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Original Research Article

Study on drug profile used in diabetic foot ulcer

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ABSTRACT

Background: The objective was to study about the drugs used in management of diabetic foot ulcer (DFU) and to grade the wounds using Wagner's scale.
Methods: An observational study was conducted at Department of Pharmacy, Rajah Muthiah Medical College Hospital over a period of six months from November 2018 to April 2019. The data was collected from 85 patients using data collection form. The patients were selected based on inclusion and exclusion criteria.
Results: Overall 85 patients were enrolled in this study. The prevalence of DFU found to be 36% more in males 58 (68%) than in females 27 (32%). Considering the age group, higher prevalence was reported in patients among the age group of 60-70. This study shows, patients were found commonly to have habits of alcohol 18 (21%), smoking 11 (13%) and both 22 (26%). Overall, 23 classes of drugs were used in this study. Among these, mostly were antibiotics 12 (52%) then hypoglycemic drugs 5 (21%) and others are analgesics (9%), anti-ulcerant and vitamins. This study shows that the common antibiotics prescribed are metronidazole 39 (24%), cefotaxime 36 (22.7%), ciprofloxacin 25 (15.8%) and piperacillin 21 (13.2%). The common hypoglycemic drug used were of insulin 63 (74%), metformin 43 (77%), glimepiride 12 (14%) and metformin and glimepiride 12 (14%). By using Wagner's scale, out of 85 patients, most of the ulcer were predominantly between grade IV and V.
Conclusions: Targeting range of glycaemic levels and proper antibiotics is the best way of treating DFU. This study has provided the base line data regarding management of DFU which helps to improve therapeutic outcome.

Keywords: Diabetic foot ulcer, Wagner's scale, Antibiotics, Hypoglycemic drugs

INTRODUCTION

Prescribing pattern studies are valuable tools to study the role of drugs in society and to ensure the rational use of the drugs which may help to avoid drug resistance and improving the therapeutic outcomes.

Diabetic foot ulcer (DFU) is an open sore or wound which is the most common complication of diabetes. It is located on the bottom of the foot. A non-healing or poorly healing lesion of the skin.[1]

Diabetic foot ulcer is characterized by several pathological complications such as neuropathy, peripheral vascular disease, foot ulceration and infection with or without osteomyelitis, leading to the development of gangrene and even necessitating limb amputation. The majority 60-80% of foot ulcers will heal, while 10-15% of them will remain active, and 5-24% of them will finally lead to limb amputation. Neuropathic wounds are more likely to heal over a period of 20 weeks, while neuro ischemic ulcers take longer and will more often lead to limb amputation.[2]

Disease of small blood vessels impairs blood supply to and around the extremities. If peripheral neuropathy is present, sensation is reduced can cause the small injury to the foot may go unnoticed, especially when there is a visual impairment. DFU healing is slower and injuries easily worsen if aggravated may become gangrenous, sometimes to the extent that amputation is required.[3]

Diabetes mellitus (DM) is one among the major health system problem that cause to high economic burden worldwide.[4] Considering the epidemiological surveys, the prevalence of DM increased from about 177 million cases in 2000 to 285 million in 2010, estimating reaches, more than 360 million cases by 2030.[5]

Diabetes can cause many serious complications like diabetic ketoacidosis, foot ulcer, cardiovascular disturbances, diabetic macroangiopathy, renal failure and visual impairments is the leading cause of hospitalization in diabetic patients.

METHODS

An observational study was conducted at Rajah Muthiah Medical College and Hospital, tertiary care teaching hospital, Annamalai University, Annamalai Nagar, Tamil Nadu, from the period of November 2018 to April 2019.

Sample size

Totally 85 cases were enrolled in this study, it is calculated as follows.

$$N = \frac{Z^2 \times P\,(1-P)}{d^2}$$

Inclusion criteria

Inclusion criteria were patients got admitted to the surgery department with a diabetic foot ulcer and patients who are willing to participate in the study.

Exclusion criteria

Exclusion criteria were patients with comorbidities, conditions like hypertension, coronary artery disease, stroke and hypothyroidism were excluded from the study, pregnancy and lactating women, mentally illness patients, and patients are not willing to participate in this study.

Study method

The present study conducted among the patients admitted inpatient department under the department of surgery, RMMCH. A protocol was approved by Human Institutional Ethics Committee. A data collection form was used to collect data such as demographic details, medical histories, social histories, assessment of the wound condition during patient's hospitalization according to Wagner's scale classification, size and number of the wound, local and signs of inflammation on the wound, the presence of neo generative tissue and therapeutic management were collected from the patients and case sheets. We will be following the patient during hospitalization and recording the data around the diabetic foot ulcer management.

Wagner's classification is the widely used grading method for diabetic foot ulcer. It has the six grades which is based on the depth of the wound. The first four grades (0, 1, 2 and 3) are on the depth of the lesion. The fourth and fifth grades are based on the extent of the gangrene and lost perfusion in the foot. Grade 4 represents partial foot gangrene and grade five is completely gangrenous foot.[6] It helps to standardizing the treatment plan and to ensure the therapeutic outcome of the treatment.

According to the Wagner's classification, diabetic foot ulcers are graded to 6 groups including.[6]

Grade 0: No ulcer in a high-risk foot.

Grade 1: Superficial ulcer involving full skin thickness but not underlying tissues.

Grade 2: Deep ulcer, penetrating down to ligaments and muscle but no bone involvement or abscess formation.

Grade 3: Deep ulcer with cellulitis or abscess formation often with osteomyelitis.

Grade 4: Localised gangrene.

Grade 5: Extensive gangrene involving the whole foot.[6]

RESULTS

Overall, 85 patients were enrolled in this study. Among these patients, male patients are 58 (68%) and female patients are 27 (32%). In our study the prevalence of DFU found to be 36% more in males than in females (Table 1).

Table 1: Gender-wise distribution.

Gender	No. of patients	Percentage
Male	58	68
Female	27	32

Higher prevalence of diabetic foot ulcer was reported in patients among the age group of 60-69 i.e., 26 (30%) patients followed by 50-59 years, 23 (27%) patients then 14 (16%) patients are in 40-49 years followed by 9 (10.5%) patients are in the age group of 30-39 years, 70-79 years and 4 (4.7%) patients are above the group of 80 years (Table 2). In this study, patients were found more commonly to have habits of alcohol, smoking and both. Smoking 15 (18%), alcohol 14 (17%), both 14 (17%).

This is one of the most common causes of uncontrolled glycaemic controls, development of diabetic foot ulcer which may or may not heal (Table 3).

Table 2: Age-wise distribution.

Age group (in years)	No. of patients	Percentage
30-39	9	10.5
40-49	14	16.4
50-59	23	27
60-69	26	30
70-79	9	10.5
>80	4	4.7

Table 3: Distribution based on social habits.

Patient history	No of patients	Percentage
Smoker	11	13
Alcoholic	18	21
Both	22	26
None	34	40

Out of 85 patients enrolled in the study, diagnosed with diabetic foot ulcer, grading was based on Wagner's scale. Most of the ulcer were predominantly between grade IV and V. This signifies that most of the patients with diabetic foot ulcer are present at later grade, which implies decreased awareness of foot care among the study populations (Table 4).

Table 4: Distribution based on Wagner's scale.

Grade	No. of patients	Percentage
Grade-0	-	-
Grade-1	10	11.7
Grade-2	14	16.4
Grade-3	16	18.3
Grade-4	26	30.5
Grade-5	19	22.3

The study shows that 28 (33%) patients treated with only insulin, 22 (26%) patients treated with oral hypoglycemic drug and 35 (41%) patients were go for dual therapy who cannot be achieved targeted blood glucose level during mono therapy (Table 5).

Table 5: Distribution of hypoglycaemic drugs.

Drugs	No. of patients	Percentage
Insulin	28	33
Oral	22	26
Insulin and oral hypo-glycemic drugs	35	41

Considering the oral hypoglycemic drug, 43 (77%) patients were prescribed with metformin, 7 (12%) patients were treated with glimepiride, 4 (7%) patient treated with combination of metformin and glimepiride and 3 (4%) patients were treated with tenegliptin (Table 6).

Table 6: Distribution of oral hypoglycemic drugs.

Drugs	No. of patients	Percentage
Metformin	43	77
Glimepride	7	12
Metformin and glimepride	4	7
Tenegliptin	3	4

In our study 30 (36%) patients are treated with monotherapy, 40 (47%) patients were treated with dual therapy, 12 (15%) patients were treated with triple therapy and 3 (4%) patients were prescribed with multiple therapy. Most of the people achieved by dual therapy and mono therapy (Table 7).

Table 7: Prescribing pattern of antibiotics.

Drug pattern	No. of patients	Percentage
Monotherapy	30	36
Dual therapy	40	47
Triple therapy	12	15
Multiple therapy	3	4

Table 8: Distribution of antibiotics.

Drugs	No. of patents	Percentage
Metronidazole	39	24
Cefotaxime	36	22.7
Ciprofloxacin	25	15.8
Piperacillin	21	13.2
Amikacin	10	6.3
Ceftriaxone	9	5.6
Linezolid	6	3.7
Clavum	3	1.8
Ampicillin	3	1.8
Gentamycin	3	1.8
Doxycycline	2	1.2
Trimethoprime	1	0.6

Considering the antibiotic therapy, metronidazole which belongs to the nitroimidazole derivatives were majorly 39 (24%) prescribed followed by cefotaxime belongs from cephalosporins derivatives, followed by 36 (22.7%) then ciprofloxacin (15.8%) from quinolones derivatives followed by piperacillin 21 (13.2%) belongs from penicillin derivatives then amikacin 10 (6.3%) and gentamycin 3 (1.8%) belongs from aminoglycosides then ceftriaxone 9 (5.6%) then linezolid 6 (3.7%) and combination of amoxicillin and clavulanic acid 3 (1.8%), ampicillin 3 (1.8%) and gentamycin 3 (1.8%) followed by doxycycline 2 (1.2%) were used and doxycycline and

trimethoprim was the rarely used drugs in treating diabetic foot ulcer (Table 8).

DISCUSSION

Overall, 85 patients were enrolled in this study. Among these patients, male patients are 58 (68%) and female patients are 27 (32%). It shows the prevalence of DFU found to be 36% more in males than in females. Most of the study shows the similar results.

Higher prevalence of diabetic foot ulcer was reported in patients among the age group of 60-69 i.e., 26 (30%) patients, followed by 50-59 years 23 (27%) patients then 14 (16%) patients are in 40-49 years, followed by 9 (10.5%) patients are in the age group of 30-39 and 70-79 years 4 (4.7%) patients are above the group of 80. These results are related to Saranya et al.[7]

In this study, patients were found more commonly to have habits of alcohol 18 (21%), smoking 11 (13%) and both 22 (26%) smoking. This is one of the most common causes of uncontrolled glycaemic controls, development of diabetic foot ulcer which may or may not heal.

Based on Wagner's scale, most of the ulcer were predominantly between grade IV and V while another study shows grade III.[8] This signifies that most of the patients with diabetic foot ulcer are present at later grade, which implies decreased awareness of foot care among the study populations.

This study shows that 28 (33%) patients treated with only insulin, 22 (26%) patients treated with oral hypoglycemic drug and 35 (41%) patients go for dual therapy who cannot be achieved targeted blood glucose level during monotherapy. Considering the oral hypoglycemic drug, 43 (77%) patients were prescribed with metformin, 7 (12%) patients were treated with glimepiride, 4 (7%) patient treated with combination of metformin and glimepiride and 3 (4%) patients were treated with tenegliptin.

Targeting range of glycaemic levels and proper antibiotics is the best way of treating DFU. In our study 30 (36%) patients are treated with monotherapy, 40 (47%) patients were treated with dual therapy, 12 (15%) patients were treated with triple therapy and 3 (4%) patients were prescribed with multiple therapy. this result was similar to the study conducted by Zargarzadeh et al.[8] Most of the people achieved by dual therapy and mono therapy. Metronidazole which belongs to the nitroimidazole derivatives were majorly 39 (24%) prescribed, followed by cefotaxime belongs from cephalosporins derivatives, followed by 36 (22.7%) then ciprofloxacin (15.8%) from quinolones derivatives followed by piperacillin 21 (13.2%) belongs from penicillin derivatives which is similar to the study of Pillai et al.[10] then amikacin 10 (6.3%) and gentamycin 3 (1.8%) belongs from aminoglycosides then ceftriaxone 9 (5.6%) then linezolid 6 (3.7%) and combination of amoxicillin and clavulanic acid 3 (1.8%), ampicillin 3 (1.8%) and gentamycin 3 (1.8%) followed by doxycycline 2 (1.2%) were used and doxycycline and trimethoprim was the rarely used drugs in treating diabetic foot ulcer.

Considering the analgesics, acetaminophen 50 (59%) was majorly used analgesic drug followed by tramadol 19 (23%) were prescribed for severe pain which cannot reduced by acetaminophen then diclofenac 15 (18%) were used in diabetic foot ulcer. This result similar to Saranya et al.[7]

Supportive care treatments help to improve the patient condition and majorly vitamins and anti-ulcerant like ranitidine and pantoprazole were mostly used. Vitamin C, vitamin B complex and ferrous sulphate drugs are mostly prescribed for supportive therapy.

CONCLUSION

This study has provided the data regarding the prescribing pattern of drugs in management of diabetic foot ulcer which helps to improve the therapeutic outcome in management of DFU. Targeting range of glycaemic levels and proper antibiotics is the best way of treating DFU.

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