Prospective Randomized Comparative Study of Negative Pressure Wound Therapy (NPWT) With Negative Pressure Wound Therapy with Saline Instillation (NPWTi) In Diabetic Foot

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I. Aim:
To compare the use of negative pressure wound therapy (NPWT) with negative pressure wound therapy with saline instillation (NPWTi) in cases of diabetic foot ulcers in terms of
◦ Thickness of granulation achieved after 10 days of therapy
◦ Time taken for the wound to heal and become fit for either surgery (SSG or secondary suturing).
◦ Reduction in wound area after 7 days of therapy
◦ Length of hospital stay
◦ Number of OR visits
◦ Cost effectiveness.

II. Method:
Study setting – Department of General Surgery, Government Rajaji Hospital, Madurai Medical College.
Study period - MAY 2017 to APRIL 2018
Study population – All patients admitted in Department of General Surgery, Government Rajaji Hospital, Madurai Medical College with diabetic foot ulcers.

SAMPLE SIZE:
Sample size was calculated using “epi info” software to detect a mean difference of 1.3 in time taken to revert back and standard deviations as 1.7 and 1.36 respectively in each procedure. It came to 32 in each group which was rounded off to 30.
Confidence interval was taken as 95% and power as 80%
So 30 patients were recruited in each of the surgical procedure

OUTCOME:
◦ Efficacy between the procedures were determined based on following criteria:
  ◦ Thickness of granulation achieved after 7 days of therapy
  ◦ Time taken for the wound to heal and become fit for surgery
  ◦ Reduction in wound area
  ◦ Length of hospital stay
  ◦ Number of OR visits
  ◦ Cost effectiveness

III. Statistical Analysis:
◦ Data will be entered into Microsoft Excel (Windows 10; Version 2016)
◦ Analyses will be done using the Statistical Package for Social Sciences (SPSS) for Windows software (trial version 22.0; SPSS Inc, Chicago)
◦ Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies and percentages will be calculated for categorical variable
◦ Comparison between groups will be analysed using Independent t test
IV. Results:

- A total of 60 patients were included in the study with 30 in each surgical procedure.
- The age of the study population ranged between 41 – 70 with a mean of 61.28 and standard deviation of 7.048.

![Chart 1: Age distribution of patients](image)

![Chart 2: Distribution of study subjects by gender](image)

![Chart 3: Distribution of occupation](image)
Prospective Randomized Comparative Study of Negative Pressure Wound Therapy (NPWT) With...

**Chart 10: Mean cost of hospitalisation per procedure**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>NPWT</th>
<th>NPWTi</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness of GranTiss (mm) (mean)</td>
<td>4.47 ± 1.27</td>
<td>4.48 ± 1.58</td>
<td>-.051</td>
<td>58.000</td>
<td>.960</td>
</tr>
<tr>
<td>Reduction in Wound Area (%) (mean)</td>
<td>13.97 ±6.08</td>
<td>20.63 ±5.17</td>
<td>-4.574</td>
<td>56.530</td>
<td>.000</td>
</tr>
<tr>
<td>Length of HospStay (days) (mean)</td>
<td>5.1 ±0.85</td>
<td>1.97 ±0.72</td>
<td>15.475</td>
<td>56.539</td>
<td>.000</td>
</tr>
<tr>
<td>Time for Wound Healing (days) (mean)</td>
<td>27.5 ±2.24</td>
<td>16.47 ±1.93</td>
<td>20.461</td>
<td>56.718</td>
<td>.000</td>
</tr>
<tr>
<td>OR Visits (number) (mean)</td>
<td>2.63 ±0.57</td>
<td>1.30 ±0.54</td>
<td>9.464</td>
<td>57.914</td>
<td>.000</td>
</tr>
<tr>
<td>Cost (rs) (mean)</td>
<td>57600 ±14074</td>
<td>39200 ±8209</td>
<td>6.178</td>
<td>46.687</td>
<td>.000</td>
</tr>
</tbody>
</table>

**Table: Comparison of outcome between NPWT and NPWTi**

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