

PCV29

THE ASSOCIATION BETWEEN THE NATURE AND TIMING OF DENTAL VISITS AND C-REACTIVE PROTEIN LEVELS

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OBJECTIVES: Evidence suggests an association between dental disease and cardiovascular disease (CVD). C-reactive protein (CRP), an inflammatory marker, has been implicated as a risk factor for CVD, and dental disease can affect CRP levels. Our study examined the relationship between the timing and nature of dental visits and CRP. **METHODS:** Using data from the US-based 1999-2000, 2001-2002, and 2003-2004 National Health and Nutrition Examination Surveys, we examined the relationship between time since and reason for most recent dental visit and CRP among adults ≥ 20 years old. Participants were excluded if they were pregnant at the time of the survey, did not take part in the examination component of the survey, or were missing covariates for a logistic regression model: age, sex, race, BMI, HbA1c, WBC count, CRP measure, time since and reason for last dental visit, smoking status, cholesterol-lowering medication use, and history of asthma, cancer, rheumatoid arthritis, chronic bronchitis, or recent illness. A dichotomous elevated CRP measure was used, defined as CRP > 0.30 mg/dL. Time since last dental visit was categorized as < 6 months, 6 months to < 1 year, 1 year to < 2 years, and 2+ years ago; respondents who reported never visiting a dentist were placed in the 2+ years category. **RESULTS:** A greater proportion of the normal (≤ 0.30 mg/dL) CRP group last visited a dentist < 6 months ago ($P=0.0460$), and last visited the dentist for a "preventive" visit ($P<0.0001$), while a greater proportion of the elevated CRP group last visited the dentist for a "symptom-driven" visit ($P<0.0001$). Regression model results demonstrated that preventive visits are associated with a reduced likelihood of elevated CRP ($OR=0.722$; $P=0.0120$), regardless of the time since last visit. **CONCLUSIONS:** Given the apparent association between risk of elevated CRP and reason for the last dental visit, medical and dental providers should consider interventions specifically around appropriate dental care.

PCV30

TRADITIONAL AND NON-TRADITIONAL RISK FACTORS FOR CARDIOVASCULAR DISEASE IN TYPE 2 DIABETES: SYSTEMATIC REVIEW OF LONGITUDINAL STUDIES

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OBJECTIVES: A systematic literature review of longitudinal studies across a broad range of both general and disease specific populations was performed to understand characteristics of patients with type 2 diabetes (T2D) with risk factors for cardiovascular (CV) events and whether the magnitude of CV risk varies across different T2D populations. **METHODS:** MeSH term based literature searches were performed in the PubMed, EMBASE and Cochrane Library databases. For inclusion, studies (in any disease area) were required to have a minimum of 1,000 T2D patients and minimum 5 years follow up. After 2 rounds of review a total of 52 articles and 2 meta-analyses were included. **RESULTS:** Twenty nine articles were described as prospective studies; 13 articles were from Europe, 20 from Asia Pacific, 13 from North America, 2 from the Middle East and 4 were multinational. Six articles were sourced from general or non-diabetes specific data and 46 articles were based on diabetes studies. Several publications were from large scale diabetes registries (e.g. Hong Kong Diabetes Registry [n=6] and the Swedish National Diabetes Register [n=4]). The review also identified several post-hoc analyses from clinical trials and large scale retrospective observational/database analyses. Risk factors investigated included well characterized markers in T2D patients (e.g. HbA1c, blood pressure, lipids, proteinuria [n=20]), less well characterized factors including dietary components (n=7), biochemical measures (e.g. serum uric acid, fibrinogen; n=6), depression (n=6) and poorly characterized risk factors including oral health (n=1), erectile dysfunction (n=1) and presence of *H. pylori* (n=1). **CONCLUSIONS:** Analysis of the literature showed that in addition to traditional risk markers, factors such as depression, erectile dysfunction, poor oral health are also independent risk factors for CV disease. These factors should be taken into account when estimating the CV risk profile for patients with T2D.

PCV31

RELATION OF THE TIME IN THERAPEUTIC RANGE (TTR) OF WARFARIN TO BLEEDING INCIDENCES IN PATIENTS WITH ATRIAL FIBRILLATION

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OBJECTIVES: Warfarin use in atrial fibrillation has been established for preventing occurrence of stroke in patients with atrial fibrillation. However, safety and clinical monitoring of warfarin use is crucial due to its risk of bleeding complications. This study aims to compare and establish relation of time in therapeutic range (TTR) of warfarin in patients with atrial fibrillation in the first 6 months and 6 month thereafter of anticoagulation therapy. **METHODS:** This is a retrospective study carried out at a tertiary-care hospital with anticoagulation clinic in the state of Selangor, Malaysia. Data collected included patients' demographics, co-morbidities, and international normalized ratio (INR). TTR were determined using Rosendaal method based on records found in database (INR Desk 4.0 system) and patients' hemorrhage events were also recorded. Samples of the study were patient who started warfarin from January 2009 until March 2013. **RESULTS:** A total of 167 patients with atrial fibrillation were enrolled and only 6% (n=10) achieved TTR of more than 75% for the first 6 months of warfarin use as compared to 16.8% (n=28) of TTR more than 75% 6 months thereafter. As for bleeding incidences, 29% (n=45) of patients in the group of TTR less than 75% in the first 6 months had bleeding complications as compared to 18.7% (n=26) in patients of TTR less than 75% 6 months after. **CONCLUSIONS:** A more regular follow up is necessary during the first 6 months of new warfarin users as they tend to be out of the TTR and have a higher bleeding risk.

PCV34

STATIN USE AND RISK OF DEVELOPING DIABETES IN CARDIOVASCULAR DISEASE: SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

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OBJECTIVES: Statins are widely used for the primary and secondary prevention of cardiovascular diseases (CVDs). Studies have shown that statins may induce diabetes in non-diabetic CVD patients, as class effect. This systematic literature review aims to evaluate the risk of developing diabetes in CVD patients receiving statins. **METHODS:** Randomized controlled trials (RCTs), which used any statin as an intervention for non-diabetic CVD patients, were identified from August 2010 to June 2014 in databases such as, Embase, PubMed, and Cochrane. The timeframe of the searches was selected post the study conducted by Mills et al. in 2011. This review will also include relevant studies from the Mills et al. study until August 2010. Two researchers will independently review studies as per the Cochrane methodology for systematic reviews. The primary outcome is the incidence of diabetes. Subgroup analyses will also be performed to assess whether statin type, age, ethnicity or patient groups contribute to the intensity of the risk of developing diabetes. **RESULTS:** In total, 5238 potentially relevant studies were retrieved from the databases and are being screened for inclusion in the review. The data extraction and analyses (both qualitative and quantitative) are being performed and the full results will be presented in the poster. **CONCLUSIONS:** This systematic literature review is an update of the findings of a previous study and will hopefully throw more light on the association between statin use and the risk of diabetes in CVD patients, with special emphasis on subgroups.

PCV35

A RETROSPECTIVE STUDY OF MORTALITY IN RISK PATIENTS WITH HIGH DOSE STATIN USAGE AND NO STATIN USAGE

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OBJECTIVES: The aim of this retrospective cohort study was to calculate hazard rates of CV/non-CV related death in risk patients stratified by statin dose and to generate data for health-economic analyses. **METHODS:** Anonymous retrospective electronic medical records were extracted from a 10% sample of the Swedish population > 18 years in primary care and merged with hospital records, prescribed drugs, and death data by National Board of Health and Welfare. Cohorts were defined as diabetic (DM), Clinically-evident CardioVascular Disease (CeCVD), Acute Coronary Syndrome (ACS), Heart Failure (HF) and Ischemic Stroke (IS) patients. CV/non-CV related death was investigated. The population was divided into high dose statin users (> 40 mg simvastatin or equivalent) and non-statin users. Royston Parmar (RP) spline analysis was used to calculate hazard rates of both outcomes in each cohort to enable a smooth hazard function with good fit to data compared to ordinary Cox regression. Initial AIC-based optimization demonstrated that modeling of the log cumulative odds as a spline function of log time and three nodes gave the best fit. Crude rates were calculated for each cohort and event, and hazard rates adjusted for gender, diabetes, LDL (where applicable) and age were calculated. **RESULTS:** The total database consisted of 1.3 million patients; there were 55,778 DM, 47,581 CeCVD, 49,857 ACS, 82,835 HF and 38,949 IS patients. High dose statin users showed after initial decrease a constant/marginally increasing hazard rate, whereas the no statin group after initial decrease had a strong increase in hazard rate versus time. The overall hazard rate was always higher for the no statin group. Independent of statin status diabetics and males demonstrated an at least numeric elevated hazard rate. **CONCLUSIONS:** RP splines could be used to generate hazard rate functions for cost-effectiveness models. The death rate was lower in patients with high dose statin usage.

CARDIOVASCULAR DISORDERS – Cost Studies

PCV36

BUDGETARY IMPACT ANALYSIS OF REIMBURSEMENT VARENICLINE IN THE SMOKING CESSATION TREATMENT OF PATIENTS WITH CARDIOVASCULAR DISEASES, CHRONIC OBSTRUCTIVE PULMONARY DISEASE OR TYPE-2 DIABETES MELLITUS: A NATIONAL HEALTH SYSTEM PERSPECTIVE IN SPAIN

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OBJECTIVES: Varenicline is indicated for smoking cessation. Around 60.000 people die every year in Spain because of tobacco related diseases, particularly cardiovascular diseases (CVD), chronic obstructive pulmonary disease (COPD) and type-2 diabetes mellitus (t2DM). At present, varenicline is not reimbursed in the Spanish National Health System (NHS). The objective was to estimate the budgetary impact (BI) for the NHS of the reimbursement of varenicline in smoking cessation in patients with CVD, COPD or t2DM. **METHODS:** BI was estimated comparing the actual not-reimbursed scenario versus a reimbursed scenario using the Spanish NHS perspective. A hybrid BI model was designed using epidemiological data to estimate size of populations and a Markov modelling simulating until four quitting attempts to estimate smoking cessation rates with varenicline during a 5-year horizon. Costs of cessation attempts were considered in the reimbursement scenario only, and included varenicline, medical visits and counselling. Effectiveness of varenicline was expressed as one year of abstinence rate following a 12-weeks course of standard doses, and were derived from clinical trials. Cost savings due to smoking cessation were extracted from local published cost-of-illness studies in such populations. Results showed incremental cost-savings of reimbursed versus not reimbursed scenario. Univariate sensitivity analysis was also applied. **RESULTS:** Five-years cumulated cessation attempts increased from 140,795 in the not-reimbursed to 354,631 in the reimbursed scenario, yielding to 52,127 extra subjects

quitting smoking. Cost of 5-year reimbursement varenicline was estimated to be €63.0 millions, while smoking cessation avoided costs reached €99.9 millions, which compared with €21.1 millions savings in the not-reimbursed scenario: a net incremental cost-saving of €15.9 millions. Savings were observed since 3rd year of modelling. **CONCLUSIONS:** The BI of the reimbursement of varenicline in smoking cessation is a cost-effective health policy in the Spanish NHS, and could produce cost-savings since the 3rd year of implementation.

PCV37

BUDGET IMPACT ANALYSIS OF HYPERTENSIVE TREATMENT WITH INDAPAMIDE AND AMLODIPINE SINGLE-PILL COMBINATION IN THE POLISH SETTING

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OBJECTIVES: The aim of this study was to calculate and compare public payer and patients' costs of hypertensive treatment with indapamide 1.5 mg and amlodipine 5 mg or 10 mg single-pill combination (SPC) and free combination (FC), in the Polish setting. **METHODS:** The analysis compared two scenarios: existing and new. The existing one assumed treatment with FC of indapamide 1.5 mg and amlodipine 5 mg or 10 mg. The new one also included treatment with SPC of indapamide 1.5 mg + amlodipine 5/10 mg. Population and market shares were estimated on the basis of published reimbursement data, experts' opinion and validated with available epidemiological data. Cost data were analysed from the public payer perspective (National Health Fund) and from patient perspective, in a three-year horizon. SPC cost is based on average pharmacy price reported in April 2014 (18.13PLN and 19.75PLN respectively for 1.5+5mg and 1.5+10mg/30 tabs); 30% patient copayment was assumed. The cost of FC was calculated as an average cost of reimbursed indapamide and amlodipine products in corresponding doses. All costs present 2014 values, and are expressed in Polish zloty (PLN). Average monthly exchange rate of May 2014 was applied (1EUR=4.1790PLN). Difference in clinical effectiveness between SPC and FC was also included, in the form of cardiovascular events risk. **RESULTS:** Introduction of indapamide/amlodipine SPC on the reimbursement list next to FC brought savings from public payer perspective and from patient perspective amounting to: 509,255PLN (121,860EUR) and 5,893,941PLN (1,410,371EUR) in first year, 689,239PLN (164,929EUR) and 7,833,005PLN (1,874,373EUR) in second year, 725,965PLN (173,717EUR) and 8,328,480PLN (1,992,936EUR) in third year. Additionally it resulted in avoidance of 808 cardiovascular events in the three-year horizon. **CONCLUSIONS:** Treatment with indapamide/amlodipine SPC in comparison to FC generates significant savings both from the public payer perspective and from patient perspective in contemporary Polish setting, and reduces cardiovascular events.

PCV38

MODELING THE IMPACT OF A DIGITAL HEALTH FEEDBACK SYSTEM IN UNCONTROLLED HYPERTENSIVE PATIENTS

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OBJECTIVES: Despite the availability of numerous therapeutic agents and management tools, half of all hypertensive patients do not have their blood pressure (BP) at goal. A model was developed to estimate the incremental costs of uncontrolled vs. controlled hypertension and the impact of shifting patients to controlled status via a unique digital health feedback system. This Proteus system utilizes an Ingestible Sensor to determine medication-taking patterns, and a wearable 7-day sensor in the form of an adhesive patch to collect physiological and behavioral metrics such as heart rate, step count, and patterns of activity and rest, providing a means of determining non-response vs. non-adherence to prescribed medications and recommendations for daily routine. **METHODS:** The additional costs of outpatient services, monitoring, and cardiovascular complications were calculated for uncontrolled vs. controlled hypertensive patients from a US plan perspective for a 1 year time horizon. The clinical and utilization assumptions were derived from the literature and expert opinion, and costs were derived from the Medicare Fee Schedule and AHRQ databases. The impact of the Proteus system on BP control was based on a real-world study evaluating this technology in 164 patients with a history of uncontrolled hypertension. **RESULTS:** In a health plan of 1 million members, 7.9% (78,656) were uncontrolled hypertensive patients receiving care who were eligible for the Proteus system. The direct annual medical costs of uncontrolled hypertension were estimated to be \$60.9 million over the costs for controlled disease. The Proteus system was estimated to result in \$7.3-18.3 million in savings (\$328-\$717 per BP at goal), and lead to a 3-9% reduction in the number of coronary artery disease and stroke events in one year. **CONCLUSIONS:** Even in the short-term, a digital health feedback system appears to provide an effective way to mitigate the substantial costs of uncontrolled hypertension.

PCV39

BUDGET IMPACT ANALYSIS OF APIXABAN VERSUS OTHER NOACS FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: This study aims to perform a budget impact analysis of the use of three available novel oral anticoagulant agents (NOACs) for preventing thromboembolic events in Italian patients with non-valvular atrial fibrillation (NVAF). **METHODS:** Estimated Italian population of patients is run through a decision tree/Markov model simulating their treatment with the available therapeutic options: dabigatran at two dose levels (110 mg/bid for the over 80 years old, 150 mg/bid for younger NVAF patients), rivaroxaban, and apixaban. Effectiveness estimates derive from an adjusted indirect treatment comparison using warfarin as link. Epidemiological data and unit costs are collected from Italian published sources. The budget impact analysis evalu-

ates the financial impact of apixaban introduction by comparing expected 1,2, and 3 years costs in hypothetical scenarios: with and without apixaban. Italian NVAF patient population estimation is based on official apixaban reimbursement criteria, applying the characteristics of the trial population to national epidemiologic data. Sensitivity analysis is performed on an alternative non-experimental population of NVAF patients. **RESULTS:** Among available NOACs, apixaban is expected to be the least expensive at 1,2, and 3 years in an estimated patient population of 364,000 Italian patients, allowing for savings of over 5 million € by the third year. Results of the simulation run on an alternative non-experimental population of NVAF patients yields comparable estimates. Exclusive use of apixaban for three years in the identified population would allow for savings of € 8,832,500, € 14,446,551 and € 27,282,998 when compared with dabigatran (110 mg), dabigatran (150 mg) and rivaroxaban, respectively. **CONCLUSIONS:** The different safety and effectiveness profiles of the available NOACs emerging from the adjusted indirect comparison indicate that the introduction of apixaban could improve health care expenditure control while maintaining or increasing therapeutic appropriateness in the Italian NVAF population.

PCV40

THE BUDGET IMPACT OF NEW GENERATION CT SCANNERS FOR DIFFICULT-TO-IMAGE, LOW-RISK PATIENTS WITH SUSPECTED CAD

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE) issued diagnostic guidance on new generation computed tomography (CT) scanners recommending them as an option for the first-line imaging of coronary arteries in patients with suspected low-risk coronary artery disease (CAD) in whom imaging with old generation scanners is difficult (e.g. obese patients). The capital investment for a new generation scanner is considerably more than a standard scanner, which could hamper implementation. Based on the NICE guidance, a model was designed for use as a planning tool for rapid access chest pain clinics (RACPCs) looking to replace their current scanner with a new generation scanner. **METHODS:** An Excel[®] model was developed to estimate up to a 10-year impact of acquiring a new generation scanner. It was assumed that under standard care low-risk, difficult-to-image patients would be referred for a diagnostic invasive coronary angiography (ICA). Under the new diagnostic pathway these patients can be scanned with a new generation scanner. Whenever possible the NICE guidance was used to guide assumptions and populate default values. **RESULTS:** The model estimates that for each difficult-to-image patient a new generation scanner has the potential to save approximately £946.62 in diagnostic costs. Considering the capital investment required, a RACPC looking to replace their standard scanner and considering implementing a new generation CT scanner only need 53 difficult-to-image patients per year to see a positive return on investment over a 10-year period. **CONCLUSIONS:** The model is likely to be conservative as it focuses on difficult-to-image patients only, yet the scanner is available for all patients who will likely benefit from the better sensitivity and specificity associated with the new scanners. However, it highlights that even a low number of these difficult-to-image patients will result in a positive return on investment over the expected life-time of the scanner.

PCV41

SIMVASTATIN PLUS FENOFIBRATE AS A FIXED DOSE COMBINATION IN THE TREATMENT OF MIXED DYSLIPIDEMIA IN GREECE: BUDGET IMPACT ANALYSIS

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OBJECTIVES: To evaluate the affordability of switching patients already treated with the multi-pill therapy of simvastatin and fenofibrate to the first simvastatin and fenofibrate fixed dosed combinations (FDC) product, for the management of mixed dyslipidemia in the Greek health care setting. **METHODS:** A budget impact model was locally adapted. The analysis was conducted from a third-party payer perspective over a time horizon of 3 years. The population with mixed dyslipidemia in Greece, the market shares of available treatments and the corresponding drug acquisition costs were combined to estimate the total budgetary impact that will result from the penetration of FDC in the Greek market. Data on population with mixed dyslipidemia were derived from the National Statistical Service and published literature. Estimates of the current and future market shares were obtained from Abbott Hellas market research. Drug acquisition costs were calculated using the latest price bulletin issued and the corresponding reimbursement prices. Reimbursement prices were reduced by the patient's relevant co-payment and relative rebates. Since market prices for the FDC are not available yet in Greece, estimated retail prices provided by Abbott Hellas were considered [FDC 20/145: €13.70 (€12.22-16.27) and FDC 40/145: €16.71 (€15.22-19.23)]. **RESULTS:** Savings in pharmaceutical reimbursement on year 1 were estimated at 146,974 (€181,084-€88,503) decreasing the relevant cost by 5.87% (7.23%-3.53%). On year 2, savings of €250,544 (€322,536-€136,474) were attributed to the penetration of FDC, lowering the budget by 9.93% (12.78%-5.41%). On the 3rd year, savings were estimated at €403,405 (€509,489-€221,565) reducing spending by 15.82% (19.98%-8.69%). On average, over the 3-year time horizon of the analysis, the addition of FDC was found to decrease reimbursement costs by 10.54% (13.33%-5.88%) generating savings of €266,974 (337,703€-€148,147). **CONCLUSIONS:** The introduction of FDC reimbursement will result in a predictable budget impact which is expected to decrease the relevant pharmaceutical cost for national health insurance.

PCV42

BUDGET IMPACT ANALYSIS OF BOTULINUM TOXIN A THERAPY FOR UPPER LIMB SPASTICITY IN GERMANY

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OBJECTIVES: Upper limb spasticity (ULS) secondary to stroke has a considerable patient and caregiver burden, particularly with regards to pain, activities of daily