

lation had risk factors associated with cardiovascular events. No significant difference ($P = 0.6945$) was found in the proportion of subjects using aspirin among the non-selective NSAID, naproxen, and cox-II cohorts, with 46.8%, 48.8%, and 49.4%, respectively. Likewise, no significant differences were found among the treatment cohorts with respect to: strength, frequency, and duration of aspirin use ($P = 0.3840$, $P = 0.8088$ and $P = 0.6838$, respectively). Finally, no significant difference ($P = 0.2778$) was found in the proportion of subjects using aspirin among those with risk factors for cardiovascular events versus those without. **CONCLUSIONS:** Unexpectedly, these results indicate that aspirin utilization, strength, frequency, and duration are independent of both subjects' cardiovascular risk profile (i.e. risk vs. no risk) and the NSAID class utilized (i.e. selective vs. nonselective).

PCV73

USE OF PROPENSITY SCORE METHODOLOGY IN CARDIOVASCULAR DEVICE TRIALS: U.S. FOOD AND DRUG ADMINISTRATION PERSPECTIVES

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OBJECTIVE: Randomized, controlled trials (RCT's) are considered to be the gold standard of scientific evidence to assess safety and effectiveness of cardiovascular devices. However, RCT use is challenging to implement in certain device trials, due to logistical and ethical reasons. The FDA understands that assessment of device technologies must balance the competing demands of maximizing scientific validity against the practical realities of performing (and effectively completing) these clinical studies. Hence, non-randomized clinical trials are sometimes used in device evaluation. Propensity score analysis, as an alternative to traditional covariate adjustment methods, has been increasing in popularity as a technique to control for baseline differences between treatment groups in non-randomized cardiovascular device studies. **METHODS:** Propensity scores provide a convenient methodology for covariate adjustment when multiple covariates are involved. However, propensity score methodology does not eliminate many of the scientific limitations of non-randomized studies compared to RCT's, and should not be viewed as a substitute for performing a randomized study. In using propensity score modeling, a full pre-specification of covariates to be included and the model to be used is recommended to minimize the concern of bias introduced by post hoc model development. **RESULTS:** Furthermore, sensitivity analysis should be performed to demonstrate the robustness of study outcome in the face of hidden bias due to unmeasured or unquantifiable covariates. Lastly, it is recommended that conventional covariate adjustment as well as propensity score adjustment should be performed to demonstrate consistency of outcomes between techniques. **CONCLUSION:** Propensity score methodology has increased in popularity for covariate adjustment in non-randomized cardiovascular device studies. However, there are limitations to this methodology, which must be fully appreciated to avoid erroneous inferences from study data. Randomized trials are still preferred and strongly encouraged whenever possible, especially for the evaluation of novel cardiovascular devices.

PCV74

A BUDGET IMPACT MODEL FOR EPLERENONE IN THE TREATMENT OF HEART FAILURE POST MYOCARDIAL INFARCTION

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OBJECTIVES: The Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival Study (EPHESUS) showed that the addition of eplerenone to optimal medical therapy reduced both morbidity and mortality in patients with acute myocardial infarction (AMI) complicated by left ventricular dysfunction and heart failure whilst reducing the number and duration of heart failure re-hospitalisations. A budget impact model was developed to estimate the effects of adding eplerenone to standard care in the UK National Health Service (NHS). **METHODS:** Within the model the efficacy of eplerenone is based on the EPHESUS study. This is applied to UK epidemiological data on the incidence of AMI, proportion of survivors developing heart failure and their prognosis. UK drug acquisition costs and NHS hospital inpatient costs and average length of stay for England are included. All costs are expressed in pounds sterling. The model estimates the incremental costs and benefits of adding eplerenone to standard care in heart failure resulting from AMI from the perspective of NHS health care decision makers over a three-year period. Input variables include population, incidence of AMI and annual rate of eplerenone uptake. **RESULTS:** If all eligible patients are treated in an NHS Primary Care Trust of population 250,000, the estimated cost per life year saved is 6,701 pounds in year three, for an additional expenditure of £256,959. This level of treatment results in a reduction of 101 bed days for re-hospitalisations due to heart failure, at a cost per bed day avoided of €1207. **CONCLUSIONS:** With hospital inpatient care the biggest single health care cost in heart failure, reduction in hospitalisation is a key priority within the UK NHS. Models such as the one described here enable the economic consequences of using a new drug to be identified and clarify the role of drug treatment in delivering NHS priorities.

PCV75

COST-EFFECTIVENESS OF EPTIFIBATIDE IN NSTEMI PATIENTS IN POLAND

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OBJECTIVES: To estimate incremental cost-effectiveness of adding a GPIIb/IIIa inhibitor (eptifibatide) to percutaneous coronary intervention (PCI) and standard medical management (MM) versus PCI + MM alone in Poland for patients with non-ST-elevation myocardial infarction (NSTEMI) at high risk of recurrent ischemia or cardiovascular death. **METHODS:** A Markov model was constructed to estimate the additional costs and benefits of a GPIIb/IIIa inhibitor on top of standard care. The model has 4 disease states (no event, post-ischemia, post-MI, death) and two tunnel states (refractory ischemia, non-fatal MI). PCI + MM include beta blockers, ACE inhibitors, aspirin, heparin and clopidogrel. The model takes the Polish national health payer perspective and runs for the expected lifetime of the patient. The effectiveness parameters were taken from a 6-month GPIIb/IIIa clinical trial and extrapolated to 45 years with an estimated Weibull function. Event and follow-up costs are based on assumed treatment patterns. The results of the model were expressed in total (discounted) costs and life years per patient, and incremental cost per life year gained. A series of one-way sensitivity analyses has been conducted on the major model inputs. **RESULTS:** The lifetime discounted costs for the base case analysis are 13,856 PLN per patient for the PCI + MM group and 15,570 PLN for the eptifibatide group (a difference of 1714 PLN). The use of eptifibatide provides an additional average of 0.05 year of life per patient compared with PCI + MM. The incremental cost effectiveness ratio for the lifetime model, with

costs and outcomes discounted at 5%, equals 33,622 PLN (7815 €) for each year of life gained. **CONCLUSIONS:** In a population of high risk NSTEMI patients, adding eptifibatide is a cost-effective way of achieving health benefits in terms of cardiovascular events avoided, and ultimately life years saved. This result is much below thresholds accepted in Poland (60,000 PLN—dialysis).

PCV76

COST-EFFECTIVENESS ANALYSIS OF THE USE OF ACETYLSALICYLIC ACID COMPARED TO CLOPIDOGREL IN THE SECONDARY PREVENTION OF PATIENTS WITH PREVIOUS MYOCARDIAL INFARCTION

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OBJECTIVES: To perform an economic evaluation of the use of low dose acetylsalicylic acid (Adiro) in comparison with clopidogrel (Plavix) in the prevention of cardiovascular events in patients with a previous myocardial infarction (MI) using a cost-effectiveness analysis in the setting of the Spanish National Health Service. **METHODS:** Using the efficacy data from the CAPRIE study on the incidence of new cardiovascular events in a group of patients with a previous MI, the sanitary and economic consequences of the use of the two treatments, acetylsalicylic acid and clopidogrel, in this indication were modeled. The costs used in this analysis refer to the year 2004 in the Spanish National Health Service setting. **RESULTS:** In the base case, the total cost of the acetylsalicylic acid treatment (€1515) was considerably inferior to that of clopidogrel (€2942). The efficacy results in the subgroup of patients with a previous MI, are comparatively better with acetylsalicylic acid, however the difference is not statistically significant. With the assumptions adopted in the base case, treatment with acetylsalicylic acid is superior (better or equal efficacy and less cost) when compared to treatment with clopidogrel. The treatment with acetylsalicylic acid was found to be superior to that of clopidogrel in all of the scenarios studied in the analysis of sensitivity. **CONCLUSIONS:** The treatment with acetylsalicylic acid is effective, safe and cost-effective in the secondary prevention of cardiovascular events in patients with a previous MI, and is still the first choice antiplatelet therapy for this indication.

PCV77

COST AND OUTCOMES AFTER FIRST ACUTE MYOCARDIAL INFARCTION HOSPITAL ADMISSION: A LONGITUDINAL STUDY USING ADMINISTRATIVE DATABASES

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OBJECTIVE: to assess the economic and epidemiologic impact of AMI in Friuli Venezia Giulia (FVG) a region of approximately 1.2 million inhabitants in the north-eastern Italy. **METHODS:** All residents of FVG are registered in to Regional Health Service (RHS) database, which keeps tracks of the use of medical care admissions and reimbursement purposes. We selected residents of FVG who had during year 2000 a first AMI hospital admission and we followed them up till death, or 31 Dec 2004 (we a priori excluded people who during the period 1995–1999 had a previous CHD event). Mortality was investigated by collecting information from Regional Citizen Register file. We obtained information on medical costs from electronic databases of prescriptions, hospitalizations, visits and diagnostic examinations in

FVG. Direct medical costs were quantified in the perspective of the RHS and are expressed in Euro 2005. **RESULTS:** We enrolled 1185 patients with incident AMI (mean age 71 ± 13 y.o.), 59% were men. The average cost person/year was €4913.32; 71.2% attributable to hospitalisations, 19.3% to drugs. The 38.5% patients died during the follow up period, with a mean age of 79.3 ± 10.1 statistically different ($p < 0.0001$) from survivors (mean age 65.0 ± 12.0 y.o.). There was no significant difference in mortality between men and women adjusting for age. **CONCLUSIONS:** AMI imposes a huge economic burden on NHS and society because of the large number of hospitalisation and the high rate of mortality after the first event. Future investigations will be conduct to asses the relationships between comorbidity, costs, therapy and survival.

PCV78

THE DIRECT COSTS OF SELECTED CARDIOVASCULAR DISEASES IN AUSTRIA

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OBJECTIVES: To measure the direct costs of selected cardiovascular diseases within the Austrian health care system for the first year including the event, as well as from the second year onward. **METHODS:** In this study, we analyzed the direct costs of angina pectoris (AP) and myocardial infarction (MI) in Austria. The direct costs were identified as resource consumption for hospitalization, inpatient rehabilitation, outpatient treatment, medication and transportation. Costs for inpatient care were calculated according to the tariffs of the Austrian Diagnosis Related Group (DRG) system and the average number of allocated points to AP and MI. Costs for inpatient rehabilitation treatment were calculated with tariffs per day taken into account the mean duration of stay. For outpatient treatment costs we considered the average number of consultations and the fee for service, which is mainly paid by social insurance. Medication costs were calculated and assessed with tariffs according to the distribution of type and amount of prescribed agents. Costs for transportation after the event were included with the tariffs per ride. **RESULTS:** The total costs for the treatment of MI in the first year of event in 2004 were calculated with €8.960, rehabilitation contributing to 68% of this amount. Since there were no inpatient rehabilitation costs to consider from the second year onward, costs declined to approximately €1.490 per year. Costs due to AP amounted about €2.180 for the first year and declined on average to €1.190 from the second year onward. **CONCLUSIONS:** In line with the study direct costs for cardiovascular diseases were calculated for the first time in Austria. As one of the main finding we would like to point out the high direct inpatient rehabilitation costs as the main cost driving factor for MI in the first year of event.

PCV79

POSTMYOCARDIAL INFARCTION CARDIAC REHABILITATION IN LOW RISK PATIENTS. RESULTS WITH A COORDINATED PROGRAM OF CARDIOLOGICAL AND PRIMARY CARE

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OBJECTIVES: To assess the efficacy of cardiac rehabilitation with a mixed primary and cardiological care program in patients