

A Clinical Study to Assess the Efficacy and Safety of Laser Photocoagulation in Patients of Diabetic Retinopathy

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Abstract

Objectives: To study the efficacy and safety of laser photocoagulation in patients with diabetic retinopathy.

Place and Duration of Study: This study was conducted at Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh, India from May 2019 to June 2020 for a period of 14 months.

Study design: Prospective cross-sectional type of study.

Materials and Methods: A clinical study to assess the efficacy and safety of laser photocoagulation in patients of diabetic retinopathy in Department of Ophthalmology, Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh From May 2019 to June 2020. A total 100 patients fulfilled the inclusion criteria. Out of which 94 patients were included in the study (6 patients were dropped out). Thus, study was conducted as per declaration of Helsinki 2000 and institutional Ethical Committee as needed.

Result: In patients with diabetic retinopathy treated by pan retinal photocoagulation there is significant change in central macular thickness noticed in follow up after one month, three month and six months. There was also significant improvement in BCVA after pan retinal photocoagulation.

Conclusion: Proliferative Diabetic Retinopathy cases treated by pan retinal photocoagulation presented by significant improvement in BCVA and there was significant change in central macular thickness noticed after one month, three months and six months.

Keywords: Proliferative Diabetic Retinopathy, pan retinal photocoagulation, central macular thickness, spectral Domain Optical Coherence Tomography.

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I. Introduction

Diabetic retinopathy is one of the leading causes of blindness in the world^[1]. Duration of diabetes is probably the strongest predictor for the development and progression of retinopathy. Diabetic retinopathy is a common complication of DM characterized by macular edema and frequently accompanied by lipid exudation. The pathogenesis of diabetic retinopathy is not completely understood, but established risk factors include poor glycemic control, hypertension, increasing age, and duration of diabetes. Other than retina, diabetes may affect anterior segment structures of the eye such as cornea, iris, ciliary processes and lens. Diabetic retinopathy (DR) is predominantly a microvascular disease. It affects the smaller vessels by causing multilayering of the basement membrane and degeneration of the endothelial cells and the pericytes that lead to capillary occlusion and leakage. DR is divided into two main groups namely the non-proliferative diabetic retinopathy (NPDR) and the proliferative diabetic retinopathy (PDR) (Suraida et al., 2018).

ARGON GREEN LASER

Argon laser obtains its energy delivery in the ions of argon gas. It has an ability to produce tens of watts of continuous wave power in the region of blue (488 nm) and green (514.5 nm) wavelengths. In addition, since the blue wavelength of argon can cause damage to inner retina, the green wavelength is more commonly used for photocoagulation of the neurosensory retina and RPE (L'Esperance 1989^[2], Karlin 1995^[3]). **Modified - ETDRS focal photocoagulation technique** is currently recommended for treatment of DME. This technique requires **50 mm of burn size and 0.05–0.1 sec of burn duration** for both direct treatment on leaking microaneurysms and grid treatment on all areas of edema not associated with the microaneurysms.

It has been proposed that PRP improves the oxygenation of ischemic inner retinal layers by destroying some of the metabolically highly active photoreceptor cells, leading to a greater flow of oxygen from the choriocapillaris to the inner layers of the retina (Iwase et al., 2017).

II. Materials And Methods

A clinical study to assess the efficacy and safety of laser photocoagulation in patients of diabetic retinopathy in Department of Ophthalmology, Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh From May 2019 to June 2020. A total 100 patients fulfilled the inclusion criteria. Out of which 94 patients were included in the study (6 patients were dropped out). Thus, study was conducted as per declaration of Helsinki 2000 and institutional Ethical Committee as needed.

Inclusion criteria: Patients with PDR as confirmed by fundus fluorescein angiography and clear ocular media.

Exclusion criteria: Retinal detachment, intraocular inflammation, previous argon laser sessions, history of intravitreal injection of anti-VEGFs, ocular media opacity interfering with imaging.

Intervention and outcome measures:

After meeting all inclusion criteria, the patients were evaluated by full medical/ophthalmic history including: Onset and duration of diabetes. History of ocular surgeries, History of laser intervention, Complete ophthalmic examination including (Best corrected visual acuity, slit lamp examination to the anterior segment, Detailed fundus examination by slit lamp bio microscopy, Measurement of IOP using Goldmann's applanation tonometry) Fundus fluorescein angiography (FFA) was done using fundus camera Topcon (TRX-50DX) to confirm diagnosis of PDR (NVDs, NVEs) and macular edema.

Spectral domain optical coherence tomography (SD-OCT) was done to all eyes. SD-OCT this was done before starting PRP, one month, three months and six-month following laser session. These scans were marked as the patient's baseline and were used for referencing the subsequent scans using the "follow-up" function of the SD-OCT, assuring us that the scans would be performed in the same position. All images were taken as close to the fovea as possible in order to ensure, to the best extent possible, that the same retinal area was being scanned.

Data will be analyzed by the Statistical Package for the Social Sciences (SPSS for windows, version 24.0). Descriptive statistics included the mean and standard deviation for numerical variables, and the percentage of different categories for categorical variables. Group comparison will be done by the paired t-test test for categorical variables. A probability (P) of less than 0.05 was considered significant.

Pan Retinal photocoagulation

In all cases treatment was delivered by an argon laser through a Goldmann 3-mirror or a Rodenstock pan-fundus contact lens. Spot size was 500 μm when using the Goldmann and 200 μm when using the Rodenstock contact lens with a duration of 0.1 to 0.2 s. The power level was adjusted to give slight blanching of the retinal pigment epithelium. The end point of treatment was complete regression of new vessels, or complete regression of vessels with gliosis, or residual fine, flat new vessels with fibrosis which remained static for at least six months.

Lens used: Goldmann 3-mirror, Rodenstock pan-fundus contact lens

Laser Parameters used for pan retinal photocoagulation

Total number of burns: 1600-2000

Spot size: 100 to 500 μm

Power: 200-400mw

Duration: 100-200 msec

This procedure was done in 2 to 3 sittings. At follow up of 1st month 3rd month, 6th month visual acuity and detailed retinal examination (using indirect ophthalmoscopy) was done and any problems recorded. Slit lamp examination with +78D/90D lens was done to examine the macula. Fundus photography was done in selected cases. For those with persisting lesions fundus fluorescein angiography was repeated and additional pan retinal photocoagulation was done.

Visual acuity was defined 'stable' when vision at baseline was maintained after PRP; 'decreased' when the baseline vision decreased by 2 lines and 'improved' when the baseline vision improved by 2 lines after PRP at the end of one year. Poor visual acuity was defined as a corrected visual acuity less than 6/60 on the Snellen's chart in the eye that received pan retinal photocoagulation.

III. Results

This study was conducted in the Department of Ophthalmology, Maharani Laxmi Bai Medical College, Jhansi over a period of 14 months from May 2019 to June 2020. A total of 200 eyes of 100 patients who fulfilled the inclusion criteria, were included in this study. Out of total 100 patients satisfying the inclusion criteria, 94 patients were included in the study, six were rejected.

The mean age in studied patients was 59.63 ± 6.632 years with minimum age of 40 years and maximum age of 70 years (range 40 – 70 years). There were 35 males (37.23%) and 59 females (62.77%) in studied patients. The mean disease duration in studied patients was 11.99 ± 4.972 years.

Table 1: Age wise distribution

Age (in years)	Number of Patients	Percent
40-50 years	14	14.89%
51-60 years	42	44.68%
61-70 years	38	40.43%
Total	94	100%

Table 2: Mean age distribution

Age (yrs.)	Study Group
Mean	59.63
SD	± 6.632

Table 3: Sex wise distribution

Sex	Number of Patients	Percent
Male	35	37.23%
Female	59	62.77%
Total	94	100%

Table 4: Duration of Diabetes (in years)

Duration of DM (in years)	Numbers	Percent	Mean	SD
5-10 years	40	42.55%	11.99	± 4.972
11-15 years	38	40.43%		
>15 years	16	17.02%		

Table 5: Comparison between pre-PRP, 1-Month, 3-Months and 6-month post-PRP (BCVA, Central Macular thickness (in μm) OCT) in studied patients.

Variables		Pre-PRP (mean + SD)	1-month Post-PRP (mean + SD)	3-month Post-PRP (mean + SD)	6-month Post-PRP (mean + SD)
BCVA (LogMAR)	RE(n=53)	1.11 ± 0.477	0.81 ± 0.139	0.73 ± 0.160	0.67 ± 0.160
	LE(n=41)	1.14 ± 0.470	0.79 ± 0.151	0.70 ± 0.148	0.66 ± 0.172
Central Macular thickness (in μm) OCT	RE(n=53)	586 ± 21.858	529.47 ± 24.036	372.09 ± 38.337	292.08 ± 25.510
	LE(n=41)	579.63 ± 21.782	519.66 ± 17.021	360.05 ± 29.672	284.88 ± 21.857

Family history of Diabetes was taken, and it was seen that out of 94 patient's, positive family history of diabetes was present in 55 (58.51%) of patients. In the study group history of hypertension was present in 25(26.60%) patients out of 94 patients.

In the study mean baseline central macular thickness (μm) of right eye 586 ± 21.858 and left eye 579.63 ± 21.782 .

The follow up mean visual acuity BCVA as per logMAR right eye after Laser photocoagulation at **1 month** is 0.81 ± 0.139 and, **3 months** is 0.73 ± 0.160 , at **6 months** is 0.67 ± 0.160 . The **p value was <0.05** , as calculated with the help of paired t-test, indicating that there was **a significant difference in Best corrected visual acuity**.

The follow up mean visual acuity BCVA as per logMAR left eye after Laser photocoagulation at **1 month** is 0.81 ± 0.139 and, **3 months** is 0.79 ± 0.151 , at 3 months is 0.70 ± 0.148 , at **6 months** is 0.66 ± 0.172 . The **p value was <0.05** , as calculated with the help of paired t-test, indicating that there was **a significant difference in Best corrected visual acuity**.

At **1 month** the follow up mean central macular thickness (CMT) thickness right eye affected with DR after laser photocoagulation is 529.47 ± 24.036 . **After 3 months**, CMT is 372.09 ± 38.337 , **After 6 months** of follow up the CMT is 292.08 ± 25.510

At **1 month** the follow up mean central macular thickness (CMT) thickness left eye affected with DR after laser photocoagulation is 519.66 ± 17.021 . **After 3 months**, CMT is 360.05 ± 29.672 , **After 6 months** of follow up the CMT is 284.88 ± 21.857 .

IV. Discussion

Diabetes affected an estimated 347 million people worldwide in 2014. According to the World Health Organization, this number is expected to double by 2030. Diabetic Retinopathy (DR), which occurs in approximately 30% of patients with Diabetes Mellitus (DM), is a leading cause of vision loss in the working age population, 20 to 74 years old. In the United States alone, approximately 1 of every 25 persons above the age of 40 with diabetes has DME in at least 1 eye^[4].

According to the latest World Health Organization (WHO) report, India has 31.7 million diabetic subjects, and the number is expected to increase to 79.4 million by 2030^[116].

Diabetic macular edema (DME), one of the major complications of diabetic retinopathy (DR), is also one of the leading causes of visual impairment in the working-age population. DME occurs in nearly 12% of patients with DR and causes more than 10,000 new cases of blind.

Our study was conducted at MLB Medical College in the year May 2019 to June 2020 which included 94 patients who fulfilled the inclusion criteria per year.

In our study mean of age is 59.63±6.632. Our results were also consistent with the finding of **Michael Larsen, Maria Wang et al, (2005)**^[5] did a prospective study of twelve eyes in 12 patients aged 39 to 78 years (mean age 57) with fovea-involving diabetic macular edema and 14 eyes in 7 healthy volunteers aged 30 to 70 years (mean age 57). **Ling Yeung, Chi-Chin Sun, et al (2009)**^[6] was also found the mean age of diabetic patients is 62.2 years in his study.

In our study mean duration (in years) is 11.99±4.972. Similar results were seen in other studies also like **Donald S. Fong, et al, (2003)**^[7]. This study state, the incidence of retinopathy also increased with increasing duration. The 4-year incidence of developing proliferative retinopathy in the WESDR younger-onset group increased from 0% during the first 5 years, to 27.9% during years 13–14 of diabetes. After 15 years, the incidence of developing PDR remained stable.

Studies have shown that the improvement in BCVA occurs by using various treatment modalities and the BCVA finding is consistent with **Islam F, (2016)**^[8] There is a moderate correlation between visual acuity and degree of foveal thickening in diabetic macular edema. **Pei-pei Wu, MD; Shizhou Huang, et al, (2015)**^[9], Both 532-nm subthreshold laser grid photocoagulation and threshold laser grid photocoagulation can improve the visual acuity and reduce CMT in DME patients. Analyses of visual change after photocoagulation therapy in a retrospective study by **Murat Dogru et al**^[10] had done in 1998 revealed that 73% of the eyes with early PDR had stable vision or improvement by ≥ 2 lines at the end of 10 year follow up visit. The figures were 62% and 52% for eyes with advanced and end stage PDR respectively. In a study, **Qian Z et al**^[11] proved that PRP was effective in 122 eyes (85.31%) out of 143 eyes. Visual acuity improved in 32 eyes (23.38%), vision was maintained in 87 eyes (60.84%) and there was a decrease in 24 eyes (16.78%).

Studies have shown that the reduction of central macular thickness (CMT) by using various treatment modalities. **David J. Browning, et al, (2007)**^[12]. This theory state that visual improvement occur if CMT decreases after receiving laser therapy. The correlation coefficients for visual acuity versus OCT center point thickness were 0.52 at baseline and 0.49, 0.36, and 0.38 at 3.5, 8, and 12-months post-laser photocoagulation. **Mahmoud A Abouhuse, (2016)**^[13]. In decrease in central retinal thickness observed after receiving micro-pulse laser photocoagulation. The baseline best-corrected visual acuity was 0.42±0.15 logMAR, which improved to 0.3±0.26 logMAR at the final follow-up ($P<0.043$). The central subfield thickness was 354.3±32.96 μm at baseline and the final central subfield thickness was 310.7±52.62 μm ($P<0.002$). Subthreshold micro-pulse yellow 577-nm laser photocoagulation is effective in treating DME.

Howard Schatz et al^[14] reported laser scar enlargement following grid laser treatment for diffuse retinal vascular leakage and macular edema in 11 of 203 eyes of patients with diabetes. Other studies have shown similar complications such as progressive enlargement of laser scars, subretinal fibrosis and visual field loss. McDonald followed 175 eyes treated with PRP for a median of 15 months and a range of 3–48 months. He found that 43% (75 eyes) developed increased macular edema 6–10 weeks after PRP, which persisted in 27% (47 eyes). Eight percent (14 eyes) developed chronic macular edema and visual loss of two or more lines.

V. Conclusion

Most patient in this study were in the age group >50 years and most common duration was >10 years for diabetes. We saw after Pan retinal photocoagulation, the macular edema which was measured in terms of CMT (μm) by OCT at interval of 1 month, 3 months and 6 months follow up. It was found that the central macular edema subsided with every follow up and the BCVA improved as well. Diabetic retinopathy after treatment was assessed by improvement in mean CMT and mean BCVA, which correlated with each other. PRP in high-risk PDR reduces the risk of severe visual loss by more than 50%. In our study PRP has shown to induce regression of neovascularization and arrest of progression of diabetic retinopathy. Also, laser treatment is preferable to no treatment, but a timely applied treatment is more affective as far as visual prognosis. Laser

treatment, if carried out properly rarely causes serious complications. Some of the complications encountered were vitreous hemorrhage, pre retinal hemorrhage, macular edema, and epiretinal membrane.

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