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Assessment Of Quality Of Life In Diabetic Patients With Diabetic Foot Ulcers (DFU) And Without Foot Ulcers: A Cross Sectional Study

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Abstract

One significant risk factor for long-term, chronic diabetes mellitus is impaired blood glucose levels which contribute to the development of diabetic complications such as diabetic neuropathy, nephropathy and retinopathy. The utmost frequent and notable complication among these is the pathogenesis of diabetic foot ulcer due to prolonged diabetic neuropathy, critically impacting the well-being of patients suffering from it.

This study evaluated and compared the quality of life between people with diabetic foot ulcers and those without them.

A cross sectional study was conducted using SF 36 questionnaire consisting of questions related to quality of life in seven domains. This questionnaire was distributed to all diabetic patients admitted to surgery department, at Victoria Hospital, Bengaluru. Socio demographic and clinical characteristics of the patients like age of patients, duration of diabetes, treatment taken, presence or absence of autonomic neuropathy also obtained.

The analysis comprised a total of one hundred patients. Of these 59 patients had foot ulcer and 41 were without foot ulcer. The answered questionnaire was analyzed using descriptive statistics and it showed low scores in all seven domains of SF-36 questionnaire.

Low scores in all seven questionnaire domains, with physical health and pain being the most affected, show that diabetes individuals with foot ulcers have significantly lower health-related quality of life metrics than those without foot ulcers.

Keywords: Diabetic patients, foot ulcer, assessment, comparison, questionnaire, quality of life

INTRODUCTION

Diabetes mellitus is a leading metabolic disorder wherein there will be impairment of blood glucose level resulting in hyperglycemia. It could be because of deficient insulin secretion or decreased insulin sensitivity or both.

About 425 million people worldwide suffer from diabetes, and that number is expected to rise to 628 million by the year 2045¹. As per WHO statistics more than one million deaths are attributed to diabetes mellitus².

The poor prognosis seen in patients with diabetes is attributed to poor glycemic control seen in chronic and uncontrolled diabetes mellitus. ³

Diabetic neuropathy, nephropathy, and retinopathy are examples of the vascular consequences of diabetes⁴. Of all the diabetes consequences, peripheral neuropathy is the most prevalent with paresthesia, numbness and pain being the predominant symptoms. Lower extremities are more often involved than upper extremities. It ultimately progresses to loss of sensations, predisposing the patients to repeated minor traumas and injuries and hence the development of diabetic foot ulcer.

Diabetes patients' quality of life is greatly impacted by diabetic foot ulcers (DFUs), which cause financial hardship for them as well as disability and lower extremity amputation.^{5,6}

The primary contributory factors for foot ulcers caused by diabetes include diabetic neuropathy, uncontrolled hyperglycemia, and peripheral artery disease. ⁷

The quality of life is greatly affected in patients with foot ulcers such as reduced mobility leading to social isolation, frequent treatment and regular foot care leading to financial burden.⁶

Patients with foot ulcers have significant reductions in mobility, which can lead to social isolation, frequent medical interventions, and ongoing foot care, which can be expensive ⁶.

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In order to assess the parameters affecting the quality of life of patients with diabetic foot ulcers and to distinguish it from diabetic patients without foot ulcers, there is growing interest in the demographic and clinical factors influencing the health-related quality of life of people with chronic diabetes, with or without foot ulcers⁷.

To the greatest of our information, no data exists in this area currently that compares the quality of life between diabetes individuals who have foot ulcers and those who do not. Thus, using health-related quality of life (HRQoL) measures, this study was conducted to evaluate and compare the quality of life of diabetes individuals with and without feet ulcers.⁸

Aims and objectives.

1. To evaluate the quality of life in individuals suffering from ulcers in their diabetic feet
2. To compare it to diabetic individuals who do not have feet ulcers.

MATERIALS AND METHODS

After receiving approval from the institutional Ethical committee, a cross-sectional investigation was undertaken in the Surgery unit of Victoria Hospital in Bangalore. All diabetes patients admitted between November 2018 and May 2019 participated in the trial. All patients provided written permission.

Criteria for inclusion:

1. Diabetic individuals of either gender who have a foot ulcer and are over the age of 18
2. Diabetic individuals over the age of 18 who do not have a foot ulcer
3. Patients who are eager to provide written, informed permission and take part in the study.

Criteria for exclusion:

1. Individuals having foot ulcer of other etiology like venous ulcer or traumatic ulcer
2. Participants unwilling to provide informed consent in writing.
3. Persons aged more than 80 years, psychiatric patients, and pregnant women.

Patient's socio-demographic data like name, age, gender, education level and employment status were recorded in a data entry form.

The clinical data such as date of admission to hospital, duration of diabetes, current and previous history, other co morbidities, BMI, type of treatment for diabetes like oral medications, insulin or both, medication regularity and presence or absence of autonomic neuropathy as well as other complications of diabetes were also documented in the data entry form.

The SF_36 questionnaire was used to assess the patients' quality of life.⁹

All eligible study participants were administered with the questionnaire and answers were recorded and analyzed. Quality of Life analysis

There are 36 items in 7 domains on the SF 36 health questionnaire, which includes general health (6 items), limitation of activities (10 items), physical health problem (4), emotional health problem (3), energy and emotions (9), social activities (2) and pain (2)

RESULTS

One hundred patients of diabetes mellitus were included in this study. Among these, 59 patients had diabetic foot ulcer and 41 were without foot ulcer.

The socio- demographic characteristics of all the participants are presented in table 1. The mean age of study participants is 54. The socio-demographic parameters such as education and personal income were comparable in both groups, except for the employment status which was statistically significant.

The clinical characteristics of study participants are presented in table 2. Majority of patients with diabetic foot ulcer were having diabetes duration for 10 and more years and only few cases were seen with newly diagnosed diabetic patients. The basal metabolic index (BMI) was comparable in both the groups of patients. Out of 100 diabetic patients, 77 patients had other comorbidities such as hypertension, coronary artery disease, arrhythmias etc.

More than 50% of the patients were taking both insulin and oral hypoglycemics for control of hyperglycemia on a regular basis.

Autonomic neuropathy was present in diabetic group with foot ulcer in contrast to the other group, which directs diabetic neuropathy as one of the important reasons of developing foot ulcer.

Assessment of diabetic foot ulcer:

The clinical characteristics of diabetic foot lesion is presented in graph Most of the patients (66.1%) had single lesion.

Lesions were more on the right foot (52.5%), as compared to the left foot (47.4%), forefoot (40.6%) and hindfoot (42.3%) were more affected as compared to midfoot (16.9%). On local examination, the skin around the ulcer was scaly and dry and most ulcers were neuro-ischemic in origin. Ulcer duration was more than 2 weeks in most cases, and they were receiving systemic antibiotics for infection. 20% of the patients required debridement of ulcer and only 5% of them had undergone NPWT (negative pressure wound therapy). Completely healed ulcer was seen in 40% of patients, whereas 67% had incompletely healed ulcer. 3 patients had below knee amputation and 2 patients died because of systemic infection.

Health related quality of life (HRQoL) parameters are presented in table 3. It shows an average score of seven domains in the SF-36 questionnaire. Diabetics with foot ulcers had lower average scores in all seven SF-36 domains, indicating that diabetic patients with foot ulcers have considerably poorer HRQoL than diabetic patients without foot ulcers.

Table 1: Socio-demographic characteristics

Variables	Total Diabetic patients (100)	Presence of foot ulcers in diabetics (59)	Absence of foot ulcer in diabetics (41)	Chi square	P value (<0.05)
Age in years (Mean)	54.01	51.03 12.1	52.01	NA	0.69
Gender	60 (60%)	37 (62.7%)	23 (56%)	0.44	0.5
Male	40 (40%)	22 (37.2%)	18 (43.9%)		
Female					
Education Illiterate	18 (18%)	11 (18.6%)	7 (17%)	1.1	0.5
Higher education	67 (67%)	41 (69.4%)	26 (63.4%)		
Graduation	15 (15%)	7 (11.8%)	8 (19.5)		
Employment Status	82 (82%)	42 (71.1%)	40 (97.5%)	11.4	0.001
Employed	18 (18%)	17 (28.8%)	1 (2.4%)		
Unemployed					
Personal Income	23 (23%)	14 (23.3%)	9 (21.9%)	0.58	0.7
INR/month < 10,000	70 (70%)	40 (66.6%)	30 (73.1%)		
10,000-50,000	7 (7%)	5 (8.3%)	2 (4.8%)		
>50,000					

NA- Not applicable

Table 2 Clinical attributes

Variables	Total Diabetic patients (100)	Presence of foot ulcers in diabetics (59)	Absence of foot ulcer in diabetics (41)		P value (<0.05)
<u>Duration of diabetes</u>					
Newly diagnosed	8 (8%)	1 (1.6%)	7 (19.5%)	17.8	0.0004
Less than 10 years	31 (31%)	15 (27.1%)	16 (36.5%)		
10-20 years	39 (39%)	23 (38.9%)	16 (39%)		
More than 30 years	22 (22%)	20 (33.8%)	2 (4.8%)		
<u>No. of other comorbidities</u>					
0	23 (23%)	15 (25.4%)	8 (19.5%)	0.7	0.8
1	37 (37%)	22 (37.2%)	15 (36.5%)		
2	30 (30%)	16 (27.1%)	14 (34.1%)		
>2	10 (10%)	6 (10.1%)	4 (9.7%)		
<u>Type of treatment</u>					
Oral hypoglycemics	30 (30%)	18 (30.5%)	12 (29.2%)	0.9	0.6
Insulin	16 (16%)	11 (18.6%)	5 (12.1%)		
Oral hypoglycemics + Insulin	54 (54%)	30 (50.8%)	24 (58.5%)		
<u>Autonomic neuropathy</u>					
Present	83 (83%)	55 (93.2%)	28 (68.2%)	10.6	0.001
Absent	17 (17%)	4 (6.7%)	13 (31.7%)		

Ulcer characteristics

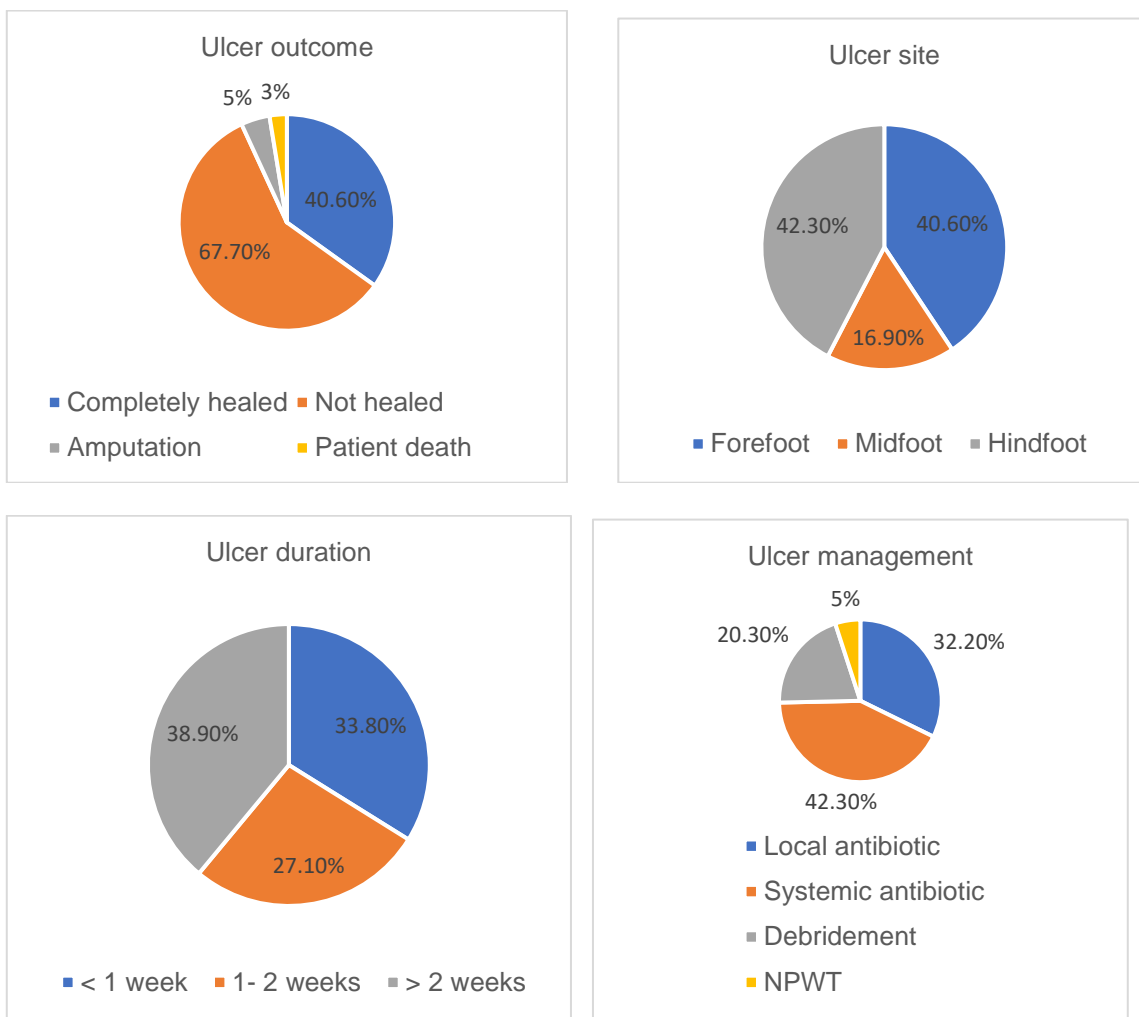


Table 3: Health related quality of life

SF-36 scales	No. of items	Diabetic patient with foot ulcer (59)	Diabetic patient without Foot ulcer (41)	P value (<0.05)
General health	6	57.2 16.1	70.3	0.0001
Limitation of activities	10	53.6	62.2	0.01
Physical health problem	4	47.7	61.7	0.0003
Emotions and energy	9	48.1	69.5	0.0001
Emotional health problem	3	46.6	80.3	0.0001
Social activities	2	60.3	63.1	0.45
Pain	2	35.7	75.6	0.0001

DISCUSSION

Complications of diabetes mellitus significantly affect the quality of life of patients suffering from it. The most studied and common complication is foot lesion in diabetes. The SF-36 questionnaire is used in this study to measure the impact of diabetic foot lesions on quality of life.

The majority of the research participants were over 50 years old, with an average age of 54 ±11.91 years., which is comparable with the clinical study of leg ulcers done by Vamsidhar L et al¹⁰. Al Rubean et al. study demonstrated that being 45 years of age or older is an important predictor for the development of foot ulcers in diabetes individuals.

Unlike the findings of Alsadrah Sana ⁷, which showed female preponderance of diabetic foot ulcer, the current study shows male dominance.

As diabetic foot ulcers are more common with longer duration of diabetes, in current study approximately 70% of the cases are seen in patients with diabetes duration of 10 or more years. This finding is in line with the studies conducted by New J et al¹² and Schaper N et al ¹³.

The number of comorbidities between both sets of patients did not differ significantly in the current investigation, which is in line with the findings of the study by M. Mazlina et al. ¹⁴. The medical comorbidities seen in patients

were hypertension, ischemic heart disease, dyslipidemia peripheral vascular disease etc and approximately 37% of the patients were having more than one comorbidity at the time of assessment.

The treatment of diabetes includes oral hypoglycemics, insulin or combination of both. The majority of patients (54%) in the current study were receiving a combination of insulin and oral hypoglycemics; the types of treatments obtained by individuals did not vary much between the two groups. This finding is inconsistent with the study done by M Mazlina et al¹⁴, where majority of the patients in both the groups received oral hypoglycemics. This difference could be due to many reasons such as type of diabetes, difference in practice in different geographical location, impaired blood glucose etc. Presence of autonomic neuropathy is an obvious indicator for development of risk factor, in this study more than 80% of the patients were having autonomic neuropathy which is similar to the findings of Alsadrah Sana⁷

Patients with diabetes may experience a significant decline in their quality of life as a result of diabetic foot ulcers. As indicated in table 3, the SF-36 questionnaire, which has 36 questions across seven categories, was used in this investigation to assess the HRQoL of diabetic individuals with and without foot ulcers. We found substantial differences in all seven domains amongst participants with and without feet ulcers which is akin to the study conducted by M Mazlina et al¹⁴. Patients with foot ulcers score lower than diabetic patients lacking foot lesions in every domain, suggesting a lower quality of life for them. Emotional health and pain were the most severely affected domains, as evidenced by the largest score variation among the two patient categories. This is in contrast to the findings of the other studies conducted by Valensi et al.¹⁵ and Meijer et al.¹⁶, which demonstrated that the physical domain had the greatest score difference between the two groups and the mental health domain had the least difference. This difference could be due to different management protocol in different geographical locations, hospital setting etc.

In our study, the low scores documented in physical domain and bodily pain is because of the limitations of activity, restricted mobility, and pain at the site of ulcer.

Strength of study: As far as the authors are aware, this is the earliest study in the area comparing the quality of life between diabetics who have foot ulcers and those who do not.

Limitations of study: limited sample size, differences in the duration of disease and treatment in both the groups, follow up of patients for recurrence of ulcer was difficult since most of the patients were from rural areas and were not willing to come for follow up.

CONCLUSION

Quality of life of people is greatly affected by diabetic foot ulcer, particularly affecting the physical domain and bodily pain as indicated by low scores of SF 36 questionnaire used in this study.

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