and warfarin do not differ significantly in real-world rates of composite stroke and myocardial infarction, major, intracranial, or GI bleeding. Rivaroxaban was associated with significantly fewer VTE events and better treatment persistence compared with warfarin.

PCV6  RISK OF NEW ONSET DIABETES WITH ROSUVASTATIN THERAPY AND QUALITY OF LIFE

Siwalka A, Khan A, Gut M, Rastry S, Sakharkar P

Roosevelt University College of Pharmacy, Schaumburg, IL, USA

OBJECTIVES: Statins have been shown to significantly reduce the cardiovascular risk. In recent studies, high potency statins have been associated with elevated fasting plasma glucose (FPG) and glycated hemoglobin A1C (HbA1C) level. Rosuvastatin is widely prescribed statin medication for treating dyslipidemia. A systematic review was conducted to examine rosuvastatin’s effect on glycemia levels and quality of life. Methods: Medical searches were conducted in US and non-US databases. Trials represented changes in FPG, HbA1C, incidence of new onset diabetes and quality-adjusted life years (QALYs) with rosuvastatin therapy were included in this systematic review. Studies that were open label, non-randomized, observational, with combination therapies, case series, and 16 health outcomes studies, three clinical (n = 24,714, rosuvastatin arm = 12,332) and four outcomes studies met the inclusion criteria. The mean study follow up ranged from 1.9 to 3.9 years. Incidence of diabetes was reported in 55% (4.8%) patients in rosuvastatin arm compared to 51% (4.7%) in placebo arm (HR 1.3, 95% CI 1.306-1.291). Only one study reported median change in FPG (4mg/dl) and HbA1c (0.2%) on two years of therapy QALYs gained over a lifetime with rosuvastatin therapy in patients with cardiovascular risk score (FRS) ≤ 10% was estimated 0.14, FRS-10% 0.33, and with FRS-20% 0.42 per patient, respectively. Rosuvastatin therapy for primary or secondary prevention of cardiovascular events in a high-risk population showed a median change in FPG levels (mg/dl) compared to low risk patients from 8.7 to 9.0.

CONCLUSIONS: Overall, there was an increase in new onset diabetes with rosuvastatin therapy. However, the benefit of reducing cardiovascular risk and improved quality of life with rosuvastatin therapy outweighs the risk of diabetes.

PCV7  RISK OF DIABETES IN PATIENTS ON ATORVASTATIN THERAPY FOR TREATING HYPERCHOLESTEROLEMIA

Khan A, Gut M, Siwalka A, Rastry S, Sakharkar P

Roosevelt University College of Pharmacy, Schaumburg, IL, USA

OBJECTIVES: Statins have been shown to significantly reduce the risk of heart attack and stroke. However, in recent studies, there were found to raise blood sugar levels resulting in diabetes. Atorvastatin is most widely prescribed medication among statins for treating hypercholesterolemia. A systematic review of randomized clinical trials (RCTs) was conducted to evaluate Atorvastatin’s effect on glycemia levels and incidence of diabetes. METHODS: MEDLINE, PubMed, Google Scholar and Cochrane Central Register of Controlled Trials (CENTRAL) were searched through July 2013. RCTs that evaluated Atorvastatin in patients with hypercholesterolemia and reported at least one of the following: glycated hemoglobin (HbA1C), fasting blood glucose and new onset of diabetes were included. Studies that were open label, shorter than four weeks, and published in other than English language were excluded. The primary outcome measure was change from baseline in fasting glucose, HbA1C level and/or development of diabetes. RESULTS: The final analysis of this systematic review included four RCTs out of 104 full text articles retrieved the onset our inclusion criteria. The study population in these studies ranged from 3,806 to 7,461 with a follow up ranging from 3 to 4.9 years. The change from baseline of fasting glucose blood ranged between 8 to 10.6mg/dL and the incidence of new onset diabetes reported ranged from 4.2% to 9.3%. Atorvastatin doses studied were 40 and 80mg. Studies included in this systematic review showed high degrees of heterogeneity in data reporting and analyses. CONCLUSIONS: Use of Atorvastatin in these studies showed a significant increase in fasting blood glucose and development of diabetes. However, high degree of study heterogeneity limited finding’s generalizability to a larger population. Atorvastatin’s cardiovascular benefit still clearly outweighs the potential risk of reported incident diabetes. Physicians should weigh the risks and benefits when prescribing Atorvastatin for their patients in treating hypercholesterolemia.

PCV8  ESTIMATING THE RISK OF ANGOEDEMA ASSOCIATED WITH USE OF DIPETIDYLPEPTIDE INHIBITORS

Ramachandran S

University of Cincinnati, University, MS, USA

OBJECTIVES: To estimate the risk of angioedema and angioedema related side-effects caused by the use of dipetidylpeptide inhibitors (DPP-4), angiotensin converting enzyme inhibitors (ACEI) and their interaction in patients suffering from diabetes mellitus and hypertension. METHODS: A retrospective analysis employing a case control design was performed using Mississippi Medicaid fee-for-service data from January 1st 2008 to December 31st 2012. Beneficiaries using oral anti-diabetics or diuretics were included in the study cohort. Angioedema was identified using ICD-9-CM codes in the medical claims dataset. Beneficiaries with and without an incidence of angioedema were matched based on age, sex, race and whether they had diabetes or hypertension. Drug use was analyzed in the 180 days before the incidence of angioedema. RESULTS: A total of 10,449 cases were obtained. Women comprised nearly 70% of the population after matching the cases. 62% of the population was African American and nearly 30% was Caucasian. 8% of the population had diabetes alone and approximately 15% had both diabetes and hypertension. 77% of the population was identified as having only hypertension. Only seven controls and none of the cases were found to be using DPP-4, either alone or along with ACEI, in the study period. None of the patients in this study had an incidence of angioedema. No evidence was found to support the hypothesis that DPP-4 increase the incidence of angioedema when used alone or in combination with ACEIs. CONCLUSIONS: All cases of angioedema that were found in patients who were taking DPP-4, did not receive the therapy associated with a significant degree of correlation, if not causality. However, this study can only predict that if there were cases of DPP-4 induced angioedema, they could not be identified. Any changes in angioedema caused by DPP-4 themselves or an interaction between DPP-4 and ACEi could not be established by this study.

PCV9  PREDICTION OF NEWLY DIAGNOSED ATRIAL FIBRILLATION WITH CO-MORBIDITY TO THE MAJOR ADVERSE CARDIOVASCULAR EVENT: A NATIONWIDE DATABASE OUTCOME RESEARCH IN TAIWAN


Chang Gung University, Tao-Yuan, Taiwan, 1Chang Gung Memorial Hospital, Tao-Yuan, Taiwan, 2Chang Gung University, Taoyuan, Taiwan, Taiwan

OBJECTIVES: Atrial Fibrillation (AF) is the most common cardiac arrhythmia for older patients. However, its impact has been less studied in Taiwanese. The purpose of this study is to identify the risk factors of AF in Taiwan. METHODS: Data extracted from the National Health Insurance Research Database for this observational retrospective cohort study between 2006 and 2010. Using 1 to 4 propensity score matching method, it resulted in 3,737 NDAF patients and 14,948 non-AF subjects without the history of AF. The baseline characteristics of study population were compared. Logistic regression analyses were conducted to identify the risk factors of AF. RESULTS: After propensity score matching, there was no baseline demographic characteristics difference in patients between NDAF and non-AF groups. There is a statistical significance of MALE gender with HR = 3.4, 95% CI = 3.2, 3.6, p < 0.0001. When comparing to the non AF subjects without any comorbidity, the HRs were 8.45, 8.71, 12.27, and 12.42 for NDAF alone, NDAF with Dyslipidemia, DM, and HTN, respectively. All p values < 0.0001. Moreover, the HR of MACE between NDAF with all three comorbidities compared to non-AF without any comorbidity resulted in a higher HR of 13.54. CONCLUSIONS: This study has demonstrated that NDAF risk alone is highly associated with a higher risk of MACE as compared to those without AF. Adjusting age and gender, NDAF, with known comorbidity HTN, DM and Dyslipidemia, will have even higher risk for MACE outcome.

PCV10  USING THE CLALIT HEALTH SERVICES ELECTRONIC MEDICAL RECORD DATABASE FOR SAFETY RESEARCH: A FEASIBILITY CASE STUDY

Feldman B., Hoshen M.B., Brody J., Balicer RD

1Clalit Research Institute, Tel Aviv, Israel, 2Rambam Health, New York, NY, USA, 3Clalit Health Services, Tel-Aviv, Israel

OBJECTIVES: Previous published criticisms of safety studies based on secondary databases suggest significant methodological flaws, including substantial missing data, admission criteria under-reporting, and poor transparency in data analytics. Clalit Health Services (CHS) is a payer-provider comprehensive health fund, with 4 million members. The administrative and clinically-oriented CHS data, which includes inpatient and outpatient pharmacy data. Leveraging published safety studies of the association between the risk of venous thromboembolism (VTE) and arterial thromboembolism (ATE) among Oral Contraceptives (OCs) users of differing progestogens, we tested if the completeness of the CHS’ EMR database could compensate for prior criticisms of secondary database-conducted safety studies. METHODS: Data for all CHS female members aged 15-49 were accessed. A retrospective cohort study design 1,2008-2011 identified new OC users in 2008, following up until study end year VTE and ATE incidence was determined and Cox-regression models estimated time-to-event across OC groups. RESULTS:Among 755,824 women in 2008, 94,792 new OC users were identified using comprehensive pharmacy dispensing data. Monthly demographic data and periodically measured clinical data (like BMI and smoking) are recorded following strict quality measures, resulting in only 9.5% missing smoking status and 2.1% missing BMI values among this sample. Community-based and hospital EMRs are centrally collated. Cardiovascular outcomes were validated via patient file review. As VTE-related hospitalization is independent of gynecologist referral we expect minimal bias on this account. Symptomatic effects requiring intervention are fully reported as cost-related procedures. Out-of-pocket copayments are minimal, not predisposing against referrals. Transparency and quality are assured by detailed epidemiology and biostatistics protocols followed explicitly, statistical programming using cross-validation and code and people. CONCLUSION: A retrospective case-control study of 271,198 women aged ≥ 50 years was conducted analyzing data from the Taiwan