and warfarin do not differ significantly in real-world rates of composite stroke and systemic embolism and 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

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**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:** Double-blind, randomized, clinical trials reporting changes in FBG, 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 reports, less than four weeks duration and published in other than English language were excluded. Search was performed using MEDLINE, PubMed, Google scholar and Cochrane Central Register for Controlled Trials (CENTRAL) using key words and MeSH terms through July 2013. **RESULTS:** From the total of 535 clinical 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 yrs. Incidence of diabetes was reported in 595 (4.8%) patients in rosuvastatin arm compared to 519 (4.2%) in placebo arm (RR 1.15, 95% CI 1.026-1.291). 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 Framingham 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 more QALYs gained compared to low-risk patients from the health system perspective. **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

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**OBJECTIVES:** Statins have been shown to significantly reduce the risk of heart attack and heart disease. However, in recent studies, they 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 measures were 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 that met our inclusion criteria. The sample size in these studies ranged from 3,806 to 7,461 with a follow up ranging from 2 to 4.9 years. The change from baseline fasting blood glucose 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 ANGIOEDEMA ASSOCIATED WITH USE OF DIPEPTIDYL-PEPTIDASE INHIBITORS

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**OBJECTIVES:** To estimate the risk of angioedema and angioedema related side-effects caused by the use of dipeptidylpeptidase inhibitors(DPP-4), angiotensin converting enzyme inhibitors (ACEI) and their interaction in patients suffering from diabetes and/or 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 anti-hypertensives were included in the study. 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 1,109 cases and 1,109 controls 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 only 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-4s, either alone or along with ACEI, in the study period. None of the patients on DPP-4s had an incidence of angioedema. No evidence was found to support the hypothesis that DPP-4s 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 using DPP-4s, did not have the temporal association that is required to establish some degree of correlation, if not causality. However, this study can only predict that if there were cases of DPP-4s induced angioedema, they could not be identified. Any chances of angioedema caused by DPP-4s themselves or an interaction between DPP-4s and ACEIscould 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

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**OBJECTIVES:** Atrial Fibrillation (AF) is the most common cardiac arrhythmia for adults. It may cause severe health problems, and is associated with significant morbidity and resulting high mortality. We investigated the hazard ratios (HR) of major adverse cardiovascular events (MACE) between new-diagnosed AF (NDAF) with different comorbidities and non-AF subjects without any comorbidity. **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 with 3,737 NDAF patients and 14,948 non-AF patients. The baseline comorbidity of hypertension (HTN), diabetes mellitus (DM), dyslipidemia, gender, and age (65 years) were used in the matching process. Log rank test and Cox proportion hazard models were used to estimate and to predict the HR of risk factors associated with MACE. **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 MACE between NDAF and non-AF with HR = 3.4, 95% C.I.of (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 comparing 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 MACEs as compared to those without AF. After 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

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**OBJECTIVES:** Previous published criticisms of safety studies based on secondary databases suggest significant methodological flaws, including substantial missing data, biased diagnoses, outcome 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 database encompasses a decade of integrated inpatient, outpatient, laboratory and 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 comprehensiveness of the CHS' EMR database could overcome 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 1.2008-6.2013 identified new OC users in 2008, following-up until study period end. VTE and ATE incidence was determined and Cox-regression models estimated time-to-event across OC groups. RESULTSAmong 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-checked validated code and peer-reviewed statistical analyses **CONCLUSIONS:** As a result of unique historical circumstances and policy decisions, Clalit's comprehensive and integrated data warehouse was able to overcome previously identified flaws in secondary databases for use in safety studies.

PCV11

RISK OF VENOUS THROMBOEMBOLISM ASSOCIATED WITH ANTIPSYCHOTIC USE AMONG POSTMENOPAUSAL WOMEN

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**OBJECTIVES:** The risk of venous thromboembolism (VTE) associated with antipsychotic use has been examined in a variety of populations but not in postmenopausal women prone to VTE. This study aimed to assess the VTE risk related to antipsychotics after menopause. **METHODS:** A nested case-control study of 271,198 women aged ≥ 50 years was conducted analyzing data from the Taiwan