

Drug Prescribing Patterns in Diabetic Foot Ulcer Patients

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Abstract

Prescribing pattern studies are powerful exploratory tools to ascertain the role of drugs in society. In a tertiary care Centre, prescribing is expected to be judicious, appropriate, safe, effective and economical. A prospective observational study was carried out at inpatient department of General surgery in Tertiary care teaching hospital, Tirupati from November 2016 - April 2017 during regular ward rounds. The demographic details and treatment data of 84 patients were collected in a specially designed Proforma. In this study male patients were listed more 52 (61.9%) than the female patients 32 (38.1%). Majority of patients was in 61 - 70 years age group 25 (29.6%) followed by 18 (21.4%) patients are in 51 - 60 years. In our study most of the patients have comorbidities 56 (66.7%). In total 84 patients, 884 drugs were prescribed among them majority of drugs were antibiotics 285 (32.3%) followed by vitamin supplements 184 (20.8%). Among 285 antibiotics prescribed, majority were penicillin's 96 (33.68%). All the drugs in the study were prescribed according to WHO Essential drug list. This study reveals that most of the antibiotics were prescribed empirical and only a few patients undergoes in culture sensitivity test it may result in development of antibiotic resistance. The periodic study on the usage of antibiotics and sensitivity pattern in the hospital setup is to be developed which enables the healthcare professionals to select the appropriate one to promote the rational use of antibiotics.

Keywords: Prescribing Patterns; Diabetic Foot Ulcers; Antibiotics; Antidiabetics; Rational Drug Use

Abbreviations

DFU: Diabetic Foot Ulcer; PTC: Pharmacy and Therapeutic Committee; WHO: World Health Organization; EDL: Essential Drug List; NLEM: National List of Essential Medicines; FBS: Fasting Blood Sugar; RBS: Random Blood Sugar; PPBS: Post Prandial Blood Sugar; MDR: Multi Drug Resistant; CHF: Congestive Heart Failure; PAD: Peripheral Artery Disease; HbA1C: Glycosylated Hemoglobin; ABPI: Ankle Brachial Pressure Index; TCC: Total Contact Casts; WBP: Wound Bed Preparation; DFI: Diabetic Foot Infection; CVA: Cerebro Vascular Accident; CAD: Coronary Artery Disease; COPD: Chronic Obstructive Pulmonary Disease; CCF: Congestive Cardiac Failure; AKI: Acute Kidney Injury; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; S/C: Subcutaneous; MVI: Multi Vitamin Injection; IEC: Institutional Ethics Committee

Introduction

A prescription is a written advice that mentions drugs and other instructions given to either pharmacist or chemist to dispense the drugs to patients for the proper treatment of disease. It provides information like an adequate dose of the drug to be given, its duration and the way it has to be taken [1]. Prescribing pattern studies are powerful exploratory tools to ascertain the role of drugs in society. In a tertiary care centre, prescribing is expected to be judicious, appropriate, safe, effective and economical. The ultimate goal is to achieve rational and effective medical care, particularly in the economically developing countries. Considering these facts, this study is planned to

analyze the prescribing pattern in diabetic foot ulcer patients at a tertiary care teaching hospital. Drug therapy is considered to be major component of management of diabetic foot ulcers (DFU's) in healthcare setting like hospital. Effective medical treatment of diabetic patient is based upon an accurate diagnosis and optimum course of therapy, which usually involves a medication regimen [2].

Unnecessary prescribing of drugs particularly antibiotics and injections leads to development of resistance to antibiotics, adverse effects and economic burden on patients and the society. Rational use of medicines requires that patients receive medications appropriate to their clinical needs [3]. Diabetes, considered as a disease of developed countries, is one of the endocrine disorders that have reached epidemic proportions worldwide. There are currently 285 million people living with diabetes worldwide, and the number of affected people is predicted to reach 438 million by 2030, with 62 million diabetic individuals currently diagnosed with the disease in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India as a consequence of longer life expectancy, sedentary lifestyle and changing dietary patterns [4].

As per a report, neuropathy affects 20 - 50% diabetic patients. Asia is considered to be the epicenter of the epidemic of diabetes. World's most populous countries such as China with 20% of the world's population and India with more than one billion have the greatest number of people with diabetes, and are likely to remain in this position in 2025, with an expected 20 million affected individuals. According to clinical guideline for diabetes mellitus all patients should be screened annually to found their risk for foot ulceration. Many infections are seen more frequently in diabetes and they are indications of poor diabetic control. Foot infections in diabetic patients are initially treated empirically. Hence, while selecting antibacterial, one should consider severity of infection, route of drug administration, co-morbidities and spectrum of organisms to be covered. Therapy directed at known causative organisms can significantly improve the outcome and reduce infection related morbidity and mortality. The increasing association of multi-drug resistant (MDR) pathogens with DFUs further challenges the physician or the surgeon in treating diabetic ulcers without resorting to amputation [5].

A Cochrane review assessed the effectiveness of patient education on DFU prevention (Valk., et al. 2001)- existing data suggests that patient education, particularly in high risk groups, improves foot care knowledge and positively influences patient behaviour in the short term which may reduce foot ulcerations and amputation. Practitioners therefore have a responsibility to provide structured education and training to all patients which should be revisited on a regular basis [6].

Diabetes is often accompanied by serious complications of diabetes and is the leading cause of hospitalization in diabetic patients. Diabetic foot 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 within a period of 6 - 18 months after the first evaluation. Neuropathic wounds are more likely to heal over a period of 20 weeks, while neuroischemic ulcers take longer and will more often lead to limb amputation. It has been found that 40 - 70% of all no traumatic amputations of the lower limbs occur in patients with diabetes. Furthermore, many studies have reported that foot ulcers precede approximately 85% of all amputations performed in diabetic patients [7].

The main aim of prescribing pattern research is to facilitate the rational use of drugs in populations i.e., the prescription of a well-documented drug at an optimal dose, together with the correct information. Information on the past performance of prescribers is vital for any auditing system. A precise knowledge of how drugs are being prescribed and used is essential to initiate a discussion on rational drug use or to suggest measures to improve prescribing habits. Keeping the above things in mind, the present study was taken up to evaluate the prescribing patterns of drugs used in the management of DFUs.

Methodology

This prospective study was carried out after obtaining the permission of Institutional Ethics Committee (IEC Proposal No: SPSP/2016-2017/PB01), Sri Padmavathi School of Pharmacy, Tiruchanoor, Tirupati, Andhra Pradesh, India. All patients (above 20 years), admitted in the general surgery in-patient ward of SVRRGGH, between December 2016 to May 2017 (6 months) was included in the study. A specially

designed Proforma was used for collection of the data which includes patient demographics, social habits, past medical history, family and surgical history, co-morbidities, diagnosis and present medications prescribed for each patient. The data was obtained by direct patient interview with their consent and from patient case profiles. 84 cases were collected from the general surgery ward, according to study criteria.

Results and Discussion

Total 84 patients are included in the study. Among them 56 (66.7%) were only DFU patients and 28 (33.4%) were along with comorbid patients. These results are similar to the Srinivasan T., *et al.* (2017) Comparative Study of Foot Infections among Diabetic and Non-Diabetic Individuals reveals that predominant of DFU than the comorbidity [8]. Considering the gender wise distribution of comorbidities, 28 patients have comorbid conditions. of them, 18 (62.5%) were male patients followed by female patients 10 (37.5%).

Considering the co-morbid conditions among patients, out of 84 patients 32 were suffering from other co-morbid conditions like hypertension, CVA, Asthma etc. among them 19 (59.4%) patients were suffering from hypertension followed by 4 (12.5%) patients were suffering from CVA then 3 (9.4%) patients were suffering from peripheral vascular disease. Out of remaining 6 patients, each patient is suffering from one of the following co morbidities like Asthma 1 (3.1%), CAD 1 (3.1%), COPD 1 (3.1%), Hemiplegia 1 (3.1%), CCF 1 (3.1%) and AKI 1 (3.1%).

Considering the gender wise distribution, among 84 patients, 52 (61.9%) were male patients and 32 (38.1%) were female patients. These findings are in related according to the Chomi EI., *et al.* (2015) Clinical Profile and Prognosis of Diabetes Mellitus Type 2 Patients with Diabetic Foot Ulcers in Chomi Medical and Surgical Clinic, General Santos City, Philippines reveals that predominant of male patients than the female patients [9].

Considering the age group, the majority number of patients was in 61 - 70 years 25 (29.6%) patients followed by 51 - 60 age group 18 (21.4%) patients then 41 - 50 age group 14 (16.66%) patients followed by < 40 age group patients were 9 (10.71%), 71 - 80 age group patients were 9 (10.71%) and > 80 age group patients were 9 (10.71%). These findings are in contrast to the Edward w. Gregg., *et al.* (2004) Prevalence of Lower-Extremity Disease in the U.S. Adult Population > 40 Years of Age With and Without Diabetes which reveals that age group between 41 to 70 years are commonly affected with DFU [10].

Considering the social habits, out of 84 patients, 47 have the habits like smoking and alcohol consumption. The majority of patients are both alcoholic and smoker 18 (38.2%) followed by alcohol 8 (17.0%) then past alcohol 7 (14.8%) and past smoker 7 (14.8%) followed by past alcohol and smoker 3 (6.3%). These results are in related to the Bikramjit Pal., *et al.* (2016). A study on the impact of smoking and alcoholism as determinant factors in the prognosis and outcome of diabetic foot ulcer disease which reveals that addiction to smoking and alcohol poses a great threat to the patients with diabetic foot ulcer disease which may be the determinant factors in the ultimate outcome of the disease [11].

Considering the duration of hospitalization, the majority number of patients 41 were stayed in hospital for 0-1 week (48.8%) followed by 23 patients were stayed in hospital for 1 - 2 weeks (27%) then 14 patients were stayed in hospital for 2 - 3 weeks (16.66%) and 4 patients were stayed in hospital for 3 - 4 weeks (4.76%) and 2 patients were stayed in hospital for more than 1 month (2.38%). Considering the number of drugs per each prescription, 6 - 10 drugs were prescribed majorly in 35 patients (41.66%) followed by 11 - 15 drugs were prescribed in 30 patients (35.71%) then 16 - 20 drugs were prescribed in 13 patients (15.47%) followed by 21 - 25 drugs were prescribed in 3 patients (3.57%), less than 5 drugs were prescribed in 2 patients (2.38%) and more than 25 drugs were prescribed in 1 patients (1.19%).

Considering the route of administration of drugs, majority of drugs were administered by oral route which was 292 (33.03%) followed by intravenous route which was 247 (27.94%) then subcutaneous route which was 98 (11.08%) followed by intramuscular route which was 87 (9.84%) followed by inhalational route which was 80 (9.04%) and topical route which was 80 (9.04%).

Considering the surgery details, total 40 patients have undergone surgery. Of them, the majority of patients i.e. 20 underwent debridement (50%), followed by 11 patients have undergone amputation (27.5%), then 8 patients have undergone disarticulation (20%) and 1 patient has undergone both disarticulation and amputation (2.5%). These results are similar to the Prathap Balakrishna, *et al* (2014). A study on the use of cephalosporins in patients with Diabetic foot infections which reveals that debridement was the majorly performed surgical intervention in the management of DFU's followed by disarticulation and amputation [12].

Considering the therapy wise distribution in 84 patients, majorly pharmacological therapy was prescribed in 48 (57.1%) patients followed by the combination of surgery and pharmacological therapy was prescribed in 36 (42.8%). Considering the category wise distribution of drugs in prescription, total 884 drugs were prescribed. The majority of drugs prescribed were antibiotics 285 (32.2%) followed by vitamin supplements 184 (20.8%) then followed by analgesics 144 (16.2%) followed by other classes of drugs. These results are similar to the study conducted by Nikhil Peter, *et al.* (2017) Study of prescribing pattern and use of antibiotic in the management of wound infection which reveals that the antibiotics were prescribed majorly followed by vitamin supplements and then other classes of drugs [13].

Considering the pharmacological class wise distribution of antibiotics, total 285 antibiotics were prescribed. Penicillin's were prescribed majorly 96 (33.68%) followed by Nitroimidazoles (Metronidazole) 73 (25.61%) then followed by Cephalosporin's 61 (21.4%), Aminoglycosides 20 (7.01%), Quinolones 19 (6.66%), Carbapenems 10 (3.5%), Macrolides 4 (1.4%) and Lincosamides 2 (0.7%). These results were similar to the study conducted by Shashi R., *et al.* (2015). Prescribing patterns of antimicrobials in Diabetic foot ulcer in a tertiary care teaching rural hospital [9]. Considering the therapy wise distribution of antibiotics, the majority of antibiotics were prescribed as dual therapy 24 (30%) followed by triple therapy 18 (22.5%) then quadruple therapy 15 (18.7%), 14 prescriptions contain more than 4 antibiotics (17.5%), only 9 prescriptions contain monotherapy (11.2%). These results are similar to the study conducted by Elahe Elhami, *et al.* (2016) Prescribing pattern of different antibiotics and analgesics used in patient with Diabetic foot ulcer [7].

Considering the pharmacological class wise distribution of Antidiabetics, Plain Insulin were prescribed majorly 48 (51.06%) followed by biguanides 22 (23.4%), sulfonyl ureas 13 (13.82%), mixtard insulin 10 (10.63%), thiazolidinediones 1 (1.06%). These results are in contrast to the study conducted by the Javedh Shareef, *et al.* where in their study Metformin and Glimepiride are majorly prescribed drugs than plain insulin [4]. Considering the therapy wise distribution of antidiabetics, the majority of antidiabetics were given as monotherapy 44 (41.9%), followed by quadruple therapy 35 (33.3%), dual therapy 18 (17.14%), and triple therapy 8 (7.6%). Considering the distribution of analgesics, 140 were prescribed. The majorly prescribed drug was Acetaminophen 70 (50%) followed by Tramadol was 42 (30%), Serratiopeptidase was 23 (16.42%), Diclofenac was 5 (3.57%). These results are in contrast to the Elahe Elhami, *et al.* study where in their study Tramadol and Lignocaine HCl are majorly prescribed drugs than Acetaminophen [7].

Considering the distribution of antiulcerants, total 77 drugs were prescribed. The majorly prescribed class of drug was PPI's i.e. 74 (96.1%) followed by Antihistamines i.e.; 3 (3.89%). Considering the distribution of antihypertensives, total 29 drugs were prescribed. The majorly prescribed class were dihydropyridines i.e. 12 (41.37%) followed by diuretics i.e. 8 (27.58%) then angiotensin-1 receptor blockers i.e. 5 (17.24%) followed by ACE inhibitors i.e. 4 (13.79%).

Considering the distribution of vitamin supplements, total 184 drugs were prescribed. The majorly prescribed drug was Vitamin C i.e. 65 (35.32%) followed by Vitamin B complex was 37 (20.1%) then Iron folic acid was 35 (19.02%) both MVI and Cap A&D were prescribed equally which was 21 each (11.41%) followed by calcium which was 5 (2.72%).

Considering the distribution of antiplatelets, total 16 drugs were prescribed. Both Aspirin and Clopidogrel were prescribed equally in 7 prescriptions each which shares 43.75% followed by cilostazol in 2 (12.5%) prescriptions. Considering the distribution of antiasthmatics and antitussives, total 8 drugs were prescribed. Theophylline was prescribed majorly which was 5 (62.5%) followed by Salbutamol was 3 (37.5%). Considering the distribution of other classes of drugs, total 18 drugs were prescribed. The majorly prescribed drug was Chymotrypsin which was 6 (33.33%) followed by Lignocaine was 5 (27.78%) then Acetylcysteine was 4 (22.22%) Pentoxifylline was 2 (11.11%) and Hydrocortisone was 1 (5.55%). In this study all the drugs were prescribed according to the WHO Essential Drug List (EDL) and National List of Essential Medicines (NLEM).

This study has provided data regarding the prescription pattern of drugs in diabetic foot ulcer patients. Antibiotics, vitamin supplements, analgesics and antidiabetics were the most frequently prescribed drugs. Most of the diabetic foot ulcer patients have co morbid conditions and require more than one antibiotic, vitamin supplement, antidiabetic and analgesic drug for their treatment. The use drugs from the essential medicine list to reduce the cost of treatment and to improve compliance of the patients must be encouraged. Most of the antibiotics were prescribed empirical and only a few patients undergoes in culture sensitivity test it may result in development of antibiotic resistance. The periodic study on the usage of antibiotics and sensitivity pattern in the hospital setup is to be developed which enables the healthcare professionals to select the appropriate one to promote the rational use of antibiotics.

Conclusion

This study has provided data regarding the prescription pattern of drugs in diabetic foot ulcer patients. Antibiotics, vitamin supplements, analgesics and antidiabetics were the most frequently prescribed drugs. Most of the DFU patients have co-morbid conditions and require more than one antibiotic, vitamin supplement, antidiabetic and analgesic drug for their therapy. The use of drugs from the EML is to reduce the cost of therapy and to improve compliance of the patients must be encouraged.

This study reveals that most of the antibiotics were prescribed empirically and only a few patients undergoes in culture sensitivity test so it may result in development of antibiotic resistance. The periodic study on the usage of antibiotics and sensitivity pattern in the hospital setup is to be developed which enables the health care professionals to select the appropriate one to promote the rational use of antibiotics.

In our study most of the patients were from lower socio-economic lifestyle, hence there will be a risk of developing gangrene and higher chances of amputation of the foot. Here comes the role of the clinical pharmacist who plays an important role in patient counseling about diabetic foot care and selecting the antibiotics which are rational. Today India faces lot of setbacks in the irrationality of drug use, especially in the prescription pattern of antibiotics. The rational use of drug requires five R's. Right drug, right dose, right route, right frequency and of right duration, moreover it should be lowest cost to them and their community.

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