Orthoptist-Led Diabetic Retinopathy Screening: A Pilot Quality Assurance Audit of the Reliability of Orthoptists in Diabetic Retinopathy Screening

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ABSTRACT

Background: The aim of this study was to investigate the inter-rater agreement between orthoptists and ophthalmologists in the diagnosis and clinical pathway or management decisions of patients with diabetes presenting to an orthoptist-led diabetic photography clinic in a tertiary hospital in Victoria.

Methods: A sample of patients who attended an orthoptist-led diabetic screening clinic during a 12-month period were selected for inclusion. A senior orthoptist and principal ophthalmologist were provided the de-identified clinical notes and retinal images of these patients and their agreement on the diagnosis and referral pathway management was analysed.

Results: A total of 100 patients, 200 eyes, were included in the study. Agreement between the orthoptist and the ophthalmologist in identifying signs of retinopathy or diabetic macular oedema was noted for 188 (94%) of the eyes assessed, demonstrating near perfect agreement (κ = 0.913; CI 0.854, 0.972). Agreement for the referral recommendation was 82%, showing substantial agreement between practitioners (κ = 0.667; CI 0.536, 0.798), with the urgency of the review agreed upon in 91% of cases with substantial inter-rater agreement (κ = 0.673; CI 0.475, 0.871).

Conclusion: Substantial to near-perfect inter-rater agreement was found between the orthoptist and ophthalmologist in the care of patients referred for diabetic eye screening. This suggests that there may be a role for trained orthoptists in the screening and monitoring of diabetic patients.

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INTRODUCTION

Health systems are in a constant state of evolution with a complex and ever changing health workforce.[1] Some of the current factors influencing change in health care are an ageing population, increases in the incidence of chronic disease, technological advancements in patient care, escalating costs of healthcare including changes in funding models and the emerging evidence base regarding adaptations to service delivery models.[1-3] In particular, the increase in chronic disease across the population, in addition to the increase in rates of multimorbidity is leading to a significant rise in clinical demand, presenting challenges for the health care system.[3] This rapidly changing environment means that the health and community service workforce need to adapt and innovate to meet future patient needs.

Diabetes is one of the epidemics of the 21st century with an estimated 1.2 million Australians, 4.9% of the total population, having diabetes in 2017-18.[4] Diabetic retinopathy is the most common microvascular complication of diabetes and is one of the leading causes of preventable blindness in adults.[5] Diabetic retinopathy occurs in over 15% of Australians with diabetes,[6] with diabetic macular oedema, a complication of diabetic retinopathy that can lead to debilitating vision loss, occurring in almost seven percent of the diabetic population.[5,7] With diabetes estimated to increase substantially in the coming decades,[6] an increased burden on eyecare services is also expected. As such, innovative alternatives to traditional clinical service delivery models will be required to meet the increasing demand on services. This includes optimising the current support roles in eye health care and extending practice roles for nursing and allied health practitioners, particularly orthoptists, whose clinical skills are often underutilised in traditional models of care.

To date only a few studies have explored the role extension of orthoptists in the management of diabetic retinopathy, despite role extension being an essential tool in meeting the increasing demand for healthcare. Georgievski, Koklanis, Fenton and Koukouras[8] reported that orthoptists performed extremely well when assessing fundus photographs and indicated that orthoptists met the guidelines for the National Health and Medical Research Council for diabetic retinopathy screening. In addition, a recent paper investigating the skills of orthoptists leading diabetic retinopathy screening clinics in Melbourne found that orthoptists are reliable in detecting and diagnosing diabetic retinopathy, but concluded that the role of orthoptists needs further evidence to support their involvement in new and improved models of eye service delivery.[9] The aim of this study was to build on this evidence by investigating the agreement between orthoptists and ophthalmologists in the diagnosis and clinical management decisions of patients with diabetes presenting to an orthoptist-led diabetic clinic.

METHODS

Participants

This study included a senior orthoptist involved in an Orthoptist-Led Diabetic Photographic Screening Clinic (ODPSC) within a Victorian tertiary hospital. The purpose of the ODPSC was to screen patients diagnosed with diabetes mellitus for diabetic retinopathy. The senior orthoptist who participated was registered with the Australian Orthoptic Board and had twenty years of clinical experience within general and retinal subspecialties at the time of the study. No specific or additional training was provided for diabetic retinopathy screening or the ODPSC. The ophthalmologist was a principal consultant within the ophthalmology department and specialised in retinal disorders. They had completed a retinal fellowship and had been working as a consultant for approximately five years when involved in the audit.

Patient population

A sample of patients who attended the ODPSC clinic during a 12-month period were included in the study. A total of 318 patients (636 eyes) attended the ODPSC during this period and a sub-set of this group was included based on a random selection of dates. Patients of the ODPSC were diagnosed with type 1 (T1DM) or type 2 (T2DM) diabetes mellitus or suspected of being pre-diabetic and referred to the clinic via external or internal hospital pathways. External referrals were received from general practitioners, optometrists or ophthalmologists and triaged to the ODPSC for a baseline diabetic retinopathy examination. Internal hospital referrals were generally from the endocrinology clinic where patients' diabetes was being managed.

Procedures

In the ODPSC an ocular examination was undertaken by a senior orthoptist to screen for diabetic retinopathy. This included a medical history, assessment of best-corrected visual acuity (BCVA), measurement of intraocular pressure (IOP), undilated fundus photography (FP) and spectral-domain optical coherence tomography (SD-OCT). Table 1 includes the clinical assessment protocol for the ODPSC.

Table 1. Clinical assessment in the Orthoptist-Led Diabetic Photographic Screening Clinic (ODPSC)

Clinical assessment	Investigation
Medical history	Complaints or concerns Type and duration of diabetes HbA1c (if known)
Best-corrected visual acuity	LogMAR visual acuity Subjective refraction (as required) Vertometry (as required)
Intraocular pressure	iCare Tonometer TA01i (Tiolat Oy, Helsinki, Finland)
Fundus photography	45° colour macula and disc photos Zeiss VISUCAM®PRO NM (Carl Zeiss Meditec, Jena, Germany)
Ocular coherence tomography	Fast macular thickness protocol Spectralis HRA+OCT (Heidelberg Engineering, Heidelberg, Germany)

For the purposes of the study, the de-identified ODPSC clinical notes and diagnostic images of the selected patients were extracted from the medical histories. As per the ODPSC protocol, clinical notes included relevant patient information such as duration and type of diabetes, HbA1c (if known) and any relevant complaints or observations that the patient noted. Diagnostic results included BCVA, IOP, FP and OCT. Clinical summaries or management decisions were excluded. The consultant ophthalmologist was asked to review the de-identified clinical notes and diagnostic tests of each patient and to make a clinical judgement thereafter. This included identifying any signs of diabetic retinopathy and/or any other ocular signs or symptoms. After making a diagnostic clinical judgement, the patient's referral pathway was determined; patients were either 'flagged' to be reviewed by the ophthalmology team or 'not flagged' and to be reviewed in ODPSC by the orthoptist or discharged to the community (Figure 1).

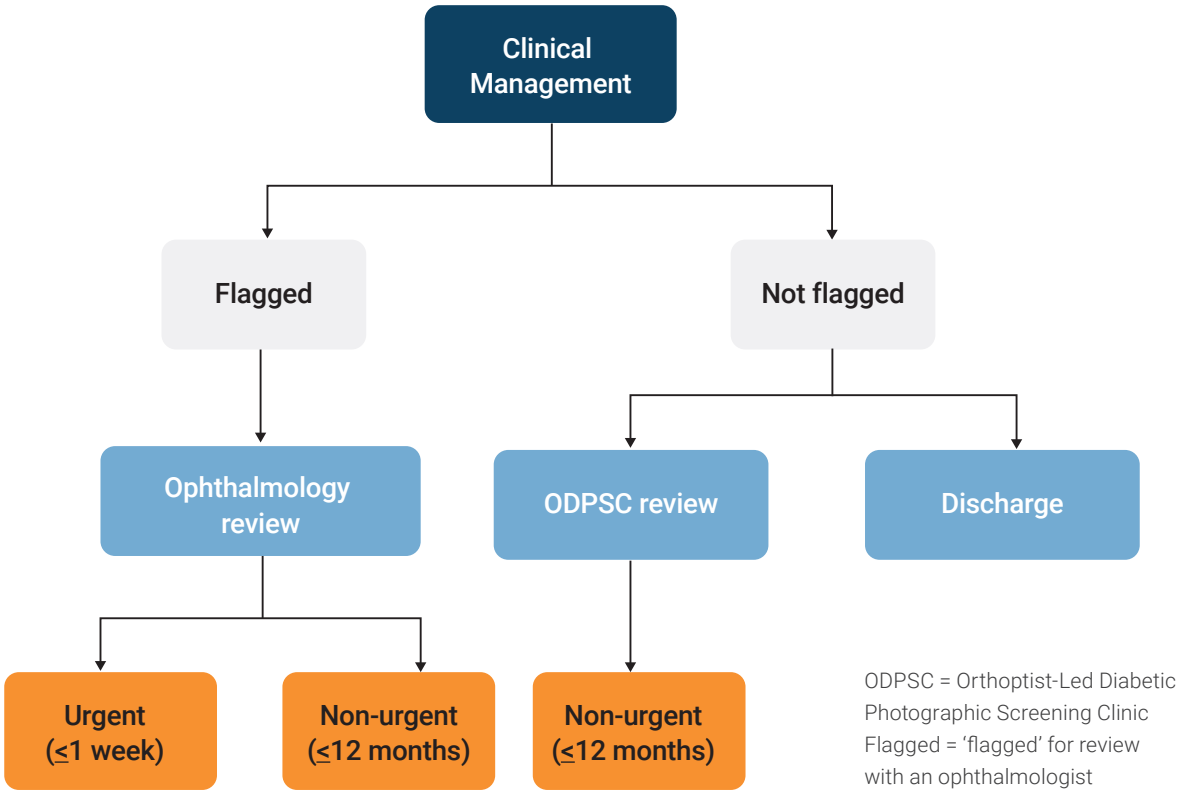

Figure 1. Clinical management and referral pathway.

Patients 'flagged' to be reviewed by an ophthalmologist were further subdivided into 'urgent' or 'non- urgent', as per the ODPSC protocol. All patients to be reviewed in ODPSC or discharged to the community were considered non-urgent. An 'urgent' review triggered a review within one week, whilst a 'non-urgent' review within 12 months. No set guidelines were provided for when a patient should be reviewed by the ophthalmology team. This was left to clinical judgement of the participating clinicians.

The clinical decisions of the ophthalmologist regarding diagnosis and referral management were considered the gold standard response for this study.

The identical de-identified clinical notes and diagnostic images were given to the participating orthoptist. The orthoptist was masked to the ophthalmologist's decisions. The same instructions were provided to the orthoptist; they were required to make a diagnostic clinical judgement as well as a management decision regarding the referral pathway and urgency of the review where relevant, based on the de-identified clinical information provided.

The initial diagnosis and management in the medical history made by the orthoptist in ODPSC was excluded from the analysis, given that this decision was based in real time with the patient present and may have influenced the outcome.

Data analysis

All data collected was entered into an excel spreadsheet and later imported into SPSS version 26 (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp) for statistical analysis. Descriptive statistics were used to describe the cohort of patients and a kappa analysis was performed to assess the agreement between the orthoptist and ophthalmologist. Kappa was interpreted in accordance with the Landis and Koch[10] recommendation, whereby 1.00 – 0.81 = near perfect agreement; 0.80 – 0.61 = substantial agreement; 0.60 – 0.41 = moderate agreement; 0.40 – 0.21 = fair agreement; 0.20 – 0.01 slight agreement; <0 = poor agreement. Additionally, a 95% confidence interval (CI) was calculated to evaluate the agreement between the practitioners.

RESULTS

Patient population

A total of 100 patients, 200 eyes, were included in the study. This represented 31.4% of the total number of eyes reviewed within the sample period. The mean age at the time of attendance was 65.9 years (SD ±14.9) with a range from 18.7 to 92.1 years. Of these patients, 42 were females, 66 were diagnosed with T2DM, 30 with T1DM and 4 were diagnosed as pre-diabetic. Of those with T2DM the mean duration of diabetes was 12.0 years (SD ±14.9) with a range from 1 to 32 years and for those with T1DM

the mean duration of diabetes was 15.1 years (SD ±8.7) with a range from 1 to 40 years.

Of the 200 eyes, the ophthalmologist reported that 47 eyes of 25 patients had an additional unrelated suspected pathology. The mean age of these patients was 66.7 years (SD ±15.5) with a range from 25.3 to 90.2 years. Of these patients, 11 were females, 17 were diagnosed with T2DM, 9 with T1DM. The unrelated suspected pathologies included conditions such as cataracts and glaucoma.

Agreement between practitioners

Agreement of diagnosis

Diagnosis was divided into four groups: no signs of retinopathy, signs of diabetic retinopathy, diabetic macular oedema or both diabetic retinopathy and diabetic macular oedema. Of the 200 eyes, 140 (70%) were diagnosed with no signs of retinopathy by the orthoptist and 137 (68.5%) by the ophthalmologist. Forty-four patients (22%) were diagnosed with signs of diabetic retinopathy by the orthoptist and 50 (25%) by the ophthalmologist. Sixteen patients (8%) were diagnosed with both signs of diabetic retinopathy and diabetic macular oedema by the orthoptist and 13 by the ophthalmologist (6.5%). No eyes were found to have diabetic macular oedema alone by either the orthoptist or ophthalmologist. Diagnostic agreement was overall found for 188 (94%) of the eyes assessed, demonstrating near perfect agreement (κ = 0.913; CI 0.854, 0.972).

Of the 200 eyes included, the ophthalmologist noted unrelated pathologies in 47 eyes (23.5%). The orthoptist also noted unrelated pathologies in 38 eyes (19%). These pathologies included conditions such as glaucoma, cataract and uveitis. When the 47 eyes with unrelated pathologies were removed from the analysis, the agreement for the detection of diabetic retinal signs remained similar (κ = 0.903; CI 0.838, 0.968).

Agreement of referral pathway

For the purposes of the analysis, the clinical pathway was divided into two groups: referral to an ophthalmologist or referral to the orthoptist for photography screening or for community care, the latter being a discharge from the hospital outpatient clinic. Of the 100 patients, 37% were flagged for an ophthalmology review by the orthoptist and 45% by the ophthalmologist. Additionally, 63% of patients were referred to ODPSC or for discharge to the community by the orthoptist whilst the ophthalmologist referred 55% to this pathway. Overall, the referral agreement was 82% demonstrating substantial agreement (κ = 0.667 CI 0.536, 0.798). The agreement improved slightly when the 47 patients with unrelated pathologies were excluded (κ = 0.705 CI 0.578, 0.831).

Agreement of timing of review

The orthoptist indicated that 17% of the 100 patients required an urgent review, with 16% identified as urgent by the ophthalmologist. Eighty-three percent of patients were considered for a non-urgent review by the orthoptists and 84% by the ophthalmologist. In 91% of cases the orthoptist agreed with the ophthalmologist for the timing of the review which equates to substantial agreement (κ = 0.673 CI 0.475, 0.871). In five of these cases where there was a disagreement the orthoptist indicated an urgent referral was required, whilst the ophthalmologist indicated non-urgent. In four of the cases the orthoptist underestimated the urgency when compared to the ophthalmologist's judgement.

Agreement improved slightly when the 47 patients with unrelated pathologies were excluded (κ = 0.788 CI 0.646, 0.929).

DISCUSSION

This study demonstrates a high inter-rater agreement between an orthoptist and consultant ophthalmologist for the detection of signs of diabetic retinopathy and in the management of patients screened for retinopathy as related to decisions regarding the patient referral. This finding supports the evidence that orthoptists have the potential to expand their role in diabetic screening. This is in alignment with previous studies which have reported significant agreement between orthoptists and ophthalmologists in diabetic eye care.[8,9] It is also in alignment with a previous study reporting the decision agreement rate related to indication for treatment for patients with neovascular age-related macular degeneration[11] and similarly the agreement rate between orthoptist and ophthalmologist in glaucoma monitoring.[12]

Given that this study used a random sample of patients who had been referred and reviewed in an orthoptist-led diabetic screening clinic, a real-world clinical representation of patients was included. Interestingly, agreement for diagnosis and referral management remained high despite some patients having additional ocular pathologies. This suggests that orthoptists are able to safely screen and manage patients with diabetes, even in the presence of other ocular pathologies. It would, however, be of interest for future studies to further explore real-world patients and the influence of other pathologies on clinical decision-making in diabetic retinopathy screening.

A limitation of the current study is that only a single orthoptist and ophthalmologist were included, restricting the generalisability of the results. It is likely that the orthoptist's workplace experience and skill level have also influenced the outcome. Furthermore, a study methodology that includes at least two ophthalmologists who agree on the diagnosis and management plan would be preferential as this would eliminate individual biases from the gold standard response. A large-scale prospective study that includes multiple orthoptists and agreement between several consultant ophthalmologists is required.

Another limitation of this study is the broad categorisation of the diagnosis of diabetic retinopathy. For the purposes of the study, the clinicians involved were only required to report the presence of diabetic retinopathy or diabetic macular oedema. Agreement of retinopathy grading or for specific signs, such as microaneurysms, retinal haemorrhages and exudates, were therefore not explored. Given the high agreement between the orthoptist and ophthalmologist it is likely that agreement would be noted in these areas, however this would be of interest to explore.

To date, most studies investigating the role of allied health practitioners in diabetic retinopathy screening have focused on optometrists.[13-16] However, it is noteworthy that the orthoptist in this study had an excellent and comparable agreement level for diagnosis and referral management in diabetic screening to the ophthalmologist and that, in general, orthoptists are well placed to contribute to task sharing for diabetic eye care. Given the educational background of orthoptists and that they work within the tertiary care sector alongside ophthalmologists, greater utilisation of their skill set has the potential to improve patient care pathways and assist in meeting the high and growing demand for eye care services. The importance of early detection and management of diabetic retinopathy in reducing the burden of disease is well established.[17] With diabetes estimated to increase substantially in the coming decades, and the resultant increased burden on eye care services, developing efficient and effective patient care pathways whilst maintaining high quality care and optimising the clinical skills of the allied health workforce, will be an integral part in meeting expected future challenges.

CONCLUSION

Significant agreement was noted between the orthoptist and consultant ophthalmologist for both identifying signs of diabetic retinopathy and referral management. The results support previous research that suggests that orthoptists could potentially be used in diabetic screening models in Australia and that it may be beneficial for existing opportunistic programs to be replaced by systematic screening for diabetic eye disease.

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