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Assessment of Health-Related Quality of Life Among Patients With Type 2 Diabetes Mellitus Receiving Oral Antidiabetic and Insulin-Based Therapy: An Observational Study Using MDQoL-17

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ABSTRACT

Background:
Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder that adversely affects physical, psychological, and social well-being. Treatment-related factors, including the use of oral antidiabetic drugs and insulin, may influence health-related quality of life (HRQoL). The present study evaluated and compared quality of life among patients with T2DM receiving oral antidiabetic therapy and insulin-based treatment using the Modified Diabetes Quality of Life-17 (MDQoL-17) questionnaire.

Methods:
A total of 110 patients with T2DM were included, comprising 62 (56.4%) receiving oral antidiabetic therapy and 48 (43.6%) receiving insulin-based treatment. Demographic and clinical characteristics, including age, sex, diabetes duration, body mass index (BMI), and glycated haemoglobin (HbA1c), were assessed. Quality of life was evaluated across seven MDQoL-17 domains. Between-group comparisons were performed using Welch's independent-samples t-test or Mann–Whitney U test, as appropriate. Spearman's rank correlation was used to assess associations between clinical variables and total MDQoL-17 scores. Bonferroni correction was applied for multiple domain comparisons.

Results:
The mean age was 54.75 ± 10.15 years, and 56.4% of participants were female. Age, diabetes duration, and HbA1c were comparable between treatment groups ($p > 0.05$). BMI was significantly higher in the insulin group (28.57 ± 3.16 versus 26.41 ± 3.16 kg/m²; $p < 0.001$). Patients receiving oral therapy demonstrated higher mean scores across all seven quality-of-life domains. Nominally significant differences were observed in physical role limitations ($p = 0.031$), emotional well-being ($p = 0.013$), and social functioning ($p = 0.016$). The reported total MDQoL-17 score was higher in the oral-treatment group (440.24 ± 133.83 versus 377.04 ± 144.85; $p = 0.021$). However, no domain comparison remained statistically significant after Bonferroni correction. Total scores showed no significant correlations with HbA1c, diabetes duration, age, or BMI (all $p > 0.05$).

Conclusion:
Oral antidiabetic therapy was associated with numerically higher quality-of-life scores than insulin-based treatment, particularly in physical role limitations, emotional well-being, and social functioning. However, these exploratory differences require cautious interpretation because of multiple testing, potential confounding, and treatment-specific scoring. Further longitudinal studies are warranted.

KEYWORDS: Type 2 diabetes mellitus; quality of life; MDQoL-17; oral antidiabetic drugs; insulin therapy; health-related quality of life.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a major global public health challenge characterised by chronic hyperglycaemia resulting from progressive pancreatic β-cell dysfunction and insulin resistance. Beyond its metabolic consequences, T2DM is associated with cardiovascular disease, nephropathy, retinopathy, neuropathy, and premature mortality, imposing substantial clinical, psychological, and socioeconomic burdens. According to the International Diabetes Federation (IDF), approximately 589 million adults aged 20–79 years were living with diabetes worldwide in 2024, with projections reaching 853 million by 2050.1 These estimates emphasise the increasing need for comprehensive diabetes management strategies extending beyond glycaemic control.

India contributes substantially to the global diabetes burden. The IDF estimated that approximately 89.8 million Indian adults were living with diabetes in 2024, with this number projected to increase to 156.7 million by 2050.1 The Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) study reported approximately 101 million individuals with diabetes, highlighting the considerable burden across diverse Indian populations.2 Differences between estimates reflect variations in

study populations, age ranges, and estimation methods. Rapid urbanisation, sedentary lifestyles, dietary transitions, obesity, and population ageing have contributed to the growing challenge. Consequently, improving long-term outcomes requires attention not only to metabolic parameters but also to patients' functional abilities and psychosocial well-being.

Health-related quality of life (HRQoL) is an important patient-centred outcome encompassing physical functioning, emotional health, social relationships, and perceived general health. Patients with T2DM frequently experience fatigue, limitations in daily activities, psychological distress, fear of complications, and challenges associated with lifelong treatment. These factors may adversely influence treatment adherence, self-management behaviours, and overall well-being. The multinational Diabetes Attitudes, Wishes and Needs (DAWN2) study highlighted the substantial psychosocial burden of diabetes, demonstrating that emotional distress and impaired quality of life remain important concerns despite advances in pharmacological management.[3] Thus, assessment of HRQoL provides complementary information that cannot be adequately captured through glycated haemoglobin (HbA1c) measurements alone.3

Pharmacological management of T2DM includes oral antidiabetic agents, injectable therapies, and insulin, selected according to glycaemic status, comorbidities, individual preferences, and treatment response. Oral antidiabetic medications may offer convenient administration, whereas insulin therapy is frequently required when glycaemic targets cannot be achieved through other treatment strategies. However, insulin administration may introduce additional challenges, including injection-related discomfort, fear of hypoglycaemia, weight gain, treatment complexity, and increased self-monitoring requirements. Conversely, improved glycaemic control and symptom relief following insulin initiation may positively influence HRQoL.4 Therefore, the relationship between treatment modality and quality of life is complex and cannot be explained solely by medication type.

Evidence from the Indian A1chieve study demonstrated improvements in HRQoL following initiation or modification of insulin analogue therapy, indicating that insulin treatment may enhance patient-reported outcomes when accompanied by improved diabetes management.4 Nevertheless, differences in disease severity, treatment burden, and psychosocial circumstances may influence quality-of-life outcomes between patients receiving oral medications and insulin.

Assessment of diabetes-related quality of life requires appropriate, culturally relevant instruments. Nagpal et al. developed and validated the Quality of Life Instrument for Indian Diabetes Patients (QOLID), demonstrating the importance of evaluating domains relevant to Indian patients.5 The Modified Diabetes Quality of Life-17 (MDQoL-17) questionnaire provides a multidimensional assessment of physical functioning, role limitations, energy/fatigue, emotional well-being, social functioning, and general health. Domain-specific evaluation may identify difficulties that remain undetected during routine clinical assessment.6

Despite increasing recognition of patient-reported outcomes, comparative Indian evidence examining quality-of-life domains across oral antidiabetic and insulin-based treatment groups remains clinically relevant. Furthermore, associations between HRQoL and age, diabetes duration, body mass index, and HbA1c require evaluation within different patient populations. Therefore, the present study aimed to compare MDQoL-17 domain and total scores among patients with T2DM receiving oral antidiabetic therapy or insulin-based treatment and to examine their associations with selected demographic and clinical characteristics.Objectives

Primary objective: To compare the baseline-to-six-month change in MDQoL-17 overall score between oral-treatment and insulin-based treatment groups. Secondary objectives: To describe domain-level changes, evaluate trajectories at baseline, three and six months, and explore associations with age, sex, diabetes duration, BMI, glycaemic control and hypoglycaemic events..

MATERIALS AND METHODS

Study design and setting. The investigation was described as a prospective, comparative, observational follow-up study conducted in the Department of Community Medicine, Hind Institute of Medical Sciences, Ataria, Sitapur, Uttar Pradesh, India. The documented study period extended from May 2025 to June 2026. All the study participants written informed consent singed before recruitment.

Participants included in cohort comprised 110 adults aged 18 years or older with diagnosed T2DM. Sixty-two participants were classified in the oral-antidiabetic-treatment group, and 48 in the insulin-based-treatment group, which could include concomitant oral medication. Excluded from study inability to complete the questionnaire, severe acute illness and pregnancy.

Data collection and follow-up: The recording of each cases included age, sex, educational attainment, occupation, socioeconomic characteristics, duration of diabetes, body mass index (BMI), comorbidities, diabetes complications, medication regimen, HbA1c, fasting plasma glucose and hypoglycaemia history. Quality of life was scheduled for assessment at baseline, month 3 and month 6.

Outcome assessment. The supplied MDQoL-17 instrument contained 17 questions across physical, emotional, social and general-health domains.4 Crucially, the provided questionnaire assigned different numerical weights to identical response categories for oral-treatment and insulin-treatment patients.

Statistical Analysis

Continuous variables were summarized using mean ± standard deviation, and categorical variables as frequencies and percentages. The Shapiro–Wilk test assessed normality separately within each treatment group. Welch's independent-samples t-test was used for approximately normally distributed continuous variables; otherwise, the Mann–Whitney U test was used. Pearson's chi-square test was used for categorical comparisons, with Fisher's exact test indicated when expected cell frequencies were inadequate. Spearman's rank correlation evaluated associations between clinical characteristics and total MDQoL-17 score. All tests were two-sided, with $p < 0.05$ indicating nominal significance. Seven domain-level comparisons were additionally considered using a Bonferroni-adjusted threshold of $p < 0.0071$.

RESULTS

Demographic and clinical characteristics

A total of 110 patients with type 2 diabetes mellitus were included. Of these, 62 (56.4%) received oral antidiabetic therapy and 48 (43.6%) received insulin-based treatment. The overall mean age was 54.75 ± 10.15 years. There were 62 females (56.4%) and 48 males (43.6%). Age, diabetes duration and HbA1c did not differ significantly between treatment groups ($p > 0.05$). BMI was higher in the insulin group (28.57 ± 3.16 vs 26.41 ± 3.16 kg/m²; $p < 0.001$).

Table 1. Clinical characteristics by treatment group

Variable	Oral (n=62)	Insulin (n=48)	Test	p-value
Age, years	53.92 ± 11.50	55.83 ± 8.08	Welch's t	0.308
Duration, years	8.50 ± 4.99	8.09 ± 3.76	Welch's t	0.630
BMI, kg/m²	26.41 ± 3.16	28.57 ± 3.16	Welch's t	<0.001
HbA1c, %	8.40 ± 1.42	8.12 ± 1.05	Welch's t	0.247

The mean ± SD for all variables presented in table-1. The preceding analysis reported no significant differences in sex ($p = 0.714$), education ($p = 0.657$), occupation ($p = 0.262$), comorbidity presence ($p = 0.967$) or complication presence ($p = 0.385$).

MDQoL-17 domain comparisons

The mean scores were numerically higher in the oral-treatment group across all seven domains. Nominally significant differences were reported for physical role limitations, emotional well-being and social functioning. None of the seven domain comparisons met the Bonferroni-adjusted significance threshold.

Table 2. MDQoL-17 scores by treatment group

Domain	Oral mean ± SD	Insulin mean ± SD	Test	p-value
Physical functioning	46.21 ± 12.46	40.28 ± 16.65	Mann–Whitney U	0.338
Physical role limitations	22.13 ± 10.83	19.17 ± 12.00	Mann–Whitney U	0.031
Emotional role limitations	20.56 ± 9.27	17.56 ± 10.24	Mann–Whitney U	0.081
Energy/fatigue	19.81 ± 12.37	16.71 ± 9.73	Mann–Whitney U	0.056
Emotional well-being	21.08 ± 8.40	17.15 ± 7.83	Welch's t	0.013
Social functioning	21.01 ± 8.79	17.16 ± 7.75	Welch's t	0.016
General health	23.76 ± 10.05	21.71 ± 10.04	Mann–Whitney U	0.283
Total MDQoL-17 score	440.24 ± 133.83	377.04 ± 144.85	Welch's t	0.021

The total MDQoL-17 score was numerically higher in the oral-treatment group (440.24 ± 133.83) than in the insulin group (377.04 ± 144.85; nominal $p = 0.021$). Interpretation of group differences is limited by the treatment-specific item scoring.

Table 3. Spearman correlations with total MDQoL-17 score

Clinical variable	Spearman's ρ	p-value
HbA1c	0.061	0.527
Diabetes duration	0.056	0.562
Age	−0.076	0.431
BMI	−0.166	0.083

There is no statistically significant correlation was observed between total MDQoL-17 score and HbA1c, diabetes duration, age or BMI.

DISSCUSSION:

The present study evaluated health-related quality of life (HRQoL) among 110 patients with type 2 diabetes mellitus (T2DM), comparing patients receiving oral antidiabetic therapy with those receiving insulin-based treatment using the Modified Diabetes Quality of Life-17 (MDQoL-17) questionnaire. The findings demonstrated numerically higher quality-of-life scores across all seven domains among patients receiving oral antidiabetic therapy. Differences in physical role limitations, emotional well-being, and social functioning were statistically significant at the conventional threshold of $p < 0.05$. However, none of the seven domain comparisons remained statistically significant after Bonferroni correction for multiple testing (adjusted significance threshold, $p < 0.0071$). These findings suggested a possible association between treatment modality and patient-reported quality of life, although the evidence was insufficient to establish an independent or causal effect of insulin treatment.

The study population had a mean age of 54.75 ± 10.15 years, with females accounting for 56.4% and males for 43.6% of participants. The oral antidiabetic group comprised 62 patients (56.4%), whereas 48 patients (43.6%) received insulin-based treatment. The mean age, duration of diabetes, and HbA1c levels were comparable between the two treatment groups,

suggesting that these measured characteristics were unlikely to explain substantial baseline differences between the groups. However, the insulin-treated group had a significantly higher mean BMI than the oral-treatment group (28.57 ± 3.16 versus 26.41 ± 3.16 kg/m²; $p < 0.001$).

The higher BMI observed among insulin-treated patients may have reflected differences in underlying metabolic characteristics, treatment history, or weight changes associated with insulin therapy. Nevertheless, the cross-sectional group comparison did not establish whether increased BMI preceded or followed insulin initiation. In addition, the absence of significant differences in measured clinical characteristics did not exclude confounding by disease severity, previous glycaemic control, hypoglycaemic episodes, treatment duration, or other unmeasured factors.

The present study found higher mean scores in the oral antidiabetic group across physical functioning, physical role limitations, emotional role limitations, energy/fatigue, emotional well-being, social functioning, and general health. Physical role limitations showed a nominally significant difference between groups (22.13 ± 10.83 versus 19.17 ± 12.00; $p = 0.031$). Similarly, emotional well-being (21.08 ± 8.40 versus 17.15 ± 7.83; $p = 0.013$) and social functioning (21.01 ± 8.79 versus 17.16 ± 7.75; $p = 0.016$) were higher among patients receiving oral antidiabetic treatment.

These observations may reflect the greater day-to-day demands associated with insulin administration, including injection schedules, glucose monitoring, concerns about hypoglycaemia, and the need to coordinate treatment with meals and daily activities. However, such mechanisms were not directly measured in the present study and should therefore be regarded as possible explanations rather than demonstrated causes.

The overall MDQoL-17 score was also higher among oral-treatment recipients (440.24 ± 133.83) than among insulin-treated patients (377.04 ± 144.85; $p = 0.021$). This nominal difference suggested an association between treatment group and the reported total score. However, the interpretation of this finding required particular caution because treatment-specific item scoring could affect the comparability of the total MDQoL-17 scores. Consequently, the observed difference should not be interpreted as definitive evidence of superior overall quality of life with oral therapy until scoring equivalence has been established.

The present study did not identify statistically significant correlations between total MDQoL-17 score and HbA1c ($\rho = 0.061$; $p = 0.527$), duration of diabetes ($\rho = 0.056$; $p = 0.562$), age ($\rho = -0.076$; $p = 0.431$), or BMI ($\rho = -0.166$; $p = 0.083$).

These findings suggested that the measured clinical characteristics were not strongly associated with the total quality-of-life score in this study population. The weak negative correlation between BMI and total MDQoL-17 score did not reach statistical significance, although it could warrant further investigation in larger studies.

The lack of a significant association between HbA1c and quality of life indicated that glycaemic control alone might not adequately represent the patient's overall experience of diabetes. Psychosocial well-being, treatment burden, functional limitations, and social circumstances may contribute to quality of life independently of a single HbA1c measurement. However, the absence of statistically significant correlations should not be interpreted as evidence that these clinical variables have no influence on quality of life.

The findings of the present study were partially consistent with those reported by Shirali et al. (2026), who evaluated quality of life among 272 insulin-treated patients with T2DM in tertiary care hospitals in Mangalore, India. Using the Quality-of-Life Instrument for Indian Diabetes Patients (QOLID), the investigators reported a mean overall score of 126.36 ± 21.69, with relatively low scores in role limitations, physical endurance, and emotional health. Patients receiving insulin combined with oral antidiabetic drugs reported better physical endurance and overall quality of life than those receiving insulin alone. These findings supported the importance of treatment-related factors in patient-reported well-being. However, direct numerical comparison with the present study was inappropriate because different quality-of-life instruments and treatment-group definitions were used.7

Mishra et al. (2024) conducted an Indian study at the Indira Gandhi Institute of Medical Sciences, Patna, evaluating HRQoL among patients with T2DM using the EQ-5D-5L questionnaire and visual analogue scale. Their study included patients receiving oral hypoglycaemic agents, insulin, or combination therapy. They observed significant associations between age and quality-of-life measurements. In contrast, the present study found no significant correlation between age and total MDQoL-17 score ($\rho = -0.076$; $p = 0.431$). This difference could reflect variation in study populations, sample sizes, quality-of-life instruments, and analytical approaches.8

Similarly, Rangari et al. (2025), in a hospital-based cross-sectional study involving 297 patients with T2DM in Yavatmal, Maharashtra, reported a mean age of 55.18 ± 11.09 years, closely resembling the mean age of 54.75 ± 10.15 years in the present study. Using WHOQOL-BREF, they observed the highest mean domain score for social relationships (58.78 ± 15.49) and the lowest for physical health (51.83 ± 12.31). Education and socioeconomic status were significantly associated with quality-of-life domains. Although education did not differ significantly between the treatment groups in the present study ($p = 0.657$), this result did not establish that education was unrelated to quality of life, because the analysis assessed group comparability rather than the direct association between educational status and MDQoL-17 scores.9

A recent Indian study by Shirali et al. also identified poor glycaemic control and diabetic complications as important determinants of reduced quality of life. This contrasted with the absence of a significant correlation between HbA1c and total MDQoL-17 score in the present study ($\rho = 0.061$; $p = 0.527$). Differences in measurement instruments, population characteristics, and the distribution of diabetic complications may have contributed to the discrepancy. Furthermore, a single HbA1c measurement may not adequately capture long-term glycaemic variability, hypoglycaemic burden, or the cumulative impact of diabetes on daily functioning.7

An important earlier Indian investigation was the A1chieve study, which evaluated health-related quality of life in 20,554 Indian patients with T2DM following initiation or modification of insulin analogue therapy. Quality of life was assessed at baseline and after 24 weeks using the EQ-5D questionnaire. Significant improvements were observed across insulin regimens, including among insulin-naïve and previously insulin-treated patients. These findings differed from the lower scores observed among insulin-treated patients in the present study. However, the A1chieve study evaluated within-patient improvement following insulin treatment, whereas the present analysis compared two treatment groups. Therefore, the findings were not necessarily contradictory. Insulin therapy may improve quality of life through better glycaemic control while simultaneously imposing additional treatment-related demands.10-11

The importance of psychosocial factors was also demonstrated in the multinational Diabetes Attitudes, Wishes and Needs (DAWN-2) study, which included 8,596 adults with diabetes across 17 countries. The investigators reported likely depression in 13.8% and poor quality of life in 12.2% of respondents. Diabetes adversely affected physical health, family relationships, and other aspects of everyday life. These findings provided broader support for the present study's emphasis on emotional well-being and social functioning. However, depression and diabetes-related distress were not separately measured in the present analysis, preventing direct comparison of their prevalence. 12

More recent international evidence also suggested that the relationship between insulin treatment and quality of life depended on treatment characteristics. Polonsky et al. (2024), using patient-reported outcomes from the ONWARDS clinical trial programme, reported improved treatment satisfaction with once-weekly insulin icodec compared with once-daily basal insulin. This suggested that reducing treatment frequency and complexity could improve patient experience. Therefore, lower quality-of-life scores in insulin-treated patients should not automatically be attributed to insulin itself; injection frequency, treatment complexity, individual preferences, and glycaemic outcomes may all influence patient-reported well-being.13

The present findings highlighted the importance of incorporating patient-reported outcomes into routine diabetes management. Although oral antidiabetic therapy was associated with numerically higher quality-of-life scores, treatment decisions should not be based solely on these unadjusted comparisons. Insulin remains an essential therapeutic option for patients requiring additional glycaemic control.

The findings supported the potential value of individualised diabetes education, counselling regarding insulin administration, assessment of treatment burden, screening for emotional distress, and appropriate family involvement. Particular attention to physical limitations, emotional well-being, and social functioning may help clinicians identify difficulties that are not apparent from routine biochemical investigations.

The present study assessed seven distinct quality-of-life domains among patients receiving two commonly used treatment approaches, providing a multidimensional assessment of patient-reported health. The inclusion of clinical variables such as HbA1c, BMI, age, and diabetes duration also permitted exploratory evaluation of their relationships with overall quality of life. Nevertheless, several limitations should be acknowledged. The relatively modest sample size of 110 patients may have limited statistical power, particularly for detecting small associations. Treatment allocation was not randomised, and unmeasured confounding, including differences in disease severity, treatment history, hypoglycaemia, and socioeconomic circumstances, may have influenced the findings. No adjusted multivariable comparison was presented.

Although three domains demonstrated nominally significant between-group differences, none remained significant after correction for seven comparisons. Furthermore, treatment-specific MDQoL-17 scoring may have compromised direct comparison of total scores between the oral and insulin groups. Finally, the supplied results did not include paired baseline and six-month measurements. Therefore, changes in quality of life over six months could not be established from these analyses, despite the longitudinal wording of the proposed study title.

CONCLUSION

The present study demonstrated numerically higher MDQoL-17 scores among patients with T2DM receiving oral antidiabetic therapy compared with those receiving insulin-based treatment. Nominally significant differences were observed in physical role limitations, emotional well-being, social functioning, and the reported total score. However, none of the seven domain comparisons remained significant after adjustment for multiple testing. No significant correlations were identified between the total MDQoL-17 score and age, diabetes duration, HbA1c, or BMI. These findings highlighted the multidimensional nature of diabetes-related quality of life and the need for further longitudinal studies using comparable, validated scoring methods and adjusted analyses to clarify the independent relationship between treatment modality and patient-reported outcomes.

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