Biological and Clinical Sciences Research Journal
eISSN: 2708-2261; pISSN: 2958-4728
www.bcsrj.com
DOI: https://doi.org/10.54112/bcsrj.v6i3.1612
*Biol. Clin. Sci. Res. J., Volume 6(3), **2025**: 1612*
Original Research Article

Efficacy and Safety of Suprachoroidal Triamcinolone Acetonide in Cases of Resistant Diabetic Macular Edema

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(Received, 24th January 2025, Accepted 8th March 2025, Published 31st March 2025)

Abstract: *Diabetic macular edema (DME) in people with diabetes often resists standard treatments. Suprachoroidal triamcinolone acetonide injections target therapy, potentially improving outcomes with fewer side effects. This study aims to advance understanding of its efficacy and safety in managing DME, adding to the limited literature.* ***Objective:*** *To evaluate the safety and effectiveness of SCTA injection in patients with resistant diabetic macular edema.* ***Methods:*** *The study was conducted at the Department of Ophthalmology, Sir Ganga Ram Hospital, Lahore. The study duration was 6 months from 5th June 2024 to Dec 5th 2024. After approval, 30 patients with resistant DME and meeting the inclusion criteria were enrolled in the study after taking informed written consent. A special technique was used to administer suprachoroidal triamcinolone acetonide. Patient follow-up was done at 1 month and 3 months after treatment to measure change in study variables from the baseline.* ***Results:*** *The study involved 30 participants. Mean logMAR BCVA decreased significantly at 1 month (0.56±0.053) and 3 months (0.42±0.072) from baseline (0.83±0.048), p=0.000. Mean CMT at 1 and 3 months was significantly lower than baseline, p=0.000, with a significant decrease between these periods. Mean IOP was significantly higher at 1 month (13.80±1.65 mmHg, p=0.000) compared to baseline (12.43±1.63 mmHg), and was insignificantly higher at 3 months (12.6±1.63 mmHg, p=0.056).* ***Conclusion:*** *Our study highlights suprachoroidal triamcinolone acetonide's efficacy in treating refractory diabetic macular edema, showing significant visual acuity improvement and central macular thickness reduction. Transient intraocular pressure increases were observed but reverted to baseline, affirming treatment safety and effectiveness.*

Keywords: Best Corrected Visual Acuity, Central Macular Thickness, Resistant Diabetic Macular Edema, Suprachoroidal Triamcinolone Acetonide

[***How to Cite:*** Jamil MI, Ahmed NI, Ashraf B, Afzal S, Javed M, Qayum A. Efficacy and safety of suprachoroidal triamcinolone acetonide in cases of resistant diabetic macular edema. *Biol. Clin. Sci. Res. J.*, **2025;** 6(3): 52-55. doi: https://doi.org/10.54112/bcsrj.v6i3.1612

Introduction

Diabetic Macular Edema (DME) is one of the major causes of central vision loss in diabetic patients. The management of Diabetic Macular Edema has undergone significant advancements over the past decade. Anti-Vascular Endothelial Growth Factor (anti-VEGF) agents have replaced laser therapy, previously the recommended initial treatment (1, 2). Bevacizumab, Ranibizumab, and Aflibercept are commonly used intravitreal anti-VEGFs. It is observed that not all patients show the desired response to anti-VEGF therapy (3). Various other factors, including cost and compliance, can further influence treatment outcomes compared to controlled clinical trials (4).

When patients are not responding well to anti-VEGF drugs, Intra-Vitreal Triamcinolone Acetonide (IVTA) has become a possible alternative for treatment. IVTA has shown promising results in reducing macular edema (5, 6). However, it is associated with certain drawbacks, such as the need for repeated injections due to diminishing efficacy, rebound macular edema, and potential side effects, including the formation of cataracts and raised intraocular pressure (7, 8). Protocol I of the Diabetic Retinopathy Clinical Research Network (DRCR.net) has demonstrated the effectiveness of intravitreal steroids as first-line treatment in DME patients who have undergone cataract surgery (9). However, there was a notable occurrence of increased intraocular pressure in patients receiving intravitreal steroids (10).

Recent advancements in eye medication delivery have renewed interest in using steroids for treatment. Two notable examples are biodegradable dexamethasone intravitreal implants (called Ozurdex) and nonbiodegradable fluocinolone acetonide intravitreal implants (called Iluvin), both of which provide a steady release of steroids into the eye over an extended period and have gained FDA approval. Ozurdex remains in the eye for 6 months, while Iluvin is designed to provide treatment for 24 months. Although numerous studies have been done, additional research is still required to fully understand the therapeutic potential of implants in cases of chronic and heavily treated DME (11, 12).

Because of the side effects of intravitreal steroids, researchers are interested in exploring the suprachoroidal space as a route for safely delivering drugs to the posterior segment (of the eye). Researchers are evaluating the risk-to-benefit ratio, considering factors such as the level of intervention, frequency of drug delivery, and drug concentrations in the posterior segment compared to the anterior segment and systemic concentrations (13).

A study was conducted at Ain Shams University in Cairo, Egypt, comparing the efficacy and the safety of suprachoroidal triamcinolone injection with intravitreal injections for treating Diabetic macular edema. This study included 32 patients with a total number of eyes 45, who were diagnosed with DME, were randomized into three groups: first group included those patients who were injected IVTA, second group included those patients who were injected 4 mg/0.1 mL SCTA, and third group included those patients who were injected 2 mg/0.1 mL SCTA. Patients were on follow-up for six months. The results showed that best-corrected visual acuity (BCVA) and central macular thickness (CMT) improved in all three groups, with the most significant reduction observed in the second group (4 mg/0.1ml SCTA). After six months, significant improvement of BCVA and CMT was found in the second group, while values returned close to the baseline in the other groups. SCTA was a more secure and efficient treatment option, compared to IVTA, for DME (14).

Another prospective interventional study, conducted in 2018 at Al Ehsan Welfare Eye Hospital, Lahore, Pakistan, enrolled 24 treatment-resistant DME patients. Follow-ups at one and three months post-injection showed significant improvements in CST and BCVA, suggesting that SCTA might be a well-tolerated and effective treatment option for Diabetic

Macular Edema patients who do not respond to conventional therapies (15).

Motivated by these recent findings, we intend to conduct a study on supra-choroidal Triamcinolone Acetonide (SCTA) as a treatment for DME cases resistant to other therapies. Our study aims to investigate the safety and efficacy of SCTA as a viable treatment option. Research has shown potential benefits of SCTA, including enhancing patient outcomes, reducing the number of injections, and minimizing the risk of raised intraocular pressure that could lead to glaucoma.

Through our study, we want to evaluate and understand the safety and effectiveness of Supra-Choroidal Triamcinolone Acetonide (SCTA) in reducing CMT and improving BCVA in patients suffering from treatment-resistant DME.

Methodology

This prospective non-randomized interventional study was conducted at the Ophthalmology Department, Sir Ganga Ram Hospital, Lahore, after approval from the CPSP and the Hospital Ethical Review Committee for 6 months from 5th June 2024 to 5th Dec 2024. Using the WHO calculator, a sample size of 30 patients was calculated using the mean CMT score before and after Suprachoroidal injection (535.0±157.24 vs. 319.55±127.30 µm) (16). Inclusion criteria of the study were Diabetic Macular Edema patients who did not respond adequately to other therapies (Treatment-Resistant DME). Exclusion criteria were patients with macular edema not caused by DME, intraocular pressure (IOP) above 21 mmHg, macular ischemia, any history of intraocular surgery, diagnosed with uveitis, ocular hypertension, treatment naïve DME, or cataract. Patients already treated with triamcinolone acetonide, whether periocular or intravitreal, will also be excluded from the study. Treatment-resistant DME was labeled if a patient's diabetic macular edema does not respond to intravitreal anti-VEGF injection (any drug) at a regular interval of three months. A specialized technique was used for the administration of suprachoroidal triamcinolone acetonide. A 30-gauge 1cc insulin syringe, a 24-gauge intravenous cannula of 24-gauge, and a 40mg/ml triamcinolone acetonide (TA) injection were used. Before performing SCTA injections, all patients underwent pupil dilation. After carefully withdrawing the needle from the cannula, the cannula was trimmed so that only 1 millimeter of the insulin syringe could protrude from the cannula's edge. Triamcinolone acetonide (TA) was centrifuged for 30 minutes to allow for sedimentation, and the supernatant was discarded; the remaining TA was collected. The syringe was then filled with prepared TA up to the 0.1 ml mark. To prepare the eye, 5% diluted povidone iodine solution was instilled into the fornices and allowed to remain for 30 seconds. Then we draped the eye. After draping, a point was marked 4mm from the limbus in the superotemporal quadrant. Then we inserted the needle straight into the sclera at 4 mm from the limbus in the marked quadrant. 0.1 mL (4mg) of prepared triamcinolone acetonide was injected into the suprachoroidal space. After injecting, the needle was withdrawn slowly. We applied a cotton-tipped applicator at the injection site to ensure minimal reflux. Then, we verified the central retinal artery patency and checked for any potential drug spillage into the vitreous cavity, with the help of an indirect ophthalmoscope, immediately after completing the procedure. If occlusion of the central retinal artery is found, we perform anterior chamber paracentesis using a 30-gauge insulin syringe. After the procedure, a single drop of the topical antibiotic (fluoroquinolone) was instilled in the eye.

Follow-ups were done on the first and third months after injection. BCVA, IOP, and CST were recorded at each follow-up visit for subsequent data analysis. Changes at the end of the third month, CST and BCVA from baseline, were taken as the primary outcome measures. Statistical analysis was carried out using SPSS 26.0. Group mean values were compared using measures of central tendency (mean) and variability (standard deviation). Changes within each group were evaluated using paired sample t-tests. Frequency distributions across groups were analyzed using the chi-square test. A significance level of $p \leq 0.05$ was used to determine statistically significant results.

Results

The study involved 30 participants, with a mean age of 46.80±10.44 years. Most participants were 41-70 years old, comprising 119 individuals (72.1%), while 46 participants (27.9%) were aged between 20 and 40. Regarding gender distribution, males constituted the majority at 61.8% (102 individuals), with females comprising the remaining 38.2% (63 individuals). The mean duration of the disease was 11.80 ±4.86 years. The affected side was predominantly the OS (62.4%) compared to the OD (37.6%). The participants received a mean of 6.37±1.87 anti-VEGF injections. The study also assessed various ocular parameters at baseline, including Best Corrected Visual Acuity (BCVA) at 0.83±0.048, Central Macular Thickness (CMT) at 486.13±51.32, and Intraocular Pressure (IOP) at 12.43±1.63, as given in Table 1.

Mean logMAR BCVA at 1 month (0.56±0.053) and 3 months (0.42±0.072) was significantly less than the baseline (0.83±0.048) with p-value=0.000. Moreover, the mean decrease in logMAR BCVA between 1M and 3M was also significant, taking 1M data as a base for the analysis. Mean CMT at 1 month (344.77±54.49) and 3 months (245.17±56.68) was significantly less than the baseline (486.13±51.32) with p-value=0.000. Moreover, a decrease in CMT between 1M and 3M was also significant, taking 1M data as a base for the analysis. Mean IOP at 1 month (13.80±1.65 mmHg) was significantly higher than baseline (12.43±1.63 mmHg) with p-value=0.000. However, the mean IOP at 3 months (12.6±1.63 mmHg) was insignificantly higher with p-value=0.056. The mean decrease in IOP from 1 month to 3 months was also significant, as shown in Table 2.

Table 1: Baseline Characteristics of the Study Sample

Characteristics	Participantsn=30
Age (years)	46.80±10.44
• 20-40 years	46 (27.9%)
• 41-70 years	119 (72.1%)
Gender	
• Male	102 (61.8%)
• Female	63 (38.2%)
Side Involved	
• OD	62 (37.6%)
• OS	103 (62.4%)
Duration of Disease (years)	11.80±4.86
Number of Anti-VEGF Injections	6.37±1.87
Best Corrected Visual Acuity (BCVA)	0.83±0.048
Central Macular Thickness (CMT)	486.13±51.32
Intraocular Pressure (IOP)	12.43±1.63

Table 2: Change in BCVA at Different Time Intervals

Variable	Before Treatment	1 Month After Treatment	3 Months After Treatment	p-value		
				Baseline vs. as at 1 Month	Baseline vs. as at 3 months	As of 1 Month and 3 Months
BCVA (logMAR)	0.83±0.048	0.56±0.053	0.42±0.072	0.000	0.000	0.000
CMT (µm)	486.13±51.32	344.77±54.49	245.17±56.68	0.000	0.000	0.000
IOP (mmHg)	12.43±1.63	13.80±1.65	12.63±1.56	0.000	0.056	0.000

Paired sample t-test, taking p-value ≤0.05 as significant.

Discussion

Diabetic macular edema (DME) presents a difficult challenge, often leading to vision loss in diabetic patients (16, 17). While treatment options exist, resistant cases persist, highlighting an unmet need. Suprachoroidal triamcinolone acetonide, a promising avenue, lacks comprehensive data on its efficacy and safety in refractory DME (18, 19). So, this study was initiated to evaluate its effectiveness and safety profile to address the dire need to determine alternative therapeutic strategies in managing this condition.

The mean age of the patients in this study was 46.80±10.44 years. The mean age in patients with resistant diabetic macular edema reported by other studies was 52.29±8.17 years by Tayyab et al. (2020) in Pakistan, 59.7±13.7 years by Zhang et al. (2022) in China, and 53.7±10.3 years by Nawar (2022) in Egypt (14-16). However, these age variances may be attributed to the inclusion criteria of each study.

Regarding gender, 61.8% (102 patients) were females, while the remaining 38.2% (63) were males. This female supremacy in the study population was also previously reported by some other studies. Male participants were reported as 45.83% by Tayyab et al. (2020), as 46.9% by Ahmad et al. (2023), and as 30.8% by Nawar (2022) (14, 15, 20). However, an exact 50% participation of each gender was reported by Zhang et al. (2022). These variations suggest potential demographic influences and underscore the importance of considering gender distribution in research analyses.

The mean duration of the disease was 11.80 ±4.86 years, slightly lower than 14.9±4.1 years reported by Nawar (2022) (14). The affected side was predominantly the OS (62.4%) compared to the OD (37.6%). The participants received a mean of 6.37±1.87 anti-VEGF injections, which is almost similar to 6.95 (range 4-11) reported by Tayyab et al. (2020) (15).

In this study, mean BCVA at 1 month (0.56±0.053) and 3 months (0.42±0.072) was significantly less than the baseline (0.83±0.048) with p-value=0.000. Moreover, the mean decrease in logMAR BCVA between 1M and 3M was also significant. Our findings are supported by other studies where mean logMAR BCVA was reported as significantly less than at 1 and 3 months by Tayyab et al. (2020) (15). Similarly, baseline logMAR BCVA of 1.05±0.041 was decreased to 0.73±0.41 with p-value <0.000 as reported by Zhang et al. (2022) (16). Nawar (2022) reported a significant reduction in logMAR BCVA, which was 0.92±0.2 at 1 month, 0.92±0.3 at 3 months, and 0.76±0.3 at 12 months, and the mean change from baseline logMAR BCVA of 119.3±0.2 was significant (14). Ahmad et al. (2023) reported a mean baseline logMAR BCVA of 0.8±0.19, which was reduced at 1 and 3 months to 0.49±0.29 and 0.39±0.02, respectively, and the mean change from baseline was significant at both intervals (20). These consistent findings highlight the effectiveness of the intervention in improving visual outcomes over time.

In this study, mean CMT at 1 month (344.77±54.49 µm) and 3 months (245.17±56.68 µm) was significantly less than the baseline (486.13±51.32 µm) with p-value=0.000. Moreover, a decrease in CMT between 1M and 3M was also significant. Our findings are similar to results reported by Tayyab et al. (2020), where the mean baseline CMT of 636.5±200µm was reduced to 302.66±66.93µm at three months (15). Zhang et al. (2022) also reported similar results where baseline CMT of 535.00±157.24 µm was reduced to 319.55±127.30 µm at three months with p-value<0.001 (16). Mean baseline CMT of 478.7±170.2 µm was reported by Nawar (2022), which was reduced to 295.9±108.9µm and 326.5±136.4µm, respectively (14). However, mean CMT again decreased for all subsequent months till 12 months. These consistent findings underscore the efficacy of the intervention in reducing macular edema over time.

This study's mean IOP at 1 month (13.80±1.65) was significantly higher than baseline (12.43±1.63) with p-value=0.000. However, the mean IOP at 3 months (12.6±1.63) was insignificantly higher with p-value=0.056. The mean decrease in IOP from 1 month and at 3 months was also significant. Increase in IOP from baseline (13.37±2.81 mmHg) to 1 month (13.95±3.24) and 3 months (13.45±2.32), respectively, was also reported by Tayyab et al. (2020) (15). However, the increase was insignificant at both intervals, with p-values of 0.131 and 0.714, respectively. An insignificant increase in IOP at 3 months from the baseline was reported by Nawar (2022) with p-value=0.185 (16). Nawar (2022) reported a base IOP of 12.31 mmHg, which significantly increased to 13.3±0.5 at 1 month but showed an insignificant change from baseline at 3 months with IOP 12.28±0.2 mmHg (11). Ahmad et al. (2022) also reported a significant increase in IOP at 1 month (14.82 mmHg) and 3 months (14.48 mmHg) from the baseline figure (12.32 mmHg) (20). These findings highlight the need for close monitoring of IOP in patients undergoing treatment for diabetic macular edema.

Conclusion

In conclusion, our study emphasizes the efficacy of suprachoroidal triamcinolone acetonide in managing resistant diabetic macular edema, with significant improvements in visual acuity and a reduction in central macular thickness. Transient increases in intraocular pressure were noted, but they gradually reverted to baseline intraocular pressure, thereby demonstrating the overall safety and effectiveness of the treatment.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-BS-05587-23)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

MIJ (PGR)
Manuscript drafting, Study Design,
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BA (PGR)
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Study Design, manuscript review, and critical input.
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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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