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Association Between Antidiabetic Drug Therapy and Biochemical Markers of Glycemic Control, Lipid Profile, and Renal Function Among Patients with Type 2 Diabetes Mellitus: A Cross-Sectional Observational Study.

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Abstract

Background:
Type 2 diabetes mellitus requires individualized antidiabetic therapy because glycaemic status, dyslipidaemia, and renal dysfunction commonly coexist and influence treatment selection. Biochemical monitoring helps clinicians identify patients with poor metabolic control and early renal risk.

Objectives:
To assess the association between antidiabetic drug therapy and biochemical markers of glycaemic control, lipid profile, and renal function among patients with type 2 diabetes mellitus.

Methods:
This cross-sectional observational study included 100 patients with type 2 diabetes mellitus attending Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India, from February 2025 to January 2026. Demographic details, duration of diabetes, body mass index, comorbidities, antidiabetic therapy, fasting blood glucose, postprandial blood glucose, HbA1c, lipid parameters, serum urea, serum creatinine, estimated glomerular filtration rate, and urine albumin-creatinine ratio were recorded. Associations were analysed across therapy groups.

Results:
The mean age was 53.2 ± 10.6 years, and males constituted 56.0%. Metformin monotherapy was used in 26.0%, metformin with sulfonylurea in 24.0%, DPP-4 inhibitor-based therapy in 18.0%, insulin-based therapy in 20.0%, and SGLT2 inhibitor-based therapy in 12.0%. Overall mean HbA1c was 8.2 ± 1.4%. Insulin-based therapy was associated with higher HbA1c, higher triglycerides, lower eGFR, and higher albuminuria, whereas SGLT2 inhibitor-based therapy showed comparatively favourable glycaemic and lipid parameters.

Conclusion:
Antidiabetic drug therapy showed significant association with glycaemic, lipid, and renal biochemical markers. Poorer profiles among insulin-treated patients reflected greater disease burden and longer diabetes duration rather than a direct drug effect.

Recommendations:
Routine integrated assessment of HbA1c, lipid profile, eGFR, and albuminuria is recommended during diabetes follow-up.

Keywords: *Antidiabetic drugs; type 2 diabetes mellitus; glycated haemoglobin; lipid profile; renal function; sodium-glucose cotransporter-2 inhibitors; dipeptidyl peptidase-4 inhibitors*
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Introduction

Type 2 diabetes mellitus is a chronic metabolic disorder characterized by insulin resistance, progressive beta-cell dysfunction, and persistent hyperglycaemia. Its clinical importance extends beyond blood glucose elevation because long-standing disease is closely linked with dyslipidaemia, hypertension, chronic kidney disease, cardiovascular morbidity, and premature mortality. Modern diabetes care therefore uses biochemical markers not only to judge glycaemic control but also to estimate vascular and renal risk. Current standards emphasize individualized pharmacological therapy, periodic HbA1c assessment, cardiovascular risk reduction, and early screening for kidney disease in routine clinical practice [1-3].

Antidiabetic therapy in real-world outpatient practice commonly involves metformin, sulfonylureas, dipeptidyl peptidase-4 inhibitors, sodium-glucose cotransporter-2 inhibitors, and insulin. These therapies are often selected according to glycaemic status, diabetes duration, body weight, hypoglycaemia risk, renal function, cost, availability, and associated comorbidities. Metformin remains a preferred foundational agent in most patients when renal function permits. Sulfonylureas provide effective glucose lowering but require caution regarding hypoglycaemia and weight gain. DPP-4 inhibitors are frequently used because of oral administration and acceptable tolerability, while SGLT2 inhibitors have gained importance because of glycaemic, renal, and cardiovascular advantages demonstrated in major outcome trials [1,8-13].

Patients with type 2 diabetes frequently show an atherogenic lipid pattern, usually expressed as elevated triglycerides, reduced high-density lipoprotein cholesterol, and increased low-density lipoprotein cholesterol or small dense LDL particles. This pattern contributes to residual cardiovascular risk even when glucose control receives primary attention [4,5]. Renal impairment is another clinically silent but serious complication. Albuminuria and reduced estimated glomerular filtration rate identify patients with higher risk of kidney failure, cardiovascular events, and death [3,14]. Hence, evaluation of lipid profile and renal markers along with fasting blood glucose, postprandial glucose, and HbA1c gives a broader assessment of diabetic risk burden.

Although randomized trials provide strong evidence for the efficacy and safety of individual antidiabetic drugs, hospital-based cross-sectional studies remain useful because they describe how therapies are used in routine clinical settings and how biochemical profiles vary among treated patients. Such data are especially relevant in Indian tertiary care settings where patients often present with variable disease duration, delayed intensification, obesity, dyslipidaemia, and renal risk. The present study was conducted with the objective of assessing the association between antidiabetic drug therapy and biochemical markers of glycaemic control, lipid profile, and renal function among patients with type 2 diabetes mellitus attending Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India. The analysis aimed to support practical outpatient monitoring and therapeutic review in similar hospital settings.

Methodology

Study design and setting

This hospital-based cross-sectional observational study was conducted at Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India. The institute is a tertiary care teaching hospital providing outpatient and inpatient services across general medicine, allied specialties, laboratory medicine, and chronic disease follow-up clinics. The study was carried out from February 2025 to January 2026 among patients with type 2 diabetes mellitus attending the General Medicine clinic.

Study population and sampling

Adults with previously diagnosed type 2 diabetes mellitus attending the General Medicine clinic during the study period were assessed against the eligibility criteria. Consecutive sampling was used, and 100 eligible participants were enrolled. Participants were classified according to the antidiabetic therapy documented at the time of biochemical assessment: metformin monotherapy, metformin with a sulfonylurea, metformin with a dipeptidyl peptidase-4 inhibitor, insulin with or without oral antidiabetic drugs, and sodium-glucose cotransporter-2 inhibitor-based therapy.

Sample size justification

A formal a priori power calculation was not documented in the available study record. The adequacy of the achieved sample was therefore evaluated using the single-population proportion formula $n = Z^2p(1-p)/d^2$. Using a 95% confidence level ($Z = 1.96$), a conservative expected proportion of 50% ($p = 0.50$) because no reliable local estimate was available, and an absolute precision of 10% ($d = 0.10$), the minimum sample was $n = (1.96^2 \times 0.50 \times 0.50)/(0.10^2) = 96.04$, approximately 96 participants. The final sample of 100 participants exceeded this precision-based minimum. This calculation is presented as a quantitative adequacy justification and does not replace the absence of a documented pre-study power calculation.

Inclusion criteria

Patients aged 18 years or older with established type 2 diabetes mellitus, receiving a stable antidiabetic regimen for at least three months, and providing written informed consent were eligible for inclusion.

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Exclusion criteria

Patients with type 1 diabetes mellitus, gestational diabetes mellitus, acute hyperglycaemic crisis, acute kidney injury, active infection, chronic liver disease, malignancy, recent surgery, pregnancy, or incomplete laboratory records were excluded to reduce clinical heterogeneity and ensure complete biochemical assessment.

Missing data

Data completeness was checked before analysis. The 100 participants included in the final analytical dataset had complete information for the variables reported in the study, and no imputation was performed. The submitted study record did not separately document the number of patients excluded before enrolment specifically because of incomplete laboratory records; this screening count should be inserted from the original screening log if available.

Data collection and study variables

Demographic details, sex, age, duration of diabetes, body mass index, hypertension, dyslipidaemia, family history of diabetes, smoking status, and current antidiabetic therapy were recorded using a structured proforma. Biochemical parameters included fasting blood glucose, postprandial blood glucose, HbA1c, total cholesterol, triglycerides, LDL cholesterol, HDL cholesterol, serum urea, serum creatinine, estimated glomerular filtration rate, and urine albumin-creatinine ratio. HbA1c <7.0% was considered adequate glycaemic control as per accepted diabetes care targets [2]. Renal assessment was based on serum creatinine, eGFR, and albuminuria, consistent with current chronic kidney disease risk evaluation principles in diabetes [3].

Bias reduction

Consecutive enrolment was used to reduce selection bias. Laboratory values were obtained from standard hospital laboratory reports generated during routine care. Drug therapy was recorded from prescriptions and patient records instead of patient recall alone. Patients with acute illnesses likely to alter glucose, lipid, or renal parameters were excluded. Data were checked for completeness before analysis.

Statistical analysis

Data were entered into a spreadsheet and analysed using standard statistical methods. Continuous variables were summarized as mean ± standard deviation when approximately normally distributed and as median with interquartile range for skewed variables. Categorical variables were expressed as frequency and percentage. One-way analysis of variance was used to compare normally distributed continuous biochemical variables across the five therapy groups. The Kruskal-Wallis test was used for urine albumin-creatinine ratio. Pearson's chi-square test was used only to compare the categorical distribution of glycaemic control (HbA1c <7.0% versus HbA1c ≥7.0%) across therapy groups. All tests were two-sided, and $p<0.05$ was considered statistically significant.

Ethical considerations

Approval was obtained from the Institutional Ethics Committee of Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, before initiation of the study. Patient identifiers were anonymised during data entry, analysis, and reporting to maintain confidentiality.

Informed consent

Written informed consent was obtained by the study investigators from each participant before enrolment after explaining the purpose and nature of the study, the information to be collected, confidentiality safeguards, and the voluntary nature of participation. Participation or refusal did not alter routine clinical care.

Results

Participant flow

The final analysis included 100 consecutively enrolled eligible participants. The final analysed sample was n=100

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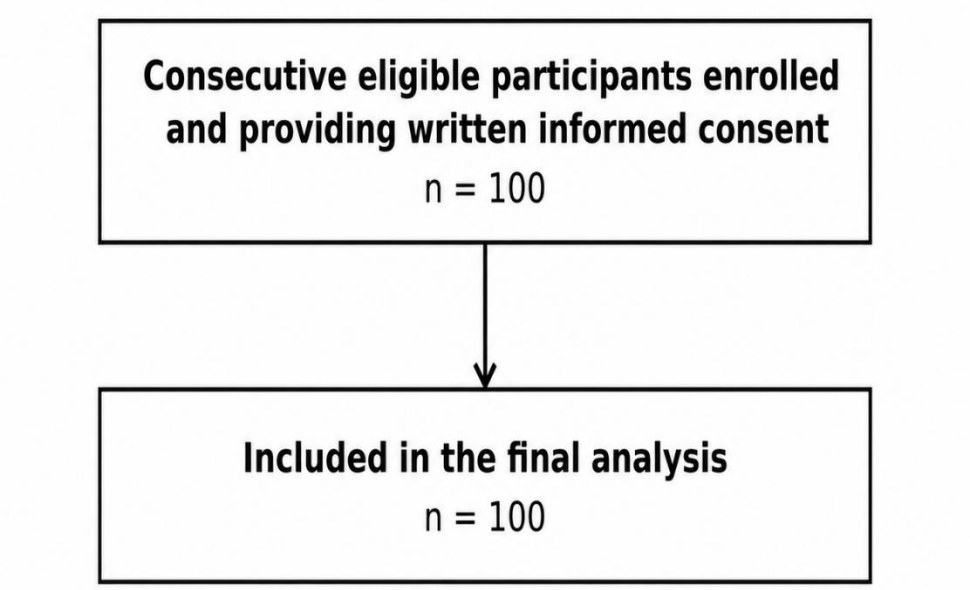
Figure 1. Participant flow through the study



A total of 100 patients with type 2 diabetes mellitus were included in the study. The mean age was 53.2 ± 10.6 years. Males constituted 56.0% of the study population. Most patients had diabetes for 5-10 years, followed by >10 years. Overweight and obesity were observed in 46.0% and 26.0% of patients, respectively. Hypertension was present in 42.0%, while dyslipidaemia was documented in 48.0% of patients. Metformin monotherapy was the most common antidiabetic therapy, followed by metformin with sulfonylurea and insulin-based therapy (Table 1).

Table 1. Baseline characteristics and antidiabetic drug therapy pattern among study participants (n=100)

Variable	Frequency	Percentage
Age group		
<40 years	12	12.0
40-49 years	24	24.0
50-59 years	38	38.0
≥60 years	26	26.0
Sex		
Male	56	56.0
Female	44	44.0
Duration of diabetes mellitus		
<5 years	28	28.0
5-10 years	42	42.0
>10 years	30	30.0
Body mass index category		
Normal BMI	28	28.0
Overweight	46	46.0

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Variable	Frequency	Percentage
Obese	26	26.0
Hypertension	42	42.0
Dyslipidaemia	48	48.0
Family history of diabetes mellitus	36	36.0
Current smoking	22	22.0
Antidiabetic drug therapy		
Metformin monotherapy	26	26.0
Metformin + sulfonylurea	24	24.0
Metformin + DPP-4 inhibitor	18	18.0
Insulin with or without oral antidiabetic drugs	20	20.0
SGLT2 inhibitor-based therapy	12	12.0

The overall mean fasting blood glucose was 158.6 ± 45.2 mg/dL, mean postprandial blood glucose was 236.8 ± 68.4 mg/dL, and mean HbA1c was 8.2 ± 1.4%. Mean glycaemic markers differed across the antidiabetic therapy groups. Patients receiving insulin-based therapy had higher mean fasting blood glucose, postprandial blood glucose, and HbA1c levels. Adequate glycaemic control, defined as HbA1c <7.0%, was observed in 30.0% of patients. Although the proportion with HbA1c <7.0% was numerically highest in the sodium-glucose cotransporter-2 inhibitor-based group and lowest in the insulin-based group, the categorical distribution of HbA1c control did not differ significantly across therapy groups (Pearson $\chi^2(4)=7.36$, $p=0.118$) (Table 2).

Table 2. Association between antidiabetic drug therapy and glycaemic control markers

Therapy group	Fasting blood glucose, mg/dL	Postprandial blood glucose, mg/dL	HbA1c, %	HbA1c <7.0%, n (%)	HbA1c ≥7.0%, n (%)
Metformin monotherapy	143.2 ± 36.4	213.5 ± 55.8	7.6 ± 1.0	10 (38.5)	16 (61.5)
Metformin + sulfonylurea	163.8 ± 42.6	239.4 ± 62.1	8.3 ± 1.3	6 (25.0)	18 (75.0)
Metformin + DPP-4 inhibitor	156.4 ± 39.8	230.6 ± 58.7	8.0 ± 1.1	6 (33.3)	12 (66.7)
Insulin ± oral drugs	182.5 ± 54.2	272.8 ± 78.6	9.0 ± 1.5	2 (10.0)	18 (90.0)
SGLT2 inhibitor-based therapy	140.6 ± 34.5	210.2 ± 52.4	7.5 ± 1.0	6 (50.0)	6 (50.0)
Overall	**158.6 ± 45.2**	**236.8 ± 68.4**	**8.2 ± 1.4**	**30 (30.0)**	**70 (70.0)**
p-value	**0.012**	**0.006**	**0.004**	**0.118**	**0.118**

Note. *Fasting blood glucose, postprandial blood glucose, and HbA1c means were compared using one-way analysis of variance. HbA1c control category (<7.0% vs ≥7.0%) was compared using Pearson's chi-square test; $\chi^2(4)=7.36$, $p=0.118$.*

The mean total cholesterol was 190.4 ± 42.6 mg/dL, mean triglyceride level was 176.8 ± 64.5 mg/dL, mean LDL cholesterol was 116.2 ± 34.8 mg/dL, and mean HDL cholesterol was 42.6 ± 9.8 mg/dL. Lipid profile varied across treatment categories. Patients receiving insulin-based therapy showed higher total cholesterol, triglycerides, and LDL cholesterol, with lower HDL cholesterol. SGLT2 inhibitor-based therapy was associated with a comparatively favourable lipid profile (Table 3).

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Table 3. Association between antidiabetic drug therapy and lipid profile

Therapy group	Total cholesterol, mg/dL	Triglycerides, mg/dL	LDL cholesterol, mg/dL	HDL cholesterol, mg/dL
Metformin monotherapy	184.6 ± 36.8	165.4 ± 55.2	110.5 ± 30.4	44.2 ± 9.1
Metformin + sulfonylurea	198.2 ± 44.5	187.6 ± 66.8	122.4 ± 35.6	41.1 ± 10.2
Metformin + DPP-4 inhibitor	189.8 ± 40.2	175.8 ± 60.4	115.6 ± 33.2	43.0 ± 10.0
Insulin ± oral drugs	203.6 ± 48.7	198.4 ± 72.6	126.8 ± 38.4	39.4 ± 9.3
SGLT2 inhibitor-based therapy	171.2 ± 32.5	145.6 ± 48.3	101.7 ± 28.6	47.1 ± 8.4
Overall	**190.4 ± 42.6**	**176.8 ± 64.5**	**116.2 ± 34.8**	**42.6 ± 9.8**
p-value	**0.046**	**0.039**	**0.052**	**0.041**

The overall mean serum creatinine was 1.02 ± 0.32 mg/dL and the mean estimated glomerular filtration rate was 78.4 ± 21.6 mL/min/1.73 m². Renal function markers showed significant variation across therapy groups. Insulin-based therapy was associated with higher serum urea, higher serum creatinine, lower eGFR, and higher urine albumin-creatinine ratio. This group also had the longest mean duration of diabetes mellitus, suggesting that insulin therapy was more common among patients with advanced disease burden (Table 4).

Table 4. Association between antidiabetic drug therapy, renal function markers, and diabetes duration

Therapy group	Duration of diabetes, years	Serum urea, mg/dL	Serum creatinine, mg/dL	eGFR, mL/min/1.73 m²	Urine ACR, mg/g
Metformin monotherapy	5.2 ± 2.8	28.4 ± 8.1	0.89 ± 0.19	91.2 ± 16.4	28 (18-62)
Metformin + sulfonylurea	7.9 ± 3.6	32.6 ± 10.2	0.98 ± 0.25	79.6 ± 19.2	52 (24-118)
Metformin + DPP-4 inhibitor	8.6 ± 4.1	34.2 ± 11.8	1.04 ± 0.31	76.8 ± 20.1	68 (28-135)
Insulin ± oral drugs	12.4 ± 5.2	40.5 ± 14.6	1.25 ± 0.41	62.4 ± 21.8	126 (55-280)
SGLT2 inhibitor-based therapy	7.1 ± 3.4	31.8 ± 9.5	0.96 ± 0.22	82.6 ± 17.9	42 (20-90)
Overall	**8.1 ± 4.9**	**33.5 ± 11.9**	**1.02 ± 0.32**	**78.4 ± 21.6**	**56 (24-134)**
p-value	**<0.001**	**0.006**	**<0.001**	**<0.001**	**0.002**

Overall, antidiabetic drug therapy showed significant association with markers of glycaemic control, lipid profile, and renal function. Insulin-based therapy was associated with poorer glycaemic control and greater renal risk burden, while SGLT2 inhibitor-based therapy showed comparatively better glycaemic and lipid parameters. However, as this was a cross-sectional observational study, these findings should be interpreted as associations and not as direct causal effects of the drug therapies.

Discussion

The present cross-sectional observational study evaluated the association between antidiabetic drug therapy and biochemical markers among 100 patients with type 2 diabetes mellitus. The study population showed a middle-aged clinical profile, male predominance, overweight and obesity burden, and frequent coexistence of hypertension and dyslipidaemia. These findings reflect the clustering of cardiometabolic risk factors seen in routine diabetes practice. Current standards emphasize that drug selection should consider glycaemic efficacy, hypoglycaemia risk, body weight, renal function, cardiovascular profile, cost, and patient-specific factors [1].

The overall mean HbA1c was 8.2 ± 1.4%, and only 30.0% of patients achieved HbA1c <7.0%, indicating suboptimal glycaemic control. Patients on insulin-based therapy had the highest fasting glucose, postprandial glucose, and HbA1c values. This pattern should not be interpreted as a harmful effect of insulin. In clinical practice, insulin is commonly intensified in patients with longer diabetes duration, beta-

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cell decline, higher baseline glycaemia, and metabolic complications. The UKPDS demonstrated that intensive glucose control with metformin, sulfonylureas, or insulin reduced microvascular outcomes, and long-term follow-up confirmed durable benefit [6-8].

Categorical glycaemic-control comparison

The proportion achieving HbA1c <7.0% varied numerically among treatment groups; however, this categorical comparison was not statistically significant (Pearson $\chi^2(4)=7.36$, $p=0.118$). Interpretation of treatment-group differences should therefore rely on the continuous glycaemic measures and the observational design rather than on the categorical control proportions alone.

The lipid findings demonstrated higher total cholesterol, triglycerides, and LDL cholesterol among insulin-treated patients, whereas SGLT2 inhibitor-based therapy showed a comparatively favourable lipid profile. Diabetic dyslipidaemia is typically characterized by elevated triglycerides, low HDL cholesterol, and qualitative LDL abnormalities, contributing to atherosclerotic risk even when LDL cholesterol is not markedly raised [5]. The lipid differences in the present study probably reflect combined effects of disease duration, adiposity, insulin resistance, comorbid hypertension, and background lipid-lowering practices rather than antidiabetic therapy alone.

Renal markers differed significantly across therapy groups. Insulin-based therapy was linked with higher serum urea, higher serum creatinine, lower eGFR, and higher urine ACR. Diabetes is a leading contributor to chronic kidney disease, and albuminuria with reduced eGFR identifies patients with high cardiovascular and mortality risk [3,4,14]. Major outcome trials have shown renal and cardiovascular benefits with SGLT2 inhibitors, including empagliflozin and canagliflozin, in patients with type 2 diabetes and high-risk renal or cardiovascular profiles [11-13]. DPP-4 inhibitor trials such as SAVOR-TIMI 53 and TECOS support cardiovascular safety [9,10].

These findings reinforce the need for integrated diabetes review instead of glucose-only follow-up. In cross-sectional data, therapy groups represent clinical prescribing decisions made for patients with different disease severity. Therefore, higher biochemical risk in insulin-treated patients is best understood as treatment intensification in advanced disease. The results support regular monitoring of HbA1c, lipid profile, serum creatinine, eGFR, and albuminuria, with early optimization of pharmacotherapy and cardiovascular risk management in eligible patients.

Generalizability

The study findings are most applicable to adult patients with type 2 diabetes mellitus receiving care in tertiary teaching hospital settings with similar outpatient and laboratory services. Because the sample was hospital-based and included only 100 patients, direct extrapolation to community populations, primary care clinics, and patients with newly diagnosed diabetes requires caution. Nevertheless, the observed clustering of poor glycaemic control, dyslipidaemia, and renal risk is clinically relevant for comparable Indian hospital populations.

Conclusion

In this cross-sectional observational study of 100 patients with type 2 diabetes mellitus, antidiabetic drug therapy showed significant association with biochemical markers of glycaemic control, lipid profile, and renal function. Insulin-based therapy was associated with higher fasting and postprandial glucose, higher HbA1c, greater triglyceride burden, lower eGFR, and higher albuminuria. SGLT2 inhibitor-based therapy showed comparatively better glycaemic and lipid parameters. These findings indicate that biochemical profiles vary meaningfully across treatment groups, mainly reflecting disease duration, metabolic burden, and treatment intensification. Routine combined assessment of HbA1c, lipid profile, eGFR, and albuminuria is essential for comprehensive diabetes care and timely risk stratification in clinical practice, particularly in patients with long-standing diabetes and comorbidities.

Limitations

The study had a cross-sectional design, so temporal relationships and causality could not be established. The sample size was limited to 100 patients from a single tertiary care centre. Drug adherence, diet, physical activity, statin use, and dose variation were not analysed in depth. Follow-up outcomes and changes after therapy modification were not assessed. Confounding from socioeconomic status was also not evaluated.

Recommendations

Patients with type 2 diabetes mellitus should undergo periodic integrated biochemical assessment including fasting and postprandial glucose, HbA1c, lipid profile, serum creatinine, eGFR, and urine albumin-creatinine ratio. Treatment review should consider disease duration, renal function, cardiovascular risk, hypoglycaemia risk, obesity, and affordability. Patients with poor glycaemic control, dyslipidaemia, declining eGFR, or albuminuria require early treatment optimization and lifestyle reinforcement. SGLT2 inhibitor-based therapy should be considered in eligible patients with renal or cardiovascular risk after clinical assessment. Larger prospective studies are recommended to evaluate longitudinal biochemical changes after therapy modification in Indian clinical settings. Periodic audit of prescribing patterns can improve local protocols.

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Abbreviations
ACR: albumin-creatinine ratio;
BMI: body mass index;
CKD: chronic kidney disease;
DPP-4: dipeptidyl peptidase-4;
eGFR: estimated glomerular filtration rate;
FBG: fasting blood glucose;
HbA1c: glycated haemoglobin;
HDL: high-density lipoprotein;
LDL: low-density lipoprotein;
PPG: postprandial blood glucose;
SGLT2: sodium-glucose cotransporter-2;
T2DM: type 2 diabetes mellitus.

Source of funding
The study has no funding

Conflict of interest
The authors declare no conflict of interest.

Author contributions
NT-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of the manuscript. **KN** -Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, revision of the manuscript. **CRA -**Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation.

Availability of data
The de-identified data supporting the findings of this study are available upon reasonable request from the corresponding author.

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