PCV4

FIRST ANALYSIS OF CLINICAL SIGNIFICANT INTERACTIONS IN HIGH-RISK CARDIOVSCULAR PATIENTS ENROLLED INTO HOPE-TOO TRIAL IN SLOVAKIA IN THE THIRD YEAR OF TRIAL PARTICIPATION

Foltánová T[1], Thurzo M[2], Lietava J[2], Tumova I[1], Lonn E[3], Fodor JG[4]
[1]Faculty of Pharmacy, Comenius University, Bratislava, Slovakia; [2]2-nd Department of Internal Medicine, Comenius University, Bratislava, Slovakia; [3]Hamilton University, Hamilton Canada; [4]University of Ottawa Heart Institute, Ottawa, Canada

OBJECTIVES: To monitor the therapy of high risk cardiovascular patients enrolled into HOPE TOO trial in Slovakia and to determine the prevalence of clinical significant interactions in this cohort in the third year of the investment. **METHODS:** Therapy of 849 high-risk ischemic heart disease (IHD) patients (defined as age over 55 yrs), symptomatic IHD [defined as myocardial infarction (MI), unstable angina pectoris (UAP)], stroke, peripheral vascular disease and diabetes mellitus (DM) with at least one more risk factor (arterial hypertension or hypercholesterolemia or smoking) was analysed during HOPE-TOO study enrollment and during the second year visit. **RESULTS:** High risk cohort aged 69.27 yrs (57–90) consisted of 79.9% pts with arterial hypertension, of 62.5% with DM, of 45.6% pts with prior MI, and of 17.7% pts with stroke. In third year of the trial participation average number of drugs was 6.57 (0–20) and 442 (60.47%) pts used more than 6 drugs. Clinically important interactions (grade1,2) were presented in 241 (32.97%) pts. Most frequent interactions were with digoxin coprescribed with furosemid—61 (8.34%) pts., digoxin-simvastatin—19 pts. (2.60%), digoxin-amilorid—16 (2.19%) pts. Average age in the women's group was 69.5 yrs. Women took an average of 7.22 medications and the average interaction was 0.24. Average age in the men's group was 69.04 yrs. Compared to the women, men took only 5.96 drugs and the average interaction was 0.24. **CONCLUSION:** High-risk cardiovascular patients are directly endangered by polypragmacy and drug interactions even during a three year follow up. Structure of their therapy must be carefully monitored.

CARDIOVASCULAR

CARDIOVASCULAR—Cost Studies

PCV79

THE COST-EFFECTIVENESS OF IRBESARTAN IN THE TREATMENT OF HYPERTENSIVE TYPE 2 DIABETIC PATIENTS WITH MICROALBUMINURIA IN CHINA

Hu S[1], Chen W[1], Annemans L[2]
[1]Fudan University, Shanghai, China; [2]HEDM, Meise, Belgium

OBJECTIVES: To project the cumulative incidence of end-stage renal disease (ESRD), life expectancy and costs in China of treating patients with diabetes, hypertension, and microalbuminuria (DHM) with either standard hypertension treatment alone or standard hypertension treatment plus irbesartan 300 mg daily. **METHODS:** A peer-reviewed Markov model that simulated progression from microalbuminuria to nephropathy, doubling of serum creatinine, ESRD, and all-cause mortality in patients with DHM was adapted to China. Three strategies were compared: A) early use of irbesartan (i.e. start treatment in subjects with microalbuminuria) versus B) late use of irebesartan (i.e. as from overt nephropathy), or C) standard hypertension care (with comparable blood pressure control). Cumulative incidence of ESRD, costs and life expectancy were projected for a hypothetical cohort of 1000 subjects. Treatment-specific progression and mortality probabilities were derived from published trials: IRMA-2 (in microalbuminuria) and IDNT (in overt nephropa-

thy). Medical management and cost data per state were obtained from published local sources. A flexible time horizon up to 25 years and third party payer perspective were used. Future costs and LE were discounted at 3% yearly. **RESULTS:** When compared to standard blood pressure control, early irbesartan was projected to reduce the cumulative incidence of ESRD from (mean ± standard deviation) 22% to 8%, save RMB 30,348 (US $3,667), and add 0.638 life years per treated patient. Late irbesartan was dominant to control but dominated by early irbesartan. The superiority of early use of irbesartan over standard care was robust for most variables, except for the cost of dialysis and the time horizon. Break-even occurred after 13 years. **CONCLUSIONS:** Treating DHM patients with early irbesartan was projected to reduce the incidence of ESRD, extend life and reduce costs. Treating patients at a later stage is still beneficial, however to a lower extent. Applying flexible time horizons shows additional relevant information to decision makers.

PCV5

LONG-TERM COST-EFFECTIVENESS OF CLOPIDOGREL® IN PATIENTS WITH ACUTE CORONARY SYNDROME WITHOUT ST-SEGMENT ELEVATION IN GERMANY

Brüggenjürgen B[1], Ehlken B[2]
[1]Alpha Care GmbH, Celle, Germany; [2]MERG, Medical Economics Research Group, Munich, Germany

OBJECTIVE: Patients with acute coronary syndrome without ST-segment elevation receiving Clopidogrel in addition to acetylsalicylic acid (ASS) showed 20% risk reduction in the CURE trial. Economic models for assessing the impact on costs exist for several countries, however not for Germany on a long-term basis. The objective of this model adaptation is to assess the long-term economic impact of Clopidogrel taken in addition to ASS in Germany. **METHODS:** A Markov model with six states (at risk, first year with stroke, following years with stroke, first year with new myocardial infarction (MI), following years with MI and death) was adapted for Germany. Model outcome was life-years saved. Cost and effects of one year treatment were calculated based on the CURE trial. Resource use for the different health states during follow-up were based on desk research or on expert opinion, which included costs for drugs, physician visits, hospitalisation, rehabilitation and nursing. Risk data for MI and stroke were based on Swedish data. The model calculates life-time costs and survival length. Costs were estimated from the payers'l perspective within the German health care system. Sensitivity analysis varied follow-up treatment costs at −50% and +100%. **RESULTS:** The Markov analysis resulted in 8.89 life-years saved for the placebo treatment group and 9.02 for the Clopidogrel® treatment group. The cumulated cost were 9288 and 9653 resp. The incremental cost effectiveness ratio (ICER) was 2670€ for each life-years saved. In the sensitivity analysis halving of follow-up cost lead to an ICER at 3666€ and doubling to 677€. **CONCLUSION:** Our results are in line with results in other Health Care systems. Adding Clopidogrel in addition to ASS for patients with acute coronary syndrome without ST-segment elevation generates an additional life-year saved at a comparably low value of 2670€ in Germany.

PCV6

AN ECONOMIC EVALUATION OF CLOPIDOGREL VS. ASPIRIN IN SECONDARY PREVENTION OF ISCHEMIC EVENTS IN HIGH RISK ATHEROTHROMBOTIC PATIENTS IN ITALY

Rudelli G[1], Annemans L[2], Spiesser J[3], Novelli M[4], Walker A[5], Gabriel S[3]
[1]Sanofi-Synthelabo, Milan, Italy; [2]HEDM, Meise, Belgium; [3]Sanofi-Synthelabo Recherche, Bagneux, France; [4]Bristol-Myers Squibb, Roma, Italy; [5]Bristol-Myers Squibb, Rueil-Malmaison, France

OBJECTIVES: To determine in Italy the incremental cost per life year saved (ICLYS) of clopidogrel versus ASA in secondary prevention of ischemic stroke (IS), myocardial infarction (MI), or vascular death in four high risk atherothrombotic populations: 1) with prior IS or MI to index event; 2) treated for hypercholesterolemia and/or with diabetes; 3) polyvascular; and 4) with prior cardiac surgery (CABG). METHODS: The economic analysis was performed from the Italian Health Care System perspective using only direct medical costs. A Markov model designed with 7 clinical states calculated ICLYS as the cost needed to achieve an extra life year with a two-year treatment with clopidogrel compared to ASA, over a lifetime horizon. The model combined clinical outcomes from the CAPRIE trial database and survival data derived from the Saskatchewan database. The costing of events, including acute care and two-year follow-up, was evaluated using official data for DRGs, tariffs and/or charges (physicians fees, examinations, lab tests). A discount rate of 3% was applied to costs and lifetime effects. RESULTS: Per 1000 patients treated with clopidogrel the additional ischemic events avoided and the gain in life years were: 27 events and 119 years in prior IS or MI patients; 28 events and 130 years in hypercholesterolemic and/or diabetic patients; 24 events and 138 years in polyvascular patients; 82 events and 474 years in prior CABG patients. The ICLYS of clopidogrel compared to ASA were 9055€ in prior IS or MI group, 7880€ in patients treated for hypercholesterolemia and/or diabetes, 8216€ in polyvascular patients and 2001€ in CABG patients. Results were robust under a wide variation of key parameters. CONCLUSION: In Italy a two-year treatment with Clopidogrel as an alternative to ASA is a cost-effective strategy in secondary prevention of ischemic fatal and non-fatal events for high-risk atherothrombotic patients.

PCV7

THE COST-EFFECTIVENESS OF CLOPIDOGREL IN ACUTE CORONARY SYNDROMES WITHOUT ST-SEGMENT ELEVATION IN POLAND

Pietrasik A[1], Niewada M[1], Spiesser J[2], Gabriel S[3]
[1]Medical University of Warsaw, Warsaw, Poland; [2]Sanofi-Synthelabo Recherche, Bagneux, France; [3]Sanofi-Synthélabo, Bagneux, France

OBJECTIVES: The CURE study has demonstrated that treatment strategy involving clopidogrel plus aspirin, comparing to aspirin alone, significantly reduced the risk of cardiovascular death, myocardial infarction and stroke in patients with ACS without ST-segment elevation. For every 1000 patients treated with clopidogrel there were 20 less strokes, myocardial infarctions or cardiovascular deaths (crude NNT = 50). The purpose of the present study was to evaluate cost-effectiveness of clopidogrel in Poland based on CURE trial efficacy data. METHODS: Data on resource use i.e. hospitalizations, medical procedures, concomitant medications and study drug were derived from case report form of CURE trial. Unit costs were calculated using drugs retail prices and medical procedures tariffs contracted by National Health Found. Cost-effectiveness was expressed as cost per cardiovascular event avoided. The time horizon was the mean study duration of 9 months. All costs are expressed in EURO and EURO-PPP (1EURO = 2.08 PLN' PPP2003). RESULTS: Mean direct treatment cost per patient was higher in clopidogrel than control group (2395 and 1931€; 5074€, and 4100€, PPP, respectively). The observed difference was attributable mostly to a higher acquisition cost of clopidogrel. The mean cost of initial and subsequent hospitalizations (including study drug) was reduced for clopidogrel group by 18 and 24€, 40, and 53€-PPP, respectively. The estimated incremental cost per event avoided amounted to 23,076€ and 48,497 EURO-PPP. CONCLUSIONS: Treatment with clopidogrel resulted in reduction of

initial and subsequent hospitalizations costs. The cost per event avoided with clopidogrel in patients with ACS is consistent with results from other countries and compares well to other treatment strategies in patients with cardiovascular disease.

PCV8

THE ECONOMIC IMPACT OF CLOPIDOGREL IN PATIENTS WITH UNSTABLE CORONARY ARTERY DISEASE UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI): POLISH PERSPECTIVE

Pietrasik A[1], Niewada M[1], Spiesser J[2], Gabriel S[3]
[1]Medical University of Warsaw, Warsaw, Poland; [2]Sanofi-Synthelabo Recherche, Bagneux, France; [3]Sanofi-Synthélabo, Bagneux, France

OBJECTIVES: Results from the PCI-CURE trial demonstrated that treatment strategy involving clopidogrel plus aspirin, comparing to aspirin alone, significantly reduced the risk of cardiovascular death, myocardial infarction and stroke in patients with acute coronary syndromes (ACS) without ST-segment elevation undergoing percutaneous coronary interventions (PCI). The purpose of the present study was to evaluate cost per event avoided in the PCI subgroup of CURE trial, in Poland. METHODS: Data on resource use, i.e. hospitalizations, medical procedures, concomitant medications and study drug were derived from case report form of PCI-CURE trial. Unit costs were calculated using drugs retail prices and medical procedures tariffs contracted by National Health Found. Cost-effectiveness was expressed as cost per cardiovascular event avoided. The time horizon was the mean study duration of 8 months. All costs are expressed in EURO and EURO'PPP (1€ = 2.08 PLN' PPP2003). RESULTS: Mean direct treatment cost per patient was higher in clopidogrel than control group (2700 and 2248€, 5711, and 4759€'PPP, respectively). The observed difference was attributable mostly to a higher acquisition cost of clopidogrel. The mean cost of initial hospitalizations (including study drug) was reduced for clopidogrel group by 26€, 57€'PPP. The estimated incremental cost per event avoided amounted to 12,858€, 27,043€'PPP. CONCLUSIONS: Treatment with clopidogrel resulted in reduction of initial hospitalizations costs. The cost per event avoided with clopidogrel in patients undergoing a PCI is comparable to other interventions in this area considered as cost-effective.

PCV9

COST-EFFECTIVENESS ANALYSIS OF ALTEPLASE COMPARED WITH STREPTOKINASE AND ABSENCE OF THROMBOLYTICAL THERAPY FOR MYOCARDIAL INFARCTION

Derkach E, Avxentieva M, Vorobjov PA
Moscow medical academy, Moscow, Russia

OBJECTIVE: to perform cost-effectiveness analysis of alteplase compared with streptokinase and absence of thrombolytical therapy for myocardial infarction (MI) in Russia. METHODS: Data on effectiveness of treatment and resource use were extracted from hospital medical charts randomly selected from 10 city hospitals in a retrospective study. A total of 133 patients received alteplase, 97 patients received streptokinase and 131 patients did not receive thrombolytical therapy. Effectiveness was assessed by death rate, presence of anginal pains, arrhythmia and heart failure at discharge. Direct medical costs were calculated on the basis of price-lists for medical services of an insurance company and median prices for drugs given in a wholesale pharmaceutical informational bulletin. Incremental cost-effectiveness ratio (ICER) was calculated for alteplase vs streptokinase and no thrombolytical therapy and for streptokinase vs no thrombolytical therapy. RESULTS: There was no significant difference in death rate between 3 groups. Patients from alteplase group significantly less often had heart failure by the end of hospital treat-