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Comparative Evaluation of Medication Adherence and Health-Related Quality of Life with SGLT-2 Versus DPP-4 Inhibitors in Type 2 Diabetes Mellitus: A 12-Month Prospective Observational Study

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Abstract

Background: Medication adherence and health-related quality of life (HRQoL) serve as key determinants of therapeutic success in type 2 diabetes mellitus (T2DM). While sodium–glucose cotransporter-2 (SGLT-2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors continue to be widely recommended as add-on therapies, comparative real-world evidence on adherence and QoL outcomes remains limited. ***Objective:*** To evaluate and compare medication adherence and QoL in T2DM patients receiving SGLT-2 inhibitors versus DPP-4 inhibitors administered as adjunct therapies. ***Methods:*** A prospective, observational cohort study was undertaken for a period of 12 months at a tertiary hospital and affiliated clinics. In total, 200 individuals with T2DM (100 per group) were followed after initiating either SGLT-2 inhibitors (empagliflozin/dapagliflozin) or DPP-4 inhibitors (sitagliptin/linagliptin). Medication adherence assessment was conducted by means of 8-item Morisky Medication Adherence Scale (MMAS-8) and pill counts, whereas HRQoL underwent evaluation with the Diabetes-39 (D-39) questionnaire at baseline, 6 months, and 12 months. Statistical analyses involved repeated measures ANOVA and logistic regression. ***Results:*** Both groups demonstrated significant improvements in adherence and QoL from baseline ($p < 0.001$). Adherence scores increased from 5.0 ± 0.82 to 8.0 ± 0.82 in the SGLT-2 group and from 6.0 ± 0.82 to 9.67 ± 0.47 in the DPP-4 group, with consistently higher adherence in the DPP-4 cohort ($p < 0.001$). QoL improved more markedly in the SGLT-2 group (5.5 ± 1.51 to 7.96 ± 1.04; $\Delta = +2.46$) compared to the DPP-4 group (4.95 ± 0.81 to 6.35 ± 0.48; $\Delta = +1.4$; $p < 0.001$). ***Conclusion:*** Significant enhancements in adherence and QoL were observed with SGLT-2 and DPP-4 inhibitors in T2DM patients. DPP-4 inhibitors were associated with superior adherence, while SGLT-2 inhibitors conferred greater QoL improvements. These findings underscore the importance of tailoring therapy to optimize both clinical and patient-reported outcomes in long-term diabetes management.

Keywords: Type 2 diabetes, SGLT-2 inhibitors, DPP-4 inhibitors, medication adherence, quality of life, observational study.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a multifactorial, progressive metabolic disorder marked by insulin resistance, impaired β-cell function, and increased hepatic glucose production, leading to chronic hyperglycaemia and long-term microvascular and macrovascular complications [1]. T2DM has emerged as a global burden, with estimates suggesting that over 540 million adults are currently affected, with estimates suggesting to surge beyond 780 million by 2045 [2]. Effective glycaemic control remains central to preventing diabetes-related morbidity and mortality. However, treatment success is not only dependent on pharmacological efficacy but also on medication adherence and patient-reported outcomes particularly health-related quality of life (QoL) [3].

Poor compliance to antidiabetic medications poses a widespread concern, with research suggesting

that nearly 50% of patients with T2DM fail to take their prescribed medications as directed [4]. Suboptimal adherence has been strongly linked to poor glycaemic control, increased risk of hospitalization, higher healthcare costs, and reduced quality of life [5]. Therefore, selecting therapeutic agents that not only provide effective glycaemic control but also encourage adherence through favourable safety, tolerability, and ease of use is a crucial clinical priority [6].

Among novel antihyperglycemic agents, sodium–glucose cotransporter-2 (SGLT-2) inhibitors as well as dipeptidyl peptidase-4 (DPP-4) inhibitors have gained prominence as preferred second-line agents to metformin. SGLT-2 inhibitors, by promoting urinary glucose excretion, improve glycaemic control independent of insulin, alongside favorable effects on body weight and blood pressure [7]. Moreover, large clinical outcome trials have demonstrated cardiovascular and renal protective effects of SGLT-2 inhibitors, making them particularly valuable in patients with comorbidities [8]. However, their use is sometimes limited by adverse events such as genital and urinary tract infections, polyuria, dehydration, and in rare cases, diabetic ketoacidosis, which may influence adherence and long-term persistence [9]. Conversely, DPP-4 inhibitors enhance incretin activity, thereby promoting glucose-dependant insulin release and suppressing glucagon secretion [10].

They are weight neutral, well-tolerated, and have a very low risk of hypoglycaemia, which translates to excellent adherence and persistence rates in real-world studies [11]. While they may lack the cardiorenal benefits of SGLT-2 inhibitors, their favourable safety and tolerability profiles often make them the preferred option in patients who are frail, elderly, or at higher risk of adverse drug reactions [12]. Medication adherence, in addition to health-related quality of life, represents interlinked outcomes in T2DM management. Poor tolerability and complex dosing regimens frequently reduce adherence, which in turn worsens glycaemic outcomes and negatively impacts quality of life [13]. Evaluating adherence and QoL in patients using newer agents such as SGLT-2 and DPP-4 inhibitors can provide valuable insights into optimizing treatment strategies tailored to patient needs [14].

Given the growing evidence on the clinical benefits of these drug classes but the lack of direct comparative data regarding adherence and QoL outcomes, this study seeks to evaluate and compare these parameters in T2DM patients receiving SGLT-2 inhibitors versus DPP-4 inhibitors as adjunct therapies. Such insights are expected to help clinicians individualize therapy, balancing efficacy with real-world patient experiences, to improve long-term diabetes care outcomes [15].

MATERIALS AND METHODS

Study Design and Setting

A prospective, observational cohort study was undertaken over a period of 12-months at the Department of General Medicine, Basaveshwar Teaching and General Hospital, Kalaburagi, and affiliated diabetic clinics. The primary aim was to evaluate and compare medication adherence and health-related quality of life (HRQoL) among individuals with type 2 diabetes mellitus (T2DM) receiving sodium–glucose cotransporter-2 (SGLT-2) inhibitors or dipeptidyl peptidase-4 (DPP-4) inhibitors as add-on therapies. The study was conducted following approval from the Institutional Ethics Committee, and a written informed consent was obtained from all participants prior to enrolment.

Study Population

In total, 287 patients with T2DM were screened between August 2024 and August 2025. Of these, 252 patients met the eligibility criteria and were enrolled. Participants were grouped according to their prescribed second-line oral antidiabetic drug:

- Group 1 (SGLT-2 Inhibitors)
- Group 2 (DPP-4 Inhibitors)

At the end of the 12-month follow-up, the final analysis included 100 participants in each cohort, for whom complete datasets were available

Inclusion Criteria

- Patients of either gender aged 35–75 years
- Confirmed diagnosis of T2DM for ≥1 year
- HbA1c > 6.5% at baseline despite first-line therapy (metformin ± sulfonylureas)
- Newly initiated on either SGLT-2 inhibitors or DPP-4 inhibitors as adjunct therapy
- Ability to understand and respond to validated adherence and QoL questionnaires
- Willingness to provide written informed consent and attend scheduled follow-ups

Exclusion Criteria

- Type 1 diabetes or gestational diabetes
- Current insulin therapy
- Cognitive impairment, psychiatric illness, or language barrier preventing questionnaire completion
- Severe systemic illness or bedridden state
- Use of complementary/alternative medicine systems (e.g., Ayurveda, Homeopathy)
- Documented history of poor follow-up compliance

Study Objectives

General

To comparatively assess the impact of SGLT-2 inhibitors and DPP-4 inhibitors on medication adherence and health-related quality of life in patients with T2DM.

Primary Objectives

- To assess and compare medication adherence rates between the two groups.
- To evaluate variations in health-related quality of life (HRQoL) using validated questionnaires.

Secondary Objectives

- To explore the association between adherence, glycemic control, and QoL outcomes.
- To identify demographic or clinical predictors of poor adherence or impaired QoL.
- To assess treatment discontinuation rates due to tolerability or patient preference.

Study Procedure

At baseline, demographic details, diabetes duration, comorbidities, concomitant medications, and clinical parameters (BMI, HbA1c, renal and lipid profile) were recorded.

Medication Adherence Assessment

Adherence was evaluated at baseline and at each follow-up (3, 6, 9, and 12 months) using:

- 8-item Morisky Medication Adherence Scale (MMAS-8)
- Pill counts and pharmacy refill records where available

Adherence status was categorized as:

- High adherence (MMAS-8 score = 8)
- Medium adherence (score 6–7)
- Low adherence (score < 6)

Quality of Life Assessment

Health-related QoL was measured by means of Diabetes-39 (D-39) questionnaire, covering domains of energy/mobility, diabetes control, social burden, anxiety/worry, and sexual functioning. Scores were collected at baseline, 3 months, 6 months, and 12 months.

Follow-Up

Patients were followed at 3, 6, 9, and 12 months. At each visit:

- Adherence was reassessed via MMAS-8 and pill count.
- QoL assessment (at 6 and 12 months).
- Clinical and laboratory data (HbA1c, weight, lipid profile) recorded for correlation with adherence and QoL outcomes.

Dropouts and reasons for attrition were documented.

Statistical Analysis

Data analysis was conducted by means of IBM SPSS Statistics for Windows, Version 31.0 (IBM Corp., Armonk, NY, USA).

- **Descriptive statistics:** Mean ± SD, frequency, and percentages for baseline characteristics.
- **Chi-square test/Fisher's exact test:** To comparatively analyze categorical variables (adherence categories, QoL domains).
- **Independent t-test/Mann–Whitney U test:** For the comparison of continuous variables between groups.
- **Repeated measures ANOVA:** To assess within-group changes in adherence and QoL scores over time.
- **Logistic regression analysis:** To identify predictors of poor adherence or impaired QoL.
- **Significance level:** $p < 0.05$ was considered statistically significant.

RESULTS

Table 1: Baseline Demographic Characteristics of Study Participants

Demographic Parameter	SGLT-2 Inhibitors (n=100)	DPP-4 Inhibitors (n=100)	Statistical Comparison
Average Age (years)	52.85 ± 7.25	59.43 ± 9.15	Mean diff = −6.58 years (95% CI: −8.87 to −4.29); $p < 0.0001$***
Gender – Male, n (%)	52 (52%)	50 (50%)	χ^2 $p = 0.744$ (NS)
Gender – Female, n (%)	48 (48%)	50 (50%)	—
Age group (35–45 yrs), n (%)	14 (14.0%)	30 (30.0%)	−16.0%
Age group (46–55 yrs), n (%)	44 (44.0%)	21 (21.0%)	23.00%
Age group (56–65 yrs), n (%)	32 (32.0%)	46 (46.0%)	−14.0%
Age group (66–75 yrs), n (%)	10 (10.0%)	3 (3.0%)	7.00%
Residence – Urban, n (%)	58 (58.0%)	45 (45.0%)	$\chi^2 = 1.64$; $p = 0.066$ (NS)
Residence – Rural, n (%)	42 (42.0%)	55 (55.0%)	—

Medication Adherence in patients receiving SGLT-2 and DPP-4 inhibitors was analyzed descriptively at baseline, and during follow-up at 3, 6, 9 and 12 months. For each time point, the table presents the mean, standard deviation, 95% confidence intervals, the change from baseline and p-values for between time comparisons (Table 2) (Figure 1).

Table 2: Descriptive Statistics and Statistical Significance of Medication Adherence Changes Over Time for SGLT-2 Inhibitors (n=100) and DPP-4 Inhibitors (n=100)

Time Point	Group	Mean Adherence Score	Standard Deviation (SD)	95% CI (Lower – Upper)	Change from Baseline	p-value vs Baseline
Baseline	SGLT2	5	0.82	4.84 – 5.16	–	–
	DPP-4	6	0.82	5.84 – 6.16	–	–
3 Months	SGLT2	6	0.82	5.84 – 6.16	1	<0.001 ***
	DPP-4	7	0.82	6.84 – 7.16	1	<0.001 ***
6 Months	SGLT2	7	0.82	6.84 – 7.16	2	<0.001 ***
	DPP-4	8	0.82	7.84 – 8.16	2	<0.001 ***
9 Months	SGLT2	7	0.82	6.84 – 7.16	2	<0.001 ***
	DPP-4	9	0.82	8.84 – 9.16	3	<0.001 ***
12 Months	SGLT2	8	0.82	7.84 – 8.16	3	<0.001 ***
	DPP-4	9.67	0.47	9.58 – 9.76	3.67	<0.001 ***

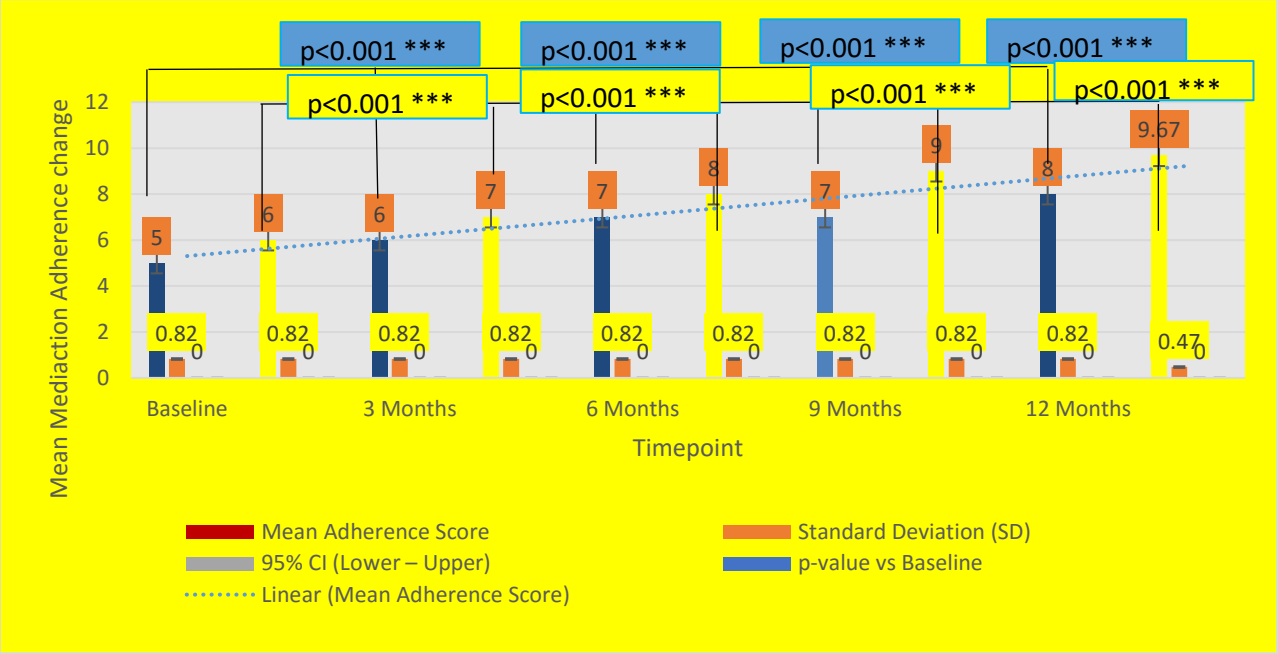

Figure 1: Mean Medication Adherence Changes Over Time for SGLT-2 and DPP-4 Inhibitors

Quality of life (QoL) in patients receiving SGLT-2 and DPP-4 inhibitors was analyzed descriptively at baseline, and during follow-up at 3, 6, 9 and 12 months. For each time point, the table presents the mean, standard deviation, 95% confidence intervals, the change from baseline and p-values for between time comparisons (Table 3) (Figure 2).

Table 3: Descriptive Statistics and Statistical Significance of Quality-of-Life Changes Over Time for SGLT-2 Inhibitors (n=100) and DPP-4 Inhibitors (n=100)

Time Point	Group	Mean QOL	Standard Deviation (SD)	95% CI (Lower – Upper)	Change from Baseline	p-value vs Baseline
Baseline	SGLT2	5.5	1.51	5.20 – 5.80	–	–
	DPP-4	4.95	0.81	4.79 – 5.11	–	–
3 Months	SGLT2	6.3	1.28	6.05 – 6.55	0.8	<0.001 ***
	DPP-4	5.2	0.6	5.08 – 5.32	0.25	<0.001 ***
6 Months	SGLT2	7.16	1.29	6.90 – 7.42	1.66	<0.001 ***
	DPP-4	5.7	0.56	5.59 – 5.81	0.75	<0.001 ***
9 Months	SGLT2	7.4	1.12	7.18 – 7.62	1.9	<0.001 ***
	DPP-4	6	0.78	5.85 – 6.15	1.05	<0.001 ***
12Months	SGLT2	7.96	1.04	7.75 – 8.17	2.46	<0.001 ***
	DPP-4	6.35	0.48	6.26 – 6.44	1.4	<0.001 ***

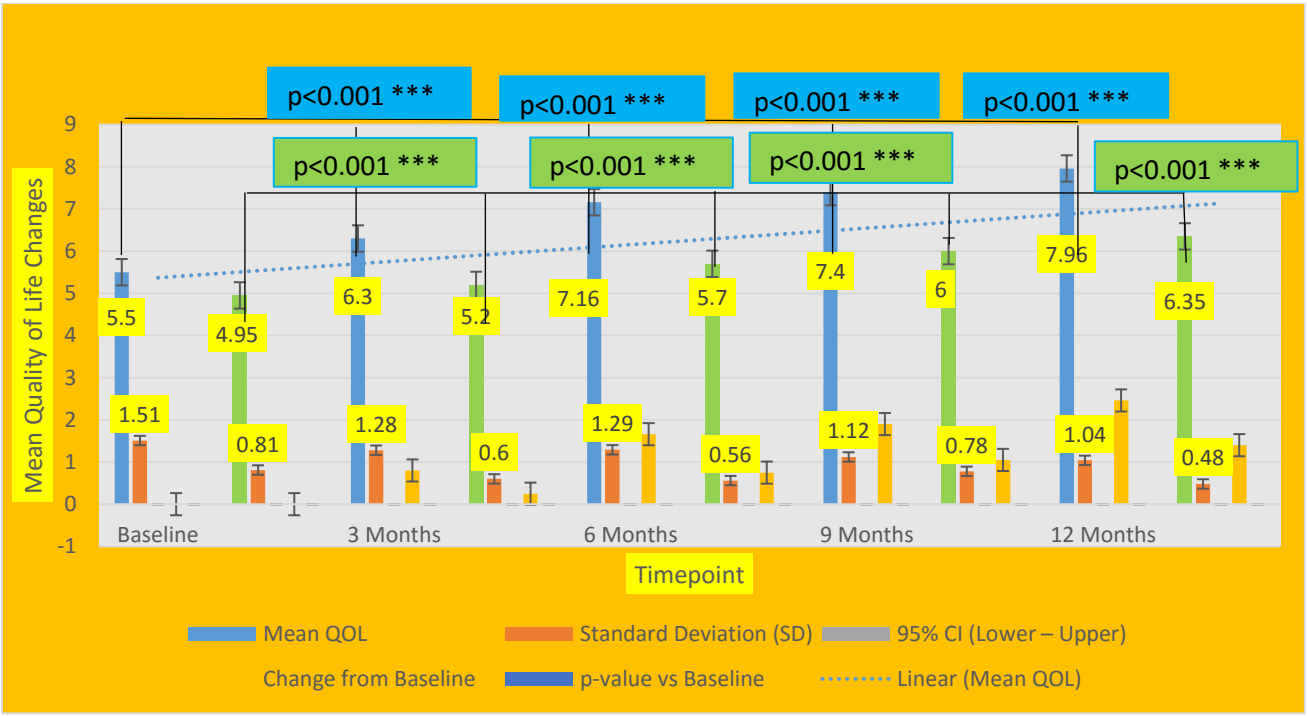

Figure 2: Mean Quality of Life Changes Over Time for SGLT-2 and DPP-4 Inhibitors

DISCUSSION

Over the 12-month follow-up period, a significant and progressive improvements in medication adherence scores from baseline were demonstrated by both the treatment groups. At baseline, the mean adherence score was 5 ± 0.82 for the SGLT-2 group and 6 ± 0.82 for the DPP-4 group. By 3 months, adherence increased by 1 point in both groups (SGLT-2: 6 ± 0.82, DPP-4: 7 ± 0.82, $p < 0.001$). This upward trend continued at 6 months (SGLT-2: 7 ± 0.82, DPP-4: 8 ± 0.82, $p < 0.001$) and was sustained at 9 months (SGLT-2: 7 ± 0.82, DPP-4: 9 ± 0.82, $p < 0.001$). By 12 months, adherence peaked at 8 ± 0.82 for SGLT-2 users and 9.67 ± 0.47 for DPP-4 users, reflecting a total improvement of +3 and +3.67 points from baseline respectively ($p < 0.001$ for all time points vs. baseline).The consistently higher adherence in the DPP-4 group throughout the study period, along with the slightly greater overall improvement (+3.67 vs. +3), suggests that patients on DPP-4 inhibitors may find the regimen more manageable or acceptable, potentially due to factors like dosing convenience, fewer side effects, or patient preference. Nonetheless, both treatment arms achieved statistically significant and clinically meaningful gains in adherence over time.

In alignment with our findings, the retrospective claims analysis by Gor et al.[16] demonstrated that patients receiving DPP-4 inhibitors exhibited better adherence and persistence compared to those treated with pioglitazone. Although their study targeted a CKD-specific cohort and used a different adherence metric (proportion of days covered, PDC ≥ 0.80), the overall pattern reflects a consistent advantage of DPP-4 inhibitors in medication-taking behaviour. In our real-world study, adherence improved steadily over time in both groups, but the DPP-4 inhibitor group maintained a statistically significant edge throughout the 12-month follow-up, with a greater net gain in adherence score (+3.67 vs. +3). This mirrors the adjusted odds ratio of 1.41 in favour of DPP-4 inhibitors reported by Gor *et al.,* The enhanced adherence in the DPP-4 group in both studies may be attributed to factors such as once-daily oral dosing, better tolerability, and fewer side effects. However, it is noteworthy that Gor *et al.,* also observed temporal variations in pioglitazone adherence influenced by generic availability and safety concerns, highlighting how external market dynamics can modulate adherence trends. Our study, by contrast, maintained a uniform observational frame, suggesting that clinical characteristics and patient acceptability of DPP-4 inhibitors may independently support better adherence, even in non-CKD populations. Together, both studies underscore the favourable adherence profile of DPP-4 inhibitors, potentially reinforcing their role in long-term T2DM management strategies.

Over the 12-month follow-up period, statistically significant improvements in quality-of-life (QoL) scores from baseline were demonstrated by both treatment groups; however, the magnitude and trajectory of improvement differed notably between the groups. At baseline, the mean QoL score was 5.5 ± 1.51 in the SGLT-2 group and 4.95 ± 0.81 in the DPP-4 group. By 3 months, QoL scores increased modestly in both groups, with a change of +0.8 in the SGLT-2 group (6.3 ± 1.28, $p < 0.001$) and +0.25 in the DPP-4 group (5.2 ± 0.6, $p < 0.001$). This upward trend continued at 6 months, with a more pronounced rise in the SGLT-2 group (7.16 ± 1.29, $\Delta = +1.66$, $p < 0.001$) when compared to the

DPP-4 group (5.7 ± 0.56, Δ = +0.75, $p < 0.001$). At 9 months, QoL scores further improved to 7.4 ± 1.12 in the SGLT-2 group (Δ = +1.9) and 6.0 ± 0.78 in the DPP-4 group (Δ = +1.05), both statistically significant ($p < 0.001$). By 12 months, the SGLT-2 group achieved a peak QoL score of 7.96 ± 1.04, reflecting a total improvement of +2.46 points from baseline, whereas the DPP-4 group reached 6.35 ± 0.48, with a cumulative gain of +1.4 points (both $p < 0.001$ vs. baseline). The consistently greater QoL gains in the SGLT-2 group suggest a more favourable impact of this treatment on patients' overall well-being, possibly reflecting benefits such as weight reduction, better glycaemic control, improved energy levels, and cardiovascular or renal effects, which are well-documented in literature. Overall, while both drug classes contributed to improved patient-reported quality of life, SGLT-2 inhibitors demonstrated a significantly superior and sustained benefit across all time points.

These findings align with evidence from the DECLARE–TIMI 58 trial, Wiviott SD *et al.,* [17] which evaluated the long-term cardiovascular and renal outcomes associated with dapagliflozin, a representative SGLT-2 inhibitor. Although QoL measures were not the primary endpoint, the trial showed that dapagliflozin significantly minimized the incidence of cardiovascular death or hospitalization due to heart failure (HR 0.83; 95% CI, 0.73–0.95; p = 0.005), as well as renal events (HR 0.76; 95% CI, 0.67–0.87). These cardiorenal benefits are strongly associated with improvements in patients' physical functioning, symptom burden, and overall well-being, as supported by prior studies measuring QoL in similar populations. Moreover, the DECLARE–TIMI 58 trial enrolled a broad population, including over 10,000 patients without established atherosclerotic cardiovascular disease, making its findings generalizable to real-world settings like ours. The reduction in heart failure hospitalizations and renal deterioration likely translates into improved patient-reported outcomes, helping explain the superior QoL gains observed with SGLT-2 inhibitors in our cohort. While our study directly captured QoL improvements, and DECLARE–TIMI 58 did not, the physiological and clinical advantages of dapagliflozin reported in the trial offer a biological rationale for the improved quality of life we observed. Conversely, DPP-4 inhibitors, though effective for glycaemic control, have shown more neutral cardiovascular and renal profiles, which may partly explain the relatively modest QoL improvements in our DPP-4 group.

CONCLUSION

Both SGLT-2 and DPP-4 inhibitors significantly enhanced adherence and QoL in T2DM patients. DPP-4 inhibitors were associated with superior adherence, while SGLT-2 inhibitors conferred greater QoL improvements. These findings underscore the importance of tailoring therapy to optimize both clinical and patient-reported outcomes in long-term diabetes management

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of HKES's Basaveshwar Teaching and General Hospital, Kalaburagi, in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. IEC Approval Number: HKES/MRMCK/IEC/2024/230. Written informed consent was obtained from all participants prior to enrolment, and confidentiality of patient data was strictly maintained throughout the study.

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Conflict of Interest

The authors declare that there are no conflicts of interest, financial or otherwise, related to the conduct, analysis, or publication of this study.

Authors' Contributions

All authors contributed substantially to the conception and design of the study. Data collection, patient follow-up, and questionnaire administration were performed by the investigators. Statistical analysis and interpretation of data were jointly undertaken by the authors. All authors critically reviewed the manuscript, approved the final version, and take full responsibility for the integrity and accuracy of the work.

Data Availability Statement

The datasets generated and/or analysed during the current study are available from the corresponding author upon reasonable request, subject to institutional and ethical regulations.

Limitations of the Study

- The observational, open-label design inherently restricts causal attribution and remains vulnerable to treatment-selection and indication bias.
- Conducting the study within a single tertiary-care centre and its affiliated clinics constrains the external validity and limits extrapolation to diverse healthcare systems and practice settings.
- Medication adherence assessment relied predominantly on self-reported instruments, which are intrinsically prone to recall error and social desirability bias, despite partial triangulation through pill counts and pharmacy refill records.
- Although the 12-month follow-up exceeds that of many real-world studies, it may still be insufficient to characterize long-term adherence persistence and durability of HRQoL benefits.
- Residual confounding cannot be excluded, as key determinants such as socioeconomic status, health

literacy, behavioural factors, and lifestyle modifications were not comprehensively captured, potentially influencing adherence trajectories and patient-reported outcomes.

Clinical Implications

The findings of this study highlight the importance of incorporating patient-centred outcomes such as medication adherence and health-related quality of life when selecting add-on therapies for T2DM. While DPP-4 inhibitors may be preferred in patients where adherence and tolerability are paramount, SGLT-2 inhibitors may offer superior quality-of-life benefits, particularly in individuals who can tolerate their adverse-effect profile. These insights support individualized, shared decision-making in routine diabetes care

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