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Original research

Comparison of subthreshold diode laser micropulse therapy versus conventional photocoagulation laser therapy as primary treatment of diabetic macular edema

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Abstract

Purpose: The aim of the present study was to investigate the effect of subthreshold diode laser micropulse in comparison with conventional laser photocoagulation in the treatment of the diabetic macular edema.
Methods: Sixty-eight eyes from 68 patients with clinically significant diabetic macular edema were divided randomly into two equal groups. In the first group, subthreshold diode laser micropulse photocoagulation was employed, while conventional laser photocoagulation was performed on the eyes of the second group. Central macular thickness, central macular volume, and best corrected visual acuity were measured before, 2, and 4 months after intervention, and the results were compared.
Results: The mean central macular thickness was 357.3 and 354.8 microns before the treatment in Groups 1 and 2, respectively ($P = 0.85$), and decreased significantly to 344.3 and 349.8 after 4 months, respectively ($P = 0.012$ and $P = 0.049$). The changes in the central macular thickness was statistically higher in the first group ($P = 0.001$). The mean central macular volume significantly decreased in Group 1 ($P = 0.003$), but it was similar to pretreatment in Group 2 after 4 months ($P = 0.31$). The best corrected visual acuity improved significantly in Group 1 ($P < 0.001$), but it remained unchanged in Group 2 ($P = 0.38$).
Conclusions: In this study, subthreshold diode laser micropulse was more effective than conventional laser photocoagulation in reducing central macular thickness and central macular volume and improving visual acuity in patients with diabetic macular edema.

Keywords: Diabetic macular edema; Subthreshold diode laser micropulse; Conventional laser photocoagulation

Introduction

Diabetic macular edema (DME) is one of the most important causes of visual deterioration in working-age patients who have diabetes mellitus.[1–3] DME was defined as retinal thickenings and/or edema threatening or involving the fovea that is visible by fundus examination or optical coherence tomography (OCT). When it involves the fovea, returning to the previous visual status is almost impossible.[4,5] DME is classified as focal and diffuse. The traditional treatment for macular edema had been laser photocoagulation, focal laser to induce photocoagulation of microaneurysms in focal DME, and grid pattern laser for diffuse type.[6]

Currently, intra-vitreal anti vascular endothelial growth factors (VEGF) injections with or without laser photocoagulation is the standard of care for patients with DME, and newer

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methods of laser such as subthreshold diode laser micropulse photocoagulation (SDM) are under investigation in an attempt to improve the efficacy while reducing the adverse events. The studies evaluating the safety and efficacy of SDM, in comparison with conventional laser therapy for macular edema, are limited.[3,7–9]

Our study was designed to compare the efficacy of SDM with conventional laser as a primary treatment of DME.

Methods

This single-blind, prospective, randomized, clinical trial was performed in the ophthalmology center of Feiz Hospital, Isfahan, Iran, between 2015 and 2016. The study was approved by the Ethics Committee of the Isfahan University of Medical Sciences and was registered in the Iranian Clinical Trial Registry (registration number IRCT2015122721890N2). We explained the aim of our study to the patients, and informed consent was obtained. Diabetic patients who were suffering from clinically significant macular edema (CSME)[10] and non-proliferative diabetic retinopathy (NPDR) in fundus exam were enrolled in the study. The inclusion criteria of our study were: the minimum Best Corrected Visual Acuity (BCVA) 20/200 or 1.00 Logarithm of the Minimal Angle of Resolution (LogMAR), the best corrected vision less than 20/25 or 0.10 LogMAR, and diabetic macular edema with the minimum central macular thickness of 300 microns on OCT basis. The exclusion criteria were: monocular patients, diabetic macular edema with central macular thickness more than 450 microns on the Optical Coherence Tomography OCT, pregnant patients or pregnancy during the study, uncontrolled hypertension defined by systolic blood pressure (SBP) more than 160 mmHg and/or diastolic blood pressure (DBP) more than 110 mmHg, any history of intra-ocular surgery except uncomplicated phacoemulsification cataract surgery in past six months, any history of previous intra-ocular injections, any history of previous conventional laser photocoagulation of retina or subthreshold diode micropulse laser, previous history of glaucoma or ocular hypertension or an increase in IOP during the study, macular diseases such as vitreo macular traction (VMT), epi retinal membrane (ERM), age-related macular degeneration (AMD), extensive non-capillary perfusion of macula in fluorescein angiography (FA), any visible scar in ophthalmic examination or fundus photograph after the study in the group treated with subthreshold diode micropulse laser, severe cataract not allowing the surgeon to observe the fundus, and lack of patient follow-up.

Sixty-eight patients were divided into two equal groups by block randomization. The first group was treated with SDM (Quantel-medical Co, Cournon-d'Auvergne, France), and the second group underwent the conventional macular laser photocoagulation (Quantel-medical Co, Cournon-d'Auvergne, France). In both groups, the wavelength of laser therapy was 810 nm.

All laser treatments was performed by an ophthalmologist (F.F). Prior to starting treatment with SDM, a test burn was performed in the nasal side to determine threshold power required for a visible tissue reaction for each patient. This test was done with 125 um spot, 200 ms exposure duration, and adjusted upward the power in the continuous wave (CW) emission mode until a light grayish visible burn was observed. When the threshold power of the patient achieved, the laser was changed to MicroPulse emission mode with 15% duty cycle, and the power was doubled with the same exposure duration.

SDM was conducted via dilated pupil as follows: adjustable power began from 1000 milli-joules with duration time of 300 μs, 15% duty cycle, and 75 to 125 micron spot size. All areas of clinically visible thickened and edematous retina in the macular area were treated excluding the FAZ with a safety margin of 100 microns around FAZ. Conventional laser photocoagulation was done via dilated pupil in the eyes of the second group as follows: adjustable power with 50–100 micron spot size, and 0.1 s duration time. Focal laser was applied in the distance of 500–3000 microns of the foveal avascular zone (FAZ) as well as on microvascular lesions with an exudative ring. In addition, grid laser was applied on clinically visible thickened retina in the macular areas excluding FAZ and a safety margin of 500-micron around the FAZ and 500-micron from the optic disc. For both groups, the laser treatment was performed once.

An ophthalmologist carried out laser treatment and the ophthalmic examination of the patients, including best corrected visual acuity (BCVA), slit lamp biomicroscopy, intraocular pressure (IOP) measurement using Goldman applanation tonometer, and fundus examination after pupil dilation to confirm CSME and NPDR. These examinations and OCT were repeated in 2 and 4 months after the intervention, and the information of these evaluations was gathered in special sheets. Only one ophthalmologist performed all of the examinations and interventions for all of the patients. Logarithm of the minimum angle of resolution (logMAR) was utilized to calculate BCVA. Cycloplegic refraction was done by autorefractometer (Topcon Medical system Inc. Tokyo, Japan) before the intervention and 2 and 4 months after the intervention.

The lens opacity was classified according to lens opacity classification III[11] as nuclear sclerosis, cortical cataract, or posterior subcapsular. After that, lenses were classified according to red reflex and physical examinations such as observing fundus, vascular branches, and head of optic nerve and especially surgeon experiments as mild, moderate, and severe. Very severe dense cataracts were excluded as explained above.

Central macular thickness (CMT) (microns) was automatically calculated by optical coherence tomography (OCT) for all eyes (SD-OCT Heidelberg Engineering, Heidelberg, Germany). Baseline FA (Heidelberg Engineering Co, Heidelberg, Germany) was performed to evaluate areas of leakage and capillary non-perfusion. Fundus photographs (Engineering Heidelberg Co, Heidelberg, Germany) were taken before and at the end of the study to compare retinal changes.

After laser therapy, all patients were evaluated for the following possible complications: vitreous and intra-retinal

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