Original Research Article

A study on clinical grading and bacteriological profile of diabetic foot ulcers in tertiary care centre

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Received: 03 June 2020
Revised: 18 June 020
Accepted: 19 June 2020

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ABSTRACT

Background: Diabetes is one of the commonest diseases worldwide and diabetic foot ulcer and its complications are associated with significant morbidity and even amputation. Early detection of colonizing agent of these ulcers help in reduced morbidity and hospital stay. We targeted this subgroup of patients to study Wagner’s grade, identify the bacterial agent and its antibiotic sensitivity and ankle-brachial pressure index (ABPI) assessment to detect PAD, for the best treatment outcome of diabetic foot ulcers.

Methods: The present study was conducted in the Department of Surgery of SGMCRF, Venjaramoodu on 210 patients with diabetic foot ulcers between November 2017 and May 2019. Wagner’s grading of ulcer, culture and antibiotic sensitivity of microbe were done as well as ABPI was measured. Outcome of ulcers was compared to ABPI and ABPI was compared to time of healing.

Results: Out of 210 patients 122 were males and 88 females, 62.9% had neuropathy and 66.7% had vasculopathy. Most patients presented with Wagner’s grade-II ulcers. Most common microbe isolated was pseudomonas aeruginosa which was most sensitive to piperacillin and tazobactam combination. Majority of lesions 62.9% had ABPI in range of 0.5-0.89.

Conclusions: Wagner’s grading and presence of neuropathy are predictors of major amputation. Piperacillin and tazobactam should be empirical choice of antibiotic. ABPI was inversely related to time of healing and has got significant association with treatment outcome.

Keywords: Diabetic foot ulcer, Ankle brachial pressure index, Peripheral arterial disease

INTRODUCTION

According to the International Diabetes Federation (IDF) diabetes atlas (8th Edition), India had a diabetic population of 7.2 million in 2017. This gives India the dubious distinction of being termed the “diabetes capital of the world”.

In diabetic patients, the commonest devastating complication is non-traumatic lower limb amputation mostly due to diabetic foot ulcers and infections. Early recognition of lesions and prompt initiation of appropriate antibiotic therapy, as well as aggressive surgical debridement of necrotic soft tissues and bones, and a modification of host factors like hyperglycaemia, concomitant arterial insufficiency are all equally important for successful outcome. Initial therapy of diabetic foot infections is frequently empiric because reliable culture data is lacking. There is variability in prevalence of common bacterial pathogens in diabetic ulcers. The choice of empirical antimicrobial therapy is influenced by various factors. These include the severity of the illness (Wagner grading), the most likely type of
causative organism, and coexisting complications, such as underlying osteomyelitis.\(^3\)

Identifying peripheral arterial disease among patients with foot ulceration is important because it can cause delay in wound healing which will prolong hospital stay. Ankle-brachial index (ABI) is used to assess the arterial insufficiency or PAD. In asymptomatic persons, an ABI <0.9 has a sensitivity >95% and a specificity approaching 100% as compared with arteriography.

This aim of this clinically profile the grade of the ulcers and for the early detection of colonising organisms thereby helping in better management of patients with diabetic foot ulcers.

**METHODS**

A prospective observation study was conducted from November 2017 to May 2019 (18 months) on patients admitted with diabetic foot ulcers at Sree Gokulam Medical College and Research Foundation. Inclusion criteria had patients with Wagner’s grade 2-5 diabetic foot ulcer who were willing to consent for the study. Excluded were Wagner’s grade 1 diabetic foot ulcer, venous ulcers, pressure ulcers, traumatic ulcers.

The patients were selected by simple random sampling for the study and briefed about nature of the study, the interventions used and written informed consent was obtained. On the day of admission descriptive data of the participant like name, age, sex, detailed history, were obtained by interviewing the participants and clinical examination. The observation and necessary Haematological, biochemical, microbiological and radiological investigation were carried out as enumerated in the proforma using standard procedures. The ulcers were debrided and material for culture collected with cotton tipped sterile swab from the deeper parts of the foot ulcer. The swab was transported immediately to the microbiology department for culture and sensitivity. Swabs were cultured on Blood agar and the plates incubated overnight at 37°C. Colonies obtained were identified by using standard techniques. Antibiotic sensitivity was done using Kirby Bauer’s disc diffusion technique as described in clinical laboratory standard institute guidelines 2012.\(^4\)

Wagner’s classification was determined after clinical examination. The duration of lesion prior to admission in hospital and duration of lesion from the time of admission to stage of healed ulcer or scar was noted and this gives the total duration of lesion. Complete cover by healthy granulation tissue and neo epithelisation at the periphery of the ulcer is taken as the end point; either during hospital stay or in follow up in OP clinic. This is because we do not take into account, the variation with size & depth of ulcer. A completely healed stump or scar is the end point in amputees.\(^5\)

ankle-brachial pressure index (ABPI) of the affected limb was measured with Hand held Doppler. The observations were recorded in a predesigned and presented proforma. All the patients received regular dressing with betadine and normal saline or hydrogen peroxide. They were skin grafted, debridement/disarticulated or amputation done as per the decision of the treating doctor. No topical antibiotics were applied. The patients were followed up monthly.

The outcome of the foot was correlated with ABPI that was measured and analysis was done. Those patients having ABPI<0.9 is presumed to have peripheral vascular occlusion disease.\(^6\) The prevalence of peripheral vascular occlusion disease being analysed Data obtained was tabulated using SPSS version 14 software. Means, standard deviation and percentages were used to describe the samples.

Pearson test was used to identify the association of ABPI with healing time. For comparisons of ABPI and treatment outcome Kruskal-Wallis test was used and p<0.0001 was considered significant.

**RESULTS**

In the present study it was seen that incidence of diabetic foot ulcers was more common in 58.1% males as compared with 41.9% females in 218 patients. Diabetic foot ulcers are common between 60-69 years of age in both sexes. In our study 68.6% of patients were suffering for a duration of 10 years (Table 1 and 2).

### Table 1: Age distribution.

| Age in years | Male Count | Male Percent | Female Count | Female Percent |
|--------------|------------|--------------|--------------|----------------|
| 40-49        | 8          | 33.3         | 16           | 66.7           |
| 50-59        | 32         | 45.7         | 38           | 54.3           |
| 60-69        | 52         | 72.2         | 20           | 27.8           |
| 70-79        | 22         | 61.1         | 14           | 38.9           |
| ≥80          | 8          | 100.0        | 0            | 0.00           |

| Mean±SD      | 63.8±4.9   | 58.1±10      |

### Table 2: Duration of diabetes.

| Duration in years | Count | Percent |
|-------------------|-------|---------|
| <10               | 144   | 68.6    |
| 10-20             | 48    | 22.9    |
| >20               | 18    | 8.6     |

| Mean±SD          | 8.3±7.5 |

The analysis also showed that 80 (38.2%) of patients had elevated HbA1c more than 8 and 56 (26.7%) had anaemia (Table 3 and 4). The present study also showed that most of the infections were caused by a single organism 68.5%, the most common organism being *Pseudomonas aeruginosa* in 68 patients 25.37%, followed by *Staph. aureus* 56 (20.89%) and *Klebsiella pneumonia* 48...
Most sensitive antibiotic for *Pseudomonas aeruginosa* was found to be piperacillin and tazobactam combination followed by ciprofloxacin. Most sensitive antibiotic for *Staphylococcus aureus* and *Klebsiella pneumonia* was amoxicillin and clavulanic acid.

**Table 3: HbA1C.**

| HbAIC | Count | Percent |
|-------|-------|---------|
| 6-8   | 130   | 61.9    |
| 8-10  | 44    | 21.0    |
| 10-12 | 18    | 8.6     |
| >12   | 18    | 8.6     |
| Mean±SD | 8.1±2.1 |

**Table 4: Anaemia.**

| Anaemia | Count | Percent |
|---------|-------|---------|
| Absent  | 154   | 73.3    |
| Present | 56    | 26.7    |

**Table 5: Distribution according to Wagner’s grading.**

| Wagner’s grading | Count | Percent |
|------------------|-------|---------|
| II               | 126   | 60      |
| III              | 44    | 20.95   |
| IV               | 22    | 10.47   |
| V                | 18    | 8.57    |

**Table 6: Time for healing.**

| Total time for healing | Count | Percent |
|------------------------|-------|---------|
| <30                    | 104   | 49.5    |
| 30-90                  | 72    | 34.3    |
| 90-120                 | 26    | 12.4    |
| >120                   | 8     | 3.8     |
| Mean±SD                | 45.8±37.7 |

Wagner’s class II to V were included in the study. class II ulceration 126 (60%) was the commonest followed by class III, IV and V. The outcome of diabetic foot ulcers was studied in each Wagner’s class. Neuropathy was present in 132 (62.9%) and vasculopathy was present in 66.7% of the study group.

**Table 7: Treatment outcome.**

| Treatment outcome | Count | Percent |
|-------------------|-------|---------|
| Dressing alone    | 4     | 1.9     |
| Dressing and debridement | 88 | 41.9 |
| Dressing, debridement and SSG | 24 | 11.4 |
| Toe amputation    | 56    | 26.7    |
| Fore foot amputation | 12 | 5.7 |
| Below knee amputation | 18 | 8.6 |
| Above knee amputation | 8 | 3.8 |

104 (49.5%) patient’s ulcer healed within 30 days. Majority of diabetics with foot lesions had ABPI in the range of 0.5-0.89. That was 62.9%; only 25 persons accounting to 23.8% of the total had ABPI in the normal range. Only 3.8% had low ABPI to suggest critical limb ischaemia. Pearson’s calculation of ABPI and time of healing with $x = -0.895$, $p \leq 0.001$ which shows that there is an inverse relation between ABPI and time of healing.

Most of lesions got healed by dressing and debridement alone 41.9%; next most common type was toe or digital amputation coming to about 28 in no and 26.7%. Only 12.4% went for major amputation.

Major amputation was associated with the presence of neuropathy. $P = 0.002$, which was statistically significant. Major amputation was associated with grades of Wagner’s classification $P$ values was 0.0001 which statistically highly significant. Thereby presence of neuropathy and Wagner’s grading are good predictors of major amputation in diabetic foot ulcers.

**Table 8: Factors associated.**

| Variables         | Major amputation |   |   |
|-------------------|------------------|---|---|
|                   | No | Count | Percentage | Yes | Count | Percentage | $X^2$ | $P$ value |
| Neuropathy        |    |       |            |     |       |            |      |           |
| Absent            | 76 | 41.3  | 2          | 77  | 58.7  | 24         | 9.631* | 0.002     |
| Present           | 108| 58.7  | 24         | 92.3| 7.6   | 8          |       |           |
| Wagner’s grading  |    |       |            |     |       |            |      |           |
| II                | 124| 67.4  | 2          | 77  | 32.6  | 8          | 93.65**| <0.0001  |
| III               | 42 | 22.8  | 2          | 77  | 77.2  | 8          |       |           |
| IV                | 14 | 7.6   | 8          | 53.8| 92.3  | 24         |       |           |
| V                 | 4  | 2.2   | 14         | 53.8| 97.8  | 2          |       |           |
Table 9: Microbes isolated.

| Microbes                  | Count | Percentage |
|---------------------------|-------|------------|
| Pseudomonas aeruginosa    | 68    | 25.3       |
| Staphylococcus aureus     | 56    | 20.8       |
| Klebsiella pneumonia      | 48    | 17.9       |
| Escherichia coli          | 32    | 11.9       |
| Enterococcus faecalis     | 16    | 5.9        |
| Enterobacter cloacae complex | 10 | 3.7        |
| Acinetobacter             | 14    | 5.3        |
| Streptococcus sp.         | 8     | 2.9        |
| Aeromonas                 | 4     | 1.4        |
| Serratia sp.              | 4     | 1.4        |
| Morganella morganii       | 2     | 0.7        |
| Citrobacter sp.           | 4     | 1.4        |
| Protease sp.              | 2     | 0.7        |

DISCUSSION

Foot ulceration are the leading cause of hospital admission in diabetes. Peripheral neuropathy, peripheral vascular disease and susceptibility to infection are the three most important cause for development of diabetic foot ulcers. Diabetes is the most common non traumatic cause of amputation of lower limb. Major causes of amputation in diabetes include ischaemia. Vascularity is the most important prognostic factor for diabetic foot ulcers.\(^7\)

Selection of the proper amputation level is crucial not only to preserve the maximal length of the viable extremity, but to minimize morbidity and mortality when overly distal amputation is selected, the blood supply must be adequate for wound healing and additional surgery may be required. Repeated amputation, which may cause greater morbidity or mortality, should be avoided.\(^8\) Overly proximal amputation without prosthesis may lead to difficulty in ambulation.

Unlike an ischaemic foot in non-diabetic patient, diabetic foot is deceptive. A non-diabetic ischaemic foot shows classical signs of ischaemia, but this is not always true in diabetics. An ischaemic diabetic foot can be warm due to associated autonomic neuropathy causing lack of autonomic tone in the capillary circulation which causes shining of blood from arteries directly into veins, bypassing the tissues that need nutrition. This results in foot that feels warm with bounding pulses and dilated veins. Claudication pain may be absent even critical limb ischaemia in diabetes due to peripheral neuropathy.\(^9\)

Clinical decision regarding conservative treatment or radical surgery in ischaemic lower limbs in diabetics is always very difficult because diabetic foot ulcers are deceptive as mentioned above. Such a patient is subjected to multiple debridement and finally when the ulcer shows no signs of healing, the decision for amputation is taken. Prolonged hospital stays are in evitable in such patients. Prolonged hospital stays are an economic burden to the family plus the patient will not earn his livelihood as long as he is admitted in hospital. Other problems like anaemia, hypoproteinaemia, bedsores, hospital acquired infections, weight loss and psychological problems accompany prolonged hospital stay.

Early and proper decision making in a key to avoid all these problems. An investigation that will aid in early decision making is the need of the hour. Angiography is the gold standard for accurate vascular assessment, but angiography cannot be performed in patients with chronic renal failure or acute renal failure. Affordability is also a concern.

Ankle brachial pressure index is the ratio of ankle systolic pressure to brachial systolic pressure. ABPI has been studied earlier in peripheral vascular disease.\(^8\) It has a sensitivity of 70.6% and specificity of 88.5% in diagnosing peripheral vascular disease. Ankle brachial pressure index has been a reliable non-invasive alternative to DSA in assessment of lower extremity arteries in peripheral vascular diseases. ABPI also helps to assess the delay in healing of diabetic foot ulcers. Also, early recognition of the lesion and prompt initiation of appropriate antibiotic treatment as well as aggressive surgical debridement are important for a successful outcome. Initial therapy is empirical because reliable culture data is lacking. There is a variability in the prevalence of common bacterial pathogens isolated, as shown in different studies.

The choice of empirical bacterial therapy is influenced by various factors which include the severity of the lesion (Wagner grading), the most likely type of causative organism and co-existing complications.

The present study was conducted in Sree Gokulam Medical College Hospital, Venjaramoodu to clinically assess diabetic foot ulcers according to Wagner's classification, to assess ABPI of all diabetic ulcer patients and to identify bacterial agent and antibiotic sensitivity.

In the present study it was seen that incidence of diabetic foot ulcers was more common in 58.1% males as compared with 41.9% females. Diabetic foot ulcers are common between 60-69 years of age 34.3%. In our study 68.6% of patients were suffering for a duration of 10 years.

The analysis also showed that 38.2% of patients had elevated HbA1c and 26.7% had anaemia. These anaemic patients were given haematinics and blood transfusion. This enhanced wound healing in them. The present study also showed that most of the infections were caused by a single organism accounting for 68.5%, the most common organism being Pseudomonas aeruginosa 25.37%, followed by S. aureus 20.89% and K. pneumoniae 17.91%. Most sensitive antibiotic for P. aeruginosa was found to be piperacillin and tazobactam combination.
followed by ciprofloxacin. Most sensitive antibiotic for \textit{S. aureus} and \textit{K. pneumoniae} was amoxicillin and clavulanic acid. In study by Nageen the commonest organism was \textit{S. aureus}.\textsuperscript{11}

Wagner’s class II to V were included in the study. Maximum patients had class II ulceration 60% followed by class III, IV and V. The outcome of diabetic foot ulcers was studied in each Wagner’s class. Neutropathy was present in 62.9% and vasculopathy is present in 66.7% of the study group. P value is significant, meaning Wagner’s classification and assessment of neutropathy are good predictors of outcome in diabetic foot ulcers. These findings were comparable to Praveena et al.\textsuperscript{12}

Comparing the total time for healing on ABPI; it was found that there was in a delay in healing time when p value decreases according to Pearson’s calculation. At p value <0.001, there is a relation between ABPI and time of healing.

On assessing the association between ABPI and treatment outcome, it was found that at p<0.001, there is significant difference in the medial net ABPI values of different treatment groups. Hence, there is association between ABPI and treatment outcome.

CONCLUSION

Wagner’s classification and assessment of neutropathy are good predictors of outcome in diabetic foot ulcers and lower the ABPI more the time to heal the ulcer. The commonest organism cultured was \textit{Pseudomonas aeruginosa}. The presence of vasculopathy and neuropathy hinder the wound healing and increase morbidity.

ACKNOWLEDGEMENTS

I would like to that the department of surgery who supported me through this study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Hamza M, Thomas TK. A study on clinical grading and bacteriological profile of diabetic foot ulcers in tertiary care centre. Int Surg J 2020;7:2342-6.