

Journal of Ophthalmology of Eastern Central and Southern Africa

(Formerly East African Journal of Ophthalmology)

www.coecsa.org

ISSN 2308-6327

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Special edition on diabetic retinopathy

Welcome readers to this special edition of JOECSA on the management of diabetic retinopathy. With the increase of the prevalence of non-communicable diseases in the region, more and more people are currently being diagnosed with diabetes mellitus. These people carry a lifetime risk of developing Diabetic Retinopathy (DR). When not diagnosed early and properly managed, these people end up developing preventable severe visual impairment or blindness. The use of anti-Vascular Endothelial Growth Factors (anti-VEGF) in the management of DR has totally changed its management in the recent past. New guidelines continue to be developed in line with the new discoveries. Regionally, it is important to look into these new guidelines and adopt them in ways practical to the region. In Kenya for example, a Diabetic Retinopathy Technical Working Group has come up some guidelines

for screening, diagnosis and management of diabetic retinopathy in Kenya. These guidelines have been published in this special edition to guide eye care workers in Kenya and the whole Eastern, Central and Southern Africa (ECSA) region on how the recent advances in the management of DR can be adopted in the region. More research needs to be done regionally to establish what works and what does not work in our situation. This edition also features two more original papers on the some of the ways researchers in the region are trying to improve the screening and management of diabetic retinopathy. With this we envision a renewed interest in research of innovative ways of tackling DR in the region.

Dr. E. M. Nyenze
Editor –in- Chief

Clinical guidelines for diabetic retinopathy in Kenya: an executive summary of the recommendations

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ABSTRACT

All persons living with Diabetes Mellitus (DM) have a lifetime risk of developing Diabetic Retinopathy (DR), a potentially blinding microvascular complication of DM. The risk increases with the duration of diabetes. The onset and progression of DR can be delayed through optimization of control of blood glucose, blood pressure and lipids. The risk of blindness from DR can be reduced through cost-effective interventions such as screening for DR and treatment of sight-threatening DR with laser photocoagulation and anti-VEGF medications.

Several factors make it important to provide guidance to clinicians who provide services for diabetes and diabetic retinopathy in Kenya. First, the magnitude of both DM and DR is expected to increase over the next decade. Secondly, as the retina is easily accessible for examination, the early signs of retinopathy may provide clinicians with the first evidence of microvascular damage from diabetes. This information can be used to guide subsequent management of both DM and DR. Thirdly, there are notable gaps in service delivery for the detection, treatment and follow-up of patients with DR, and the services are inequitable. Strengthening of service delivery will require close collaboration between diabetes services and eye care services.

Following a systematic and collaborative process of guideline development, the first published national guidelines for the management of diabetic retinopathy have been developed. The purpose of this paper is to highlight the recommendations in the guidelines, and to facilitate their adoption and implementation.

Key words: Clinical practice guidelines, Diabetic retinopathy, Kenya

INTRODUCTION

Diabetes Mellitus (DM) is a priority non-communicable disease that requires multidisciplinary care and continuity of care. Its prevalence and incidence is increasing in every country. According to the STEPwise survey¹ for risk factors of non-communicable diseases in 2015, DM affects an estimated 2% of the Kenyan population aged 18-69 years with the highest proportion (5%) being in the 45-59 years age group. Every patient with diabetes is at risk of potentially blinding ocular complications, particularly Diabetic Retinopathy (DR). In turn, visual loss from diabetic retinopathy is associated with additional morbidity, such as falls, fractures and difficulties with seeing and taking medications. Both DM and DR are silent diseases that patients may be unaware of until they

cause complications. Clinicians attending to patients with these conditions have a role to reduce the associated morbidity, disability and mortality.

Diabetic Retinopathy (DR) is the leading cause of blindness in diabetes, and for this reason it warrants specific attention. It is estimated that a third of the people with diabetes have diabetic retinopathy, and one third of the latter (or 10% of those with diabetes) have vision threatening DR². Early signs of retinopathy or maculopathy in a patient with diabetes, identified on retinal examination, may be the first evidence of generalised microvascular damage from poor control of diabetes. This information would be very useful in planning subsequent holistic management of the patient. There is therefore need to strengthen links between eye care services and diabetes services.

The risk factors for DR include both modifiable and non-modifiable factors. Epidemiologic studies have identified the non-modifiable risk factors to include increasing duration of diabetes and genetic factors^{2,3}. The leading modifiable risk factors include poor control of blood sugar, poor control of blood pressure and dyslipidaemia^{2,4-6}. Service providers need to pay attention to these factors, as well as to other lifestyle factors associated with diabetes in order to delay onset or progression of DR. These are interventions for primary prevention of blindness from DR.

Stronger service delivery for DR is required within the existing health system⁷⁻⁹. Currently there are notable gaps in the screening, diagnosis, referral, treatment and follow-up. Although screening for DR and laser treatment are cost-effective interventions for prevention of blindness from DR¹⁰, there are inequities in access to them. Some of the services are underutilised and of insufficient quality. DR guidelines and use of clinical guidelines is an important step towards ensuring that all people with diabetes have access to quality DR services.

The purpose of these clinical practice guidelines is to give guidance regarding screening and diagnosis of DR, management of diabetes as it pertains specifically to DR, and treatment of DR. These guidelines apply to all patients with type 1 or type 2 diabetes who are at least 12 years old, who receive care at the primary, secondary or tertiary level of the health system. They should be used by health workers providing diabetes services and eye care services, as well as by administrators and policy-makers who plan for the resources for these services.

METHODOLOGY FOR GUIDELINES DEVELOPMENT

The development of these guidelines was a systematic, widely consultative process guided by an expert technical group over a lengthy period and involving many stakeholders. The process was guided by the use of several toolkits and guidelines which include: ADAPTE toolkit¹¹, PGEAC framework¹², AGREE 11 instrument¹³ and WHO handbook for guidelines development¹⁴.

The guidelines were adapted from existing relevant standards and guidelines, particularly the American Diabetes Association standards for medical care in diabetes¹⁵ International Council of Ophthalmology guidelines for diabetic eye care¹⁶ Canadian Diabetes Association's retinopathy guidelines¹⁷ and the Royal College of Ophthalmologists' diabetic retinopathy guidelines¹⁸. The following guidelines were also reviewed, and the recommendations are in line with their provisions: Kenya national guidelines for management of diabetes¹⁹, Kenya national strategy for the prevention and control of non-communicable diseases²⁰, and International Diabetes Federation's diabetes eye health guide for health professionals²¹. The adaptation strategy

was chosen instead of de novo development in order to avoid duplication of effort, to use the available resources cost-effectively and to facilitate customization of the guidelines to reflect local context. These guidelines were identified through a literature search followed by application of the AGREE 11 instrument to evaluate the quality of the guidelines. Previous drafts of local DR guidelines were also reviewed. Care was taken to ensure that the guidelines are evidence-based, locally applicable, of high quality, and that the process of adaptation was consultative. The guidelines were subjected to external review by a multidisciplinary team as well as pilot-testing in various health facilities.

The process of guideline development is discussed in detail in a separate paper.

Key messages

1. Stronger service delivery is needed for People Living with Diabetes (PLWD) in Kenya in relation to DR. There is need to develop strong links between diabetes services and eye care services within the existing health system.
2. Blindness from DR is avoidable, but only if diabetes care givers and eye health professionals perform their roles in ensuring early detection and treatment of DR.
3. Screening is important for early detection of treatable diabetic retinopathy. It is also a cost-effective intervention for reducing blindness from DR. All patients with diabetes aged 12 years and above should have a retinal examination (usually a dilated eye examination or a retinal photograph) once a year or more frequently if recommended by the eye specialist.
4. Consistent and appropriate metabolic control reduces the onset and progression of sight-threatening diabetic retinopathy.
5. Laser photocoagulation therapy, local intraocular pharmacological therapy and surgery reduce the risk of significant visual loss.

Recommendations

Domain: Strengthening links between diabetes services and eye care services at primary, secondary and tertiary level of care

1. All health workers providing diabetes services should raise awareness of PLWD on diabetic retinopathy and support them to access eye examination (Panel 1).
2. The health worker attending to a PLWD at any health care level should use a checklist (Panel 2) to identify whether the patient has had a retinal examination in the preceding 12 months. Any patient who has not should be referred to the nearest facility for screening for DR.

- Panel 1: Key messages for health workers attending to PLWD*

1	Send all newly diagnosed patients with diabetes for a baseline retinal examination.
2	Ensure all patients with diabetes have an annual retinal examination.
3	Refer any patient with diabetes who has poor vision to an eye specialist urgently.

4	Do not wait for visual loss to refer patients with diabetes to an eye specialist- ‘prevention is better than cure.’
5	Glycated hemoglobin (HbA1c) is a good indicator for long-term sugar control and should be done at least annually for all patients. Good glycemic control prevents or delays diabetic retinopathy.
6	Assess for other end organ damage- oral examination, diabetic foot review, renal and cardiac function, tests for neuropathy at least annually
7	Assess for hypertension, hyperlipidemia and other co-morbidities as these may impact negatively on diabetes and diabetic retinopathy.
8	Send all pregnant patients with diabetes for a retinal examination at least each trimester and post-delivery, or more frequently if recommended by the eye specialist.

Have an eye check: as soon as possible / in the next months at..... health facility

Annual dilated and comprehensive eye examination is recommended for all patients with diabetes, aged 12 years and above, starting at the time of diagnosis of diabetes mellitus, unless the eye specialist recommends a different frequency. For type 1 diabetes, an eye exam should be done at diagnosis, at 5 years of diagnosis and annually thereafter.

Domain: Patient-centred care

1. Health workers should provide verbal and written information on diabetes, diabetic retinopathy, and on the health care that is needed, including self-management.
2. All PLWD should receive regular and individualised self-management support on healthy diet, appropriate physical activity and weight reduction if they are overweight. All smokers should be encouraged to quit smoking.
3. Patient education materials such as posters, leaflets, booklets and flyers on DR should be available (Panel 3) to patients and to peer support groups.
4. Diabetes support and structured self-management education should also be provided to family members of PLWD.
5. PLWD should be treated with dignity and involved in decision-making for their care. The results of their examination and the implications should be explained to them, and they should be encouraged to ask questions. The presence of co-morbidities should be taken into consideration in the care of each patient.

*Panel 3: Key messages for patients***DID YOU KNOW THAT DIABETES AFFECTS THE EYES?**

What can you do to prevent blindness?

1	Diabetes mellitus is marked by high sugar levels in blood. High blood sugar destroys small blood vessels in the body including those at the back of the eyes, leading to a condition called diabetic retinopathy.
2	Damage to the eyes is slow, painless, gets worse with time and finally leads to blindness if not treated in good time.
3	The damage to the eyes needs to be detected early, before permanent damage occurs.
4	An eye check by an eye specialist can detect damage to the eyes before symptoms develop. During the examination, the eye specialist will check vision, and instil an eye drop to assess the damage in the eye. Both eyes need to be examined.
5	For prevention and treatment of diabetic retinopathy, the eye specialist may advise on sugar, blood pressure, and lipid control.
6	For treatment of diabetic retinopathy, the eye specialist may perform laser or administer injections in the eye or perform eye surgery.
7	All persons with diabetes should have their eyes checked once every year by an eye specialist, even before any symptoms or poor vision develop or as frequently as recommended by the eye specialist.

8	A child with diabetes should have the eyes checked annually from the age of 12 years, or more frequently if recommended by the specialist.
9	A pregnant mother with diabetes should undergo an eye check by an eye specialist at least once every trimester, and soon after delivery, or as frequently as recommended by the eye specialist.
10	If the eyes are found to be normal at your eye check by an eye specialist, please continue with an eye check annually. If you notice any abnormality with your eyes, visit the eye specialist as soon as possible.

Domain: Metabolic control

1. All PLWD should be asked about the level of control of glucose, blood pressure and lipids.
2. To prevent the onset and delay the progression of diabetic retinopathy, people with diabetes should be treated to achieve optimal control of blood glucose.
3. Regular monitoring of blood sugar at home should be encouraged.
4. Regular monitoring of blood pressure in a health care setting or at home should be encouraged. Target blood pressure is 140/90 mmHg. Drugs blocking the Renin-Angiotensin System (RAS) may have benefits, particularly for mild retinopathy, but should be discontinued during pregnancy.
5. A comprehensive biochemical profile (risk assessment) should be done at least annually, and include fasting lipid profile, HbA_{1c}, urine microalbumin among other tests.
6. Aim for a target glycosylated haemoglobin (HbA_{1c}) of <7%.
7. Serum fasting lipid profile should be assessed at diagnosis and annually. Consider statins in primary and secondary prevention of DR but discontinue statins in pregnancy.

Domain: Pregnancy

1. All female PLWD of reproductive age should be asked if they are pregnant.
2. Patients should be assessed for diabetic retinopathy before pregnancy, at least once every trimester of pregnancy, as well as within 6 months after delivery or more frequently if recommended by the eye specialist.
3. Statins and angiotensin inhibitors should be discontinued in patients who are planning for pregnancy.
4. All women of child-bearing age who have diabetes should be educated that pregnancies should be planned.

Domain: Screening programs for DR

1. All PLWD should be screened for DR at least once a year, irrespective of whether they have ocular symptoms or not.
2. Screening programs can utilise whatever screening method is available (ophthalmoscopy, slit-lamp biomicroscopy and retinal photography), and should be conducted by a suitably trained person. Pupil dilation is recommended. Visual acuity should be assessed before pupil dilation.
3. Photography based screening
 - a. Where a fundus camera is available, ideally the fundus camera should be located in the diabetes clinic.
 - b. Fundus photographers should be trained to identify cataract, other causes of media haziness and glaucoma on the images. Patients who have these pathologies should be referred to an ophthalmologist. Ultrasonography may be useful in assessing the posterior segment in the presence of cataract or vitreous haemorrhage.
 - c. Regular retraining in form of short courses (either online courses or standard contact courses) should be provided for screeners.
4. The following patients should be referred to an ophthalmologist:
 - a. Where the screening examination is unsuccessful, or the results of the visual acuity test or retinal examination are unclear
 - b. Where the retinal examination is unsuccessful, for example due to additional pathologies
 - c. Any grade of retinopathy, except mild non-proliferative retinopathy
 - d. Visual acuity worse than 6/12 and all patients with ocular symptoms
5. Screening should identify true positives (patients with DR). For this to be achieved, it is important to use the correct equipment, adhere to the standards of practice, make correct diagnosis and have a quality assurance mechanism. The guidelines for quality assurance are provided as an addendum to the guidelines.
6. All health workers have a role in ensuring patients undergo screening. All health workers should also document and collect data on screening activities, as the data is useful for planning and monitoring services. Health workers at each health facility will collect this data using standard monthly data collection forms. The Ophthalmic Services Unit in the Ministry of Health will coordinate the collection of data.

Domain: Diagnostic evaluation of patients at the eye clinic

Once the person with diabetes has been referred to an eye specialist, he or she should undergo a complete ophthalmic assessment. Ophthalmic evaluation by an eye care worker is available at the secondary level of the health system. This should include taking medical history, assessing visual acuity, and identifying and grading DR or Diabetic Macula Oedema (DME), using standard procedures described in the guidelines.

Domain: Referral pathway

Once a decision for referral for evaluation or treatment has been made, it should be carried out as soon as possible. The nearest health facility offering DR services will be identified (mapping of services has been conducted, and this information is provided as an addendum to the guidelines), and patients will be referred to reach the facility on the designated days that the services can be provided.

Domain: Treatment interventions

The ophthalmologist will make the final diagnosis and the decision on the treatment that the patient should receive. There is evidence from Cochrane systematic reviews included in Panel 4 to support the use of laser photocoagulation in proliferative diabetic retinopathy²² anti-VEGF injections in diabetic macula oedema²³ and intravitreal steroids in refractory diabetic macula oedema²⁴. Laser or intravitreal injections can be administered by the ophthalmologist at secondary level. Surgical interventions for DR will be provided by the vitreo-retinal surgeon at tertiary level. Practical information on these procedures is provided in the guidelines.

Panel 4. Evidence from Cochrane systematic reviews for Interventions used to treat diabetic retinopathy.

Laser photocoagulation is beneficial in reducing the risk of severe visual loss and the risk of progression 12 months after treatment in patients with proliferative diabetic retinopathy compared to no treatment or deferred treatment. However most trials here are old and the quality of evidence is judged as low²².

There is very low or low quality evidence from randomized controlled trials that anti-VEGF injections are effective in patients with proliferative diabetic retinopathy but they prevent intraocular bleeding²⁵.

There is high quality evidence that anti-VEGF injections are effective in preserving and improving vision in patients with diabetic macula oedema compared to grid laser²³.

Intravitreal steroids delivered either by injection or implants may improve visual outcomes in patients with persistent or refractory diabetic macula oedema but it is unclear whether they are beneficial in other earlier stages²⁴.

Domain: Follow up

All PLWD screened for DR will require follow up. The frequency of follow-up depends on the clinical findings, and the grading/severity of DR, as described in the guidelines.

Domain: Patients with low vision

Refer the patient with low vision (best corrected visual acuity of <6/18) for rehabilitation. PLWD who would benefit from counselling and social services should be referred as appropriate.

Domain: Monitoring DR services

Specific process and outcome indicators will be used to monitor services on a quarterly basis at each level of service delivery, using the hospital health management and information system. Health workers at each health facility will therefore collect this data using standard monthly data collection forms. The Ophthalmic Services Unit will coordinate the collection of data. The indicators of interest are listed in the guidelines.

CONCLUSIONS

Patients with diabetes require specific care relevant to diabetic retinopathy, which includes patient education, screening, referral, treatment and follow-up. These are the first published national clinical practice guidelines for the screening and management of diabetic retinopathy. Their goal is to ensure best practice throughout the whole pathway from primary care to tertiary care. Implementation of the guidelines has potential to reduce blindness from DR.

The Working Group welcomes feedback from all users of these guidelines. In particular, data on the enablers and challenges experienced in the use of the guidelines would be very useful in informing revisions on the guidelines. Please email feedback to the Ophthalmic Services Unit, Ministry of Health, through ophthalmicserviceske@gmail.com.

ACKNOWLEDGEMENTS

We acknowledge The Fred Hollows Foundation for funding the process of guidelines development.

Conflict of interest: Nothing to declare.

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Evaluation of the Kenyatta National Hospital diabetic retinopathy screening program 2015-2016

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ABSTRACT

Objective: This operational evaluation was conducted to determine the effect of having a screening fundus camera in the diabetes clinic on the demand for eye clinic diabetic retinopathy services at the Kenyatta National Hospital (KNH).

Methods: A before-after evaluation design was used. The reference point was installation of a screening retinal fundus camera in the KNH diabetes clinic in May 2016. The 'before' period was January to June 2015 and the 'after' period was June to November 2016. The one-year gap between the evaluation periods was used for program development and user training. The primary measure of outcome was a comparison of the mean numbers of patients seen and treated before and after starting the screening program. Data was obtained from the medical records on both the diabetes and eye clinics.

Results: The total number of diabetic patients screened in the two periods was 3011 (monthly mean=502, SD=44) and 2739 (monthly mean=457, SD=38) respectively. The total number referred to the eye clinic increased from 494 (monthly mean=82, SD=16) to 1065 (monthly mean=178, SD=30) while the total number of patients treated with lasers or intravitreal injections increased from 107 (monthly mean=18, SD=5) to 333 (monthly mean=56, SD=39).

Conclusions: Starting a diabetic retinopathy screening program using a fundus camera used based at the diabetes clinic doubled the number of patients referred for further evaluation at the eye clinic (2.2-fold increase) and tripled the number of diabetics who received treatment for diabetic retinopathy (3.1-fold increase).

Key words: Diabetes mellitus, Diabetic retinopathy, Screening, Fundus camera

INTRODUCTION

Globally, Non-Communicable Diseases (NCD) including diabetes, hypertension, cancers and heart disease are gradually becoming an epidemic and important cause of morbidity and mortality. In sub-Saharan Africa (SSA) mortality from NCD is rising while that from communicable diseases is falling¹. In the Nigeria national blindness and visual impairment survey, about half (48%) of patients found to have diabetes did not know they had the disease². In 2015 the Kenya stepwise survey estimated that 1.9% of the adult population aged 18-69 years (about 420,000 people) have raised blood sugar defined as plasma venous value ≥ 7.0 mmol/L or currently on medication for diabetes while 3.1% had impaired fasting glycaemia³. From the same study raised blood pressure (defined as having systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg or on medication for raised blood pressure) was found in 23.8% of respondents. Twenty seven percent were either overweight or obese, and women more than men (38.5% vs 17.5%).

The most common type of diabetes is type 2, usually found in adults. After a number of years (usually 20), diabetes mellitus type 2 seems to cause diabetic retinopathy which in turn leads to loss of vision from bleeding, retinal scars and macular edema. Type 1 occurs in younger ages and causes diabetic retinopathy earlier and more frequently than type 2. There appears to be no primary prevention of diabetic retinopathy so far. Early detection and management is therefore important. Recent estimates from the East African region show that about one in every three diabetics has diabetic retinopathy; 35.9% (95% CI 29.7-42.6) in Kenya and 27.9% (95% CI 26.4-29.5) in Tanzania^{4,5}. This means that about 140,000 diabetics have diabetic retinopathy in Kenya. It is estimated that about 42,000 (10%) diabetics in Kenya have vision-threatening diabetic retinopathy. The most common causes of vision loss in diabetics are diabetic retinopathy, cataracts and glaucoma. One of the most difficult-to-detect causes of vision loss in Diabetics is Macula Edema (DME). The prevalence of clinically significant macula edema in a Kenyan study was reported to be 8.7% in newly diagnosed diabetics at Kenyatta National Hospital⁶. A health system

assessment for diabetes and diabetic retinopathy in 2016 showed that only 32.6% of people living with diabetes in Nairobi had ever had a retinal examination, and only 15.7% of them had the examination in the preceding 12 months yet the recommendation is an annual retinal examination⁷.

Diabetic retinopathy is thus an important public health problem. Its epidemiology is well understood in various parts of the world but in Kenya we have little information. However, planning for a large epidemiological study in conjunction with Kenya Medical Research Institute KEMRI-Welcome Trust is at an advanced stage. The natural history of the disease is well known across the world and we have no reason so far to believe that the course of disease is different in our population save for the effect of late presentation with advanced disease.

Screening has been shown to be effective in detecting early diabetic eye disease⁸. Screening methods involve examination of the retina using indirect ophthalmoscopes or taking retinal fundus photographs of diabetics. Photographs may be reported on site or remotely via telemedicine by an eye specialist. There are softwares that can do an initial analysis and distinguish referable patients for further assessment. The pictures for referable patients can be seen by an expert retinal reviewer (usually retinal sub specialist) who would recommend referral. This model is not routinely used in Kenya. A telemedicine study in Kenya for diagnosis of glaucoma in diabetic patients in Murang'a demonstrated 77.5% positive predictive value⁹. This study utilized a solitary image analyzer housed at the Aga Khan University Hospital in Nairobi. National diabetic retinopathy screening guidelines in Kenya are in the process of development.

Effective treatment of diabetic retinopathy (includes laser photocoagulation, surgery and intravitreal injections of anti-Vascular Endothelial Growth Factor (antiVEGF) is available at the Kenyatta National Hospital (KNH). The National Health Insurance Fund (NHIF) pays for anti-VEGF treatment.

Before 2014, diabetics from the main diabetes clinic at KNH running on Fridays would be referred to the eye clinic for examination if they had visual concerns. In 2014 the Diabetic Retinopathy Network (DR Net) launched a public awareness of the effects of diabetic retinopathy at the London School of Hygiene and Tropical Medicine¹⁰. Three Kenyans attended the meeting; the head of Ophthalmic services unit at the Ministry of Health, one ophthalmologist with an interest in retina from the Department of Ophthalmology (MG) at the University of Nairobi (UON) and a nurse in charge of the KNH eye clinic. Afterwards, he undertook a full retina fellowship in India. In the meantime, another ophthalmologist (JM) from the same department was undertaking a retina fellowship training in Canada. In 2015, he returned to Kenya and was taken to Kitwe, Zambia to see a diabetic retinopathy screening program. The design of a potential screening program in Kenya started developing. A trial

fundus camera similar to the one in current use was installed and used from 1st September 2015 to 31st October 2015 to begin training the hospital staff and residents. The technician was provided by the supplier of the camera.

In May 2016, a non-mydratic retina camera (Canon CR-2AF, Japan) was installed at the diabetes medical clinic in KNH. This was a first in a Kenyan public hospital. In the same month, a diabetic retinopathy team was taken to Lusaka, Zambia for training in photo grading and camera maintenance. It consisted of a clinic technician and an ophthalmic clinical officer. When they returned an experienced technician from the University Hospitals Coventry and Warwickshire NHS Trust, a partner and collaborator linked to the University of Nairobi through the DR Net and ICO Links program visited Kenya to further train the team.

From Monday to Thursday diabetic patients are attended to in what is commonly called a mini-diabetes clinic run by clinical officers. Those that need endocrinology specialist attention are referred to a specialist diabetes clinic on Fridays. At each of these clinics all the patients are invited to have a retinal screening fundus photograph taken by a technician who grades them. Any patient with a normal fundus photograph is asked to return for screening in one year. Any with an abnormality in the retina is referred to the eye specialist. They are given appointments to be seen within a week of taking the photograph. At the retina clinic, a dilated stereoscopic fundus examination is performed. There are two retina clinics every week, one on Wednesday and the other on Fridays. The following illustration shows the two-level screening program design.

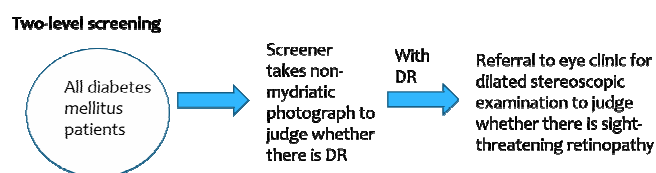


Figure 1: A model of the KNH diabetic retinopathy screening program

This operational evaluation was conducted to determine the effect of having a screening fundus camera in the diabetes clinic on the demand for eye clinic diabetic retinopathy services.

MATERIALS AND METHODS

A before-after evaluation model was adopted. Installation of the fundus camera in May 2016 was considered the beginning of the screening intervention. The 'before' period was considered January to June 2015. The 'after' period after was considered June to November 2016. Six month periods were considered adequate to review the

after period and short enough to avoid the seasonal effects and other background effects of the before period. There was a one year gap between both periods which was used for program development and user training.

The measure of outcome was to compare the mean numbers of patients seen and treated before and after starting the screening program. We analysed the mean number (and standard deviations) of patients screened in the diabetes clinic, referred to the eye clinic and the number treated for diabetic retinopathy with laser and/or anti-VEGF injections. We focused on these two treatment parameters without the number that had surgery (vitrectomy) as there are more barriers to surgery such as finance and logistics that may push patients to delay or seek care elsewhere. Data were obtained from medical registers in the diabetes and eye clinics, from the camera and from the registers for treatments offered in the eye clinic.

RESULTS

The overall effect comparing the before and after period are shown in Table 1.

Table 1: Summary of patients seen before and after camera screening

	Before (Jan-Jun 2015)	After (Jun-Nov 2016)	Change	% Change	Before: After ratio
Diabetic patients screened at the KNH daily mini diabetes clinic	3011	2739	-272	-9.0%	1:0.9
Diabetic patients referred to KNH eye clinic	494	1065	571	+115.6%	1:2.2
Diabetic patients treated with laser/injections at KNH Eye clinic	107	333	226	+211.2%	1:3.1

There was a 9% drop in the total number of patients screened in the daily mini diabetes clinic. In the six months before the intervention a total of 3011 patients was screened (monthly mean=502, SD=44) compared to a total of 2739 patients afterwards (monthly mean=457, SD=38). Despite this reduction, there was a 2-fold increase in the number of patients referred to the eye clinic from a total of 494 before to 1065 after (before: after ratio of 1:2.2) and a 3-fold increase in the number of diabetic patients receiving treatment with laser plus/ or anti-VEGF injections from a total of 107 before to 333

after (before:after ratio of 1:3.1).

Over the whole 2015-2016 period covered by the evaluation, the trends in services at the diabetes clinics and eye clinics were as shown in Figure 2. The trends in the diabetic retinopathy eye services on a month-by-month basis are shown in Figure 3.

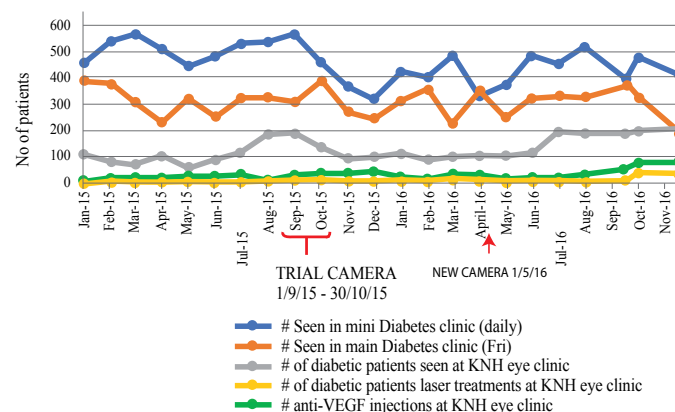


Figure 2: Summary statistics for diabetes and eye clinics over the evaluation period

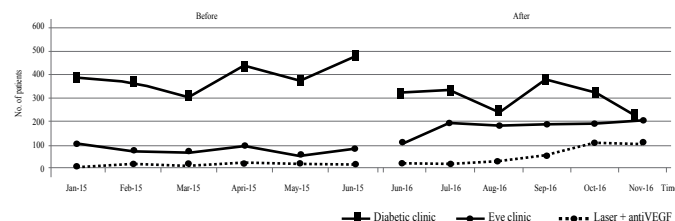


Figure 3: Month-by-month comparison of the before and after period for diabetic retinopathy services at the eye clinic

DISCUSSION

Implementation of a diabetic retinopathy screening program using a fundus camera placed in the diabetes clinic increased both the number of patients referred to the eye clinic and the number that received treatment for diabetic retinopathy. It is not clear why there was a 9% reduction in the number of patients seen at the diabetes clinic. In November 2016, there was a nationwide industrial action by health workers (doctors, clinical officers and nurses) which may have had an effect both at the hospital and health facilities lower down the referral system. This however may suggest that had the numbers in the diabetes clinic stayed the same or increased, there would have been an even greater increase in the diabetic retinopathy treatment service.

The increase in patients referred to the eye clinic to 178 patients per month with 2 retina clinics running every week translates to a case-load of 23 patients per retina clinic from diabetic retinopathy alone. The retina clinic attends to other retina problems apart from diabetic retinopathy. This increase has logistical implications on the quality of service offered at the retina clinic. If each patient needs to be dilated, a process that takes about

30-45 minutes, this would take a long time with the risk of hypoglycaemia if the patients are kept in the clinic for very long. The retina clinics are known to run from morning long into the afternoon. We now have two retina specialists and this may shorten the waiting time.

There were various weaknesses with this evaluation. Starting a new initiative such as a screening program is likely to change behaviour of health workers and patients with a higher level of awareness and emphasis on data recording after the intervention than was present before the introduction of the camera. This inherent shortcoming of before-after evaluations means the baseline (before) data is not always as accurate as the 'after' data. Secondly, the trends observed from 2015 to 2016 may include a seasonal element in the annual ebbs and flows of patients seen in the hospital that may not be fully attributable to the screening program. Also, every year around September a team from the diabetes clinic goes on outreach to different parts of the city which may lead to a sudden increase in the number of patients seen in both the diabetes and eye clinic.

Another important evaluation parameter is whether screening increases detection of vision-threatening diabetic retinopathy. This can be the subject of another study to be done by looking at individual medical records rather than patient registers such as the ones we used.

There were collateral benefits of the screening program. The residents had access to fundus photographs for discussion of cases in the weekly journal club held at the UON Department of Ophthalmology. Patients are now able to see 'the back of their eye' looks instead of only relying on the health worker's description.

Future developments in the program would need to include linking diabetes clinic and eye clinic data with the camera in one database. It would help to identify if we are losing any patients by tracking the number screened and not screened, the number referred to the eye clinic, and the number that attends or does not attend the eye clinic referral. Presently, there are no reminder systems for patients to enable compliance with follow up appointments. The use of short text messages (SMS) has been shown in various health settings to improve compliance with medication and attendance at health appointments¹¹. Further, the issuance of pre-paid referral vouchers at the diabetes medical clinic may improve the number that do attend the eye clinic referral. How to fund this can be discussed.

Various services may further augment the screening service. The gold standard for diagnosis of DME is Optical Coherent Tomography (OCT). It has a high sensitivity and specificity of about 80%^{12,13}. However, OCT is a very expensive technology in the developing world. In Kenya there are only 3 machines, all in private healthcare facilities in Nairobi. The teaching hospitals have none. A new OCT costs at least KSh 5 Million (US\$ 50,000) in Kenya. Vitrectomy surgery, laser, anti-VEGF (vascular endothelial growth factor) treatments

for diabetic retinopathy are costly and only available in various private facilities in Nairobi; Kenyatta National Hospital being the only public hospital offering this together with PCEA Kikuyu Eye Unit, a faith-based hospital just outside Nairobi. The University of Nairobi medical school has no equipment for vitreo-retinal surgery. Such equipment would consist of a vitrectomy machine to remove vitreous haemorrhages, laser machine to treat retinopathy, OCT to diagnose macula edema, and anti-VEGF injections for macula edema. Training of future generations of vitreo-retinal sub-specialists locally would become possible in such a unit.

CONCLUSIONS AND RECOMMENDATIONS

Introduction of a diabetic retinopathy screening program at KNH had a big impact. It increased the access to diabetic retinopathy services 2-fold from a mean of 82 patients referred per month (SD=16) to 178 patients per month (SD=30). The number of patients who received either laser or anti-VEGF injections tripled from a mean of 18 patients per month (SD=5) before to 56 patients per month (SD=39).

We recommend conducting baseline situation analysis for County-level hospital-based screening projects then replicate the pilot screening program in other County Referral Hospitals. A repeat evaluation of the KNH program one more year later would provide further information on sustainability. Nationally there is a need to institute mechanisms to manage the rise in case load in the eye clinics.

ACKNOWLEDGEMENTS

We would like to acknowledge all the staff in the diabetes and eye clinics who helped to provide data for this study and Matron R. Mutuku for collating the data.

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Validity of smartphone fundus photography in diagnosing diabetic retinopathy at Mbarara Regional Referral Hospital, South Western, Uganda

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ABSTRACT

Objective: To determine the sensitivity and specificity of smartphone funduscopy in diagnosing and staging Diabetic Retinopathy (DR) in diabetics attending Mbarara Regional Referral Hospital (MRRH).

Design: Analytical, hospital based cross sectional study.

Setting: Diabetic clinic of MRRH, Mbarara.

Participants: Diabetic patients (n=207) $\geq$ 18 years were recruited from the diabetic clinic of MRRH.

Measures: Sensitivity and specificity of smartphone photographs was analysed using indirect ophthalmoscopy as the gold standard.

Results: Sensitivity of smartphone in diagnosing DR was 70% and specificity 94%. The sensitivity and specificity of the smartphone in grading proliferative diabetic retinopathy was 100% and 99.4%. For macular edema, sensitivity was 38.5% and specificity 97.9%. Kappa agreement was 0.86 in diagnosing DR and 0.84 in grading diabetic retinopathy. The prevalence of DR was 13.5%.

Conclusion: The study found that the sensitivity of the smartphone in diagnosing diabetic retinopathy was only 70%. Hence we do not recommend this device to be used in the screening of patients with diabetes.

INTRODUCTION

Approximately 347 million people worldwide have diabetes¹. The prevalence of diabetes is expected to double by 2030 as a result of increased urbanization and sedentary lifestyles. Patients with Diabetic Retinopathy (DR) are 25 times more likely to become blind than non-diabetics². More than 75% of patients who have diabetes for more than 20 years will experience vision loss from diabetic retinopathy³. The American Diabetes Association⁴, recommends annual retinopathy screening beginning at the time of diagnosis of diabetes for all patients aged 30 years and older. Bobb-Semple *et al.*, 2014 (Unpublished work) found that only 13.3% of patients seen at MRRH and Ruharo Eye Centre were referred from their diabetic clinic for ophthalmic evaluation as a result of their long standing diabetes. The remaining 86.7% only sought medical attention when they already had ocular symptoms. If screening for diabetic retinopathy is instituted through diabetic screening clinics, the majority of blinding diabetic retinopathy can be prevented as they would be detected earlier and managed appropriately.

Teleophthalmology, a newly emerging discipline of medicine, can be used to identify, grade and monitor diabetic retinopathy. The gold standard in fundus photography is the mydriatic fundus camera, this machine doesn't lend itself to be used in low cost and rural settings as it is very expensive. Smartphone funduscopy is a new and emerging concept which is still being studied in order to be validated. This novel study served to validate the use

of the smartphone in diagnosing, staging and monitoring diabetic retinopathy. Also, it can promote the use of smart phones in diabetic screening programmes where the standard and more expensive fundus camera is not readily available, once its sensitivity and specificity are found to be excellent.

MATERIALS AND METHODS

Study design: This was an analytical and descriptive hospital-based cross sectional study. The study period was from 21st July 2016 to 8th December 2016.

Study setting: The Mbarara Regional Referral Hospital's Diabetic clinic was the site for the execution of this research. Mbarara Regional Referral Hospital (MRRH) is a tertiary level health facility, located in Mbarara Municipality, South western Uganda.

Study population: The study population included all patients with a diagnosis of diabetes mellitus, who attended the diabetic clinic of MRRH during the specified study period.

Inclusion criteria: Diabetic patients aged 18 years and above, all patients with a laboratory diagnosis of diabetic mellitus, who are members of the Diabetic clinic of the Mbarara Regional Referral Hospital and patients who gave informed consent.

Exclusion criteria: Patients who were critically ill, adult diabetic patients with mental disorders who may not fully

cooperate for the examination with two instruments, patients who did not give informed consent and patients with significant cataract.

Sample size and sampling: Using Buderer's formula for calculation of sample size for sensitivity, sample size was calculated as 187. A 15% addition was added and gave a total sample size of 215 patients. A systematic, random sampling technique was employed. We targeted a total of 20 patients per clinic day. Following the diabetic clinician's review, the patient was then taken to the eye examination room where informed consent, questionnaire administration and eye examinations were performed.

Data collection: All patients recruited in this study were examined with the Welch Allyn panophthalmoscope which boasts a 25 degree coverage of the posterior segment without pupil dilation⁵ with a Samsung Galaxy S6 Edge smart phone attached to it.



Figure 1: Welch Allyn Panophthalmoscope with Samsung Galaxy S6 Edge and one field of view

Patients who were recruited for the research were administered a questionnaire which provided baseline demographic information for this study. Each recruited patient first had their visual acuity for each eye done, with and without pinhole, and with spectacle correction if they were found to have a refractive error. Thereafter, each patient's pupils were dilated with Gutt 1% Tropicamide in each eye. While an individual patient was being dilated, anthropometric measurements were taken and blood pressure as well as fasting blood sugar testing was done. Anthropometric measurements were recorded for each patient; fasting blood glucose, blood pressure, weight (kilograms) and height (metres) were recorded before ophthalmic fundus photography. Patients then had both of their eyes examined using an indirect ophthalmoscope and a +20 diopter lens by the Medical retina fellow, followed by smartphone funduscopy.

Instrumentation details: The gold standard used in our study was the binocular indirect ophthalmoscope with the

+20 diopter condensing lens. Indirect ophthalmoscopy is the gold standard for examination of the posterior segment of the eye. Indirect ophthalmoscopy was done by the Medical retina fellow first and documentation of the findings was recorded on the patient's examination record. The International Clinical Disease Severity grading system of diabetic retinopathy was employed in our study.

The principal researcher then took fundus photographs with the smartphone afterwards. The images were captured on the 16 MP (2988 × 5312 pixels) of the Samsung Galaxy S6 Edge camera sensor. The light was set to the lowest intensity to minimize patient discomfort. In this study, mydriatic 7 field photography was done by the principal researcher. The 7 fields photographed were the macula, optic disc, superior temporal, superior nasal, inferior nasal, inferior temporal and temporal macula fields of each eye (Figure 2).

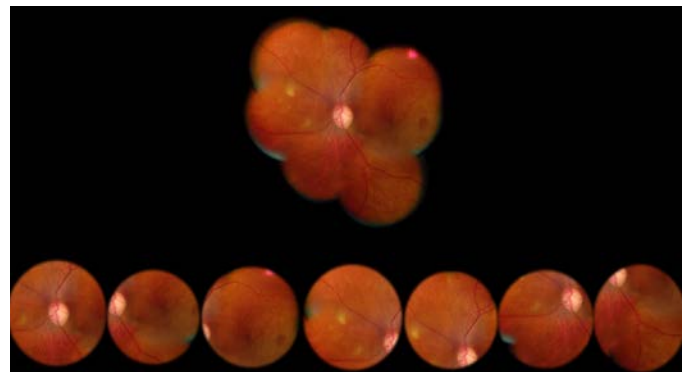


Figure 2: Seven Field Mydriatic Smartphone Retina Composite Image

Photographs were taken and immediately after each photograph, image quality was assessed and images reacquired when necessary. Only the principal researcher performed all image acquisition for each individual to ensure a standard technique. Each photograph was then coded with an identification number and uploaded to a secure database. Each of the 7 fields captured by the smartphone was then compiled into a composite retinal image using the Adobe Photoshop CS3 programme and presented to the Retinal specialists for diagnosis and staging of diabetic retinopathy. All fundus photographs were analysed at the end of the study period by the same Medical Retina Fellow who had done indirect ophthalmoscopy on the study patients. He was masked to the confirmed diagnosis of the patient, for diagnosis and staging of diabetic retinopathy. When no lesion of DR was seen, the absence of DR was recorded. If any lesion was seen, the presence of DR was recorded and the severity assigned on the basis of scoring according to the International Clinical Disease Severity grading system for diabetic retinopathy.

Image quality: Based on the study done by Rajalakshmi *et al*⁶, the photographs taken with the smartphone were graded on a 5 level grading scheme as follows:

Grade 0 – Ungradable (no detail was visible due to media opacities like dense cataract or total vitreous hemorrhage)

Grade 1– Poor (only gross retinal details, larger lesions like blot haemorrhages and dense hard exudates were detectable)

Grade 2 – Average (major retinopathy details visible; minor degrees of retinopathy like microaneurysms, Intra-Retinal Microvascular Abnormalities (IRMA) or subtle new vessels not clearly detectable)

Grade 3 – Good (retinal details fairly clear, most of retinopathy changes detectable)

Grade 4 – Excellent (all retinal details and retinopathy lesions clearly visible).

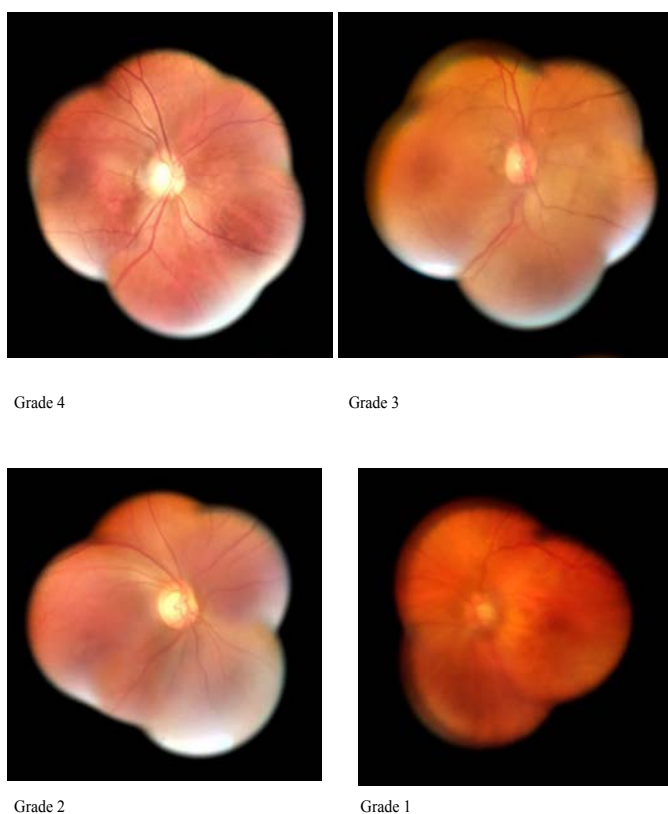


Figure 3: Image quality grades for smartphone photographs

Data analysis: Questionnaire information was entered into Microsoft Excel 2010 then imported into STATA 13.0 to be analysed. Representation of baseline characteristics, univariate analysis using one-way tables of frequencies were used to generate proportions and means or medians. Establishing the validity of the smart phone (Samsung Galaxy S6 Edge) in diagnosing and staging DR, using the indirect ophthalmoscope with the +20 diopter lens as gold standard, the sensitivities, specificities, negative and positive predictive values, were generated in 2x2 tables using STATA 13 statistical software. Thereafter, the sensitivity, specificity, positive and negative predictive values and 95% confidence intervals were reported in a tabular form.

Quality assurance: The principal researcher conducted a pre testing of the instrument for two weeks on twenty diabetic patients at the Mbarara Regional Referral Hospital's Diabetic clinic before commencement of the study period to ensure standardization of results. As seen necessary at the end of the study, we considered an external quality control on randomly selected patients' fundus photographs. This was done by an independent Ophthalmologist, a Vitreoretinal specialist, whose responsibility was to validate the accuracy of results generated from this study. The inter observer agreement using this model, served to determine the accuracy of the two readers in the diagnosis and staging of diabetic retinopathy using the smartphone. The Ophthalmologists were blinded to the funduscopic findings and bio data of the recruits when reading photographs, in an effort to eliminate biased results from prior knowledge of the patient's disease status. The Principal investigator underwent training in the use of the fundus camera at the Agarwal's Eye Institute in Kampala, Uganda before the start of the study; following standard operating procedures of use of the equipment

Ethical consideration: Approval was sought from the Department of Ophthalmology, Faculty of Research and Ethics Committee, Research Ethics Committee of Mbarara University of Science and Technology, and Uganda National Council of Science and Technology. Informed consent was obtained from each participant. Participants' names were not collected, instead unique identifiers were utilized for each patient.

RESULTS

A total of 263 diabetic patients were screened at the Diabetic Clinic of Mbarara Regional Referral Hospital during the study period. Of these, 56 patients were excluded as a result of not fulfilling the eligibility criteria; some were uninterested in participating, others were too busy to have dilated serial funduscopic examinations or were too hypoglycaemic and others had bilateral grade 4 cataracts which precluded their enrollment. In this study, 207 patients completed serial dilated funduscopy (first with the indirect ophthalmoscope and +20 diopter lens, followed by smartphone funduscopy using the Samsung Galaxy S6 Edge. The patients' baseline characteristics and demographic data are presented in Table 1.

The participants had a mean age of 54.9 ± 12.1 years at examination, with 141 participants (68.1%) being >50 years and 63 patients (30.4%) being male. They had a mean body mass index of 26.4 (5.1), median fasting blood glucose of 8.5 mmol/dL (IQR: 6.6-11.4), median (IQR) for duration of diabetes was 4 years (1-10) and 94 participants (45.4%) were hypertensive. There were only 10 participants (4.8%) who were not using treatment for diabetes mellitus and 134 of the 195 patients using treatment, were on oral hypoglycaemic drugs.



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OF VISION^{1,a}



ON AVERAGE,
PATIENTS ACHIEVED AT LEAST

87%

OF MEAN VISION
GAINED AT YEAR 1^{2,3,b}



REDUCING
BURDEN
WITH
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DOSING

^aData from a pooled analysis of VIVID DME and VISTA DME.¹

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^aNo requirement for interim monitoring between injections.⁴

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3. Data on file (VIVID and VISTA BCVA plot points through Year 1).
4. EYLEA / 40 mg/mL solution for injection / CCDS / Version 10 / 19 Apr 2016

Prescribing Information¹ (For full product information, refer to the product package insert and / or contact Bayer East Africa Ltd)

EYLEA, 40 mg / mL solution for injection

Composition: One milliliter solution for injection contains 40 mg aflibercept. **Indication(s):** EYLEA is indicated for the treatment of: neovascular (wet) age-related macular degeneration (wet AMD, macular edema secondary to central retinal vein occlusion (CRVO), macular edema secondary to branch retinal vein occlusion (BRVO); diabetic macular edema (DME) and myopic choroidal neovascularization (myopic CNV).

Dosage and method of administration: EYLEA is for intravitreal injection. The recommended dose for EYLEA is 2 mg (equivalent to 50 microliters).

Contraindications: ocular or periocular infection; active severe intraocular inflammation and known hypersensitivity to aflibercept or to any of the excipients. **Special warnings and precautions for use:** Endophthalmitis (Proper aseptic injection technique must always be used when administering EYLEA); Increase in intraocular pressure (Special precaution is needed in patients with poorly controlled glaucoma).

Pregnancy and lactation: EYLEA should not be used during pregnancy unless the potential benefit outweighs the potential risk to the fetus. EYLEA is not recommended during breast-feeding. A decision must be made whether to discontinue breast-feeding or to abstain from EYLEA therapy.

Effects on ability to drive or use machines: Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations.

Undesirable effects: very common (conjunctival hemorrhage, eye pain), common (retinal pigment epithelial tear, detachment of the retinal pigment epithelium, cataract, cataract cortical, cataract nuclear, cataract subcapsular, corneal erosion, corneal abrasion, intraocular pressure increased, vision blurred, vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, lacrimation increased, eyelid edema, injection site hemorrhage, punctate keratitis, conjunctival hyperemia, and ocular hyperemia)

Presentation: 1 vial (4 mg/0.1 ml) and 18G filter needle

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Table 1: Participants' baseline characteristics

Characteristics	No.	
Age in years, mean (SD)	207	54.9 (12.1)
Age categories in years, n (%)	207	
<50		66 (31.9)
>50		141 (68.1)
Sex, n (%)	207	
Male		63 (30.4)
Female		144 (69.5)
District, n (%)	203	
Mbarara		114 (56.1)
Isingiro		27 (13.3)
Greater Bushenyi		21 (10.3)
Ibanda		8 (3.9)
Others		33 (16.3)
Tribe, n (%)	207	
Munyankore		161 (77.8)
Muganda		15 (7.3)
Mukiga		22 (10.6)
Others		8 (4.4)
Body Mass Index, mean (SD)	207	26.4 (5.1)
Fasting blood sugar in mmol/dL, median (IQR)	207	8.5 (6.6 - 11.4)
Hypertension history, n (%)	207	
Present		94 (45.4)
Absent		113 (54.6)
Duration of diabetes in years, median (IQR)	207	4 (1 - 10)
Use of treatment for diabetes, n (%)	206	
Yes and compliant		184 (89.3)
Yes but non compliant		12 (5.8)
No but on diet		5 (2.4)
Not on any treatment		5 (2.4)
Type of treatment for diabetes, n (%)	195	
Insulin injection		37 (19.0)
Oral hypoglycaemic		134 (68.7)
Both		24 (12.3)

The sensitivity and specificity of this smartphone in diagnosing diabetic retinopathy were 70% (95% CI, 47.1-86.8%) and 94% (38.8-77.6) respectively. A positive predictive value of 59.3% and a negative predictive value of 96.0% were found (Table 2).

Table 2: Validity of smartphone funduscopy (Samsung Galaxy S6 Edge) in diagnosing diabetic retinopathy

Validity indices	(%)	95% CI
Sensitivity	70	47.1-86.8%
Specificity	94	89.3-96.9%
Positive predictive value	59.3	38.8-77.6%
Negative predictive value	96.0	91.9-98.4%

The performance of the smartphone in staging diabetic retinopathy is shown in Table 3. For Nonproliferative Diabetic Retinopathy (NPDR), the sensitivity and specificity were 60.9% (95% CI, 38.5-80.3%) and 94.3% (95% CI, 89.8-97.2%) respectively with a positive predictive value of 58.3% and a negative predictive value of 94.9%. However, for proliferative diabetic retinopathy, the sensitivity and specificity were 100% (95% CI, 29.2-100%) and 99.4% (95% CI, 97.0-100%). The positive predictive value was found to be 75% and negative predictive value, 100%. For macular edema, the sensitivity and specificity were 38.5% (95% CI, 13.9-

68.4%) and 97.9% (95% CI, 94.7-99.4%) respectively with a positive predictive 55.6% and negative predictive value of 95.9%.

Table 3: Validity of smartphone funduscopy in staging of diabetic retinopathy

Smartphone funduscopy stage	Sensitivity [95% CI]	Specificity [95% CI]	Positive predictive value (PPV)	Negative Predictive value (NPV)	+ Likelihood Ratio [95% CI]	- Likelihood Ratio [95% CI]
NPDR	60.9% [38.5-80.3%]	94.3% [89.8-97.2%]	58.3% [36.6-77.9%]	94.9% [90.5-97.6%]	10.7 [5.4-21.3]	0.4 [0.25-0.69]
PDR	100% [29.2-100%]	99.4% [97.0-100%]	75.0% [19.4-99.4]	100% [98.0-100%]	181.0 [25.6-1278]	0.00
Macular edema	38.5% [13.9-68.4%]	97.9% [94.7-99.4%]	55.6% [21.2-86.3%]	95.9% [92.0-98.2%]	18.17 [5.5-59.6]	0.63 [0.4-0.9]

DISCUSSION

In our study, there were a total of 388 eyes from 207 patients which were analysed. Of the 207 study patients, 28 were diagnosed by indirect ophthalmoscopy as having diabetic retinopathy. Thus the prevalence of diabetic retinopathy in this study was 13.5%. Comparable findings were observed in studies done also at MRRH, Uganda⁷, which found a prevalence of 16.8% and in Nigeria⁸ which found a prevalence of 15% of diabetic retinopathy.

The male to female ratio in this study was 1:2.3. This is similar to the 1:2 male to female ratio reported at MRRH, Uganda⁷ and 1:2.4 male to female ratio reported in a hospital based study of the prevalence of diabetic retinopathy in Zimbabwe⁹. There are usually differences in the sex ratio across countries and this can be as a result of the biologic makeup, culture, lifestyle and the environment.

Mean age in this study was 56 years, this correlates with the previous study done on diabetics attending MRRH in 2014⁷ who also found a mean age of 56 years. Similar findings were also observed in Mbarara, Uganda where a mean age of 57.8 years was found¹⁰ and in Yemen which was 55.3 years¹¹. This is in accordance with knowledge that the risk of developing diabetes increases with age.

With reference to the gold standard utilized in our study, we found that the overall sensitivity of smartphone funduscopy in diagnosing diabetic retinopathy using the Samsung Galaxy S6 Edge, was 70% with a specificity of 94%. This sensitivity is much lower than that which was found in similar studies which had sensitivities of 96%¹² and 92.7% respectively in diagnosing diabetic retinopathy⁶. This finding can possibly be explained by a number of factors. Firstly, most participants in our study who had a diagnosis of diabetic retinopathy, had Nonproliferative (NPDR) of which the majority were mild

NPDR. Mild NPDR is characterized by microaneurysms alone and the researchers observed that the Welch Allyn panophthalmoscope and S6 Edge didn't perform well enough to identify subtle changes in the retina e.g. single microaneurysms.

Secondly, although the principal researcher, an ophthalmology resident, received some training in fundus photography, her skillset and technique may not be quite as versed as that of a Retina specialist. Thus, explaining the lower sensitivity seen in our study as compared to the above mentioned studies where smartphone fundus photography was performed by a trained retinal photographer or a retinal specialist.

Although the sensitivity of diagnosing diabetic retinopathy in our study was 70%, which was lower than other studies, another study observed that their sensitivity of diagnosing diabetic retinopathy by smartphone fundus photography with the Iphone 5, was only 50% with a specificity of 94%¹³. Their justification was that a medical student with limited training in fundus photography performed the smartphone photography, whereas another study where a retinal specialist performed fundus photography had a much better sensitivity of 92.7%⁶. Indicating that if the person has received intensive training and has extensive expertise in fundus photography, this diagnostic test will most likely perform better.

This study revealed a sensitivity of 100% and a specificity of 99.4% for proliferative diabetic retinopathy which is similar to what was observed in other studies done by Russo *et al*¹² and Rajalakshmi *et al*⁶. This is explained by the advanced disease and very obvious fibrovascular membranes seen obliterating the optic discs and extending to the macula in the patients who were diagnosed as having proliferative diabetic retinopathy in our study. These were easily identifiable in the Samsung S6 Edge smartphone photos. The studies done by Rajalakshmi *et al*⁶ combined sensitivities and specificities for both proliferative diabetic retinopathy and macular edema, as well as Toy *et al*¹⁴ who combined sensitivities and specificities for macular edema, moderate NPDR, severe NPDR and PDR rather than illustrating the findings separately as done in our study.

The excellent sensitivity in grading proliferative diabetic retinopathy found in our study, was offset by a poor sensitivity in identifying macular edema, which was observed to be 38.5% but with a specificity of 97.9%. The reason for this was that macular edema could not be clearly distinguished from maculopathies including drusen in the macular area. Hence, there was a large number of false negative patients who had macular edema but this was erroneously identified as macular drusen on smartphone fundus photography. Additionally, unless the crystalline lens was completely clear, the photo quality of the macular reflex was suboptimal, thereby interfering with the ophthalmologist's ability to clearly diagnose macular edema.

In our study the kappa agreement for diagnosis of diabetic retinopathy was 0.86. This was consistent

with the kappa agreement found in Rajalakshmi *et al*'s⁶ study (0.9) but better than that found in Ryan's study. This perfect agreement score indicated that there was an exceptionally good agreement in diagnosing diabetic retinopathy using smartphone photographs between the two readers in this study. In terms of grading of diabetic retinopathy, the kappa agreement in our study was 0.84, which was comparable to 0.80 for sight threatening diabetic retinopathy⁶.

CONCLUSION AND RECOMMENDATIONS

The sensitivity of the Samsung S6 Edge Galaxy in diagnosing diabetic retinopathy was observed to be 70% and its specificity 94%. However, the smartphone had a sensitivity and specificity in staging proliferative diabetic retinopathy of 100% and 99.4% respectively.

Based on the sensitivity and specificity of smartphone funduscopy in diagnosing and staging diabetic retinopathy derived from our study, the use of the smartphone as a screening tool in diabetics is not recommended. However, a further study should be done by a well-trained person, who is skilled in the use of this gadget so that conclusive observations can be made about the sensitivity and specificity of smartphone funduscopy.

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Epidemiology of red eyes in a teaching hospital in Ghana

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ABSTRACT

Objective: To determine the epidemiological characteristics and aetiology of red eyes in a teaching hospital in Ghana.

Design: This was a retrospective hospital-based case study.

Materials and Methods: The files/ folders of new patients with red eyes during the study period were retrieved. The epidemiological characteristics and diagnosis were perused and the relevant data extracted using a structured questionnaire for each patient and the data was analysed.

Results: Nine hundred and six (47.09%) new patients who presented to the eye clinic had a red eye. There was no statistically significant difference between males and females among new patients who presented with a red eye and those who presented with other eye disease ($p=0.75$). Six hundred and seventy four (74.40%) new patients with red eyes were below the age of 30 years and 521 (57.51%) were children and/or students ($p<0.00$). The top 5 eye diseases that accounted for the red eye in our study were conjunctivitis (48.23%), ocular trauma (39.85%); infective keratitis/corneal ulcer (5.96%), uveitis (3.42%) and scleritis (1.10%).

Conclusion: The red eye represented approximately 47% of all new patients that attended the Eye Clinic during the study period and most of the causes were avoidable, preventable and/or treatable.

Key words: Epidemiology, Red, Eye, Ghana

INTRODUCTION

The red eye is the cardinal sign of ocular inflammation, almost any part of the eye, including the lacrimal glands and eyelids, or faulty tear film can lead to red eye and it is one of the most common ophthalmologic conditions in the primary care setting¹. In a study done on the differential diagnosis of red eye: a survey of medical practitioners from Eastern Europe and the Middle East, red eyes accounted for approximately 15% of consultations with ophthalmologists².

In a study done in Nigeria on the pattern of red eye in a tertiary eye clinic, 4,550 patients presented to the eye clinic, out of which 2,623 (57.6%) presented because of red eye³. In a rural setting, in the Bawku Hospital eye unit in Ghana, a total of 21,391 patients were seen as outpatients, out of which 8,931 were red eyes, representing over 40% of the total number of patients screened⁴.

Redness in the eye can be caused by many conditions and injuries that can lead to irritation, blood in the eye, or swelling of blood vessels⁵. Allergic conjunctivitis was the most common diagnosis (35%), followed by dry eye (25%) and bacterial conjunctivitis (24%) in a study done in Eastern Europe and the Middle East on the differential diagnosis of red eye in 2006². The major causes of red

eye were due to ocular allergy 1,288 (49.1%), microbial conjunctivitis 293 (11.2%), and ocular trauma 286 (10.9%) in Nigeria³. In 2004, the common causes of acute red eye in Ghana were conjunctivitis, trachoma, corneal ulcer, acute iritis, acute glaucoma, injury (or trauma) and use of harmful traditional medicines for other eye conditions⁴.

While the more serious causes of red eye need prompt recognition and management by an eye specialist, in many cases red eye can be managed at the first point of health care (primary level)⁶. Primary care physicians often effectively manage red eye, although knowing when to refer patients to an ophthalmologist is crucial⁷. If primary health care workers are able to differentiate the various causes of red eye and provide primary level treatment, patients would be managed quicker at all levels and tertiary centres would also be relieved of treating simple conditions⁶. This would enable more time and resources to be allocated to eye conditions that need the attention of specialists in tertiary centres thereby improving quality and standards of eye care at all levels. Notwithstanding, studies on red eyes are scarce in our setting. This study was done to determine the epidemiological characteristics and aetiology of red eyes in Tamale Teaching Hospital, Ghana.

MATERIALS AND METHODS

Study design and setting: This study was a retrospective hospital-based case series. The study population included all new patients who attended the Tamale Teaching Hospital (TTH) Eye Clinic on out-patient basis or admitted at TTH eye ward during the study period. The study setting is a teaching and referral hospital located in Tamale, Ghana. Tamale is about 500km north of Accra, Ghana's capital city.

Data collection procedure: Data was collected by liaising with the medical information/record officers working at the records office. All new patients with a red eye from 1st January to 31st December 2010 were included. The patients' numbers were obtained from the out-patient attendance record and the in-patient record book in the clinic and the ward, respectively. This information was then used to retrieve all new patients' files at the medical information and records department. Patients with missing files/folders were excluded. The relevant data such as epidemiological characteristics and diagnosis were reviewed, collected and entered into a structured questionnaire. Any additional information or clarification was obtained from the medical staff where necessary.

Data management: Each questionnaire had a serial number which was the unique key identifier variable and each patient's medical record/file was linked to this serial number. A separate code book was used to store this information including the out-patient and in-patient numbers. Each questionnaire was cross checked for completeness after data collection for each day. The original medical record was used to fill in missing blanks. Data was validated prior to entry. Double entry of questionnaire into computer's Microsoft Excel data base 2010 was done to reduce errors.

Statistical analysis: The data was then exported into STATA version 12 (Stata Corp, College Station, Texas). Descriptive analysis was done to determine the frequencies and proportions for the various variables (continuous/categorical) and presented in figures or tables where appropriate. Fisher's exact test and Chi-square test for trend were used to test for associations among categorical variables. A p-value of less than 0.05 was considered significant in all statistical analysis.

RESULTS

A total of 2,027 new patients with various eye diseases attended the Tamale Teaching Hospital (TTH) Eye Clinic during the study period. One thousand nine hundred and twenty four files/folders were analyzed. One hundred and three files/folders were missing and thus were excluded from the study. A data collection flow chart is illustrated in Figure 1. Approximately 47% of new patients presenting to the eye clinic had a red eye as illustrated in Figure 1.

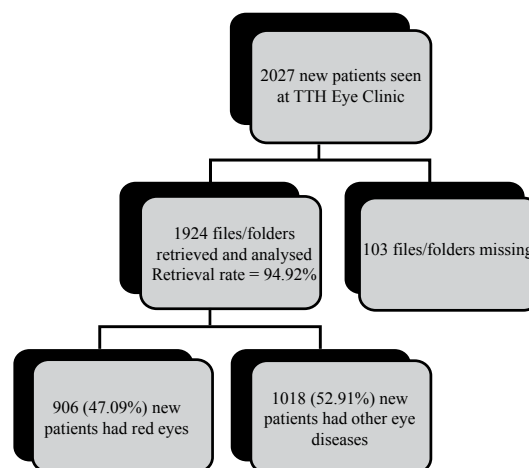


Figure 1: Flow chart showing data collection at TTH Eye Clinic

Table 1: Demographic characteristics of new patients with a red eye and other eye diseases attending the eye clinic

Characteristics of patients	Red eye No. (%)	Other eye diseases No. (%)
Sex		
Male	389 (42.94)	447 (43.91)
Female	508 (56.07)	566 (55.60)
Unrecorded	9 (0.99)	5 (0.49)
Total	906 (100)	1018 (100)
Age (years)		
0-9	232 (25.61)	53 (5.21)
10-19	202 (22.30)	90 (8.84)
20-29	240 (26.49)	107 (10.51)
30-39	123 (13.58)	190 (18.66)
40-49	57 (6.29)	152 (14.93)
50-59	26 (2.87)	121 (11.89)
60-69	25 (2.76)	292 (28.68)
70-79	0 (0.00)	2 (0.20)
80-89	1 (0.11)	11 (1.08)
Total	906 (100)	1018 (100)
Occupation		
Child/student	521 (57.51)	198 (19.45)
Farmer	53 (5.85)	61 (5.99)
Manual	158 (17.44)	225 (22.10)
Professional	75 (8.28)	159 (15.62)
Unemployed	47 (5.19)	91 (8.94)
Retired	11 (1.21)	239 (23.48)
Unrecorded	41 (4.53)	45 (4.42)
Total	906 (100)	1018 (100)

The male to female ratio for patients with red eyes was 1:1.3. There was no statistically significant ($p=0.75$) difference between males and females among new patients who presented with a red eye and those who presented with other eye disease in this study. The red eye was most common among the 20-29 year age group.

Six hundred and seventy four (74.40%) were below the age of 30 years. Approximately 58% were children and/or students ($p<0.00$) as shown in Table 1.

Table 2: Distribution of patients by eye disease presenting with a red eye

Eye disease presenting with red eye	No. (%)
Conjunctivitis	437 (48.23)
Ocular trauma	361 (39.85)
Infective keratitis/corneal ulcer	54 (5.96)
Uveitis	31(3.42)
Scleritis	10(1.10)
Endophthalmitis	8(0.88)
Acute angle-closure glaucoma	2(0.22)
Herpes zoster ophthalmicus	2 (0.22)
Panophthalmitis	1 (0.11)
Total	906(100)

The top 5 eye diseases that accounted for the red eye in this study were conjunctivitis, ocular trauma, infective keratitis/corneal ulcer, uveitis and scleritis as illustrated in Table 2.

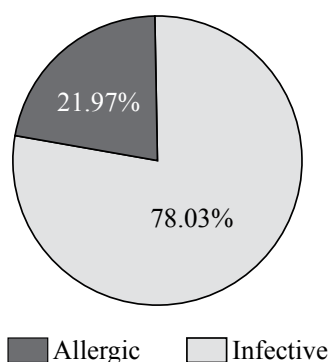


Figure 2: Distribution of patients by type of conjunctivitis (n=437)

Allergic conjunctivitis was the commonest (n=341) cause of conjunctivitis as shown in Figure 2. Males were 154(45.16%) and females 187(54.84%) with a sex ratio of 1:1.2 ($p=0.41$). Two hundred and ninety four (86.22%) were children and/or students ($p<0.00$) and the majority, 121(35.48%), were in the 10 – 19 year age group ($p<0.00$). Mild blunt trauma was the most common (n=273) category of ocular trauma as shown in Figure 3.

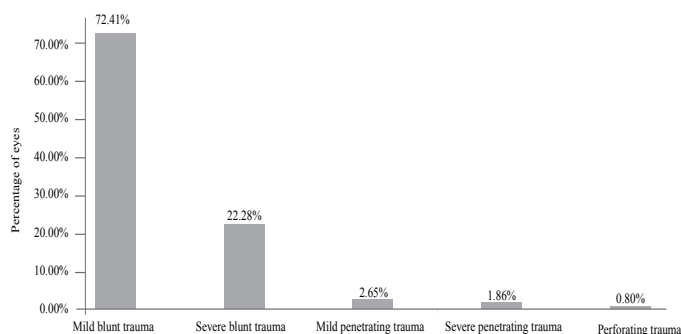


Figure 3: Distribution of eyes by category of ocular trauma (n=377)

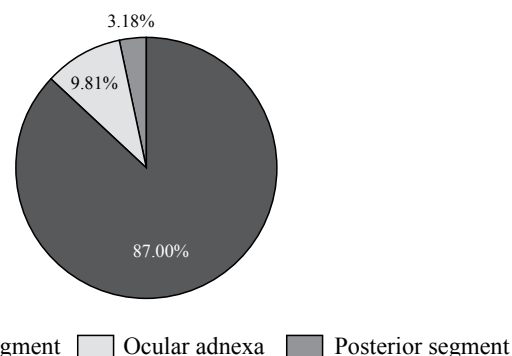


Figure 4: Distribution of eyes with ocular trauma by adnexa, anterior and posterior segment involvement (n=377)

The anterior segment was the most common (n=328) part of the eye involved in ocular trauma as illustrated in Figure 4.

DISCUSSION

Nine hundred and six (47.09%) new patients who presented to the eye clinic had a red eye in our study. This is consistent with a previous study done in the Bawku Hospital Eye Unit, Ghana, where red eyes represented over 40% of the total number of patients screened⁴. Also, in a tertiary eye clinic in Nigeria, 57.6% of patients presented to the eye clinic because of red eyes³. However, the proportion of patients with red eye was rather lower in other studies. In a teaching hospital in Nigeria, 4,723 new patients were seen in the eye clinic and 693 patients (14.8%) had red eyes⁸ and in a survey of medical practitioners from Eastern Europe and the Middle East, red eyes accounted for approximately 15% of consultations with ophthalmologists². The higher proportion of red eye in our study may be partly due to the few primary and secondary level eye health care personnel and scarce specialists who are only stationed at the study facility.

The male to female ratio for new patients with red eyes was 1:1.3. There was no statistically significant differences ($p=0.75$) between males and females among new patients who presented with a red eye and those who presented with other eye disease in this study. This is consistent with other studies where 356 males and 337 females (M:F= 1.1:1) were seen with red eyes⁸. However, a study done on the epidemiology and symptoms of red eyes in patients from Northern Iran revealed a preponderance of males (62.5%) over females (37.5%)⁷.

The red eye was most common, 240 (26.49%), among the 20-29 year age group closely followed by the 0-9 year age group, 232 (25.61%) and the 10-19 year age group 202 (22.30%). Six hundred and seventy four (74.40%) new patients with red eyes in our study were below the age of 30 years. In other studies; the majority of patients were within the age group 0-15 years (39.6%) followed by the age group 16-31 years (32.8%)³ and 63% of the

patients with a red eye were below the age of 20 years⁸. Five hundred and twenty one (57.51%) patients with red eyes were children and/or students. This is consistent with a study done on the pattern of red eye in a tertiary eye clinic, where the majority, 50.09%, were preschool children and students³.

The top 5 eye diseases that accounted for the red eye in this study were conjunctivitis, 437 (48.23%); ocular trauma, 361 (39.85%); infective keratitis/corneal ulcer, 54 (5.96%); uveitis, 31 (3.42%) and scleritis, 10 (1.10%). In other studies, the major causes of red eye were due to ocular allergy 1,288 (49.1%), microbial conjunctivitis 293 (11.2%), and ocular trauma 286 (10.9%)³ and in a teaching hospital in Nigeria, the common cause of the red eye was allergic conjunctivitis in 40% of the patients⁸. Also, allergic conjunctivitis was the most common diagnosis (35%), followed by dry eye (25%) and bacterial conjunctivitis (24%) in a study done in Eastern Europe and the Middle East on the differential diagnosis of red eye².

Conjunctivitis included both allergic, 341 (78.03%) and infective, 96 (21.97%) causes. Fasasi *et al*⁹ found that of 200 patients that presented with conjunctivitis, 163 (82%) patients were due to allergic conjunctivitis. This is consistent with our study. Among patients with allergic conjunctivitis males were 154 (45.16%) and females 187 (54.84%) with a sex ratio of 1:1.2 ($p=0.41$). This agrees with a hospital-based retrospective study of new patients with allergic conjunctivitis in Jos-Nigeria, where 474 (48.8%) males and 498 (51.2%) females with M:F ratio of 1:1.05¹⁰ and with a study done on allergic conjunctivitis in a tertiary eye hospital were 80 males and 83 females were affected⁹.

In terms of occupation, 294 (86.22%) were children and students. The majority, 121 (35.48%) were in the 10 – 19 year age group. In Nigeria, allergic conjunctivitis was more prevalent in those aged 1–16 years, 38.4%¹⁰. In another study, majority (43.6%) of the patients were within the age groups of 17–33 years, followed by 0–16 years (42.3%)⁹.

Mild blunt trauma was the most common, 273 (72.41%), category of ocular trauma that caused a red eye in this study. Bonsaana *et al*¹¹ reported that majority of ocular trauma patients presented with minor injuries which healed without complications. In contrast to our study, Rafindadi *et al*¹², found that 49.3% of patients had mild blunt trauma in their study. The high cases of mild blunt trauma in our study may be partly a reflection of the very few ophthalmic health care providers at all levels of care who are only stationed in the hospital where the study was done. This situation was vindicated in a related study in Ghana where approximately 68% of ocular trauma patients were seen at a teaching and referral hospital without a referral¹¹. The anterior segment was the most common, 328 (87%), part of the eye involved in ocular trauma in our study. This is consistent with a

study done in Ethiopia in which the anterior segment was involved in 80% of the cases¹³ and in India¹⁴ where majority of the patients presented with only anterior segment involvement (86.67%). This may be due to the fact that the anterior segment is the most exposed part of the eye to the external environment and thus vulnerable to external insults.

CONCLUSION

Red eyes accounted for approximately 47% of all new patients seen with equal male to female ratio and the peak incidence occurred in children and /or students. The top 5 eye diseases that accounted for the red eye in this study were conjunctivitis, ocular trauma, infective keratitis/corneal ulcer, uveitis, and scleritis. Most causes of the red eye were in the majority of cases avoidable, preventable and treatable.

LIMITATIONS

This was a single hospital-based study and may not be a true representative of what pertains in the general population. The inherent nature of retrospective study might have affected the distribution of cases in this study.

Disclosures: The authors have no actual or potential conflict of interest in relation to this research work.

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Work related ocular injuries in small scale industries

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ABSTRACT

Background: The risks of ocular trauma are reported to have increased among small scale industrial workers in developing countries.

Objective: The aim of this study was to evaluate the magnitude and causes of ocular injuries as well as the use of personal protective devices in small scale industries in Woliso town, central, Ethiopia.

Methods and subjects: This cross sectional study design was carried out over one month, August 22-September 16, 2011 in Woliso town. Technical workers of forty one small scale industries were traced and participated in the study. Data collection and ocular examination were performed by the principal investigator on site.

Results: Of the total 233 technical workers in 41 small scale industries, 224 participants were included in the study making a response rate of 96.1%. Seventy seven (34.4%) of them had history of ocular injuries. Majority of ocular injuries, 32/77 (41.6%), occurred among metal workers. The main causative agents were iron chips in 24 (31.2%) cases. Most study participants, 128 (57.1%), did not use personal protective devices at all. Regardless of its appropriateness, only 13 (16.9%) cases with ocular trauma used some kind of protective devices at the time of injury.

Conclusion: Work-related eye injuries are found to be common (34.4%) among small scale industry workers. More than half of the workers do not use personal protective equipments. These necessitate the need for health education focused on appropriate health and safety training for workers and employers. Provision of appropriate personal protective devices and strict supervision of workplace is strongly recommended.

Key words: Injury, Industry, Work-related

INTRODUCTION

Ocular trauma has recently been highlighted as a major cause of visual morbidity. Ocular injuries are common and largely preventable causes of monocular visual impairment and blindness¹. Globally more than half a million blinding injuries occur every year, there are approximately 1.6 million people blind from eye injuries, 2.3 million bilaterally visually impaired and 19 million with unilateral visual loss². Ocular injury is a significant cause of monocular visual impairment in Ethiopia^{3,4} whose prevalence accounted for 5.1% according to a community based study⁵.

Small scale industries are considered as the backbone of the private sector all over the world, which assures their role in production, employment and sales⁶. Small Scale enterprises have a dominant place in the Ethiopian economy. The sector is the second largest source of employment next to agriculture⁷. The risks of ocular trauma have been reported to have increased among small scale industrial workers in developing countries because of poor working conditions, longer hours at work and poor safety precautions⁸. Ninety percent of all eye injuries can be prevented by using appropriate protective eye wear^{9,10}.

Almost 100 years ago, more than 70% of all serious injuries occurred at the workplace². There is significant shift from workplace to home as a place of eye injuries as most studies show but the workplace remains the most important site in the developing countries^{3,4,11}. Extension of on-the-job safety to the home environment and the application of modern principles of surgical salvage also contribute to prevention of ocular trauma and minimizing the effects of ocular trauma on vision respectively^{9,10}.

Although small scale industries are expanding in Ethiopia in recent years, not much data is available on occupational health and workers practice. The objective of this study was, therefore, to evaluate the magnitude and causes of ocular injuries as well as the use of personal protective devices in small scale industries in Woliso town, central Ethiopia.

MATERIALS AND METHODS

This cross sectional study was carried out over 1 month, August 22nd-September 16th, 2011, in Woliso town. Woliso is a town in central Ethiopia located at 115 km southwest of Addis Ababa. Woliso has an estimated total population

of 45,537 of whom 21,940 were male and 23,597 were female. The town has 5 medium scale industries (soap, oil and flour factories) employing more than 500 workers and more than 50 small scale industries (grain mills, metal work, wood work, cement brick production and garages) in the town employing more than 350 workers.

The study was carried out after getting permission from the ethical clearance committee of the Department of Ophthalmology, Faculty of Medicine, Addis Ababa University. Data was collected after getting written consent from Woliso Town administration. Informed verbal consent was obtained from the owners of each industry and study participants. Non-technical workers and absentees during the whole period of data collection were excluded.

Information and addresses of small scale industries were obtained from micro finance and small scale industries bureau and trade bureau in the town. Then, with the help of programme coordinators, 41 small scale industries were traced and participated in the study. All technical workers in these industries were included in the study. Data was collected by the principal investigator with face to face interview using standardized questionnaire which includes socio-demography, type of work, use of personal protective devices and history of work related injury.

Ocular examination was done on site. Visual Acuity (VA) was taken using Snellen's chart at 3 mts and pinhole test was applied when VA was less 6/18. Anterior segment examination was made using portable slit-lamp while fundus evaluation was made using direct ophthalmoscope. When there was more than one injury, the most frequent or more severe one was taken. At each site, the participants were provided with brief information about how to prevent work related injuries and individual participants with minor ocular disorders were treated on site.

The following operational definitions were used. Small scale industries are establishments employing less than ten persons and using motor operated equipment¹². Work related injury is a condition sustained by a worker in connection with the performance of his or her work on site or as assignment¹³. Data were analyzed using SPSS for Windows version 16.0. Associations between variables were checked by Chi-Square test and significance considered when $p < 0.05$.

RESULTS

A total of 224 participants were included in the study. The majority of study participants 215 (95.9%) were males. The mean (SD) age of respondents was 23.9($\pm$ 6.63) years, ranging from 15 to 54. Ninety four (40.0%) respondents were high school graduates. One hundred and sixty six (74.1%) respondents had five years and below service duration (Table 1).

Table 1: Socio-demographic characteristics of the study population

Variables	No. (%)
Sex	
Male	215(95.9%)
Female	9(4.1%)
Age (years)	
15-24	162 (72.3%)
25-34	45 (20.4%)
35-44	11 (4.9%)
>44	6 (2.7%)
Educational status	
Illiterate	1 (0.4%)
Read & write	27 (12.1%)
Primary school(1-8)	72 (32.1%)
Secondary school	94 (42.0%)
12+	30 (13.4%)
Service duration (years)	
≤ 5	159 (71.0%)
>5	95 (29.0%)

Male dominance is clearly revealed from this table

Majority of the study participants 66 (29.5%) were working in grain mills followed by 54 (24.1%) who were working in metal workshops. Seventy seven (34.4%) participants had history of ocular injuries, of which 47(61.0%) had more than one ocular injuries. Majority of ocular injuries, 32 (59.3%), occurred among metal workers, followed by workers in blocket production 7 (38.9%) (Table 2). The relative risk of ocular trauma among workers in metal workshop and blocket production compared to grain mill workers were 3.26 and 2.14 respectively.

Table 2: Distribution of work related eye injuries by type of industry

Type of industry	Total number of workers	Cases with eye injury (%)	Relative risk
Grain mills	66	12(18.2)	1
Wood work shops	50	14(28.0)	1.54
Garages	36	12(33.3)	1.83
Blocket production	18	7(38.9)	2.14
Metal work shops	54	32(59.3)	3.26
Total	224	77(34.4)	

Workers of metal work-shops are relatively at higher risk of getting eye injuries

The main specific activities the workers were doing at the time of injury were grinding 23 (29.3%), welding 16 (20.7%), saw mill 13 (16.8%), stone shaping 9 (11.7%), mixing 8 (10.4%), drilling 5 (6.4%) and others 3 (3.9%). The main causative agents were iron chips in 24 (31.2%), followed by welding light and smoke in 16 (20.8%) of the injured cases (Table 3).

Table 3: Causes of ocular injuries in small scale industries in Woliso town

Causative agents	Cases with eye injury	
	No.	(%)
Iron chips	24	31.2
Welding light and smoke	16	20.7
Sand and stone	16	20.7
Wood chips	11	14.6
Hand tools	5	6.5
Chemicals	2	2.3
Others	3	4.0
Total	77	100

Trauma with iron chips was more common among small scale industries.

Most study participants, 128 (57.1%), did not use personal protective devices at all and only 17 (7.6%) used any kind of protective devices available all the time. Frequent personal protective devices use was higher among metal workers 43(79.6%), followed by garage workers 22 (61.1%) (Table 4). The main reasons given for not using personal protective devices were negligence in 93 (45.0%), absence of the devices in 51 (24.5%), lack of awareness in 38 (18.5%) and decrease of clarity and work performance in 25 (12.0%) of workers.

Table 4: Use of personal protective devices (PPD) by type of industry

Type of industry	Frequency of PPD,N (%)			Total (100%)
	Always	Occasionally	Never	
Metal work shops	16(29.6%)	27(50%)	11(20.4%)	54
Garages	1(2.8%)	21(58.3%)	14(38.5%)	36
Wood work shops	0	22(44%)	28(56%)	50
Cement brick production	0	2(11.2%)	16(88.9%)	18
Grain mills	0	7(10.6%)	59(89.4%)	66
Total	17(7.6%)	79(35.3%)	128(57.1%)	224

Although metal workers sustained more trauma to their eyes, they seem to use protective devices often compared to workers of other categories.

Majority of participants, 193 (86.2%), had neither training on occupational health and safety nor training in connection to the work they were doing in 194 (86.6%). Sixty four (83.1%) did not use personal protective devices at the time of injury. Chi-square test was used to see the association between ocular injury and certain socioeconomic and work environment variables. As a result, educational level, type of industry, duration of service and failure to use personal protective device was statistically significantly associated with ocular trauma (P-value <0.05). However, sex, age, occupational health and safety training did not show significant association with ocular injury (Table 5).

Table 5: Risk factors for work related eye injuries

Variables	Yes N(%)	No N(%)	p-value
Sex			0.43
Male	75(34.9)	140(65.1)	
Female	2(22.2)	7(77.8)	
Age (years)			0.62
15-34	72(34.8)	135(65.2)	
>35	5(29.4)	12(70.6)	
Educational status			0.01
Primary school and below	22(22)	78(78)	
Secondary school (9-12)	42(44.7)	52(55.3)	
12+	13(44.3)	17(56.7)	
Type of industry			0.001
Metal work	32(59.3)	22(40.7)	
Blocket production	7(38.9)	11(61.1)	
Garage	12(33.3)	24(66.7)	
Wood work	14(28.0)	36(72.0)	
Grain mill	12(18.2)	54(81.8)	
Service duration			0.01
≤5 years	46(28.9)	113(71.1)	
>5 years	31(47.7)	34(52.3)	
Job training			0.13
Yes	14(46.7)	16(53.3)	
No	63(32.5)	131(67.5)	
Occupational health and safety training			0.08
Yes	15(48.4)	16(51.6)	
No	62(32.1)	131(67.9)	
PPE use at time of injury			0.001
Yes	13(16.9)		
No	64(83.1)		

Among the 77 injured participants, 41(53.2%) had treatment by untrained friends, 19 (24.7%) had self-treatment and (22.1%) had treatment in a health institution. Treatment by one self or friend was done using paper tips to remove foreign bodies in 21 (35%), water flushing in 16 (26.7%), eye drops in 14 (23.3%), fine wood sticks in 6 (10%) and other methods in 3 (5.0%) cases. Residual corneal opacity was detected in 11(14.3%) of injured patients. Best corrected visual acuity in the injured eyes was better than 6/18 in 72 (93.5%) participants and between 6/18-6/60 in 3 (3.9%) cases. There were two patients, (2.6%), with severe injuries; the first had evisceration while the second one had severe visual impairment from corneal opacity due to work related trauma.

DISCUSSION

Occupational eye injuries are common and preventable. Despite well publicized standards for industrial protection in developing countries, eye injuries in the workplace are a major cause of socioeconomic damage, morbidity, and disability¹. In our study, 77 (34.4%) of participants had history of ocular injuries. Majority of ocular trauma 32 (59.3%) occurred among metal workers, followed by workers in blocket production 7(38.9%) and garages

12 (33.3%). This is because grinding and hammering is commonly involved in these categories of jobs.

Our study showed that the main specific activities at the time of injury were grinding (29.3%) and welding (20.7%). Other studies from Pakistan¹⁴ and Victoria, Australia¹⁵ also reported grinding as the main activity at the time of injury. The main causative agents found were iron chips 24 (31.1%), followed by welding light and smoke 16 (20.7%) which is in agreement with other reports^{14,16}. Consistent use of personal protective devices was found to be 7.6% and this was also reported from Gondar, Ethiopia (unpublished data), Pakistan¹⁴ and Nigeria¹⁶.

Majority of participants 89 (92.7%) used plano or non plano (prescribed for refractive error) safety glasses while only 5 (5.2%) used goggles and 2 (2.1%) used face shield. Better use of goggles and face shield was reported previously^{15,17} which is determined by the economic standard, level of awareness, commitment of employers and supervisors.

We found that small scale industries are dominated by young male workers. In our study, age and sex did not show significant association with ocular injury although the proportion of females was small (4.1%) for comparison. A study done in Nigeria by Iyiade *et al*¹⁶ showed similar results. Another study by Dupesa *et al*¹⁸ also showed that young males are prone to eye injuries which may be because of male population dominating the industry.

As level of education increases, the magnitude of ocular trauma increases in our study. This may be because highly educated ones are assigned to more risky jobs or more tasks which may increase the risk of ocular injury. In addition, education only cannot eliminate injury when the level of hazards is high and when the use of reliable techniques and safe work organization are limited. A study from Nigeria by Iyiade *et al*¹⁶ showed similar results where educated ones were less aware of personal protective devices. A study from Gondar, Northern Ethiopia¹⁹, however, reported that educated individuals are less prone to eye injury.

Occupational health and safety training did not show any significant difference with regard to ocular injury in our study. This is not in agreement with another study conducted in Gondar, Northern Ethiopia¹⁹. This may be due to the fact that occupational health and safety training does not necessarily mean practice which is influenced by attitude, negligence, availability of personal protective devices and commitment of employers and supervisors.

Eye injuries are common among more experienced workers because the longer one works, the more likely the ocular trauma. With experience, negligence and fatigue to use personal protective devices may also occur. Type of industry showed statistically significant association with the occurrence of eye injuries. Given the low utilization of personal protective devices in our study, jobs which require hammering and grinding becomes a high risk for

eye injuries. A report from Gondar, Ethiopia¹⁹ showed similar results.

Failure to use appropriate personal protective devices is significantly associated with eye injuries. This is in agreement with many other studies^{14,17}. There was poor eye care seeking behaviour among workers. Only a quarter of the individuals who sustained eye injuries obtained treatment at health institutions by an ophthalmologist or ophthalmic nurses with low payment. A study from Gondar¹⁹ showed similar results. However, a Korean study by Jinky and Leilanie²⁰ revealed injured cases to be treated at health institutions. This could be due to differences in culture, economy, occupational health and safety regulations.

In conclusion, work-related eye injuries are common among small scale industrial workers. Majority of the workers do not use personal protective equipments and there is a very low eye care seeking behaviour as well. Based on these, we strongly recommend provision of health education and appropriate health and safety training for workers and employers. In addition, provision of appropriate and affordable personal protective devices, strengthening strict supervision of workplace and working conditions will reduce work related eye injuries.

ACKNOWLEDGEMENTS

We would like to thank St. Luck Hospital in Woliso Town for funding the research. We would also like to thank all the study subjects for their willingness and time to participate in the study. Our appreciation also goes to the administration, micro and small scale industry bureau and trade bureau of Woliso town for their help in tracing the working places. Our acknowledgement also extends to Dr Solomon Melaku and Dr Sadik Taju, who were helpful while we were conducting the study.

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Syringocystadenoma of the eyelid: a case report

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ABSTRACT

Syringocystadenoma papilliferum (SCAP) is a rare, benign tumour with varied presentations that arises from the apocrine glands and at times can lead to a diagnostic dilemma. Eyelid SCAP is exceedingly rare. The lesion is frequently misdiagnosed as basal cell carcinoma or cyst or squamous cell carcinoma. We report a case of SCAP diagnosed after histological examination.

Key Words: Syringocystadenoma papilliferum, Basal cell carcinoma, Squamous cell carcinoma, Eyelid tumour

INTRODUCTION

Syringocystadenoma papilliferum is a rare benign hamartomatous adnexal tumour¹ that can rarely affect eyelid skin². It thus presents a diagnostic dilemma, whereby it is usually misdiagnosed clinically as either basal cell carcinoma or squamous cell carcinoma since its clinical features are fairly non-specific². Although syringocystadenoma papilliferum of the eyelid can be associated with other benign lesions, no malignant transformation or association with malignant neoplasms has been reported and management should be conservative complete surgical excision^{1,2}.

CASE REPORT

A 52 year old female presented at SekuruKaguvi Hospital Eye Unit, Parirenyatwa Group of Hospitals with a mass on the left medial aspect of the lower eyelid near the punctum. She had the mass for the past 5 years and there was gradual increase in the size of the tumour. The main reason for presenting was the cosmetic concern and irritation she had recently developed.

Physical examination revealed a solitary, round, fleshy nodular mass measuring about 0.4cm X 0.4cm. (Figure 1A). The lesion looked lighter than the rest of the eyelid skin with some hyperkeratotic areas on its surface with a central umbilication. The posterior lamellar of the eyelid was not involved and the mass was not attached to deeper skin structures. She had several warty hyperpigmented growths on her lower eyelids and cheeks. There was no regional lymphadenopathy. A pterygium was also noted in the left eye. The rest of ocular examination (including that of the right eye) and general physical examination was unremarkable.



Figure 1A and B. In A, there is a nodular, fleshy and round mass with central umbilication on the lower eyelid. A pterygium can also be seen. In B, the defect after excision

Provisional diagnosis of a basal cell carcinoma was made and the patient was advised to have excision biopsy of the lesion done. The mass was excised in theater under local anaesthesia with a 2mm margin of healthy skin. A full thickness excision was done creating a defect (looks like <1/3) of the eyelid. Primary closure was therefore successfully done with 5/0 silk suture at the grey line of the lid margin followed by 6/0 vicryl suture in two layers up to the skin (Figure 2 after repair).



Figure 2: Appearance post-operative

The histology of the excised lesion showed acanthotic skin with a cystic lesion with papillary projections. The papillae were lined by a layer of columnar cells with an underlying layer of cuboidal to attenuated cells. Within the stroma, numerous plasma cells were seen. The lesion was continuous with the epidermis (Figure 3A and B at different magnifications). The findings were consistent with a diagnosis of syringocystadenoma papilliferum of the eyelid.

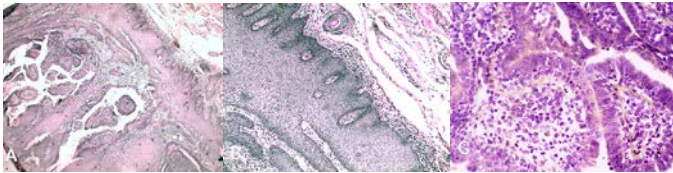


Figure 3A and B: Lower magnification showing cystic spaces with papillary projections. C, at higher magnification, showing that the papillae are lined by two layers of epithelium (columnar and cuboidal)

DISCUSSION

Syringocystadenoma papilliferum (SCAP) is a rare benign skin tumour, it is even rarer on locations like the eyelid². SCAP was first described by Stokes in 1917 when it was termed “Nevus Syringocystadenoma papilliferum”³. It is believed to arise from apocrine or eccrine adnexal structures⁴⁻⁶.

The tumour can be present at birth, adolescence and in adults. Usually a clinical diagnosis of basal cell carcinoma or squamous cell carcinoma of the eyelid is made before a histological specimen confirms a SCAP². In a series of 14 patients, most cases had a preoperative diagnosis of basal cell carcinoma or cyst. None of the lesions was associated with a malignant neoplasm⁷.

Cauliflower like, verrucous, papillary, hyperkeratotic, or sometimes moist fleshy excrescences have also been described². Some tumours may show central umbilications⁸ as in the presented case. Most of the lesions develop and enlarge slowly, although a few can increase significantly within a short period. Also, the lesion can develop ulceration and secondary infection².

The most frequent sites are the scalp, neck and face (75%), with already reported uncommon sites: eyelids, arms, buttocks, auricular pavilion, scrotum, vulva, back and abdomen which are very rare locations^{5,6}. SCAP has been associated with sebaceous nevus of Jadassohn in scalp locations⁹.

Squamous cell carcinoma and syringocystadenocarcinoma papilliferum were also reported as a progression of SCAP, but are extremely rare¹⁰. Treatment is usually surgical excision, but there are cases in which

removal was effective with CO₂ laser in locations unfavorable for surgery⁵.

CONCLUSION

This is the first reported case of syringocystadenoma papilliferum seen on a black Zimbabwean. The condition is benign and very rare, forms part of differential diagnosis to eyelid growths and is usually misdiagnosed as malignant basal cell carcinoma or squamous cell carcinoma and requires conservative surgical treatment.

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NOTES

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Healthy Eyes, Healthy People