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OBJECTIVES: Data are limited on the course of patients after an acute venous thromboembolism (VTE) event under clinical practice conditions. **METHODS:** We present current data on the re-hospitalization of patients with deep venous thrombosis (DVT) or pulmonary embolism (PE) from the PREFER in VTE registry in 7 Western European countries (France, Italy, Spain, Germany, UK, Austria and Switzerland). The current interim analysis includes data of 2863 patients. 1689 patients had DVT alone and 1174 had PE (±DVT) as qualifying event for inclusion. **RESULTS:** At baseline, 72.2% of the patients received heparin, 11.9% fondaparinux, 48.0% vitamin K antagonists, 25.4% non-VKA oral anticoagulants, 7.0% acetylsalicylic acid, 2.1% other antiplatelets and 1.6% thrombolysis agents. Within the first 6 months, 14.7% of VTE patients were hospitalized for any reason (DVT: 12.9%, PE: 17.5%). Hospitalization rates varied between countries (Spain 10.7%, Germany 10.8%, France 12.5%, Italy 19.3%, UK (at 3 months) 7.5%). The mean number of hospitalizations was 1.3 ±0.85 (1.1 to 1.5 in the various countries; median 1, range 1-6). The documented reasons for hospitalization, among others, were VTE (15.3%), surgery/trauma (13.5%), bleeding (7.4%), or stroke/TIA (3.7%). Mean duration of all combined hospital stays was 9.8 ±12.61 days (4.0 days in Germany, 4.7 in France, 9.0 in Spain, 14.0 in Italy). The overall median duration of hospitalization was 6 days (interquartile range 2-12), for DVT cases it was 6 days (IQR 3-13), for PE cases it was 5 days (IQR 2-11). **CONCLUSIONS:** Under real-life conditions, one in seven patients had to be readmitted to hospital in the first 6 months after the DVT or PE event. However, the majority of hospitalizations were not due to the thromboembolic disease or bleeding. The duration of hospital stays showed a wide range across Western European countries.

PCV2

DISCONTINUATION AND HOSPITALISATION RATES IN PATIENTS WITH ATRIAL FIBRILLATION: FOLLOW-UP RESULTS OF THE PREFER IN AF REGISTRY

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OBJECTIVES: The great majority of patients with atrial fibrillation (AF) require lifelong antithrombotic therapy for prevention of stroke. For optimal treatment, it is important to investigate treatment discontinuations, as those might be associated with increased hospitalization rates. As potential indicator for unstable anticoagulation efforts we assessed hospitalization rates for non-vitamin K antagonist oral anticoagulants (NOAC) and for warfarin under real-life practice conditions. **METHODS:** PREFER in AF (The PREvention oF thromboembolic events – European Registry in Atrial Fibrillation) is a prospective non-interventional disease registry of patients with AF in 7 countries in Western Europe. Discontinuation rates were assessed looking at all patients (n=6412), whereas hospitalization rates reported at Baseline (BL) and 1 year Follow-Up (FU) focused on two groups: patients treated with warfarin (BL=1379, FU=1571) and patients treated with NOAC (BL=194, FU=424). Descriptive statistics were applied. **RESULTS:** Out of 6412 patients, 9 to 18% of patients treated with vitamin K antagonists (VKA) discontinued therapy (warfarin 10.3%, phenprocoumon 9%, acenocoumarol 10.4%, fluinidone 18%). The discontinuation rates for patients on NOAC were 9.4% for rivaroxaban and 10.3% for dabigatran, respectively. Reported hospitalization rates (irrespective of reason) were 19.8%/10.0% for NOAC, and 24.1%/11.6% for warfarin at BL or FU, respectively. Mean duration of hospitalization was 1.3±4.0/ 0.9 ±5.1 days for NOAC, and 2.0±6.1/ 1.0 ±4.2 days for warfarin. **CONCLUSIONS:** No major differences were observed in the discontinuation rates between VKA and NOAC on the class level nor the various available NOAC drugs. Hospitalization rates and corresponding number of days in hospital reported at BL were substantially higher compared to FU. Patients on NOAC had lower hospitalization rates and less days in hospital compared to those on warfarin. Further analyses are needed to explore the reasons for hospitalizations.

PCV3

THE ADDITIONAL COSTS OF CLINICAL COMPLICATIONS IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE REPLACEMENT IN THE GERMAN HEALTH CARE SYSTEM

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OBJECTIVES: Transcatheter aortic valve replacement (TAVR) is a relatively new alternative to surgical replacement of the aortic valve. Recent development of third generation systems and new products have shown reductions in the frequency and severity of complications associated with the procedure. The aim of this study was to identify the cost impact of complications for patients undergoing TAVR in a German hospital. **METHODS:** Data was derived from a prospective observational study, whereby a total of 163 consecutive patients were treated either with transfemoral (TF-, n=97) or transapical (TA-) TAVR (n=66) between February 2009 and December 2012. Predefined clinical endpoints were analyzed, "in-hospital" costs determined from the hospital perspective (2012=100) and results reported within the seven most relevant cost categories. **RESULTS:** TF-TAVR patients experienced more minor access site bleeding (p=0.017), major non-access site bleedings (p=0.026), minor vascular complications (p=0.002), stage 2 acute kidney injury (AKI, p=0.043) and permanent pacemaker implantation (p<0.001) compared with TA-TAVR. However, total in-hospital costs did not differ between groups (mean €40,348; SD €15,851). Costs were proportioned in either categories (staff = 26%, materials = 62% and infrastructure = 12%) or units (normal ward = 13%, ICU = 15%, catheter laboratory or operating room = 62% and other = 10%). The average additional cost of any single complication was €3,438 (p<0.01). Life-threatening non-access site bleeding was associated with the highest additional costs (€47,494; p<0.05), followed by stage 3 AKI (€20,468; p<0.01), implantation of a second valve (€16,767; p<0.01) and other severe cardiac dysrhythmia (€10,611 p<0.05). Interestingly, censoring cases of in-hospital mortality is associated with a substantial decrease in the additional costs. **CONCLUSIONS:** Bleeding complications, severe kidney failure, and implantation of a second valve are the most important cost drivers in TAVR patients, and strategies to reduce those complications may have the potential to generate significant in-hospital cost reductions.

PCV4

CLOTTING FACTOR (CF) PRODUCT USE AND SAME-DAY RISK FOR THROMBOTIC ADVERSE EVENTS (TES), AS RECORDED IN LARGE HEALTH CARE DATABASE DURING 2008-2013 STUDY PERIOD

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OBJECTIVES: There has been an increase in the number of clotting factor (CF) products available in the U. S. in recent years. Thrombotic events (TEs) are serious adverse events that can occur following administration of CFs. The objective of this study is to assess the same-day TE risk following exposure to CF products. **METHODS:** A retrospective cohort study of individuals exposed to CF products during January 2008 through June 2013 was conducted using HealthCore Integrated Research Database (HIRD[SM]). CF products were identified by Health care Common Procedure Coding System (HCPCS) codes, and TEs were ascertained via ICD-9-CM diagnosis codes. Crude same-day TE rates (per 1,000 persons exposed) were estimated overall, by congenital clotting factor deficiency status and by specific CF products, age, and gender. **RESULTS:** Of 3,801 individuals exposed to CFs, 117 (30.8 per 1,000 persons) had TEs recorded on the same-day as CF exposure. The crude same-day TE rate (per 1,000) was higher for CF users without congenital CF deficiency, 70.2 (102 of 1,452), as compared to those with congenital CF deficiency, 6.4 (15 of 2,349), unadjusted rate ratio of 11.0 (95% CI 6.4-18.9). For individuals without congenital CF deficiency, the crude TE rates (per 1,000) were 15.9 for under 15 years of age, 16.1 for 15 to 44 years, 62.8 for 45 to 64 years, and 160.9 for 65 years and older. The unadjusted same-day TE rates (per 1,000) ranged from 12.8 for Factor VIII to 204.1 for Factor IX complex product(s). Multivariable analyses are underway to control for potential confounders and identify recipient risk factors. **CONCLUSIONS:** The study shows an increased risk of same-day TEs for CF users without congenital CF deficiency and suggests a potentially substantial off-label use of CFs, which needs further investigation. In addition, study findings suggest elevated same-day TE rates for specific CF products with additional multivariable investigation ongoing.

PCV5

THE EFFECT OF ATRIALA FIBRILLATION IN ACUTE MYOCARDIAL INFARCTION PATIENTS IN TAIWAN

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OBJECTIVES: Acute myocardial infarction (AMI) is a major cause of mortality and disability worldwide. AMI occurs when blood flows irregularly into heart and thus heart muscle is injured due to insufficient constant oxygen received. It will cause severe complications or co-morbidities if the condition is lasting. Hence, we hypothesized the atrial fibrillation (AF) is an independent risk factor to the major severe cardiovascular events (MACE) after AMI occurred. **METHODS:** The AMI patient is defined by the patient treated in the emergency room at the beginning of the illness. Frequencies and costs of AMI data were extracted from the National Health Insurance Research Database for this observational retrospective cohort study between 2007 and 2012 in Taiwan. ICD-9-CM 410 was used to extract the AMI patients. Fisher's exact test and categorical data analytic method were utilized to assess the AF as a risk factor to MACE in the AMI patients. **RESULTS:** We mainly focused on the AMI adults without any prior MACE occurred. As a result, there were 3,452 AMI who can be divided into 2 groups: 2,939 AF patients and 513 non-AF patients. The average medical cost was USD$ 3142.8 and the mean LoS was 10.4 days with st. d. 29.0 days. There were 1,791 MACE identified among the AF patients (60.9%), while there were 251 MACE among the non-AF patients (48.9%). In consequence, the AMI with AF resulted more MACE than those in non-AF (RR = 1.63, C.I. = (1.35, 1.97), p <0.0001). The difference of cost was not significant between both groups. The mean LoS in AF was 16.6 days, which was significantly smaller than that in non-AF (19.1 days). The difference was probably due to higher fatalities in AF. **CONCLUSIONS:** This study has demonstrated that AF risk is associated with MACE in patients after AMI occurred.

PCV6

DEVELOPMENT OF A COLLABORATIVE EUROPEAN PHARMACOEPIDEMIOLOGIC POST-AUTHORIZATION SAFETY STUDY (PASS) PROGRAMME EXAMINING RIVAROXABAN USE IN ROUTINE CLINICAL PRACTICE

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BACKGROUND: Proactive, post-authorization monitoring of drug safety and effectiveness is of increasing importance. Rivaroxaban is a Factor Xa inhibitor with multiple indications, including: treatment of venous thromboembolism (VTE) and prevention of recurrent VTE; stroke prevention in atrial fibrillation; and prevention