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Original article

Cardiovascular involvement in patients with diabetic macular oedema treated with intravitreal ranibizumab in routine clinical practice[☆]

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ABSTRACT

Objective: To determine the cardiovascular events in naïve patients with diabetic macular oedema, before and after being treated with intravitreal ranibizumab.

Material and methods: A retrospective and descriptive study was conducted on patients with diabetic macular oedema and foveal involvement, who started treatment with intravitreal ranibizumab in 2014 in the Hospital Universitario Nuestra Señora de Candelaria and the Hospital Universitario y Politécnico La Fe. During the follow-up until August 2015, a record was made of parameters, including the prevalence and incidence of stroke and myocardial infarction.

Results: Among the 1324 intravitreal ranibizumab injections administered in 2014, only 159 of them corresponded to treatment initiation in 99 patients, with more than half requiring treatment of both eyes. The study patients included 58.4% males, in the 6th decade of life (mean = 65.93 ± 11.24 years), non-smokers (86.7%), type 2 diabetes (91.9%), hypertension (70.7%), and with dyslipidaemia (65.7%). Prior to treatment initiation, it was found that 6 patients (6.1%) suffered from an acute myocardial infarction, and 8 (8.1%) from stroke, and only one (1%) with post-stroke ($p = 0.039$).

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Conclusion: In our experience it seems that the intravitreal ranibizumab in diabetic macular oedema could be a safe alternative in patients with a history of stroke and myocardial infarction.

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Afectación cardiovascular en pacientes con edema macular diabético tratados con ranibizumab intravítreo en la práctica clínica habitual

R E S U M E N

Palabras clave:

Ranibizumab intravítreo
Edema macular diabético
Eventos sistémicos adversos

Objetivo: Analizar la afectación cardiovascular a corto plazo de los pacientes *naïve* con edema macular diabético, tratados con ranibizumab intravítreo, tanto pre- como postratamiento.

Material y métodos: Estudio retrospectivo y descriptivo de pacientes con edema macular diabético con afectación central, que hubieran iniciado tratamiento con ranibizumab intravítreo en 2014 en el Hospital Universitario Nuestra Señora de Candelaria y el Hospital Universitario y Politécnico La Fe. Se siguieron hasta agosto de 2015, estudiando, entre otras variables, la prevalencia e incidencia de accidente cerebrovascular y de infarto agudo de miocardio.

Resultados: De las 1.324 inyecciones de ranibizumab intravítreo que se administraron en 2014, solo 159 fueron como inicio de tratamiento, repartidas entre un total de 99 pacientes, ya que más de la mitad de ellos precisó tratamiento de ambos ojos (58,6%). El 58,4% de los pacientes fueron hombres, en la sexta década de la vida ($\bar{X} = 65,93$ años $\pm 11,24$) y, en su mayoría, no fumadores (86,7%), diabéticos tipo 2 (91,9%), hipertensos (70,7%) y dislipidémicos (65,7%). Se encontraron 6 pacientes (6,1%) con infarto agudo de miocardio y 8 (8,1%) con accidentes cerebrovasculares (ACV) previos al inicio del tratamiento, y solo uno (1%) con accidente cerebrovascular posterior ($p = 0,039$).

Conclusión: En nuestra experiencia el ranibizumab intravítreo en pacientes con edema macular diabético, con antecedentes de accidente cerebrovascular e infarto agudo de miocardio podría ser una alternativa segura.

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Introduction

At present, diabetes mellitus (DM) affects over 340 million people worldwide¹ and has become one of the most severe health problems of our time, not only due to the high and rising prevalence but due to the multiple complications it entails. One of the most relevant ocular complications, with a prevalence of 7.9% among the Spanish population with DM type 2,¹ is diabetic macular oedema (DME) which has become the main cause of severe visual impairment in developed countries.²

DME is a process with a multifactorial and complex etiopathogeny³ that gives rise to different types of macular oedema. The central involvement oedema is the one that compromises visual acuity with greater severity and accordingly the one that benefits more from antiangiogenic therapy. Intravitreal ranibizumab (RBZ), that has demonstrated excellent results in multicenter clinical trials carried out to date,⁴⁻⁸ is one of the anti-VEGF treatments indicated for DME⁹. However, and even though the adverse effects of intravitreal anti-VEGF are mainly ocular, its use involves a theoretical and potential risk of systemic arterial thromboembolic events

(hemorrhages, CVA, AMI),⁹ and this has raised doubts about its systemic safety.

The objective of the present study is to analyze the prevalence and incidence of short-term systemic cardiovascular events in *naïve* patients with DME and central involvement, interpreted as the involvement within the EDTRS area measured with OCT and treated with intravitreal RBZ as monotherapy in the context of routine clinical practice at the Hospital Universitario Nuestra Señora de Candelaria (HUNSC) and at the Hospital Universitario y Politécnico La Fe.

Subjects, material and methods

A descriptive and retrospective study of patients with DME and central involvement without previous treatment (*naïve*) who initiated intravitreal RBZ in monotherapy between January and December 2014 at the HUNSC of Tenerife or the Hospital Universitario y Politécnico La Fe of Valencia.

The endpoint of the study was set in August 2015 and 17 variables were studied: age, sex, weight, height, body mass index, tobacco smoking, arterial hypertension (AHT), dyslipidemia, DM type, years of evolution thereof, use of insulin, use

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