



Saint Paul Hospital Millennium Medical College
Graduate Study Program

PATTERN OF RETINOPATHY AMONG PATIENTS ON
HEMODIALYSIS, SAINT PAUL HOSPITAL MILLENNIUM MEDICAL
COLLEGE ADISS ABABA, ETHIOPIA.

BY:

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Addis Ababa, Ethiopia

July, 2022



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HEMODIALYSIS, SAINT PAUL HOSPITAL MILLENNIUM MEDICAL
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A Research Project to be submitted to the department of ophthalmology: presented in Partial fulfillment of the requirements for the Degree of ophthalmology specialty: Saint Paul Hospital Millennium Medical College.

Addis Ababa, Ethiopia
July, 2022

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Research Project Submission Template

Name of Investigator	Dr Gizachew Gebrie(Ophthalmology Resident)
Full title of research Project	Pattern of retinopathy among patients on hemodialysis, Saint Paul Hospital Millennium Medical College, Addis Ababa, Ethiopia.
Duration of the Project	From January 2020 to July 2022
Study Area	Saint Paul Hospital Millennium Medical College renal transplant unit
Total Cost of the Project	32,790 Ethiopian birr
Source of Funding	Saint Paul Hospital Millennium Medical College
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Abstract

Background: Retinopathy is any of various non-inflammatory disorders affecting the retina marked by damage to retinal blood vessels, retinal swelling or abnormal growth of new blood vessels. The type of retinopathy is often specified as arteriosclerotic or hypertensive retinopathy. A pathophysiological mechanism of hemodialysis related retinopathy could be associated with cause of end stage renal disease or treatment related. The major causes of end stage renal disease requiring hemodialysis includes diabetes mellitus, hypertension and glomerulonephritis. In Ethiopia unidentified causes, diabetes mellitus, hypertension and glomerulonephritis accounts for majority of end stage renal disease requiring hemodialysis.

Objective of the study was to describe pattern of retinopathy among patients on hemodialysis at SPHMMC renal transplant unit from September 2020 to December 2021.

Methods: A cross- sectional descriptive hospital based study was undertaken from September 2020 to December 2021 at SPMMC national renal transplant unit center which is located in Addis Ababa. It is one of few public RRT center in the country established in 2014 and was providing hemodialysis for 59 patients during study period. The study was conducted among all 59 patients who had undergone hemodialysis during this period. Ocular, medical and nephrology history was recorded from the patient's chart using checklist. Best correct visual acuity using snellen scale and dilated fundus examination using Slit lamp bio microscopy with noncontact 90 diopter lens and indirect ophthalmoscope was done for presence of retinopathy. Data was entered and analyzed using SPSS version 25.0 after data quality control checking and result was presented with frequency tables and graphs for categorical variables and mean, median and standard deviations were calculated for numeric variables. Association between dependent and independent variables was tested using the chi-square test and P-value < 0.05 was taken as statistically significant association.

Result: A total number of 59 case with 118 eyes of chronic kidney disease patients on hemodialysis were analyzed. Out of 59 study cases 35(59.3%) participants were males. Mean age of total patients was 36.9 years with a standard deviation of 11.995 (ranging from 17–72 years) and the male: female ratio was 1.46:1. Most study subjects 35 (59.3 %) were between 20 to 40 years of age. Most study participants 52(88.1 %) were from urban area. The result of this study showed that about 26 (44.1%) of study participants and 52(44.1%) examined eyes from total 59 study subjects and 118 examined eyes undergoing hemodialysis had retinopathy. The most common pattern of retinopathy was hypertensive retinopathy for 35(67.31%) eyes, mixed retinopathy for 12(23.08%) eyes and diabetic retinopathy for 4(7.69%) eyes of retinopathy. This study showed statistically significant association between both history and duration of diabetes, and hypertension and history of ocular screening with presence of retinopathy with p value less than 0.05 with 95% CI.

Conclusion This study showed presence of retinopathy among patients undergoing HD was high. HR was the most common pattern of retinopathy followed by mixed retinopathy.

ACKNOWLEDGMENT

I would like acknowledge my advisors Dr Tsedeke Asaminew, Dr Habtom Hagose and Mr Tariku Shimelis for their relevant guidance and important comments during conducting proposal and writing of this study project.

I want to extend my appreciation to SPHMMC renal transplant unit staffs for their help in providing official data.

Deep gratitude also goes to SPHMMC and ophthalmology department for aiding to undertake this study project.

Lastly I want to extend my acknowledgment to Sr Hiliwa Hassen for her willingness for data collection and facilitation for slit lamp examination of patients at ophthalmology clinics.

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LIST OF ABBREVIATIONS/ACRONYMS

ADED.....	Advanced Diabetic eye disease
BCVA.....	Best Corrected Visual Acuity
BMI.....	Body Mass Index
BP.....	Blood Pressure
BRVO.....	Branch Retinal Vein Occlusion
CRVO.....	Central Retinal Vein Occlusion
CKD.....	Chronic Kidney Disease
CRF.....	Chronic Renal Failure
DM.....	Diabetes Mellitus
DN.....	Diabetic Nephropathy
DR.....	Diabetic Retinopathy
DN.....	Diabetic Nephropathy
ESRD.....	End Stage Renal Disease
ETDRS.....	Early Treatment of Diabetic Retinopathy Study
FBS.....	Fasting Blood Sugar
GFR.....	Glomerular Filtration Rate
HTN.....	Hypertension
HR.....	Hypertensive Retinopathy
HD.....	Hemodialysis
LP.....	Light Perception
Mg/ml.....	Milligram per milliliter
NPDR.....	None Proliferative Diabetic Retinopathy
OD/RE.....	Oculus Dexter/Right Eye
OS/LE.....	Oculus sinister /Left Eye
PDR.....	Proliferative Diabetic Retinopathy
PI.....	Principal Investigator
RRT.....	Renal Replacement Therapy
SPHMMC.....	St. Paul's Millennium Medical College
SPSS.....	Statistical Package for Social Sciences
USA.....	United States of America
VH.....	Vitreous Hemorrhage
WHO.....	World Health Organization

INTRODUCTION

BACKGROUND

Retinopathy is any of various non-inflammatory disorders affecting the retina of the eye marked by damage to retinal blood vessels, swelling of the retina or abnormal growth of new blood vessels and resulting in blurred vision, vision loss or blindness. The type of retinopathy is often specified as arteriosclerotic retinopathy, diabetic retinopathy or hypertensive retinopathy.⁽¹⁾

Given that the kidney and the eye share anatomical, physiological, developmental, pathogenic, and genetic pathways, renal and ocular disease may be closely related. A renal condition may also be predicted by changes in retinal vascular factors. Additionally, diabetes mellitus, hypertension, smoking, obesity and other vascular risk factors as well as pathogenic pathways such as inflammation, oxidative stress, endothelial dysfunction, and vascular dysfunction are shared by both chronic kidney disease and retinopathy.⁽²⁾

Hemodialysis is a procedure where a dialysis machine and a special filter called a dialyzer are used to clean blood in end stage renal disease patients. The final stage of chronic kidney disease necessitating RRT when the GFR is less than 15 ml/min/1.73 m² is known as end stage renal disease. End-stage renal disease is still mostly treated with conventional hemodialysis, which is typically done three days a week for three to five hours.⁽³⁾

Increased plasma colloid osmotic pressure, electrolyte changes and chronic inflammation may also play a role in the pathophysiology of hemodialysis-related retinopathy. Eye problem can range from slight increases in intraocular pressure to retinal detachments with profound vision loss that call for immediate treatment. Uremia, metabolic abnormalities, and the dialysis process all have an impact on hemodialysis patients.^(2, 4)

A large group of inherited and non-inherited malformations and multi-systemic diseases, including metabolic or developmental defects, vascular or autoimmune disease, infection, neoplasm, or toxicity result in combined disorders of the eyes and kidneys. The two conditions that are by far most common for the visual abnormalities related renal pathology are diabetes mellitus and hypertension.^(2, 5)

STATEMENT OF THE PROBLEM

Retinopathy is a serious ophthalmic condition that causes vision impairment. It is the main cause of poor vision in adults undergoing hemodialysis. Retinopathy is usually a sign of ocular manifestation of another systemic and ocular medical condition. Retinopathy can be broadly categorized into proliferative and non-proliferative types. Common causes of non-proliferative damage include diabetic, hypertensive and sickle cell retinopathy. ^(6, 10)

Retinopathy, disc oedema and retinal vein occlusion are common posterior segment findings in chronic kidney disease patients receiving haemodialysis. Patients with chronic kidney diseases frequently experience hypertensive retinal alterations, which are most severe in renal failure. Diabetic retinopathy also gets worse when renal function declines, especially when blood pressure control is inadequate. Diabetes and hypertension are two prevalent systemic conditions known to cause pathologic change in the eye. ^(7, 22)

The two conditions most frequently responsible for visual problems linked to renal pathology are diabetes mellitus and hypertension. Retinopathy frequently occurs in people with diabetes and hypertension. The leading cause of blindness in adults between the ages of 25 and 64 years is diabetic retinopathy. The systemic disease most commonly associated with non-diabetic retinopathy is probably hypertension. About 11% of hypertensive non-diabetic adults over 43 have been discovered to have retinopathy. ^(7, 8)

More than 2.5 million people receive RRT globally and that number is increasing by 8% a year. The two most significant end stage renal disease risk factors are hypertension (74.5 million individuals affected) and diabetes (23.6 million people affected). Overall, 45% of people with end stage renal disease have diabetes and 28% of those with end stage renal disease have hypertension. Patients on hemodialysis have a higher risk of developing diabetic retinopathy and hypertensive retinopathy as severe GFR decline and renal disease progression. ^(3, 8)

In diabetic individuals with nephropathy as opposed to patients without proteinuria, blindness from proliferative retinopathy occurs around five times more frequently. The ocular signs of chronic kidney disease can indicate control of the disease and posterior segment finding can be used to monitor treatment. Retinopathy is frequently asymptomatic during the phase where treatment is most effective, and delaying diagnosis can significantly raise the risk of vision loss. Early detection and treatment of retinal disease are crucial since the posterior segment contains the most vision threatening that can impair vision among chronic kidney disease patients on haemodialysis. ^(9, 10)

According to the majority of the research literature frequent causes of end-stage renal disease that result in hemodialysis treatment can result in retinopathy and ocular condition is also an indicator of the metabolic control of the disease process. There was no published study that reveals the pattern of retinopathy among patients receiving hemodialysis in Ethiopia and study setting, but one study on incidence rate of diabetic retinopathy among diabetic patients at Black Lion Hospital in 2018 was 2.65% among 377 study participants. ⁽¹¹⁾

SIGNIFICANCE OF THE STUDY

End-stage renal disease requiring hemodialysis is currently more and increasing which places a financial and social burden on the person, family, community and public health system. Most literature evidence showed that common causes of end stage renal disease requiring hemodialysis treatment can cause retinopathy and ocular condition is also an indicator of the metabolic control of the disease process. The pattern of retinopathy among patients receiving hemodialysis wasn't well known in the context of this study setting and no published data from Ethiopia. Determining and evaluating the pattern and risk variables will therefore provide information on the pattern of the issue in the study setting.

The findings of this study will shed light on how early eye examinations can identify asymptomatic disease processes and ocular findings in order to prevent further damage leading to vision loss. It will also give SPHMMC doctors, nurses and ophthalmologists insight on how to create optimal ophthalmologic connections for early detection and treatment to prevent retinopathy-related blindness or vision impairment in hemodialysis patients. The outcome also acts as a benchmark for upcoming studies.

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LITREATURE REVIEW

An analysis result of 76 hemodialysis patients at Fatima Memorial Hospital in 2011 revealed that 50 (65.7%) of the patients had diabetes mellitus and of them 42 (84%) also had hypertension. Most of them were in their sixties. Dialysis onset time ranged from 6 months to 8 years, with a mean of 2.16 ± 1.47 and the mean duration of hypertension was 8.28 ± 8.07 years. Diabetes affected 65.7% of people with end-stage renal illness. 29 people (58%) had retinopathy, 18 (36%) had diabetes, and 11 (22%) had hypertensive alterations. A similar study that evaluated the ocular results in 64 chronic renal disease patients receiving hemodialysis in Croatia, aged 24-83 years (34 males and 30 females), revealed hypertensive vascular alterations in 44 (68%) of the patients. Seven patients had diabetes mellitus and diabetic retinopathy was observed in 5 (71.43%) cases. ^(12, 13)

According to a cross-sectional study conducted on 121 individuals with 242 eyes, 68 (56.2%) of whom were men and 53 (43.8%) of whom were women receiving hemodialysis in Iran between 2016 and 2017 diabetes mellitus was the most common cause kidney disease leading to hemodialysis accounting for 39.67% of cases, followed by hypertension in 38.84% of cases. Of the study group, 54 (22.31%) eyes had hypertensive retinopathy, 28 (11.57%) eyes had vitreous hemorrhage, 51 (21.07%) eyes had macular edema, and 70 (28.92%) eyes had PDR. In a related study, 81 hemodialysis patients (48 men and 33 women) at the medical college for women and hospital were found to have hypertension in 42 instances, diabetes mellitus in 19 cases and other causes of chronic renal disease in 20 cases. About 14 (73.68%) of the 19 diabetes patients had diabetic retinopathy, with NPDR being the most prevalent kind. All 42 cases had hypertensive retinopathy with (32.26%) of the 42 patients with hypertensive retinopathy had grade I hypertension retinopathy. ^(14, 15)

According to a study conducted to determine the prevalence of diabetic retinopathy among 49 hemodialysis patients at a military hospital in Pakistan, 19 (38.7%) of the patients had diabetes. Six (31.5%) of these individuals had solely diabetes mellitus, while the other 13 (68.4%) had both diabetes and hypertension. All Diabetic patients (38.7%) had diabetic retinopathy. Four patients (21%) had NPDR. Nine patients (47.3%) had pre-proliferative and six (31.5%) had advanced diabetic retinopathy in the worst eye with four having VH. Age of patients with diabetic retinopathy ranged from 45 years to 68 years, mean age of patients was 57.5 years. Of diabetic patients eleven were males and nine were females. ⁽¹⁶⁾

According to study result at Indian Justice Charitable Hospital among 144 study subjects mean age was 55.9 years and male: female ratio was 1.3:1. The commonest cause of end stage renal disease was hypertension for 77 (53.4%) cases. Combined hypertensive and diabetes mellitus in 28 patients (19.4%), Diabetes mellitus only in 23 patients (15.9%). About 33% of eyes had corrected visual acuity $< 6/18$. Hypertensive retinopathy was detected in 142 (49.3%) eyes followed by Diabetic retinopathy in 92 (33.3%) eyes, maculopathy in 39 (13.5%) eyes and VH in 20 (6.94%) eyes. ⁽¹⁷⁾

A study done at Gandhi Hospital from 64 total patients 23 females and 41 males on hemodialysis showed that hypertensive retinopathy was found in 28(44%) patients. Diabetic retinopathy was found in 20 (3.1%) patients, NPDR in 13 (20%), PDR in 4 (6%) patients. Hospital based study at Pradesh University of medical sciences among 128 total patients (96 (75%) males and 36 (25%) females) on hemodialysis showed that mild retinopathy was the most common in 60 (46.88%) patients followed by moderate retinopathy in 18 (14.06%) cases. Hypertensive retinopathy was most common retinopathy accounting for 39 (30.47%) patients followed by mixed retinopathy in 31 (24.22%) patients, diabetic retinopathy found in 12 (9.38%). Male to female ratio was 4:1 with mean age of patients' 34.55 ± 12.98 years. Average duration of HD was 2.61 ± 1.75 years. ^(18, 19)

Cross-sectional study carried among twenty-three patients (6 males and 17 females) with 44 eyes to assess abnormal ocular findings on chronic hemodialysis at Agouza Hospital on 2017 showed forty-three percent of total 44 eyes had corrected visual acuity $> 6/18$ and diabetic retinopathy was the commonest finding in 38.6%, hypertensive retinopathy in 4.5% cases. The mean age was 50.95 with SD 8.15 years. The mean duration of hemodialysis was 6.60 years with SD 2.06. About 9 (39.1%) patients were diabetic while 7 (30.4%) patients were hypertensive and one patient had both diabetes mellitus and hypertension. ⁽²⁰⁾

About 160 eyes of 80 patients were included in a cross-sectional study on patients with chronic kidney disease at Tanta University in Egypt over a 6-month period. Visual acuity ranged from 6/6 to 6/18 in 80 (50%) eyes and a fundus exam confirmed that about total of 82 eyes with varying degrees of retinopathy had hypertensive retinal alterations while diabetic retinopathy was discovered in 30 (18.75%) eyes. ⁽²¹⁾

About 170 eyes were evaluated between March 2013 and October 2013 in a teaching hospital in Nigeria to ascertain the prevalence and aetiology of retinopathies among patients with chronic kidney disease receiving haemodialysis. The examination of a total of 30 (35.4%) females and 55 (64.6%) males resulted in a male to female ratio of 1.8:1. In 58 (68.2%) of the cases, Hypertensive retinopathy of various grades was the most frequent posterior segment finding. ⁽²²⁾

According to cross sectional study on ocular disorders in renal transplant patients at SPHMMC from 2017 to 2018 among a total of 135 renal transplant subjects including 95(70.4%) male and 40(29.6 %) female the mean age of all the study subjects were 34.4 ± 12.1 . The cause of end stage renal disease was not known in 112(83%) of study subjects and the remaining 23(17%) cases had a known chronic disease like hypertension in 9(6.7%) and diabetes in 7(5.2%). Only 11(7.3) cases had retinal problem mostly retinal pigmentary changes. ⁽²³⁾

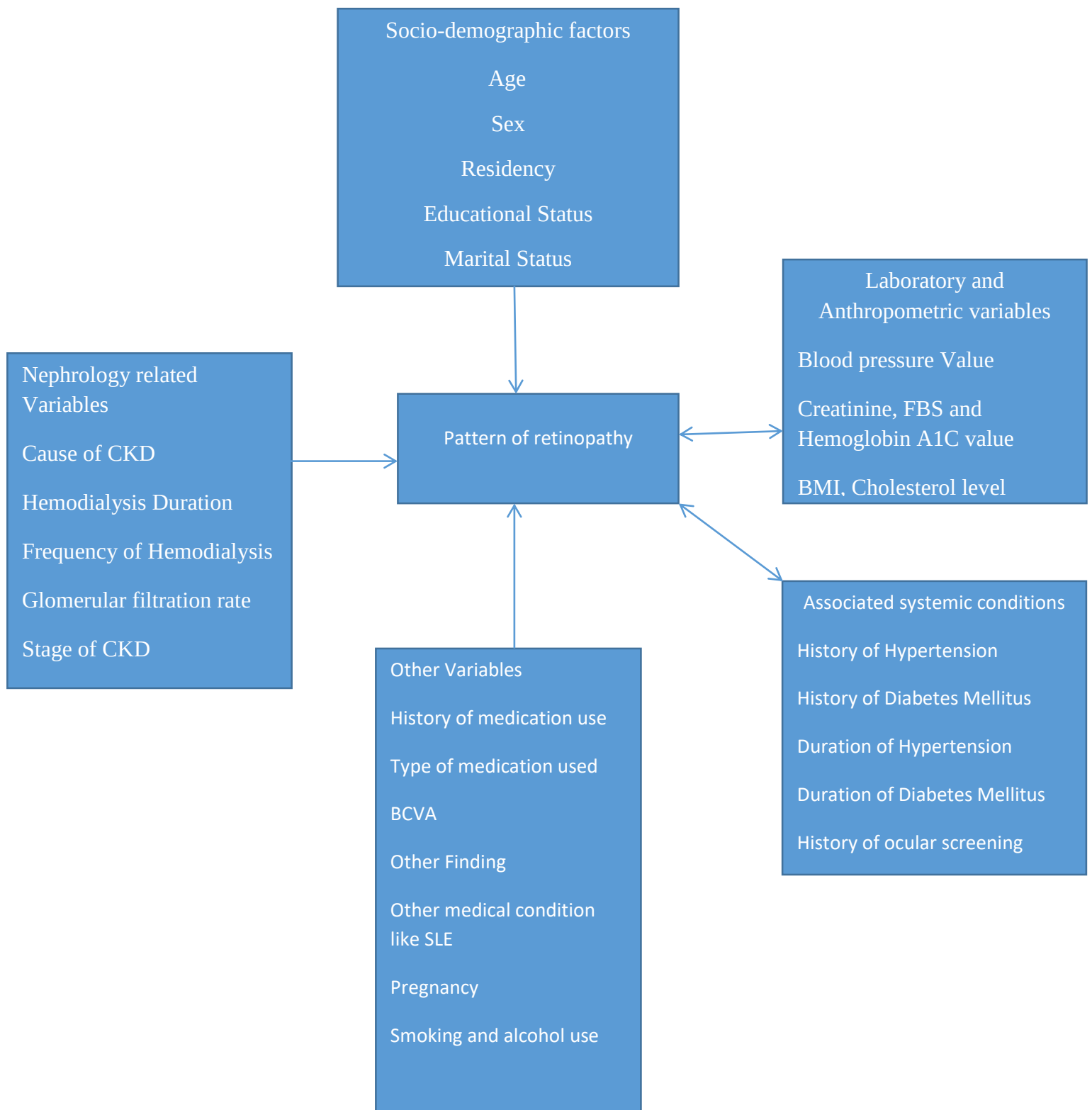


Fig 1 Conceptual Frame Work

OBJECTIVE

General objective

- ✓ To describe the pattern of retinopathy among patients on hemodialysis at SPHMMC renal transplant unit from September 2020 to December 2021.

Specific objectives:

- ✓ To describe pattern of retinopathy among patients on hemodialysis at SPHMMC renal transplant unit from September 2020 to December 2021.
- ✓ To describe association between the presence of retinopathy and associated comorbidity factors among patients on hemodialysis at SPHMMC renal transplant unit from September 2020 to December 2021.

Methods

Study Setting

The study was conducted at SPHMMC national kidney transplant center which is located in Addis Ababa. It is one of public renal replacement center in the country established in 2014 as renal transplant center and in 2016 as hemodialysis center after two years of its establishment in collaboration with University of Michigan, USA as only government renal transplant service in the county. Now it has about 10 nephrologists and also provides teaching activities. Since its establishment it provides renal transplant for 142 patients.

For the year 2020/21 it performed hemodialysis for about 59 patients using 32 dialysis machines with three shift. Each dialysis services takes up to four hours and the patients receive the service two/three times a week. The ophthalmology department is one of specialty department at SPHMMC that provides most of ophthalmic service including retinopathy screening and treatment. Retinopathy screening and treatment can be facilitated by strengthening linkage and consultation between ophthalmology and urology department staff of the transplant unit.

Study Design and Study period

A Cross sectional hospital based study was conducted from September 2020 to December 2021 among chronic kidney disease patients undergoing hemodialysis.

Source and Study Population

Source Population

The source population for this study were all cases of patients attending SPHMMC national transplant unit during study period.

Study Population

Study populations were all chronic kidney diseases patients on hemodialysis during study period.

Inclusion and exclusion

Inclusion Criteria

All patients of chronic kidney disease on maintenance hemodialysis

Exclusion Criteria

- ✓ Study subjects undergo renal transplantation during the study
- ✓ Presence of bilateral media opacity
- ✓ Loss of vision of both eyes
- ✓ Who were not willing, irritable or in coma

Sample Size and Sampling Procedure

Sample size Calculation

Sample size calculation was done using population proportion formula by $X = Z_{\alpha/2}^2 * p * (1-p) / d^2$, and $Z_{\alpha/2}$ is the critical value of the normal distribution at α is 0.05 for a confidence level of 95% and the critical value is 1.96), d is the margin of error, p is the sample proportion was taken to be 50% to give power of 80%.

The calculated sample size was **385** study subjects. However due to small number of patients undergoing hemodialysis at study setting all 59 patients with total of 118 eye on hemodialysis were convenient to this study and enrolled after consideration of inclusion and exclusion criteria and obtaining an informed verbal consent from all of them.

Operation Definition

- DR considered as vascular disease of the retina and characterized by typical clinical retinal changes among diabetes study subjects with ETDRS standard classification.⁽¹⁾
- Mild NPDR: Micro-aneurysm, dot and blot hemorrhage, exudate and cotton wool spot
- Moderate NPDR: Severe retinal hemorrhage in 1-3 quadrants, significant venous beading no more than one quadrant and cotton wool spot.
- Severe NPDR: One severe retinal hemorrhage in 4 quadrants, Venous beading in more than two quadrants, Moderate micro-vascular abnormality more than one quadrants.
- ADED: Preretinal hemorrhage, tractional retinal detachment
- HR :consists of a spectrum of retinal vascular change from elevated blood pressure among hypertensive patients and was graded on the basis of Scheie classification⁽¹⁾
- Grade I Mild arteriolar attenuation, broadening of arteriolar light reflex
- Grade II Severe arteriolar constriction associated with arterio-venous crossing
- Grade III Copper wiring of arterioles, hemorrhages, cotton-wool spots, hard exudates
- Glomerular filtration rate: Was calculated and categorized based on Cockcroft Gault formula adjusted for age and sex⁽³⁾
- Body mass index: was calculated using weight/height² and categorized based on WHO 2020 guideline

Data Collection Method and Tool

Ocular, medical and nephrology history was recorded from all patient's chart using checklist adapted from other research material. Duration of hemodialysis, Frequency of hemodialysis, Blood pressure value, haemoglobin A1C level, Creatinine level, Fasting sugar value, Stage and cause of chronic kidney disease leading to hemodialysis was recorded from patient card during initial time of hemodialysis using checklist by trained BSc nurse.

Socio demographic variables such as age, sex, place of residency, marital status, history of medication use, history of diabetes, duration of diabetes, history of hypertension, duration of hypertension and history of ocular screening was recorded to the same checklist by trained nurse with study subject interview. Body mass index and GFR was calculated using weight and height and Cockcroft Gault adjusted for age and sex respectively. After completing nephrology, ocular and medical history all 59 patients' were linked to ophthalmology clinics. All 59 study subjects and 118 eye undergone ophthalmic examination starting from best corrected visual acuity using snellen scale. Dilated fundus examination was done using Slit lamp bio microscopy with noncontact 90 diopter lens and indirect ophthalmoscope by principal investigator.

Hypertensive and diabetic retinopathy was graded based on Scheie classification and ETDRS respectively for each eye. Data was collected using checklist which was prepared in English translated to Amharic to ask patient socio-demographic characteristics and history of study group during data collection by trained nurse. To increase the quality of data most of the questions was adapted from previously conducted studies and result was reviewed and checked by principal investigator and fundus examination for presence of retinopathy and classification was done by principal investigator so that there was no inter-observer variation.

Study Variables

Dependent (Outcome) Variables

- ✓ Pattern of retinopathy

Independent Variables

- ✓ Age
- ✓ Sex
- ✓ Place of Residency
- ✓ Marital status
- ✓ History of medication use
- ✓ History of Diabetes
- ✓ Duration of Diabetes
- ✓ History of hypertension
- ✓ Duration of hypertension
- ✓ History of Ocular screening
- ✓ Duration of Hemodialysis
- ✓ Frequency of Hemodialysis
- ✓ Blood Pressure value
- ✓ Body mass index
- ✓ Haemoglobin A1C Value
- ✓ Creatinine level
- ✓ Glomerular filtration rate value
- ✓ Fasting blood sugar value

- ✓ Stage of chronic kidney disease
- ✓ Cause of chronic kidney disease
- ✓ Best corrected visual acuity with WHO scoring

Data Processing and Analysis

After data collection each check list was checked for completeness and consistency. Data was entered to SPSS version 25.0. For descriptive statistics the result was presented in terms of frequency and percentage using frequency tables, figures and charts for categorical variables and mean, median and standard deviation was calculated for numerical variable by SPSS 25.0. All statistical analysis was done using SPSS 25.0 software program. Age, sex, residency, education, marital status, haemodialysis frequency and duration, medication history, ocular screening, hypertension, diabetes mellitus, BMI, GFR, Creatinine level, fasting blood sugar level, haemoglobin A1C level, blood pressure value were considered as independent variables.

Category was done based on normal value and similar classification from similar study. Category for BMI was based on 2020 WHO classification, age, duration of DM and HTN was categorized based on similar study, GFR was categorized based on national kidney foundation 2016 guideline, blood pressure level was categorized based on joint national committee 8 classification, Hemoglobin A1C and fasting sugar value was categorized based on American diabetic association criteria to diagnose diabetes. Association between dependent and independent variables was calculated using SPSS version 25.0 with chi-square test and p-value <0.05 was considered as level of statistically significant association between presence of retinopathy and independent variable with 95% CI.

Data Quality Assurance

Data was collected using structured checklist adapted from other study by trained nurse with supervision of PI. The collected data was checked for completeness immediately after data collection. Incomplete information was corrected during next visit to HD. The result was reviewed and checked again with PI. Dilated fundus examination for the presence of retinopathy and grading of its pattern was done only by PI to decrease inter-observer variation.

Ethical Consideration

Before the data collection ethical clearance was obtained from SPHMMC institutional review board. (Ref pm23/390) The director of the renal transplant unit was informed about the study and appropriate permission secured. The purpose of the study was explained to all study participants. Study subjects were informed that all of their responses was confidential and have all the right not to be involved in the study or not to answer any of the questions.

RESULTS

During the study time there were a total number of 59 cases of CKD on HD including 35(59.3%) males and 24(40.1%) females study participants. Mean age of total patients was 36.9 with a standard deviation of 11.995 (ranging from 17–72 years) with median age 35 and the male: female ratio was 1.46:1. Most study subjects 35 (59.3 %) were between 20 to 40 years of age. Most study participants 52(88.1 %) were from urban area and about 36(60.1 %) study subjects were above secondary school. (**Table 1**)

Table 1 Demographic characteristics of the study population at SPHMMC from Sep 2020 to December 2021(n=59)

Background Characteristics		Frequency	Percent	Remark
Age (years)	< 20	4	6.8	Category was done based on reference 23 Mean 36.9 years SD11.995 and mode 35 years
	20-39	35	59.3	
	40-59	18	30.5	
	60 Years and above	2	3.4	
Sex	Male	35	59.3	M:F 1.46:1
	Female	24	40.7	
Place of residence	Urban	52	88..1	
	Rural	7	11.9	
Level of Education	Can't read or write	4	6.8	
	Primary Level	5	8.5	
	Secondary	14	23.7	
	College & Above	36	61.0	
Marital status	Single	28	47.5	
	Married	27	45.8	
	Widowed	3	5.1	
	Divorced	1	1.7	

From all 59 study participants only 9 (15.3%) study participants had a history of diabetes at the time HD was initiated, while 47 (70.7%) of the participants had history of HTN. Most HTN cases were less than five years duration for 23 (48.94%) cases, and most diabetic cases were more than ten years duration for 5 (55.56%) cases. About 57(96.6%) of the 59 study participants reported a history of drug use and a total of 18 (30.5%) of the study participants had previously undergone ocular screening and 41 (69.49%) participants had no prior history of eye screening. (Table 2)

Table 2-Comorbidity factors among study population at SPHMMC from September 2020 to December 2021(n=59)

Variables	Value	Frequency	Percent	Remark
History of DM	Yes	9	15.3	
	No	50	84.7	
Duration of DM	Newly diagnose to five years	3	33.3	Category was based on similar study
	Six to ten Years	1	11.1	
	More than 10 years	5	55.6	
History of HTN	Yes	47	79.7	
	No	12	20.3	
Duration of HTN	Newly diagnosed to five years	23	48.94	Category was based on similar study
	Six to ten years	13	27.66	
	More than ten years	11	23.4	
Medication use	Yes	57	96.6	
	No	2	3.4	
Type of medication used	Anti HTN and DM Medication	35	61.4	
	Others like EPO, Ca, Iron	22	38.6	
History of ocular screening	Yes	18	30.51	
	No	41	69.49	

Most study subjects 35(59.32%) had body mass index between 18.5 to 24.9 kilogram/m² and 14 (23.73%) cases had less than 18.5 kilogram/m² and 9 (15.25 %) cases had body mass index between 25 to 29.9 kilogram/m² based on WHO 2020 BMI category. (Fig 1)

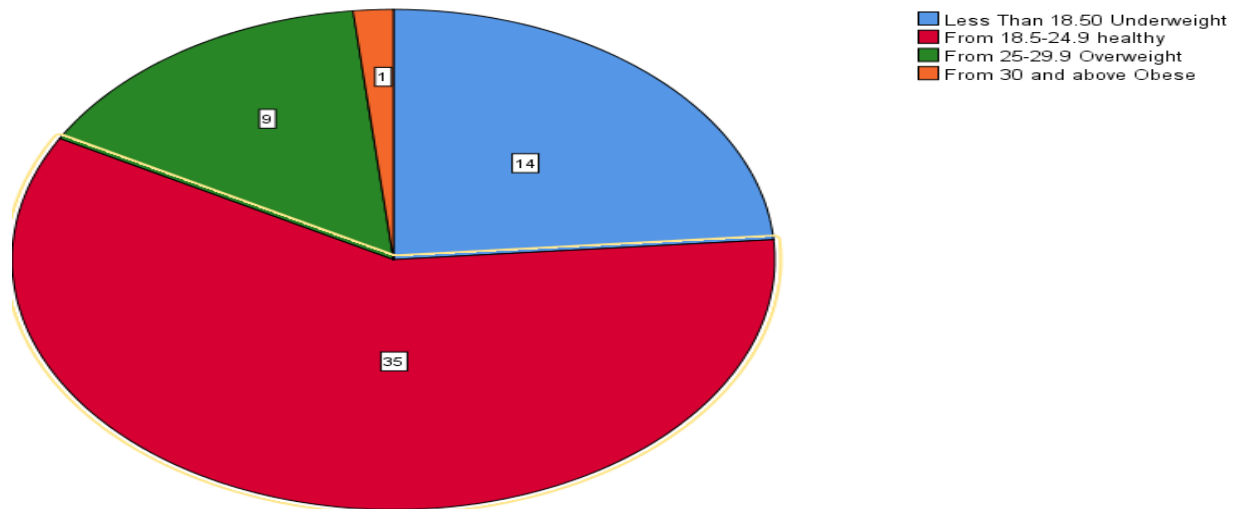


Fig 2 Body mass index value among study population at SPHMMC from Sep 2020 to December 2021(n=59)

According systolic blood pressure value measured for the study subject during initiation of hemodialysis about 26 (44.1%) cases had systolic blood pressure with JNC 8 stage I hypertension range, 15(25.42%) cases within normal range, 10(16.95%) cases within prehypertension range and 8(13.53%) cases within stage II hypertension range. (Figure 2)

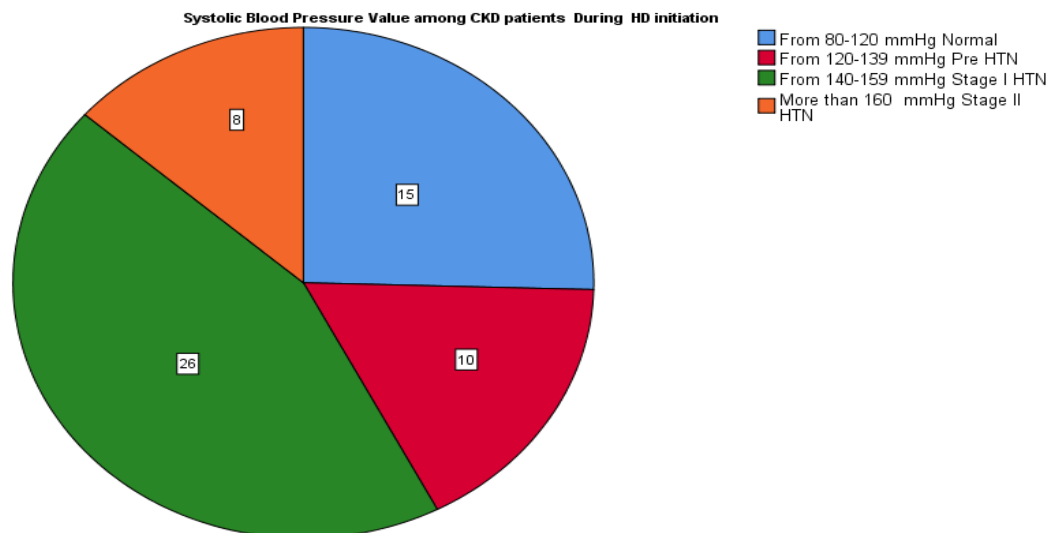


Fig 3 Systolic Blood pressure value among study population at SPHMMC from Sep 2020 to December 2021(n=59)

According Diastolic blood pressure value measured for the study subject during initiation of hemodialysis about 30 (50.85%) cases had diastolic blood pressure within normal range, 15(25.42%) cases with stage I hypertension range, 8(15.56%) cases within stage II hypertension range and 6(10.17%) cases within pre-hypertension range as joint national committee 8 classification system. (Figure 3)

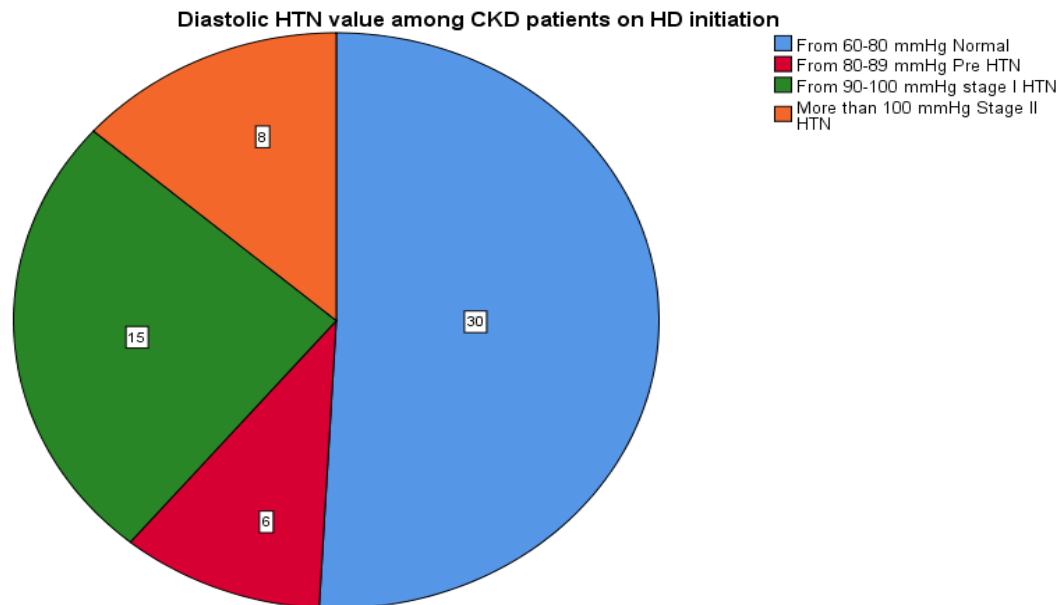


Fig 4 Diastolic Blood pressure value among study population at SPHMMC from September 2020 to December 2021(n=59)

The majority of patients about 51 (86.4%) cases receive HD three times per week. The study subjects' HD cases ranged in duration from one to five years in 36 (61%) cases, more than five years in 18 (30.5%) cases with mean of 4.21 years ranging from 2 months to 11 years, with a standard deviation of 1.985 and median HD of 4 years. Among the 59 study participants majority 39(66.1%) cases were staged as stage V. For 51 (86.4%) of cases of CKD patients undergoing HD the cause of CKD wasn't identified, 6 (10.2%) of the cases were due to HTN and 2 (3.4%) of CKD patients on HD was caused by both DM and HTN. Age and sex adjusted GFR was less than 15 ml/minute at the time of HD initiation in 49 (83.1%) cases. The mean GFR was 10.85 ml/min, ranging from 4.8 ml/min to 34.7 ml/min with a standard deviation of 6.45 and a median GFR of 9.0 ml/min/1.73 m². (Table 3)

Table 3-Nephrology related profile of study population at SPHMMC from September 2020 to December 2021(n=59)

Variables	Value	Frequency	Percent	Remark
Frequency of HD	Three times/week	51	86.44	
	Two times/week	8	13.56	
Duration of HD	Less than six months	3	5.1	Category was done based on similar study
	Six month to one year	2	3.4	
	One to five years	36	61.0	
	More than five years	18	30.5	
Cause of CKD	Unknown	51	86.4	
	HTN	6	10.2	
	Both DM and HTN	2	3.4	
Stage of CKD	Stage V	39	66.1	Category was done based on National Kidney Foundation reference number 3
	Stage IV	15	25.4	
	Stage I to III	5	8.5	
GFR value in ml/min/1.73 m ²	< than 15 ml/min/1.73m ²	49	83.1	
	15-29 ml/min/1.73m ²	8	13.6	
	> 30 ml/min/1.73m ²	2	3.4	

From a total of 59 study participants, the mean fasting blood sugar level was 138.92 mg/dl, with a standard deviation of 50.18 ranging from 79 mg/dl to 321 mg/dl and a median fasting blood sugar level of 128 mg/dl for 50(84.75%) cases in which fasting blood sugar level was measured. Regarding hemoglobin A1C measurement about 55(93.22%) cases of study subjects had more than 6.4% value. The mean hemoglobin A1C was 9.63% with standard deviation of 1.94 ranging from 3.89 to 14% and median value of 9.5 %. The median creatinine level for the study participants was 8.36 mg/dl and the mean creatinine level was 8.54 mg/dl with a standard deviation of 3.14 ranging from 1.28 mg/dl to 16.60 mg/dl. ([Table 4](#))

Table 4-Laboratory results of study population at SPHMMC from September 2020 to December 2021(n=59)

Variables	Value	Value	Remark
Creatinine value	Mean $\pm$ SD	8.54 $\pm$ 3.14	Minimum 1.28 and maximum 16.0 mg/dl
	Median	8.36	
	Mode	4.86	
	Standard Deviation	3.14	
	Range	15.32	
FBS Value	Mean $\pm$ SD	138.92 $\pm$ 50.18	Minimum 79 and maximum 321 mg/dl
	Median	128	
	Mode	129	
	Standard Deviation	50.18	
	Range	242	
Hemoglobin A1c value	Mean $\pm$ SD	9.63 $\pm$ 1.94	Minimum 3.89 and maximum 14.0 %
	Median	9.50	
	Mode	10.60	
	Standard Deviation	1.94	
	Range	10.11	

BCVA for 106 (89.83%) eyes had more than 6/18 vision, 9 (7.5%) eyes had between 6/60 and 6/24 vision and 3 (2.54%) eyes had less than 6/60 vision among 118 eyes examined. Cataract was the cause of the vision impairment, whereas CRVO in one eye and ADED in two eyes were the cause of low vision. About total of 59 patients with 118 eyes evaluated, 26 (44.1%) patients and 52 (44.1%) eyes overall showed signs of retinopathy brought by hypertension, combination of DM and HTN, diabetes and central retinal vein occlusion. [\(Table 5\)](#)

Table 5 BCVA and Retinal finding among study groups at SPHMMC from September 2020 to December 2021(n=59 subjects and 118 eyes)

Variables	Values	Number of eyes	Percentage
BCVA based on WHO vision function score	Good vision $\geq 6/18$	106	89.83
	Impaired vision 6/60 – 6/24	9	7.63
	Legally blind $<6/60$	3	2.54
Fundus examination showing Retinopathy	Yes	52	44.1
	No	66	55.9
Type of retinopathy	HTN	35	67.31
	Both DM and HTN	12	23.08
	DM alone	4	7.69
	CRVO	1	1.92
Grades for HTN Retinopathy	Grade I	16	33.34
	Grade II	25	52.08
	Grade III	6	12.5
	CRVO	1	2.08
Grade of Diabetic Retinopathy	Mild NPDR	4	25.0
	Moderate NPDR	8	50.0
	Severe NPDR	2	12.5
	ADED	2	12.5

Hypertensive retinopathy was the most pattern of retinopathy in 35 (67.31%) of the eyes, followed by mixed retinopathy in 12 (23.08%) eyes and diabetic retinopathy in only 4(7.69%) eyes. Twenty-four (92.31%) of the total 26 cases of retinopathy had hypertensive retinopathy. Most common grade of hypertensive retinopathy was grade II in 25 (52.1%) of the eyes, followed by grade I in 16 (33.33%) of the eyes, grade III in 6 (12.5%) of the eyes and CRVO in one (2.1%) of the eyes, which contributed to impaired vision. Six of the eight patients with diabetic retinopathy also had hypertensive retinopathy, while two of the patients had solely diabetic retinopathy.

The most common type of DR was moderate NPDR for 8 (50%) eyes, mild NPDR for 4(25%) eye and 2(12.5%) eyes for severe NPDR and ADDED each. (Table 5)

Chi square and fissure exact test association statistics test showed a statistically significant association between history and duration for both diabetes and hypertension and patient ocular screening history with p value less than 0.05 and 95% CI. However this study showed that there was no statistically significant association between sex, fasting blood sugar level, blood pressure value, creatinine level, body mass index, Hemoglobin A1C, stage of CKD, frequency and duration of hemodialysis with presence of retinopathy among chronic kidney disease patients undergoing hemodialysis having a level of significance greater than 0.05 with a 95% CI. (Table 6)

Table 6 Cross tab associational analysis of presence of retinopathy and associated comorbidity factors of study participants undergoing HD at SPHMMC from September 2020 to Dec 2021

Variable	Value	Pattern of Retinopathy		X ²	df	Significance level p-Value	Remarks
		Yes	No				
History of ocular screening	Yes	13	5	8.67	1	0.004	Chi-square test odd ratio 2.28
	No	13	28				
History of DM	Yes	8	1	8.67	1	0.003	Chi-square test odd ratio 2.47
	No	18	32				
Duration of DM	Newly to 5 year	2	1	9.557	3	0.023	Chi-square test
	6-10 years	1	0				
	> Ten years	5	0				
Duration of HTN	Newly to 5 year	5	18	20.361	3	0.000	Chi-square test
	Six-ten years	10	3				
	>10 years	9	2				
History of HTN	Yes	24	23	4.59	1	0.032	Chi-square test odd ratio 3.06
	No	2	10				
Duration of HD	<5 Years	17	28	3.044	1	0.081	Chi-square test
	>5 Years	9	5				

FBS level during HD initiation	<126 mg/dl	8	18	1.923	1	0.166	Chi-square test
	>126 mg/dl	12	12				
History of medication use	Yes	25	32	0.003	1	1.00	Fisher's exact test
	No	1	1				
GFR During HD initiation	< 15 ml/min	23	26	0.402	1	0.488	Fisher's exact test
	>15 ml/min	3	7				
Hemoglobin A1C	< 6.4%	0	5	2.572	1	0.061	Fisher's exact test
	>6.4%	26	28				
SBP during HD initiation	<140 mmHg	9	19	2.23	1	0.116	Fisher's exact test
	>140 mmHg	17	14				
DBP during HD initiation	<90 mmHg	13	5	8.33	1	0.005	Fisher's exact test
	>90 mmHg	13	28				
Frequency of HD	Two Times	2	6	1.365	1	0.446	Fisher's exact test
	Three times	24	27				

For variables with cell values that were less than 80% of the expected count, the fissure exact test was performed. For the fissure exact test and chi-square test's assumptions dichotomy competition was conducted for the blood pressure value, GFR, haemodialysis duration, fasting blood sugar value and haemoglobin A1C value. Due to the existence of more cells with values lower than expected counts, chi-square association tests for age, education level, marital status, body mass index, creatinine value, stage, and cause of chronic renal disease was not conducted.

DISCUSSION

In total 59 case and 118 eyes with CKD on HD were examined and analysed for this study. Out of 59 study cases 35 participants (59.3%) were males with a male to female ratio of 1.46:1. With a median age of 35 years and a mean age of 36.9 (range from 17 to 72 years) with standard deviation of 11.995. The majority of study participants about 35 (59.3%) study subjects were between the ages of 20 and 40 years. A similar cross sectional study among 121 subjects of which 68 (56.2%) males and 53 (43.8%) females at Iran, study on 81 study subjects among 48 males and 33 females with ESRD patients on HD at medical college for women and Hospital and study at Jinnah Hospital among 100 subjects with 55% males and 45% females showed similar male to female ratio to this study^(14, 15, 19)

Only 9 (15.3%) of the 59 study participants in this study had a history of diabetes at the time of HD, while 47 (70.7%) of the subjects had a history of HTN. Most HTN cases were less than five years for 23 (48.94%) cases and more than ten years for 5 (55.56%) of the diabetic cases. Of the 59 research participants about 57 (96.6%) had a history of using medications, 18 (30.5%) had undergone ocular screening in the past and 41 (69.49%) had never undergone ocular screening. In a cross-sectional study conducted in 2011 at Fatima Memorial Hospital from 76 patients with HD included for the study 50 (65.7%) had DM and of these, 42 (84%) also had HTN. This higher prevalence of diabetes and nearly identical prevalence of hypertension could be related to regional variations in the causes of CKD that result in HD.⁽¹²⁾

In this study causes of CKD leading to HD was unknown in 51 (86.4%) cases, HTN in 6 (10.2%) cases and both DM and HTN in 2 (3.4%) patients who underwent HD during the study period. This is comparable to a cross-sectional study on ocular disorders in renal transplant patients conducted at SPHMMC from 2017 to 2018. Of the 135 renal transplant study participants, 95 (70.4%) were men and 40 (29.6%) were women. Among 112 (83%) study participants, the cause of ESRD was unknown and the remaining 23 (17%) had a known chronic disease like HTN in 9 (6.7%) cases and diabetes in 7(5.2%) cases. According to research findings at the Indian Justice Charitable Hospital the average age of the 144 study participants was 55.9 years and the male to female ratio was 1.3:1. HTN accounted for 77 (53.4%) cases of ESRD, making it the most frequent cause. DM alone in 23 (15.9%) patients, combined HTN and DM in 28 (19.4%) and glomerulonephritis in 6.3% of cases which is higher than this study's setting could be the result of small sample size, initial lack of cause identification ability, younger age group of this study and geographic variation for causes of CKD leading to HD.^(17,23)

About 106 (89.83%) of the 118 eyes evaluated in this study had vision better than 6/18, 9 (7.5%) had vision between 6/60 and 6/24 and 3 (2.54%) eyes had vision less than 6/60. Cataract was the cause of impaired vision and ADED in two eyes and CRVO in one eye were the causes of low vision. About 52 (44.1%) of the 118 eyes that were evaluated overall showed signs of retinopathy. Hypertensive retinopathy was the most common pattern for 35 (67.31%) eyes of retinopathy, followed by mixed retinopathy in 6 (23.8%) cases and DR in 2 (7.69%) cases.

Twenty-four (92.31%) patients out of the total 26 cases of retinopathy had hypertensive retinopathy. Grade II HR affected 25 (52.1%) of the eyes, grade I HR affected 18 (37.5%) eyes and grade III HR affected 6 (12.5%) of the eyes. Six of the eight patients with diabetic retinopathy had mixed hypertensive and diabetes retinopathy, two patients had exclusively DR.

The most frequent pattern of DR were moderate NPDR for 8 (50%) of the eyes, mild NPDR for 4 (25%) of the eyes and severe NPDR and ADED for 2 (12.5%) of eyes respectively. Low vision was a result of CRVO in one eye and ADED in two eyes. This study has similar findings from a hospital-based study at the Pradesh University of Medical Sciences, ⁽¹⁹⁾

According cross-sectional study carried among 23 cases with 44 eyes to assess abnormal ocular findings on chronic HD at Agouza Hospital on 2017 showed 43% of total 44 eyes had BCVA > 6/18 and DR was the commonest finding in 38.6%, HR in 4.5%, macular hemorrhage in 2.3% cases which has lower BCVA than this study setting with DR commonest cause. Other result of cross sectional study among 121 subjects on HD at Iran from 2016 to 2017 indicated the most prevalent etiology for HD was DM in 39.67%, followed by HTN in 38.84% of cases. Of this study group 70 (28.92%) had PDR, 51 (21.07%) had macular edema, 28 (11.57%) had VH and 54 (22.31%) had HR lower than this study setting with DR most common cause as previous result. This could be due to younger study group and different cause of retinopathy. ^(19,20)

A cross sectional study result done at Taro Egypt from 80 patients and 160 eyes examined showed that the most common visual problems in HD patients that lead to visual loss were hypertensive and diabetic retinopathy. A total of 82 eyes with varying degrees of retinopathy had hypertensive retinal alterations. DR was discovered in 30 (18.75%) eyes.

Similar result showed from 170 eyes were evaluated in Nigeria that in 58 (68.2%) of the cases, HR of various grades was the most frequent posterior segment finding. ^(21, 22) This study result has similar result with most frequent pattern of retinopathy with study at Croatia, Gandhi Hospital, Indian Justice Charitable Hospital, Tanta University in Egypt, and teaching hospital study in Nigeria. Different pattern of retinopathy result with study result at Fatima Memorial Hospital, medical college for women and hospital, Iran study, Pakistan military hospital and Agouza Hospital in Egypt in which diabetic retinopathy was most common causes. This variation of result could be as result of geographic variation in cause, younger study group and smaller sample size of this study.

Limitation and Strength of the Study

Limitation of the study

- ✓ This study was the first in this research topic and it would be better to be done with large sample size involving multiple hemodialysis center.
- ✓ The major limitation of the study was small sample size and involves only one center.
- ✓ Retinal examination and kidney measurements were taken at different visits

Strength of the study

- ✓ It was the first study in Ethiopia and study setting including all patients to describe pattern of retinopathy among patients on hemodialysis could be considered as strength of this study. It uncovers asymptomatic higher presence of retinopathy among the study subjects.

Conclusion and Recommendation

Conclusion

- ✓ This study showed the presence of retinopathy among patients undergoing haemodialysis was high.
- ✓ The most common pattern of retinopathy was hypertensive retinopathy for 35(67.31%) eyes, followed by mixed retinopathy for 12(23.08%) eyes and diabetic retinopathy for 4 (7.69%) eyes and 1 eye had CRVO among 118 examined eyes of study subjects.
- ✓ This study showed statistically significant association between both history and duration of diabetes and hypertension and patients history of ocular screening with presence of retinopathy among chronic kidney disease patients undergoing hemodialysis with p value less than 0.05 with 95%CI.

Recommendation

- ✓ SPHMMC ophthalmology department could arrange regular screening program for retinopathy among chronic kidney disease patients undergoing haemodialysis
- ✓ Detailed ocular examination could be undertaken in all chronic kidney diseases patients on undergoing on haemodialysis for early diagnosis and treatment of retinopathy
- ✓ SPHMMC renal transplant unit could consider eye screening as part of management
- ✓ A prospective study involving multiple centres should be done to determine true prevalence rate of retinopathy among chronic kidney disease patients on haemodialysis.

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ANNEXES

Annex I Check list

SPHMMC DEPARTMENT OF OPHTHALMOLOGY

Informed Written Consent Form

I am a graduate of ophthalmology specialty at SPHMMC. As part of the requirements for graduation; I am collecting data for a thesis project. The purpose of this study is to determine the prevalence of Retinopathy among patients on hemodialysis at SPHMMC in order to suggest useful interventions for retinopathy among patients on hemodialysis.

To attain this purpose your genuine participation for filling the checklist with truth information and become voluntary for full ocular examination is very important and highly appreciated.

I would like to inform you that your responses are entirely confidential. No one in the process will see the answer you give and documented results from your card, so please answer the questions as honestly as possible. You have full right to refuse, to take part of, or to interrupt the study at any time. But the information that you will give is quite useful to achieve the study in order to bring change in management and follow up of retinopathy among patients on hemodialysis.

Finally, I would like to thank in advance for taking time for participating in this survey.

MRN.....Signature of Study Subject.....Date

THANK YOU FOR YOUR VALUABLE INFORMATION!!

Name: Gizachew Gebrie (MD, Ophthalmology Resident)

Phone Number: +251983650626

Email address: gizachew.gebrie@yahoo.com

Addis Ababa, Ethiopia

DATA COLLECTION CHECK LIST

1. Background Characteristics
 - 1.1 Age in years.....
 - 1.2 Sex 1. Male 2. Female.....
 - 1.3 Place of Residence 1. Rural.....2. Urban
 - 1.4 Education 1 Can't read or write 2 Primary Level 3.Secondary Level 4 Above 2^{ry} level
 - 1.5 Marital Status 1. Married 2, Single 3. Divorced 4. Widowed
 - 1.6 History of medication use 1. Yes..... 2. No.....
 - 1.7 If medication use, type of medication use list of drugs used 1. Antibiotics... 2. Steroid. 3. Chemotherapy...4 DM Anti HTN drugs 5.Others like EPO, and NSAIDs
 - 1.8 History of diabetes mellitus 1 Yes.....2. No....
 - 1.9 If there was history of diabetes mellitus its duration in years.....
 - 1.10 History of hypertension 1. Yes 2. No.....
 - 1.11 If there was history of hypertension its duration in years.....
 - 1.12 Previous history of ocular screening 1. Yes.....2. No.....
 - 1.13 If history of previous ocular screening is there retinopathy diagnosed? 1Yes 2. No
 - 1.14 If retinopathy diagnosed it pattern and treatment given.....
2. Nephrology, Anthropometric and Laboratory Result
 - 2.1 Duration of hemodialysis in years/months.....
 - 2.2 Frequency of Hemodialysis per week 1. Two times 2, Three times
 - 2.3 Stage of chronic kidney disease 1. ARF 2. Stage 1 to III 3.Stage IV 4. Stage V
 - 2.4 Cause of chronic kidney disease 1. DM.... 2. HTN.... 3. Both DM and HTN... 4. Unknown cause..... 5. Other list.....
 - 2.5 GFR in ml/min/1.73 m².....
 - 2.6 Creatinine level in mg/dl.....
 - 2.7 Fasting blood sugar value in mg/dl.....
 - 2.8 Hemoglobin A1C value in %.....
 - 2.9 Blood pressure value 1. SBP.....2. Diastolic blood pressure.....in mmHg
 - 2.10 Weight in kilogram.....Height in meter.....
 - 2.11 Calculated Body mass index in kilogram/ m².....
3. Best corrected visual acuity and Dilated fundus examination Finding
 - 3.1 BCVA OD.....OS.....
 - 3.2 Is there sign of retinopathy for right eye 1. Yes..... 2. No.....
 - 3.3 Is there sign of retinopathy for left eye 1. Yes..... 2. No.....
 - 3.4 If yes for 3.2 pattern of retinopathy for right eye 1. Hypertensive Retinopathy 2. Diabetic retinopathy 3. Mixed Retinopathy 4. Others list.....
 - 3.5 If yes for 3.3 pattern of retinopathy for left eye 1. Hypertensive Retinopathy 2. Diabetic retinopathy 3. Mixed Retinopathy 4. Others list.....
 - 3.6 If retinopathy is hypertensive retinopathy its grade 1. Right eye Left Eye.....
 - 3.7 If retinopathy is diabetic retinopathy its grade 1. Right eye Left Eye.....
 - 3.8 Other finding.....

ANNEX III Assurance of Principal Investigator

I the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I provided timely progress report to my advisors and seek the necessary advice and approval from my advisors in the course of the research. I declare that this thesis is my original work in partial fulfillment of the requirements for specialty in ophthalmology. All the sources of the materials used for this thesis and all stakeholders and institutions who gave support for this work were fully acknowledged.

Name of the Resident: Gizachew Gebrie (MD, Ophthalmology Resident)

Signature: _____

Date: _____

Place of submission: SPHMMC, Department of Ophthalmology

Approval of the First Advisor

Name: Dr Tsedeke Asaminew (Ophthalmologist, VR Surgeon)

Signature: _____

Date: _____

Approval of the Second Advisor

Name: Dr Habtom Hagos (MD, Ophthalmologist)

Signature: _____

Date: _____

Approval of Public health Advisor

Name: Mr Tariku Shimelis (BSc, MSc)

Signature: _____

Date: _____