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An Ambispective Observational Study to Assess the Association of Clinicomicrobiological Profile with Outcome in Diabetic Foot Ulcers in a Tertiary Care Setup

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Abstract: <u>Background</u>: Diabetes is a dynamic, long term metabolic disorder and affects an estimated 537 million people worldwide which accounts to 10.5% of all adults in the age range of 20 to 80 years. About one in four diabetic patients tend to develop a foot ulcer during their lifetime. It has been observed that 80% of amputation in diabetic patients are preceded by a diabetic foot ulcer. The present study was undertaken to assess any association between type of microorganism and foot ulcers leading to amputations along with change in microbial culture and antibiotic sensitivity. <u>Materials and methods</u>: This study is an ambispective observational study which has been conducted at department of general surgery, Bangalore Medical College and Research Institute from March 2022 to March 2024 on 165 patients having diabetic foot ulcer. The study was divided into two groups, one included retrospective chart review from march 2022 to July 2023 and other prospective follow up from July 2023 to march 2024. <u>Results</u>: In initial 12 months of period based on MAC of antibiotics most sensitive antibiotic was found to be piperacillin - tazobactam and imipenems. In following period, majority of isolates were resistant to carbapenams and piperacillin tazobactam. And was found to be sensitive mostly to tigecycline, linezolid. Also, pseudomonas was isolated more in patients with prolonged morbidity and death in the initial period which was significant, and a shift to Acinetobacter was seen in the following period. <u>Conclusions</u>: Hence, a periodic basis wound swabs should be sent for culture and antibiotic sensitivity, so that antibiotic protocol and organism can be monitored and a better treatment protocol can be derived periodically to decrease the morbidity and mortality in diabetic foot ulcers.

Keywords: diabetic foot ulcer, amputation, culture, antibiotic sensitivity, morbidity, mortality

1. Introduction

Diabetes mellitus is the fastest growing pandemic, with increasing rate of morbidity and mortality globally. An estimated 537 million people worldwide which accounts to 10.5% of all adults in the age range of 20 to 80 years are diabetic. One of the major attributes to morbidity and mortality in diabetic patients is diabetic foot ulcer. Statistics has revealed that one in every four develops diabetic foot ulcer. The rate of increasing diabetic foot and further increasing of amputation is worrisome.50 - 70% of all non traumatic amputations occur in diabetics. The majority of the amputations is seen in patients seeking medical attention in an advanced stage having poor glycemic control.

Diabetic foot ulcer shows wide range of clinical manifestation from a simple ulcer to osteomyelitis, articular destruction, and gangrenous changes due to neuropathy or vasculopathy. Scoring systems like wagner grading, mangled extremity severity score, diabetic ulcer severity score helps surgeons to take a decision of appropriate treatment. Healing diabetic foot ulcers are challenging and majority requires aggressive debridement, disarticulation, minor amputations, major amputations in follow up period further increasing the morbidity. Radiological assessment with doppler ultrasonography, arterial angiography and a proper systemic

and local wound treatment with appropriate antibiotic coverage, glucose lowering and lipid lowering agents, appropriate medications to improve vascular functions like antiplatelets, vasodilators can altogether help in proper management of diabetic foot ulcer.

With increasing multidrug resistant organisms and with increasing incidence of diabetic foot ulcers and amputations, the need for frequent assessment is required. Objectives of the study was to understand the emerging variation of pathogen associated with diabetic foot ulcer along with their susceptibility pattern and the pathogen pattern associated with amputations and death.

2. Materials And Methods

An ambispective observational study was done on 165 patients from March 2022 to March 2024 in Department of General Surgery, Bangalore Medical College and Research Institute and hospitals attached to it. After obtaining institutional ethical clearance, the study was carried, it was divided into two groups, one included retrospective chart review from March 2022 to march 2023 (T1 period) and other prospective follow up from march 2023 to March 2024 (T2 period). A retrospective chart review 149 patients were done in T1 time period after application of inclusion and exclusion

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criteria with help of medical records which included baseline sociodemographic data, investigations, treatment history, additional data were obtained by phone interview. At 12 months data collected for 134 patients and prospective follow up was done. Parameters such as age, gender, diabetic status and its treatment status, first culture isolate on admission with antibiotic sensitivity and outcomes like debridement, disarticulation, minor amputations, major amputations like below knee and above knee amputation were noted.

3. Results

Among the 149 patients, 57.7% were male, this is depicted in figure.1, 36.9% at the age group of 50 - 65yrs, this is depicted in figure.2, highest isolate was of pseudomonas aeruginosa in initial 12 months period with a shift to Acinetobacter Baumanii noted at the end of T2 period, this is depicted in figure 3, 4 and 5.

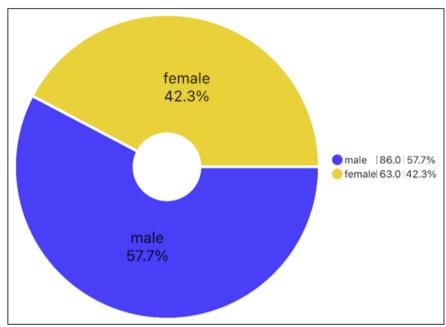


Figure 1: Gender distribution in diabetic foot ulcers

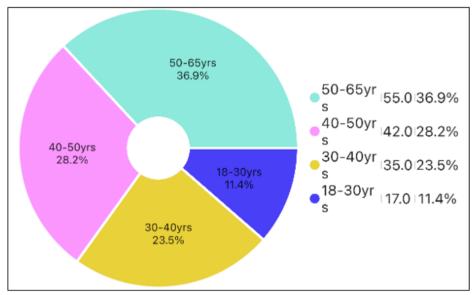


Figure 2: Age distribution in diabetic foot ulcers.

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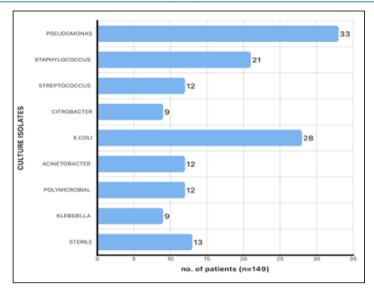


Figure 3: Isolates from wound at beginning of T1 period

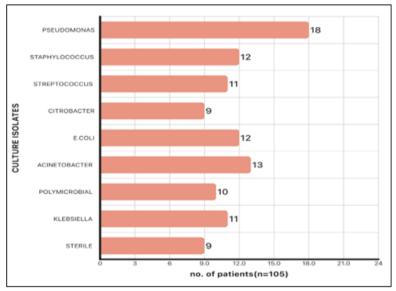


Figure 4: Isolates from wound at end of T1 period

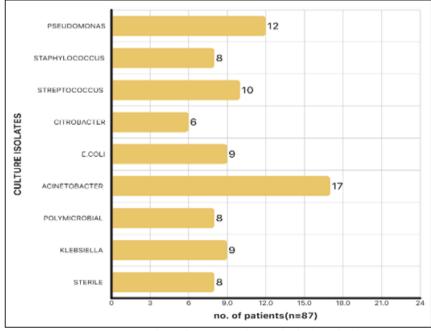


Figure 5: Isolates from wound at end of T2 period

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149 cases recorded at beginning of T1 period among which 48 patients required debridement, 38 patients required disarticulation, 20 patients required minor amputations and 34 patients required major amputations among which 14 patients underwent below knee amputation and 20 patients underwent above knee amputation, 9 cases died, and 6 lost to follow up, this is depicted in figure 6.

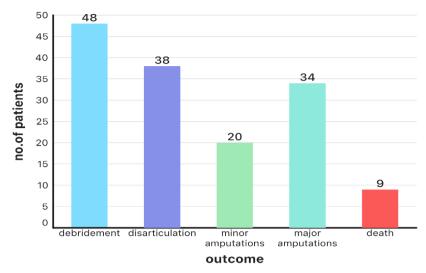


Figure 6: Morbidity and mortality in diabetic foot ulcers at beginning of T1 period

After 12 months out of 134 patients, 29 patients were found to have healthy wound needing no further intervention, 24 patients were managed by Disarticulation, 30 underwent disarticulation, 12 cases underwent minor amputations, 33 patients underwent major amputations which included 3 revision above knee amputations, 18 above knee amputation,

among which 7 patients had previously underwent below knee and trans metatarsal amputation, 12 underwent below knee amputation, among which 3 patients already underwent above knee amputation of other limb, death was recorded for 6 patients, 11 patients were lost to follow up, this is depicted in figure.7

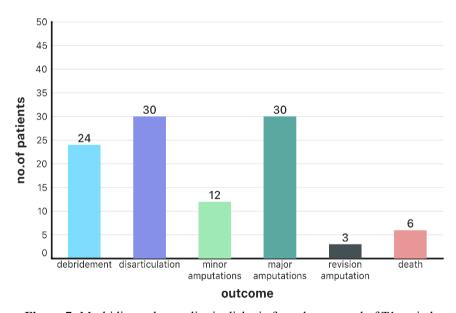


Figure 7: Morbidity and mortality in diabetic foot ulcers at end of T1 period

117 patients were followed up.30 patients were having healed wounds, 87 cases were recorded.6 deaths recorded. In 87 cases, 41 patients wound was managed with debridement, 23 cases underwent Disarticulation procedure, 3 patients

underwent minor amputations, 13 underwent major amputations, 1 patient underwent revision amputation, this is depicted in figure 8.

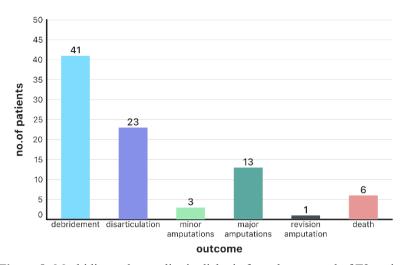


Figure 8: Morbidity and mortality in diabetic foot ulcers at end of T2 period

At initial 12 months of period based on MAC of antibiotics, most sensitive antibiotic was found to be piperacillin - tazobactam and imipenem followed by cephalosporin. Tigecycline, linezolid, Colistin was sensitive to almost all culture isolate.

In following period, majority of isolates were resistant to carbapenems and piperacillin tazobactam. And was found to be sensitive mostly to tigecycline, linezolid and in some cases only to colistin, with majority antibiotics showing resistant pattern.

The assessment of association between highest isolated organism which was pseudomonas and outcomes were done, where outcomes were morbidity and mortality, morbidity being considered as minor amputations, major amputations. Out of 99 patients undergoing minor and major amputations in 1 year period, pseudomonas species was isolated from 36 wound, rest were non pseudomonas isolates and out of 15 deaths in 1 year period, pseudomonas species, was isolated from 11 wound. This is depicted in table 1.

 Table 1: isolate association with outcomes.

	Pseudomonas	Non pseudomonas isolates
Morbidity	36	63
Mortality	11	4

On application of chi square test. The p - value comes out to be 0.006715 which is significant at p <0.05. The chi square statistic with yates' correction is 5.9011. The p value is 0.015131 which is significant at p<0.05. Hence, a significant association is noted between Pseudomonas species and morbidity and mortality.

The assessment of association between highest isolated organism at end of T2 period which was Acinetobacter and outcomes were done. Out of 17 patients undergoing minor and major amputations in Acinetobacter species was isolated from 3 wounds, rest were non - Acinetobacter isolates and out of 6 deaths in Acinetobacter was isolated from only 1 wound. This is depicted in table 2.

Table 2: isolate association with outcomes.

	Acinetobacter	Non - Acinetobacter isolates
Morbidity	3	14
Mortality	1	5

After application of chi square. The p – value comes out to be 0.956561 which is not significant at p<0.05. The chi square statistic with yates' correction is 0.3271. The p value is 0.567366 which is not significant at p<0.05.

Though a shift is noted from pseudomonas to acinetobacter species as major isolate from T1 to T2 period, no association is noted between morbidity and mortality and the microorganism.

4. Discussion

In our study, majority of the study subjects were in the age group of 50 to 65 years, predominant study subjects were male with a ratio of 1.4: 1 which correlates with many studies. The culture and sensitivity burden in our study was carried mainly by Pseudomonas, Acinetobacter, E. coli which varies with other studies where E. coli, Staphylococci predominate. Pseudomonas was the major isolate in the first year of study and a shift to Acinetobacter was seen by the end of the study which varies from other studies. Pseudomonas species was related with higher morbidity and mortality which is similar to Ramani et al. but a significant association was noted in our study unlike Ramani et al. Limitations of the study was only first culture isolate with antibiotic susceptibility report was considered for evaluation.

5. Conclusion

Patients with diabetic foot ulcers have an increased risk of morbidity and mortality. An aggressive multidisciplinary approach is required from an early period to reduce the risk of death. Emphasis should be made for an aggressive multidisciplinary approach for patients having culture isolate as pseudomonas, and a well follow up should be done. A periodic antibiotic protocol in tertiary care hospitals based on the changing microorganism pattern should be made.

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Appropriate intervention at appropriate time will help to reduce the morbidity and mortality.

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