

# **Research Article**

# **Evaluation of Survival Rate in Patients with Diabetic Foot Ulcer with Comorbid Conditions in Tertiary Care Hospital**

# Sk. Salma Sultana<sup>1</sup>\*, Sk. Musfira Kauser<sup>2</sup>, S. Sirisha Reddy<sup>3</sup>, Md. Muddasseer<sup>4</sup>, K. Venkata Krishna<sup>5</sup> Dr.G.V.Prakash<sup>6</sup>, Dr. Kudipudi Harinadha Baba<sup>7</sup>

<sup>1</sup>\*Department of Pharmacology, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.
<sup>2</sup>Pharm D, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.
<sup>3</sup>Pharm D, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.

<sup>4</sup>Pharm D, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.
<sup>4</sup>Pharm D, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.

<sup>5</sup>Pharm D, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002.

<sup>6</sup>Department of General Surgery, Narayana Medical College, Chinthareddypalem, Nellore -524002.

<sup>7</sup>Department of Pharmaceutical Analysis, Narayana Pharmacy College, Chinthareddypalem, Nellore - 524002.

## Abstract

**Aim:** Diabetic foot ulcer is the most common complication of diabetic foot ulcer and has a significant life threatening impact on the patients especially patients with other comorbidities predominantly diabetes mellitus. Therefore, the purpose of this study is to estimate the survival rate in various patients suffering from DFU associated with comorbidities such as hypertension, Diabetes Mellitus, Cardiovascular diseases and other complications.**Materials and methods:** An observational retrospective cohort study was conducted on approximately 120 patients in general surgery department of Narayana medical hospital over a period of 6 months October 2022 to May 2023. Ethical clearance also has been acquired from the Institutional review committee at Narayana Medical College. **Results:** Among the 120 patients observed during the study, DFU along with only DM comorbidity were recorded in highest number i.e., 31 (35.83%). 16.66% and 11.66% DFU patients were suffering from DM along with hypertensions and CVS diseases respectively. Maximum no.of deaths were recorded in DFU patients with CVS diseases (43.75%) when compared to other comorbid conditions. Based on the data collected, 86.6% survival risk probability was observed in patients with CVS diseases indicating lower survival chances. **Conclusion:** Based on the available data collected during the study, after assessing the data and acquiring the results, it was concluded that patients with DFU associated with CVS diseases comorbidities has lower survival based on over survival rate. **Keywords:** Diabetic foot ulcer, Survival Rate, Retrospective cohort study, comorbid conditions

#### Article Info

\*Corresponding Author Sk. Salma Sultana Department of Pharmacology, Narayana Pharmacy College, Chinthareddypalem, Nellore-524002...



#### Article History: Received 12 March 2023, Accepted 19 June 2023, Published online 24 Aug 2023

©2023 Production and hosting by Asian Journal of Medical and Pharmaceutical Sciences, All rights reserved.

This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

**Citation:** Sk. Salma Sultana, et al. Evaluation of Survival Rate in Patients with Diabetic Foot Ulcer with Comorbid Conditions in Tertiary Care Hospital. A. J. Med. Pharm, Sci., 2023, 11(1): 25-30.

#### Contents

| 1. Introduction           | 26 |
|---------------------------|----|
| 2. Methodology            | 26 |
| 3. Results and Discussion | 27 |
| 4. Conclusion             | 29 |
| 5. References             | 29 |

## 1. Introduction

Diabetic foot ulcer is the most common complication in patients with DM<sup>[1]</sup>. DFU is caused by bacterial invasion which results in infection and decay, these ulcers occur in any part of the body particularly in the distal part of the lower leg<sup>[2]</sup>. There are three types of DFU namely, neuropathic ulcers (diabetic ulcers), arterial leg ulcers (ischemic ulcers) and venous leg ulcers (stasis ulcers)<sup>[3]</sup>. Depending upon the severity, based on Wagner's classification, DFU is classified into Grades. No ulcer, superficial ulcer, Deep ulcer, ulcer with abcess, localized gangrene and extensice gangrene are classified as grade 0, 1, 2, 3, 4 and 5respectively<sup>[4]</sup>.

#### Epidemiology

During their lifetime 15 % of them are suffered from DFU.[17] In DFU patients 85% of the amputation takes place. The proportion of DFU includes that 54%, 34%, and 10% of the individuals are suffered from non-ischemic, ischemic and purely ischemic ulcers<sup>[5]</sup>.

## Etiology

DFU is mainly caused by bacteria (both gram positive and gram negative) predominatly S.aureus, E.coli and Klebsiella species<sup>[6]</sup>. Other causative factors include peripheral neuropathy, high foot plantar pressure and trauma. In peripheral neuropathy, loss of pain sensation may lead to unnoticed repetitive injuries at pressure points facilitating the formation of ulcer<sup>[7]</sup>. Some of the contributive factors include Atherosclerosis and diabetes<sup>[7]</sup>.

## Pathophysiology

In neuropathic condition, predominantly sensory neuropathy, the unnoticed trauma may progress into lesions due to loss of pain sensation. In the lesion, tissue necrosis and callus formation develops into the cavities filled with serous fluid that leads into the formation of ulcers. Skin infections, abcess formation, sepsis and gangrene are some of the complications of DFU<sup>[8]</sup>. In vasculopathy (microangiopathy and macroangiopathy), arterial occlusion occurs either due to increased basement membrane thickness or artherosclerosis of arteries that leads to decreased blood circulation to the ulcer<sup>[8]</sup>.

#### Symptoms

Common symptoms of DFU include skin discolouration(darkened skin), pain, numbness, loss of hair. Instead, ischemic ulcer donot have callus formations but are represented with gangrene at regions such as ankles and toes<sup>[9]</sup>. Stasis ulcer has presented with hardened skin and swelling around the ulcer site.creased circulation to the injury site which inturn prolongs healing of an ulcer<sup>[10]</sup>.

## Diagnosis

They are diagnosed as foot ulcer by examining the local site of the ulcer including parameters pertaining to size, region, type of discharge and severity of the ulcer<sup>[11]</sup>. They are diagnosed using X rays, MRI scan, CT scan, blood test, highfoot plantar examination etc.,<sup>[12]</sup>

# Treatment<sup>[13]</sup>

Based on severity of the ulcer, treatment using medications include,

| Table 1     |                                      |  |
|-------------|--------------------------------------|--|
| Severity    | Treatment                            |  |
| Mild to     | Cephalexin 500 mg-QID,               |  |
| moderate    | Amoxicillin/clavulanate – 875/125 mg |  |
| Moderate    | Clindamycin 300 mg TID,              |  |
| severe      | Ampicillin/sulbactam 3g TID          |  |
| Life        | Imipenem/ cilastin 500 mg QID,       |  |
| threatening | clindamycin+Ampicillin+Tobramycin    |  |
|             | (900mg+5.1mg+500mg) QID              |  |

Surgical methods include Incision, Debridement, Wound lavage, wound closure and Amputation. Debridement is carried out by the removal of devitalized tissue. It is the most effective method as it reduces the risk and shortens the healing time<sup>[14]</sup>. Primary closure is the closure of the wound at the end of the surgery prolonging healing time for infection<sup>[14]</sup>. Amputation is removing the infected portion of the limb or whole limb to save the rest of the portion<sup>[14]</sup>.

#### 2. Methodology

Inpatient department [IPD] of general surgery in tertiary care hospital i.e Narayana medical college and hospital inNellore region.

STUDY DESIGN

It is a Observational Retrospective cohortstudy.

#### STUDY POPULATION

In this study the patients who had diagnosed with diabetic foot ulcer and other comorbid conditions of about 120 patients were included for follow up study period October 2022-May 2023.

STUDY CRITERIA

#### **INCLUSION CRITERIA**

Patient with DFU and othercomorbid conditions Aged > 18 years old

Continuous existence of diabetic foot lesion for a minimum of 4 weeks EXCLUSION CRITERIA

Severe Anemia which is not causedby an infection Pregnancy

Unavailable medical records and unequipped data Simultaneous participation in other investigational trials/previous participation in trials

STUDY MATERIAL: Data were collected by interviewing the patients and from the data collection proforma, Case sheets of the patients.

## Study Variables

The study variables include patient had any other chronic problems, Family history and socio demographic details [Age, Sex, Place of birth, Personal history, Habits and Employment status] and comorbid condition Includes DM, CVD, HTN, Renal diseases, Respiratory diseases, Thyroid conditions and others. The main outcome of the study was to determine the survival rate of Diabetic foot ulcer and other comorbid conditions. The risk factors for development of DFU includes in this study were Age, Sex,Diabetes duration, any foot appearance {Foot deformities, Peripheral Neuropathy, Peripheral artery diseases [PAD]}, HTN, Fasting plasma glucose, HbA1C, LDL.

## **Statistical Analysis**

All data was collected and analysis was performed. It includes descriptive analysis where in patients clinical condition and various variables were analyzed for their respective frequencies and percentages. Statistical analysis was used to determine whether there is a significant difference between the survival rate of patients with DFU in different comorbid conditions. The statistical analysis used is paired t-test that is to determine the significant difference between the no.of patients affected and no.of patients survived.

 $t = d \leq \sqrt{n}$ 

# 3. Results and Discussion

- In this study a total of 120 patients with DFU along with comorbid conditions who visited the inpatient department of general surgery at tertiary care hospital were included.
- The age groups of the subjects were taken from 20-90 years among them the age group between 41-50 years [30] are more affected with DFU the percentage was found to be 25%, 71-80 years age group subjects i.e., 29 of them are affected with the DFU[24.1666%], 23 subjects [19.1666%] were affected with DFU between the age group of 61-70, 21 subjects [17.5%] between the 51-60 years, 11 subjects[9.1666%] between 31-40 years, 3 [2.5%] of them between 21-30 and 81-90 age groups [Table 1]
- Subject characteristics based on ulcer size were shown in Table- 2. In this study majority of subjects i.e 86 [71.6%] had the ulcer size within the range of 0-10 cms, 16 [13.3%] of them had ulcer size of 11-20 cms, ulcer size between the range of 50- 110 cms were found in least subjects.

- According to the study, Patients with DFU along with different comorbid condition has shown in Table- 3. 3 [25.83%] subjects had only DM, investigational methods used to detect other comorbid conditions has revealed that 20 [16,66%] had HTN along with DM, 14[11.66%] had cardiovascular diseases [ CAD, Atherosclerosis], 6[5%] had renal[CKD,AKI] and respiratory diseases[Asthma, COPD], 3[2.5%],2[1.66%], 38[31.66%] had psychiatry, thyroid, other disease conditions [SLE,LEA] respectively.
- Among 120 patients most of them 37[30.83%] had undergone surgery of debridement to prevent the wound of the ulcer, Ray severity of the amputation, Below knee amputation, Toe amputation has been performed in about 14[11.6%], 96[6.66%] patients 26[21.6%]. respectively to remove the infected toe or limb so, that the further, posterior spread of the wound would be ceased, Fasciotomy has been performed in about 8-12 patients [7.5%] to relieve wound pressure, Primary suturing, Tendelberg procedure, Disarticulation has been performed as a supportive treatment along with conservative management.[Table-4]
- Among the admitted patients with DFU, majority of the subjects 7[43.25%] with cardiovascular diseases recorded as death, 4 deaths [25%] were recorded in subjects with HTN along with DM, 2 death [12.5%] were recorded in subjects with thyroid diseases and subjects with DM only.[Table-5]
- The Survival probability of patients with CVD was found to be 0.5[50%], DM probability was 0.935[93.5%], DM with HTN was 0.8[80%], Respiratory and thyroid conditions had the survival probability of 0[100%], Renal, Psychiatry, other disease conditions had the survival probability of 0.834[83.4%], 0.667[66.7%], 0.9737[97.37%] respectively.[Table-6]







## Sk. Salma Sultana et al, A. J. Med. Pharm, Sci., 2023, 11(1): 25-30

Table 2

|                 | Only | DM with | DM with     | DM with  | DM with  | DM with    | DM with  | DM with  |
|-----------------|------|---------|-------------|----------|----------|------------|----------|----------|
|                 | DM   | HTN     | Respiratory | CVS      | Renal    | Psychiatry | Thyroid  | other    |
|                 |      |         | diseases    | diseases | diseases | diseases   | diseases | diseases |
| No. of patients | 31   | 20      | 6           | 14       | 6        | 2          | 3        | 38       |
| effected        |      |         |             |          |          |            |          |          |
| No. of patients | 29   | 16      | 6           | 7        | 5        | 2          | 2        | 37       |
| survived        |      |         |             |          |          |            |          |          |
| No. of patients | 2    | 4       | 0           | 7        | 1        | 0          | 1        | 1        |
| died            |      |         |             |          |          |            |          |          |

From the above data, the t-value calculated s 2.3665, Whereas t-tabled value at 5% LOS with 7 DOF is 1.895. Since tcal > ttab ,We reject H0 and We accept  $H_1$ 

Where,  $H_0$  – There is no significant difference between the no. of patients affected &no. of patients survived

| ٦ | Table-3: Subjects | According to | their A | ge Groups |   |
|---|-------------------|--------------|---------|-----------|---|
|   |                   |              |         |           | Î |

| AGE GROUP | NO.OF SUBJECTS | PERCENTAGE |
|-----------|----------------|------------|
| 21-30     | 3              | 2.5        |
| 31-40     | 11             | 9.1666     |
| 41-50     | 30             | 25         |
| 51-60     | 21             | 17.5       |
| 61-70     | 23             | 19.1666    |
| 71-80     | 29             | 24.1666    |
| 81-90     | 3              | 2.5%       |

#### Table-4: Classification Of Subjects According to Their UlcerSize

| ULCER SIZE | NO.OF SUBJECTS | PERCENTAGE |
|------------|----------------|------------|
| 0-10 CM    | 86             | 71.6       |
| 11-20 CM   | 16             | 13.333     |
| 21-30 CM   | 6              | 5          |
| 31-40 CM   | 3              | 2.5        |
| 41-50 CM   | 1              | 0.8333     |

*Sk. Salma Sultana et al, A. J. Med. Pharm, Sci.*, 2023, 11(1): 25-30

| 51-60 CM   | 2 | 1.666  |
|------------|---|--------|
| 61-70 CM   | 1 | 0.8333 |
| 71-80 CM   | 2 | 1.666  |
| 81-90 CM   | 0 | 0      |
| 91-100 CM  | 1 | 0.8333 |
| 101-110 CM | 2 | 1.666  |

#### Table-5: Shows Data of Subjects with DFU in Different ComorbidConditions

| COMORBID CONDITION                | NO.OF SUBJECTS | PERCENTAGE |
|-----------------------------------|----------------|------------|
| Only DM                           | 31             | 25.83      |
| DM along with HTN                 | 20             | 16.66      |
| DM along with respiratory disease | 6              | 5          |
| DM along with CVS disease         | 14             | 11.66      |
| DM along with renal disease       | 6              | 5          |
| DM along with psychiatry disease  | 3              | 2.5        |
| DM along with thyroid condition   | 2              | 1.66       |
| DM along with other conditions    | 38             | 31.66      |

#### Table-6: Shows Deaths in Subjects Suffering From DFU

| Disease                     | No.of subjects | No.of subjects death | Percentage |
|-----------------------------|----------------|----------------------|------------|
| Only DM                     | 31             | 2                    | 12.5       |
| DM with HTN                 | 20             | 4                    | 25         |
| DM with respiratory disease | 6              | 0                    | 0          |
| DM with CVS disease         | 14             | 7                    | 43.75      |
| DM with renal disease       | 6              | 1                    | 6.25       |
| DM with psychiatry          | 3              | 0                    | 0          |
| DM with thyroid condition   | 2              | 1                    | 6.25       |
| DM with other conditions    | 38             | 1                    | 6.25       |

#### Table-7: Data Shows Survival Probability of IndividualComorbid Condition

| Comorbidcondition      | No.of subjects<br>affected | No.of subjects survived | Probability    |
|------------------------|----------------------------|-------------------------|----------------|
| DM                     | 31                         | 29                      | 0.9354[93.54%] |
| DM with HTN            | 20                         | 16                      | 0.80[80%]      |
| Cardiovasculardiseases | 14                         | 7                       | 0.50[50%]      |
| Respiratory diseases   | 6                          | 6                       | 0[100%]        |
| Thyroid diseases       | 2                          | 2                       | 0[100%]        |
| Renal diseases         | 6                          | 5                       | 0.834[83.4%]   |
| Psychiatry diseases    | 3                          | 2                       | 0.667[66.7%]   |
| Other conditions       | 38                         | 37                      | 0.9737[97.37%] |



#### 4. Conclusion

Two years overall survival probability of DFU was 0.866[86.6%].Patients with cardiovascular diseases are high risk for development of foot ulcer have lower survival probability when compared with the other comorbid conditions [Renal diseases, DM with HTN, Thyroid condition, DM, Respiratory, Psychiatry diseases.

#### 5. References

 Oliver TI, Mutluoglu M. Diabetic foot ulcer. Rosyid FN. Etiology, pathophysiology, diagnosis and management of diabetics' foot ulcer. International Journal of Research in Medical Sciences. 2017 Oct, 5(10): 4206-13.

- [2] Alexandrescu Va, Deleeuw P, Kovanda Js. Ischemic and Venous Wound Identification: What We Look For. Crit Limb Ischemia. 2017;16(5):1-6.
- [3] Shah P, Inturi R, Anne D, Jadhav D, Viswambharan V, Khadilkar R, Dnyanmote A, Shahi S, Shah PP, Inturi Jr R, Dnyanmote AS. Wagner's classification as a tool for treating diabetic foot ulcers: Our observations at a suburban teaching hospital. Cureus. 2022 Jan 22; 14(1).
- [4] Chahine EB, Harris S, Williams R. Diabetic foot infections: an update on treatment. US Pharm. 2013;38(4):23-6.
- [5] Rosyid FN. Etiology, pathophysiology, diagnosis and management of diabetics' foot ulcer. International Journal of Research in Medical Sciences. 2017 Oct;5(10):4206-13.
- [6] Syafril S. Pathophysiology diabetic foot ulcer. InIOP Conference Series: Earth and Environmental Science 2018 Mar 1 (Vol. 125, No. 1, p. 012161). IOP Publishing. Dendale A. DermNet New Zealand.
- [7] Ashcroft E. Recognizing and treating venous stasis ulcers. DeepesTissues: Wounds Australia newsletter. 2017 Sep 1:36-9.
- [8] Chahine EB, Harris S, Williams R. Diabetic foot infections: an update on treatment. US Pharm. 2013;38(4):23-6.