



INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH



ASSESSMENT OF QUALITY OF LIFE AND RISK FACTORS IN PATIENTS WITH DIABETIC FOOT ULCER

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ARTICLE INFO

Article history

Received 01/11/2021

Available online

01/12/2021

Keywords

Amputations;

Diabetes;

Diabetic Foot Ulcer;

Observational Study;

Quality Of Life;

Wagner Classification.

ABSTRACT

Diabetic foot ulcer is poorly or non-healing full thickness wound through the dermis, below the ankle in an individual with Diabetes. The main objective of the study was to assess the impact of wound on the quality of life of subjects with Diabetic foot ulcer. Diabetic foot ulcer causes changes in the daily lives of patients, creates limitations to perform daily activities and has an enormous impact on the quality of life both physically and mentally. The study also aimed to determine the risk factors contributing to the development of Diabetic foot ulcer. A total of 42 subjects were enrolled in the study. The mean age of the study population was 57.95 ± 9.95 . In DFS the obtained mean and standard deviation of total QOL of patients was 58.68 ± 8.72 . Also, there was a significant association found between the variables gender, age, BMI and presence of neuropathy with the QOL domains. The major risk factors identified towards the development of DFU are Peripheral Neuropathy (66.66%), lack of foot care (76.19%) and poorly controlled blood sugar level (61.90%). The study found out that the quality of life and its dimension in patients with DFU's are in low range. While health education is a fundamental obligation of health care professional it is paramount that patients adopt the guidelines of feet care and integrate them into daily life in trying to prevent diabetic foot and its consequences.

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Please cite this article in press as **Geetha Jayaprakash** et al. Assessment of Quality of Life and Risk factors in Patients with Diabetic Foot Ulcer. *Indo American Journal of Pharmaceutical Research*.2021;11(11).

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INTRODUCTION

Diabetic foot is a foot that exhibits any pathology that results directly from DM and may be defined as a syndrome in which neuropathy, angiopathy and infection will lead to tissue breakdown resulting in morbidity and possible amputations [1]. Diabetic foot ulcer is non-healing or poorly healing full thickness wound through the dermis, below the ankle with an individual with Diabetes. In Indian scenario, out of 62 million, 25% develop DFU of which 50% become infected, requiring hospitalizations while 20% need amputation. After a major amputation, 50% of the people will have another limb amputated in two years. DFUs contribute to approximately 80% of all the non-traumatic amputations in India, annually. Patients with a history of DFU have 40% higher 10-year death rate than those without. In India, it is estimated that approximately 40,000 legs are being amputated every year, of which 75% are neuropathic with secondary infection. In 1997 WHO defined QOL as 'individuals' perception' of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and outcomes. HRQOL is a multidimensional concept that includes aspects of survival; the effect of disease or impairment on social, psychological, and physical function; patient health perception; social opportunity; and satisfaction. Diabetic foot ulcers negatively affect patient's HRQOL due to decreased mobility and consequently the inability to perform daily activities and increasing dependence on others. Moreover, the perceived stress linked to wound healing or re-ulceration and the fear of foot amputation both increase the negative mood and lead to sleep disturbance in patients [2,3]. Reduction of QOL in such patients not only affects the outcome of treatment but also increases the health care expenditures as a result of the frequent referring to physicians and clinical care settings. Hence, this study was conducted with the primary aim of assessing the quality of life in patients with diabetic foot ulcer. Also, understanding the risk factors associated and evaluating the knowledge, attitude and practice among the study population were taken up as secondary objectives. Early recognition, classification, diagnosis, and treatment of foot complications are needed to optimize outcomes in patients with diabetes. It is not only the patients but also physicians and surgeons at primary and secondary care levels who need to be sensitized, educated, and trained regarding foot care. Early detection and treatment of diabetic ulcer can halt the development of the complications and save the foot from possible amputation. Therefore, a conscious effort by the health care providers and professional bodies to challenge this upcoming epidemic of diabetes and DFU in India is needed.[4]

MATERIALS AND METHODS

Study Ethics

Ethical approval was obtained from the Institutional Ethics Committee (IEC) of ESIC Medical College & PGIMS Hospital Rajajinagar, Bengaluru.

Subject recruitment and Study population

Patients aged 18 years and above with cases of Diabetic foot ulcer admitted to the Inpatient ward of the Department of Surgery were included in the study. Patients with foot infections like ulcers and gangrene without diabetic etiology and not consenting to participate in the study were excluded. Informed consent was taken from patients who were incorporated and consented to partake in the study.

Study Tools

A self-designed case report form was used to collect patient details like demography, chief complaints, history of present illness, medication, co-morbidities and other relevant information. Diabetic foot ulcer scale questionnaire was employed in assessing the impact of foot ulcers and their treatment in patient's quality of life. It consists of 58 items grouped into 11 domains namely: Leisure, physical health, daily activities, emotions, non-compliance, family, friends, positive attitude, treatment, satisfaction and financial. The HR-QOL in subjects with chronic ulcers in the lower limb were assessed using the Cardiff Wound Impact Scale. It consists of 47 questions found in the four domains: Well-being (7 questions) Physical symptom & Daily Living (24 questions) Social life (14 questions) and Overall QOL (2 questions) graded on a 4 point Likert scale and 10 point Likert scale respectively.

Statistical Analysis

Statistical analysis was performed using Chi square test to find the association between the grade of ulcer and amputation. Kruskal Wallis test was also applied to find out the association between the socio-demographic and clinical variables with the mean score of DFS QOL subscales. Mann-Whitney U test was used to find the association between the mean scores of domains of DFS and gender. The data collected for the study was analysed statistically by using the statistical program for social sciences (SPSS version 20). The results were expressed in 95% confidence interval. The results were also presented in the form of frequency format and diagrammatic representation whenever necessary. For inferential statistics the relationship between quality of life and variables (Age, Gender, Presence of Neuropathy, greater BMI), the results were considered statistically significant whenever the p-value was less than 0.05.

RESULTS AND DISCUSSION

The study included a total of 42 subjects whose average age was found to be 57.95 ± 9.95 years. Age group 56-65 years were in majority accounting for 35.71% of the total population and age group 36-45 years were minimal in number i.e., 9.52%. Out of 42 subjects in the study 34 were male (80.95%) and 8 were female (19.04%). Habit such as smoking was seen in 11 subjects (26.19%) whereas 4 subjects (9.52%) were indulged in alcoholism and 4 subjects (9.52%) were indulged in both smoking and alcoholism and the remaining 23(54.76%) subjects were not indulged in any of the habits. The data revealed that 8 subjects (19%) were found to be illiterate. The highest number of subjects received high school education (30.95%) followed by PUC (28.57%) whereas 9 subjects (21.42%) did not complete the schooling. Type 2 DM was seen in 41 subjects (97.62%) and Type 1 DM was seen only in 1 patient (2.38%). Among the 42 subjects, 16 (38%) subjects had good control of blood glucose level whereas 26 (61.90%) subjects had poor control over blood glucose level. About 27 (64.29%) subjects were suffering from DM for 10 years or less and 15 (35.71%) subjects were suffering from DM for more than 10 years. The BMI classification of subjects according to World Health Organization (WHO) found that 2 (4.76%) subjects were underweight, 18 (42.86%) subjects were normal, 19 (45.24%) subjects had overweight and 3 (7.14%) subjects were obese.

According to Wagner classification 7 (16.67%) subjects had Grade 1 foot ulcer while 17 (40.58%) subjects had Grade 2 foot ulcer, being the highest. Likewise, 10 (23.81%) subjects had Grade 3 foot ulcer, 5 (11.90%) subjects had Grade 4 ulcer and 3 (7.14%) subjects had Grade 5 ulcer. Among the 42 subjects, 4 (11.9%) subjects underwent major amputation i.e., below knee amputation while 15 subjects (33.33%) underwent minor amputations i.e., amputations below the level of ankle after getting admitted to the hospital and 23 (54.76%) subjects didn't undergo amputation as shown in Table no.1

Table 1 Association between Wagner's grade of ulcer and amputation.

Amputation	Grade1	Grade2	Grade3	Grade4	Grade5	Total (n)
None	6	11	5	1	0	23
Minor	1	6	5	3	0	15
Major	0	0	0	1	3	4
Total	7	17	10	5	3	42

$$\chi^2 = 37.289,$$

$$p = 0.001,$$

$$\text{degree of freedom} = 8$$

In this study, Chi square test was performed to find the association between grade of ulcer and amputation. A significant association was found between them ($p=0.001$) indicating that as the grade of Wagner classification increased number of amputations also increased. The findings in this study was similar to the study performed by (O.Samson et al., 2001)[9]. The grade of ulcer at presentation was significantly associated with lower extremity amputation. Increasing stage, regardless of the grade is associated with increased risk of amputation. Analysis of HRQOL in the study population using Cardiff Wound Impact Schedule (CWIS) revealed the average of well-being (WB), Physical symptom and Daily living (PSDL), Social life (SL) and overall Quality of life assessment to be $23 \pm 3.39, 34.77 \pm 6.13, 20.13 \pm 4.39, 6.21 \pm 1$ & 6.76 ± 1.1 respectively. The domain Physical symptom & Daily living had the highest average i.e. 34.77 and social life had the least average i.e. 20.13 as shown in Table no:2 This study was similar to the study performed by (Costa.A et al.,2019)[5]. These results demonstrate that the presence of wound has negative effects on social-life and well-being and is directly associated with the emotional response to physiological conditions. The domain QOL self- assessment only had two questions for which the average is listed accordingly in Table no:2.

Table 2: Mean scores of domains of Cardiff Wound Impact Schedule.

Cardiff Wound Impact Schedule						
Type of patients	Well-being	Physical symptom and daily living	Social life	QOL Self-Assessment		
	Mean \pm SD	Mean \pm SD	Mean \pm SD	How good is your QOL	Satisfaction with QOL	
				Mean \pm SD	Mean \pm SD	
Inpatient	23 ± 3.39	34.77 ± 6.13	20.13 ± 4.39	6.21 ± 1	6.76 ± 1.1	

Kruskal-Wallis test result also revealed that there is no significant relationship ($p < 0.05$) between any characteristics of wound and QOL domains.

Diabetic foot ulcer scale was also used to assess the quality of life in the subjects to have a better understanding that particularly in which domain the subject's quality of life was low. It has 11 domains as shown in Figure 1 and the overall average score of all the domains of DFS-SF was 58.68 ± 8.72 . The scale revealed that among the 42 subjects, domain Daily activities, Treatment and Positive attitude the quality of life had lower mean score compared to other domains which was similar to the study performed by (Spanos.K et al., 2017)[7].

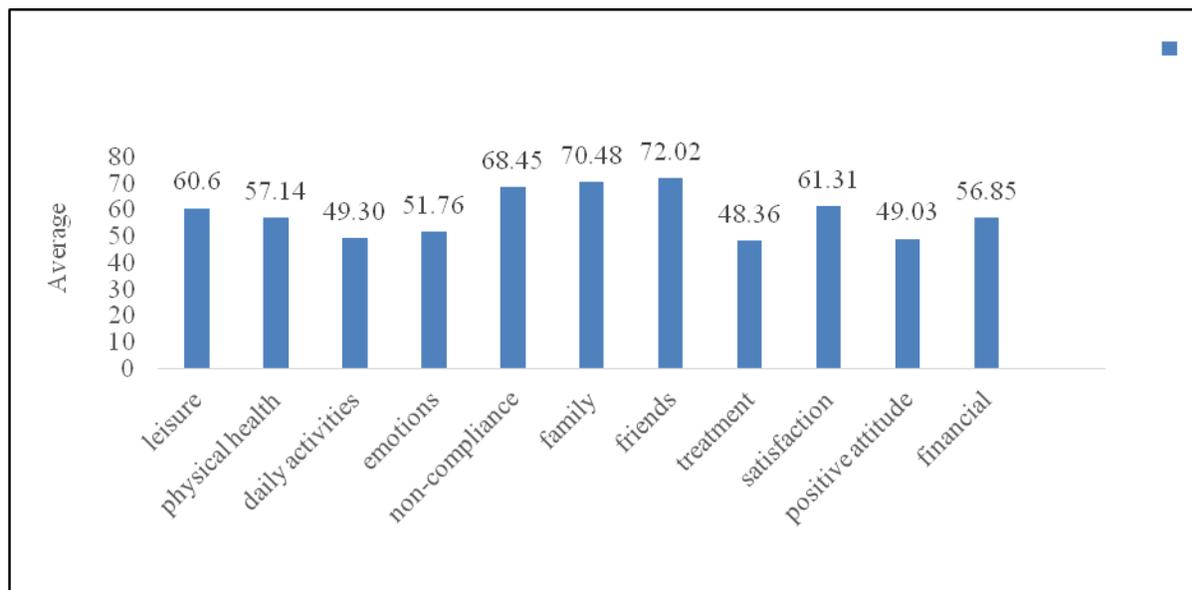


Figure 1: Diabetic foot ulcer scale summary.

Kruskal Wallis test was also applied to find out the association between the socio-demographic and clinical variables with the mean score of DFS QOL subscales. The test revealed that there was a significant association found between the domain Physical Health with Age groups ($p=0.035^*$) indicating that as the age progresses the physical health of the subjects decreases affecting their QOL. The test also showed that age had no significant effect on rest of the domains Table 3 shows association between the mean scores of domains of DFS and different age groups.

Table 3: Association between DFS subscale mean scores and different age groups.

Var	DOMAINS											
	L*	PH*	DA*	E*	NC*	FA*	FR*	T*	S*	PA*	F*	
AGE												
36-45	61.25 ±14.93	63.54 ±11.47	62.49 ±21.25	53.31 ±20.18	71.87 ±21.35	62.50 ±30.96	77.50 ±15	48.44 ±17.95	62.5 ±14.43	53.75 ±14.93	59.38 ±15.73	
46-55	61.53 ±8.99	61.54 ±15.97	52.56 ±12.80	55.09 ±13.36	70.19 ±13.05	68.85 ±21.90	76.53 ±10.28	50.96 ±13.22	65.38 ±19.19	52.31 ±12.35	54.81 ±18.07	
56-65	62.81 ±12.51	58.33 ±13.77	49.58 ±19.06	52.11 ±18.06	69.53 ±22.34	73.13 ±9.81	70.93 ±14.05	49.61 ±14.34	56.25 ±19.36	45.62 ±15.15	60.15 ±17.81	
>65	55± 12.25	45.83 ±7.79	39.35 ±13.68	45.64 ±13.82	62.50 ±10.83	71.66 ±9.35	65±20.1 6	42.36 ±11.17	63.89 ±18.16	48.33 ±8.28	52.77 ±16.27	
p value	0.491	0.035*	0.101	0.453	0.494	0.951	0.334	0.694	0.594	0.718	0.777	

L*= Leisure, PH*= Physical Health, DA*=Daily activities, E*= Emotions, NC*= Non-compliance, FA* = Family, FR*= Friends, T*=Treatment, S* Satisfaction, PA*= Positive attitude, F*= Financial.

For inferential statistics the relationship between quality of life and variables, the results were considered statistically significant whenever $P < 0.05$

Mann-Whitney U test was used to find the association between the mean scores of domains of DFS and gender. The test revealed that there was a significant association found between the domains Physical Health, ($p= 0.004^*$) Daily activities ($p=0.034^*$) and negative emotions ($p=0.002^*$) with gender as shown in Table 4. This indicates that the females were more likely to be concerned about their health conditions, their dependency on others to perform their activities and their impact on the family environment which may lead to poorer QOL. The study which was performed by (Yekta.Z et al.,2011) [6] also revealed that females had significantly lower quality of life than males. When the mean scores were compared for gender, male subjects had higher scores in 9 of the 11 domains, and lower QOL scores in relation to Non-compliance and Satisfaction domain, whereas female subjects had lower QOL scores in 7 domains.

Table 4: Association between DFS subscale mean scores and gender.

DOMAINS											
Var.	L	PH	DA	E	NC	FA	FR	T	S	PA	F
GENDER											
Male	62.06 ±10.95	60.05 ±13.99	52.33 ±16.58	54.93 ±15.31	67.65 ±17.44	71.91 ±15.57	73.82 ±13.09	49.63 ±13.31	59.56 ±19.48	50.14 ±13.34	57.35 ±17.71
Female	54.38 ±13.21	44.79 ±7.64	37.49 ±14.77	38.29 ±10.37	71.87 ±17.36	64.38 ±20.08	64.38 ±19.89	42.97 ±14.34	68.75 ±11.57	44.38 ±10.84	54.69 ±14.85
p value	0.14	0.004*	0.034*	0.002*	0.838	0.248	0.304	0.421	0.261	0.147	0.718

There was a significant association found between the domain Positive Attitude and Neuropathy ($p=0.011^*$) as shown in Table no 5 indicating that the subjects with Peripheral Neuropathy didn't have positive attitude which resulted in them not taking care of the foot or themselves in general.

Table 5: Association between DFS subscale mean scores and Neuropathy.

DOMAINS											
Var.	L	PH	DA	E	NC	FA	FR	T	S	PA	F
Neuropathy											
Yes	59.46 ±9.93	54.90 ±12.1	50.14 ±15.65	49.68 ±16.53	68.75 ±23.37	70.17 ±14.04	70.35 ±11.05	46.02 ±12.88	61.60 ±17.32	46.79 ±9.64	54.02 ±15.98
No	62.86 ±14.64	61.61 ±17.54	48.21 ±20.33	59.91 ±13.97	67.85 ±23.37	70.07 ±21.23	75.35 ±20.52	52.68 ±14.44	60.71 ±21.29	53.58 ±17.47	62.50 ±18.34
Pvalue	0.319	0.203	0.640	0.204	0.761	0.403	0.221	0.107	0.825	0.011*	0.166

Table 6 shows the association between the mean scores of domains of DFS and Body Mass Index. The test revealed that there was a significant association found between the domains "Treatment" ($p=0.023^*$) and "Satisfaction" ($p=0.038^*$) with the BMI categories (underweight, overweight, normal weight and obese) indicating that the subjects who were overweight & obese were not satisfied with the treatment they were receiving with the mean rank being 17.63 & 18.50 respectively Even if they were receiving the treatment the overweight and the obese subjects were extremely bothered to keep their weight off the ulcer, the time taken for dressing and the odour coming from the wound along with the wound leaking, which had a negative impact on the domain "Treatment" affecting the patients QOL. In our study subjects who had BMI $>25\text{kg/m}^2$ had a negative effect on the QOL of the patients which was similar to the study performed by (A.Ahmed et al., 2016).

Table 6: Association between DFS subscale mean scores and BMI.

DOMAINS											
Var.	L	PH	DA	E	NC	FA	FR	T	S	PA	F
BMI											
Underweight	52.5±10 .60	52.08± 26.52	29.16 ±5.89	44.85 ±3.12	50 ±17.67	62.50 ±3.53	72.50 ±24.74	37.50 ±17.68	-	57.50 ±3.53	56.25 ±26.52
Normal	64.72±1 0.91	58.1±1 4.88	51.16 ±15.27	56.45 ±18.86	66.66 ±20.56	68.61 ±23.62	76.94 ±12.96	55.55 ±10.69	69.44 ±18.30	47.50 ±16.81	62.50 ±18.19
Overweight	57.11±1 1.82	58.11± 13.71	48.46 ±17.85	48.78 ±12.74	71.05 ±14.46	73.68 ±8.31	67.63 ±16.19	43.42 ±13.73	55.26 ±17.83	49.47 ±10.12	53.29 ±14.33
Obese	63.33±1 0.41	48.61± 10.48	56.95 ±24.41	47.06 ±16.96	-	66.67 ±2.89	-	43.75 ±10.82	58.33 ±14.43	50±5	45.83 ±19.09
p value	0.202	0.704	0.294	0.325	0.301	0.262	0.340	0.023*	0.038*	0.685	0.276

In this study, the risk factors which contributed to the development of DFU were determined checking the previous histories of the subjects, through personal interviews and with the help of case-sheets. It was observed that subjects who presented with DFU had Peripheral Neuropathy as a major risk factor (66.66%) as shown in Table no 7. The occurrence of neuropathy increases the risk for foot ulceration due to increased pressure load and sheering forces. A similar study conducted by (Mariam.T et al.,2016)[8] observed that Neuropathy was another variable which had strong role with foot ulcers in diabetic patients. Another contributing factor for the development of DFU was poor control over diabetes where 61.90 % subjects had uncontrolled blood sugar level. The subjects with high blood glucose level were exposed to micro vascular complication and neuropathy. The possible explanation for this could be that the subjects were not following the diet properly or were ignorant about the treatment to be taken which was similar to the study conducted by (E.Andrew et al., 2013) [12] Another risk factor contributing to the development of DFU in our study was subjects who were overweight and obese. When the BMI of the subjects were looked upon it was observed that 52.38 % of the subjects who had a BMI $< 25\text{kg/m}^2$ had developed DFU. A study conducted by (Mariam T et al.,2016)[8] also shared similar findings that subjects who were overweight and obese were at higher risk of developing ulcer than the ones who were not.

Another study which was performed by (Bokyo EJ et al.,1999)[11] also revealed that Neuropathy and greater body mass influenced foot ulcer risk providing support for a multifactorial etiology for Diabetic foot ulceration. Similarly in this study, the subjects who lacked proper foot care were found to develop DFU at higher rates (76.19%) which was similar to the study conducted by (P.Susana et al.,2016)[13] where foot care seemed to be the least performed self-care in patients owing to the development of foot ulcers.

Table 7: Risk factors associated with Diabetic Foot Ulcer.

Risk factors	Frequency	Percentage (%)
Previous history of foot ulcer		
Yes	19	45.23
No	23	54.76
Duration of DM		
≤ 10 years	27	64.29
>10 years	15	35.71
Peripheral Neuropathy		
Yes	28	66.67
No	14	33.33
Blood glucose level controlled		
Good control	16	38.095
Poorly controlled	26	61.90
Smoking		
Yes	15	35.71
No	27	64.28
Body Mass Index		
Underweight(≤18.5)	2	4.76
Normal weight(18.5-24.9)	18	42.86
Overweight(25-29.9)	19	45.24
Obese >30	3	7.14
Lack of foot care		
Yes	32	76.19
No	10	23.81

CONCLUSION

The study found out that the quality of life and its dimension in patients with DFU's are in low range. The quality of life in these patients were hindered at various aspects and the most affected domain in majority of the patients were Daily activities, Positive attitude and Treatment. Female gender, greater body mass, presence of Neuropathy and age of the subjects were the most important factors associated with lower QOL. In this study, the major risk factors contributing to the development of DFU in the patients were found to be greater BMI, presence of Peripheral Neuropathy, lack of foot care and poor control over the blood sugar level.

But if diagnosed and treated at an early stage it would prevent the occurrence of lower extremity amputation. Regardless of the extreme consequence that this disease leads to no proper care and attention has been given towards it. In order to control this and improve the QOL in patients, risk factors should be identified and addressed. Health care professionals should strive to increase awareness, prevention, and continuity of care using ongoing education with their practice. Closing the gaps in education for both patients and health care professionals will help minimize hospital admission, re-admissions, and diabetic ulcer wound chronicity.

ACKNOWLEDGEMENT

We express our heartfelt gratitude to Dr Vidya Ravi, Professor of Statistics, JSS College of Pharmacy, Mysore and Dr Gangabaraiah A, Professor of Statistics, Department of Community Medicine, KIMS, Bengaluru for their contribution to the statistical analysis of our study. We also stretch out our sincere appreciation to Dr Geetha Jayaprakash, Grade I Assistant Professor, Department of Pharmacy Practice for her helpful direction in each and every step of this work.

Conflict of Interest

The authors declare that they have no conflict of interest.

Funding support

The authors declare that they have no funding support for this study.

ABBREVIATION

BMI	Body Mass Index
CWIS	Cardiff Wound Impact Schedule
DA	Daily Activity
DFS	Diabetic foot scale
DFU	Diabetic foot ulcer
DM	Diabetes Mellitus
E	Emotions
FA	Family
F	Financial
FR	Friends
HR-QOL	Health- Related Quality of Life
L	Leisure
NC	Non-Compliance
PA	Positive Attitude
PH	Physical Health
PSDL	Physical Symptoms & Daily living
QOL	Quality of Life
S	Satisfaction
TR	Treatment
WB	Well-Being
WHO	World Health Organization

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