Abstracts

HUMANISTIC BURDEN AND HEALTH RESOURCE UTILIZATION AMONG NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AMD) PATIENTS IN FRANCE Soulbrane G, Zlateva G, Xu X, Goss TF, Bugguge R, Kosa M 1
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OBJECTIVES: This controlled cross-sectional observational study was conducted in 4 EU countries and Canada to assess the burden of bilateral neovascular AMD on patient-reported functioning and health resource utilization (HRU). METHODS: Of the total 401 bilateral neovascular AMD patients and 471 elderly non-AMD (control) subjects, 87 and 92 respectively were French. After recording of Demographic and treatment data, National Eye Institute Visual Function Questionnaire (NEI VFQ-25), EuroQol (EQ-5D), Hospital Anxiety and Depression Scale (HADS), history of falls, fractures and HRU were investigated through a telephone survey. Comparisons needed chi-square tests, analysis of variance, and multivariate regression models. RESULTS: Mean age of AMD patients was 79 and 64% were female. Comparisons were adjusted for age, gender, and comorbid diseases. The mean (95% CI) NEI VFQ overall scale scores were 44.4 (36.2, 52.6) in AMD patients, vs 91.8 (86.2, 97.5) for controls p < 0.0001. AMD patients also differed on the HADS scales: anxiety score: 8.5 (6.3, 10.8) vs. 5.1 (3.5, 6.7), p = 0.0005; depression scores: 7.1 (5.1, 9.1) vs. 2.9 (1.5, 4.4), p < 0.0001. A negative trend is observed on EQ-5D: 0.6 (0.5, 0.7) vs. 0.7 (0.6, 0.8), p = 0.0893. In addition, 11.5% of AMD patients fell in the past 12 months vs 3.3% of controls, p = 0.053. Furthermore 41.4% of the AMD patients received assistance for daily activities vs 6.5% of controls, p < 0.0001. CONCLUSION: Bilateral AMD patients in France reported substantially worse QOL, poorer vision-related functioning, and more anxiety and depression symptoms compared with a control group.

CULTURAL ADAPTATION AND PARTIAL VALIDATION OF THE GLAUCOMA SYMPTOM SCALE (GSS) TO SPANISH

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OBJECTIVES: To adapt the Glaucoma Symptom Scale (GSS) to Iberian Spanish, and to study the psychometric properties of the new version. The GSS scale is composed by 10 items, measuring impact of glaucoma symptoms. Items should be answered for both eyes. METHODS: An expert panel composed of two ophthalmologists, one gerontologist, two methodologists and one pharma-economist supervised the adaptation procedure. Two samples were recruited, one composed by 16 patients used to check comprehension of the first version, and 100 sample used to obtain psychometric estimates. Patients were recruited in Madrid, Zaragoza and Barcelona. Psychometric properties were assessed for each eye and for between eyes average scores. Item analysis, exploratory factor analysis and reliability estimates were obtained. RESULTS: Patients ranged from 57 to 89 years old and 50% were female. Symptoms were selected by 30% to 51% of patients, with a slight lower (p = 0.09) presence of symptoms in the right eye (mean = 4.3, SD = 3) than in the left eye (mean = 4.6, SD = 3). A high correlation in the number of symptoms present in each eye was found (r = 0.84, p < 0.001). The scale could match the original proposed structure of a functional domain and a non visual ocular symptom domain, explaining 53% of available variance, but two items “tearing” and “halos around lights” don’t exhibit high loadings. A three dimensional structure would exhibit a better fit. Dimensions show mild correlations (0.14-0.36). Internal consistency is good (Cronbach alpha = 0.82) and correlation between odd and even items is moderate 0.653. Content validity was ensured by the original researchers work. CONCLUSION: The Spanish version of the GSS questionnaire shows acceptable psychometric properties. The two dimensional solution is supported although it does not explain properly all symptoms. Further validity evidence should be collected with special concern on screening properties and responsiveness should be also evaluated.

GI DISORDERS—Clinical Outcomes Studies

DETERMINATION OF MINIMAL IMPORTANT DIFFERENCES (MIDS) AND INTERPRETATION OF SF-36 SCORES IN PATIENTS SUFFERING FROM MODERATE-TO-SEVERE CROHN’S DISEASE

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OBJECTIVES: The SF-36, a generic health-related quality of life measure, comprises 8 domains (Ware 2000) for which physical and mental component summaries (PCS and MCS) can be derived (Ware, Kosinski 2001). Until now, no MID for the SF-36 domains and summary scores have been reported for patients with active Crohn’s disease (CD). Our aims were to determine the MID for SF-36 using data from the PRECiSE 1 trial (Sandborn et al. 2006), and to use these MIDs for the interpretation of results from the PRECiSE 2 trial investigating certolizumab pegol maintenance treatment (Schreiber et al. 2005). METHODS: SF-36 MIDs were estimated by anchor-based methods using known meaningful changes in reference measures (Inflammatory Bowel Disease Questionnaire [IBDQ] and CD Activity Index [CDAI]). The a priori approach was to select the SF-36 MID according to the most correlated anchor. Agreement of the anchor-derived MIDs with results obtained using Standardised Effect Sizes, Standard Errors of Measurement and Standard Errors of the Difference was also evaluated. RESULTS: The two anchors gave similar values of meaningful changes. The IBDQ, which correlated most closely to SF-36 score changes, was selected to derive the SF-36 MIDs. Results obtained with other methods were in agreement with these derived MIDs and were representative of small to moderate changes (effect sizes ranging from 0.2 to 0.5). Based on these calculations, it was shown that a significantly higher proportion of patients showed a clinically meaningful response in the SF-36 PCS and MCS after certolizumab pegol maintenance treatment compared to patients receiving placebo. CONCLUSION: A multi-faceted approach to...