

A Study on Prevalence and Prescription Pattern of Diabetic Foot Ulcer

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ABSTRACT

Background: Patients with Diabetes mellitus (DM) were prone to multiple complications such as diabetic foot ulcer (DFU). It is considered as a major source of morbidity and a leading cause of hospitalization in patients with diabetes. On the other hand, once DFU has developed, there is an increased risk of ulcer progression that may ultimately lead to amputation.

Objectives: To assess the prevalence and prescription pattern of Diabetic foot ulcer. To determine the most common microorganism prevailing in the infected diabetic foot ulcer inpatient along with use of antimicrobial agent.

Methodology: The study will be conducted in General Medicine, Surgical and Orthopaedics Department of Basaweshwara Medical College Hospital & Research Centre, Chitradurga

Results: 150 diabetic patients were included in the study aged ≥ 30 years, out of this 35(23.3%) were diagnosed as diabetic foot ulcer. Among this 26 were males and 09 were females. The most common isolates from culture were Gram negative bacteria 30(73.2%). Higher utilization of Nitroimidazole 28(26.1%) and Cephalosporin 23(21.4%) was noticed for the management of bacterial Infection. Biguanides 31(44.9%) were the most commonly prescribed oral hypoglycaemic agents in patients followed by Sulphonylureas 25(36.2%). Short acting + intermediate acting insulin 14(40.2%) was most commonly given for hyperglycaemic management.

Conclusion: The study reveals prevalence of diabetic foot ulcer in diabetic patients. The effective definitive therapy of antimicrobials and antidiabetic treatment and an education of the patients on the adequate care of their lesions

were essential in increasing the welfare of patients.

Key words: Diabetes mellitus, Diabetic foot ulcer, Amputation, Prevalence, Prescription pattern

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 hyperglycaemia 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]

The diabetic foot may be defined as a group of syndromes in which neuropathy, ischemia and infection lead to tissue breakdown, resulting in morbidity and possible amputation.^[2] Diabetic foot lesions have significant health and socioeconomic problems holding adverse effects on the quality of life of the patient and imposing a heavy economic burden on the patient's family.^[3]

The primary management goals for DFU are to obtain wound closure as expeditiously as possible. In patients with DFU, glucose control is the most important metabolic factor. Inadequate control of blood sugar is the primary cause of DFU. Insulin therapy is the cornerstone in managing hyperglycaemia in diabetic foot patients in view of their long duration of

diabetes and co-existent microvascular complications and other co-morbidities. Insulin-sensitizing drugs (metformin and pioglitazone) and other oral antihyperglycaemic agents can be used as an adjunct. Achieving euglycaemia is one of the cornerstones of effective management of diabetic foot ulcer.^[4]

In an acute presentation with diabetic foot infection (DFI), there is frequently a delay in the identification of the causative organism, which may compel use of empirical antibiotic. Antibiotic therapy choice is influenced by efficacy, organism susceptibility and side effect profile. The optimum duration of antibiotic treatment is of significant clinical importance, as under-treatment will lead to persistence of infection with inherent risk of amputation and systemic sepsis, while over-treatment may increase the risk of multi-drug-resistant organisms and antibiotic-associated infections. Guidelines recommend a course of antibiotic therapy of 1-2 weeks for most mild and moderate infections and for severe 1-4 week. Parenteral therapy should be administered initially for severe infections and some moderate infections, with a switch to oral therapy when the infection is responding.^[5] Irrational use of drugs is a major health concern of present day medical practice. Drug prescribing studies can identify irrational prescribing pattern and can suggest modification in the current prescribing practices, which will not only reduce the treatment cost, non-compliance but will also help in reducing the complications. Therefore, this study designed to explore the drug-prescribing pattern among the adult diabetic patients.^[6] The World Health Organization (WHO) developed a core prescribing indicators to measure the degree of poly pharmacy, the tendency to prescribed drugs by generic name and overall level of use of antibiotics and injections. Ineffective treatment, unnecessary prescription of drugs particularly antimicrobials and as injections, development of resistance to antibiotics, adverse effects and economic burden both

on the patients and the society are inevitable consequences.^[7]

Therefore from the above consideration and facts it is necessary to conduct a “study on Prevalence and Prescription pattern of diabetic foot ulcer”.

MATERIALS AND METHODS

Study design: A prospective observational study.

Study site: The study was conducted on In-patient of General Medicine, Surgical Department and Orthopaedic department of Basaweshwara Medical College Hospital & Research Centre Chitradurga.

Study period: The study was conducted for a period of six months.

Study subjects: The study included the patients who met the following criteria

Inclusion Criteria:

Age: 30 years and above

Patient of both genders

Patients who are diagnosed with Diabetic Mellitus

Patient who are diagnosed with Diabetic foot infection

Exclusion Criteria:

Pregnant women

Psychiatric patients

Non diabetic foot infections

Patient who are not willing to give consent form

Ethical approval:

The study was approved by the Institutional Ethical Committee of Basaweshwara Medical College Hospital & Research Centre, Chitradurga.

Sources of data:

Medical records of the patient

Direct communication with the patient

Laboratory results

Microbiological profile

Study procedure:

The study was started after obtaining the approval from Institutional ethical

committee (IEC) of SJM college of pharmacy

Subjects who satisfy the above criteria were enrolled for the study after taking the consent.

Diabetic patients were identified and collected demographic details such as name, age, gender, diagnosis as well as current medication therapy and microbiological data was documented into an Individualized Case Record Form (ICRF).

The collected data was assessed for prevalence of diabetic foot ulcer, prescription pattern and monitor possible drug-drug interaction, adverse drug reaction and to find out pattern of microorganism prevailing diabetic foot ulcer

Statistical analysis:

The data was entered in Microsoft excel and analyzed by SPSS software version 19

Categorical data were presented as frequency and percentage and quantitative data were analyzed by descriptive method

RESULTS

A total of 150 Diabetic mellitus in-patients with complication were considered for the study. Among them 35 in-patients were diagnosed with Diabetic foot ulcer as Diabetic complication. The prevalence of Diabetic foot ulcer was found to be 23.3%.

Distribution according to Diagnosis

On the basis of demographic details of the patient, patient history and laboratory value the diagnosis is made based on the complications of diabetes mellitus. Out of these, the most commonly occurring are cardiovascular disease 72(48%), then diabetic foot ulcer 35(23.3%), followed by diabetic nephropathy 20(13.3%), diabetic ketoacidosis 11(7.3%), stroke 9(6%), and diabetic retinopathy 3(2.1%).

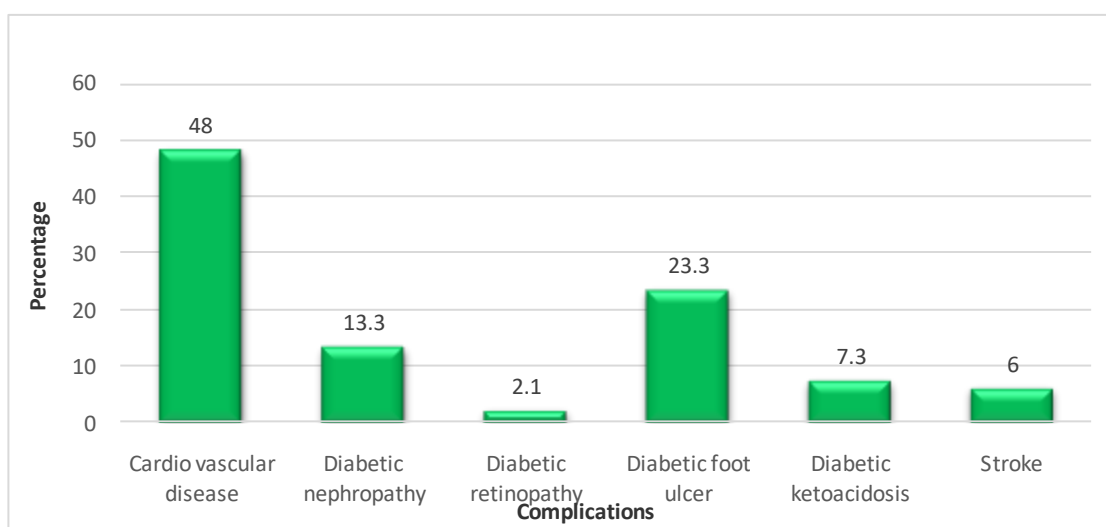


Fig 1: Distribution according to the Diagnosis

Distribution of Diabetic foot ulcer patient according to the age and gender

A total of 35 patients, 26 were males and 09 were females. According to age and gender patient with age groups 61-75(34.2%) were males and patients with age group 31-45(11.4%) were females are suffering from Diabetic foot ulcer. This study showed that male patients were more prone to Diabetic foot ulcer than female.

Pattern of use of oral hypoglycemic agents prescribed in DFU patients

Total 69 oral hypoglycaemics were prescribed in 35 Diabetic foot ulcer patients, among these Biguanides 31(44.9%) is most commonly prescribed oral hypoglycaemics agent followed by sulfonylurea 18(36.2%), Thiazolidinedione 5(7.2%), Alpha-glycosidase inhibitor 3(7.2%) and other oral hypoglycaemics agents were 5(7.2%).

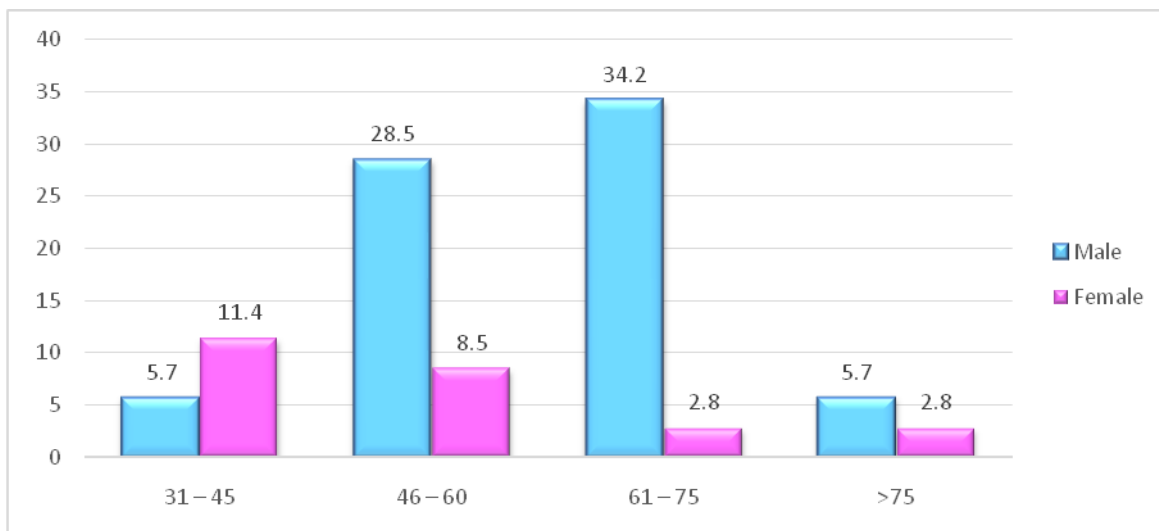


Fig2: Distribution of Diabetic foot ulcer patient according to the age and gender Prescription Pattern

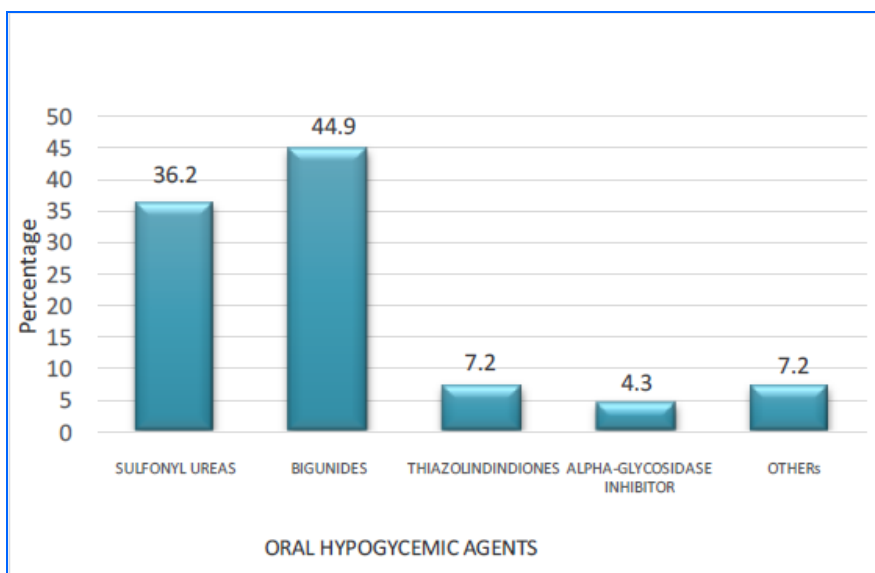


Fig3: Pattern of use of oral hypoglycemic agents prescribed in DFU patients

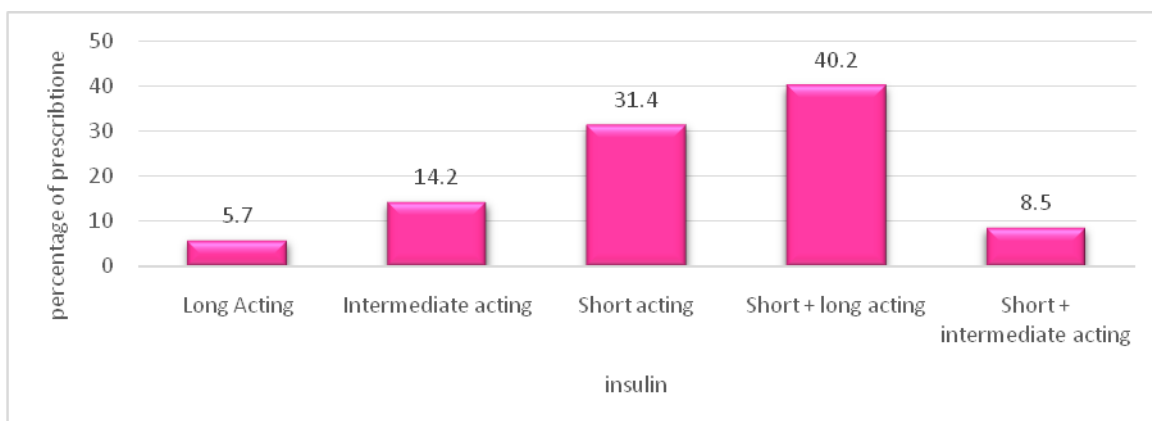


Fig4: Pattern of use of Insulin prescribed in DFU patient

Pattern of use of Insulin prescribed in DFU patient

Total 35 insulin are prescribed in 35 Diabetic foot ulcer patient. Among them the most commonly prescribed insulin type is short + long acting 14(40.2%) followed by short acting insulin 11(31.4%).

Prescription pattern of Antimicrobials in diabetic foot ulcer patients

Total 107 antibiotics including empirical antibiotic were prescribed in 35 Diabetic foot ulcer patient. Among these Nitroimidazole 28(26.1%) is most commonly prescribed antibiotics followed by Cephalosporin's 23(21.4%), Aminoglycosides 17(15.8%), penicillin's 13(12.1%), Carbapenems 12(11.2%), Fluoroquinolones 6(5.6%), Macrolides 3(2.8%) and others 5(4.6%).

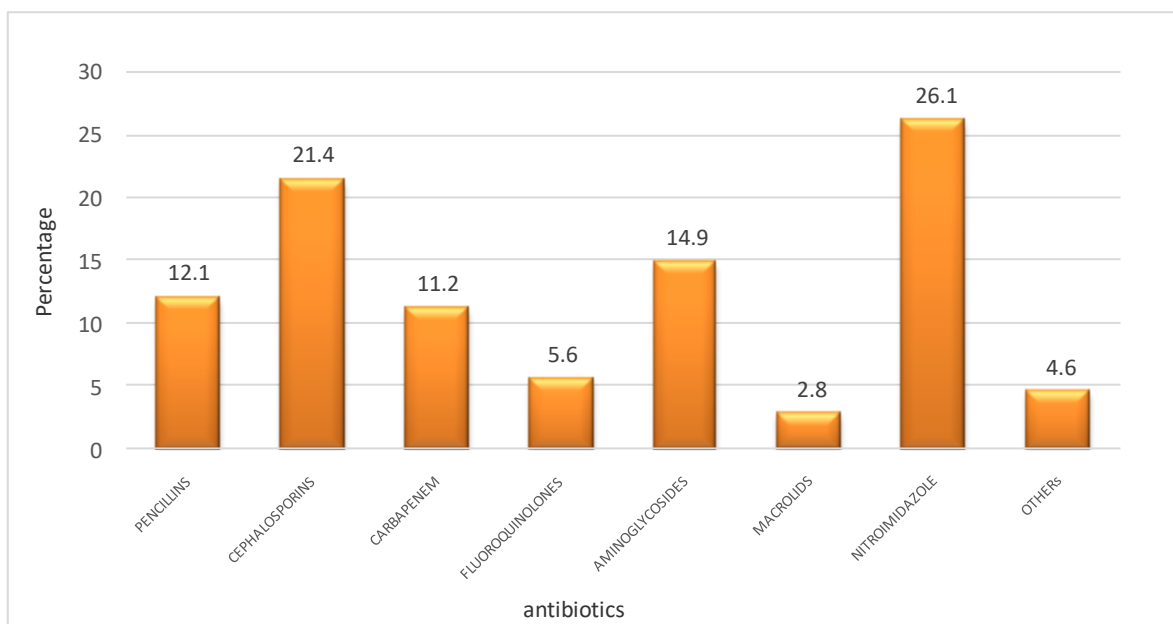


Fig 5: Prescription pattern of Antimicrobials in diabetic foot ulcer patients

Distribution of antimicrobials treatment pattern in DFU patients

Out of 35 prescriptions most common antibiotic treatment pattern is Two drug combinations of antibiotics 17(48.5%) followed by Three drug combination of antibiotics 10(28.7%).

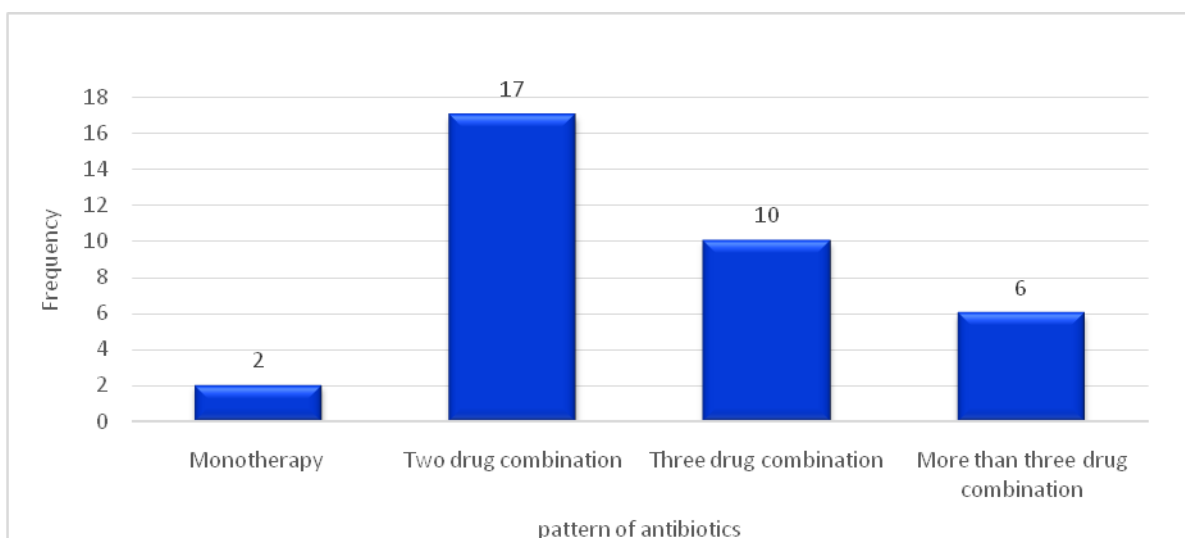


Fig 6: Distribution of antimicrobials treatment pattern in DFU patients

Drug Related Problems

Drug interaction

Out of 35 Diabetic foot ulcer in-patients prescriptions, 73 drug interactions were

found. Among them moderate drug interaction were more 54(73.9%) followed by minor 17(23.2%) and major 2(2.7%) drug interactions.

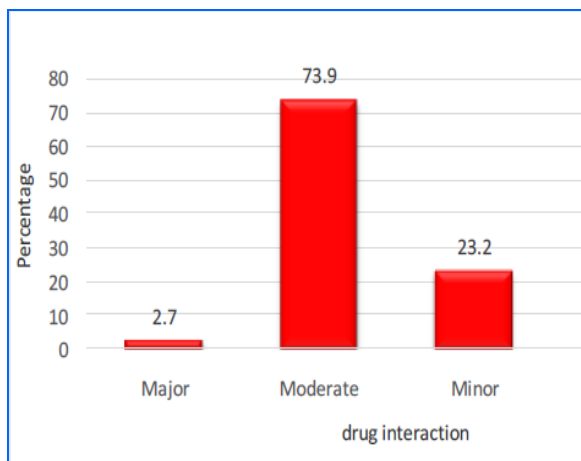


Fig 7: Drug interaction

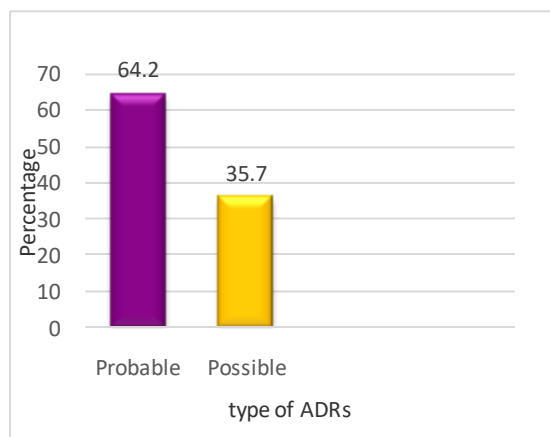


Fig 8: Adverse drug reaction

Adverse drug reaction

Out of 35 Diabetic foot ulcer patient, 28 ADRs were found by using Naranjo ADR assessment scale. In the study we found 18(64.2%) probable ADRs and 10(35.7%) possible ADRs. Among them probable were more than that of possible.

Prevalence of Bacteria in Diabetic Foot Ulcer Patients

Total 41 bacteria of different type organism were isolated in 35 DFU samples. Among them most commonly isolated bacteria is Staphylococcus Aureus 11(26.8%) followed by E-Coli 9(21.9%), Non fermented gram negative bacilli 8(19.5%), Pseudomonas Aeruginosa 7(17.07%), Klebsiella oxytoca 4(9.7%) and Proteus Vulgaris 2(4.8%). From this most common type of bacteria isolated is Gram negative bacteria 30 (73.1%) then Gram negative bacteria 11(26.8%).

Table 1: Distribution of bacteria in DFU patients (N=41)

Type of Organisms	Name of Organisms	Frequency	Total	Percentage (%)
Gram positive	Staphylococcus Aureus	11	11	26.8
	Pseudomonas Aeruginosa	7		17.07
Gram negative	E-Coli	9	30	21.9
	Proteus Vulgaris	2		4.8
	Klebsiella oxytoca	4		9.7
	Non fermented gram negative bacilli	8		19.5
	Total	41		100

DISCUSSION

A prospective observational study was conducted to identify the prevalence and prescription pattern of Diabetic foot ulcer in the hospitalized patients of Basaweshwara medical college hospital, Chitradurga. A total of 150 patients were enrolled randomly in the study among which 35 patients having Diabetic foot ulcer.

A wide spectrum of diabetic complication clinical diagnoses was observed among 150 patients, the most commonly occurring complication were

cardiovascular disease 72(48%), then diabetic foot ulcer 35(23.3%), followed by diabetic nephropathy 20(13.3%), diabetic keto acidosis 11(7.3%), stroke 9(6%), and diabetic retinopathy 3(2.1%) are reported in Basaweshwara medical college and research center hospital, Chitradurga. This finding is consistent with the studies conducted in 4585 white, Asian Indian, and Afro-Caribbean UKPDS patients, by Stratton M I *et al.*, The incidence of clinical complications was significantly associated with glycaemia. 21% for deaths related to

diabetes, 14% for myocardial infarction, and 37% for microvascular complications.^[8]

150 diabetic patients were included in the study aged ≥ 30 years and 35(23.3%) of them had diabetic foot ulcer. Among the diabetic foot ulcer inpatients 26 were males and 09 were females. Majority of the male patients were of age group 61-75(34.2%) and female were of age group 31-45(11.4%) were higher in diabetic foot ulcer. The study done by Mariam G T *et al.*, shows study result revealed that the prevalence of diabetic foot ulcer among diabetic patients who attend diabetic clinic follow-up was 13.6% (95% CI: 9.3, 17.2). This finding is in line with the studies done with diabetic patients in Arbaminch, Ethiopia (14.8%), and Mekele, Ethiopia (12%) which were in contrast to our study result. However, this study finding was higher than the study conducted in Arbaminch, Ethiopia, and Mekele, Ethiopia. This variation might be due to difference in sample size or due to differences in geographical location of the studies as well as sociocultural variation of the study participants.^[9]

Diabetic foot ulcers are more prone to bacterial infections that spread rapidly, leading to irreversible tissue damage. The finding of our study showed that the most common isolates from culture were Gram negative bacteria 30(73.2%) and higher utilization of Nitroimidazole 28(26.1%) and Cephalosporin 23(21.4%) was noticed for the management of bacterial infection in Diabetic foot ulcer. Similar observation is reported in another study conducted on the in-patients Departments of Endocrinology and Metabolism, General Surgery, and General Medicine of Medical Sciences, Banaras Hindu University, Varanasi, India by Tiwari S *et al.*, and this study conclude Gram-negative bacteria (68%) were most prevalent in diabetic foot infection and suggests that piperacillin/tazobactam should be the treatment of choice on an empirical basis prior to a definitive bacteriological study and in cases with negative culture reports.^[10] The antimicrobial treatment was differ from our study with conclusion of

Tiwari S and shows significance with the other study of Drug utilization of antibiotics in surgical ward of a tertiary care hospital by Venkateswarlu B *et al.*, which shows higher utilization of cephalosporin's 161 (80.5%) was noticed. Cephalosporins are commonly prescribed due to their relatively lower toxicity and broader spectrum activity. Cephalosporin's often used in combination with aminoglycosides due synergistic activity and broader coverage of organisms for several serious gram negative infections.^[11]

During the study period we observe that Biguanides 31(44.9%) were the most commonly prescribed oral hypoglycemic agents in Diabetic foot ulcer patients followed by Sulphonylureas 25(36.2%) and Short acting + intermediate acting insulin 14(40.2%) is most commonly given for hyperglycemic management. When we compare with the study of Mokta J *et al.*, shows Sulphonylureas were the commonest anti-diabetic drug prescribed by the primary care providers followed by metformin. Insulin was prescribed to 2.23% only.^[6]

Long duration of diabetes, even after controlling for age, was a statistically significant finding in several studies. This prospective observational study found that chance of diabetic foot ulcer is higher in the patient with diabetes mellitus which is comparable with previous studies. However, the positive results of culture sensitivity will always receive priority over the molecular study results for the selection of antibiotics. If we have knowledge regarding the characteristics of infection, i.e., the type of bacteria commonly found and the clinical evidence of infection, the antibiotic selection can be close to appropriate, even if the culture reports are not available at the time of initiation of antibiotic therapy.^[10] Conservative treatment consists of control of diabetes with human actrapid / human mixtard/Lente/Glargine insulin along with appropriate oral or iv antimicrobials along with simple dressing was effective in majority subjects.^[2]

CONCLUSION

According to the analyzed results and from view of literature, the conclusions made are; Male patients were more prone to get Diabetic foot ulcer.

In Diabetic complications, cardiovascular disease was the most commonly diagnosed followed by Diabetic foot ulcer.

The most commonly prescribed oral hypoglycemic agent was found to be Biguanides followed by sulfonylureas in DFU patient

The most common type of insulin prescribed in DFU was found to be short + long acting Insulin.

The most commonly prescribed antimicrobials for Diabetic foot infection was found to be Nitroimidazole (Metronidazole) followed by Cephalosporin's (Ceftriaxone)

The most common antimicrobials treatment pattern in DFU patients was Two drug combination of antimicrobials

The main drug related problems in DFU was found to be drug interactions, followed by adverse drug reaction.

Most commonly isolated bacteria is Staphylococcus Aureus

Most common type of organism isolated is Gram negative bacteria.

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