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Original Article

Evaluating the impact of optical coherence tomography in diabetic retinopathy screening for an Aboriginal population

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Abstract

Importance: Optical coherence tomography is used routinely in management of diabetic eye disease but has not been evaluated in Australian outreach settings for screening programmes.

Background: The study aims to evaluate the use of optical coherence tomography combined with a fundus camera compared with a fundus camera only in a telehealth diabetic retinopathy screening programme for Aboriginal Australians.

Design: Retrospective comparative study was used.

Participants: The study included patients with diabetes at two Aboriginal Health Services.

Methods: An intervention group was studied in 2015 using a Topcon 3D optical coherence tomography-1 Maestro combined with optical coherence tomography/fundus camera. A control group was studied in 2014 using a DRS non-mydriatic fundus camera. Fundus photographs were emailed to trained retinal graders for review. Optical coherence tomography scans were graded by ophthalmologists via remote TeamViewer access.

Main Outcome Measure: Referral rates to an eye health professional and the rate of inadequate photographs.

Results: Two hundred and twenty-two patients were included, with 80 in the control group and 142 in the intervention group. There was a significantly higher rate of inadequate fundus photographs in the intervention group (31.0% *vs*. 13.8%). Although there was a higher rate of referral to an eye health professional in the intervention group (39.6% *vs*. 30.0%), this was not significant. Diabetic retinopathy and maculopathy was evident in 32.3% and 12.0% of adequate fundus photographs, respectively. Diabetic macular oedema was present in 3.6% of optical coherence tomography scans.

Conclusions and Relevance: The combined optical coherence tomography fundus camera provided no advantage for diabetic retinopathy screening compared with fundus photography in an Australian programme. The rate of referral to an eye health professional was not reduced with a higher rate of inadequate fundus photographs.

Key words: diabetic retinopathy, macular edema, mass screening, optical coherence tomography.

Introduction

Diabetic retinopathy (DR) is the leading cause of blindness in working-aged adults in developed countries.[1,2] In Australia, DR is seven times more common in Indigenous Australians than in non-Indigenous Australians as a result of higher diabetes prevalence.[3] This is exacerbated by the increased rate of progression of DR in Indigenous Australians.[4] Despite this, there is limited eye care access, with only 20% of Indigenous adults with diabetes surveyed meeting Australian guidelines for annual

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eye examinations.[5,6] Diabetes-related blindness is 14 times greater in Indigenous Australians than non-Indigenous Australians.[7]

Telehealth fundus photograph systems have been shown to be both reliable at detecting DR and cost-effective.[8–10] Furthermore, staff require only minimal training to perform fundus photography, and patient accessibility is improved.[8,10–12] Telehealth diabetic retinal screening results in decreased rates of DR-related vision loss and blindness when compared with all other forms of retinal evaluation.[13–16]

However, DR screening with fundus photography is limited in its ability to reliably diagnose diabetic macular oedema (DMO).[17,18] This may result in unnecessary referrals to ophthalmology clinics or instances of undiagnosed DMO in a screening population.[18–20] Early detection of DMO is important given that it is the most common cause of vision loss in diabetics and is prognostic for future vision loss.[1,21] It is also now more treatable with recent advances in anti-VEGF therapy.[22]

Optical coherence tomography (OCT) is now regarded as the gold standard diagnostic tool for DMO and, with increasing affordability and usability, has potential in DR screening programmes.[17,18] Research in the UK DR screening programme has demonstrated the advantages of using OCT before clinic referral in those patients deemed higher risk for having DMO based on fundus photograph findings.[23,24]

The literature to date for OCT in DR screening is limited to the scan being performed on a minority of patients only after an initial fundus photograph. The efficiency of outreach eye services could be enhanced by reducing unnecessary referrals for the purpose of excluding DMO using OCT. This study therefore explores the practicalities of using OCT as an initial screening tool concurrently with fundus photography in all screening patients.

Methods

Two Aboriginal Health Services within the Lions Outback Vision DR screening programme were selected – one urban and one remote. Camera operators included nurses and Aboriginal health workers. Ethical approval for the study was obtained from the Western Australian Aboriginal Health Ethics Committee.

Outcomes

The primary outcome of the project was to assess how the rate of patient referrals to an eye health professional was affected by the introduction of OCT. Secondary outcomes included the adequacy of imaging techniques and the prevalence of DR, maculopathy and DMO in a screening population.

Study design

The sample population included two Aboriginal Medical Services: Derbarl Yerrigan Health Service in Perth (Western Australia's capital city) and Wirraka Maya Health Service in Port Hedland (1650 km from Perth). Inclusion in the study required a previous diagnosis of diabetes. Individuals also needed to be screening patients, meaning they were not being reviewed by another eye health professional and had not received previous eye treatment.

An intervention group was studied prospectively during a 4-month period (May–August) in 2015 following the introduction of the combined OCT camera at both sites. The combined OCT camera is a Topcon 3D OCT-1 Maestro (Tokyo, Japan), which can simultaneously provide a high-resolution 45° colour fundus photograph and an OCT scan (50 000 A-scans/s at 12 mm wide × 9 mm height). A control group was audited retrospectively during the same 4 months in 2014 when sites used a CentreVue DRS fundus camera (Padova, Italy), which provides a high-resolution 45° colour fundus photograph. Both devices are non-mydriatic and semi-automated. In the control group, camera operators had been trained and were familiar with the DRS fundus camera. For the intervention group, initial training and ongoing technical support was provided to camera operators with the introduction of the combined OCT camera. A delay in the commencement of data collection of 2 months provided time for operators to adjust to the new camera.

Grading

All retinal photographs in the study were graded using international guidelines.[25] Ophthalmology referral is required for diabetic changes that are severe, proliferative or with maculopathy.[25] Furthermore, all photographs with moderate DR are reviewed by an eye health professional, although most are not referred. Maculopathy refers to any diabetic change, including microaneurysms only, found within one disc diameter of the foveal centre.[23,26] Retinal photograph graders were masked to the OCT scan for the intervention group and made a clinical interpretation and plan.

Optical coherence tomography grading for the intervention group was performed using the method outlined by Prescott *et al.*,[23] which incorporates the Early Treatment Diabetic Retinopathy Study (ETDRS) nine subfield map.[27] These criteria were based upon the findings of Massin *et al.*,[28] who compared various methods for quantifying

macular thickness in DMO.[23,28] Each of these nine subfields is shown on the OCT with the average retinal thickness measure. DMO is determined to be present when

- Retinal thickness is ≥250 μm in the central foveal region or ≥300 μm in the surrounding four (parafoveal) regions
- Visible intraretinal cyst/subretinal fluid on cross-section
- No other cause for macular oedema

Optical coherence tomography grading was performed by one of two ophthalmologists (a consultant and fellow), masked to the retinal photograph report. The ophthalmologist could view the retinal image and other clinical information at this stage. TeamViewer was installed on the combined cameras' computers so that the OCT scans could be remotely accessed from Lions Outback Vision. The final report sent back to screening sites incorporated the OCT results and subsequent management.

Screening pathway

There are three possible follow-up options for screening patients: ophthalmology referral, optometry referral or a repeat photograph in 12 months. This is summarized in Figure 1.

The key change in patient management for the intervention group occurred for those with mild–moderate DR and maculopathy. Previously, all such patients were referred for ophthalmology review to determine the presence of DMO. Referral to clinic would continue for those showing DMO on their OCT scan.[26] However, OCT scans showing more minimal changes could remain as screening patients with a repeat photograph and scan in 6 months.[26]

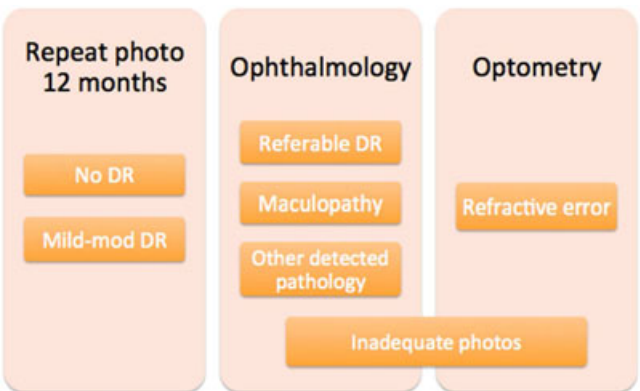

Figure 1. Patient management based on screening findings. DR, diabetic retinopathy.

Data collection and analysis

Data were collected from the centralized database of screening reports with analysis conducted through SPSS 22 (IBM, USA). Statistical tests for association used odds ratios (OR) and Pearson chi-square tests with Phi coefficients.

Results

There were 85 screening reports in the control group, of which 80 were included. In the intervention group, there were 157 screening reports of which 142 were included. This made for a total of 222 included reports. A total of 20 reports were excluded across both years for being screened twice within the same period (7), being managed already by ophthalmology or optometry services (6) or having received previous laser treatment (7). Two patients had no date of birth submitted and so were excluded from analysis using age, but were otherwise included. Three patients in the intervention group had only a fundus photograph and so were not included in analysis of OCT scans.

Patient characteristics

Of the 220 reports with a date of birth, the mean age was 53.5 years (95% confidence interval [CI] of 52.0 to 55.1). Ages ranged from 18 to 84 years. A total of 117 of the 222 screening reports were for male patients (52.7%, 95% CI 46.1–59.2%), with 105 (47.3%) for female patients.

Retinal photograph quality

The rate of adequate fundus photographs, by year and in total, is shown in Table 1. There was a significantly higher rate of inadequate photographs in the intervention group compared with the control group, shown with an OR associating the intervention group with adequate photographs of 0.355 (95% CI 0.171–0.736, $P < 0.05$).

Optical coherence tomography scan quality

Optical coherence tomography scans were performed in 139 patients in 2015 of which 79.1% were adequate in both eyes (95% CI 71.6–85.1%). A quality comparison of OCT scans and fundus photographs

Table 1. Photograph quality by year

	2014		2015		Total
Adequate	69	86.3%	98	69.0%	**167**
Inadequate	11	13.8%	44	31.0%	**55**
Total	**80**		**142**		**222**

These figures are bolded as they represent summative or total numbers (i.e. the sum of the other numbers in their respective columns or rows).

is displayed in Table 2. There was a strong association between referrals having an inadequate fundus photograph and an inadequate OCT scan, $x^2(1) = 28.14$, $P = 0.000$, $\varphi = 0.450$, reflecting the higher rate of inadequate OCT scans in those with inadequate fundus photographs compared with adequate photographs (52.3% *vs.* 8.4%).

Diabetic retinopathy prevalence and severity

Diabetic retinopathy was identified in 54 patients with adequate fundus photographs across both years (32.3%, 95% CI 25.7–39.8%). Mild DR accounted for the majority of identified DR (55.6%, 95% CI 42.4–68%). A further 38.9% were of moderate grade (95% CI 27.0–52.2%), with only three instances of severe or proliferative disease. Although DR prevalence was higher in the intervention group (35.7% *vs.* 27.5%), this was not significant, $x^2(1) = 1.238$, $P = 0.266$. In those with DR, there was no significant association between the screening year and DR severity (mild *vs.* more severe), $x^2(1) = 0.102$, $P = 0.75$.

Maculopathy and diabetic macular oedema

Maculopathy was identified in 12% of referrals with adequate photographs ($n = 20$, 95% CI 7.8–17.9%) and 37% of those with DR (95% CI 25.4–50.4%). DMO was diagnosed in 3.6% of referrals with an OCT scan ($n = 139$, 95% CI 1.2–8.2%) and 30% of those with maculopathy ($n = 10$, 95% CI 10.3–60.8%). In adequate fundus photographs, no DMO was identified in patients without maculopathy ($n = 85$, 95% CI 0–5.2%). Therefore, there was no DMO identified in patients not requiring referral based on only fundus photograph findings.

Patient management – fundus photographs only

Management rates using only the grading of fundus photographs (without considering the OCT scan result) were analysed. There was a higher rate of referrals to an eye health professional in 2015 than 2014 (46.5% *vs.* 30.0%), which was significant (OR 2.03, 1.14–3.62, $P < 0.05$).

Table 2. Screening referrals by fundus photograph and optical coherence tomography (OCT) scan quality

	Adequate OCT	Inadequate OCT	Total
Adequate photograph	87	8	**95**
Inadequate photograph	23	21	**44**
Total	**110**	**29**	**139**

These figures are bolded as they represent summative or total numbers (i.e. the sum of the other numbers in their respective columns or rows).

Patient management – including optical coherence tomography review

There were 139 referrals with an OCT scan in the intervention group. Nine of these referrals had their management changed following OCT review. For adequate photographs initially referred to an ophthalmology clinic (for DR, maculopathy or other pathology), 52.9% ($n = 17$, 95% CI 27.8–77.0%) had management changed to 'continue screening' following OCT review.

The intervention group had a referral rate to an eye health professional of 39.6% following OCT review, which was higher than the control group (30.0%). However, this increase was not significant (OR 1.574, 0.876–2.829, $P < 0.05$). This is shown in Table 3.

Visual acuity

Visual acuity measurements were recorded in the audit as being ≥6/6, ≥ 6/12 or <6/12. This was carried out for each eye for both unaided vision and best corrected (if glasses were used). Visual acuity information was provided in 210 of 222 included screening referrals, or 94.6%. The remaining 12 referrals were excluded from the following analysis.

Analysis was conducted to determine whether any association existed between vision impairment (<6/12) in either eye ($n = 45$) and other findings. Adequate fundus photographs were less common when vision impairment was present (51.1% *vs.* 80.6%), with an OR of 0.25 (0.13–0.51, $P < 0.05$). Patients 55 years old and over were significantly more likely to be identified with vision impairment than those under 55 (29% *vs.* 13.9%, OR 2.53, 1.26–5.08, $P < 0.05$). Patients with DR were more likely to have vision impairment (16.0% *vs.* 14.2%), but this was not significant (OR 1.16, 0.455–2.94, $P < 0.05$). There was no significant difference in visual impairment between the intervention and control groups (22.9% *vs.* 19.0%, OR 1.27, 0.63–2.54, $P < 0.05$). Analysis was insufficiently powered to determine an association between vision impairment and higher grades of DR severity, maculopathy or DMO.

Discussion

This study applies a proven technology in a novel way. To our knowledge, it is the first study that incor-

Table 3. Management rates between groups

	Control group	Intervention group
Continue screening	70.0% (56)	60.4% (84)
Ophthalmology	21.3% (17)	29.5% (41)
Optometry	8.8% (7)	10.1% (14)
Total	***n* = 80**	***n* = 139**

These figures are bolded as they represent summative or total numbers (i.e. the sum of the other numbers in their respective columns or rows).

porates OCT into a DR screening programme for all patients using a combined OCT/retinal camera device. It is also the first study to use OCT for screening of Indigenous patients or patients in a rural setting with remote access being required for the OCT review.

Change in patient management

In addressing the study's primary outcome, there was no significant difference in the rate of referrals to an eye health provider between the control group (2014) and the intervention group (2015), although the former had a lower rate of referrals (30.0% *vs.* 39.6%). OCT scan capability did not result in any additional referrals to clinic because all of the patients identified with DMO were in those already referred based on fundus photograph alone. This is consistent with the research by Olson *et al.*[24] suggesting 100% sensitivity for diagnosing DMO with grading criteria for maculopathy that warrants referral. The intention for using OCT in screening is to reduce unnecessary referrals to strained outreach clinics by identifying those who do not have DMO. In the intervention group, of the individuals with adequate photographs initially requiring referral, over half could continue screening following OCT review. However, patients with inadequate fundus photographs represented a majority (78.2%, 43 of 55) of referrals made to an eye health professional in the intervention group. This offset any reduction in referrals from OCT diagnosis of DMO because OCT findings could not change patient management in cases of inadequate fundus photographs.

Inadequate photographs

One of the key findings from this study was the significant association between the intervention group and inadequate fundus photographs with 31% of photographs inadequate. In contrast, the control group had a rate of 13.8%, which is comparable with other similar programmes.[8,29] In our study, the combined OCT camera system is inferior to the DRS camera system for producing adequate colour fundus photographs. The difference in photograph quality between the control and intervention groups clearly influences our other findings, including management rates.

Possible contributing factors to the high rate of inadequate photographs were explored. No significant association was shown between photograph quality and the screening site, age or gender. There was a significant association between inadequate photographs and vision impairment, which likely relates to cataracts, an inability to fixate and other pathological causes.[30] However, there was no significant difference in visual impairment between years. A lack of mydriatic drop use was also considered. However, both cameras were non-mydriatic, and a 2011 meta-analysis concluded that for non-mydriatic cameras, there was overall no significant decrease in sensitivity or specificity without mydriasis.[11] Importantly, mydriasis does not explain the significant increase in inadequate photographs in the intervention group given that there was no change in the camera operator protocol between years.

Diabetic retinopathy prevalence

The study's findings of DR prevalence of 32.3% are consistent with other studies in similar populations.[3]

Study limitations

Using two 4-month study periods resulted in a small sample size, which limited the study's power. It is also possible that a variable other than the change in camera confounded the results. Although time was provided for training and adjusting to the combined OCT camera, operators were less experienced with this than the DRS camera. However, every effort was made to ensure the new camera was the only change to the screening system. This included using the same 4-month timeframe in each study period and using the same two screening sites. Similar graders performed photograph grading using the same criteria in each year. Furthermore, quality control and review was conducted by the same optometrist, with two ophthalmologists also available for review across the 2 years. A final limitation was the need for a retrospective audit, which meant that certain data, such as rare mydriatic use or Aboriginal status, were not obtainable across the audit population.

Conclusion

The results of this study support the continued use of non-mydriatic retinal cameras for screening programmes. Although OCT plays an important role in DMO management for ophthalmology outreach clinics, there is no evidence to endorse the widespread use of the combined OCT/ retinal camera device that was tested in DR screening in the Australian Indigenous clinic context. This is primarily due to the significant increase in inadequate fundus photographs demonstrated in this study.

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