



Assessment of Risk Factors in the Causation & Outcomes of Diabetic Foot

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Authors' contributions.

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Diabetic foot identifies a Diabetic patient foot that has a potential risk of pathological risk effects that includes inflammation, ulceration and deep tissue destruction consistent with neurological disorders, differing degrees of Peripheral arterial disease, and lower limb with metabolic complications. An ulcer is a breach of the continuity of skin, epithelium of mucous membrane in the body which is caused by removal of necrotic tissue. Foot ulcers may be caused by numerous medical conditions. The key to treatment is daily sterile dressing till the formation of healthy granulation tissue, infection control by appropriate use of antibiotics, surgical interventions such as debridement or amputation if needed.

Methods: It will be a observational study, done on the patients with Diabetic foot. It will be conducted at Dept. of General Surgery, J.N.M.C. and AVBRH, Sawangi (Meghe), Wardha of DMIMS (DU). The study will be conducted on patients of foot ulcers.

Objectives:

- To evaluate the microbiological and clinical characteristics of diabetic foot infection
- To analyze the outcomes of a patient with diabetic foot with underlying risk factors HBA1c, Hypertension, Smoking, Diabetic Neuropathy, Recurrence, Obesity, Peripheral arterial

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diseases.

- To analyze the association of Risk factors in the causation of Diabetic foot.
- To predict outcome parameters based on Risk factors and its treatment modalities.

Results: The results will be analyzed after data collection in SPSS software.

Conclusion: Conclusion will be drawn on findings of study.

Keywords: Diabetic foot; ulcer; amputation/debridement.

1. INTRODUCTION

Diabetic foot identifies a Diabetic patient foot that has a potential risk of pathological risk effects that includes inflammation, ulceration and deep tissue destruction consistent with neurological disorders, differing degrees of Peripheral arterial disease, and lower limb with some metabolic complications. Studies have shown that diabetic foot occurrence is approximately 3 to 4 % for around 1 million patients with this condition [1,2] Worldwide, the prevalence of diabetes is growing with 65.1 million diabetic patients, India ranks second in the world [3] The prevalence rate of diabetes in Indians is 2.4 % in rural areas and 12-17 % in urban communities [4] Peripheral neuropathy, charcoat arthropathy, foot ulcers and lower extremity amputations [5] are the multiple lower limb problems in diabetic patients which may contribute to hospitalization and impairment in diabetics [6]. Foot ulcers are widely feared diabetic complications and new findings have shown that the likelihood. The prevalence of foot ulcer production is as high as twenty five percent in India [7]. In patients with diabetes, the incidence of foot ulcers is three percent less than The prevalence of foot ulcer production is as high as 25% in India [7]. In patients with diabetes, the incidence of foot ulcers is 3 percent, less than In the population of the West [8].

Diabetes is estimated to account for more than fifty % of amputations [3,8] of which 85 % of lower amputations in patients with Diabetes are followed by foot ulcers [9]. Owing to, the prevalence of peripheral neuropathy and vascular disease, the burden of diabetic foot disease may increase in the future is more than 10 % of patients during the diagnosis of Diabetes [10] and in the first year after the initial diagnosis of Diabetes, there is a potential period for foot ulcer and amputation [11]. One of the most dreaded diabetes complications is Diabetic foot which is the main cause of hospitalization of diabetic patients. Diabetic patients are at risk of contracting ulceration of the foot. Diabetic ulcers

are 15-46 times stronger than foot ulcers because of other causes of leg amputations. About 40-60 % of non-traumatic lower limb amputations have been reported to be due to diabetic foot. Hence there is a need to spot on predictors in diabetic foot.

Some important predictors of complications in diabetic foot are:

- a) HBA1c
- b) Hypertension
- c) Peripheral arterial diseases
- d) Smoking
- e) Neuropathy
- f) Recurrence
- g) Obesity

Defining modifiable risk factors is the key step to reduce lower extremity amputation rates. Most important modifiable risk factors are

- A) Obesity- Body mass index
- B) Glycaemic control (Hba1c)
- C) Smoking

Peripheral vascular disease is common among patients with diabetes. Among diabetic patients, intermittent claudication is as twice as frequent as among non-diabetic patients. The risk of ulceration and amputation particularly in diabetic patients increases by two to four times, regardless of the form of diabetes, with the progression of age and duration of the diabetes.

Several longitudinal epidemiological studies have also shown that the incidence of life-long foot ulcer in patients with diabetes is around 25 %, comprising two-thirds of all non-traumatic amputations. Foot ulceration is a preventable disease that, through services that may minimize the risk factors, easy measures can reduce amputations by up to 70 %. Identifying the status of risk factors contributing to this condition would allow health care providers to develop better preventive programs that will increase the quality of life of patients and henceforth, minimize the economic expense of both the patient and the

health care system. Identifying the position of risk factors leading to this disorder would allow health providers to set up improved prevention services that may result in improving patients quality of life and henceforth , reducing the economic cost on both the patient and the health care system .

Diabetic patients may be oblivious of the presence of infectious or ulcerative lesions because of peripheral neuropathy and a reduced capacity to experience pain with severe tissue damage from a combination of delayed presentation and impaired immune function so that infection can easily advance rapidly in these kind of population. In patients with Diabetic foot, compromised micro-vascular circulation restricts the access to phagocytes favoring the growth of Escherichia coli, Proteus- spp, Pseudomonas – spp , Staphylococcus aureus and Enterococcus -spp infection are the most prevalent pathogens that contribute to the progressive and widespread degradation of tissue.

Methicillin-resistant staphylococcal aureus (MRSA) has often been isolated from diabetic wounds .The increasing association of (MDR) pathogens with Diabetic foot ulcers further compounds the challenge of treating Diabetic ulcers without resorting to amputation .Diabetic foot infections are often polymicrobial. This study would thus be conducted to assess the risk factors and microorganisms in the causation of diabetic foot.

2. OBJECTIVES

- To evaluate the clinical and microbiological characteristics of diabetic foot infection
- To analyze the outcomes of a patient with diabetic foot with underlying risk factors HBA1c, Hypertension, Smoking, Diabetic Neuropathy, Recurrence, Obesity, Peripheral arterial diseases.
- To analyze the association of Risk factors in the causation of Diabetic foot.
- To predict outcome parameters based on Risk factors and its treatment modalities.

3. METHODOLOGY

It is a observational study, done on the patients with Diabetic foot. It will be conducted at Dept. of General Surgery, J.N.M.C and AVBRH, Sawangi (Meghe), Wardha of DMIMS (DU).

Study design: observational study.

Study Setting: A.V.B.R.H. Sawangi (Meghe) Wardha.

Duration of study: 3 years (July 2020-August 2023)

Sample Size-100

Study Population: Patient with Diabetic mellitus and foot ulcers admitted in AVBRH Hospital.

Inclusion Criteria:-

- Patients of any age with foot ulcers due to Diabetes mellitus.
- Ulcers with/without involvement of bone.

Exclusion Criteria:-

- Patients with Hemoglobin less than 10 gm%
- Patients with Low platelet count (<1,50,000)
- Ulcers due to **Arterial insufficiency**
- **Venous** ulcers
- Patients with **Diabetic ulcer** other than foot.
- Patient with bleeding disorder.

3.1 Study Protocol

On the basis of the inclusion and exclusion requirements given above,

All patients admitted with foot ulcers related to Diabetic will be assessed for participation in the study.

3.2 Initial Evaluation

Detailed demographic profile and full history of the patient including current disease history , sporadic claudication , length of pre-gangrenous and gangrenous changes , period of ulcer, history of precipitating incidents such as trauma , history of illness , acute or chronic pressure such as constant pressure from ill -fitting shoes , history of Diabetes and duration , smoking, hypertension, advanced age, obesity, hypothyroidism, peripheral arterial and venous diseases, anticoagulant and coagulation disorders; pervious history of treatment, surgical interventions (debridement or amputation), and other relevant details will be recorded and documented. All the baseline investigations including Complete blood count, Kidney function test, Liver function test, Urine routine

µscopy, Urine culture &sensitivity, Blood culture & sensitivity, FBS, PMBS, HbA1c,Color Doppler of the affected limb, X- ray foot AP view & Lateral view ,Wound swab for culture and sensitivity from the affected part.

3.3 Clinical Examination

Inspection: A thorough clinical examination, systemic examination will be taken. Local examination of the skin of affected limb, trophic changes, description of ulcer with (site, size, edge, margin, floor, base).Wound swab for culture and sensitivity will be taken on first presentation after initial clinical assessment in patients who are eligible according to the inclusion criteria. Patients would be followed up on day 7, 14, 21 and 28 after first presentation.

3.4 Outcome Assessment

Outcomes of the study would be evaluated comparing the risk factors and underlying medical comorbidities in the patient with microorganisms through a structured Excel sheet. Risk factors would be evaluated on the basis of history and blood investigations. Wound swab for culture and sensitivity will be taken on first presentation after initial clinical assessment in patients who are eligible according to the inclusion criteria. Patients would be followed up on day 7th, 14th, 21stand 28th day after first presentation& followed by 3rd and 6th month. Suitable antibiotics will be started according to culture & sensitivity report. Percentage reduction in size of any ulcer in all dimensions will be taken into consideration. Resultant reduction in rate of amputation among these patients will be calculated.

1. Prognosis on the basis on growth of single micro-organism or polymicrobial growth

2. Co-relation with risk factors and microorganisms in the management of diabetic foot.
3. Clinical presentation of local site on admission.
4. Managed conservatively or surgically. (medically/ debridement followed by skin cover or secondarily healed).
5. Status of patient after treatment. Recovered completely /discharged on request).

4. TREATMENT

CONSERVATIVE MANAGEMENT –

- BMI MONITORING WEEKLY TILL 3 MONTHS
- INPUT-OUTPUT CHARTING
- VITALS CHARTING
- ANTIBIOTICS BASED ON CULTURE SENSITIVITY
- ANALGESICS
- OTHER SUPPORTIVE CARE

SURGICAL MANAGEMENT – BASED ON THE MERIT OF THE CASE

Investigations:

- Complete blood counts
- Liver function test
- Kidney function test
- Urine routine & microscopy
- Urine culture &sensitivity
- Blood culture& sensitivity
- FBS,PMBS, HbA1c
- Color Doppler of the affected limb
- X- ray foot AP view & Lateral view
- Electrocardiography
- Wound swab for culture and sensitivity from the affected part

4.1 Follow up

Table 1. The patient will be followed up on Day-1,7,14,21,28 and 3rd month , 6th month

| Follow up day | Clinical examination | Investigation |
|------------------------|------------------------|------------------------|
| DAY-1 | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| DAY-7 | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| DAY-14 | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| DAY-21 | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| DAY-28 | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| 3 RD -MONTH | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |
| 6 TH MONTH | WOUND SIZE MEASUREMENT | WOUND SWAB IF REQUIRED |

4.2 Analysis Plan

Analysis will be done with the intention to treat principles. All participants with available data at baseline and follow up visits will be included. The impact of missing values will be explored in sensitivity analysis. The data will be entered into the excel spread sheets and statistical analysis will be conducted using SPSS software.

Descriptive analysis of age, sex, and treatment compliance will be performed. The histogram will be plotted to observe the distribution of all variables and continuous variables which are normally distributed will be described using mean and standard error. The effect size will be expressed in terms of relative risk and risk difference along with their 95 % confidence interval.

5. RESULTS

From this study we expect that there should be at least 15 % reduction in the wound size. This would be beneficial in cost reduction of treatment of foot ulcers.

6. DISCUSSION

In a study conducted in south India, P. Gunasekaran et al concluded that the prevalence of Gram -negative infection in diabetic foot patients [12]. The coexistence of Gram -negative and Gram -positive microorganisms was more common in cases of poly- microbial infection. The highest sensitivity was demonstrated by piperacillin-tazobactam and can be initiated empirically based on the clinical characteristics. A number of related studies were reviewed [13-16]. Ambad et. al. reported about relationship between uric acid and creatinine in pre-diabetic and diabetic patients [17]. Biswas et. al. reflected on meditation, diet, and exercise in type-2 diabetic patients [18]. Kshirsagar et. al. studied efficacy of Platelet Rich Plasma for the treatment of ulcers over foot [19]. Studies on Ulcer Preventive Mattresses have been reported [20]. Related studies on diabetes care facilities in this region were reported [21-23]. Awareness of the isolates and antibiotic susceptibility trend from diabetic foot infections is important for preparing the proper care of these cases until obtaining the susceptibility reports. Diabetic Patients with serial monitoring of risk factors will have Guarded prognosis in the outcomes [24-27].

7. CONCLUSION

Diabetic Patients with serial monitoring of risk factors will have Guarded prognosis in the outcomes.

ETHICAL APPROVAL & CONSENT

Informed consent will be obtained from all the patients and institutional ethical committee approval, DMIMS (DU) will be taken.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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