The Prevalence of Diabetic Retinopathy on Screening Patients with Diabetes Mellitus, admitted to a Tertiary Care Centre in Rural South India

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ABSTRACT
Background: Diabetic retinopathy is recognized as one of the ocular diseases with public health implications in India. The number of diabetic patients are rising rapidly; most of whom are not even aware of its complications. The risk of sight-threatening retinopathies is higher in diabetics. Screening of patients with diabetic retinopathy (damage to microvascular system of the retina due to prolonged hyperglycemia) is important in early detection and prevention of blindness. The relationship between duration of diabetes and severity of retinopathy can be assessed to figure out a remedy.

Objectives:
1. To evolve a screening programme for early detection of diabetic retinopathy (DR) in patients with Diabetes Mellitus (DM) admitted to this tertiary care hospital.
2. To find out how factors such as glycemic control and duration of illness affect severity of diabetic retinopathy in these patients.

Methodology: The study covered 70 diabetic patients from a rural tertiary care hospital. Demographic data, diabetic history and investigations were recorded in the case study form. The student investigator, who has earlier been trained in the skills lab and has practiced observing the fundus under supervision of ophthalmologists will perform a fundoscopic examination on the patient. They will then classify the patients into five groups. The data were collected and analyzed using chi-square test.

Results: The prevalence of DR (35.7%) was found to be higher in males. Risk of developing it was more in uncontrolled diabetics. 24.3% among those with retinopathy had mild non-proliferative retinopathy.

Conclusion: The study revealed that the risk of developing retinopathy was higher in male patients with uncontrolled diabetes. In this screening programme we were able to diagnose retinopathy in 25 of the 70 diabetic patients enrolled (35.7%). We hope this screening programme will continue for early detection of retinopathy.

Keywords: Diabetes Mellitus, Diabetic Retinopathy, fundoscopy, glycemic control, hyperglycaemia.
INTRODUCTION

An estimated 57 million people in India may be diabetic by 2025 (195% increase from 1995) and as the risk of sight-threatening retinopathies is higher in diabetic adults with Diabetes mellitus (DM), the early detection and treatment of diabetic retinopathy is imperative.\[1]\n
Diabetic retinopathy (DR) can be defined as damage to the microvascular system in the retina due to prolonged hyperglycaemia. DR is a vision threatening complication of diabetes, caused by damage to the tiny blood vessels that nourish the retina. Blood and fluids leak out causing swelling of retinal tissue and clouding of vision.\[1]\n
DR is classified into non-proliferative and proliferative diabetic retinopathy. Mild non-proliferative DR is the earliest stage where microaneurysms occur causing fluid to leak into the retina. In severe non-proliferative diabetic retinopathy many more blood vessels are blocked, depriving blood supply to areas of the retina. These areas secrete growth factors that signal the retina to grow new blood vessels. Proliferative DR is distinguished by the growth of new blood vessels on the retina and posterior surface of the vitreous. In the advanced stage, growth factors secreted by the retina trigger the proliferation of new blood vessels, which grow along the inside surface of the retina and into the vitreous humour. The new blood vessels are fragile, which make them more likely to leak and bleed. This can cause diabetic macular oedema and accompanying scar tissue can contract and cause retinal detachment.

The CURES eye study showed that the major risk factors for onset and progression of DR are duration of diabetes, degree of glycaemic control and hyperlipidaemia.\[2]\n
A recent population based study from South India found a prevalence of 1.3% among self-reported diabetic patients above the age of 50 years\[3]\n
while another study with over 5900 participants showed that the duration of diabetes is the strongest predictor for DR.\[4]\n
A hospital-based study from Western India showed that prevalence of DR increased with duration of diabetes and that hypertension was a risk factor for development of DR.\[5]\n
Patients with DR had higher insulin resistance and low-density lipoprotein cholesterol and triglyceride levels, however at multivariate regression analysis, insulin resistance was the only independent marker of severity of DR.\[6]\n
Screening of patients with DM is important as early detection of DR can be treated with laser and other modalities that are proven to decrease the risk of vision loss.\[7]\n
Even in the US, 60% of patients who require vision-preserving laser surgery do not receive treatment on time.\[8]\n
This study was planned to screen patients with diabetes mellitus to find the prevalence of DR in patients with diabetes mellitus coming to this institution. We would like to assess the severity of DR by grading the retinopathy into the four stages mild non-proliferative retinopathy, severe non-proliferative retinopathy, proliferative retinopathy and retinopathy with clinically significant macular oedema. We would also like to find out if there is a relationship between severity of DR and glycaemia control and duration of DM and. We hope this study will help to evolve a screening programme for early detection of DR in our institution.

MATERIALS AND METHODS

This study was a hospital based cross-sectional study to screen for diabetic patients coming to this institution for management. The study was conducted on 70 diabetic patients visiting this rural tertiary care hospital with the aim of implementing a regular screening programme for all diabetic patients coming to this institution.

Study population: All consenting patients with Diabetes mellitus (DM) admitted to this in the medicine ward were serially recruited for this study if they fulfilled the selection criteria.

Inclusion criteria: Patients admitted with established DM, over the age of 30 years with blood sugar levels available and at least one record of HbA1c in the past 6 months >6.
Exclusion criteria: Patients who are very ill and those who do not permit ophthalmoscopy.

Sample Size: The sample size using the prevalence of DR in the study by Narendran et al [3] of 26.8% with a precision of 10.5% and confidence interval of 95% was found to be 68 subjects with diabetes mellitus. We therefore recruited 70 participants for this study.

Study Procedure: After obtaining approval from the institutional review board and the ethics committee, consecutive patients who were willing and fulfilled the selection criteria were screened in the ophthalmology department for DR by a senior consultant. The demographic data of the patients were collected. Duration of diabetes, diabetic history, co-morbidities, investigations and eye examination details were recorded. After fundoscopy and diagnosis the participants were grouped into two categories based on the presence of retinopathy. The participants with retinopathy (n=25) were further classified into

a) with mild non-proliferative retinopathy,
b) severe non-proliferative retinopathy,
c) proliferative retinopathy and those with
   d) clinically significant macular edema.

The data was then entered into Microsoft excel spreadsheet and statistically analysed using the statistical program for social sciences (SPSS) software. The prevalence of DR in diabetic patients and frequencies of the variables were obtained. Pearson’s Chi-square test was used to estimate the significance of the various risk factors in the participants who were diagnosed to have DR compared to those who did not.

Ethical considerations: A senior consultant in ophthalmology performed the fundoscopy and made the diagnosis of DR. The student investigator was trained to do the fundoscopy and worked under the direct supervision of the ophthalmologist. All patients detected to have DR were given appropriate treatment. The medicine department were informed about the study to initiate a protocol by which all diabetic patients coming to this institution can be routinely screened at optimal intervals for DR.
RESULTS
The study involved 70 diabetic patients recruited to the study 38 (54.3%) were males and 32 (45.7%) were females. Table 1 shows the baseline data of the participants.

Table 1: Baseline data of study population (n=70)

| Variables                  | DM patients without Retinopathy (%) n=25 | DM patients with Retinopathy (%) n=45 | Total Number (%) n=70 | p value |
|----------------------------|------------------------------------------|---------------------------------------|------------------------|---------|
| **Gender**                 |                                          |                                       |                        |         |
| Male                       | 18 (40.0)                                | 20 (80.0)                             | 38 (54.3)              | .001    |
| Female                     | 27 (60.0)                                | 5 (20.0)                              | 32 (45.7)              |         |
| **Age (years)**            |                                          |                                       |                        | .138    |
| 30-45                      | 12 (26.7)                                | 5 (20.0)                              | 17 (24.3)              |         |
| 46-60                      | 20 (44.4)                                | 15 (60.0)                             | 35 (50.0)              |         |
| >61                        | 13 (28.9)                                | 5 (20.0)                              | 18 (25.7)              |         |
| **Physical activity**      |                                          |                                       |                        | .233    |
| Physically active          | 40 (88.9)                                | 24 (96.0)                             | 64 (91.4)              |         |
| Sedentary                  | 5 (11.1)                                 | 1 (4.0)                               | 6 (8.6)                |         |
| **Co-morbidities**         |                                          |                                       |                        |         |
| Hypertension               | 6 (13.3)                                 | 4 (16.0)                              | 10 (14.3)              | .266    |
| Cardiac disease            | 1 (2.2%)                                 | 3 (12.0)                              | 4 (5.7)                | .113    |
| Others                     | 3 (6.7%)                                 | 4 (16.0)                              | 7 (10.0)               | .150    |
| **Glycemic control**       |                                          |                                       |                        | .001    |
| Controlled                 | 22 (48.9)                                | 3 (12.0)                              | 25 (35.7)              |         |
| Uncontrolled               | 23 (51.1)                                | 22 (88.0)                             | 45 (64.3)              |         |
| **Duration of Diabetes**   |                                          |                                       |                        | .027    |
| <1 year                    | 11 (24.4)                                | 3 (12.0)                              | 14 (20.0)              |         |
| 1-5 years                  | 20 (44.4)                                | 9 (36.0)                              | 29 (41.4)              |         |
| >5 years                   | 14 (31.1)                                | 13 (52.0)                             | 27 (38.6)              |         |
| **Visual acuity (Snellen’s Test)** |                                  |                                       |                        | .470    |
| Right Eye                  | 27 (60.0)                                | 14 (56.0)                             | 45 (58.6)              |         |
|                            | 18 (40.0)                                | 11 (44.0)                             | 25 (41.4)              |         |
| Left Eye                   | 28 (62.2)                                | 14 (56.0)                             | 41 (60.0)              | .398    |
|                            | 17 (37.8)                                | 11 (44.0)                             | 28 (40.0)              |         |
| **Diagnosis by Fundoscopy**| 45 (64.3)                                | 25 (35.7)                             | 45 (64.3)              | .001    |
The prevalence of DR was significantly more in male diabetic patients than in females ($p=0.001$). Half the patients in the study belonged to the age group 45 to 60 and 44.4% of patients with DR were in this age group. Though more patients who had less physical activity among the Diabetic patients had retinopathy this was not significantly different from those who did not. The presence of co-morbidities such as hypertension and cardiac disease or the visual acuity of the patient indicated by the Snellen’s test were not significantly different in the two groups. Uncontrolled diabetics had a significantly greater risk of having DR however the duration of being diabetic did not seem to be a significant factor in patients with DR compared to those who did not have DR.

The frequency distribution of the various stages of DR seen in the study participants is shown in figure 2.

**DISCUSSION**

Our study to initiate a screening programme for patients with diabetes mellitus enrolled 70 consecutive patients with diabetes mellitus aged between 30 and 80 years, coming to the out-patient service of this rural tertiary care centre. Similar studies conducted earlier included larger number of patients.

The reported prevalence of diabetic retinopathy in India ranges from 17.6% to 28.2%. In this study was found to be 35.7%. The higher percentage in this study may be because this is a hospital-based study. In a nationwide population based cross-sectional study conducted as an initiative of AIOS, 6218 patients were screened across 194 centres. 5130 were considered suitable for further evaluation. Among these 61.2% were males. About 88.6% of those screened were between 40 and 80 years of age. The prevalence of DR in the entire data set was 21.7%; more in males. Our study consisted of 38 males and 32 females. 50% of the patients were in the age group of 46-60 years. Risk of retinopathy was found to be more in males.

The duration of diabetes was taken into consideration in this study. The prevalence of DR was 9.23 for those less than 6 months, 15.12 for those between 6 months and 5 years and 35.12 for those greater than 5 years. Age wise distribution was also analysed and showed highest prevalence of 25.04% amongst those aged between 61 and 80 years; least amongst 0 to 20 years of age. Our study showed prevalence of 20 for those less than a year, 41.4 for those between 1 to 5 years and 38.6 for those more than 5 years.

A pooled analysis of 35 population-based studies including data for 22896 individuals was undertaken. The overall prevalence of any DR was 34.6%, while the prevalence for proliferative DR was 6.96% and for diabetic macular edema was 6.81%. The prevalence for proliferative DR in our study was 2.9% and for macular oedema was 4.3%. Eleven studies reported on associations of risk factors for development of DR; and all the studies which included duration of diabetes, found that it was a significant risk factor. Ten studies included increasing age as a risk factor and only 2 found a significant association with DR. Eight studies considered level of glycaemic control as a risk factor and 6 of them found a significant association with DR. Our study showed a significant association of gender and glycemic control with retinopathy.
In a recent study of retinopathy status at presentation in self-reported type-2 diabetes in a tertiary care facility, 73.7% patients reported in NPDR stage though only 51% had good vision.

CONCLUSION
In our study the prevalence of diabetic retinopathy in patients with diabetes mellitus was found to be 35.7%. There was a greater prevalence of diabetic retinopathy among males. Our study showed that those who had uncontrolled diabetes were more prone to develop retinopathy. The duration of diabetes and its relationship to severity of retinopathy turned out to be statistically insignificant.

We have initiated a system whereby all diabetic patients coming to this institution can have periodic screening done for diabetic retinopathy.

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