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Original Research Article

Morphological and Functional Changes after Intravitreal Steroid Implant in Macular Edema

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Abstract

Background: Macular edema (ME) is a major cause of visual impairment and can occur secondary to diabetic macular edema (DME), retinal vein occlusion (RVO), and pseudophakic cystoid macular edema (CME). It results from the breakdown of the blood–retinal barrier due to vascular hyper permeability, ischemia, and inflammation. Intravitreal dexamethasone (DEX) implants provide sustained anti-inflammatory, anti-angiogenic, and anti-permeability effects, potentially reducing treatment burden compared to anti-VEGF therapy. This study aimed to evaluate morphological and functional changes after a single intravitreal DEX implant in ME of varied etiologies.

Material and Methods: A prospective, non-randomized observational study was conducted at a tertiary eye care hospital from July 2018 to August 2020, including 30 eyes with ME secondary to DME, non-ischemic RVO, or pseudophakic CME. Exclusion criteria included prior intravitreal therapy, uncontrolled glaucoma, active infection, or traumatic ME. Baseline evaluation included best-corrected visual acuity (BCVA), intraocular pressure (IOP), slit-lamp and fundus examination, and optical coherence tomography (OCT) for central foveal thickness (CFT). All patients received a single 0.7 mg intravitreal DEX implant under aseptic conditions. Follow-up visits were at day 1, week 1, month 1, and month 3, assessing BCVA, CFT, IOP, and adverse events.

Results: Of 30 patients (mean age 57.8 years; 53.3% male), 15 had DME, 12 RVO, and 3 pseudophakic CME. Mean CFT decreased significantly from 641.8 ± 195.9 µm at baseline to 323.7 ± 132.6 µm at month 3 ($p < 0.001$). Mean BCVA improved from 1.05 ± 0.37 to 0.59 ± 0.26 logMAR ($p < 0.001$), with maximum recovery in the first month. IOP remained stable ($p = 0.70$). Minor adverse events included subconjunctival hemorrhage (13.3%), pain (6.7%), and floaters (6.7%); no serious complications occurred.

Conclusion: A single intravitreal DEX implant produced significant anatomical and visual improvement in ME secondary to DME and RVO, with minimal adverse effects and stable IOP. The treatment was less effective in pseudophakic CME, likely due to small sample size. DEX implants are a safe and effective short-term option, particularly in DME and RVO.

Keywords: Macular Edema, Diabetic Macular Edema, Retinal Vein Occlusion, Pseudophakic Cystoid Macular Edema.

Introduction

Macular edema (ME) is defined as the pathological accumulation of fluid within the retinal layers of the macula, leading to thickening and impaired central vision. [1] It results from breakdown of the inner and/or outer blood–retinal barrier (BRB) due to vascular hyperpermeability, ischemia, or inflammation. [2] Common causes include diabetic macular edema (DME), retinal vein occlusion (RVO), postoperative cystoid macular edema (Irvine–Gass syndrome), and uveitis. [3] DME remains the leading cause of vision loss in working-age diabetics, while RVO-associated ME significantly impacts older adults. [4] Pathogenesis involves elevated vascular endothelial growth factor (VEGF) levels, inflammatory cytokines, and prostaglandins, which disrupt tight junction integrity and increase vascular leakage. [5] Mechanical factors such as vitreomacular traction can further aggravate fluid accumulation. Modern imaging tools, especially spectral-domain optical coherence tomography (SD-OCT) and fundus fluorescein angiography (FFA), have improved diagnosis, quantification, and monitoring of ME, enabling targeted treatment strategies.- [6,7] While

anti-VEGF agents are first-line in many cases, they require frequent injections and may have reduced efficacy in certain patient subgroups. [8] Intravitreal corticosteroids, particularly sustained-release dexamethasone (DEX) implants, offer an alternative or adjunct, providing potent anti-inflammatory, anti-angiogenic, and anti-permeability effects. [9] The biodegradable DEX implant delivers 0.7 mg of dexamethasone over several months, maintaining effective intraocular levels, reducing treatment burden, and minimizing systemic exposure. [10] It is approved for ME secondary to RVO, non-infectious posterior uveitis, and DME, and is especially useful in pseudophakic eyes, anti-VEGF nonresponders, and vitrectomized eyes. [11]

Clinical studies demonstrate that DEX implants significantly improve best-corrected visual acuity (BCVA) and reduce central foveal thickness (CFT) with an acceptable safety profile. [12] Adverse effects include transient intraocular pressure (IOP) rise and cataract progression; serious events such as implant migration are rare. [13]

Given the visual and socioeconomic burden of ME, optimizing its management is essential. The present study was done to analyse the morphological and functional changes in patients with macular edema following intravitreal injection of a dexamethasone implant. Specifically, the objectives were to evaluate the resulting visual outcomes, and document any procedure- or drug-related adverse events associated with the dexamethasone implant.

Material and Methods

This prospective, non-randomized observational clinical study was conducted at a tertiary eye care hospital between July 2018 and August 2020, enrolling 30 eyes of patients with macular edema secondary to diabetic macular edema (DME), retinal vein occlusion (RVO), or pseudophakic cystoid macular edema (CME).

Patients with traumatic macular edema, unstable metabolic control, uncontrolled glaucoma or raised intraocular pressure, active ocular surface infection, a history of steroid responsiveness, or prior intravitreal therapy were excluded. Preoperative assessment included detailed ocular and systemic history, best-corrected visual acuity (BCVA) measurement using Snellen's chart, slit-lamp examination, Goldmann applanation tonometry for intraocular pressure (IOP), indirect ophthalmoscopy and slit-lamp biomicroscopy with a 90-diopter lens for macular evaluation, optical coherence tomography (OCT) for central foveal thickness (CFT) measurement, and fundus photography. On the day of injection, IOP (by non-contact tonometry), blood pressure, and random blood glucose levels were recorded, and written informed consent was obtained. The dexamethasone implant (Ozurdex® 0.7 mg) was administered in the operation theatre under aseptic conditions after instillation of topical anesthesia (proparacaine 0.5%) and 5% povidone–iodine preparation.

The implant was injected intravitreally through the pars plana using a 22-gauge applicator in a biplanar technique, with slow actuator depression over approximately three seconds to minimize impact force. Post-procedure, optic nerve head perfusion was checked, and patients were instructed to report symptoms suggestive of endophthalmitis. Post-injection follow-up was performed at day 1, week 1, month 1, and month 3, including BCVA, IOP measurement, slit-lamp and fundus examination, OCT for CFT assessment, and fundus photography. Outcome measures included changes in BCVA and CFT over the follow-up period, as well as documentation of any ocular or systemic adverse events.

Results

The study included 30 eyes of 30 patients, comprising 16 males (53.3%) and 14 females (46.7%), with a mean age of 57.8 years (range: 35–85 years). The most common diagnosis was diabetic macular edema (DME) in 15 eyes (50%), followed by non-ischemic retinal vein occlusion (RVO) in 12 eyes (40%), and pseudophakic cystoid macular edema (CME) in 3 eyes (10%). At baseline, the mean central foveal thickness (CFT) was 641.8 ± 195.9 μm, which reduced significantly to 527.4 ± 221.2 μm at day 1, 445.5 ± 166.8 μm at week 1, 390.2 ± 146.2 μm at month 1, and 323.7 ± 132.6 μm at month 3 ($p < 0.001$, Friedman test). Pairwise comparisons confirmed statistically significant reductions in CFT at all follow-up intervals compared to baseline ($p < 0.001$).

Table 1: Distribution of study participants according to Eye affected and diagnosis

			Frequency	Percent
Eye affected	LE		14	46.7
	RE		16	53.3
Diagnosis	RVO	CRVO	4	13.3
		IT BRVO	3	10.0
		ST BRVO	5	16.7
	DME	Cystoid DME	8	26.7
		Cystic spongy DME	7	23.3
	Pseudophakic CME		3	10.0

The mean best-corrected visual acuity (BCVA), measured in logMAR units, improved from 1.05 ± 0.37 at baseline to 0.93 ± 0.35 at day 1, 0.82 ± 0.28 at week 1, 0.68 ± 0.25 at month 1, and 0.59 ± 0.26 at month 3 ($p < 0.001$). Maximum visual recovery occurred within the first month after injection, with subsequent stabilization. Mean intraocular pressure (IOP) remained stable throughout the study, with baseline values of 17.17 ± 3.36 mmHg and no statistically significant change at any follow-up point ($p = 0.70$).

Table 2: Comparison of Log MAR between different time intervals according to diagnosis - DME

Log MAR	N	Mean (SD)	Range	Median (Q1-Q3)	Friedman test	
					Chi Square value	p-value
Pre	15	1.15 (0.41)	0.5 - 1.78	1 (0.8 - 1.47)	41.61	<0.001*
Day 1	15	1.04 (0.35)	0.5 - 1.47	1 (0.8 - 1.47)		
1 week	15	0.96 (0.30)	0.5 - 1.3	1 (0.6 - 1.3)		
1 month	15	0.79 (0.25)	0.5 - 1.3	0.8 (0.5 - 1)		
3 months	15	0.70 (0.21)	0.3 – 1	0.6 (0.6 - 0.8)		

Subgroup analysis showed similar trends across etiologies. In RVO eyes, mean CFT decreased from 648.0 ± 194.8 µm to 296.3 ± 161.3 µm at month 3, with BCVA improving from 1.02 ± 0.32 to 0.48 ± 0.30. In DME eyes, mean CFT decreased from 662.1 ± 208.7 µm to 342.6 ± 112.5 µm, with BCVA improving from 1.15 ± 0.41 to 0.70 ± 0.21. In pseudophakic CME eyes, CFT decreased from 472.0 ± 118.6 µm to 354.0 ± 103.7 µm, while BCVA improved modestly from 0.80 ± 0.20 to 0.53 ± 0.06; however, these changes were not statistically significant due to the small sample size.

Table 3: Post injection adverse effects

Adverse effects	Frequency	Percentage%
SCH	4	13.3
Pain	2	6.7
Floaters	2	6.7
No Adverse Effects	22	73.3
Total	30	100

Adverse events were minimal and transient. No cases of endophthalmitis, retinal detachment, or sustained IOP elevation were observed. The majority of patients (73.3%) experienced no adverse effects during follow-up.

Discussion

In our study were 12 patients with non-ischemic Retinal Venous Occlusion of which 4 had non ischemic CRVO & 8 had non-ischemic BRVO, who received single intravitreal dexamethasone implant, which showed a mean change in logMAR vision and central foveal thickness from1.09(±0.32) to 0.59(±0.31) and 648.00(+-194.79) to 296.33(±161.27) respectively showing rapid and sustainable improvement in visual acuity as well as central foveal thickness of the patient with no significant change in intraocular pressure with no significant adverse effect showing the efficacy and safety of the drug.

A similar study conducted by Catharina Busch at al. (2019) [14] in patients with either naïve or recurrent MO secondary to CRVO/BRVO treated with DEX implant which showed improvement in visual acuity and central foveal thickness which was statistically significant after intravitreal injection of steroid implant and the early treatment response were identified as possible predictors for long-term outcome.

Our study included 15 patients of Diabetic Macular Edema which included cystoid and cystic-spongy type of edema, who received single intravitreal dexamethasone implant with improvement in mean visual acuity and central foveal thickness showing improvement in visual acuity and central foveal thickness from 1.15(±0.41) to 0.70(±O.21) and 472.00(±118.58) to 354.00(±103.71) 3 months post injection in all types of edema with no significant change in intra ocular pressure and no systemic/local side effects showing safety and efficacy of drug.

A similar study was conducted by Elena pacella et al (2013) [15] in Seventeen patients (20 eyes) affected by DME. The slow-release intravitreal dexamethasone implant, Ozurdex, produced significant improvements in best-corrected visual acuity and central macular thickness from the third day of implant in DME sufferers, and this improvement was sustained until the third month.

In our study on 3 patients who received single intravitreal dexamethasone implant in Pseudo-phakic CME showed effective improvement in vision and central foveal thickness showing mean change in vision in logMAR from 0.80(±0.20) to

0.53 and decrease in central foveal thickness in Microns from 472.00(±118.58) to 354.00s (±103.71) with no significant adverse effects suggesting the safety and efficacy of the drug. A similar study conducted by Chafik.keilani et al.(2016) [16] "evaluation of best corrected visual acuity and central macular thickness after intravitreal dexamethasone implant injections in patients with Irvine-Gass syndrome" in Patients with ME secondary to cataract surgery who underwent intravitreal injections of dexamethasone implant showed both mean BCVA and mean CMT had significantly improved from baseline after treatment with dexamethasone implant in patients with Irvine-Gass syndrome.

Overall adverse effect noted among different patients were subconjuctival haemorrhage in 4 patients, pain in 2 patients and floaters in 2 patients which were eventually resolved in follow up period. Rest patients did not have any complain suggesting the safety of drug. [17]

Limitation

The study was limited by a small sample size of 30 eyes, which may reduce the generalizability of results. Follow-up duration was restricted to 3 months, limiting assessment of long-term outcomes. No comparison group receiving alternative treatments was included, restricting comparative efficacy evaluation.

Conclusion

Our study demonstrated that intravitreal dexamethasone implant is an effective and well-tolerated short-term treatment for macular edema secondary to DME and RVO, with significant improvement in visual acuity and reduction in central foveal thickness over three months. The safety profile was favorable, with stable intraocular pressure and only minor, transient adverse effects. Although PCME cases did not show significant benefit, this may be attributable to the small sample size. Despite limitations such as cost and limited follow-up, the findings support the implant as a valuable therapeutic option, particularly for DME and RVO, while emphasizing the need for larger, long-term studies to establish sustained efficacy and safety.

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