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A PROSPECTIVE STUDY ON DIABETIC FOOT ULCER AND ASSOCIATED FACTORS AMONG DIABETIC PATIENTS

Nadeem Mahshooque T. C.[1]*, Sanjay Sreekumar K.[2], Dhanya G. Pillai[1], Samar P.[1] and Swathi Krishna[1]

[1]Pharm. D Intern, Devaki Amma Memorial College of Pharmacy, Chelembra Malappuram, Kerala, India.
[2]Assistant Professor, Devaki Amma Memorial College of Pharmacy, Chelembra Malappuram, Kerala. India.

***Corresponding Author: Dr. Nadeem Mahshooque TC.**

Pharm. D Intern, Devaki Amma Memorial College of Pharmacy, Chelembra Malappuram, Kerala, India.

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ABSTRACT

Background: Studies about prevalence and risk factors of diabetic foot has much importance, because it is one of the most common complication of diabetes mellitus. **Objective**: To determine the rate of occurrence and influence of lifestyle and duration of diabetes in foot ulcer. To determine the glycemic level changes with interaction of hypoglycemics with the drugs used of foot ulcer. **Methodology**: A prospective observational study conducted at PVS Hospital (P) Ltd, Calicut. The necessary data were collected from patient medical charts by using the data collection forms. Diabetic patients treated with at least one anti-diabetic drug with or without comorbidities were included. **Results**: Out of 200 collected data39 patients had diabetic foot. Diabetic patients who had neuropathy were 12.25 times more likely to develop diabetic foot ulcer as compared to those diabetic patients without neuropathy (OR= 12.25; 95% CI: 5.146, 26.66; P < 0.0001). History of previous amputation, peripheral vascular disease, poor foot self-care practice, and smoking were other risk factors to develop diabetic foot ulcers. Percentage reduction in fasting blood sugar was seen more while taking triple therapy of antibiotic (28.37%) than the monotherapy of antibiotic(18.46%). **Conclusion**: The prevalence of diabetic foot ulcer among diabetic patients was found to be 19.50%. Neuropathy, previous amputation, peripheral vascular diseases and foot self- care practice were factors significantly associated with diabetic foot ulcer. Antidiabetic agents had an additive effect or synergistic effect when taken together with antibiotics which were used to treat diabetic foot ulcer.

KEYWORDS: Diabetic foot ulcer, lifestyle influence, hypoglycemic interactions.

INTRODUCTION

Diabetic foot ulcer is a most feared complication of diabetes in which an open sore or wound is present on the foot of a person, most commonly located on its. It could result from both vascular and neurological disease processes. Amputations could be prevented by regular inspection and good care of the foot. There are two main foot problems, each of which has serious complications. Prolonged periods of high sugar level in the blood can wreak havoc on many area of the body including feet.

Loss of Feeling, Numbness or Tingling Sensation, Blisters or other Wounds without pain, Skin Discolouration, Staining on socks, Deformed foot appearance were the clinical signs and symptoms of diabetic foot. Relief from diabetic symptoms and improvement in quality of life, Prevention of macrovascular complications like cardiovascular, cerebrovascular and peripheral vascular diseases, Prevention of infections were the major objectives of diabetic foot ulcer treatment. Non-surgical options such as maintain hygiene, hyperbaric oxygen therapy, immobilisation devices are normally initial treatment for Diabetic foot. When non-surgical treatment fails to treat diabetic foot problems, surgery may be considered. Surgical treatment option include, Removal of decaying or dead tissue, Amputation, varying from toe or part of the foot to amputation of the leg below the knee, or above the knee in some cases were the major surgical treatment.

MATERIALS AND METHODS

Study setting: The study was conducted at PVS Hospital (P) Ltd, a 350 bedded multi-specialty tertiary care hospital, Calicut.

Study design: Prospective observational study using patient's medical records.

Study population and sample size: All inpatients attending the hospital with diabetes during November 2018 to April 2019. The eligible patients who fulfilled following inclusion and exclusion criteria were enrolled in the study.

Inclusion criteria: Diabetic patients treated with at least one anti-diabetic drug with or without comorbidities.

Exclusion criteria: Gestational diabetes and Juvenile diabetes.

Data collection: The necessary data were collected from patient medical charts by using the data collection forms. Study was carried out using medication orders within the study period. Case sheets of inpatients of various wards in the study site, Literatures relevant to the study, Data collection form were the materials used in this study. Data collection forms were used to record the drug therapy in patients with diabetic foot ulcer, blood sugar level chart, social habits and lifestyles of patient. Average duration to develop diabetic foot in diabetic patients was calculated. Various risk factors of diabetic foot were analysed after collecting such information with the help of data collection form. Prevalence of diabetic foot was calculated using the formula,

Prevalence (%) = (No. of patients with diabetic foot / No. of diabetic patients in study) X 100

Drug interaction between anti-diabetic drugs with drugs used to treat the foot ulcer was done with the help of variation in blood sugar level. That was done with the help of monitoring the FBS level before starting the antibiotic therapy and after antibiotic therapy.

Statistical analysis: Data was entered into Microsoft Excel. Data were analysed during statistical software GraphPad Prism version 8.0.

RESULTS

DEMOGRAPHIC DATA OF THE STUDY SAMPLE

The data of 200 diabetic patients were collected and analysed. The gender analysis showed that 122 (61%) patients were male and 78 (39%) patients were female. The mean (±SD) age of total participants was 56.98± 14.2.

PREVALENCE OF DIABETIC FOOT

Out of 200 collected data of diabetic patients, 39 patients had diabetic foot.

Prevalence (%) = (No. of patients with diabetic foot/ No. of diabetic patients in study) X 100

The Prevalence of diabetic foot ulcer among diabetic patients was found to be 19.50%.

AGE-GENDER DISTRIBUTION OF DIABETIC FOOT PATIENTS

The Diabetic Foot patients were categorized into five age groups. The number of males and females of each group were also categorized. Majority of the patients (36%) were in the age group of 61-70 years. The mean age of the total diabetic foot patients was found to be 62.26 years [Table 1]. The mean (±SD) age of total diabetic foot patients was 62.26± 9.24 years.

Table 1: Age-Gender Distribution of Diabetic Foot patients.

Age Group (Years)	Number of Diabetic Patients				Number of Diabetic Foot Patients				% of DFU Patient
	Male	Female	Total	%	Male	Female	Total	%	
41-50	29	20	49	24.5	4	3	7	17.95	14.29
51-60	35	30	65	32.5	5	7	12	30.77	18.46
61-70	31	15	46	23	13	1	14	35.90	30.43
71-80	21	11	32	16	4	1	5	12.82	15.63
81-90	5	3	8	4	1	0	1	2.56	12.50

Majority of the diabetic patients seen in the age range of 51-60 years. Majority of diabetic foot patients was in the age range of 61-70 years (Mean ± SD : 66.43 ± 3.39).

PATTERN OF ANTIBIOTICS DISTRIBUTION

Most of the patients (74.36%) received more than one antibiotic for the treatment of diabetic foot. Only 10 patients out of 39 received mono therapy. Antibiotic mono therapy may not be sufficient to control diabetic foot infection [Table 2].

Table 2: Pattern of Antibiotics Distribution.

S.No	Antibiotic	Number	Percentage
1.	Cephalosporins	26	66.67
2.	Fluoroquinolones	9	23.08
3.	Metronidazole	12	30.77
4.	Linezolid	12	30.77
5.	Macrolides	1	2.56
6.	Penicillins	12	30.77

DURATION TAKEN TO DEVELOP DIABETIC FOOT

Duration taken to develop diabetic foot in an individual from incidence of Diabetes Mellitus may vary from one person to another. The mean (±SD) duration taken to develop diabetic foot was 9.53 ± 4.23 years. From the collected data the duration taken to develop diabetic foot in these diabetic foot patients were analysed [figure1].

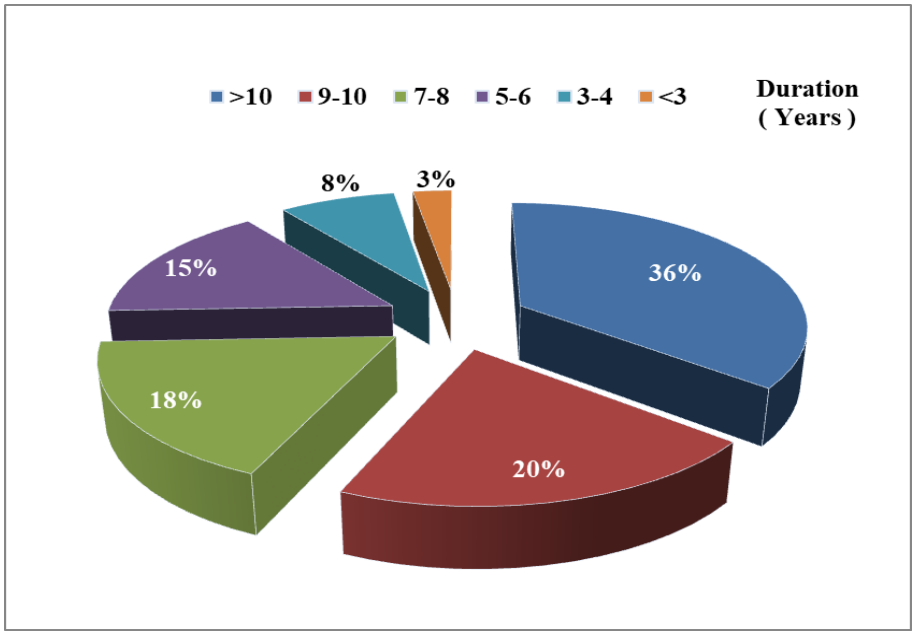

Figure 1: Duration of Diabetes to develop Diabetic Foot.

PATIENT LIFE STYLE AND RISK FACTORS

Influence of patient lifestyle in developing diabetic foot was found by taking patient medical history. According to the literature, the risk factors of foot ulceration vary from one study to another and some of them may common. In this, Neuropathy was the major risk factor which leads to diabetic foot [Table 3]. 53.85% of Diabetic foot patients were in the risk of Neuropathy. Those diabetic patients who had Neuropathy were 12.25 times more likely to develop diabetic foot ulcer as compared to those diabetic patients without neuropathy [OR= 12.25; 95% CI: 5.146, 26.66; P < 0.0001]. Those diabetic patients who had not practiced foot self-care were 3.32 times more likely to develop diabetic foot ulcer as compared to those diabetic patients who had practiced foot self-care [OR= 3.325; 95% CI: 1.145, 7.740; P: 0.0044]. Those diabetic patients who had history of previous amputation were 9.78 times more likely to develop diabetic foot ulcer as compared to those diabetic patients without history of amputation [OR= 9.78; 95% CI: 3.476, 24.75; P < 0.0001]. Those diabetic patients who had Peripheral Vascular Disease was 2.39 times more likely to develop diabetic foot ulcer as compared to those diabetic patients without Peripheral Vascular disease [OR= 2.39; 95% CI: 1.100, 5.118; P: 0.0257].

Other than this People who were not adherent to the treatment, had uncontrolled diet, Unhygienic conditions and improper footwear were more prone to develop diabetic foot ulcers.

Table 3: Patients risk factors and odds ratio.

Risk Factor	Number of Patient	Percentage	OR	95% Confidence Interval (CI)	P
Neuropathy	21	53.85	12.25*	5.146-26.66	<0.0001
Previous Amputation	12	30.77	9.778*	3.476-24.75	<0.0001
Poor Foot Self Care Practice	11	28.20	3.328*	1.445-7.740	0.0044
Peripheral Vascular Disease	13	33.33	2.390*	1.100-5.118	0.0257
Smoking	5	12.82	4.588*	1.378-15.03	0.0125
Chewing Tobacco	4	10.26	1.803	0.5843-6.273	0.3435
Varicose Vein	5	12.82	1.246	0.4759-3.381	0.6865
Immobility	2	5.13	1.136	0.4431-2.692	0.7859
Overweight	2	5.13	1.630	0.6829-3.831	0.2825

***Variable with P value of < 0.05 in univariate analysis (Statistically significant). Statistical test used was Chi- Square Test. **OR** stands for odds ratio, computed by Baptista-Pike method.*

DRUG ACTION AND EFFECT ON GLYCAEMIC CONTROL

Patients categorized into three groups that,
Group A: Patient undergo Antibiotic Mono Therapy
Group B: Patient undergo Antibiotic Dual Therapy
Group C: Patient undergo Antibiotic Triple Therapy

Table 4: Percentage reduction in FBS on type of Antibiotic Therapy.

Type of Antibiotic Therapy	Average FBS Level (mg/dl)		Percentage Reduction in FBS Level
	Before Initiation of Antibiotic Therapy	Second Day of Antibiotic Therapy	
Mono Therapy	202.71	165.29	18.46
Dual Therapy	187.47	139.76	25.45
Triple Therapy	178	127.5	28.37

Average of FBS in Groups A, B, and C before initiation of Antibiotic therapy was 202.71 mg/dl, 187.47 mg/dl and 178 mg/dl respectively. After 2 day of Antibiotic therapy, an average of FBS in Groups A, B, and C was reduced to 165.29 mg/dl, 139.76 mg/dl and 127.50 mg/dl respectively. Percentage reduction of FBS level in Groups A, B, and C was 18.46%, 25.45% and 28.37% respectively [Table 4].The percentage FBS reduction was seen more in patients taking triple therapy of antibiotic than FBS reduction in patients taking monotherapy of antibiotics [Figure 2]. FBS level percentage reduction and number of antibiotic used along with antidiabetic agent was positively correlated[Karl –Pearson's correlation coefficient: 0.3937; P<0.05].

DISCUSSION

Prevalence of diabetic foot found his study finding was lower than the study conducted in Addis Ababa, Ethiopia, and Nigeria which found diabetic food ulcer prevalence to be 31.1% and 41.1%, respectively.[1,2] 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. On the other hand, the finding of the current study is higher when compared to a study conducted in Kenya which was stated as the prevalence of diabetic foot ulcer among diabetic patients was 4.6%,[18] study of Bakri FG *et. al.* among patients attending the National center for Diabetes, Endocrinology, and Genetics (Amman, Jordan) was 4.6%.[19] and various other studies were also done which resulted in lesser prevalence.[5-10] The possible explanation for this difference could be due to difference in knowledge-related diabetic foot self-care practice, knowledge on diabetes mellitus, and also possibly due to difference on health-seeking behaviour practice between the two study populations.

Age and gender distribution of diabetic foot patients was similar to study result of Ali N et al The In-Practice Prescribing Pattern for Antibiotics in the Management of Diabetic Foot at university of Malakand.[11] and study conducted by Deribe B et. Al.[12]

More than a majority of patients, i.e. 26 (66.67%) patients were received Cephalosporin antibiotics for the treatment of diabetic foot infection. This results were coincides with study result of Ali N et al The In-Practice Prescribing Pattern for Antibiotics in the Management of Diabetic Foot at university of Malakand.[11] This study also reveals that Cephalosporin class of antibiotics were most commonly prescribed for the treatment of Diabetic foot Ulcer. In this most of the patient received Third generation cephalosporins such as Ceftriaxone, Cefotaxime, cefixime etc.

Chances of developing Diabetic foot ulcer were more in patients with more than 10 year duration of diabetes. This was seen in study by Nabil Abd El Fatah Al Kafrawy et al, on Risk factors of diabetic foot ulcer in Menoufia University Hospitals.[13]

Neuropathy was the major risk factor which leads to diabetic foot. 53.85% of Diabetic foot. This finding is in line with the study The Foot at Risk in Nigerians with Diabetes Mellitus-The Nigerian Scenario by Ogbera AO et. al.[2] various studies also reveals that Neuropathy was a major risk factor of Diabetic foot ulcer.[4,5,7-9] Apart from neuropathy, Previous amputation, poor foot self-care practice, peripheral vascular disease, smoking, varicose vein, immobility, overweight and chewing tobacco all are other risk factors which leads to diabetic foot. This was similar to findings of various studies on diabetic foot.[14-18]

The chances of developing infectious diseases were more in diabetic patients.[19] As well as in infected condition the blood sugar level will increase. So the antibiotic action to reduce and control infection may leads to reduction in blood sugar level. Percentage reduction in FBS Level may or may not depend upon the class of antibiotics when taken with antidiabetic agent. But Percentage reduction in FBS level influenced by type of antibiotic therapy. The reduction was seen more while taking Triple therapy of antibiotic than the Mono therapy of antibiotic. It revealed that there was a synergistic action of antibiotic in glycemic control of antidiabetic agents when these take together.

CONCLUSION

The Prevalence of diabetic foot ulcer among diabetic patients was found to be 19.50%. Cephalosporin class of antibiotics were most commonly prescribed for the treatment of Diabetic Foot Ulcer. The chances of occurring diabetic foot were increases with increase in duration of diabetes. Diabetic Patients with more than 10 year duration of diabetes were in high risk to develop diabetic foot ulcer.

Neuropathy, Previous amputation, Peripheral Vascular Diseases and foot self- care practice were factors significantly associated with diabetic foot ulcer. Most of these risk factors of diabetic foot ulcer identified in these study were correctable or atleast controllable, with an opportunity for early prevention and treatment with a

subsequent reduction in patients suffering from diabetic foot ulcer and its sequel of amputation.

Antidiabetic agents had an additive effect or synergistic effect when taken together with antibiotics which were used to treat Diabetic foot ulcer.

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