n=40).

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Group A (n=20)</th>
<th>Group B (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>37.98 ± 6.275</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range (min-max)</td>
<td>16-45 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site of wound n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot</td>
<td>26 (65)</td>
<td>08 (20)</td>
<td></td>
</tr>
<tr>
<td>Thigh</td>
<td>02 (5)</td>
<td>02 (5)</td>
<td></td>
</tr>
<tr>
<td>Gluteal region</td>
<td>02 (5)</td>
<td>02 (5)</td>
<td></td>
</tr>
<tr>
<td>Arm/Forearm</td>
<td>02 (5)</td>
<td>02 (5)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>02 (5)</td>
<td>02 (5)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14 70</td>
<td>15 75</td>
<td>0.718</td>
</tr>
<tr>
<td>Female</td>
<td>06 30</td>
<td>05 25</td>
<td></td>
</tr>
</tbody>
</table>

Table-II: Outcomes of the Subjects in both the groups.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group A (NPWT)</th>
<th>Group B (NPWTi)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (days) to final surgical procedure, mean (SD)</td>
<td>27.4 ± 2.2</td>
<td>21.92 ± 3.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Number of operative visits</td>
<td>5.7 ± 0.4</td>
<td>3.8 ± 0.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
cost of management\textsuperscript{10,11}. Ours is a developing country with limited resources so delay in the healing process poses burden on the health care system as well as deprive the individual from being fully functional and carry on his job and daily activities. Final surgical closure is the ultimate treatment of all the traumatic wounds\textsuperscript{10}. Good initial management, preparation with daily dressings and strict control of infection can significantly reduce the time to make the patient reach that ultimate goal\textsuperscript{13}. Various treatment options have been used for this purpose. NPWT has been studied in the past and it has a clear role in wound healing, wound bed preparation, inhibition of bacterial growth and reduction of infection\textsuperscript{13}. Similarly role of instillation of an antiseptic solution to the infected wound has also been well established\textsuperscript{14}. They work by quickening the process of resolution of edema and improving local microcirculation\textsuperscript{15}. Question for the treating surgeons is that whether these two modalities which are individually effective, can their combination be more effective than the individual therapies? The answer to this question generated by our study is positive and in accordance with the similar studies done in recent past in different parts of the world\textsuperscript{9,14}. The positive answer generated by our as well as other studies is a ray of hope for both the patients and the treating surgeons. Cost effective and quick route to recovery is a real key for both the parties.

Combination of both the therapies not only shortened the time required to prepare the wound for the surgery but also reduced the number of operative visits. Various other studies done in the past have also revealed the same results\textsuperscript{14,6}. The two parameters which were taken as markers of recovery in our study were clinically relevant to both the patients and the surgeon and also to the health care administrators that how the use of a relatively cost effective modality can change the fate of the wound and the whole pathway of recovery.

Various antiseptic solutions have been used in the past but results and safety of normal saline makes it superior to other solutions. This is cost effective, easily available and safe solution which can make the prognosis of traumatic wound better without posing much burden on him and the health care system\textsuperscript{16}. So all these qualities make this solution best for the combination with negative pressure wound therapy. A recent study has concluded that both simple and complicated wounds can be effectively managed with Negative pressure wound therapy with instillation, resulting in markedly accelerated tissue granulation and thus earlier closure of the defect\textsuperscript{17,18}.

Our study had few limitations. As negative pressure wound therapy and normal saline had to be administered in each group so blinding of patients and the staff was not possible. Moreover there was no placebo control group in our study. Furthermore, the inclusion and exclusion criteria did not allow to study on degloved and very deep wounds, decreasing the generalizability of this study. Outcome of this study can also not be generalized due to small sample size so we suggest further trials on a broader based and a more representative sample size to generate the generalizable results on this very important intervention.

CONCLUSION

Negative pressure wound therapy with instillation of normal saline was a better treatment option as compared to NPWT alone in the initial management of acute traumatic wounds. Number of days required to make the wound ready for the final surgical procedure were significantly reduced in the patients treated with the combination therapy.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES