







Time to Diabetic Nephropathy and its Predictors Among Diabetic Patients Treated in Wolaita and Dawuro Zone Hospitals, Ethiopia: A Retrospective Cohort Study

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Background: Diabetic kidney disease (DKD) develops in nearly half of patients with type 2 diabetes mellitus (DM) and one-third of those with type 1 DM during their lifetime. The incidence of DKD as a cause of end stage renal disease is increasing each year. So this study aimed to assess the time to develop diabetic nephropathy and predictors among diabetic patients treated in Wolaita zone hospitals.

Methodology: A ten-year retrospective cohort study had conducted among 614 diabetic patients using systematic random sampling in Wolaita and Dawuro zone hospitals. Bivariable and multivariable Cox proportional hazards regression had used to identify the possible associations between variables. Those variables with a p-value of less than 0.25 in bivariable analysis exported to multivariable Cox regression analysis. Finally, variables with p-value less than 0.05 at multivariable Cox regression were considered significantly significant. The Cox-proportional hazard model assumption had checked using the Schoenfeld residual test.

Results: Of the total participants, 93 (15.3%; 95% CI = 12.45–18.14) patients had developed nephropathy in 820,048 people year observation. A mean time to diabetic nephropathy in this study was 189.63 (95% CI, 185.01, 194.25) months. Being illiterate (AHR: 2.21, 95% CI: 1.34–3.66), being hypertensive (AHR: 5.76, 95% CI: 3.39–9.59), and being urban dwellers (AHR: 2.25, 95% CI: 1.34–3.77) increases the hazard of nephropathy.

Conclusion: According to this follow-up study, the overall incidence rate is substantially high over ten year follow-up period. The mean time to develop diabetic nephropathy was sixteen years. Educational status, place of residence, and being hypertensive were the predictors. So stakeholders should work on complication reduction measures and awareness creation of the impact of comorbidities.

Keywords: chronic disease, complication, survival analysis, longitudinal study, high blood sugar

Background

Diabetic kidney disease (DKD) is a progressive increase in albuminuria or/and a glomerular filtration rate less than 60 mL/min/1.73 m². It occurs as common complications in both types of diabetes. Studies show it is the leading cause of end-stage renal disease (ESRD). Diabetes-related hyperglycemia affects kidney function and alters the usual process of removal of waste products and excess fluid from the body.^{1–3}

Kidney disease attributed to diabetes is a major but under-recognized contributor to the global burden of disease. In 2017, the global prevalence of chronic kidney disease (CKD) was greater than 10%, which are approximately 800 million cases.^{4,5} In Ethiopia according to systematic review and Meta-analysis the prevalence of CKD was 21.71%.⁶ DKD develops in almost half of patients with type 2 diabetes mellitus (DM) and one-third of those with type 1 DM during their lifetime. It will also increase with age in both men and women.^{7,8}

The incidence of DKD as a cause of ESRD is increasing each year. Also, a considerable number of patients who develop ESRD require renal replacement therapies (dialysis and/or transplantation). It is estimated that by the year 2030, more than 70% of patients will be residents of developing countries.^{9–11}

Current findings show that the prevalence of DM is rapidly increasing, as a result, the number of complications that affect patients' quality of life, health service demand, and economic costs will also increase.^{12,13}

DM is identified as a leading cause of ESRD. Several studies have found that its burden is higher than that of other chronic illnesses because more money is spent on treating and managing its complications.^{14–16} Therefore, this study is aimed at assessing the time to develop diabetic nephropathy and its predictors among diabetic patients treated in Wolaita and Dawuro zone hospitals.

Specific Objectives

- To determine time to develop diabetic nephropathy among diabetic patients treated in Wolaita and Dawuro zone hospitals
- To identify the predictors of diabetic nephropathy among diabetic patients treated in Wolaita and Dawuro zone hospitals

Materials and Methods

Study Setting and Period

The study was carried out at public hospitals in the Dawuro and Wolaita zones. They have located about 328 km and 515 km south of Addis Ababa respectively. There are a total of six hospitals (one governmental teaching and referral hospital and five governmental primary hospitals) and 68 health centers found in the Wolaita zone; and three hospitals (one governmental general hospital, two governmental primary hospitals) and 21 health centers in the Dawuro zone. The study was conducted from January 1–30, 2022.

Study Design

An institution-based retrospective cohort study was conducted and strengthening the Reporting of Observational Studies in Epidemiology (STROBE) is used while reporting the study.

Source Participants

The study participants were all medical records of patients who were attending a diabetic clinic from September 1, 2012 to August 30, 2021.

Study Participants

The study participants were selected medical records of patients who were attending a diabetic clinic from September 1, 2012 to August 30, 2021.

Inclusion and Exclusion Criteria

Medical records of diabetic patients who were in follow-up in two zones from September 1, 2012 to August 30, 2021 were included in this study. While medical records of pregnant women, initially presenting with any renal complication, patient charts with no baseline records or those patient cards with incomplete charts or diagnosis year or month missing and patients who had a history of renal complication from other underlying causes will be excluded.

Operational Definitions

Time to Diabetic Nephropathy

It was the time starting from the patient has confirmed as a diabetic patient to the development of a renal complication.

Censored

Patients who were not experiencing renal complications until the end of the study or died or were lost to follow-up before experiencing renal complications within the study period.

Right Censoring

When a subject's follow-up time terminates before the outcome of interest is observed.

Left Censoring

Observed when an individual had developed the event of interest before the beginning of the study.

Event

The development of a renal complication.

Diabetic Nephropathy

Defined as an estimated Glomerular Filtration Rate (eGFR) < 60 mL/min/1.73 m² estimated by the Cockcroft-Gault equation.

Sampling Technique and Sample Size Determination

The sample size was determined by using a double population proportion using the previous study as a reference.^{17–20} By assuming a confidence level of 95%, a power of 90% and by adding 10% for the non-response rate, the final sample size was 614.

Sampling Technique and Procedures

Medical records of diabetic patient were filtered first from the DM registration book according to their entry time and then the samples were proportionally allocated to each hospital according to their total patients. A systematic random sampling technique was used.

Variables of the Study

Dependent Variable

“Time” (Survival time to develop renal complication in months) and “Status” (eGFR) < 60 mL/min/1.73 m² = 1, Censored = 0)

The Independent Variables

- Socio-demographic characteristics (Sex, Residence, Age of patients, Marital status, Level of education, Duration of diagnosis)
- Health history (Diabetic types, Family history, Blood pressure, Weight, Height, Fasting Blood Sugar [FBS], hemoglobin A1c, HDL, LDL)
- Comorbidity (Heart disease, Pulmonary disease, Other chronic diseases)
- Behavioral factors (Alcohol use, Tobacco use)

Data Collection

Patients' follow-up cards, DM registration books and computer files were used to collect the data by using structured data extraction checklists by nurses. To ensure the quality of data, the filled sheet was checked for completeness and consistency by supervisors and the principal investigator. Cross-checking was done while the data entry and clarifying any missing data were also done.

Data Processing and Analysis

The data was collected by ODK application and exported to STATA version 14 for analysis. Descriptive statistics like proportion, percentages, means, and standard deviation was calculated. Kaplan Meier survival curve jointly with the Log rank test was done to estimate the survival curve and for the presence of a difference in survival among independent variables. Bivariable and multivariable Cox proportional hazards regression were used to identify the possible associations between

independent and outcome variables. Variables with p-value lower than 0.25 during bivariable analysis were exported to multivariable Cox-regression analysis. Finally, variables with p-value less than 0.05 at multivariable Cox-regression were considered as significant. The model assumption was checked using the Schoenfeld residual test.

Data Quality Assurance

Training was provided to data collectors and the supervisor. The questionnaire was initially prepared in English language, and then translated into Amharic, and back to English to verify its consistency. The collected data were reviewed on-site for completeness and consistency daily. Also pre-test was conducted on 5% of the sample size on patients before the year of study period.

Ethical Clearance

Ethical approval is obtained from the institutional review board (IRB) of Wolaita Sodo University College of Health Science and Medicine (ref. No. CRCSD/27/02/2014) and conducted per the Declaration of Helsinki. The patient data was kept confidential. Informed consent was exempt from institutional review board of Wolaita Sodo university due to the retrospective nature of the study.

Result

Socio-Demographic Characteristics

A total of 614 cards were reviewed and included in the analysis. The mean age of the participants was 44.61 with SD \pm 13.64 years. More than half of the study participants (365 [59.4%], 333 [54.2%], and 353 [57.5%]) were male, unemployed and rural dwellers, respectively. Most of the diabetic patients (532 [86.4%] and 427 [69.5%]) were ever married and literate (Table 1).

Health History of the Participants

Accordingly, the majority of participants ((581 [94.6%] 561 [91.3%], and 539 [87.7%]) do not have comorbid hypertension, are non-smokers, and do not have an alcoholism history, respectively. More than half (346 [56.4%]), near to half (302 [49.2%]), and more than three-quarters (475 [77.4%]) of patients take oral hypoglycemic agents, are in the normal weight range, and type 2 DM patients, respectively. Diabetic retinopathy and foot ulcers were seen among 402

Table 1 Socio-Demographic Characteristics Among Diabetic Patients Treated in Wolaita and Dawuro Zone Hospitals, Ethiopia (n = 614)

Variables	Category	Frequency (%)
Gender	Male	249 (40.6%)
	Female	365 (59.4%)
Marital status	Never married	82 (13.4%)
	Ever married	532 (86.4%)
Occupation	Employed	281 (45.8%)
	Unemployed	333 (54.2%)
Educational status	Literate	427 (69.5%)
	Illiterate	187 (30.5%)
Residence	Urban	261 (42.5%)
	Rural	353 (57.5%)

Table 2 Health History of Diabetic Patients Treated in Wolaita and Dawuro Zone Hospitals, Ethiopia (n = 614)

Variables	Category	Frequency (%)
BMI	<18.5	75 (12.2%)
	18.5-<25	302 (49.2%)
	25-<30	163 (26.5%)
	≥30	74 (12.1%)
Hypertension	Yes	33 (5.4%)
	No	581 (94.6%)
Smoking history	Current smoker	10 (1.6%)
	Past smoker	23 (3.7%)
	Non smoker	581 (94.6%)
Alcoholism history	Yes	73 (11.9%)
	No	541 (88.1%)
Type of DM therapy	Oral	346 (56.4%)
	Injection	169 (27.5)
	Both	99 (16.1%)
Diabetic retinopathy	Yes	212 (34.5%)
	No	402 (65.5%)
Foot ulcer	Yes	588 (95.8%)
	No	26 (4.2%)
Type of DM	Type 1	139 (22.6%)
	Type 2	475 (77.4%)
Fasting blood glucose	Mean = 196.82, SD ±103.57	
Systolic blood pressure	Mean = 131.25, SD ±19.69	
Diastolic blood pressure	Mean = 79.33, SD±10.28	

(65.5%) and 26 (4.2%) patients, respectively. Additionally, the study participants had a mean of = 196.82, SD ±103.57, 131.25, SD ±19.69, and 79.33, SD±10.28 fasting blood glucose, systolic blood pressure, and diastolic blood pressure respectively (Table 2).

Diabetic Nephropathy Mean Time and Test Equality Among Different Covariates

The Log rank test was performed to test the equality of diabetic nephropathy survival curves for the presence of any significant differences among categorical variables. Accordingly, the mean nephropathy time for female diabetic patients was longer than males (195 months) and it was statistically significant with (p-value = 0.001). Also never married diabetic patients had longer 10-years overall nephropathy-free survival time than ever married patients (199 vs. 187 months, with a P-value of 0.0035). Those who are living in rural areas live longer free of nephropathy than those living in urban areas (199 vs. 187 months with a P-value of 0.001). Those patients having comorbid hypertension had shorter nephropathy-free survival times than their counterparts. This difference was statistically significant p-value = 0.000) (Table 3).

Table 3 Diabetic Nephropathy Overall Survival Rates and Mean Time to Nephropathy Among Diabetic Patients Treated in Wolaita and Dawuro Zone Hospitals, Ethiopia (n = 614)

Variables	Category	Mean Time to DN (95% CI)	P-value with Log Rank
Gender	Male	180.08 (172.47–187.68)	0.001***
	Female	195.14 (189.62–200.67)	
Marital status	Never married	199.22 (189.97–208.46)	0.035***
	Ever married	187.70 (182.59–192.80)	
Occupation	Unemployed	190.13 (184.22–196.03)	0.704
	Employed	188.15 (181.19–195.11)	
Educational status	Literate	192.61 (187.47–197.76)	0.062
	Illiterate	182.90 (173.36–192.43)	
Residence	Urban	199.55 (193.90–205.20)	0.001***
	Rural	180.76 (174.25–187.27)	
Hypertension	Yes	131.37 (108.26–154.46)	0.000***
	No	194.51 (190.13–198.89)	
Smoking history	Current smoker	172.00 (122.41–221.58)	0.777
	Past smoker	186.26 (165.00–207.52)	
	Non smoker	190.27 (185.57–194.97)	
Alcoholism history	Yes	191.25 (178.57–203.94)	0.592
	No	189.42 (184.48–194.35)	
Type of DM therapy	Oral	193.17 (187.37–198.97)	0.100
	Injection	189.33 (180.35–198.31)	
	Both	174.16 (162.41–185.91)	
Diabetic retinopathy	Yes	183.63 (176.01–191.26)	0.246
	No	191.80 (186.28–197.33)	
Foot ulcer	Yes	165.73 (138.26–193.21)	0.232
	No	190.32 (185.68–194.96)	
Type of DM	Type 1	190.61 (180.94–200.27)	0.736
	Type 2	189.31 (184.05–194.56)	

Incidence of Diabetic Nephropathy

Of the total participants, 93 (15.3%; 95% CI = 12.45–18.14) developed nephropathy in 820,048 person year-long observation. The incidence rate of diabetic nephropathy was 1.14 per 10,000 people over a 10 year follow-up period. In the present study, diabetes clients were followed up for a total of 120 months, with a mean time to develop nephropathy being 189.63 months (95% CI, 185.01, 194.25) (Figure 1).

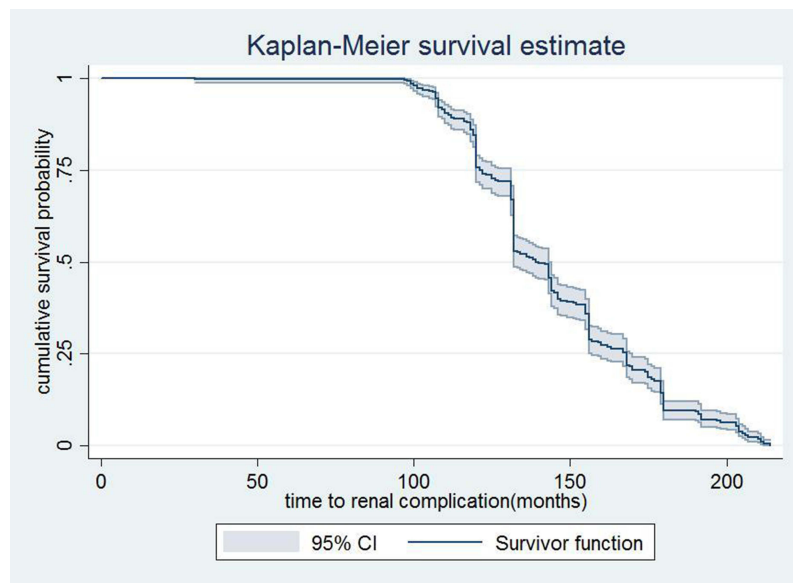


Figure 1 KMC mean time to develop nephropathy among diabetic patients treated in Wolaita and Dawuro zone hospitals, Ethiopia (n = 614) June; 2022.

Predictors of Diabetic Nephropathy

At first, nine variables with a P-value of <0.25 become a candidate for multivariable Cox-regression; then three variables, educational status, residence, and being hypertensive become the predictors of nephropathy. Illiterate patients were at a two times higher risk of diabetic nephropathy as compared to literate (AHR: 2.21, 95% CI: 1.34–3.66). Hypertensive patients were at a six times higher risk of diabetic nephropathy as compared to their counterparts (AHR: 5.76, 95% CI: 3.39–9.59). Patients who were living in urban areas were at a two times higher risk of diabetic nephropathy as compared to rural dwellers (AHR: 2.25, 95% CI: 1.34–3.77) (Table 4).

Discussion

According to this cohort study, the overall incidence rate of diabetic nephropathy during 820,048 person-year observation was 1.14 per 10,000 person-years, which is lower than the study conducted in Addis Ababa¹⁷ (3.6 per 100), Jimma (2.29 per 1000),²¹ and Gonder (14 per 10,000).²² This difference is due to sampling size, the demographic nature of the participants, the type of food they consume, and the urbanization level of the cities.

Whereas of the total participants, 15.3% of patients had developed nephropathy over 10 year follow-up period; nearly similar to the Jimma study (15.56%).²¹ It is lower than a study conducted in Addis Ababa (19.65%),¹⁷ this may be due to people living in more urbanized cities being prone to a sedentary way of life and as a result, it predisposes them to early complications of chronic disease.

But higher than the study of Harari (14.5%)²³ and Addis Ababa (14.25%),¹⁹ this might be the difference in socio-demographic characteristics and socioeconomic characteristics of the study participants.

Accordingly, more than half of the patients were not experiencing diabetic nephropathy until the end of the study. The mean time to develop nephropathy in this study was 189.63 (95% CI, 185.01, 194.25) months. This is different from previous studies, this might be the duration of the study, and the period of the study matters for the development of a long-term complication.

In this study educational status of diabetic patients has an association with the development of a complication. Illiterate patients were two times higher risk of diabetic nephropathy as compared to literate (AHR: 2.21, 95% CI: 1.34–3.66).

A different study finding has indicated that educational status is one risk factor for chronic diseases and their complications.^{24,25}

Table 4 Factors Associated with Diabetic Nephropathy Among Diabetic Patients Treated in Wolaita and Dawuro Zone Hospitals, Ethiopia (n = 614) June; 2022

Variables	Category	Diabetic Nephropathy		Crude HR (95% CI)	P-value	AHR (95% CI)
		Yes	No			
Gender	Female	53	196	1		1
	Male	41	324	1.93 (1.28–2.91)	0.002***	0.81 (0.51–1.29)
Educational Status	Illiterate	35	152	1.48 (0.97–2.25)	0.065	2.21 (1.34–3.66)***
	Literate	59	368	1		1
Marital status	Never married	6	76	1		1
	Ever married	88	444	2.36 (1.03–5.40)	0.042***	1.50 (0.57–3.92)
Retinopathy	Yes	38	174	0.78 (0.51–1.18)	0.249	1.00 (0.60–1.68)
	No	56	346	1		1
Hypertension	Yes	24	9	0.15 (0.09–0.24)	0.000***	5.70 (3.39–9.59)***
	No	70	511	1		1
Residence	Urban	94	520	2.18 (1.37–3.47)	0.001***	2.25 (1.34–3.77)***
	Rural	70	283	1		1
Type of medication	Oral	45	301	1		1
	Injection	26	143	1.16 (0.71–1.89)	0.536	1.60 (0.89–2.86)
	Both	23	76	1.71 (1.03–2.84)	0.035***	1.25 (0.72–2.16)
Foot ulcer	Yes	6	500	0.60 (0.26–1.39)	0.782	0.46 (0.19–1.08)
	No	88	500	1		1
Body mass index	<18.5	5	70	1		1
	18.5–<25	42	260	2.09 (0.82–5.30)	0.118	1.64 (0.63–4.20)
	26–<30	29	134	2.66 (1.03–6.89)	0.043***	1.81 (0.67–4.89)
	>=30	18	56	3.87 (1.43–10.4)	0.007***	2.36 (0.84–6.64)

Note: ***Indicates statistical significance.

The multi-morbidity accelerates the occurrence of chronic disease complications and vice-versa. Hypertensive patients were at a six times higher risk of diabetic nephropathy as compared to their counterparts (AHR: 5.76, 95% CI: 3.39–9.59). This is consistent with the findings of the study done in Jimma²¹ and the Amhara region.²⁶

Hypertension and CKD are closely interlinked patho-physiological states; sustained hypertension can lead to worsening kidney function, and progressive decline in kidney function can conversely lead to worsening blood pressure (BP) control.^{27,28}

Place of residence has a link with the incidence of complications. According to this study Patients who were living in urban areas were at a two times higher risk of diabetic nephropathy as compared to rural dwellers (AHR: 2.25, 95% CI: 1.34–3.77). Different studies also showed that the urbanization level was positively associated with physical inactivity and increases the risk of being overweight; resulting in chronic disease.^{29,30}

Limitations

We face difficulty to generalize the finding because of only hospitals from two zones' was taken from the region, due to budget constraints and some important blood tests are missed in some hospitals.

Conclusion

According to this follow-up study the overall incidence rate is substantially high over ten years follow up period. The mean time to develop renal complication was 16 years. Educational status, place of residence, and being hypertensive were the predictors. So stake holders should work of complication reduction measures and awareness creation of impact of comorbidities.

Data Sharing Statement

The data sets used during the current study are available from the corresponding author on reasonable request.

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We would like data collectors, and Wolaita Sodo University.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All the authors declare that they have no competing interests.

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