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Determinants of Diabetic Nephropathy among Diabetic patients at St. Paul's Hospital Millennium Medical College: A case-control study

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Abstract

Background: Diabetic nephropathy is one of the impending complications of Diabetes Mellitus that might lead to end-stage renal disease and death. Though there are burgeoning reports on diabetic nephropathy elsewhere in the world, studies regarding the determinants of the condition within the Ethiopian context are scarce and inconsistent across different settings. The study aimed to assess determinants of diabetic nephropathy at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, in 2019.

Methods: Unmatched case-control study design with a 1:2 ratio employed to identify determinants of Diabetic Nephropathy. All diabetic patients who developed diabetic nephropathy were considered as cases and all diabetic patients who were free of proteinuria were controls. The total sample size calculated by Epi info 7 software was 261, 87 cases, and 174 controls. A simple random sampling technique was applied. Samples from cases and controls were interviewed by lottery method as they came to the clinics during data collection. Simple binary logistic regression was used first to identify possible factors for further analysis then factors with p-value <0.25 were entered to multiple binary logistic regression to identify significant associations of variables with a p-value of <0.05.

Result: Among 261 study participants, 87 cases, and 174 controls, the median age was 60 and 46.5 respectively. On multiple binary logistic regression; duration of diabetes >10 years, (AOR=3.107, 95% CI= 1.215-7.947), drinking alcohol (AOR=2.896, 95% CI= 1.531-5.480), no adherence to regular physical exercise (AOR=4.378, 95% CI= 2.297-8.344) and presence of systolic hypertension (AOR=2.995, 95% CI= 1.547-5.795) were significantly associated with diabetic nephropathy.

Conclusion: Duration of diabetes, drinking alcohol, non-adherence to regular physical exercise, and systolic hypertension were the significant factors of diabetic nephropathy. Health education campaigns on controlling blood glucose level, blood pressure, cessation of behavioral factors like alcohol drinking, and performing regular physical exercise shall be designed on regular basis.

Keywords: Case-control, Determinants, Diabetic nephropathy, Addis Ababa, Ethiopia

Background

Diabetes Mellitus (DM) is a chronic, heterogeneous non-communicable disease. It is characterized by high blood glucose due to impaired insulin production, the impaired release of insulin at high blood glucose levels, and the impaired effect of insulin in the target cells or a combination of these factors (1, 2).

Diabetes of all types can lead to complications in many parts of the body and can increase the overall risk of morbidity and mortality. Common chronic complications of diabetes are cardiovascular disease, neuropathy, nephropathy, retinopathy, and foot ulcer. Among these complications, diabetic nephropathy is the serious complication of diabetes that leads to end-stage renal failure and death (1, 3-5).

Diabetic nephropathy affects about 30% of the people with type 1 diabetes, and 25-40% of the people with type 2 diabetes(6). It has been suggested to be more frequent among patients with diabetes in Africa as compared to those in the developed world due to limited screening for diabetes, scarcity of diagnostic resources leading to delayed diagnosis, and inadequate treatment leading to poor control of blood sugar at an early stage (1, 6-9). Prevalence of diabetic nephropathy in Ethiopia, from the studies of diabetic complications, varies from 15.7% to 29.5% which has a significant effect on the socioeconomic status of the country (5, 10, 11).

The most common risk factors of diabetic nephropathy are socio-demographic characteristics like age and sex; clinical factors like body mass index (BMI), hypertension, poor glycemic control, specific medication, type of diabetes, cholesterol level, fasting blood sugar, duration of diabetes, and behavioral factors like negative attitude towards diabetes, poor treatment adherence, unhealthy diet, smoking, and alcohol drinking (1, 4, 8, 12-14).

Diabetes accounted for 10.7% of global all-cause mortality. People with diabetes and clinical nephropathy experience 50% higher health expenditures compared to those with diabetes without clinical nephropathy; this indicates how diabetic nephropathy has an impact on social, economic, and the health aspect of the society as a whole and the quality of life as an individual (2).

Even though there are burgeoning reports on diabetic nephropathy elsewhere in the world and even in Ethiopia, studies regarding the determinants of diabetic nephropathy within the Ethiopian context are scarce. This in turn enhances the gap for possible prevention and timely management of the case (1, 7, 8). Some studies conducted worldwide showed that factors of Diabetic Nephropathy are not common to every country and even vary from one study to another. Therefore, this study has aimed to identify determinants of diabetic nephropathy to set programs, identify priority groups in allocating resources, educate diabetic patients, prioritize tasks and interventions in the prevention and overall treatment of diabetic nephropathy, and as baseline information for further studies.

Methods

Study design and Study population

An unmatched case-control study was conducted in Saint Paul's Hospital Millennium Medical College (SPHMMC), outpatient DM and renal clinics, from June to August 2019. SPHMMC is found in the capital city of Ethiopia, Addis Ababa. It gives service to over 2 million clients per year in different departments. Under the outpatient department, the institution gives service three times per week for over fifty thousand patients annually. All diabetic nephropathy patients having follow-up in the renal clinic are considered as cases and all diabetic patients who were free of nephropathy having follow-up in the diabetic clinic are considered as controls.

Inclusion and Exclusion criteria

Patients who were diagnosed with diabetic nephropathy by physicians and already had a follow-up in the renal clinic were included in the study as cases. Diabetic patients who were free of nephropathy during the time of data collection and who had to follow up in the diabetes clinic were considered as controls. Patients who were seriously ill and couldn't give consent were excluded from the study. Also, diabetic patients whose urine dipstick test gave mild and heavy proteinuria during data collection time were excluded from controls to reduce selection bias.

Sample size determination and sampling technique

The sample size was determined by Epi info 7 software of double population proportions Using 95% confidence interval (CI), power (P) 80%, ratio of control to case=2:1, OR=2.22 i.e. The ratio of odds of poor glycemic control among patients with nephropathy to

odds of poor glycemic control among diabetic patients without nephropathy. Proportion (p1) was taken from the same study conducted in Tigray, thus, Proportion (p1) =50.15% (the proportion of study subjects with poor glycemic control among nephropathy free diabetic patients(1). The total sample size calculated using the software was 261 (87 cases and 174 controls). A simple random sampling technique was applied to collect data from study participants. Cases and controls were interviewed by lottery method as they came to renal and DM clinics during data collection and his/her documents were reviewed.

Data collection tools and quality

Structured questionnaires and checklists were used to collect data. The questionnaire was prepared in English and translated to Amharic and then back to English. Pretest was done at Zewditu Hospital on 5% samples. The questionnaire includes socio-demographic variables, behavioral factors, and clinical data of patients. To ensure the quality of data, training was provided to the data collectors and supervision done by the principal investigator. During the data collection process, each questionnaire was checked for its completeness, consistency, and accuracy.

Data processing and analysis

Once the collected data were checked manually, the data were entered into Epi Info 7software, and then exported to Statistical Package for the Social Sciences (SPSS) version 20 for cleaning and analysis. Descriptive statistics such as means, frequencies, proportions, and rates of variables were calculated. Simple binary logistic regression was used first to select possible factors for further analysis. Then factors with a P-value <0.25 were entered into a multivariable binary logistic regression to identify significant associations of independent variables with the outcome variable, Diabetic Nephropathy. A *P*-value of less than 0.05 was considered as statistically significant and an adjusted odds ratio (AOR) with 95% CI was used to determine the association.

Operational definitions

Adherence to regular physical exercise: Strenuous physical activity performed for >20 minutes at a time for >1 times per week was considered as adhered to regular physical exercise unless not considered as adhered(13).

Cigarette Smokers: Are those currently smoking and had smoked cigarettes in his/her lifetime at least once or more per month.

Alcohol drinkers: Are those currently drinking and/or previously drinkers of alcohol and traditional herbs (alcohol with or without known alcohol content) at least once or more than per week.

Adherence to medicines: Taking medication as prescribed and/or agreed between the patients and the health care provider was considered as adhered to medicines (15).

Hypertension: Based on International Diabetes Federation (IDF) at screening hypertension is defined as mean systolic blood pressure ≥ 140 mmHg, or diastolic blood pressure ≥ 90 mmHg on three measurements(2).

Glycemic control: It is determined by hemoglobin A1C (HbA1C). It is either good if HbA1C<7.5% or poor if HbA1c >7.5 %(16). Alternatively, if three consecutive FBS measurements are under the normal range, it is considered as good.

Adherence to blood glucose measurement at home: Measuring blood glucose at least one time per day at home is considered as adhered (15).

Adherence to diet: Taking dietary contents as advised by the health care provider and avoiding those food contents advised to restrict were considered as adhered to the diet.

Results

Sociodemographic characteristics

Among 261 study participants enrolled in this study, 87 were cases and 174 were controls. The median age of cases was 60 and that of controls was 47.5 years. Sixty-four (73.9%) of cases and 89 (51.1%) of controls were males. A higher number of participants, 81 (93.1%) of cases and 155 (89.1%) of controls were from urban areas. Majority of cases 55 (63.2%) and controls 112 (64.45) were married (Table 1). Among cases, 54 (62.1%) were alcohol drinkers whereas only 44 (25.3%) of controls were drinkers. Only 20 (23.0%) of cases and 6(3.4%) controls were cigarette smokers, 57(65.5%) of cases and 133 (76.4%) of controls were adherents to their medications. Unlike cases, the majority of controls 115(66.1%) have adhered to their diet (Table 2).

Table1: Socio-demographic characteristics of 87 Diabetic Nephropathy and 174 Diabetes Mellitus patients at SPHMMC, Addis Ababa, Ethiopia, 2019 (n=261)

Variable	Category	Cases (%)	Controls (%)
Age	18-35	11(12.6)	36(20.7)
	36-50	28(32.2)	62(35.6)
	51-65	37(42.5)	63(36.2)
	>65	11(12.6)	13(7.5)
Sex	Male	64(73.6)	89(51.1)
	Female	23(26.4)	85(48.9)
Religion	Orthodox	54(62.1)	111(63.8)
	Muslim	14(16.1)	29(16.7)
	Protestant	16(18.4)	34(19.5)
	Others	3(3.4%)	0(0)
Residence	Urban	81(93.1)	155(89.1)
	Rural	6(6.9)	19(10.9)
Educational status	Illiterates	13(14.9)	33(19.0)
	Literates	74(85.1)	141(81.0)
Occupational status	Government Employee	28(32.2)	63(36.2)
	Self & private employee	52(59.8)	97(55.7)
	Farmers and others	7(8)	14(8)
Marital status	Married	55(63.2)	112(64.4)
	Unmarried	32(36.8)	62(35.6)
Monthly income	<600	3(3.4)	8(4.6)
	601-5250	43(49.4)	130(74.7)
	5251-10900	37(42.5)	34(19.5)
	>10901	4(4.6)	2(1.1)

Table 2: Behavioral factors of 87 Diabetic Nephropathy and 174 Diabetes Mellitus patients at SPHMMC, Addis Ababa, Ethiopia, 2019 (n = 261)

Variable	Category	Cases (%)	Controls (%)
Alcohol drinking	Drinkers	54(62.1)	44(25.3)
	Not drinkers	33(37.9)	130(74.7)
Cigarette smoking	Smokers	20(23.0)	6(3.4)
	Non-smokers	67(77.0)	168(96.6)
Adherence to medication	Adhered	57(65.5)	133(76.4)
	Not adhered	30(33.5)	41(23.6)
Adherence to diet	Adhered	31(35.6)	115(66.1)
	Not adhered	56(64.4)	59(33.9)
Adherence to regular physical exercise	Adhered	33(37.9)	140(80.5)
	Not adhered	54(62.1)	34(19.5)
Adherence to blood glucose measurement at home	Adhered	28(32.2)	87(50.0)
	Not adhered	56(67.8)	87(50.0)

Twelve (13.8 %) of cases and sixty (34.5%) of controls were less than 5 years of duration since being diagnosed as DM. The majority of cases and controls were Type 2 Diabetic (71 (81.6%), 135 (77.6%) respectively). Sixty-two (71.4%) of cases had systolic hypertension whereas only 47 (27.0%) of controls had systolic hypertension. Forty-seven (54.0%) of cases and 127 (73.0%) of control's BMI were within the normal range. Forty-two (48.3%) of cases and 119(68.4%) of controls had good glycemic control (Table 3).

Table 3: Clinical characteristics of 87 Diabetic Nephropathy and 174 Diabetes Mellitus patients at SPHMMC, Addis Ababa, Ethiopia, 2019 (n = 261)

Variable	Category	Cases (%)	Controls (%)
Duration of diabetes	<5 Years	12(13.8)	60(34.5)
	5-10 Years	37(42.5)	85(48.9)
	>10 Years	38(43.7)	29(16.7)
Type of diabetes mellitus	Type 1	16(18.4)	39(22.4)
	Type 2	71(81.6)	135(77.6)
Another complication of diabetes mellitus	Yes	52(59.8)	49(28.2)
	No	35(40.2)	125(71.8)
Systolic hypertension	Yes	62(71.3)	47(27.0)
	No	25(28.7)	127(73)
Diastolic Hypertension	Yes	41(47.1)	23(13.2)
	No	46(52.9)	151(86.6)
Body Mass Index	Underweight	4(4.6)	5(2.9)
	Normal	47(54.0)	127(73.0)
	Overweight	33(37.9)	34(19.5)
	Obese	3(3.4)	8(4.6)
Glycemic control	Good	42(48.3)	119(68.4)
	Poor	45(51.7)	55(51.7)
Presence of Dyslipidemia	Yes	34(39.1)	45(25.9)
	No	53(60.9)	129(74.1)

Determinants of Diabetic Nephropathy

On simple binary logistic regression: Age, sex, duration of DM in years, Alcohol drinking, cigarette smoking, adherence to medicines, adherence to diet, adherence to exercise, adherence to glucose measurement at home, presence of other complications of DM, presence of both systolic and diastolic HTN, BMI, being overweight and obese, poor glycemic control, and presence of dyslipidemia had P-value <0.25 and were entered to multiple binary logistic regression (Table 4).

The odds of the duration of DM since diagnosis of >10 years was three times higher (AOR=3.107, CI= (1.215-7.947)) among DM patients with diabetic nephropathy compared to controls. The odds of being an alcohol drinker were three folds (AOR=2.896, CI= (1.531-5.480)) among DM patients with diabetic nephropathy than DM patients without nephropathy. The odds of having systolic hypertension were higher with three folds (AOR=2.995, CI= (1.547-5.795)) among DM patients with diabetic nephropathy compared to DM patients without nephropathy.

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compared to DM patients without nephropathy.

Table 4: Binary logistic regression of determinant factors associated with diabetic nephropathy among diabetic patients at SPHMMC, Addis Ababa, Ethiopia, 2019 (n = 261)

Variables	Cases	controls	Crude OR(95% CI)	Adjusted OR(95% CI)
Age Category				
18-35	11	36	1.00	1.00
36-50	28	62	1.478(0.658-3.320)	0.855(0.312-2.343)
51-65	37	63	1.922(0.874-4.226)	0.267(0.085-0.846)
>65	11	13	2.769(0.970-7.907)	0.221(0.047-1.031)
Sex				
Female	23	85	1.00	1.00
Male	64	89	2.658(1.516-4.660)	1.782(0.837-3.795)
Duration of DM				
≤5 years	12	60	1.00	1.00
5-10 years	37	85	2.176(1.049-4.517)	1.841(0.795-4.266)
>10 years	38	29	6.552(2.986-14.378)	3.107(1.215-7.947)*
Alcohol Drinking				
Not drinkers	33	130	1.00	1.00
Drinkers	54	44	4.835(2.735-8.394)	2.896(1.531-5.480)***
Cigarette smoking				
Not smokers	67	168	1.00	1.00
Smokers	20	6	8.358(3.216-21.726)	3.168(0.935-10.735)
Adherence to medicines				
Adhered	57	133	1.00	1.00
Not adhered	30	41	1.707(0.971-3.001)	0.758(0.328-1.748)
Adherence to diet				
Adhered	31	115	1.00	1.00
Not adhered	56	59	3.521(2.053-6.039)	1.899(0.975-3.698)
Adherence to exercise				
Adhered	33	140	1.00	1.00
Not adhered	54	34	6.738(3.800-11.947)	4.378(2.297-8.344)***
Adherence to glucose measurement at home				
Adhered	28	87	1.00	1.00
Not adhered	56	87	2.107(1.229-3.613)	1.222(0.585-2.554)
Another complication of DM				
No	35	125	1.00	1.00
Yes	52	49	3.790(2.206-6.511)	1.579(0.722-3.456)
Presence of Systolic HTN				
No	25	127	1.00	1.00
Yes	62	47	6.701(3.781-11.878)	2.995(1.547-5.795)***
Presence of Diastolic HTN				
No	46	151	1.00	1.00
Yes	41	23	5.852(3.186-10.748)	1.454(0.581-3.640)
BMI				
Normal & below	51	132	1.00	1.00
Overweight & Obese	36	42	2.218(1.280-3.846)	0.687(0.313-1.506)
Glycemic control				
Good	42	119	1.00	1.00
Poor	45	55	2.318(1.367-3.931)	1.346(0.662-2.739)
Presence of Dyslipidemia				
No	53	129	1.00	1.00
Yes	34	45	1.839(1.063-3.1820	0.765(0.332-1.761)

*Where, * p ≤ 0.05; ** p ≤ 0.01; *** p ≤ 0.001; 1.00 = reference; CI = Confidence Interval.*

The odds of having systolic hypertension were higher with three folds (AOR=2.995, CI= (1.547-5.795)) among DM patients with diabetic nephropathy compared to DM patients without nephropathy. The odds of being poor adherent to regular physical exercise was four times higher (AOR=4.378, CI= (2.297-8.344)) among DM patients with diabetic nephropathy compared to DM patients without diabetic nephropathy. Therefore, duration of DM since diagnosed, alcohol drinking, poor adherence to regular physical exercise, and presence of Systolic Hypertension were significantly associated with the development of Diabetic Nephropathy.

Discussion

This study identified factors associated with diabetic nephropathy. Duration of DM since diagnosed, alcohol drinking, poor adherence to regular physical exercise, and presence of Systolic HTN were significantly associated with the development of nephropathy among diabetic patients. The odds of the duration of DM since diagnosis of >10 years was three times higher among DM patients with diabetic nephropathy than their counterparts. This is consistent with numerous studies and confirms diabetes duration as an important predictor of diabetic nephropathy (1, 4, 7, 17). The possible explanation is that diabetic nephropathy is a progressive kidney disease, therefore, progressive alterations in the glomerular capillary, tubular structure, and function will result in a progressive decline in the glomerular filtration rate, and increased arterial blood pressure.

Alcohol drinking was the other variable that was significantly associated with the development of diabetic nephropathy in diabetic patients. In this study, the odds of being an alcohol drinker were threefold among DM patients with diabetic nephropathy. Alcohol consumption by diabetic patients can worsen their blood sugar control. It can result in excessive blood sugar levels in well-nourished diabetics, dangerously low blood sugar levels in diabetics who are not adequately nourished, and also can cause the accumulation of certain acids in the blood. Alcohol consumption can also worsen diabetes-related medical complications, such as

kidney, nerve, and eye disease (18). However, studies conducted in Ethiopia, Ayder hospital, and Shakiso health center don't support this study. This may be due to differences in sample size, study population, and design (1, 4).

The odds of being poor adherent to regular physical exercise was four times higher among DM patients with diabetic nephropathy compared to patients without nephropathy. The result of this study was not similar to other studies conducted in Ayder and Shakiso. This may be due to differences in the study area and study population. Currently, physical exercise is limited in urban areas like Addis Ababa than rural areas due to various reasons (1, 4).

This study also showed that the odds of having systolic hypertension were higher with three folds among DM patients with diabetic nephropathy compared to DM patients without nephropathy. The result was supported by different studies (1, 4, 8, 13, 17, 19, 20). This is due to poor treatment and control of hypertension which results in the development and progression of hypertensive nephrosclerosis and proteinuria (4).

Glycemic control which is the universal factor in other studies (1, 7, 13, 19, 20), was not associated with diabetic nephropathy in this study; this may be since HbA1c, which is the gold standard diagnostic investigation for glycemic control was not feasible and not measured to many of diabetic patients in this hospital. Instead, three consecutive fasting blood sugar tests were taken to determine the glycemic control of study participants. This underestimates glycemic control to be the determinant factor of diabetic nephropathy. The same study conducted in Shakiso revealed that glycemic control is not associated with Diabetic Nephropathy, in fact, this study also used FBS as a diagnostic investigation to determine glycemic control (4).

In this study, the age of study participants was not significantly associated with the development of diabetic nephropathy which is an independent factor in other similar studies (1, 4, 7, 20, 21). This variation might be due to the sample size and source population of the studies. Additionally, most of the studies conducted were specific to the type of diabetes, unlike this study.

This study has some limitations. There might be a chicken-egg dilemma of the development of diabetic nephropathy with independent variables like HTN. For some variables; the study depended on the patient information which might have been influenced by recall bias. Another limitation of the study was that HbA1c of study subjects was not available. Instead, the three consecutive fasting blood sugar measures were used to determine glycemic control, which may underestimate the result.

In conclusion, duration of DM since diagnosis, poor adherence to regular physical exercise, drinking alcohol and systolic hypertension were determinants of diabetic nephropathy. Health education campaigns on alcohol cessation; physical exercise and blood pressure control shall be designed. As some of these factors were behavioral and modifiable, identifying risky groups and designing targeted interventions must be given emphasis by stake holders.

Abbreviations

BMI- Body Mass Index

CKD- Chronic Kidney Disease

DM- Diabetes Mellitus

DN- Diabetic Nephropathy

EDA- Ethiopian Diabetic Association

ESRD- End-Stage Renal Disease

FBS- Fasting Blood Sugar

HbA1c- Hemoglobin A1C or glycated hemoglobin

IDF-International Diabetic Federation

IRB- Institutional Review Board

LDL-C- Lower Density Lipoprotein Cholesterol

OR- Odds Ratio

RBS- Random Blood Sugar

SPHMMC- Saint Paul's Hospital Millennium Medical College

TG-Triglyceride

WHO - World Health Organization

Declarations

Ethical approval and consent to participate

Ethical approval was obtained from the Institutional Review Board (IRB) of SPHMMC. Written informed consent was taken from each study participant. The study was done based on the declaration of Helsinki. Moreover, the privacy of the study participants and confidentiality of the information gathered were maintained and assured.

Consent for publication

Not applicable.

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Authors' contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The dataset used and or analyzed during this study are available from the corresponding author on a reasonable request from Mr. Mulugeta Ayana (email address: muluayana19@gmail.com).

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