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A Summary Continuation Analysis Evaluating the Prevalence and Predictors of Diabetic Retinopathy in Newly Diagnosed Type 2 Diabetic Patients

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Abstract

Context: *Diabetic retinopathy (DR), the leading cause of acquired blindness in adults, affects approximately 93 million people globally. It is a serious complication of type 2 diabetes, resulting from prolonged damage to the blood vessels in the retina. Although largely preventable and treatable, DR continues to be the main cause of vision loss among working-age adults and significantly impacts quality of life. While most studies on DR in Nepal have focused on its prevalence through cross-sectional methods, this study aimed to assess the incidence of DR and explore the risk factors associated with its development in individuals with type 2 diabetes.* ***Methods:*** *Between January 5, 2023, and November 2024, a hospital-based retrospective follow-up study was conducted involving 420 individuals newly diagnosed with type 2 diabetes. Data from medical records were extracted, entered Epi Info version 7.2.2.6, and subsequently analyzed using Stata 14. To identify factors associated with diabetic retinopathy, both bivariate and multivariable Cox proportional hazards models were applied. Variables with a p-value less than 0.05 in the multivariable Cox model were considered significant predictors of diabetic retinopathy.* ***Results:*** *A median survival duration of 30.4 months was associated with the development of diabetic retinopathy in 19.5% (95% CI: 16.2–23.8) of the study population. Diabetic retinopathy was found to be predicted by congestive heart failure [AHR: 2.53 (95% CI; 1.49, 4.29)], chronic renal disease [AHR: 5.02 (95% CI; 2.73, 9.26)], hypertension [AHR: 2.07 (95% CI; 1.17, 2.89)], and HBA1c [AHR: 10.5 (95% CI; 5.6, 19.6)].* ***Conclusion:*** *In the study setting, the incidence of diabetic retinopathy among individuals with type 2 diabetes was notably high. Special care should be given to patients with heart failure, chronic kidney disease, elevated baseline blood pressure (over 140/90 mmHg), and high baseline HbA1c levels (≥7%).*

Keywords: Diabetic retinopathy, Type 2 diabetes, incidence, risk factors, Cox proportional hazards model, HbA1c, hypertension, chronic kidney disease

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INTRODUCTION

Diabetes mellitus (DM) is a metabolic condition characterized by persistently elevated blood glucose levels and disorders of protein, lipid, and carbohydrate metabolism brought on by issues with either insulin function or synthesis [1, 2]. It is estimated that the global prevalence of diabetes among adults aged 20–79 was 9.3% in 2019 (affecting 463 million people) and is projected to rise to 10.2% by 2030 (578 million people) and 10.9% by 2045 (700 million people) [3]. A comprehensive study conducted in 2018 estimated the prevalence of type 2 diabetes in Nepal at 4.83%. [4]. Paraphrase this sentence. The main causes of morbidity and premature death are complications linked to the rising type 2 DM burden, and the negative economic effects have led to public health issues [5–7]. The most prevalent cause of blindness in adults is diabetic retinopathy (DR), a potentially fatal consequence of type 2 diabetes that arises from cumulative damage to the retinal blood vessels over time [8, 9]. Diabetic retinopathy (DR) mainly impacts individuals with type 2 diabetes (T2DM) and can lead to vision loss due to diabetic macular edema (DMO). It is marked by indicators of retinal ischemia, including abnormalities in the retinal microvasculature, microaneurysms, hemorrhages, cotton wool spots, neovascularization, and/or heightened retinal vascular permeability [10]. The diabetes epidemic presents serious socioeconomic and public health issues due to diabetic consequences, of which diabetic retinopathy (DR), or damage to the retina's tiny blood vessels, is the most prevalent and dreaded diabetic condition that causes blindness [11].

Around the world, 93 million people have DR [12]. Research conducted in numerous nations revealed that the prevalence of DR varied by region, even in low- and middle-income nations [13]. A systematic analysis found that 30.2–31.6% of diabetic patients in Nepal have DR. In particular, the incidence of DR is rising quickly, placing a significant financial strain on these nations [13–15]. Numerous studies conducted in Nepal have demonstrated that the prevalence and seriousness of DR-related consequences are a growing cause of disability and early death [15, 16]. According to a retrospective follow-up analysis, the incidence rate of diabetic retinopathy was 2.65 (95% CI 2.54, 4.05) per 1000 person-years of observation at Kathmandu Hospital Pvt Ltd, Kathmandu 44600, Nepal [15]. Multiple studies have identified several factors as predictors of diabetic retinopathy (DR) in individuals with type 2 diabetes mellitus (T2DM), including older age, male gender, elevated body mass index (BMI), hypertension, poor blood sugar control, high blood pressure, increased cholesterol levels, and a longer duration of diabetes since diagnosis [17, 18].

Although diabetic retinopathy (DR) is often preventable and treatable, it remains the leading cause of blindness among working-age adults in developed countries. It significantly reduces quality of life and is a major contributor to vision loss in this population, often resulting in severe consequences [18–20]. According to certain Nepalese research papers, the prevalence of DR among individuals with type 2 diabetes is rising, and the reasons of DR vary according on the environment. There is little information on the suggested study in the field that investigates possible risk factors of DR to implement evidence-based therapies for individuals with type 2 DM, despite the disease's burden and the fact that its causes vary throughout studies. Most epidemiological studies on DR in Nepal have so far only included cross-sectional study prevalence estimates. The incidence of retinopathy and its determinants in individuals with type 2 diabetes at chronic follow-up were ascertained in this investigation.

In addition to its economic crises and social stigma, type 2 diabetes and its long-term effects, particularly DR, are the main causes of morbidity in Nepal. To prevent DR outcomes, reduce dependency, and lessen societal stigma, it is critical to quantify the disease's burden and identify risk factors early. There were not enough literature sources demonstrating the factors aggravating DR. Thus, it would be crucial to investigate additional possible risk factors and avoid DR. There is insufficient data on the prevalence and causes of DR in Nepal. At Kathmandu Pvt Limited Comprehensive Specialised Hospital, this endeavour attempted to evaluate the prevalence and causes of DR among diabetic patients.

Additionally, the study's findings inform policymakers, health care providers, medical facilities, and administrative offices on how to best prevent and minimise the risk of complications and death from DR in patients with type 2 diabetes by closely monitoring their health conditions and enforcing strict follow-up.

METHODS

Study Characteristics

At the chronic follow-up clinic at the Kathmandu Pvt Limited Comprehensive Specialised Hospital in Kathmandu, Nepal, a hospital-based retrospective follow-up study was carried out among newly diagnosed type 2 diabetic patients who were enrolled between January 5, 2023, to November 2024.

Study Location and Time Period

The study was carried out at the Comprehensive Specialised Hospital, Kathmandu's chronic follow-up facility, located in Kathmandu. It serves as a referral hub for specialised healthcare services in the Kathmandu region. Kathmandu, through a network of both urban and rural health facilities centered around Kathmandu Hospital, has steadily developed infrastructure for managing chronic conditions, such as diabetes, hypertension, and heart disease – effectively serving both urban and rural populations. Diabetes care is an integral part of the chronic disease management program. For over two decades, the same healthcare team has been responsible for providing routine diabetes care at both the central hospital and its rural branches. Among the hospital's wide range of inpatient and outpatient services is a chronic illness follow-up clinic. Each year, approximately 24,552 patients receive follow-up care for chronic conditions, including around 8,800 individuals with diabetes. Of these, about 5,000 are adults aged 18 and above with type 2 diabetes, coming from various regions.

DEFINITIONS OF OPERATIONS

Diabetic Retinopathy

Diabetic retinopathy is a microvascular consequence of diabetes that is assessed by ophthalmologists using indirect ophthalmoscopy or clinical examination. The ophthalmologists' decision determines whether the condition is present (yes) or absent (no) on the charts [21].

Time to DR

Time to DR was the number of years that passed between receiving a diabetes mellitus diagnosis and experiencing one's first episode of DR [21].

Censored

Patients who died or were not able to be followed up with prior to experiencing DRI during the study period, and who did not experience DR until the end of the study [21].

Event

Type 2. DM patients experiencing DR throughout the follow-up period [21].

Body Mass Index

According to World Health Organisation criteria, body mass index was classified as low (low < 18.5 kg/m^2), normal (18.5–24.9 kg/m^2), and high (≥25 kg/m^2) based on physiological factors measured in weight in kilograms per square meter of height (kg/m^2) [22].

Hypertension

Based on the record review, hypertension was defined as having an average systolic or diastolic blood pressure of 140/90 mmHg or higher on at least two separate days [23]. Glycemic control was considered good if the fasting blood sugar (FBS) level was below 130 mg/dL, while values equal to or above this threshold were categorized as poor glycemic control [24].

METHODS FOR GATHERING DATA AND ENSURING DATA QUALITY

Cohort data was gathered from medical records using a pre-tested, standardised checklist from earlier research. Sociodemographic, baseline clinical, and treatment-related characteristics are included in the checklist. We looked at the forms used for patient cards, follow-up cards, DM registration logbooks, and laboratory requests. Following the collection of diabetic patients' medical records from the chronic care follow-up clinic, the patient folder was taken from the card room. Principal investigators assisted two Bachelor of Science (BSc) nurses in conducting the record reviews. Prior to extraction, data extractors received training; 5% of patients underwent pre-testing.

After examining and gathering information from each patient's chart, a code that was widely accepted by data collectors was provided to avoid data recollection. Each patient's outcome was classified as either developing DR or being censored. Prior to the actual data collection, the data collection checklist was pre-tested to ensure that the data items on 5% [20] of the patient charts were complete. Data collectors received two days of training that included the questionnaire's description and how they get information from patient charts. Data collectors were given a thorough explanation of each item on the checklist. The supervisor kept a careful eye on the data collection procedure. Lastly, the checklist's completeness was examined.

PROCESSING AND ANALYSING DATA

Following a consistency and completeness check, the lead investigator coded the data, imported it into Epi info version 7.2.2.6, and exported it to Stata 14 for analysis. The study's sociodemographic, clinical, and treatment-related factors were described using a statistical summary. Both the incidence and the rate of DR were computed for the duration of the investigation. The incidence rate of new diabetic retinopathy (DR) cases during the follow-up period was calculated by dividing the number of new cases by the total person-time of observation, and the result was expressed per 1,000 person-years. To compare different survival probability groups, the Kaplan–Meier curve and log-rank test were utilized.

The Schoenfeld residual test (p-value = 0.2042) and a graphic check of the PH assumption were performed, and the Cox–Snell residual technique was used to evaluate the model's goodness of fit. To find predictors of DR, factors having a p-value less than 0.2 were added to the multivariable Cox proportional hazard model following the application of bivariable analysis. In the multivariable Cox proportional hazards model, variables with a p-value less than 0.05 were considered independent predictors of diabetic retinopathy (DR), and 95% confidence intervals for the hazard ratios were computed [25–27].

RESULTS

Baseline Attributes of Research Subjects

400 of the 403 patient charts that were evaluated were used in the analysis. Males made up 60.25% of this group. The study participants were 50.5 ± 13.3 years old, with a median and standard deviation of that age. More than half of the research participants lived in cities, 18.25% worked for the government, and 77.5% were married. A history of hypertension was present in almost 56.25% of the clinical variables that were found, congestive heart failure in roughly 25.75%, diabetic neuropathy in roughly 17%, and chronic kidney disease in roughly 9.5%. About 46.75% of patients were using aspirin, and almost 32.25% were receiving insulin, according to treatment-related characteristics (Table 1).

400 patients in all were monitored for 1081.603 person-years. Patients who experienced their first episode of DR had a median survival length of 30.4 months, with follow-up times ranging from 0.0333 to 71.867 months. DR developed in 78 patients during the follow-up. DR developed in 19.5% (95% CI: 16.2–23.8). Six per 1000 person-year observations was the overall incidence density (Figure 1).

≥ 7% [AHR: 10.5 (95% CI: 5.6–19.6)] remained significant predictors of DR among adults with type 2 diabetes (refer to Table 2 and Figure 2). These same variables – congestive heart failure, chronic kidney disease, hypertension, and elevated HbA1c – were also confirmed as predictors of DR based on the log-rank test for equality of survival across different explanatory variable categories.

The findings are less than those of longitudinal follow-up research carried out in Kathmandu, which found that the overall incidence of DR was about 36 instances per 1000 patients annually. The study design and follow-up duration variations may be the cause of this discrepancy [28]. The incidence found in this study is higher than that reported in a prospective cohort study from China, which observed an incidence density of 1.81 cases per 1,000 person-years among individuals with type 2 diabetes. This difference may be attributed to variations in sample size and study design (i.e., prospective cohort) [29]. Similarly, the incidence in this study also exceeds that of a cohort study in the United States, which reported a 7.2% incidence rate. This variation could be due to differences in participant demographics (such as age being over 21) and the availability of early diagnosis and regular follow-up for diabetic

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patients. In the U.S., stringent monitoring of complications and a well-developed healthcare system may contribute to a lower incidence of diabetic retinopathy [30].

Table 1. The sociodemographic, clinical, laboratory, and therapeutic characteristics of 400 persons with recently diagnosed type 2 diabetes.

Variable	**Category**	**Frequency**	**Percent (%)**
Sex	Male	241	60.25
	Female	159	39.75
Age	<40	105	26.25
	40–49	75	18.75
	50–59	95	23.75
	60–69	84	21.00
	70–79	34	8.50
	≥80	7	1.75
Marital status	Single	27	6.75
	Married	311	77.75
	Divorced	22	5.50
	Widowed	40	10.0
Residence	Urban	231	57.75
	Rural	169	42.25
Occupation	Gov't employee	73	18.25
	Private work	90	22.50
	Farmer	82	20.50
	Unemployed	12	3.00
	Housewife	95	23.75
	Retired	40	10.0
	Others	8	2.0
Hypertension	Yes	225	56.25
	No	175	43.75
Congestive heart failure	Yes	103	25.75
	No	297	74.25
Chronic kidney disease	Yes	38	9.5
	No	362	90.5
Stroke	Yes	31	7.75
	No	369	92.25
Diabetic neuropathy	Yes	68	17
	No	332	83
Total cholesterol, mg/dl	<200	284	71
	≥200	116	29
Triglyceride, mg/d	<150	284	71
	≥150	116	29
LDL cholesterol, mg/dl	<100	226	56.50
	≥100	174	43.50
HDL cholesterol, mg/dl	<40	154	38.5
	≥40	246	61.5
Insulin exposure	Yes	129	32.25
	No	271	67.75
Aspirin exposure	Yes	187	46.75
	No	213	53.25

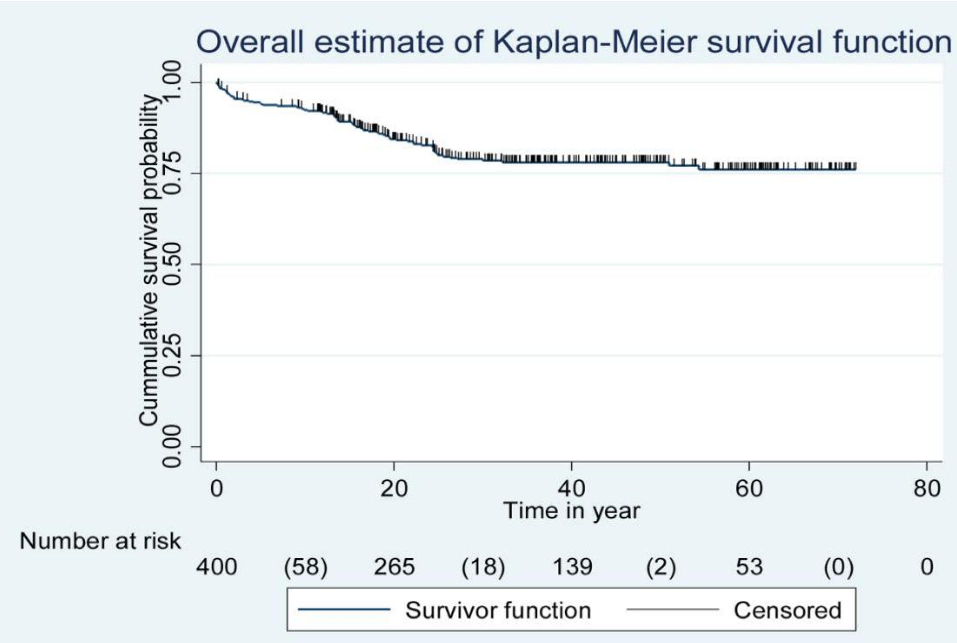

Figure 1. DR-free survival probability Kaplan–Meier curve for type 2 diabetes patients at long-term follow-up.

Table 2. Cox regression analysis of predictors of DR among cohorts of type 2 diabetes patients at chronic follow-up clinic. Independently significant predictors of DR at P-value < 0.05.

Variables	Survival Status Event Censored		CHR (95% CI)	Adjusted AHR (95% CI)
Hypertension				
Yes	70	155	7.6 (3.66, 15.8)	*2.07 (1.17, 2.89)**
No	8	167	1.00	1.00
Congestive heart failure				
Yes	49	54	6.06 (3.82, 9.62)	*2.53 (1.49, 4.29)**
No	29	268	1.00	1.00
Chronic kidney disease				
Yes	30	8	8.87 (5.55, 14.2)	*5.02 (2.73, 9.26)**
No	53	313	1.00	1.00
Stroke				
Yes	14	17	2.96 (1.65, 5.28)	1.32 (0.68, 2.56)
No	64	305	1.00	1.00
Diabetic neuropathy				
Yes	42	26	7.23 (4.62, 11.33)	1.59 (0.89, 2.83)
No	36	296	1.00	1.00
DM status				
uncontrolled	39	74	2.67 (1.71, 4.16)	1.09 (0.62, 1.91)
controlled	39	248	1.00	1.00
HBA1c				
≥ 7%	25	53	1.79 (7.54, 21.69)	*10.5 (5.6, 19.9)**
< 7%	58	284	1.00	1.00
Aspirin				
Yes	50	137	2.16 (1.36, 3.43)	1.06 (0.61, 1.84)
No	28	185	1.00	1.00

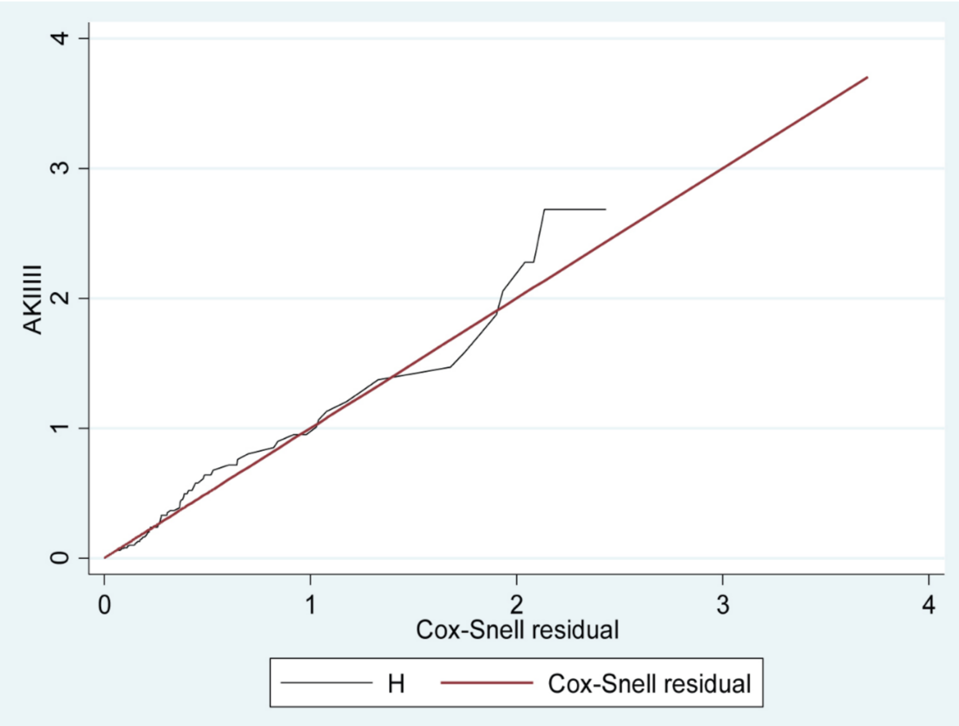

Figure 2. For newly diagnosed type 2 diabetic patients at a chronic follow-up clinic, shows the Cox–Snell residuals for the Cox-regression PH models.

The results of this study were higher than those of studies conducted in Spain (8.07%, 95% CI = 7.04–9.22). This difference may be since type 2 DM patients in Spain receive high-quality care, which may help to reduce the incidence of DR. Other possible explanations for this discrepancy include the different study design (prospective follow-up study) and the different contextual differences between the two countries [31]. Based on information extracted from the patients' medical follow-up chart, this study evaluated the risk of diabetic retinopathy associated with the patients' sociodemographic, clinical, laboratory, and treatment-related factors. Diabetic retinopathy was found to be significantly predicted by the following factors: hypertension, congestive heart failure, HBA1c, and chronic kidney disease. We discovered in this study that DR was independently correlated with hypertension. After controlling for several variables, patients with hypertension exhibited a 2.07-fold increased risk of developing DR compared to those without [AHR: 2.07 (95% CI; 1.17, 2.89). The results were in line with research from China [29], Taiwan [32].

This may be because chronic hyperglycaemia in the case of hypertension triggered the renin-angiotensin system, which in turn caused an increase in the level of Angiotensin II (AII) in vitreous fluid in patients with diabetic macular edema and PDR. DR is ultimately caused by AII's promotion of neovascularization and enhanced vascular permeability [33]. When all other factors were held constant, this study discovered that patients with congestive heart failure had a 2.53-fold higher anticipated hazard ratio of diabetic retinopathy than patients without congestive heart failure [AHR: 2.53 (95% CI; 1.49, 4.29)]. Given that microangiopathy in the heart has been linked to retinal haemorrhage due to capillary micro-aneurysms, microvascular spasm, and thickening of the capillary basement membrane, this may be related to congestive heart failure in diabetic patients [34].

Patients with type 2 DM had a 5.02-fold higher risk of developing DR compared to those without chronic renal disease [AHR: 5.02 (95% CI: 2.73, 9.26)]. This could have something to do with In CKD, inflammatory processes are linked to retinal pathologic characteristics. These mechanisms involve the thickening of the retinal basement membrane, leading to diabetic retinopathy (DR), along with circulatory disturbances and reduced vascular responsiveness [35]. In this study, patients with HbA1c levels above 7% had a 10.5 times higher risk of developing DR compared to those with HbA1c levels below 7% [AHR: 10.5 (95% CI: 5.60–19.9)]. This finding aligns with studies conducted in Madrid, Spain [36], and China [29]. One possible explanation is that individuals with type 2 diabetes and elevated HbA1c levels are more likely to also have hypertension.

LIMITATIONS

The current study's lack of behavioural and institutional factors is one of its main drawbacks, since it may understate the effects and individual differences in the development of diabetes retinopathy. Secondly, due to the retrospective design of the study, we were unable to include certain important diabetes-related complications – such as chronic kidney disease – that are strongly linked to diabetic retinopathy, as the data were collected through chart reviews. Recall bias was reduced because the extracted data was not dependent on the patient's memory because it was previously recorded when the patient visited the medical facility.

CONCLUSION AND RECOMMENDATION

The results of this retrospective follow-up study demonstrated that type 2 diabetes patients at the Kathmandu Comprehensive Specialised Hospital's chronic follow-up clinic had a significant incidence of diabetic retinopathy. Hypertension, congestive heart failure, chronic kidney disease, and elevated HbA1c levels were identified as predictors of diabetic retinopathy among individuals with type 2 diabetes. Given this discovery, patients with heart failure, chronic renal disease, high baseline blood pressure (>140/90 mmHg), and high baseline HBA1c (≥7%) should receive extra attention on top of their usual therapy. It is important to regularly assess, monitor, and document these elements. It would be preferable if medical staff in the DM follow-up clinics worked to lower the prevalence of DR by improving patient self-care and treatment quality. All diabetic patients should receive eye assessment services at least twice a year, as advised by the WHO. It would be preferable for patients to verify their general assessment at each follow-up, particularly regarding ocular disorders, even though the suggested follow-up varies depending on blood glucose control status. Lastly, it is strongly advised to do a prospective study to determine the actual factors that influence DR.

Ethical Clearance and Consent

To comply with the Institutional Review Board (IRB), ethical clearance and approval were acquired from the Kathmandu Hospital's ethical review committee. After receiving this approval, the coordinator of the chronic clinic follow-up at Kathmandu Comprehensive Specialized Hospital provided written permission to carry out the study using the medical records of diabetes patients. To maintain confidentiality, patient identities were not recorded on the data collection forms, and all information was kept anonymous. The data was used solely for research purposes.

Disclosure

No conflicts of interest are disclosed by the authors.

Abbreviations

DR:	Diabetic Retinopathy
DM:	Diabetes Mellitus
HTN:	Hypertension
CHF:	Congestive Heart Failure
CKD:	Chronic Kidney Disease`
Cr:	Creatinine
HBA1c:	Haemoglobin BA1c
HDL:	High Density Lipoprotein
LDL:	Low Density Lipoprotein

AHR:	Adjusted Hazard Ratio
CHR:	Crude Hazard Ratio
AOR:	Adjusted Odds Ratio
ATR:	Adjusted Time Ratio
CI:	Confidence Interval
SRS:	Simple Random Sampling

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