



MACULAR LASER GRID ALONE VERSUS COMBINED WITH INTRAVITREAL TRIAMCINOLONE PLUS BEVACIZUMAB FOR DIABETIC MACULAR EDEMA

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ABSTRACT

Diabetic retinopathy is the leading cause of blindness among individuals of working age in advanced societies, most of the vision loss resulting from diabetic macular edema (DME). Macular laser photocoagulation or intravitreal triamcinolone or anti-vascular endothelial growth factor injection are modalities of therapy for diabetic macular edema. This study aim was to present the clinical outcomes of 60 eyes of 41 patients with diffuse DME who treated with macular laser grid (MLG) alone or combined with intravitreal triamcinolone (IVTA) and intravitreal bevacizumab (IVB) injection. Thirty eyes (group 1) treated with MLG and 30 eyes (group 2) treated with MLG + IVB + IVTA. The values of BCVA, central macular thickness (CMT), intraocular pressure (IOP) and complications were compared between two groups. At baseline, BCVA was 0.35 ± 0.18 LogMAR (logarithm of the minimum angle of resolution) in the group 1 and $0.36 \pm 0.36 \pm 0.14$ logMAR in the group 2. At 6 and 20 months after initial treatment in both groups had no significant improvement in BCVA, whereas had a significant improvement in CMT ($p < 0.001$) compared with baseline. An increase in IOP was present in 13 % and cataract was developed in 6.7 % in the group 2. At 6th and 20th month, MLG and MLG + IVTA + IVB provided improvement of BCVA and CMT in the both groups. There was no significant difference in BCVA and CMT between two groups. Increased IOP and development of cataract was recorded in the group 2 secondary to IVTA. MLG may be preferred for treatment of DME because of side events of IVTA + IVB.

Keywords: Bevacizumab; diabetic macular edema; intravitreal triamcinolone; laser photocoagulation, IOP

INTRODUCTION

Diabetic macular edema (DME) is a major cause of visual loss in patients with diabetes.^{1,2} Modalities of treatment of diabetic macular edema are laser grid photocoagulation, intravitreal anti-vascular endothelial growth factor (VEGF) injection and intravitreal steroid injection. In this study, we reported clinical outcomes of 60 eyes of 41 patients who treated with macular laser grid (MLG) alone or combined with injection of intravitreal bevacizumab (IVB) and intravitreal triamcinolone acetate (IVTA) for DME.

MATERIALS AND METHODS

The study design was a retrospective interventional comparative evaluation of 60 eyes of 41 patients with diffuse diabetic macular edema treated with MLG (group 1, n = 30 eyes) alone and combined with IVTA + IVB (group 2, n = 30 eyes). Unlike the ETDRS definition, diffuse macular edema was defined as a diffuse thickening of the retina up to the vascular arcades including the fovea and an optical coherence tomography (OCT) measured central macular thickness > 320 μ m. Macular laser grid photocoagulation was performed in spots of 80–100 μ m diameter in the macular area, at a distance of one to two spots from one to another, in concentric lines, with an exposure time of 0.1–0.12 second, sparing of the central area using contact lens. Combined IVTA + IVB + MLG treatment was used as below in the group 2: Macular laser grid was performed, after a period ranging from 2 to 3 weeks from IVTA + IVB injection according to ETDRS guidelines.³ Intravitreal re-injection of IVTA + IVB was performed after at least 3 months according to reported suggestions.⁴ Exclusion criteria for treatment were the presence of dense or opaque media, ocular trauma, inflammation, history of intraocular surgery in the last 6 months, previous or during follow up received pan-retinal photocoagulation; glaucoma or IOP > 21 mm Hg in a measurement before the treatment, optic neuropathy,

amblyopia, poorly controlled (not responding to treatment) diabetes, hypertension or nephropathy, eyes with macular ischemia, retinal vein occlusion and vitreomacular traction. Macular ischemia was defined as angiographic evidence of foveal avascular zones 1000 μ m or larger, or broken perifoveal capillary rings at the borders of the foveal avascular zone, with distinct areas of capillary non-perfusion within one disc diameter of the foveal centre, as seen in the transit phase of fluorescein angiography. Data collection included the evaluation of best-corrected visual acuity (BCVA) according to the Early Treatment Diabetic Retinopathy Study (ETDRS) LogMAR scale, clinical examination, mean thickness in the central (1 mm diameter) area (CMT) of macula at OCT (Optovue Inc, RTVue 4.0, model 100, Fremont, CA) and IOP. Patients were observed by one month intervals. At baseline, between 6 months and 20 months from first treatment colour fundus photographs and fluorescein angiography were performed. On each follow-up visit, possible side effects of the treatment (IOP > 21 mm Hg, anterior chamber reaction, severe lens opacity, vitreous haemorrhage, endophthalmitis, retinal detachment, significant blood pressure increase, thromboembolic events) were ruled out. All injections were performed in the operating room through the pars plana under topical anaesthesia (Proparacaine HCL 0.5 %) according to standard procedures.⁵ Patients were treated with intravitreal bevacizumab (1.25 mg / 0.05 mL prepared from Avastin; Genetech Inc., south San Francisco, CA) and 2 mg / 0.05 mL prepared from Triamcinolone acetate (2 mg / 0.05 mL prepared from Kenacorte-A, Bristol-Myers Squibb, Sermoneta, Latina, Italy). Each patient was informed of the off-label status of bevacizumab and triamcinolone acetate and informed consent was obtained. Re-treatment was based on clinical findings or OCT-based evidence of persistent macular edema or loss of one or more line in visual acuity. Re-treatment period for macular edema was least interval of 3 months for

both groups. The study followed the tenets of the Declaration of Helsinki. Approval of local Ethics Committee was obtained.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (version 17.0, SPSS Inc,

Chicago, IL, USA). Repeated measures ANOVA for multiple comparisons was used to compare follow-up to baseline data within a treatment group. Baseline demographic and clinical parameters were compared between two groups using Student's t-test for continuous variables and χ^2 -tests for the categorical variables. A P value of < 0.05 was considered statistically significant.

Table 1: Demographic Characters of Patients

Group	Group 1 (MLG)	Group 2 (MLG + IVTA + IVB)	p
N (eyes)	30	30	NS
Gender (F / M)	11 / 9	11 / 10	NS
Mean age \pm SD (years)	63.7 \pm 8.1	62.1 \pm 8.1	NS

MLG: macular laser grid, IVTA: intravitreal triamcinolone acetamide, IVB: intravitreal bevacizumab, F / M: female / men SD: Standard deviation

Table 2: Data of Two Groups Before and After Treatment

Parameters	Group 1	Group 2	p
Follow-up (month)	20.4 \pm 12.3	20 \pm 12.0	NS
VA baseline	0.35 \pm 0.18	0.36 \pm 0.14	NS
VA at 6 months	0.38 \pm 0.12	0.39 \pm 0.11	NS
VA at 20 months	0.38 \pm 0.12	0.38 \pm 0.11	NS
CMT(μ m) baseline	436 \pm 59	437 \pm 108	NS
CMT at 6 months	282 \pm 31	281 \pm 40	NS
CMT at 20 months	288 \pm 41	292 \pm 55	NS
Mean injection at 6 months	--	1.13 \pm 0.13	S
Mean injection at 20 months	--	2.03 \pm 0.9	S
Sessions MLG at 6 months	1.23 \pm 0.43	1.03 \pm 0.18	S
Duration of DM (Mean \pm S.D, years)	8.5 \pm 2.5	8.7 \pm 2.4	NS
HbA1c (%)	8.2 \pm 1	8.1 \pm 0.8	NS
IOP(mm Hg) baseline	17.4 \pm 1.5	17.3 \pm 1.6	NS
IOP at 6 months	17.2 \pm 1.5	19.3 \pm 2.7	S
IOP at 20 months	17.3 \pm 1.5	19.7 \pm 2.9	S
DME recurrence	3	2	NS
Glaucoma	0	4	S
Cataract	0	2	S
IVH	0	0	NS
Endophthalmitis	0	0	NS
Retinal Detachment	0	0	NS

MLG: macular laser grid, logMAR: logarithm minimum of angle resolution, DM: diabetes mellitus, DME: diabetic macular edema, IVTA: intravitreal triamcinolone acetamide, IVH: intravitreal hemorrhage, IVB: intravitreal bevacizumab, VA: visual acuity, IOP: Intraocular pressure, CMT: central macular thickness, SD: standard deviation, HbA1c: glycosylated hemoglobin, NS: nonsignificant, p > 0.05, S: significant, p < 0.05

RESULTS

Demographic data is shown in Table 1. BCVA, CMT, IOP and complications are summarized in Table 2. Thirty eyes (group 1) of 20 patients with DME were treated with MLG alone. Thirty eyes (group 2) of 21 patients with DME were treated with combined laser grid treatment and intravitreal triamcinolone (2 mg) + intravitreal bevacizumab (1.25 mg). No significant differences were present between two groups regard regarding to sex, age, duration of diabetes and baseline BCVA, IOP and CMT. Duration of DM was 8.5 \pm 2.5 years in the MLG group and 8.7 \pm 2.4 years in the MLG + IVB + IVTA group. Mean BCVA was 0.38 \pm 0.12 logMAR at 6th in the MLG group; 0.39 \pm 0.11 logMAR in the MLG + IVTA + IVB group (p = NS). Mean BCVA was 0.38 \pm 0.12 logMAR at 20 months in the MLG group; 0.38 \pm 0.11 logMAR in the MLG + IVTA + IVB group (p = NS). Mean number of Macular Laser Grid sessions was 1.23 \pm 0.43 at 6 months and 1.43 \pm 0.50 at 20 months in the MLG group (p < 0.05). Mean number of Macular Laser Grid sessions was 1.03 \pm 0.18 at 6 months and 1.27 \pm 0.52 at 20th months in the MLG + IVTA + IVB group. After 6 and 20 months, improvement of BCVA was present in both groups, but this improvement was not statistically significant. The gain in BCVA was similar in two groups. Mean number of sessions of laser photocoagulation was higher in the MLG group than in the combined group (p < 0.001) at 6 and 20 months. Intraocular

pressure elevation was statistically significant in group 2 (p < 0.001). During follow-up IOP increased in 4 of 30 (13.3%) eyes treated with MLG + IVTA + IVB and decreased to normal values in three of them after anti-glaucomatous treatment and one patient needed filtration surgery after 15 months. Cataract was developed in two (6.7 %) cases in group 2. This two cases were operated (phacoemulsification + intraocular lens implantation) for cataract at 15th months. There was no systemic side events in group 2.

DISCUSSION

For patients presenting with DME for the first time, macular laser grid (MLG) photocoagulation is currently the standard treatment. The Early Treatment of Diabetic Retinopathy Study showed that MLG reduced moderate visual loss in eyes with clinically significant macular edema.³ Intravitreal injection of triamcinolone acetamide (IVTA) has been reported to improve visual acuity and to reduce the macular thickness in eyes with diffuse DME,^{6,7} by inhibition of the arachidonic acid pathway and downregulation of the production of VEGF. Triamcinolone acetamide has important side effect such as cataract formation or increased intraocular pressure (IOP).^{8,9} The use of intravitreal bevacizumab (IVB), for the treatment of DME showed promising functional and anatomical results in short- and long-term studies.^{10,11} This is

supposed to be the first study comparing MLG alone and combined with IVTA + IVB for treatment of diffuse DME as our knowledge. The previously published studies were compared IVB or IVB + IVTA versus (vs) MLG¹², IVB vs IVTA¹³ and IVB + IVTA¹⁴, IVB versus IVTA¹⁵, IVB vs IVB + MLG¹⁶, IVTA vs MLG^{17,18}, IVB vs IVTA + IVB¹⁹, IVB vs IVTA + MLG²⁰, IVB vs MLG²¹ and IVB vs IVB + MLG²². There was modest correlation between CMT and visual acuity after focal laser treatment for DME. A lower correlation was found between BCVA and CMT, as already reported.²³ In this study the mean visual acuity was improved but this improvement was not statistically significant whereas significant anatomical improvement in the central macular thickness was observed in both groups at 6 and 20 months. Our patients underwent more sessions of photocoagulation in the MLG alone than IVB + IVTA + MLG group ($p < 0.05$). In this study macular laser grid photocoagulation was performed later 2-3 weeks from IVTA IVB, this timing was similar to the literature.²⁴⁻²⁶ Initial improvement and following recurrence of macular edema was recorded at 6 months 1;1 case; at 20 months 3;2 cases in the MLG and IVTA + IVB + MLG group, respectively. The synergistic effects of MLG after IVTA injection have been examined by several recent studies, with conflicting results.²⁷⁻²⁹ The most frequent adverse effects with corticosteroids are cataract formation and elevation of IOP.^{20,30} No side effects (cataract or increase in IOP) were recorded in the MLG group, whereas cataract formation and intraocular pressure increase (> 21 mm Hg) was reported in 13.3 % of eyes treated with MLG + IVTA + IVB group. Several retrospective studies support the local and systemic safety of intravitreal anti-VEGF^{12,31}. In this study, there was no observed systemic side effects in MLG + IVTA + IVB. The major limitations of this study are small numbers of patients in both groups, baseline central macular thickness was not considered for choice of modality of treatment, there was no groups that received only IVB or IVTA and the retrospective study design.

CONCLUSION


Combined MLG + IVTA + IVB and MLG showed similar effectiveness in improving visual acuity and reducing macular thickness in DME during the first 6 and 20 months. Intravitreal injection of triamcinolone plus bevacizumab is associated with IOP elevation, not always responding to anti-glaucomatous treatment. Intravitreal bevacizumab plus IVTA injections have no additive effect on final visual acuity and CMT at 6 and 20 months. When performed intravitreal injection we have to think about complication of drug that administered with injection. We have to think about several complications of drugs used in intravitreal injections for DME treatment before performing. Endophthalmitis, retinal detachment, vitreous hemorrhage and systemic side effects can occur after IVTA + IVB.

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