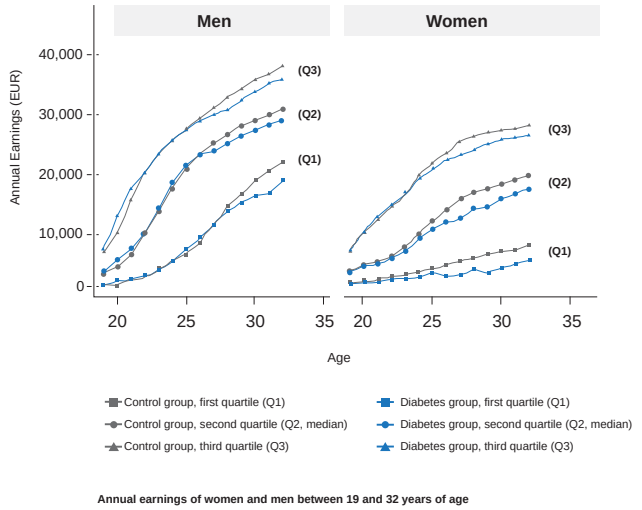
Figure 1. Earnings Through Early Adulthood in Patients With T1DM in Sweden



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Long-Term Ranibizumab Effective in Diabetic Macular Edema

Written by Emma Hitt, PhD

In patients with diabetic macular edema (DME), long-term intravitreal injections of ranibizumab maintains best-corrected visual acuity (BCVA) and central retinal subfield thickness (CRT) improvements over 36 months, with no new or increased safety concerns. Anna Boixadera, MD, Hospital Vall D'Hebron, Barcelona, Spain, presented the final analysis of the 36-month study comprising: A 12 Month Core Study to Assess the Efficacy and Safety of Ranibizumab (Intravitreal Injections) in Patients With Visual Impairment Due to Diabetic Macular Edema and a 24 Month Open-Label Extension Study [RESTORE; NCT00687804].

In patients with diabetes, the most common cause of vision loss is macular edema, which is a leading cause of visual impairment in the working-age population [Ciulla TA et al. *Diabetes Care* 2003]. The RESTORE core trial demonstrated that ranibizumab treatment as monotherapy or in combination with laser therapy was superior to laser therapy alone in patients with visual impairment due to DME over 12 months [Mitchell P et al. *Ophthalmology* 2011]. The purpose of the extension study was to evaluate the long-term efficacy and safety of ranibizumab 0.5 mg intravitreal injections [Boixadera A, Garcia-Arumi J. EASD 2013 (abstr 54)].

In the open-label, multicenter RESTORE extension study, 240 patients were eligible to receive ranibizumab as needed according to prespecified BCVA stability and DME progression-based retreatment criteria for 24 months. Laser therapy was allowed. The extension study was completed by 208 patients, and 19% and 25% of patients did not require ranibizumab injections during the extension study. The mean age of participants ranged from 61.7 to 63.8 years and the mean duration of DME ranged from 1.5 to 1.7 years.

The most common ocular adverse events (AEs) during the 36-month RESTORE core and extension studies were cataracts (16.3%) and eye pain (15.4%). Serious ocular AEs were reported in 2.4% to 4.1% of patients; there were no incidents of retinal tear or detachment, and no reports of endophthalmitis during the 36 months. The most frequent nonocular AEs included nasopharyngitis (23.3%) and hypertension (13.3%). The most frequent nonocular serious AEs included coronary artery disease and cerebrovascular accident (1.7% each).

The mean BCVA gain and CRT reductions observed from baseline to Month 12 were maintained through Month 36 in patients treated with prior ranibizumab in both the core and extension phase (+8.0 letters, –145.9 µm [prior ranibizumab], +6.7 letters, –142.1 µm [prior ranibizumab plus laser]). In addition, patients who had received laser monotherapy in the core study experienced progressive BCVA improvement (+6.0 letters) and CRT reduction (–142.7 µm) during the extension trial (Months 12 to 36) with ranibizumab treatment. The mean change in the Visual Functioning Questionnaire scores over the 36 months for the ranibizumab monotherapy, ranibizumab plus laser therapy, and laser monotherapy arms were +12.2, +7.8, and +8.4, respectively, for near activities and +2.6, +4.1, and +3.5, respectively, for distance activities, and the mean change in the composite score was +5.0, +4.3, and +3.9, respectively.

Prof. Boixadera stated that, in her opinion, the data from the RESTORE core and extension studies indicate that there are no new or increased safety issues with long-term intravitreal ranibizumab injections. In addition, patients could maintain their BCVA and CRT improvements gained in the first year of ranibizumab treatment with decreasing frequency of ranibizumab injections in subsequent years.

Left Ventricular Remodeling Reduced With Olmesartan in ROADMAP

Written by Mary Mosley

A prespecified analysis of left ventricular hypertrophy (LVH) as evaluated by electrocardiography (ECG) from the Olmesartan Medoxomil in Diabetes Mellitus study [ROADMAP] showed that olmesartan significantly