ASSESSMENT OF THE QUALITY OF LIFE OF DIABETIC FOOT PATIENTS IN COMPARISON WITH NON DIABETIC FOOT PATIENTS AND ROLE OF CLINICAL PHARMACIST IN PATIENT COUNSELLING –A CROSS SECTIONAL STUDY

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ABSTRACT

In this study an endeavour is made to assess the quality of life of a diabetic foot patient in comparison with a non-diabetic patient and to improve their Quality of life (QOL) with the help of patient counselling by the involvement of clinical pharmacist. During the study diabetic and non-diabetic patients were enrolled after obtaining the consent from them. After collecting the required data from 160 patients A cross sectional observational study was done among the post operative ward of ESI Hospital Indiranagar, for 6 months period, QOL was analysed for their different criterias like economic and employment status, social habits, BMI, ulcer and amputation, complication of diabetes. It was found that the overall QOL of a diabetic patient foot is lower when compared with a non-diabetic foot patient in most of the criteria after assessment. Hence, patient counselling was done to all the diabetic foot patients involved in the study. This study has shown that the physical domain of QOL was significantly affected in diabetic persons. Out of 160 patients with Diabetic and Non Diabetic foot ulcers 128(80%)male and 32(20%)female. Statistical analysis showed that Overall perceptions about QOL and Health (P= **0.007)** had a statistically significant relationship with QOL and its dimensions.So, apart

from taking regular medications and health checkup, there is a requirement to tackle other components of physical domain so that their QOL will improve. While it might not be easy to change clinical outcomes with good services and support, it might be much more effective in bringing a change in QOL.

KEYWORDS: Quality of life(QOL), A Cross sectional study, BMI.

1. INTRODUCTION

Chronic diseases like Diabetes is more prevalent and serious complication, now- a days we see more globalization and industrialization, worldwide life span is declining day by day because of changes in their lifestyles. A consequence of these modifications will be shifts in the patterns of diseases especially diabetes.[1]

Main public health problem is diabetic foot and is a severe that threatens the QOL. Hyperglycemia revealed a pathogenic role in microvascular diseases **(nephropathy, retinopathy, and neuropathy)** and accelerates macrovascular complications **[cardiovascular disease (CVD) such as stroke and coronary heart disease]** associated with diabetes foot. In fact, individuals with diabetes particularly complication of CVD is the foremost reason of premature death.[2]

Health-related quality of life (HRQOL) was affected in People with chronic disease, have to face many problems particularly type 2 diabetes,. Many studies which are recent have indicate abundant risk factors associated with diabetic foot ulcers, such as walking bare footed, male gender, diabetic for more than 10 years, gediatric patient, high BMI, and other comorbid conditions such as persistant impaired blood glucose level, foot deformity, high planter pressure, infection, inappropriate foot self-care habit.[3]

It is estimated that about 5% of all diabetic patient present with a history of foot ulceration. About 60 – 80% of foot ulcers will heal, while 10 – 15% of them will remain active, and only 5 – 24% of them will lead to amputation within a period of 6 – 18 months after the first evaluation.[4]

The diabetic foot ulcers can be classified by two classification system, they are:
- **The Wagner Ulcer Classification System[5]**
- Grade 1:Superficial diabetic ulcer

- Grade 2: Ulcer extension involving ligament, tendon, joint capsule, or fascia with no abscess or osteomyelitis
- Grade 3: Deep ulcer with abscess or osteomyelitis
- Grade 4 : Gangrene to portion of forefoot
- Grade 5: Extensive gangrene of foot
- **University of Texas Wound Classification System[5]**

Stages	Description
Stage A	No infection or Ischemia
Stage B	Infection present
Stage C	Ischemia present
Stage D	Infection and Ischemia present

2. AIM AND OBJECTIVES

The main purpose of this study was to assess the quality of life(QOL) of patients with diabetic foot Vs non diabetic foot, to determine the clinical and sociodemographic factors that affect the quality of life of these patients, investigate the factors and improve QOL by involvement of clinical pharmacist to create awareness about DFU to the patients.

3. METHODOLOGY

This is **A cross-sectional study** was performed on 160 patients (128 males and 32females) hospitalized for DFU, performed through convenience sampling. Data related factors and the QOL questionnaire for patients with DFU were reduced. This questionnaire hasquestions in different dimensions of **Physical, Psychological, Social, Environmental** which evaluate the QOL in patients with DFU. The scoring method for this tool is Descriptive and analytic statistical methods were used to analyse the data.

Study Sample: A total of **(N= 160)** patients both men and women of diabetic foot and non diabetic foot cases were taken from post operative ward, who satisfied the study criteria and consented to participate in this study were included for the study.

Study Site: The study was conducted in the men and women n post-operative ward of **ESI Hospital, Indiranagar, Bangalore.**

Study Design: This was A Prospective, Cross-sectional and Observational study and was performed on these patients to assess their knowledge about their present condition and well–being, to understand their state and then to educate them to improve their quality of life.

Study Period: The study was conducted over a period of **six months** from September 2018 to February 2019.

Ethical Approval: Ethical committee clearance was obtained by the Institutional Ethical Committee of ESI Hospital.

STUDY CRITERIA

Inclusion Criteria

- Patients who are diabetic and non-diabetic.

- Patients from either sex and above 20 years of age.

- Patients who are willing to participate in the study.

Exclusion Criteria

- Patients who are not willing to participate in the study.

- Patients who are below the age of 20years.

- Unconscious and comatose patients, and other co-morbid conditions were excluded.

Source of Data: Patient's demographics, clinical findings, laboratory and therapeutic data was collected from inpatients and the main sources of data was:

- Patient's case sheet

- Treatment Chart

- Lab Data

- Patients Discharge sheets

- Data collection form

STUDY PROCEDURE

Methods of Data Collection

All patients admitted to the post-operative ward of ESI Hospital, Bangalore, during the study period were educated on improving their QOL. Those who met the inclusion criteria were enrolled for the study. After the diagnosis was confirmed by the physician, the relevant & necessary baseline information such as socio-demographic details of the patient were obtained from patient's case notes. Like patient age, educational background, date of admission, date of discharge, the occupation was collected. Therapeutic data such as name of drugs, doses, and route of administration, Ulcer status, duration of disease, surgery(Amputation) & other laboratory data were undertaken and comparision was done

between diabetic foot and non-diabetic foot patients in a suitably designed data collection form.

4. RESULTS

A total of 160 patients with Diabetic and Non Diabetic foot ulcers were considered into present study. Out of them 128(80%) were male and 32(20%) female. Statistical analysis showed that Overall perceptions about QOL and Health (P= **0.007**) had a statistically significant relationship with QOL and its dimensions. Other variables are like Scoring pattern of QOL of Diabetic Cases and Non-diabetics Control Subjects P value is varying accordingly the criteria like Physical, Psychological, Social, Environmental.

Table 1: General Characteristics of study Subjects.

Variables	Diabetic Subjects	Nondiabetic Subjects	Total (N = 160)
Age (years)	**N=76**	**N=84**	
20 - 35	12(15.7%)	9(10.7%)	21(13.1%)
35 - 50	25(32.8%)	26(30.9%)	51(31.8%)
50 - 65	30(39.4%)	32(38%)	62(38.7%)
65 - 80	9(11.8%)	17(20.2%)	26(16.25%)
Gender			
Male	61(80.2%)	67(79.7%)	128(80%)
Female	15(19.7%)	17(20.2%)	32(20%)

Table 2: Data of Economic and employment Status.

Employment Status	Diabetic Subjects N=76	Nondiabetic Subjects N=84	Total (N = 160)
Employed	21(27.6%)	29(34.5%)	50(31.2%)
Unemployed	55(72.3%)	55(65.4%)	110(68.7%)
Income Status	**Diabetic Subjects N=76**	**Nondiabetic Subjects N=84**	**Total (N = 160)**
High	12(15.7%)	14(16.6%)	26(16.2%)
Moderate	29(38.1%)	28(33.3%)	57(35.6%)
Low	35(46%)	42(50%)	77(48.1%)

Table 3: History of Social Habits.

History Of Smoking	Diabetic Subjects N=76	Nondiabetic Subjects N=84	Total (N = 160)
Present	46(60.5%)	33(39.2%)	97(60.6%)
Absent	30(39.4%)	51(60.7%)	63(39.3%)
Consumption of Alcohol			
Present	27(35.5%)	19(22.6%)	46(28.75%)
Absent	49(64.4%)	65(77.3%)	114(71.25%)

Table 4: History of BMI and Healthy Habits.

BMI	Diabetic Subjects N=76	Nondiabetic Subjects N=84	Total (N = 160)
Less than 18.5	9(11.8%)	12(14.2%)	20(12.5%)
18.5 to 24.9	15(19.7%)	19(22.6%)	34(21.2%)
25 to 29.9	29(38.1%)	22(26.1%)	51(31.8%)
More than 30	23(30.2%)	31(36.9%)	54(33.7%)
Regular exercise			
Yes	24(31.5%)	38(45.2%)	62(38.7%)
No	52(68.4%)	44(52.3%)	96(60%)

Table 5: History of Diabetics.

Family History of diabetics	Diabetic Subjects N=76	Nondiabetic Subjects N=84	Total (N = 160)
Present	31(42.4%)	35(41.6%)	66(41.2%)
Absent	45(59.2%)	49(58.3%)	94(58.7%)
Duration of diabetics			
More than 3 yrs.	13(17.8%)	12(14.2%)	25(15.6%)
3 to 5yrs	29(38.1%)	32(38%)	61(38.1%)
More Than 5yrs	34(44.7%)	40(47.6%)	74(46.2%)

Table 6: History of ulcer and Amputation.

History of ulcer	Diabetic Subjects N=76	Nondiabetic Subjects N=84	Total (N = 160)
Present	49(64.4%)	31(36.9%)	80(50%)
Absent	27(35.5%)	53(63.0%)	80(50%)
Amputation			
Done	31(40.7%)	23(27.3%)	54(33.7%)
Not Done	45(59.2%)	61(72.6%)	106(66.2%)

Table 6: Complications of Diabetics.

Complications of Diabetics	Diabetic Subjects N=76	Non-diabetic Subjects N=84	Total (N = 160)
Present	47(61.8%)	32(38%)	79(49.3%)
Absent	29(38.1%)	52(61.9%)	81(50.6%)
Gangrene			
Present	30(39.4%)	33(39.2%)	63(39.3%)
Absent	46(62.1%)	51(60.7%)	97(60.6%)

Table 7: Overall perceptions about QOL and Health.

Criteria	Diabetic subjects	Nondiabetic Subjects n(%)	Total, N(%)	P
Overall QOL				
Good	28(36.8%)	44(52.3%)	72(45%)	
Bad	11(14.4%)	13(15.4%)	24(15%)	
Average	36(47.3%)	27(32.1%)	63(39.3%)	**0.007**
Overall general health				

Satisfied	27(35.5%)	38(45.2%)	65(406%)
Unsatisfied	18(24.6%)	17(20.2%)	35(21.8%)
Neutral	31(40.7%)	29(34.5%)	60(37.5%)

Table 7: Scoring pattern of QOL of Diabetic Cases and Non-diabetics Control Subjects.

Domain	Diabetic Subject Mean (SD)	Non-Diabetic subjects Mean (SD)	P
Physical	56.62(17.23)	64.34(14.21)	0.004
Psychological	57.18(18.10)	65.26(15.32)	0.097
Social	64.32(20.26)	51.42(11.29)	0.072
Environmental	51.29(14.17)	60.23(11.34)	0.612
Total	56.89(15.34)	61.23(11.12)	0.634

Table 8: Categories Based on QOL Scores.

Domain	Diabetic Subject		Non-Diabetic subjects		P
	Poor	**Good**	**Poor**	**Good**	
Physical	45(59.2%)	40(52.6%)	27(32.1%)	53(63%)	0.005
Psychological	38(50%)	32(42.1%)	39(46.4%)	46(54.7%)	0.359
Social	36(47.3%)	40(52.6%)	50(59.5%)	48(57.14%)	1.00
Environmental	45(59.2%)	42(55.2%)	34(40.1%)	38(45.2%)	0.005
Total	47(61.8%)	47(61.8%)	58(69%)	51(60.7%)	0.612

5. DISCUSSION

In our study, 97(60.6%) of patients were smokers. A similar high prevalence of smoking (41.6%) was reported by Aghamollaeiet al.[6]

A regular program of physical activity helps reduce body weight and decline glucose intolerance and visibility in the episodes of complications.[7] In spite of the significance of exercise, only 62(38.7%) of our both diabetic and non diabetic foot patients exercised regularly with out skipping.

Gurkovaa et al studied 104 known cases of diabetes and found that about 68% of the study subjects had complications of diabetes, while in our study about 49.3% of the subjects had complication of diabetes.[8]

Yekta et al, concludes that patients with diabetic foot ulcers have a poorer QOL that patients without any chronic disease. Comparable results have been observed in our study too.[9]

Most participants in our sample were men (80%), similar sex distribution was found in the samples of studies on QOL of patients with diabetic footcarried out by Renata et al.[10]

In this study, out of 160 about 50% patients were having foot ulcers. As per a study done by Kahsu et.al[11] 12% were having foot ulcer. Another study done by found that 27.40% out of 146 were having foot ulcers.[12]

6. CONCLUSION

Altered aspects of life with diabetic foot ulcer can reduce patient's QOL. To improve the care, have better control of foot ulcers and improve the QOL for these patients, Different criteria were considered which is essential to plan for care and health needs in these patients. Good treatment compliance leads to good glycemic control and results in good quality of life. The major origin for the occurrence of the complication like diabetes foot ulcer in diabetic patients is non-compliance. This study has shown that the physical domain of QOL was significantly affected in diabetic foot persons. So, apart from taking regular medications and health checkup, there is a need to address other components of physical domain so that their QOL will improve. Thus, QOL measurements should become a habitual part of clinical management of diabetic patients. Clinical pharmacist has taken core responsibility in patient education regarding his disease and importance of adherence to treatment, timely monitoring of blood glucose, proper foot care will improve to reduce progression of disease. Proper Counseling can improve patient's knowledge about disease, treatment and self care improving in adherence aspect.

7. PATIENT COUNSELLING BY CLINICAL PHARMACIST

The patients are advised to maintain a good and clean environment to promote the healing process.

1. Carefully examine,wash your feet daily with warm or hot water, including the tops, sides, heels, and between the toes to prevent infections, Feet should be totally dried, mainly in between the toes.

2. Quit smoking, because it accelerates damage to blood vessels, especially the small blood vessels. This can lead to blood flow decline, which is a major risk factor for foot infections which may ultimately lead to amputations.

3. Adhere to your medication schedule and monitor blood glucose routinely to make sure the blood glucose level is under control.

4. Never take out corns without seeking the advice of your physician.

5. To prevent foot injuries, do not walk barefoot, especially outdoors.

6. Wear cotton,supportive, enclosed shoes or wool socks that are spongy and dry to absorb moisture which fits well and protect your feet.

8. PREVENTION

Early detection of potential risk factors for ulceration can decrease the frequency of wound development. It is recommended that all patients with diabetes undergo a foot examination at least annually, to determine the predisposing conditions to ulceration.[11]

Patients should be educated regarding the importance of maintaining a good glycemic control, wearing proper footwear, avoiding all trauma, and by performing frequent self-examinations.

1. Primary prevention: Screening of high-risk feet and proper advice on preventive footwear
2. Secondary prevention: Management of foot lesions such as callus removal, treatment of nail pathologies, deroofing blisters, and so on.
3. Tertiary prevention: Refer a specialist for advanced foot lesions.[9,11]

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