

# Medication Utilization Practices In Patients with Diabetic Foot Ulcers in the Department Of General Surgery, Kims Hospital and Research Centre, Bangalore

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## Abstract

**Background:** Diabetic foot ulcer is a serious complication of diabetes mellitus which results in significant morbidity and mortality and results in increased risk of progression of ulcer that may lead to amputation.

**Objectives:** The aim of study was to assess the prescribing practices of medications used in the management of Diabetic foot ulcer, Prevalence of patients in the department of surgery and Preparation of patient information leaflet.

**Methodology:** A prospective observational study was conducted in the department of surgery KIMS Hospital and Research Centre for a period of 6 months. Data collection form with patient consent was used for collecting data.

**Results:** 52 patients were included in the study and a total of 395 drugs were prescribed. The commonly prescribed drugs were metronidazole (26%) and combination dose (52%) of antibiotics, regular insulin (87.23%) as hypoglycemic agent, paracetamol (40.9%) and combination therapy (57.6%) of analgesics and antipyretics, Pantoprazole (36.3%) and monotherapy (59.6%) of anti-emetics and acid reducers, metoprolol (22%) and combination therapy (11.5%) of antihypertensive, combination of trypsin and chymotrypsin (44.4%) and combination therapy of anti-inflammatory drugs. Vitamins, dietary and nutritional supplements were given alongside; vitamin C being the most commonly used antioxidant (52.9%).

**Conclusion:** The study revealed that the prevalence of diabetic foot ulcer was more in males. Effective medication utilization practices of drugs and education of the patient on care and management of ulcers were required to increase the well-being and quality of life of patients.

**Keywords:** Diabetes Mellitus; Diabetic Foot ulcer; Medication utilization

## Introduction

Diabetes mellitus (DM) is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency in turn leads to chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism. As the disease progresses tissue or vascular damage which can

result in inadequate circulation to the peripheral body. This places the foot at higher risk of ulceration and infection [1].

Diabetic foot ulcer (DFU) is an open sore or wound on the foot of a patient with diabetes, most commonly located on the sole surface or bottom of the foot [2].

Diabetic foot problems, such as ulcerations, infections, and gangrene are the most common cause of hospitalization among diabetic patients. Routine ulcer care, treatment of infections, amputations and hospitalizations cost billions of dollars every year and place a tremendous burden on the health care system [3].

Approximately 15 percent of patients with diabetes will suffer from DFU's. Of those who develop a foot ulcer, 6 percent will be hospitalized due to infection or other ulcer-related complication [4].

Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations in the industrialized world. The risk of lower extremity amputation is 15 to 46 times higher in diabetics than in persons who do not have diabetes mellitus. Furthermore, foot complications are the most frequent reason for hospitalization in patients with diabetes, accounting for up to 25 percent of all diabetic admissions in the United States and Great Britain [5].

Global diabetic foot ulcer prevalence is 6.3%, which is higher in males (4.5%) than in females (3.5%) and higher in type 2 diabetic patients (6.4%) than in type 1 diabetics (5.5%). The patients with diabetic foot can be older, have a lower body mass index, longer diabetic duration, and more hypertension, diabetic retinopathy and smoking history than patients without diabetic foot [6].

The etiology for diabetic foot ulcer is multi factorial. The common underlying causes are poor glycemic control, calluses, foot deformities, improper foot care, ill-fitting footwear, underlying peripheral neuropathy and poor circulation, dry skin, etc. [7].

## Common risk factors for the development of foot ulcers in diabetics include:

- Peripheral vascular disease
- Neuropathy
- Poor glycemic control
- Cigarette smoking
- Diabetic nephropathy
- Previous foot ulcerations/amputations

The two most common risk factors are neuropathy and peripheral vascular disease [8].

## Quality of Life

Major amputation is done when the ulcerated foot either threatens patient survival or when reasonable function can no longer be expected. However, inappropriate conservative approach could conceivably enhance suffering by condemning a person to months of incapacity before they die with a non-healed ulcer. The consideration of the quality of life in patients with non-healed ulcers or different levels of amputation is therefore, of importance. With non-healing ulcers diabetic patients run a high risk of depression [9].

The gold standard for diabetic foot ulcer treatment includes debridement of the wound, management of any infection, revascularization procedures when

indicated, and off-loading of ulcer [10].

An evidence-based approach is applied when managing diabetic foot; these include controlling blood glucose level, managing co-morbid conditions, improving blood supply, removing necrotic tissue, and applying appropriate foot care. Ulcers, as previously stated, could be subdivided by characteristics such as depth of the wound, i.e. superficial and deep ulcers. Superficial ulcers undergo debridement of dead tissue until bleeding starts –a sign of healthy tissue. Negative- pressure wound closure is applied to extract any infectious residue. Gangrene may develop in superficial ulcers with underlying critical limb ischemia; this is an indication for urgent therapy.

Deep ulceration in a diabetic foot is an end-result of inappropriate treatment of an ulcer or infected gangrenous condition [11]. It is a well-known concept that blood supply is the most important factor in wound healing. Therefore, re-vascularization is a cornerstone in the management of diabetic foot. Endovascular revascularization, performed by a radiologist and vascular surgeons, is done to reduce the need for amputation [12].

## Treatment

- Control of diabetes: It is an important part of the treatment of diabetic foot ulcer.
- Diabetes precipitates infection which worsens the diabetic status. These ulcers are better managed, at least in the initial period using insulin rather than oral anti-diabetic drugs. Plain insulin is given depending upon the requirement.
- Control of infection: Once culture/sensitivity report is available, appropriate antibiotics are started. Commonly gram-positive, gram-negative and anaerobic infections exist.
- Triple antibiotics may have to be continued for a long time depending upon the nature, type and severity of infection. Presence of high grade fever with chills and rigors suggests development of multiple abscess pockets that need to be drained rather than indiscriminate change and usage of antibiotics. If infection is not controlled properly, ketoacidosis can occur.
- Local treatment of diabetic ulcer foot: Diabetic ulcer is a non- healing ulcer. Hence, initial treatment is debridement/ dressings or iodine solution and when the ulcer is converted into a healing ulcer, with pink granulation tissue, a split skin graft is applied. Small ulcers heal by granulation tissue. Dakin's solution is a chlorine releasing agent. It is bactericidal and it loosens necrotic tissue. Colistin solution contains 75 mg colistin in 50 ml normal saline, can be used if *Pseudomonas* and anaerobic organism are present.
- Various type of surgeries for diabetic foot
  - Spreading ulcer with slough- Debridement
  - Healing ulcer- Skin grafting/flaps (reverse sural flap)
  - Abscess- Incision and drainage
  - Gangrene toe- Disarticulate toe
  - Involvement of metatarsal bones- Excision of metatarsal bones
  - Gangrene confined to toes- Forefoot amputation
  - Spreading cellulitis/necrotizing fasciitis- Multiple fasciotomy/ decompression/ debridement
  - Spreading cellulitis with gangrene- Amputation below knee or above knee.
  - Ischemic limb- Revascularization, infrainguinal bypass
  - Care of the patient as a whole Recovery and healing of diabetic ulcer of the foot may range from a few weeks to a few months. During this period there are various other aspects to be looked after apart from infection and insulin.

## Role of pharmacist in DFU management

- Develop, evaluate and document pharmaceutical care practices in DFU.

- Collaborate with other health care professionals to develop treatment guidelines for DFU. Educate all health professionals who participate in pharmaceutical care.
- Participate in health screening for diabetes, and DFU (HbA1c, FBS, PPBS, etc.).
- Conducting health promotion and education programs for smoking cessation, obesity control, DFU self-practice, DFU preventive measures DFU awareness camp etc.
- Educate and collaborate community pharmacist and their services in the prevention and management of DFU.
- Referral for management from counselling centres and community pharmacies
- Research in the field of pharmacotherapeutics pharmacoepidemiology; pharmacy practice; health economics in diabetes and DFU
- To evaluate and document the results of research in order to improve all aspects of pharmaceutical care
- Participate in the formulation of antibiotic policy and its regulations
- To develop professional standards and audit procedures [13] professional standards and audit procedures [13]

## Materials & Methods

**Study design:** A prospective observational study was conducted in the Department of General Surgery for the management of diabetic foot ulcers.

**Study site:** The study was conducted at the Department of General Surgery, KIMS hospital and research centre, 1100 bedded multi-specialty hospital, Bangalore, Karnataka.

**Study duration:** The study was conducted for a period of 6 months from January 2021 to June 2021.

**Sample size:** 52 patients

### Study criteria:

Inclusion criteria:

- Age: Patients above 20 years
- Patients of both the genders
- Patients with history of diabetes for more than 10 years
- Patients willing to give the informed consent

Exclusion criteria:

- Patients with HIV/AIDS, Hepatitis B, Tuberculosis or Cancer
- Pregnant women
- Patients with complicated diabetic foot ulcers going for amputation
- Patients with multi-organ failure

**Ethical approval:** The study was approved by Institutional Ethical Committee of Kempegowda Institute of Medical Sciences Hospital and Research Centre, Bangalore.

**Study Method:** The present study was conducted to assess the medication utilization practices of patients with diabetic foot ulcer at the Department of General Surgery of the tertiary care teaching hospital, KIMS Hospital and Research Centre, Bangalore. The study started after obtaining the approval and clearance from the Institutional Ethical Committee (IEC). Patients who satisfy the above criteria were enrolled for the study after taking their consent. Data like age, gender, demographic details, and income, past medical history, past medication history, medication chart review, and therapeutic management were collected from patients and documented in Individualized Case Record Form (ICRF). The collected data were assessed for distribution of drugs, prescription pattern of drugs and possible drug-drug interactions. The number of patients coming to the Outpatient Department with DFU was documented and analysed for understanding the prevalence of diabetic

foot ulcer. Health Information Leaflets (HILs) were prepared with the help of standardized HIL available online and in literatures along with research articles. HILs were prepared in easily understandable languages and were given to the hospitalized diabetic foot ulcer patients or during the time of their visit to the hospital in the study period.

**Statistical analysis:** The data was entered in Microsoft Excel and analyzed. Categorical data were presented as frequency and percentage, and quantitative data were analyzed by descriptive method.

## Results and Discussion

A total number of 52 patients were recruited in the study. Recruited patient's demographic characteristics, drug therapy, drug interactions etc. were studied and analyzed. Out of 52 patients studied, 32 were males (61.5%) and 20 were females (38.5%). Age wise distribution is given in Fig: 1. (Figure 1)

Different classes of drugs prescribed to patients with diabetic foot ulcer are given in table 1. (Table 1, 2, 3)

Out of the 8 oral hypoglycemic drugs prescribed, Metformin was given to 4 (50%) patients, followed by metformin & glimepiride given to 3 (38%). Human Actrapid (short acting insulin) was given to 41 (87%) patients, Human Mixtard (fast acting + long acting) was given to 3 (5.7%) patients and both H. Actrapid and H. Mixtard was given to 3 (5.7%) patients. H. Actrapid was the commonly used type of insulin to manage hyperglycemia.

Mono therapy of analgesics and antipyretics were given to 19 (36.5%) patients and combination therapy was prescribed to 30 (57.6%) patients. Paracetamol was given to 27 (40.9%) patients, tramadol was given to 24 (36.3%) patients and combination of tramadol and paracetamol (ultracet) was given to 15 (22.7%) patients. Out of the 66 analgesics and antipyretics prescribed, paracetamol was the most commonly found analgesic drug. (Figure 2)

Out of the 52 patients involved, 32 (62%) were males and 20 (38%) were females. The overall data represents that there was a predominance of DFUs in males compared to females. Comparably, male population was prone

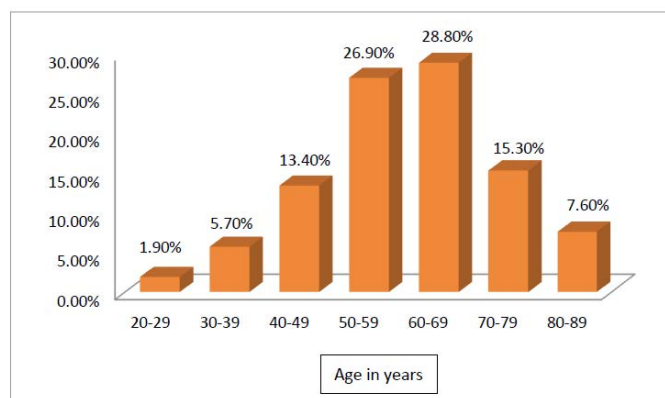


Figure 1: Age distribution.

Table 1: classes of drugs prescribed to patients with diabetic foot ulcer.

Class of drugs	No. of prescriptions	% of prescriptions
Antibiotics or Antimicrobials	88	22.2 %
Analgesics & Antipyretics	66	16.7 %
Hypoglycaemic agents	58	14.6 %
Anti-Emetics	66	16.7 %
Anti-Hypertensive	18	4.5 %
Anti-Hyperlipidemic	3	0.7 %
Antioxidants	36	9.1 %
Anti-Inflammatory	18	4.5 %
Vitamin & Nutritional supplements	26	6.5 %
Probiotics & Prebiotics	6	1.5 %
Dietary Supplements	10	2.5 %

Table 2: Distribution of Hypoglycemic drugs.

Drug	No. of patients	% Of patients
Insulin(monotherapy)	39	75%
Oral hypoglycemic drugs(monotherapy)	0	0%
Both insulin and oral hypoglycemics	8	15.3%

Table 3: Table showing distribution of Antibiotics/Antimicrobials.

Antibiotics/ Antimicrobials	No. of patients	% of patients
Amoxicillin/Clavulanate	9	10.2 %
Cefixime/Clavulanate	2	2.2 %
Cefixime/Ornidazole	1	1.1 %
Cefoperazone/Sulbactam	5	5.6 %
Ceftazidime/Tazobactam	3	3.4 %
Ceftriaxone	2	2.2 %
Ceftriaxone/Sulbactam	6	6.8 %
Cefuroxime Axetil	1	1.1 %
Ciprofloxacin	4	4.5 %
Clindamycin	4	4.5 %
Cotrimoxazole	1	1.1 %
Faropenem	1	1.1 %
Levofloxacin	1	1.1 %
Linezolid	7	7.9 %
Meropenem	2	2.2 %
Metronidazole	23	26 %
Nitrofurantoin	1	1.1 %
Piperacillin/Tazobactam	15	17 %

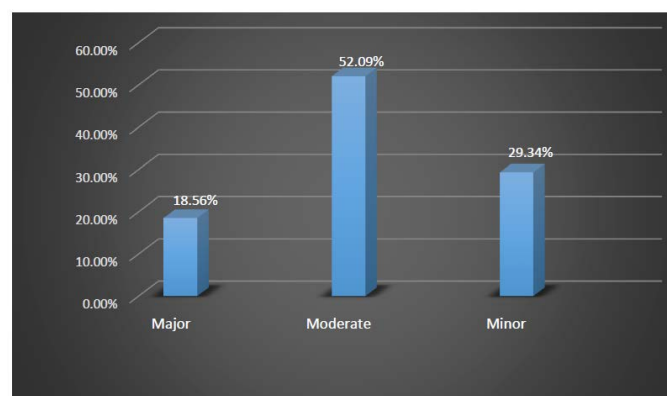


Figure 2: severity level of drug-drug interactions in the management of DFU.

to development of diabetic neuropathy resulting in DFUs. The result was comparable with the findings of a study conducted by Ramesh R et al. where the prevalence of DFU was found to be 36% more in males than in females.

Figure 1 represents the age wise distribution of diabetic foot ulcers. Out of 52 patients involved in the study, 15 patients (28.8%) in the age group 60-69 years showed highest susceptibility to DFUs. It was followed by 14 patients (26.9%) in the age group 50-59 years. The age group of 50-59 and 60-69 years were found to have the highest number of DFU. This may be due to uncontrolled glycemic levels or personal habits that lead to ulcers that do not heal. The result was comparable with the findings of a study conducted by Ramesh R et al. where the age group of 60-69 years showed the highest no. of patients with DFU.

Table 1 shows the classes of drugs prescribed to patients with DFU. Out of 395 drugs prescribed, 88 (22%) drugs were antibiotics, followed by 66 (17%)

analgesics and antipyretics and 66 (17%) anti-emetics and then 58 (15%) hypoglycemic drugs and other classes of drugs. Out of all the classes of drugs prescribed, antibiotics were found to be the most prescribed followed by analgesics and antipyretics and anti-emetics. The least prescribed drugs were found to be vitamins and nutritional supplements. The results were comparable with the study conducted by PV Saranya et al. where it was found that antibiotics (32.2%) are the most prescribed drugs followed by vitamin supplements (20.8%) followed by analgesics and antipyretics (16.2%) followed by other classes of drugs.

Table 2 represents the distribution of hypoglycaemic drugs. Out of the 47 hypoglycemic drugs, 39 (75%) patients were prescribed with insulin alone and no oral hypoglycemic drugs were prescribed alone. Both insulin and oral hypoglycemic dose were given to 8 (15.3%) patients. 5 patients were not prescribed with any of the hypoglycemic agents. This may be due to the increased effectiveness and least adverse effects of insulin that helps in the effective management of glycaemic levels in the blood. Out of the 8 oral hypoglycemic drugs prescribed, Metformin was given to 4 (50%) patients, followed by metformin & glimepiride given to 3 (38%). It was observed that different oral hypoglycemics were co administered like combination of metformin and glimepiride with vildagliptin and others showing a variation in the distribution pattern. It was found that metformin was the most prescribed oral hypoglycemic drug. Oral hypoglycemic drugs were given along with insulin in all the cases of study subjects. This result was comparable to the study conducted by Athira Pillai V et al. where biguanides were found to be the most prescribed pattern.

Out of all the 88 antibiotics prescribed, metronidazole (nitro-imidazole) was the most prescribed followed by combination of piperacillin/tazobactam (penicillin antibiotic). This result was comparable to the study conducted by Ramadi et al. where metronidazole (nitro-imidazole) and cephalosporin were found to be the highest choice of antibiotic drug in the treatment of DFUs. Figure 2 shows the severity level of drug-drug interactions in the management of DFU. Out of the 52 prescriptions analyzed, 14 prescriptions did not have any drug-drug interactions. A total of 167 drug-drug interactions were found in 38 prescriptions.

The data showed 31 (19%) major drug-drug interaction that was life threatening and had to be monitored closely; ondansetron and tramadol was the most common major drug-drug interactions found. Combining these medications can increase the risk of serotonin syndrome and an irregular heart rhythm, both rare but potentially life-threatening effects of these drugs.

87 (52%) moderate drug-drug interactions were found. The most common moderate drug-drug interaction was Metformin and human insulin whose combination can increase the risk of hypoglycemia or low blood sugar. In such cases, dose adjustments or more frequent monitoring of blood sugar is required.

49 (29%) minor drug-drug interactions were found which were bothersome or had little effect to the patient. Metronidazole and tramadol interaction was the most common minor drug-drug interaction. Q-T prolongation has been reported with metronidazole which may increase the risk of ventricular arrhythmias.

## Conclusion

In this study of medication utilisation practices, medications were more frequently used in the middle to older age group, most of them being male subjects. Majority of the patients visited the out-patient department (OPD). Metronidazole, Regular Insulin, Paracetamol, Pantoprazole, Metoprolol, Trypsin/Chymotrypsin, Vitamin C were most frequently prescribed antibiotic,

hypoglycaemic agent, analgesic, anti-emetic, anti-hypertensive, anti-inflammatory, antacid, respectively for the management of DFU. Fixed dose combinations (FDC) were the preferred mode of therapy via oral, subcutaneous or IV route of drug administration. These medications are essential for clinical management of wide range of DFI. From the study, dietary and nutritional supplements were prescribed along with these medications for prevention of further ulcers and potential complications. Drug-drug interactions were observed in the study.

The study concluded that the prescribing pattern in the surgery department to be rational. Pharmacist plays an important role in patient's healthcare. Pharmacist is now becoming more patient oriented than product oriented and have brought many changes in the life of patients. Education programmes, patient counselling, alertness enhances patient compliance and improve the quality-of-life outcomes in DFU. Drug interaction combinations must be avoided in order to bypass its adverse effect on the therapy provided and improve better patient care.

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