A REAL WORLD COMPARISON OF COMBINED LIPID TARGET ATTAINMENT BETWEEN COMBINATION NIACIN EXTENDED-RELEASE+ANY STATIN THERAPY AND FIXED DOSE SIMVASTATIN+EZETIMIBE
Simko RJ1, Quimbo RA2, Cziraky MJ3, Balu S4
1Abbott Laboratories, Abbott Park, IL, USA, 2HealthCore Inc, Wilmington, DE, USA, 3HealthCore, Inc, Wilmington, DE, USA, 4Abbott Labs, Abbott Park, IL, USA
OBJECTIVES: Use of niacin extended-release with statin mono-therapy (SM) for combined lipid target attainment (CLTA) of LDL-C, HDL-C, and triglycerides (TG) has been limited. The objective was to compare real-world CLTA among patients receiving niacin extended-release+any statin (NER+S) versus fixed-dose simvastatin+ezetimibe (S+E) combination therapy.
METHODS: A retrospective analysis was conducted on patients aged ≥18 years, newly initiating NER+S or S+E therapy between July 1, 2000–June 30, 2006 (index date), with health plan eligibility of at least 12 months pre- and post-index date, and at non-target HDL-C (<40 mg/dL) and TG levels (≥150 mg/dL) at index date using a large integrated research claims database. CLTA, assessed at the last laboratory visit within 12 months of index date, was defined according to NCEP ATP III, ADA, and AHA Women’s guidelines where appropriate. A propensity score, controlling for differences in index date age, gender, LDL-C, HDL-C, and TG levels, was included as a covariate in a multivariate logistic regression model comparing odds of achieving CLTA between treatment groups. RESULTS: A total of 883 patients were analyzed, 445 initiating NER+S and 438 initiating S+E. NER+S patients were significantly older (54 ± 9 years vs. 51 ± 8 years; p < 0.0001), more male (81% vs. 55%; p < 0.0001), hypertensive (80% vs. 67%; p < 0.0001), and with prior cardiovascular disease (CVD) (46% vs. 17%; p < 0.0001) than S+E patients. All NER+S patients and some S+E patients (48%) were prescribed SM prior to index date. Mean baseline values for LDL-C (98 ± 36 vs. 136 ± 43 mg/dL; p < 0.0001) and HDL-C (37 ± 9 vs. 44 ± 11 mg/dL; p < 0.0001) were significantly lower among NER+S patients. Logistic regression analysis indicated 64% (OR: 1.64; 95% CI: 1.02–2.61) increase likelihood of CLTA among NER+S patients versus S+E patients. CONCLUSIONS: Dyslipidemia patients initiating NER+S therapy were more likely to achieve CLTA than patients initiating S+E therapy in a real-world setting, thus implying a greater potential reduction in cardiovascular risk.

EFFECTIVENESS OF CLOPIDOGREL IN ADDITION TO ASPIRIN COMPARED TO ASPIRIN ALONE AFTER ACUTE CORONARY SYNDROME
Liew D1, Price N2, Chew DP3
1The University of Melbourne, Melbourne, Australia, 2Sanofi-aventis Australia, Sydney, Australia, 3Flinders University, Bedford Park, SA, Australia
OBJECTIVES: To assess the effectiveness of clopidogrel in addition to aspirin versus aspirin alone after acute coronary syndrome (ACS) in an Australian context. METHODS: A Markov model was constructed to simulate the onset of major cardiovascular events (composite of myocardial infarction, ischemic stroke and cardiovascular death), major bleeding events and non-cardiovascular death in a representative cohort of 1000 subjects experiencing ACS. In the first year post ACS, underlying risks of events were drawn from the nationwide Australian Acute Coronary Syndromes Prospective Audit (ACACIA) registry (n = 2533). In subsequent years, risks from Australian participants of the Reduction in Atherothrombosis for Continued Health (REACH) registry (n = 2567) were used. Decision analysis compared the two interventions and follow-up was simulated for ten years. Relative risks of cardiovascular and bleeding events associated with clopidogrel were drawn from the Clopidogrel in Unstable Angina to Prevent Recurrent Events (CURE) trial, and assumed to be sustained as long as subjects remained on treatment. Uncertainty analyses were undertaken via Monte Carlo simulation. RESULTS: The modeled outcomes from the simulated follow-up of 1000 subjects in the ten year model were major CV events, major bleeding events and deaths. There were fewer CV events and deaths in the clopidogrel arm but more bleeding events than aspirin. The number needed to treat (NNT) to avoid a major CV event was 14 (9–29); to avoid a death was 33 (14–207). Overall, there were 8413 life years gained in clopidogrel compared with 8191 in aspirin alone. CONCLUSIONS: In the simulated cohort, the addition of clopidogrel to aspirin represents a highly effective strategy for the secondary prevention of death and cardiovascular events following ACS. Although there is a small increase in bleeding in the simulated cohort, the net effect remains a significant prevention of cardiovascular events, saving of lives and years of life gained.

CLINICAL EFFECTIVENESS OF BOSENTAN, EPOPROSTENOL, ILOPROST, SILDENAFIL AND TREPORSTINIL IN THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION—A SYSTEMATIC REVIEW
Becla L, Osiska B, Malottki K, Lipska I
Agency for Health Technology Assessment, Warsaw, Poland
OBJECTIVES: The aim of this systematic review (SR) is to compare efficacy and safety of boventan, epoprostenol, iloprost, sildenafil and treprostinil with conventional treatment (CT) in patients with pulmonary arterial hypertension (PAH). METHODS: Analysis was performed according to “Polish
Guidelines on Health Technology Assessment”, 2007 and “Cochrane Handbook for Systematic Reviews of Interventions”. In order to identify RCTs medical databases were searched: e.g. Medline, Embase and Cochrane Library. Calculations and metaanalyses were performed using StatsDirect statistical software.

RESULTS: Nineteen RCTs (treatment period 2–16 weeks), in which a total number of 1795 patients with PAH participated, were included in the SR. All patients continued CT with anticoagulants, vasodilators, diuretics and/or digitalis glycosides. Bosentan, epoprostenol, iloprost and sildenafil significantly increase exercise capacity (according to the NYHA classification) comparing to placebo in the PAH population: bosentan vs. placebo: OR = 2.25 (95%CI: 1.21; 4.18); epoprostenol vs. placebo: OR = 37.99 (95%CI: 8.43; 171.22); iloprost vs. placebo: OR = 2.25 (95%CI: 1.02; 5.13); sildenafil vs. placebo: OR = 6.94 (95%CI: 2.78; 17.31). In bosentan, iloprost, sildenafil and treprostinil groups significantly higher improvement in exercise capacity, measured using the 6-minute walk test, was found comparing to placebo: WMD = 43.33 m (95%CI: 27.55; 59.12) for bosentan vs. placebo; 36.4 m (p = 0.004)—iloprost vs. placebo; 55.82 m (95%CI: 38.03; 73.61)—sildenafil vs. placebo and 16.00 m (95%CI: 4.40; 27.60)—treprostinil vs. placebo. In safety analysis no statistically significant differences were observed between bosentan and placebo as well as sildenafil and placebo groups. Comparing to placebo, in epoprostenol group significantly more often jaw pain, nausea and diarrhea occurred, in iloprost group there was higher incidence of serious syncope or flushing and jaw pain and in the treprostinil group—sudden vasodilation, edema, jaw pain and reaction, pain, hemoptea or induration at the injection site. CONCLUSIONS: The use of these five drugs in addition to CT is more effective than CT alone.

PCV8

CLINICAL AND ECONOMIC IMPACT OF DRUG-ELUTING STENT AND BARE METAL STENT IN HONG KONG—A SINGLE CENTRE “REAL WORLD” EXPERIENCE

Lee VYW1, Kurn L, Lee T1, Wong W1, Chan C, Mak C, Lee KK, Yu CM1

The Chinese University of Hong Kong, Shatin, Hong Kong

OBJECTIVES: The effectiveness of drug-eluting stents (DES) and bare-metal stents (BMS) in reducing restenosis and rate of major adverse cardiac events (MACE) in selected patients has been demonstrated by the randomized controlled trials. Despite the better efficacy of DES over BMS in reducing revascularization, the initial cost of DES is much higher than BMS, which limits its use in clinical practice. We aimed to evaluate the clinical outcome of BMS and DES placement in coronary artery disease patients and estimate the cost of BMS and DES placement in a Chinese population.

METHODS: It was a retrospective cross-sectional study. We included all patients who underwent PCI with stent placement of either DES or BMS in a tertiary public hospital in Hong Kong during January to December 2005. Patients were followed up for the occurrence of MACE within 12 months of the index stent placement. MACE was defined as cardiac death, non-fatal myocardial infarction and target lesion revascularization. Direct medical costs were estimated based on the procedural cost, hospitalization, medications, cardiac follow-up and repeated interventions taken.

RESULTS: This analysis included 447 patients. Twelve-month MACE rate was 10.6% in BMS versus 3.0% in DES (p = 0.001). Rate of cardiac death was 2.9% in BMS versus 0.0% in DES group (p = 0.109). The mean 12-month cost per patient after index PCI was USD 9802.9 ± 8303.8 (median = 8721.8) in BMS and USD 10052.1 ± 5624.9 (median = 8766.7) in DES. On average, DES costs USD 1605.1 more than BMS per patient. CONCLUSIONS: DES demonstrated a significant reduction in 12-month MACE compared with BMS. Although DES carried a higher procedural cost, it had similar 12-month costs with BMS due to less post-PTCA intervention. DES was proved to be cost-effective to be used in Hong Kong public hospitals.

PCV9

AN ANALYSIS OF THE ANTIHYPERTENSIVE EFFECTIVENESS OF IRBESARTAN VS. CANDESARTAN

Sharplin P1, Beckham C1, Hogan S1, Chamberlain G1
1 CRC, Cardiff, UK, 2 Bristol-Myers Squibb, Uxbridge, UK, 3 Sanofi-Aventis, Guildford, UK

OBJECTIVES: To explore the efficacy of irbesartan in reducing blood pressure (BP) compared to candesartan, in a real-world setting.

METHODS: We analysed the records of 10,338 (5,425 candesartan; 4,913 irbesartan) adult patients with hypertension who were initiated on the two agents between 1998 and 2006 using the UK THIN GP database. The analyses presented report the comparisons for General hypertensive patients (systolic BP ≥ 140 mmHg, diastolic BP (DP) ≥ 90 mmHg) and Severe hypertensive patients (SBP ≥ 180 mmHg, DBP ≥ 110 mmHg) on either ARB over the first 2 years of treatment.

RESULTS: In the General hypertensive group mean SBP reductions at 1 year reached 14.7 mmHg for irbesartan vs. 13.6 mmHg for candesartan. Mean DBP reductions reached 8.5 mmHg for irbesartan and 7.1 mmHg for candesartan. In the Severe group, mean SBP reductions reached 31.6 mmHg for irbesartan vs. 31.2 mmHg for candesartan. Mean DBP reductions reached 15.8 mmHg for irbesartan vs. 13.4 mmHg for candesartan. Similar comparisons were observed in the second year analysis. All but one of the comparisons were statistically significant in a multivariate analysis after adjusting for baseline BP, age, sex, weight, diabetes status, practice effect, socioeconomic status, 1st line vs. subsequent line usage, number of prior comorbidities, hypertension diagnosis status and type of and number of co-therapies prescribed. In the General hypertensive population, patients receiving irbesartan showed a greater mean reduction in SBP of 1.18 mmHg (p < 0.001) and of 0.55 mmHg (p < 0.001) in DBP over 2 years compared to those receiving candesartan. Similar differences among therapies were observed in Severe patients, 1.79 mmHg in SBP (p = 0.02), ~0.10 mmHg in DBP (p = 0.747). Significance may have been affected by the small number of patients in the Severe group.

CONCLUSIONS: In a real-world setting, patients receiving irbesartan are observed to achieve greater BP reductions compared to those receiving candesartan.