PCV142

ASSESSING THE QUALITY OF QUALITY OF LIFE MEASURES IN HEART FAILURE: A COMPARISON OF AVAILABLE INSTRUMENTS

Herdman M[1], Garin O[1], Vilagut G[1], Ribera A[2], Permanyer-Miralda G[2], Ferrer M[3], Rajmil L[4], Valderas JM[5], Alonso J[3]

[1]CIBER en Epidemiología y Salud Pública (CIBERESP), Barcelona, Cataluña, Spain, [2]Hospital Vall d'Hebrón, Barcelona, Cataluña, Spain, [3]Institut Municipal d'Investigació Mèdica, Barcelona, Cataluña, Spain, [4]Catalan Agency for Health Technology Assessment and Research, Barcelona, Cataluña, Spain, [5]University of Manchester, Manchester, UK

OBJECTIVES: To evaluate and compare the performance of available disease-specific health-related quality of life (HRQL) instruments for use in heart failure. **METHODS:** A systematic review identified 5 disease-specific HRQL questionnaires for use in heart failure (Minnesota Living with Heart Failure questionnaire [MLHFQ], Chronic Heart Failure questionnaire [CHFQ], Kansas City Cardiomyopathy questionnaire [KCCQ], Left Ventricular Disease Questionnaire [LVDQ], and the Quality of Life in Severe Heart Failure Questionnaire [QLSHFQ]). The 5 questionnaires were evaluated using EMPRO (*Evaluating Measures of Patient Reported* Outcomes), a tool for the standardized assessment of the psychometric properties and usability of patient reported outcome measures. Groups of four expert appraisers evaluated 8 attributes for each instrument and gave an overall recommendation after a consensus procedure. Scores ranged from 0 (worst possible score) to 100 (best possible score). Inter-rater agreement (intra-class correlation coefficient – ICC) was analyzed and median scores and ranges for all EMPRO attributes were calculated. An overall recommendation was provided (highly recommended, recommended with provisos, not recommended, unsure). **RESULTS:** Inter-rater agreement for EMPRO was generally acceptable (ICC of 0.48 – 0.93 for individual attributes). Median overall EMPRO ratings and attribute score ranges were: MLHFQ (59.8, 33.3–69.4), CHFQ (54.9, 38.1–72.2), KCCQ (47.2, 38.1–100), LVDQ (47.7, 11.1–76.7), and QLSHFQ (7.7, 5.6–26.6). The highest scores for all instruments except the QLSHFQ were on responsiveness (median scores from 5.6 to 100). Three of the questionnaires (MLHFQ, CHFQ, KCCQ) were recommended with provisos; the LVDQ and QLSHFQ were not recommended. **CONCLUSIONS:** Of the 5 instruments evaluated, 2 (MLHFQ, CHFQ) scored well on EMPRO and were recommended, whilst the others may be limited to use in particular types of study or require further investigation. This type of assessment can provide useful information for questionnaire selection. Funding: This work was supported by grants from Instituto de Salud Carlos III FEDER, (PI08/90724).

PCV143

EXPLORING PATIENTS' SATISFACTION WITH ANTICOAGULANT TREATMENT BY APPLYING STRUCTURAL EQUATION MODELS TO THE PERCEPTION OF ANTICOAGULANT TREATMENT QUESTIONNAIRE (PACT-Q)

Regnault A[1], Gilet H[1], Carita P[2], Arnould B[3]

[1]Mapi Values France, Lyon, France, [2]Sanofi Aventis R&D, Paris, France, [3]Mapi Values, Lyon, France

OBJECTIVES: To explore the process of patients' satisfaction with anticoagulant treatment using Structural Equation Modeling (SEM). **METHODS: The Perception** of AntiCoagulant Treatment Questionnaire (PACT-Q) includes 2 modules: a 7-item module assessing patient expectations of anticoagulant treatment and a 20-item module assessing treatment convenience and patient satisfaction. It was completed by deep venous thrombosis, atrial fibrillation and pulmonary embolism patients in 3 clinical trials assessing anticoagulant treatments. The first module was administered at baseline (BL) and the second after 3 (M3) and 6 months (M6). SEM was applied to pooled data from the three trials. SEM specifications were supported by the questionnaire conceptual model, satisfaction theory and the scoring rules of the instrument. The goodness of fit of the models was assessed using a set of commonly used fit indices including the Root Mean Square of Approximation (RMSEA). Association between latent variables was assessed using Standardized Path Coefficients (SPC). **RESULTS:** A total of 986 patients had fully completed PACT-Q at BL, M3 and M6. PACT-Q items allowed good measurement of Convenience (RMSEA = 0.054) and Satisfaction (RMSEA = 0.028) at M3. The 7 expectation items were kept independent. An overall model involving two expectation items (expectations of symptom relief, worries about making mistakes) and both Satisfaction and Convenience at M3 and M6 was estimated (RMSEA = 0.032). In this final model, Convenience had a stronger impact on Satisfaction at M3 than at M6 (respective SPC: 0.57 vs 0.48). Convenience at M6 was very strongly related with Convenience at M3 (SPC: 0.80) while the relationship between Satisfaction at M3 and M6 was weaker (SPC: 0.52). **CONCLUSIONS: The** application of SEM to the PACT-Q data allowed the prominent role of patients' expectations and perception of treatment convenience in the process of anticoagulant treatment satisfaction to be highlighted. Convenience was also shown to be more stable over time than satisfaction.

PCV144

HEALTH-RELATED QUALITY OF LIFE AND RESOURCE USE IN PATIENTS WITH METABOLIC SYNDROME: A COMPARISON OF THE UNITED STATES, EUROPE, AND JAPAN

Wagner S[1], Fukuda T[2], Nagae T[3], Gupta S[1], DiBonaventura M[1], Stankus AP[1]

[1]Consumer Health Sciences International, Princeton, NJ, USA, [2]University of Tokyo, Bunkyo, Tokyo, Japan, [3]York Pharma KK, Tokyo, Japan

OBJECTIVES: To compare health-related quality-of-life (HRQoL) and resource use in patients with metabolic syndrome across three geographies. **METHODS:** Data used from the 2008 National Health and Wellness Survey (NHWS), an annual internet survey of adults in the US, EU (Germany, Spain, Italy, UK, and France), and Japan (JPN). Metabolic syndrome was defined as having at least three of: diabetes, BMI >= 30, high cholesterol, or hypertension. Resource use included emergency room (ER) visits, hospitalizations, and visits to traditional health care providers. Linear regression was used to determine the effects of geography on the physical component summary score (PCS) and mental component summary score (MCS) of the SF-12, and Poisson regression for resource use, controlling for age, gender and total number of comorbidities. **RESULTS:** Of the 11,131 patients with metabolic syndrome 2,503, 185 and 8,443 were from EU, JPN, and US, respectively. All prevalence numbers were significantly different from one another ($p < 0.05$). Mean MCS scores were 45.86, 45.84, and 47.39 for EU, JPN and US, respectively, with a significant difference between EU and US ($p < 0.05$). The PCS score for JPN (44.86) was significantly higher than both US (38.76) and EU (38.41) PCS scores ($p < 0.05$). After controlling for confounders, JPN MCS scores were 2.87 points lower than the US ($p < 0.05$), while EU scores were 2.09 points lower ($p < 0.05$). JPN PCS scores were 4.92 points higher ($p < 0.05$), and EU scores were 1.22 points lower than the US ($p < 0.05$). The regression results for resource use showed JPN with fewer ER visits than US, and both JPN and EU with more hospitalizations, and more provider visits ($p < 0.05$). **CONCLUSIONS:** There are significant differences in prevalence and possibly awareness of metabolic syndrome across the three regions. Also, significant differences were seen in both HRQoL and resource use. Further research is needed to describe the burden of metabolic syndrome globally.

PCV145

IMPACT OF HOSPITALIZATION ON HEALTH-RELATED QUALITY OF LIFE IN ATRIAL FIBRILLATION PATIENTS

Reynolds MR[1], Hui G[2], Zimetbaum P[1]

[1]Beth Israel Deaconess Medical Center, Boston, MA, USA, [2]Harvard Clinical Research Institute, Boston, MA, USA

OBJECTIVES: Hospitalization is recognized as an important endpoint in atrial fibrillation (AF) clinical trials. The association between hospitalization and reduced health-related quality of life (HRQOL) has not been studied. Therefore, a large AF registry was used to characterize the impact of hospitalization on HRQOL. **METHODS:** The FRACTAL study was an observational registry of patients enrolled in the United States and Canada with new-onset AF. HRQOL was assessed with the SF-12 and the AF Symptom Checklist at baseline, 3, 6, and 12, 24 and 30 months. Mixed linear regression models were fitted to estimate the impact of hospitalization on HRQOL summary scores (physical and mental component scores of SF-12, symptom frequency and severity, and utilities from the SF-12), adjusting for demographic and clinical variables known to influence HRQOL in this population. **RESULTS:** Of 933 subjects who completed HRQOL questionnaires and were not hospitalized during the baseline study visit, 303 (32%) were hospitalized a total of 490 times during an average of 2.0 years of follow-up. The majority (64%) of these admissions were for cardiovascular causes. The adjusted effect of any hospital admission (vs. none) on symptom frequency and severity scores over time was +1.3 and +1.1 points, respectively ($p < 0.01$ for both), with higher scores indicating greater symptom burden. The adjusted effect of any admission on the SF-12 physical score was –2.7 points ($p < 0.0001$) and a decrement on utility of 0.03 ($p < 0.0001$). In contrast, hospitalization had little effect on longitudinal SF-12 mental scores (–0.7 points, $p = 0.15$). **CONCLUSIONS:** In a real life long term AF registry, hospitalizations during follow-up were associated with significant increases in AF symptoms and decrements in generic physical HRQOL and utilities. Based on these results which may be limited by the study design, interventions that reduce hospital admissions in AF patients would be expected to improve or preserve HRQOL.

PCV146

HAS THE TYPE OF ATRIAL FIBRILLATION DIFFERENT IMPACT ON HRQOL?

Arribas F[1], Ormaetxe JM[2], Peinado R[3], Fernandez C[4], Ramírez P[4], Badia X[5]

[1]Hospital 12 de Octubre, Madrid, Spain, [2]Hospital de Basurto, Bilbao, Spain, [3]Hospital La Paz, Madrid, Spain, [4]MEDA Pharma, Madrid, Spain, [5]IMS Health, Barcelona, Spain

OBJECTIVES: To assess whether the type of atrial fibrillation (AF) could have a different impact on patients' HRQoL. **METHODS: An observational, prospective, mul**ticentre study among 29 cardiologists specialized in arrhythmia, in the context of usual clinical practice was carried out to validate the AF-QoL questionnaire. AF patients (paroxysmal, persistent or permanent) were included. Variables recorded were age, NYHA scale, symptoms (number and frequency), emergency visits and AF-QoL score. **RESULTS:** A total of **341 AF patients were included (43% with persistent AF, 37%** with paroxysmal AF and 20% with permanent AF). Paroxysmal AF patients were the youngest, with a mean age (SD) of 57(13) years, and reported better physical state, according to NYHA scale (67%, class I). Palpitations were the most prevalent symptom in paroxysmal AF patients (91%); dyspnea was the most prevalent symptom in persistent (70%) and permanent AF (77%). Paroxysmal AF patients reported the greatest number (4.5(2.5)) and frequency of symptoms (30% reported weekly symptoms), as well as the major number of emergency visits (2.2(1.7)) ($p < 0.05$). Permanent AF patients showed better HRQoL in the psychological dimension of AF-QoL (47(28) points vs 38(26) and 37(26) in paroxysmal and persistent AF, respectively) ($p = 0.03$). The rest of AF-QoL domains were similar between AF patients. The presence of symptoms was associated to a decrease in HRQoL in all AF patients, especially palpitations in paroxysmal AF patients and palpitations, dyspnea and chest pain in permanent AF. Moreover, the more frequent the symptoms, the lower the AF-QoL score ($p < 0.05$). A correlation was observed between the increase of emergency visits