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ORIGINAL ARTICLE

Relationship between visual outcomes and retinal fluid resorption in patients with diabetic macular edema treated with ranibizumab☆

Relation entre le résultat fonctionnel et l'assèchement rétinien chez les patients traités par ranibizumab pour un oedème maculaire diabétique

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KEYWORDS
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Summary
Purpose. — We assessed the relationship between visual acuity (VA) recovery and a qualitative criterion - complete retinal fluid resorption (CRFR) - among patients treated with ranibizumab for diabetic macular edema (DME)
Methods. — All consecutive diabetic patients with central DME received a loading dose of 3 monthly injections of ranibizumab 0.5 mg, followed by retreatments on an as-needed basis as determined by monthly follow-up. Patients were divided into 3 groups: CRFR (defined as a CRT < 300 μm and restoration of the foveolar pit) with BCVA ≤ 70 letters (group 1: G1), CRFR with BCVA > 70 letters (20/40) (G2), and persistent retinal fluid throughout the follow-up (G3).

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Results. — Forty eyes were included. Mean baseline VA was 48.7 letters and no patient had VA > 70 letters. Twenty-four (60%) eyes achieved CRFR: 12 (30%) in G1 and 12 (30%) in G2. In 16 patients (40%), the efficacy of the treatment was partial without CRFR (G3). At the time of the initial CRFR, VA was 57.4 letters in G1 (min—max: 30—65) and 77.5 letters in G2 (71—85). In G3, maximal VA during follow-up was 55 letters (25—70) and no patient achieved a VA > 70 letters.
Conclusions. — In this study, CRFR was required but not sufficient to achieve a VA > 70 letters.

MOTS CLÉS
Anti-VEGF ;
Œdème maculaire diabétique ;
Rétinopathie diabétique ;
Assèchement rétinien ;
Ranibizumab

Résumé
Objectif. — Evaluer la relation entre le résultat fonctionnel et un critère qualitatif—la résorption complète du fluide intra rétinien (RCFR) — parmi des patients traités par ranibizumab pour un œdème maculaire diabétique (OMD).
Méthodes. — Tous les patients diabétiques consécutifs traités pour un OMD ont reçu un traitement initial de 3 injections mensuelles de ranibizumab 0,5 mg suivi par des retraitements en cas de récidive au cours d'un suivi mensuel. Les patients ont été divisés en 3 groupes : RCFR (défini par une épaisseur rétinienne centrale < 300 μm et une restauration anatomique de l'entonnoir fovéolaire) et une meilleure acuité visuelle corrigée (MAVC) ≤ 70 lettres (groupe 1 : G1), RCFR avec MAVC > 70 lettres (20/40) (G2), persistance de fluide rétinien et RCFR jamais obtenue tout au long du suivi (G3).
Résultats. — Quarante yeux ont été inclus. La MAVC initiale moyenne était de 48,7 lettres et aucun patients n'avait une MAVC initiale > 70 lettres. Vingt-quatre (60 %) yeux ont atteint une RCFR : 12 yeux (30 %) dans le groupe G1, 12 (30 %) dans le groupe G2. Chez 16 patients (40 %), l'efficacité du traitement était partielle sans RCFR (G3). Au moment de la première RCFR, la MAVC était de 57,4 lettres dans le groupe G1 (min—max : 30—65), 77,5 lettres dans le groupe G2 (71—85). Dans le groupe G3, la MAVC durant le suivi était de 55 lettres (25—70) et aucun patient n'a atteint un seuil de MAVC >70 lettres.
Conclusions. — Dans cette étude, une RCFR était indispensable mais non-suffisante pour atteindre un seuil d'acuité visuelle finale de 70 lettres.

Introduction

Diabetic macular edema (DME) is the main cause of blindness among diabetic patients in developed countries [1,2]. In diabetes mellitus, DME has been reported in 4.8—7.8% of patients [3,4]. In recent years, intravitreal injections of anti-VEGF have become the first-line therapy for central DME with impaired visual acuity (VA) [5—7]. Patients treated by ranibizumab over one year achieve a visual gain between +7.9 [5] to +11.2 letters [8], associated with a decrease of central retinal thickness (CRT). Nevertheless, most studies that have compared VA improvement to CRT have shown a modest correlation [9,10]. On ranibizumab, a complete retinal fluid resorption (CRFR), with CRT < 275 μm, is achieved in 37—56% of cases at one year [5,6,8].

The aim of this study was to investigate the value of a dry retina to assess the relationship between a qualitative criterion, the CRFR recovery, and the VA.

Patients and methods

Patients: The records of diabetic patients with central DME and visual impairment treated with ranibizumab in our department between November 2011 and November 2013 were reviewed. An informed consent was obtained from all subjects.

Inclusion criteria were: age > 18 years, type 1 or 2 diabetes mellitus with $HbA1_C$ < 12%, follow-up > 6 months. Both eyes of the same patient could be included.

Exclusion criteria were: untreated proliferative diabetic retinopathy, previous intravitreal steroids or bevacizumab injections or focal photocoagulation < 3 months, thromboembolic arterial event < 3 months, pregnancy, uncontrolled glaucoma, uveitis, another vitreoretinal pathology or condition that could contribute to the visual loss.

Design At baseline, a complete ophthalmological examination was performed, including best-corrected visual acuity (BCVA) based on the ETDRS chart, slit-lamp and non-contact fundus examination (Superfield Volk), fluorescein angiography (Topcon TRC-50DX Retinal Camera, Topcon Medical Systems, Inc, Japan) and OCT (OPKO OCT/SLO, OPKO Health, Inc, OTI, USA).

All patients received a loading dose of 3 monthly injections of ranibizumab 0.5 mg, followed by retreatments on an as-needed basis (PRN regimen) based on VA as recommended in European medicines agency (EMA) guidelines [11].