European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 9, Issue 6, 2022

ORIGINAL RESEARCH

Outcome of eyes with diabetic macular edema with laser treatment

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ABSTRACT

Background: Diabetic macular edema (DME) is a leading cause of visual impairment and its treatment is a public health challenge. Antiangiogenic agents are the gold standard treatment, but they are not ideal, and subthreshold laser (SL) is a viable and promising treatment in certain cases. The purpose of this study was to evaluate its usefulness in a real-world environment.

Methods: A retrospective case series of 54 eyes of 32DME patients admitted to the center treated with SL monotherapy. Treatment was performed using the EasyRet® photocoagulator with the following parameters in one session: 5% duty cycle, 200 ms pulse duration, 160 µm spot size, and barely visible.Output at 50% of threshold. A high-density pattern was then applied across the edematous region using multi-spot mode. Best-corrected visual acuity (BCVA) and optical coherence tomography (OCT) data were obtained at baseline and approximately 3 months after treatment.

Results: 54 eyes of 32 patients were included (38% female, mean age 63.8 years). The mean time from treatment date to follow-up visit was 12±6 weeks. BCVA (Snellen transformed to logMAR) was 0.59±0.32 and 0.43±0.25 at baseline and follow-up, respectively (p=0.002). 32% had previously undergone pan-retinal photocoagulation (p = 0.011). The average laser power was 555 ± 150 mW and the number of spots was 1,109 ± 580. Intraretinal and subretinal fluid (SRF) were observed in 96 and 41% of eyes at baseline and improved in 35 and 74% of eyes, respectively, after treatment. Quantitative analysis of changes in central macular thickness (CMT) was performed in a subset of 23 eyes, of which 43% showed a greater than 10% reduction in CMT after treatment.

Conclusions: Subthreshold laser therapy is known to have RPE function as a major target that normalizes heat shock protein activation and cytokine expression. In the present study, cases of DME associated with SRF showed excellent physiological responses, whereas laser monotherapy did not respond to a reduction of intraretinal edema. BCVA and macular thickness showed a mild response, suggesting the need for combined treatment in most patients. may be a viable treatment option.

Keywords: Diabetic macular edema, non-damaging retinal Laser, Retinal photocoagulation.

INTRODUCTION

Diabetic macular edema (DME) remains the leading cause of visual impairment in people with diabetes, but it is also one of the leading causes of legal blindness worldwide.[1] A recent study by the Diabetic Retinopathy Clinical Research Network (DRCR) shows that the gold standard treatment for DME is the combination of delayed laser photocoagulation and ranibizumab at evidence level better eyesight and improvement.[2] Other studies using antiangiogenic agents and corticosteroids have also shown favorable physical and functional outcomes. However, the disadvantages are the short duration of intravitreal medication, the need for frequent injections, frequent visits and ancillary examinations, safety concerns (endophthalmitis, increased intraocular pressure, corticosteroids, risk of cataracts), and a high financial burden. [3] DME treatments for patients and healthcare systems around the world, and all factors combine to make the search for cost-effective and safe treatments a top priority.[4] Diabetic macular edema (DME) is one of the main causes of visual impairment and its treatment is a public health challenge. Although there are antiangiogenic drugs.The gold standard treatment is not ideal, subthreshold laser (SL) is a viable and promising treatment in selected cases. The purpose of this study was to evaluate its usefulness in a real-world setting.[5]

In contrast, laser therapy is available in 85% of hospitals in the public health sector,14 is relatively inexpensive, and does not require close monitoring.[6] This makes laser application in CSME and PDR remain the treatment of choice when affordability and follow-up are always issues. Several studies have shown the efficacy of laser therapy in PDR.This study aims to examine the efficacy of laser therapy in CSME.

METHODS

This was an interventional study conducted in a tertiary care hospital equipped and staffed for diabetic retinopathy (DR) screening and laser treatment. The Research Ethics Committee (REC) gave ethical approval to the study. All newly enrolled DAP patients, regardless of caste, socioeconomic status, religion, and gender, were referred to an ophthalmology clinic for retinal screening and DR treatment. Informed consent, data on demographic and clinical parameters were collected from each patient on a pre-tested performa. The best corrected visual acuity of each patient was recorded and input to the performers by the optometrist.

IMAGE ACQUISITION

Retinal examinations were performed by an optometrist trained in fundus photography using a Canon CR-1 non-mydriatic retinal camera. The screening was performed without mydriasis. Two 45° retinal images were taken, one centered on the optic disc and one centered on the macula of each eye, and stored on the hard disk and compact disc (CD) with the patient's name and identification number. The acquired images were read by an ophthalmologist trained in fundus photography. Patients with normal fundus were invited for follow-up and excluded from the study. Patients with clinically signs of retinopathy or indeterminate images were referred to an ophthalmologist.

GRADING OF RETINOPATHY

Each patient underwent complete ophthalmoscopy with slit-lamp biomicroscopy and binocular indirect ophthalmoscopy using a 90-D fundus lens after full-bridge dilation with 1% tropicamide. If fundus assessment was still difficult after pupil dilation, patients were referred to an eye center for treatment. Diabetic retinopathy was classified according to the Airliehouse classification adopted and revised by the Early Treatment Research Group in Retinopathy (PDR), macula. Edema alone or with NPDR/PDR or advanced diabetic eye disease (ADED). Mild, moderate and severe NPDR without CSME were classified into the

non-observable RD (NSTDR) group and follow-up was recommended. PDR, CSME alone or in combination with other types of DR were included in the STDR category and laser treatment was recommended. A patient with advanced diabetic eye disease (ADED) was referred for pars plana vitrectomy.

LASER APPLICATION

All patients signed a written informed consent. Socio-demographic data were recorded on a prescribed form including age, sex, address, contact number, occupation and level of education. The pupil was fully dilated. A consultant (RA) performed all lasers using a dual-frequency YAG laser (532 nm) with a pan-fundus lens. The study included patients with CSME alone or with other types of diabetic retinopathy. Patients were treated with a grid pattern or focal laser in one session. For grating lasers, the burn size used was 50–100 μm and the duration 0.05–0.1 s. Burn injury was applied to the macular region of diffuse retinal thickening and treated within 500 μm of the fovea and 500 μm of the optic disc. Adjust power for smooth response. The focal laser has a spot size of 75–100 μm and a duration of 0.05–0.1 s. Burn lesions were placed 500 = 3000 μm from the fovea.

Follow-up: Patients were advised to follow-up monthly, then quarterly for 1 year. Best-corrected visual acuity (BCVA) was recorded and fundus photographs were taken at each visit.

STATISTICAL ANALYSIS

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0.

RESULTS

A total of 54 eyes were analyzed from 32 patients with complete data. These patients included her 12 females (37.8%) and her 20 males (62.1%), with a mean age of 63.5 ± 8.1 years (range 47–75 years). Sixteen eyes had previously been treated with PRP, all at least 6 months prior to study entry. The mean interval between treatment days and follow-up visits was 16.1 ± 2.1 weeks. All treatment sessions were performed by a retinal surgeon (RMP or FKM) familiar with the treatment of diabetic retinopathy. (Table 1) summarizes the baseline and characteristics and treatment parameters.

BCVA at baseline was 0.59 ± 0.32 logMAR, which improved to 0.43 ± 0.25 logMAR ($p = 0.002$) at follow-up. Qualitative analysis revealed that intraretinal fluid (IRF) was present in 54 (96.4%) eyes at baseline. At follow-up visits, 19 (35%) eyes showed resolution or improvement in this parameter. Subretinal fluid (SRF) was present in 23 eyes (41.1%) at baseline. At follow-up visits, 17 (74%) eyes showed resolution or improvement in this parameter. IRF improvement was associated with VA gain ($p = 0.018$), but not SRF resolution or improvement ($p = 0.343$). Obstruction of the oval zone was present in 32 eyes (57.1%) at baseline OCT. The presence of this biomarker was not associated with her VA change at follow-up ($p = 0.779$).

Previous presence of PRP was associated with better functional outcome ($p = 0.011$) as shown in Figure 1. Only 22 eyes had both baseline and follow-up CMT measurements using the same OCT device, so absolute quantitative analysis of CMT changes could not be performed across samples. Statistical analysis of quantitative parameters was not performed due to the small number of patients per OCT device. Regarding only eyes that had baseline and follow-up assessments with the same device, 15 (65%) eyes had a decrease in CMT at follow-up ($p = 0.815$) and 10 (43%) had no CMT for ≥10% of baseline CMT.

Sub-analyses investigated only phakic eyes with clear lenses or without posterior capsular opacification. No different associations were obtained for baseline retinal biomarkers and changes in VA at follow-up. No treatment-related complications occurred in this regard, but

no specific tests were performed to investigate this (autofluorescence/microperimetry). No patients received other treatments for DME, including anti-VEGF injections, during the follow-up period. Some patients, at the discretion of the surgeon, regressed on her second SL application 4 months later (18% of eyes).

Table 1: Demography Patients with Diabetes

Characteristics	% Frequency
Age	63.5±8.1
Male	62.2
Female	37.8
NPDR%	44.6
Previous Panphotocoagulation%	32.1
Previous Macular Laser%	21.4
Intraretinal Fluid%	96.2
Subretinal Fluid%	41.3
Ellipsoid Disruption%	56.4
Follow-up weeks	13.9 ± 3.2
BCVA logmar mean±SD	0.60 ± 0.32
Laser power (mW)	545 ± 130.34
Number of spots	1120.9 ± 560.2
Retreatment %	18%

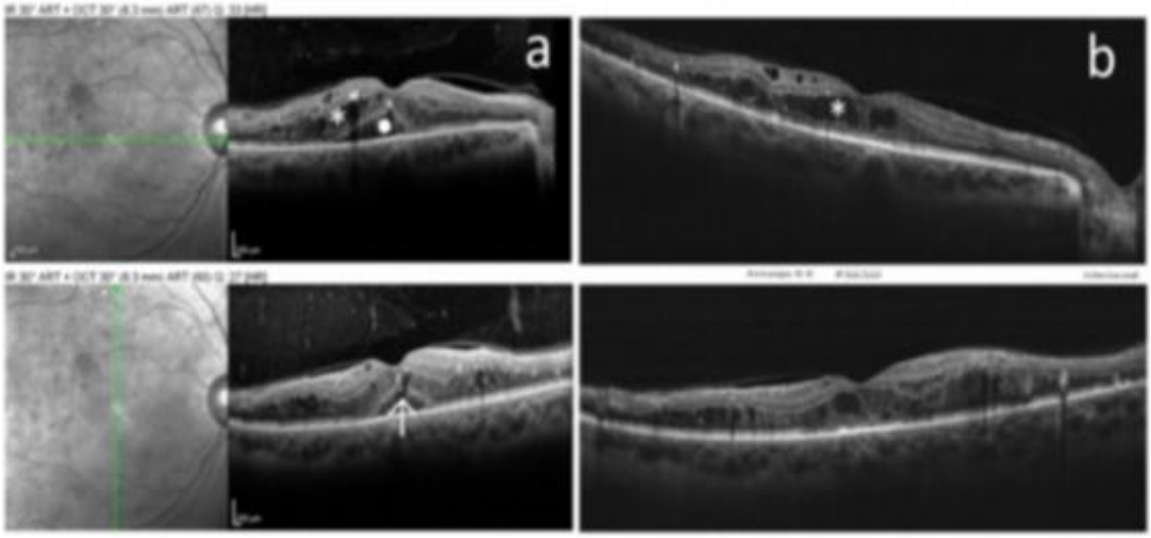

Figure1: a: Baseline OCT depicting intraretinal fluid and subretinal fluid. b: 3 months after SL treatment

DISCUSSION

Laser photocoagulation became the standard treatment for diabetic macular edema in 1990 after the publication of the results of the initial treatment study for diabetic retinopathy.[7] The ETDR results showed that focal photocoagulation, grid laser, or both were effective in reducing the risk of moderate vision loss due to diabetes.[8,9] Macular Edema However, macular edema results in thickening of the retina, which acts like a prism and scatters light, leading to large, diffuse burns and unpredictable results. This has forced researchers to look for alternative treatments. Triamcinolone was a promising drug in Vitriol, however, it was associated with glaucoma and cataract formation-including CSME without advanced macular ischemia, it was noted that anti-VEGF therapy requires regular visits, monitoring, and repeated injections[10-14] After laser photocoagulation, follow-up is less important for

ongoing care than with anti-VEGF. Additionally, injections per month is not tolerable for most patients. Even the cheapest anti-VEGF, bevacizumab, remains unaffordable and unavailable to patients in semi-urban and rural areas.[15-17]

This study shows that laser treatment is highly effective in maintaining visual acuity in DME. These results are comparable to international studies[18,19].National studies have shown favorable results of laser treatment in PDR. In Chandka's study[20], 39.6% (143) of eyes reported improvement and 50% (183) reported a decrease in visual acuity. It was concluded that laser PRPP using a pattern scanning laser is safe and effective in patients with combined symptoms of PDR and DME [21-23]. Current research shows that laser treatment alone is highly effective.

There were few confounding factors in certain study, Diabetic control parameters were fasting (109 mg/l) and postprandial blood glucose (140-190 mg/l), Lipid profile and HB A1C were performedinpatients. Another confounding factor was the lack of OCT and FFA as diagnostic and monitoring tools.[24,25] The diagnosis of CSME was clinically performed. All patients were referred for OCT and those who consented to the study were referred to a tertiary center, for the purpose of the study we considered that visual results are indicative of treatment. Many cases of DME had baseline OCTs exhibiting intraretinal hard exudates, confluent degenerative cystic edema and disrupted ellipsoid zones (57.1% of cases), suggesting chronically ill retinas that might not respond ideally to the laser's regenerative stimulus.

It was found in some study that may be the pattern of patient follow-up affected,it was observed that follow-up was as per the patient's convenience rather than following the study protocol (monthly and quarterly). Follow-up during reported study was a minimum of 1 year and a maximum of 45 months.[26] It was observedin previous study that almost all the patients visited the center at least once. Of the total 464 macular edema patients in theFilho et.al study, 43.7% (203) had 1 participant, 42.65 (198) had 2 participants, 4.5% (21) had 3 participants, 6.8% (32) had 4 participants.2.1% (10) attended 5 times.[27] This is an important indicator of patient behavior that demonstrates the importance of considering patient convenience when giving follow-up dates.It seems that severe structural changes in the neurosensory retina and microvasculature seen at late stages of DME may prevent a good response with subthreshold laser alone, which relies on the existence of a viable intra-cellular machinery to work properly and a certain degree of cell viability and retinal integrity.

CONCLUSION

Laser therapy is an effective treatment to stabilize/improve vision in diabetic macular edema, especially in centers where only organ lasers are available and facilities like OCT, FFA etc. are not available. Subthreshold laser therapy is known to primarily target RPE function, modulating heat shock protein activation and normalizing cytokine expression. In the present study, cases of DME associated with SRF had an excellent physiologic response, whereas intraretinal edema did not respond to laser monotherapy. BCVA and macular thickness showed a mild response, suggesting the need for combined treatment in most patients given the effect of SRF on reabsorption.

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