

PCV2

ADVERSE DRUG REACTIONS, MEDICATION ADHERENCE AND PHYSICIANS' PRESCRIBING BEHAVIOR: WHICH RELATIONSHIP? A DATABASE ANALYSIS ON STATIN USE

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OBJECTIVES: Pharmacological adherence plays an essential role in controlling hypercholesterolemia. Pharmacological care is also affected by the prescribing inappropriateness and adverse drug reactions (ADRs). ADRs can lead to a perceived lack of therapy effectiveness and subsequent suboptimal adherence. Our aim was to evaluate the impact of statin-induced, muscle-related ADRs on patients' therapy adherence, and how this relationship may compromise the efficacy of physicians' prescribing choices and health outcomes in clinical practice. **METHODS:** A retrospective cohort study was performed using data from databases of 4 Local Health Units (LHUs) located in Emilia-Romagna, Toscana and Umbria regions, with an overall population of about 1.1 millions of inhabitants. All subjects aged ≥ 18 years with a first prescription for statins in the period 01/01/2007-30/06/2008 were included. Baseline and follow-up LDL-C levels were considered. **RESULTS:** A total of 71,855 patients (51% men, age 68.6 ± 10.6) were included. Among them, 31,544 (43.9%) had ≥ 1 LDL-C values during the follow-up period: only 37.4% of these patients achieved LDL-C target. 23.6% of patients underwent ≥ 1 CPK measurement: out of range values were identified in 37.8% of them. Patients with steadily normal values of CPK showed a better medication-taking behavior compared to patients whose CPK values were out of normal range. Furthermore, a greater percentage of switching to other statin drug and/or dosage was observed in patients with out of range CPK levels compared to those with normal serum CPK levels. **CONCLUSIONS:** Our findings indicate that physiological serum CPK levels were associated with greater adherence to statin therapy, supporting a causal link between non-adherence behavior and muscle-related ADRs occurrence. Since statin benefits are associated with their chronic use, physicians should be aware about the relevance of monitoring their patients for this harmful link to prevent unsuitable therapeutic decisions, further decreasing adherence, and achieve long-term health outcomes

PCV3

LEAD DAMAGE IN THE FIRST-YEAR FOLLOWING CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) REPLACEMENT: INCIDENCE AND COSTS BASED ON DEVICE TYPE

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OBJECTIVES: This study evaluated the incidence and costs of lead damage within one year of pacemaker (PM), implantable cardiac defibrillator (ICD), and cardiac resynchronization therapy defibrillator (CRT-D) device replacement. **METHODS:** Using Truven US insurance claims (1/1/2009 - 12/31/2013), we identified patients who underwent a CIED generator replacement. We excluded patients with existing lead damage or active infection. Data were analyzed for one year prior to and following the replacement procedure, with device replacement the index date for analysis. During follow-up we considered lead damage to have occurred if there was any recorded visit with a procedure code for lead revision or repair and no concurrent code for infection. A Cox model, adjusted for baseline demographics and comorbidities, was used to evaluate variables associated with risk of lead damage. **RESULTS:** The study cohort included 45,250 patients (72% male), including 22,557 (50%) PMs, 20,632 (46%) ICDs, and 2,061 (5%) CRT-Ds. Lead damage was observed in 406 (0.90%) patients. The incidence of lead damage was significantly influenced by CIED type (PM: 0.46%; ICD: 1.27%; CRT: 1.94% $p < .001$). Similarly, total hospitalization cost associated with lead revision/repair was influenced by CIED type (PM: \$19,959; ICD: \$24,885; CRT: \$46,229, $p=0.048$). As compared to PMs, ICDs (HR = 2.14, 95% CI 1.68 - 2.74) and CRTs (HR = 2.97, 95% CI 1.99 - 4.43) had a significantly higher risk of lead damage. **CONCLUSIONS:** This is the first nationally representative study to assess the incidence and associated costs of lead damage following CIED generator replacement in the US. Patients with an ICD or CRT have a significant 1-2% risk of lead damage, which is associated with substantial hospitalization-related costs. Strategies are needed at the time of generator replacement to minimize inadvertent lead damage.

PCV4

NETWORK META-ANALYSIS OF ORAL ANTICOAGULANTS FOR PRIMARY PREVENTION, TREATMENT AND SECONDARY PREVENTION OF VENOUS THROMBOEMBOLIC DISEASE, AND FOR PREVENTION OF STROKE IN ATRIAL FIBRILLATION

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OBJECTIVES: To determine the best oral anticoagulant(s) across four medical conditions: stroke prevention in atrial fibrillation (AF), primary prevention of venous thromboembolic disease (VTE), acute treatment of VTE, and secondary prevention of VTE; using network meta-analysis to compare novel oral anticoagulants (NOACs) with warfarin and/or low molecular weight heparin (LMWH). **METHODS:** We undertook four systematic reviews and network meta-analyses of randomised controlled trials. An extensive search and risk of bias assessment were followed by network meta-analyses within each condition, and additionally we performed combined meta-analyses across the four reviews for key safety outcomes. Through consultation between clinicians and methodologists, we needed to make various decisions about groupings of interventions and doses, and of different endpoints, for analysis. **RESULTS:** 85 trials were included across the reviews, including a mixture of phase III trials and phase II dose-ranging trials. For stroke prevention in AF, apixaban (5mg bd) was among the best interventions for a range of efficacy and safety outcomes with mean rank 2.35

in relation to stroke or systemic embolism and mean rank 1.15 for major bleeding. Edoxaban (60mg od) was also highly ranked (means 3.24 and 1.92, respectively). We did not see strong evidence that NOACs have advantages over LMWH in primary prevention, or over warfarin in acute treatment and secondary prevention of VTE, but risk of bleeding complications was lower for some NOACs than for warfarin. In sensitivity analyses, key decisions we made in the process did not materially affect the results. **CONCLUSIONS:** NOACs have advantages over warfarin for stroke prevention in AF and acute treatment of VTE, but we found no evidence that they should replace the standard treatments for primary and secondary prevention of VTE.

PCV5

ASSESSMENT OF A PREDICTIVE RISK MODEL FOR CLASSIFYING PATIENTS WITH MULTIMORBIDITY IN THE BASQUE COUNTRY

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OBJECTIVES: To describe the rate of unplanned admissions in patients with multimorbidity and calculate the percent of patients with at least one unplanned admission by risk classification based on the results of a predictive model. **METHODS:** Cross-sectional study. In September 2013 all Basque Country citizens were classified in risk groups based on a prediction model that used data from a 2 year period: age, sex, diagnoses, procedures, prescriptions and costs from the first year as the explanatory variables and healthcare cost in the second year as the dependent one. A Patient with multimorbidity was defined as following: 2 or 3 from diabetes, chronic obstruction pulmonary disease and chronic heart failure; or multimorbidity definition used by Ollero et al published elsewhere. People younger than 14 or with a diagnosis of cancer, a transplant or dialysis were excluded. Multimorbidity was classified in three risk groups based on the expected healthcare cost percentiles (<75; 75-95; >95). Case-mix Adjusted Clinical Groups (ACG) was used for both prediction and definition of multimorbidity. Rate of unplanned admissions and the probability of one or more unplanned admissions by risk group during the following year to their classification were calculated. **RESULTS:** A total of 24,247 people met the criteria of multimorbidity (61.3% males) with a mean age of 75.5 years. 2,795 were classified as low-risk, 10,598 as medium-risk and 10,853 as high-risk. The rate of unplanned admissions was 148.4/1000 in the low-risk group, 340.3/1000 in the medium-risk group and 861.6/1000 in the high-risk group (Mantel-Haenszel trend test $p < 0.001$). 11.4%, 22.8% and 44.6% of the patients in each risk group required one or more unplanned admissions during the following year, respectively ($p < 0.001$). **CONCLUSIONS:** Predictive risk models, based on ACG, allow classifying patients with multimorbidity in risk groups. This makes possible a better development of personalized, cost-efficient and patient-centered care plans

PCV6

CLINICAL AND ECONOMIC IMPACT OF CHRONIC HEART FAILURE IN GENERAL PRACTICE: ANALYSIS OF 13.633 PATIENTS

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OBJECTIVES: Update epidemiology and estimate Chronic Heart Failure (CHF) related costs in general practice setting. **METHODS:** We used Health Search, an Italian general practice database formed by about 1,000 GPs. We collected demographics, clinical informations, drug prescriptions, co-morbidities, and lifestyle measurements, reflecting "real world" practice. **RESULTS:** We analyzed data of 13,633 CHF (mean age was 76.78 years) patients that resulted in a prevalence of 1.25%. We observed similar prevalence in men and women; prevalence increased significantly with age, in both men and women. There were some substantial differences across regions (eg.: Emilia Romagna 1.54% vs. Sardinia 0.61%). Incidence rate was slightly lower than that reported in the literature (1.99*1000 person-years) with some regional differences: 3.24*1000 Emilia Romagna as opposed to 1.21*1000 in Puglia and Marche. Women had a higher incidence rate than men (2.05*1000 vs. 1.92*1000). Overall, mean cost in a cohort of 7.710 patients (excluding 67,7% of patients that had a null cost registered by physicians) was 950.22€/patient/year (DS: 1135,27), while median cost was 643,16€. Age and NYHA class seemed to influence costs for elderly patients, while ex-smokers, alcohol abusers and patients with alcohol related diseases had a significant reduction of costs. **CONCLUSIONS:** Real world data is needed to understand the epidemiology of and costs due to CHF in primary care. The epidemiology of CHF here reported is in line with current literature. Concerning CHF-related costs and the respective determinants, this is the first study examining the Italian general practice setting. The present analysis gives an important contribution in updating epidemiology and estimating CHF-related costs.

PCV7

SYSTEMATIC LITERATURE REVIEW OF THE BURDEN OF ILLNESS IN HYPERTRIGLYCERIDEMIA

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OBJECTIVES: Hypertriglyceridemia (HTG) is a common condition characterized by elevated triglyceride (TG) levels with the threshold inconsistently defined but often appearing as ≥ 2.26 mmol/L; patients with TG levels ≥ 5.6 mmol/L have severe HTG (sHTG). The objective of this study was to evaluate the burden of HTG and report unmet needs. **METHODS:** MEDLINE and Embase-indexed databases were systematically searched, pairing keywords for elevated TG levels with outcomes, to identify English-language articles published from 1/1/2002-4/14/2014. Conference proceedings from the past four years were also reviewed. Studies evaluating clinical, patient-centered, economic, and epidemiologic outcomes in adults with TG levels ≥ 2.26 mmol/L were included. **RESULTS:** Of the 1,225 articles identified, 160 studies were included. Prevalence of HTG (1.2%-55.8% globally) was reported inconsistently. Significant associations were identified between HTG and cardiovascular