

**OBJECTIVES:** Romiplostim and eltrombopag are thrombopoietin receptor (TPOr) agonists that promote megakaryocyte differentiation, proliferation and platelet production. Both are orphan drugs mainly indicated for the treatment of adult chronic idiopathic thrombocytopenic splenectomised patients who are refractory to other treatments. Due to increasing platelet counts above the normal range may represent a risk for thromboembolisms, we assessed whether TPOr agonists affect thromboembolisms occurrence by a systematic review and meta-analysis of randomised controlled trials (RCTs). **METHODS:** We searched PubMed, SCOPUS, Cochrane Central Register, regulatory agencies websites and publicly available registries of manufacturers (before January 2011). RCTs using romiplostim or eltrombopag in at least one group were included. Absolute risk ratios (ARR) and number needed to harm (NNH) were calculated to provide the population health impact of the exposure. Relative risks (RR) were also provided. Data were pooled using fixed-effects models. Heterogeneity was analysed using Cochran's Q and I<sup>2</sup> tests. **RESULTS:** Of 373 publications identified, 8 studies met the inclusion criteria (n=1,180 patients). In the TPOr agonist group, as compared with the control group (e.g. placebo and/or standard of care), the meta-ARR for thromboembolisms was 1.8% (95% CI, 0.0% to 3.6%), and the meta-RR was 1.5 (95% CI, 0.7 to 3.3). Fifty-five patients would have to be treated using TPOr agonists to produce thromboembolisms in a patient (meta-NNH=55). Non heterogeneity was found (Cochran's Q test, P = 0.9; I<sup>2</sup> = 0.0%). **CONCLUSIONS:** Although the small numbers reported, thromboembolisms should be considered as identified risks for these drugs. Healthcare providers should use caution when administering these agents to patients with known risk factors for thromboembolisms.

#### PCV6

##### COMPARISON OF BLEEDING RATES BETWEEN STATIN AND STATIN-FREE PATIENTS ON WARFARIN: A CLAIMS DATABASE APPROACH

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**OBJECTIVES:** In a recent study in patients receiving warfarin, the initiation of statins that are cytochrome P450 3A4 inhibitors was associated with an increased risk of hospitalization for gastrointestinal bleeding in a Medicaid-insured population, while the initiation of pravastatin was not. The present research attempted to address some of the study limitations and assess whether similar findings are applicable in a more recent, commercially-insured U.S. population. **METHODS:** A retrospective matched-cohort design was used to compare baseline characteristics and bleeding rates (e.g. gastrointestinal and non-gastrointestinal) between statin and statin-free patients receiving warfarin concomitantly. Patients were matched on a 1:1 ratio to balance patient characteristics, and a cox proportional hazard model was used to control for confounding factors. The analyses were performed for a matched "stabilized" population, i.e., patients who had been on warfarin for ≥6 months, did not have prior bleeding events, and did not use another statin before the index date. For the matched "stabilized" populations, sub-group analyses were performed on patients with atrial fibrillation, patients with venous thrombosis, patients age ≥65 years, patients age ≥75 years, prevalent/persistent warfarin users, and by statin therapy. **RESULTS:** The method produced a small matched sample of 6306 (3.82%) out of 123,328 statin users and 41,734 statin-free patients. There were no statistically significant differences in bleeding rates between statin users and statin-free patients. Results were similar for the sub-group analyses. **CONCLUSIONS:** Using a claims database approach, high degree of heterogeneity between statin users and non-users was found, resulting in a low matching rate. This high degree of heterogeneity suggests that claims databases may be insufficient to detect/conclude as to differences in bleeding rates between statin versus statin-free patients on warfarin. Alternative methods and additional clinical information are needed to more accurately characterize bleeding rates in patients taking warfarin and a statin therapy concomitantly.

#### PCV7

##### TOBACCO ADDICTION INFLUENCE IN LATER DEVELOPMENT OF CARDIOVASCULAR EVENTS: 3 YEARS FOLLOW-UP

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**OBJECTIVES:** To determinate tobacco consumption effects on metabolic control (biochemical/anthropometrics parameters), mortality and on CVE relapses incidence during a 3 year follow-up. **METHODS:** Multicentric observational study undertaken through the retrospective review of the medical records of patients at six primary health-care centres and two hospitals. Inclusion criteria: subjects > 30 years, who requested health care after suffering a CVE between 2003 and 2007. Follow-up: 36 months. Groups: smokers, ex-smokers and non-smokers. Main measures: sociodemographics, morbidity, biochemical/anthropometrics parameters (systolic and diastolic arterial pressure (mmHg), baseline glycaemia (mg/dL), body mass index (kg/m<sup>2</sup>), serum triglycerides (mg/dL), total cholesterol (mg/dL), HDL-cholesterol and LDL-cholesterol (mg/dL)), mortality and later CVE (ischemia, infarction, strokes, ischemic accident, peripheral arthropathy). Statistical analysis: logistic regression model and Kaplan-Meier curves. **RESULTS:** 2,540 patients fulfilled the inclusion criteria (smokers: 8.4%, exsmokers: 52.9%, non-smokers: 38.7%). Mean age: 68.1 years old; men: 60.7%. By groups: patients showed a similar distributions of comorbidities. 19.1% of smokers still smoked after the first CVE. Smoking addiction was related with COPD (odds ratio, OR=2.4; 95%CI: 1.7-3.5) and depressive syndrome (OR=1.5; 95%CI: 1.1-2.2). The smoking condition mean time was 24.4 (14.5) years for smokers and 4.2 (1.2) years for ex-smokers. Comparing baseline (during hospitalization) and final (3 years follow-up), in the non-smokers group, all

parameters showed a significant reduction (8 to (8/8), in exsmokers (6/8) and in smokers group only 4/8. All mortality causes (intrahospital and follow-up included) was 4.2% (N=106; 95%CI: 3.4-5.0%), in smokers: 4.2%; ex-smokers: 5.9% and non-smokers: 1.8%; p<0.001. Incidence rate of new CVE's was 15.2% (95%CI: 13.8-16.6%) in smokers: 18.6%; ex-smokers: 16.5%; non-smokers: 9.6%; p<0.001. CVE's were present in 8.2%, 6.0% and 3.3% respectively, p<0.05. **CONCLUSIONS:** In routine medical practice, smokers compared with ex-smokers and with non-smokers still support a high future risk of suffering CVE and higher mortality rates.

#### PCV8

##### EFFECT OF SIADH ON PATIENT OUTCOMES AND HEALTH CARE RESOURCE UTILIZATION IN HOSPITALIZED PATIENTS

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**OBJECTIVES:** Syndrome of inappropriate antidiuretic hormone hypersecretion (SIADH) is a common cause of hyponatremia contributing to 30-50% of hyponatremia cases. Little is known of the influence of SIADH on healthcare resource utilization. This study assessed the effect of SIADH on inpatient total and intensive care unit (ICU) cost and length of stay (LOS), the likelihood of ICU admission, and 30-, 90-, and 180-day readmission. **METHODS:** The Premier hospital database was utilized to identify US hospital inpatients discharged between January 1, 2007 and June 30, 2009. Hyponatremic/SIADH patients were identified using primary or secondary ICD-9 codes (n=430,731) and were matched to a control group (n=430,731) using exact matching on age, gender, provider region and 3M™ APR-DRG assignment. Matching was further refined using propensity scores based on additional patient and hospital covariates. Due to the contribution of congestive heart failure and cirrhosis on hyponatremia development, these patients were excluded from the analysis. The final analytic sample contained 65,973 SIADH patients and 407,874 non-hyponatremia/SIADH patients. Cost was analyzed using gamma regression, LOS with negative binomial regression. ICU admission and hospital readmission were analyzed using multivariate logistic regression. **RESULTS:** In contrast to non-SIADH patients, patients with SIADH had significantly higher total inpatient cost (55.53%, CI=52.53-58.60; p<0.0001), ICU cost (38.07%; CI=33.18-43.15; p<0.0001), total LOS (45.11%, CI=43.20-47.03; p<0.0001), and ICU LOS (42.72%, CI=38.36-47.23; p<0.0001). SIADH patients were significantly more likely to be admitted to the ICU (OR=2.131; p<0.0001), and readmitted at 30- (OR=1.399; p<0.0001), 90- (OR=1.495; p<0.0001), and 180-days (OR=1.459; p<0.0001) in comparison with non-SIADH patients. **CONCLUSIONS:** The presence of SIADH in hospitalized patients is significantly associated with increased total and ICU cost and LOS, likelihood of ICU admission, and likelihood of readmission. Words = 297

#### PCV9

##### OPTIMAL TREATMENT SHORTFALLS AND WORSE 12-MONTH OUTCOMES FOR DIABETIC ACUTE CORONARY SYNDROME PATIENTS AFTER PERCUTANEOUS CORONARY INTERVENTION IN CONTEMPORARY PRACTICE: DATA FROM THE MULTINATIONAL, PROSPECTIVE, ANTIPLATELET TREATMENT OUTCOMES REGISTRY (APTOR)

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**OBJECTIVES:** To compare treatment and 12-month outcomes after percutaneous coronary intervention (PCI) of acute coronary syndrome (ACS) patients with and without diabetes mellitus (DM). **METHODS:** Data were from APTOR, robust, prospective, observational registries of 14 European countries from 2007-2009. Kaplan-Meier (KM) estimates 12-months post-PCI were calculated for cardiovascular (CV) event (unstable angina [UA], non-ST-elevation myocardial infarction [NSTEMI], STEMI, urgent target vessel revascularization, acute heart failure, ischemic and hemorrhagic strokes or CV death), bleeding, and mortality. **RESULTS:** A total of 21% (N=942) of patients had DM (median age: 66yrs) and 79% (N=3603) did not have DM (median age: 61 yrs). More patients with DM tended to be women (28% vs. 20%); have hyperlipidaemia (64% vs. 47%) and hypertension (75% vs. 53%); and have prior MI (28% vs. 18%) or PCI (27% vs. 16%) compared to patients without DM. For DM/non-DM patients respectively, ACS presentation was 29%/21% with UA, 35%/30% with NSTEMI, 36%/49% with STEMI; the use of glycoprotein IIb/IIIa inhibitors was 28%/33% and the use of ≥1 drug-eluting stent (DES) was 52%/39%. DM/non-DM patients received similar treatment at hospital discharge and 12-months post-PCI with the exception of ARB/ACE inhibitors at discharge (75% vs. 69%) and 12-months post-PCI (79% vs. 71%). The respective DM/non-DM 12-month outcomes were 17.3% (95% CI: 14.8-19.7%) vs. 13.8% (12.7-15.0%) for CV event, 3.0% (1.9-4.1%) vs. 2.7% (2.2-3.2%) for bleeding, and 4.9% (3.5-6.3%) vs. 1.8% (1.4-2.3%) for mortality. Optimal therapy (≥5 of the following at hospital discharge and at one-year post-PCI: aspirin, clopidogrel, statins, beta-blockers, ARB/ACE-inhibitors, and exercise or diet) was observed with 49%/42% of DM/non-DM patients. **CONCLUSIONS:** Patients with DM more often received DES and ARB/ACE but still incur worse 12 month outcomes compared to non-DM. Evidence-based prescribing post ACS-PCI is still sub-optimal and newer more potent strategies should be considered for diabetic patients to reduce the cardiovascular mortality and morbidity disparity.