OBJECTIVES: Cardiac rhythm management devices (CRM®’s) have shown their clinical impact on the outcome of patients with cardiac rhythm disorders. This study described the complications rates related to implantations of CRM®’s, and estimated the additional hospital stay and cost associated with managing these complications. METHODS: Patients who underwent implantation of a PM or ICD from January 1, 2010, to February 28, 2012, at four centers were included. Baseline characteristics of the recipients were subjected to CRM®’s implantation and furthermore were recruited and followed up for 2 years. Finally, data were analyzed for 986 patients who completed the first year’s follow-up, with a total of 149 independent patients with varying hospital courses from admission to discharge whom an initial cranial computerized tomography (ICD) was performed to determine the outcome. Preliminary results suggest regional differences in chemotherapeutic treatment patterns.

OBJECTIVES: There has been an increasing concern about the link between statins and the risk for cataract. This study detects and clarifies signals of cataract formation and operation associated with lipid-lowering drugs (LLD), including statins, from postmarketing adverse event reports. METHODS: A pharmacovigilance analysis of adverse event reports submitted to the FDA Adverse Event Reporting System between October 1997 and Sep 2012 was conducted. Multi-item Gamma Poison Shrinker algorithm was used to evaluate signals of cataract formation and cataract operation. The most common comorbidities were COPD (30.5%) and diabetes (6.1%). Patients from the non-South regions, 72% of the study population, were matched 1:4 using propensity score methods. Study outcomes were major complications (37% of patients), there weren’t any complications neither in uncomplicated hospitalizations (60%) nor in replacement (31%) and cost attributed to these complications depends on the nature of complication.

OBJECTIVES: During the last decade, the standard of care to treat acute coronary syndrome (ACS) patients was typically a combination of clopidogrel and aspirin. However, newer antiplatelet agents were approved recently. The main purpose of this study was to assess the effect on time-to-readmission and resource utilization of prasugrel vs clopidogrel in prasugrel treated patients after hospitalization with an ACS event. METHODS: Based on the Truven Health Analytics MarketScan database from January 2009 through July 2012 a matched-cohort was created. Inference for average treatment effect on time-to-readmission and numbers of hospitalizations, ER visits, and outpatient visits in prasugrel treated patients at 30 days and 1 year were performed by (1) frequentist Kaplan-Meier estimation with a log-rank test and Lin method p-values all < 0.01). The posterior probability of equivalence between drugs for time-to-readmission at a margin of 10% was 98.7%, and based on the Bayes factor for superiority there is little evidence of superiority. Based on Bayesian analyses of utility outcomes there are high probabilities of equivalence at a margin of 10% and little evidence of superiority for all outcomes except for number of hospitalizations at 30 days (p = 0.03), however evidence of equivalence for the test and control groups, although the probability that prasugrel is non-inferior to clopidogrel at the 10% margin is 0.765. CONCLUSIONS: ACS patients treated with prasugrel had time-to-readmission and resource utilization outcomes equivalent to what they would have been if treated with clopidogrel.

OBJECTIVES: Real-world comparative effectiveness and safety of rivaroxaban in nonvalvular atrial fibrillation patients. METHODS: Health care claims from Symphonie Health Solutions’ Patient Transactional Datasets from 5/2011-7/2012 were analyzed. Adult patients newly initiated on rivaroxaban or warfarin, with ≥2 AF diagnoses (ICD-9-CM: 427.3), and a CHADS2 score ≥ 1 during the 180-day baseline period were included. Cohorts were matched 1:4 using propensity score methods. Study outcomes were major bleeding, intracranial hemorrhage (ICH), gastrointestinal (GI) bleeding, composite stroke and systemic embolism, and venous thromboembolism (VTE) events (deep vein thrombosis [DVT] and pulmonary embolism [PE]), and hospital costs. Sensitivity analyses were performed using rivaroxaban as the reference therapy. RESULTS: The matched sample included 3,654 rivaroxaban and 14,616 warfarin patients. Rivaroxaban was associated with significantly lower rate of treatment non-persistence (HR = 0.66, 95%CI: 0.60-0.73, p < 0.001).

CONCLUSIONS: rivaroxaban was shown to be effective in reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF) in a randomized controlled trial setting. The study objective was to assess real-world safety, effectiveness, and persistence of rivaroxaban and warfarin in nonvalvular AF patients. METHODS: Health care claims from Symphonie Health Solutions’ Patient Transactional Datasets from 5/2011-7/2012 were analyzed. Adult patients newly initiated on rivaroxaban or warfarin, with ≥2 AF diagnoses (ICD-9-CM: 427.3), and a CHADS2 score ≥ 1 during the 180-day baseline period were included. Cohorts were matched 1:4 using propensity score methods. Study outcomes were major bleeding, intracranial hemorrhage (ICH), gastrointestinal (GI) bleeding, composite stroke and systemic embolism, and venous thromboembolism (VTE) events (deep vein thrombosis [DVT] and pulmonary embolism [PE]), and hospital costs. Sensitivity analyses were performed using rivaroxaban as the reference therapy. RESULTS: The matched sample included 3,654 rivaroxaban and 14,616 warfarin patients. Rivaroxaban was associated with significantly lower rate of treatment non-persistence (HR = 0.66, 95%CI: 0.60-0.73, p < 0.001).