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Original Research Article

A prospective observational study of drug prescription pattern of antibiotics in diabetic foot ulcer in tertiary care teaching hospital

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ABSTRACT

Background: Our aim was to study a prescribing pattern of antibiotics used in diabetic foot ulcer (DFU).
Methods: 50 patients were selected by inclusion and exclusion criteria basis. It was a prospective observational study conducted in Department of Surgery, Rajah Muthiah Medical College Hospital (RMMCH), Annamalai University.
Results: This study reveals that male patients 60% are more prone to develop diabetic foot ulcer than the female patients 40%. Patients of 50 to 60 age group 32% has higher prevalence of DFU. The most commonly prescribed antibiotics are metronidazole 48% and cefotaxime 48% followed by piperacillin and tazobactam combination 30%, ciprofloxacin 20%, linezolid 18%, amoxicillin and clavulanic acid combination 12%, cefixime 6%, clindamycin 4%, amikacin 4%, faropenam 4%, ceftriaxone 2%, amoxicillin 2%, gentamicin 2%, cefoperazone sodium and sulbactam combination 2%.
Conclusions: Lack of antibiotic sensitivity test leads to growth of organism, wrong antibiotic selection and irrational use of antibiotics. And also observed patient developed resistance to linezolid antibiotic when used as a first choice of drug to treat diabetic foot infection including methicillin-resistant Staphylococcus aureus (MRSA) infected patients.

Keywords: DFU, Antibiotic sensitivity, Prescription pattern, MRSA

INTRODUCTION

Diabetic foot ulcer, major problem that can impair the quality of life, require prolong hospitalization and entails high cost to the patient. Diabetic foot disease affects about 5% of diabetic patients foot disease affects about 15% of diabetic patients.[1,2] It is estimated that 19-34% of patients with diabetes are likely to be affected with a diabetic foot ulcer in their life times and the International Diabetes Federation reports that 9.1-26.1 million people will develop DFUs annually.[3,4] Infection is a common and serious complication of diabetic foot wounds. Infection leads to formation of microthrombi, causing further ischemia, necrosis, and progressive gangrene. Massive infection is the most common factor leading to amputation. Local trauma and/or pressure (often in association with lack of sensation because of neuropathy), in addition to microvascular disease, may result in various diabetic foot infections that run the spectrum from simple, superficial cellulitis to acute and chronic osteomyelitis and deep-skin and soft-tissue infections.[5] DFUs are relatively common. Once the protective layer of a skin is broken, deep tissues are exposed to a bacterial infection that progress rapidly. DFUs frequently requires amputation of the lower limbs and is the predominant factor.[6,7] The incidence of foot

ulcers ranges from 8-11 percent in India.[8] The clinician seeing a patient with a diabetic foot ulcer always assess for the presence of and infection and if, present classify the infection's severity.[9] The clinical diagnosis of foot infection is based on the presence of purulent discharge from an ulcer or the classic signs of inflammation i.e., erythema, pain, tenderness, warmth or induration.[10] If the ulcers appear infected tissue sample testing in a microbiology laboratory may be helpful in identifying the types of bacteria causing the infection and choosing and appropriate antibiotic. An infected ulcer is usually treated with an oral antibiotic for 1 to 2 weeks. If the bone has infected only for a short time or if removing the dead bone is not possible, a patient may be prescribed a long course of intravenous antibiotics.[11] Most moderate to severe soft tissue diabetic foot infections are polymicrobial (i.e., due to gram-positive, gram-negative, aerobic, and anaerobic pathogens). Empiric antibiotic therapy should include broad-spectrum antibiotics capable of covering the most common pathogens found in diabetic infections.[12] Establishing presence of infection is an important component of ulcer care. Not all ulcers are infected and given increasing antibiotic resistance and risk of antibiotics related adverse events including diarrhoea and *Clostridium difficile* infection, the goal for antibiotic use in foot ulceration is to treat and active infective process, aiming to tailor therapy to the appropriate pathogen(s) [13]. It is mandatory upon all doctors to use medicines rationally, particularly in respect of antibiotics. The "Rule of Right" - right medicine in the right manner (dose, route, frequency, and duration of administration) in the right patient at right cost - must be followed while using antibiotics. Unfortunately, irrational use of antibiotics is rampant and as common as the infectious diseases are. Irrational use of antimicrobials in clinical practice leads to several problems such as, failure of treatment, adverse drug reactions, superinfections, prolongation of therapy, development of antimicrobial resistance and increase in cost of therapy. Causes of irrational use of antimicrobials include, inadequate medical training, non-availability of diagnostic facilities, large-scale availability and use of irrational, fixed dose drug combinations of antimicrobials, and ignoring the basic principles of selection and use of antimicrobials.[14] Prescription pattern monitoring studies (PPMS) are drug utilization studies with the main focus on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored drugs and reduction of abuse or misuse of monitored drugs.[15]

The aim of PPMS is to facilitate the rational use of drugs in a population. Irrational use of medicines is a major problem worldwide. World Health Organisation (WHO) estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and the half of all patients fail to take them correctly. The rational use of medicines (RUM) is defined as patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.[16,17]

Objectives

The present study was conducted with an aim to study a prescribing pattern of antibiotics used in diabetic foot ulcer (DFU).

METHODS

Prospective observational study. Study period and duration from October to December 2019 and 3 months, sample size 50. The study was done Department of Surgery, Rajah Muthiah Medical College Hospital (RMMCH), Annamalai University.

Inclusion criteria

Inclusion criteria were patients with history of diabetes, patients of both genders, patients more than 30 of age and less than 80 of age, and prescription with antibiotics.

Exclusion criteria

Exclusion criteria were patients with comorbidities such as hypertension, coronary artery disease (CAD), history of diabetes mellitus type 1, pregnant and mentally ill patients, and over the count medications (OTC).

Patients details collected through patient data collection form. Patient data collection of form consists of details such as patient gender, age, in-patient number, date of admission and date of discharge, chief complains, history of present illness, past history, laboratory investigations, diagnosis, medications.

Antibiotic culture sensitivity test includes sample type, organism isolated, organism growth and antibiotic susceptibility, antibiotic resistance of drugs. Further information of patient underwent surgery methods.

Risk factors are useful to consider which patient are in risk category. Grading score calculated by using Saint Elian wound score system and infectious disease society of America.[22]

RESULTS

On the basis of inclusion and exclusion criteria 50 patients were included in this study. Male patients are more affected with DFU than female patients (Table 1). Age of 50 to 60 patients are more prevalence of DFU (Table 2).

Risk factors classified into 3 categories and they are normal plantar sensation 18%, loss of plantar sensation 14%, loss of plantar sensation with either high pressure or poor circulation 4%and history of amputation or ulceration or neuropathic fracture 68% (Table 3).

According to grading Saint Elian wound score system and infectious disease society of America, infection classified as mild 16%, moderate 72%, severe 12% (Table 4).

Surgical procedures used in DFU are wound debridement 56%, grafting 8%, amputation 30% and osteotomy 6% (Figure 1).

The most commonly prescribed antibiotics are cefotaxime 48% and metronidazole 48% and the combination used are piperacillin with tazobactam 30%, amoxicillin with clavulanic acid 10%, cefoperazone sodium with sulbactam 2% and others are ciprofloxacin 20%, cefixime 6%, ceftriaxone 2%, clindamycin 4%, linezolid 18%, amoxicillin 2%, gentamycin 2%, faropenam 4%, amikacin 4% (Table 5).

Only 6% patients are not infected with bacteria. Organisms isolated from the patient samples are gram positive cocci 28% and gram-negative bacilli 24% and 2% of both gram-positive cocci with gram negative bacilli (Table 6).

Table: 1 Gender wise distribution.

Gender	Number of patients	Percentage of patients (%)
Male	30	60
Female	20	40

Table 2: Age wise distribution.

Age (in years)	Number of patients	Percentage of patients (%)
30-40	4	8
40-50	6	12
50-60	16	32
60-70	9	18
70-80	6	12

Table 3: Risk factors.

Risk category	Number of patients	Patients (%)
Normal plantar sensation	9	18
Loss of plantar sensation	7	14
Loss of plantar sensation with either high pressure or poor circulation	2	4
History of amputation or ulceration or neuropathic fracture	34	68

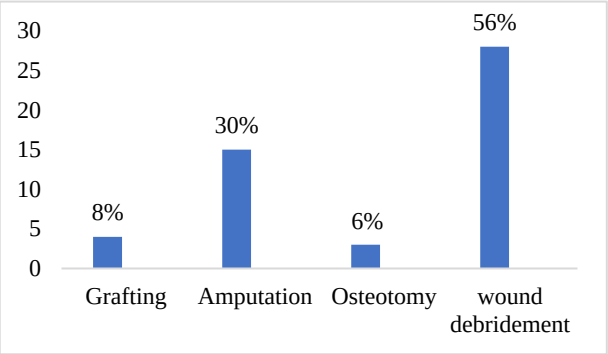

Figure 1: Surgical procedure used in DFU.

The most commonly gram-positive cocci present in the samples are methicillin-resistant *Staphylococcus aureus* 26% and *Streptococcus pyogenes* 2% (Table 7). The most commonly gram-negative bacilli present in the samples are *Pseudomonas aeruginosa* 10%, *Escherichia coli* 6%, *Klebsiella pneumoniae* 6%, *Proteus vulgaris* 2% and *Staphylococcus aureus* 2% (Table 7).

Table 4: Grading-classification of diabetic foot infections; Saint Elian wound score system and infectious disease society of America.

Description	Severity grade	Score	Number of patients	Percentage of patients (%)
No signs or symptoms of infection	Not infected	0	0	0
Erythema between 0.5 mm-2 cm, induration, tenderness, warmth and purulent discharge	Mild	1	8	16
Erythema >2 cm, muscle, tendon or bone or joint infection	Moderate	2	36	72
Any local infection with systemic inflammatory response manifested by at least 2 of following: temperature >38 F or <36, heart rate >90 beats/min, respiratory rate >20 breaths/min, white blood cell count >12000 cells/cu.mm	Severe	3	6	12

31 patients tested for antibiotic sensitivity. *Proteus vulgaris* in sample shows resistance to ampicillin, ciprofloxacin, cefazolin, co-trimoxazole and susceptibility to amikacin, gentamycin, imipenem, cefuroxime, piperacillin and tazobactam. *Escherichia coli* in sample mostly susceptible towards amikacin followed by gentamycin, piperacillin and tazobactam, gentamycin and resistant towards ampicillin, cefuroxime, ceftriaxone, cefazolin, ciprofloxacin and co-trimoxazole shows both resistant and susceptible.

Table 5: Distribution of antibiotics prescribed.

Drugs	Number of patients	Percentage of patients (%)
Cefotaxime	24	48
Ceftriaxone	1	2
Cefixime	3	6
Cefoperazone sodium and sulbactam	1	2
Clindamycin	2	4
Amikacin	2	4
Gentamycin	1	2
Amoxicillin	1	2
Amoxicillin and clavulanic acid	5	10
Piperacillin and tazobactam	15	30
Ciprofloxacin	10	20
Metronidazole	24	48
Linezolid	9	18
Faropenam	2	45

Pseudomonas aeruginosa in sample mostly susceptible towards piperacillin and tazobactam followed by imipenem, meropenem and resistant towards amikacin, ciprofloxacin, ceftazidime, tobramycin, amoxycillin, clavulanic acid and gentamycin shows both resistant and susceptible.

Table 6: Microbiological culture report.

Clinical details	Number of patients	Percentage of patients (%)
No bacteria seen	3	6
Gram positive cocci	14	28
Gram negative bacilli	12	24
Gram positive cocci and gram-negative bacilli	1	2

Klebsiella pnumoniae in sample shows mostly susceptible towards ciprofloxacin followed by nalidixic acid, amikacin and resistant to ampicillin, cefuroxime, ceftriaxone, cefazolin, co-trimoxazole and piperacillin, tazobactam, and gentamycin shows both resistant and susceptible.

Table 7: Distribution of gram-positive organisms and gram-negative organisms.

Gram positive-organisms and gram-negative organisms	Number of patients	Percentage of patients (%)
Streptococcus pyogenes	1	2
MRSA	13	26
Escherichia coli	3	6
Staphylococcus aureus	1	2
Pseudomonas aeruginosa	5	10
Proteus vulgaris	1	2
Klebsiella pneumoniae	3	6

Streptococcus pyogenes in sample shows resistance to erythromycin, tetracycline, oxacillin, co-trimoxazole, ciprofloxacin and susceptibility to chloramphenicol, clindamycin, gentamycin, amikacin, linezolid. MRSA in sample shows mostly both susceptible and resistant towards amikacin followed by co-trimoxazole, tetracycline, chloramphenicol, linezolid, clindamycin, ciprofloxacin, erythromycin, ceftriaxone and susceptible towards to norfloxacin, tobramycin, cefuroxime and resistant towards to oxacillin, imipenem, nalidixic acid, ofloxacin. *Escherichia coli* and *Pseudomonas aeruginosa* in sample shows resistance to ampicillin, cefuroxime, nalidixic acid, ciprofloxacin, ceftazidime, tobramycin, co-trimoxazole, cefazolin, amoxycillin, clavulanic acid and susceptibility to ceftriaxone, piperacillin and tazobactam. *Staphylococcus aureus* and *Pseudomonas aeruginosa* in sample shows resistance to erythromycin, tetracycline, amikacin, gentamycin, ciprofloxacin, ceftazidime, ceftriaxone, clindamycin, tobramycin, co-trimoxazole and susceptibility to linezolid, imipenem, chloramphenicol (Table 8). Antibiotics prescribed in both oral 42% and intravenous injection form 72% (Figure 2).

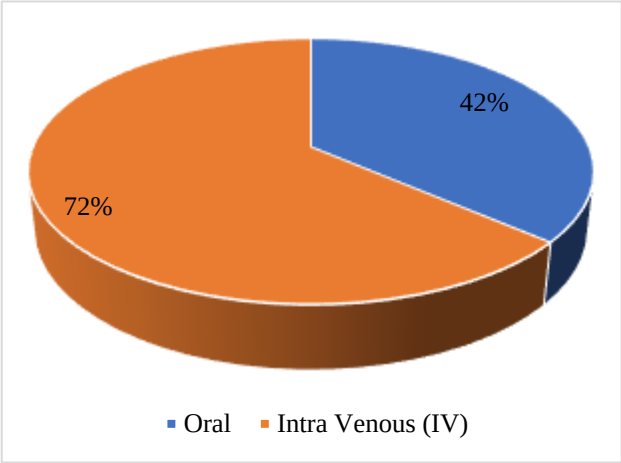

Figure 2: Route of administration of antibiotics.

Table 8: Antibiotic sensitivity (n=31).

Organisms isolated	Antibiotics	Number of susceptibility (S)	Number of resistance (R)
Escherichia coli	Ampicillin	-	2
	Cefuroxime	-	2
	Ciprofloxacin	-	2
	Ceftazidime	-	1
	Co-trimoxazole	1	1
	Cefazolin	-	1
	Ceftriaxone	-	2
	Piperacillin and tazobactam	1	-
	Amikacin	2	-
	Gentamycin	1	-
Proteus vulgaris	Ampicillin	-	1
	Ciprofloxacin	-	1
	Cefazoline	-	1
	Co-trimoxazole	-	1
	Amikacin	1	-
	Gentamycin	1	-
	Imipenem	1	-
	Cefuroxime	1	-
	Piperacillin and tazobactam	1	-
Klebsiella pnumoniae	Ampicillin	-	3
	Gentamycin	1	2
	Cefuroxime	-	2
	Piperacillin	2	1
	Tazobactam	-	3
	Ceftriaxone	-	3
	Cefazoline	-	3
	Co-trimoxazole	-	3
	Amikacin	1	-
	Ciprofloxacin	2	-
	Nalidixic acid	1	-
Pseudomonas aeruginosa	Amikacin	-	3
	Gentamycin	1	2
	Ciprofloxacin	-	3
	Ceftazidime	-	2
	Tobramycin	-	2
	Amoxycillin and clavulanic acid	-	2
	Meropenem	1	-
	Piperacillin and tazobactam	3	-
	Imipenem	1	-
MRSA	Linezolid	6	6
	Oxacillin	-	11
	Gentamycin	4	7
	Co-trimoxazole	7	5
	Tetracycline	7	4
	Clindamycin	4	5
	Norfloxacin	1	-
	Chloramphenicol	7	5
	Ciprofloxacin	4	7
	Amikacin	9	2
	Erythromycin	2	6
	Ceftriaxone	1	1

Continued.

Organisms isolated	Antibiotics	Number of susceptibility (S)	Number of resistance (R)
	Imipenem	-	1
	Nalidixic acid	-	1
	Tobramycin	1	-
	Ofloxacin	-	1
	Cefuroxime	1	-
Streptococcus pyogenes	Erythromycin	-	1
	Tetracycline	-	1
	Oxacillin	-	1
	Co-trimoxazole	-	1
	Ciprofloxacin	-	1
	Chloramphenicol	1	-
	Clindamycin	1	-
	Gentamycin	1	-
	Amikacin	1	-
	linezolid	1	-
Staphylococcus aureus and Pseudomonas aeruginosa	Erythromycin	-	1
	Tetracycline	-	1
	Amikacin	-	1
	Gentamycin	-	1
	Ciprofloxacin	-	1
	Ceftazidime	-	1
	Ceftriaxone	-	1
	Clindamycin	-	1
	Tobramycin	-	1
	Co-trimoxazole	-	1
	Linezolid	1	-
	Imipenem	1	-
	Chloramphenicol	1	-
Escherichia coli and Pseudomonas aeruginosa	Piperacillin and tazobactam	1	-
	Ceftriaxone	1	-
	Ampicillin	-	1
	Cefuroxime	-	1
	Nalidixic acid	-	1
	Ceftazidime	-	1
	Tobramycin	-	1
	Co-trimoxazole	-	1
	Cefazolin	-	1
	Amoxicillin and clavulanic acid	-	1

DISCUSSION

The first WHO global report on diabetes demonstrates that the number of adults living with diabetes has almost quadrupled since 1980 to 422 million adults. This dramatic rise is largely due to the rise in type 2 diabetes and factors driving it include overweight and obesity. In 2012 alone diabetes caused 1.5 million deaths. Its complications lead to heart attack, stroke, blindness, kidney failure and lower limb amputation.[18]

In our study about patient developed foot ulcer with pre-existing diabetes mellitus type and it shows male patients are more than female patient with diabetic foot ulcer. And this result is similar to other study it shows male patients are more prone to get DFU.[19] Age group of 50 to 60 patients had higher prevalence of DFU this result was similar in other study.[20] Based on the international diabetic federation (IDF) patient history are classified as risk categories.[21]

In our study according to Saint Elian wound score system and infectious disease society of America patients are mostly falls under grade 2 but in another study, patients are mostly in grade 1.[22] The most commonly prescribed antibiotics in DFU are cefotaxime 48% and metronidazole 48% and also another study shows similar class of antibiotics are prescribed such as cephalosporins 21.4% and nitroimidazole 26.1 in total of 35 diabetic foot ulcer patients.[19]

The most common organism present in the isolated samples are classified as gram-positive organisms 28% and gram-negative organisms 24% where in another study gram-negative organisms 73.1% are more than the gram-positive organisms 26.8% present in total of 41 patients.[19]

Both gram-negative organism and gram-positive organism present in the sample 2% is less when compared to another study that had both gram- negative organism and gram-positive organisms 57.5% of 46 patients.[23]

The gram-negative organisms are *Escherichia coli* (6%), *Staphylococcus aureus* (2%), *Pseudomonas aeruginosa* (10%), *Proteus vulgaris* (2%), *Klebsiella pneumoniae* (6%) where in another study *Proteus* species (12.6), *E. Coli* (12.0%), Pseudomonas aeruginosa (9.8%), *Klebsiella* species (6.6%).[23] The gram-positive organisms are *Streptococcus pyogenes* (2%) and MRSA (26%) where in another study MRSA is more (47.8%) of 59 infected patients.[24]

MRSA is present in the most of the patient pus samples and it is difficult to treat because most of the antibiotics are resistance towards MRSA. MRSA strains play a significant role as an important pathogen in diabetic foot infection (DFI) and have become a public health concern due to their increased virulence and resistance to an increasingly broad spectrum of antibiotics.[25]

CONCLUSION

In our study shows that most of the prescribed antibiotics for DFU are cephalosporin and macrolide class of antibiotics. And also observed only moderate level culture sensitivity test are done. MRSA organism is mostly isolated in samples.

Lack of antibiotic sensitivity test leads to growth of organism, wrong antibiotic selection and irrational use of antibiotics. And also observed patient developed resistance to linezolid antibiotic when physician used as a first choice of drug to treat diabetic foot infection including methicillin-resistant *Staphylococcus aureus* (MRSA) infected patients. So, our study may help to considering antibiotics which shows susceptible to organisms.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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