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Impact of Patient Counseling on Health-Related Quality of Life in Diabetic Foot Ulcer Patients



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Subodh S Satheesh^{a,*}, Rakesh K R Jat^a, Subash Philip^b

^aResearch Scholar, Shri Jagdishprasad Jhabarmal Tibrewala University Chudela, Jhunjhunu, India.

^aDirector and coordinator of PhD (Pharmacy), Shri Jagdishprasad Jhabarmal Tibrewala University Chudela, Jhunjhunu, India. ^bVice principal, Joseph marthoma institute of pharmaceutical sciences and research, Kayamkulam, India

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ABSTRACT

Diabetes mellitus imparts a deteriorated health related quality of life (HRQoL) among its patients. The chronic complications of diabetes like Diabetic foot syndrome adversely affect the HRQoL in diabetes mellitus patients. A patient centered program can be pivotal in developing counseling adherence and elevating foot care practices. Patient education interventions can be incorporated into the poor HRQoL in patients and develop a self care practice among them to deal with the disorder and its complications. The study employed was a hospital based cross sectional, prospective and observational study carried out among type 2 diabetes patients (N=252). The study was conducted in the community and primary health centers of Kollam district of Kerala. EQ5D5L questionnaire and EQ-VAS scales were used to evaluate HRQoL in patients. The EQ5D5L results had shown high scores in selfcare, usual activities, anxiety pain and mobility. Wilcoxon rank test analyzed the effect of interventions on HRQoL using mean. High scores of EQ5D5L gives the evidence of problems faced by the DFU patients and their depleted quality of life (Mean score <50). The non healing DFU had compromised the domains like mobility and self care. All the 5 subscales of HRQoL had shown statistical differences after counseling. The mean percentage of health status among patients was about 68% before interventions and the interventions have improved it to 72%. The P value score of (<0.245) indicated that the evaluation is clinically significant. The study paves the way for a multidisciplinary approach in health care services in prevention and management of diabetic foot infections. Besides being affordable and least resource purposive, the study opens up relief in social, financial and emotional deprivations due to diabetic foot syndrome.

INTRODUCTION

Patient counseling is a key component in achieving pharmaceutical care. The patient counseling process plays an important role in rectifying patients concerns and enquiries regarding treatments and medications. In diabetic ulcer patients, the basic knowledge about the disease and the need for lifestyle modification is vital in successful combating of the disease. India has an estimated diabetic population of 41M that encompasses 15% of total diabetic population in the world. Diabetic foot ulcerations are the most devastating complication of diabetes mellitus and is a common scenario in Indian population. Every year 45000 legs are amputated in India and 75% of them are due to neuropathic foot and they are curable [1,2]. Lack of awareness and proper care are underlying reasons behind the everrising number of amputations.

Diabetes mellitus imparts a deteriorated health related quality of life (HRQoL) among its patients. The chronic complications of diabetes like Diabetic foot syndrome aggravate the HRQoL in diabetes mellitus patients. DFU anguishes the patients with burdens on social, economic, psychological and physical well being. DFU leads to long stretches of hospital stay and financial impairments. The recurrence of ulcers, limited mobility and fear of lower extremity amputations leaves the patients with devastating emotional and physical burdens [3,4]. Recent studies suggests that the treatment modalities involved in diabetic foot ulcers require more financial back up than other diseases like CCF, renal diseases and even some forms of cancer. To counter the DFU, patients must be mentally resilient and they must be motivated to overcome its hazardous effects [5]. Patients with DFU have a death threat of 2.5 times than that of diabetic patients without complications.

HRQoL and its related functional concepts were evaluated by using different tools of generic and disease specific properties. Generic measurements were carried out using EQ5D5L tool developed by Euro Quality of Life which is an internationally accepted and reliable tool in measurement of HRQoL. Visual Analog scale was the disease specific tool used for assessment of quality of life. VAS scale analyzed the overall social and emotional well being in chronic foot infections due to diabetes. The assessment of quality of life at different grades of ulcers can be evaluated. VAS scale can differentiate the health status of patients at different grade of ulcers. The changes in status of wounds at different degree of ulcers and the response of the patients between worst possible health and best possible health were evaluated[6,7].

To assess the HRQoL there is a need for holistic approach by the aid of a multidisciplinary team. Many studies had highlighted the need of health care professionals in understanding the barriers that a DFS patient goes through. The absence of podiatrists and other diabetic specialists are evident in the rising number of lower extremity amputations in rural areas. Lower socioeconomic status, late presentations and lack of awareness worsens the foot ulcers in rural areas[8]. The education regarding HRQoL can be instrumental in developing a treatment plan that considers patients perceptions as well as clinical parameters. Health care professionals can be elemental in educating patients about selection of footwear, controlling hyperglycemia, nail care, regular foot screening practices and maintaining foot hygiene. Reports and studies from all over the world had exhibited the anguishes and incompetence that the foot ulcer patients experienced [9,10]]. The basic ideas and data about diabetic foot ulcers will make the community pharmacists capable of identifying a diabetic foot. They can perform physical examination of the patients and identify the neuropathic and ischemic symptoms. They can understand the severity of the complications and refer them if needed[11].

A patient centered program can be pivotal in developing counseling adherence and elevating foot care practices [12,13]. Patient education interventions can be incorporated into the poor HRQoL in patients and develop a self care practice among them to deal with the disorder and its complications. The phantom limb comes as a nightmare for the DFS patients and deteriorates them with ever dangling experience of grievances [14]. The treatment modalities employed in diabetic foot ulcers should be pain relieving as well as efficient enough to cope up with the emotional distress caused by the DFU. The knowledge gained from researches around the world suggests that a holistic approach is vital in countering DFS. Thereby by the aid of delivering a multidisciplinary approach effective HRQoL can be administered. Indian health care system had been always a physician centered one[15,16]. Therefore we decided to conduct a community pharmacist oriented patient education program in the health centers of South India.

METHODOLOGY

The study employed was a hospital based cross sectional, prospective and observational study carried out among type 2 diabetes patients (N=252). The study was conducted in the community and primary health centers of Kollam district of Kerala after obtaining ethical clearance. (SI.No 6/2014/2/19-GHEC).

Study subjects

Among the diabetic foot ulcer patients that visited the hospitals, 252 patients were recruited for the study. The patients selected were mainly from lower and middle socioeconomic backgrounds. The period of study was for 2 years (2018-2019). Patients above 18 years of age were considered for the study. Pregnant women and patient with impaired cognition were excluded from the study. All the patients were informed about the objectives and the nature of the study and consent was taken. A data collection form was used to obtain the details on socio-demographic data, behavioral data and clinical parameters. The degree of ulcers was classified on the basis of University of Texas wound classification system[17]. Additional information's were collected using response on EQ5D5L Questionnaire.

Patient education

A direct interview was set up for data collection from patients. The trained Pharmacists had interviewed the patients and each interview had duration of 35 minutes. Patients were provided with English and Malayalam versions of EQ5D5L and EQ-VAS. The patient's response were noted down and evaluated. VAS scale measured the health status that the patients experienced. 100% response rate was obtained from the patients.

Measurement of HRQoL

EQ5D5L Scale was used for measuring health related quality of life. The questionnaires used measures 5 domains of health, namely self care, mobility, anxiety/depression, pain and usual activities[18]. The scale measures 5 levels of health status, where level 1 represents "no problems" and level 5 represent severe problems. The scores of each domain are converted to measurements and high scores represent poor health status and low scores indicate good health. The EQVAS scale measures the worst and best possible health status. The scores of "0" is the worst possible health and "100" the best possible one.

Statistical methods

The demographic and clinical parameters were analyzed by descriptive statistics and health related quality of life by using Mean. Willcoxon signed rank test was used for analysis of the domains. P value <0.01 was considered as significant. The results were assessed in SPSS software.

RESULTS

The basic demographic details of the patients for instance, gender, lifestyle variables, characteristics of diabetes etc are presented in table 4.1. Among the 252 patients recruited for the study 184 (73%) were men and 68 (27%) were women. The result indicated that men were more vulnerable to foot ulcer than women. The age group of the patients was assessed and (5.6%) belonged to an age group of (31-45), (39.7%) in age group (46-60), the age group of (61-75) were the predominant ones in diabetic foot ulcer with nearly half (46.8%) of the recruited population and (7.9) patients were there in the age group of (76 and above). The educational profile of the recruited was assessed and the results suggested that secondary education (47.2%) was predominant among the study population. 46 patients (18.3%) were educated up to primary.

Table 1: Grade of foot ulcers

Variables	Frequency	Percentage (%)
Age n (%)		
31-45	14	(5.6)%
46-60	100	(39.7)%
61-75	118	(46.8)%
76 and above	20	(7.9)%
Sex n(%)		
Male	68	(27.0)%
Female	184	(73.0)%
Education Levels (%)		
No formal	3	(1.2)%
Up to primary	46	(18.3)%
Up to secondary	119	(47.2)%
Up to higher education	63	(25.0)%
Degree and above	21	(8.3)%
Employment n(%)		

Unemployed	77	(30.6)%
Govt/private/Retire	54	(21.4)%
Farmer	29	(11.5)%
Daily wage labour	42	(16.7)%
No history of diabetes	12	(4.8)%
History of diabetes	240	(93)%
Clinical Parameters (Mean)		
FBS	232.16	
PPBS	290.45	
HbA1c	7.72	

Table 2: Prevalence of foot ulcers

Grade 0	129	(51.2)%
Grade I	86	(34.1)%
Grade II	30	(11.9)%
Grade III	7	(2.8)%
Ulcer size cm² n%		
≤1	48	(53.8)%
≤3	28	(31.4)%
>3cm	13	(14.6)%

The assessment of clinical variables like FBS, PPBS and HbA1c were carried out. The mean Fasting Blood Sugar level of the participants was found as 172 and the Post Prandial Blood Sugar levels provided a mean of 244. The HbA1c levels were analyzed and a mean of 7.72 was obtained. The wounds were classified using UT DFS wound classification system and results indicated that among the participants (51%) had grade 0 foot ulcers. Grade 1 foot

ulcers were present in 86(34.3%) patients and grade 2 in 12% of patients. 2.8% of patients had shown Grade 3 foot ulcers. The pretest study results suggested that 48 patients (Mean 5.7) had ulcer size of ≤ 1 cm, 24 patients had ulcer size ≤ 3 cm and 11 patients were in ulcer size of > 3 cm.

Among the recruited patients 23.9% had difficulties in physical functioning. They were in need of a caretaker for performing usual activities. About 25% of patients were unable to perform self care and 74% went through with their usual activities without any hindrance. Nearly 70% of the recruited patients had mild pain and 27.8% had severe pain in their feet. Anxiety or depression was observed in 24.7% of patients who had foot ulcers. The baseline data indicated that patients with chronic foot ulcers exhibited poor health outcomes. Wilcoxon rank test analyzed the effect of interventions on HRQoL using mean. The mean value of mobility was 1.29 in the baseline data and after intervention, the mean value was reduced 1.00.

It suggested that the walking ability of the patients have improved after intervention. The significance of the study was supported by the p value < 0.001 . The intervention was found as clinically significant in improving mobility in foot disorder patients. The pretest value of selfcare was 0.98 before intervention and post test results indicated improvement in selfcare (0.87). The intervention was found as clinically significant with p value < 0.025 . The mean value obtained from pretest was 0.95 for usual activities and the post test scores suggested that the mean value had decreased to 0.82. P value obtained ($P < 0.003$) suggested that the intervention have elicited a significant response on usual activities. The pre-test scores of pain (Mean 1.35) had decreased (1.02) after interventions and education. The significance of the study was confirmed by the P value < 0.029 .

The mean percentage of health status among patients was about 68% before interventions and the interventions have improved it to 72%. Grade 0 and grade 1 foot ulcer patients had a health status of 75% before intervention and have risen to 82.2% after intervention. Grade 2 and grade 3 foot ulcer patients indicated poor health outcomes and with a VAS percentage of 52% and patient education have promoted it to 56%. The P value score of (< 0.245) indicated that the evaluation is clinically significant.

DISCUSSION

Diabetic foot ulcer and its devastating nature make it the most dreadful complication of diabetes mellitus. It leads to deteriorated productivity, prolonged hospital stay and diminished socio-economic well being. DFU and its complications deplete the HRQoL in patients. The demographic details observed from the study shows that predominant number of males was present in the recruited patients. 71% of the patients involved were males and 29% were females. Kalaivani et al, 2014 [19] had reported that prevalence of foot infections increases with age and are predominant in men. The daily wage laborers and farmers contributed to about 35% of employed population. Peoples involved in professions like farming, construction works, outdoor works, rubber tapping, mason works etc require to undergo high degree of plantar pressure. The people involved in outdoor works are always vulnerable to injuries due to equipments and tools used in their labor. Patients had reported with macerations due to pickaxe, knives, tapping tools and bites from insects. . Majority of the patients involved in the study were type2DM patients with elevated levels of hyperglycemia. Poor glycemic control was evident in the HbA1c (Mean value-8.12) and FBS/PPBS levels. Deep ulcers were the hallmark of patients in rural areas with late diagnosis and presentation being the major reason. Ulcers were of sizes greater than 1cm² in majority of them. The study from Sonal Sekhar et al 2015 [20] also suggests that deep ulcers are a common scenario in rural population.

Health related quality of life in patients with DFU was analyzed by using EQ5D5L, where different responses are marked on the basis of 0-4. In this scale, 0 represents absence of health issues and 4 represents poor health status. The increase in score represents diminished quality of life. Visual audio scale analysis of EQ5D5L evaluated the statuses of different domains in 100. A mean score below 60 indicated characteristics of low quality in life. HRQoL was considered good and satisfactory in scores ranging from 60-100. The baseline data of foot ulcer patients exhibited poor quality of life in higher degree of ulcers and those with ulcers of diameter greater than 1cm. Poor health related quality of life was evident in patients with chronic diabetic foot ulcers according to Hadadi et al, 2014.

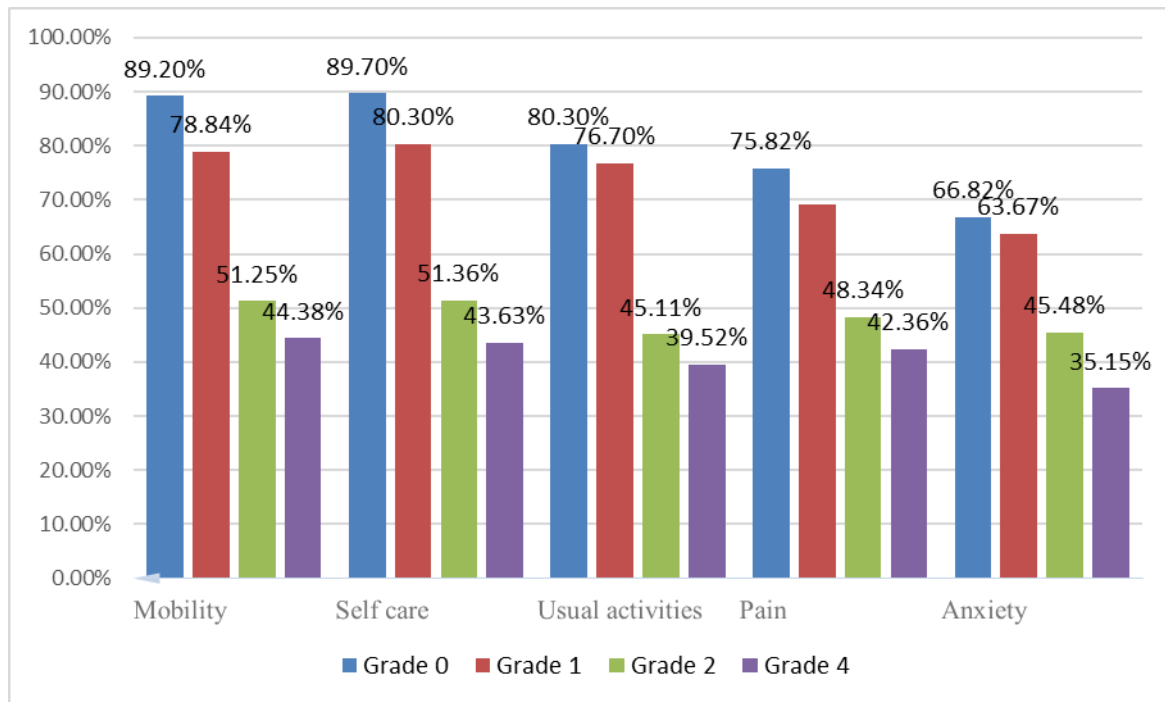


Figure No. 1: HRQoL domains in diabetic foot ulcer patients at different grade of ulcers - baseline

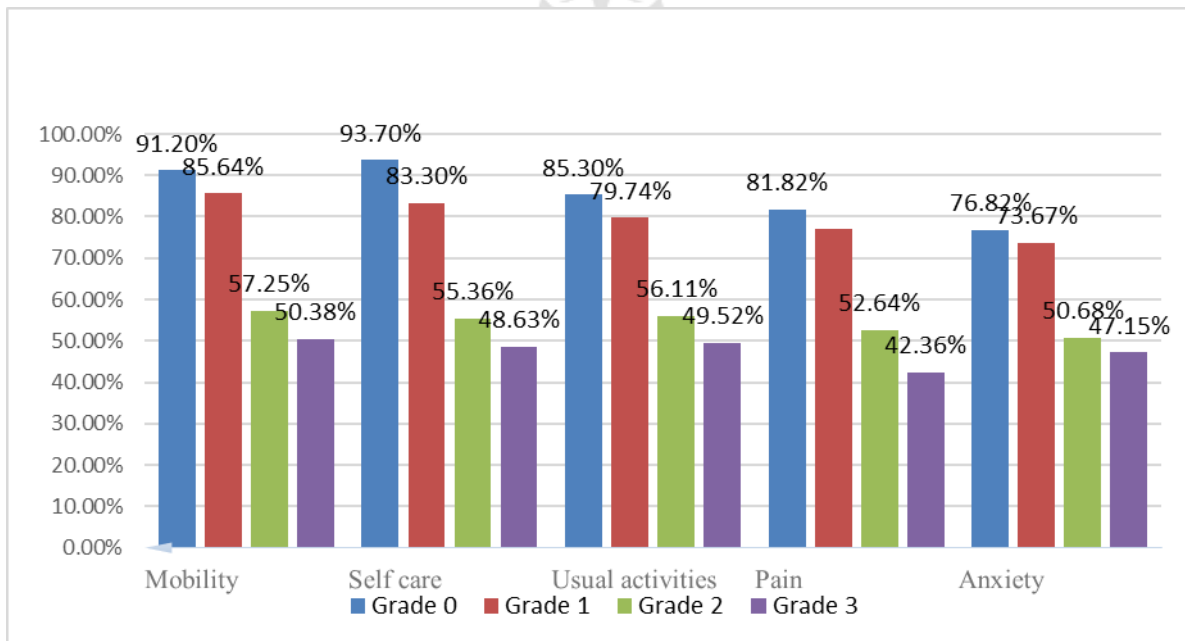


Figure No. 2: HRQoL domains in diabetic foot ulcer patients at different grade of ulcers – After intervention

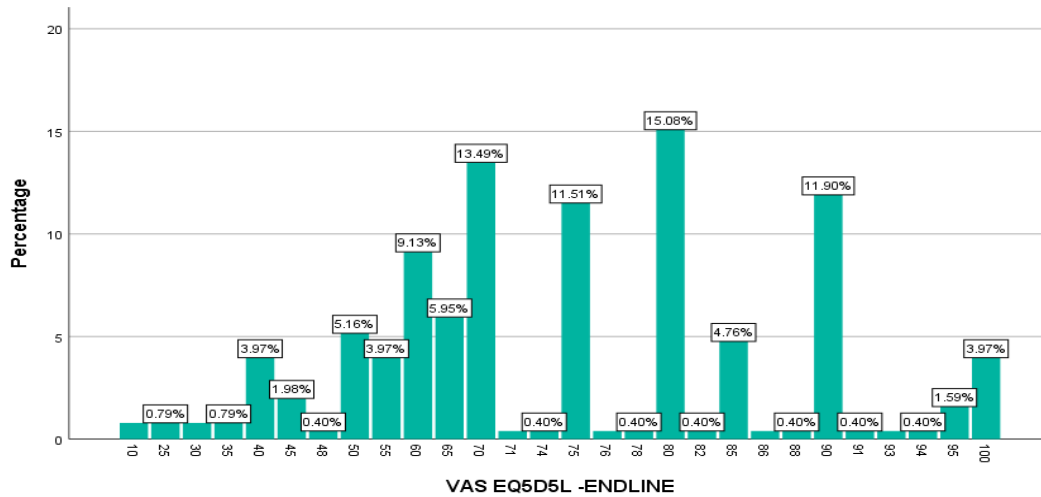


Figure No. 3: VAS results after intervention.

EQ5D5L variables scores of QOL is a denotation of ability of a patient to involve in self care and management of hyperglycemia. The EQ5D5L results had shown high scores in selfcare, usual activities, anxiety pain and mobility. High scores gives evidence of problems faced by the DFU patients nad their depleted quality of life. The non healing DFU had compromised the domains like mobility and self care. The VAS results had found that DFS patients had reported poor health status. Sonal Sekhar et al 2015[20] had reported a similar finding. The compromises that the patients experienced due to DFU had severe impacts on their physical and social well being. Decreased mobility, inability to carry out usual activities and self care had severely deteriorated their physical and mental health. The burdens on caregivers and family members had also pulled the patient into frequent breakdowns’. Patients with recurrent ulcers were anxious about lower extremity amputations and it had severely affected their mental health[21]. Patient education projects can revitalize them and motivate them to perform self care and follow lifestyle plans. Studies related with DFU and HRQoL had concentrated on improving patient education, selection of footwear, self care and regular foot screening practices. Our study aimed at improving self management, diet plans, ulcer healing and reducing glycemc levels and thereby allround refinement in Quality of life.

CONCLUSION

Diabetic foot ulcers and its complications unveil a devastating effect in the quality of life of patients. The results from EQ5D5L analysis had revealed depleted quality of life in DFU patients. The DFS patients showed reduced mobility, difficulty in self care and usual activities and were anxious about future complications and lower extremity amputations. The

findings using VAS scale gives evidence towards poor health status reported by DFS patients. We have noted a significant improvement in patient's domains like selfcare, activities and pain after interventions. The physical and mental status of health had improved after education. Most of the patients recruited were from rural areas, so educational interventions had been vital in upgrading their awareness in self care and management of foot ulcers and its complications [22]. Health care in India is predominantly under the guidance of physicians with a trivial role for other health care professionals. The study paves the way for a multidisciplinary approach in health care services in prevention and management of diabetic foot infections. Besides being affordable and least resource purposive, the study opens up a relief in social, financial and emotional deprivations due to diabetic foot syndrome.

Implications

The study helps in identifying the DFS patients with limited HRQoL and can be provided with care and support. A multidisciplinary health care team can be selected and empowered to conduct foot screening practices and promoting self care. The study enabled the patients with early diagnosis and thereby salvaging their feet. The research has empowered community pharmacists to impart their knowledge in foot care and explore earlier denied access to health care. Foot care specialized clinics should be opened with the assistance of a podiatrist to elevate foot screening practices and percolate knowledge among the patients.




Competing interest

The author declares that there are no financial or personal competing interests.

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	<p>Subodh S Satheesh*</p> <p>Research Scholar*, Shri Jagdishprasad Jhabarmal Tibrewala University Chudela, Jhunjhunu</p>
	<p>Dr Rakesh K R Jat</p> <p>Director and coordinator of PhD (Pharmacy) , Shri Jagdishprasad Jhabarmal Tibrewala University Chudela, Jhunjhunu</p>
	<p>Dr Subash Philip</p> <p>Vice principal, Joseph marthoma institute of pharmaceutical sciences and research, Kayamkulam</p> 