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A Cross-sectional Study to assess the "Quality of Life" and their impact on employment among Diabetic foot patients in a Tertiary care Hospital in a Metropolitan city

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Abstract

Background: India leads the world with largest number of diabetic patients earning the dubious distinction of being termed the **"**Diabetes Capital of the World**.**The most frequent consequence of diabetes mellitus is diabetic foot ulcer. Quality of life is decreased by diabetic foot illness. It is linked to reduced productivity and early retirement. This research was done to assess the health related quality of life.among those who have diabetic foot ulcers, as well as to assess the impact on employment status of diabetic foot ulcer. **Objectives:** To assess the impact of employment status among diabetic foot ulcer patients. To assess the impact of diabetic foot ulcer on health related quality of life among diabetic foot patients. **Materials and methods:** This was a cross sectional observational study among 196 diabetic foot ulcer patients of either sex visiting the General surgery OPD of a tertiary care hospital in a metropolitan city.Complete enumeration method was used in this study. A semi-structured predesigned pretested questionnaire was used in this study. It contains socio -demographic details, General examination, disease and treatment related details, and employment related characteristics.A standardized questionnaire**, SF-36 v2**, was used to measure QOL of diabetic foot patients. **Results:** Majority of participants are in paid employment (n=70, 35.71%) followed by unemployed (n=58, 29.59%) then self-employed (n=38, 19.38%) and 30 (15.30%) are retired respectively. the mean days lost due to diabetic foot was 145.5±31.5 while the mean wages lost per day is Rs.322±295. **Conclusion:** In the present study majority of study participants had poor health related quality of life in environmental,physical and mental health.Majority of participants are in paid employment (n=70, 35.71%) followed by unemployed (n=58, 29.59%) with diabetic foot ulcer and reported of having left a job/changed job.

Keywords: Diabetic foot ulcer, HRQOL, Employment, SF-36 v2

Introduction

Diabetes mellitus (DM) is a chronic metabolic disease which affects about 415 million adults worldwide as in 2015, and it is projected to increase to 642 million in 2040[1]. India leads the world with largest number of diabetic patients earning the dubious distinction of being termed the **"Diabetes Capital of the World."** According to the Diabetes Atlas 2015 (7th Edition) published by the International Diabetes Federation, the number of people with diabetes in India, currently around 69.2 million is expected to increase to 123.5 million by 2040[2].

Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected, requiring hospitalization while 20% need amputation. Eight out of 10 non-traumatic limb amputations are attributable to diabetes, of which 85% are due to DFU annually[3]. Patients with a history of DFU have 40% higher 10-year death-rate, than those without. Average time required for healing of DFUs is 28 weeks (range 12-62 weeks[4]. Two studies indicated that patients with DFUs spent four times more than those without (Satyavani, 2013: Rs.19,020 (~$295.95) vs. Rs.4,493(~$69.91)) and (Shobhana,2001:Rs.15,450 (~$240.40)vs Rs. 4,373(~$68.04)[5].

Objectives

1. To assess the employment impact on Quality of life Diabetic foot ulcer among diabetic foot patients.

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2. To assess the impact of diabetic foot ulcer on health related quality of life among diabetic foot patients.

Methodology

The present study is ahospital based Cross- sectional study carried out in a diabetic foot patients attending in general surgery outpatient department in a tertiary care hospital in a metropolitan city during the period from May 2020 to December 2021.A total of 196 patients included in the study. Complete enumeration method was used in this study.

Therefore based on this method we included all the diabetic foot patients who are attending the surgery OPD for the study.

Inclusion criteria

1) All the Diabetic foot ulcer patients who attended the surgery OPD.
2) Subjects who were willing and able to participate in the study.
3) Subjects who were currently receiving treatment for diabetic foot ulcer or previously had diabetic foot ulcer.

Exclusion criteria

1) Pregnant women.
2) Any mental disease and cognitive impairment.
3) Individuals with Malignant neoplasm & ongoing chemotherapy.

Steps of Methodology

1. Designing of Questionnaire.
A Predesigned pretested semi-structured interview schedule questionnaire was prepared in accordance with study objectives. The questionnaire was prepared inEnglish and interview was conducted in the language which they best understood.

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A standardized questionnaire, **SF-36 v2**, was used to measure QOL of diabetic foot patients[48].

2. Ethical consideration

Official Permission was taken from Dean and Head of the Department, Dept of General Surgery of a Tertiary Care Hospital who permitted to undertake this study. Permission to conduct the study and ethical clearance was obtained from the Institutional Ethics Committee.Participants were fully informed about the purpose, procedures, and benefits of participation in the study through informed consent form.Participation in this study was voluntary. Participants were informed that allrecords pertaining to the study would be confidential, and that numbers instead ofnames would be used to identify the participants. Data was used for academic purpose only.

3. Identification of Study subjects and rapport building

Study subjects were identified from the General Surgery OPD of a Tertiary care hospital. A preliminary self-introduction orientation about the study, purpose of the study and manner in which it will be carried out was explained to every subject. Each study participant was interviewed by face-to-face interview with the help of standardized SF-36 v2 QOL questionnaire.

4. Data collection by interview technique.

It included a questionnaire based oral interview of the study participants, and the interview was conducted by the investigator after taking informed consent of the study subjects. Face to face interviews were carried out in language which they best understood.

Data collection Tool

Semi-structured predesigned pretested questionnaire. It contains socio -demographic details, General examination, Disease and treatment related details, and Employment related characteristics.A standardized questionnaire, **SF-36 v2**, was used to measure QOL of diabetic foot patients.(48).Institutional ethics committee approval was obtained.Informed consent was taken.This questionnaire SF-36v2 has **two components** and each component contains **four domains** for measuring the QOL. The four domains representing **physical component** summary containing physical functioning (PF), Body pain (BP), general health (GH) and role physical (RP). **Mental component** summary (MCS) containing the domains are vitality (VT), mental health (MH), social functioning (SF), and role emotional (RE) .A final item, termed self -reported health change ,is answered by the client but is not included in the scoring process.

The SF-36 offers a choice of recall format at a standard (4 week) or acute (1 week) frame. Likert scales and yes/no options are used to assess function and wellbeing on this 36-item questionnaire .To score the SF-36, scales are standardized with a scoring algorithm to obtain a score ranging from 0-100.Higher scores indicate better health status and a mean score of 50 has been articulated as a normative value for all scales.

Data analysis

All responses were tabulated by the investigator using Microsoft excel 2016 software. Graphical representation were made where ever necessary. Statistical analysis of all data collected were made using the SPSS version 22.0 software .Data was analysed in the form of Mean, Standard deviation, Percentage. The demographic and clinical characteristics of the study sample were analysed using descriptive and analytical statistical functions of the software.To determine inter-group differences, **independent t-test** using a two-tailed test was used to compare mean values of continuous data. **Kruskal Wallis test** was used when variables were ordinal or in case of skewed data.

Results

Table no1: Sociodemographic profile of study subjects

Gender	Frequency(n)	Percentage (%)
Male	106	54.08
Female	90	45.92
Marital status		
Married	168	85
Unmarried	15	8
Divorce	14	7
Type of family		
Nuclear family	101	51.50
Joint family	69	35.20
Extended	26	13.30
Occupation		
Semiprofessional	7	3.57
Skilled	81	41.33
semiskilled	7	3.57
unskilled	26	13.27
unemployed	75	38.26
Hba1c values		
<7	5	2.55
≥7	191	97.45
BMI		
<18.5	4	2
18.5- 24.9	91	46.60
25- 29.9	83	41.90
>30	18	9.50

Maximum study subjects 153 (78.06%) belong to 51-60 years of age followed by 26 (13.26%) in 41-50 years of age followed by 17(8.67%) above 60 years of age with mean age of 53.74 (SD=3.83).Among 196 participants majority of them are males ie , 106 (54.08%) & 90 (45.9%) were females .The majority of study subjects were married i.e. 168 (85%) followed by 15 (8%) unmarried and 14 (7%) were divorced. Most of them belonged to Nuclear family was 101(51.5%) followed by the Joint family i.e.69 (35.2%) and 26 (13.2%) belonged to the extended type of family .The majority of study subjects belongs to skilled workers 81 (41.33%) followed by unemployed 75(38.27%), unskilled workers 26 (13.27%), semiskilled 7(3.57%) & semiprofessional 7(3.57%).Maximum study subjects, i.e. 88 (45%) had completed their high school followed by 51 (26%)

middle school followed by 28 (14.2%) primary school & 23 (12%) diplomate followed by 5 (3%) graduate.

The majority of study subjects, 98 (50%) belonged to lower-middle, followed by 53 (27.04%) Upper middle followed by 8 (2.9%) were upper lower class and lower class belongs to 14(7.14%) followed by 9 (4.5%) of upper class. The majority of participants 146 (74.48%) had diabetes for <10 years followed by >10 years ie, 50 (25.51%) . Mean duration of diabetes was 9.53 (SD=2.28) years

The majority of the participants (97.4%) ie, 191 were having HbA1c values ≥7 and (2.55%) ie,5 participants were having values <7.Hba1c values were in the range of 6.8 to 12%.Majority of study subjects belongs to BMI between 18.5 to 24.9 ie, 91 (46.5%) followed by BMI 25- 29.9, 83 (41.9%) belong to BMI > 30 , 18 (9.5%) & less than 18.5, 4 (2%).Most of them belong to grade III ie, 81 (41.32%) followed by grade II, 48 (24.48%) followed by grade IV, 41 (20.91%) & grade V, 3 (1.53%) followed by grade I ,23 (11.73%).The majority

of study subjects have a family history of diabetes ie,138 (70.4%) and (29.59%) ie, 58 of them are not having any family history of diabetes. Majority of participants are in paid employment (n=70, 35.71%) followed by self-employed (n=52, 26.53%), unemployed (n=44, 22.44%) and 30 (15.30%) are retired respectively.Among 70 participants who were in paid employment, 21(30%) of the subjects lost job opportunities due to diabetic foot ulcer.Among 70 participants who were in paid employment mean days lost due to diabetic foot was 145.5 ± 31.5 while the mean wages lost per day is Rs.322±295.It was observed that there is a significant difference between employed and unemployed participants with the social functioning domain of the SF-36. (p=0.045).Mean scores of physical functioning domain observed was 42.58, mental health was 40.26, bodily pain was 38.03, vitality was 48.4 and general health 41.10 and these domains are showing poor health-related quality of life.

Impact on Employment related characteristics

Table 2: Distribution of study subjects according to Employment status of Diabetic foot ulcer(N=196)

Employment status	Frequency	Percentage
Paid Employment	70	35.71%
Self employed	38	19.38%
Unemployed	58	29.59%
Retired	30	15.30%
Subjects who lost job prospect / opportunities due to foot ulcer		
Yes	21	30
No	49	70
Total	70	100
Estimates of employment related characteristics (N=70)	**Mean ±SD**	
Days lost due to foot ulcer	145.5± 31.5	
Wages lost per day (Rs)	322 ± 295	

The above table shows distribution of the participants according to employment status of diabetic foot ulcer. Majority of participants are in paid employment (n=70, 35.71%) followed by unemployed (n=58, 29.59%) then self-employed (n=38, 19.38%) and 30 (15.30%) are retired respectively.
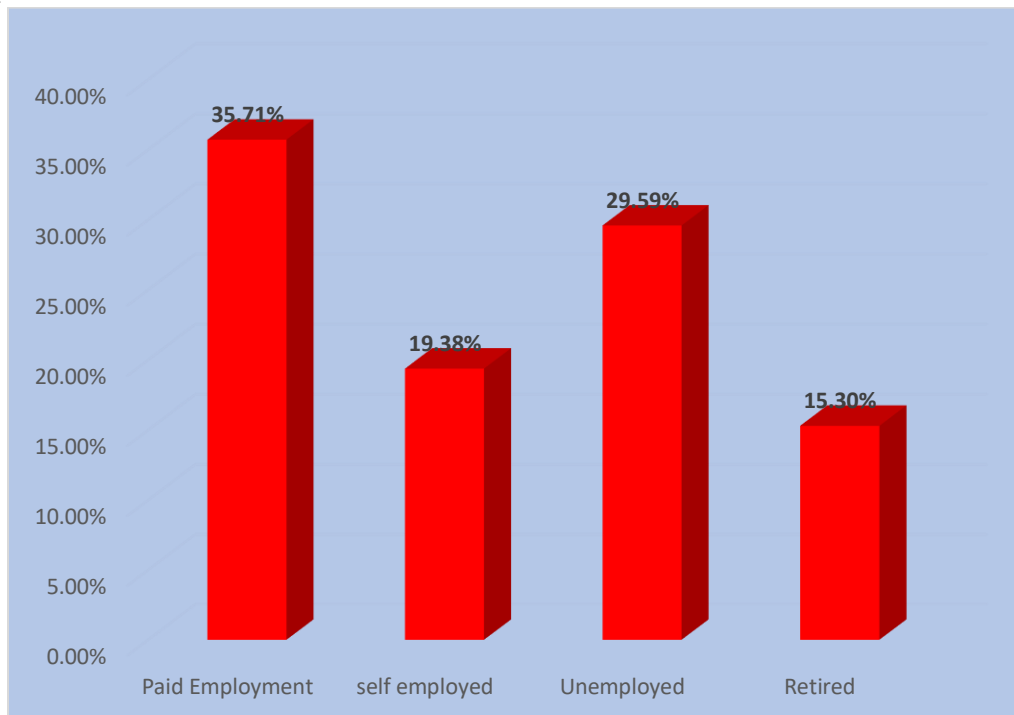
Figure 1: Distribution of study subjects according to Employment status

The above table shows distribution of the participants who lost job prospect/opportunities due to diabetic foot ulcer. Among 70 participants who were in paid employment 21(30%) of the study subjects lost job opportunities due to diabetic foot ulcer.
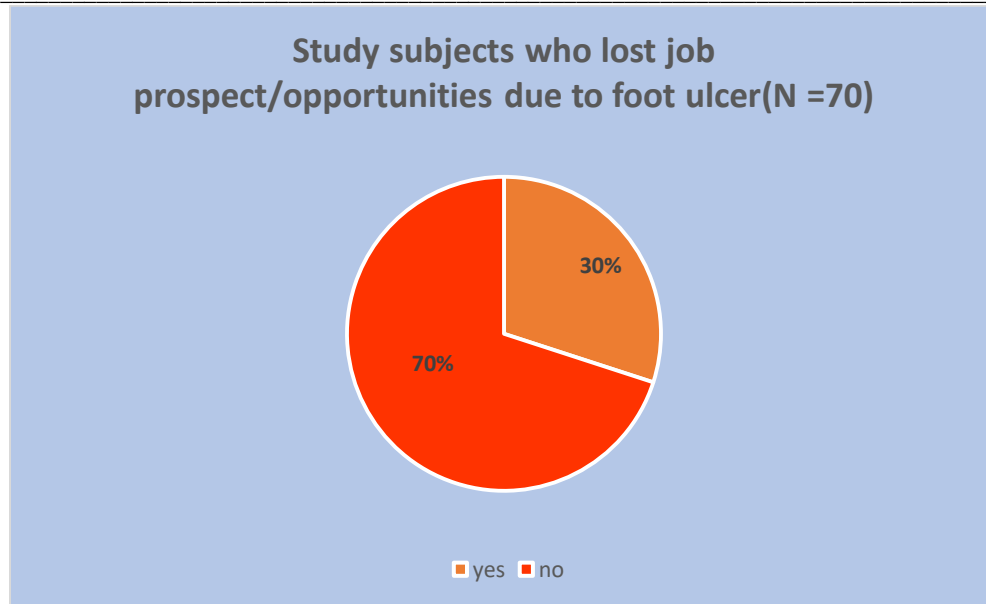
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Figure 2: **Study subjects who lost job prospect/opportunities due to foot ulcer (N=70)**

The above table depicts that the mean days lost due to diabetic foot was 145.5±31.5 while the mean wages lost per day is Rs.322±295.
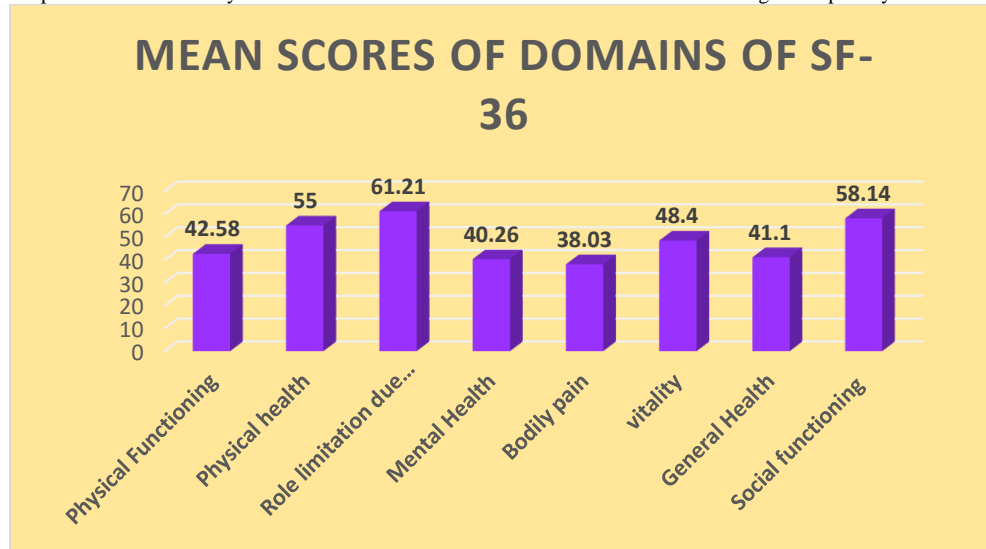

Figure 3: Graph showing mean scores of domains of SF-36

In the present study from mean scores of physical functioning domain observed was 42.58, mental health was 40.26, bodily pain was 38.03,vitality was 48.4 and general health 41.10 and these domains are showing poor health related quality of life.

Table 3: Distribution of Employment status according to SF-36 domains of diabetic foot ulcer(N=196)

Domains	Employment status (Mean ±S.D)		Significance test	
	Employed	**Not employed**	**P value**	**t value**
Physical functioning	42.17±8.86	43.18±7.95	0.208	0.827
Role physical health	55.78±19.21	53.97±20.37	0.895	0.638
Body pain	38.54±11.72	37.35±12.43	0.495	0.684
General health	40.55±6.88	41.81±6.87	0.203	1.278
Vitality /Energy	49.30±10.44	47.55±9.76	0.232	1.201
Social functioning	59.83±12.90	56.39±12.28	**0.045***	1.961
Mental Health(Emotional well-being)	39.81±11.93	40.75±11.69	0.592	0.537
Role limitation due to emotional problems	90.12±18.93	87.12±21.69	0.302	1.034
Values are presented as mean± standard deviation and analyzed using independent t test.				
(*) represents statistical significant difference.				
*Here employed includes paid employed & self-employed and not employed includes unemployed & retired.				

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In Table no: 3 it was observed that there is significant difference between employed and not employed participants with the social functioning domain of the SF-36. (p=0.045)

Table 4: Distribution of SF-36 V2 domain scores by wound status of study subjects(N=196)

Domains	Healed ulcer (Mean ±S.D)	Non healed ulcer (Mean ±S.D)	P-value	t value
Physical functioning	40.90±9.14	43.88±7.76	**0.007***	2.457
Role physical health	61.68±5.26	60.85±5.86	0.503	1.019
Body pain	39.84±11.85	36.69±12.07	0.347	1.817
General health	40.18±6.64	41.78±7.03	0.183	1.613
Vitality	48.67±9.47	48.34±10.70	0.221	0.221
Social functioning	59.33±13.36	57.58±12.25	0.470	0.948
Mental health (Emotional well being)	40.91±12.34	39.78±11.45	0.476	0.659
Role limitation due to emotional problems	86.74±20.78	90.17±19.82	0.123	1.171
Values are presented as mean± standard deviation and analysed using independent t test.				
(*) represents statistical significant difference.				

In Table no: 4 it was observed that there is significant difference between healed and non healed ulcer with physical functioning domain of SF-36 (p=0.007).

Table 5: Influence of Hba1c on health-related quality of life of the study population (N=196)

Domains	Hba1C levels (Mean ±S.D)		Statistical test	
	<7	>7	P -value	t value
Physical functioning	44.23±7.59	42.51±8.53	0.481	0.706
Role physical health	53.84±20.01	55.05±19.74	0.832	0.213
Body pain	36.73±8.31	38.10±12.26	0.693	0.396
General health	42.69±4.38	41.01±7.02	0.397	0.850
Vitality /Energy	53.07±5.96	48.19±10.38	0.094	1.682
Social functioning	52.88±10.40	58.67±12.80	0.113	1.543
Mental Health(Emotional wellbeing)	36.30±6.80	40.50±12.04	0.217	1.240
Role limitation due to emotional problems	61.84±5.56	61.15±5.62	0.670	0.426
Values are presented as mean± standard deviation and analyzed using independent t test.				
(*) represents statistical significant difference.				

In Table no: 5 it was observed that there is no significant difference between Hba1C values and domains of SF-36 (p>0.05)

Table 6: Distribution of SF-36 V2 domain scores with grading of foot ulcer (N=196) by Kruskalwallis test

Grading of foot ulcer	Physical functioning	Role Physical health	Role emotional	Emotional well being	Social functioning	Energy	General health	Body pain
Grade 0	37.39±7.81	58.95±8.71	89.85±18.62	40.69±10.62	64.13±15.12	46.95±9.50	41.7±7.77	39.56±13.89
Grade 1	43.65±7.10	59.40±5.75	92.03±17.49	37.87±9.11	60.47±14.47	50.29±9.64	41.56±7.49	37.42±11.29
Grade 2	42.69±8.84	61.94±5.16	85.52±23.30	40.15±12.45	58.05±12.36	49.01±10.36	41.51±6.16	37.36±12.29
Grade 3	41.17±9.62	62.29±5.76	88.65±18.79	42.97±12.82	57.18±10.97	45.7±10.26	40.21±7.29	39.62±12.84
Grade 4	48.33±5.77	65.33±4.61	77.77±38.49	46.16±18.90	54.16±7.21	43.33±10.56	40.00±0.00	39.16±11.54
P value	0.000*	0.034*	0.267	0.093	0.288	0.069	0.903	0.872
Values are presented as mean± standard deviation and analyzed using Kruskalwallis test.								
(*) represents statistical significant difference.								

From table no: 6 it was observed that there is significant difference between grading of foot ulcer with physical functioning domain (p=0.000)and rolephysical health (p=0.034) domains of SF-36.

Discussion

Table no: 1 shows the distribution of the participants according to the employment status of diabetic foot ulcers. Majority of participants are in paid employment (n=70, 35.71%) followed by self-employed (n=52, 26.53%), unemployed (n=44, 22.44%) and 30 (15.30%) are retired respectively. Table no:2 shows the distribution of the participants who lost job prospects/opportunities due to diabetic foot ulcers. Among 70 participants who were in paid employment, 21(30%) of the subjects lost job opportunities due to diabetic foot ulcers.

Al Ayed et al in 2019, found in their study that among 81 participants (29.6%) ie, 24 are employed and 70.4% (57) are unemployed[5].These results are similar to the present study.

Pavla Kudlová1, Ilona Kočvarová in 2020,found in their studythat among 167 respondents participated in the study, with an average age of 65 years.18 respondents (11%) were government employees, 12 (7%) were self-employed, 116 (69%) were retired, 21 (13%) were retired due to invalidity[6]. These results are not similar to the present study.

In table no: 2 it was found that the mean days lost due to diabetic foot was 145.5±31.5 while the mean wages lost per day is Rs.322±295.**SP sithara et al** 2012, observed in their study that among 81 patients studied it was found that the mean days lost due to diabetic foot was 146±199 while the mean wages lost per day is 626±810. This study is showing similar results to our study[7].

Jayaprakash P et al 2009 says that negligence or under treatment due to the financial crisis is a major roadblock in the treatment and eventually may lead to amputation, which further accentuates the depressive state due to disability. The dominant part detailed that they needed to take early retirement, had a loss of openings for work, and needed to change their work because of the event foot ulcer[8].

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Conclusion

The SF-36 questionnaire is accurate and trustworthy in measuring health-related quality of life in people with a variety of chronic illnesses, and it can be used to estimate HRQOL.

The current study concludes that sex, duration of diabetes, family history of diabetes, employment status, wound status, grading of foot ulcer, hypertensive status, and dyslipidemia have positive effects on physical functioning, role physical health, role emotional, social functioning, mental health(emotional well being), body pain, general health and vitality (energy).

Recommendation

The health system must focus on ensuring the early healing of a wound by proper patient education and treatment modalities. To reduce the burden of diabetic complications, proper health education should be emphasized on good habits, nutrition control, physical exercise and diabetic medication compliance.To lessen the social and economic effects of diabetic foot ulcers, a multidisciplinary approach is required. For the treatment of foot ulcers, the health system should enlist the help of a diabetologist and a podiatrist. In addition, the system should be capable of providing attentive management with diverse modalities for early foot ulcer healing. As with diabetes in general, a regular and repeated preventive treatment strategy is optimal for maintaining a healthy, intact diabetic foot.

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