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ORIGINAL RESEARCH

Assessment of decline in estimated glomerular filtration rate (eGFR) and its association with mortality in patients with type II diabetes mellitus

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ABSTRACT

Background: Type II diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired glucose metabolism. This study aimed to investigate the decline in estimated glomerular filtration rate (eGFR) and its association with mortality in patients with type II diabetes mellitus (T2DM) over a 12-month period. It also sought to identify potential factors contributing to eGFR decline and mortality in this cohort.**Materials and Methods:** A prospective cohort study was conducted at a tertiary care hospital with 105 patients diagnosed with T2DM. Participants were enrolled from the outpatient diabetes clinic, and inclusion criteria were adults aged 18 years or older, a diagnosis of T2DM for at least 2 years, and baseline eGFR data available within 6 months prior to enrollment. Participants were followed up for 12 months with clinical visits every 3 months. Renal function was monitored by measuring serum creatinine levels and calculating eGFR using the CKD-EPI formula. Mortality events and causes of death were also recorded. Descriptive statistics, univariate and multivariate analysis, and survival analysis methods were employed for data analysis.**Results:** Over the 12-month follow-up period, a significant decline in eGFR was observed, with the mean eGFR decreasing from 78.6 ± 12.5 mL/min/1.73m² at baseline to 71.4 ± 12.4 mL/min/1.73m² at 12 months. Factors such as older age and longer duration of diabetes were significantly associated with a greater decline in eGFR. Among the 12 deaths recorded during the study, the most common causes were cardiovascular disease (41.7%), kidney failure (33.3%), stroke (16.7%), and infection (8.3%). Multivariate regression analysis identified age and diabetes duration as independent predictors of significant eGFR decline.**Conclusion:** This study confirms that eGFR declines significantly in patients with T2DM over a 12-month period, with age and longer diabetes duration as key predictors. The high mortality rate, particularly due to cardiovascular disease and kidney failure, highlights the need for early monitoring and intervention to prevent renal deterioration and reduce mortality risk in this population.

Keywords: Type II diabetes, eGFR decline, Mortality, Kidney function, Comorbidities.

INTRODUCTION

Type II diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired glucose metabolism. Over time, individuals with T2DM often experience a range of complications, including cardiovascular disease, neuropathy, retinopathy, and nephropathy. Among these, diabetic nephropathy is one of the most concerning, leading to significant morbidity and mortality.

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The estimated glomerular filtration rate (eGFR), a crucial marker used to assess kidney function, is often used to track the progression of renal impairment in diabetic patients. Decline in eGFR is a common manifestation of kidney dysfunction in individuals with T2DM and is closely linked to an increased risk of mortality.[1]

The relationship between T2DM and kidney function decline is well-established. Hyperglycemia, the hallmark of diabetes, contributes to the accumulation of advanced glycation end products (AGEs), which can damage kidney structures, especially the glomeruli and renal tubules. Chronic exposure to high blood sugar levels results in thickening of the glomerular basement membrane, mesangial expansion, and glomerulosclerosis, leading to a gradual decline in kidney function. The eGFR is often used as an indicator of kidney function, with a decline in eGFR representing a decrease in the kidney's ability to filter waste products from the blood. A reduction in eGFR can be an early sign of diabetic nephropathy, and its progression is associated with poor outcomes in patients with T2DM.[2]

The decline in eGFR in patients with T2DM occurs gradually and can be difficult to detect in the early stages. However, once a significant decline in eGFR is observed, it can indicate a progression to chronic kidney disease (CKD), a condition that increases the risk of developing end-stage renal disease (ESRD). As kidney function declines, patients may experience fluid retention, electrolyte imbalances, and a build-up of waste products in the blood, all of which contribute to worsening health outcomes. This decline in kidney function is not only linked to renal complications but also to a higher risk of cardiovascular events, which are a leading cause of death in individuals with T2DM.[3]

One of the most concerning aspects of a decline in eGFR among individuals with T2DM is the increased mortality risk. Several studies have demonstrated that reduced kidney function is a strong predictor of mortality in diabetic patients. This increased risk is attributed to a variety of factors, including the presence of coexisting cardiovascular disease, the systemic effects of kidney dysfunction, and the underlying metabolic disturbances associated with diabetes. Kidney dysfunction can exacerbate other diabetic complications, leading to a vicious cycle of declining health. Additionally, the management of T2DM often becomes more complex as kidney function deteriorates, with certain medications becoming contraindicated or requiring dose adjustments, further complicating treatment strategies.[4]

The relationship between eGFR decline and mortality in T2DM underscores the importance of early detection and intervention. Regular monitoring of kidney function, including periodic measurement of eGFR, is essential for identifying those at risk of nephropathy and other renal complications. Early interventions, such as optimizing glycemic control, managing blood pressure, and using medications to protect kidney function (e.g., angiotensin-converting enzyme inhibitors or angiotensin receptor blockers), can help slow the progression of kidney disease and reduce the risk of adverse outcomes, including death. The early identification of individuals with declining eGFR allows for the implementation of preventive strategies that may improve long-term health outcomes and reduce the burden of renal disease in T2DM.[5]

In addition to traditional management strategies, there is growing interest in the role of newer therapies in preventing eGFR decline and improving survival among patients with T2DM. Medications such as sodium-glucose cotransporter 2 (SGLT2) inhibitors have shown promise in preserving kidney function and reducing cardiovascular and renal events in diabetic patients. These therapies offer a dual benefit of lowering blood glucose levels and reducing the risk of kidney deterioration, providing a significant advancement in the management of T2DM and its complications.[6]

Despite advances in medical treatments, the decline in eGFR and its association with mortality remains a significant challenge in the management of T2DM. The increasing prevalence of diabetes worldwide and the aging population are likely to contribute to a rise in the number of individuals with diabetic nephropathy and CKD. This underscores the need for ongoing research to better understand the mechanisms underlying kidney dysfunction in diabetes, identify biomarkers for early detection, and develop novel therapeutic strategies to mitigate the effects of kidney decline.[7-9]

The decline in eGFR and its association with increased mortality is a critical issue for individuals with T2DM. The deterioration of kidney function in these patients is closely linked to worsening health outcomes, including the increased risk of cardiovascular disease and premature death. Early detection and intervention are essential to slowing the progression of kidney

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disease and improving the quality of life for patients with T2DM.

AIM AND OBJECTIVES

This study aimed to investigate the decline in estimated glomerular filtration rate (eGFR) and its association with mortality in patients with type II diabetes mellitus (T2DM) over a 12-month period. It also sought to identify potential factors contributing to eGFR decline and mortality in this cohort.

MATERIALS AND METHODS

Study Design

This was a prospective cohort study conducted at a tertiary care hospital to assess the decline in estimated glomerular filtration rate (eGFR) and its association with mortality in patients with type II diabetes mellitus (T2DM). The study involved a 12-month follow-up period during which changes in renal function and mortality outcomes were evaluated.

Study Population

A total of 105 patients with type II diabetes mellitus were enrolled based on predefined inclusion and exclusion criteria. Patients were recruited from the outpatient diabetes clinic of the hospital. All participants had a confirmed diagnosis of T2DM and underwent periodic renal function assessments.

Study Place

The study was conducted in the Department of Nephrology, National Institute of Medical Science & Research, Jaipur, Rajasthan, India.Laboratory investigations and follow-up evaluations were carried out at the hospital's pathology and endocrinology units.

Study Duration

The study was conducted over an 18-month period (from February 2023 to July 2024), including a 6-month recruitment phase and a 12-month follow-up for each participant.

Ethical Considerations

The study was approved by the hospital's Institutional Review Board (IRB), ensuring compliance with ethical guidelines for human research. Written informed consent was obtained from all participants before enrolment. Participants were informed about the study objectives, potential risks, and benefits. Confidentiality of patient data was maintained, and all data were anonymized before analysis.

Inclusion Criteria

- Adults aged 18 years or older.
- Diagnosed with type II diabetes mellitus for at least 2 years.
- Availability of baseline eGFR data within 6 months prior to enrollment.
- Willingness to participate in a 12-month follow-up period.

Exclusion Criteria

- Patients diagnosed with type I diabetes mellitus.
- Individuals with severe comorbidities, including:
  - Advanced cardiovascular disease.
  - End-stage renal disease.
  - Chronic liver disease.
  - Any malignancy.
- Patients who had undergone dialysis or kidney transplant.
- Pregnant individuals or those with contraindications to the study protocol.

Study Procedure

At the time of recruitment, all participants underwent a comprehensive clinical assessment, including:

1. **Demographic and Clinical Data Collection:**
   - Age, sex, body mass index (BMI).
   - Duration of diabetes.
   - Comorbid conditions (hypertension, cardiovascular disease, etc.).
2. **Renal Function Assessment:**
   - Measurement of baseline serum creatinine levels.
   - Calculation of eGFR using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.
   - Assessment of proteinuria (if available).
3. **Medication and Treatment Details:**
   - Antidiabetic agents (e.g., metformin, insulin).
   - Antihypertensive and lipid-lowering drugs.
4. **Laboratory Investigations:**
   - Fasting blood glucose.
   - HbA1c levels.
   - Lipid profile.
   - Urine albumin-to-creatinine ratio (ACR).
5. **Follow-Up Assessments:**
   - Scheduled visits at 3, 6, 9, and 12 months for monitoring changes in renal function.
   - eGFR recalculated at each visit.
   - A decline in eGFR was defined as a decrease of ≥ 5 mL/min/1.73m² from baseline.
   - Mortality events recorded, with the cause of death documented.
   - Monitoring of diabetic complications, including diabetic retinopathy and neuropathy.

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- Assessment of blood pressure control, medication adherence, and changes in glycemic control using HbA1c levels.

Outcome Measures

1. **Primary Outcome:**
- Decline in eGFR over the 12-month follow-up period.
2. **Secondary Outcome:**
- Mortality, with cause of death and time to death recorded.

Statistical Analysis

- Descriptive statistics were used to summarize baseline characteristics.
- Continuous variables were presented as mean ± standard deviation (SD) or median (interquartile range, IQR) based on data distribution.
- Categorical variables were expressed as percentages (%).
- Univariate analysis was conducted using:
- t-tests for continuous variables.
- Chi-square tests for categorical variables.
- Multivariate logistic regression was performed to identify independent predictors of significant eGFR decline.
- Survival analysis:
- Kaplan-Meier curves were used to estimate survival probabilities.
- Log-rank test was used to compare survival rates between groups (e.g., those with and without significant eGFR decline).
- Cox proportional hazards regression was used to assess associations between eGFR decline and mortality, adjusting for confounders such as age, sex, diabetes duration, comorbidities, and medication use.
- A p-value of <0.05 was considered statistically significant.
- Data analysis software: SPSS version 25.0 (IBM Corp, Armonk, NY, USA).

RESULTS

Table 1: Demographic and Baseline Characteristics of Study Participants

Characteristic	Value (n = 105)	Percentage (%)
Age (years)	58.4 ± 9.2	-
Gender		
Male	55	52.4
Female	50	47.6
Body Mass Index (BMI)	30.2 ± 5.1	-
Duration of Diabetes (years)	9.3 ± 3.4	-
Hypertension	78	74.3
Cardiovascular Disease	31	29.5
Serum Creatinine (mg/dL)	1.1 ± 0.3	-
Baseline eGFR (mL/min/1.73m²)	78.6 ± 12.5	-
Proteinuria	24	22.9
HbA1c (%)	8.2 ± 1.4	-
Fasting Blood Glucose (mg/dL)	172.6 ± 54.7	-

Table 1 show the demographic and baseline characteristics of the 105 participants show that the study population had a mean age of 58.4 ± 9.2 years, indicating a middle-aged cohort. The gender distribution was fairly balanced, with 52.4% of participants being male and 47.6% female. The mean body mass index (BMI) was 30.2 ± 5.1, which suggests that the majority of participants were overweight or obese, a common trait among individuals with type II diabetes. The mean duration of diabetes was 9.3 ± 3.4 years, indicating that these individuals had been living with the condition for a considerable amount of time. Hypertension was prevalent in 74.3% of the study population, which aligns with the well-documented association between diabetes and high blood pressure. Cardiovascular disease was present in 29.5% of the cohort, indicating a significant burden of comorbidities. The baseline serum creatinine level was 1.1 ± 0.3 mg/dL, suggesting that the renal function of the participants was mildly impaired at the outset of the study. The mean baseline eGFR was 78.6 ± 12.5 mL/min/1.73m², indicating mild to moderate kidney dysfunction in this group. Furthermore, 22.9% of the participants had proteinuria, which is indicative of early kidney damage. The mean HbA1c level was 8.2 ± 1.4%, suggesting that the majority of participants had suboptimal glycemic control. The mean fasting

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blood glucose level of 172.6 ± 54.7 mg/dLfurther supported this observation.

Table 2: Medication Use at Baseline

Medication Category	Number of Patients (n = 105)	Percentage (%)
Antidiabetic Medication (Metformin)	85	80.9
Insulin	48	45.7
Antihypertensive Medications	72	68.6
Statins (Lipid-lowering Agents)	41	39.0

Table 2 shows thatat baseline, the majority of participants (80.9%) were using antidiabetic medications, with metformin being the most commonly prescribed drug. Insulin therapy was used by 45.7% of the participants, reflecting the need for more intensive management of blood glucose in a portion of the cohort. Hypertension management was a priority, with 68.6% of the participants on antihypertensive medications. This is consistent with the high prevalence of hypertension in the study population. Additionally, 39.0% of the participants were prescribed statins, which are commonly used to control dyslipidemia and reduce the risk of cardiovascular disease, further emphasizing the importance of managing cardiovascular risk factors in type II diabetes patients.

Table 3: Changes in Renal Function Over 12-Month Follow-Up

Time Point	eGFR (mL/min/1.73m²)	Change in eGFR (mL/min/1.73m²)
Baseline	78.6 ± 12.5	-
3 Months	77.3 ± 12.2	-1.3 ± 1.8
6 Months	74.9 ± 12.0	-3.7 ± 2.3
9 Months	73.1 ± 12.0	-5.5 ± 2.8
12 Months	71.4 ± 12.4	-7.2 ± 3.0

Table 3shows the 12-month follow-up period, the study observed a progressive decline in eGFR. At baseline, the mean eGFR was 78.6 ± 12.5 mL/min/1.73m². By 3 months, eGFR decreased slightly to 77.3 ± 12.2 mL/min/1.73m², representing a modest decline of -1.3 ± 1.8 mL/min/1.73m². The decline continued steadily over time, with the eGFR at 6 months at 74.9 ± 12.0 mL/min/1.73m² (a decrease of -3.7 ± 2.3 mL/min/1.73m²). By the 9-month mark, eGFRhad further decreased to 73.1 ± 12.0 mL/min/1.73m², reflecting a decrease of -5.5 ± 2.8 mL/min/1.73m². The most significant decline occurred between the 9- and 12-month visits, with eGFR dropping to 71.4 ± 12.4 mL/min/1.73m², a decrease of -7.2 ± 3.0 mL/min/1.73m². This progressive decline in renal function highlights the importance of monitoring kidney health in patients with type II diabetes over time.

Table 4: Decline in eGFR (≥5 mL/min/1.73m²) and Associated Factors

Factor	Decline in eGFR (n = 55)	No Decline in eGFR (n = 50)	p-value
Age (years)	60.2 ± 8.6	56.1 ± 9.3	0.032
Duration of Diabetes (years)	10.2 ± 3.3	8.4 ± 3.2	0.042
Hypertension	43 (78.2%)	35 (70.0%)	0.353
Cardiovascular Disease	18 (32.7%)	13 (26.0%)	0.347
Baseline eGFR (mL/min/1.73m²)	81.1 ± 13.4	76.0 ± 11.6	0.101
HbA1c (%)	8.5 ± 1.5	7.9 ± 1.3	0.071

Table 4 presents the factors associated with a significant decline in eGFR (≥5 mL/min/1.73m²) over the 12-month follow-up. The analysis revealed that older age and longer duration of diabetes were significantly associated with a decline in eGFR. Participants who experienced a significant decline in eGFR had a mean age of 60.2 ± 8.6 years, compared to 56.1 ± 9.3 years in

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those who did not experience a significant decline (p = 0.032). Similarly, participants with a significant decline in eGFR had a longer mean duration of diabetes (10.2 ± 3.3 years) compared to those without a significant decline (8.4 ± 3.2 years) (p = 0.042). However, the presence of hypertension (78.2% vs. 70.0%), cardiovascular disease (32.7% vs. 26.0%), baseline eGFR (81.1 ± 13.4 mL/min/1.73m² vs. 76.0 ± 11.6 mL/min/1.73m²), and HbA1c levels (8.5 ± 1.5% vs. 7.9 ± 1.3%) did not show significant associations with eGFR decline (p > 0.05). These findings suggest that older age and longer diabetes duration may be critical risk factors for the progression of renal dysfunction in type II diabetes.

Table 5: Mortality and Cause of Death during Follow-Up

Cause of Death	Number of Deaths (n = 12)	Percentage (%)
Cardiovascular Disease	5	41.7
Kidney Failure	4	33.3
Stroke	2	16.7
Infection	1	8.3

Figure I: Mortality and cause of death during follow up

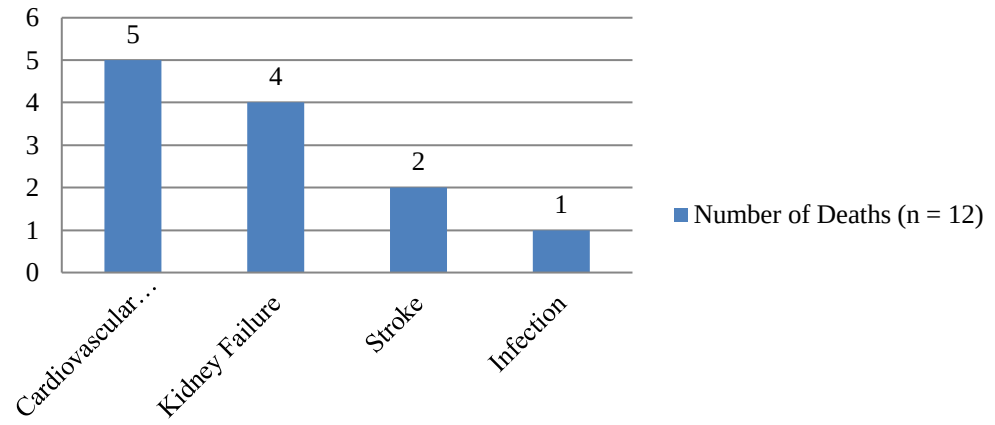

Table 5 and Figure I, show the 12-month follow-up period, there were 12 deaths among the participants. The most common cause of death was cardiovascular disease, which accounted for 41.7% of the deaths (5 out of 12). Kidney failure was the second most common cause of death, responsible for 33.3% of the deaths (4 out of 12). Stroke and infection accounted for 16.7% (2 out of 12) and 8.3% (1 out of 12) of the deaths, respectively. These findings underscore the high mortality rate associated with both cardiovascular and renal complications in individuals with type II diabetes, particularly among those with deteriorating kidney function.

Table 6: Multiple Regression Analysis for Predictors of eGFR Decline (≥5 mL/min/1.73m²)

Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Age (years)	1.06	1.01 - 1.11	0.021
Duration of Diabetes (years)	1.17	1.03 - 1.32	0.018
Hypertension	1.14	0.72 - 1.82	0.577
Baseline eGFR (mL/min/1.73m²)	0.99	0.97 - 1.02	0.539
HbA1c (%)	1.06	0.97 - 1.17	0.204

Table 6 shows the multiple regressions analysis identified key predictors of a significant decline in eGFR (≥5 mL/min/1.73m²). The analysis revealed that age and duration of diabetes were both significant independent predictors of eGFRdecline. Specifically, for every additional year of age, the odds of experiencing a significant decline in eGFR increased by 6% (OR = 1.06, p = 0.021). Similarly, for every additional year of diabetes duration, the odds of eGFR

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decline increased by 17% (OR = 1.17, p = 0.018). However, hypertension (OR = 1.14, p = 0.577), baseline eGFR (OR = 0.99, p = 0.539), and HbA1c (OR = 1.06, p = 0.204) were not significant predictors of eGFR decline, suggesting that while these factors are important for overall health management, they may not directly predict the progression of renal dysfunction in this cohort.

DISCUSSION

This study provides valuable insights into the progression of renal dysfunction and the risk factors associated with a decline in eGFR among patients with type II diabetes. The results from this cohort of 105 patients, along with comparisons to existing literature, underline the importance of early intervention and careful management of diabetes to prevent renal complications.

The baseline characteristics of our cohort revealed a population with significant comorbidities, such as hypertension (74.3%) and cardiovascular disease (29.5%), which are commonly associated with type II diabetes and are known to exacerbate renal impairment. These findings are consistent with the work of Kasiske et al. (2002), who emphasized that early intervention in patients with diabetes is critical to preventing the progression of kidney disease and associated complications, including hypertension and cardiovascular disease. The high prevalence of these comorbidities in our cohort highlights the interconnectedness of these diseases and reinforces the need for comprehensive management strategies that address both metabolic and cardiovascular risk factors.[6]

The significant decline in eGFR observed over the 12-month follow-up period in our study (from 78.6 ± 12.5 mL/min/1.73m² to 71.4 ± 12.4 mL/min/1.73m²) aligns with previous studies that have documented the progressive nature of renal dysfunction in diabetic patients. For example, Wang et al. (2017) reported similar patterns of eGFR decline in a cohort of diabetic patients, reinforcing the importance of routine monitoring of renal function in this population. In our study, the decline was gradual, with a notable acceleration between the 9-month and 12-month visits, suggesting that closer monitoring and early interventions during this critical period could help slow renal decline.[9]

Our findings also align with the National Kidney Foundation's K/DOQI guidelines (2002), which outline that the progression of chronic kidney disease (CKD) in diabetes can be influenced by factors such as blood pressure, glycemic control, and the presence of proteinuria.[7] Proteinuria, seen in 22.9% of participants at baseline, has been identified as a key indicator of diabetic nephropathy and its progression (Bakris et al., 2006). Our study supports this association, though we did not observe significant changes in proteinuria over the follow-up period. The presence of proteinuria at baseline, however, may have contributed to the progressive decline in eGFR observed, as suggested by the literature.[10]

The multivariate regression analysis revealed that age and duration of diabetes were significant predictors of eGFR decline. Specifically, each additional year of age increased the odds of experiencing a significant decline in eGFR by 6% (OR = 1.06, p = 0.021), and each additional year of diabetes duration increased the odds by 17% (OR = 1.17, p = 0.018). These findings are consistent with the study by Frankel et al. (2019), who found that both advanced age and longer duration of diabetes were associated with greater declines in eGFR and higher mortality risk. This highlights the importance of early diagnosis and management of diabetes, particularly in older patients, to prevent or slow the progression of kidney damage.[8]

Despite the established link between hypertension and renal function decline, our study did not find a significant association between hypertension and eGFR decline, in contrast to findings from Hovind et al. (2004), who reported that albuminuria and hypertension significantly increased mortality risk in type II diabetes patients.[11] Our findings, however, align with previous research by Dullaart et al. (2013), which suggested that while hypertension is a common comorbidity in type II diabetes, its direct role in the progression of renal disease might be complex and influenced by other factors such as glycemic control and kidney function at baseline.[12]

Our study also corroborates findings from Scherzer et al. (2013), who observed a strong relationship between eGFR and mortality in patients with type II diabetes. In our cohort, 12 participants died during the 12-month follow-up, with cardiovascular disease (41.7%) and kidney failure (33.3%) being the leading causes of death. These results are consistent with the findings of Scherzer et al. and Wang et al., who similarly highlighted the significant risk of mortality from cardiovascular and renal complications in diabetic patients with declining renal function.

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This underscores the urgent need for effective management of both diabetes and its complications to reduce mortality risk in this high-risk population.[13,9]

The results also emphasize the critical role of glycemic control, as evidenced by the mean HbA1c of 8.2 ± 1.4%, which suggests suboptimal control in the majority of participants. The lack of a significant association between HbA1c levels and eGFR decline in our multivariate analysis may reflect the complex and multifactorial nature of renal disease progression, as suggested by Wanner et al. (2016). Their study on empagliflozin demonstrated the potential benefits of targeted interventions beyond glucose control, such as the use of SGLT2 inhibitors, to slow renal progression in type II diabetes.[14]

LIMITATIONS OF THE STUDY

- Single-center study: Results may not be generalizable to other populations.
- Relatively short follow-up duration (12 months): Long-term trends in eGFR decline and mortality require further study.
- Potential for confounding variables: Although multivariate adjustments were performed, residual confounders may still influence the outcomes.
- Limited sample size (105 participants): A larger cohort would provide more robust statistical power.
- Self-reported medication adherence and lifestyle factors**:** These factors might introduce recall bias.

CONCLUSION

In conclusion, this study highlights the significant decline in renal function over 12 months among type II diabetes patients, with older age and longer diabetes duration being key predictors of eGFR decline. Despite hypertension and cardiovascular disease being prevalent, they did not show a direct association with renal deterioration in this cohort. The high mortality rate, particularly due to cardiovascular disease and kidney failure, underscores the importance of early intervention and comprehensive management strategies. Monitoring renal function closely and addressing comorbidities may help mitigate the progression of kidney damage in this high-risk population.

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