0.50-NUR; 0.42-PH) and low or insignificant for Pain (0.32-FAM; 0.40-NUR; 0.18-PH) and Anxiety/Depression (0.26-FAM; 0.28-NUR; 0.14-PH). The variables associated to the difference between the VAS score of patient and carriers were studied using lineal regression. Mean (S.D) PCS and MCS of caregivers were 48.4 (13.8) and 48.0 (11.3). Multiple regression analysis showed that higher ZS and older patient age were associated to lower PCS of the caregiver (R² = 0.15; p < 0.001) and that higher ZS and lower FSS of the caregiver, and lower MCS of the patient were associated to lower MCS of the caregiver (R² = 0.29; p < 0.001). Lower FSS, PCS and MCS of the caregiver and higher age and lower PCS and MCS of the patient were associated to higher score on ZS of caregivers (R² = 0.49; p < 0.001).

CONCLUSIONS: Agreement between patients and carriers was moderate for “objective” dimensions of HRQoL and low for “subjective” ones. HRQol of FAM is slightly worse than that of the general population. The burden of FAM depends on perceived social support, patient’s age and health status of carrier and patient.

QL4

VARIABILITY IN QOL QUESTIONNAIRES AND THE HANDLING OF MISSING DATA IN PATIENTS WITH NON-SMALL CELL LUNG CANCER TREATED WITH CHEMOTHERAPY

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OBJECTIVES: To review quality of life (QoL) questionnaire use and methods for handling missing data in published chemotherapy studies [2000–2005 (Jan)] of non-small cell lung cancer (NSCLC). METHODS: We conducted a detailed search of the published literature on quality of life, NSCLC, and chemotherapy, excluding studies with limited total sample size (<30). Thirty-five studies covering 10 QoL questionnaires and 17 chemotherapy drugs were reviewed. RESULTS: Most studies were conducted in Europe (primarily Italy and the U.K.), and the average sample size was 137 patients per treatment arm (range: 16, 406). QoL questionnaires were typically self-administered at baseline and every 3 weeks thereafter until disease progression (roughly 2 years duration). The EORTC QLQ-C30 and EORTC QLQ-LC13 (QLQ-LC13) questionnaires were most often used in Europe (15 of 24 European studies); however, the FACT-L questionnaire was commonly used in the U.S. (7 of 13 U.S. studies). The EORTC QLQ-C30/QLQ-LC13 combination detected significant differences for QoL outcomes in 14 out of 15 studies which reported EORTC domain scores, while the FACT-L detected differences in 3 of 7 studies. Both questionnaires contain similar domains, but the EORTC QLQ-C30/QLQ-LC13 includes more items on chemotherapy symptoms and FACT-L includes items on patients’ attitude towards their cancer. Several studies examined potential non-random bias due to missing data resulting from death or disease progression. One study detected conflicting results when including (versus excluding) missing data from their analyses. Another study observed different QoL results when comparing cycle-to-cycle data at similar time points rather than study completion data using the last observation carried forward. CONCLUSIONS: Although EORTC QLQ-C30/QLQ-LC13 and FACT-L are both widely used, are similar in content, and can detect differences in NSCLC patients, they are used preferentially in Europe and the U.S., respectively. Inappropriate assumptions concerning the randomness of missing data can result in biased estimates of QoL.

Cost Evaluation Studies in Interventional Cardiology

THE COST-EFFECTIVENESS OF DRUG-ELUTING STENTS BASED ON THE A SYNTHESIS OF THE RESULTS OF 15 RANDOMISED CONTROLLED TRIALS

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OBJECTIVES: To inform coverage decisions regarding drug-eluting coronary stents by assessing their cost-effectiveness for particular high-risk patient subgroups. METHODS: The analysis compared the cost-effectiveness of the two drug eluting stents (DES) available in the UK (Cypher and Taxus) and bare-metal stents (BMS). A review was undertaken of randomised trials including one or both of the DES. Individual patient data were available for some of these trials. The model parameters extracted from the trials were further revascularisation rates, undertaken for clinical reasons, either percutaneous interventions or bypass surgery, during follow-up. Three subgroups were considered on the basis of their higher baseline risk of repeat revascularisation: small vessels, long lesions and diabetics; a fourth subgroup without these risk factors was also considered. The evidence synthesis was implemented as a Bayesian hierarchical logistic model. A probabilistic decision model was developed. RESULTS: Evidence from 15 trials was incorporated into the synthesis, 5 of which supplied individual patient data. The probability of repeat percutaneous interventions was lowest with Cypher and highest with BMS. Both DES had lower probabilities of subsequent bypass surgery than BMS, and the probability for Taxus was slightly lower than for Cypher. Cost-effectiveness results were sensitive to the stent prices. At current UK prices (£908 BMS, £1300 Taxus, £1341 Cypher), Taxus is dominated by Cypher in diabetic patients and subject to extended dominance in all other subgroups. Cypher has an incremental cost per QALY gained, compared to BMS, of £13,759, £23,086, £13,740 in patients with small vessels, long lesions and diabetics, respectively. In patients with no risk factors, this increases to £35,865. CONCLUSIONS: Given existing list prices, Cypher is likely to be considered more cost-effective than BMS and Taxus in patients at high baseline risk of further revascularization. This conclusion may change following any changes in the relative stent prices.

PREDICTING THE COST-EFFECTIVENESS OF THE ABT-578 COATED DRIVER CORONARY STENT (ENDEAVOR) IN DE NOVO NATIVE CORONARY ARTERY LESIONS

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OBJECTIVES: Endeavor combines the Driver stent, the drug ABT-578 and a PC polymer into a new drug-eluting coronary stent (DES) system. As results from long-term trials of Endeavor are not yet available, economic modeling techniques must be employed to evaluate the cost-effectiveness of this new treatment option. The study undertook the first assessment of the cost-effectiveness of Endeavor DES, compared to the Driver bare-metal stent (BMS), in the treatment of de novo lesions in native coronary arteries. METHODS: A Markov model was developed simulating the results of the ENDEAVOR II trial at nine months follow-up, and extrapolating to five years using the BENESTENT I trial. No difference was assumed between the outcomes with the two stents after the first year. The events modeled were target vessel revascularisations, AMIs, cere-
brovascular accidents and death. The expected costs were calculated for 2005 from the perspective of the UK NHS. Each event was associated with a transient decrement in health-related utility due to recurrent symptoms while waiting for a repeat intervention and to pain and distress of events or further interventions, relative to a baseline asymptomatic coronary heart disease value based on the ARTS and SoS trials. A probabilistic sensitivity analysis was undertaken. RESULTS: Although the price premium of Endeavor is above £500, the total cost of Endeavor treatment was only slightly higher at five years than Driver (£6094 vs. £6058) due mainly to the reduced need for revascularisations in the first year. Endeavor was also associated with QALY gains (0.0053 per patient), and therefore had an incremental cost-effectiveness ratio of £6700/QALY. The probability of Endeavor being cost-effective at a threshold of £30,000/QALY was 58%. CONCLUSIONS: This exploratory analysis shows the Endeavor DES to be cost-effective. Results of long-term trials are awaited to confirm model predictions.

HEALTH ECONOMIC EVALUATION OF BIVALIRUDIN IN THE MANAGEMENT OF PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN BELGIUM

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OBJECTIVE: To determine the cost-effectiveness (CE) from the Belgian societal perspective of anticoagulation with bivalirudin vs. heparin + glycoprotein inhibitors (GPIIb/IIIa) in patients undergoing percutaneous coronary intervention (PCI).

METHODS: Efficacy data were taken from REPLACE-2, EPITENT and ESPRIT trials which documented probabilities of PCI outcomes: death, myocardial infarction, urgent revascularization, and major/minor bleedings according to TIMI definition. Costs data were drawn from Belgian literature except for drug costs which were valued using REPLACE-2 actual dosages and official Belgian tariffs. We considered unfractionated (UFH) and low-molecular weight (LMWH) heparins. Abciximab was the only GPIIb/IIIa considered as it is the only one indicated for PCI in Belgium. A 30-day time frame analytical model was developed from an original model by The Swedish Institute for Health Economics (IHE), to estimate the incremental costs per life year gained (LYG). Costs and LYG were discounted at 3.0% per annum. In the base case analysis, GPIIb/IIIa was given in 27.5% of the patients receiving heparin (consensus estimate between the Belgian Working Group in Interventional Cardiology and expert opinions).

RESULTS: Giving bivalirudin to the average patient undergoing PCI in Belgium resulted in extra 0.0794LYG and €90.1 vs. UFH (incremental cost-effectiveness ratio (iCER) = €1134.8/LYG). LMWH was dominated. A threshold analysis, varying from 0% to 100% the percentage of patients in the heparin branches who receive additional GPIIb/IIIa, revealed that when this percentage is above 34%, bivalirudin dominates both heparin strategies. When no patient at all was given additional GPIIb/IIIa, the iCER vs. UFH was €3993.3/LYG. Other variables were much less sensitive. CONCLUSION: Our analysis suggests that the use of bivalirudin during PCI is a cost-effective alternative to the current approach of heparin + GP IIb/IIIa in the Belgian health care setting. The percentage of patients given GPIIb/IIIa with heparin is the key factor driving the iCER of bivalirudin.