Comparative Study on Healing Of Diabetic Plantar Foot Ulcers Treated By Conventional Measures Alone Vs Conventional Measures Along With Bohler Iron Plaster Cast

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Abstract:
Background And Objectives: India, being diabetic capital of the world and the most common complication of diabetes mellitus is diabetic foot ulcer. The aim of the study is to compare the healing of diabetic plantar foot ulcers when treated with conventional measures alone vs conventional measures along with bohler iron plaster cast. Bohler iron plaster cast provides complete offloading of foot thus causing dispersion of pressure points away from ulcer site.

Methods: A prospective comparative study for a duration of 1 year from 2017 – 2018 was undertaken in patients with diabetic plantar foot ulcers in Government Rajaji Hospital, Madurai. A total of 60 patients were recruited for the study based on the eligibility criteria and after obtaining informed written consent. Relevant data regarding history, clinical examination, investigations were collected and properly recorded. The patients would be divided into Group A and Group B. The former (Group A) treated with conventional measures alone and the latter (Group B) treated with conventional measures along with bohler iron plaster cast. The patients were followed up for 1 month and healing of ulcer is assessed by means of Pressure Ulcer Scale for Healing (PUSH) scores before and after intervention in each group.

Results: Out of the 60 patients, none of the patients developed any new ulcers. There was a good ulcer healing evidenced by significant reduction in the mean Pressure Ulcer Scale for Healing score after 1 month of intervention. There is a statistical difference as the mean of pre-PUSH scores of 10.27 is greater than Post-PUSH score 7.60 in the group A and the mean of Pre-PUSH scores 8.65 is greater than post PUSH score 5.93 in the group B.

Conclusion: On analysis, it is found that there is significant decrease in ulcer size, exudate amount and change in type of tissue when treated with conventional measures along with bohler iron plaster cast. Thus by using appropriate offloading device which enables pressure dispersion from the ulcer site promotes better wound healing of diabetic plantar foot ulcers thereby preventing major complications which results in morbidity and mortality in most diabetic patients.

Keywords: Pressure Ulcer Scale for Healing (PUSH) scores, Bohler iron plaster cast, conventional dressings.

I. Introduction

India, being diabetic capital of the world and the most common complication of diabetes mellitus is diabetic foot ulcer. The major tenets in diabetic foot ulcer healing are

1. Debridement
2. Regular dressings
3. Appropriate antibiotics if infection supervenes
4. Offloading (pressure dispersion from ulcer site)

Offloading of unperceived areas of plantar stress is critical for preventing and effectively treating diabetic foot ulcer disease. The complications of diabetes mellitus can be acute or chronic based on presentation. Acute complications include diabetic ketoacidosis, Hyperglycemic hyperosmolar state and hypoglycemia. Chronic microvascular complications include retinopathy, nephropathy, neuropathy and diabetic foot ulcer disease. Macrovascular complications include accelerated atherosclerosis, myocardial infarction, stroke and lower extremity gangrene.
II. Aims And Objectives

The aim of the study is to compare the healing of diabetic plantar foot ulcers when treated with conventional measures alone vs conventional measures along with bohler iron plaster cast. Thus by using bohler iron plaster cast it enables visualization of ulcer through the window made in the cast which favours daily dressing and minimal debridement.

Bohler iron plaster cast provides complete offloading of foot thus causing dispersion of pressure points away from ulcer site.

III. Review Of Literature

MATERIALS AND METHODS
DESIGN OF STUDY:
Prospective study

PERIOD OF STUDY:
1 year

COLLABORATING DEPARTMENT:
Nil

SAMPLE SIZE:
60 patients are enrolled for the study after obtaining valid consent

SELECTION OF STUDY SUBJECTS:
Diabetic patients presented to surgical OPD with plantar foot ulcers in Government Rajaji Hospital, Madurai, satisfying the inclusion criteria were recruited for this study after obtaining valid consent.

ETHICAL CLEARANCE:
Obtained

CONSENT:
Individual written and informed consent

CONFLICT OF INTEREST:
None

FINANCIAL SUPPORT:
Nil

PARTICIPANTS:
Diabetic patients presented to surgical OPD with plantar foot ulcers in Government Rajaji Hospital, Madurai, satisfying the inclusion criteria were recruited for this study after obtaining valid consent.

INCLUSION CRITERIA
1. Diabetic patients with plantar ulcers (forefoot/midfoot/hindfoot),
2. Patients with wagner ulcer grading 2 or 3,
3. Patients with palpable peripheral pulses,
4. Patients consented for inclusion in the study according to designated performa.

EXCLUSION CRITERIA
1. Patients with wagner ulcer grade 4 or 5,
2. Patients with lowerlimbedema,
3. Patients requiring assistive device for unstable motility,
4. Patients not consented for inclusion in the study.

STUDY DESIGN
This is a prospective study on healing of Diabetic plantar foot ulcers treated with conventional measures alone vs conventional measures along with bohler iron plaster cast.
BOHLER IRON PLASTER CAST
It incorporates orthotic metal upright with rubber heel footplate with cast and a window over ulcer site.

PROCEDURE
The patients are seen in surgical OPD routine hours and were diagnosed on the basis of history, clinical examination and investigations like Doppler.

In one group of subjects, the ulcer is debrided conventionally, until healthy tissue is encountered, if pus is present, appropriate antibiotics are given. Patients were taught home dressing which has to be done daily & foot care education imparted to unaffected foot, i.e., avoidance of bare foot walking, daily foot inspection, hygiene, proper trimming of nails.

In another group of subjects, ulcer is managed conventionally with debridement, antibiotics and dressings, along with a Bohler Iron Plaster Cast being used as an offloading device.

In case of Bohler Iron cast, Casting procedure begin with covering soft cotton roll adequately to protect the skin, particularly over bony prominences and plaster of paris cast applied from below knee upto sole of foot. The toes are left free. A window is left in the cast boot at the ulcer site to allow daily wound care by conventional measures. A bohler iron upright placed over cast on medial and lateral border of leg & over the heel and it incorporates a rubber heel foot plate one and half inch away from foot. Roller bandage applied over bohler iron to secure it in place. One inch heel raise given to contralateral foot (as half inch compensated in gait during foot clearance).

Subjects are evaluated twice i.e., before and after 1 month in both the groups. A questionnaire which included history, clinical examination, pressure ulcer scale for Healing (PUSH) are used in both.

PRESSURE ULCER SCALE FOR HEALING (PUSH)

<table>
<thead>
<tr>
<th>Length * Breadth (cm^2)</th>
<th>0</th>
<th>1 &lt;0.3</th>
<th>2 0.3 – 0.6</th>
<th>3 0.7-1.0</th>
<th>4 1.1-2.0</th>
<th>5 2.1-3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6</td>
<td>7 4.1-8.0</td>
<td>8 8.1-12.0</td>
<td>9 12.1-24</td>
<td>10 &gt;24.0</td>
<td></td>
</tr>
<tr>
<td>Exudate Amount</td>
<td>0</td>
<td>None</td>
<td>1 Light</td>
<td>2 Moderate</td>
<td>3 Heavy</td>
<td></td>
</tr>
<tr>
<td>Tissue Type</td>
<td>0</td>
<td>Closed</td>
<td>1 Epithelial tissue</td>
<td>2 Granulation tissue</td>
<td>3 Slough</td>
<td>4 Necrotic tissue</td>
</tr>
</tbody>
</table>

Total PUSH Score = A+B+C
Max. score = 17 (Not healed)
Min. score = 0 (completely healed)

Thus, by means of pressure ulcer scale for healing (PUSH) scores, we can assess the healing of ulcer. Higher the score, ulcer is not healing and lower the score, ulcer is healing well.
RESEARCH HYPOTHESIS
Offloading of foot by means of bohler iron plaster cast in diabetic foot ulcers will result in pressure dispersion from ulcer site, moreover it offloads the entire foot, not only the ulcer site. Thus in management of diabetic plantar foot ulcers by conventional measures along with bohler iron cast will hastens healing process.

STATISTICAL ANALYSIS
Study sample - 60
Participants are randomized into two groups
Group A - Conventional measures alone
Group B - Conventional measures with Bohler Iron Plaster Cast
Paired test is used to compare Pressure ulcer scale for healing scores of each group before and after 1 month of intervention.

IV. Results

AGE AND GENDER DISTRIBUTION
The following table shows age distribution among group A.

<table>
<thead>
<tr>
<th>Age group</th>
<th>No.of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>0</td>
</tr>
<tr>
<td>21-40</td>
<td>10</td>
</tr>
<tr>
<td>41-60</td>
<td>15</td>
</tr>
<tr>
<td>61-80</td>
<td>5</td>
</tr>
</tbody>
</table>

The following table shows age distribution among group B.

<table>
<thead>
<tr>
<th>Age group</th>
<th>No.of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>0</td>
</tr>
<tr>
<td>21-40</td>
<td>10</td>
</tr>
<tr>
<td>41-60</td>
<td>18</td>
</tr>
<tr>
<td>61-80</td>
<td>2</td>
</tr>
</tbody>
</table>
The following table shows the gender distribution among Group A and Group B.

<table>
<thead>
<tr>
<th>Group</th>
<th>Males (%)</th>
<th>Females(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Group B</td>
<td>73</td>
<td>27</td>
</tr>
</tbody>
</table>

**GENDER DISTRIBUTION AMONG GROUP A AND GROUP B**

Outcomes are measured based on the Pressure Ulcer Scale for Healing in Group A and Group B. Out of the 60 patients, none of the patients developed any new ulcers.

There was a good ulcer healing evidenced by significant reduction in the mean Pressure Ulcer Scale for Healing score after 1 month of intervention.

There is a statistical difference as the mean of pre-PUSH score of 10.27 is greater than Post-PUSH score 7.60 in the group A and the mean of Pre-PUSH score 8.65 is greater than post PUSH score 5.93 in the group B.

**V. Discussion Of The Study**

In this study, comparison of healing of diabetic plantar foot ulcers treated with conventional measures alone with healing of diabetic plantar foot ulcers treated with conventional measures along with Bohler iron plaster cast has been made.

Patients included in this study are categorized into group A and group B. Patients in the group A and group B are evaluated with help of pressure ulcer scale for healing (PUSH) score before and after intervention. Each group constitutes 30 patients and their PUSH scores are calculated individually and compared between the two groups.

**COMPARISON OF PRE PUSH AND POST PUSH SCORES**

In the group A, means of pre PUSH score is 10.27 and means of post PUSH score is 7.60. There is decrease post PUSH score after intervention which has been statistically measured.
In the group B, means of pre PUSH score is 8.65 and means of post PUSH score is 5.93. There is a decrease in post PUSH score after intervention which has been statistically measured. The test is statistically significant with the p value <0.05, thus confirming that there is significant decrease in size, exudate and tissue type, thus augmenting healing process in diabetic ulcer foot patients.

VI. Conclusion

The study revealed that healing of diabetic foot ulcers treated with conventional measures along with Bohler iron plaster cast facilitates better healing when compared with that of ulcers treated with conventional measures alone.

This has been evident by calculating pressure ulcer scale for healing (PUSH) scores before and after intervention.

On analysis, it is found that there is significant decrease in ulcer size, exudate amount and change in type of tissue when treated with conventional measures along with Bohler iron plaster cast.

Thus by using appropriate offloading device which enables pressure dispersion from the ulcer site promotes better wound healing of diabetic plantar foot ulcers thereby preventing major complications which results in morbidity and mortality in most diabetic patients.

VII. Summary

- This is a prospective study of 60 patients of diabetic plantar foot ulcers in Madurai Medical College.
- The most common complication of diabetes is diabetic ulcer foot disease, which left untreated can lead to unexpected consequences like amputation.
- The major tenets in diabetic ulcer foot healing are debridement, dressings and offloading.
- Offloading devices enable dispersion of pressure from the ulcer site.
- Diabetic plantar foot ulcers treated with conventional measures along with Bohler iron plaster cast facilitates better wound healing when compared with those treated with conventional measures alone which has been evident by PUSH scores.

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