

Impact of Anti-Diabetic Medications on Quality of Life in Persons with Type 2 Diabetes Mellitus

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Abstract

Introduction: Type 2 diabetes mellitus (T2DM) has been found to be associated with poor quality of life (QOL). The aim of this study was to measure QOL in T2DM patients and examine if the patients' socio demographic, diabetes-related clinical characteristics and insulin usage are associated with better quality of life. **Materials and Methods:** This clinic based cross-sectional study analyzed data from outpatients with T2DM attending a referral clinic between January and June 2016. Association between Diabetes Attitudes, Wishes and Needs (DAWN) QOL and few demographic, socioeconomic, clinical and biochemical predictors were examined using multivariate logistic regression model. A total of 518 patients completed the interview. **Results:** The HbA1c level of insulin ± oral anti-diabetic (OAD) cohort was significantly lower (7.89 ± 1.98) than the OAD cohort (8.79 ± 1.96), $P < 0.001$. Compared to their counterparts in the OAD cohort, patients on insulin were older with longer duration of diabetes mellitus. Co-morbid confounders like obesity, hypoglycemia, and blood pressure control or socio demographic confounders like income, education were almost similar in both the cohorts. The incidence of hypertension, coronary artery disease (CAD) and statin usage was significantly higher in the insulin cohort. The overall composite DAWN QOL scores of the insulin ± OAD cohort (25.42 ± 4.35) was marginally higher than that of the OAD cohort (23.62 ± 5.06) ($P = 0.067$). Analog insulin users were also found to have significantly higher composite DAWN QOL scores compared to human insulin users (25.77 ± 5.73 vs. 24.13 ± 4.88 , $P = 0.037$). **Conclusions:** The insulin cohort, despite being older and having longer duration of diabetes, had significantly higher diet compliance score, and enhanced QOL owing to better diabetes-related knowledge and treatment adherence characteristics than non-insulin users. Questionnaires-based evaluation of QOL can provide better understanding of the patient's experience of the illness, self-care, psychological and emotional functioning, and choice of therapeutic modality enhancing the quality of care.

Keywords: Diabetes mellitus, India, insulin, patient-reported outcomes, quality of life

INTRODUCTION

According to the Diabetes Atlas 2019,^[1] the prevalence of diabetes in India is enormous and remained at 11.8% in the last four years. Approximately 77 million people are living with diabetes while nearly 43.9 million (57%) of cases of diabetes are undiagnosed. As per the ongoing trends, by the year 2035 almost 592 million people, or one in 10 adults, are expected to suffer from diabetes. This would result in nearly three newly diagnosed diabetes cases every 10 or almost 10 million cases yearly.^[1] QOL, which is the major health outcome in people with diabetes (PWD), is defined as "how good or bad an individual feels their life is".^[2] This vision emphasizes that the most crucial feature is to measure QOL of an individual by self-assessment of their own QOL and not what others perceive it to be.^[3,4] Studies on QOL are deemed

useful to improvise well-being of patients, compliance, and continuity of care in the diabetes clinic.^[5] A comfortable doctor-patient relationship in addition to adequate lifestyle modification (LSM) encompassing proper compliance in diet, medications, and self-monitoring of blood glucose (SMBG) is required to ensure better glycemic control and QOL.^[6-8] These measures can be implemented in day-to-day schedule with very nominal extra financial burden. Co-morbidity with

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other diseases associated with T2DM majorly influence QOL of T2DM patients. Poor management of T2DM leads to several complications and end organ damage that ultimately impairs the Health-Related Quality of Life (HRQOL) in the individuals.^[9]

The DAWN program was an international venture initiated in 2001 by Novo Nordisk in partnership with the International Diabetes Federation to improve diabetes care outcomes by omitting the psychosocial and behavioral barriers and providing effective diabetes management. The goals of the DAWN study were to promote active self-management, enhance psychological care, enhance communications between people with diabetes and health care providers (HCPs), and promote communication and coordination to reduce barriers to effective therapy.^[10] This study, including HCPs involved in diabetes care across 13 countries, was designed to address psychosocial factors of improved health outcomes and QOL for diabetic individuals.^[11] Most HCPs reported that PWD experienced psychological problems (including depression, anxiety, and stress) and that these problems affected adherence to diabetes regimens.^[12] The second DAWN study (DAWN2)—a global partnership for the advancement of patient-centered care (PCC) for PWD—extended the findings of the original DAWN study.^[13] The DAWN2 study, executed globally across 17 countries including India, highlights the implementation of PCC, addressing patient needs.^[14] With respect to India, almost 52% of PWD reported diabetes-related distress.^[15] Although the quality of patient-provider relationships is generally good, HCPs need a better understanding of the social and psychological problems that PWD encounter. The DAWN program was successful in implementing a few concrete initiatives to bridge the gaps existing in diabetes care, namely self-management, psychological anguish, and quality of relationships between patients and their HCPs, and barriers to effective medication therapy for diabetes. Therefore, feedback from HCPs, PWD and their family members are extremely necessary to comprehend if healthcare is being imparted optimally.^[15] These measures along with self-management education, have been reported to make a difference in diabetes self-care, adherence, and improved clinical, psychosocial and QOL outcomes.^[16,17]

Studies conducted by Houlden *et al.*^[18] and Akinci *et al.*^[19] concluded that T2DM patients taking insulin had better quality of life than those using OADs. However, similar finding was not seen in a later study.^[20] The aim of this study was to assess and compare the DAWN QOL score in patients with T2DM on insulin with that of their counterparts on OADs in an urban clinic setup in India, and to examine if patients' socio-demographic, diabetes-related clinical and biochemical characteristics, and insulin usage are associated with improved QOL.

MATERIALS AND METHODS

T2DM patients aged 18 years or older attending our referral clinic situated in the northeastern part of India between

January and June 2016 were enrolled. The patients were willing and able to give informed consent and complete the questionnaire-based interview. Informed consent was obtained from patients by explaining how their enrollment into the study would help in assessing the impact of diabetes on their lives and how it would help in improving their current treatment strategy and the QOL outcome. Patients who expressed dissent and who did not have adequate command in English to be able to respond to the questionnaire were excluded from the study.

Based on the ongoing pharmacotherapy, the participants were categorized into two comparator groups, namely insulin ± OAD cohort and OAD cohort. Their socio-demographic and clinical history details were recorded in the in-house data collection software of the outpatient clinic. Data recorded were details of age, gender, anthropometry, education level, living conditions, employment and marital status, lifestyle management issues, disease duration, essential biochemical test findings, mode of treatment and related comorbidity. Dietary and exercise compliance scores were recorded as per a unique scoring system undertaken routinely in the clinic when each of the newly registered patient with diabetes mellitus is interviewed by the dietician or diabetic counsellor [Table 1]. Quality of life data were collected using DAWN QOL questionnaire as shown in Table 2.^[10] Our independent socio-demographic variables were age, gender, and level of education. We also measured weight and height to determine the body mass index (BMI). Socioeconomic status (SES) was assessed using the Modified Kuppaswamy's Socioeconomic scoring system updated for July 2015.^[21] Glycemic control was determined by concomitant or most recent glycated hemoglobin (HbA1c) results from the in-house Diabetes, Endocrinology and Metabolic Disease Information Management System (DEMIMS®) and defined as good (≤7%) and poor (>7%).

Patients were interviewed after obtaining proper informed consent pertaining with the Helsinki Declaration of 1975, as revised in 2000, and clinical and biochemical data were collected retrospectively from clinic database.

Table 1: Scoring order of DEMIMS® lifestyle assessment system

DEMIMS® lifestyle assessment score for assessments of Dietary and Exercise compliance [#]	Attribute of the patient
1	Knows insufficiently, Executes inadequately
2	Knows sufficiently, Executes inadequately
3	Knows sufficiently, Executes adequately

[#]The unique scoring system was undertaken routinely in the clinic when each of the newly registered patients with diabetes mellitus was interviewed by the dietician or diabetic counselor. DEMIMS®, Diabetes, Endocrinology and Metabolic Disease Information Management System

Table 2: Health status and diabetes self-care activities questionnaire

	Completely (6)	Partially (5)	Rarely (4)	Never (3)	No recommendation (2)	Don't know/refused (1)
Diet (DAWN QOL-A)						
Exercise (DAWN QOL-B)						
Taking medications as prescribed (DAWN QOL-C)						
Testing yourself (DAWN QOL-D)						
Keeping appointments with healthcare professionals (DAWN QOL-E)						

Adopted from original Diabetes Attitudes, Wishes and Needs (DAWN) survey to investigate how well patients followed recommended treatments^[10] QOL, Quality of Life

Statistical analysis

Descriptive statistical analysis was carried out with SAS (Statistical Analysis System) version 9.2 for Windows, SAS Institute, Inc., Cary, NC, USA and Statistical Package for Social Sciences (SPSS Complex Samples) version 21.0 for Windows, SPSS, Inc., Chicago, IL, USA, with Microsoft Word and Excel being used to generate graphs and tables.

Results on continuous measurements are presented as Mean \pm SD and results on categorical measurements are presented in Number (%). Significance is assessed at a level of 5%. Normality of data was tested by Anderson Darling test, Shapiro-Wilk, Kolmogorov-Smirnoff test and visually by QQ plot. Chi-square/Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups.

RESULTS

Socio-demographic data and clinical characteristics of study participants according to insulin usage

The present study comprised of 518 patients who completed the assigned questionnaire. The overall ratio of male to female patients was 1.66:1, 1.37:1 in the insulin \pm OAD ($n = 165$) and 1.94:1 in the OAD only cohort ($n = 353$). 60.62% of the overall population belonged to the medium-income group whereas 38.03% belonged to the high-income group. A great majority of the study participants (82.63%) had completed secondary school level of education. The patients were on the following OADs during this study: sulfonylureas (SU), pioglitazones, dipeptidyl peptidase 4 inhibitors (DPP-4-i), alpha-glucosidase inhibitors (AGI), glinides and sodium-glucose co-transporter 2 inhibitors (SGLT2i). In the OAD only cohort, majority (60.06%) used SUs either alone or as part of combination therapy as against mere 8.2% using newer OADs like DPP-4i or SGLT-2i without SUs. In the insulin \pm OAD cohort, 56.36% used analogs which comprised of basal, premix and rapid acting types. The patients in the insulin \pm OAD cohort were older and had suffered from diabetes longer than their counterparts in the OAD cohort. While the incidence of hypertension, CAD, and statin usage was significantly higher in the insulin \pm OAD cohort, other clinical confounders like obesity and hypoglycemia, or socio-demographic confounders like income and education were almost similar in both the cohorts. As regards the

diabetes-related biochemical parameters, HbA1c, fasting plasma glucose (FPG), post prandial plasma glucose (PPPG), and low density lipoprotein-cholesterol (LDL-c) were significantly lower and serum creatinine was significantly higher in the insulin \pm OAD cohort. The DEMIMS[®] diet compliance score of the insulin cohort was significantly higher than that of the OAD cohort, whereas the score for exercise compliance was not different between the two cohorts [Table 3]. With respect to the safety parameters of study participants, the occurrence of hypoglycemia, whether or severe was not significantly different amongst the two cohorts [Table 3].

Comparison of the two cohorts based on their DAWN quality of life scores

The mean DAWN QOL-A (Diet) scores of the insulin \pm OAD cohort (5.35 ± 0.89) was significantly higher than that of the OAD only cohort (4.95 ± 1.14 ; $P = 0.001$). Similarly, the mean DAWN QOL-C (taking medicines as prescribed) and DAWN QOL-E (keeping appointments with HCPs) scores of the insulin \pm OAD cohort was significantly higher ($P = 0.05$) than that of the OAD cohort. The overall mean DAWN QOL scores of the insulin cohort (25.42 ± 4.35) was numerically higher than that of the OAD cohort (23.62 ± 5.06), but statistically not significant ($P = 0.067$) [Table 4]. Analog insulin users had significantly higher composite DAWN scores compared to human insulin users (25.77 ± 5.73 vs 24.13 ± 4.88 , $P = 0.037$).

DISCUSSION

Our study measured the DAWN QOL status in PWD (T2DM) attending an urban referral clinic in northeast India and examined if patients' socio-demographic variables, diabetes-related clinical characteristics, and insulin usage are associated with better QOL. We also compared the QOL outcomes between the patients on OAD alone and on insulin \pm OAD.

In our study, the HbA1c (%) levels of the PWD in the insulin \pm OAD cohort were significantly lower than the OAD alone cohort (7.89 ± 1.98 vs 8.79 ± 1.96 ; $P < 0.001$), indicating better glycemic control with insulin usage. This happened despite our patients on insulin having a longer duration of the disease. Similar to the findings of two earlier studies, PWD with higher HbA1c levels had lower DAWN

Table 3: Socio-demographic, clinical and biochemical characteristics of study participants according to insulin usage

Variable	Overall cohort, n=518	Insulin±OAD cohort, n=165	OAD cohort, n=353	P#
Gender (Male:Female), n (%)		1.37:1	1.94:1	0.158 (NS)
Age (in years), Mean±SD	51.75±2.67	53.65±12.45	49.86±11.29	<0.001
Level of education,				
School level, n (%)	90 (17.38)	58 (35.15)	32 (9.07)	0.897 (NS)
Secondary	175 (33.79)	55 (33.33)	120 (33.99)	
Graduate & above, n (%)	253 (48.84)	52 (31.51)	201 (56.94)	
Income,				
High, n (%)	197 (38.03)	61 (36.96)	136 (38.52)	0.468 (NS)
Medium, n (%)	314 (60.62)	103 (62.42)	211 (59.77)	
Low, n (%)	7 (1.35)	1 (0.62)	6 (1.69)	
Body weight (kg), Mean±SD	70.39±1.18	71.23±12.42	69.56±12.06	0.162 (NS)
BMI (kg/m ²), Mean±SD	26.58±2.22	26.42±4.21	26.74±3.97	0.416 (NS)
Waist Circumference (cm), Mean±SD	98.67±7.93	99.33±9.61	98.01±9.38	0.196 (NS)
SBP (mmHg), Mean±SD	130.97±16.72	131.18±18.71	130.76±16.74	0.806 (NS)
DBP (mmHg), Mean±SD	80.51±2.61	79.36±8.70	81.63±8.49	0.471 (NS)
Pulse (BPM), Mean±SD	83.34±10.50	83.33±10.50	83.36±9.85	0.641 (NS)
Duration of Diabetes (years), Mean±SD	10.17±6.29	12.19±7.53	6.15±5.49	0.0008
DEMIMS [®] diet compliance score, Mean±SD	1.56±0.41	1.68±0.51	1.44±0.51	0.006
DEMIMS [®] exercise compliance score, Mean±SD	1.52±0.28	1.57±0.54	1.47±0.52	0.633 (NS)
Glucometer usage, n (%)	276 (53.28)	107 (64.84)	169 (47.87)	0.00012
Mild hypoglycemia, n (%)	26 (5.01)	12 (7.27)	14 (3.96)	0.243 (NS)
Severe hypoglycemia, n (%)	3 (0.58)	1 (0.06)	2 (0.57)	0.791 (NS)
Hypertension, n (%)	292 (56.37)	107 (64.84)	185 (52.41)	0.023
Cerebrovascular accident, n (%)	8 (1.54)	2 (1.21)	6 (1.70)	0.672 (NS)
Coronary artery disease, n (%)	45 (8.69)	21 (12.72)	24 (6.80)	0.048
Cancer, n (%)	6 (1.16)	4 (2.42)	2 (1.21)	0.201 (NS)
HbA1c (%), Mean±SD	8.34±1.86	7.89±1.98	8.79±1.96	0.00002
FPG (mg/dL), Mean±SD	181.54±69.71	172.65±68.86	190.44±80.84	0.011
PPPG (mg/dL), Mean±SD	257.32±98.01	247.56±91.84	267.08±98.81	0.040
Serum Creatinine (mg/dL), Mean±SD	0.85±0.32	0.89±0.39	0.80±0.20	0.002
eGFR (cm ³ /min/1.73 sqmBSA), Mean±SD	99.32±31.72	96.36±42.84	102.26±29.28	0.094 (NS)
Uric Acid (mg/dL), Mean±SD	5.49±1.52	5.57±1.98	5.41±1.83	0.728 (NS)
LDL-c (mg/dL), Mean±SD	98.42±36.92	92.79±39.78	104.05±38.61	0.006
Statin Usage, n (%)	231 (44.6)	93 (56.36)	138 (39.09)	0.0004

between insulin (±OAD) and OAD only cohorts. $P < 0.05$ is considered significant. $P > 0.05$ is non-significant. BMI, Body Mass Index; BPM, Beats Per Minute; BSA, Body Surface Area; DBP, Diastolic Blood Pressure; DEMIMS[®], Diabetes, Endocrinology and Metabolic Disease Information Management System; eGFR, Estimated Glomerular Filtration Rate; FPG, Fasting Plasma Glucose; HbA1c, Glycated Hemoglobin; LDL-c, Low-Density Lipoprotein Cholesterol; OAD, Oral Anti-Diabetic Drug; PPPG, Post Prandial Plasma Glucose; SBP, Systolic Blood Pressure

Table 4: Comparison of DAWN-QOL: Insulin users vs Non-insulin users

	Insulin±OAD cohort, n=165		OAD cohort, n=353		P (Mann-Whitney U test)
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
DAWN QOL-A [6--1]	5.35±0.89	6 (5-6)	4.95±1.14	5 (4-5)	0.0008
DAWN QOL-B [6--1]	4.41±1.23	5 (4-5)	4.54±1.17	5 (4-5)	0.238
DAWN QOL-C [6--1]	5.69±0.95	6 (5-6)	5.25±1.13	5 (4-5)	0.004
DAWN QOL-D [6--1]	5.16±1.08	5 (5-6)	4.99±1.26	5 (5-6)	0.139
DAWN QOL-E [6--1]	5.26±1.08	6 (5-6)	3.99±1.33	5 (4-5)	0.034
Total	25.42±4.35	26 (24-28)	28.04±4.87	26 (23-28)	0.067

DAWN, Diabetes Attitudes, Wishes and Needs; OAD, Oral Anti-Diabetic Drug; QOL, Quality of Life

QOL scores in our study, underscoring the negative impact of poor metabolic control on QOL.^[22,23] It was observed that average DAWN score was highest (27.13 ± 4.92) in the individuals with well-controlled glycemic status. In line with these findings, almost 72% (119 out of 165) of individuals reported HbA1c < 7% in the insulin \pm OAD cohort whereas the same was observed in 33% (116 out of 353) of individuals in the OAD only cohort. Patients on insulin were older with more prolonged duration of diabetes behind them compared to their counterparts in the other group. Apparently, both confounding factors could not undermine the positive impact of better metabolic control arguably due to insulin therapy. It could have been possible that many patients in the OAD only cohort required treatment intensification with up-titration of OAD doses, or more liberal usage of newer OADs or insulin initiation, which may have been delayed due to inertia on the clinician's part. Although the benefits of early insulin treatment have been proven in studies,^[18] delayed initiation is still common in daily practice causing rise in HbA1c, which in turn can affect the QOL of the patients.^[24,25]

There are contradictory findings in scientific literature with regard to superiority of treatment with insulin versus that with OAD in improving the quality of life of PWD.^[19,20,26] As per the patient's response on DAWN QOL questionnaire, majority of the patients enjoyed moderate to good quality of life in both the cohorts. In our study, in 3 out of 5 DAWN QOL parameters (A, C, E) scores were significantly higher amongst the insulin users. However, overall mean score was insignificantly higher in the insulin \pm OAD cohort [Table 4]. Interestingly, DAWN QOL scores of analog insulin users (25.77 ± 5.73) were significantly higher than patients on human insulin [24.13 ± 4.88]; Odds ratio, OR = 1.236, 95% CI: 1.161 to 1.532, $P = 0.037$]. Our study findings could validate earlier reports^[27] which confirmed association of insulin analogs with lower risks of hypoglycemia, lower levels of PPG excursions, enhanced patient adherence to treatment regimen, and enhanced quality of life.

Significantly higher usage of SU (60.06%), remarkably lower exclusive usage of newer agents like DPP-4i and SGLT-2i (8.21%) amongst patients not taking insulin could be the likely reason for lack of difference in hypoglycemia incidence between the two groups [Table 3]. The OAD usage clearly reflects the concomitant practice pattern of the period when the study was conducted (early 2016).

We adopted a unique tool called DEMIMS[©] lifestyle management score for dietary and exercise compliance [Table 1]. The diet compliance score of the insulin \pm OAD cohort was significantly higher than that of the OAD only cohort suggesting that T2DM patients on insulin therapy adhered to better dietary patterns and maintained a better QOL. This finding was in line with an earlier Indian study.^[28] Even DAWN QOL-A (Diet) score for insulin \pm OAD cohort was significantly higher than that of the comparator group. Such similarity

indicates the validity, reproducibility and adaptability of a novel DEMIMS[©] scoring system [details in Table 1].

It has been observed in earlier prospective and cross-sectional studies that diabetic patients are prone to develop macro- and micro-vascular complications and absence of these comorbidities have significant positive impact in QOL.^[29,30] Incidence of a common macrovascular complication namely CAD was significantly higher ($P = 0.048$) in the insulin \pm OAD cohort (12.72%) whereas CVA was marginally lower (1.21%) [Table 3]. We did not collect data for microvascular complications. Ours was not an interventional study, and we had to rely only on the recalling ability of the participants. Documentary proof of the different past event or past laboratory test results were not always available for validation. Hence, a definitive conclusion cannot be drawn in this regard. Also, there were significantly higher numbers having hypertension in the insulin cohort (64.84% vs 52.41%; $P = 0.023$); [Table 3]) Additionally, our study reflected an increase in statin users in the insulin \pm OAD cohort versus OAD only cohort (56.36% vs. 39.09%, $P < 0.001$). This may indicate better motivation on the part of HCPs and of PWD towards treatment intensification to achieve both glycemic and extra glycemic goals. On the other hand, intense insulin usage may mediate positive effects on the lipid profile including reductions in LDL-c levels and dramatic improvement of glycemic control.^[31,32] The same is also reflected in our study where there is significant lowering ($P = 0.006$) of LDL-c levels in the insulin cohort.

QOL scores were possibly not influenced by co-morbid confounders like obesity, hypoglycemia, blood pressure control, or socio-demographic confounders like income and education as these parameters were almost similar in both the cohorts [Table 3]. Nevertheless, better education coupled with more frequent visits to diabetes educators for insulin teaching might have contributed to better knowledge in insulin users.

Study limitations

The results of this study required to be analyzed on the background of several limitations. This study, being a cross-sectional study, only discusses association analysis and not causation. As the questionnaire was filled up in the clinic in presence of HCPs and not done in a blinded manner some biases in response by PWD cannot be ruled out. Secondly, though both socio-demographic and clinical variables were analyzed, health behavioral factors such as diabetes self-management, alcohol consumption, and smoking were not assessed. These variables also might have had an impact on the overall analysis. Consequently, despite these limitations, our findings are robust in providing future directives for improving the care of diabetic patients.

CONCLUSIONS

Concerted and collaborative efforts are required to revolutionize diabetes care. Future focus needs to be placed on implementation and international sharing of effective QOL tools for executing

a person-centered approach in chronic disease management and prevention. It is also pertinent to strike a balance between metabolic control and QOL eventually to improve patient satisfaction. Overall, insulin ± OAD users scored better, reported enhanced QOL owing to better diabetes-related knowledge and treatment adherence characteristics than their counterparts that used OAD alone, despite age of individuals and duration of diabetes being significantly higher amongst the former group.

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Conflicts of interest

There are no conflicts of interest.

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