decreased while PGA increased. A 1998–2003 linear extrapolated market share would have predicted a crossing of the two curves around 2005, reinforced by the new 1st line indication of PGA authorized by the EMEA in 2002. This did not occur which might be explained by the non-reimbursement of PGA for first line therapy in Italy. Accordingly, yearly Padova area drug spending was €150,000 less than predicted, on a €600,000 yearly budget. The comparison of IMS data shows two countries where the BB are still prescribed more than PGA, Italy and Germany. The latter is a country where physicians’ fees are reduced if their glaucoma prescription costs exceed their government set budget. PGA monotherapy treatment persistence was longer than with BB, according to Padova and UK GPRD data, in PGA-naive patients. This holds true for first line and second line treatment (UK GPRD); the persistency of a second line PGA equaled first line BB treatment. A short treatment persistency is known to be associated with high cost and disease progression.

CONCLUSIONS: Health care regulation impacted glaucoma prescribing and might be one of the reasons for differences observed between the five European countries. Evaluations of both the cost consequences beyond the drug budget and the public health impact should always accompany the establishment of health care regulations.

SENSORY SYSTEMS DISORDERS—Conceptual Papers & Research on Methods

DERMATOLOGY LIFE QUALITY INDEX IS MORE SENSITIVE THAN PSORIASIS AREA AND SEVERITY INDEX TO MEASURE TREATMENT EFFECT IN PATIENTS WITH PSORIASIS:

FINDINGS FROM THE PHOENIX I TRIAL

Lebwohl M1, Schenkel B2, Han C3, Papp KA4, Krueger GG5

1Mount Sinai School of Medicine, New York, NY, USA, 2Johnson and Johnson Pharmaceutical Services, LLC, Horsham, PA, USA, 3Probity Medical Research, Waterloo, ON, Canada, 4University of Utah Health Sciences Center, Salt Lake City, UT, USA

OBJECTIVES: This analysis evaluated whether the Dermatology Life Quality Index (DLQI) and the Psoriasis Area and Severity Index (PASI) have different responsiveness to measure change of treatment effect in moderate to severe psoriasis patients.

METHODS: In PHOENIX I, 766 patients were randomized to ustekinumab 45 mg or 90 mg at weeks 0 and 4 and then q12 weeks thereafter, or placebo at weeks 0 and 4 with crossover to ustekinumab at week 12. Ustekinumab-randomized patients achieving PASI75 response at weeks 28 and 40 were re-randomized at week 40 to continue maintenance ustekinumab or be withdrawn from treatment until loss of response. DLQI and PASI were assessed at weeks 0, 2, 12, 28, 40, and 52. Multiple regression models were used to assess treatment effect on DLQI by adjusting for PASI improvement.

RESULTS: Significantly greater proportions of patients receiving ustekinumab achieved PASI75 response (66.7%) and clinically meaningful improvement (≥5 points) in DLQI (67.8%) compared with placebo (31.1% and 6.0%, each p < 0.001) at week 12. There was a significant correlation between the change in DLQI and change in PASI (r = 0.65, p < 0.001). After adjustment for baseline DLQI, baseline PASI, and change in PASI, ustekinumab was still associated with significant improvement in DLQI (p < 0.001). For patients originally randomized to ustekinumab, the median improvement from baseline was higher in DLQI (37.5%) than in PASI (21.4%) at week 2, with 11.4% of patients achieving a DLQI score of ≥1, but only 1% achieving a PASI75 response. At week 28 and 40, the DLQI and PASI achieved and maintained similar improvements of ≥90% from baseline. For those who achieved and maintained a PASI75 response from week 12 through week 40, but lost response at week 52, the median improvement in DLQI decreased more significantly (100% at week 40 to 46% at week 52, a 54% reduction) than PASI that decreased from 88.9% at week 40 to 57.6% at week 52 (35.0% reduction).

CONCLUSIONS: The DLQI may be more responsive to change of disease status due to treatment intervention than PASI.

SYSTEMIC DISORDERS/CONDITIONS—Clinical Outcomes Studies

A SYSTEMATIC REVIEW OF THE EFFICACY OF RECOMBINANT ACTIVATED FACTOR VII (rFVIIa) AND ACTIVATED PROTHROMBIN COMPLEX CONCENTRATE (aPCC) IN THE ON-Demand TREATMENT OF MINOR TO MODERATE BLEEDING EPISODES FOR HAEMOPHILIA PATIENTS WITH INHIBITORS

Knight C1, Dano AM2, Kennedy-Martin T3

1RTI Health Solutions, Manchester, UK, 2Novo Nordisk A/S, Virum, Denmark, 3KMHQ, Brighton, UK

OBJECTIVES: The primary treatment for minor to moderate bleeding disorders in haemophilia patients with inhibitors is either rFVIIa or aPCC. The efficacy of both products has been evaluated in individual studies; however, there has not been an overall review and attempt to establish a valid estimate of the effectiveness of rFVIIa and aPCC. We undertook a systematic review of the literature in an attempt to establish robust estimates of the efficacy, speed of bleed resolution, and adverse event profile of both rFVIIa and aPCC. METHODS: We identified 11 open-label cohort studies, six randomized clinical trials, including two head-to-head clinical trials and a meta-analysis. The definition of efficacy varies between these studies, but is usually a composite measure of definite relief of pain, reduction in the size of the haemorrhage, and cessation of bleeding. The individual making the interpretation of efficacy (i.e., the clinician, the patient/caregiver, or a combination of both) and the time from treatment initiation to the recording of the efficacy endpoint also varies across the studies.

RESULTS: Overall, estimates of efficacy based on randomized clinical trials using dosing regimens in line with guidelines are higher for rFVIIa (81%–91%) than for aPCC (64%–80%). Conclusions from a meta-analysis suggest that treatment with rFVIIa may be associated with a faster time to joint bleed resolution than aPCC due to higher efficacy levels at 12, 24 and 36 hour time points. The results from a comparative trial support the improved efficacy rates associated with rFVIIa compared to aPCC. CONCLUSIONS: In general, the studies do report higher efficacy and bleed cessation rates for rFVIIa than for aPCC; however, the measurement of effectiveness of the agents is open to interpretation due to variety of methods being used to evaluate effectiveness. Further head-to-head trials should incorporate a standardized measurement for defining efficacy.
HGT, has contributed to advancing the understanding and management of Fabry disease—a rare lysosomal storage disorder caused by deficiency of the enzyme α-galactosidase A.

METHODS: FOS—a prospective database that collects information on demographics, signs and symptoms, investigations and patient-reported outcomes for patients with a confirmed diagnosis of Fabry disease—was established in 2001. Working groups were appointed to analyse, interpret and publish data to further the understanding of the natural history of the disease and the response to enzyme replacement therapy with α-galactosidase alfa.

RESULTS: As of May 2008, 19 countries have enrolled 1528 patients (799 females, 729 males). Of these, 138 are girls and 123 boys less than 18 years of age. Significant peer-reviewed published findings include evidence of the range and progression of signs and symptoms in males and females (Mehta et al., 2004; Deegan et al., 2006), which have shown that affected women are not simply ‘carriers’ of the disease, but may experience a wide range of symptoms. FOS has also demonstrated that boys and girls may experience symptoms from an early age (Ramawami et al., 2006). Evidence on the effectiveness of α-galactosidase alfa (>2 years of treatment) on various signs and symptoms such as renal function (Schwarting et al., 2006), pain (Hoffmann et al., 2007a) and gastrointestinal symptoms (Hoffmann et al., 2007b) has also been reported.

CONCLUSIONS: FOS has provided an important evidence base that has helped to advance the management of Fabry disease in males and females across all ages. Evidence on the onset and progression of the disease in females and children has been especially important to help achieve an early diagnosis, support clinical decision making and guide management to help optimize patient care.

OBJECTIVES: The study was performed to estimate the prevalence of obesity and associated risk factors such as type 2 diabetes or dyslipidaemia in the Korean adult population.

METHODS: The third Korean National Health and Nutrition Examination Survey in 2005 (KNHANES III) data was used. For the estimation of prevalence of overall obesity (defined by body mass index, BMI) in this report, subjects were selected as adults over 18 years old and completed health examinations. Each sampling weights was used for the analysis. Weights were given as an inverse of the probability of selection, and a non-response adjustment weight. Prevalence of obesity was calculated as the weighted number of obese people divided by the weighted number of all eligible people. Numbers of people with obesity and related metabolic abnormalities were estimated with multiplying the calculated prevalence by the total Korean population.

RESULTS: Among the Korean adult population (age 18 years or more), proportions of people with BMI ≥ 25.0 kg/m², ≥27.0 kg/m² and ≥30.0 kg/m² were estimated to 28.1%, 13.2% and 3.2%, respectively. Within the group BMI ≥ 27.0 kg/m², 9.1% had type 2 diabetes. Among them, 64.6% were diagnosed for T2DM and 21.5% of the diagnosed were untreated. In the same group, the people who had any HDL/LG abnormality without T2DM were 49.4% and only 8.2% of them were previously diagnosed by physician. Overall 70% of the people with BMI ≥ 27.0 kg/m² or higher had at least one metabolic abnormality like T2DM, HDL/LG, abnormality, pre-diabetes or high serum LDL-C.

CONCLUSIONS: This study showed the current situation of obesity and related metabolic abnormalities among Korean population based on KNHANES III data. It will be a good reference for the development of national strategy to improve the management or treatment for obese adults with metabolic abnormalities.

OBJECTIVES: Immune thrombocytopenic purpura (ITP) is a rare and life-threatening autoimmune disease characterized by increased destruction and impaired production of blood platelets by auto-antibodies. International epidemiological studies reported yearly incidence and prevalence of respectively 2 and 10 cases/100,000 persons. No Belgian epidemiological data are currently available. To estimate the incidence and prevalence of adult chronic ITP in Belgium using hospital records.

METHODS: The incidence of adult chronic ITP was estimated using the National statistics on Diagnosis Related Group for splenectomy (DRG 650, year 2004). The prevalence was estimated using the longitudinal IMS Hospital Disease Database (year 2006), including data of 34.3% of Belgian hospitals. All admissions to hospital with a diagnosis of Primary Thrombocytopenia (ICD-9-CM 287.3) were retrieved for patients aged >20 years. The repartition of cases by age and sex was investigated.

RESULTS: A total of 229 splenectomies were performed in adults in 2004. Assuming that 10–30% of splenectomies are ITP-related and 20–40% of chronic ITP patients are splenectomized, this results in a yearly incidence of 0.7–4.3 new ITP cases per 100,000 adults, i.e. 57–344 new cases/year. In 2006, 657 admissions for primary thrombocytopenia were recorded in the Hospital Disease database, for 350 distinct adult patients. This corresponds to an estimated prevalence of 12.6 per 100,000 adults per annum, i.e. 1020 patients. A quadratic increase of the prevalence was observed with age: from 5.8 to 39.8 cases per 100,000 per year in the age groups of 20–29 years to ≥75 years. The prevalence was 2.7 times higher in women aged 20–55 years vs. men (p < 0.001), but similar in patients aged older. CONCLUSIONS: Although non-hospitalized patients were not captured in this analysis, these Belgian incidence and prevalence data are consistent with published international data. The prevalence of ITP increases substantially with age. Prevalence is also higher in women in younger age groups.

OBJECTIVES: To determine the correlations between diseases, patients, drugs factors and systemic lupus erythematosus (SLE) disease activity. To establish model for predicting SLE disease activity. METHODS: The Cross-sectional survey method was applied, SLE patients who visit rheumatologist at Nopparat Rajanatane hospital were interviewed during November 1, 2007 to February 29, 2008, disease duration, infection, SLE knowledge, self management, stress and compliance were collected and evaluated to find correlation with disease activity scores (measure by MEX-SLEDAI). Multiple Regression Analysis was applied to identify model for predict the disease activity. RESULTS: Data