

Original Research Article

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Clinico-bacteriological study of diabetic foot ulcer and its management based on Wagner's classification and HbA1c as an indicator for duration of antibiotic therapy in a tertiary hospital in Sullia

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ABSTRACT

Background: Diabetic foot ulcer is a serious and common complication of diabetes mellitus. 12%–25% have a risk of developing a foot ulcer during their lifetime. Diabetic neuropathy and micro- or macro-ischemia are the two main risk factors that cause diabetic foot ulcer.

Methods: A cross sectional study was conducted in dept of general surgery, KVG MCH between 1st November 2019 and 30th August 2020 among 90 pts with diabetic foot ulcers, selected by systematic random sampling methods. Considering prevalence of DFU, among the diabetic pts as 8.8%, the sample size was estimated to be 90 using the formula $4pq/L^2$, with absolute error as 6%. Patients will be managed conservatively with antibiotics like aminoglycosides, cephalosporins, penicillin derivatives and dressings and if needed surgical interventions will be performed.

Results: Maximum number of pts had HbA1c levels of >8% and they accounted for 35.55%. Almost 98% of the patients had neuropathy, 50% of them had signs of ischemia and 80% had infection. Maximum number of patients (58.88%) presented with diabetic ulcers belonging to Class 2 of Wagners classification. The most commonly isolated *P. aeruginosa* was sensitive to colistin, imipenem and amikacin. Most diabetics with HbA1C levels >8, had mean antibiotic duration of 19.04±4.65 days.

Conclusions: Prevention is the best treatment. Wagner's classification helps in correlating appropriate treatment to proper grade of lesion with better outcome. Effective glycemic control and education are of key importance for decreasing diabetic foot disease.

Keywords: Diabetic foot, HbA1C, Wagner's

INTRODUCTION

Diabetic foot is defined the foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurological abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes in the lower limb.¹

Approximately 425 million adults (20-79 years age range) are living with diabetes, by 2045 this will rise to 629 million. In India, there are over 72.9 million cases of diabetes in 2017. Prevalence of diabetes in adults in India is 8.8%.²

Diabetic foot ulcer is a serious and common complication of diabetes mellitus. 12%–25% have a risk of developing

a foot ulcer during their lifetime. The most common cause of morbidity and mortality in diabetic foot ulcer is infections, which are seen in 40%–80% of the cases. Diabetic neuropathy and micro- or macro-ischemia are the two main risk factors that cause diabetic foot ulcer. These types of situations necessitate limb amputation. Thus, accurate diagnosis of the causative organism is essential for the management of these cases. Mostly, the diabetic foot infections are mixed bacterial infections, and the proper management of these infections requires an appropriate antibiotic selection, based on the culture and the antimicrobial susceptibility testing results. Hence, the present study was conducted to determine clinical profile of the patients, to diabetic foot ulcers according to Wagner’s classification and their appropriate management with their bacteriological profile of organisms and antibiotic susceptibility patterns. This study also aims at determining relationship between HbA1C and duration of antibiotic therapy in patients with diabetic foot ulcers.

METHODS

A cross sectional study was conducted in Dept of general surgery, KVG MCH between 1st November 2019 and 30th August 2020, among 90 pts with diabetic foot ulcers, selected by systematic random sampling methods. The Institutional Ethical Committee’s clearance was obtained prior to conducting the study. Considering prevalence of DFU , among the diabetic pts as 8.8%, the sample size was estimated to be 90 using the formula $4pq/L^2$, with absolute error as 6%. Detailed history will be elicited by pre-prepared case file, clinical examination, investigations, and relevant special investigations. The wound swab of the patient will be sent to department of microbiology for bacteriological study, the isolates if detected, will be subjected to standard methods for identification and antibiotic sensitivity testing.⁵ Patients will be managed conservatively with antibiotics like aminoglycosides, cephalosporins, penicillin derivatives and dressings and if needed surgical interventions will be performed. Statistical analysis will be made using descriptive statistic and SPSS version 21 was used for analysis.

Wagner’s classification for diabetic foot disease.⁴

- Grade 0– High risk foot and no ulceration,
- Grade 1– Superficial Ulcer; Total destruction of the thickness of the skin,
- Grade 2– Deep Ulcer (cellulitis); Penetrates through skin, fat, ligaments not affecting bone,
- Grade 3– Osteomyelitis with Ulceration or abscess,
- Grade 4– Gangrenous patches limited to toes or part of the foot,
- Grade 5– Gangrene of the entire foot.

Inclusion criteria

- The patients with Type 1 and 2 Diabetes Mellitus with foot ulcer admitted to KVG Medical College Hospital, Sullia during the period of study.

Exclusion criteria

- Patients with foot ulcers other than diabetes.
- Pregnant and Lactating women.

RESULTS

Maximum number of pts had HbA1c levels of >8% and they accounted for 35.55%.

Table 1: Comparison of HbA1c levels.

| Glycated Haemoglobin | | |
|----------------------|----|--------|
| 4-5.6% | 0 | 0% |
| 5.7-6.4% | 8 | 8.8% |
| 6.5-8% | 32 | 35.55% |
| >8% | 50 | 55.55% |

Table 2: Location of the ulcer.

| Site of wound | No. of patients | Percentage (%) |
|-------------------------------|-----------------|----------------|
| Great Toe | 21 | 23.33 |
| Metatarsal head of other Toes | 23 | 25.55 |
| Fore Foot | 19 | 21.11 |
| Heel | 18 | 20 |
| Medial Malleoli | 7 | 7.77 |
| Lower 1/3 rd of LL | 2 | 2.22 |

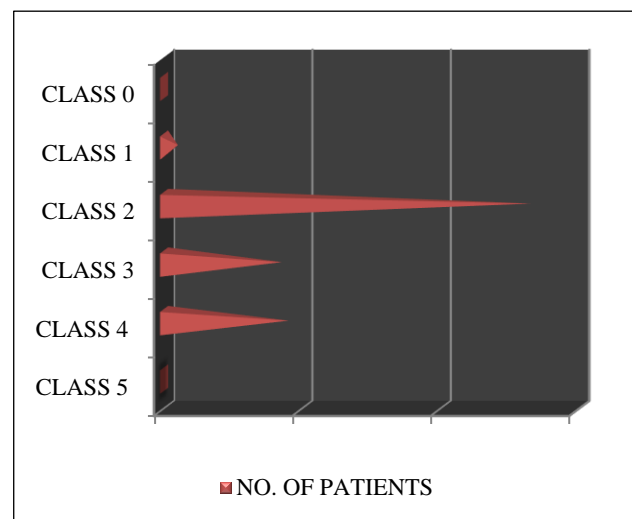


Figure 1: Distribution of patients based on Wagner's classification.

Maximum number of patients (25.55%) presented with diabetic ulcers over the metatarsal head of toes , followed by great toe (23.33%).

Maximum number of patients (58.88%) presented with diabetic ulcers belonging to Class 2 of Wagners classification followed by 20%.

Most patients (11.11%), in arterial doppler had both anterior and posterior tibial artery involved equally.

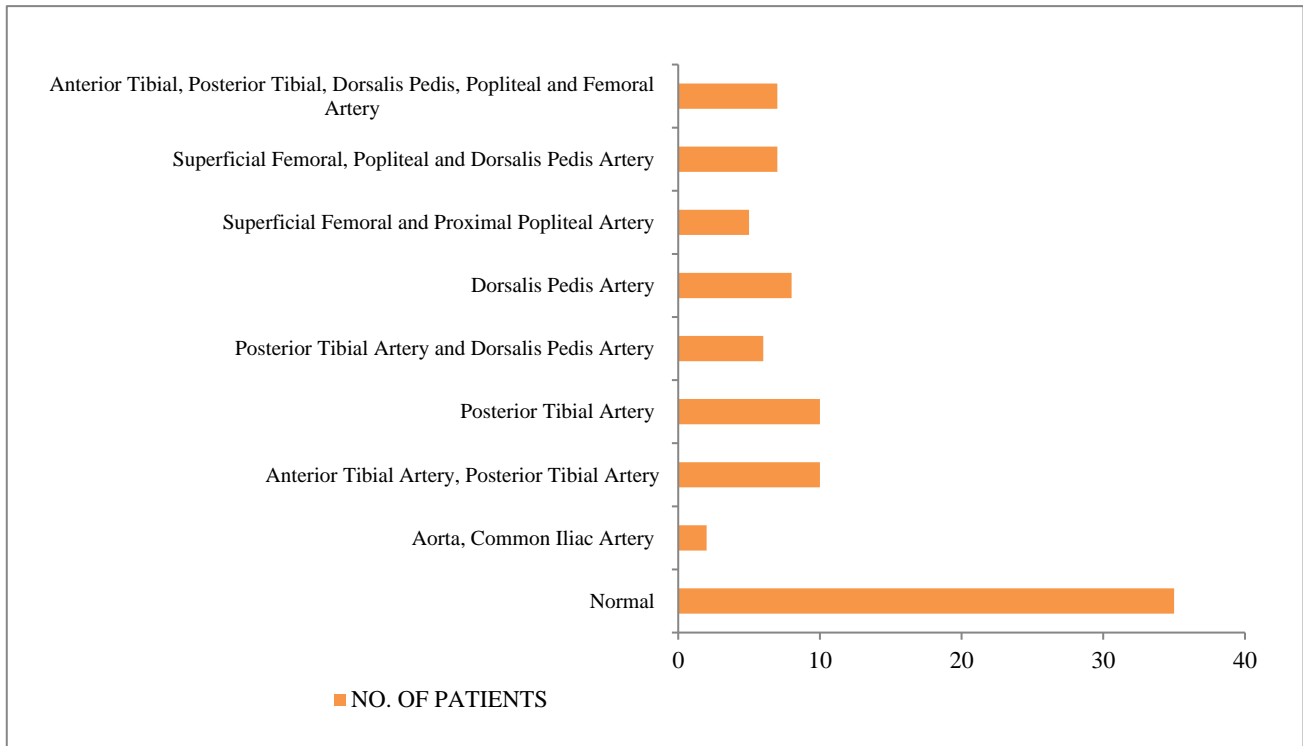


Figure 2: Level of peripheral artery disease.

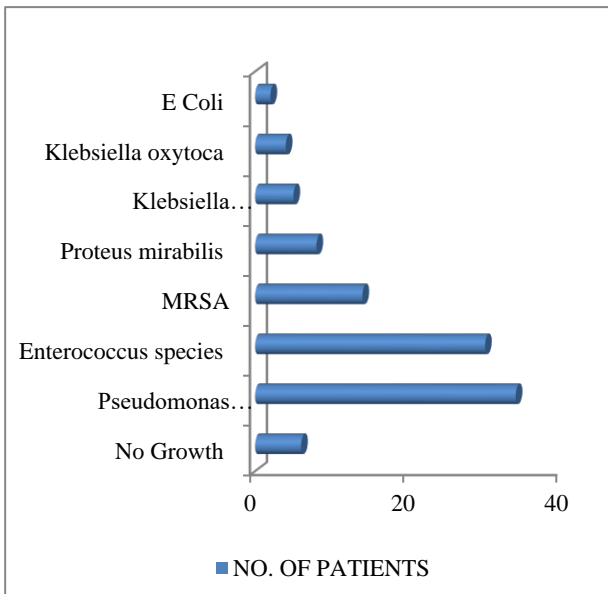


Figure 3: Organisms isolated from culture of diabetic foot.

Pus C/S showed predominance of *Pseudomonas aeruginosa* (37.77%) in pts with DFU.

The duration of hospital stay and antibiotic therapy was 11-20 days (62.22%) in pts with DFU. Average duration being 16.88±5.32.

The most commonly isolated *P. aeruginosa* was sensitive to colistin, imipenem and amikacin. Second most commonly isolated *Enterococcus spp.* was sensitive to gentamicin and ampicillin.

The most commonly isolated *P. aeruginosa* was resistant to cefaperazone/sulbactam, ceftriaxone and cefotaxime. Second most commonly isolated *Enterococcus spp.* was resistant to cotrimaxazole, erythromycin and azithromycin.

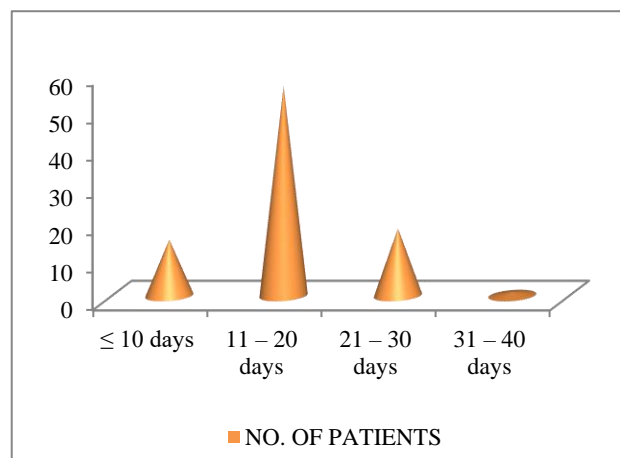


Figure 4: Duration of hospital stay.

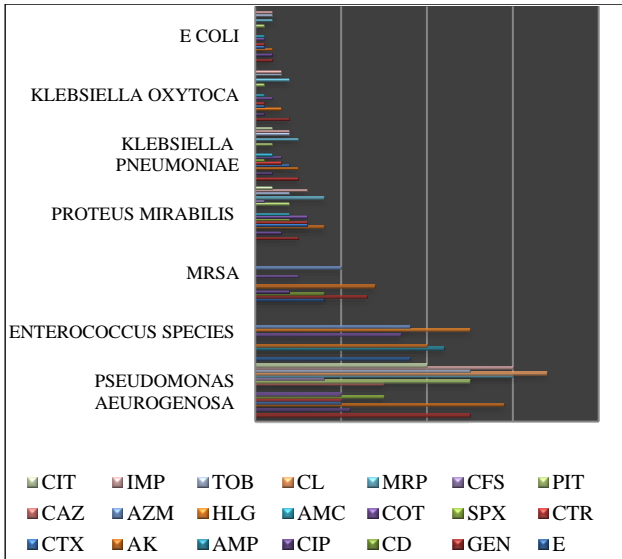


Figure 5: Sensitivity pattern of organisms isolated.

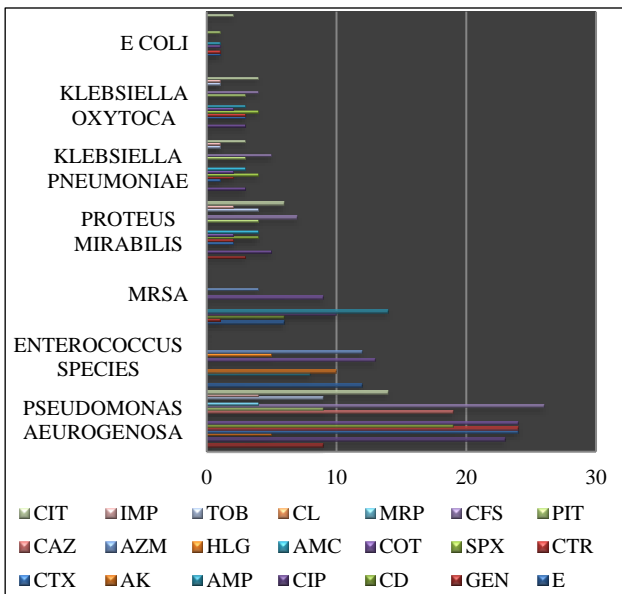


Figure 6: Resistance pattern of organisms isolated.

Table 3: Final management of Diabetic foot ulcer.

| Treatment | Clas | Class 1 | Class 2 | Class 3 | Class 4 | Class 5 |
|-------------------------------|------|---------|---------|---------|---------|---------|
| Conservative | - | 2 | - | - | - | - |
| Debridement only | - | - | 53 | 10 | - | - |
| Debridement a disarticulation | - | - | - | 7 | - | - |
| Fore Foot amputation | - | - | - | - | 16 | - |
| Below Knee amputation | - | - | - | - | 1 | - |
| Above Knee amputation | - | - | - | - | 1 | - |

Table 4: Mean duration of antibiotic therapy according to HbA1c levels.

| HbA1c levels | Mean duration of antibiotics | F value | P value |
|--------------|------------------------------|---------|----------|
| 5.7 to 6.4% | 10.75±2.31 | 12.5285 | <0.0001* |
| 6.5 to 8% | 16±5.10 | | |
| > 8 % | 19.04±4.65 | | |

Tukey HSD Post-hoc Test.

Group 1 vs Group 2: Diff=5.2500, 95%CI=0.8416 to 9.6584, p=0.0154*

Group 1 vs Group 3: Diff=8.2900, 95%CI=4.0433 to 12.5367, p=0.0000*

Group 2 vs Group 3: Diff=3.0400, 95%CI=0.5152 to 5.5648, p=0.0141*

DISCUSSION

Diabetic foot ulcers are one of the most difficult and threatening complications which a diabetic patient faces during the period of uncontrolled glycemic control along with other complications. In the present study Wagners classification has been used to grade the foot ulcers due to diabetes.

In the present study, the proportion of males suffering from DFS were more compared to females (83.3% Vs 16.7%). These findings were similar to that of studies done by Jeffcoate EJ et al (67%) and Shailesh Shahi et al (71.13%) were they found that the proportion was higher in males when compared to females.^{5,6} Study conducted by Tjokorda et al shows that there is equal proportion of males and females affected.⁷ The reason for males being more commonly affected may be because they are more exposed to hard work with higher risk of trauma in their work place.

The average age of the study population was 56.48. This was similar to another study done by Dalem Pemayun TG et al were the mean age was 54.3±8.6 years.⁸ There is more chance of elderly people to have long standing diabetes, peripheral neuropathy, gait abnormalities, and poor vision which makes them more susceptible for ulcers.

In the present study, 97.7% of the patients had neuropathy, 50% had ischemia and 80% were infected. Nyamu PN et al studied 1780 diabetic patients and found that 47.5% of the ulcers were neuropathic, 30.5% were neuroischemic and 18% were ischemic.⁹ Lack of proper blood sugar control, hypertension, lack of proper self care and infections are considered as significant risk factors for the development of ulcers.

Zhang P et al, carried out a systematic review and meta analysis and found that increasing age, more duration of diabetes and smoking were associated with the diabetic foot ulcer.¹⁰ Almost 90% of our study population had HbA1c levels more than 6.5 and 34% of them had some associated comorbidities.

In the present study, it was found that *P. Aeruginosa* (37.77%) was the most common organism isolated, followed by *Enterococcus* species (33.33%). Some studies show that *S. aureus* was the most frequent pathogen, followed by *E. coli*.¹¹⁻¹³ In contrast, another study carried out by Ako-Naiet al showed *E. coli* as the frequent bacterial pathogen, while *P. aeruginosa* was reported as the most common pathogen by Shankar et al and Jayashree Konar.¹⁴⁻¹⁶

Pseudomonas was sensitive to imipenem, amikacin and gentamicin. Commonly used antibiotics like ceftriaxone and ciprofloxacin were resistant. Biofilms, present in chronic wounds, are a defensive mechanism for bacteria against the effects of antibiotics and can explain the rise in AMR.^{17,18} Unjustified use of antibiotics is another cause of AMR, misuse of health resources and a burden to patients and their families.¹⁹⁻²¹ From this present study, amikacin is effective against most Gram-negative bacteria. The high AMR to ampicillin should warrant care during empirical treatment of DFUs in this setting.²²

An ulcer is the most common presentation of diabetic foot, whereas plantar callus is a risk factor for ulceration.^{23,24} The great toe is the most common site of callus formation.²³ In our study, metatarsal heads were the most common site of foot ulcer followed by the great toe. Some patients had ulcers on the gaiters area. In another study, 44% foot ulcers were found on the toes and 43% on the plantar surface.²⁵

Previous studies have shown that a 1% decrease in HbA1c results in a 21% reduction in all diabetic complications.^{26,27} However, this correlation is affected by many external factors and its relation to the duration of antibiotic therapy is not clearly defined. For this reason, it is important to examine the relationship between HbA1C levels and duration of antibiotic therapy which is an important indicator of diabetes regulation.²⁴⁻²⁹ When the results of the present study was examined, it was seen that the duration of treatment was prolonged in the patient group who had HbA1C value above 7% and this was found to be statistically significant also. The level of HbA1C 7% is recommended to deal with other complications of diabetes, mainly cardiovascular disease risk.³⁰ When patients were grouped according to HbA1C levels, patients with higher HbA1C levels (excluding >15% group) had a longer treatment duration.

The main limitations of our study were that of patients were limited to the patients admitted to our hospital. Specifically, the association of HbA1C levels with the duration of antibiotic use may provide inspiring ideas for large-scale prospective studies concerning antibiotic use and duration of hospitalisation, of patients with diabetic foot ulcers.

CONCLUSION

Foot ulceration in diabetic patients is resource consuming, disabling morbidity that often is the first step towards lower extremity amputation. This study showed that most common organism present in Diabetic foot ulcer was *P. aeruginosa*. These observations from our study are important, especially for patient management and development of empirical antibiotic guidelines. The prolongation of antibiotic therapy has been associated with elevated HbA1C levels and poor prognosis in many studies in literature. Wagner's classification helps in correlating appropriate treatment to proper grade of lesion with better outcome. Lesser grade lesion respond well to conservative treatment with antibiotics and debridement, while those with higher lesion require some kind of amputation. Keeping the HbA1C level <7% in the development of diabetic foot wounds is important for the prevention of diabetic foot and other major complications. Treatment of diabetic foot infections with a multidisciplinary approach can be accomplished, and morbidity can be reduced.³¹ Thus from our study, we can ascertain that timely and most effective approach to diabetic foot wound infections can reduce morbidity, shorten treatment time and prevent other complications of diabetes.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee of KVG Medical College and Hospital, Sullia, Karnataka, India

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