OBJECTIVES: Evaluate, using a markovian probabilistic model, the development of renal impairing complications, 24% (26%) continued with IVIg, and 4 (21%) alternated corticosteroids and IVIg. In total, 41 patients (68%) received 22 treatments with corticosteroids and 10 (17%) received treatments other than corticosteroids and IVIg (3 patients received azathioprine, 3 rituximab, 2 platelet transfusions, 1 anti-D immunoglobulin, 1 danazol and 1 mycophenolate mofetil). CONCLUSIONS: Patterns of treatment of ITP in Spain usually followed recently introduced recommendations from international consensus guidelines. However, in most patients, corticosteroid treatment was given repeatedly, which exceeds current recommendations, i.e., rapidly tapering corticosteroid dose and stopping after 4 weeks. Future research is needed with a larger sample size, to explore the place of splenectomy in treatment sequencing, and better understand the role of combination therapy.

SYSTEMIC DISORDERS/CONDITIONS – Conceptual Papers & Research on Methods

PSY66

WEB VERSUS FACE-TO-FACE (FTF) ADMINISTRATION OF A HEALTH UTILITY SURVEY IN THE GENERAL PUBLIC: RESULTS FROM A TIME-TRADE-OFF (TTO) SURVEY ON IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP)

Stauder A1, Schelle H2, Brazier J3

1Covance, Leeds, West Yorkshire, UK; 2Covance, Guilderston, MD, USA; 3University of Sheffield, Sheffield, UK

OBJECTIVES: Web-based administration of health utility interviews offers the potential to recruit larger, more representative samples with reduced time and costs compared to FTF administration. This analysis compared health utilities elicited through web vs. FTF administration. METHODS: Six distinct ITP health states were included in a TTO and visual analogue scale (VAS)-based health utility valuation, which was administered FTF (n = 63) and via web (n = 339) to members of the UK general public. The Wilcoxon rank-sum test was used to compare utilities using both methods. The interaction between administration method and respondent characteristics was assessed by regression analyses on each pair of health utilities. An additional analysis of exclusion criteria was conducted from least strict to most strict. RESULTS: Demo- graphic characteristics in the FTF and web survey were generally comparable to the UK general population 2001 census data. The mean time to complete the TTO survey was 10.2 minutes in the FTF and 9.9 minutes in the web survey. Valid TTO response rates were higher in the FTF sample (85% to 96%) compared to the web sample (88% to 80%) across health states. Higher proportions of web respondents reported that the TTO exercise was ‘very’ or ‘somewhat unclear’ (17% vs. none) that all or most decisions were difficult to make (41% vs. 30%) compared to the FTF sample. Utilities were statistically significantly lower in the web vs. the FTF survey (P = 0.05). TTO scores were sensitive to exclusion criteria: TTO vs. FTF vs. web respondents. VAS ratings were similar across the two administration methods and less sensitive to exclusion criteria selection. CONCLUSIONS: Our study highlighted trade-offs between the advantages and challenges of web administration. More research is warranted to further improve data quality in web-based utility surveys.

PSY67

PREDICTING EQ-5D UTILITIES FROM NEUROPATHIC PAIN SCORES: COMPARING INDIRECT MAPPING OF PREDICTED ITEM RESPONSES WITH DIRECT MAPPING OF SCORES

Gill N1, Bell CJ1, Xie C1, Battenman P1, van Hout BA2

1Pharmex North America, LLC, Bethesda, MD, USA; 2GlaxoSmithKline, Research Triangle Park, NC, USA; 3University of Sheffield, Sheffield, UK

OBJECTIVES: To predict EQ-5D utilities from neuropathic pain scores using indirect mapping of pain scores to EQ-5D utilities (scores subsequently converted into utilities), or direct mapping of pain scores into utilities. METHODS: Mappings were based on baseline data from three longitudinal surveys of adults (n = 2,719) who had ≥3 months of painful diabetic peripheral neuropathy (pDPN) or post-herpetic neuralgia (PHN), were receiving pain medications, and completed EQ-5D and pain questionnaires. In indirect mapping, ordered logit regression was used to predict and simulate EQ-5D responses using the following predictors: age, gender, and pain scores ranging from 0 (“no pain”) to 10 (“pain as bad as you can imagine”). Utilities were computed based on predicted responses using a U.S. algorithm. In direct mapping, DLS regression was used to directly predict utilities using the same predictors. Cross-validations were conducted separately in pDPN and PHN respondents. Comparisons were made between actual and estimated values on mean utilities, mean square/absolute errors (MSE/MAE). RESULTS: Both computed utilities were constrained within the 0 to 1 range along the increment/decrement of the pain scores. Direct mapping explained 29% of the variance and had an estimated mean utility close to the observed data [0.594 (MSE = 0.31; MAE = 0.148)]. Indirect mapping resulted in lower mean utility [0.388 (MSE = 0.054; MAE = 0.184)] but its distribution was more consistent with the actual values.
Higher MSIs found in indirect mapping were mostly pronounced in lower utilities (<0.2). Predicted utilities were slightly higher than actual values when population average was used for input (0.3–3%). Similar findings were noted in sub-samples.

CONCLUSIONS: Both methods produced robust results. Compared to direct mapping, indirect mapping better represents the EQ-5D’s descriptive information, although with higher MSE/MAE. This research provides algorithms for estimating EQ-5D item responses and utilities on the basis of pain scores in absence of direct utility evidence. Further investigation using out-of-sample predictions is encouraged.

**HEPATITIS C-SPECIFIC QUALITY OF LIFE IS NOT PROPERLY MEASURED BY EXISTING INSTRUMENTS**

**OBJECTIVES:** Measures commonly used in Hepatitis C (HCV) Health-Related Quality of Life (HRQoL) research were investigated to determine whether they effectively encompass the disease-specific experience of HCV. METHODS: Important HCV-HRQoL dimensions were identified via a review of qualitative and quantitative literature. Medline and Embase were interrogated for appropriate studies. Quality and relevance of HCV HRQoL studies were assessed against FDA and EMEA guidelines. The review facilitated construction of a conceptual framework of HCV HRQoL. The framework was compared against HRQoL measures used in HCV research, including the SF-36, Hepatitis Quality of Life Questionnaire (HQLQ), Chronic Liver Disease Questionnaire (CLDQ), Liver Disease Symptom Index (LDSI 2.0), and Hepatitis B Quality of Life instrument (HBQoL). RESULTS: Numerous dimensions encompassing the HCV HRQoL experience were not adequately represented by common measures. Absent from the measures were consideration of treatment adherence and management, and management of side effects; HIV/HCV co-infection issues; drug addiction; resilience and coping; contagiousness and transmission-related issues; illness uncertainty and unpredictability; and changes in body image. HCV dimensions needing further attention were fatigue; illness uncertainty; psychiatric complications including emotional volatility; cognitive impairment during daily activity; sexual dysfunction; the multidimensional nature of stigma; and fatigue variability. CONCLUSIONS: The disease-specific experience of HCV is not fully addressed by any single existing measure. An HCV HRQoL instrument that is sensitive to the identified dimensions and issues would be of considerable benefit. Such a measure would help health care providers plan individual interventions for problematic HRQoL domains, as well as improve patient monitoring during treatment and clinical research trials, and contribute to determining the value and efficacy of treatment programs.

**URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies**

**PSY68**

**CONTRAST-INDUCED NEPHROPATHY IN PATIENTS WITH CHRONIC KIDNEY DISEASE UNDERGOING COMPUTED TOMOGRAPHY: A COMPARATIVE SAFETY META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS**

**Carola Lopedo F, Arana E**

1Spanish Medicines and Healthcare Products Agency (AEMPS), Madrid, Spain; 2Fundación Instituto de Investigación en Servicios de Salud, Valencia, Spain

**OBJECTIVES:** We conducted a systematic review and meta-analysis comparing the incidence of contrast-induced nephropathy (CIN) in patients at risk with chronic kidney disease (CKD) undergoing computed tomography (CT). METHODS: Randomized controlled clinical trials designed to evaluate the nephrotoxicity related to iosomolar contrast media (IOMC) compared to low-osmolar contrast media (LOCM) were searched in the following electronic databases: PubMed, MEDLINE, EMBASE, ISI Web of Knowledge and Virtual Health Library (BVS-BIREME), as well as abstracts presented at related scientific societies meetings. Prior to data extraction, definitions of nephrotoxicity were established. We applied a random effects model of DerSimonian and Laird, with heterogeneity (Q statistic), publication bias (Egger and Begg test) and sensitivity analyses. RESULTS: Five studies were included with 716 randomized patients. When CIN was defined as increased serum creatinine (SCr) ≥ 25%, the relative risk (RR) was 0.71 (95% CI 0.40 to 1.26)—in favor of IOMC—and when it was defined as SCr ≥ 0.5 mg/dL it showed a RR 1.48 (95% CI 0.37 to 5.87)—favoring LOCM—in the four studies used this criterion. CONCLUSIONS: In patients with CKD undergoing CT there is a similar risk of CIN with the administration of any contrast media studied. CIN incidence depends on the chosen criteria and is lower with the definition of SCr ≥ 0.5 mg/dL at 24–72 h.

**COMORBIDITY EFFECT ON HOSPITAL READMISSION RATES IN PATIENTS WITH RENAL FAILURE**

**Riazi Y, Walker DR, Inglesse G**

1Northwestern University, Chicago, IL, USA; 2Baxter Healthcare Corporation, McGaw Park, IL, USA

**OBJECTIVES:** To examine the effects of comorbidities on the hospital readmission rate in renal failure (RF) patients on dialysis. METHODS: We used 2005–2007 U.S. MarketScan claims database to identify RF patients under 64 years old, RF dialysis patients were identified using ICD-9 and CPT codes. RF patients had to be continuously eligible for at least 6 months after the initial dialysis diagnosis date (index dates). Comorbidity scores were measured by the Charlson Comorbidity Index (CCI). We identified readmission rates to the hospital within 15 days after the index date. ANOVA tests and logistic regression were performed to compare outcomes by CCI. RESULTS: A total of 6117 patients were diagnosed with RF. Among those who initiated dialysis treatment, 13.9% and 86.1% were treated with peritoneal dialysis and hemodialysis, respectively. Over half of all patients were male (55.2%) and the average age was 52.4 years. The most frequent comorbid conditions were hypertension (69.1%), diabetes (34.3%), congestive heart failure (CHF) (26.3%), and anemia (26.4%). The majority of patients had low (78%), score < 3 (moderate) or (2.0%, score 4–5) CCI scores. 7.2% of patients had a score of 6–7 and 12.0% had a score > 8. Older patients had significantly more severe CCI scores (P < 0.001). The average age in the moderate and severe co-morbidity groups was 51.7 and 57.4 years old, respectively, a total of 1.3% of RF dialysis patients were readmitted to the hospital within 15 days. Their readmission rates were significantly associated with the CCI score (P < 0.001). Patients over age 50 were significantly more likely to readmit to the hospital (P < 0.001). Those with a higher CCI score were more likely to readmit to the hospital within 15 days (moderate group OR: 3.0, P < 0.001, very high group OR 4.04, P < 0.001). CONCLUSIONS: For patients with RF, the presence of severe comorbid physical conditions was significantly associated with hospital readmission within 15 days.

**ASSESSMENT OF COMORBIDITIES IN PATIENTS WITH OVERACTIVE BLADDER (OAB) DISORDER: AN ELECTRONIC MEDICAL RECORD (EMR) DATA ANALYSIS**

**Ausha C, Kim J, Chakravart P, Anderson KE**

University of Utah College of Pharmacy, Salt Lake City, UT, USA; University of Utah, Salt Lake City, UT, USA; Novartis Pharmaceuticals, East Hanover, NJ, USA; Wake Forest University Baptist Medical Center, Winston-Salem, NC, USA

**OBJECTIVES:** To compare OAB patients to non-OAB patients by assessing their pre-existing OAB diagnosis on electronic medical record (EMR) data. METHODS: This retrospective cohort study used the General Electric (GE) Centricity EMR database. The study subjects were from between January 1, 1996 to March 30, 2007. The index date for OAB patients was defined as the date of their first prescription for an antimuscarinic agent or a diagnosis for OAB identified by ICD-9 codes. The index date of non-OAB subjects without diagnosis or pharmacy claim was defined as a year after the first activity date in the EMR. Subjects ≥18 years old were included and had 393 days of continuous enrollment before and after the index date. Non-OAB subjects were matched to OAB subjects on 1:1 propensity score matching based on age, body mass index (BMI) and gender at baseline. Two linear regressions were constructed using the outcome variables of the Charlson Comorbidity Index (CCI), using ICD-9 codes, and the Chronic Disease Score (CDS), using prescribed drugs, respectively. RESULTS: There were 38,739 OAB subjects [mean age 61.8 (SD:13.26) years; 85.67% women] and 38,739 matched non-OAB subjects [mean age 61.17 (SD: 13.24) years; 85.70% women]. Patients with OAB had higher mean CCI and CDS than subjects without OAB ([CCI]: 1.17 vs. 1.11 (p-value < 0.001); [CDS]: 2.95 vs. 1.74 (p-value < 0.001)). After controlling for other covariates, the linear regressions (n = 22,544) showed that OAB patients had higher CCI and CDS than subjects without OAB by 0.037 (p-value < 0.001) and by 0.881 (p-value < 0.001), respectively. CONCLUSIONS: This study determined that pre-existing comorbidities were more prevalent in OAB patients than in non-OAB patients. These comorbidities should be taken into account when making the decision on the most appropriate treatment option for each individual patient.

**PSY28**

**A SYSTEMATIC REVIEW OF IMMUNOSUPPRESSIVE REGIMENS IN LOWER IMMUNOLOGICAL RISK RENAL TRANSPLANT RECIPIENTS**

**Eun Ah MH, Kim HJ, Ko RK, Ko SK**

Pharmaceuticals Korea Ltd., Seoul, South Korea

**OBJECTIVES:** In this study, we conducted a systematic review of three immunosuppressive regimens in lower risk renal transplantation and compared their efficacy. METHODS: MEDLINE were searched and two independent reviewers assessed studies. We limited the search to English, Randomized controlled trial, human and publication between January 1, 1999-May 31, 2010. Studies which were conducted with adult renal transplant patients (>18 years) with lower immunological risk were included. Sirolimus + steroid regimen with 3 months cyclosporine, and CNI (Calcineurin inhibitor: cyclosporin or tacrolimus) regimen with MMF and steroid were eligible for inclusion, a total of 434 studies were retrieved from MEDLINE. Firstly, by reviewing title, abstracts and full text, 10 studies were eligible for the inclusion finally. As outcome data, we extracted patient survival and graft survival. RESULTS: There was no head-to-head clinical trial which compared the three regimens concurrently. But results from 2 studies shows trend of higher patient and graft survival with low dose CNI regimen than standard dose cyclosporine. ELITE-Symphony Study illustrated patient and graft survival of 96.5% and 89.3% for standard dose cyclosporine, 98.2% and 93.1% for low dose cyclosporine, 97.2% and 94.2% for low dose tacroliumus at 1 year. And CAESAR Study showed 97.1% and 92.4% for standard dose cyclosporine, 97.8% and 94.5% for low dose cyclosporine at 1 year. 5 reports from ‘Rapamune Maintenance Regimen Study’ showed outcomes for sirolimus based regimen during 5 years. At 1 year, patient and graft survival were 98.1% and 97.2% and decreased thereafter. One study of tacrolimus based regimen reported 2-year