

COMPARATIVE STUDY OF QOL IN TYPE 2 DIABETES MELLITUS PATIENTS WITH AND WITHOUT FOOT ULCERS ATTENDING NAVODAYA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE

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Received Date: 09/10/2023 Acceptance Date: 11/11/2023 Publication Date: 08/12/2023

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Abstract

Background: Diabetic foot syndrome is not only an important factor of mortality among patients with diabetes but also decreased the quality of life. Present study was aimed to compare QOL (Quality of Life) in type 2 diabetes mellitus patients with and without foot ulcers attending Navodaya medical college hospital and research centre. **Material and Methods:** Present study was hospital-based case control study, conducted in patients with type 2 diabetes mellitus, with diabetic foot ulcer (cases) & without diabetic foot ulcer (controls) 30 participants in each group. **Results:** Mean duration of disease in cases and controls was 4.7yrs and 6yrs respectively. 22% and 70% of the participants in cases and controls were having RBS within normal limits. 10% and 16% of the cases and controls do physical exercise respectively and shows statistically significant association. 73.3% and 66.6% of the cases and controls occasionally maintain diet. 80% and 90% of the cases and controls do regular blood checkup respectively. 6% of the participants delayed treatment due to unavailability of services, thought of self-healing and lack of support. Foot care is poor in both cases and controls but better in controls than when compared to cases. Quality of life is better in Controls than in Cases. All the domains are affected by ulcer. Quality of life is better in controls than in cases. Quality of life is better in females than in males. Gender has significantly associated with Ulcer. Physical activity is less in cases than in controls and it significantly associated with quality of life. Waist circumference shows significant negative correlation in controls. **Conclusion:** QoL is better in controls than in cases, factors which affect the quality of life were: habit of tobacco chewing, less physical activity (sedentary life style), uncontrolled sugar levels, increased BMI, increased waist circumference. **Keywords:** Diabetic foot ulcer, type 2 diabetes mellitus, Quality of life, morbidity

Introduction

Health is a multidimensional construct that compresses physical, mental and social domains. Diabetes Mellitus is a major public health problem with rising prevalence worldwide, 6th leading cause of the death, attributing to 5 million deaths globally in 2015.^{1,2} Recording to recent estimates 69.2 million people are affected with diabetes in India.³ Diabetic foot Ulcer is one of the most significant and devastating complication of diabetes and is defined as a group of syndromes in which neuropathy, ischemia and infection had to tissue breakdown, gangrene requiring limb amputation.⁴

Around 15% of diabetic patients will develop foot ulcers in their life time and this is known to precede amputation in 85% of the cases. It is estimated that approximately 45000 lower limbs are amputated every year in India and the vast majority of these are probably preventable. Diabetic foot syndrome is not only an important factor of mortality among patients with diabetes but also decreased the quality of life.⁴

QOL (Quality of Life) is defined by a subjective evaluation of the life circumstances of an individual with respect to his/her values. Identification of diabetes with DFS and its associate factors is the key to reduce further complications.^{5,6} Regular compulsory foot examination, patient education on foot care like simple hygiene practices, provision of appropriate foot care, prompt treatment of minor injuries and multidisciplinary approach can decrease ulcer occurrence by 50% and amputations up to 80%.^{5,6} Present study was aimed to compare QOL (Quality of Life) in type 2 diabetes mellitus patients with and without foot ulcers attending Navodaya medical college hospital and research centre

Material And Methods

Present study was hospital-based case control study, conducted in department of community medicine, Navodaya Medical College Hospital and Research Centre, India. Study duration was of one month March 2022. Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Cases - Patients with type 2 diabetes mellitus, with diabetic foot ulcer, willing to participate in present study.
- Controls - Patients with type 2 diabetes mellitus, without diabetic foot ulcer, willing to participate in present study.

Exclusion criteria

- i) Patients with other co morbidities
- ii) Severely ill patients
- iii) Patients with type 1 diabetes mellitus
- iv) Pregnant women
- v) Patients who do not give consent

A pretested semi-structured questionnaire was used for data collection, which includes socio demographic details, disease and its management, Anthropometry, details of foot ulcer and foot care. SF-36(36 item short form)questionnaire developed by RAND was used to assess the quality of life. It includes general health, daily activities, physical health, emotional health and social activities. The study was briefly explained to the participants and informed verbal consent was taken before data collection.

Height was measured by non-stretchable measuring tape and weight was measured by calibrated digital weighing machine. Waist circumference was measured using non stretchable measuring tape with minimal clothing. Measured at approximate midpoint between the lower margin of last palpable rib and the top of the iliac crest(WHO).

All data were recorded in Microsoft excel chart, and statistical analysis was done by Statistical Package for Social Sciences (SPSS Statistics for Windows, Version 20.0. SPSS Inc., Chicago) software version 20. Continuous data presented as mean $\pm$ SD and analysed by Independent t-test. The categorical data presented as frequency and percentage and analysed by Chi-square test data. The p value of <0.05 considered as significant.

Results

In present study 30 cases & 30 controls were studied. 65% of the participants were having >50 yrs of age. Mean age in cases and controls was 57.8yrs and 59.63yrs respectively 70% of the participants were male. 51.6% of the participants were unemployed and 13% were semi-skilled worker. 58.3% of the participants were having no formal education and 11% were having 7th and 10th standard of education. 55% belonged to Class IV and Class V Socio Economic Status. 43% and 33% of the Cases and Controls were obese respectively. Mean BMI in Cases and Controls was 24.2 and 23.7 respectively. Mean waist circumference among cases and controls was 81cm and 86cm respectively.

Table 1: General characteristics

	Cases		Controls	
	Frequency	Percent	Frequency	Percent
Age (years)				
<50 yrs.	11	36.67	10	33.33
>50 yrs.	19	63.33	20	66.67
Mean Age (years)	57.8 $\pm$ 10.35		59.63 $\pm$ 10.65	
Gender				
Male	20	66.67	22	73.33
Female	10	33.33	8	26.67
SES				
Class I	3	10	2	6.67
Class II	5	16.67	6	20
Class III	4	13.33	5	16.67
Class IV	11	36.67	9	30
Class V	7	23.33	8	26.67
BMI		0		0
Underweight	0	0	1	3.33
Normal	15	50	13	43.33
Over weight	2	6.67	6	20
Obese	13	43.33	10	33.33
Mean BMI	24.20 $\pm$ 3.7		23.7 $\pm$ 3.1	
Mean Waist circumference	81.27 $\pm$ 10.9		86.53 $\pm$ 11.5	

63.6%, 63.2 and 25% of the participants Smoke, consume Alcohol and chew Tobacco respectively. Mean years of smoking, alcohol consumption and tobacco chewing were 6.5yrs,

11yrs and 2.3yrs respectively among Cases.

Among controls, 36%, 36% and 75% of the participants smoke consume alcohol and chew tobacco respectively. Mean duration of smoking, alcohol consumption and tobacco chewing were 4.8yrs, 5.6yrs and 7.3yrs respectively.

Table no 2: Habits of the participants

Habits		Cases(DFU)		Controls(DM)		p value
		Frequency	Percent	Frequency	Percent	
Smoking	Yes(11)	7	63.6%	4	36.4%	p =0.317
	No(49)	23	46.9%	26	53.1%	
	Mean duration	6.5yrs(SD=12.1)		4.8yrs(SD=12.7)		
Alcohol	Yes(19)	12	63.2%	7	36.8%	p =0.165
	No(41)	18	43.9%	23	56.1%	
	Mean duration	11.1yrs(SD=14.1)		5.6yrs(SD=12.1)		
Tobacco chewing	Yes(12)	3	25%	9	75%	p =0.053 SIG
	No(48)	27	56.3%	21	43.7%	
	Mean duration	2.3yrs(SD=7.2)		7.3yrs(SD=13.8)		

Mean duration of disease in cases and controls was 4.7yrs and 6yrs respectively. 22% and 70% of the participants in cases and controls were having RBS within normal limits. Mean RBS in Cases and Controls was 190mg/dl and 161mg/dl respectively. 96% and 40% of the cases take oral hypoglycaemic drugs regularly and take insulin respectively. Among Controls all take oral hypoglycaemic drugs regularly and 13% participants take insulin

Table no 3: Details of Diabetes among the participants

		Cases(DFU)		Controls(DM)		p value
		Frequency	Percent	Frequency	Percent	
Diabetes duration		4.7yrs(SD=3.2)		6yrs(SD=5.01)		
Current status	Controlled(27)	6	22.2%	21	70%	p=0.000 SIG
	Not controlled(33)	24	72.7%	9	27.2%	
Oral Hypo-Glycaemic drugs	Regular	28	93.3%	30	100%	p=0.150
	Irregular	2	6.4%	0	0	
Insulin	Taken	12	40%	4	13.3%	p=0.020
	Not taken	18	60%	26	86.6%	
RBS(mg/dl)		190.6(SD=80)		161(SD=86.7)		

10% and 16% of the cases and controls do physical exercise respectively and shows statistically significant association. 73.3% and 66.6% of the cases and controls occasionally maintain diet. 80% and 90% of the cases and controls do regular blood checkup respectively.

Table no 4: Lifestyle modifications of cases and controls

		Cases(DFU)		Controls(DM)		
		Frequency	Percent	Frequency	Percent	
Physical activity	No work(7)	5	16.6%	2	6.6%	p=0.001
	Household activity(34)	22	73.3%	12	40%	
	Exercise(min 30min brisk walk(19)	3	10%	16	53.3%	
Diet maintenance	No maintenance(12)	6	20%	6	20%	p=0.683
	Occasional(42)	22	73.3%	20	66.6%	
	Strict(6)	2	6.6%	4	13.4%	
Regular blood	Yes(51)	24	80%	27	90%	0.278

glucose check up	No(9)	6	20%	3	10%	
Regular Eye check up	Yes(13)	3	10%	10	33.3%	0.028
	No(47)	27	90%	20	66.7%	

16% of the participants had diabetic foot ulcer since 2-5months. 80% and 83% of the participant's ulcer were infected and healing respectively. 76% of the participant's undergone debridement.

Table no 5: Details of diabetic foot ulcer

Cases(30)		Frequency	Percent
Diabetic ulcer duration	<2 months	9	15.0
	2-5 months	10	16.7
	5-12 months	9	15.0
	>12 months	2	3.3
Diabetic ulcer	Infected	24	80
	Not-infected	6	20
	Healing	25	83.4
	Non-healing	5	16.6
Treatment strategy	Dressing only	4	13.4
	Debridement	23	76.6
	Amputation	3	10

6% of the participants delayed treatment due to unavailability of services, thought of self-healing and lack of support.

Table no 6: Reasons for delay in treatment

Reasons for delay	Frequency	Percent
Negligence	1	3.3
Financial problem	1	3.3
Unavailability of health services	2	6.7
Thought of self-healing	2	6.7
Lack of support	2	6.7
Resorted to traditional methods	0	0

Foot care is poor in both cases and controls but better in controls than when compared to cases.

Table no 7: Details of foot care

Foot care	Cases(30)		Controls(30)	
	Frequency	Percent	Frequency	Percent
Daily washing feet	30	100	30	100
Keeping feet dry	3	10	0	0
Keeping skin soft	2	6.67	0	0
Often checking for blisters, cuts, sores	1	3.33	1	3.33
Wearing clean socks	4	13.33	3	10
Never walk bare foot	3	10	13	43.33
Examining shoes for damage	3	10	1	3.33
Loss of foot sensation	6	20	0	0

Quality of life is better in Controls than in Cases. All the domains are affected by ulcer.

Table no 8: SF-36 Quality of life score of each domain

Domains of SF-36	Cases		Controls	
	Mean	Std Deviation	Mean	Std Deviation
Physical functioning	10.5	5.5	20.5	5
Role of limitations due to physical health	0.2	1.1	9.1	2.8
Role of limitations due to emotional problems	2.4	3.5	7.1	1.8
Energy/Fatigue	5.7	0.9	7.2	1.0
Emotional well-being	7.6	2.5	10.2	1.2
Social functioning	3.04	0.9	4.1	0.8
Pain	2.5	0.9	5.5	0
General health	5.7	1.5	7.6	1.3

Quality of life is better in controls than in cases. Quality of life is better in females than in males. Gender has significantly associated with Ulcer.

Table no 9: Association between QOL and gender among cases and controls

T test	Gender	N	Mean	Std. Deviation	p value
Cases	Males	22	36.8434	8.34063	0.18
	Females	8	43.1944	11.60082	
Controls	Males	20	70.0556	6.60169	0.016 SIG
	Females	10	78.8750	9.00828	

Physical activity is less in cases than in controls and it significantly associated with quality of life. As the physical activity decreases quality of life decreases.

Table no 10: Association between QOL and Duration of tobacco chewing

ANOVA	Physical activity	N	Mean	Std. Deviation	p value
Cases	No work	5	27.8333	6.72830	0.017 SIG
	Household activity	22	40.7134	8.71442	
	Exercise	3	40.4167	9.38297	
Controls	No work	2	73.2639	6.18718	0.610
	Household activity	12	74.8611	10.78645	
	Exercise	16	71.5625	6.75320	

Waist circumference and BMI is more in cases than in controls. They are negatively correlated to quality of life. Waist circumference shows significant negative correlation in controls.

Table no 11: Association between QOL and waist circumference and BMI

Type of participants/Quality of life		Mean	Std. Deviation	N	r	P
Cases	Waist circumference	81.27	10.938	30	0.143	0.45
	BMI	24.20	3.76158	30	-0.083	0.66
Controls	Waist circumference	86.53	11.563	30	-0.55	0.02
	BMI	23.74	3.15416	30	-0.035	0.855

Discussion

Lack of awareness due to illiteracy in villages, lack of doctors and paramedical staff trained in diabetes, limited access to health care and poverty are some of the major obstacles to delivering diabetes health care to rural areas.

Health Related and Quality of Life (HRQOL) assessment can provide a landscape and global health of diabetes patients and lower limb function in particular, which in turn raises patients' awareness of healthcare and possible outcomes. Indeed, several trials showed that patients with foot ulceration have significantly decreased Health Related and Quality of Life (HRQOL) compared to those without the complications.^{7,8}

In our study, out of 60 participants 30 were cases. 73.3% were males and 26.7% were females. Out of 30 controls, 66.7% were males and 33.3% were females. Mean age of cases was 57.8(SD=10.35) and 59.63(SD=10.65) of controls. Similar study done by Al Sana *et al.*,⁹ showed that out of 250 participants, 100 were cases. Among them, 28% were males and 72% were females. Out of 150 controls, 27% were males, 73% were females. Mean age of cases and controls were 56.5 years and 56.9 years respectively.

In our study among cases 50% were urban and 50% rural. Among controls, 83.3% and 16.7% were from urban and rural area respectively. 53.3% and 63.3% were having no formal education among cases and controls respectively. Similar studies done by Tejaswi L Y *et al.*,¹⁰ showed that among 80 Diabetic Foot Ulcer patients, 66.2% and 33.7% were from rural and urban areas respectively. 48.75% had no formal education and 41.2% belonged to semiprofessional occupation, 55% belonged to Class IV and Class V Socio Economic Status. Similar study done by Al Sana *et al.*,⁹ showed that among controls 19.3% and 80.7% were urban and rural respectively. Among cases, 29% and 71% were from urban and rural areas respectively. 11% and 10.7% were illiterate in cases and controls respectively. 15% were illiterate each in cases and controls.

In our study, 23.3% and 13.3% were smokers in cases and controls respectively. 40% and 23.3% were alcoholics in cases and controls respectively. 10% in cases and 30% in controls were tobacco chewers. As the duration of tobacco consumption increases in cases the quality-of-life decreases ($r = -0.98$, $p = 0.003$). Similar study done by Al Sana *et al.*,⁹ showed that 94% in cases and 92.7% in controls were smokers.

In our study, among cases 93.3% were taking oral hypoglycemics and all controls were taking oral hypoglycemics regularly. Among cases and controls, 40% and 13.3% were on insulin respectively. Similar study done by Al Sana *et al.*,⁹ 76% were on oral hypoglycemics in cases as well as controls. 14% and 11.3% were on insulin among cases and controls respectively. 79% of cases and 85.3% of controls take medications regularly.

In our study among cases and controls mean duration of diabetes mellitus was 4.75 years(SD=3.25) and 6 years (SD=5.01) respectively. Among cases, 16.7% participants have DFU since 2 to 5 yrs. Similar study done by Al Sana *et al.*,⁹ 49% of cases and 48.7% of controls were having diabetes mellitus for less than 10 years.

In our study, among cases 43.3% and 33.3% among controls were obese. Among 60 participants 26.2% and 44.4% were having waist circumference >94 cms for males and >80 cms for females respectively. As waist circumference is less in controls than in cases, QoL score is more in controls. It shows negative correlation between them ($r = -0.55$, $p < 0.05$). BMI and waist circumference is positively co-related with each other in cases than in controls which shows statistically significant association ($r = 0.648$, $p < 0.05$)

Among cases Mean QoL for males and females was 36.84(SD=8.34) and 43.19(SD=11.6) respectively. Among controls, mean QoL for males and females was 70.05 (SD=6.60) and 78.87(SD=9.00) respectively. This shows statistically significant association

($p < 0.05$) between a diabetic foot ulcer and QoL. QoL is better in control than in cases. Also, the QoL is better in the urban participants than in rural areas. Similar study done by Al Sana *et al.*,⁹ showed that Mean QoL score for cases and controls was 40.5(SD=10.6) and 49.4(SD=12) respectively. It shows statistically significant association.

The physical activity is less in cases than in controls so the mean quality of life score is more in cases than in controls and shows statistical association between them($p < 0.05$). The present study shows that more than 90% of the participants lack in taking care of their feet due to lack of knowledge and foot care and its complications related awareness.

Diabetic foot is associated with severely impaired HRQoL in both physical and mental health aspects.^{11,12} Many studies have illustrated the mechanism of stress in slowing the healing rate of acute and chronic ulcers, which leads to long-term ulcer care and this creates further burden, pressure and low QoL.^{13,14,15,16} An understanding of the determinants of DFU patients' QoL may help health professionals in clinical decision-making, specifying risk groups, and allowing the planning of interventions.

Limitations of present study were, small sample size, we could not assess effect of DFU on occupation, we could not assess effect of DFU on QOL of caregivers(or family members) & we could not assess out-of-pocket expenditure.

Awareness to be created in urban and rural areas regarding foot care management. Health care facilities are to be strengthened in early screening of diabetic complications. Awareness regarding effects of alcohol consumption, smoking, tobacco chewing on quality of life, motivation regarding this should be given & rehabilitation for the disabled diabetic foot ulcer patients should be provided.

Conclusion

The present study shows the impact of diabetic foot ulcer on quality of life(using RAND SF-36 tool). The QoL is better in controls than in cases. The results show that quality of life is better in females than in male patients. The factors which affect the quality of life were: participants living in rural areas, habit of tobacco chewing, less physical activity(sedentary life style), uncontrolled sugar levels ,increased BMI, increased waist circumference.

Conflict of Interest: None to declare

Source of funding: Nil

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