DISSERTATION

PREVALENCE, RISK FACTORS AND STAGE OF DIABETIC RETINOPATHY AMONG PATIENTS ATTENDING THE MEDICAL CLINIC AT JUBA TEACHING HOSPITAL, SOUTH SUDAN

DR. NYIBONG ALBINO WILLIAM

H58/69389/2013

A DISSERTATION PRESENTED IN PARTIAL FULFILLMENT OF THE REQUIRMENT FOR DEGREE OF MASTER OF MEDICINE (OPHTHALMOLOGY) AT THE UNIVERSITY OF NAIROBI,

DECLARATION

I declare that this dissertation is my original work and has never been published or presented for a degree in any other University.

Signed: _____ Date: _____

DR. NYIBONG ALBINO WILLIAM

APPROVAL BY SUPERVISORS

This dissertation has been submitted with our approval as Supervisors:

1. **DR. JOSEPH NYAMORI MAINA**

   MBChB (Nairobi), M.Med (Nairobi), FEACO, ICO Retina Specialist

   Lecturer Department of Ophthalmology, University of Nairobi

   Signed_____ Date_____

2. **DR. MUKIRI MUKURIA**

   MBChB (Nairobi), M.Med (Ophthalmology) (Nairobi), FEACO

   Lecturer Department of Ophthalmology, University of Nairobi

   Signed_____ Date_____

3. **DR .WANI MENA**

   MBChB (Harare) M.Med. (Ophthalmology) (Harare) Msc. ClinEpi

   Signed_____ Date_____

DEDICATION

This work is dedicated to the soul of my late father, my mother and beloved wife for continuous support during period of my study.

ACKNOWLEDGEMENTS

I would like to acknowledge the following people for their support towards this study:

- Dr. Joseph Nyamori, Dr.Mukiri Mukuria, and Dr. Wani Mena for their advice, guidance and on time corrections during the study period
- All my lecturers, my fellow colleagues for their support and encouragement
- My sponsors sight savers .org, for the financial support towards my study
- The statistician Mr. Alex Mukungu for assisting me with data analysis.
- My uncle major general Akoten Yor for his logistic facilitation during data collection.

TABLE OF CONTENT

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

BCVA – Best Corrected Visual acuity

BP – Blood Pressure

CDC – Centre for Disease Control

COECSA – College of Ophthalmology for Eastern, Central and Southern Africa

CSME – Clinically Significant Macular Edema

CURES – Chennai Urban Rural Epidemiological Study

DCCT – Diabetes Control and Complication Trial

DR – Diabetic Retinopathy

DRS – Diabetic Retinopathy Study

ERC – Ethics and Research Committee

ETDRS – Early Treatment of Diabetic Retinopathy Study

FBS – Fasting Blood Sugar

HBA1c – Glycosylated Haemoglobin

HRPDR – High Risk Proliferative Diabetic Retinopathy

IDDM – Insulin Dependent Diabetes mellitus

IFG	–	Impaired Fasting Glucose
IGT	–	Impaired Glucose Tolerance
KNH	–	Kenyatta National Hospital
MOU	–	Memorandum of Understanding
NHRPDR	–	Non High Risk Proliferative Diabetic Retinopathy
NVD	–	Neovascularisation at the disc
NVE	–	Neovascularisation Elsewhere
OHA	–	Oral Hypoglycemic Agents
PDR	–	Proliferative Diabetic Retinopathy
SPSS	–	Statistical Package for Social Science
UKPDS	–	United Kingdom Prospective Diabetic Study
UoN	–	University of Nairobi
WHO	–	World Health Organization

ABSTRACT

Background: Diabetes is considerable cause of morbidity and mortality that is associated with microvascular complications resulting in, blindness, kidney failure, neuropathy, amputations, heart disease, and stroke. Diabetic Retinopathy is a serious microvascular complication of diabetes that can ultimately lead to blindness. The prevalence and pattern of DR in Juba is not known.

Objective: To determine the prevalence, risks factors and Stage of diabetic retinopathy among diabetic patients attending the medical clinic at Juba Teaching Hospital, South Sudan.

Study Design: A hospital based cross sectional study.

Study Population: All diabetic patients attending the medical clinic at Juba Teaching Hospital during the study period.

Study Period: A total of 147 patients were examined at Juba TH from 15th October to 15th November 2016.

Method: We performed dilated funduscopy using indirect ophthalmoscope with 20D lens, followed by slit lamp examination with 78D lens and entered findings in a questionnaire using ETDRS grading for DR. Data was analysed using the SPSS version 20. Confidence level was taken as 95% ($p < 0.05$) where applicable.

Results: The M: F ratio of patients with DM was **1:1.1** Type II diabetes 96.6%) was more common than type I diabetes (3.4%). Most (81%) of the patients examined did not have retinopathy; diabetic retinopathy was present in 19.0% of the 147 patients evaluated. Patients

with retinopathy had a higher mean age (55) compared to those without DR. The most prevalent type of DR was mild non-proliferative diabetic retinopathy (60.7%).There was a statistically significant higher presence of retinopathy in those with longer duration of diabetes (p 0.000). We found that the prevalent of DR was 19%.

Recommendations: Screening for diabetic retinopathy and follow-up upon diagnosis of diabetes is recommended. Awareness campaigns may improve follow-up and primary prevention for patients with DR; ideal comprehensive diabetic center at JTH should incorporate counseling and include an adequate number of physicians and ophthalmologists.

1.0 INTRODUCTION

Diabetes mellitus is characterised by reccurent or persistent high blood sugar, and is diagnosed by demonstrating any one of the following: (1) fasting plasma glucose level ≥7.0 mmol/l (126 mg/dl), (2) plasma glucose ≥ 11.1 mmol/l (200 mg/dl), and (3) glycosylated haemoglobin (HbA_{1C}) ≥ 48 mmol/mol (≥ 6.5 DCCT%). [1] DR is a vascular disorder affecting the microvasculature of the retina. This condition affects a third of all diabetic patients and its prevalence increases with the duration of diabetes. [2]

The number of adults with diabetes in the world is estimated to be 366 million in 2011 and by 2030 this would have risen to 552 million. The number of people with type 2 diabetes is increasing in every country, 80 % of people with diabetes live in low- and middle-income countries.[3]

In 2010 12.1 million people were estimated to be living with diabetes in Africa, and this is projected to increase to 23.9 million by 2030.[7] Diabetes, is the most common non-communicable disease in south Sudan, and is having an increasing impact on rates of morbidity and mortality in the country.[4] The spread of sedentary lifestyles and adoption of western dietary habits (high in refined carbohydrates and fat) are driving an increase in the number of people with obesity-related type 2 diabetes.[5] [7]

2.0 LITERATURE REVIEW

2.1 Types of Diabetes Mellitus

2.1.1 Type 1

The body does not produce insulin, and daily insulin injections are required. It accounts for 5-10% of all diabetes. There does appear to be a genetic component to Type 1 diabetes, but the cause has yet to be identified. [9]

2.1.2 Type 2

It is the result of failure to produce sufficient insulin and insulin resistance. It is much more common and accounts for 90-95% of all diabetes. It is typically diagnosed during adulthood. [10]

2.2 Diagnostic Criteria of DM

There is abundance of data indicating that hyperglycaemia is harmful. However there are limitations in the data and the methodologies used to derive cut off points at which this level of harm is specifically increased and which clearly differentiates diabetes from non-diabetes. It is thus difficult to accurately define normal glucose levels. [9] [10] Despite the limitations with the data from which the diagnostic criteria for diabetes are derived, the current WHO criteria distinguish a group with significantly increased premature mortality and increased risk of microvascular and cardiovascular complications (see Appendix No 7.4).

2.3 Diabetic Retinopathy

DR is a chronic progressive, potentially sight-threatening disease of the retinal microvasculature associated with the prolonged hyperglycaemia and other conditions linked to diabetes mellitus such as hypertension. [11]

2.3.1 Stages of Diabetic Retinopathy

Often occurring without noticeable symptoms, DR damages the blood vessels of the retina in four stages: [12]

Stage 1: Mild Non-proliferative retinopathy – At this earliest stage, micro-aneurysms occur, which are small areas of balloon-like swelling within the retina's tiny blood vessels.

Stage 2: Moderate Non-proliferative retinopathy-As the disease progresses, some of the blood vessels that nourish the retina become blocked. This stage is characterized by hemorrhages, hard exudates, and dilation of veins.

Stage 3: Severe Non-proliferative retinopathy – In severe cases, many more blood vessels are blocked, depriving several areas of the retina of blood supply. These areas of the eye then send signals to the body to grow new blood vessels in order to provide critical nourishment for the retina. More blot hemorrhages, hard exudates, venous loops and cotton wool sports characterize this stage

Stage 4: Proliferative retinopathy - At this advanced stage, a lack of oxygen causes fragile blood vessels to grow along the retina and within the vitreous gel that fills the inside of the eye. Without timely treatment, these new blood vessels can bleed cloud vision and destroy the retina.

The main characteristics of this stage are growth of new vessels at the disc (new vessels at the disc NVD) and new vessels elsewhere (NVE). Very severe proliferative DR is characterized by pre-retinal and vitreous hemorrhages, fibrous tissue in the retina and tractional retinal detachment. In more severe cases rubeosis of the iris may occur resulting in neovascular glaucoma.

Diabetic macular edema (DME) - Is the largest cause of visual acuity loss in diabetes. It affects central vision from the early stages of retinopathy, and it is the most frequent sight-threatening complication of diabetic retinopathy, particularly in older type 2 diabetic patients. Its role in the process of vision loss in diabetic patients and its occurrence in the evolution of the retinal disease are being increasingly recognized. Although macular edema is a common and characteristic complication of diabetic retinopathy and shows apparent association with the systemic metabolic alterations of diabetes, it does not necessarily fit the regular course of diabetic retinopathy progression. It may occur at any stage of diabetic retinopathy, whether nonproliferative, moderate, or severe, or even at the more advanced stages of the retinopathy. Classified into four clinical fissures:

1. Focal maculopathy, characterized by incomplete of exudate due to focal leakage of microaneurysms and dilated capillaries segments
2. Diffused maculopathy, characterized by diffused retinal thickening, that may be associated with macular oedema
3. Ischemic maculopathy, as a result of capillary non perfusion at the fovea
4. Clinical significant macula oedema, characterized by retinal thickening and hard exudate within 500µm from the centre of macular [13]

2.3.2 Screening for Diabetic Retinopathy

The abnormalities that characterize diabetic retinopathy occur in a predictable progression with minor variations in the order of their appearance. [14] If used appropriately, a number of tests ancillary to the clinical examination may enhance patient care, e.g. fundus camera will reveal early signs of DR. [15] [16] [17] [18] [19]

2.4 Global Overview of Diabetic Retinopathy

Bamashmus *et al*. [21] Presented a series of patients with diabetes mellitus (DM) who attended an eye hospital in Sanaa, Yemen during 2004. The prevalence of DR was 55% (95% CI 49.6-60.1). The proportions of background diabetic retinopathy (BDR), preproliferative diabetic retinopathy (PPDR)|, proliferative diabetic retinopathy (PDR) and diabetic macular edema were 20%, 13%, 17% and 22% respectively. Duration of DM was the predictor of DR. One-fifth of the patients had sight-threatening DR and needed laser treatment.

Study by Memon *et al.*[22] Estimated the frequency of diabetic retinopathy by age, sex and type of diabetes and to identify possible risk factors for diabetic retinopathy in Gadaap Town and Jamshed Town. The diabetic retinopathy of any grade was detected 28.8% (151 subjects out of 525). Out of them NPDR (Mild to severe) was 33.1%, PDR was 2.65%, clinically significant macular oedema with NPDR was 50.33%.

Khandekar *et al.*, (2015) [23] conducted a study to estimate the magnitude and determinants of DR among persons with diabetes registered at the employee health department of King Khaled Eye Specialist Hospital (KKESH). DR was present in 40% of those examined. Good glycemic

control was noted in 42% of participants. The lens opacity and glaucoma rate was 15% and 8.3%, respectively.

Klein *et al (1992)* [24] reported results from the Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR study) in southern Wisconsin. Proliferative diabetic retinopathy (PDR) was found to be a prevalent complication - 23% in the younger-onset group, 10% in the older-onset group that takes insulin, and 3% in the group that does not take insulin.

Wong *et al.*(2008) and Wong *et al.*(2006) [25] [26] conducted a systematic review of rates of progression in diabetic retinopathy during different time periods. The authors concluded that since 1985, a lower rate of progression to PDR was reported by the studies included in the review. These findings reflected an increased awareness of retinopathy risk factors; earlier identification and initiation of care for patients with retinopathy; and improved medical management of blood glucose, blood pressure, and serum lipids.

Study by Shrestha (2011) [27] NPDR was most common among the various stages with 13.28% of diabetic population, while 7.03% had proliferative retinopathy. In one study almost 19% of participants had NPDR with only 1.59% having PDR while another study reported 38.3% with non-proliferative and 6.5% with proliferative diabetic retinopathy.

The UKPDS [28] found out that compared with the conventional group, there was a 25% risk reduction in the intensive group in microvascular endpoints, including the need for retinal photocoagulation. Patients allocated metformin, compared with the conventional group, had risk reductions of 32% for any diabetes-related endpoint.

Study by Palmberg [29] described the natural history of diabetic retinopathy in 461 people with juvenile-onset insulin-dependent diabetes mellitus (IDDM). At diagnosis no DR was found, with prevalence of 50% at 7 years duration and 90% at 17-50 years duration. Proliferative diabetic retinopathy (PDR) was first seen at 13 years with 26% prevalence at 26-50 years duration.

2.5 Over view of Diabetic Retinopathy in Africa

Njikam (2011) [30] carried out a study on the magnitude and pattern of diabetic retinopathy at central hospital of Yaoundé, Cameroon. He found out that the prevalence of diabetic retinopathy was 49.2%. Severe NPDR was found in 12(3.2%) patients, CSME was found in 30 (8.1%) patients, PDR in 53 (14.3%) patients and vision threatening diabetic retinopathy was found in 27.3% of patients. There was a statistically significant association between diabetic retinopathy and duration of diabetes, high blood pressure and nephropathy.

Akpalu (2011) [31] carried out a study to determine the magnitude, pattern and level of awareness of DR. NPDR with clinically significant macula oedema was found in 44 participants (14.1%). DR was statistically associated with long duration of diabetes, high blood pressure, high FBS and HbA1c.

Study by Abdirahman (2012) [32] determined the prevalence, pattern and associations of Diabetic retinopathy in Somali patients. Prevalence of DR was found to be 15.1% with 8.6% and 2.2 % patients having CSME and PDR, respectively and vision threatening retinopathy in 9.7% patients. There was a statistical significant association between age, poor vision and duration of diabetic retinopathy.

Lawan & Mohammed (2013) [33] aim of the study was to determine the pattern of retinopathy seen in diabetic patient. Forty nine patients (23%) had IDDM while 165 patients (77%) had NIDDM. There was statistically significant difference in presence of retinopathy in patients with IDDM compared to those with NIDDM. DR was significantly more common in patients with disease duration of 15 years or more compared with those with disease duration of 14 years or less.

Study by Wambugu (2011) [34] determined the prevalence, pattern and associations of DR in black African diabetic patients. The prevalence of DR was found to be 31.9% with 8.8% having clinical Macula Oedema. Patients who had previous fundus examination were 47.2% and 5.5% of the total number of patients had received laser treatment for either PDR or CSME. There was a statistically significant association between duration of DM and development of DR.

Kariuki (1999) [35] conducted a study to determine the prevalence, pattern and associations of Diabetic retinopathy among black African diabetics. She found out that the prevalence of DR was 49.8%. Macular edema was present in 40.3% of the patients with diabetic retinopathy, of whom 67.2% had clinically significant macular edema.

Study by Wondimagegn (2009) [36] aimed to determine the prevalence and pattern of DR. The prevalence of DR was found to be 41.4%; severe NPDR was found in 7 (2.2%) patients, CSME in 16 (4.9%) patients, and DR in 7.3% patients. A statistically significant association was found between DR and duration, Fasting Blood Sugar (FBS), and mean systemic blood pressure.

Study by Njambi (2012) [37] determined prevalence of diabetic retinopathy in diabetic patients. The overall prevalence of DR was 41%. Moderate NPDR was the most prevalent grade of DR

(20%). Vision threatening DR (PDR and macular oedema) was found in 21 (8.3%) patients. Most of the patients (74%) had hypertension. Duration of diabetes and systolic blood pressure had a significant association with DR ($p< 0.05$).

Mutangana (2008) [38] determined the prevalence and pattern of DR and its associations in Diabetic patients. DR was detected in 114 (29.2%) of the 391 patients with diabetes and 237 (60.6%) patients had never had a fundus exam. DR was associated with high blood pressures, long duration of diabetes and high fasting blood sugars.

3.0 JUSTIFICATION

Siham *et al.* (2014) [39] point out that Knowledge of the diabetes epidemic in south Sudan is limited. The most recent data come from a small-scale study that was carried out in 2013 in Sudan. The results of the study indicated a prevalence of 30.1 % (Siham *et al.*, 2014) [39]

The exact prevalence of diabetic retinopathy in south Sudan is not known. In fact, a study on the prevalence and pattern of diabetic retinopathy among diabetic patients has not yet been done. We focused on the high-risk population (diabetic patients) to help national prevention of blindness programmes in the country. To establish such a system, evidence-based information on diabetes and diabetic retinopathy is needed.

In addition, In spite of blinding eye complications and ways to prevent/delay the progression, risk factors are less attended, and compliance of annual eye screening is often low and, therefore, all efforts for improving their compliance are suggested. With early intervention having greater benefits than late intervention, this study will be of great importance from the public health perspective. Thus, the study will determine the prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan

4.0 OBJECTIVES

4.1 Main Objective

To determine the prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan

4.2 Specific Objectives

1. To determine the prevalence of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan.
2. To determine the pattern of diabetic retinopathy by standardized grading using the ETDRS guidelines.
3. To determine the association between diabetic retinopathy and the following selected risk factors:
    (i) Age
    (ii) Duration of diabetes
    (iii) Glycaemic control
    (iv) Blood pressure

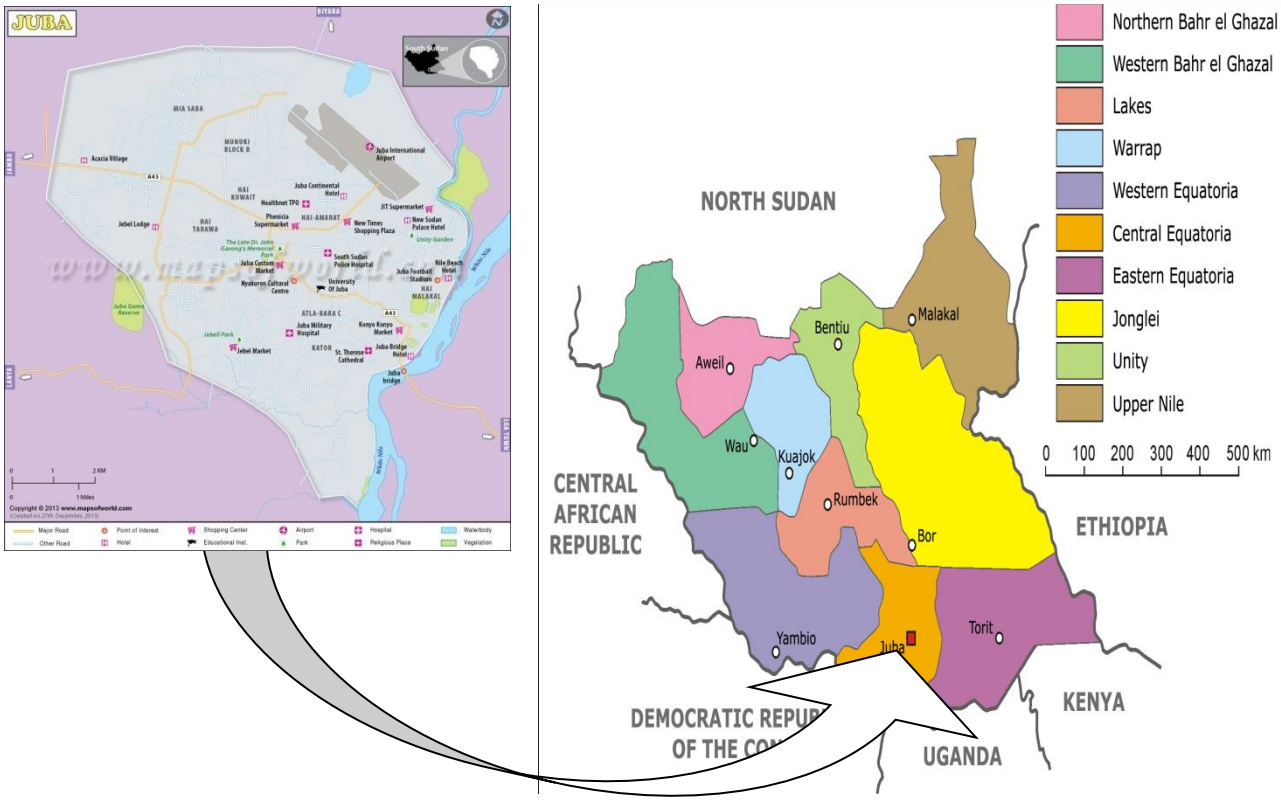
5.0 MATERIAL AND METHODS

5.1 Study Design

This study was a hospital based cross sectional study.

5.2 Study Area

Figure 5. 1: *Map of South Sudan showing Juba County (map of previous 10 states, during the approval of proposal December 2014 before creation of 32 states in Oct. 2015)*



The study was done at medical clinic at Juba Teaching Hospital. It is a general clinic receiving all medical cases, from Monday to Sunday, with estimated number of new diabetic cases about 2 to 3 patients per day. Juba Teaching Hospital is located in the capital of South Sudan Juba, in

Central Equatorial State, one of the ten states of the South Sudan, with a catchment area of about 150 km/s with population of 350,000 (Sudan Census, 2008). [40]

5.3 Target Population

Study targeted all diabetic patients aged 16 years and older attending the medical clinic during the study period..

5.4 Inclusion Criteria

1. All diabetic patients aged 16 years and older, attending medical clinic during the study period.
2. Informed consent was given by the patient

5.5 Exclusion Criteria

1. Opaque ocular media not allowing adequate visualization of the fundus for grading of diabetic retinopathy.
2. Diabetic children aged less than 16 years, because most studies have shown that diabetic retinopathy evolves after 10 years of onset of diabetes mellitus thus it was appropriate to focus on patients aged 16 years and older.

5.6 Sample Size

The following sample size determination formula for finite population correction (Wanga & Lameshow, 1991) [41] was used to estimate the proportion of population study size.

$$n^1 = \frac{NZ^2\mathrm{P}(1-P)}{d^2(N-1)+Z^2\mathrm{P}(1-P)}$$

Where:

n' = sample size with finite population correction,

N = size of the target population = size of the target population = 150 (estimated number of patients seen in the medical clinics, Juba Teaching hospital , approximately 3 to 5 patients new cases are diagnosed per day according to the registry book)

Z = statistic for 95% level of confidence

P = estimated proportion of diabetic patients with DR is 31.1% (Siam Ahmad et al),2013[38]

d = margin of error = 2.1%

$$n^1 = \frac{150x1.96^2x0.30x0.7}{(0.021^2x149)+(1.96^2x0.3x0.7)}$$

n^1 = 138.81

140 Patients

5.7 Materials

1. Structured questionnaire was used for data collection
2. Tropicamide 1% eye drops
3. Log MAR chart for visual acuity
4. Slit lamp with 90D.
5. Indirect binocular ophthalmoscope with 20D

6. Mercury sphygmomanometer BP machine.
7. Weight – Height scale

5.8 Data Collection Procedures

All diabetic patients, both old and newly diagnosed, were recruited from medical clinic when they come for their visit to the physician

All patients visiting the medical clinic were first registered at the nurses' station where the vital signs including height and weight using standard weight and height scale, blood pressure using (mercury sphygmomanometer) was measured and recorded in the patients file and sent to the physician room.

Once the diabetic patients were seen by the physician, they were directed by the research assistant to the eye examination room to obtain informed written consent. A pre-tested questionnaire was used to record all study data from the patient. Demographic data was recorded before proceeding with examination.

Presenting visual acuity was assessed for each eye using Log MAR chart at 6 meters, for all patients. Anterior segment examination using a slit lamp before dilating the pupils was done. The pupils was then dilated using 1% tropicamide eye drops and the posterior segment examined using a binocular indirect ophthalmoscope with 20D, after which stereoscopic binocular examination of the fundus using a slit lamp with 90D was performed. A senior ophthalmologist reviewed all available information on the participants and determined the diabetic retinopathy status of each patient.

Diabetic retinopathy was graded according to the ETDRS classification (see Appendix 7.5 for WHO ETDRS classification). After examination, the findings were explained (see appendix 7.1 for questionnaire) to the patient and those requiring medical treatment, Laser or retinal surgery were referred to the hospital of their choice particularly, Nairobi, Khartoum and Cairo.

The patients were sent to a specific private laboratory located opposite the hospital gate. The laboratory technician took the blood sample for HbA1C and FBS (2 ml per patient) and analysed using Biolis 50i auto-analysis machine model. The patient received the result on the same day. All laboratory cost was paid through the research budget.

5.9 Data Management and Analysis

All filled questionnaires were checked by the principal investigator for completeness. Data analysis was done using the SPSS version 23. Descriptive analysis was done to determine means, frequencies and proportions of the various variables and findings presented by means of graphs, tables and charts where appropriate. Chi-square was used to test factors associated with diabetic retinopathy. Confidence level was taken as 95% ($p < 0.05$) where applicable.

5.10 Ethical Considerations

5.10.1 Confidentiality

The identity of the patients was kept anonymous during data collection. No record of the identity of the patient or file number was made. No photocopies of medical records were made. The questionnaires were only available to the statistician and investigator for analysis only.

5.10.2 Approval by Patient/Parent

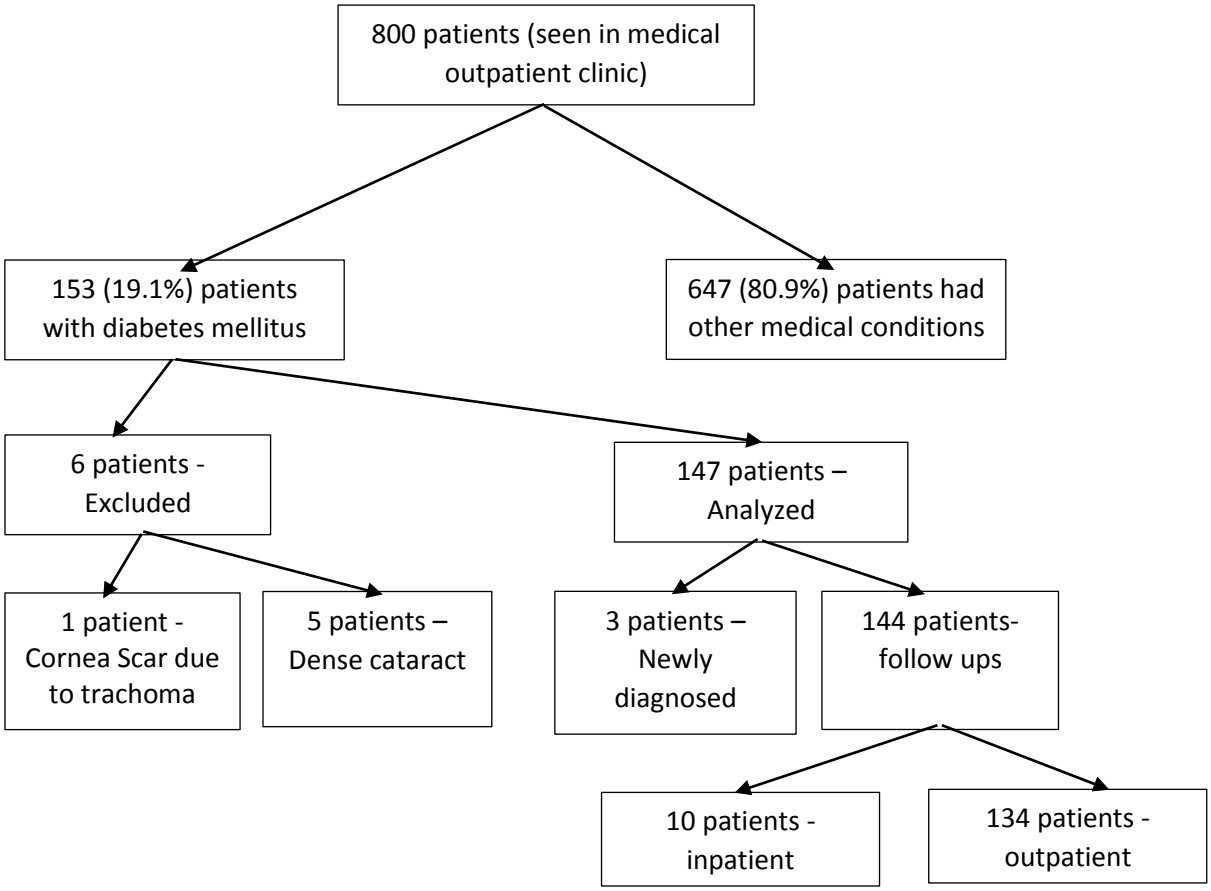
Written consent to participate in the study was sought from the patients for approval. Approval to participate (assent form) in the research was also sought from parents, particularly for 16-17 years old patients.

5.10.3 Approval by Ethics Committees

Written ethical approval to conduct the study was sought from the Ethics Research Committee of University of Nairobi and Kenyatta National Hospital (combined ethical committee). Approval to conduct the research was also sought from Juba Teaching Hospital and Ministry of Health Republic of South Sudan.

6.0 RESULTS

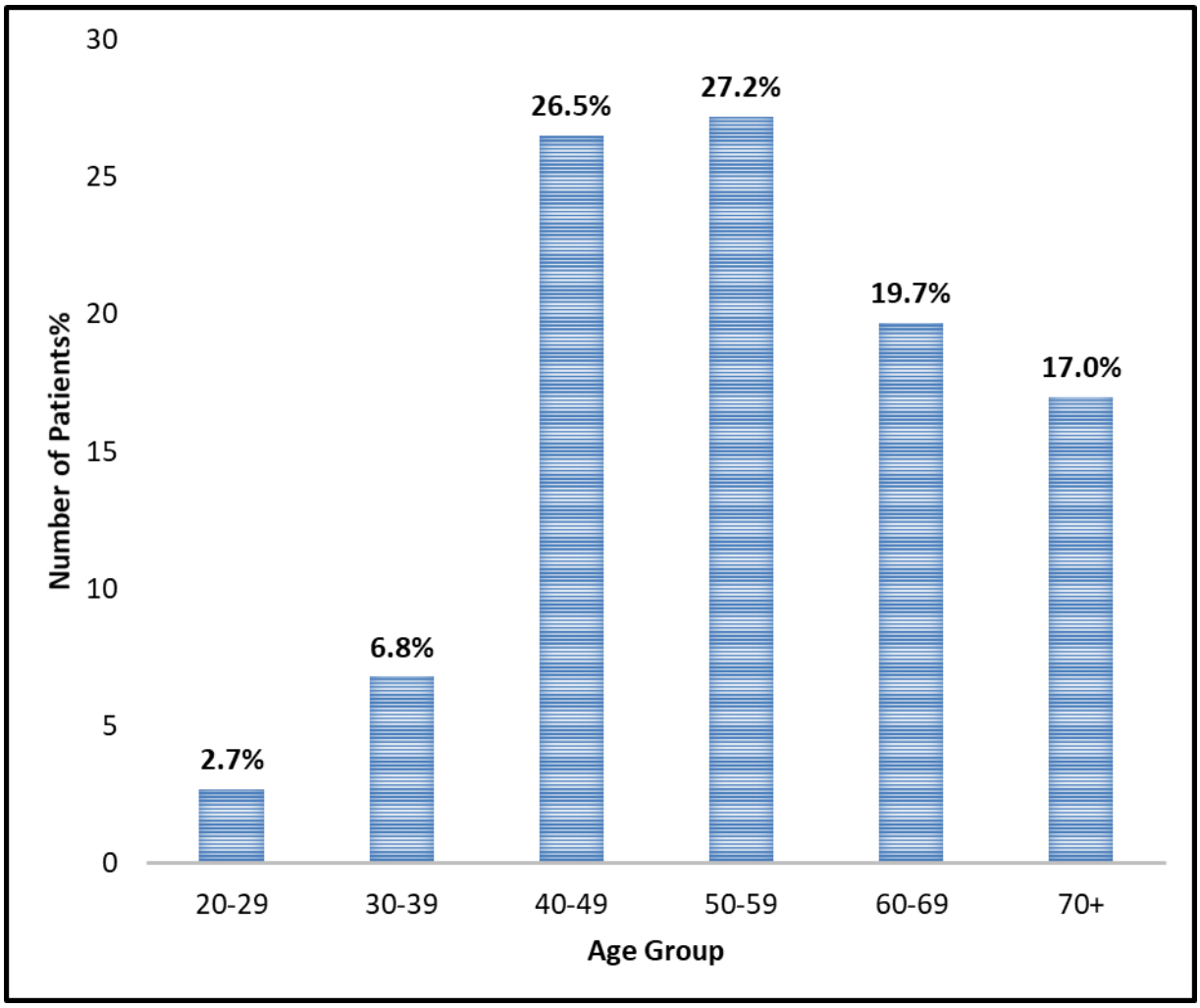
Figure 6. 1: *Flow Chart showing the data collection of patients attending medical clinic in Juba Teaching Hospital, South Sudan*



A total of 147 patients fulfilled the inclusion criteria.

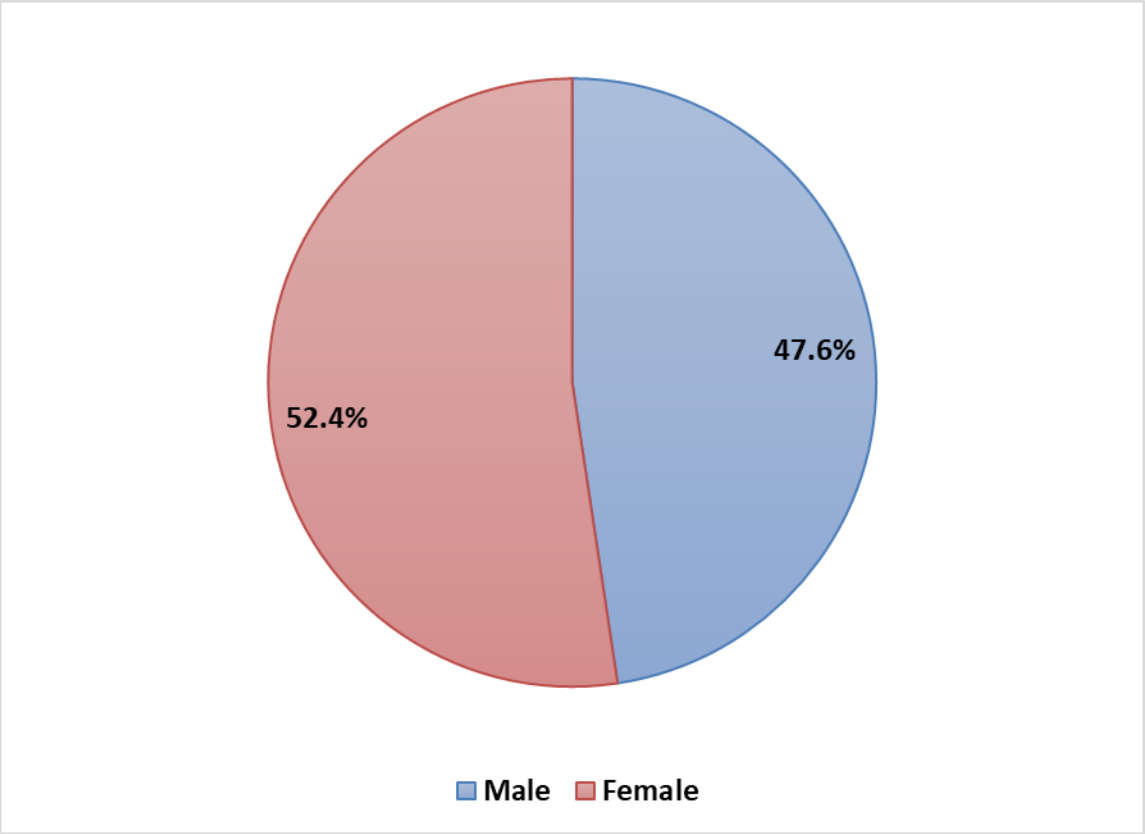
.

Figure 6. 2: *Distribution of diabetic patients by age (n=147 patients)*



The patient's age ranged from 21 years to 80 years with mean age 54.63 (median = 51.00) ± 13.362 years.

Figure 6. 3: *Distribution of diabetes patients by sex (n=147 patients)*



Male: Female = 1:1.1

Figure 6. 4: Distribution by *Type of diabetes mellitus in the study population (n=147 patients)*

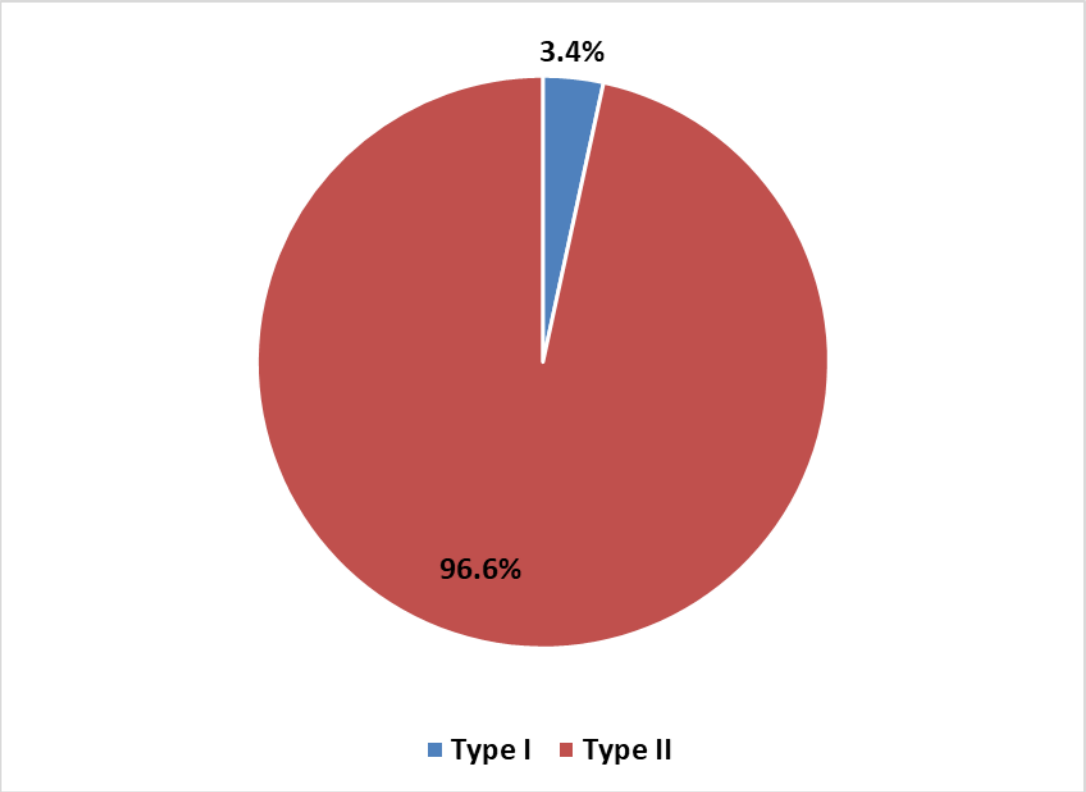


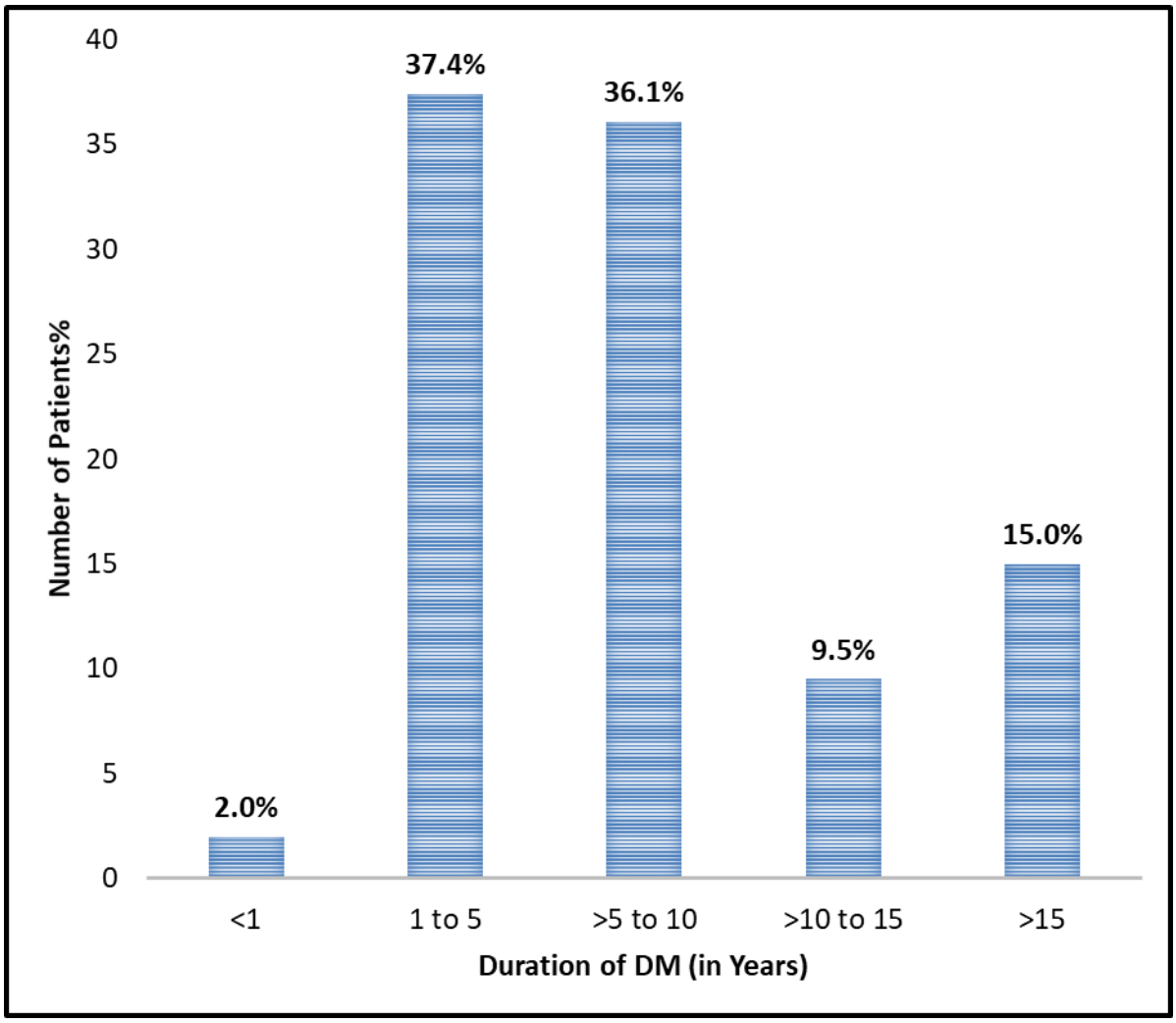
Table 6. 1: *Distribution by age and type of DM (n = 147 patients)*

Type of DM	**Age (in Years)**	
	<40	**40+**
Type I	3 (21.4)	2 (1.5)
Type II	11 (78.6)	131 (98.5)
Total	**14 (100.0)**	**134 (100.0)**

Table 6. 2: *Distribution by sex and type of DM (n = 147 patients)*

Type of DM	**Sex**	
	Male	**Female**
Type I	3 (4.3)	2 (2.6)
Type II	67 (95.7)	75 (97.4)
Total	**70 (100.0)**	**77 (100.0)**

Figure 6. 5: *Duration of diabetes (n=147 patients)*



Mean= 8.7±6.9 (range=0-30)

Table 6. 3: *Presenting visual acuity for the better eye (n = 147 eyes)*

Presenting vision	**Number**	**Percent**
Normal Vision (6/6-6/18)	27	18.4
Visual Impairment (<6/18-6/60)	103	70.1
Severe Visual Impairment (<6/60-3/60)	9	6.1
Blind (<3/60)	8	5.4
Total	**147**	**100.0**

Table 6. 4: *Prevalence of diabetic retinopathy (n = 147 patients)*

	Number of Patients	**Percent**
DR	28	19.0
No DR	119	81.0
Total	**147**	**100.0**

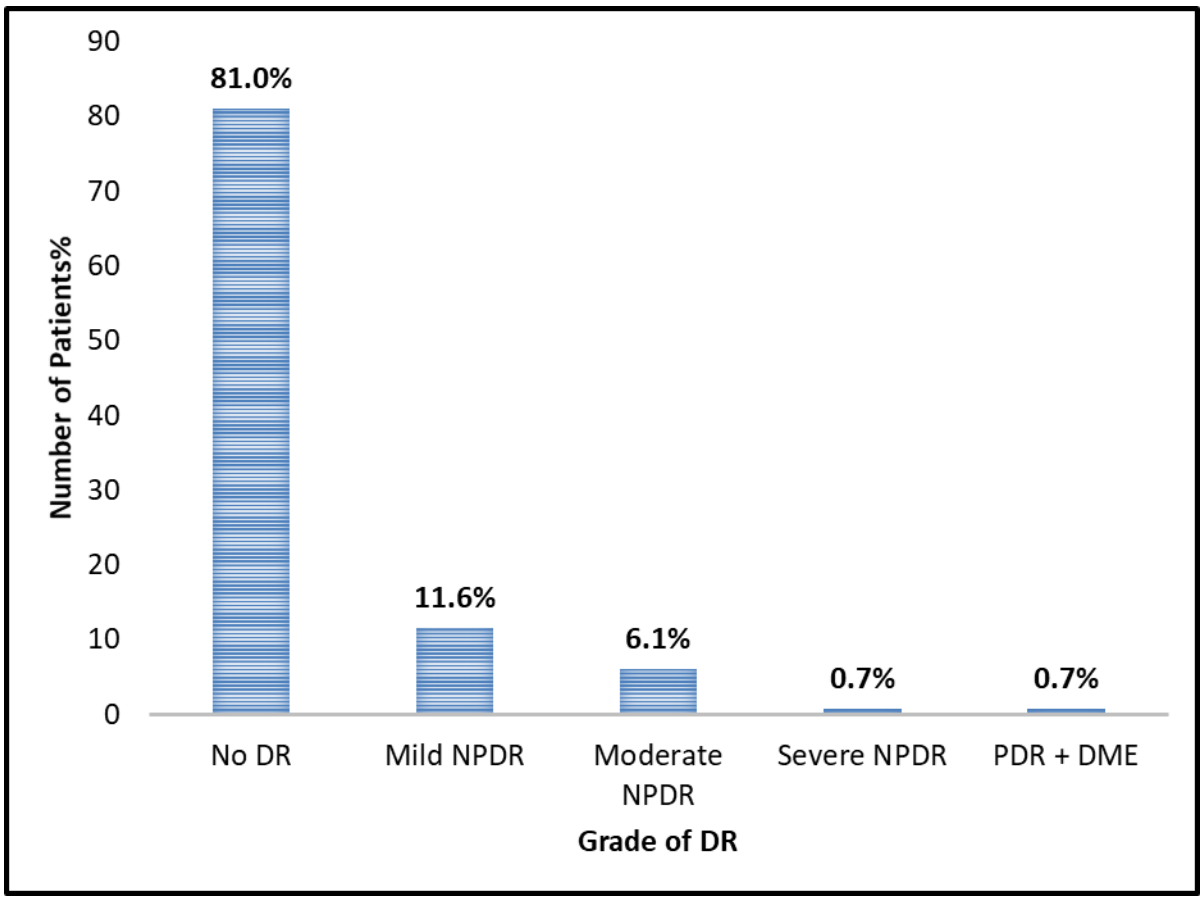


Figure 6. 6: *Grade of diabetic retinopathy on worse eye (n=147 patients)*

Table 6. 5: *Univariate analyses of association between diabetic retinopathy and selected risk factors*

Variables	Total	Diabetic Retinopathy		OR (95% CI)	*p* – value
		Yes (n=28)	No (n=119)		
Age (in years)					
20-29	4	0 (0.0)	4 (3.4)	NA	
30-39	10	1 (3.6)	9 (7.6)	0.453 (0.055-3.728)	0.461
40-49	39	1 (3.6)	38 (31.9)	0.079 (0.010-0.603)	0.014
50-59	40	4 (14.3)	36 (30.3)	0.384 (0.124-1.188)	0.097
60-69	29	5 (17.9)	24 (20.2)	1	
70+	25	17 (60.7)	8 (6.7)	21.443 (7.549-60.91)	0.000
Sex					
Male	70	9 (32.1)	61 (51.3)	1	
Female	77	19 (67.9)	58 (48.7)	0.450 (0.189-1.076)	0.068
Type of Diabetes					
Type 1 (IDDM)	5	1 (3.6)	4 (3.4)	1	
Type 2 (NIDDM)	142	27 (96.4)	115 (96.6)	1.065 (0.114-9.913)	0.956
Duration of DM					
<1	3	0 (0.0)	3 (2.5)	NA	
1-5	55	4 (14.3)	51 (42.9)	1	
6-10	53	6 (21.4)	47 (39.5)	0.418 (0.158-1.107)	0.079
11-15	14	5 (17.9)	9 (7.6)	2.657 (0.815-8.664)	0.105
>15	22	13 (46.4)	9 (7.6)	10.593 (3.871-28.99)	0.000
Systolic BP					
<120	21	1 (3.6)	20 (16.8)	0.183 (0.024-1.428)	0.105
120-139	67	7 (25.0)	60 (50.4)	1	
140-159	43	15 (53.6)	28 (23.5)	3.750 (1.595-8.818)	0.002
160+	16	5 (17.9)	11 (9.2)	2.134 (0.677-6.734)	0.196
Diastolic BP					
<80	52	6 (21.4)	46 (38.7)	1	
80-89	52	3 (10.7)	49 (41.2)	0.171 (0.049-0.600)	0.006
90-99	38	14 (50.0)	24 (20.2)	3.958 (1.666-9.407)	0.002
100+	5	5 (17.9)	0 (0.0)	NA	
Insulin Treatment					
Yes	27	5 (17.9)	22 (18.5)	1	
No	120	23 (82.1)	27 (81.5)	0.958 (0.328-2.800)	0.938
OHA Treatment					
Yes	142	27 (96.4)	115 (96.6)	1	
No	5	1 (3.6)	4 (3.4)	0.939 (0.101-8.743)	0.956
Diet Control					
Yes	29	4 (14.3)	25 (21.0)	1	

No	118	24 (85.7)	94 (79.0)	0.627 (0.199-1.973)	0.421
Presenting VA					
6/6-6/18	27	10 (35.7)	17 (14.3)	1	
<6/18-6/60	103	13 (46.4)	90 (75.6)	0.279 (0.119-0.655)	0.003
<6/60-3/60	9	4 (14.3)	5 (4.2)	3.800 (0.950-15.203)	0.059
<3/60	8	1 (3.5)	7 (5.9)	0.593 (0.070-5.022)	0.631
Awareness about Effect of Diabetes on Eyes					
Yes	67	8 (28.6)	59 (49.6)	1	
No	80	20 (71.4)	60 (50.4)	0.407 (0.166-0.996)	0.045
Medical History of Hypertension					
Yes	45	19 (67.9)	26 (21.8)	1	
No	102	9 (32.1)	93 (78.2)	7.551 (3.056-18.656)	0.000
History of Smoking					
Yes	27	8 (28.6)	19 (16.0)	1	
No	120	20 (71.4)	100 (84.0)	2.105 (0.810-5.473)	0.121
HbA1c					
< 6.5%	39	3 (13.6)	36 (36.0)	1	
≥ 6.5%	83	19 (86.4)	64 (64.0)	3.562 (0.986-12.868)	0.053
FBS					
< 7.0 mmol	54	1 (3.6)	53 (44.5)	1	
≥ 7.0 mmol	93	27 (96.4)	66 (55.5)	21.682 (2.852-164.8)	0.003

7.0 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

7.1 Discussion

DR is a public health challenge in South Sudan similar to other developing countries. This result was correlated with Abdel-Aal *et al.* (2008), they reported that mean age of diabetic patients was 54.3 ± 10.9 years with 54.4 ± 10.9 in male and 53.7 ± 10.6 in female. Concerning to place of residence, 137 (93.2%) of study participants were from Juba. Duration of DM was <5 years in 39.4%, 5- 10 years in 36.1%, and > 10 years in 24.5% patients. This implies that the longer the duration of diabetes the higher chances of developing DR.

Type II diabetes (96.6%) was more common than type I diabetes (3.4%), this is not surprising as type II diabetes is globally more prevalent. The rate of type II diabetes found in our study is higher than the findings from UAE, India and Oman where rates of 19%, 26% and 6.3% were reported, respectively (Jamal-un-Din et al., 2006; Nerendran et al., 2002; and Khandekar et al., 2009). However, our results are similar to regional studies that found that majority of the patients have Type-II diabetes mellitus (82%), type I (18%) (Kariuki, 1999);

Most of the patients examined had no retinopathy; diabetic retinopathy was present in 19.0% of the 147 patients considered for evaluation. Prevalence for this study is almost similar to that of Njambi *et al* (2012), who found a prevalence of 20.0% patients. However, other studies have given different figures for the prevalence of diabetic retinopathy. For example, several studies presented slightly higher prevalence of diabetic retinopathy compared to our current study (Lawan & Mohammed, 2013; Niazi *et al*., 2010; and Wambugu, 2011).The lower prevalence

could be due to the fact that fundus photography was not used in the study which might have picked more peripheral leisons that may be missed on ophthalmoscopic examination

The patient's age ranged from 21 years to 80 years with mean age 54.63 (median = 51.00) ± 13.36 years. Association of age with retinopathy has been clearly demonstrated (Billah *et al.*, 2016). The mean age of the study population was in the early fifties (54.6 years). Patients without retinopathy have a younger mean age (51.3 years) and not surprisingly, those with retinopathy have a higher mean age (68.9 years). Older patients particularly those with prolonged disease duration are more likely to develop retinopathy (p = 0.000). This same finding was reported in Garissa, Kenya by Abdirahman and Oman by Khandekar et al. Study by Wambugu (2011) however, shows that patient's age was not significantly different between the patients with DR and those without DR. Association of age with retinopathy could be explained by the prolonged exposure to hyperglycaemia coupled with other risk factors. As noted earlier, advanced age has an impact on developing of DR.

The most prevalent type of DR in our study was Mild non-proliferative diabetic retinopathy which accounted for 60.7% of the cases. Non proliferative diabetic retinopathy accounted for 96.4% of the cases compared with 92%, 89.3 to 94.1% and 69.8% in studies conducted in Australia, India and Oman, respectively (Klien *et a*l., 1984). We found a low frequency of proliferative diabetic retinopathy out of all retinopathies (3.6%). Study conducted in Kenya found the prevalence of PDR to be 14.3% (Kariuki et al.) higher than what was found in our study. Though accessing medical services may be a challenge in a war torn country, patients with vision threatening diabetic retinopathy need immediate laser photocoagulation treatment according to ETDRS recommendations.

There was a statistically significant difference in the presence of retinopathy between those with less years of disease duration and those with longer disease period (p=0.000). There was a strong relationship between duration of diabetes mellitus and retinopathy. DR appeared more in patients whose duration was 15 years and above. Study by Lawan & Mohammed (2013)[65] shows similar results, they found out that patients with disease duration of 15 years are likely to have DR compared with those with disease duration of 14 years or less. Our study showed a clear and parallel relationship between disease duration and development of retinopathy. Window of opportunity to avoid progression by screening. Other studies that also found out a significant association between duration of diabetes and DR were: Abdirahman, 2012 (p = 0.001); Njikam, 2011 (p = 0.001); and Niazi *et al.,* 2010, (p = 0.001). Early detection of diabetes through screening and regular follow-up and primary prevention of DM is therefore recommended to reduce the risk of severe blinding complications of DR.

Our study established that a rise in HbA1c is associated with a higher risk of DR (0.053). Other studies that shared similar results were Kariuki *et al.,* and UKPDS.The findings in this study could be as a result of poor initial as well as long-term glycaemic control in the patients. HbA1c shows the glycaemic control over the past three months and is thus a more reliable test than RBS, which is variable. A single HbA1c reading in patients who have been diabetic for many years should however be interpreted with caution. Abrupt improvement in blood sugar control is known to worsen pre-existing DR. This occurs after aggressive lowering of blood sugar on detection of complications, mostly by introducing insulin or increasing its dosage. In such cases, serial HbA1c measurements would be more beneficial as they would show previous derangements in HbA1c, which predisposed the patient to DR in the first instance.

7.2 Conclusion

1. Type II diabetes was more common than type I diabetes.
2. Most of the patients examined had no retinopathy; diabetic retinopathy was present in 19.0% of the 147 patients evaluated.
3. Patients with retinopathy had a higher mean age.
4. The most prevalent type of DR was Mild non-proliferative diabetic retinopathy which accounted for 60.7% of the cases.
5. There was a statistically significant presence of retinopathy in those with longer duration of diabetes
6. It was established that high HbA1c is associated with a higher risk of DR

7.3 Recommendations

1. Due to the threat of permanent loss of sight due to DR early and continuous screening is advocated.
2. Equip eye centers with infrastructure and equipment to diagnose and treat effectively diabetic retinopathy
3. Organize awareness campaigns among health workers and general public to improve referrals, increase regular follow-up and primary prevention for patients with DR.
4. Start laboratory diagnostic services within the hospital.
5. Start a comprehensive diabetic center at JTH with counseling.
6. Increase the number of physicians and ophthalmologists.

7.4 Study Limitations

1. There was low sample population and so the results may not be a true representation of the whole population.
2. The classification of DM into type 1 and type 2 was clinical. It is likely that some patients in either group could have been classified wrongly.
3. Other forms of screening that have been shown to be more accurate like OCT, fundus photography, and FFA were not used due to technical limitations.
4. Study did not address DME yet it involves the same group of people since it was not part of the study objectives

8.0 REFERENCES

1. WHO/IDF, "Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia," World Health Organization, Geneva, 2006.

2. Ding J. and Wong T. , "Current epidemiology of diabetic retinopathy and diabetic macular edema," *Curr Diab Rep.*, vol. 12, p. 346–54, 2012.

3. King H. , Aubert R. and Herman W. , "Global burden of diabetes, 1995–2025 prevalence, numerical estimates and projection," *Diabetes Care*, vol. 21, p. 1414–31, 1998.

4. Ahmed A. , "Diabetes mellitus in Sudan: size of the problem and possibilities of efficient care," *Pract Diabetes Int.*, vol. 18, pp. 324-7, 2001.

5. Ahmed A., Ahmed N. and Abdalla M., Pattern of hospital mortality among diabetic patients in Sudan, *Pract Diabetes Int.*, vol. 17, pp. 41-3, 2000.

6. Rosenbloom A., Joe J. , Young R. et al, "Emerging epidemic of type 2 diabetes in youth," *Diabetes Care*, vol. 22, no. 2, pp. 345-354, 1999.

7. Sicree R., Shaw J. and Zimmet, The Global Burden: Diabetes and Impaired Glucose Tolerance. Diabetes Atlas, IDF. 4th edition., Brussels: International Diabetes Federation, 2009.

8. Levitt N. , "Diabetes in Africa: epidemiology, management and healthcare challenges," *Heart*, vol. 94, no. 11, pp. 1376-82, 2008.

9. Diabetes research & Wellness Foundation, "What is Diabetes," Diabetes research & Wellness Foundation (DRWF), Washington, D.C, 2013.

10. American Diabetes Association, "Economic consequences of diabetes mellitus in the U.S. in 1997," *Diabetes Care*, vol. 21, no. 2, pp. 296-309, 1998.

11. American Diabetes Association, "Diabetic retinopathy," *Diabetes Care*, vol. 25, p. 590–593, 2002.

12. National Eye Institute, "Facts About Diabetic Retinopathy," 1 October 2009. [Online]. Available: http://www.nei.nih.gov/health/diabetic/retinopathy.asp. [Accessed 10 December 2012].

13. CDC, "Diabetic retinopathy. Vision Health Initiative (VHI)," CDC, 22 October

2010. [Online]. Available: http://www.cdc.gov/visionhealth/basic_information/eye_disorders.htm#5. [Accessed 22 October 2010].

14. Fenwick E. , Pesudovs K. and Ree G.s , "The impact of diabetic retinopathy: understanding the patient's perspective," *Brit J Ophthalmol,* vol. 95, pp. 774-82, 2011.

15. American Academy of Ophthalmology, "Retina/Vitreous Panel, Preferred Practice Pattern Guidelines. Diabetic Retinopathy," American Academy of Ophthalmology, San Francisco, CA, 2014.

16. Fong D., Aiello L. and Gardner T., "Retinopathy in diabetes," *Diabetes Care,* vol. 27, no. 1, pp. 84-7, 2004.

17. Kaiser P., Riemann C.,Sears J. et al, "Macular traction detachment and diabetic macular edema associated with posterior hyaloidal traction," *Am J. Ophthalmol,* vol. 131, pp. 44-9, 2001.

18. Davis M., Bressele S. and Aiello L., "Comparison of time-domain OCT and fundus photographic assessments of retinal thickening in eyes with diabetic macular edema," *Invest Ophthalmol Vis Sci,* vol. 49, pp. 1745-52, 208.

19. Sunness J., "The pregnant woman's eye," *Surv Ophthalmol,* vol. 32, pp. 219-38, 1988.

20. Pardianto G., "Understanding diabetic retinopathy," *Mimbar Ilmiah Oftalmologi Indonesia,* vol. 2, p. 65–6, 2005.

21. Bamashmus M., Gunaid A. and Khandekar R., "Diabetic retinopathy, visual impairment and ocular status among patients with diabetes mellitus in Yemen: a hospital-based study," *Indian J Ophthalmol,* vol. 57, pp. 293-8, 2009.

22. Memon W. U., Jadoon Z., Qidwai U., et al., "Prevalence of Diabetic Retinopathy in Patients of Age Group 30 Years and Above Attending Multicentre Diabetic Clinics in Karachi," *Pak J Ophthalmol,* vol. 28, no. 2, pp. 99-104, 2012.

23. Khandekar R., Al Hassan A., Al Dhibi H., et al., "Magnitude and determinants of diabetic retinopathy among persons with diabetes registered at employee health department of a tertiary Eye Hospital of central Saudi Arabia," *Oman Journal of Ophthalmology,* vol. 8, no. 3, pp. 162-165, 2015.

24. Klein R., Klein B. and Moss S., "Epidemiology of proliferative diabetic retinopathy," *Diabetes Care,* vol. 15, no. 12, pp. 1875-91, 1992.

25. Wong T., Cheung N.,Tay W., et al., "Prevalence and risk factors for diabetic retinopathy: the Singapore Malay Eye Study," *Ophthalmology,* vol. 115, no. 11, pp. 1869-75, 2008.

26. Wong T., Klein R., Islam F., et al., "Diabetic retinopathy in a multi-ethnic cohort in the United States," *Am J Ophthalmol,* vol. 141, no. 3, pp. 446-55, 2006.

27. Shrestha R., "Ocular manifestations in diabetes, a hospital based prospective study," *Nepal Med Coll J,* vol. 13, no. 4, pp. 254-256, 2011.

28. UK Prospective Diabetes Study Group, "Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes," *Bmj,* vol. 317, no. 7160, pp. 703-13, 1998.

29. Palmberg P.,Smith M.,Waltman S., et al., "The natural history of retinopathy in insulin-dependent juvenile-onset diabetes," *Ophthalmology,* vol. 88, no. 7, pp. 613-8, 1981.

30. Njikam J. E., "The Magnitude and Pattern of Diabetic Retinopathy at Central of Yaoundé, Cameroon," Faculty of Medicine, Department of Ophthalmology, University of Nairobi, Nairobi, 2011.

31. Akpalu J. A., "Magnitude, Pattern and Level of Awareness of Diabetic Retinopathy at Korle-Bu Teaching Hospital Accra-Ghana," Faculty of Medicine, Department of Ophthalmology, University of Nairobi, Nairobi, 2011.

32. Abdirahman A. A. H., "The Prevalence and Pattern of Diabetic Retinopathy among Somali Patients Attending the Medical Diabetes Clinic at Garissa Provincial General Hospital," Faculty of Medicine, Department of Ophthalmology, University of Nairobi, Nairobi, 2012.

33. Lawan A. and Mohammed T. B., "Pattern of diabetic retinopathy and other blinding eye diseases in a low income African country," *Diabetes,* vol. 4, no. 6, p. 62, 2013.

34. Wambugu N. M., "The Prevalence, Pattern and Associations of Diabetic Retinopathy in Black African Diabetic Patients Attending Medical Diabetes Clinic at Kenyatta National Hospital: A Review," University of Nairobi, Nairobi, 2011.

35. Kariuki M. M., "The Prevalence, Pattern and Associatin of Diabetic Retinopathy

among Black African Diabetics Attending the Medical Diabetes Clinic at the Kenyatta National Hospital," University of Nairobi, Faculty of Medicine, Nairobi, 1999.

36. Wondimagegn G. S., "The Magnitude and Pattern of Diabetic Retinopathy in Jimma University Hospital, Jimma, Ethiopia," Faculty of Medicine, Department of Ophthalmology, University of Nairobi, Nairobi, 2009.

37. Njambi L., "Prevalence of Diabetic Retinopathy and Barriers to Uptake of Diabetic Retinopathy Screening At Embu Provincial General Hospital, Central Kenya," *JOECSA*, vol. 16, no. 1, 2012.

38. Mutangana F. K., "The magnitude and pattern of Diabetic Retinopathy as seen at three Hospitals in Kigali, Rwanda," Faculty of Medicine, Department of Ophthalmology, University of Nairobi, Nairobi, 2008.

39. Siham A. B., Ahmed H. A. and Awadelkareem M. A., "Prevalence of diabetes, knowledge and attitude of rural population towards diabetes and hypoglycaemic event, Sudan 2013," *American Journal of Health Research,* vol. 2, no. 6, pp. 356-360, 2014.

40. Central Bureau of Statistics, "The Fifth Population Census of Sudan," Sudan Central Bureau of Statistics, 2008.

41. Wanga S. and Lemeshow S., Sample size determination in health studies. A practical manual, Ginebra: World Health Organization, 1991.

9.0 APPENDICES

9.1 Questionnaire

Date: ---------- code----------

Age ---------- sex: male ------- female----------

Residence ----------

Type of Diabetes Mellitus: Duration ----------

A) Type I ☐

B) Type II ☐

BP ----------mmHg weight----------kg, height----------cm

Mode of treatment:

a) Insulin ☐ duration-------

b) OHA ☐ duration ---------

c) Diet control ☐

BCVA:

a) LE ☐

b) RE ☐

Any Awareness about effect of diabetes on the eyes:

a) Yes ☐

b) No ☐

Any visual complain

A) Yes ☐

B) No ☐

If yes

a) Reading difficulties ☐

b) Far vision problem ☐

Any spectacle correction

a) Near correction ☐

b) Far correction ☐

Any previous ocular examination

A) Yes ☐

B) No ☐

C) If yes by who

1) Ophthalmologist ☐
2) Optometrist ☐
3) Ophthalmic nurse ☐

Past medical history

A) Hypertension ☐

B) Renal disease ☐

Social habit

a) Smoking ☐

Ocular examination:

Fundoscopy:

NON PROLIFERATIVE	RE	LE
NO DR		
MILD NPDR		
MODERATE NPDR		
SEVERE NPDR		
VERY SEVERE NPDR		
PDR		
MACULA OEDEMA		

9.2 Time Frame

ACTIVITY	TIME (YEAR & MONTH)																
	2015 – 2017																
	S	0	N	D	J	F	M	A	M	J	J	A	S	0	N	D	J
Concept and Preparation of Proposal																	
Presentation to Department																	
Ethical Approval																	
Budget Approval																	
Preparation of Study Materials																	
Data Collection																	
Data Analysis and Results Presentation																	
Preparation and Submission of Thesis																	

9.3 Budget: For Cross Sectional Study for Duration of One Month

Items	Quantity	Unit cost in ksh	Total
Book printing	1	5*47(pages)	470
Book photocopying	2	2*47	376
Binding of book	6	150	900
Ethic fee KNH/UON	1	2000	2000
Ethic fee/MOH/Juba	1	3000	3000
Sub total	----------	----------	6746

Data collection

Items	**Quantity**	**Unit cost in ksh**	**Total**
Questionnaire(printing)	2	5 *2	10
Questionnaire photocopying	140*2 copies	2 *280	560
Flash disc	1 (8G)	1500*1	1,500
Pencils	5	50	250
Eraser	5	50	250
Amithocaine eye drops	30 battles	200	6,000
Topicamide 1% eye drops	30 battles	200	6,000
Clean tissues/ gauze	30 bands	200	6,000
Aseptic solution(spirit)	5 liters	1000	5,000
HbA1c	140 patients	1000	140,000
Fasting blood sugar	140 patients	150	21,000
Final book / printing/photocopying/binding	3 copies	500	1,500
Sub total			188,070

Supportive staff:

Item	Quantity	Unit cost	Total
Trial nurse	1* 26 days	1000*26	26,000
Nurse for BCVA + dilating drops application	1* 26 days	1000*26	26,000
Statistician	1	50000	50,000
Tickets	2ways	60000	60,000
Subtotal	----------	----------	162,000Ksh
Grand total		162000+188070+6746	356,816 ksh

Funding source of the research budget:

The budget for the research will be covered by Sight savers organization, which is sponsoring the scholarship through COECSA as per term of MOU between Government of South Sudan and Sight savers organization.

9.4 Diagnostic Criteria/ETDRS Classification

Diabetic Retinopathy (ETDRS Classification)	Finding observable on dilated ophthalmoscopy
No apparent retinopathy	No abnormalities
Mild NPDR	Microanuerysms only
Moderate NPDR	More than just microanuerysms but less than severe NPDR
Severe NPDR	Any of the following: Internal hemorrhages (20 or more in each of the quadrants) Definite venous beading (in 2 quadrants) Intraretinal microvascular abnormalities (in 1 quadrant) And no sign of PDR
PDR	One or more of the following: Neovascularization Vitreous /preretinal hemorrhage

9.5 Consent Information and Consent Form

Introduction

My name is Dr. Nyibong Albino William. I am a post graduate student in the department of ophthalmology at the University of Nairobi.

I am conducting a study on: Prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic at Juba Teaching Hospital, South Sudan.

Purpose of the Study

To determine the prevalence of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan; to determine the pattern of diabetic retinopathy by standardized grading using the ETDRS guidelines; and to determine the association between diabetic retinopathy and the following selected risk factors: age of patients, duration of diabetes, glycaemic control, and blood pressure.

Basis of Participation

Your participation will be purely voluntary. You are free to withdraw at any time during the course of the study period. Your refusal to participate or withdrawal at any time during the study period will not in any way affect the quality of your treatment.

Confidentiality

All information obtained in the study will be treated with utmost confidentiality.

I shall NOT use your name in any of my reports.

Benefits

The results of this study may be published in a medical book or journal or for teaching purposes and will be given to the community for better understanding of this topic. The investigations cost will be paid by researcher, participant will be told about examination finding of his eyes; if there

is a need for urgent intervention which is not available in the hospital, participant will be referred for further management to a neighboring country of his/her choice.

Risk and Discomfort

The examination process with indirect ophthalmoscope with low illumination will cause no damage to the retina.

Topical local anesthesia will be applied to minimise discomfort.

Request for Information

You may ask more questions about the study at any time or at this moment. You will be informed of any significant findings.

You may contact Dr. Nyibong Albino William on +254716218191/+211956327294 or Dr. Joseph Nyamori on +254721961411 (UON Department of Ophthalmology) or Dr. Mukiri Mukuria on +254722294426 (UON Department of Ophthalmology) or KNH/UON Ethical Review Committee Secretariat P.O. Box 20723 – 00202, Nairobi, Telephone Number: +254 2726300 Ext. 44102 and email address uonknh_erc@uonbi.ac.ke

Consent

Having read this consent form, all my questions have been answered; my signature below indicates my willingness to participate in this study and my authorization to use and share with others.

I…….. (patient/guardian) of…….. After reading and having the study purpose explained to me by Dr. Nyibong Albino William, do hereby give informed consent to participate in the study: **Prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan.**

Signed ……. Date ……

Thumb Print …… Date ……

I confirm that I have explained to the patient the above statement.

Signature of questionnaire Investigator (Dr. Nyibong Albino William) ……

Dr. Nyibong Albino William

Phone No.: +254 716218191/ +254 789111839 or +211956327294(South Sudan line)

9.6 Assent Form

Introduction:

My name is Dr. Nyibong Albino William. I am a post graduate student in the department of ophthalmology at the University of Nairobi.

I am conducting a study on: Prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan.

Purpose of the Study

To determine the prevalence of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan; to determine the pattern of diabetic retinopathy by standardized grading using the ETDRS guidelines; and to determine the association between diabetic retinopathy and the following selected risk factors: age of the patients ,duration of diabetes, glycaemic control, and blood pressure.

Basis of Participation

Your child participation will be purely voluntary. You are free to withdraw him/her at any time during the course of the study period. Your refusal to him/her to participate or withdrawal at any time during the study period will not in any way affect the quality of his/her treatment.

Confidentiality

All information obtained in the study will be treated with utmost confidentiality.

I shall NOT use your name in any of my reports.

Benefits

The results of this study may be published in a medical book or journal or for teaching purposes and will be given to the community for better understanding of this topic. The investigations cost will be paid by researcher, participant will be told about examination finding of his eyes; if there is a need for urgent intervention which is not available in the hospital, participant will be referred for further management to a neighboring country of his/her choice.

Risk and Discomfort

The examination process with indirect ophthalmoscope with low illumination will cause no damage to the retina.

Topical local anesthesia will be applied to minimize discomfort.

Request for Information

You may ask more questions about the study at any time or at this moment. You will be informed of any significant findings in the eyes of your child.

You may contact Dr. Nyibong Albino William on +254716218191/+211956327294 or Dr. Joseph Nyamori on +254721961411 (UON Department of Ophthalmology) or Dr. Mukiri Mukuria on +254722294426 (UON Department of Ophthalmology) or KNH/UON Ethical Review Committee Secretariat P.O. Box 20723 – 00202, Nairobi, Telephone Number: +254 2726300 Ext. 44102 and email address uonknh_erc@uonbi.ac.ke

Assent:

Having read this consent form, all my questions have been answered; my signature below indicates my willingness to allow my son/daughter to participate in this study.

I…….. (guardian) of…….. After reading and having the study purpose explained to me by Dr. Nyibong Albino William, do hereby give informed consent to participate in the study: **Prevalence and pattern of diabetic retinopathy among diabetic patients attending medical clinic in Juba Teaching Hospital, South Sudan.**

Signed ……. Date ……

Thumb Print …… Date ……

I confirm that I have explained to the patient the above statement.

Signature of questionnaire Investigator (Dr. Nyibong Albino William) ……

Dr. Nyibong Albino William

Phone No.: +254 716218191/ +254 789111839 or +211956327294(S.Sudan line)

9.7 Ethical Approval KNH – UoN ERC

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/417

21st October 2016

Dr. Nyibong Albino William
Reg. No.H58/69389/2013
Dept. of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Nyibong

REVISED RESEARCH PROPOSAL: PREVALENCE AND PATTERN OF DIABETIC RETINOPATHY AMONG DIABETIC PATIENTS ATTENDING MEDICAL CLINIC IN JUBA TEACHING HOSPITAL, SOUTH SUDAN (P397/05/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 21st October 2016 – 20th October 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

9.8 Ethical Approval Ministry of Health Juba

The Republic of South Sudan

Ministry of Health

23/01/2017

To: Nyibong Ajang William
University of Nairobi

RESEARCH APPROVAL LETTER

Dear Ajang,

SUBJECT: Prevalence of Diabetic Retinopathy among Diabetic Patients Attending medical Clinic

I am writing in response to the request for authorization for the study on "**Prevalence of Diabetic Retinopathy among Diabetic Patients Attending medical Clinic in Juba Teaching Hospital"**.
After close review on further clarifications and amendments to the proposal made, I am glad to inform you that the ethical committee at the Ministry of Health for the Republic of Southern Sudan have approved the study. The Ministry acknowledges the importance of the study for early intervention of the diseases to prevent further complications that might be caused by the disease.

Please, keep the Ministry of Health informed in case of any changes regarding the implementation and its progress. I look forward to the report, especially the recommendations that will be generated. Note that any information generated should not be published without the consent of the Ministry.

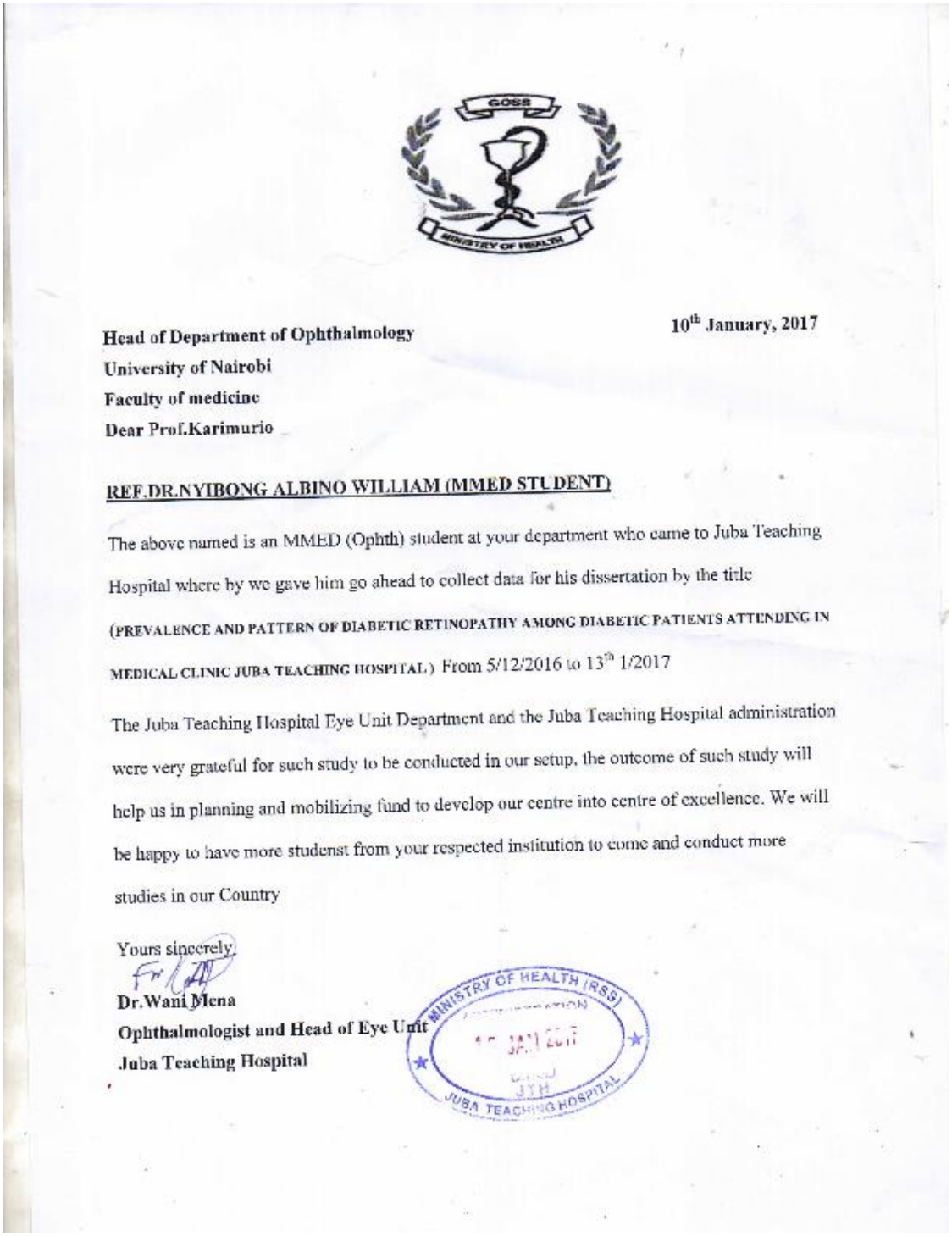
Good luck and don't hesitate to get in touch should there be any queries.

MINISTRY OF HEALTH 23 JAN 2017

Dr. Richard Laku Lino
Director General Policy, Planning, Budgeting and Research
CC: Under Secretary, MOH-RSS
CC: Director Generals Juba Teaching Hospital-Jubek State
CC: Director General of Primary Health Care-RSS

Headquarters, Ministerial Complex. Juba, South Sudan - P.O.Box 88, Juba.
Tel: +211 (0) 177 800 281 / +211 (0) 177 800 278

9.9 Data Collection Approval Letter



Head of Department of Ophthalmology
University of Nairobi
Faculty of medicine
Dear Prof.Karimurio

10th January, 2017

REF.DR.NYIBONG ALBINO WILLIAM (MMED STUDENT)

The above named is an MMED (Ophth) student at your department who came to Juba Teaching Hospital where by we gave him go ahead to collect data for his dissertation by the title (PREVALENCE AND PATTERN OF DIABETIC RETINOPATHY AMONG DIABETIC PATIENTS ATTENDING IN MEDICAL CLINIC JUBA TEACHING HOSPITAL) From 5/12/2016 to 13th 1/2017

The Juba Teaching Hospital Eye Unit Department and the Juba Teaching Hospital administration were very grateful for such study to be conducted in our setup, the outcome of such study will help us in planning and mobilizing fund to develop our centre into centre of excellence. We will be happy to have more studenst from your respected institution to come and conduct more studies in our Country

Yours sincerely

Dr.Wani Mena
Ophthalmologist and Head of Eye Unit
Juba Teaching Hospital

MINISTRY OF HEALTH (RSS)
JUBA TEACHING HOSPITAL