86

Clinical Management of Diabetic Macular Edema by Spanish Retina Specialists in Real-World Practice: OBSERVAR Study

A. Pareja[1], *M.J. Abraldes*[2], *M. Roura*[3], *From The Observar Study Group*[3]

[1]Hospital Universitario de Canarias, Tenerife, Santa Cruz de Tenerife, Spain; [2]Complexo Hospitalario Universitario de Santiago de Compostela, Universidad de Santiago de Compostela, A Coruña, Spain; Red Temática de Investigación Cooperativa en Salud (RETICS), Instituto de Salud Carlos III, Madrid, Madrid, Spain; [3]Novartis Farmacéutica, S.A., Barcelona, Barcelona, Spain

Introduction: Treatments that inhibit vascular endothelial growth factor (VEGF) are widely used to treat retinal vascular disorders, such as diabetic macular edema (DME). We aimed to describe the clinical management of DME by Spanish retinologists in clinical practice.

Methods or Study Design: Observational, retrospective, multicenter study. Forty-two retinologists collected clinical and demographic characteristics from clinical histories of adult DME patients and completed questionnaires about diagnosis, treatments and follow-up patterns.

Results: 256 DME patients 351 eyes [161 (46%) unilateral; 190 (54%) bilateral] with a mean age of 65.2 [standard deviation (SD) 10.4] years were analyzed. Of those, 60.9% were men. Retinologists considered progressive loss of visual acuity (VA) the main symptom suggesting DME (40.9%). Most common diagnostic tests were ETDRS, biomicroscopy, OCT (95.5% each) and fluorescein angiography (68.2%). 59.1% of retinologists based DME first-line treatment on anti-VEGF drugs (100% ranibizumab), and 95.5% opted for laser photocoagulation as concomitant treatment. 52.3% of retinologists used 3 initial anti-VEGF injections, and 47.7% scheduled bi-monthly follow-up visits during the first year post-diagnosis, extended to quarterly visits afterwards (38.6%). The ETDRS during follow-up showed stabilization or even improvement of VA after treatment, improving from 60.4 [SD 17.7] to 65.7 [SD 19.6] mean letters for unilateral and 59.7 [SD 18.8] to 64.8 [SD 15.2] for bilateral DME patients. OCT also revealed a reduction in mean foveal thickness measurement: 409.9 [SD 119.8] μm to 318.7 [SD 76.8] μm for unilateral and 416.2 [SD 126.5] μm to 346.5 [SD 105.0] μm for bilateral DME patients.

Conclusions: Our data suggest Spanish retinologists use homogeneous criteria regarding diagnosis, treatment and follow-up of DME and that treatments used achieved clinically relevant improvements in visual acuity and reduction in foveal thickness in clinical practice. Treatments include anti-VEGF injections used by the majority of retinologists (59.1%) to treat VA impairment due to DME.

Acknowledgements: The authors thank TFS for the medical writing support.

Study sponsored by Novartis Pharma AG.

Keywords: Diabetic Macular Edema, Ranibizumab, Real World Clinical Practice.

103

Comparison of Panretinal Photocoagulation for High Risk Proliferative Diabetic Retinopathy Using Single Session of Pattern Scan Laser versus Multiple Sessions of Conventional Laser

Emin Kurt, Göktug Recep Seymenoglu, Hüseyin Mayali

Celal Bayar University, Manisa, Turkey

Introduction: To evaluate the results of panretinal photocoagulation (PRP) via a single session of pattern scan laser (PASCAL) in comparison with multiple sessions of conventional laser in patients with proliferative diabetic retinopathy (PDR).

Methods or Study Design: Charts of 35 eyes which were treated with PASCAL and an equal number of eyes which were treated with conventional laser were retrospectively reviewed. Persistence and/or recurrence of neovascularization, incidence of complications, total number of laser spots, mean power used were compared.

Results: Patients treated with the PASCAL received significantly higher number of laser spots than those treated with conventional laser (2,885 vs 1,642, $p = 0.001$). The PASCAL and conventional laser systems required an average power of 650 vs 330 mw, respectively ($p = 0.001$). Patients treated with the PASCAL showed similar rates of treatment failure within 12 months of follow up compared with patiens treated with conventional laser (14% vs 11%, $p > 0.05$).

Conclusions: Our study confirms that single session PRP with the PASCAL is as effective as conventional laser and has an acceptable side-effect profile.

Acknowledgements: I am grateful to my clinic and co-worker.

Keywords: Proliferative Diabetic Retinopathy, Pattern Scan Laser, Panretinal Photocoagulation.

113

Treatment Modality with Anti-VEGF (Bevacizumab) in Diabetic Maculopathy

Romualdo Malagola, Luigi Pattavina, Raffaele Migliorini, Rossella Giannotti, Loredana Arrico

University Sapienza Department of Ophthalmology, Rome, Italy

Introduction: Assessment of the therapeutic efficiency of Bevacizumab in the treatment of diabetic macular edema. Prospective study with 180-day follow-up.

Methods or Study Design: 30 eyes of 25 patients with diabetic macular edema underwent a cycle of 3 intravitreal injections (each dose: 1.25 mg/0.05 ml of Bevacizumab – Avastin 100), with an interval of a month between each other. The anterior segment and fundus oculi of the patients were controlled the following day. 30 days after each injection and three months after the last injection, visual acuity (BCVA) and central macular thickness using OCT were determined.

Results: The mean value of BCVA at baseline was 0.80 ± 0.46 logMAR. After the first injection, it reached 0.76 ± 0.47 logMAR, with a further increase after the second administration (mean val-

ue 0.66 ± 0.48 logMAR; p = 0.02). After the third injection, a small reduction of BCVA (0.69 ± 0.45 logMAR p = 0.03) was noted; in spite of this, the value was better than the one at baseline. At the end of the cycle, the final result showed: 15 eyes (50%) with an improvement of visual acuity, 12 eyes (40%) that remained stable and 3 eyes (10%) with a reduction of visual acuity as compared to baseline. The average value of macular thickness at the last control was down about 85 μm as compared with the baseline.

Conclusions: Although the therapeutic efficiency of Bevacizumab was evident already after the first injection, a repeated treatment shows add-on effects in time.

Acknowledgements: The Authors have no financial interest in any of the products mentioned in the manuscript.

Keywords: Diabetic Retinopathy, Macular Oedema, Intravitreal Bevacizumab, OCT, Macular Thickness.

129

Short Term Results of Sequential Therapy with Dexamethasone Intravitreal Implant and Intravitreal Ranibizumab in Patients with Persistent Diabetic Macular Edema

Recep Göktug Seymenoglu, Saban Kiliç, Emin Kurt

Celal Bayar University Department of Ophthalmology, Manisa, Turkey

Introduction: The purpose of the study was to evaluate the efficacy and safety of combined intravitreal dexamethasone implant (IVDI) and ranibizumab in patients with persistent diabetic macular edema (DME) refractory to various treatments.

Methods or Study Design: Thirty-six eyes of 28 patients were included in this prospective study. Patients included had central macular thickness (CMT) of ≥300 μm and received at least 3 consecutive monthly intravitreal injections of anti-VEGF and/or focal/grid laser photocoagulation previously. Patients underwent a single injection of IVDI and followed up for 6 months. Patients were allowed for additional treatment with intravitreal ranibizumab who showed a worsening of their functional or structural condition during follow up. Primary outcome measures were the mean changes in best corrected visual acuity (BCVA), CMT and intraocular pressure (IOP).

Results: At baseline; mean BCVA was 0.65 ± 0.3 logMAR, mean CMT was 501.2 ± 145.9 μm. Mean BCVA improved to 0.54 ± 0.31 (p = 0.014) logMAR and mean CMT decreased to 351.0 ± 112.3 μm (p = 0) after the 3rd month. Starting at the end of Month 3, DME recurrence was noted in 26 eyes of 19 patients during the study period and these eyes were given IVRB. Mean BCVA improved to 0.50 ± 0.32 (p = 0) logMAR and mean CMT decreased to 360.2 ± 140.1 μm (p = 0) at 6th month after additional treatment. No significant changes were observed in IOP at last follow-up.

Conclusions: IVDI produced significant improvements at the first 3 months in patients with persistent DME. However, additional treatment with IVRB became necessary in order to sustain this improvement, after the 3rd month.

Acknowledgements: The authors thank Dr. Beyhan Özyurt, for her assistance with statistical analysis.

Keywords: Anti–vascular Endothelial Growth Factor, Combination Therapy, Dexamethasone, Diabetic Macular Edema, Ranibizumab.

146

Electroretinographic Changes in Response to Intravitreal Ranibizumab Treatment in Patients with Diabetic Macular Edema

Umit U. Inan, Kenan Yigit, Sibel Inan, Mustafa Dogan, Guliz F. Yavas

Kocatepe University Medical School Department of Ophthalmology, Afyon, Turkey

Introduction: To establish whether an improvement in neuroretinal function accompanies to probable improvements in visual acuity and macular thickness with intravitreal ranibizumab treatment in patients with diabetic macular edema (DME).

Methods or Study Design: Sixty-four patients with diabetic macular edema were enrolled in this prospective, interventional study. The patients were treated by monthly injections of intravitreal ranibizumab over 3 months and PRN regimen during the follow-up period of at least 12 months. In all monthly visits, best-corrected visual acuity (BCVA) and optical coherence tomography (OCT) were performed. In addition, mf-ERG recordings were obtained at month 0.3, 6.9 and 12 and ff-ERG was performed at baseline and month 12.

Results: Fifty-eight patients completed the study. Mean injection rate over the one year was 6.1. BCVA improved from 0.30 to 0.45. Macular thickness decreased from 413.5 μm to 329.5 μm at month 12. Recording of mf-ERG N1 mean value amplitude density of central macular zone was increased from –20.3 nv/deg2 at baseline, to –21.6 nv/deg2 at month 6, –22.0 nv/deg2 at month 9 and –23.6 nv/deg2 at month 12. In addition, as a recording of mf-ERG P1 mean value amplitude density of central macular zone was increased from 39.8 nv/deg2 at baseline, to 42.6 nv/deg2 at month 6, it was decreased to 37.6 nv/deg2 at month 9 and increased to 44.7 nv/deg2 at month 12. Improvements in BCVA and OCT assessments were statistically significant in all visits. Statistically significant improvement in mean value of central mf-ERG recordings was started at month 6 and continued until to month 12.

Conclusions: While BCVA and macular thickness improves in even early term in response to the ranibizumab treatment, improvement in neuroretinal function takes a longer time in patients with diabetic macular edema.

Acknowledgements: Kocatepe University Committee of Scientific Research Projects.

Keywords: Mf-ERG, Ff-ERG, OCT, DME, Ranibizumab.