A PROSPECTIVE STUDY ON THE HEALING OUTCOMES OF DIABETIC FOOT ULCER AFTER THE IMPLEMENTATION OF CLINICAL PHARMACIST INTERVENTION GUIDELINE

1Dr K Ramswarup Jawahar, 2Dr B Akshay, 3Dr B Bhargav

1Department of General Medicine, 2,3Department of Radiology, 1,2,3Konaseema Institute of medical Sciences Research Foundation, Amalapuram, Andhra Pradesh, India

*Corresponding author : dr.bhargavb321@gmail.com (Dr Bhargav)

Abstract

This present research focuses on diabetes and its complications are quickly suitable for the world wide considerable cause of morbidity and mortality. Diabetic Foot Ulcer (DFU) causes major health issues in diabetes patients. 15% to 25% of diabetic patients get affected by DFU in their life time. Diabetic foot ulcers are the cause for physical disability and poor quality of life among diabetic patients which leads to the loss of limb, major health as well economic sufferings and even death. Clinical pharmacy is a health care discipline which focuses on clinical pharmacist’s involved patient care programmes to provide rationality in drugs use, to improve health and prevention and management of diseases. The aim of the study was to identify the essential domain in the management of DFU in comparison with the international standards and to implement guidelines for the effective management of Diabetic foot ulcer. The prospective study was conducted on determination of wound ulcer outcome among 50 DFU patients admitted in the surgery wards of tertiary care hospital by wound classification, switching over of antibiotics, culture tests, hospital stay, and recurrence of DFU and wound healing rate after the implementation of clinical pharmacist intervention guideline. The healing of ulcers improved while outcome percentage was found to 16% in the control group and 32% in the interventional group. The ulcer healing impression was found to be healed in (4 vs. 8 patients), partially healed (10 vs. 11 patients), requiring surgical intervention (7 vs. 5 patients) and unhealed (4 vs. 1 patient) in the control vs. Intervention group, respectively. There was improved healing impression in the control vs Intervention group. Implementation of clinical pharmacist’s intervention guideline and antibiotic policy brought a significant improvement in terms of reduction in the number of ulcers, size of ulcers, ulcer grade and improved ulcer healing duration.

Keywords: Diabetic foot ulcer, Clinical pharmacy services, patient education, wound care

How to cite this article: Jawahar R, Akshay, Bhargav (2020): A prospective study on the healing outcome of diabetic foot ulcer after the implementation of clinical pharmacist intervention guideline, Ann Trop Med & Public Health; 23(S21): SP231933. DOI:

1 Introduction
Diabetes mellitus (DM) is a metabolic disorder caused by acquired and additionally procured insufficiency in the insulin secretion by the pancreas, or by the incapability of the insulin produced. It leads to extended amount of blood glucose, which can harm many body structures and organs like the veins and nerves. 15% to 25% of diabetic patients get influenced in their lifetime. Diabetes and its complications are rapidly becoming the world’s most significant cause of morbidity and mortality. It is predicted that by 2040 there will be over 642 million people with diabetes in the world. Foot ulcer prognoses to physical disability and poor quality of life, leading to loss of limb, major sufferings and cost and even death. Patients with DM are inclined to various confusions, for example, diabetic foot ulcers (DFU) [3]. DFU is a typical complexity of DM that has indicated an expanding pattern over earlier many years. Altogether, it is assessed that 15% of patients with diabetes will experience the ill effects of DFU during their lifetime. Albeit exact figures are hard to acquire for the pervasiveness of DFU, the predominance of this difficulty goes from 4%-27%. Clinical pharmacy is a healthcare discipline that focuses on clinical pharmacists involved patientcare programmers to provide rationality in drug use, to improve health and prevention and management of diseases. The aim of the study was to identify the essential domain in the management of DFU in comparison with the international standards and to implement guidelines for the effective management of Diabetic foot ulcers.

MATERIAL AND METHODS
The prospective study was performed to evaluate the improvement in healing outcomes of diabetic foot ulcer viz., reduction in the number and size of ulcers, healing duration, status at the time of discharge, change of antibiotics and reduction in wound grade in the control and clinical pharmacist intervened group. The revision was conduct among the DFU patients admit in the departments of surgery of a tertiary care hospital. The study protocols were approved by the Institutional Ethical Committee and every patient’s consent was obtained.
Inclusion Criteria:
- Diabetic patients with foot ulcer
- Patients prescribed with antibiotics

Exclusion Criteria:
- Patients who are unable to undergo all the studies related procedures
- Patients who had any other concurrent illness or undergone major surgery
- Patients who were pregnant or lactating

Figure 1 Prospective study design on wound ulcer outcome in DFU patients

Infectious Diseases Society of America (IDSA) and IWGDF Diabetic Foot Infection classifications were adopted in the clinical pharmacist guideline to characterize the injury and recommend anti-infection agents. The University of Texas grouping is considered as a thorough scale and incorporates hazard stratification and communicates tissue breakdown, contamination and gangrene independently. In spite of the fact that Texas arrangement depicts the review of the injury in more subtleties, it does exclude proportions of neuropathy or ulcer zone.

Figure 2 Guideline on Treatment Algorithm for Treating Diabetic Foot Ulcer
Table.1. Classification system has analysis in University of Texas

<table>
<thead>
<tr>
<th>Stage</th>
<th>Grade</th>
<th>0</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Pre or post ulcerative completely epithelialized lesion</td>
<td>Superficial wound</td>
<td>Wound penetration up to tendon or capsule</td>
<td>Wound penetration up to bone or joint</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Infection</td>
<td>Infection</td>
<td>Infection</td>
<td>Infection</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Ischemia</td>
<td>Ischemia</td>
<td>Ischemia</td>
<td>Ischemia</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Infection and Ischemia</td>
<td>Infection and Ischemia</td>
<td>Infection and Ischemia</td>
<td>Infection and Ischemia</td>
<td></td>
</tr>
</tbody>
</table>

The IDSA rule demands profound tissue acquired as the sample for performing culture test to get exact outcomes than the swab samples from insufficiently debrided wounds. Type 1 and 2 diabetic patient's foot care by National Institute of Clinical Excellence (NICE) rule demand understanding focused consideration as indicated by per quiet individual needs. Data collected for the study was tabulated and the result analysis was done using GraphPad Prism 7.0. Descriptive statistics includes the calculation of mean, standard deviation and percentage. Paired T test and ANOVA was used to compare the significance between the baselines and follow up within the control as well as in interventional group. Unpaired T test was performed to compare the significance between the control and interventional group. The effects were found to be significant to the least significant difference at 5% level of significance.

RESULTS
The ulcer size was found to be ≤ 1 cm in 7 and 6 patients, ≤ 3 cm in 13 and 11 patients and > 3 cm in 5 and 8 patients, in the control and interventional group, respectively during the admission and the ulcer size was found to ≤ 1 cm in 5 and 9 patients, ≤ 3 cm in 7 and 2 patients and > 3 cm in 3 and 1 patient, in the control vs. interventional group, respectively during the discharge. There is notable wound size reduction in the interventional group from > 3 cm to ≤ 3 cm or ≤ 1 cm in the interventional group compared to control group (Fig3).
The healing of ulcers improved outcome percentage was found to 16% in the control group and 32% in the interventional group. The ulcer healing impression was found to be healed in (4 vs. 8 patients), partially healed (10 vs. 11 patients), requiring surgical intervention (7 vs. 5 patients) and unhealed (4 vs. 1 patient) in the control vs. intervention group, respectively. There was improved healing impression in the control vs. intervention group (Table 2).

The DFU Healing Duration was 1 week for 6 and 9 patients, 2 weeks for 6 and 7 patients, 3 weeks for 6 and 3 patients, 4 weeks for 7 and 4 patients and 5 weeks for 4 and 2 patients in the control vs. intervention group respectively. There was improvement in the healing duration in the intervention group compared to control group (Fig 4).
The number of switching over of antibiotics was found to be once in 7 vs. 3 patients and 18 vs. 1 patient in the test group compared to interventional group. There was improved outcome percentage in the intervention compared to control group (Fig5).

**DISCUSSION**

**Development of Guideline and its Outcome**

Clinical practice is continuously evolving because of significant changes in the incidence; increasing consequent clinical evidences on new and existing treatments especially in non-communicable diseases will influence the disease occurrence clinically. Belatti\(^\text{10}\), D.A., Markowitz, J.S researches identifies the highly effective treatment and the ineffective treatment influences on basis of guidelines adopted. This is one of the pioneer studies which explains on the effective guideline that focuses on the management and prevention of diabetic foot ulcer\(^\text{11}\). Importantly this is the first if its kind for the clinical, hospital and community pharmacist.
prepared by the clinical pharmacist. This guideline is prepared on the base of existing NICE guideline on DFU and the present scenario revealed by our retrospective study. Understanding the implementation of the evidence obtained through the studies by Aydin, K., and Lepäntalo, M., and clinical pharmacists practice skill the practical guideline was framed from the perspectives, 1) improving patient health safety outcomes, 2) designing the policies to encourage use of appropriate antibiotics, culture sampling techniques and effective management, 3) advising community and clinical pharmacist on evidence based patient education and counseling on DFU prevention and management. The guideline implementation was enormously welcomed by the community and clinical pharmacists and was evaluated by the clinical pharmacist experts for the quality and feasibility. This guideline highlighted points over the wound classification, first line and second line antibiotics choice and patient education were well suited for the current scenario. This will help in minimizing the switching over of antibiotics, effective treatment outcome, reduction of stay in hospital and thereby reducing the considerable direct and indirect expenses. The prospective study followed the guideline policies and proved the best results.

**Wound outcome**

As per the literature reviews and our previous studies, it was found that the guideline implementation on antibiotics use and treatment is very important. IDSA and NICE guidelines were found to be the best guidelines as they were developed with the outputs from the various study reports. A complete guideline on antibiotics use and clinical pharmacist role was prepared carefully under the supervision of a Diabetologist and it was revised by a Clinical Pharmacologist. The guideline was adopted while treating the patients and the outcomes were recorded until the patients were discharged. The ulcer size was found to be ≤ 1 cm in 7 and 6 patients, ≤ 3 cm in 13 and 11 patients and > 3 cm in 5 and 8 patients, in the control and interventional group, respectively during the admission and the ulcer size was found to ≤ 1 cm in 5 and 9 patients, ≤ 3 cm in 7 and 2 patients and > 3 cm in 3 and 1 patient, in the control vs. interventional group, respectively during the discharge. There is notable wound size reduction in the interventional group from > 3 cm to ≤ 3 cm or ≤ 1 cm in the interventional group compared to the control group. The healing of ulcers improved outcome percentage was found to 16% in the control group and 32% in the interventional group. The ulcer healing impression was found to be healed in (4 vs. 8 patients), partially healed (10 vs. 11 patients), requiring surgical intervention (7 vs. 5 patients) and unhealed (4 vs. 1 patient) in the control vs. intervention group, respectively. There was an improved healing impression in the control vs. intervention group. The DFU Healing Duration was 1 week for 6 and 9 patients, 2 weeks for 6 and 7 patients, 3 weeks for 6 and 3 patients, 4 weeks for 7 and 4 patients and 5 weeks for 4 and 2 patients in the control vs. intervention group, respectively. There was an improvement in the healing duration in the intervention group compared to the control group. The study by Warriner R.A., in 2012, worked on the study on foot ulcer outcomes when the patients were monitored closely through the follow-ups. They found...
that 63.8% of wounds healed in patients who visited hospital weekly for one month were compared with 2.0% of patients who visited every other week, patients who had vascular lower ulcers 78 of 105 wounds (52%) closed in week group compared with 0% in the every-other-week group (P = 2.40 × 10). The number of switching over of antibiotics was found to be once in 7 vs. 3 patients and 18 vs. 1 patient in the test group compared to interventional group. There was improved outcome percentage in the intervention compared to control group.

CONCLUSION

Implementation of clinical pharmacist prepared guideline and antibiotic policy brought a significant improvement in terms of reduction in the number of ulcers, size of ulcers, ulcer grade and improved ulcer healing duration. Effective implementation of antibiotic policy in empirical and therapeutic use among DFU patients reduces the switching over of antibiotics which in turn reduce the resistance to antibiotics. Teamwork of uniting various departments comprising physician, surgeon, nurse, pathologists, and clinical pharmacologists along with clinical pharmacist enhances the management of DFU management.

REFERENCES