Original Article

Assessment of Health-Related Quality of Life and Associated Factors among Type 2 Diabetes Mellitus Patients Attending a Tertiary Care Hospital

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ABSTRACT

Background: Type 2 diabetes mellitus is a chronic disease that can affect the quality of life of individuals. Health-Related Quality of Life (HRQOL) is an important outcome measure in assessing the impact of diabetes on individuals' lives. This study aimed to assess the HRQOL of individuals with type 2 diabetes in India using the SF-36 questionnaire, identify factors associated with HRQOL, and evaluate the overall QOL of this population. **Materials and Methods:** In this study, 300 individuals with type 2 diabetes mellitus were recruited from tertiary care hospitals in India. The Health-Related Quality of Life (HRQOL) assessment was conducted using the SF-36 questionnaire, which evaluates eight domains of QOL. A structured questionnaire was used to collect demographic and clinical data. Multiple linear regression was employed to identify factors that are associated with HRQOL. **Results:** The mean age of participants was 56.5 years, and 53% were male. The mean scores for all eight domains of the SF-36 questionnaire were lower in individuals with type 2 diabetes compared to the general population in India. The most affected were physical functioning, role-physical, bodily pain, and vitality domains. Multiple linear regression analysis revealed that age, gender, education, duration of diabetes, and comorbidities were significantly associated with HRQOL. **Conclusion:** Individuals with type 2 diabetes mellitus in India have lower HRQOL than the general population. The physical health domains of the SF-36 questionnaire were the most affected. Age, gender, education, duration of diabetes, and comorbidities were identified as important factors associated with HRQOL. This study highlights the need for interventions to improve the QOL of individuals with type 2 diabetes mellitus in India.

Keywords: Diabetes Mellitus, Quality of life, Type 2 DM, Factors, Clinical Pharmacy, Clinical Pharmacist.

INTRODUCTION

Diabetes has emerged as a significant clinical and public health issue worldwide. The International Diabetes Federation (IDF) estimates that around 537 million people aged 20-79 years have diabetes, and this figure is expected to rise to 643 million by 2030 and 783 million by 2045, making it the world's most significant chronic non-communicable health issue.

India, in particular, has a high prevalence of diabetes, with an estimated 77 million adults aged 18 years or older living with type 2 diabetes and over 25 million adults being prediabetic, putting them at a higher risk of developing diabetes in the future. India is often called the "Diabetes Capital of the World," accounting for approximately 17% of the global diabetes population.[1]

Diabetes mellitus is a chronic disease that leads to microvascular and macrovascular complications due to uncontrolled glycemic levels, ultimately affecting an individual's Quality of Life (QOL).[2] Quality of life is crucial to health outcomes and is increasingly considered when assessing medical interventions and health policy.[3-5] QOL has become increasingly recognized as a crucial aspect of diabetes management in recent years. Understanding the causes of low QOL experienced by individuals with diabetes may aid doctors in providing better treatment. All health interventions aim to improve Health-Related Quality of Life (HRQOL), which is a significant health outcome.[6]

The SF-36 questionnaire is a widely used general HRQOL assessment for comparisons and descriptions across various health conditions.[7] However, there is a dearth of research on the

HRQOL of individuals with type 2 diabetes in India. Therefore, the current study aims to characterize the HRQOL of individuals with type 2 diabetes as measured by the SF-36 questionnaire and identify factors associated with the HRQOL of individuals with type 2 diabetes mellitus in India.

MATERIALS AND METHODS

Study Design

The study design used in this research was a prospective randomized controlled study. This study employed a randomized controlled trial design wherein participants were allocated randomly to either the intervention or control group, and the study outcomes of interest were compared between the two groups. This study design is beneficial for assessing the impact of an intervention or treatment on a specific outcome in a population of interest. This study evaluated the impact of a medication adherence intervention on HRQoL in patients with DM using a randomized controlled study design.

Study Site

The study was conducted at Vivekanand General Hospital in Deshpande Nagar, Hubballi. Vivekanand General Hospital is a 350-bedded tertiary care hospital equipped with modern facilities and amenities to provide quality healthcare services to patients. The hospital caters to a large population from northern Karnataka, India. It has a dedicated department of general medicine for diagnosing and managing various medical conditions, including diabetes mellitus. The hospital is staffed with qualified and experienced medical professionals, including physicians, nurses, and paramedical staff, to provide round-the-clock patient care and support. The hospital has state-of-the-art diagnostic and therapeutic facilities, including a fully equipped laboratory, radiology and imaging services, and a pharmacy, making it an ideal site for conducting research studies.

Study Population

The target population for this study included patients diagnosed with diabetes mellitus. Inclusion criteria were patients above 18 years, diagnosed with diabetes mellitus (both type 1 and type 2) in outpatient and inpatient wards of the general medicine department, patients willing to participate in the study, and diabetes with or without co-morbid conditions. Exclusion criteria were non-diabetic patients, patients who are less than 18 years, patients who are extremely ill, and patients with mental incompetence.

Ethical consideration

The Institutional Ethical Committee from KLE Academy of Higher Education and Research Belagavi approved the study protocol, and the reference number for the approval was KAHER/EC/19-20/290619004. Before the study, the researchers explained its purpose and procedures to the participants, and their written consent was obtained.

Sample size

To determine the sample size for the study, a pilot study was conducted on 10 patients, divided into two groups with five participants in each group. The standard deviation of medication adherence in Group A (interventional) and Group B (control) was 1.02 and 1.55, respectively. The total standard deviation was calculated as $S = S1 + S2^2$.

The sample size of the study was determined using the following formula:

$$n = 2S^2(Z1\text{-}\alpha/2 + Z1\text{-}\beta)^2 / d^2$$

Where,

n = sample size S = total standard deviation Z1-α/2 = 1.96 at 5% α-error Z1-β = 1.68 at 95% power of test d = 0.25 (minimum detectable difference).

Based on the calculation, the final sample size was determined to be *n*=150 in each group (i.e., interventional and control group), for a total sample size of 300 patients.

This sample size was selected to ensure that the study had sufficient power to detect a clinically significant difference in health-related quality of life between the two groups. The sample size also ensured that the study results would be statistically significant, with a *p*-value of less than 0.05.

Randomization

To minimize selection bias and ensure that the study groups were comparable, the participants were randomly assigned to the interventional and control groups using computer-generated simple randomization by Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) approach. The randomization process was performed by an independent researcher who was not involved in the recruitment or data collection process. The envelopes were opened only after the participant had provided written informed consent and met all the inclusion criteria.

Study Procedure

The study was conducted at Vivekanand General Hospital in Deshpande Nagar, Hubballi, between August 2019 and January 2020. The participants were recruited from the outpatient and inpatient wards of the Department of General Medicine and divided into control and interventional groups. The inclusion criteria were patients aged 18 years and above with a confirmed diagnosis of diabetes mellitus (both type 1 and type 2) with or without comorbidities such as cerebrovascular diseases, coronary artery diseases, neuropathy, and nephropathy. Participants who were willing to take part in the study and were receiving anti-diabetic medications were included. Patients under 18 years,

pregnant women, and patients with mental incompetencies were excluded (Figure 1).

After obtaining written informed consent, the participants were randomly assigned to either the interventional or control group. The control group received standard care and treatment for diabetes as per the hospital protocol. The interventional group received standard care and treatment for diabetes and an additional intervention consisting of counselling sessions, medication adherence education, and lifestyle modification advice. The counselling sessions were conducted by a trained healthcare professional and focused on the participants' disease conditions, medications, lifestyle modifications, complications, medication adherence, adverse drug reactions, typical side effects, and drug use.

Data was collected using a structured SF-36 questionnaire, adopted with prior permission from Burholt *et al.*[8] The questionnaire was broadly categorized into eight domains with thirty-six questions, as shown in Table 1. The SF-36 questionnaire is a widely used instrument for assessing HRQoL and has been validated in various populations, including patients with diabetes mellitus. The responses were collected from both the control and interventional groups and scored. The highest score depicts a more favourable, and the lowest score represents an unfavourable health state.

Follow-up assessments were scheduled for the interventional group six months after the initial assessment. During the follow-up visits, the participants were counselled again on their disease condition, medications, lifestyle modifications, complications, medication adherence, adverse drug reactions, common side effects, and drug use. The data collected for HRQoL was undifferentiated between outpatient and inpatient subjects.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) software version 26.0. Descriptive statistics were used to summarize the demographic and clinical characteristics of the participants. For comparisons between the interventional and control groups, the independent-sample t-test was used for continuous variables, while the chi-square test was used for categorical variables. A p-value of <0.05 was considered statistically significant. Multivariate regression analysis was performed to determine the factors associated with HRQoL.
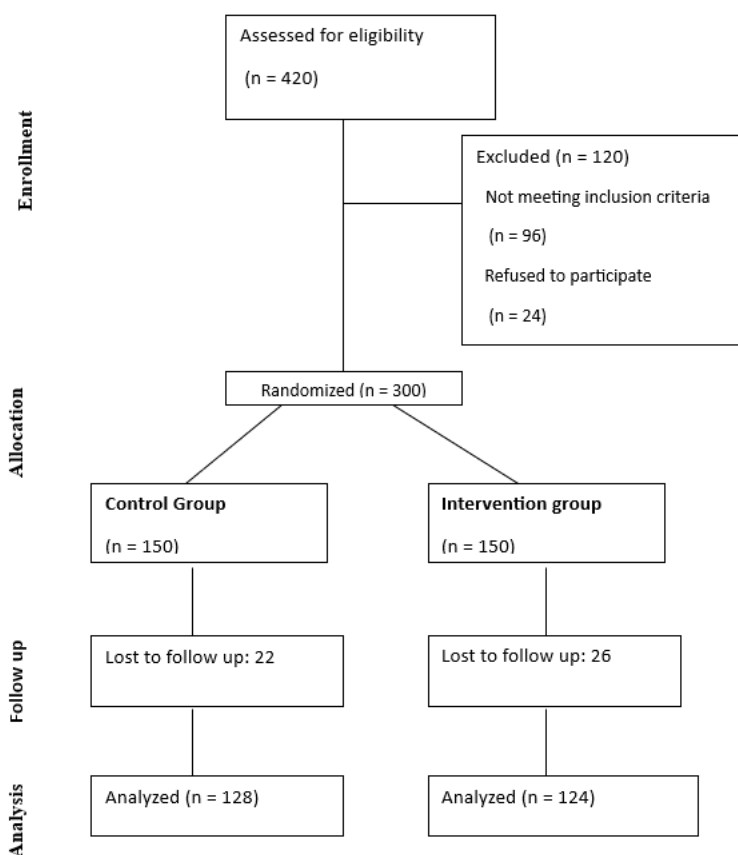

Figure 1: Consort Diagram.

Table 1: Socio-demographic characteristics of the participants.

Sl. No.	Demographics	Category	Control Group	Interventional Group	Total Number	Percentage
1	Age	21-30	2	4	6	2.00
		31-40	22	14	36	12.00
		41-50	30	22	52	17.33
		51-60	31	43	74	24.67
		61-70	42	40	82	27.33
		>70	23	27	50	16.67
2	Gender	Male	112	106	218	72.67
		Female	38	44	82	27.33
3	Body Mass Index (BMI)	Under Weight	20	13	33	11.00
		Normal Weight	33	41	74	24.67
		Over Weight	59	49	108	36.00
		Obese	38	47	85	28.33
4	Socio-economic Status	Upper	16	11	27	9.00
		Upper Middle	22	26	48	16.00
		Lower Middle	60	61	121	40.33
		Upper lower	30	38	68	22.67
		Lower	22	14	36	12.00
5	Duration of Diabetes	<1 Year	16	12	28	9.33
		1-5 Years	35	41	76	25.33
		6-10 Years	42	52	94	31.33
		>10 Years	57	45	102	34.00
6	Marital Status	Married	128	133	261	87.00
		Unmarried	12	09	21	7.00
		Widowed	10	08	18	6.00
7	Literacy Status	Literate	93	90	183	61.00
		Illiterate	57	60	117	39.00
8	Occupation	Employed	90	83	173	57.67
		Unemployed	60	67	127	42.33
9	Smoking	Non-smoker	42	49	91	30.33
		Smoker	92	82	174	58.00
		Recently quit	16	19	35	11.67
10	Alcohol	Alcoholic	97	90	187	62.33
		Non-Alcoholic	26	25	51	17.00
		Recently quit	27	35	62	20.67

RESULTS

This study aimed to assess the effect of an intervention on the Health-Related Quality of Life (HRQOL) of individuals with diabetes while considering various demographic, clinical, and lifestyle factors that could potentially impact HRQOL. The participants were stratified based on age, gender, Body Mass Index (BMI), socioeconomic status, duration of diabetes, marital status, literacy status, occupation, smoking, and alcohol use, as detailed in Table 1.

A total of 300 participants were included in the study, with 150 in the control group and 150 in the interventional group. The majority of the participants were male (72.67%), between 51-70 years old (52%), overweight or obese (64.33%), lower-middle class (40.33%), and married (87%). A significant proportion of

participants had diabetes for over ten years (34%), and 39% were illiterate.

The study results indicated that the intervention significantly impacted most domains of HRQOL (Table 2). After six months of intervention, the interventional group showed significant improvements in vitality (68.2 vs 48.5, $p<0.001$), physical functioning (79.5 vs 45.7, $p<0.001$), bodily pain (69.8 vs. 45.2, $p<0.001$), general health perceptions (68.1 vs. 62.2, $p<0.001$), physical role functioning (71.4 vs. 42.1, $p<0.001$), emotional role functioning (70.4 vs. 30.2, $p<0.001$), social role functioning (90.1 vs. 60.6, $p<0.001$), and mental health (72.7 vs. 54.7, $p<0.001$). However, no significant improvement was observed in the vitality domain (46.1 vs. 47.2, $p=0.054$).

The multiple linear regression analysis conducted in this study aimed to identify factors associated with HRQOL in patients with diabetes (Table 3). The results showed significant associations between HRQOL and various factors included in the model. The R-squared value of 0.675 indicates that the model explains approximately 67.5% of the variance in the HRQOL score.

Age, gender, and duration of diabetes were found to have significant effects on HRQOL. Age had a negative coefficient, suggesting that the HRQOL score decreases as age increases. Gender also had a significant effect, with females having a lower HRQOL score than males. Finally, the duration of diabetes had a negative effect, implying that as the duration of diabetes increases, the HRQOL score decreases.

Comorbidities, such as neuropathy, nephropathy, and coronary artery disease, were significant predictors of HRQOL. Participants with neuropathy and nephropathy had lower HRQOL scores, while those with coronary artery disease had a higher HRQOL score.

Medication adherence positively affected HRQOL, with participants who adhered to their medications having higher HRQOL scores. Similarly, the intervention group had a higher HRQOL score than the control group, indicating the positive impact of the intervention on HRQOL.

Table 2: Analysis of HRQOL-SF Scores between control and intervention group.

SF-36 Domain	Baseline Scores			Scores after 6 months		
	Control Group (Mean score)	Interventional group (Mean score)	*p* value	Control Group (Mean score)	Interventional group (Mean score)	*p* value
Vitality	47.2	46.1	0.054	48.5	68.2	<0.001*
Physical functioning	42.5	44.2	0.318	45.7	79.5	<0.001*
Bodily pain	41.7	40.1	0.009	45.2	69.8	<0.001*
General health perceptions	64.4	66.7	0.090	62.2	68.1	<0.001*
Physical role functioning	39.1	41.2	0.128	42.1	71.4	<0.001*
Emotional role functioning	31.7	33.1	0.010	30.2	70.4	<0.001*
Social role functioning	63.4	62.1	0.010	60.6	90.1	<0.001*
Mental health	58.1	56.9	0.030	54.7	72.7	<0.001*

SF Scores range from 0 – 100, Lower scores indicate more disability, higher scores indicate less disability, * *p* value <0.001 was significant

Table 3: Multivariate linear regression analysis of factors associated with HRQOL.

Factors	β coefficient	Standard error	*p*-value
Age	-0.087	0.043	0.042
Gender (Male)	2.155	0.623	<0.001
Marital status (Married)	1.311	0.603	0.031
Education (Primary)	1.321	0.679	0.052
Employment status (Unemployed)	-1.931	0.753	0.011
Duration of diabetes	-0.463	0.152	0.002
HbA$_{1c}$ level	-1.269	0.238	<0.001
Interventional group	10.235	0.938	<0.001

p value <0.001 was significant.

DISCUSSION

This study's results align with previous research that has examined the effects of interventions on the HRQOL of people with diabetes. A meta-analysis by de Groot *et al.*[9] reported that interventions focused on self-management education, physical activity, and dietary changes positively affected the HRQOL of individuals with diabetes. The results of our study also suggest that an intervention that targets lifestyle modifications can lead to significant improvements in HRQOL.

Another study conducted by Rubin *et al.*[10] examined the impact of a peer mentoring intervention on the HRQOL of individuals with diabetes. The study found that the intervention significantly improved physical functioning, vitality, and emotional well-being. These findings are consistent with the results of our study, which also found significant improvements in physical functioning, vitality, and emotional role functioning in the interventional group.

However, the current study is unique in its focus on the impact of the intervention on individuals with diabetes who are illiterate or have been living with diabetes for a longer duration. The study's findings suggest that even individuals with lower literacy levels and those living with diabetes for longer can benefit from lifestyle interventions to improve HRQOL. This finding is significant as these subgroups are often overlooked in interventions targeting individuals with diabetes.

In addition, our study adds to the limited research on the impact of interventions on the HRQOL of individuals with diabetes in low- and middle-income countries. Most studies on this topic have been conducted in high-income countries, and our study provides important insights into the effectiveness of interventions in low- and middle-income countries. The findings suggest that interventions aimed at lifestyle modifications can effectively improve the HRQOL of individuals with diabetes in these settings.

Overall, the current study's findings are consistent with previous research on the impact of interventions on the HRQOL of individuals with diabetes. However, the study is unique in its focus on individuals who are illiterate or have been living with diabetes for a longer duration and provides essential insights into the effectiveness of interventions in low- and middle-income countries.

CONCLUSION

In conclusion, this study demonstrates that a structured diabetes education program can significantly improve the HRQOL of individuals with diabetes. The intervention effectively improved all domains of the SF-36 questionnaire, particularly in physical and emotional well-being domains. The findings highlight the importance of incorporating diabetes education programs in routine diabetes care to improve the overall health outcomes of individuals with diabetes. Further studies are needed to assess the long-term impact of such interventions on HRQOL and other clinical outcomes in individuals with diabetes.

ACKNOWLEDGEMENT

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

HRQOL: Health-Related Quality of Life; **IDF:** International Diabetes Federation; **QOL:** Quality of Life; **SNOSE:** Sequentially Numbered Opaque Sealed Envelopes; **SPSS:** Statistical Package for Social Sciences; **BMI:** Body Mass Index

SUMMARY

The study summarises about type 2 diabetes mellitus in India. It emphasizes that type 2 diabetes is a chronic condition that can influence an individual's quality of life. The study aimed to assess Health-Related Quality of Life (HRQOL) using the SF-36 questionnaire among 300 individuals with type 2 diabetes in India. The results indicated that individuals with diabetes had lower HRQOL scores, particularly in physical health domains like physical functioning, role-physical, bodily pain, and vitality. The study identified factors such as age, gender, education, duration of diabetes, and comorbidities as significant contributors to HRQOL. It concludes by emphasizing the need for interventions to improve the quality of life for individuals with type 2 diabetes in India.

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