

Anatomical and Functional Outcome of Suprachoroidal Triamcinolone Injection in Patients of Refractive Diabetic Macular Oedema

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Abstract: The most frequent cause of central vision loss in people with diabetes with diabetic retinopathy is diabetic macular edema (DME). Recently, there has been a greater interest in investigating the suprachoroidal space for medication administration to lessen the adverse effects of intravitreal steroids. **Objective:** "To determine mean change in macular thickness and best corrected visual acuity after suprachoroidal triamcinolone injection in patients of refractive diabetic macular oedema. Quasi-experimental study. Department of Ophthalmology, DHQ Hospital, Sahiwal, from 07-12-2021 to 07-06-2022. **Methodology:** Sixty eyes fulfilling selection criteria were enrolled and received an injection of triamcinolone acetate. All patients were dilated before injection, and an indirect ophthalmoscope was placed in their hands to examine the fundus after injection. At baseline and after one month, the central macular thickened, BCVA was measured, and the change was calculated. **Results:** The mean age was calculated as 59.06 ± 6.02 years. Duration of diabetes was 5.36 ± 1.94 years and duration of symptoms 18.15 ± 6.57 days. Baseline BCVA was 0.28 ± 0.02 , and post-treatment BCVA was 0.67 ± 0.11 . Baseline central macular thickness was 469.31 ± 24.12 , and post-treatment central macular thickness was 292.48 ± 8.38 . The distribution of change in BCVA was 0.39 ± 0.09 , and central macular thickness was 176.83 ± 15.74 ($p=0.000$). Our study had 75.0% ($n=45$) males and 25.0% ($n=15$) females. Distribution of lateral side was done, 66.7% ($n=40$) had left side affected and 33.3% ($n=20$) had right side. **Conclusion:** Thus, suprachoroidal triamcinolone injection may help improve macular thickness and BCVA in patients with refractive diabetic macular oedema.

Keywords: Suprachoroidal triamcinolone injection, Diabetic macular edema, Best-corrected visual acuity, Central macula thickness

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Introduction

The most frequent cause of central vision loss in people with diabetes with diabetic retinopathy is diabetic macular edema. Today, the cornerstone of managing diabetic macular edema differs from ten years ago. The initial treatment for diabetic macular edema is no longer lasers.(1)Age-related macular degeneration, diabetic retinopathy, retinal vein blockage, and uveitis are common causes of permanent blindness.(2)While regular intravitreal injections of corticosteroids or anti-vascular endothelial growth factor-A (anti-VEGF-A) medicines have shown remarkable outcomes in randomised controlled studies,(3, 4) "Due in part to undertreatment, real-world results fall short of these results, indicating an unmet need for more permanent and effective treatment.(5-7)This issue is especially significant due to the growing number of people with diabetes and the resulting diabetic retinopathy, as well as the aging population and the consequent rise in age-related macular degeneration.(8)

Not every patient responds to this treatment, even though the Food and Drug Administration (FDA) has approved it.(9)Additionally, compared to typical controlled clinical studies, two additional variables that may result in a lower response in diabetic macular edema in real-world settings are cost and compliance.(10)As demonstrated by Protocol I of the Diabetic Retinopathy Clinical Research Network, locally administered steroids have been effective in specific clinical scenarios as first-line therapy, such as diabetic macular edema with pseudophakia, which responds equally well to steroids and ranibizumab.(11)Determining the anatomical and functional results of suprachoroidal triamcinolone injection in individuals with refractive diabetic macular oedema is the rationale for this investigation. It has been shown in the literature that while suprachoroidal

triamcinolone injections can considerably reduce macular thickness, they also cause a drop in BCVA. However, not much work has been done in this area, and there is not much local literature either (just one research about suprachoroidal triamcinolone injection was found). Therefore, to enhance our practice, we wish to carry out this study to ascertain the function of suprachoroidal triamcinolone injection in a local situation. to potentially apply the findings of this study to the local population in the future, forecast the effects of suprachoroidal triamcinolone injections, and ascertain how the BCVA and central macular thickness would evolve. Additionally, this would enhance our expertise and proficiency. Thus, the objective of the study is to determine mean change in macular thickness and best corrected visual acuity after suprachoroidal triamcinolone injection in patients of refractive diabetic macular oedema".

Methodology

This quasi-experimental study was done at the Department of Ophthalmology, DHQ Hospital, Sahiwal, from 07-12-2021 to 07-06-2022. A sample size of 60 eyes is calculated with 95% confidence level, $d=0.02$ and magnitude of mean change in BCVA, i.e. 0.33 ± 0.06 with suprachoroidal triamcinolone injection in patients of refractive diabetic macular oedema. ¹²Patients were enrolled via a non-probability, consecutive sampling technique.

Patients aged 30-70, both genders, diagnosed with refractive diabetic macular oedema were enrolled. Refractive diabetic macular oedema was defined as persistent macular thickness $>300 \mu\text{m}$ on optical coherence tomography due to diabetes (BSR $>200\text{mg/dl}$ for > 1 year).



Patients with a history of periocular or intravitreal triamcinolone acetonide treatment within the last 6 months were omitted.

Sixty eyes fulfilling the selection criteria were enrolled in the study from the OPD. Informed consent was obtained. Demographic information was noted. At baseline, central macular thickness and BCVA were assessed. Then, patients were given an injection of triamcinolone acetonide. A 30 gauge 1cc insulin syringe (BD Insulin Syringe) was used to inject the triamcinolone acetonide 40mg/ml (Kenakort A by GlaxoSmithKline Brentford, Middlesex, TW8 9GS, United Kingdom). All patients were dilated before injection, and an indirect ophthalmoscope was placed in their hands to examine the fundus after injection. Then, after one month, the central macular thickened, and BCVA was measured again, and the change in central macular thickens and BCVA were calculated (per operational definition). All this information was recorded on a pro forma document (attached).

Change in central macular thickness in μm after one month of injection compared to baseline on optical coherence tomography.

Change in best corrected visual acuity after one month of injection compared to baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart.

The collected data were analysed statistically by using SPSS version 27. A paired sample t-test was applied to determine the mean change in BCVA and central macular thickness, keeping P-value \leq 0.05 as significant.

Results

A total of 60 patients were enrolled with a mean age of 59.06 ± 6.02 years. The age distribution of the patients was done, and it showed that out of 60

patients, 25.0 % (n=15) were in the age group of 30-55 years, and 75.0 % (n=45) were in the age group of 56-70 years. Gender distribution of the patients was done, and it showed that 75.0 % (n=45) were male, whereas 25.0% (n=15) were female. The distribution of the duration of diabetes was 5.36 ± 1.94 years, and the duration of symptoms was 18.15 ± 6.57 days. Distribution of lateral side was done, 66.7 % (n=40) had left side affected and 33.3 % (n=20) had right side. (Table No. 1)

The distribution of baseline BCVA was 0.28 ± 0.02 , and post-treatment BCVA was 0.67 ± 0.11 . The distribution of change in BCVA was 0.39 ± 0.09 , and central macular thickness was 176.83 ± 15.74 . The baseline central macular thickness distribution was 469.31 ± 24.12 , and the post-treatment central macular thickness was 292.48 ± 8.38 . Mean change in BCVA and central macular thickness was done using paired sample t test and showed a significant result (p=0.000). (Table No. 2).

Table no. 1: Demographics of patients with refractive diabetic macular oedema (n = 60)

	Frequency (%)
Mean age (years)	59.06 \pm 6.02 years
30-55 years	15 (25.0%)
56-70 years	45 (75.0%)
Gender	
Male	45 (75.0%)
Female	15 (25.0%)
Duration of diabetes (years)	5.36 \pm 1.94 years
Duration of symptoms (days)	18.15 \pm 6.57 days
Lateral side	
Yes	40 (66.7%)
No	20 (33.3%)

Table no. 2: Assessment of BCVA and central macular thickness at baseline and after treatment (n = 60)

Variables	Baseline	After treatment	Change	p-value
BCVA	0.28 \pm 0.02	0.67 \pm 0.11	0.39 \pm 0.09	0.000
Central macular thickness	469.31 \pm 24.12	292.48 \pm 8.38	176.83 \pm 15.74	0.000

Table no. 3: comparison of mean change in BCVA in different age and gender groups

		Mean change in BCVA	p value
Age group	30-55 years	0.39 \pm 0.09	0.000
	56-70 years	0.38 \pm 0.11	
Gender	Male	0.37 \pm 0.02	0.000
	Female	0.41 \pm 0.11	
Lateral side	Left	0.38 \pm 0.11	0.000
	Right	0.38 \pm 0.09	
Duration of diabetes	1-7 years	0.39 \pm 0.11	0.000
	>7 years	0.36 \pm 0.12	
Duration of ocular symptoms	1-14 days	0.39 \pm 0.11	0.000
	>14 days	0.38 \pm 0.11	

Table no. 4: comparison of mean change in central macular thickness in different age and gender groups

		Mean change in CMT	p value
Age group	30-55 years	170.46 \pm 32.81	0.000
	56-70 years	178.95 \pm 24.25	
Gender	Male	176.06 \pm 24.81	0.000
	Female	179.13 \pm 32.27	
Lateral side	Left	172.57 \pm 27.21	0.000
	Right	185.35 \pm 23.74	
Duration of diabetes	1-7 years	175.69 \pm 28.32	0.000
	>7 years	181.91 \pm 17.07	
Duration of ocular symptoms	1-14 days	181.83 \pm 29.31	0.000
	>14 days	175.58 \pm 26.07	

Discussion

Diabetic macular edema (DME) is the most frequent cause of central vision loss in people with diabetes with diabetic retinopathy. Today, the foundation of DME management is very different from what it was ten years ago. For DME, lasers are no longer the primary line of treatment.(1)Three anti-VEGF medications are now being used to treat DME: Avastin®, Genentech Inc., San Francisco, CA, USA; Lucentis®, Novartis, Basel, Switzerland; and Eylea®, Bayer, Leverkusen, Germany.(9)Even though the Food and Drug Administration (FDA) has approved this treatment, not every patient responds. Additionally, compared to conventional controlled clinical trials, compliance and cost are two additional variables that may result in a lower response in DME in real-world settings.(12)(13)

Intra-Vitreous Triamcinolone Acetonide (IVTA) has long been used as a substitute when anti-VEGF medications are ineffective or when patient compliance has been a problem. IVTA is quite effective in reversing macular edema and restoring the damaged blood retinal barrier. However, several undesirable side effects have hampered its usage. The most prominent of these is the requirement for repeated injections as a result of rebound macular edema and IVTA's diminishing impact. Additionally, using it causes cataract development and increased intraocular pressure (IOP). As demonstrated by Protocol I of the Diabetic Retinopathy Clinical Research Network (DRCR.net), the use of locally administered steroids has been shown their effectiveness in specific clinical scenarios as first line therapy. For example, DME with pseudophakics responds equally well to steroids and ranibizumab. Additionally, this investigation demonstrated a clinically significant incidence of increased intraocular pressure in IVTA patients.(14-16)

Since scientists have developed new methods for injecting steroids into the eye, interest in steroids has recently changed. Among these, Ozurdex® and Iluvein® are the most well-known. The dexamethasone implant, Ozurdex® (Allergan, Inc., Irvine, USA), is intended to remain in the vitreous cavity for six months before biodegrading. The steroid is gradually released into the vitreous cavity. The FDA and most European nations have authorised its use for DME patients. However, several research studies have shown that using Ozurdex® is also linked to a rise in IOP.(17)

Recently, there has been a greater interest in investigating the suprachoroidal space for medication administration to lessen the adverse effects of intravitreal steroids. Researchers have considered the frequency of drug delivery, the degree of intervention, and the achievable posterior segment concentrations in comparison to systemic and anterior segment concentrations when deciding on the suprachoroidal route for steroid delivery to the posterior segment.

In the current study, we measure the best-corrected visual acuity and mean change in macular thickness in individuals with refractive diabetic macular oedema following injections of suprachoroidal triamcinolone. An analysis of the patients' ages revealed that, of the 60 patients, 25.0% (n=15) were between the ages of 30 and 55, and 75.0% (n=45) were between the ages of 56 and 70. The computed mean age was 59.06 ± 6.02 years. The length of symptoms was 18.15 ± 6.57 days, while the duration of diabetes was 5.36 ± 1.94 years. The BCVA was 0.28 ± 0.02 at baseline and 0.67 ± 0.11 after therapy. The central macular thickness was 469.31 ± 24.12 at baseline and 292.48 ± 8.38 at the end of treatment. The central macular thickness was 176.83 ± 15.74 ($p=0.000$), and the BCVA change was 0.39 ± 0.09 . In our study, there were 75.0% (n=45) men and 25.0% (n=15) women. When the lateral side was distributed, the left side was impacted in 66.7% of cases (n = 40) and the right side in 33.3% (n = 20). According to one research, injectable triamcinolone increased BCVA from 0.8 ± 0.24 to 0.47 ± 0.3 (change = 0.33 ± 0.06), and the mean

improvement in central macular thickness was 331.96 ± 132.68 (from 636.5 ± 200.1 to 304.54 ± 67.43).(18)

The foundation of SCTA's safety and effectiveness for DME in treatment-naïve and previously treated groups was discovered in a recent study (HULK Trial; N = 20). The mean number of injections administered in the previously treated group was 21.6, while the number of injections administered in our research was 6.9. Our study differed from the HULK trial in that we did not include individuals who had never received therapy before, nor did we combine the initial SCTA injection with Aflibercept. Our study's mean pre-treatment CST was 636.5 ± 200.11 μm , while the HULK trial's previously treated group had a mean of 473 μm . The mean CST in HULK decreased to 369 μm at six months, while the mean CST in our research was 302.66 ± 66.93 μm at three months. The distinction here is the length of the follow-up period, which might conceal any DME rebound in our patients. Even though the initial CST of the HULK trial was lower than ours, our study's CMT after the follow-up period was lower than that of the HULK trial. We did not re-inject SCTA, although the HULK trial did so as necessary. The pre-injection mean BCVA was 45 letters in our research compared to 67.2 letters in the HULK trial. While the mean rise in our study was 12 letters from the baseline, the HULK trial found a mean increase of seven letters at the end of three months. In contrast to our work, which lacks such data, the HULK study documented a sustained rise in BCVA over six months. The most plausible explanation for our trial's apparent higher letter gain is that, in comparison to the HULK study, our baseline BCVA was lower. Additionally, the HULK research participants had longer histories of prior treatments (21.6 vs. 6.9 injections), which may indicate that the individuals in the study had chronic conditions. Our research's mean intraocular pressure (IOP) was 13.37 ± 2.81 mmHg at baseline and 13.45 ± 2.32 mmHg at the 3-month follow-up. After receiving topical antiglaucoma therapy (AGT), we documented one patient whose IOP increased from 19 to 24 mmHg at one-month follow-up and then dropped down to 16 mmHg at three months. According to the HULK research, two individuals needed AGT to manage their IOP. The authors of a related investigation found no rise in IOP with SCTA. Nine patients received injections as part of their trial, and there were no adverse effects and a statistically significant decrease in retinal edema.(19-21)

We had no instances of unintentional intravitreal triamcinolone spilling. However, HULK reported one. Although there are some variations in patient selection and follow-up period, overall, the safety and effectiveness of SCTA are comparable across the two trials.

In addition to DME, injections of suprachoroidal triamcinolone have been tested for posterior

uveitis and retinal vascular occlusion (RVO). The effectiveness of SCTA and intravitreal aflibercept in RVO patients was contrasted in the TANZANITE research. The TANZANITE research has shown positive results, with combination injections demonstrating superior visual outcomes and prolonged edema clearance with fewer injections. SCTA was utilised for non-infectious posterior uveitis in a related trial (DOGWOOD), and the authors found good outcomes in terms of a sustained decrease in CST and an improvement in BCVA. Comparable research has been done to evaluate the safety and effectiveness of SCTA (PEACHTREE Phase III study).(22-25).

Conclusion

In the current study, we determined the mean change in macular thickness and best corrected visual acuity after suprachoroidal triamcinolone injection in patients with refractive diabetic macular oedema. We concluded that a suprachoroidal triamcinolone injection may help improve visual acuity.

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-MMNCS-0331d-24)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution**MA (PGR)**

Manuscript drafting, Study Design,

WA (Resident PGY3)

Review of Literature, Data entry, Data analysis, and drafting article.

SAM (Associate Professor)

Conception of Study, Development of Research Methodology Design,

SA (Lecturer)

Study Design, manuscript review, critical input.

SA

Manuscript drafting, Study Design,

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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