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Comparison of Suprachoroidal Triamcinolone Injection and Modified Grid Laser in Treatment of Refractory Diabetic Macular Edema

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ABSTRACT

Diabetic macular edema is the leading cause of blindness in diabetic eye disease. The most important cause of visual impairment is diabetes-induced macular edema also called DME which involves central part of the macula lutea. **Objective:** To compare the outcome of suprachoroidal triamcinolone injection and modified grid laser in the treatment of refractory diabetic macular edema. **Methods:** This prospective cohort study was done for 12 months (January 2021 to December 2021) on 56 patients having refractory diabetic macular edema. The technique of non-probability consecutive sampling was used. Patients in Group A received a suprachoroidal injection of 4 mg triamcinolone. Patients in Group B underwent modified grid photocoagulation. After 4 months of treatment, the patients' visual acuity and central macular thickness were assessed again using Snellen's chart and Optical Coherence Tomography (OCT) respectively. **Results:** After 4 months, the mean BCVA in Group-A was 0.57 + 0.127 and in Group-B was 0.83 + 0.150 (P=0.000) while the mean improvement (change line) was 1.6 + 0.318 and 0.89 + 0.229 (P=0.001), respectively In Group-A, improvement in Central Macular Thickness (CMT) was observed in 24 (85.7%) patients, while in Group-B, improvement in Central Macular Thickness was seen in 17 (60.7%) patients. After 4 months, the mean CMT in Group-A was 302.68 + 14.427 um and in Group-B was 339.71 + 54.821 um (P=0.009) while the mean improvement (change) was 153.89 + 30.902 um and 95.57 + 41.111 um (P=0.024), respectively. **Conclusion:** Suprachoroidal triamcinolone injection was found to be more effective than modified grid laser in treatment of DME.

INTRODUCTION

Diabetes is major health issue of the 21st century [1]. Worldwide 425 million patients are diabetic presently and it is projected that this figure can approach 629 million in 2045 [2]. A microvascular consequence of diabetes called diabetic retinopathy affects around 34.6% of diabetic people. Diabetic macular edema (DME) is a complication of diabetic retinopathy that affects 6.8% of diabetic patients. It is a major cause of blindness [3]. Diabetic macular edema can be present at any stage of diabetic retinopathy (DR), however, as the disease advances there are more chances of developing Diabetic macular edema [4]. High blood sugar level, hypertension, low blood protein levels, and smoking are major risk factors of DME [5]. Macular edoema is defined as an abnormal accumulation of fluid within the macula's retinal layers [6] A delicate balance between fluid entering and leaving the retinal layers usually exists. To maintain tissue transparency, this balance is necessary for retinal homeostasis [7]. Macular edoema is characterized by fluid deposition between the retinal layers, resulting in progressive vision deterioration that can lead to chronic vision loss [8]. Due to metabolic changes and inflammatory responses, diabetic individuals may also experience loss of

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endothelial tight junctions and subsequent blood-retinal barrier (BRB) disruption [9]. DME Treatment has achieved major change over the years. Previously photocoagulation by Argon laser was a treatment option for DME and it was discovered by the Early Treatment of Diabetic Retinopathy Study (ETDRS) group. More than 50% decreased incidences of moderate visual loss with reduction in central macular thickness (CMT) were observed in treated eyes after 03 years of macular laser [10]. However, many complications occurred like subretinal fibrosis, choroidal neovascularization (CNV), visual field scotomas and progressive photoreceptor atrophy, due to grid and focal macular laser [11]. Anti-VEGF injections have been demonstrated by Diabetic Retinopathy Clinical Research Network (DRCR.net) to be a more effective and safe form of treatment for DME, with better visual results [12]. Numerous researches have looked into the pharmacologic properties of the suprachoroidal region for administering medications, particularly triamcinolone acetonide, to the eye [13]. For the treatment of DME, advanced methods are being used i.e. Injection Suprachoroidal Triamcinolone Acetonide so an alternative treatment option could be tried for refractory DME [14].

The study aimed to compare the outcome of suprachoroidal triamcinolone injection and modified grid laser in treatment of refractory diabetic macular edema.

METHODS

This prospective cohort study was done in 12 months (January 2021 to December 2021) with 56 patients, 28 in each group, with refractory diabetic macular edema in the Ophthalmology Department of Services Hospital Lahore. Prior informed consent was taken from the study participants. The duration of the study was 12 months, after approval of synopsis. Participants with age 40-80 years, both genders were included in the study. Patients already taken treatment of intravitreal corticosteroids, peribulbar steroid injection in last 6 months, photocoagulation 15 weeks before, panretinal scatter photocoagulation four months before, or PPV (on medical record), patients who had open-angle glaucoma or steroid-induced rise of intraocular pressure and needed treatment to decrease intraocular pressure and patients with intraocular pressure ≥25 mm Hg were excluded from the study. Diabetic macular edema with central macular thickness more than 300 micrometers. A sample size of 56 cases; 28 in each group, was calculated with 80% power of the study, 5% level of significance, and confidence level of 95%, and taking an expected percentage of improvement in central macular thickness i.e. 63% with Suprachoroidal triamcinolone [15] and 37% with Modified Grid Laser [16] by using the following formula:

$$n = (Z\alpha/2+Z\beta)2 * (p1(1-p1) + p2(1-p2)) / (p1-p2)2$$

The non-probability consecutive sampling technique was used. Subjects were divided into two groups using the lottery method. Patients in Group A received a suprachoroidal injection of 4 mg triamcinolone. Patients in Group B underwent modified grid photocoagulation. After 4 months of treatment, the patient's visual acuity and central macular thickness were assessed again using Snellen's chart and OCT respectively. The hospital ethical committee of SIMS approved the study (Ref No. IRB/2020/735/SIMS), which involved 56 patients. The researcher performed every procedure, explained it to the patients, and obtained their informed consent. Every patient's profile was noted, including their gender, age, diabetes duration, HbA1c, lateral side, and duration of ocular symptoms. Subjects were then split into two groups at random using the lottery method. Subjects in group A received a suprachoroidal injection of triamcinolone at a dose of 4 mg/0.1ml. Subjects in group B received modified grid photocoagulation. Visual acuity and central macular thickness were measured at the beginning point. Then, patients were checked on at the OPD at 7 days, 1- and 4-month intervals. After four months of intervention, the patients underwent a second evaluation of their visual acuity using the Snellen chart and an OCT scan to measure the central macular thickness. On the Snellen chart, improvements in visual acuity of one or more lines were detected. On optical coherence tomography, it was observed that the central macular thickness had decreased by more than 50% from the starting point. On the proforma, all the information was accurately recorded. Data analysis was done using the SPSS software, version 20,0. After stratification, the outcomes of the two groups were compared using the chi-square test and t-test for each stratum, with a p-value of 0.05 was considered significant.

RESULTS

Table indicates that in Group-A, improvement in visual acuity was observed in 25 (89.3%) patients while in Group B, improvement was observed in 21 (75.0%) patients (P=0.016) showing there is a significant association present. For non-improvement also significant association was found between the groups with a p-value of 0.001.

Table 1: Comparison of Improvement in Visual Acuity between Groups

Visual Acuity	Group – A (Suprachoroidal Triamcinolone Injection)	Group – B (Modified Grid Laser)	Chi-Square = 1.913
	Frequency (%)	Frequency (%)	P-Value
Improved	25 (89.3%)	21 (75.0%)	0.016
Not Improved	3 (10.7%)	7 (25.0%)	0.001
Total	28 (100%)	28 (100%)	–

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Table 2 shows that among both groups of patients, improvement after 4 months of treatment was observed regarding BCVA (best-corrected visual acuity) with a statistically significant difference. Pretreatment mean BCVA in Group-A was 0.920.104, while 1.070.411 in Group-B. After 4 months, the mean BCVA in Group-A was 0.570.127 and in Group-B was 0.860.150 (P=0.000) and the p-value suggest significance statistically as p-value is less than 0.05, while the mean lines improvement was 1.60.318 and 0.890.229 (P=0.001) and this p-value shows there is significant association between the two groups, respectively.

Table 2: Comparison of Mean BCVA between Groups

Mean BCVA (logMAR)	Group – A (Suprachoroidal Triamcinolone Injection)	Group – B (Modified Grid Laser)	T-Test P-value
Baseline	0.92 0.104	1.07 0.411	0.011
After 4 Months	0.57 0.127	0.86 0.150	0.000
Change	1.71 0.713	0.65 0.629	0.001
Lines Improvement	1.6 0.318	0.89 0.229	0.001

Table 3 asserts that 24 (85.7%) patients were observed having improvement in central macular thickness in Group-A while 17 (60.7%) patients showed improvement in Group-B (P=0.010) and shows statistical significance between groups and for non-improvement the p-value is 0.016 which also shows significant statistically.

Table 3: Comparison of Improvement in Central Macular Thickness Between Groups

CMT	Group – A (Suprachoroidal Triamcinolone Injection)	Group – B (Modified Grid Laser)	P-value
Improved	24 (85.7%)	17 (60.7%)	0.010
Not Improved	4 (14.3%)	11 (39.3%)	0.016
Total	28 (100.0%)	28 (100.0%)	-

Table 4 depicts that among both groups' patients' improvement after 4 months of treatment was observed regarding CMT (central macular thickness) with statistically significant difference. After 4 months, the mean CMT in Group-A was 302.68+14.427 um and in Group-B was 339.71+54.821 um (P=0.009). A p-value of 0.009 revealed statistically significant difference, indicating Group A had a greater reduction in CMT, while the mean improvement (change) was 153.89+30.902 um and 95.57+41.111 um (P=0.024), respectively. There was no statistically significant difference in baseline CMT between the groups with a p-value of 0.051.

Table 4: Comparison of Mean Central Macular Thickness between Groups

Mean CMT (um)	Group – A (Suprachoroidal Triamcinolone Injection)	Group – B (Modified Grid Laser)	T-Test P-value
Baseline	456.57 + 40.428	435.50 + 57.953	0.051
After 4 Months	302.68 + 14.427	339.71 + 54.821	0.009
Change	153.89 + 30.902	95.57 + 41.111	0.024

Table 5 elucidates that among Group A and B, patients who were <50 years old, the mean BCVA was 0.560.114 and 0.80142 (P=0.107) respectively, while among patients who were >50 years old, the mean BCVA was 0.58151 and 0.900.149 (P=0.149) respectively. However, Group-A and B, patients who were <50 years old, the mean CMT was 304.24+17.587 um and 323.1148.306 um (P=0.000) respectively, while among patients who were >50 years old, the mean CMT was 300.277.525 um and 374.78+53.427 um (P=0.000), respectively.Group-A and B patients, who had duration of diabetes <5 years, the mean BCVA was 0.530.176 and 0.880.114 (P=0.003) respectively. While patients who had duration of diabetes >5 years, the mean BCVA was 0.590.096 and 0.790.169 (P=0.005) respectively. However, Group-A and B patients, who had a duration of diabetes <5 years, the mean CMT was 302.11+13.214 and 354.3158.774 (P=0.000), respectively. Among patients who had da duration of diabetes >5 years, the mean CMT was 302.9515.310 um and 327.07+49.658 um (P=0.036), respectively.

Table 5: Comparison of Age and Duration of Diabetes with Mean BCVA (logMAR) and Mean CMT (µm) after Treatment between Groups

Category	Group A Mean BCVA (logMAR)	Group B Mean BCVA (logMAR)	T-Test P-value (BCVA)	Group A Mean CMT (µm)	Group B Mean CMT (µm)	T-Test P-value (CMT)
Age <50 yrs	0.56 ± 0.114	0.80 ± 0.142	0.107	304.42 ± 17.587	323.11 ± 48.306	0.000
Age <50 yrs	0.58 ± 0.151	0.90 ± 0.149	0.149	300.27 ± 7.525	374.78 ± 53.427	0.000
Duration <5 years	0.53 ± 0.176	0.88 ± 0.114	0.003	302.11 ± 13.214	354.31 ± 58.774	0.000
Duration <5 years	0.59 ± 0.096	0.79 ± 0.169	0.005	302.95 ± 15.310	327.07 ± 49.658	0.036

DISCUSSION

Diabetes mellitus is thought to be the leading global health problem of the twenty-first century, and diabetic macular edema is a major cause of blindness in diabetic eye disease. The DME involving the Macular Centre is a major cause of vision loss. Argon grid laser and intravitreal triamcinolone acetonide have been used to treat patients who have not responded to anti-VEGF endothelial growth factor agents. Currently, triamcinolone injected through the suprachoroidal pathway has demonstrated comparable efficacy with less risk of increased intraocular pressure. As

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a result, the current study compared the efficacy of modified grid laser and suprachoroidal triamcinolone injection in the treatment of refractory diabetic macular edoema. To acquire adequate results, 56 patients were included in the study and divided into two equal groups (28 patients in each group) namely Group A and -B. In Group-A, patients were treated with Suprachoroidal Triamcinolone Injection (STI) while in Group-B, patients were treated with Modified Grid Laser (MGL). Age is a leading factor as increasing age boosts the severity of diseases. It is believed that elderly patients are more affected by diabetic macular edema due to the long duration of diabetes. The findings of our study showed that in both groups (Suprachoroidal Triamcinolone Injection [STI] and Modified Grid Laser [MGL]) more than half of the patients were up to 50 years old (60.7% vs. 67.9%) while the remaining proportion was above 50 years old. (39.3% vs. 32.1%). The mean age of the patients in the STI group was 49.46+5.022 years while in the MGL group was 49.82+5.004 years. However, the findings of a study undertaken by Abdelshafy Tabl *et al* [17] showed that the mean age of the patients treated with STI was 55+3 years while a study done by Khanzada and colleagues [15] reported the mean age of the patients treated with MGL was 59.45+8.23 years. It was found during the study that most of the patients in both groups were female (STI: 53.6% vs. MGL: 60.7%). The results of our study are comparable with a study undertaken by Munir and associates who also confirmed that the disease was more prevalent among female patients (64.0%) treated with STI [18]. However, the results of a study conducted by Khanzada and colleagues highlighted that male patients (53.2%) treated with MGL were in the majority [16]. For DME, elevated HbA1c is also a major risk factor like several other risk factors namely diabetes duration, history of cardiovascular disease, and use of diuretics. The study demonstrated that patients in the STI group had a mean HbA1c of 9.036+0.5933% while in MGL group had 9.457+0.8561%. The results of a similar study carried out by Khanzada and colleagues [16] are better than our study results which reported that the mean HbA1c among patients with DME was 7.85+0.78%. The STI group was found much better than MGL groups regarding visual acuity as improvement was observed among 89.3% of patients in the STI group while 75.0% in the MGL group (P=0.016). When a comparison was made among patients of both groups regarding BCVA, the study showed better improvement among patients treated with suprachoroidal triamcinolone injection than with modified grid lasers. In the STI group, the mean BCVA (best-corrected visual acuity) was 0.920.104 at baseline and after 4 months of treatment was 0.570.127 while in the MGL group, the mean BCVA was 1.070.411 and after treatment was 0.860.150. The mean line improvement (change) after treatment in the STI group was observed better (1.60.318) than in the MGL group (0.890.229) with statistically significant results (P=0.001). When a mean comparison of BCVA was performed in both groups after treatment. Insignificant results (P>0.05) were found regarding age in both groups. For gender, significant results were in the STI group but insignificant results (P>0.05) in the MGL group. Insignificant results for the lateral side in both groups while significant results for the duration of diabetes and HbA1c in both groups. However, significant results for the duration of symptoms in the STI group while insignificant results for the MGL group. A study conducted by Tufan *et al* [19], revealed statistically not significant, best correct visual acuity (BCVA) improvement was observed in the third and sixth months following IVTA injection. A statistically significant decrease in central macular thickness (CMT) occurred in the third month, and this effect persisted after six months. Previous research has shown that intra-vitreal triamcinolone acetonide improves visual acuity (VA) and reduces diffuse macular edema. [20, 21]. Likewise, when the mean comparison of CMT was performed in both groups after treatment, significant results were found regarding age while insignificant results regarding gender. Insignificant results were found regarding the lateral side, while significant results regarding the duration of diabetes, HbA1c, and symptoms were found in both groups. A study conducted by Aslam *et al* [22] revealed that there was not any significant association between the two groups at baseline CMT with a p-value of 0.29, although a significant association was found at 3-month CMT with a p-value less than 0.001. There were not many complications found in either group.

CONCLUSIONS

This study concluded that suprachoroidal triamcinolone injection is superior to modified grid laser therapy for treating diabetic macular edema that is resistant to Anti-VEGF treatment.

Authors Contribution

Conceptualization: NA, MAA
Methodology: TR, NA
Formal analysis: NUA, HMUA
Writing, review and editing: NA, FR

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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