

PREVALENCE AND ASSOCIATED FACTORS OF DIABETIC RETINOPATHY AMONG RECENTLY DIAGNOSED TYPE 2 DIABETES MELLITUS PATIENTS AT SPHMMC ADDIS ABABA , ETHIOPIA ,2019

A Research Report Submitted to Department of Ophthalmology , Saint Paul's Hospital Millennium Medical College ,in Partial Fulfillment of The Requirement for the Specialty in General Ophthalmology



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ACRONYMS AND ABBREVIATIONS

1.CSME –Clinically Significant Macular Edema

2 .DM- Diabetes Mellitus

3. DFE- Dilated Fundus Exam

4 .DR-Diabetic Retinopathy

5. GMOPD –General Medical Out Patient Department

6.PDR -Proliferative Diabetic Retinopathy

7.SPHMMC –Saint Paul ‘s Hospital Millennium Medical College

8.SPSS-Statistical Package for the Social Science

9.VTDR-Vision Threatening Diabetic Retinopathy

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ABSTRACT

Background: Diabetes mellitus (DM) is becoming the new burden both globally, to our continent and our nation. DM causes high levels of glucose (a form of sugar) in the bloodstream, over time these damages blood vessels, with devastating effects in many different parts of the body, leading to heart attacks, stroke, foot amputations, kidney failure and vision loss due to retinopathy. In Ethiopia the prevalence diabetes mellitus in a recent systematic review reported in 2019 ranged 2.0%-6.5 and most noted associated complication were retinopathy(2.7%-25%),neuropathy(4.8%-35%),depression(13.0%-61.0%),kidneydisease(18.2%-23.8%),hypertension(23.0%-54.8%),anemia(19%). Even though a few studies were done in Ethiopia, this study is different in study area, population coverage and in assessing diabetic retinopathy (DR) prevalence in a

recently diagnosed type 2 DM. This study will generate new information which will give us DR burden in recently diagnosed type 2 DM patients so that screening program, and intervention to halt blindness due to diabetic retinopathy will be given attention

Objective: to assess the prevalence of DR in recently diagnosed type 2 DM patients in St. Paul's Hospital Millennium Medical College (SPHMMC) General Medical Out Patient Department (GMOPD)

Methods: Hospital-based descriptive cross sectional design was used. The data was entered and analyzed by using SPSS version 20.

Result: A total of 143 eyes of 72 patients were evaluated those patient coming to the GMOPD from January 2019-October 2019. The median age of participants was 50yrs and mean time of diagnosis was 8 month. The prevalence of DR in this patients was 15.3% [95%CI: 6.9, 23.6] from those who had DR 5.6% had a vision threatening diabetic retinopathy. Clinical significant association was seen in those patient diagnosed more than 6month ($p=0.049$) uncontrolled blood pressure ($p=0.015$).

Conclusion: the study showed there is a significant number of patient who were diagnosed recently with type 2 DM that developed DR and out of this one third had a vision threatening DR .Therefore according to this study early screening immediately after diagnosis and strict blood pressure control is mandatory to alleviate this problem.

1. INTRODUCTION

1.1. STATEMENT OF THE PROBLEM

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production and this metabolic dysregulation associated with DM causes secondary pathophysiologic changes in multiple organ systems that impose a

tremendous burden on the individual with diabetes and on the health care system (1) . International Diabetes Federation (IDF) estimates that there are 415 million adults living with diabetes worldwide. No country is immune from this epidemic: 70% of people with diabetes live in low- and middle—income countries it is estimated that one third of people with DM have diabetic retinopathy (DR) (2). WHO estimated the number of diabetic cases in Ethiopia to be 800,000 by the yr 2000, and the number is expected to increase to 1.8 million by 2030(3).

Type 2 diabetes accounts for over 90% of all cases. The increment in type 2 diabetes is associated with modern—day lifestyles, Characterized by unhealthy eating (foods high in sugar: salt and fat), physical inactivity and increasing obesity . Globally, diabetic retinopathy (DR) accounts for 5% of all blindness, affecting 2 million people(4). The gravity of this problem is highlighted by the finding that individuals with DM are 25 times more likely to become legally blind than individuals without DM. Blindness is primarily the result of progressive diabetic retinopathy and clinically significant macular edema. Diabetic retinopathy can be classified into two broad categories: Non-proliferative DR (NPDR) and proliferative DR (PDR). PDR and diabetic macular edema (DME) are both sight-threatening and can result in visual impairment and/or blindness.

The major risk factors for DR are long duration of diabetes. poor glycemic control and hypertension (1) .There is evidence from Clinical trials that early treatment of PDR and DME can preserve visual acuity(4). Visual loss from DR is, therefore,

potentially avoidable. Indeed, it has been estimated that blindness from DR could be reduced by as much as 90% if agreed treatment protocols and standardized care for diabetics were to be implemented. According to the systematic review report, there are approximately 93 million people with DR affects 7—63% of sub Saharan diabetic patients (5).In a study done at in Jimma University Hospital Prevalence of diabetic retinopathy was 41 .4%(6).

1.2 Literature review

1.2.1 MAGNITUDE OF THE DIABETIC RETINOPATHY

There are studies done on prevalence of DR at different level worldwide at community level ,hospital setting because DM has become the newly emerging epidemic.

On a research done at a global level a population based studies done in 4 continents a total of 35 studies from 1980 to 2008 was conducted, the prevalence of DR was 34.6% of this proliferative diabetic retinopathy (PDR) accounts for 6.96% diabetic macular edema (DME) 6.81% and Vision threatening diabetic retinopathy VTDR (DME+PDR) accounts 10.2 % (5).

In systematic review done in 21 African countries, 62 studies were included of which 32 were clinical based ,11 were hospital based ,9 eye clinic based , 5 case control, 3 population based, 2 cohort and the result from the studies is as follows in the population based it was found the prevalence of DR was 30.2% -

31.6 %,PDR 0.9% - 1.3%, maculopathy 1.2%- 4.5% in the clinical based studies DR 7.0%- 62.4%, PDR 0.6 %—90%, maculopathy 1.2— 31.1% (7).

In a cross sectional retrospective study done between January 2005 and May 2008 using data from the national diabetes database on Diabetic retinopathy at diagnosis of type 2 diabetes in Scotland and the prevalence was 19.3%, and for referable retinopathy it was 1.9%(8).

A hospital based Cross -sectional studies done in West India type 2 DM population from October 2007— September 2009 the overall prevalence of DR was 33.9% and the non-proliferative diabetic retinopathy (NPDR) and PDR were 25.5 % and 8.33 % respectively and that of CSME was 6.5 %(9).

The study done in Integrative Community Health Centre in a community in Hong

Kong firm “January 2006 to August 2009 the prevalence of diabetic retinopathy was 18.2 % among the recently diagnosed diabetic patients. Most of the patients had mild non- proliferative diabetic retinopathy ,7 % had sight—threatening retinopathy that included significant macular oedema, all of whom required monitoring(10).

The prospective study on newly diagnosed type 2 DM patients from Romania done between January 2001- March 2002 the prevalence of DR was 14.37% and of these 11.70 % were mild NPDR 1.43% had CSME , PDR and preproliferative DR were 1.02% and 0.20 % respectively(11).

In the cross-sectional done in Jordan DR in the newly diagnosed type 2 DM patients was 7. 9% of those 40% had CSME(12).

A descriptive cross sectional descriptive cross-sectional study conducted at Ayub teaching hospital and Northern Institute of Medical Sciences Abbottabad Pakistan 17% of type 2 diabetic patients had retinopathy within one month of diagnosis mild retinopathy was predominant (12%) followed by pre-proliferative (4%) and proliferative (1%) lesions(13).

All newly diagnosed type 2 diabetes mellitus patients Ferdous and Yarmouk Health Care Diabetic Clinics in Farwaniya and Asma Health Areas in Kuwait,

respectively, during the period of January 2002 to July 2004 , diabetic retinopathy was present in 7 (7.6%) patients ,2 of the 7 patient 5 had maculopathy (14).

The prevalence of retinopathy at diagnosis of NIDDM in South Indian subjects among the 60 newly diagnosed NIDDM, 4 (6.7%) subjects had background diabetic retinopathy(15).

In a cross sectional hospital based study on prevalence and pattern of DR in a newly diagnose type 2 DM patients in a eye clinic Of Kenyatta national hospital, Nairobi, Kenya from May 1st 2001 and February 28th 2002 it s was found that the prevalence of DR and CSME was 30.4% & 8.7% respectively(16).

The hospital based cross sectional study done in our country in Arbaminch generalized hospital from November to January 2015 prevalence was 13%(17).

On the research done in Jimma University Hospital the prevalence of DR was found to be 41.4% of these 2.2% had sever NPDR and 6% had CSME and 7.3% had VTDR(6).

1.2.2 ASSOCIATED RISK FACTORS OF DIABETIC RETINOPATHY

In the global study done the prevalence estimates of any DR and VTDR were similar in men and women and were highest in African Americans and lowest in Asians, any DR increased with diabetes duration (21.1 vs. 76.3%, Comparing <10 with > 20 years), HgA1c (18.0 vs. 51.2%, comparing levels <7.0 with >9.0%), and blood pressure (30.8 vs. 39.6%, comparing BP <140/90 or >140/90)(5).

In multivariate analysis from the study done in Africa no obvious association between prevalence and income level of the country was detected(7).

In the study done in Scotland any retinopathy at screening was associated with male sex, HgA1c increase, systolic BP increase, time to screening and Obesity(8).

The Romanian study most patients age was between the age of 40—65yrs and average age 58-59 yrs .Systolic and diastolic hypertension was associated with severity of DR(14) .

The association observed in the Jordan study was HgA1c and age were associated with DR(12).

The study in Pakistan mean age of patients with DR was 45.1+/- 3.2 yrs,60% were females(13).

Microalbuminuria was weakly associated with DR($p=0.08$) in the Kuwait study(14).

With the use of weighted linear regression analysis and percentage of retinopathy in relation to duration estimated hyperglycemia could have been present 4.1 yrs before diagnosis in the study done in South India(15).

In a study done in Hong Kong the presence of hypertension or smoking was not

significantly associated with the prevalence of diabetic retinopathy in recently diagnosed diabetic patients(10).

Kenyan study there was a positive association between diabetic retinopathy and systolic blood pressure(16).

In the study done in Arbaminch in hospital since baseline age >60 years, baseline systolic blood pressure level >140 mmHg, duration of diabetes >6 yrs and patients with family history of diabetes were statistically and significantly related with diabetic retinopathy(17).

In the study done in Jimma there was a statistically significant association between diabetic retinopathy and duration of diabetes, fasting blood sugar, and systemic blood pressure ($p < 0.05$)(6).

1.3 SIGNIFICANCE OF THE STUDY

In Ethiopia, few hospital based studies were done concerning the prevalence of diabetic retinopathy. But there is no published study on prevalence of DR in recently diagnosed type 2 patients and this will serve as a baseline data for further follow up studies and emphasis on screening program to the recently diagnosed patient and facilitate management of treatable types of DR to halt blindness

2. OBJECTIVES

2.1. General Objective

To assess the prevalence of diabetic retinopathy in a recently diagnosed type 2 DM patient coming to the GMOPD in SPHMMC

2.2. Specific Objectives

To determine the prevalence of DR in a recently diagnosed type 2 DM patients

To describe the patterns of DR

To evaluate associated risk factors affecting DR

3. Methods

3.1 Study design

Hospital—based descriptive cross sectional study was conducted.

3.2 Study area and period

The study was conducted in SPHMMC, the hospital was built in 1969 G .C has 392 beds, 200,000 patients are seen on average annually with catchment population of 5 million and the college was established 2007 G.C. The total number of diabetic patients were 11,000 and of these those diabetic patents seen in GMOPD were 2829 the study period was January 2019-October 2019.

3.3 Source population

All recently diagnosed type 2 DM patients attending GMOPD of SPHMMC .

3.4 Study population

All patients who are recently diagnosed type 2 DM within the past 1 yr starting from January 2019 and randomly selected to be enrolled in the study.

3.5. Inclusion and exclusion criteria

3.5 .1 Inclusion criteria:

Recently diagnosed type 2 DM within the past 1 yr. aged 30 yrs and above .

3.5.2 Exclusion criteria:

Patients with gestational diabetes mellitus

Patients with media opacity that obscure fundus View (corneal opacity, dense cataract)

3.6 Sample Size Determination: by single proportion formula

$$n = \frac{(Z_{\alpha/2})^2 P(1 - P)}{d^2}$$

$Z_{\alpha/2} = 1.96$ at 95% confidence level

P = taken from the study done study on prevalence and pattern of DR in a newly diagnosed type 2 DM Kenya $p=30.4\%$

d = margin of error 5%

The sample size (n) = 325

An estimate of total population seen at MGOPD = 2829

Reduction formula was used $n/1+n/N$
= 292

3.7. Sampling technique and procedures

The total DM population visiting the SPHMMC at GOPD at 2018 was 2829 so

based on the systematic random sampling method every 10th patient will be

selected and sent to our clinic.

3.8. Variables of the Study

3.8.1. Dependent variable

Diabetic Retinopathy

3.8.2. Independent variable

Age

Sex

Address

Smoking

Blood pressure

Microalbuminiuria

HgA1c

3.9 Operational Definition

Recently diagnosed Type 2 DM: Diabetic patients diagnosed with type 2 DM in

the last 1 yr.

3.10. Data collection procedures

Patients coming to the GMOPD that were evaluated by a general practitioner and those type 2 diabetic diagnosed within the last 1 year were recruited as a reminder paper were posted on the walls sent candidate patient for the research came with a form filled by the nurses working at OPD that contains demographic data (age, sex, address) time of first diagnosis, previous history of hypertension, smoking history, recent FBS, HgA1C. Then in the ophthalmology department V/A, IOP with non-contact tonometry was taken and a thorough ophthalmic evaluation done by a resident and mentor seniors and DFE (dilated fundus exam) and diabetic retinopathy was graded according to ETDRS (early treatment diabetic retinopathy study).

3.11 Data quality control

The questionnaire prepared made the quality clear and the collection was handled by BSC nurses at OPD and the ophthalmic evaluation was done by residents and cases overseen by seniors, data quality insured through monthly supervision and sample will be cross-checked by principal investigator.

3.12 Data processing and analysis

The data was entered and analyzed by using SPSS version 20. Frequency, mean, medians was calculated. Binary logistic regression was used to determine the associated factors. The variables that are found with $P < 0.2$ at binary logistic regression were entered to multivariate analysis and those variables with p -value less than 0.05 were considered statically significant.

3.13 Ethical Consideration

Ethical clearance was obtained from the institutional review board of SPHMMC.

.The purpose of the research was explained to the study population. The privacy and confidentiality of all participants was secured and informed Consent was prepared both in English and Amharic and those who were willing were be enrolled in the study.

4. RESULT

4.1 Socio-demographic characteristics of the study population

A total of 143 eyes of 72 patients were evaluated those patient coming to the general MOPD from January 2019-October 2019 the median age from the participants was 50years, majority of the patients lies between 40-49 years . Among the patients 39(54.2%) were male and most of them lived in urban area 57(79.2%).

Table 1: Socio-demographic characteristics of the study participants from GMOPD St Paul's hospital, Addis Ababa, Ethiopia 2019(n=72)

Variable	Frequency (%)
Age	
30-39	11(15.3%)
40-49	22(30.6%)
50-59	15(20.8%)
60-69	18(25%)
70-79	6(8.3%)
Sex	
Male	39(54.2%)
Female	33(45.8%)
Address	
Urban	57(79.2%)
Rural	15(20.8%)

4.2. Clinical characteristics of study participant

The study population first time of diagnosis of the diabetes mellitus was of 12months 33(45.8%) followed by one month of diagnosis 9(12.5%) and the mean time of diagnosis was 8month .Among the study population most had no history Of smoking 62(86.1%) followed by past history of smoking 6(8.3%).Thirty five of the patients (48.6%) had history hypertension.

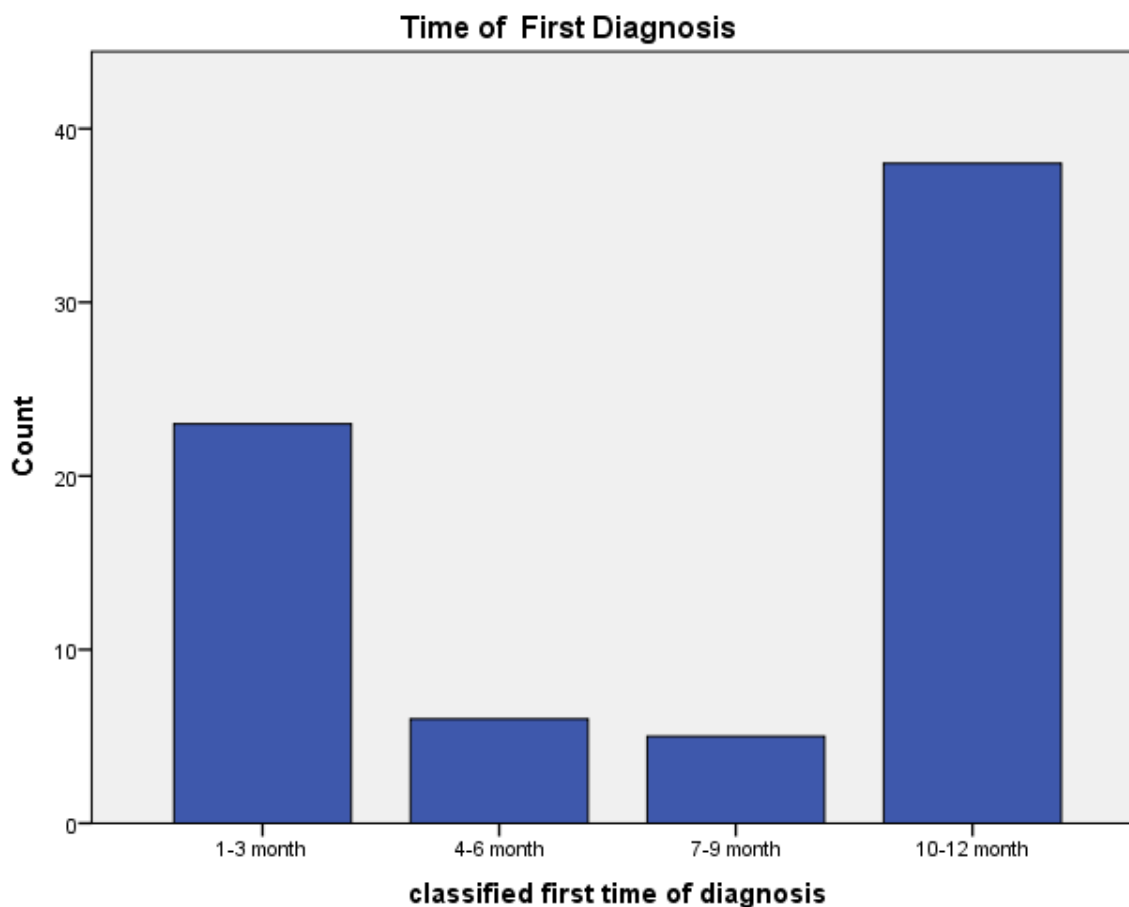


Figure 1: Time of diagnosis for study participants with recently diagnosed type 2 DM patient seen at GMOPD of SPHMMC

The mean fasting blood sugar and HgA1c of the study participants was 161.7 mg/dl(<130mg/dl) and 8.98%(<9%) respectively. There was no proteinuria in most patient who were recruited in the study 62(86.1%).

Table 2: Clinical characteristics of study participant with recently diagnosed type 2 DM patient seen at GMOPD of SPHMMC

Variable	Frequency (%)
Smoking	
Yes	4 (5.6%)
No	62(86.1%)
In the past	6 (8.3%)
Hypertension	
Yes	35(48.6%)
No	37(51.4)
Blood pressure	
120/70	31 (43.1%)
130/80	18 (25.0%)
140/90-150/90	16 (22.2%)
160/100	7(9.7%)
Microalbuminuria	
Yes	10(13.9%)
No	62(86.1%)
HgA1c	
<7%	31(43.1%)
8-9%	15(20.8%)
>9%	26(36.1%)

The prevalence of diabetic retinopathy in patients with a diagnosis of

Diabetes up to one year was 11(15.3%) [95%CI: 6.9, 23.6] out of this

5.6% had a vision threatening diabetic retinopathy (sever NPDR, early PDR, and

high risk PDR or CSME) .The pattern of diabetic retinopathy among the patients

is as followed No DR 61(84.7%), mild NPDR accounted 5(6.9%) followed by

moderate NPDR 2(2.8%).

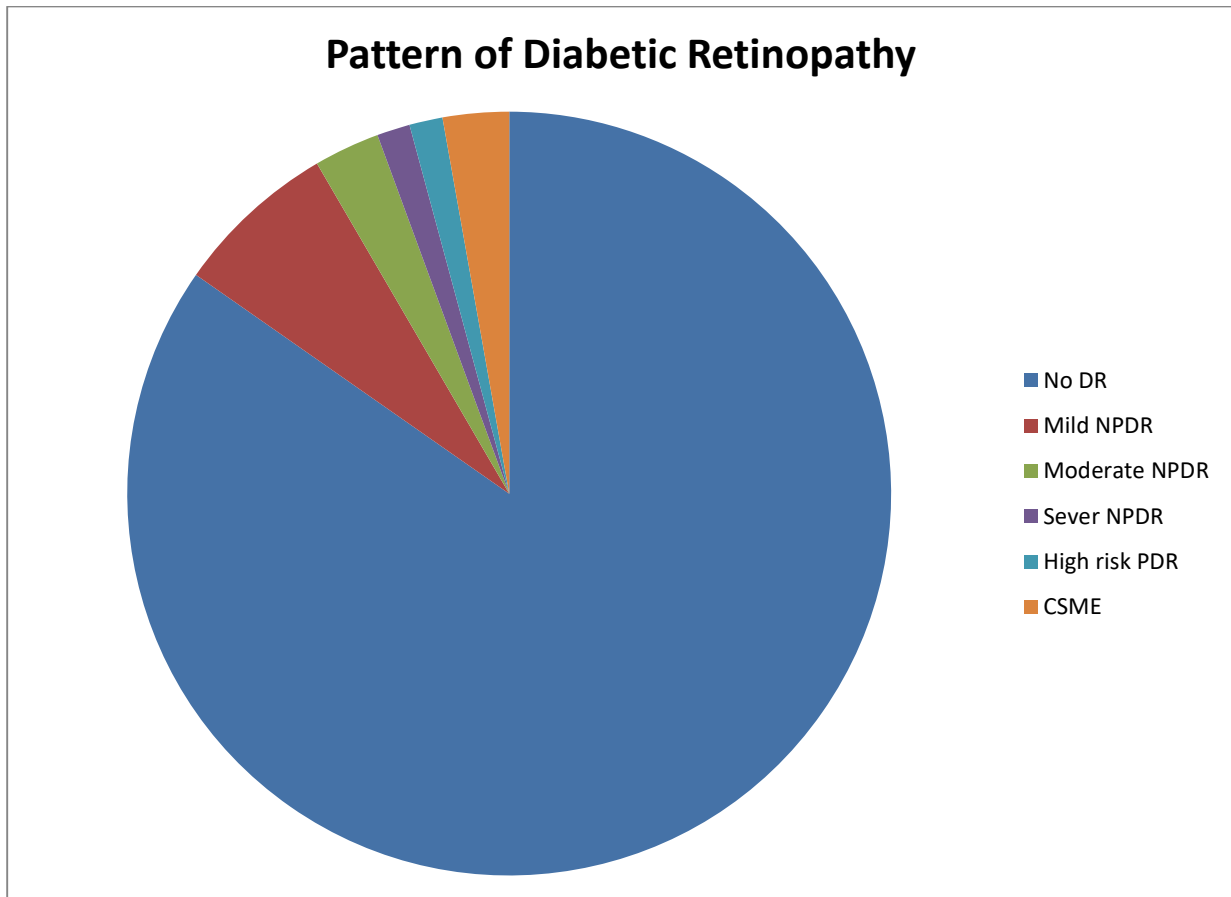


Figure 2: Pattern of diabetic retinopathy in recently diagnosed type 2 DM patient seen at GMOPD of SPHMMC.

Concerning the associated factors analyzed by binary logistics regression there were 4 factors that were associated address ($p=0.179$), time of diagnosis ($p=0.122$), blood pressure (0.021) and HgA1c ($p=0.175$) and it was run again by multivariate logistic regression and there was significant association with uncontrolled blood pressure ($p=0.015$).

Table 3: Factors associated with diabetic retinopathy in recently diagnosed type 2 DM patient seen at GMOPD of SPHMMC.

Variables	COR (95%CI)		p-value	AOR(95%CI)		p-value
	Univariate Regression	Logistic		Multivariate Regression	Logistic	
Age						
30-39	1.00					
40-49	0.99(-20.9, 20.1)		0.648			
50-59	0.49(-19.4,20.1)		0.851			
60-69	0.25(-1.30,21.2)		0.454			
70-79	0.93(-21.2,19.4)		0.415			
Address						
Urban	1					
Rural	0.162(-2.38,149)		0.179*	0.305(-20.551,2.388)		0.242
First time of diagnosis						
<6month	1					
>6month	0.92(-0.268,20.241)		0.122*	0.012(0.469,22.585)		0.049*
Blood pressure						
<130/80	1					
>130/80	0.006(-3.409,-0.139)		0.021*	0.006(-21.819,-0.235)		0.015*
HgA1c						
<9%	1					
>9%	0.153(-2.515,0.552)		0.175*	0.138(-20.451,0.771)		0.142
Microalbuminuria						
Yes	0.540(-2.196,19.756)		0.656			
No	1					

5. Discussion

In this current study the prevalence of diabetic retinopathy in a recently diagnosed type 2 patients is 15.3% [95%CI: 6.9,23.6] compared to other countries the burden is comparable to a study done in Pakistan which accounted for 15% but there difference in that the time of diagnosis was only of two month duration and there are studies with lower prevalence in Kuwait 7.5%¹¹, and in Jordan 7.9%¹² and in the study done in Kenya it accounted around 30.4%¹⁶ the detection rate was higher and fundus photo was used and same thing observed in the study done Hong Kong , Scotland fundus photo was used and the prevalence was 18.2%¹⁰ and 19.3%⁸ respectively higher than this study but there were comparative studies that showed the sensitivity and specificity of biomicroscopy to be 91.2% and 97.9%¹⁹ respectively .

The pattern of diabetic retinopathy as observed in this study is majorly No DR followed by Mild NPDR, Moderate NPDR and in most studies the same pattern is observed.^{10,12,16} The vision threatening DR those more than sever NPDR and CSME in this current study was 5.6% and was comparable to the studies done in Kenya 6.6%¹⁶, Hong Kong 6.8%¹⁰. In Scotland this vision threatening DR (referable DR) was 1.9% and the reason suggested for a lower rate being patients in Scotland are screened within an acceptable interval.

The association seen between uncontrolled hypertension and diabetic retinopathy was also noted in the study done in Kenya, Scotland ,Romania ^{16,8,14} and other studies in Jordan ,Hong Kong didn't show association with hypertension rather in the study done in Jordan the observed association was with HgA1c and increased age.

Limitation of the study

The major drawback of this study is the calculated sample size was not attained and even though there going to be continuation of the study the sample size will affect the current association observed.

Conclusion and Recommendation

Diabetes mellitus as current epidemic to our nation the complications has to be dealt with and regarding this, the study showed there is a significant number of patient who were diagnosed recently with type 2 DM that developed diabetic retinopathy and out of this one third had a vision threatening DR .Therefore I recommend early screening immediately after diagnosis as per protocol and give feedback to the internist or endocrinologist to refer patient on time and advise on strict blood pressure control because this study showed strong association with uncontrolled blood pressure.

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Annexes

Annex 1

Data extraction form for prevalence of diabetic Retinopathy the recently diagnosed type 2 diabetic patients

Code No _____

Date: _____

Card No _____

Demographic Data		
Age		
Sex	1 male	2 female
Address	1 urban	2 rural

History		
Time of first diagnosis		
Previous history of hypertension	Yes	No
Smoking history	Yes	In the past No

Investigation

BP		
FBS		
U/A	Protein	No protein
HgA1C		

Ophthalmic evaluation

	OD	OS
Visual Acuity		
IOP		
Dilated Funds Exam		
Grade of DR	OD	OS
1. No DR		
2. Mild NPDR		
3. Moderate NPDR		
4. Sever NPDR		
5. Early PDR		
6. High risk PDR		
7. Advanced PDR		
8. CSME		

Annex 2

Informed Consent

Good morning/afternoon, my name is _____ I am an ophthalmology resident at SPHMMC. I am studying the prevalence of DR in a recently diagnosed type 2 patients by asking questions and doing physical and ocular examination. Your answers to our questions are important to know the burden of DR and to give the results governmental officials for intervention requiring DR. Your answers will be confidential and secret and there won't be incentives for you to take part in this research If you decide that, you do not want to participate in the study your right is reserved.

Do I have your permission to continue?

If yes thank you and continue _____

If no, thank you and go to next study subject _____

Data collector

Name _____ Signature _____ Date _____

Checked by supervisor

Name _____ Signature _____ Date _____

የፌቃድ መጠየቂያ ቅጽ

እኔ ዶ/ር ቅንጂት ፍቃዱ የቅዱስ ዳውሎስ ሆስፒታልሚሲንዩም ህክምና ኮሌጅ የዐደን ህክምና የድህረ ምረቃ ተማሪ ስሆን የምሰራውም ጥናት በቅርቡ የሁለተኛ ዓይነት ስኬት ሲገኝ ህመም የተያዙ ግለሰቦች የውስጥ ዓይናቸው ሳይ ያስውን የተፅኑ ብዛት መውቅ ሳይ ያተኩራል ። በዚህ ጥናት ሳይ መሳተፍም በፍቃደኝነትዎ ብቻ ሳይ የተመሠረተ ሲሆን ፤ የሚሰጡትም መረጃ ስትሆንህልኝ ፤ ስጥናትና ምርምር ብቻ ይውሳል፡ ፡መረጃውን በሚሰጡበት ወቅት ስምና ስድራሻዎን መጥቀስ ወይም መሳተፍ ስደጠበቅብዎትሁ፡፡ ስላደረጉኝ ትብብር ክስብ ስመሰግናለሁ፡፡

የስምምነት መግለጫ

እኔ ከሳይ የተዘረዘሩትን መረጃዎች ስንብቤና ተረድኼ ብሎም በጥናቱ ሂደት ስመሳተፍ ተስማምቻለሁ

የተሳታፊ ስም -----

ፊርማ-----

ቀን -----

የጥናቱ መረጃ ሰብሳቢ ስም-----

ፊርማ-----

ቀን-----