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.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

**PR51**

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

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OBJECTIVES: National asthma treatment guidelines recommend the use of low dose ICS plus a LABA or moderate to high dose ICS as the preferred treatment for moderate asthma. The purpose of this study was to determine if physicians prescribe low/moderate dose fluticasone propionate/salmeterol (FSC) or moderate/high dose fluticasone propionate (FP) to subjects with similar asthma clinical profiles, medication use, and symptomatology. METHODS: This was a retrospective observational study using medical, pharmacy, and enrollment information from a large, US managed care plan and linked medical chart data comparing 3 years of baseline characteristics and medication treatment patterns in adult asthma patients initiating FSC or FP. Data acquired from medical and pharmacy claims included provider specialty, baseline asthma medication resource use, occurrence of spirometry testing, and Deyo-Charlson comorbidity score. A random sample of medical charts (n = 460) was abstracted for baseline symptomology. RESULTS: A total of 32,189 subjects (average age: 46.6 [14.4] years; 72% female; and recent diagnosis and initiation of FSC or FP) was identified. Baseline co-morbidity scores were similar in FSC and FP patients (1.02 [1.31] vs. 1.11 [1.50]; p = 0.488). A greater proportion of patients receiving FSC had a baseline spirometry compared to FP patients (32.6% vs. 20.4%; p = 0.003). Shortness of breath was reported more often for FSC (48.7% vs. FSC vs. 38.3% in FP; p = 0.024). Other asthma symptoms were reported a similar rate across both groups and no significant differences in baseline use of other asthma medications were observed. CONCLUSIONS: Few significant differences in either clinical outcomes or baseline asthma symptomology were observed between patients prescribed low/moderate dose FSC or moderate/high dose FP for the first time. Overall, physicians seem to be prescribing low/moderate dose FSC and moderate/high dose FP similar to asthma patients in alignment with national asthma treatment guidelines.

**PR52**

A NOVEL METHODOLOGY FOR MEASURING THE INFLUENCE OF COMORBIDITY IN HEALTH OUTCOME STUDIES

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OBJECTIVES: In most studies, the influence of comorbidity is modelled additively as the number of comorbidities present or by an index (such as Charlson’s) without regard to the outcome of interest. We question these approaches with a novel methodology noting that: outcome may not be associated linearly with comorbidity count, the weights combining a set of binary comorbidities need not be positive (i.e. hypothesis B that outcome worsens with increasing comorbidity may be false), and our ability to identify specific interactions influencing prognosis is lost. METHODS: We analyzed a retrospective cohort of 3332 patients, aged 50–72 years in the UK General Practice Research Database diagnosed with COPD between 1990 and 1998, and with the first COPD hospitalisation. Some 17 binary comorbidities were analysed in relation to risk of mortality and re-hospitalisation. We tested the null hypothesis (A), that comorbidity was similar in each layer of the two outcomes, crudely and adjusting for age and sex. Our methodology relies on logistic and log-linear modelling strategies for multidimensional contingency tables RESULTS: For both outcomes, hypothesis (A) was rejected (p < 0.001). Although comorbidity was found to influence death and rehospitalisation, the patterns of influence on the two outcomes were not similar and there were some with negative influence (i.e. comorbidities more frequent among survivors or those not rehospitalised); several significant 2-way interactions were revealed. Whilst most significant interactions were positive (especially for re-hospitalisation) there was negative interaction for death (e.g. peripheral vascular disease and CHF (HR: 3.3 p < 0.7%; PRC = 3.2%, PR98 = 4.7%)). Some 2,938 dead patients were matched to 5792 survivors. The most contributors to mortality risk were: CHF (HR: 1.3 p < 0.0001; PRC = 15.6%, PR98 = 18.2%), lung cancer (HR: 20.4 p < 0.0001; PRC = 0.7%, PR98 = 1.8%), and CVD (HR: 4.1 p < 0.0001; PRC = 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; PRC = 0.3%, PR98 = 0.4%); suggesting such patients could be excluded in a trial of interest. But, diabetes-without-complication was common but with little effect on risk (HR: 1.2 p > 0.37, PRC = 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 outcome.

**PR53**

THE PREVALENCE OF COMORBID CONDITIONS IN U.S. PATIENTS DIAGNOSED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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OBJECTIVES: COPD is the 4th leading cause of death among U.S. adults. Retrospective observational studies, including outcomes research, can provide important comparative analyses to help identify optimal treatment patterns and therapies. However, such comparisons often require multivariate analysis, propensity score matching, a comorbidity index or other methods to adjust for differences in patient characteristics. Rates reported in clinical trials often vary significantly from those observed in clinical practice. Using this study data we determined the frequency of diagnosed comorbid conditions in the COPD population and serve as a reference research for future comparative studies. METHODS: Private practitioner medical claims (CMS1500 records) from SJD Health’s data warehouse were extracted for each calendar year from November 1, 2007 to October 21, 2008. Patients were identified as those who were first diagnosed COPD diagnosis during the study period. Qualifying patients had 2 or more claims for COPD; a valid age and gender; and were observed in the dataset for 12 months or more from their index date. Patients could be diagnosed with COPD prior to the study period or new to the condition. Comorbid conditions of interest were defined a priori. As possible, MEDRA codes used in clinical trials were crosswalked to corresponding ICD-9 codes. All payer types were included. RESULTS: Of the 751,794 qualifying study patients, the mean age was 67.5 years (STD = ±13) and 59% were female. The 1 year prevalence of diagnosed conditions included was: Supraventricular Arrhythmia 13.2%, Atrial Fibrillation 9.7%, Depression 9.0%, Suicide 0.1%, Insomnia 4.1%, Ischemic disease (ATPC composite) 28.8%, Metabolic Syndrome 0.4%, and Other Mental Health conditions 14.7%. CONCLUSIONS: Patients with COPD have a variety of significant comorbid conditions observed in real-world, clinical practice. These factors can affect findings of comparative studies and are important considerations for future research.