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<u>RESEARCH ARTICLE</u>

# Quality of Life in patients experiencing Diabetic Foot Ulcer: A cross sectional study in a Clinical Pharmacist's Perspective

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## **ABSTRACT:**

The objective of the study was to compare the quality of life (QOL) in men and women with diabetic foot ulcer (DFU) using RAND-36 Questionnaire and also to improve their quality of life by structured patient education. The study was designed to be a cross sectional study in which 82 men and 78 women with diabetic foot ulcer were enrolled. Socio-demographic variables were documented and assessed using RAND SF-36 a questionnaire for all subjects. RAND SF-36 scale scores were compared using statistical descriptive and analytical method. QOL was found to be worse in women when compared to men. Out of 160 study participants, 51% were male and 48 % were female with a mean (+ SD) age of 45 (+3) and 43 ( $\pm$  7.3) respectively. The QOL score analysis demonstrated that the physical health was subsequently limited due to physical activity (p<0.0001) and pain (p<0.0001) with a significant difference between men and women. However, analyzing the social functioning scores of the subjects showed a non-significant relationship of p value (0.7133) and general health (p=0. 3427). Although on further evaluation, the scores of emotional well being and energy scores of the patient showed a significant difference with a p value of <0.0001 and 0.0004 respectively. The correlation between the age and physical function exhibited a significant difference between the genders (p<0.0001). Female patients with DFU had a lower score for quality of life when all the 8 domains in RAND SF-36 questionnaire were assessed. Adapting patient educational programs and appropriate life style modifications can improve the quality of life in these patients.

**KEYWORDS:** Quality of life, diabetes, Foot ulcer, patient counseling.

## **INTRODUCTION:**

Diabetic foot ulcer (DFU) is one of the major complications associated with diabetes. DFU affects the quality of life of an individual creating a huge impact on their life. DFU has been considered as one of the major cause for hospitalization affecting approximately 15% of the diabetic population during their lifetime<sup>1</sup>, this may also be attributed to several social and cultural practices such as walking bare foot, lack of facilities for diabetes care, poor awareness and economic conditions; thereby their quality of life is further deprived.<sup>2</sup>

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Studies also report that DFU is the major reason for lower limb amputations in patients with diabetes mellitus, foot ulceration is a condition where an area of skin has broken down and the underlying tissues are visible, they occur especially on the lower legs or feet. The skin normally heals quickly when it is cut, but in people with diabetes mellitus the broken skin on the feet takes a longer time to heal or does not heal and hence is prone to formation of ulcer which may further lead to amputation. Limb amputations not only distorts the image of the body but also increases the dependency and cost of treatment for foot ulcers during hospitalization<sup>3</sup>. Diabetic foot ulcer is the most significant reason for the increase in mortality rate associated with the comorbidities heart attack and stroke, among the people with diabetes<sup>4</sup>. The mortality rate has been increased,

influence the healing of foot ulcer are diabetes, sociodemographic conditions like age, gender and comorbidities.5,6

Foot ulceration is preventable if simple interventions are followed such as self foot care, patient education and life style modification<sup>7</sup>. Educating the patients about their disease and the drugs they take might help them to take the responsibility to be vigilant in their disease management like blood glucose monitoring, body weight monitoring, personal hygiene, healthy lifestyle with proper diet and physical activity. This can further help in reducing the amputations up to 80%. Considering the mortality rate and the significant position of the diabetic foot ulcer<sup>9,10</sup>, this study was structured to compare the quality of life (OOL) in men and women with diabetic foot ulcer (DFU) using RAND-36 Questionnaire and also to improve their quality of life by structured patient education.

## **MATERIALS AND METHOD:**

This cross sectional, observational study was conducted in patients with diabetic foot ulcer in a tertiary care hospital. The study proposal was approved by the institutional ethics committee (IEC/DOPV/2015/20). Diabetic foot ulcer patients of both genders above 18 years willing to participate in the study were included where as participants above 70 years of age, pregnant women and patients with psychiatric complications were excluded in this study. Patient's pertinent data like name, date of admission, age, gender, medication history, biochemical investigations and diagnosis, previous history of diabetes, and current and previous history of diabetic foot ulcers were documented in a structured data entry form. The qualities of life of patients were studied using a validated questionnaire. In our study, RAND SF-36 was used for assessing the quality of life in the study participants.

The questionnaire was administered for the study population and the answers recorded were analyzed further. All the patients were given appropriate patient education on diabetes and diabetic foot ulcer at the end of the study.

## **OOL** analysis:

Every patient enrolled in the study was administered with the quality of life questionnaire (RAND SF 36 Health Survey Tool 1.0). The RAND-36 health survey contains 36 questions in 8 domains, which includes physical functioning (5items), Physical health (4 items), Emotional problems (3 items), Energy/Fatigue (4 items), Emotional well being (5 items), Social functioning (2 items), Regarding Pain (2 items), General health (6 items). The scores ranging from 0 (poor QOL) to 100

from 50% to 60% in the current scenario. Factors that (good OOL) were evaluated and analyzed for each and every domain and was compared between the genders. Statistical analysis

> All statistical analysis was performed using statistical software. Pearson's correlation was used to determine the linear dependency of the domains of the quality of life on individual parameters. Unpaired student t-test was used to compare two groups and p value less than 0.05 was considered statistically significant throughout the study (95% confidence interval).

## **RESULTS:**

Overall, 160 patients were enrolled in to this study of Quality of life. Patients' quality of life was assessed depending on the age groups and other chronic medical condition; using RAND SF-36 Health survey 1.0. Table.1 represents the socio-demographic parameters of the study population. About 51% of the study population was male respondents with a mean age of 45 (+3) years. However no significant difference in age between the genders was observed. Majority of the male participants had habit of smoking (18%) and alcoholism (49%). Most of the study participants were diabetic for a period of approximately 8 to 10 years. Among the study population, about 57 % of male suffered from hypertension as co-morbidity which was greater than the female (50%).

The scores of 8 domains were analyzed based on physical functioning (5items), Physical health (4 items), Emotional problems (3 items), Energy/Fatigue (4 items), Emotional well- being (5 items), Social functioning (2 items), regarding Pain (2 items), General health (6 items). Among which the female has indicated the lowest mean score when compared to male in all 8 domains. (Table 2). The Quality of life based on physical health, role of limitations due to physical health and pain showed a significance difference (p<0.0001) between the genders. However, social functioning and general health showed no significant difference (p=0. 713) and (p=0. 342). On further analysis of the scores of emotional functioning and energy level between the genders showed a significant difference of (p<0.0001) and (p=0. 0004). Factors such as pain, physical function, and emotional disturbances have affected the general health of the diabetic foot ulcer patients.

Figure.1. represents the overall comparison of RAND SF-36 between male and female which exhibits the lower quality of life in female wen compared to male. Statistically significant inverse correlation was found between age and physical functioning (Person's correlation coefficient (r2=-0.570, p<0.0001) (Figure. 2).

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#### Table 1.Socio-demographic parameters

DISTRIBUTIONS	MALE (n=82)	FEMALE (n=78)	P-VALUE
AGE; years mean(±SD)	40(±10)	45(±12)	0.006**
Smoking habit (%)	15(18%)	-	0.220
Alcohol consumption	15(18%)	-	0.020
Smoking+ alcohol	40(49%)	-	0.003**
Hypertensive	47(57.3%)	39(50%)	0.590
History of diabetes (duration)			
<5years%	12.19%	6.4%	0.04
5-10 years%	73.17%	64.1%	0.06
>10 years%	14.63%	29.4%	0.08

\*, \*\* - signifies significant and very significant

#### Table 2. SF-36 score scale

SEX	PF	RLP	RLE	EWB	E&F	SF	Pain	G.H
MALE%	34.08	47.25	73.17	55.3	63.12	54.57	57.31	28.76
FEMALE%	22.88	21.79	56.83	46.79	49.07	53.84	42.94	30.66
P-VALUE	<0.0001***	<0.0001***	0.0003**	<0.0001***	0.0004**	0.7133	<0.0001***	0.3427

PF-Physical function, RLP-Role of limitations due to physical functioning, RLE-Role of limitations due to emotional functioning, EWB-Emotional well being, E&F- Energy and Fatigue, SF- Social functioning, G.HEALTH-General health

\*, \*\* - signifies very significant and highly significant



Figure.1. Comparison of RAND-36 scale score between men and women diabetic foot ulcer patients PF-Physical function, RLP-Role of limitations due to physical functioning, RLE-Role of limitations due to emotional functioning, EWB-Emotional well being, E&F- Energy and Fatigue, SF- Social functioning, G.HEALTH-General health



Figure 2. Pearson's correlation between age and physical functioning of the patietns

#### **DISCUSSION:**

This cross sectional study explored the quality of life in male and female patients with DFU. From our findings on quality of life evaluated using RAND SF-36 questionnaire specially focusing on the areas of physical health, emotional well being of the patients was found to be affected more in females when compared to male. All comparison between the scores showed significant difference except in social functioning and general health between the genders. In a study conducted by Johnson et al a significant difference was observed between age and quality of life in both genders, whereas in our study a significant difference was observed in all 5. domains except social functioning and general health.<sup>8</sup> In a study conducted by valensi et al  $^{1}$ , in the year 2005, showed that age significantly correlated with the various domains of RAND SF-36 such as daily living, physical health, depending on others; whereas in our study significant difference existed between age and physical functioning.

Ribu et al reported that age has a significant difference in the quality of life, which is due to physical health, emotional disturbances, and pain, which is similar to our study. Similarly a study conducted by oyibo et al., reported that age is one of the social factors affecting the quality of life of diabetic foot ulcer patients<sup>13,14</sup>.

In other words younger patients have more positive attitude towards diabetic foot ulcer<sup>15</sup>. On the other hand older patients suffer from chronic medical complications of diabetes and achieve a lower on quality of life<sup>15</sup>. It seems that patients with a diabetic foot ulcer experience the highest rate of decreased quality of life when compared between the genders<sup>16</sup>. However, when foot ulcer is developed, patients suffer from psychological hopelessness that makes no importance for them and they ponder more regarding the cure of their ulcer.

## **CONCLUSION:**

Diabetic foot ulcer lowers the quality of life of patients by limiting their mobility, physical and emotional functioning and also by inducing pain. The impact of these limitations over the quality of life was observed to be more in the female than male. From administration of RAND SF-36 questionnaire, we found that most of the domains in it were affected by the patient's gender. Female patients with a diabetic foot ulcer had a lower score for quality of life when all the eight domains were assessed. Adapting appropriate medical interventions at the right time like lifestyle modifications and framing suitable educational programs can improve the quality of life of diabetic foot ulcer in either gender.

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