Lombardy. The monthly cost in the first year was €1249 per person (77% attributable to HAs, 15% to pharmaceuticals and 8% to outpatient claims), decreasing to €309 in the following years (54% HAs, 31% pharmaceuticals, 16% outpatient). CONCLUSIONS: This large study on the burden of AMI shows the epidemiological, economic and clinical impact of the disease. DENALI, with its large population followed over time is a powerful and dynamic tool for epidemiological and health economic research.

OBJECTIVES: Acute coronary syndromes (ACS) are life-threatening disorders requiring intensive medical management or invasive cardiovascular procedures. CABG is an important therapeutic procedure among these patients. In Brazil almost 21,000 CABG were performed in public hospitals costing the government R$73779.49 each in average. The aim of this study is to determine the direct medical costs of CABG among different regions of Brazil. METHODS: Retrospective cohort study analyzed administrative claims data for patients with ACS submitted to CABG in 2007–2008. From a nationwide database with 1,801,344 people all the patients with ACS submitted to CABG were selected. The patients were split according to the Brazilian geographical region where the procedure was performed. Student T-test was used to compare the costs among different regions. RESULTS: We identified 263 patients with ACS submitted to CABG. 67% of the procedures were performed in Southeast (SE) region, 25% in Middle West (MW) and 8% in the south region. The average age SD, quartile 25%, median and 75% of the CABG cost of whole sample were R$15,849.72 ± R$37,553.69, R$12,153.84, R$14,605.45 and R$18,735.46, respectively. The same parameters for the SE, MW and S regions were, respectively R$13,721.23 ± R$30,974.89, R$14,155.23 ± R$14,398.47 and R$18,657.87; R$16,744.15 ± R$54,212.57, R$13,340.36, R$15,688.26 and R$19,321.96; and R$14,033.01 ± R$6,272.96, R$19,455.33 ± R$14,163.88 and R$17,103.31. There was no statistical difference among the different regions of Brazil of total CABG cost. There was no statistical difference among the different regions and the total sample average. CONCLUSIONS: The CABG average cost we found represent the average Brazilian private setting health cost independent of the region studied. The average total CABG cost in the private setting is at least the double in relation to the average total CABG cost in the public setting.

A CONCEPTUAL ANALYSIS OF THE COSTS OF CARE FOR A “MAJOR BLEED” IN STUDIES OF ANTIPATELLATE AND ANTITHROMBOTIC THERAPIES

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OBJECTIVES: Antplatelet and antithrombotic therapies have long been the focus of extensive clinical and economic investigations. In many of these studies, the primary endpoint was the incidence of “major bleeding,” which does not have a standard or universal definition. Major cardiovascular studies such as GUSTO, CURE, TIMI and the International Society on Thrombosis and Haemostasis (ISTH) have each established definitions that result in vastly different outcomes. Additionally, none of the common definitions were designed for patients undergoing surgery as part of their care. Analyses that compare outcomes from multiple trials must carefully examine the definitions used. METHODS: We analyzed the effect of applying 6 major bleeding definitions on the incidence and costs of care for acute coronary syndrome (ACS) patients undergoing coronary artery bypass graft surgery (CABG) in their index hospitalization in a previously developed database of ACS patients from 14 health systems across the United States. RESULTS: Our comparison found that application of the different definitions could result in a large variance in the primary outcome of “major bleeding,” with equal impact on the comparisons for the cost of care. The incidence of major bleeding varied by as much as 50% as did the cost of treatment. The data review included ACS patients who underwent CABG between January 2003 and December 2006. CONCLUSIONS: Comparing the incidence, impact and costs of treating major bleeding between various clinical trials requires a careful assessment of the definitions used. Development of a single standard definition of “major bleeding” for use in clinical and observational trials is recommended.

COST-EFFECTIVENESS OF EZETIMIBE/SIMVASTATIN VERSUS SIMVASTATIN: WILL THE INCREASED RISK OF CANCER MAKE EZETIMIBE/SIMVASTATIN AN INAPPROPRIATE TREATMENT CHOICE?

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OBJECTIVES: Although ezetimibe/simvastatin (10/40 mg/day) combination therapy may have a superior cholesterol-lowering profile and be more effective cost than statin monotherapy, recent data suggest an increased risk of cancer. We estimate the cost-effectiveness of ezetimibe/simvastatin vs. simvastatin (40 mg/day) monotherapy, evaluating the effect of this risk. METHODS: A Markov model, employing a 1-year cycle, was employed to estimate the incremental cost, outcomes, and cost-effectiveness ratio (ICER) over a 5-year time horizon. Efficacy data were obtained from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study, the Scandinavian Simvastatin Survival Study, and the Heart Protection Study. Costs were estimated from fee schedules, diagnosis-related groups, and average wholesale prices. Utility weights were obtained from the peer-reviewed literature. All costs and outcomes after the first year were discounted 3% annually in the base-case. Deterministic and probabilistic sensitivity analyses were conducted to evaluate the effect of parameter uncertainty and assumptions on the model results. A cost-effectiveness acceptability curve displays the probability that ezetimibe/simvastatin is cost effective. RESULTS: Ezetimibe/simvastatin was non-inferior (i.e., cost less, result in better outcomes) in the base-case. For a 1 million-patient cohort, ezetimibe/simvastatin would cost $1,674,715,703 less than monotherapy and would result in 15,906 additional quality-adjusted life-years (QALYs). One-way sensitivity analyses indicate that higher incidence of cancer, lower monotherapy costs, and higher risk of myocardial infarction (MI) reduce the cost-effectiveness of ezetimibe/simvastatin substantially. According to probabilistic analyses, ezetimibe/simvastatin is cost-effective at $50,000/QALY only 36.7% of the time; even at a willingness-to-pay of $50,000/QALY, ezetimibe/simvastatin is cost effective less than 50% of the time. CONCLUSIONS: Although our study suggests that simvastatin/ezetimibe treatment is cost effective, policy makers should interpret these results in light of possible uncertainty surrounding the incidence of cancer, incidence of myocardial infarction, and the true cost of simvastatin treatment following generic approval.

COST-EFFECTIVENESS ANALYSIS OF ADD-ON ALISKIREN TO LOSARTAN TREATMENT FOR PATIENTS WITH TYPE II DIABETES, HYPOPHYSIS, AND NEPHROPATHY IN THE CZECH PATIENTS FROM MAJOR PERSPECTIVE

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OBJECTIVES: Persistent high blood pressure is one of the leading causes of microalbuminuria and progression of nephropathy in patients with type 2 diabetes. A large number of studies have shown effective reduction of microalbuminuria after antihypertensive therapy and reducing progression of nephropathy to end-stage renal disease (ESRD). In the AVOID study aliskiren once daily as an add-on therapy provide a significant additional reduction in proteinuria compared to losartan alone. The objective of our model was to evaluate a long-term cost utility of the two strategies. METHODS: AVOID was a multinational, randomized, double-blind study to evaluate the possible renoprotective effect of aliskiren in the primary endpoint – the change in the urinary albumin to creatinine ratio (UACR) when added aliskiren to existing losartan and optimal antihypertensive therapy for six months in hypertensive patients with type 2 diabetes and nephropathy. However the duration of this study was short to evaluate the incidence of ESRD. The AVOID cost-effectiveness Markov model is designed to estimate progression to ESRD using the primary endpoint of AVOID – superior reduction in UACR for aliskiren versus placebo – and project associated local costs and clinical outcomes in Czech patients suffered by type 2 diabetes, hypertension and nephropathy. RESULTS: AVOID demonstrates that combination of aliskiren with losartan showed systematically improved effectiveness compared with losartan alone. Effectiveness was expressed as QALY gained throughout the model time horizon. The incremental cost-effectiveness ratio (ICER) of the aliskiren add-on base case was below € 1027 per QALY gained and in the extended case improved with real-life cost of dialysis and renal transplantation on cost-saving therapeutic approach. CONCLUSIONS: Aliskiren once daily as add-on therapy to losartan is highly cost-effective option for hypertensive patients with type 2 diabetes and nephropathy.

INCREASED PATIENT THROUGHPUT AND REDUCTION IN LABORATORY STAFF AND LABOR INTENSITY WITH THE USE OF REGADENOSON

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OBJECTIVES: Regadenoson is a vasodilating stress agent used in patients undergoing myocardial perfusion imaging (MPI) for detection of coronary artery disease. Its rapid injection administration and weight-independent dosing may result in shortened administration time versus adenosine or diprydamide. We assessed whether the use of regadenoson results in overall MPI reduction in lab personnel time and consequentially increased patient throughput. METHODS: An economic model was developed comparing regadenoson versus adenosine and diprydamide on MPI cost, clinical and patient satisfaction and patient throughput through reduction in administration time and staff labor. We developed a pharmacologic stress agent survey (n = 19) to evaluate the laboratory personnel time and patient throughput. The results of this survey were used to populate the model. We included the three specific anti-ADENOSINE agents as a group and associated adverse events for MPI. We solicited key opinion leaders including nurses, nuclear technologists and cardiologists to complete this survey in April and May of 2009. RESULTS: Laboratory efficiency is reliant in part upon medication characteristics (e.g. different stress agent dose, administration time, use of rapid injection vs.