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The profile of sight-threatening diabetic retinopathy in patients attending a specialist eye clinic in Hangzhou, China

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ABSTRACT

Background/aims To examine the profile of diabetic retinopathy, awareness and self-help in patients attending a specialist eye clinic in Hangzhou, China.

Methods A total of 199 consecutive patients with diabetes (mean age = 57 years, SD = 11) attending eye clinic at the School of Medicine, Zhejiang University, Hangzhou were examined in a cross-sectional study. Clinical/demographic data were obtained from patients' records. Fundus photographs obtained from each patient were graded using Early Treatment of Diabetic Retinopathy Study (ETDRS) criteria; severe non-proliferative, proliferative retinopathy and/or macular oedema (hard exudates/thickening around fovea) were classified as sight-threatening diabetic retinopathy (STDR). Optical coherence tomography was used to confirm the diagnosis of macular oedema. Data on knowledge/awareness about diabetes and self-help/lifestyle were collected using a structured questionnaire.

Results STDR was found in 80% patients of whom 18% had visual acuity of ≤counting fingers in at least one eye. Male gender, longer diabetic duration and use of insulin were significantly associated with STDR ($p \leq 0.05$). Of the total, 41% patients reported that they were attending for the first time. Of all the first-time attendees, 67% had STDR. Also of all the first-time attendees, 14% were unclear whether diabetes affected their eyes. Fifty-one per cent of patients who thought their diabetes was well controlled had fasting blood sugar ≥6.5 mmol/L ($p < 0.001$). Of the total, 65% patients reported not doing ≥4 hours/week of physical exercise.

Conclusions The majority of patients with diabetes presented to this eye clinic suffered with late-stage retinopathy. Our results advocate the need to improve diabetic diagnosis, management and awareness and to set up eye screening for diabetics in Hangzhou, China.

Key messages

What is already known about this subject?

► The prevalence of diabetic retinopathy varies in different parts of China. Various clinical factors influence the risk of diabetic retinopathy.

What are the new findings?

► A large proportion of patients (80%) attending an eye clinic in Hangzhou, Eastern China had high levels of sight-threatening diabetic retinopathy. These patients demonstrated lack of knowledge about diabetes, and inadequate self-help and lifestyles.

How might these results change the focus of research or clinical practice?

► There is a need for early intervention including retinopathy screening, improved awareness and better lifestyles in Eastern China.

INTRODUCTION

A recent report by the WHO indicates that the number of adults living with diabetes has increased nearly fourfold since 1980, reaching the current estimation of over 422 million globally.[1] A large cross-sectional survey conducted by Xu *et al*[2] showed that in China alone, about 12% of the adult population (approximately 113.9 million) is estimated to be suffering from diabetes, which accounted for around 30% of the world adult diabetic population in 2014. Management of diabetic complications has, therefore, become a significant public health challenge for China.[2 3]

Diabetic retinopathy (DR) is a major complication of diabetes in which progressive damage to retinal microvasculature occurs, which can lead to a profound loss of vision.[4] Recently, the Vision Loss Expert Group,[5] part of the Global Burden of Disease Study, reported that diabetic-related blindness increased by 27% worldwide from 1990 to 2010, and visual impairment by 64% in the same 20-year period. A previous study from China in 2010 estimated the prevalence of DR to be 23% in the diabetic population.[6] This is lower than the 34.6% of prevalence of DR reported globally in the same year by Yau *et al*.[7] Another study reported the prevalence of DR in rural areas to be significantly higher (58%) than in urban areas of China (31%).[8] The same study also reported the sight-threatening consequence of DR to be higher in the rural areas (14.2%) compared with the urban areas (6.3%). Liu *et al*[9] reported the prevalence of DR to be 14% in patients living in the Fengyutan Community of Shenyang city in north-east China.

DR has been found to be associated with longer diabetic duration, a higher concentration of glycosylated haemoglobin A1c (HbA1c), higher systolic blood pressure, lower body mass index and the use of insulin in Chinese patients with diabetes.[10]

It is well known that the control of diabetes is important for reducing the risk of sight-threatening DR (STDR), as suggested by several studies including the UK Prospective Diabetes Study and Diabetic Retinopathy Clinical Research.[11–14] The role of self-help (taking medicine in time, not missing doctor's appointments, monitoring blood sugar levels regularly)[15] and improved awareness about diabetes in controlling sight-threatening complications of DR is less well documented. There is evidence in the literature to suggest that improving diabetic self-help, or knowledge/awareness about diabetes and its risk factors, plays an important role in the control of diabetes and DR.[15–18] A recent Cochrane review of 66 randomised clinical trials highlights the fact that interventions in the form of educational programmes to increase awareness about DR is vital in improving attendance for DR screening; more specifically, interventions provided in the form of education, reminders and promotion of self-care targeting patients, healthcare professionals or the healthcare system, were found to improve attendance for DR screening by 12%.[19]

A self-administered questionnaire study conducted in the community setting in Shenyang, Liaoning Province of China on 475 patients with diabetes found that only 37% of the patients were aware that DR can result in blindness.[16] Fundus examination of all 475 patients had shown that 190 (40%) patients had DR, of which about 68% were not actually aware of their retinopathy. The authors highlighted the importance of providing awareness programmes to control diabetes and reduce the risk of STDR in patients living in China. The study did not explore other parameters of diabetic self-help (eg, attending hospital appointments) and lifestyle regimen (eg, regular physical exercising) which this study explores.

The objective of this cross-sectional study was to examine the profile of DR, awareness and self-help about diabetes and its sight-threatening complications in patients attending an eye clinic in Hangzhou, China from clinical records and using a structured questionnaire. Hangzhou is the capital and the most densely populated city of Zhejiang Province in east China with an estimate of 9 018 000 people inhabiting this city in 2015 (www.zj.stats.gov.cn).

MATERIALS AND METHODS

Study design and setting

A cross-sectional study was conducted on patients with diabetes attending a specialist clinic at the Eye Centre, Second Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, China. The hospital saw 600 000 outpatients in the preceding 2 years of the study, with patients from both urban and rural areas. The size of the catchment area served by the hospital is the eastern region of China, which is greater than one million square kilometres. Data were collected between May and December 2016.

Participants

In all, 199 eligible consecutive patients with diabetes (mean age=57 years, SD=11) were recruited. The study protocol was approved by the Ethics Committee of the Second Affiliated Hospital, School of Medicine, Zhejiang University. All patients provided informed consent for taking part in the study. Participants were treated in accordance with applicable ethical guidelines that followed tenets of Helsinki Declaration. Information that could identify individual participants during or after data collection were not recorded. We used the Strengthening the Reporting of Observational Studies in Epidemiology cross-sectional reporting guidelines.[20]

Patient and public involvement

All participants were informed that the study was about diabetes, and involved recording clinical measurements and administering questionnaire in the local language. Participants were not involved in the development or design of the study, and interpretation or writing up of the data.

Sample size calculation

According to a recently published study, the prevalence of DR in patients with diabetes living in China is approximately 15%.[21] With a 15% prevalence rate, precision error of 5% and type 1(α) error of 5%, the required sample size would be 196. A slightly greater number (n=199) has been used in this study. This sample size is similar to, or greater than, some of the studies that are included in recent systematic reviews investigating the prevalence of DR in China.[6 21]

Procedures

Consecutive patients attending an eye clinic meeting the inclusion criteria (below) were examined by the consultant ophthalmologist (ZC). The following criteria were applied to identify the eligibility of participants: all patients who had diabetes were invited to take part. The following exclusion criteria were applied: patients with ocular pathologies such as advanced glaucoma, matured cataract and severe uveitis in whom retinopathy grading would be difficult.

Two experienced ophthalmologists graded the photographs independently and data were compared. Where there was any discrepancy, the photographs were discussed and a consensus was reached. We carried out further data analysis, in which another consultant ophthalmologist was requested to grade the photographs, and the inter-class correlation (ICC) was determined. The average measure of ICC was 0.88 with a 95% CI from 0.776 to 0.873.

A questionnaire in Chinese was administered to each patient (author ZC) to obtain information about demographics, duration and treatment of diabetes,

knowledge/awareness about diabetic control, self-help and lifestyle parameters. The English version of the questionnaire is provided as a online supplementary file. The questionnaire was similar to the one used in our previous studies.[11 15] It was piloted on a small number (n=10) of patients who were not enrolled in this study. The questionnaire was translated into the local Chinese language and then translated back into English. The answers were also translated back into English by an independent investigator who is fluent in both languages.

Visual acuity (VA) for each eye was recorded using an internally illuminated Snellen's chart and was later converted into Logarithmc of Minimum Angle of Resolution (logMAR) VA. Dilated (tropicamide, 0.5%) fundus examination, including retinal photography, was performed for both the eyes. Fasting blood sugar (FBS) and blood pressure were measured on the same day of data collection. Cut-off criterion of FBS level for diabetes risk was considered as >6.5 mmol/L.[22] Retinopathy severity was graded according to the Early Treatment of Diabetic Retinopathy Study (ETDRS) classifications.[23] STDR was defined as severe non-proliferative, proliferative retinopathy and/or macular oedema in at least one eye.[23 24] STDR is typically characterised by retinal neovascularisation of the optic disc or elsewhere, preretinal and vitreous haemorrhage and/or macular oedema.[24] Milder retinopathy was classified as non-sight-threatening DR (NSTDR). Optical coherence tomography was used to confirm macular oedema. All patients were able to respond to all the questions in the questionnaire without any help. Since patients did not have any documentation regarding the duration of diabetes, and it was not possible to retrieve these details from hospital records, we asked them to self-report the duration of their diabetes.

Statistical analysis

Data were analysed using descriptive and inferential descriptive statistics. χ^2 test (Fisher's exact) was used to establish relationships between the categorical variables (eg, gender vs retinopathy severity) and an independent samples t-test or a Mann-Whitney test was used to compare means of two continuous variables. A p value of≤0.05 was considered to be statistically significant for rejecting null hypothesis.

Primary outcome measures

Retinopathy severity, profile of knowledge/awareness, self-help and the lifestyle regimen for patients with STDR and non-STDR (NSTDR). We also compared awareness about diabetes and lifestyle profiles between patients who had attended diabetic eye examination previously and those who had not.

RESULTS

In all, 98 male patients (mean age=55.5 years, SD=11.7) and 101 female patients with diabetes (mean age=58.0 years, SD=10.3) were included in the study. Of the total patients, 82% were older than 50 years, 91% had type two diabetes, 57% were on insulin (or combined with tablet or diet control) treatment, 53% reported having diabetes for >10 years and 88% reported being literate (able to read and write in Chinese).

A very large percentage, 80% (n=159) of patients were classified as having STDR (76 males, 83 females). A significant proportion of total patients (62%) reported to seeking urgent medical help owing to 'episodes' of uncontrolled blood sugar in the last year. Seventy-four per cent of the patients reported not forgetting to take their medicine. Of the total patients, 28% reported not being aware that poorly controlled diabetes can affect eyes or lead to vision loss despite attending the eye clinic, and 65% reported not doing moderate to vigorous physical activities such as jogging, hiking, swimming and cycling for at least 4 hours per week. The moderate to vigorous physical exercise for 4 hours per week for patients with diabetes is recommended by Hu *et al*[25] and Diabetes, UK.

Mean logMAR VA for the better eye and the worse eye for patients with STDR were 0.4 (SD ±0.4) and 0.7 (SD ±0.4), respectively, and for patients with NSTDR the values were 0.2 (SD 0±0.3) and 0.3 (SD ±0.3), respectively. The Mean logMAR VA for both better and worse eyes differed significantly between the STDR and NSTDR patient groups (p<0.001, Mann-Whitney test). Men, use of insulin and longer duration of diabetes (over 10 years) were significantly associated with STDR (χ^2 test, p≤0.05). Age and literacy status were not significantly associated with STDR (p≥0.45).

The mean FBS values of patients with STDR (7.7 SD ±2.3) and NSTDR (7.5 SD ±2.0) were not statistically different (p=0.7). The systolic blood pressure of patients with STDR (mean=135.1 mmHg, SD ±17) and NSTDR (mean=129.6 SD±12.6) differed with marginal significance (p=0.06). Diastolic blood pressure was not significantly different between the groups (p=0.99).

We thought it would be of value to examine awareness, lifestyle and retinopathy profile of those patients who were attending for the first time compared with those who had attended diabetic eye examination previously. Out of the total 199 patients, 82 patients (41%) reported that their current appointment was the first attendance for diabetic eye examination (36 patients were not sure and have been omitted). The data for those who had diabetic eye examination previously and for those attending for the first time are compared in table 1. Significantly greater number of patients who self-reported as attending for the first time reported being unaware that diabetes affects eyes when compared with those who self-reported as having previous visits. Also a significantly greater percentage of STDR was found in those attending for the first time compared with those who self-reported attending diabetic eye examination previously.

In patients who visited diabetic eye examination for the first time 67% presented with STDR. Even though nearly half of these patients (45%) had diabetes for over 10 years, this was the first time ever they were visiting

Table 1 Summary of the data that differed significantly between those patients whose current appointment was the first attendance for diabetic eye examination and those who reported to attending diabetic eye examination previously

Variable/question	Parameters explored	Response category	No. of patients	% of overall total	Visit for diabetic eye examination		P value
					Had visited previously (n=81)	Visiting for the first time (n=82)	
Fundus examination: Retinopathy severity	Clinical	STDR	130	79.8	75 (92.6%)	55 (67.1%)	<0.001*
		NSTDR	33	20.2	6 (7.4%)	27 (32.9%)	
How long had you had diabetes?	Diabetic duration	>10 years	90	55.2	53 (65.4%)	37 (45.1%)	0.01*
		≤10 years	73	44.8	28 (34.6%)	45 (54.9%)	
Can diabetes affect eyes?	Knowledge	Yes	122	74.8	69 (85.2%)	53 (64.6%)	0.004*
		No/not sure	41	25.2	12 (14.2%)	29 (35.4%)	
Does diabetes restrict your everyday activities?	Awareness	Yes	67	41.1	40 (49.4%)	27 (32.9%)	0.04*
		No/not sure	96	58.9	41 (50.6%)	55 (67.1%)	
How often last year you had to go hospital for uncontrolled blood sugar?	Diabetic control	≥1–10 times	100	61.3	58 (71.6%)	42 (51.2%)	0.01*
		0 times	63	38.7	23 (28.4%)	40 (48.8%)	

*significant p values obtained by using χ^2 (Fisher's exact) test.
NSTDR, non-sight-threatening diabetic retinopathy; STDR, sight-threatening diabetic retinopathy.

the eye clinic for diabetic eye examination. Additionally, 35% were not aware that diabetes can affect their eyes and 51% reported having at least one episode of uncontrolled blood sugar in the last year for which they had to seek urgent medical help.

In patients who had visited diabetic eye clinics previously, 93% had STDR. Nearly two-thirds (65%) of these patients with STDR had diabetes for a duration of over 10 years. Despite having attended an eye clinic at least once before, 14% of these patients were not sure if diabetes affected their eyes. Forty-nine per cent reported that diabetes affected their everyday activities and 72% reported having at least one episode of uncontrolled blood sugar in the last year for which they had to seek urgent medical help.

Out of all the patients who had visited for diabetic eye examinations previously, 35% reported that they were on tablets and 65% on insulin. All the patients who had visited previously had received some form of treatment for their eyes (eg, surgery, laser). A higher proportion of patients (60%) who had attended previously also reported that diabetes affected their everyday life (χ^2 test, p=0.04).

Summary of the data for those who were not sure if their current appointment was their first attendance for diabetic eye examination is provided as supplementary data (online supplementary table 1). Secondary analyses showed that these data did not differ significantly from the other two groups (ie, those who reported that they had attended diabetic eye examination previously and those who reported that current appointment was their first attendance for diabetic eye examination).

We had also questioned all our patients on whether physical activity was important for controlling diabetes and the number of hours per week they exercised. While 72% of patients reported knowing that exercise was important to control diabetes, only 35% of these patients carried out physical activity for at least 4 hours per week, although it is recommended that patients with diabetes do moderate to vigorous physical activity for at least 4 hours per week.[25]

Furthermore, 122 patients thought that their diabetes was controlled. However, more than half of these patients (51%) were found to have the FBS greater than the internationally recommended target level of ≤6.5 mmol/L (p<0.001).[22]

DISCUSSION

In this hospital-based cross-sectional study, we examined the retinopathy profile of 199 consecutive patients with diabetes. We examined severity of DR (STDR, NSTDR), VA, FBS, and the duration and treatment of diabetes. We also examined the diabetic awareness, self-help and lifestyle regimen of patient using a structured questionnaire.

Patients were presenting at the eye clinic with very late-stage DR and with a reduced level of VA. A very high percentage (80%) of patients were found to have STDR. In 2017, Zhang *et al*[26] conducted a cross-sectional study among patients with diabetes attending eight hospitals located across Central and South China. The definition of retinopathy was similar to ours (STDR was defined as the presence of pre-proliferative DR, proliferative DR and/or maculopathy). Across the eight hospitals, the percentage of DR ranged from 23% to 47% and for STDR the values ranged from 9% to 29%. These values are different from ours. It is known that the risk of DR increases with longer diabetic duration. The mean duration of diabetes in the Zhang *et al*[26] study was 7.5 years, while in our study, 53% of patients had a diabetic duration of >10 years (27% had very high durations of >15 years).

There are also several methodical differences between our study and published prevalence rates of DR or STDR in China. First, our study's aim was to examine the profile of patients attending a specialist eye clinic in the hospital. The data, therefore, cannot be directly compared with population-based prevalence studies. The Xu *et al*[10] study, in which patients were recruited from 15 community centres across Beijing, found the overall prevalence of DR to be 25%. They used the Modified Airlie House classification system to identify DR (the presence of at least one micro-aneurysm was taken as the minimum criterion for diagnosing DR). They did not report prevalence rates for STDR and therefore a direct comparison is difficult. Liu *et al*[27] conducted a cross-sectional study in six provinces of mainland China, in which patients were mixed: one-third of the patients were city residents, one-third were rural residents and one-third were hospital patients. They found the prevalence of any form of DR to be 34%, and STDR to be 13%. DR was classified using UK guidelines. The profile of patients was different to ours as people from the community were also recruited; therefore, a direct comparison is not again meaningful. Another community-based study by Xie *et al*[8] examined the prevalence of DR in self-reported cases of diabetes in four urban and rural communities of Beijing. The prevalence of DR was found to be 37% and vision-threatening DR to be 5%. Retinopathy severity was graded according to the ETDRS classifications. Again, direct comparison becomes difficult as these patients were not attending a specialist hospital.

A meta-analysis carried out in 2012 reported the prevalence rates of 23% for DR, 19.1% for pre-proliferative DR and 2.8% for proliferative DR in patients with diabetes.[6] Here, the classification of retinopathy is different; as we have also included severe pre-proliferative as STDR, it is expected that our percentages would be higher. Interestingly, a recent report on methodology has also included pre-proliferative retinopathy in the 'vision-threatening category.[28]

Second, we calculated the percentage of STDR based on the total number of patients rather than on the total number of eyes examined.[29] Therefore, even if only one eye has STDR, this would have added onto the overall percentage. We believe this to be an important parameter to report on the risk of retinopathy in patients.

Third, since, 41% of our patients (ie, those who were attending for the first time) were self-referred, it is likely that they were visiting the hospital only after they noticed that vision in one, or both of their eyes, had deteriorated significantly. It is to be expected, therefore that the percentage of STDR would be higher than in the community studies.

Fourth, it is also possible that geographical variations exist. Hangzhou is in the Eastern region of China. A recent systematic review and meta-analysis by Song *et al*[21] of 31 studies conducted across China found the prevalence of any DR, non-proliferative DR and proliferative DR in patients with diabetes to be 18.5%, 15.1% and 1.0%, respectively. They also found regional differences and our hospital is based in an area that is estimated to have the second highest number of people with DR in China. In addition, it is also likely that the lack of DR screening programmes in Hangzhou and surrounding areas would have contributed to the high percentage of STDR in our study.

In other parts of the world, Glover *et al*[30] reported 19.7% cases of STDR in patients attending a hospital in sub-Saharan Africa. STDR has been reported to be much lower (<6%) in the community setting, for example, in China, India and other Asian countries.[5 8 31]

Forty-one per cent of our patients with STDR had not attended any diabetic eye examination before. A significant proportion of the total patients (62%) reported seeking urgent medical help owing to 'episodes' of uncontrolled blood sugar in the last year. Twenty-eight per cent of the total patients reported not being aware that poorly controlled diabetes can lead to vision loss and 65% reported not carrying out physical activity for at least 4 hours per week as recommended by Hu *et al*[25] and Diabetes, UK.

In general, patients in our study were found to have poor diabetic control, self-help and lifestyle regimen. A large number of the patients who attended diabetic eye clinic for the first time (67%) were not aware that diabetes can affect their eyes. Furthermore, despite having attended an eye clinic at least once before, 14% of them were not sure if the diabetes can affect eyes.

It is likely that lack of awareness of diabetes and its complications would lead to inadequate self-help and poor lifestyles. A significant percentage of patients lacked awareness of diabetes and how it would affect the eyes. Our data also showed that a significant proportion of patients had to seek urgent medical help, suggesting episodes of uncontrolled diabetes and a need for close monitoring of blood sugar levels.

A previous study conducted in a community setting in the Liaoning province of China showed that 68% patients with DR were not aware that diabetes can affect eyes.[16] One might expect that this percentage would be lower for a study conducted in a hospital setting and indeed this was the case. Our data showed that 25% of all our patients were not aware that diabetes can affect the eyes. However, the proportion of the patients attending for the first time who reported to not knowing that diabetes can affect eyes was higher at 35%.

Our findings emphasise the need for early screening of DR. It also calls for improved awareness, self-help and lifestyle. A previous report indicates intervention and awareness programmes are not readily available at local communities in most parts of China, although there were moves to rectify this.[16]

A potential limitation of this study is that we did not question patients on their knowledge about HbA1c and blood pressure. Literature suggests that HbA1c and blood pressure are important risk factors for retinopathy and it might have been useful to have included

questions and measurements of these in this study.[21 26] Our pilot study had showed that most people did not know much about HbA1c levels. [21] We do not believe that this reduces the impact of the message that this study aims to demonstrate. In addition, the results are not representative of the general population as data were collected from patients attending a specialist eye clinic, and we did not use random sampling to recruit participants. However, the aim of the study was to examine the retinopathy profile of patients with diabetes attending an eye clinic in a hospital setting.

CONCLUSION

Our study shows that a large number of patients were presenting to the hospital very late when they had already developed sight-threatening retinopathy. There is an urgent need for early DR screening and for improving knowledge and awareness of diabetes in Hangzhou, China.

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Contributors SP and RS conceived and designed the study. ZC and DZ did questionnaire translations. ZC collected data. RS and SP analysed the data: RS, SP, DZ and ZC wrote and revised the paper.

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Competing interests None declared.

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