Managing Patients with early Diabetic Maculopathy via Virtual SD-OCT clinics

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Abstract

Aims: It isn't that long ago that Diabetic Retinopathy was the leading cause of blindness amongst the working age population in the UK. The UK NHS Diabetic Eye Screening Programme is rapidly expanding due to increasing levels of diabetes and has resulted in a large number of M1 patient referrals with maculopathy requiring further assessment in already busy hospital eye services. We have introduced a virtual Spectral Domain-Optical Coherence Tomography (SD-OCT) clinic which has enabled a large number of patients to be stratified in order to determine whether further ophthalmologist review is indicated. We have audited the virtual SD-OCT clinic over a one year period to evaluate its performance and outcome.

Method: A retrospective analysis was performed of patients referred to the hospital from our local UK Diabetic Eye Screening Programme to the SD-OCT virtual clinic over 1 year. The clinic was staffed by screener/graders and the OCTs and colour photographs were graded by a specialty doctor in the Ophthalmology department. Results: Out of 920 patients with appointments, 700 attended the SD-OCT clinic (76%) and of these 272 (39%) were subsequently referred on to the medical retina clinic. Of these, 129 (47%) patients had clinically significant M1, 59 (22%) were non DR referrals and 84 (31%) had moderate to severe non proliferative retinopathy or proliferative disease where 41 (15%) required treatment.

Conclusion: Based on our experience, the virtual clinic is an alternative way of managing a large cohort of referred patients with relatively few resources whilst ensuring that appropriate treatment is provided when necessary.

Keywords: Diabetic Eye Screening Programme, Diabetic Maculopathy, Optical Coherence Tomography, Diabetic Macular Odema, CSMO.

Introduction

Diabetes Mellitus (DM) currently affects over 170 million people worldwide and its prevalence is predicted to increase to 366 million by 2030.[1] Diabetic retinopathy (DR) and diabetic maculopathy or diabetic macular oedema (DMO) are well characterised complications of DM associated with changes within the retinal vasculature and retinal thickening respectively, which can ultimately result in permanent loss of vision. The development of these complications correlates with the duration of diabetes so earlier onset of diabetes, increasing life expectancy, in addition to the growing number of patients with type 2 DM, is likely to result in a significantly higher prevalence of DR globally. DR has been declared a priority eye condition by the World Health Organization as timely intervention can prevent or delay loss of vision.[2]

In the UK, the Diabetic Eye Screening Programme, which was proposed in 2002 and implemented nationally between 2003 and 2008, has become pivotal in identifying patients who may be at risk of retinopathy.[2] In 2010-11, the UK was estimated to have over 2 million diabetic patients with a screening uptake of 79% nationally.[2,3] Persons with diabetes over 12 years of age are routinely invited to an annual screening appointment. Digital retinal photographs are obtained and graded according to the National Eye Screening Criteria for evidence of DR and diabetic maculopathy **(Table 1)**.

In DR, background retinopathy (R1) linearly progresses through moderate to severe stages of retinopathy identified by IRMA, haemorrhages and vascular changes such as venous beading (R2)[4]. Although proliferative retinopathy (R3), associated with neovascularisation can be sight-threatening, diabetic macular oedema (DMO) associated with thickening of the central retina is a more common cause of vision loss especially in type 2 DM.[5]

Patients with evidence of maculopathy, based on the presence of surrogate markers as specified in the M1 grade of the NHS Diabetic Eye Screening Programme criteria are routinely referred to the medical retina clinic for further assessment. The Grade M1 of the National Programme Grading Criteria is defined as one of three entities [1]) 'the presence of any exudate within 1 disc diameter of the centre of the fovea; [2]) any group of exudates within the macula region which is >1/2 disc area in size or 3) any microaneurym or haemorrhage within 1 disc diameter of the centre of the fovea when associated with best VA of worse than 6/12. This grade is a very broad category encompassing patients from mild non-sight threatening maculopathy through to those with CSMO requiring treatment, which can be very variable in its nature and extent of involvement. Clinically Significant Macular Oedema (CSMO), as defined by the ETDRS study is associated with retinal thickening which involves or threatens the centre of the macula even if visual acuity is not affected.[6] The presence of CSMO is an indication for laser treatment; intervention prior to this stage has been shown to be of minimal benefit.[6] Those with CSMO therefore form a small subgroup of the much larger cohort of M1 patients and dividing these patients with OCT scanning can help to streamline resources as those who do not require treatment place a substantial burden on medical retina clinics.

In view of this, we have introduced a 'virtual' clinic where Topcon-2000 SD-OCT technology is used to generate high resolution images of the retina in order to quantify macular thickness and identify CSMO of a magnitude that requires treatment or is close to threshold. Colour photographs of the posterior pole and the nasal retina are also taken. The aim of the virtual clinic is to further screen and stratify patients referred from screening to determine those needing treatment and therefore referral to the Medical Retinal clinic from those who require further surveillance. In this study we have evaluated the performance of the virtual SD-OCT clinics in managing diabetic patients referred from the local Diabetic Eye Screening Programme in South London.

Table 1: UK Diabetic Eye Retinopathy Grading Criteria.

Retinopathy			
Grade	**Description**	**Features**	**Action**
R0	None		Annual screening
R1	Background	- microaneurysm(s); - retinal haemorrhages; - venous loops - CWS in presence of other R1 features; - retinal exudates ± exudates(s)	Annual screening
R2	Pre-proliferative	- venous beading and reduplications - intraretinal microvascular abnormality (IRMA) - visible on colour photography - multiple deep, round or blot haemorrhages	Referable
R3	Proliferative	- new vessels on the disc (NVD) - new vessels elsewhere (NVE) - pre-retinal or vitreous haemorrhage - pre-retinal fibrosis ± tractional retinal detachment	Referable
R3(S)	Stable treated proliferative	Treated with Pan Retinal Photocoagulation and Stable	Surveillance
Maculopathy			
Grade	**Description**	**Features**	**Action**
M0	Non-referable Maculopathy	Not fulfilling criteria for M1	Annual screening
M1	Maculopathy	- exudate within 1 disc diameter of the centre of the fovea - retinal thickening within 1 disc diameter of the centre of the fovea (if stereo available) - group of exudates within the macula (>1/2 disc area) - any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea only if associated with best VA of < 6/12	Referable

Methods

A retrospective analysis was performed of M1 patients referred to the SD-OCT virtual clinic from the local UK Diabetic Eye Screening Programme which covers 40,000 diabetic patients, over the course of a year. The SD-OCT virtual clinic was held weekly in the medical retina unit and was staffed by Screener/graders from the local Programme. Patients were booked in the virtual clinic within 6 to 8 weeks from their grading date if they were classified as having background retinopathy (R1) with mild referable maculopathy (M1) **(Figure 1)**. Senior graders referred all those patients with moderate to severe M1 (more than a single streak of exudates in the centre 1 disc diameter) directly to the medical retinal clinic rather than to the virtual clinic as these were considered likely to need treatment.

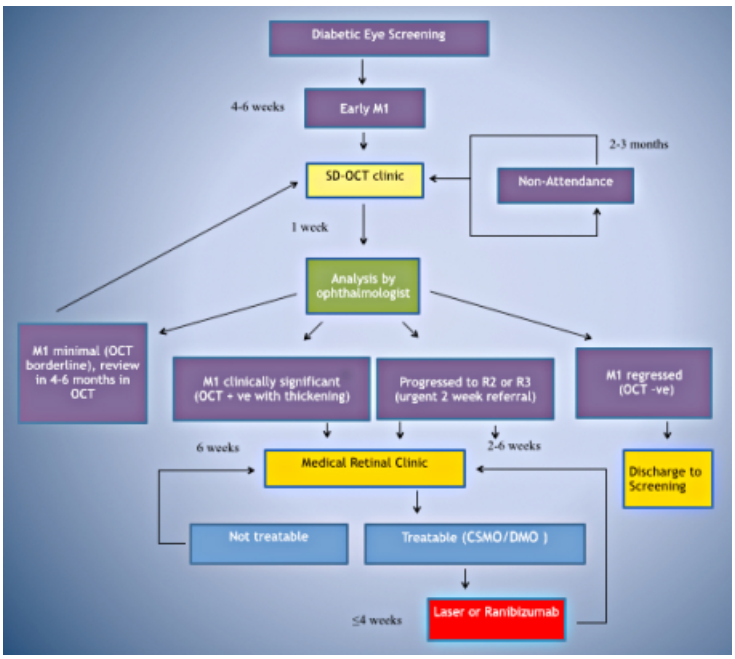

Figure 1: Patient pathway: from annual diabetic eye screening to treatment to SD-OCT virtual clinic.

At the Virtual clinic appointment, 18-20 patients were booked to be assessed per clinic by a technician for best corrected visual acuity (BCVA), intraocular pressures measurement (Icare tonometer) and then pupils were dilated with 1% tropicamide drops as in the local Programme. A Screener/ Grader then used a SD (Spectral Domain) OCT-2000 machine (Topcon Inc.) to scan the macula of both eyes and colour fundus photographs were captured of the nasal and macula areas using the same device. All measurements and visions were recorded on specially designed proformas (to record gradings/outcome details) and in the hospital notes. Patients were then sent home and informed that their results would be sent to them.

All images were then assessed virtually two days later by a trained specialty doctor in ophthalmology on a weekly basis to assess the degree of retinopathy and maculopathy and graded accordingly. OCT scans were scored as either (1) negative (M1 but clinically not visible on OCT) in which case patients were discharged back to the screening programme, (1) borderline (where some early intra-retinal changes were visible on the OCT scan with no definite thickening seen); these patients were reviewed at 4-6 months but remained in the OCT clinic, or positive (M1 clinically significant with thickening seen on the OCT scan) which resulted in a referral to the medical retina clinic in 6 weeks **(Figure 2)**. The degree of retinopathy was also assessed from the colour images and evidence of severe non-proliferative retinopathy (R2) or proliferative retinopathy (R3) was also referred appropriately to the medical retina clinic. Patients were informed of the outcome of their appointment via post and informed to contact their GP about their systemic control of blood sugar and blood pressure. Those who failed to attend an appointment were re-scheduled for another appointment in two-three months time. Failure to attend twice resulted in discharge back to the screening programme.

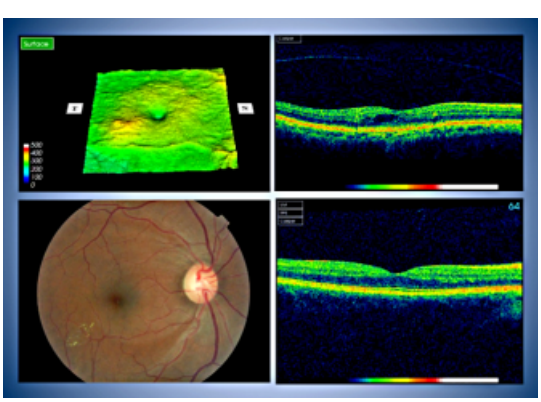

Figure 2: from top left, clockwise

a) OCT map showing evidence of significant maculopathy (+ve SD-OCT scan);

b) Cross-sectional OCT showing example of borderline changes;

c) Cross-sectional OCT showing no significant thickening (-ve OCT scan);

d) Colour fundus photograph showing a group of exudates in the macula region: example of M1 grading.

Results

Out of 920 patients due to attend their appointment over a 12 months period (jan 2011-jan 2012), 76% (700/920) attended and were assessed at the SD-OCT clinic. 20% (182/920) failed to attend their appointment; the remaining 4% of patients had their appointment cancelled; either by the patient (37/920) or by the clinic and was then rescheduled (1/920) (**Figure 3a.)**.

From the total number of patients that attended their appointment, 43% (301/700) of patients were assessed as having maculopathy not requiring referral (OCT borderline). Since they were still classified to be grade M1, surveillance was continued in the OCT clinic with a follow up appointment within 4-6 months. 15% (106/700) were discharged back to the screening programme due to no evidence of OCT changes (OCT negative) or drusen diagnosed rather than exudate. A total 39% (272/700) of patients out of those who attended required referral to the medical retina clinic where clinical examination was performed including slit lamp biomicroscopy **(Figure 3b.)**. The remaining 3% patients were rescheduled for various reasons as they could not be assessed/ scanned on the day. Of those referred, 47% (129/272) patients were assessed as clinically significant M1 (with early thickening seen on OCT) and 31% (84/272) as having moderate to severe non-proliferative retinopathy or proliferative disease (grade R2 or R3). The remaining 22% (59/272) of patients were referred to the clinic for other reasons including raised intra-ocular pressure, unexplained reduced visual acuity or images that could not be assessed. Ultimately, of the total number of patients referred to clinic, 15% needed laser treatment (13% macular laser (35/272) for CSMO and 2% (6/272) pan-retinal laser photocoagulation for proliferative diabetic retinopathy).

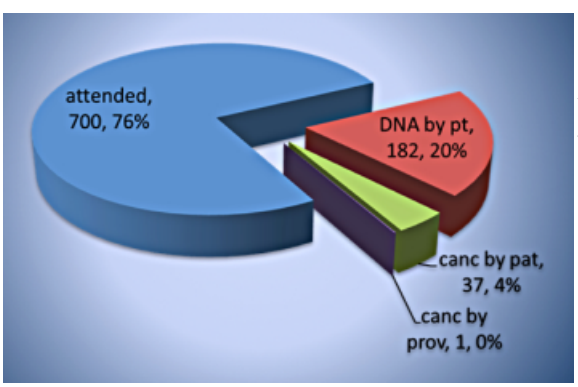

Figure 3a: Outcome of patients with appointments from January 2011-12 at the SD-OCT virtual clinic (n=920).

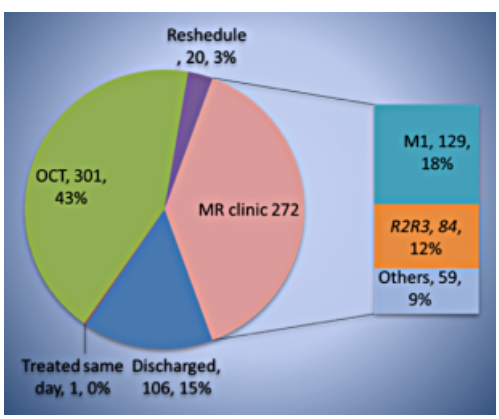

Figure 3b: Outcome of patients who attended SD-OCT clinic (n=700).

Discussion

Diabetic retinal changes can be delayed or prevented with appropriate screening and improvement of systemic control. Additionally newer treatments for maculopathy such as anti-VEGF agents (Ranibizumab) are putting increasing demand on medical retinal clinics. As the number of diabetic patients increases, monitoring and treating large numbers of patients is becoming increasingly challenging. We have demonstrated that a virtual clinic is an effective way of monitoring a large cohort of patients for progression of diabetic retinopathy. Patients were evaluated using advanced SD-OCT technology and colour fundus photography (Topcon 2000) which allows high resolution imaging and can elucidate retinal thickness and structure, allowing macular oedema to be objectively quantified. Since its commercial introduction in 1996, OCT has become a well-established modality with high repeatability allowing early changes in retinal thickness to be identified.[10,11]

In performing this service evaluation, we have monitored a total of 700 patients over the course of a year. Using this new model with relatively few staff to monitor these patients in virtual clinics has enabled medical retina clinics appointments to remain available for those who required more urgent treatment. This clinic also allowed a shorter visit time for patients as they did not have to wait to see an ophthalmologist. From this cohort, patients were closely monitored and referred to medical retina clinic so that any thickening seen on the OCT scans could be further evaluated within the medical retina clinic. Patients were also referred if severe non proliferative changes or proliferative retinopathy were identified on the fundal images. A single ophthalmologist assessed a large number of images from 18-20 patients each week in one 4 hour session, obtained from the virtual clinic, thus increasing efficacy of this task. In medical retina clinics, treatment was provided promptly to 15% of patients when indicated.

Overall, the virtual clinic has several advantages: It allows a large cohort of patients to be screened and further stratified by one ophthalmologist, a SD OCT machine and a technician and a screener/grader, rather than referring each patient with an M1 to the main medical retinal clinic. This is also advantageous as it allows those with significant macula oedema or advancing non-proliferative disease to still be reviewed in clinic and treated appropriately with anti-VEGF agents or laser treatment as required.

This OCT assessment clinic could also potentially be set up in a community setting once the cost of OCT machines reduces (the current cost of the OCT machine is the main limitation of this model), and allows education and information to be passed on to the patient about glucose and blood pressure control by the screener/grader to try to reduce the natural progression of retinopathy8 in addition to lessening the burden on Hospital Eye Services.

Furthermore, senior graders are now being trained to grade the OCT's and this will allow replacement of the ophthalmologist in these clinics to reduce the costs further. Since the introduction of the UK Eye Screening Programme, a large number of M1 patients have been referred to medical retina clinics making it increasingly difficult to see those that require treatment. The need for increased capacity in clinics is especially important since the implementation of NICE guidance and anti-VEGF treatment of Diabetic Macular Oedema. With the provision of virtual SD-OCT clinics, our department have identified an alternative way of managing this increasing cohort of patients.

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Conflict of Interest

The authors declare no conflict of interest.

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