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Vision related quality of life and daily visual functioning in patients undergoing pan-retinal photocoagulation for proliferative diabetic retinopathy

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全视网膜光凝术改善 PDR 患者的视觉相关生活质量及日常视觉功能

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摘要

目的:评估全视网膜光凝术(PRP)对糖尿病视网膜病变(PDR)患者在视觉相关生活质量及日常视觉功能的影响。

方法:研究纳入 30 例(男 13 例,女 17 例)接受全视网膜光凝术治疗糖尿病视网膜病变患者。国家眼科研究所发布的视觉功能量表(VFQ-25)用来评估全视网膜光凝术治疗前后视觉相关生活质量及日常视觉功能。患者在接受全视网膜光凝术治疗前和治疗后 6mo 分别填写 VFQ-25 量表,比较视觉相关生活质量及日常视觉功能差异。运用配对 t 检验对治疗前后 VFQ-25 评分对比。

结果:全视网膜光凝术治疗前平均 VFQ-25 综合评分为 74.79±15.7,术后平均综合评分为 74.08±19.1。术前与术后的平均 VFQ-25 综合评分无统计学意义(P=0.875)。

结论:全视网膜光凝术(PRP)对糖尿病视网膜病变(PDR)患者在视觉相关生活质量及日常视觉功能无不利影响。

关键词:全视网膜光凝术;糖尿病视网膜病变;视觉功能量表

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Abstract

• AIM: To evaluate the effect of pan - retinal photocoagulation (PRP) on vision related quality of life and daily visual functioning in patients having proliferative diabetic retinopathy (PDR).

• METHODS: Thirty patients (13 males, 17 females) with PDR and undergoing PRP were included in this study. Visual Function Questionnaire (VFQ-25) developed by the National Eye Institute (NEI) of America, was used to evaluate the vision-related quality of life and daily visual functioning before and after PRP. The VFQ-25 was filled in by the authors before and at 6mo after the completion of PRP in order to compare any changes in visual related quality of life and daily visual functioning. The pre and post treatment VFQ-25 scores were compared using paired t-test.

• RESULTS: Mean VFQ-25 composite score before PRP was 74.79±15.7 and after PRP treatment it was 74.08±19.1 (P=0.875). The difference between pre and post PRP VFQ-25 composite scores was not statistically significant.

• CONCLUSION: PRP has no significant detrimental effect on vision related quality of life and daily visual functioning in patients having PDR.

• KEYWORDS: pan-retinal photocoagulation; proliferative diabetic retinopathy; Visual Function Questionnaire

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INTRODUCTION

Pan-retinal photocoagulation (PRP), first performed by Meyer - Schwickerath[1], still remains an effective treatment for proliferative diabetic retinopathy (PDR). The beneficial effects of PRP for diabetic retinopathy and its effectiveness in decreasing the incidence of blindness were established almost 20y ago by a multicentre study, the diabetic retinopathy study (DRS).

Both DRS and the early treatment diabetic retinopathy study (ETDRS) provided data to establish the guidelines for detection and effective treatment of PDR. While the DRS findings demonstrated that PRP reduces the risk of severe visual loss in patients with high-risk PDR by 50-60%, ETDRS reported the effectiveness of using photocoagulation to treat PDR and recommended that documented PRP should be initiated early to be most effective in the management of PDR[2-3].

While the exact mechanism for how PRP achieves its therapeutic effect is an area of active investigation, one theory as to mechanism of laser treatment is that it reduces neo-vascular disease by killing retinal cells in the poorly perfused portions of the retina, reducing relative ischemia, thus decreasing the production of angiogenic factors and increasing oxygenation of the viable retina[3]. Since photoreceptors are the most metabolically active and numerous cells in the retina, PRP for PDR involves the purposeful destruction of a fraction of the photoreceptors. Laser therapy is typically titrated to a visible clinical effect (graying or whitening of the retina), which corresponds to necrosis of the photoreceptors, and at higher settings, to the inner retina.

Although clinically highly effective at halting angiogenesis, PRP can lead to untoward side effects. Systematic clinic-pathological analysis of laser-induced retinal lesions over time has demonstrated that longer exposure time and higher intensity typically produce retinal lesions that affect not only RPE and photoreceptors, but also the inner nuclear layer (INL), ganglion cell layer (GCL), and nerve fiber layer (NFL). This phenomenon can lead to complications including significant patient discomfort during laser application, permanent retinal scarring, and decreased color, and night vision. Nerve fiber and visual field defects can result from the laser lesions that affect the inner retina. Constricted visual field, defective hue discrimination, increased glare and reduced contrast sensitivity have been reported in previous studies[4-7, 8-16].

Aims of the study The impact of above mentioned complications on patient's daily visual functioning and quality of life has not been much studied in the past. The purpose of our study was to: a) compare the pre- and post-laser daily visual functioning and vision related quality of life (VFQ-25) in patients about to undergo PRP treatment for PDR; b) analyze the impact of PRP on patient-reported vision-related quality of life and daily visual functioning.

MATERIALS AND METHODS

Study Settings This study was performed at the department of ophthalmology, B. V. Hospital, Bahawalpur, Pakistan from Sep. 2015 to Nov. 2015.

Ethical Considerations Before commencement of the study, written permission was taken from the local ethical committee of the hospital. Thirty patients (13 males, 17 females) having PDR and undergoing PRP were included in this study. The study was conducted in accordance with the tenets of the Declaration of Helsinki. We obtained written and verbal information related to the study. All the participants gave their written informed consent.

Subjects Data collected from the patients included a thorough history including the age, gender, duration and age at onset of diabetes mellitus, presence or absence of hypertension, body mass index, use of insulin or oral hypoglycemic agents, presence of other systemic diabetic complications and other general illnesses.

Clinical Assessment Ocular parameters were assessed at baseline by recording the best-corrected visual acuity (BCVA) using Snellen's chart, the BCVA thus obtained was then converted to LogMAR acuity by using online Snellen to LogMAR converter[17]. Intraocular pressure (IOP), slit-lamp examination, retinal examination, stereo color fundus photographs and fundus fluorescein angiography (FFA). IOP was recorded with the Goldman applanation tonometer. Slitlamp examination details including the presence or absence of cataract was documented. Nuclear sclerosis was graded from +1 (mild) to +4 (very dense). Cortical and posterior sub-capsular cataracts were each given an additional score of +1.

Detailed fundus examination was performed by the authors using slit-lamp biomicroscopy with 90D lens. Colored fundus photographs were taken by the authors using the Topcon TRC50-VT (Topcon, Tokyo, Japan) fundus camera. The areas photographed included stereo pictures of the macula, the disc, and the superior-temporal and inferior-temporal retinal quadrants.

The location and extent of neo-vascularization were assessed based on clinical examination, colored fundus photographs and FFA pictures. The presence of active neo-vascularisation of disc (NVD), neovascularisation elsewhere (NVE) were recorded.

Treatment Protocol Treatment of PDR was done according to the guidelines provided in the ETDRS[1]. A complete PRP was performed with frequency doubled Nd: YAG continuous wave laser (LIGHTMED Ltd, San Clemente, CA, USA) with wavelength of 532 nanometer. A total number of 2500-3000 burns were delivered using 300-500 microns spot size in two to three sittings. The number of visits and the number of burns needed to complete the initial treatment was also recorded. The need for additional laser treatment was decided by the clinical presentation, which was documented by colored fundus photographs and FFA at 3-6mo follow-up examinations.

The VFQ-25 Questionnaire Vision related quality of life and the daily visual functioning of the patients was assessed before and at 6mo after performing the PRP by using the Visual Function Questionnaire-25 (VFQ-25, Version 2000) developed by RAND (RAND Inc. Santa Monica, California, United States) and funded by the National Eye Institute (NEI/NIH, Rockville Pike, Bethesda, USA)[18].

VFQ-25 is an eye specific questionnaire that reflects the respondent's self-reported vision related quality of life and daily visual function in subscales *i. e.* general health; general vision; ocular pain; near activities; distance activities; driving; color vision; peripheral vision social functioning; role difficulties; and dependency.

The VFQ-25 is a public document available without charge to all the researchers. The VFQ-25 consists of a base set of 25 vision targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question. All items in the VFQ-25 are from the 51-item field test version; no new items were developed for use in

the VFQ-25. The VFQ-25 is available in two formats, the "self administered" format and the "interviewer administered" format. Since most of our patients were uneducated, we chose to use the interviewer administered format. The VFQ-25 takes approximately 10min on average to administer in the interviewer format.

VFQ-25 composite scores achieved by each patient were recorded by the authors before and at 6mo after applying the PRP. The composite scores were calculated in three steps. First, original numeric values from the VFQ-25 survey were recorded as reported by the patients. Each item of VFQ-25 was then converted to a 0-100 scale so that the lowest and highest possible scores were set at 0 and 100 points, respectively. In second step, items within each sub-scale were averaged together to create the 12 sub-scale scores. Hence, the scores represented the average for all items in the subscale that the respondent answered. To calculate an overall composite score for the VFQ-25, we simply averaged the vision-targeted subscale scores. By averaging the sub-scale scores rather than the individual items we were able to give equal weight to the each sub-scale.

Data Analysis The statistical analysis was performed using IBM SPSS statistics (IBM Inc. North Castle, NY, USA). Paired sample *t*-test was used to compare the pre and post-laser composite scores. We followed the guidelines of VFQ-25 (online version) for calculating the scale conversions and subscale scores with 11 vision-related constructs plus an additional single-item general health question. We calculated the results for our 30 patients according to the VFQ-25 manual. Results were considered statistically significant at $P<0.05$.

RESULTS

Study Participants There were 30 patients who participated in this study.

Patient Demographicsand Characteristics The patient's age and sex distribution is given in Table 1. The mean age of the study group was 53±9.1y. More than fifty percent of the study subjects were females.

The mean duration of diabetes was 14.4±6.4y in the study group. NVE was observed in 76% and NVD in 34% of the study participants (Table 2).

The mean LogMAR BCVA score before PRP treatment was 0.78±0.26; post-laser score for BCVA was 0.30 ±0.35 ($P=0.0001$) as shown in Table 3.

All the patients had bilateral PRP at baseline. A total of 60 eyes of 30 patients had received PRP during the study period. Thus all the 60 eyes were subjected to analysis.

Vision Related Quality of Life and Daily Visual Functioning (VFQ-25) With VFQ-25, none of the subscale scores had a statistically significant difference between before and after PRP.

The pre- and post-laser scores were lowest for the subscale of general health (mean ±SD) viz. 35.65±22.04 and 35.00±18.0 respectively. The highest pre- and post-laser score was observed for the subscale of dependency (mean± SD) *i. e.* 93.48±18.12 and 91.32 ±11.4 respectively (Table 4).

Table 1 Patient demographics

Variables	Sex distribution		Total
	M	F	
Age (a)			
40-50	4	3	7 (23%)
51-60	5	7	12 (40%)
61-70	3	5	8 (27%)
71-80	1	2	3 (10%)
Total	13 (44%)	17 (56%)	30 (100%)

Table 2 Nature of PDR

Variables	PDR with NVE	PDR with NVD	Total
M	09 (30%)	04 (13%)	13 (43%)
F	14 (47%)	03 (10%)	17 (57%)
Total	23 (77%)	07 (23%)	30 (100%)

PDR: Proliferative diabetic retinopathy; NVE: Neo-vessels elsewhere; NVD: Neo-vessels on the disc.

Table 3 Best corrected visual acuity (LogMAR)

Pre-laser BCVA (mean ±SD)	Post-laser BCVA (mean±SD)	$P<0.05$ (statistically significant)
0.78±0.26	0.30±0.35	0.0001

BCVA: Best corrected visual acuity.

At 95% CI, the difference between the pre- and post-laser subscale scores for the general health and the dependency were not statistically significant ($P=0.9009$ and 0.5826 respectively).

Pre- and post-laser VFQ-25 composite scores (mean±SD) were 74.79±15.7 and 74.08±19.1 respectively and as can be observed from Table 4, this difference between pre and post PRP composite scores was not statistically significant ($P=0.875$).

DISCUSSION

In this study, we recruited patients from outdoor patient department of our own hospital. The patient sample in the present study was relatively small. However, this study provides valuable information about patients offered treatment for PDR in clinical settings.

In most of the VFQ-25 subscales, patients with PDR had pre PRP scores comparable to the post-laser scores. The findings of our study are in line with the findings of some similar studies performed in the recent times [19-20]. Regarding health-related quality of life measured using the VFQ-25; we found no significant differences in pre- and post-laser scores. This means that PRP has insignificant effect on overall vision related quality of life and the daily visual activities of the patients. This finding in our study is contrary to some of the previous studies in which it was observed that PRP leads to visual field constriction [6-7,8,11,21-25]. Our findings appear to indicate that the diabetic population with PDR in the real-world setting is benefited from the laser treatment.

The most unexpected result in this study was the low scoring on the NEI VFQ-25 subscale for general health-both from a

Table 4 VFQ-25 sub-scale and composite scores

VFQ-25 subscales	Pre-laser score (mean±SD)	Post-laser score (mean±SD)	$P<0.05$ (statistically significant)
General health	35.65±22.04	35.00±18.00	0.900
General vision	61.10 ±18.00	58.62±20.30	0.618
Ocular pain	85.80 ±19.40	90.30±15.50	0.325
Near activities	59.90±21.50	62.84±18.00	0.568
Distant activities	75.60±23.50	72.20±20.20	0.550
Social functioning	88.80±20.00	86.50±21.50	0.669
Mental health	75.50±21.85	73.34±20.87	0.696
Role difficulty	79.80±25.70	76.22±23.50	0.575
Dependency	93.48±18.12	91.32±11.40	0.582
Driving	73.20±32.00	73.00±10.00	0.974
Color vision	91.80±19.40	92.00±15.40	0.964
Perfiferal vision	76.86±20.90	77.69±18.00	0.869
Composite score	74.79±15.70	74.08±19.10	0.875

VFQ:Visual Function Questionnaire.

clinical viewpoint and when compared to other similar studies and in studies on patients with glaucoma and patients diagnosed before the age of 30y[18-19,12,14,21,25-30]. One possible explanation for this finding is that all the patients in our sample had PDR and it is a well known fact that the neo-vascular proliferation in PDR has a substantial negative impact on the vision related quality of life as well as the general health of the patients. However, one weakness with this study is the lack of a control group, which does not allow a direct comparison with a comparable patient cohort or sample.

We measured the BCVA using Snellen chart and then converted it to LogMAR acuity with the help of an online converter. It is so because LogMAR gives an accurate value, especially if visual acuity is reduced. One disadvantage was that it was more time consuming than acuity testing using the Snellen chart. In real-world settings, as was the case in the present study, the LogMAR chart is generally preferable for diagnosis and follow-up of the eyes subject to PRP treatment.

Our study found that patients with diabetes who were going to undergo PRP treatment for visual impairment due to PDR gave a low rating for their general health as measured with the help of VFQ-25 but there was no statistically significant difference in the overall pre- and post-laser VFQ-25 (subscale and composite) scores.

This study had a relatively small sample size due to the number of patients that received the PRP treatment. But the value of the study is that if it is implemented in real-world settings, the results of the study can be generalized for the group of diabetic patients about to undergo PRP treatment for sight-threatening PDR.

In conclusion, this study found that in patients having PDR, PRP treatment has no significant detrimental effect on vision related quality of life and daily visual functioning as measured through VFQ-25. In order to increase our understanding of the mechanism by which PRP reduces the risk of severe visual loss in patients having PDR, it is important to regularly follow the patient cohorts or samples for any changes in VFQ-25 scores.

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