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THE PROSPECTIVE OBSERVATIONAL STUDY ON COMPARING THE EFFICACY OF CEFTRIAXONE AND COMBINATION THERAPY OF CEFTRIAXONE AND METRONIDAZOLE IN PATIENTS WITH DIABETIC FOOT INFECTION

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ABSTRACT

Background information: Ceftriaxone and metronidazole are the antibiotic medications used for the management of bacterial infections and in the treatment of diabetic foot infection. **Objectives:** To determine the efficacy of the ceftriaxone monotherapy and the combination therapy of ceftriaxone and metronidazole in patients with diabetic foot infection. To identify the microbes causing infection in diabetic foot patients. **Methods:** A prospective observational study. Was carried out in general surgery department, Krishna Rajendra hospital, Mysuru for a period of 6 months. The study include participants with diabetic foot infection and the patients were divided based on the severity by using Wagner classification of diabetic foot and treatment was given accordingly and their efficacy has been analyzed. **Result:** 120 people are included in our study population, of which 35.8%(n=43) were male and 64.2% (n=77) were female patients having diabetic foot infection. The ceftriaxone and metronidazole showed 83.30% (n=50) of effectiveness, 15%(n=9) of moderately effectiveness and 1.70%(n=1) of not effectiveness. The ceftriaxone showed 28.30%(n=17) of effectiveness, 33.30%(n=20) of moderately effectiveness and 38.31%(n=23) of not effectiveness. Over all the combination therapy of ceftriaxone and metronidazole was more effective in diabetic foot infection. **Conclusion:** The study evaluated the effectiveness of ceftriaxone and metronidazole with ceftriaxone for treating diabetic foot infection. Results showed the ceftriaxone was more effective in mild cases, while combination therapy was more effective in moderate cases. The study emphasizes the importance of early diagnosis, careful antibiotic selection and patient education for better prognosis and quality of life.

KEYWORDS: Diabetic foot, Ceftriaxone, Ceftriaxone + Metronidazole, Efficacy.

INTRODUCTION

Diabetes is a metabolic disease that causes long term harm, organ failure and persistent hyperglycemia as a result of abnormalities in insulin supply and activity. Diabetes arises from pathological mechanism, such as the autoimmune breakdown of pancreatic β-cells and insulin resistance, which impact the metabolism of carbohydrates, fats, and proteins because of insufficient insulin.[1] Diabetes can be classified as, type 1 diabetic mellitus, type 2 diabetes mellitus and gestational diabetes mellitus.[2][3] Complications of diabetes mellitus are, Diabetes ketoacidosis, hyperosmolar hyperglycemic state, microvascular complications like diabetic nephropathy, diabetic retinopathy and diabetic neuropathy, macrovascular complications like cardiovascular, cerebrovascular diseases and diabetic foot infection.[2]

Diabetic foot infection is a potential risk of pathologic consequences, including infection, ulceration and destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease and metabolic complications of diabetes in the lower limb.[4] Out of 74.9 million individuals in India who have diabetes, 25% have diabetic foot infections, 50% develop the infection and need to hospitalized, 20%

need to have their feet amputated. In India diabetic care is neglected due to social, religious, and financial compulsions. Lack of education and poverty causes improper foot ware, leading to foot lesions. Over 90% of diabetic patients never consult specialist, and delays in healthcare due to alternative medicine prescriptions.[4]

According to standards from the National Institute of Clinical Excellence, every diabetes patient has to have a yearly evaluation of their diabetic foot. Neurological foot testing involves four locations on each foot for the application of 10 g monofilament and one of the following tests: vibration perception threshold, ankle reflexes, pinprick sensation, and vibration using a 128 Hz tuning fork. Foot shape: hallux valgus, large metatarsal heads/claw toes, muscular atrophy, or Charcot deformity. Dermatological: erythema, perspiration, and calluses. Vascular: Doppler waveforms, ankle brachial index, and foot pulses.[5]

Management of diabetic foot infection includes, Glycemic control, wound dressing, improving vascularization, negative pressure wound therapy, debridement, offloading and multidisciplinary team input.[5]

MATERIALS AND METHODS

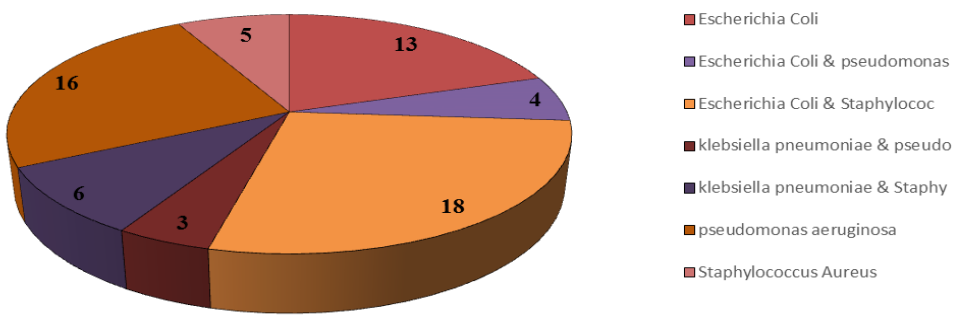
This is a prospective observational study. The study includes patients with diabetic foot infection. The necessary data was collected from medical records of the patient, by interviewing patients and communicating with the surgeons and clinicians. The study includes patients above 18 years of either gender who are taking ceftriaxone or ceftriaxone and metronidazole, and excludes pregnant and lactating women and pediatrics. A data collection form was prepared for the study which includes demographics, clinical and therapeutic data. Patients were informed about the study and consent was obtained, with illiterate patients consent was obtained from caretakers. The efficacy scale measures the effectiveness of treatment for diabetic foot infection by using 3-point Likert scale. The questionnaire assesses a drug's effectiveness by focusing on pain management, blood sugar control, infection management, wound discharge and healing process. A scoring system (AGREE=2, NEUTRAL=1, DISAGREE=0) evaluates drug effectiveness based on patient feedback. The questionnaire was validated by five experts, including clinicians from the surgery department, community medicine, head of the department, and an assistant professor, based on relevance, clarity, simplicity and ambiguity. The questionnaires were collected and scored for relevance, clarity, simplicity and ambiguity. Internal content validation was calculated using Cronbach's alpha, with a coefficient of 0.7 for corrected items. The efficacy scale consists of five questions on pain management, disease progression and lifestyle modification and is scored based on participants responses ranging from 0-4 EFFECTIVENESS, 5-7 MODERATIVELY EFFECTIVE and 8-10 NOT EFFECTIVE.

RESULT

The study screened 120 patients in which 35.8% (n=43) were male and 64.2% (n=77) were female. The study found a mean age of 54.6 years, with the majority of patients aged 51-60, the maximum age was 78 years. In the study population 55.80% (n=67) were affected with right diabetic foot and 44.20% (n=53) were affected with left diabetic foot infection. The Wagner classification was used to grades of the diabetic foot infection.[6] A maximum of 48.4% (n=58) of patients had deep ulcer to a bone, ligament or joint, classified as GRADE 2, 23.3%(n=28) have a limited superficial ulcer, classified as GRADE 1. 12%(N=15) have deep abscess and osteomyelitis, classified as GRADE 3 and 15.8%(n=19) are classified as GRADE 4, which includes forefoot and toe gangrene.

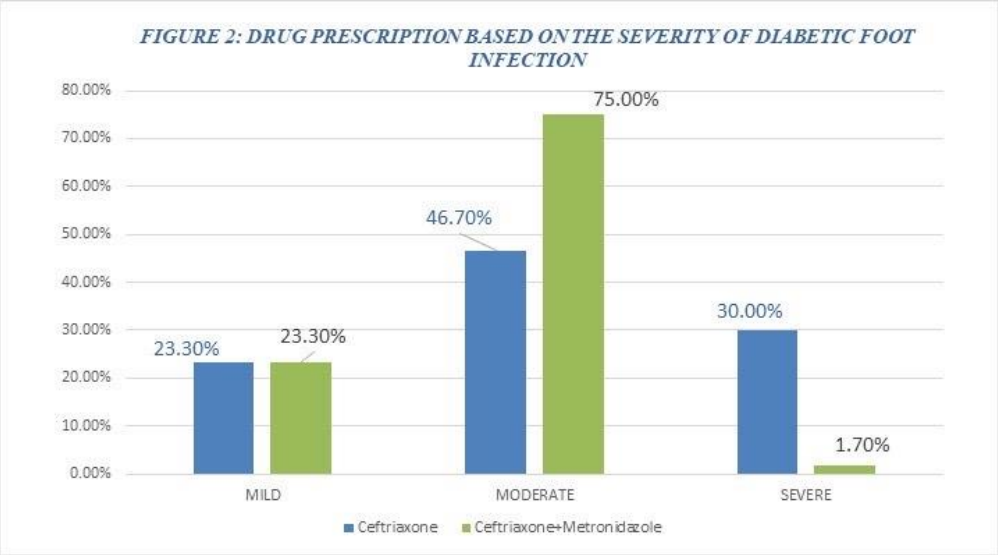
The diabetic foot infection was categorized as mild, moderate and severe based on severity of foot infection. In which 60.8% (n=73) of the study population were classified as moderate, 23.4% (n=28) were classified as mild and 15.8%(n=19) were classified as severe diabetic foot infection. In the total study population wound culture was conducted in (n=65) Patients and were divided according to the strains of organisms found in the culture sensitivity test results. *(As showed in the figure 1)*

FIGURE 1: ORGANISM STRAINS PRESENT IN DIABETIC FOOT CULTURE



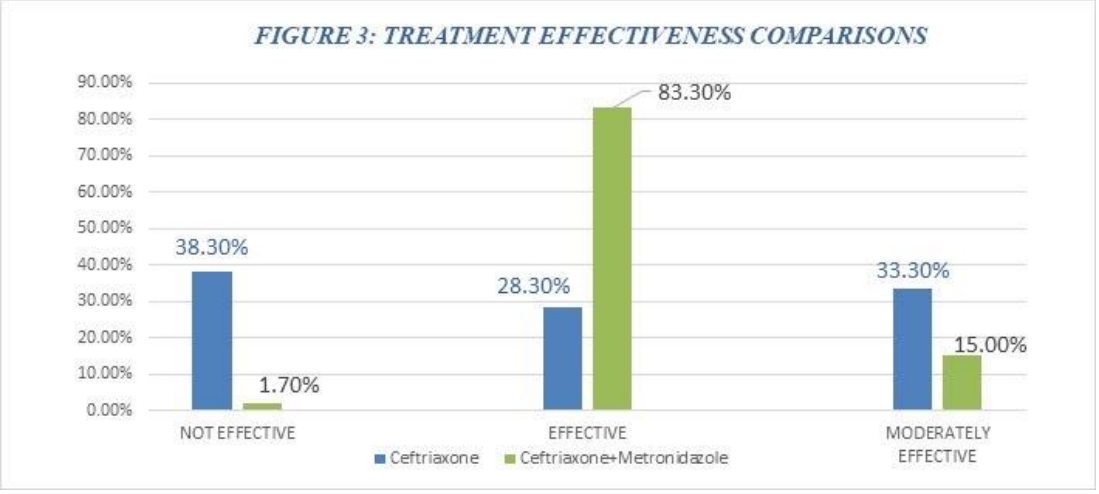
A minimum of 2.5% (n=3) of *klebsiella pneumoniae* & *Pseudomonas*, 3.3%(n=4) of *Escherichia coli* & *Pseudomonas*, 4.2% (n=5) of *Staphylococcus aureus*, and 5% (n=6) of *Klebsiella pneumoniae* & *Staphylococcus* organism were identified. Maximum strains found in the test results were 15% (n=18) of *Escherichia coli* & *Staphylococcus*, 13.4%(n=16) of *Pseudomonas aeruginosa*, and 10.8%(n=13) of *Escherichia coli* organisms.

Based on the severity of the foot ulcers evaluated, two antibiotic prescription patterns were given to 120 patients: Ceftriaxone and a combination of Ceftriaxone and Metronidazole. Grade 1: 23.30% (n=14) of the patients receive ceftriaxone, and 23.30% (n=14) receive both ceftriaxone and metronidazole. In grade 2, 35% of patients (n=21) receive ceftriaxone, while 61.70% of patients (n=37) receive both ceftriaxone and metronidazole. In grade 3, 11.70% (n=7) of the patients receive ceftriaxone, while 13.30% (n=8) receive both ceftriaxone and metronidazole. In grade 4, 30% of patients (n=18) receive ceftriaxone, while 1.70 percent of patients (n=1) receive both ceftriaxone and metronidazole. *(As showed in the figure 2)*



Based on the medication prescription pattern for two antibiotic regimens ceftriaxone and ceftriaxone with metronidazole patients with different degrees of severity from diabetic foot infections were separated from the study group. In mild cases, 23.30% (n=14) of the patients receive ceftriaxone, and 23.30% (n=14) receive both ceftriaxone and metronidazole. In Moderate, 46.70% (n=28) of the patients receive ceftriaxone, and 75% (n=45) of the patients receive both ceftriaxone and metronidazole. In Severe, 30% of patients (n=18) receive ceftriaxone, while 1.70% of patients (n=1) receive both ceftriaxone and metronidazole.

Treatment efficacy for diabetic foot patients was compared in the entire study population between ceftriaxone and combination therapy of ceftriaxone with metronidazole. Ceftriaxone and metronidazole combined therapy demonstrates 83.30% (n=50) of effectiveness, 15% (n=9) of moderate effectiveness, and 1.70% (n=1) of ineffectiveness. Ceftriaxone demonstrates an effectiveness rate of 28.30% (n=17), a moderate effectiveness rate of 33.30% (n=20), and an ineffective rate of 38.31% (n=23). *(As showed in the figure 3)*



DISCUSSION

In diabetic foot patients effective management can reduce the severity of complications, the severity of diabetic foot has been classified based on Wagner classification of diabetic foot. In which majority of study population were ranging from 55-65 years in which 66% of population were men and 34% of population were women with diabetic foot infection.[6] The diabetic foot ulcer is a severe diabetes related condition mainly caused by bacterial infection. The more prevalent bacteria are gram negative bacteria such as Escherichia coli, Pseudomonas aeruginosa, Klebsiella and proteus species.[7] In mild diabetic foot infection the combination therapy of metronidazole and levofloxacin was more effective when compared to ceftriaxone.[8]

In our study the Wagner classification for diabetic foot has been used to classify the severity of diabetic foot infection, the study demonstrates the comparable outcomes, such as early diagnosis and effective therapy can decrease the severity of diabetic foot infection. In the study population which includes people ranging from 51-60 in 53.8% of men and 64.2% of women. This study shows that the majority of bacteria causing diabetic foot infection are *Escherichia coli* and *Staphylococcus*, followed by *Pseudomonas and Klebsiella.* As a result, patients with diabetic foot infection have been treated accordingly. The efficacy of ceftriaxone monotherapy and combination therapy of ceftriaxone and metronidazole was compared, the study indicates that combination therapy is more effective in patients with moderate diabetic foot infection.

CONCLUSION

The study reveals that the selection of antibiotics for treating diabetic foot infections varies across states. Combination therapy of ceftriaxone and metronidazole is more effective in moderate cases, while ceftriaxone alone is more effective in mild cases. The study emphasizes the importance of early diagnosis, proper antibiotic selection and patient education on life style factors in preventing antibiotic resistance and improving patient outcome. Future research and collaboration in pharmacy practice are needed.

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REFERENCE

1. American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care, 2010 Jan 1; 33(Supplement_1): S62–9.
2. Wells BG, DiPiro JT, Schwinghammer TL, DiPiro CV. Pharmacotherapy Handbook. 9th ed. New York: McGraw-Hill Education, 2015.
3. Punthakee Z, Goldenberg R, Katz P. Definition, Classification and Diagnosis of Diabetes, Prediabetes and Metabolic Syndrome. Canadian Journal of Diabetes, 2018 Apr; 42: S10–5.
4. Ministry of Health & Family Welfare, Government of India. The Diabetic Foot: Prevention and Management in India. New Delhi: Government of India, 2017; 116. Report No.: 978-93-82655-21-3. Available from: https://qps.nhsrcindia.org/
5. Lim JZM, Ng NSL, Thomas C. Prevention and treatment of diabetic foot ulcers. J R Soc Med., 2017 Mar; 110(3): 104–9.

6. Mehraj DrM. A review of Wagner classification and current concepts in management of diabetic foot. Int J Orthop Sci., 2018 Jan 1; 4(1n): 933–5.
7. Kale D, Karande G, Datkhile K. Diabetic Foot Ulcer in India: Aetiological Trends and Bacterial Diversity. Indian Journal of Endocrinology and Metabolism, 2023 Mar; 27(2): 107–14.
8. Patil SV, Mane RR. Comparison of efficacy of levofloxacin-metronidazole combination versus ceftriaxone in cases of moderate diabetic foot infection. International Journal of Basic & Clinical Pharmacology, 2016; 5(5): 1775–9.