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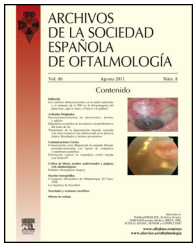

Original article

Dexamethasone intravitreal implants for diabetic macular edema refractory to ranibizumab monotherapy or combination therapy☆

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ABSTRACT

Objective: To determine the effectiveness and local safety of dexamethasone intravitreal implants as a treatment in diabetic macular edema (DME) refractory to intravitreal injections of ranibizumab monotherapy or combination therapy.

Methods: A retrospective study conducted on patients with DME refractory to ranibizumab monotherapy or combined with other treatments treated with dexamethasone intravitreal implants. The parameters analyzed were visual acuity (VA) by ETDRS (Early Treatment Diabetic Retinopathy Study) charts and foveal thickness by spectral-domain optical coherence tomography (SD-OCT) before the treatment, 2 months after treatment, and at the end of the follow-up.

Results: A total of 14 eyes of 14 patients were included, with a mean age of 64 years (SD: 9.5; range 41–78) and a mean follow-up of 7.6 months. The mean VA improved from 53 letters to 59 letters at 2 months ($p = 0.03$), and 57 at the end of the follow-up period ($p = 0.3$). The mean foveal thickness decreased from 502 μm to 304 μm at 2 months ($p = 0.001$), and 376 μm at the end of the follow-up period ($p = 0.009$).

Further treatment with intravitreal dexamethasone was required in 43% of the patients, and 21% had increased intraocular pressure, which was controlled with topical medication.

Conclusions: Intravitreal dexamethasone implant is an effective and locally safe treatment for the management of DME refractory to ranibizumab monotherapy or combined with other treatments.

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Implantes intravítreos de dexametasona en pacientes con edema macular diabético refractario a ranibizumab en monoterapia o en combinación de tratamientos

Palabras clave:
Implante de dexametasona intravítreo
Edema macular
Diabetes mellitus
Tomografía de coherencia óptica
Agudeza visual

RESUMEN

Objetivo: Estudiar la eficacia y seguridad a nivel local del implante de dexametasona intravítreo como tratamiento del edema macular diabético (EMD) refractario a ranibizumab intravítreo en monoterapia o en combinación de tratamientos.

Métodos: Estudio retrospectivo de pacientes con EMD refractario a inyecciones intravítreas de ranibizumab, en monoterapia o en combinación con otros tratamientos, a quienes se ha administrado un implante de dexametasona intravítreo. Los parámetros analizados fueron la agudeza visual (AV) medida en optotipos según el Early Treatment Diabetic Retinopathy Study (ETDRS) y el grosor foveal determinado mediante tomografía de coherencia óptica de dominio espectral (SD-OCT) previos al tratamiento, 2 meses después y al final del período de seguimiento.

Resultados: Se incluyeron 14 ojos de 14 pacientes con una edad media de 64 años (DE: 9,5; rango 41-78) y un seguimiento medio de 7,6 meses. La AV media aumentó de 53 a 59 letras a los 2 meses (p = 0,03), con 57 letras al final del período de seguimiento (p = 0,3). El grosor foveal medio disminuyó de 502 a 304 μ a los 2 meses (p = 0,001), con 376 μ al final del período de seguimiento (p = 0,009).

El 43% de los pacientes fueron tratados con un nuevo implante intravítreo de dexametasona. El 21,4% de los pacientes presentaron hipertensión ocular que se pudo controlar con medicación tópica.

Conclusiones: El implante de dexametasona intravítreo es eficaz y seguro localmente para el tratamiento del EMD en pacientes refractarios al ranibizumab en monoterapia o en combinación con otros tratamientos.

Introduction

Diabetic retinopathy and diabetic macular oedema (DME) are the main causes of blindness in the working-age population in developed countries.[1]

The diagnosis of DME is carried out with an ophthalmoscopy and with the help of the optical coherence tomography (OCT) or fluorescein angiography.[1,2]

There are several treatments for DME.

Laser photocoagulation has been the treatment of choice for the last 30 years which allows for stabilisation of visual acuity (VA) but in few cases does it show a significant improvement. It is currently used in patients with DME with no central infection or DME with VA > 20/30.[3,4]

Intravitreal injection of anti-vascular endothelial growth factor drugs, among which ranibizumab is the one with highest level of scientific evidence, are the choice for the treatment of DME with central infection and VA ≤ 20/30.[3,4] Several clinical trials such as RESTORE and RIDE/RISE have shown a significant gain of VA maintained over time, accompanied by a significant reduction of macular thickness. However, multiple follow-up visits and re-treatments are required to sustain these beneficial effects, which entail a large economic and assistance burden for the health care system. Also, some patients are resistant to repeated ranibizumab injections, probably because in these cases the DME is related to other cytokines and growth factors different from the vascular endothelial growth factor.[5,6]

Intravitreal corticosteroids injections have proved they can produce a significant reduction of macular thickness determined through OCT, although the increase of VA is limited with time due to the progression of the cataract in phakic patients. However, the study by DRCR.net has proved that VA gain in pseudophakic patients with DME is very similar if we inject triamcinolone or ranibizumab. Another potential inconvenience associated with the use of intravitreal corticosteroids is the increase of intraocular pressure, more frequent and severe with triamcinolone than with other corticosteroids.[7–9]

The dexametasone intravitreal implant (Ozurdex, Allergan) has been approved for the treatment of macular oedema secondary to venous occlusions of the retina and uveitis. Several studies have also proved to be effective for the treatment of DME.[5–9]

The goal of this study is to assess the local efficacy and safety of intravitreal dexametasone as a treatment of DME resistant to intravitreal ranibizumab.

Subjects, material and methods

This is a retrospective observational study with patients with DME treated with intravitreal dexametasone implants from May 2012 to June 2013 at Hospital Universitario de Bellvitge (Hospitalet de Llobregat, Barcelona).