·Investigation·

Hospital based epidemiological study for diabetic retinopathy: study design and preliminary results

Lei Liu , Li-Min Liu , Yue-Dong Hu , Rui Hua , Jun Chen , Yun Zhou , Chao Wan, Le-Le Huang , Jing-Yang Wu , Jin Geng , Lei Chen

Department of Ophthalmology, the First Affiliated Hospital, China Medical University, Shenyang 110001, Liaoning Province, China
Correspondence to: Lei Chen. Department of Ophthalmology, the First Affiliated Hospital, China Medical University, Shenyang 110001, Liaoning Province, China.leichen51@hotmail.com

Abstract

• AIM: To describe the design and preliminary results of the hospital based epidemiological study for diabetic retinopathy (HBESDR), an ongoing epidemiological study to estimate the prevalence of diabetic retinopathy (DR) and to elucidate the clinical, anthropometric, biochemical and any other risk factors associated with diabetic retinopathy.

• METHODS: Totally 2000 diabetes will be recruited from the Diabetes eye clinic in the First Affiliated Hospital of China Medical University. All subjects underwent blood sugar estimation and Oral Glucose Tolerance Test to diagnose diabetes. All diabetes would undergo complete questionnaire, a comprehensive eye examination. Blood and urine would be collected for biochemical investigations. All fundus photographs for any DR will be graded. Participants who need treatment will be sent to the ophthalmic clinic and follow-up interval program for all subjects will be suggested. A computerized database is created for the records.

• RESULTS: To date, 1174 diabetes have been recruited, there were 350 (29.81%) DR in all diabetes, most of them were with mild non-proliferative diabetic retinopathy (NPDR) (139, 39.71%); 71 (20.29%) moderate NPDR, 66 (18.86%) severe NPDR, 74 (21.14%) proliferative diabetic retinopathy (PDR). Females, longer duration of diabetes, family history of diabetes and hypertension had a statistically significant increase in risk of any DR.

• CONCLUSION: The study is expected to provide an estimate of the overall prevalence of DR and the prevalence with different duration of diabetes and also a better understanding of the risk factors associated with DR.

• KEYWORDS: diabetic retinopathy; prevalence; epidemiological study

INTRODUCTION

Diabetic retinopathy (DR) has been one of the foremost causes of blindness in the working age group [1] . DR is a priority disease in the "VISION 2020" initiative for the global elimination of avoidable blindness. The World Health Organization (WHO) has recommended its member countries to integrate a program approach for DR within their prevention of blindness programs. In contrast to studies in Western countries, AMD and diabetic retinopathy appear to play a minor role as a cause of visual impairment in elderly Chinese [2] .With increase of diabetics in China the prevalence of DR would be also increasing [3]. Many previous reports shown the prevalence of DR was 1.6%-6.5% in population based study in China [4,5] but there are few reports on hospitalbased big sample epidemiological study currently. This study will be done to determine the overall prevalence of DR (with different duration of diabetes, and in newly diagnosed as well as in previously diagnosed diabetics, and in type 1 and type 2 diabetics) and the risk factors associated with DR in a big sample hospital based study.

We also want to know the new method for early detection for DR.

MATERIALS AND METHODS

The hospital based epidemiological study for diabetic retinopathy (HBESDR) is an ongoing hospital based cross-sectional study in which we which want to investigate the prevalence of DR and risk factors associated with DR. This study was commenced in June 2010, and data collection is likely to be completed by June 2013. The study has been approved by the Liaoning Provincial Health Department (Liaoning Medical Peak Construction Projects Foundation)and the study confronts important ethical considerations. The study has been divided into 6 steps.

Step 1 Preliminary Work

Sample size estimation To date there are no exact estimates of DR among hospital population in China. After reviewing the reports about prevalence of DR in China, we assumed a 2% prevalence of DR among the population, the estimated sample size was 11760, because of the prevalence of diabetes was 9.7% [3], we decided the sample of diabetes for this study was 2000. All diabetes except children aged 10 years and below will be eligible.

Area for subjects recruitment We established diabetic eye clinic to recruit the subjects, do questionnaire and eye examination. This study will enroll participants from endocrinology department, ophthalmology department and any other department which has diabetes patients.

Diagnosis definition Diabetes diagnosed according to 1999 WHO criteria [6]. Diagonosis of diabetes made by a medical practitioner, or patient using hypoglycemic medications (either oral or insulin or both medications) for known diabetes. The patient whose diabetes duration was less than 1 year was considered as newly diagnosed diabetes. Duration of diabetes was the time interval between the date of diagnosis of diabetes and the date of eye examination. If the patient whose systolic BP is ≥140mmHg or the diastolic BP is ≥90mmHg or the patient is on antihypertensive treatment will be diagnosd to have hypertension. DR was graded using the modified Airlie House classification and the Early Treatment Diabetic Retinopathy Study retinopathy severity scheme [7,8].

Quality control In order to ensure accurate and reliable data, two trained ophthalmologists will do the eye examination of the patients to standardize all the examination and diagnostic procedures.

Step 2 Questionnaire A detailed questionnaire was dministered regarding the name, age, address, telephone number, medical history including diabetes duration, type, and age of onset, present and past status, treatment of diabetes or hypertension, a family history of diabetes, hypertension disease, symptoms related to DR, tobacco and alcohol history. The ocular history taken includes details of the first and last eye examination, present or past ocular complaints, and laser treatment or ocular surgery.

Step 3 Physical Examination After questionnaire, physical examination including blood pressure, thigh length, weight, body mass index were checked.

Step 4 Eye Examination Distance visual acuity (VA) was measured using an standard logarithmic visual acuity charts at a distance of 6 meters. A comprehensive examination of each subject's eyelids, palpebral and bulbar conjunctiva, sclera and cornea, anterior chamber, iris, lens was carried out using a slitlamp. The ocular pressure was measured by an applanation tonometer (Topcon). For patients suspecting to have glaucoma, the field of vision was tested on Zeiss automated perimeter. The pupils of patients were dilated by instilling one drop of 1.0% tropicamide with normal intraocular pressure. If the pupil could not dilate after 30 minutes, one more drop of 1.0% tropicamide was added to the previous one. Fundus examination was carried out using slitlamp bio-microscope and +90D Volk lens at ×16 magnification by two ophthalmologists. Fundus photography is very useful for diagnosis and follow-up. Therefore, we took photographs for any DR fields. Ultrasound of eye and fundus fluorescein angiography (FFA) were done if necessary.

Step 5 Biochemical Investigations Blood was drawn from the antecubital vein for determination of islet function, trace elements, lipid profile, fasting plasma glucose levels. Biochemical investigations also included blood hemoglobin, glycosylated hemoglobin, liver function, urea, creatinine. and urine microalbuminuria was also estimated. All chemistries were measured at a commercially available laboratory (The Endocrinology Laboratory, China Medical University, Shenyang, China).

Step 6 Treatment The diabetics with is no DR or no sight threatening DR will be advised and followed up; but the diabetics who have sight threatening DR will be sent to ophthalmology to receive laser or vitreous surgery treatment. The collected data will be entered into the computer in time and the follow up project will be suggested.

Statistical Analysis To evaluate the relationship of different factors age, gender, duration of diabetes, hypertension, family history of diabetes on the presence of DR, a multiple logistic regression model was used. $P<0.05$ were considered statistically significant. Statistical analysis was performed using SPSS 14.0 software.

RESULTS

Currently 1174 diabetes have been recruited, 93.69% were type 2, there were 350(29.81%) DR in all diabetes, most of them were mild non-proliferative diabetic retinopathy (NPDR) (n=139, 39.71%), 71 (20.29%) were moderate NPDR, 66(18.86%) were severe NPDR, 74(21.14%) were proliferative diabetic retinopathy (PDR). The mean age of patients with DR was 54.86±11.85years. 188(53.71%) were women, 106(30.29%) were hypertension, 47(13.43%) were newly diagnosed diabetes, 137(39.14%) patients had diabetes for more than 10 years, the average duration of known diabetes was 11.39±4.85(1-38) years.

Adjusted for age, gender, duration of diabetes, hypertension, family history of diabetes, the results revealed that females, patients with a longer duration of diabetes, patients with family history of diabetes, and patients with hypertension

Table 1 Results of multiple logistic regression model for DR and factors

	OR	95%CI	*P*
Age	0.89	0.78-0.96	<0.001
Female gender	2.11	1.86-2.34	0.019
Duration of diabetes			
1-10	1.88	1.65-2.01	0.031
11-20	2.23	1.77-2.85	0.023
>20	3.31	2.98-3.57	<0.001
Hypertension	3.73	3.01-4.56	<0.001
Family history of diabetes	3.43	2.98-3.43	<0.001

OR= odds ratios; CI=confidence interval

had a statistically significant increase in risk of any DR as compared to other subjects (Table 1).

The patients who were NPDR or without any DR had been followed up every year, but PDR had been suggested to obtain panretinal photocoagulation (PRP) or pars plana vitrectomy (PPV).

DISCUSSION

To our knowledge, this study is the first big sample hospital based epidemiological study for DR prevalence in north China, so accuracy of data will be much well defined and we have taken a well-prepared design to do the research. This study provides robust epidemiological information regarding the risk factors for DR. Because of the early development of DR occurs without overt clinical signs or symptoms, we check the patient as soon as finding diabetes. It will help ophthalmologist to detect DR early and prompt treatment of sight threatening DR. The present article presents the study design and provides preliminary results regarding the study.

As the preliminary results of this study, most of diabetes was type 2, so we could perceive that the prevalence of type 2 diabetes is larger than type 1 diabetes, we must increase sample to identify the prevalence of DR in type 1 and its difference between type 2. Most of subjects were known diabetics, we can see that diabetes could not receive eye examination in time and DR is associated with diabetes duration as Macky report [9]. The overall prevalence (29.81%) observed in this study was lower than (39.2%) previously report [10], but it was higher than Shanghai report 22.9% [11]. Most of them were mild NPDR suggesting this study would be helpful to early detection DR. From the results, we assume that women could be more likely to develop DR. DR was significantly associated with long duration of diabetes and hypertension, also patients with family history of diabetes.

In conclusion, this report expounded the design and methodology for research, suggested preliminary results of the prevalence and risk factor of DR. In future, we can estimate that the possibility of occurrence of DR according to the case of diabetes and control the risk factors to prevent DR in clinic using health risk appraisal (HRA) method.

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