Large retrospective databases provide valuable information to examine adverse events associated with PN, which can be reliably identified and studied. Both sensitivity analyses and model validation added credibility to our approach.

A COMPARISON OF CLINICAL PROFILES, MEDICATION USE AND SYMPTOMATOLOGY IN ASTHMATIC PATIENTS PRESCRIBED LOW/MODERATE DOSE FLUTICASONE PROPIONATE/SALMETEROL OR MODERATE/ HIGH DOSE FLUTICASONE PROPIONATE

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Abstracts

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PR54

ESTIMATION OF MORTALITY RISKS ATTRIBUTABLE TO COMORBIDITY IN COPD


OBJECTIVES: Even in late-phase trials, it is common practice to exclude patients with certain pre-existing conditions based primarily on clinical knowledge. Such exclusions can result in low recruitment and associated consequences. Comorbidities are common in chronic diseases and for a specific outcome, data on the risk attributable to each can help inform decisions on inclusion/exclusion. We present a graphical methodology for obtaining such empirical evidence. METHODS: A retrospective cohort of 23,881 patients aged 50+ in the UK-GPRED at incident COPD diagnosis between 1990-1998 provided our setting. Each death patient was matched to as many survivors from the same practice as possible, of same age, sex and COPD duration. Some 18 binary comorbidities measured at the time of death were analysed in relation to mortality. Using conditional logistic regression model, we estimated hazard ratio (HR) for each comorbidity, adjusted for key baseline characteristics as well as its prevalence at the time of COPD diagnosis (PR). Cox regression with time-varying coefficient and propensity score matching (PSM) was used for PR54s as graphs A and B respectively. RESULTS: Some 2,938 dead patients were matched to 5,792 survivors. The most contributors to mortality risk were: CHF (HR: 1.3 p < 0.0001; PR = 15.6%, PR98 = 18.2%), lung cancer (HR: 20.4 p < 0.0001; PR = 0.7%, PR98 = 1.2%), other cancers (HR: 12.3 p < 0.0001; PR = 0.7%, PR98 = 1.8%), and CVD (HR: 4.1 p < 0.0001; PR = 3.2%, PR98 = 4.7%). Newly diagnosed moderate/severe liver disease (<1 year) was rare but with a high risk (HR: 16.7 p < 0.014; PR = 0.3%, PR98 = 0.4%), suggesting such patients could be excluded in a trial of interest. We, diabetes-without-complication was common but with little effect on risk (HR: 1.2 p > 0.37; PR = 5.1%, PR98 = 7.2%), suggesting such patients could be included in a trial with recruitment concerns. CONCLUSIONS: The information provided by the tool can assist trial planning on sample size estimations as well as improve our understanding of how comorbidities influence outcomes.

COMORBIDITIES, QUALITY OF LIFE, AND HEALTH CARE ACCESS BY FRAMINGHAM RISK PERCENT FROM THE US NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)

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OBJECTIVES: To examine characteristics of demographic, clinical conditions, comorbidities, quality-of-life and health care access by risk cohorts calculated using Framingham risk percent in a United States (US) national sample. METHODS: Characteristics of 3 cohorts were derived by Framingham low risk (<10%), middle risk (10–20%) and high risk (>20%) and compared by matched propensity score factors (N=7,084) were used for 2005–2006 National Health and Nutrition Examination Survey (NHANES) data. RESULTS: The sample comprised 1,751 persons aged 220 years with all necessary analysis variables (age, total cholesterol, smoking status, HDL, systolic blood pressure, and hypertension treatment) used to calculate Framingham 10-year risk percent. Compared to respondents in low and middle risk cohorts, the high risk cohort was older (61 years old vs. 42 and 60), more male (92% vs. 45% and 84%), and reported less years of education, less married (71% vs. 32% and 32%), more smoking (57% vs. 49% and 53%), higher levels of hypertension (23% vs. 15% and 19% and 51%) and a higher proportion of overweight and obese (76% vs. 61% and 72%). More high risk cohort people reported diagnoses of hypertension (60% vs. 24% and 45%), diabetes (15% vs. 5% and 11%), asthma (47% vs. 32% and 41%), and cancer (15% vs. 7% and 13%). Less of the high risk cohort reported certain "diet and health" conditions than those in low and middle risk cohorts (70% vs. 84% and 80%). The high risk cohort was more likely to report public insurance (54%) than either low (18%) or middle (46%) cohorts. CONCLUSIONS: An NHANES-based...