

PDB32

LONG-TERM DIABETES COMPLICATIONS: INFLUENCE OF DELAY IN STARTING INTENSIFIED THERAPY AND OF PATIENT RATES TREATED TO TARGET A1C. ANALYSES WITH THE DIABETES MELLITUS MODEL (DMM)Bergemann R¹, Huppertz E², Mueller E¹, Maxion-Bergemann S¹¹Analytica International, Loerrach, Germany; ²Aventis Pharma Deutschland GmbH, Bad Soden, Germany

OBJECTIVES: The Diabetes Mellitus Model can be used to simulate the cumulative incidences of short and long-term diabetes complications over 10 years in patients with type-2 diabetes. In this study, the DMM was used to investigate the influence of 'rate of patients treated to target A1c' (responder rate) and 'delay in starting intensified therapy' on the cumulative incidence of long-term complications in patients with type-2 diabetes.

METHODS: A population of virtual patients was simulated based on published demographic and physiological baseline values at the start of the simulation (mean baseline A1c 9%), on which two analyses were carried out. In the first analysis, the responder rate was varied in 20% steps from 0–100% and 5 cohorts were simulated. The second analysis comprised 10 simulated cohorts evaluating the 'delay in starting intensified therapy, which was varied in 1-year steps between 1 and 10 years. For all simulated patients, HbA1c increased by 0.1% per year.

RESULTS: Both parameters have a large impact on the cumulative incidence of long-term complications in patients with type-2 diabetes, especially on macrovascular complications. After 10 years, the simulated cohort of 100% responders showed a 43% and 24% risk reduction for micro and macro-vascular complications compared to the cohort of 0% responders. Patients who started intensified therapy (target A1c < 6.5%) in year 1 of the simulation showed 77% and 33% risk reduction for micro and macro-vascular complications compared to patients who started intensified therapy in the tenth. A 3-year delay in initiation of intensified therapy gave a 20% risk reduction for microvascular complications versus initiation in year 10.

CONCLUSIONS: This analysis highlights the importance of responder rate and the early initiation of intensified glycaemic control therapy in patients with type 2-diabetes with respect to long-term clinical outcomes.

DIABETES**DIABETES—Methods and Concepts**

PDB33

EAGLE—DIABETES MODEL: BASIC FEATURES AND INTERNAL VALIDATION OF SIMULATING LONG-TERM DIABETIC OUTCOMES AND RELATED COSTS

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OBJECTIVES: The EAGLE (Economic Assessment of Glycemic Control and Longterm Effects) model was developed to simulate long-term effects of diabetes therapies on diabetes-related complications and costs.

METHODS: Based on a systematic review of published data for type-1 and type-2 diabetes; the EAGLE model is a stand-alone computer simulation program providing micro-simulations of virtual patient cohorts over n years in 1-year cycles with a maximum of 1000 iterations. Subsequent health economic (HE) calculations are constructed from the simulation results. For internal validation the model event rates were compared with rates of study data used to build the model. Respective deviations with confidence intervals were calculated.

RESULTS: Results from DCCT, UKPDS, and WESDR studies

were used for model calculations. Complications include micro- and macrovascular events (e.g. neuroathy, end stage renal disease, cardiovascular complications, stroke etc) and death, and are calculated over time as cumulative incidence. Risk equations for the probability of complications are based on regression analysis using linear, exponential, as well as quadratic regression formulae. Risk equations for probability of events include demographic (e.g. age, gender, duration of diabetes since diagnosis, type of diabetes) and physiological parameters (e.g. A1c, systolic blood pressure, triglycerides, HDL, LDL, albumin excretion rate). The course of A1c over time is simulated in relation to the treatment regimen. Country specific costs for diabetes treatments and complications can be assigned. HE calculations include cost of complications, cost of illness, cost-effectiveness, cost-utility and cost consequence analysis. Output data provide incidence per year, cumulative incidence after n years, all demographic and physiological parameters, and results of the health economic analyses. Internal validation demonstrated a deviation of less than 25% from original study data for all simulated events.

CONCLUSIONS: The EAGLE model is a valid tool for the analysis of long-term effects of diabetes treatment and related costs.

EYE/EAR/SKIN DISEASES/DISORDERS**EYE/EAR/SKIN DISEASES/DISORDERS—Clinical Outcomes Studies**

PESI

ASSOCIATION BETWEEN DIMINISHED ACTIVITY OF DAILY LIVING AND VISUAL IMPAIRMENT IN SUBJECTS LIVING IN THE COMMUNITY: RESULTS FROM A FRENCH NATIONAL SURVEYBrézin A¹, Lafuma A², Fagnani F², Mesbah M³, Berdeaux G⁴¹Hopital Cochin, Paris, France; ²Cemka, Bourg-La-Reine, France;³Université de Bretagne-Sud, Vannes, France; ⁴Alcon, Rueil-Malmaison, France

OBJECTIVES: The aim of this analysis was to evaluate the link between visual impairment and diminished activity of daily living.

METHODS: A national survey (1999) was conducted on a random, stratified sample of 356,208 French persons living in the community. A subset of 21,760 subjects was selected at random for further research and 16,945 were interviewed. Two years later (2001) the same subjects were interviewed again. Three groups were identified, based upon subject interviews (blind, low vision (LV) and no visual problem (NVP)). Activity of daily living (ADL) was measured by the Katz index. Loss of ADL was defined as a decrease of at least one Katz level. A weighted stepwise logistic regression was used to determine risk factors of ADL loss.

RESULTS: ADL was documented 2 years later for 12,310 subjects (72.65%). The 3 major reasons for uncompleted second interviews were a move, death and refusal to answer. The mean age at the second interview was 40.3 years, 52.3% were female and 2.06% experienced ADL loss. Age was strongly associated with ADL loss ($p < 0.001$). Handicaps were also factors: motor function (odds ratio[OR] = 2.56), speech (OR = 2.46), brain (OR = 2.05) and visceral difficulties (OR = 1.81). Visual impairment was found to be an independent factor associated with ADL loss, i.e. LV subjects' chance of ADL loss was 1.89 times greater while the figure for blind subjects was 5.43 (ORs adjusted on age-squared and other handicaps).

CONCLUSIONS: For French persons living in the community, LV and blindness are 2 independent risk factors of ADL loss within 2 years. These results suggest that preservation of visual function would contribute to maintenance of ADL.