and iloprost were 31% to 22% and 26% to 10%, respectively. Use of other PAH-specific medication among PGI2 users increased over time, from 62% in CY2010 to 69% in CY2014. Mean (standard deviation [SD]) annualized PGI2 costs ranged from \$99,919 (\$100,139) to \$118,861 (\$136,493) per CY. Use of parenteral PGI2 decreased over time (from 63.2% in CY2010 to 52.4% in CY2014), whereas non-parenteral PGI2 usage increased (from 39.7% to 49.5%). Other PAH-specific medications were used in the same CY for 74.1%-77.6% of non-parenteral PGI2 users, compared to 54.4%-64.3% of parenteral PGI2 users. Mean parenteral PGI2 costs in CY2010 were twice those of non-parenteral PGI2. By CY2014, parenteral PGI2 costs were 8% lower than nonparenteral costs. Mean (SD) PAH-related costs ranged from \$189,763 (\$167,329) during CY2010 to \$199,336 (\$194,638) during CY2013. **CONCLUSIONS:** While overall use of PGI2 was constant over the five-year period, our findings suggest a shift towards non-parenteral PGI2 and PGI2 combination therapy in clinical practice.

## THE ANALYZE OF CONSUMPTION OF FIXED COMBINATIONS OF DRUGS IN THERAPY OF HYPERTENSION

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OBJECTIVES: Hypertension is one of the major risk factors for occurrence cardiovascular disease. Drugs of the first choice in the treatment of hypertension are: diuretics, beta adrenergic blockers, calcium channel blockers, angiotensin converting enzyme inhibitors and inhibitors of angiotensin II receptor. Fixed combinations of antihypertensive drugs simplify treatment and enhance patient compliance. The aim of this study was to analyze consumption fixed combinations of drugs for the treatment of hypertension in the Republic of Serbia in the 2011-2012 year and to compared it with the results of Finland and Norway in the same period. **METHODS**: Consumption of officinals is expressed by the number of defined daily doses per 1000 inhabitants per day (DDD) according to the anatomical therapeutic chemical classification. Data on consumption of drugs are taken from the official web site for the period 2007-2012. year from the Agency for drugs and medical devices of Serbia, Finnish Medicines Agency Fima and Norwegian Institute of Public Health. RESULTS:: Fixed combination of converting enzyme inhibitors with diuretics are most frequently used drugs in Serbia (2007 (18,86 DDD), 2008 (26,61 DDD), 2009 (30,77 DDD), 2010 (27,30 DDD), 2011 (43,72 DDD) and 2012 (55,52 DDD)) compared with Norway and Finland. The use of these drugs is on the rise in Serbia. In the opposite side use of angiotensin II antagonists and diuretics in Serbia is significantly lower (2007 (0,10 DDD), 2008 (0,07 DDD), 2009 (0,12 DDD), 2010 (0,19 DDD), 2011 (0,73 DDD) and 2012 (1,70 DDD)) compared with Norway and Finland. CONCLUSIONS: Based on the results, we concluded that the use of fixed combination of drugs in therapy of hypertension in Serbia must be modified. This research was supported by Provincial Secretariat for Science and Technological Development, Autonomous Province of Vojvodina project No 114-451-2458/2011 and by Ministry of Science, Republic of Serbia, project no 41012

# A ONE-YEAR FOLLOW-UP OF INDIVIDUALS WITH DIABETES AT VERY HIGH CV RISK TREATED WITH STATINS: OUTCOMES AND HEALTH CARE COSTS

Maggioni AP1, Rossi E2, Cinconze E2, Calabria S3

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Reno, Italy, <sup>3</sup>CORE, Collaborative Outcome Research, Bologna, Italy OBJECTIVES: To assess, in a community setting, the clinical and economic outcomes of individuals with diabetes at very high cardiovascular (CV) risk (patients with type 2 or type 1 diabetes, with target organ damage, such as microalbuminuria - ESC/ EAS Guidelines 2011). METHODS: Data for over 2.9 million subjects were extracted from 6 Local Health Units (ARNO Observatory, an administrative database containing data on hospitalizations, prescriptions and diagnostic/outpatient visits). The index period lasted from January 1 to December 31, 2011. RESULTS: Of the 2,989,512 subjects identified, 101,217 patients (3.4%) had diabetes with very high CV risk. 82.9%were aged over 60 years. At 1-year follow-up, 46.1% were prescribed statin therapy, of which 56.9% being prescribed high intensity statins (Atorvastatin 40, 80 mg/dL, Rosuvastatin 20, 40 mg/dL). Adherence to treatment (20% tolerability in one year follow-up treatment - CORE Study 2013) was higher among high intensity statin users compared to low intensity statin users (53.6% vs 40.1%). Over the 1-year follow-up period, 23,116 patients (22.8%) were hospitalized for any CV events. The average yearly cost per patient, on the high risk diabetic patients, supported by NHS was 3,001 e/year (hospitalizations: 1,555e; drugs: 998e; diagnostic and outpatient visits: 449e). **CONCLUSIONS:** In this community hospital setting, diabetic patients at very high risk of CV were frequently hospitalized for CV events. Although at high risk, less than 50% of patients was prescribed on statin therapy and adherence was suboptimal. Individuals with diabetes at very high CV risk utilize a significant portion of economic resources, hospitalization being the main cost driver. Local Health Authorities together with Physicians and Patient Associations are working to close the gap between the existing evidence-based recommendations and current clinical practice which could result in a reduction of both diabetes morbidity and health cost.

# CHOICE OF ANTITHROMBOTIC DRUG IN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS IN REAL-WORLD PRACTICE

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**OBJECTIVES:** To assess the level of adherence to the guidelines for the prevention of thromboembolic risk in patients with Non-Valvular Atrial Fibrillation (NVAF). METHODS: A population-based cohort study was conducted using administrative data from a local health authority in the Campania Region (~1,000,000 inhabitants). NVAF was defined as one or more claims for atrial fibrillation (ICD-9-CM code 427.31) between July, 2013 and June, 2014 where none of the claims were associated with cardioversion or cardiac ablation during the identification period and there was no evidence of valve-related diagnoses or procedures. The cohort was

classified according to the first drug dispensing during 6 months from the discharge date. Patients were categorized in low ischemic stroke (CHA2DS2-VASc) (LR, score=0), moderate-risk (MR, score=1), high-risk (HR, score≥2). Multivariable logistic regression was used to evaluate the associations between ischemic stroke and bleeding (HAS-BLED) risk with the choice of non-vitamin K antagonist oral anticoagulants (NOACs) versus vitamin K antagonists (VKAs) therapy. RESULTS: A total of 1,963 patients were identified: 4.9% LR, 7.6% MR and 87.5% HR patients. Overall, 36.4% of patients were not treated (LR: 56.7%, MR: 55.0%, HR: 33.7% patients). Among patients treated, VKA in monotherapy was prescribed to 26.7% of the patients (LR: 23.8%, MR: 26.9%, HR: 26.8%), aspirin in monotherapy to 27.5% (LR: 31.0%, MR: 34.3%, HR: 27.0%), NOAC in monotherapy to 19.3% (LR: 23.8%, MR: 17.9%, HR: 19.2%), other antiplatelet in monotherapy to 19.4% (LR: 16.7%, MR: 13,4%, HR: 19.8%), and associations to 7.1% (LR: 4.8%, MR: 7.5%, HR: 7.2%). The ischemic stroke and bleeding risks were not significantly associated with the choice of anticoagulant drug. CONCLUSIONS: High proportion of NVAF patients with moderate or high stroke risk did not receive antithrombotic therapy as recommended by guidelines. Moreover, aspirin was commonly prescribed even in HR patients. The risk stratification did not influence the choice of anticoagulant drug.

# EPIDEMIOLOGY OF PATIENTS AFFECTED BY ACUTE CORONARY SYNDROME (ACS) TREATED WITH STATINS FOR HYPERCHOLESTEROLEMIA FROM ITALIAN ADMINISTRATIVE OFFICIAL DATABASES

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**OBJECTIVES:** The aim of this study was to assess the prevalence and characteristics of subjects with a recent ACS episode (in the year preceding statin prescription) appropriately treated with high-efficacy statins, and who have inadequate control of LDL-C levels, despite being adherent to treatment METHODS: An observational retrospective cohort analysis based on five Local Health Units administrative databases was conducted, for a total number of 1.2 Million beneficiaries. Patients who have been hospitalized with ICD9 code 410 in the year preceding their first statin prescription (between January 1, 2011 and December 31, 2012) were included. Patients were characterized back 12 months from index date to assess appropriateness and adherence to statin treatment **RESULTS:** Among patients with recent ACS enrolled (1'098 patients), 549 (50%) had no LDL-C determination, 335 (31%) and 214 (19%) displayed LDL-C under control and out of control, respectively. Among patients with uncontrolled LDL-C, 16 (7%) and 198 (93%) were not treated and treated with statins, respectively. Among patients with statins treatment, 27 (14%) and 171 (86%) were treated with low and high efficacy statins, respectively. Finally, among patients treated with high efficacy statins, 115 (67%) and 56 (33%) were non-adherent and adherent to high efficacy statin treatment, respectively. LDL-C uncontrolled high efficacy adherent patients showed different distances from their lipid target: 33.9% were less than 10% distant, 16.1% were 10-19% distant, 14.3% were 20-29% distant, 12.5% were 30-39% distant and 23.2% were more than 40% distant CONCLUSIONS: These results are topical, as new monoclonal antibodies are being marketed to address the unmet need in cholesterol statin-management of dyslipidaemia for uncontrolled patients. By projecting study percentages to the Italian population, the number of LDL-C measured patients with a recent ACS episode who are uncontrolled, despite being adherent to a high efficacy statin, would be around 6'524

# A RETROSPECTIVE, CROSS SECTIONAL STUDY ON THE PREVALENCE OF HYPERTENSION AND TREATMENT STATUS IN OBESE PATIENTS USING A HEALTHCARE DATABASE IN JAPAN

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<sup>1</sup>Pfizer Japan Inc, Tokyo, Japan, <sup>2</sup>MinaCare co.ltd, Tokyo, Japan OBJECTIVES: In Japan, real-world evidence regarding impact of obesity on the prevalence of hypertension is lacking. The objective of this study was to investigate the prevalence and treatment status of hypertension in obese patients, with a focus on resistant hypertension. **METHODS:** This was a retrospective study using a Japanese healthcare database composed of annual health checkup and claims data (MinaCare Co. Ltd.). Subjects aged >=20 years at 2012 health checkup with 2 years (2011/2012) of checkups were selected for the study. Diagnosed hypertensive subjects (ICD-10 codes I10-I15) who were prescribed with antihypertensive medications within 1 year prior to checkup were defined as "treated". Resistant hypertension was defined as uncontrolled hypertension (SBP/DBP>=140/90mmHg) with 3 classes of antihypertensives including diuretics, or the use of >=4 classes. **RESULTS:** A total of 462,323 subjects (32% female, 68% male) were analyzed. The age category 40-<50 years accounted for the largest proportion (35%) of the sample. The mean BMI was 21.8/23.7 and the proportion of obese subjects (BMI>=25) was 16.0%/29.9% (female/male). Approximately 10.4% of the subjects were "treated". For each age, sex, and treatment category, the prevalence of hypertension (defined as SBP/DBP>=140/90mmHg or "treated") increased with increasing BMI. In particular, males in 40-<50 age category, odds-ratio for the prevalence of hypertension versus BMI 18.5-<25 were 0.601, 3.607, 7.405, 15.445 for BMI categories <18.5, 25-<30, 30-<35, 35-<40, 40-, respectively. The prevalence of resistant hypertension among those diagnosed and prescribed with antihypertensives was consistently higher for obese subjects (vs non-obese) for each sex and age category; in particular, it was 4.1% (obese) vs 8.7% (non-obese) for males in 40-<50 age category. CONCLUSIONS: We demonstrated that prevalence of resistant hypertension as well as that of hypertension increased with increasing BMI using healthcare database in Japan. These results reconfirm the impact of obesity in the treatment and control of hypertension.

# EPIDEMIOLOGY OF STATIN-TREATED PATIENTS WITH UNCONTROLLED LDL LEVELS FROM ITALIAN ADMINISTRATIVE OFFICIAL DATABASES

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OBJECTIVES: The aim of this study was to assess the prevalence and characteristics of subjects appropriately treated with high-efficacy statins, and who have inadequate control of LDL-C levels, despite being adherent to treatment METHODS: An observational retrospective cohort analysis based on five Local Health Units administrative databases was conducted, for a total number of 1.2 Million beneficiaries involved. Patients with at least one LDL-C measurement between January 1, 2011 and December 31, 2012 were included. Patients were characterized back 12 months to assess appropriateness and adherence to statin treatment RESULTS: Among patients with LDL-C determination (1'218 patients), 578 (47%) and 640 (53%) displayed LDL-C under control and out of control, respectively. Among patients with uncontrolled LDL-C, 74 (12%) and 566 (88%) were not treated and treated with statins, respectively. Among patients with statins treatment, 188 (33%) and 378 (67%) were treated with low and high efficacy statins, respectively. Finally, among patients treated with high efficacy statins, 225 (60%) and 153 (40%) were non-adherent and adherent to high efficacy statin treatment, respectively. LDL-C uncontrolled high efficacy adherent patients showed different distances from their lipid target: 28% were less than 10% distant, 28.4% were 10-19% distant, 10.5% were 20-29% distant, 11.1% were 30-39% distant and 24.8% were more than 40% distant CONCLUSIONS: These results are topical, as new monoclonal antibodies - PCSK9 inhibitors - are being marketed to address the residual unmet need in cholesterol statin-management of dyslipidaemia for uncontrolled patients. By projecting study percentages to the Italian population, the number of LDL-C patients who are uncontrolled, despite being adherent to a high efficacy statin, would be around 17'825

## ASSESSING RETROSPECTIVE DATA ON THE MANAGEMENT OF ISCHEMIC STROKE

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OBJECTIVES: To identify the characteristics and assess the treatment of patients diagnosed with ischemic stroke. It was also performed to compare the management of ischaemic stroke between current practice with the recommended guideline. METHODS: Retrospective reviews of the medical records of patients who were diagnosed with ischemic stroke at the medical record's office in a teaching hospital from January 1, 2013 to December 31, 2013. Patients' medication for the treatment of stroke at discharge were reviewed and identified. RESULTS: A total of 198 patients were diagnosed with ischemic stroke. This was found to be higher in men 104 (52.5%). In this study of 198 patients, 108 (54.5%) patients were diagnosed with newly onset of stroke and 28 (14.1%) patients were diagnosed with recurrent stroke. The major co-morbidities identified were the combination of hypertension and diabetis mellitus and hypertension alone, which were seen in 45 (22.7%) patients and 39 (19.7%) patients respectively. Aspirin and statin were the most commonly prescribed agent, which were 170 (85.9%) and 182 (91.9%) respectively. CONCLUSIONS: Majority of our patients are male, Malay and in the age range of 50-59. These patients had underlying hypertension and diabetes upon their diagnosis of ischemic stroke. Aspirin and statin were mostly prescribed and widely used to treat ischaemic stroke. The current guidelines appear to have some influence on the current practice of the management of ischemic stroke.

## EPIDEMIOLOGICAL BURDEN AND MANAGEMENT OF HYPERCHOLESTEROLEMIA IN HIGH CARDIOVASCULAR RISK PATIENTS IN SPAIN: A COMPREHENSIVE PICTURE FROM A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: Elevated serum cholesterol levels are a well-known cause of cardiovascular events. The objectives of this study were: to review the epidemiology of hypercholesterolemia in Spain; to detail the proportion of diagnosed patients undergoing pharmacological treatment (PhT); the degree of attained lipid control, and associated medical costs. METHODS: A systematic literature review was carried out using Medline (pubmed) and Spanish databases as Medes and Biblioteca Virtual de la Salud. Manuscripts containing information on heterozygous familial hypercholesterolemia (HeFH); hypercholesterolemia in primary prevention (PP) (diabetes mellitus or SCORE risk >5) or secondary prevention (SP), published between January 2010 and October 2014, were included. **RESULTS:** Of the 1,947 published references initially retrieved, a full text review was done on 264 manuscripts and 120 were finally included Prevalence of hypercholesterolemia ranged from 50%-84% in diabetics, 30%-60% in patients with high cardiovascular risk, 64%-74% with chronic coronary heart disease, 33%-97% in acute coronary syndromes, 40%-70% in stroke patients, and 60%-80% in those with peripheral artery disease. Despite the finding that 30%-90% of patients were on pharmacological treatment, lipid control was found only in 15%-65% of cases in primary prevention and in 15%-56% of patients in secondary prevention. Among those with HeFH 95%-100% were treated but less than 16% achieved LDL-c target. CONCLUSIONS: An elevated prevalence of hypercholesterolemia can be seen in targeted groups at higher cardiovascular risk. Although most patients are receiving pharmacological treatment, rates of control continue to be low, both in primary and secondary prevention.

## BENEFIT-RISK OF VKA FOR ATRIAL FIBRILLATION BEFORE DOAC: A COHORT STUDY IN A CLAIMS AND HOSPITALIZATION DATABASE

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OBJECTIVES: To assess real-life outcomes in new Vitamin K antagonists (VKA) users for atrial fibrillation (AF), before introduction of direct oral anticoagulants (DOAC) for non-valvular AF (NVAF).  $\mbox{\bf METHODS:}$  Cohort study of new VKA users between

2007-2011, with a 2-year history and a 3-year follow-up censored at the end of 2012, was designed in the EGB, a 1/97 random sample of the French national healthcare claims and hospitalization database. AF population was defined as patients with full coverage for AF, hospitalization or probabilistic AF information in the database, and without other probable cause of VKA prescription. NVAF population was defined as patients of the AF population without valvular disease history. Outcomes were the first hospitalization for bleeding, arterial thrombotic event (ATE), acute coronary syndrome (ACS), and death. Incidence rate of outcomes was estimated during VKA exposure. RESULTS: Among 8,894 patients identified, 3,345 were classified in the AF population (3,977 person-years (PY)). Half were male (52%) with a mean age of 75 years, 87% had a CHA2DS2-VASc score ≥2, and 12% a HAS-BLED score >3. The incidence rate of bleeding was 28 patients (95%CI [23-34]) for 1,000 PY exposed to VKA, including 6 [3-8] cerebral, 10 [7-13] digestive, and 14 [10-17] other bleeds. Incidence rates were 16 [12-20] for ACS, 15 [11-18] for ATE, and 38 [32-44] deaths for 1 000 PY exposed to VKA. Patient characteristics and incidence rates were very close for the 2 818 patients with NVAF population criteria (3,367 PY). For this last population, incidence rates were 28 [22-34] for bleeding, 16 [12-20] for ACS, 15 [11-19] for ATE, and 35 [29-41] deaths for 1 000 PY exposed to VKA. **CONCLUSIONS:** This study provides background reference for bleeding, ischemic events, and deaths before introduction of DOAC for NVAF with quite same frequency for AF and NVAF populations.

# IMPACT OF GENETIC FACTORS ON GASTROINTESTINAL BLEEDING IN A PROSPECTIVE COHORT OF NEW WARFARIN USERS

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OBJECTIVES: Genetic factors have a great impact on the therapeutic dose of warfarin, a commonly prescribed anticoagulant. We still don't consider them when prescribing warfarin, despite the high incidence of major and minor gastrointestinal (GI) bleeds. We evaluated the potential differential impact of warfarin-related GI bleeds risk factors according to the partient's genetic profile. METHODS: This study is based on a prospective cohort of new warfarin-users whose objectives were to assess the genetic, clinical and environmental risks associated with the effectiveness and safety of warfarin. Data was collected on 1069 patients who began the treatment between May 2010 and July 2013. Patients were followed-up each three months up to a year. The outcomes were minor and major GI bleeds. We used a multivariate Cox regression analysis. RESULTS: Mean age was 70.8, 61.8% of patients were men, 68.4% had a history of hypertension and 60.8% of dyslipidemia and 76.4% had atrial fibrillation as a primary indication for warfarin. Overall, 4.8% of patients reported  $\geq 1$  minor GI bleed and 1.6% reported  $\geq\!1$  major GI bleed. Patients with  $\geq\!1$  polymorphism on both the CYP2C9 and the VKORC1 were significantly more at risk of having a major GI bleed (HR 10.72; p=0.023). Patients with a history of MI or angina were at risk of having both minor and major GI bleeds (HR=1.73 and HR=2.63; p<0.05). The impact of MI and angina disappeared for patients with no SNP on the CYP2C9 gene but was higher for patients with ≥1 SNP (HR=2.44 and HR=5.26, p<0.05). CONCLUSIONS: Our results suggest an interaction between MI or angina history and the occurrence of major and minor GI bleeds, especially in patients with  $\geq 1$  polymorphism on the CYP2C9 gene. Further analysis including concomitant drug use would help clarify clinical guidelines for this population and underlie the potential benefit of genetic testings.

# HOSPITAL READMISSIONS AND MORTALITY PATTERNS IN A COHORT WITH HEART FAILURE: 1 YEAR FOLLOW-UP FROM THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM DATABASE

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OBJECTIVES: Heart failure (HF) affects 1.6 million people in Brazil. About 30%-40% progress to death in a year. This study aims to report 1-year retrospective analyses of hospital readmissions and mortality patterns associated to HF or all-other causes (OC) in a Brazilian cohort of patients with HF. METHODS: Brazilian Hospital Information System (SIH/SUS) database was used to collect hospital readmissions and mortality data associated to HF or OC, according to ICD-10 codes (I50.0 and I50.9, and "others", respectively). Patients were followed during 1 year (January-December 2014, regardless the entry data). Eligible criteria included patients with one previous HF hospital admission. RESULTS: A cohort of 21,015 patients was considered eligible. No HF or OC hospital readmissions were observed for 13,050 (62%) and 5,241 (25%) patients, respectively. For HF, 1, 2, 3, 4, and 5 re-hospitalizations were observed for 6,053, 1,255, 395, 152, and 59 patients. One patient required ten re-hospitalizations and the same occurred for 12 and 15 hospital readmissions. Therefore, about 38%, 9%, 3% and 1% of all patients had 1, 2, 3 or 4 hospital readmissions at least. OC readmissions showed higher number of patients for each amount of hospitalizations (11,046, 2,965, 989, 415, and 184 for 1, 2, 3, 4, and 5, respectively). Seven patients required ten re-hospitalizations and 1 required 19. Compared to HF, OC showed approximately twice of all patients with 1 hospital readmission at least (75%). Mortality rate was 19.23%, 702 (3.34%) due to HF and 2,632 (12.52%) due to OC. CONCLUSIONS: The number of patients requiring hospitals readmissions for HF remain significant, despite available treatment options in Brazilian Public Healthcare System. OC results showed higher numbers, however, for this analysis all-other hospitalizations causes were included (except HF) indicating a high presence of comorbidities among this population and/or a misregistration at hospitalization time.

# HEART FAILURE IN A HEALTH AREA OF MADRID, SPAIN. DESCRIPTION AND MANAGEMENT FROM ELECTRONIC MEDICAL RECORDS

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