LONG TERM SURVIVAL AS A FUNCTION OF AIRWAY OBSTRUCTION (FEV1) IN SUBJECTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A POPULATION BASED RECORD LINKAGE STUDY IN A LARGE UK POPULATION

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OBJECTIVE: COPD increases morbidity and decreases life expectancy. Airway obstruction as measured by the forced expiratory volume in one second (FEV1) is used most commonly to measure the extent of airways obstruction but the marginal impact of FEV1 in decreasing survival is unclear. METHODS: This was a retrospective record linkage study using data from a region of Wales, UK, with a population of around 425,000 people. Data were probability matched from a number of data sources: hospital utilisation data from local hospitals, lung function data from the Respiratory Medicine Department and mortality data from the Office of National Statistics. Individual data sources were available spanning a period of 14 years to the present. Survival was characterised from the first recorded FEV1 measurement. Multivariate analysis techniques were used to standardise for potentially confounding factors such as age, sex, morbidity, BMI and smoking status. RESULTS: Among 33,357 subjects with data describing their FEV1 status, we identified 2,326 patients with COPD. Mean and median (SD and IQR) FEV1 values at first measurement were 1.04 litres and 0.89 litres (0.64 and 1.15–2.62), respectively. Mean survival at one year and at five years was 95.5% and 74.7%, respectively. In univariate analysis by FEV1 quintile (1st quintile was the lowest FEV1 value) survival at five years was 71.2%, 82.9%, 80.4% and 85.0%. After standardisation for age, sex, morbidity, smoking status and BMI using a Cox's model, the hazard ratios for the 1st, 2nd and 3rd quintile by comparison to the 4th were 2.3, 1.7 and 1.4, respectively. CONCLUSION: Airways obstruction (FEV1) was an important determinant of survival in COPD following standardisation for other potentially confounding factors.

RS4

AN EVALUATION OF THE ASSOCIATION BETWEEN HEALTH CARE UTILIZATION AND USE OF SALMETEROL AMONG SUBJECTS WITH ASTHMA

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OBJECTIVE: Evaluate whether use of salmeterol increases the risk in an asthma-related hospitalization or emergency care. METHODS: Data for this study were extracted from the MEDSTAT pharmacy and medical claims databases between January 1, 2000 and December 31, 2001. A nested case-control study design was employed to evaluate the associations of interest. A cohort representing asthma patients was identified in 2000. The hospitalized cases were then identified as those with the first-time asthma-related hospitalization in 2001, and matched to select controls from the study cohort by age (±5 years of age), sex, and number of ambulatory visits for asthma (5:1 control to case ratio). A similar selection process was used for the asthma-related emergency department (ED) visit outcome. The use of salmeterol was evaluated during the one-year period before an index date for both cases and controls. Conditional multiple logistic regressions were used to model the association of interest. RESULTS: A total of 35,312 subjects were eligible to be the study cohort. In addition, 284 and 640 subjects were identified as the hospitalized and ED cases, respectively. Current use of salmeterol was associated with a 48 percent decrease in the risk of an asthma-related hospitalization (OR = 0.52; 95% CI = 0.30 to 0.90) and a 30 percent reduction in the risk of an asthma-related ED visit (OR = 0.697; p = 0.048). The protective effect of salmeterol did not exist for those with recent or past use of salmeterol. Conversely, use of seven or more canisters of salmeterol had a decreased risk in the outcomes of interest (hospitalization: OR = 0.45; p < 0.001; ED visit: OR = 0.49; p < 0.001). CONCLUSIONS: Salmeterol decreases the risk of health care utilization if salmeterol is currently used or salmeterol is used for seven or more canisters during a one-year period.

POD IUM SESSION II

COST-EFFECTIVE ANALYSIS

PHARMACOECONOMIC EVALUATION OF SINGLE DOSE AZITHROMYCIN EXTENDED RELEASE (AZ-ER) FOR THE TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA (CAP)

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OBJECTIVE: To estimate the total medical costs per patient and cost per patient cured for AZ-ER 2g single dose compared with levofloxacin 750mg for 5 days for the outpatient treatment of mild to moderate CAP from a managed care perspective. METHODS: A cost-effectiveness model was developed to calculate the total medical costs in the first 30 days following initial outpatient treatment of CAP. Costs included those of initial medical management and antibiotic therapy, treatment of adverse events and second-line treatment, including hospitalisation. Resource use was based on the American Thoracic Society guidelines, and unit costs were assigned based on average Medicare RBRVS and DRG reimbursement for physician visits and hospitalizations and Wholesale Acquisition Costs for medications. Likelihood of cure and adverse events were obtained from clinical trial data comparing AZ-ER to levofloxacin. To investigate the effect of compliance on predicted healthcare costs, cure rates were adjusted by modeling the effects of non-compliance with therapy on retreatment rates. The base case prevalence of compliance (70%) was obtained from published sources. Sensitivity analyses were conducted to determine the impact of multiple variables on outcome measures. RESULTS: Average cost per patient was $341 in the AZ-ER group and $458 in the levofloxacin group. Average total cost per patient cured was $375 in the AZ-ER group and $361 in the levofloxacin group. The incremental cost-effectiveness ratio indicated dominance for AZ-ER, having both better outcomes and a lower total cost. Compliance with levofloxacin and cost of levofloxacin were factors having greatest impact on cost. However, AZ-ER remained the dominant therapy compared with levofloxacin at up to 94% predicted compliance with levofloxacin. CONCLUSION: Use of AZ-ER may result in lower medical costs per person than levofloxacin. As non-compliance with levofloxacin increases, the difference in predicted total costs per patient between AZ-ER and levofloxacin increases.

THE COST-EFFECTIVENESS OF ZEMPLAR IN THE NETHERLANDS

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OBJECTIVES: To assess the cost-effectiveness of paricalcitol IV in the management of eligible hemodialysis (HD) patients with secondary hyperparathyroidism (SHPT), in comparison with standard oral vitamin D treatment. METHODS: A decision tree model was used to estimate the cost-effectiveness of paricalcitol IV for HD patients with increased serum PTH levels despite standard treatment (K/DOQI guidelines). The primary perspective of the study was that of the Dutch society in 2005. Costs and clinical outcomes were discounted at 4%. The data sources included published literature, paricalcitol IV clinical trials, official price/tariff lists and national population statistics. RESULTS: The base case analysis from the society perspective shows that paricalcitol IV generates cost savings of €1714 per patient over three years compared to standard oral vitamin D treatment (€27,817 vs. €29,531). Paricalcitol IV also saves 0.10 Life Years (2.37 vs. 2.27) and leads to a gain in 0.08 QALYs (1.07 vs. 0.99). When the analysis is performed from the health insurance perspective, the total cost savings reduce from €1,714 to €983, but paricalcitol IV remains dominant over standard oral vitamin D treatment. Potential savings in the paricalcitol IV treatment arm are to be contributed to a reduction of hospitalization. Gain in utilities is to be contributed to a decreased hospitalization rate and increased survival of the paricalcitol IV treated population. Sensitivity analysis showed that the outcomes were only moderately sensitive to the changes in input variables for the model, but paricalcitol IV remained dominant in all analyses. CONCLUSION: This study showed that paricalcitol IV is a cost-saving option in the treatment of HD patients presenting SHPT in comparison to standard oral vitamin D treatment in The Netherlands. Introduction of paricalcitol IV to the Dutch reimbursement system would propagate costs savings and a gain in life years as well as QALYs.

CE3

SHORT-TERM COST-EFFECTIVENESS OF RECOMBINANT ACTIVATED FACTOR VII IN THE TREATMENT OF INTRACRANIAL HEMORRHAGE
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Intracerebral hemorrhage (ICH) is a devastating form of stroke, resulting in mortality and disability. A recent Phase IIb clinical trial has shown that recombinant factor VIIa (rFVIIa, NovoSeven) significantly reduces mortality in ICH patients and improves functional outcome. OBJECTIVES: To estimate short-term cost-effectiveness of rFVIIa compared to standard care in treating ICH from a US hospital (inpatient) perspective. METHODS: A decision-analytic model was developed to estimate the cost-effectiveness of rFVIIa 40 mcg/kg, 80 mcg/kg, and 160 mcg/kg compared to standard care in treating ICH from a hospital perspective. Costs and outcomes were estimated for a patient’s initial hospitalization. Mortality, disability, and initial hospital length of stay (LOS) was obtained from the Phase IIb clinical trial. Direct medical costs for initial hospitalization following ICH were assumed to include all costs associated with inpatient care estimated from an analysis of Medicare claims data. rFVIIa costs were based on average sales price. Costs were in 2005 US dollars. Sensitivity analyses were conducted to assess robustness. RESULTS: Treatment with rFVIIa 40 mcg/kg and 160 mcg/kg resulted in additional costs of $2283 and $6700 respectively compared to standard care, which includes the cost of rFVIIa, after factoring in relevant inpatient costs. Treatment with rFVIIa 80 mcg/kg was associated with a reduction in expected medical costs (~$333). Given the clinical trial results, the incremental cost-effectiveness ratio (ICER) per survivor for rFVIIa 40 mcg/kg, 80 mcg/kg, and 160 mcg/kg were $19,726, ~$1778 (cost-savings), and $68,723 respectively. In addition, average costs per survivor for rFVIIa 40 mcg/kg, 80 mcg/kg, and 160 mcg/kg, and standard care groups were $44,102, $41,475, $50,582 and $48,085, respectively. Results were robust to changes in model parameters. CONCLUSIONS: Treating ICH with rFVIIa 80 mcg/kg is not only cost-effective but also cost-saving to the hospital in the short-term compared to standard care. Cost-effectiveness results were driven by treatment efficacy (mortality), LOS (and corresponding inpatient costs), and rFVIIa costs.

CE4

COST EFFECTIVENESS OF DRUG ELUTING STENTS (DES) COMPARED TO BARE METAL STENTS (BMS) USING “REAL WORLD” DATA
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OBJECTIVE: To evaluate the cost-effectiveness of DES compared to BMS using outcome data derived from a cardiac patient registry in Ontario. METHODS: A decision analytic model with a 1 year time frame was used to estimate costs and effects (QALYs, revascularizations) for patients receiving DES and BMS. Prospectively collected data from the Cardiac Care Network of Ontario patient registry was used to estimate revascularization rates along with other key clinical variables to populate the model. Stent costs were obtained from manufacturers, while revascularizations costs (PCI, CABG) were obtained from a hospital in southern Ontario. Utility values applied to time with angina, post revascularization, and otherwise healthy patients were estimated using results from the ARTS trial. Parameter uncertainty was assessed by means of probabilistic sensitivity analysis. Cost-effectiveness was assessed on 22 unique patient subgroups based on diabetes status, lesion characteristics (length and diameter) and AMI within 7 days. RESULTS: Using clinical outcome data from 7953 PCI cases, the cost-effectiveness of DES was most favorable in non-post MI diabetes patients with long and narrow lesions $223,000/QALY ($9869/revascularization). This subgroup had the greatest difference in estimated 1 year revascularization rates between BMS and DES (20.6% vs. 6.0%). Cost effectiveness was found to be greater than $500,000/QALY ($20,788/revascularization) in 17 of the 22 patient cohorts (85% of patients). CONCLUSIONS: The current analysis found that the cost-effectiveness of DES to be high in all patient subgroups. The primary strength of the analysis is that revascularization rates and other key model input variables were based upon a large sample of “real world” patient data. Other published economic analyses of drug eluting and bare metal stents are at least partially based upon clinical trial data in which clinical benefits of DES are exaggerated compared to “real world” practice, thus providing more favorable, but misleading, cost-effectiveness results.

DIABETES

(For DB1 see page A42)