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Original Research Article

A retrospective study of the prevalence and management of complications of proliferative diabetic retinopathy and its visual outcome in patients in a tertiary care hospital

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ABSTRACT

Aim: To provide the prevalence of complications of proliferative diabetic retinopathy (PDR) in patients visiting the retina clinic in Dr. B. R. Ambedkar Medical College and Hospital and to evaluate their visual acuity (VA) status.

Materials and Methods: A retrospective study in which the chart review was done of the patients diagnosed with PDR, attending the retina clinic in Dr. B.R. Ambedkar Medical College and Hospital. Patients with a diagnosis of type 1 or 2 diabetes with a clinical diagnosis of active PDR in any or both eyes, who had long term follow-up for up to at least 5 years were included. Evaluating the prevalence of the complications of PDR, presenting VA of people with PDR, short-term outcomes at 6 months and 5 years are the main outcomes of the study.

Results: The most common complication of PDR was diabetic macular edema (DME). Eyes receiving treatment early in the disease course (i.e. baseline VA 6/18 or better) had significantly better VA outcomes at 5 years versus eyes treated at a later stage (i.e. baseline VA <6/18 - ≥3/60). The treatment of patients with VA <3/60 can also lead to significant improvement in visual outcome.

Conclusion: Our results suggest that early diagnosis and treatment of patients with PDR is of utmost importance in preventing severe vision loss due to advanced diabetic eye disease. People with diabetes in India need to be made aware of annual screening and treatment of their eyes to avoid vision impairment and blindness.

1. Introduction

Proliferative diabetic retinopathy (PDR) is a treatable cause of severe visual loss in people with diabetes. PDR develops in more than 50% of cases after about 25 years of the onset of disease. Therefore, it is more common in patients with juvenile onset diabetes.[1]

If left untreated, most eyes with low risk PDR progress to high risk PDR with increasing retinal or disc neovascularization. These eyes remain symptomless until the onset of complications such as vitreous hemorrhage, tractional retinal detachment or diabetic macular edema (DME).[2,3]

Systematic screening and timely treatment of PDR in countries with established screening programs have resulted in a decrease in the rate of blindness and the incidence of Advanced Diabetic Eye Disease (ADED) over time.

Screening for diabetic retinopathy (DR) is still at its early stages in most low and middle-income countries (LMIC).[4]

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According to the DRCR.net group, the treatment of macular edema was divided into centre involving and non centre involving macular edema. Centre involving macular edema was treated by intravitreal anti – VEGF injections, whereas non centre involving macular edema was treated by laser therapy.[5]

Indications for pars plana vitrectomy are severe persistent vitreous haemmorhage, progressive tractional RD and neovascular glaucoma.[6]

In countries like India, where most patients are dependent on out of pocket expenses for their healthcare, the management of diabetic eye disease is influenced by cost of care, lack of screening programs and the lack of public awareness of diabetic eye disease and the need for regular follow-up for ongoing treatment. There is also a wide variation in provision of healthcare in India, with some centers providing world-class services to others that do not have basic facilities or personnel to provide treatment.

2. Materials and Methods

A retrospective study in which the chart review was done of the patients diagnosed with PDR, attending the retina clinic in Dr. B. R. Ambedkar Medical College and Hospital.

2.1. Study population

Patients with a diagnosis of type 1 or 2 diabetes with a clinical diagnosis of active PDR with complications like VH, retinal detachment (RD), fibrovascular proliferation (FVP), neovascular glaucoma (NVG) in any or both eyes and had long term follow-up for up to 5 years were included in the study. Clinical practice for treatment of PDR involves pan retinal photocoagulation (PRP) for low and high risk PDR. Anti-vascular endothelial growth factor (VEGF) injections are given in cases with diabetic macular edema (DME). For advanced PDR appropriate surgical intervention are performed when indicated. The patients who had prior treatment in another hospital before being seen were excluded from the study.

2.2. Study design

This is a retrospective study. The patient data were identified from patient records or from registers maintained since 2016 to allow for outcome measurements at 6 months and 5 years. Consecutive patients who met the inclusion criteria were included in the study.

2.3. Baseline data

Baseline data collected included age, sex, duration of diabetes and best corrected visual acuity (BCVA), DR status in both eyes and presence of DME. PDR status was defined as per the Early Treatment Diabetic Retinopathy Study (ETDRS) classification.

High risk PDR included NVD $\frac{1}{4}$ to 1/3 disc area with or without vitreous haemmorhage (VH) or pre retinal haemmorhage (PRH), NVD < $\frac{1}{4}$ disc area with VH or PRH and NVE > $\frac{1}{2}$ disc area with VH or PRH all not obscuring the macula. Advanced PDR was defined as VH / PRH obscuring the macula.

The presence of complications like VH, RD, fibrovascular proliferation (FVP), NVG was also recorded.

At final follow up, active / persistent PDR was defined as eyes with new features suggesting reactivation or proliferation or potentially sight threatening complications of fibrous proliferation. Stable treated PDR was defined as eyes with evidence of photocoagulation, regressed neovascularization and absence of features of active disease.

2.4. Follow-up data

Available follow-up data on VA was collected at 6 months and 5 years post baseline. The number of PRP sessions, cataract surgery, treatment of DME and vitrectomy was recorded within the first 6 months when most PDR eyes should stabilize if adequate PRP is given and a total number of concomitant procedures over 5 years was collected to understand the long-term treatment requirements.

2.5. Visual acuity

It was done using Snellen's chart an ETDRS chart.

2.6. Definition of visual impairment and blindness

The WHO criteria defined no VI as 6/18 or better, VI was worse than 6/18 but no worse than or equal to 3/60 and blindness was defined as worse than 3/60. For the purpose of the study these groups will be divided into group 1 ie. VI as 6/18 or better, group 2 ie. VI was worse than 6/18 but no worse than or equal to 3/60 and group 3 ie. worse than 3/60.

2.7. Statistical analyses

Descriptive statistics was used to analyse the baseline characteristics. The visual outcomes at 6 months and 5 years were analysed for all eyes, better eye and worse eye at individual levels. Multivariable regression was used to analyse the effect of baseline factors on VI and blindness.

3. Results

Data was collected on a total of 100 patients. VA data was collected at baseline, at 6 months and at 5 years for all the patients. Of the 100 patients, 64% were male and 36% were female. Maximum number of patients was in the age group of 51 -60 years followed by 41 – 50 and 61 – 70 age group. Mainly 4 complications of PDR were identified i.e. DME, VH, RD and NVG. A maximum number of patients was found to have DME (76%). This was followed by VH (12%)

and RD (8%). The least common complication was NVG (4%).

Although PRP was the main treatment done for all eyes with active PDR, other interventions were also required over the next 5 years. Eyes with PDR and DME were mainly treated with PRP laser and anti VEGF injections. Pars plana vitrectomy was done for NVG and RD cases and a few VH cases also. PRP was done in all 100% of the cases. Anti – VEGF was given in 79% whereas pars plana vitrectomy was done in 21% of the cases.

Most of the patients presented late in the course of the disease i.e. when VA<6/18.

The visual acuity at baseline in the better eye was 27% in group1, 57% in group 2 and 16% in group 3. VA at 6 months in the better eye was 43% in group 1, 55% in group 2 and 2% in group 3. VA at 5 years in the better eye was 39% in group 1, 59% in group 2 and 2% in group 3.

VA at baseline in the worse eye was 18% in group 1, 58% in group 2 and 24% in group 3. VA at 6 months in the worse eye was 36% in group 1, 60% in group 2 and 4% in group 3. VA at 5 years in the worse eye was 24% in group 1, 72% in group 2 and 4% in group 3.

In the better eye there was a significant increase in the number of patients in group 1 at 6 months compared to that at baseline i.e. from 27% to 43% (p<0.001). Also there was a significant decrease in patients in group 3 at 6 months compared to the baseline i.e. from 16% to 2% (p<0.001).

In the worse eye also there was a significant increase in the number of patients in group 1 at 6 months compared to that at baseline i.e. from 18% to 36% (p<0.001). Also there was a significant decrease in patients in group 3 at 6 months compared to the baseline i.e. from 24% to 4% (p<0.001).

In the better eye there was a decrease in the number of patients in group 1 at 5 years compared to that at 6 months i.e. from 43% to 39% whereas the number of patients in group 3 remained constant at 2%

In the worse eye also there was a decrease in the number of patients in group 1 at 5 years compared to that at 6 months i.e. from 36% to 24% whereas the number of patients in group 3 remained constant at 4%.

Among the patients at baseline with early diagnosis in disease course (i.e. group 1) and early treatment initiation resulted in 39% of better eyes and 24% of worse eyes to maintain VA 6/18 or better at 5 year follow up. Only 4% of the better eyes and 12% of the worse eyes ended up with VA worse than 6/18 at the end of 5 years.

This was in contrast to patients at baseline in group 2 that were diagnosed late and thus treated late in the course of the disease. Only 16% of better eyes and 18% of worse eyes were able to achieve and maintain VA 6/18 and better at 6 months and as high as 41% of better eyes and 40% of worse eyes had VA worse than 6/18 at 6 months follow up (p < 0.001).

20% of worse eyes and 16% of better eyes of group 3 improved to vision of >3/60 at 6 months compared to the baseline (p<0.001). This showed that treatment of even group 3 patients can have significant improvement in vision. 2% of better eyes and 4% of worse eyes remained at the same level i.e. <3/60. All of these patients had NVG.

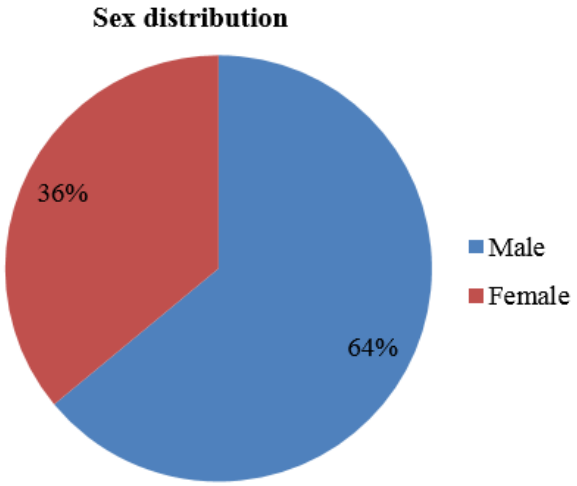

Fig. 1: Sex distribution of patients

Table 1: Age distribution of patients

Age group	Percentage
30-40	10
41-50	25
51-60	32
61-70	25
71-80	8

Table 2: Distribution of complications of PDR

Complication	Percentage
DME	76
VH	12
RD	8
NVG	4

Table 3: Distribution of interventions done

Intervention	Number of patients
PRP	100
Anti – VEGF	79
Vitrectomy	21

4. Discussion

The main outcomes of the study are evaluating the prevalence of the complications of PDR, presenting VA of

Table 4: Distribution of eyes according to VA at baseline

VA at baseline	Worse eye	Better eye
6/18 or better	18	27
<6/18 to ≥3/60	58	57
<3/60	24	16

Table 5: Distribution of eyes according to VA at 6 months

VA at 6 months	Worse eye	Better eye
6/18 or better	36	43
<6/18 to ≥3/60	60	55
<3/60	4	2

Table 6: Distribution of eyes according to VA at 5 years

VA at 5 years	Worse eye	Better eye
6/18 or better	24	39
<6/18 to ≥3/60	72	59
<3/60	4	2

people with PDR, short-term outcomes at 6 months and 5 years.

Data collected from clinical trials on PDR patients conducted in high-income countries show that PRP remains an ideal treatment option for PDR with good short and long-term visual outcomes despite a 40% dropout of patients by 5 years.[7–9]

Inadequate screening contributes to poor presenting vision in most of the low income countries especially India. VA at baseline and final visual outcomes present in thus study further reinforces the importance of screening programs.

This point further highlights the late presentation of a significant number of patients for treatment.

Gross et al compared PRP with intravitreal ranibizumab.[7] Sivaprasad et al also compared intravitreal aflibercept and PRP.[8] These studies showed that PRP is a good treatment for PDR. Also Bressler et al compared PRP with intravitreal ranibizumab.[10] This also showed PRP is a good treatment. Gross et al also compared the 5 year outcomes of PRP with intravitreal ranibizumab. PRP showed good response.[9] All these studies showed similarities to our study.

Presenting VA and severity of PDR are both predictors of visual outcome.[11,12]

Therefore, it is very important that policies are in place for systematic screening and care pathways be designed for timely treatment and follow-up of this high-risk group. The challenges include the costs of laser devices and expertise required at the treatment centers.

The reports from the Vision Loss Expert Group of the Global Burden of Disease Study show that the prevalence of blindness due to DR has not decreased from 1990 to projected figures in 2020.[13] Whilst the prevalence of PDR in people with diabetes is about 3% in India, PDR and its complications are the most common cause of DR related blindness. As PDR is initially asymptomatic, another barrier to treatment is the lack of public and patient awareness of the need for timely treatment. Therefore, more patient education and programs have to be initiated to ensure these changes. After initial PRP, most patients will require fill-in sessions. In Protocol S, 38% required further laser in the first 6 months.

This study also concluded that PRP is not a one off procedure and that the patients need to be monitored regularly over a prolonged period.

This study also shows that despite PRP, nearly 70% of the patients had VI at 5 years, suggesting that patients may be monitored less frequently than required.

Our study results are similar to those reported from short term studies in other LMIC highlighting the challenges in the management of PDR in resource constrained countries.

A population based study by Varma et al also reinforced that baseline VA is an important predictor of visual outcome in PDR.[14]

Monitoring the systemic parameters such as glycemic control, blood pressure control and the renal parameters during the follow-up of patients treated for PDR would be invaluable for sustaining improvement in visual outcomes and reducing the burden of VI. As PDR is the most common cause of blindness, the resource requirements for these individuals are higher.

There are approximately 3 million people with PDR in India and there are less than 1000 practicing vitreo-retinal surgeons equating to one surgeon for every 3000 patients. With the lack of trained human resources for vitreo-retinal surgery, it is obvious that the LMIC countries are in a vicious cycle of limited resources, lack of screening, poor presenting VA and need for vitreoretinal surgery. The only opportunity to break this cycle is to implement screening programs, strengthen the primary care system to control the risk factors of retinopathy and improve health seeking behaviors of our patients by increasing their awareness of the need for screening and frequent monitoring of their eyes.

The strength of this study is it provides both short and long-term outcomes of PDR in a LMIC. There is a paucity of these types of studies globally. The study highlights an urgent need for quality improvement of the care we provide patients with diabetes at high-risk of visual loss.

Limitations of this study include the retrospective nature of the study. Selection bias may also influence the outcome of the study. Only patients who were followed up for up to 5 years are included in this study. As these patients should ideally have received the best care compared to those who were lost to follow-up, the study results may have underestimated the prevalent and incident cases of VI and blindness. However, the magnitude of VI in this study cohort indicates the need for implementation of national improvement programs.

A further recommendation is the need for electronic medical records to ensure the roll out of frequent service evaluations and quality improvement programs.

5. Conclusion

In conclusion, the results of this study show that there is an urgent need for improved public awareness of sight threatening complications of diabetes, systematic DR screening and prompt treatment of PDR to reduce the magnitude of vision impairment and blindness in people with diabetes. It is the duty of the policymakers to increase the screening programs and strengthen the primary care system to ensure any improvement.

6. Conflict of Interest

The authors declare that there are no conflicts of interest in this paper.

7. Source of Funding

None.

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