



## GLYCEMIC CONTROL AND CARDIOVASCULAR OUTCOMES IN DIABETIC PATIENTS: A PRIMARY CARE SETTING STUDY

Dr Mohd Yasir Arafat<sup>1</sup>, Dr Arshad Hasan<sup>2\*</sup>

<sup>1</sup>Assistant Professor, Department of Pharmacology, Madhubani Medical College & Hospital, Keshopur, Madhubani, Bihar, India.

<sup>2\*</sup>Professor & Head, Department of Pharmacology, Madhubani Medical College & Hospital, Keshopur, Madhubani, Bihar, India.

**\*Corresponding author:** Dr Arshad Hasan

\*Professor & Head, Department of Pharmacology, Madhubani Medical College & Hospital, Keshopur, Madhubani, Bihar, India. Email: dr.arshadhasan@yahoo.com

### Abstract:

**Introduction:** Type 2 diabetes mellitus is a growing health crisis in India, with cardiovascular disease as a leading cause of morbidity and mortality. This study investigated the relationship between glycemic control and cardiovascular outcomes in patients with type 2 diabetes managed in primary care settings.

**Methods:** A prospective cross sectional study was conducted across a network of primary care centers. 1,200 adults with type 2 diabetes were followed for 6 months. Glycemic control was categorized based on HbA1c levels. Cox proportional hazards models assessed the relationship between glycemic control and cardiovascular events. Logistic regression identified factors associated with achieving glycemic targets.

**Results:** Only 27% of patients achieved the target HbA1c of <7.0%. Patients with poor glycemic control (HbA1c  $\geq$ 9.0%) had a nearly three-fold higher risk of cardiovascular events compared to those with well-controlled diabetes (HR 2.87, 95% CI 1.71-4.82,  $p < 0.001$ ). Factors associated with better glycemic control included older age, female gender, shorter diabetes duration, lower BMI, high medication adherence, metformin use, and regular physical activity. Low medication adherence was associated with a three-fold increase in cardiovascular risk compared to high adherence.

**Conclusion:** This study highlights the significant association between glycemic control and cardiovascular outcomes in primary care settings. The findings underscore the need for comprehensive, patient-centered approaches to diabetes management that address multiple risk factors and barriers to care, particularly medication adherence.

**Keywords:** Type 2 diabetes, glycemic control, cardiovascular outcomes, primary care, India

### Introduction:

Diabetes mellitus, a chronic metabolic disorder characterized by elevated blood glucose levels, has become a global health crisis affecting millions of people worldwide. The International Diabetes Federation estimates that by 2045, approximately 783 million adults will be living with diabetes, with a significant burden falling on developing countries like India (International Diabetes Federation, 2021). This epidemic poses substantial challenges to healthcare systems, particularly in primary care settings where the majority of diabetic patients receive their routine care and management.

In India, the prevalence of diabetes has been rising at an alarming rate, with estimates suggesting that over 77 million adults are currently living with the condition (Anjana et al., 2017). The country's rapid urbanization, changing dietary patterns, and sedentary lifestyles have contributed to this surge, making diabetes management a critical priority for the Indian healthcare system. Primary care physicians in India play a crucial role in diagnosing, treating, and monitoring patients with diabetes, often working within resource-constrained environments (Mohan et al., 2018).

Glycemic control remains the cornerstone of diabetes management, with the primary goal of preventing both acute complications and long-term microvascular and macrovascular complications. Glycated hemoglobin (HbA1c) is widely used as a marker of long-term glycemic control, providing an average of blood glucose levels over the past 2-3 months (American Diabetes Association, 2022). In India, achieving optimal glycemic control has been challenging, with studies reporting that only 31% of patients with type 2 diabetes achieve the recommended HbA1c target of <7% (Unnikrishnan et al., 2014).

The relationship between glycemic control and cardiovascular outcomes in diabetic patients has been a subject of extensive research globally. Cardiovascular disease (CVD) remains the leading cause of morbidity and mortality among individuals with diabetes, with a two to four-fold increased risk compared to those without diabetes (Einarson et al., 2018). In India, the risk is even more pronounced, with studies showing that Indians with diabetes have a higher prevalence of cardiovascular disease compared to their Western counterparts (Gujral et al., 2018).

Several landmark clinical trials have investigated the impact of intensive glycemic control on cardiovascular outcomes in diabetic patients. The United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that improved glycemic control in newly diagnosed type 2 diabetes patients was associated with a reduced risk of microvascular complications and a trend towards decreased cardiovascular events (Holman et al., 2008). However, subsequent trials such as ACCORD, ADVANCE, and VADT produced mixed results, with some showing no significant reduction in cardiovascular events and others even suggesting potential harm from overly aggressive glucose lowering in certain patient populations (Action to Control Cardiovascular Risk in Diabetes Study Group, 2008; ADVANCE Collaborative Group, 2008; Duckworth et al., 2009).

In the Indian context, the Chennai Urban Rural Epidemiology Study (CURES) has provided valuable insights into the relationship between glycemic control and cardiovascular risk factors in the South Indian population. The study found that poor glycemic control was associated with an increased prevalence of cardiovascular risk factors such as hypertension, dyslipidemia, and obesity (Deepa et al., 2011).

The management of diabetes in primary care settings presents unique challenges and opportunities. Primary care physicians are at the forefront of diabetes care, responsible for implementing evidence-based guidelines, coordinating care with specialists, and providing ongoing patient education and support. However, primary care settings often face resource constraints, time limitations, and a high volume of patients with diverse healthcare needs. In India, these challenges are further compounded by factors such as limited access to specialized care, financial constraints, and cultural beliefs that may impact diabetes management (Mohan et al., 2018).

A study by Venkataraman et al. (2019) in urban India found that only 34% of patients with type 2 diabetes managed in primary care settings achieved the recommended HbA1c target of <7%. This highlights the need for continued efforts to improve diabetes management in primary care settings, particularly in the Indian context.

The relationship between glycemic control and cardiovascular outcomes in the primary care context is particularly important to investigate. While much of the existing research has been conducted in specialized diabetes clinics or as part of large clinical trials, the real-world effectiveness of glycemic control strategies in primary care may differ. Factors such as patient adherence, accessibility of care, continuity of follow-up, and the ability to implement complex treatment regimens can all influence outcomes in this setting (Blonde et al., 2017).

In India, the concept of comprehensive cardiovascular risk management in diabetes care is gaining traction. The Indian Council of Medical Research (ICMR) guidelines for management of type 2

diabetes emphasize the importance of addressing multiple cardiovascular risk factors simultaneously, including blood pressure control, lipid management, and lifestyle modifications (ICMR, 2018). However, the implementation of these guidelines in primary care settings and their impact on cardiovascular outcomes requires further investigation.

Recent studies have also highlighted the importance of considering cardiovascular outcomes beyond traditional endpoints such as myocardial infarction and stroke. Heart failure, for instance, has emerged as a significant concern in diabetic patients, with some glucose-lowering medications showing protective effects against heart failure hospitalizations (Zelniker et al., 2019). In India, where the prevalence of heart failure in diabetic patients is high, understanding the relationship between glycemic control and heart failure outcomes in primary care settings is crucial (Huffman et al., 2018).

The advent of new classes of glucose-lowering medications, such as sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, has further complicated the landscape of diabetes management in primary care. These agents have demonstrated cardiovascular benefits in clinical trials, prompting updates to treatment guidelines that now recommend considering cardiovascular risk when selecting glucose-lowering therapies (Cosentino et al., 2020). However, the accessibility and affordability of these newer agents in primary care settings in India, and their real-world effectiveness in terms of long-term cardiovascular outcomes, require further investigation.

Another important consideration in the primary care management of diabetes is the role of patient engagement and self-management. Glycemic control is heavily dependent on patient behaviors, including medication adherence, dietary choices, physical activity, and self-monitoring of blood glucose. In India, where cultural and socioeconomic factors significantly influence health behaviors, understanding how these factors interact with glycemic control and ultimately influence cardiovascular outcomes in the primary care setting is crucial for developing effective, patient-centered management strategies (Patel et al., 2016).

The COVID-19 pandemic has introduced additional complexities to diabetes care in primary care settings globally, including in India. Disruptions to routine care, increased use of telemedicine, and the heightened vulnerability of diabetic patients to severe COVID-19 outcomes have necessitated adaptations in diabetes management practices (Ghosh et al., 2020). The long-term impact of these changes on glycemic control and cardiovascular outcomes in the Indian primary care context remains to be fully elucidated.

In light of these considerations, there is a clear need for research that specifically examines the relationship between glycemic control and cardiovascular outcomes in diabetic patients within the primary care setting. Such studies can provide valuable insights into the real-world effectiveness of current management strategies, identify barriers to optimal care, and inform the development of targeted interventions to improve outcomes.

The aim of this study is to investigate the relationship between glycemic control and cardiovascular outcomes in patients with type 2 diabetes managed in primary healthcare settings, and to identify factors associated with both glycemic control and cardiovascular risk in this population.

## **Methodology:**

### **Study Design:**

This study employed a prospective cross sectional design, following patients with type 2 diabetes managed in primary healthcare settings.

### **Study Site:**

The study was conducted in primary healthcare centers in urban and semi-urban areas.

### **Study Duration:**

The study duration was 6 months, which included patient recruitment, data collection, and initial analysis.

**Sampling and Sample Size:**

A stratified random sampling method was used to select primary care clinics from different regions. Within each selected center, consecutive patients meeting the inclusion criteria were enrolled. The sample size was calculated using G\*Power software, assuming a medium effect size (hazard ratio of 1.3), an alpha level of 0.05, and a power of 0.80. Based on these parameters and accounting for potential attrition, a target sample size of 1,200 patients was determined.

**Inclusion and Exclusion Criteria:**

The study included adult patients (age  $\geq 18$  years) with a confirmed diagnosis of type 2 diabetes who had been managed in the primary care setting for at least one year. Patients were required to have at least two HbA1c measurements in the past year. Exclusion criteria encompassed patients with type 1 diabetes, gestational diabetes, secondary diabetes, or those who received the majority of their diabetes care from endocrinologists or specialized diabetes clinics. Patients with significant comorbidities that could impact glycemic control or cardiovascular risk (e.g., advanced cancer, severe liver disease) were also excluded.

**Data Collection Tools and Techniques:**

Data were collected using a standardized case report form, which included demographic information, clinical parameters, medication history, and cardiovascular outcomes. HbA1c levels were measured using point-of-care devices that were calibrated and validated for accuracy. Blood pressure, lipid profile, and anthropometric measurements were recorded using standardized techniques. Cardiovascular outcomes were assessed through patient interviews, medical record review, and confirmation with treating physicians where necessary. A validated questionnaire was used to assess patient adherence to medications and lifestyle recommendations.

**Data Management and Statistical Analysis:**

Statistical analysis was performed using SPSS version 26.0. Descriptive statistics were used to characterize the study population, including means and standard deviations for continuous variables and frequencies and percentages for categorical variables. HbA1c levels were categorized as  $<7.0\%$  (well-controlled),  $7.0\text{--}8.9\%$  (moderately controlled), and  $\geq 9.0\%$  (poorly controlled). The primary analysis employed Cox proportional hazards models to assess the relationship between glycemic control categories and the time to first cardiovascular event (composite of myocardial infarction, stroke, heart failure hospitalization, or cardiovascular death). Models were adjusted for age, gender, socioeconomic status, BMI, blood pressure, lipid levels, smoking status, and presence of comorbidities.

**Ethical Considerations:**

The study protocol was submitted to and approved by the Institutional Ethics Committee of the coordinating institution and the ethics committees of participating clinics. Written informed consent was obtained from all participants after a thorough explanation of the study procedures, potential risks, and benefits. The consent process was conducted in the local language, and illiterate participants provided thumb impressions in the presence of an impartial witness.

**Results:****Table 1: Demographic and Clinical Characteristics of Study Participants**

Characteristic	Value (N=1200)
Age (years), mean $\pm$ SD	56.4 $\pm$ 11.2
Gender (Male), n (%)	684 (57%)
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	27.8 $\pm$ 4.3
Duration of diabetes (years), median (IQR)	7.5 (4-12)
HbA1c (%), mean $\pm$ SD	8.2 $\pm$ 1.7

Systolic BP (mmHg), mean $\pm$ SD	138 $\pm$ 18
LDL cholesterol (mg/dL), mean $\pm$ SD	112 $\pm$ 34
Smoking status (current), n (%)	216 (18%)
Hypertension, n (%)	744 (62%)
Dyslipidemia, n (%)	660 (55%)

**Table 2: Glycemic Control Categories and Cardiovascular Outcomes**

Glycemic Control Category	N (%)	CV Events, n (%)	Hazard Ratio (95% CI)	p-value
Well-controlled (HbA1c <7.0%)	324 (27%)	19 (5.9%)	1.00 (Reference)	-
Moderately controlled (HbA1c 7.0-8.9%)	516 (43%)	47 (9.1%)	1.58 (0.93-2.68)	0.089
Poorly controlled (HbA1c $\geq$ 9.0%)	360 (30%)	58 (16.1%)	2.87 (1.71-4.82)	<0.001

**Table 3: Factors Associated with Achieving Glycemic Control (HbA1c <7.0%)**

Factor	Odds Ratio (95% CI)	p-value
Age (per 5-year increase)	1.15 (1.05-1.26)	0.003
Female gender	1.32 (1.01-1.72)	0.042
Duration of diabetes (per year)	0.94 (0.91-0.97)	<0.001
BMI (per 1 kg/m <sup>2</sup> increase)	0.96 (0.93-0.99)	0.018
Adherence to medication (high vs. low)	2.41 (1.83-3.18)	<0.001
Use of metformin	1.68 (1.27-2.22)	<0.001
Regular physical activity	1.53 (1.17-2.01)	0.002

**Table 4: Cardiovascular Outcomes by Medication Class**

Medication Class	N	CV Events, n (%)	Adjusted HR (95% CI)	p-value
Metformin	984	89 (9.0%)	0.75 (0.54-1.04)	0.082
Sulfonylureas	684	79 (11.5%)	1.22 (0.91-1.63)	0.186
DPP-4 inhibitors	408	35 (8.6%)	0.88 (0.61-1.27)	0.495
SGLT2 inhibitors	192	11 (5.7%)	0.61 (0.33-1.13)	0.115
GLP-1 receptor agonists	72	4 (5.6%)	0.58 (0.21-1.57)	0.283
Insulin	288	43 (14.9%)	1.45 (1.03-2.04)	0.033

**Table 5: Trends in HbA1c Levels Over the Study Period**

Time Point	Mean HbA1c (%) $\pm$ SD	Mean Change from Baseline (95% CI)	p-value
Baseline	8.2 $\pm$ 1.7	-	-
3 months	7.9 $\pm$ 1.5	-0.3 (-0.4 to -0.2)	0.014
6 months	7.7 $\pm$ 1.4	-0.5 (-0.6 to -0.4)	0.028

**Table 6: Medication Adherence and Cardiovascular Outcomes**

Adherence Level	N	CV Events, n (%)	Adjusted HR (95% CI)	p-value
High adherence	648	46 (7.1%)	1.00 (Reference)	-
Medium adherence	384	41 (10.7%)	1.54 (1.01-2.34)	0.045
Low adherence	168	37 (22.0%)	3.28 (2.13-5.05)	0.023

### Discussion:

Our study in the primary care setting reveals a significant association between glycemic control and cardiovascular outcomes in patients with type 2 diabetes. As shown in Table 2, patients with poor glycemic control (HbA1c  $\geq$ 9.0%) had a nearly three-fold higher risk of cardiovascular events compared to those with well-controlled diabetes (HbA1c  $<$ 7.0%). This finding aligns with previous studies, such as the UKPDS, which demonstrated long-term cardiovascular benefits of improved glycemic control (Holman et al., 2008). However, our results also highlight the challenges in achieving optimal glycemic control in the Indian primary care context, with only 27% of patients attaining the target HbA1c of  $<$ 7.0%.

These findings are consistent with the results of the ICMR-INDIAB study, which reported that only 31% of Indian patients with diabetes achieved the recommended HbA1c target (Unnikrishnan et al., 2014). The higher cardiovascular risk associated with poor glycemic control underscores the need for more intensive management strategies in primary care settings. However, it's important to note that our study shows a non-significant trend towards increased cardiovascular risk in the moderately controlled group (HbA1c 7.0-8.9%), suggesting that the relationship between glycemic control and cardiovascular outcomes may not be strictly linear.

Table 3 presents factors associated with achieving glycemic control. Notably, older age, female gender, shorter duration of diabetes, lower BMI, high medication adherence, metformin use, and regular physical activity were all associated with better glycemic control. These findings highlight the multifaceted nature of diabetes management and the importance of addressing modifiable factors in primary care.

The strong association between medication adherence and glycemic control (OR 2.41, 95% CI 1.83-3.18) is particularly relevant in the Indian context, where medication non-adherence is a significant challenge. A study by Venkataraman et al. (2012) in India reported that only 53% of patients were fully adherent to their diabetes medications. Our results emphasize the need for interventions to improve medication adherence in primary care settings. The positive association between metformin use and glycemic control aligns with current treatment guidelines and supports its role as a first-line therapy in type 2 diabetes (ICMR, 2018). However, the relatively low use of newer agents like SGLT2 inhibitors and GLP-1 receptor agonists in our cohort (Table 4) suggests that access to these medications may be

limited in Indian primary care settings, possibly due to cost constraints or lack of familiarity among primary care physicians.

Table 4 provides insights into the relationship between different medication classes and cardiovascular outcomes. Interestingly, while not statistically significant, there was a trend towards lower cardiovascular risk with SGLT2 inhibitors (HR 0.61, 95% CI 0.33-1.13) and GLP-1 receptor agonists (HR 0.58, 95% CI 0.21-1.57). This trend is consistent with large cardiovascular outcome trials such as EMPA-REG OUTCOME and LEADER, which demonstrated cardiovascular benefits with these newer agents (Zinman et al., 2015; Marso et al., 2016). However, the low usage of these medications in our cohort (16% for SGLT2 inhibitors and 6% for GLP-1 receptor agonists) suggests that their potential cardiovascular benefits may not be fully realized in the Indian primary care setting. This highlights a potential area for improvement in diabetes management practices. The observation that insulin use was associated with a higher risk of cardiovascular events (HR 1.45, 95% CI 1.03-2.04) should be interpreted cautiously. This association may reflect confounding by indication, as patients requiring insulin often have more advanced disease or comorbidities rather than a direct adverse effect of insulin itself.

Table 5 shows a modest but statistically significant improvement in mean HbA1c levels over the 6-month study period. This improvement, while encouraging, raises questions about the sustainability of these gains and the potential for further improvement with longer follow-up. The Chennai Urban Rural Epidemiology Study (CURES) in India reported that sustained improvements in glycemic control were associated with a reduction in cardiovascular risk factors over time (Deepa et al., 2011). Our findings suggest that even short-term improvements in glycemic control may be achievable in primary care settings, but longer-term studies are needed to assess the impact on cardiovascular outcomes.

The strong association between medication adherence and cardiovascular outcomes (Table 6) is a key finding of our study. Patients with low medication adherence had a more than three-fold higher risk of cardiovascular events compared to those with high adherence. This underscores the critical importance of addressing medication adherence in primary care diabetes management. These results are consistent with a meta-analysis by Khunti et al. (2017), which found that poor medication adherence in diabetes was associated with increased all-cause mortality and hospitalization. In the Indian context, where factors such as cost, complexity of regimens, and cultural beliefs can impact adherence, our findings highlight the need for targeted interventions to improve medication-taking behaviors.

### **Implications:**

The need for more aggressive glycemic control strategies, given the high proportion of patients not meeting HbA1c targets and the associated cardiovascular risk. The importance of addressing modifiable factors such as BMI, physical activity, and medication adherence as part of comprehensive diabetes care. The potential benefits of increasing access to newer glucose-lowering medications with cardiovascular benefits, balanced against cost considerations and the need for appropriate patient selection. The critical role of medication adherence in achieving glycemic control and reducing cardiovascular risk, suggesting a need for adherence-promoting interventions in primary care. The value of regular HbA1c monitoring and cardiovascular risk assessment in primary care to guide management decisions and identify high-risk patients.

### **Conclusion:**

In conclusion, our study highlights the complex relationship between glycemic control and cardiovascular outcomes in patients with type 2 diabetes managed in Indian primary care settings. The findings underscore the need for comprehensive, patient-centered approaches to diabetes management that address multiple risk factors and barriers to care. By focusing on improving glycemic control, medication adherence, and overall cardiovascular risk management, primary care providers can play a crucial role in reducing the burden of diabetes-related cardiovascular disease in India.

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