

indicating high levels of random measurement error. Three of the SF-36 domains did not distinguish between WHO functional classes. Only two of the SF-36 domains (role physical and general health perceptions) met the full psychometric criteria of the study. In contrast, all CAMPHOR scales exhibited good test retest reliability and distinguished significantly between WHO functional classes. **CONCLUSIONS:** The CAMPHOR has superior psychometric properties, compared to the SF-36, in the assessment of QoL in individuals with PH.

## PCV93

## STUDY OF THE USE OF QUALITY OF LIFE QUESTIONNAIRES IN CARDIAC DISEASES IN POLAND

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**OBJECTIVES:** To assess the use of quality of life questionnaires in polish cardiac patients, as well as research methods used by polish authors in terms of international quality of life research guidelines. **METHODS:** Systematic literature review was performed in order to collect publications assessing quality of life in cardiac patients in Poland. Medical databases and the most important health agencies websites were searched for HRQoL assessment guidelines. Inclusion criteria: studies carried in the Republic of Poland; studies in which authors were using HRQoL questionnaires in cardiac patients. Exclusion criteria: Studies carried outside of Poland; studies estimating HRQoL among patients with vascular diseases; case reports; researches and review papers without HRQoL assessment. Based on the international guidelines, “checklist” consisting of 19 statements and questions was created as a basis for data extraction from accessed publications. **RESULTS:** As a result of systematic literature review and inclusion criteria application, 131 polish publications were included in this analysis. 26% of all researches were based on questionnaires designed by the authors for their own needs, of which 71% have never been validated. Results of questionnaires were calculated using official key only in 43% of publications. Among the included studies, 63% assessed HRQoL as a primary endpoint. Observational studies assessing HRQoL in polish cardiac patients without any interventions were the most common (41%). At the same time, 36% of studies were related to surgical intervention. **CONCLUSIONS:** Polish studies assessing HRQoL in cardiac patients often do not meet all the requirements stated in international guidelines. Promoting of the results of this work can increase the awareness of polish authors in terms of proper HRQoL measures.

## PCV94

## THE INFLUENCE OF DISEASE-SPECIFIC SYMPTOMS ON THE HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ATRIAL FIBRILLATION

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**OBJECTIVES:** To assess the health-related quality of life (HrQoL) in patients with atrial fibrillation (AF) in Germany and to identify the influence of the associated AF-specific symptoms on HrQoL. **METHODS:** HrQoL of AF patients recruited into a prospective cohort study was assessed by using the written version of the SF 36. General HrQoL as well as physical and mental component summary scores were calculated for each patient. Secondly, AF-related symptoms based on the EHRA AF symptoms classification (palpitations, fatigue, dizziness, dyspnea, chest pain, anxiety) were collected by asking each patient to fill out written questionnaires during visiting a GP. To identify the influence of these symptoms on HrQoL, a linear regression was conducted for each component summary score, while controlling for additional socio-demographic/AF-related clinical parameters. **RESULTS:** A total of 526 AF-patients were recruited in 71 study centers (female patients: 45.1%, average age: 73.2 years, average CHA<sub>2</sub>DS<sub>2</sub>-VASc score: 3.8). The average SF-36-physical summary score was 38.6 (SD: 10.4). The average SF-36 mental component score was 46.5 (SD: 11.8). Only 14.8% of the patients reported none of the EHRA-symptoms. The most frequent symptom was fatigue (72.1% of all patients). The results of the first multivariate regression ( $R^2=0.349$ ) showed that the most important factors explaining the SF-36-physical component score were fatigue, chest pain, dizziness and dyspnea. Only two of the control variables had a significant influence on physical HrQoL (age; number of medications taken). In the second estimate addressing mental HrQoL ( $R^2=0.349$ ), none of these factors was significant. The most important factors explaining mental HrQoL were palpitations, dizziness and anxiety. **CONCLUSIONS:** AF patients in real life care have a limited physical/mental HrQoL. AF-related symptoms significantly explain the level of HrQoL. Consequently, in order to increase/maintain the HrQoL of AF patients, it is important to control/improve scores measured for AF-related symptoms.

## PCV95

## THE PATIENT'S EXPERIENCE OF NUISANCE BLEEDING AND BRUISING WHILE ON ANTIPLATELET MEDICATIONS FOR ACS

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**OBJECTIVES:** Bleeding is a common experience for acute coronary syndrome (ACS) patients who receive anti-platelet medications. “Nuisance” bleeding and bruising – non-life threatening events that occur in the patients’ everyday lives and may impact medication adherence – is not often assessed in clinical trials and existing measures may not capture all relevant aspects. In this study, we used qualitative interviews to better understand how patients experience nuisance bleeding and bruising and its impact. **METHODS:** One-hour interviews were conducted using a semi-structured interview guide with patients who had experienced ACS in the

past year. All participants were taking clopidogrel at the time of enrollment into the study and reported experiencing nuisance bleeding and bruising. Most patients were male (70%) and white (80%) and the average age was 63.5 years old. Interview responses were coded using ATLAS.ti software. Data were analyzed by extracting relevant themes emerging from the interviews and by calculating the percent of patients expressing a specific concept related to nuisance bleeding and bruising. **RESULTS:** Prominent features included the amount of bleeding, difficulty stopping the bleeding, and the size and color of bruises. Frequency was an important issue for patients; approximately one-third of patients reported experiencing nuisance bleeding daily. Patients most often reported that bleeding events lasted only minutes, but that bruises often did not heal for weeks. Nuisance bleeding and bruising appeared to have a significant negative impact on the patients’ daily lives, as it resulted in behavior changes to avoid bleeding and bruising events and a variety of negative emotions (e.g., embarrassment, frustration, fear). **CONCLUSIONS:** Nuisance bleeding and bruising can have a significant impact on the lives of ACS patients on anti-platelet medications. The data from this qualitative interview study may allow for improved measures of nuisance bleeding and bruising that can be administered in studies examining antithrombotic therapies.

## PCV96

## RELATIONSHIP BETWEEN INFLAMMATION AND PATIENT FUNCTIONING IN CARDIOVASCULAR DISEASE: A REVIEW OF THE LITERATURE

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**OBJECTIVES:** Patients with cardiovascular disease (CVD) experience a number of symptoms, such as tiredness, that can limit their physical activities and disrupt daily life. Increased inflammation may independently contribute to the experience of these symptoms and functional limitations, in addition to increasing the risk of CVD and acute events. The goal of this study was to perform a qualitative review of published studies that address the link between inflammation and patient functioning among patients with cardiovascular disease. **METHODS:** Articles were identified through MEDLINE and PubMed. Search terms included “inflammation, inflammatory markers, CRP, TNF- $\alpha$ , and interleukins” crossed with “fatigue, depression, physical activity, sleep, function, and cardiovascular.” The search returned 938 articles, a total of 112 abstracts were reviewed, and 46 full articles were examined. Of these, 8 addressed patients with chronic or acute cardiovascular disease and were included in the review. **RESULTS:** The articles examined multiple inflammatory markers, including IL-1 $\beta$ , IL-6, TNF- $\alpha$ , CRP, IL-10, IL-8, neopterin, sICAM-1, and IL-1ra. Symptoms and functional limitations measured included fatigue/tiredness, irritability, depression, demoralization, and physical activity/exercise. Significant associations were observed in all 8 studies. The relationship between inflammation, IL-6 in particular, and tiredness was consistently seen. Evidence also supported a relationship with depressed mood, but the association was not uniform across inflammatory markers. Inflammation was also associated with physical activity, with one study showing that exercise reduced hsCRP and inflammatory cytokines. **CONCLUSIONS:** Symptoms and limitations on physical functioning can substantially burden patients with CVD. Although additional research is needed, this review suggests that inflammatory processes may independently contribute to this patient burden. Reducing inflammation may not only reduce the risk of CVD and associated events, but also directly improve symptoms and improve functioning. It will be useful to include outcomes assessing these concepts in trials examining anti-inflammatory treatments in CVD patients.

## PCV97

## BURDEN OF DYSPEPSIA AMONG PATIENTS WITH ATRIAL FIBRILLATION IN JAPAN

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**OBJECTIVES:** To assess the prevalence and impact of dyspepsia among Japanese Atrial Fibrillation (AF) patients. **METHODS:** The 2008, 2009, and 2010 Japan National Health and Wellness Survey (NHWS) datasets were used in this study. The NHWS is an Internet-based survey administered to the adult population in Japan using a random stratified sampling framework to ensure demographic representativeness. Among patients who reported a diagnosis of AF (N=565), those with comorbid dyspepsia were compared with those without dyspepsia on demographics and health history. These groups were also compared on health status (using the SF-12v2), work productivity (using the WPAI), and health care resource use (physician visits, emergency room [ER] visits, and hospitalizations) in the past six months using multivariate regression modeling and controlling for baseline differences. **RESULTS:** Dyspepsia was the most common non cardiovascular comorbidity, affecting over a third (37.4%) of AF patients. This prevalence was higher than in general population (21.3%). Its presence was not associated with any demographic or general health history variables. However, patients with dyspepsia used more AF medications (2.05 vs. 1.54) and had been diagnosed more recently (9.97 vs. 10.58 years). Adjusting for these differences, patients with dyspepsia reported significantly worse physical health status (PCS scores: 41.32 vs. 45.66) and health utilities (0.70 vs. 0.76) (all p<0.05). Those patients also reported significantly more overall work impairment (29.65% vs. 17.02%) and more physician visits (19.35 vs. 12.62), and ER visits (0.40 vs. 0.14) in the past six months (all p<.05). **CONCLUSIONS:** Dyspepsia is common among Japanese AF patients. Even after adjusting for confounding variables, dyspepsia was significantly associated with poorer health sta-

tus, greater work-related impairments, and increased health care resource use. Given the additional burden of this comorbidity, the management of dyspepsia among patients with AF should be a greater area of focus.

#### PCV98

##### HEALTH RELATED QUALITY OF LIFE AND AGE IN HYPERTENSIVE PATIENTS: SELF-PERCEPTION AND EVALUATION BY PROFESSIONALS. THE EQUALITY STUDY

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**OBJECTIVES:** To analyse the association between Health Related Quality of Life (HRQoL) and age, in hypertensive patients and the correlation between HRQoL reported by patients and evaluated by their doctors. **METHODS:** Observational, cross-sectional, multi-centre study, in Primary and Specialised Care. Inclusion of 5,031 hypertensive patients, selected by quotes according to three age groups (<65, 65-79, ≥ 80 years) was planned. Selection criteria were: patients whose age was over 18, diagnosed as having hypertension at least one year before inclusion and attended a follow-up visit. Information related to hypertension, basic socio-demographic and clinical data, the self-administered specific questionnaire MINICHAL for the evaluation of HRQoL (higher scores indicative of lower HRQoL), and a visual analogue scale (VAS) for the general evaluation of HRQoL (higher scores indicative of higher HRQoL) by patients and doctors, were recorded. Data of 4,346 eligible patients were included. HRQoL-age correlation was analysed by Spearman's-rho, differences among age groups by Kruskal-Wallis and patient/doctor agreement by the intraclass correlation coefficient (ICC). **RESULTS:** Mean age (SD) was 68.35(12.60). 38.1% of patients were under 65, 36.9% between 65 and 80 and 25.0% were over 80 years old. 54.5% were men. Mean time since diagnosis was 10.33(7.68) years. 34.2% had a family history of high blood pressure. Mean scores in MINICHAL were: State of Mind dimension 8.07(5.83), Somatic Manifestations dimension 3.24(3.06). Worsening of both dimensions was found when comparing groups of higher age ( $p < 0.001$ ) as well as significant moderate correlations of both dimensions with age (0.335,  $p < 0.001$ ; 0.397  $p < 0.001$ ). Mean(SD) VAS score for doctors' evaluation was 66.84(15.82) and 63.93(18.46) that of patients; ICC for agreement was 0.697 (0.672, 0.687 and 0.663 by age groups). **CONCLUSIONS:** An impact of age on HRQoL worsening is evidenced. Patient/doctor agreement in the evaluation of HRQoL is adequate; however doctors tend to overestimate the HRQoL of patients.

#### PCV99

##### EQ-5D UTILITIES IN PATIENTS HOSPITALISED WITH HEART FAILURE IN CANARY ISLANDS

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**OBJECTIVES:** To determine the health related quality of life (HRQOL) of patients with heart failure (HF) hospitalized in the Canary Islands and to estimate their utilities by analyzing the influence of sociodemographic and clinical factors such as gender or severity according to New York Heart Association (NYHA) classification. A secondary objective is to obtain utilities to be used in an economic model to evaluate a cardiac device. **METHODS:** Descriptive analysis within a prospective observational multicenter study of a cohort of patients with HF admitted to cardiology or internal medicine units at several hospitals in the Canary Islands, Spain. HRQOL was assessed using the EQ-5D questionnaire among others. Utility was estimated for the entire sample and for subgroups of patients, using the Spanish tariffs VAS (visual analog scale) and TTO (time trade-off). **RESULTS:** We present the results of a sample of 176 patients enrolled so far (51% male, mean age 74 years). Average utility (SD) of the entire sample is 0.5297 (0.2107) (VAS rate). Women reported poorer HRQOL than men (0.5182 vs. 0.5421); HRQOL is lower in health states of lower functional capacity: 0.6400 in patients with NYHA-I and 0.4491 in patients with NYHA-III. **CONCLUSIONS:** Differences between sub-groups and overall low HRQOL were observed, possibly due to the hospitalization of surveyed patients. These local findings coincide with the international literature and may be useful for developing the economic model.

#### PCV100

##### COMPARISON OF HEALTH-RELATED WORK IMPAIRMENT IN RUSSIAN PATIENTS WITH US AND 5EU

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**OBJECTIVES:** To compare work productivity impairment between Russian patients with those in the SEU and US and assess whether conditions have similar impact across these geographies. **METHODS:** The study included data from the 2011 Russia (N=10,039), US (N=75,000), and 5EU (N= 57,512) National Health and Wellness Survey, a survey representative of urban adults in Russia and total adult populations of the US and each 5EU country. Respondents self-reported physician diagnosis of type 2 diabetes (T2D) and cardiovascular (CV) conditions, as well as their height and weight used to calculate obesity (BMI≥30). Work productivity impairment and impairment in non-work activities was assessed with the Work Productivity and Activity Impairment (WPAI) questionnaire. Two-way ANOVAs tested for differences in work productivity impairment by geography and condition. **RESULTS:** There were regional differences in mean health-related work impairment, with Russia the highest (22.6%), followed by 5EU (19.4%) and US (14.9%;  $p < 0.001$ ). Collapsing across geographies, obesity, T2D, and CV conditions were

each associated with more impaired work productivity (all  $ps < 0.01$ ), but the magnitude of the decrement associated with each disease depended on region (all  $ps < 0.01$ ). The incremental work productivity loss associated with obesity was smallest in Russia (1.5%), compared with 5EU (3.9%) and US (2.7%). T2D patients in Russia and 5EU experienced similar incremental work productivity impairment (8.5%), while US T2D patients showed a difference of 5.0%. Similarly, Russians with CV conditions were more impaired than in 5EU and US when compared with non-CV patients (8.1% vs. 7.1% and 4.4%, respectively). **CONCLUSIONS:** Russians have greater health-related work impairment than adults in US and 5EU. The incremental burden of obesity, T2D, and CV conditions in Russia appears to differ from the US and 5EU, being relatively small for obesity but greater for T2D and CV conditions. These differences highlight the importance of country-specific information for these markets.

#### PCV101

##### JAPANESE PATIENTS AND PHYSICIANS PREFERENCES FOR ANTICOAGULANTS USE IN ATRIAL FIBRILLATION - RESULTS FROM A CONJOINT-ANALYSIS STUDY

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Anticoagulants are recommended for stroke prevention in atrial fibrillation (AF), unfortunately they also increase the risk of bleeding. For this reason, physicians face benefit-risk trade-offs when prescribing anticoagulants to AF patients. Although the unmet medical need for safer anticoagulants has been documented, the actual patients and physicians preferences for outcomes associated with anticoagulants are yet to be documented. **OBJECTIVES:** To quantify Japanese patients and physicians preferences for benefits and risks associated with the use of anticoagulants in AF and to enable cross-patient and physician comparison. **METHODS:** Patients ≥45 years old with a self-reported physician diagnosis of AF, and board-certified internists, cardiologists, neurologists and neurosurgeons currently treating AF patients were invited to complete a web-enabled, choice-format conjoint survey that included a series of trade-off questions. Each trade-off question included a pair of hypothetical anticoagulants defined by therapy-induced changes in the risk of stroke, myocardial infarction, embolism, and bleeding. In addition, respondents were asked to revisit their anticoagulant choice based on the risk of all-cause death and on the monitoring requirement. Patients were asked to choose anticoagulants for themselves, while physicians chose anticoagulants for virtual patients. Random-parameters logit was used to estimate a relative preference weight for the risk of each event based on respondents' choices in the trade-off questions. **RESULTS:** A total of 152 patients and 164 physicians completed the survey. Overall patients and physicians considered all-cause death to be the least desirable outcome. Among non-fatal outcomes, patients considered the risk of disabling stroke to be 2.6 times more important than extra-cranial major bleeding and 16 times more important than non-major clinically relevant bleeding compared to 1 time and 2.7 times for physicians. **CONCLUSIONS:** Japanese patients and physicians have different preferences for non-fatal outcomes associated with anticoagulants, with patients willing to tolerate a greater risk of bleeding for stroke prevention than physicians.

#### PCV102

##### CHARACTERISTICS INFLUENCING JAPANESE ATRIAL FIBRILLATION PATIENTS PREFERENCES FOR ANTICOAGULANTS USE

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Although effective for stroke prevention in atrial fibrillation (AF), anticoagulants increase the risk of bleeding. The relative importance of benefits and risks associated with anticoagulants is influenced by various factors and has mostly been documented only in physicians. **OBJECTIVES:** To identify patients characteristics influencing the relative importance of non-fatal outcomes associated with anticoagulants. **METHODS:** Data from a choice-format conjoint survey asking AF patients to choose between hypothetical anticoagulants were used to estimate importance weights for non-fatal outcomes associated with anticoagulants. The influence of patients characteristics was tested by evaluating the significance of interactions between importance weights and age, gender, prior use of anticoagulants, personal history of stroke, family history of stroke and personal or family history of bleeding. **RESULTS:** A total of 152 patients completed the survey. Only two patients characteristics significantly influenced the relative importance of non-fatal outcomes associated with anticoagulants. Overall, the least desirable non-fatal outcome was disabling stroke. Using disabling stroke as a reference, patients characteristics such as prior use of anticoagulants increased the relative importance of non-disabling stroke by 48%, major extra-cranial bleeding by 12% and non-major clinically relevant bleeding by 82%. On the other hand, personal or family history of bleeding increased the relative importance of major extra-cranial bleeding by 19% and non-major clinically relevant bleeding by 34% while decreasing the relative importance of non-disabling stroke by 15%. **CONCLUSIONS:** This study documents the impact of patients prior experience on relative importance of non-fatal outcomes associated with anticoagulants. Proper explanation of the benefits and risks of anticoagulants may play a role in patients understanding and