

treatment initiation. The rates of TM were significantly different across ADCs; angiotensin converting enzyme inhibitor and angiotensin receptor blocker users were less likely to receive TMs compared to other drug classes. The mean time-to-TM was >100 days for patients adding or uptitrating medications, and >150 days for those switching or downtitrating medications. The likelihood of discontinuation was significantly lower for patients intensifying treatment by adding medications vs. those uptitrating dose (HR=0.765; CI: 0.701-0.834). **CONCLUSIONS:** TMs are common among newly treated hypertensive patients. The rates of TM vary significantly across ADCs. In the real-world, TMs occur much later than the 30-day time-line recommended by clinical guidelines. Addition of drugs may be a preferred approach vs. uptitrating drug dose for intensifying treatment of patients who are at a high risk of treatment discontinuation.

PCV129

REAL-WORLD STATIN UTILIZATION AMONG PATIENTS AT HIGH RISK FOR CARDIOVASCULAR EVENTS: US ANALYSES

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OBJECTIVES: Objective: Despite the efficacy and safety of statins, real-world data suggest they are suboptimally used among dyslipidemic patients. The current study sought to describe patterns of statin utilization among high cardiovascular (CV)-risk patients initiating statin therapy. **METHOD:** Methods: Adult patients (≥18 years) with continuous enrollment who were newly initiating statins were identified from the Truven MarketScan Research databases (01/2007-06/2013). Patients were selected for and stratified into 1 of 5 mutually exclusive, high CV-risk-based hierarchical categories: recent acute CV event (hospitalization for acute coronary syndrome [ACS] or other CV event within 90 days of index), coronary heart disease (CHD), ischemic stroke, peripheral vascular disease/peripheral artery disease (PVD/PAD), and diabetes. Descriptive statistics and time-to-event analyses were used to measure proportion of days covered (PDC), time to discontinuation, and hospitalization rates. **RESULTS:** Results: Among 541,221 high CV-risk patients, 61% were in the diabetes cohort, followed by recent acute CV event (26%), PVD/PAD (5%), CHD (4%), and ischemic stroke (4%). High-intensity statins (atorvastatin 40/80 mg, rosuvastatin 20/40 mg, simvastatin 80 mg) were initiated in 15% of patients, with the percentages varying among subgroups (10% [diabetes] to 31% [ACS]). More than 20% of high-intensity statin initiators switched to a moderate- to low-intensity statin (range, 19% [PVD/PAD] to 28% [other CV event]). The PDC ranged from 56% (diabetes) to 66% (ACS). Median time to statin discontinuation among high CV-risk patients was approximately 15 months. Median time to discontinuation among patients receiving high-intensity versus moderate- to low-intensity statin was 21 months and 15 months, respectively. At 1 year, Kaplan-Meier estimates of cumulative event rates for CV-related hospitalizations were lowest in the diabetes cohort and highest for patients with recent ACS hospitalization (4% and 22%, respectively). **CONCLUSIONS:** Conclusion: Low PDC and discontinuation of statin therapy were observed among high CV-risk patients. Interventional opportunities to ensure better therapy management are warranted.

PCV130

TREATMENT PATTERN AND OUTCOMES OF INTRAVENOUS ANTIHYPERTENSIVE AGENTS IN US HOSPITAL ICH PATIENTS

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OBJECTIVES: In patients with spontaneous intracerebral hemorrhage (ICH), current guidelines recommend managing elevated blood pressure (BP) with intermittent or continuous infusion of intravenous medications. The purpose of this retrospective observational study is to evaluate the clevidipine (CLV) usage patterns and patient outcomes of continuous infusion intravenous antihypertensive agents (IVA) compared to other agents available. **METHODS:** Study data were extracted from the Premier hospital database. ICH patients were identified by primary diagnosis ICD-9 CM codes of 431 (ICH) or 432 (other or unspecified ICH) and a final MS-DRG of 64, 65, 66 (Intracranial hemorrhage or cerebral infarction). Patients who received clevidipine, nicardipine, or nitroprusside during the first two days of admission between January 2009 and June 2014 were included. Baseline demographics, outcomes, and costs were evaluated and propensity score matching comparing CLV to nicardipine (NIC) and CLV to nitroprusside (SNP) was performed to control for confounders. **RESULTS:** 165 clevidipine, 15910 nicardipine, and 1091 nitroprusside inpatients from 520 US hospitals met the inclusion criteria. Treatment pattern analysis showed nitroprusside usage decreased from 15.8% in 2009 to 1.3% in 2014, while NIC and CLV usage increased over the same time; CLV from 0.8% to 2.7%. After propensity matching, 126 patients remained in each group for the CLV-NIC pair and 90 patients in the CLV-SNP pair. Mortality rates were similar in both comparisons at 27.8% (CLV) vs 28.6% (NIC) and 31.1% (CLV) vs. 37.8% (SNP). After excluding in-hospital deaths, mean length of stay was 7.8 days (CLV) vs 8.8 days (NIC) and 8.0 days (CLV) vs 8.2 days (SNP). Inflation adjusted mean total costs were \$16903 (CLV) vs \$18634 (NIC) and \$15972 (CLV) vs \$15965 (SNP). **CONCLUSIONS:** Although CLV is <3% of use in this sample, PSM demonstrates similar outcomes in comparison with NIC and SNP.

PCV131

VENOUS THROMBOEMBOLISM TREATMENT PATTERNS IN THE EUROPEAN UNION (EU) REGION: 2013 RETROSPECTIVE CHART EXTRACTION

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OBJECTIVES: This study aims to understand unmet medical needs despite available treatment options of venous thromboembolism (VTE) treatment in Europe. **METHODS:** This retrospective cohort study included data from physicians (376 general practitioners and 307 specialists) in France, Germany, Italy, and Spain, who completed case report forms for the next 3-4 patients seen in consultation meeting inclusion criteria. Patients were assigned to mutually exclusive groups based on a hierarchy (vitamin K antagonist (VKA), rivaroxaban, low-molecular-weight-heparin (LMWH), aspirin, other anti-coagulants, no known treatment, respectively) determined by treatment data (dosing, start/end dates, and prescription duration and prescriber information, either in hospital or at discharge, following VTE, or as new treatment for first-time VTE event). Logistic regression with backward elimination identified significant predictors of treatment allocation. **RESULTS:** Patients' mean age (total n=2184) was 61.3 years (SD=14.3) and 47.4% were females. The hierarchy of treatments revealed that 63.1% of patients were using VKA, 30.6% using rivaroxaban or LMWH but no VKA, and 6.2% using other combinations. Mean treatment period was higher for VKA (168 days) than for rivaroxaban (139 days) or LMWH (46 days) patients. LMWH treatment was significantly more common than VKA among cancer patients (odds ratio (OR):2.35, P<.001), but less likely among pulmonary embolism or deep vein thrombosis patients with (OR:0.35, P=.001) or without complications (OR:0.33, P=.001), hospitalization for first VTE (OR:0.32, P<.001), and hip/knee replacement (OR:0.39, P=.028). Predictors of VKA vs. rivaroxaban included: more months since initial VTE event (OR:1.06, P<.001), no hormone replacement therapy (OR:5.83, P<.001), no chronic heart failure (OR:2.09, P=.001), and age of 40+ (OR:1.61, P=.03). **CONCLUSIONS:** Treatment patterns in the European Union show that VKA is a common treatment for VTE in addition to other anticoagulants. Attention to risk factors can play a major role in determining continuation of therapy which is likely to reduce VTE recurrence.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

TREATMENT WITH SOME BISPHOSPHONATES IS ASSOCIATED WITH AORTIC AND MITRAL VALVE CALCIFICATION

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OBJECTIVES: A signal of bisphosphonate-related cardiac valve calcification leading to cardiac valve insufficiency was detected in the European adverse event monitoring system (EudraVigilance); however no signal detection activity was conducted in the US. This pharmacovigilance analysis investigates and relationship between bisphosphonates and aortic and mitral valve calcification in the FDA Adverse Event Reporting System (FAERS). **METHODS:** Bisphosphonate-related adverse event reports submitted to FAERS between 1997 and 2013 were used to investigate the disproportional reporting of cardiac valve disorders (CVD) in relation to bisphosphonates therapy, including aortic and mitral valve calcification. Multi-item Gamma Poisson Shrinker data mining algorithm was used to calculate Empirical Bayes Geometric Mean (EBGM) and corresponding 95% confidence interval as disproportionality measures. Signals that warrant further review are defined as measures with confidence interval lower limit≥2.0. The Anatomical Chemical and Therapeutic classification was used to define bisphosphonate exposure, and the Medical Dictionary for Regulatory Activities, Preferred Term coding hierarchy was used to define cardiac valve calcification. **RESULTS:** A total of 2,010 CVD events were submitted for bisphosphonates. Of those, 116 events were for cardiac valve calcification, affecting aortic valve (n=32); mitral valve (n=83); and pulmonary valve (n=1). Signals were detected for alendronate (aortic: n=8, EBGM=3.7, 95%CI=2.03-6.34; mitral: n=15, EBGM=3.99, 95%CI=2.58-5.96); pamidronate (aortic: n=7, EBGM=9.94, 95%CI=3.27-30.3; mitral: n=25, EBGM=36.8, 95%CI=26.1-50.6); and Zoledronate (aortic: n=13, EBGM=4.44, 95%CI=2.77-6.86; mitral: n=39, EBGM=7.23, 95%CI=5.45-9.58). No signal was detected for ibadronate (aortic: n=1, EBGM=0.92, 95%CI=0.21-2.92; mitral: n=2, EBGM=1.02, 95%CI=0.32-2.58) and risedronate (aortic: n=3, EBGM=2.6, 95%CI=0.99-5.9; mitral: n=2, EBGM=1.43, 95%CI=0.45-3.61; pulmonary: n=1, EBGM=1.36, 95%CI=0.3-4.38). **CONCLUSIONS:** Treatment with some bisphosphonates might be associated with aortic and mitral valve calcification. It might be necessary for prescribers to monitor patients for CVD before and periodically during bisphosphonates therapy. Signal clarification and evaluation activities by pharmacoepidemiologic studies are recommended.

PMS2

SAFETY OF TOFACITINIB COMPARED TO BIOLOGICAL DMARDS IN RHEUMATOID ARTHRITIS PATIENTS WITH AN INADEQUATE RESPONSE TO METHOTREXATE: OVERVIEW OF SYSTEMATIC REVIEWS

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OBJECTIVES: The aim of this network meta-analysis was to compare the safety of tofacitinib to biological DMARDs for treatment of rheumatoid arthritis in patient with inadequate response to methotrexate. **METHODS:** We performed an overview of systematic reviews that evaluated biological DMARDs or tofacitinib for treatment of rheumatoid arthritis patients with inadequate response to methotrexate. The searching was carried out using the database of MEDLINE, EMBASE, Lilacs, COCHRANE, DARE and HTA restrictive to systematic review published in the last five years. The strategy of search was the similar to guideline of rheumatoid arthritis of the Ministry of Health of Colombia. Two researchers selected independently the studies and extracted the data. La risk of bias of systematic review was assessed with AMSTAR and ISPOR tools. The clinical trials were evaluated with The Cochrane Collaboration's tool for assessing risk of bias. Bayesian mixed treatment comparison method was applied for the pairwise comparison of treatments, where the common comparator was methotrexate. The outcomes were occurrence of serious adverse events, serious infections and withdrawal due to adverse event. **RESULTS:**