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) ≥ 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 diabetes[1]. 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-diabetics[2]. More than 75% of patients who have diabetes for more than 20 years will experience vision loss from diabetic retinopathy[3]. The American Diabetes Association[4], 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 Bobb-Semple *et al.,* 2014 (Unpublished work) found that only 13.3% of patients seen at MRRH and Ruharo Eye Centre were referred from their diabetic clinic for ophthalmic evaluation as a result of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 dilation[5] with a Samsung Galaxy S6 Edge smart phone attached to it.

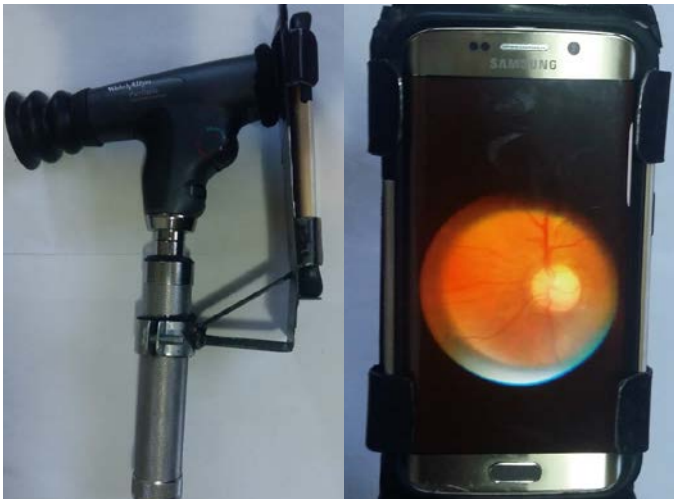

Figure 1: Welch Allyn Panophthalmoscope with Samsung Galaxy S6 Edge and one field of view

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).

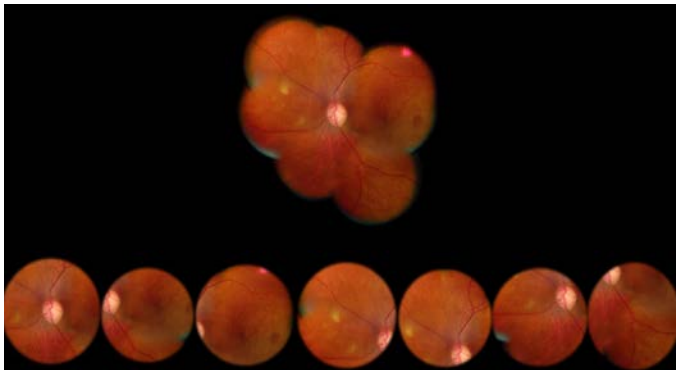

Figure 2: Seven Field Mydriatic Smartphone Retina Composite Image

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).

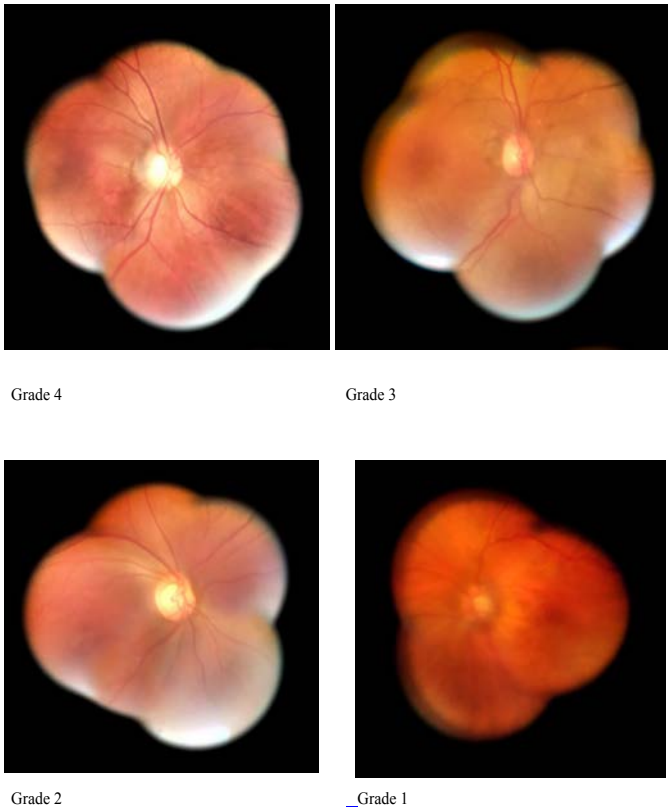

Figure 3: Image quality grades for smartphone photographs

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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3. Data on file (VIVID and VISTA BCVA plot points through Year 1).
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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 complaint		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, Uganda[7], which found a prevalence of 16.8% and in Nigeria[8] 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, Uganda[7] and 1:2.4 male to female ratio reported in a hospital based study of the prevalence of diabetic retinopathy in Zimbabwe[9]. 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 2014[7] 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 found[10] and in Yemen which was 55.3 years[11]. 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 retinopathy[6]. 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*'s[6] 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 retinopathy[6].

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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