



## Health-Related Quality of Life Among Diabetes Patients with or Without Diabetic Foot Ulcer

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### ABSTRACT

**Introduction:** Diabetes mellitus is a metabolic disorder of chronic hyperglycemia marked by anomalies in carbohydrate, protein, and lipid metabolism because of complete or partial insulin insufficiency with failure in the functioning of organs. The term "health-related quality of life" (HRQOL) refers to a patient's subjective evaluation of their mental and physical wellness as well as the impact that a condition (such as DFI) has on their standard of living.

**Objectives:** The goal is to compare the HRQOL between people with diabetes who have diabetic foot ulcers and people who do not.

**Materials and Methods:** A prospective, observational study was conducted at Adichunchanagiri Hospital and Research Centre (AH&RC), B.G Nagara. Health-related quality of life was assessed by using the Euro Quality of Life Questionnaire (EQ-5D-5L). Data was analyzed using SPSS version 20 for analysis.

**Results:** A total of 423 patients were enrolled in the study. Out of 423, only 103 were found to have diabetic foot ulcers. The average mean score of EQ-5D-5L for the DM without diabetic foot ulcer group was found to be  $11.14 \pm 2.48$  and for the DM with diabetic foot ulcer group was found to be  $12.35 \pm 2.09$  with a mean difference of 1.21. The results showed that there was a significant difference between the DM with diabetic foot ulcer group and the DM without diabetic foot ulcer group ( $p=0.00^*$ ).

**Conclusion:** The quality of life was poor for those who had diabetic foot ulcers and negatively affected patients' Quality of Life due to decreased mobility and the ability to perform daily activities and increasing dependence on others.

**Keywords:** Diabetes Mellitus, Quality of Life, Health-related quality of life, Diabetic Foot Ulcer, EQ-5D-5L questionnaire.

### INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder of chronic hyperglycemia marked by anomalies in carbohydrate, protein, and lipid metabolism because of complete or partial insulin insufficiency with failure in the functioning of organs. This condition's epidemiology has undergone a recent demographic transition, which has caused a noticeable increase in prevalence.<sup>1</sup> By 2025, it is predicted that 300 million individuals will have the condition as a result of more than 200 million people having DM.<sup>2</sup> The kidneys, heart, blood vessels, nerves, eyes, and kidneys are just a few of the numerous organs that chronic diabetes is associated with severely harming, failing, and malfunctioning.<sup>1</sup>

Lesions with a skin break and epithelium loss are known as diabetic foot ulcers. These lesions can spread into the dermis and deeper layers, occasionally impacting bone and muscle.<sup>3</sup> The most expensive and harmful consequence of diabetes mellitus, diabetic foot ulcers impacts 15% of diabetic people throughout the course of their lifetime.<sup>4</sup> It has been calculated that a diabetic patient has a 25% lifetime chance of having a foot ulcer.<sup>3</sup> A diabetic foot ulcer is most likely to occur in elderly men who smoke and drink regularly and have had type 2 diabetes for a considerable amount of time. Other important risk factors include

inadequate glucose management, neuropathy, angiopathy, nephropathy, and retinopathy.<sup>3, 5</sup>

The interdisciplinary environment and care have an impact on the standard of living for those with diabetic foot ulcers. According to several studies, both physically and psychologically, compared with individuals with diabetes, people with diabetic foot ulcers have a worse lifestyle and quality of life. and the general population.<sup>3, 5</sup> It has long been known that DFU has a detrimental effect on a patient's HRQoL, which includes physical, social, and psychological facets. Individuals with DFU frequently have severe impairments that make walking and climbing stairs difficult, as well as leg pain and discomfort from the pressure of bedding on the ulcer. Because of their diminished mobility, DFU patients may find it challenging to perform daily tasks and may need to rely on assistive devices or other people for assistance.<sup>6</sup> However, there are only a few tools available to concentrate on the quality of life of those with diabetic foot ulcers.<sup>7</sup>

Diabetes-related ulcerated feet have a negative effect on people's overall quality of life (HRQoL), since these ulcers render them more reliant on others and immobile, which makes it more difficult for them to carry out daily duties.<sup>6</sup> The term "health-related quality of life" (HRQOL) refers to a patient's subjective evaluation of their mental and physical wellness as well as the impact that a condition



(such as DFI) has on their quality of life. A patient's lower quality of life affects the outcome of their therapy but also increases the expense of the therapy by increasing the number of doctor referrals and clinical care settings.<sup>8</sup>

The measurements of quality of life vary.<sup>7</sup> Using the Euro Quality of Life Questionnaire (EQ-5D-5L), the quality of life in terms of health was evaluated. The five aspects of health measured by the EQ-5D-5L questionnaire are what are known as the "generic" qualities since they are not particular to any one patient group or medical condition. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems.<sup>9</sup>

Although the impact of diabetic foot ulcers on HRQoL was studied in many countries, the degree to which diabetic foot ulcers impair the quality of life is population-specific. Hence findings of this study are aimed at understanding the difference between health-related quality of life between diabetes mellitus with diabetic foot ulcer and diabetes mellitus without diabetic foot ulcer and determining its impact on patients' health-related quality of life.

## MATERIALS AND METHODS

### Study Design and Patients

A prospective, observational study was carried out at Adichunchanagiri Hospital and Research Centre, B.G. Nagara, Nagamangala, Mandya for a period of 6 months. The approval of the Ethics Committee of the Institution was obtained prior to the commencement of the study. This study included 422 patients from the Department of General Medicine and Department of Surgery who were diagnosed with diabetes mellitus with or without diabetic foot ulcer.

### Methods

Considering the inclusion and exclusion criteria, the eligible subjects were enrolled in the study after obtaining their written consent. For measuring the patient's quality of life, the EuroQoL- 5 Dimensions-5 levels (EQ-5D-5L) questionnaire was administered to all the patients irrespective of the presence of diabetic foot ulcer.

EQ-5D-5L is a standard questionnaire that is used to measure the patient's quality of life in 5 different health-related dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension is divided into five levels of severity: no problems (level 1), slight problems (level 2), moderate problems (level 3), severe problems (level 4), and extreme problems (level 5).

### Statistical Analysis

The collected data was initially entered into the Microsoft Excel spreadsheet. Data were entered into a Microsoft Excel spreadsheet and cross-checked for accuracy. Data was analyzed using SPSS version 20 for analysis.

Descriptive statistics were used to summarize quantitative data and were represented by Frequency and percentage. Mean and Standard Deviation. The chi-square test was used to test the relationships between categorical variables. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

During the study period of 6 months in the Department of General Medicine and Surgery we enrolled a total about 422 diabetic patients in the study out of which 103 were diabetes patients with diabetic foot ulcers.

### Age distribution

Out of the 422 samples we enrolled, we got Diabetes Mellitus patients of age ranging from 25 to 85 with almost equal frequency. Out of 103 patients with diabetic foot ulcers, we found that the majority of the patients were above the age of 50 as shown in Table 1.

Table 1: Age distribution

Age category (in years)	Frequency of Diabetes mellitus patients		Frequency of Diabetic foot ulcer patients	
	Frequency	Frequency Percentage	Frequency	Frequency Percentage
Up to 50	180	42.64%	35	33.9%
Above 50	242	57.34%	68	66.1%
Total	422		103	

### Gender distribution

Out of 422 samples enrolled for diabetes mellitus, the majority of patients were male. The same was found for diabetic foot ulcer patients. Out of 103 samples enrolled for diabetic foot ulcer, 73 were males as shown in Table 2. This concludes the prevalence of Diabetic foot ulcers is high among males.

Table 2: Gender distribution

Gender category	Frequency of Diabetes mellitus patients		Frequency of Diabetic foot ulcer patients	
	Frequency	Frequency Percentage	Frequency	Frequency Percentage
Male	270	63.98%	73	70.87
Female	152	36.01%	30	29.12%
Total	422		103	

While administering the EQ-5D-5L questionnaire to the diabetes mellitus patients without diabetic foot ulcers it was found that the self-care domain was most affected with anxiety/ depression being least affected. When the overall EQ-5D-5L mean average for all domains was taken it was found to be 11.14 as shown in Table 3.

When administering the EQ-5D-5L questionnaire to the diabetes mellitus patients with diabetic foot ulcers it was found that anxiety/ depression was the most affected whereas pain/ discomfort was least affected. When the



overall EQ-5D-5L mean average for all domains was taken, it was found to be 12.28 which reflects the quality of life of Diabetic foot ulcer patients which is scored above the mid score as noted in Table 4.

**Table 3:** Average score of EQ- 5D-5L questionnaire in diabetes mellitus patients without diabetic foot ulcer


Domain of EQ- 5D- 5L questionnaire	Score (Average)	Interpretation
Mobility	2.4	I have moderate problems in walking about
Self-care	2.6	I have moderate problems washing or dressing myself
Usual activities	2.4	I have moderate problems doing my usual activities
Pain/Discomfort	2.5	I have moderate pain or discomfort
Anxiety/ Depression	2.1	I am moderately anxious or depressed
<b>Average</b>	<b>11.14</b>	

**Table 4:** Average score of EQ- 5D-5L questionnaire in diabetes mellitus patients with diabetic foot ulcer

Domain of EQ- 5D- 5L questionnaire	Score (Average)	Interpretation
Mobility	1.8	I have slight problems in walking about
Self-care	2.4	I have moderate problems washing or dressing myself
Usual activities	2.1	I have moderate problems doing my usual activities
Pain/Discomfort	1.6	I have slight pain or discomfort
Anxiety/ Depression	2.9	I am moderately anxious or depressed
<b>Average</b>	<b>12.35</b>	

When the percentage of patient’s health on the day the questionnaire was administered, it was found that maximum patients with the diabetes mellitus with diabetic foot ulcer answered between 0-20% which reflects, their level of satisfaction with the Quality of life on the day is bad, whereas the patients without diabetic foot ulcer answered between 81-100% which reflects, their level of satisfaction about the Quality of life on the day is Good and is shown in the Table 5.

**Table 5:** Health on the day questionnaire was administered

Range	Interpretation	With DM		With DFU	
		Frequency	Frequency Percentage	Frequency	Frequency Percentage
0-20	 Best Health    Worst Health	0	0%	40	38.83%
21-40		7	1.65%	19	18.44%
41-60		24	5.68%	8	7.76%
61-80		169	40.04%	36	34.95%
81-100		222	52.06%	0	0

The average mean score of EQ-5D-5L for the DM group without diabetic foot ulcer was found to be 11.14±2.48 and for the DM group with diabetic foot ulcer was found to be 12.35±2.09 with a mean difference of 1.21. The results showed that there was a significant difference between the quality of life of Diabetes Mellitus patients and Diabetic Foot Ulcer patients (p=0.00\*).

**Table 6:** Comparison of QOL between the DM patients without Diabetic foot ulcers and DM patients by using the EQ-5D-5L questionnaire

Group	No. of Participants	Average mean (EQ-5D-5L)	SD	Mean difference	p-value
DM	422	11.14	2.48	1.21	0.00*
DFU	103	12.35	2.09		

## DISCUSSION

In our study, the majority (66.0%) of the participants were above 50 years and only 34% of the participants were below 50 years. Male patients were more affected with DFU than female patients, 73 (70.9%) versus 30 (29.1%). A similar study was conducted by Elhami E et al.,<sup>10</sup> to assess knowledge, attitude, and practice regarding foot care among Sudanese diabetic patients, in which it showed that the DFU was found to be more prevalent in the 50-60 age group, affecting 59.33% more men than women (40.66%) respectively. Our study showed that the average mean score on the EQ-5D-5L was found to be  $12.35 \pm 2.48$  for the DM group and  $11.14 \pm 2.09$  for the DFU group, with a mean difference of 1.21. The findings demonstrated a statistically significant difference between the DM group and the DFU group ( $p=0.00^*$ ). A study conducted by Jin Sothornwit et al.,<sup>11</sup> aimed to investigate health-related quality of life (HRQoL) in patients with diabetic foot problems and compare the HRQoL between diabetic patients with other comorbidities showed that the primary outcome of this study, the comparison of the utility values between the DF (0.703), COM (0.933), and CON (0.961) groups. The higher utility score reflects a better quality of life. The DF group had the lowest mean utility score, followed by the COM and CON groups. Our study showed that the patients with diabetic foot ulcers had low quality of life and had negatively affected patients' Quality of Life due to deteriorated mental health such as anxiety/ depression.

## CONCLUSION

Diabetic foot ulcerations in patients with diabetes mellitus are serious complications that can result in hospitalization, the need for amputation, and premature mortality. Patients with diabetic foot ulcers had low quality of life negatively affected patients' Quality of Life due to decreased mobility and the ability to perform daily activities and increasing dependence on others. According to different studies, the lifetime risk of a diabetic patient developing a foot ulcer has been estimated to be as high as 25%. Our study showed that the quality of life in diabetic foot ulcer patients is worse than that in diabetic people.

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