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IMPACT OF PANRETINAL PHOTOCOAGULATION ON THE QUALITY OF LIFE IN PATIENTS OF PROLIFERATIVE DIABETIC RETINOPATHY

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ABSTRACT

Importance: To evaluate the impact of panretinal photocoagulation (PRP) on the quality of life in patients of proliferative diabetic retinopathy (PDR). PRP affects various visual functions like visual acuity, contrast sensitivity, glare, visual fields. This study describes the impact of PRP on the visual functions and the quality of life in Indian population. **Objective:** To evaluate the impact of panretinal photocoagulation (PRP) on the quality of life in patients of proliferative diabetic retinopathy (PDR). **Design:** Prospective interventional study. **Setting:** Single centre study conducted at a tertiary eye hospital in North India. **Participants:** Sixty eyes of 30 patients of PDR without diabetic macular edema (DME) and planned for PRP were evaluated before PRP and 3 months after it for the following: vision for distance and near (Log Mar Chart), indirect ophthalmoscopy, visual field testing (HVF 120'2), contrast sensitivity (Low Contrast Flip Chart), grading of photophobia and quality of life (QOL) related questionnaire (IND-VFQ33). **Results:** There was a statistically significant worsening in contrast sensitivity (p= 0.02) and visual fields (p= 0.003). There was no statistically significant change in the distance and near vision (p= 0.94 and p= 0.51) as well as in photophobia (p= 0.06). The assessment of the QOL parameters showed no statistically significant worsening on the general functioning (p= 0.16), psychosocial impact scale (p= 0.17) and visual symptoms scale (p= 0.12). **Conclusion:** PRP for PDR causes a decrease in contrast sensitivity, visual fields with a possible increase in photophobia but this does not have a significant impact on the QOL of diabetic patients.

KEYWORDS: Panretinal photocoagulation, diabetic retinopathy, quality of life.

INTRODUCTION

Diabetes is rapidly emerging as a potential epidemic in India.[1] Over the past decade, its prevalence has risen faster in low- and middle-income countries than in high-income countries.[2] Diabetes is a multisystem disorder affecting several organs of the body including the eyes. Any diabetic is said to have a potential risk of developing diabetic retinopathy (DR) after ten years of the disease.[3] There are two stages of DR- non-proliferative DR (NPDR) and proliferative DR (PDR). Neovascularization of the retina is the hallmark of PDR which develops secondary to ischemia of the retina. Laser photocoagulation has been proven as an efficacious treatment modality for PDR.[4] The standard of care for PDR is multiple sittings of PRP, in which the peripheral retina is ablated and the hypoxic retina is made anoxic thereby helping in the regression of the retinal neovascularization. In the past, the impact of PRP has been studied on various visual functions like visual acuity,[5-8] contrast sensitivity,[7,9,10] glare,[11] visual fields.[7,12-14] and on vision related quality of life.[15,16] The impact on vision related quality of life has been assessed using NEI-VFQ-25 in the past.[15,16] The validity of the questionnaire has been tested on African and Asian populations. However for low income countries, IND-VFQ-33 questionnaire has been tested to be better.[17] We evaluate the impact of PRP on the various visual functions and the overall impact it has on the quality of life (QOL) of diabetic patients in Indian population using the IND- VFQ-33 questionnaire.

Methods

A prospective, interventional study was conducted at a tertiary eye hospital in North India. The study was approved by institutional ethics committee and conducted according to the principle of the Declaration of Helsinki. Informed consent was obtained for all participants. The following patients were included in the study: age more than 18 years, PDR without DME and planned for PRP, BCVA $\geq$ 6/60 in both eyes, not planned for any ocular surgery within 6 months after PRP, no history of glaucoma, no history of laser photocoagulation

or pars plana vitrectomy, no evidence of vitreous or subhyaloid haemorrhage in either eye.

Sixty eyes of 30 diabetic patients diagnosed to have PDR without any evidence of DME after a baseline ocular examination including indirect ophthalmoscopy, slit lamp biomicroscopy, optical coherence tomography(OCT) and fundus fluorescein angiography (FFA) were included. All patients were advised PRP. They were evaluated before and 3 months after PRP for the following: vision for distance and near (Log Mar Chart), indirect ophthalmoscopy, visual field testing (HVF 120'2), contrast sensitivity (Low Contrast Flip Chart), grading of photophobia[18] (Table-1) and QOL related questionnaire (IND-VFQ33).[17]

The QOL questionnaire comprised of 21 point general functioning scale, 5 point psychosocial impact scale and a 7 point visual symptoms scale. These three scales captured the semantic flavour of patient-identified problems of function, behaviour, feelings and symptoms.[17]

Technique of Laser PRP

All patients underwent laser PRP in 3 sittings with an interval of 4 to 7 days between any 2 laser sittings. PRP was done using slit lamp laser delivery system and frequency double Nd:Yag (532nm) laser of Carl Zeiss. Spot size was 300 µm and the duration was 0.10 to 0.15 sec. Two spots were kept one spot size apart. On average, 2400 -3000 spots were given in each eye.

Statistical analysis

Statistical analysis was performed using International Business Machines (IBM) Statistical Product and Service Solutions software version 16(SPSS Inc, Chicago, IL). In order to check the statistical significance of difference we applied t-test for continuous variables like distance and near vision, contrast sensitivity, mean deviation (MD) of HVF testing before and after laser. Chi-square test was used for categorical variables such as photophobia grading. The impact on QOL was assessed by IND-VFQ33 questionnaire which uses a 5-point (1-5) Likert scale for general functioning, 4-point (1-4) Likert scale for psychosocial impact and visual symptoms. Each scale scored using a simple addition of the values according to response scales (e.g. general functioning scale can score from 21 (no problems on all items in this domain) to 105 (maximum responses on all items). Paired sample t- test as well as Wilcoxon and Sign tests were used to compare the impact before and after laser. The level of significance was set to $p<0.05$.

Vision assessment

The best corrected visual acuity (distance and near) was recorded in LogMAR units. Vision gain was defined as gain of more than 3 LogMAR lines between pre- and post PRP assessments. Stable vision was defined as change in vision by ≤3LogMAR lines. Clinically significant vision loss was defined as a loss of more than 3 LogMAR lines between pre- and post PRP assessments.[19]

RESULTS

The study enrolled 40 patients. Of these 40 patients, 10 were excluded due to insufficient documentation and inadequate follow-up. The remaining 60 eyes of 30 patients were included in the analysis. There were 12 males and 18 females. The mean age of the patients was 50.6 ± 8.6 years. All the patients underwent 3 sittings of PRP. The following parameters were evaluated at baseline and 3 months post PRP.

The comparison of distance vision at 3 months after PRP with baseline parameters showed,3 out of 60 eyes (5%) having deterioration in vision while 57 eyes (95%) maintained a stable vision.(Fig.-1) The mean distant visual acuity showed no statistically significant change at 3 months after PRP (p= 0.94). (Table-2) Near vision assessment showed deterioration in 7 eyes (11.67%)while 53 eyes (88.33%) maintained a stable vision.(Fig.-1)The mean near visual acuity showed no statistically significant change at 3 months after PRP (p= 0.51). (Table-2)

Grading for photophobia showed deterioration in 24 eyes (40%) while 36 eyes (60%) showed no change. (Fig.-1) Photophobia seems to be worsening post PRP. It is not possible to conclude definitely though, the difference in distributions of photophobia grades pre and post PRP is very close to statistical significance (p =0.06). Before the treatment, photophobia was absent in 47% (28) of the patients. 40% (24 patients) had mild, 12% (7 patients) had moderate and 2% (1 patient) had severe photophobia. Post PRP the distribution changed to absent in 27% (16 patients), mild in 43% (26 patients), moderate in 28% (17 patients) and severe in 2% (1 patient) respectively (p= 0.06).(Table-3)

Contrast sensitivity showed deterioration in23 eyes (38.33%) while 37 eyes (61.67%) had no change.(Fig.-1)Mean contrast sensitivity on the low contrast flip chart showed a statistically significant decrease at 3 months follow up after PRP (p=0.02).(Table-2) Assessment of MD on HVF testing showed deterioration in 42 eyes(70%) and no change in 18 eyes(30%).(Fig.-1)MD of HVF testing showed a statistically significant worsening at 3 months follow up after PRP from -8.792 ± 4.162 to -10.474 ± 5.305 (p=0.003).(Table-2)

The results for QOL assessment with IND-VFQ33 questionnaire were as follows- the mean score for general functioning, psychosocial impact scale and visual symptoms scale did not show any statistically significant difference post PRP (p= 0.16, p= 0.17 and p=0.12 respectively). (Table-4) General functioning questionnaire score showed an improvement in 9/30(30%), deterioration in 18/30(60%) and stability in 3/30 (10%) subjects. Psychosocial impact questionnaire score showed an improvement in 7/30(23.33%),

deterioration in 10/30(33.33%) and stability in 13/30(43.33%) subjects. Visual symptoms response assessment showed an improvement in 8/30(26.67%), deterioration in 17/30(56.67%) and a stable score in 5/30(16.67%).(Fig.-2)

DISCUSSION

Diabetes mellitus is on the rise globally. 415 million people are known to have diabetes in the world in the year 2015 and 642 million people are expected to have diabetes in the world by the year 2040.[20] India and China are toppers in the prevalence of diabetes. India has 69.2 million people living with diabetes (8.7%) as per the 2015 data.[20] Diabetes is rapidly gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. According to Wild et al. the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see a significant increase in those affected by the disease.[21]

An increasing trend in the prevalence of DR is seen in high income sub-regions, Asia, North Africa and middle East. The mean age for the manifestation of DR is younger in Indian population compared to the global average.[22] PDR may develop in any diabetic patient after 10-15 years for which laser PRP has been the standard of care.[23]

In our study, the mean visual acuity for distance and near remained unaffected post PRP (p= 0.94 and 0.51 respectively). This finding matches the metaanalysis by Evans JR et al who showed little difference between eyes that received PRP and those allocated to no treatment, in terms of 15 or more letters of change in visual acuity at 1 year follow up.[4] Study by Perwez Khan et al showed visual acuity deterioration one week post PRP which improved subsequently at 3 months followup due to the resolution of macular edema.[7]

The contrast sensitivity was measured using low contrast flip chartand the mean was found to be significantly decreased after PRP(p= 0.02). The study by Preti RC et al also found a decrease in contrast sensitivity post PRP.[10] The study by Perwez Khan et al[7] and Khosla et al[9] showed reduction in contrast sensitivity 1 week post PRP which returned to baseline at 3 months follow up. This is in contrast to our study where the contrast sensitivity remained decreased at 3 months follow up.

Photophobia seems to be worse post PRP. It is not possible to conclude definitely though, the difference in distributions of photophobia grades pre and post PRP is very close to statistical significance (p =0.06). It has been shown that PRP causes increase in pupil size and hence glare in the study by Yilmaz I et al.[11]

On assessment of the visual fields by automated perimetry HFA II programme 120-2 SITA standard, mean MD of HVF testing worsened from -8.792 to -10.474(p= 0.003). Therefore there was further worsening of MD following PRP and this finding is similar to what has been reported by Perwez Khan et al.[7] Trick GL et al showed that the diabetics have significantly less peripheral visual field than their age matched normals. This decreased field in diabetics is due to sub-clinical microangiopathy.[13] Fong et al reported that 50% of the treated patients had visual field defects depending upon the intensity of PRP burns.[12]

Snellen visual acuity may fail to assess many aspects of visual disability and functioning.[24] Therefore various questionnaires were developed to assess the vision related impact on quality of life such as 51 item National Eye Institute Visual Function Questionnaire (NEI- VFQ), Visual function index- 14 (VF-14), Activities of Daily Vision Scale (ADVS), 36 item Short Form Health Survey (SF-36). However 51 item NEI- VFQ was not found suitable for assessment of visual disability in diabetic retinopathy.[25,26] The validity of NEI-VFQ-25 had been tested on the African and American patients with DR.[27] IND-VFQ33 has proven to be a psychometrically sound measure of visual function in low income countries.[17] It is found to be valid for conditions like cataract, glaucoma, age related macular degeneration and DR. Therefore in our study, IND-VFQ33 was used which has already been tested on Indian population. It is a 33 point questionnaire which includes 21 questions on general functioning, 5 on psychosocial impact and 7 on visual symptoms. Each scale was scored using a simple addition of the values according to the response scale.[24]

There was no significant impact on the general functioning, psychosocial impact scale and visual symptoms scale following PRP. This shows that laser does not lead to significant visual disablility in PDR patients undergoing PRP.

In our study there was a difference in the patient's complaint regarding performance of various activities depending on their age group. Patients across all age groups complained of photophobia however the activity which got maximally affected was different for various age groups. Patients <40 years of age had most problem in driving vehicles, patients between 40-49 years had difficulty in enjoying social functions and recognizing faces of people, patients between 50-59 years found it difficult to perform their daily core activities such as pouring water in a glass and recognising different coins or notes while patients above 60 years felt maximum incapacitated after PRP and felt that it grossly affected their social life and they felt under confident to move out of the house after dark.

As suggested by the protocol S of the DRCR.net repeated anti-VEGF injections have shown to be equally

efficacious or better in reversing PDR compared to PRP.[28] The long term treatment burden is however not discussed. In developing countries, the cost of repeated anti-VEGF injections is high and few patients can afford the treatment, therefore PRP is still widely practiced. We need to counsel the patients and take an informed consent prior to performing PRP as they may encounter problems in performing their daily core activities and need to be reassured that it will not have a significant impact on their quality of life.

This is a prospective study that compares the visual functions before and after PRP and the impact it has on the QOL. Our study has certain limitations, including small sample size. Contrast sensitivity and photophobia were also graded subjectively based on the patient's response. However objective measurement would carry more significance. Future studies with a large sample size could provide a better understanding as to how PRP can adversely affect visual function.

PRP is an effective treatment modality for PDR despite its impact on the visual functions. PRP for PDR causes a decrease in contrast sensitivity, visual fields with a possible increase in photophobia but this does not have a significant impact on the QOL of diabetic patients.

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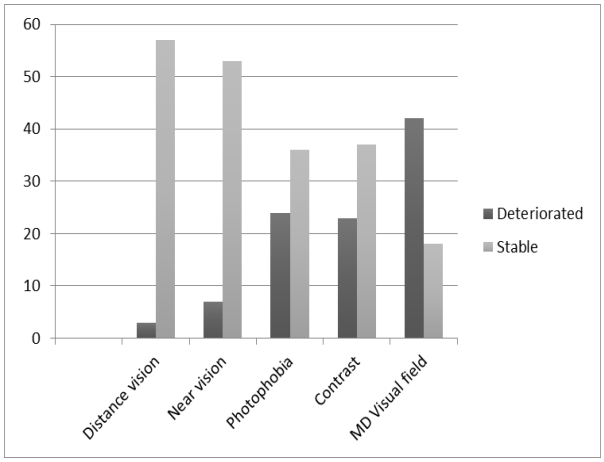

Fig. 1: Bar chart showing the impact of PRP on various parameters (x axis shows the various parameters assessed and the y axis denotes the number of eyes).

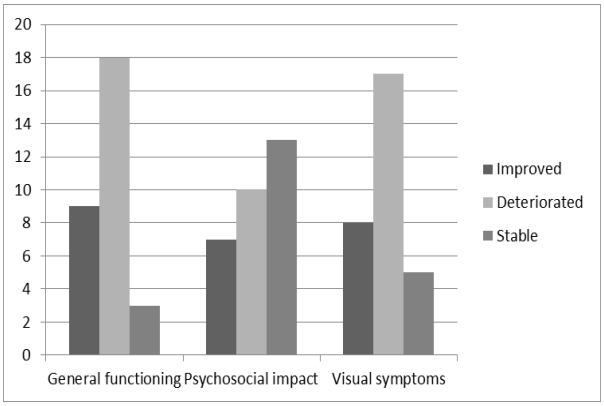

Fig. 2: Bar chart showing the impact of PRP on the quality of life of patients (x axis shows the three components of IND-VFQ33 questionnaire and the y axis denotes the number of patients).

Table 1: Grading of photophobia.

0	**Absent**	
1	Mild	Very minimal intolerance to light which may require some degree of sunglass protection to eliminate the symptom, noticed primarily in sunlight
2	Moderate	Intolerance to light associated with exposure to room light or sunlight which is only partially relieved by dark glasses or subdued light or squinting
3	Severe	Intolerance to light that is not relieved by sunglasses and is only relieved by total occlusion of the eye or eyelid closure

Table 2: Assessment of various parameters pre and post PRP (SD = Standard deviation, SE = Standard error, CI= Confidence interval, CI_UL = confidence interval upper limit, CI_LL = confidence interval lower limit, HVF = Humphrey visual field).

	t-test (SPSS)									Pre PRP			Post PRP	
N=60	Mean_Pre PRP	Mean_Post PRP	Difference	SD_Pre	SD_Post	SE_Pre	SE_Post	95% CI_LL	95% CI_ UL	95% CI	95% CI_LL	95% CI_ UL	95% CI	p-value (2 tailed)
Distance vision	0.411	0.408	0.003	0.319	0.363	0.041	0.047	0.331	0.492	(0.33 - 0.49)	0.316	0.500	(0.32 - 0.5)	0.935
Near vision	0.563	0.526	0.036	0.345	0.351	0.044	0.045	0.475	0.650	(0.48 - 0.65)	0.437	0.615	(0.44 - 0.62)	0.510
Contrast sensitivity	11.720	6.650	5.070	21.882	9.699	2.825	1.252	6.183	17.257	(6.18 - 17.26)	4.196	9.104	(4.2 - 9.1)	0.022
Mean deviation of HVF	-8.792	-10.474	1.683	4.162	5.305	0.542	0.691	-9.85	-7.73	(-9.85- (-7.73))	-11.83	-9.12	(-11.83 - (-9.12))	0.003

Table 3: Comparison of photophobia pre and post PRP.

Grade of photophobia	Pre PRP	Post PRP	p-value (chi-square)
0	28 (47%)	16 (27%)	0.057
1	24 (40%)	26 (43%)	
2	7 (12%)	17 (28%)	
3	1 (2%)	1 (2%)	
Total	60 (100%)	60 (100%)	

Table 4: Comparison of theIND-VFQ33 pre and post PRP (SD = Standard deviation, SE = Standard error, CI= Confidence interval, CI_UL = confidence interval upper limit, CI_LL = confidence interval lower limit).

	t-test (SPSS)									Pre PRP			Post PRP	
N=60	Mean_Pre PRP	Mean_Post PRP	Difference	SD_Pre	SD_Post	SE_Pre	SE_Post	95% CI_LL	95% CI_UL	95% CI	95% CI_LL	95% CI_UL	95% CI	p-value (2 tailed)
General functioning	33.430	36.630	-3.200	13.475	14.693	2.460	2.683	28.608	38.252	(28.61 - 38.25)	31.372	41.888	(31.37 - 41.89)	0.160
Psychosocial impact	7.600	8.430	-0.830	4.090	4.739	0.747	0.865	6.136	9.064	(6.14 - 9.06)	6.734	10.126	(6.73 - 10.13)	0.173
Visual symptoms	14.330	15.570	-1.240	4.604	5.110	0.841	0.933	12.682	15.978	(12.68 - 15.98)	13.741	17.399	(13.74 - 17.4)	0.123

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