ORIGINAL ARTICLE

Efficacy of Posterior Subtenon Triamcinolone Acetonide Injection with Intravitreal Ranibizumab Injection in Diabetic Macular Edema

Adel Abdelaziz M. Hasona, Nehad M. Yusef, Mohammad S. M. Shehata *

Department of Ophthalmology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Abstract

Background: ***One of the most prevalent consequences of diabetes is diabetic macular edema (DME), which can cause diabetic retinopathy (DR) and eventually blindness in young people.***

Aim: ***To compare subtenon triamcinolone acetonide injection with intravitreal ranibizumab injection in terms of diabetic macular edema (DME).***

Methods: ***Two groups were formed from forty eyes of patients with diffuse diabetic macular edema. One group had three intravitreal injections of 0.3 mg of Ranibizumab, administered in 0.05 ml, spaced one month apart. The second group also got injections, but the first one also included a 40mg/ml dose of triamcinolone acetonide administered posteriorly sub-tenon (PST), under normal aseptic techniques in the ophthalmic surgery theater. Pre- and post-injection optical coherence tomography (OCT) measurements of the central subfield macular thickness (CMT) were assessed at different time points. Visual acuity was evaluated by measuring BCVA and intraocular pressure (IOP), as well as any problems linked to these two methods.***

Results: ***At the one, two, and three-month marks, the BCVA is much better in the combination group (86.7%, 173.3%, and 206.7%) than in the intravitreal Ranibizumab only group (33.3%, 71.4%, and 76.1%). During the follow-up period, this enhancement was noted in both groups. A significant difference ($p<0.001$) was found between the two groups with respect to CMT at 2 and 3 months.***

Conclusions: ***Regarding enhancing BCVA and decreasing CMT, having the benefits of TA while avoiding risks of intravitreal TA, such as raised IOP, posterior sub-tenon triamcinolone acetonide injection with intravitreal Ranibizumab is an excellent tool for treating diabetic macular edema (DME).***

Keywords: Diabetic macular edema; Diabetes mellitus; Diabetic retinopathy; Posterior subtenon

1. Introduction

Diabetic macular edema (DME) is the leading cause of blindness in people with diabetic retinopathy (DR).[1]

The function of inflammatory mediators in DME development has received much focus in recent decades. When the retina is damaged, levels of these mediators are known to rise. It is believed that vascular permeability can be influenced by certain inflammatory cytokines, including interleukin-1 (IL-1) and IL-6. One potential component of DME pathogenesis is the disruption of capillary endothelial tight junctions caused by elevated vascular endothelial growth factor (VEGF) levels.[2]

Thus, multiple clinical trials have demonstrated that consistent intravitreal injections of anti-VEGF increase visual acuity.[3]

The anti-inflammatory, anti-VEGF, and antiproliferative properties of corticosteroid treatment—particularly dexamethasone implant—have made it a viable option to other DME treatments in recent years.[4]

Prior to the availability of anti-VEGF medications and the dexamethasone implant, the corticosteroid most commonly used to treat diabetic macular edema (DME) was triamcinolone acetonide (TA), whether it was given intravitreal (IVTA) or posterior sub-tenon (STA).[5]

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* Corresponding author at: Ophthalmology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt.
E-mail address: Mohamedkand96@gmail.com (M. S. M. Shehata).

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Previous studies found that STA was more dependable than IVTA and had the same therapeutic dosage effectiveness as IVTA.[3]

The macular area can be examined using a variety of procedures, such as biomicroscopy, optical coherence tomography (OCT), and fluorescein angiography. As a crucial clinical technique for the diagnosis and treatment of DME, fluorescein angiography (FA) has been essential in studying the pathogenesis of numerous retinal illnesses.[6]

While anti-VEFG treatment does improve diabetic macular edema's morphological and functional outcomes, patients usually have recurrence following the initial injection, requiring further injections to maintain therapeutic efficacy.[2]

Ocular discomfort, ischemic retinopathy, and endophthalmitis are among the several risks associated with multiple intravitreal injections, which may necessitate monthly injections of Ranibizumab. And because of the high cost of drugs like Ranibizumab, they often cause financial problems for the patient.[1]

Another effective method for treating diabetic macular edema is injecting steroids posterior subtenon. Additionally, it has the potential to deliver therapeutic amounts of triamcinolone to the retina in a less invasive manner compared to intravitreal injection.[6]

The purpose of this research was to determine whether injecting triamcinolone acetonide into the posterior sub-Tenon in addition to Ranibizumab intravitreally improved treatment outcomes.

2. Patients and methods

The ophthalmology departments of hospitals affiliated with Al-Azhar University are the sites of this prospective interventional comparative randomized trial. Forty eyes for the first time need intervention due to diabetic macular edema.

The research subjects were split into two groups: Twenty eyes from diabetic macular edema patients who received intravitreal injections of Ranibizumab make up Group A. A total of 20 eyes from patients undergoing treatment for diabetic macular edema with intravitreal Ranibizumab and posterior sub-tenon injections of triamcinolone acetonide make up Group B.

Participants in the study were individuals with either type 1 or type 2 diabetes mellitus who exhibited non-tractional diabetic macular edema and a foveal thickness of 300 μm or greater.

Patients with macular degeneration, cataracts, or substantial media opacities (caused by hemorrhage or cataracts) that hindered fundus examination or optical coherence tomography (OCT) imaging were not included in the study, macular edema due to other conditions (such as a history of uveitis, retinal detachment, recurrent extraretinal membranes (ERMs), vitrectomy, intravitreal steroids, antiangiogenic drugs, or macular laser photocoagulation; participants who had intraocular surgery within the preceding four months; and patients with ischaemic maculopathies were not included.

Methodology:

The following items were included in the patient's comprehensive medical and surgical history: a history of ocular infections or inflammations; a list of all medications taken; a record of any bleeding disorders or anticoagulant medication use; and a record of any eye traumas.

At the first visit and every follow-up, all patients had a quick eye exam, where we measured intraocular pressure (IOP) with a Goldman applanation tonometer, took their best-corrected visual acuity (BCVA), and used a +90F noncontact lens to do slit-lamp biomicroscopy. Every patient had a fundus fluorescein angiography done using ImageNet 2000 and Topcon TRC50IX in the beginning, which were manufactured by Topcon Corporation in Tokyo, Japan. If required, some patients underwent additional procedures during their follow-up visits. At both the pre- and post-injection follow-up appointments, all patients underwent optical coherence tomography (OCT) with a Topcon DRI-1 Swept Source SSOCT (Tokyo, Japan) to ascertain the CMT. Spectralis OCT's Auto Rescan feature makes it possible to scan each patient again for follow-up purposes.

Surgical procedure:

In the operating room, sterile conditions were maintained for all injections. At least three times, with one minute intervals in between, the eyes were numbed using topical 0.4% benzoin hydrochloride. The skin is sterilized using 10% povidone iodine. Applying 5% povidone iodine to the surface of the eye achieves total asepsis.

The first group received three intravitreal injections of 0.3 mg for Ranibizumab (Lucentis®, Genentech, Inc., South San Francisco, CA) spaced one month apart, while the second group received the same injections plus an additional 40 mg/ml injection of Triamcinolone acetonide (Kenacort -A® Bristol-Myers Squibb Company New York - Cairo) through the posterior sub-tenon (PST) in the inferotemporal quadrant. Following disinfection and draping for the posterior sub-tenon injection, a small incision was made to expose the sclera, either supero-temporal or infero-nasal to the limbus, and it was situated 7-8 mm posteriorly. The medicine was injected into the back of the eye via a blunt, curved cannula called a NAGATA® sub-tenon cannula. Subsequently, a topical antibiotic was applied, and the cannula was carefully removed while a sterile swab was applied

to mild pressure along its course.

Follow-up:

Following injections, all patients underwent ophthalmic examinations on days 1 and 7. During follow-up, the BCVA, intraocular pressure (IOP), as well as fundus microscopy, were routinely evaluated. At the monthly evaluation, the anatomical (CMT) and functional (BCVA) results were evaluated using swept source OCT and visual acuity charts, respectively.

Statistical analysis

For analysis, the data were put into IBM SPSS 21.0. New York's Armonk, IBM Corp., Numbers and percentages were used to describe the qualitative data. We can validate that the distribution is normal by using the Kolmogorov-Smirnov test. Quantitative data were described using range (min-max), mean, and standard deviation. At the 5% level, the results were deemed significant. At 1, At1,2, and 3 months after injection, we compared pre- and post-injection values for all variables using paired sample t-tests and chi-square tests. Significant p-values were less than 0.05.

3. Results

Table 1. Comparison of demographic between the two groups:

VARIABLES	GROUP A (N=20)	GROUP B (N=20)	TEST	P-VALUE
AGE				
MEAN±SD	60.6±8.1	62.8±7.9	1.25	0.96
SEX				
MALE	11(55%)	8(40%)	0.97	1.47
FEMALE	9(45%)	12(60%)		
TYPE OF DM			1.18	0.84
T1DM	2(10%)	4(20%)		
T2DM	18 (90%)	16(80%)		
DURATION OF DM			0.47	0.94
MEAN±SD	13.55±3.47	13.1±3.59		

Twenty patients, consisting of eleven males and nine females, had an average age of 60.6±8.1 (mean±SD) for the twenty eyes that were injected with intravitreal ranibizumab. In group A, two patients had type 1 diabetes and eighteen patients had type 2 diabetes, resulting in an average duration of 13.55±3.47 (mean±SD) for DM.

In group B, which consisted of 20 eyes (12 females and 8 men), the average age was 62.8±7.9 (mean±SD) for the 20 eyes injected with intravitreal ranibizumab and posterior sub-tenon triamcinolone acetonide. Group B had a mean duration of DM of 13.1±3.59 (mean±SD), with 16 patients suffering from type 2 diabetes and 4 from type 1 diabetes.

The two groups did not differ significantly in terms of age, sex, duration, or diabetes status, (table 1).

Table 2. Comparison of the two groups' BCVA results during the follow-up period:

BCVA	GROUP A (N=20)	GROUP B (N=20)	TEST	P-VALUE
BASELINE			1.09	0.47
MEAN±SD	0.22±0.14	0.10±0.09		
1 MONTH			1.98	0.28
MEAN±SD	0.30±0.15	0.28±0.11		
2 MONTH			5..94	0.003*
MEAN±SD	0.35±0.16	0.41±0.16		
3 MONTH			9.21	0.001*
MEAN±SD	0.35±0.14	0.46±0.18		

Compared to the intravitreal ranibizumab-only group, the combination group had a significantly greater BCVA at the first, second, and third months (86.7%, 173.3%, and 206.7%), (table 2: fig. 1).

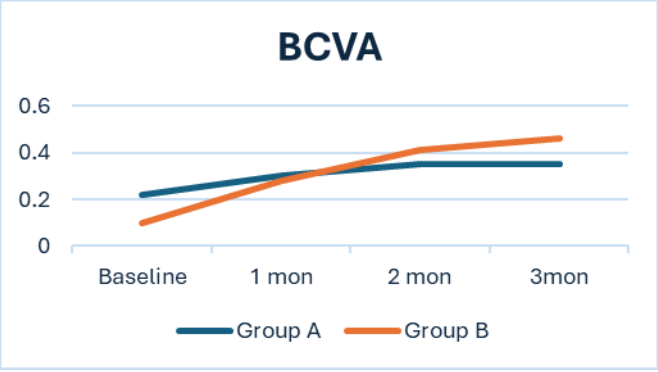

Figure 1. Evaluation of the two groups throughout the BCVA follow-up period.

Table 3. The two groups' comparison throughout the CMT follow-up period:

CFT (MM)	GROUP A (N=20)	GROUP B (N=20)	TEST	P-VALUE
BASELINE			1.98	0.092
MEAN±SD	486.55±99.56	510.05±120.33		
1 MONTH			1.52	0.42
MEAN±SD	342.9±90.07	309.5±73.81		
2 MONTH			6.15	0.002*
MEAN±SD	283.6±65.53	236.25±61.51		
3 MONTH			8.89	0.001*
MEAN±SD	300.95±77.7	229.8±23.4		

There was statistically significant between both studied groups as regards CMT at 2 and 3 months ($p<0.001$), (table 3; fig. 2).

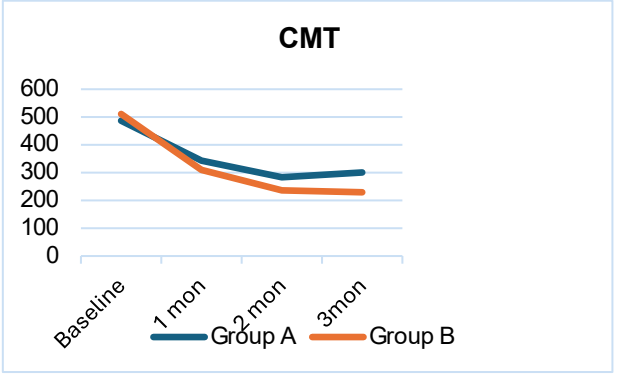

Figure 2. Comparison of the two groups' CMT results during the follow-up period.

Table 4. IOP comparison between the two groups during the follow-up period:

IOP (MMHG)	GROUP A (N=20)	GROUP B (N=20)	TEST	P-VALUE
BASELINE			1.12	0.49
MEAN±SD	13.7±1.5	14.15±1.5		
1 MONTH			3.98	0.042*
MEAN±SD	14.52±1.3	16.4±2.4		
2 MONTH			1.65	0.87
MEAN±SD	14.25±1.1	14.45±1.3		
3 MONTH			1.47	0.74
MEAN±SD	14.27±1.1	14.42±1.3		

Table 4 shows the mean intraocular pressure (IOP) of both groups over the follow-up period, which was used to compare the two groups in our investigation. In the first month after injection, Group B's intraocular pressure (IOP) rose sharply, whereas Group A's IOP was transient and well-controlled with a single anti-glaucoma drug. However, during the two- and three-month follow-up, the groups that were studied showed very little variation, (table 4; fig. 3).

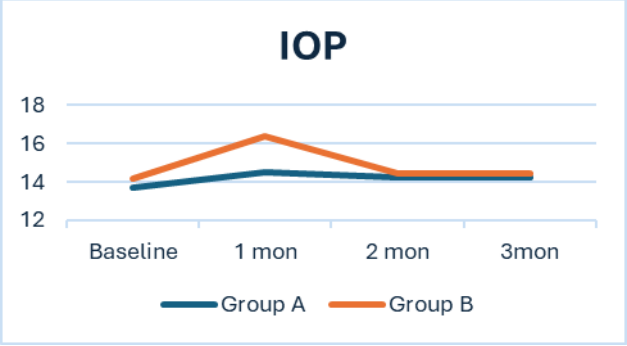

Figure 3. IOP comparison between the two groups during the follow-up period.

4. Discussion

Diabetic macular edema (DME) is a leading cause of vision loss in people with diabetes. The Early Treatment Diabetic Retinopathy Study found that grid laser photocoagulation successfully reduced the incidence of moderate vision loss in patients with clinically severe macular edema. The potential for subretinal fibrosis and a developing macular scar to diminish vision following grid/laser photocoagulation was later demonstrated in subsequent studies.[7]

More and more DME treatment options are available nowadays. Research has shown that intravitreal injections of triamcinolone acetonide (STTA), intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF), intravitreal implants releasing dexamethasone over an extended period of time, and combination therapy are all beneficial in treating DME.. Better outcomes are obtained when these medicines are combined and take into account several pathways of these complex disorders.[8]

Bakri and Kaiser,[9] assessed how TA injections into the posterior sub-tenon (PSTI) can help patients with persistent DME see better. In the first month, they noticed a notable improvement in visual clarity, which persisted for a full year.

The goal of this study was to assess the efficacy and safety of treating diabetic macular edema (DME) patients with a combination of intravitreal Ranibizumab (IVR) and posterior stent-tachycardia anaesthesia (STTA). Combination medicines have the potential to improve efficacy through cumulative effects while decreasing therapy duration and, by extension, costs.

Yolcu and Sobaci,[10] combined the two medications, which resulted in approximately 0.2 logMAR visual improvements and a discernible reduction in macular edema in 25 eyes that had previously undergone intravitreal bevacizumab or triamcinolone treatment for refractory DME.

Kim et al.,[11] combined IV bevacizumab injection with 4.0 mg PSTI-TA, which produced superior clinical outcomes than either drug alone, especially in the first month after injection.

Chiu et al.,[12] found that 15% of patients (3/20) had a BCVA improvement >0.2 logMAR at the 1-year follow-up, which is significantly lower than the combined group (P=0.022). Twelve patients, or 60%, did not see any improvement in their vision after one year because of persistent macular edema. After 6 months (P=0.043), 9 months (P=0.042), and 1 year (P=0.015) of follow-up, the combined group's BCVA was noticeably greater than the IVR alone groups'.

Similarly, Wang et al.,[13] shared the findings of their comparative analysis. Patients with DME were divided into two groups: one that received 1.25 mg/0.5 mL of intravitreal bevacizumab (IVB), and another that received 2.25 mg/0.05 mL of intravitreal timolol (IVTA) in addition to 1.25 mg/0.05 mL of IVB. Both groups showed statistically significant changes in CMT and BCVA relative to the baseline in the short-term results (three months) ($p<0.001$).

Ercalik et al.,[14] noted that whereas the control group's VA increased in the third month, the combination group patients' VA climbed in the first month before declining in the third. The impact of STTA during the first two months may be the cause of this.

By inhibiting several intraocular cytokines, such as ICAM-1, IL-6, IL-8, and VEGF, intravitreal administration of corticosteroids, which are anti-inflammatory drugs, can lessen macular edema in diabetic eyes. Another therapeutic option for eyes with DME that do not respond well to Ranibizumab is to switch to intravitreal corticosteroid monotherapy or add intravitreal corticosteroids to Ranibizumab therapy.

The combination group (IVRI+PSTA) (group B) had a mean preoperative CMT of 510.4µ±120.33µ, while the control group (group A) had a mean of 486.32µ±99.56µ. Group B's

CMT after one month of injection was 309.16±73.81µ, which was 37.5% better than baseline. Group A had improved 14.9% from the baseline, reaching 342.9±90.07µ.

Ayoub et al.,[15] proved that intravenous Ranibizumab plus pre-treatment TA injections effectively reduced CMT and increased BCVA, two measures used to manage diabetic ketoacidosis. All eyes' visual acuity was improved (100%), and CMT was successfully reduced below 300µm in 24 eyes (96%). Because recurrent and persistent edema affected eight patients (32% of the total) in the first group treated with intravenous rehydration (IVR), the combined injection greatly decreased the frequency of injections. On the other hand, residual edema, mostly due to drug reflux, was observed in just 2 cases (8%) in the group 2 combined group.

Lin et al.,[7] noticed that the combination treatment decreased CMT significantly compared to STA alone at one week (β = −157.9, P<0.001) and one month (β = −53.1, P=0.019) after injection. All eyes had a cumulative incidence of macular edema resolution of 87.7%, with the STA group having an incidence of 84.8% (28/33) and the combination group having an incidence of 90.6% (29/32).

Chiu et al.,[12] discovered that after 6-month (P=0.026) and 9-month (P=0.045) follow-up, the combined group's CFT was considerably thinner than that of the IVR-alone group. The two groups' injection numbers were similar (P=0.822).

Ahmadieh et al.,[16] looked at intravenous bevacizumab in DME with and without intravenous TA and found that the latter resulted in a more rapid improvement in visual acuity.

Eris et al.,[17] Results from IVR therapy with and without sub-tenon triamcinolone acetonide (STA) were evaluated in patients with resistant diffuse myeloma efficacy at 6 months. Both BCVA and CMT changes were shown to be statistically significant with the combo therapy; the biggest difference was noted at the first month visit of their six-month follow-up.

Ercalik et al.,[14] examined the results of combined posterior STTA and IVR treatment in DME-affected eyes. After the first and third months of treatment, the DME was considerably resolved; the first month saw a sharp drop in CMT, which may have been the cause of the triamcinolone's supplementary impact. According to reports, the first month is when anti-VEGF has an effect, whereas the first two months are when STTA has an effect. Compared to the combined group's single injection, the control group's median number of injections during a 3-month period was 2.5, which resulted in a substantial decrease in CMT. The synergistic action of IVR and the STTA may help to explain this.

To examine this positive impact of STA, Yu et al.,[18] compared the aqueous cytokine levels in DME patients after intravitreal bevacizumab (IVB) injections with those after a combined injection of IVB and STA. They showed that in the IVB+STA group, levels of IL-8, monocyte chemotactic protein-1, platelet-derived growth factor-AA, and VEGF all decreased considerably, but in the IVB group, only VEGF declined (p=0.001).

These outcomes align with our research. We think that the triamcinolone's anti-inflammatory properties contributed to the quick improvement in CMT following the first combined session. This quick effectiveness is particularly beneficial for individuals with SRD and elevated inflammatory cytokines, and it is also consistent with the length of STA activity.

Özdemir et al.,[19] additionally stated that IVTA treatment works well for SRD patients, and attributed this to its anti-inflammatory properties.

In contrast to Group A, which was temporary and effectively managed with a single anti-glaucoma medication, we showed in this study that Group B had a notable increase in intraocular pressure (IOP) following injection during the first month, while the groups' differences at the two and three-month follow-up were negligible.

Additionally, our findings are quite comparable to those of Ercalik et al.,[14] 5.2% of the eyes in the combined group experienced a moderate increase in intraocular pressure.

Ozdek et al.,20 examined the therapeutic effects of STA and IVTA in DME patients in a comparative study. They noted that STA therapy was more dependable than IVTA, particularly when it came to IOP changes, and that both administration methods were significantly and equally effective in treating macular edema.

In a similar study, Karataş et al.,[21] discovered that the STA combination study group had a 12% increase in IOP, while the IVR only control group had a 2.5% increase.

Chiu et al.,[12] discovered that only three patients (13.0%) needed an average of 1.7 IOP-lowering medications and experienced ocular hypertension during combination therapy. Following treatment, neither increased IOP nor worsened cataract development was observed in the IVR monotherapy group. In a previous multicenter study, intravitreal triamcinolone was more likely than PSTA to cause endophthalmitis, cataract development, and elevated intraocular pressure. Additionally, compared to anterior sub-tenon triamcinolone injection, PSTA demonstrated a 2.4-fold decreased risk of related IOP increase.

4. Conclusion

According to the current study's findings, combining intravitreal Ranibizumab with a posterior sub-tenon triamcinolone acetonide injection can significantly improve BCVA and lower CMT while providing the advantages of TA without the risks of intravitreal TA side effects like elevated IOP.

Disclosure

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All authors have a substantial contribution to the article

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