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A CROSS-SECTIONAL STUDY TO ASSESS THE "QUALITY OF LIFE" AMONG DIABETIC FOOT PATIENTS IN A TERTIARY CARE HOSPITAL IN A METROPOLITAN CITY.

Community Medicine

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ABSTRACT

Background 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. Diabetes foot ulcers, is a leading cause of non traumatic lower extremity amputation, often followed by a non-healing ulcer, is increasing recognized as a severe, worldwide public health issue. The main aim of our study is to assess the heath related quality of life among diabetic foot patients in a tertiary health care setting. **Objectives** The objectives are to ascertain the socio – demographic profile of diabetic foot ulcer patients and 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. The mean ±SD of healed and non-healed ulcer of physical functioning domain is 40.90±9.14 and 43.88±7.76 and it is statistically significant. The mean±SD of family history of diabetes with general health domain is 39.53±6.28 and body pain domain is 40.06±12.24 and it is statistically significant. **Conclusion** The study found that individuals with diabetic foot ulcers have a lower HRQOL, and we feel this study adds to the growing body of data showing diabetic foot problems have the most detrimental impact on HRQOL.

KEYWORDS

Diabetic foot ulcer, HRQOL, SF-36 v2

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease which affects about 415 million adults worldwide as of 2015. By 2040, that number is expected to rise to 642 million. (1) Diabetes foot ulcers, which are a major factor in non-traumatic lower extremity amputations and are frequently followed by a persistent ulcer, are becoming more widely acknowledged as a serious global public health problem. Diabetes increases the likelihood of developing foot ulcers by 15% to 20% over the course of a person's lifetime, with more than 15% of foot ulcers leading to foot or limb amputation.(2)

OBJECTIVES

1. To ascertain the socio – demographic profile of diabetic foot ulcer patients.
2. To assess the impact of diabetic foot ulcer on health related quality of life among diabetic foot patients.

Methodology

The present study is a hospital 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 in English and interview was conducted in the language which they best understood.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 all records pertaining to the study would be confidential, and that numbers instead of names 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 and observations

Table.1:Distribution of study subjects according to SF-36 domains of diabetic foot ulcer(N=196)

Domains of SF-36	Mean scores
Physical Functioning	42.58±8.44
Physical health	55.00±19.70
Role limitation due to emotional problems	61.21±5.60
Emotional wellbeing(Mental Health)	40.26±11.79
Bodily pain	38.03±12.02
Vitality	48.41±10.04
General Health	41.10±6.88
Social functioning	58.14±12.54

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.

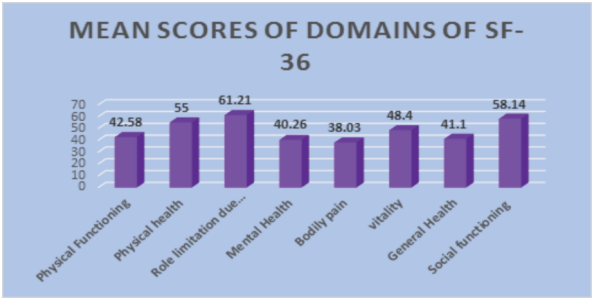

Figure 1: Graph showing mean scores of domains of SF-36

Table.2 :Distribution of SF-36 V2 domain scores by sex of study subjects(N=196)

Domains	Male (Mean±S.D)	Female (Mean ±S.D)	P-value	t value
Physical functioning	41.27±8.75	44.22±7.85	0.007*	2.46
Role physical health	54.95±20.53	55±18.81	0.480	.017
Body pain	38.11±12.56	37.88±11.44	0.342	1.30
General health	40.47±7.15	41.88±6.51	0.409	1.43
Vitality	47.73±9.1	49.44±11.25	0.176	1.17
Social functioning	59.08±12.14	57.36±13.36	0.364	0.94
Mental health(Emotional wellbeing)	39.88±11.22	40.66±12.5	0.249	0.434
Role limitation due to emotional problems	60.67±50	61.82±5.15	0.159	0.308
Values are presented as mean± standard deviation and analyzed using independent t test. (*) represents statistical significant difference.				

In Table no: 2 it was observed that there is statistical significance between gender of the participants with physical functioning domain of SF-36 (p=0.007).

Table.3:Distribution of SF-36 V2 domain scores by duration of diabetes of study subjects(N=196)

	Duration of diabetes (Mean ±S.D)	Significance test		
Domains	<10 years	>10 years	P –value	t value
Physical functioning	42.87±8.17	41.90±9.30	0.483	0.703
Role physical health	61.01±5.33	61.76±6.37	0.418	0.812
Body pain	37.39±11.71	39.80±12.85	0.224	1.220
General health	41.09±7.17	41.20±6.02	0.927	0.092
Vitality /Energy	48.83±10.01	47.60±10.60	0.459	0.741
Social functioning	57.36±12.51	61.00±13.03	0.081	1.755
Mental Health(Emotional wellbeing)	40.13±12.16	40.48±10.80	0.860	0.177
Role limitation due to emotional problems	90.86±18.57	82.66±23.50	0.013*	2.508
Values are presented as mean± standard deviation and analyzed using independent t test.				
(*) represents statistical significant difference.				

In Table no: 3 it was observed that there is significant difference between duration of diabetes with role limitation due to emotional problems domain of SF-36 (p=0.013).

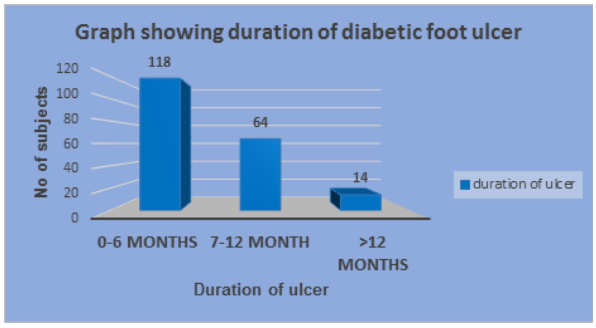

Figure 2: Graph showing duration of diabetic foot ulcer

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)	40.9112.34	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 no:5 Distribution of study subjects according to complications of diabetes(N=196)

Complications	Frequency (n)	Percentage (%)
Loss of sensation in the feet	78	39.79
Chest pain	20	10.20
Blurring of vision	20	10.20
Diabetic nephropathy	59	30.10
No complications	19	9.69
Total	196	100

The above table shows distribution of the participants according to complications of diabetes. Majority of study subjects (n=78) (39.79%) is having **neurological complications** followed by diabetic nephropathy (n=59) and followed by chest pain &blurring of vision (n=20, 10.20%).9.69% participants are without complications.

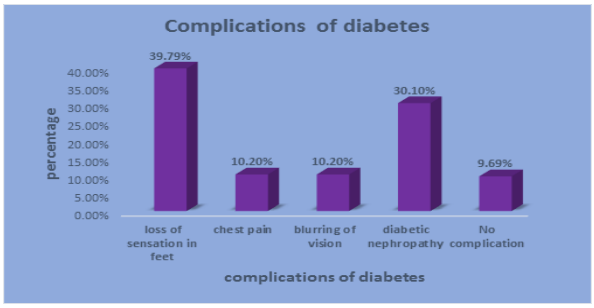

Figure 3: Graph showing complications of diabetes(N=196)

Table 6:Distribution of SF-36 V2 domain scores with grading of foot ulcer (N=196) by Kruskal wallis 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 Kruskal wallis test.								
(*) represents statistical significant difference.								

There is significant difference between grading of foot ulcer with physical functioning domain (p=0.000) and role physical health (p=0.034) domains of SF-36.

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 i.e, 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 i.e, 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 i.e, 138 (70.4%) and (29.59%) ie, 58 of them are not having any family history of diabetes. The majority of study subjects is having 0-6 months duration of foot ulcer i.e, 118 (60.20%) followed by 7-12 months, 64(32.65%) followed by duration >1 year.The majority of study subjects (n=78) (39.79%) were having neurological complications followed by diabetic nephropathy (n=59) and followed by chest pain & blurring of vision (n=20, 10.20%).9.69% of participants are without complications. Among 196 participants in the study, most of them are hypertensive (n=108, 55%) and the remaining are non-hypertensive (n=88, 45%).Most of the study subjects are having dyslipidemia (n=119, 60.71%) and the remaining are non-dyslipidemia (n=77, 39.28%).

DISCUSSION

The present study was a single centered, cross-sectional study conducted at the General Surgery OPD of a Tertiary care hospital in a Metropolitan city. A total of 196 study subjects were enrolled as per inclusion and exclusion criteria. The selection of study subjects was done as per steps mentioned in the methodology, in which all the diabetic foot ulcer patients attending the General Surgery OPD were enrolled in the study.

Previous studies on Diabetic foot ulcer and the heavy burden it poses on diabetic patients of India have shown that HRQOL is unfavorably affected by it. Unfortunately, there is a paucity of data on the detrimental effects of foot ulcers on the HRQOL of diabetes patients, which has inspired the current study. Our objective was to assess the sociodemographic profile, to assess the impact on patients employment status, and to evaluate the Health-related quality of life in patients with Diabetic foot ulcers. The results of the present study showed that the patients with Diabetic foot ulcers revealed lower HRQOL scores relating to all eight aspects of the SF-36 questionnaire.

Socio-demographic profile & clinical characteristics of study subjects

From table 2 it is observed that the majority of the participants ie, 153 (78.06%) belonged to 51-60 years of age followed by 26 (13.26%) 41-50 age group.

Al Ayed et al.2020 in their study observed that the majority of the participants belonged to 51-60 years of age. followed by 31-40 age group, the findings in the present study are different from those observed by our study and the difference can be attributed to the different socio-geographic distribution of the study population.[4] **Mazlina M et al in 2011**, found in their study that the majority of the participants 52(37%) belonged to 45-54 years age group followed by the 40(28.6%) 55-64 years age group, findings in this study are not similar to present study.[5] **Mousab Al Ayed et al in 2019**, found in their study that among 81 participants (72.8%) ie,67 are hypertensive and 27.2% are non-hypertensive. These results are similar to the present study. **Mojgan Sanjari et al in 2011**, found in their study that among 54 participants 42.5% were hypertensive and 57.5% are non-hypertensives.[6] These results are not similar to the present study.

Impact of Health-related quality of life among diabetic foot ulcer patients

In Table no: 22, it was observed that the most severely affected domain is body pain (38.03±12.02) and the least severely affected domain is role limitation due to emotional problems (61.21±5.60).**Pavla Kudlová1, Ilona Kočvarová in 2020** ,found in their study, more than half of the patients with DFU reported severe pain (62%), confirmed as having a significant impact on quality of life. [7]

In the study by **Nemcová et al. (2017),** 78% of the respondents reported pain, and the significant relationship between the experience of foot pain and QOL was confirmed. The same conclusion was reached in a study by **Vymětalová & Zeleníková (2016)** [8]**.** In the multi-centric study by Ribu et al. (2007), 75% of the respondents with DFU suffered from pain while walking or standing, and during the night.[9]

Mojgan Sanjari et al in 2011, found in their study that 30 participants (55.6%) had retinopathy,21(38.9%) had cardiac complications,23(42.5%) had hypertension,15 (27.8%)had nephropathy and 6(11%) had the previous history of stroke. These results are not similar to the present study.

It was observed in the current study that **males** with Diabetic foot ulcers tended to show poorer HRQOL compared to females, particularly in the subdomains of physical functioning, role limitation due to physical health & emotional health, General health, Energy, and Mental health.

CONCLUSION

Diabetic foot is one of the most serious complications of diabetes. It is a condition that requires the most attention by caregivers and the healthcare system. Foot ulcers can be avoided with early identification and appropriate glycemic management. 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 wellbeing), body pain, general health and vitality(energy).

Older age (more than 50 years), long duration of diabetes, peripheral neuropathy, diabetic retinopathy, nephropathy, foot deformities, past foot ulceration, and poor glycemic control were allfound to be significant risk factors for DFU in this study.

The study found that individuals with diabetic foot ulcers have a lower HRQOL, and we feel this study adds to the growing body of data showing diabetic foot problems have the most detrimental impact on HRQOL. According to the findings, wound status is a significant predictor of improved HRQOL in diabetic foot ulcer patients. To avoid a decline in quality of life, diabetic foot ulcers must be treated aggressively.

Recommendations

The health system must focus on ensuring the early healing of wound by proper patient education and treatment modalities.

To lessen the burden of diabetic complications, proper health education focused on good habits, nutrition control, physical exercise, and diabetic medication compliance is required. The patient's employment situation is negatively impacted by a diabetic foot ulcer.

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 healthy, intact diabetic foot.

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