Original article

Study of the effect of intravitreal dexamethasone implant in pseudophakic macular edema. Preliminary

L. Ortega-Evangelio*, T. Diago Sempere
Servicio de Oftalmología, Hospital Universitario de La Ribera, Alzira, Valencia, Spain

Abstract

Objective: To evaluate the efficacy of intravitreal dexamethasone implant on the treatment of pseudophakic macular edema (PME).

Materials and methods: A retrospective, observational, descriptive study was conducted on 4 patients who received an intravitreal injection of dexamethasone implant due to PME in the period from 1st January 2013 to 31st December 2013 in the Hospital Universitario de La Ribera (Alzira, Valencia, Spain). A complete ophthalmic examination was performed on these patients. Best-corrected visual acuity (BCVA), macular thickness, and duration of the effect of the treatment were studied.

Results: At baseline, the mean MT was 414 μm. After dexamethasone implant, mean values of MT decreased to 330.25 μm at month one. The mean change from baseline MT was 83.75 μm. The baseline mean BCVA was 0.3 and improved to 0.575 at month one and 3. The mean duration of the effect of the treatment was 3.5 months.

Conclusions: Intravitreal dexamethasone implant is a possible treatment for Irvine-Gass syndrome as it improved visual acuity and reduced the macular thickness of these patients.

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Estudio de la eficacia del implante intravítreo de dexametasona en el edema macular pseudofáquico. Resultados preliminares

Resumen

Objetivo: Estudiar la eficacia del implante intravitreo de dexametasona (Ozurdex) en el tratamiento del edema macular (EMQ) pseudofáquico.

Material y métodos: Se ha realizado un estudio descriptivo observacional retrospectivo de un periodo de un año de duración (desde el 1 de enero de 2013 hasta el 31 de diciembre del

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* Corresponding author.

E-mail address: leticiaortegaevangelio@gmail.com (L. Ortega-Evangelio).

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Introduction

Cystic macular edema (CME) is the accumulation of extracellular liquid between the external plexiform layer and the internal nuclear layer of the macula due to alterations in the retinal barrier permeability. CME occurring after cataract surgery is known as the Irvine-Gass syndrome.¹

When cataract surgery was performed with the intracapsular technique, the incidence of CME was 60%. Subsequently, with new techniques such as extracapsular extraction, said percentage went down to 20-30%. At present, with the use of phacoemulsification an incidence of between 1% and 2% is estimated.²

Risk factors for CME include capsular rupture, intraocular lens (IOL) dislocation, IOL in anterior chamber, patients with diabetes, epiretinal membrane and retinal venous occlusion.³

As set forth in the literature, persistent CME is treated applying topical NSAIDs, topical corticoids or posterior pericentral injection. In some cases, systemic and topical carbonic anhydrase inhibitors could be useful, as well as intravitreal triamcinolone or intravitreal anti-VEGF. In some cases, pars plana vitrectomy can be considered when CME is resistant to medical treatment.⁴

At this point in time, the use of intravitreal dexamethasone is not indicated and there are no clinical trials for this use. However some published clinic cases have reported the use of intravitreal dexamethasone for pseudophakic CME.⁵ Accordingly, at present the only indications approved for the utilization of intravitreal implant of dexamethasone (Ozurdex) are macular edema associated to retinal venous occlusion, diabetic macular edema and non-infectious uveitis in the posterior segment of the eye. However, in view of the positive response of patients treated with this drug for the Irvine-Gass syndrome, the authors have considered carrying out a retrospective observational study supported by existing data in a study published in 2013 in which the use of said drug provided statistically significant results⁶ for assessing response to treatment with dexamethasone after pseudophakic CME.

The objective of this study is to assess whether treatment with intravitreal dexamethasone improves CME caused by cataract surgery. Accordingly, considering the null hypothesis that the intravitreal implant of dexamethasone does not produce any improvement in the Irvine-Gass syndrome, the alternative hypotheses proposes that treatment with Ozurdex does improve CME caused after lens phacoemulsification.

Subjects, materials and methods

The present study is a retrospective observational descriptive case series study collecting data of all patients who in the course of a year were treated with intravitreal dexamethasone implant (Ozurdex) due to the appearance of CME in the post-operative period of cataract extraction surgery, excluding all patients with previous CME or retinal surgery prior to phacoemulsification.

The injection of the intravitreal dexamethasone implant (Ozurdex) was performed in the operating room, with previous antibiotic prophylaxis with topical ciprofloxacin every 8 h 3 days prior to the injection. In the operating room, iodine povidone was applied on the periorbital area and diluted iodine povidone in the ocular surface after placing the blepharostat. Subsequently, 2% subconjunctival lidocaine was injected for anesthesia, after which the dexamethasone intravitreal implant was injected. The entire procedure was performed with sterile gloves and mask. The patient was released the same day with the prescription of maintaining the antibiotic treatment for 5 additional days. The following day intraocular pressure was checked.

Study variables comprise macular thickness, visual acuity (VA) and duration of treatment effects. Macular thickness was measured with a Carl Zeiss optic coherence tomography equipment having the micron as unit of measure. VA was explored with the Snellen table at 6 m distance, taking the decimal scale as unit of measure. The duration of the effect was measured in months.

Results

The preliminary results obtained after analyzing data of 4 treated patients with intravitreal dexamethasone implant are the following.
Table 1 – Macular thickness evolution.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Macular thickness pretreatment (µ)</th>
<th>Macular thickness 1-month after treatment (µ)</th>
<th>Macular thickness 3 months after treatment (µ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>432</td>
<td>317</td>
<td>310</td>
</tr>
<tr>
<td>Patient 2</td>
<td>423</td>
<td>311</td>
<td>363</td>
</tr>
<tr>
<td>Patient 3</td>
<td>434</td>
<td>398</td>
<td>420</td>
</tr>
<tr>
<td>Patient 4</td>
<td>369</td>
<td>295</td>
<td>294</td>
</tr>
</tbody>
</table>

In what concerns macular thickness, the mean prior to treatment was of 414 µ (369–434) whereas one month after the dexamethasone injection, the mean was 330.25 µ with an interval between 295 and 398 µ; the mean at 3 months was of 346.75 µ (294–420) (Table 1, Figs. 1–3).

Mean VA prior to treatment was of 0.3 (0.1–0.5). One month later, the mean value 0.575 (0.3–0.9) and the mean VA at 3 months of treatment was of 0.575 (Table 2, Fig. 4).

The duration of the intravitreal dexamethasone (Ozurdex) implant effect ranged between 0 months (no effect) and 6 months. It must be taken into account that this is a study in progress and long-term data are yet to be obtained (preliminary results). The mean duration in months under these conditions is of 3.5 months (Table 3).

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Fig. 1 – Mean macular thickness prior to treatment, one month after and 3 months after the intravitreal dexamethasone implant.

Fig. 2 – Macular OCT of patient 1 prior to the injection of intravitreal dexamethasone, showing significant macular thickening which produces structural deformation of the macula.
Fig. 3 – Macular OCT of patient 1 after intravitreal dexamethasone implant, showing evident macular thickness reduction, absence of intraretinal liquid and preserved macular morphology.

Table 2 – Visual acuity evolution.

<table>
<thead>
<tr>
<th>Patient</th>
<th>VA pre-Ozurdex</th>
<th>VA 1-month post-Ozurdex</th>
<th>VA 3 months post-Ozurdex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>0.5</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>Patient 2</td>
<td>0.3</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Patient 3</td>
<td>0.1</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Patient 4</td>
<td>0.3</td>
<td>0.6</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Fig. 4 – Mean visual acuity prior to intravitreal dexamethasone implant, 1 and 3 months after treatment.

Table 3 – Duration of the effect (months).

<table>
<thead>
<tr>
<th>Patient</th>
<th>Duration of treatment effect (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>6</td>
</tr>
<tr>
<td>Patient 2</td>
<td>4</td>
</tr>
<tr>
<td>Patient 3</td>
<td>0</td>
</tr>
<tr>
<td>Patient 4</td>
<td>4</td>
</tr>
<tr>
<td>Average</td>
<td>3.5</td>
</tr>
</tbody>
</table>
**Discussion**

At present, persistent CME is treated with topical medications such as NSAIDs or corticoids, intravitreal treatments such as anti-VEGF and triamcinolone, or systemic treatments such as carbonic anhydrase inhibitors. In some cases pars plana vitrectomy can be performed with nonresponders. One of the factors to be taken into account in treatments and the administration pathway is the appearance of possible adverse effects. In the case of intraocular corticoid treatments, the effect of increasing IOP is well known as well as the appearance of cataracts. However, in the case of pseudophakic CME, an additional possible complication is unimportant because the patient has no lens, although higher intraocular concentrations will be reached with its corresponding therapeutic effects. Among intravitreal treatments, the use of bevacizumab has been researched for the Irvine-Gass syndrome with highly variable results as indicated by Brynskov et al. In what concerns the comparison between the periocular or intravitreal triamcinolone and the intravitreal dexamethasone implant, the studies carried out until now propose that the intravitreal implant of dexamethasone (Ozurdex) exhibits lower post-treatment complication rates and adverse effects when compared to triamcinolone, as demonstrated by Herrero-Vanrell et al.

Accordingly, with the preliminary results of this study it can be concluded that treatment with intravitreal dexamethasone (Ozurdex) implant for pseudophakic CME exhibits clinically significant results for anatomical and functional improvement of this condition due to the fact that it reduces macular thickness and increases visual acuity, with a mean effect duration of 4 months. As the sample size of this study is not large but exhibits promising results, additional studies could be carried out to research a new possible indication of the intravitreal dexamethasone implant.

**Conflict of interests**

No conflict of interests was declared by the authors.

**REFERENCES**