The data used for the present study had significantly lower rates of other pharmacological therapy (34.2% vs. 43.4% narcotic episodes, p = 0.048, 34.2% vs. 43.2% NSAB, p = 0.003, 17.4% vs. 26.2% muscle relaxants, p = 0.001, 10.6% vs. 20.4% corticosteroids, p < 0.001) and non-invasive therapy (16.4% vs. 35.6% choroactic therapy, p = 0.001, 13.0% vs. 34.2% physiotherapy, p < 0.001). Duloxetine-treated patients were also significantly less likely to have a back surgery during the study period compared with controls (4.0% vs. 2.0%, respectively; p = 0.021). Average 6-month direct costs were not significantly different between duloxetine-treated patients and controls ($3554 vs. $3637, respectively).

CONCLUSIONS: Duloxetine treatment in LBP patients vs. other non-surgical treatment was associated with a lower surgery rate as well as reduced rates of other non- surgical therapies without significant differences in direct costs.

HEALTH CARE UTILIZATION AND FACTOR COST IN HEMOPHILIA


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OBJECTIVES: Hemophilia is a costly chronic illness. Clotting factor accounts for over 70% of hemophilia costs. We examined health care utilization, factor use and costs in people with hemophilia A from six Hemophilia Treatment Centers in seven states.

METHODS: Eligible patients obtained prospectively through interviews and chart reviews with 329 patients aged 2 to 65 years enrolled in the Hemophilia Utilization Group Study Part V-A (2005–2007). We analyzed one-year health care utilization (outpatient, emergency room visits, and hospitalization) and total cost of clotting factor dispensed. Factor cost was estimated using average sales price from Medicare Part D. We further examined the association between these variables and clotting factor infusion strategies (epoagen to treat a bleed) versus prophylactic (administer multiple times each week) in patients with severe hemophilia using Chi-square test for categorical variables or Wilcoxon rank-sum test for continuous variables.

RESULTS: Fifty percent of patients were adults; Mean age 9.7 ± 4.5 years for children and 33.7 ± 12.5 years for adults. Two-thirds of patients had severe hemophilia. 97% used clotting factor; 68% of severe patients infused prophylactically. 89% reported using health services at least once in the past year. Total average annual disease burden of hemophilia was $24,855 (range: $6,558 – $59,000). 31% of patients had a comprehensive visit (range: 6–14) and a mean follow up of 18.5 years. 23% saw a physical therapist (range: 0–21); 19% had emergency room visits and 15% were hospitalized. Mean cost of clotting factor was $208,548 (median: $232,831) per patient-year. In patients with severe hemophilia, average number of hospital days/patient-year was 8.3 for prophylaxis users versus 13 for episodic treatment users, p = 0.14. Patients with severe hemophilia were less likely to have an emergency room visit if they were on prophylaxis (13% vs. 25%, p = 0.047). Mean factor cost was $281,151 per patient-year (median: $224,856) for patients on prophylaxis versus $15,485 (median: $162,148) for episodic treatment users (p < 0.0001). CONCLUSIONS: This study adds to the growing evidence of the beneficial impact of prophylactic infusion of clotting factors, compared to episodic treatment, may be associated with decreased health care utilization, including emergency room visits and hospitalizations.

PROCESS MEASUREMENT AND CALCULATION IN IV-PCA AT UNIVERSITY HOSPITAL OULU FINLAND


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OBJECTIVES: To describe and measure intravenous patient controlled analgesia (IV-PCA) processes in postoperative pain management in patients with moderate to severe pain in clinical practice that have undergone surgery at the University Hospital Oulu Finland. METHODS: A model was designed and visualized through Swimlane notation. Sub process levels were defined as “education”, “purchasing/depreciation/mainte- nance”, “procurement”, “supply”, “application” and “disposal”. Based on these sub process levels, data was collected by two research methods, interviews and measurement- ment forms including patient and staff satisfaction questionnaires. RESULTS: Twelve members of Oulu University Hospital personnel with different responsibilities were interviewed to define the roles and activities involved in the entire IV-PCA process. Ten different roles were defined with 151 different activities. The involved roles and the duration of each activity in the sub process levels “supply”, “application” and “disposal” were measured from 108 consecutive patients with eight different surgery types. The most common surgery types were back surgery and gynecological laparoscopy. The average duration of IV-PCA use per patient was 41 hours and 39 minutes. The staff spent on average 132 minutes in IV-PCA related activities, of which the nurse spent 91%. The average cost, including material and staff, for 24-hour use with a lower threshold IV-PCA was $122. The patients found the IV-PCA system easy to operate but hindered them in mobility and they were not able to sleep undisturbed. According to the staff the IV-PCA system operated error-free and reliably but hindered the mobilization of the patient. CONCLUSIONS IV-PCA involves many different roles and activities and intertwined sub processes. Therefore the whole system is complex and resource demanding. Comparisons of the results from similar studies at other hospitals will be very useful when trying to optimize the process.

SYSTEMIC DISORDERS/CONDITIONS – Patient-Reported Outcomes Studies

IMPACT OF OBESITY ON HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ASTHMA IN THE USA

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OBJECTIVES: To examine the impact of obesity on health-related quality of life (HRQOL) in patients with asthma. METHODS: The data used for the present study was obtained from the 2004–2006 Medical Expenditure Panel Survey (MEPS) data, a comprehensive national representative survey of the U.S. non-institutionalized popu- lation. Subjects were included if they were diagnosed with asthma or diagnosed with ICD-9 code of 493 by their physician, and did not have pregnancy, malignancy, kidney dialysis, or immunodeficiency. Asthma patients were classified as normal (body mass index(BMI): 18.5–25.0), or obese (BMI≥30). MEPS measured HRQOL using SF-12 (physical component scale (PCS-12), 49.0 vs. 47.0, p = 0.019, 13.9 vs. 5.3 for K-6, 0.6 vs. 1.1 for PHQ-2). While controlling for the study variables, QOL were worse if patients were obese, older, female, or less educated, as well as have cardiovascu- lar disease. Proportion of patients with PHQ score ≥2 was 10.5% in normal weight and 19.7% in obese patients. CONCLUSIONS: Obesity significantly deteriorates quality of life including both physical and mental components in asthma patients. The national health promotion to control weight needs to be emphasized to increase the beneficial effects of HRQOL in asthma patients.

THE RELATIONSHIP BETWEEN QUALITY OF LIFE, DISABILITY AND PAIN IN PATIENTS WITH FAILED BACK SURGERY SYNDROME

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OBJECTIVES: Patients with failed failed back surgery syndrome (FBS) and chronic neu- ropathic pain experience levels of health-related quality of life (HRQOL) that are con- siderably lower than those reported in other areas of chronic pain. Interventions aimed at reducing pain in FBS patients are expected to bring considerable HRQOL improve- ments. Using data from the multidisciplinary PROCESS trial, we investigated the longitudi- nal relationship between generic HRQOL – assessed using two instruments often used in clinical trials (i.e. the SF-36 and EuroQol SD) – and disease specific outcome measures (i.e. Oswestry Disability Index [ODI], leg and back pain visual analogue scale [VAS]) in neuropathic patients with FBS. METHODS: Multivariate hierarchical regression models to capture the longitudinal trend in the dependent variables (i.e. generic HRQOL), and to assess their relationship with patient baseline variables and clinical history. RESULTS: Generic HRQOL was unvariably consistently associated with disease specific outcome measures: ODI (correlation coefficient: 0.46 to 0.638) and leg pain VAS (correlation coefficient: 0.165 to 0.436). In multilevel regression analysis, baseline HRQOL and ODI were found to be significant predictors of generic HRQOL (all p < 0.001). Leg pain was predictive of EuroQol SD and the SF-36 physical component summary (PCS-12) at 0.001) but not of its mental com- ponent summary score (p = 0.201). Baseline socio demographic characteristics (age and gender), clinical history (time since last back surgery and number of back surgeries), location of pain and intensity of back pain were not predictive of generic HRQOL. All (p > 0.10). CONCLUSION: Reducing in leg pain and functional disability is statistically Hospital persicated with improvements in generic HRQOL. This is the first study to investigate the longitudinal relationship between generic and disease specific HRQOL of neuropathic pain patients with FBS, using multinational data.

THE HEALTH BURDEN OF NEOPLASTIC PAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS OF HEALTH UTILITIES

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Patients with neuropathic pain (Neap) report poorer health-related quality of life (HRQOL) and incur higher health care costs than non neuropathic pain patients. Although the impact of Neap on HRQOL has been the subject of previous reviews,
the health utility associated with NeuP remains unclear. Knowledge regarding this association is needed, as it impacts economic evaluations of treatments for NeuP.

OBJECTIVES: To undertake a systematic review and meta-analysis of published health utility values of patients with NeuP. METHODS: A detailed search of bibliographic and technical databases (Medline, Embase, Cochrane Library) and specialist economic databases (NHS Centre for Reviews and Dissemination Economic Evaluation Database and Health Economics Evaluation Database) was undertaken (to September 2008). Reference lists of retrieved reports were also searched. Studies reporting utility single-index measures (preference based) in NeuP were included. Random effect meta-analysis was used to pool utility estimate across studies. The association of utilities and a number of pre-defined factors (NeuP indicator, patient age, sex, duration and severity of pain and method of utility scoring) was examined using meta-regression. RESULTS: Three studies reporting utility values in patients with NeuP were included, of which 11 were randomised trials that also reported the treatment change in utility. The weighted pooled mean utility score across the studies was 0.48 (95% CI: 0.44 to 0.53). There was evidence of substantial statistical heterogeneity across studies (P = 0.0001). Although we found little evidence of variation in utility across patient characteristics or NeuP indication, increasing pain severity was found to be strongly associated with a reduction in utility. CONCLUSIONS: This study confirms that NeuP patients experience low utilities and therefore poor quality of life. Pain severity appears to be a major driver of the negative health impact of NeuP and therefore needs to be considered in future economic evaluations of interventions for this patient population.

**PSY17**

THE OBESITY TRENDS IN GENERAL POPULATION OF THE REPUBLIC OF SERBIA

Table 1, Table 2, Dijakic S, Ristic M, Tatic O*

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OBJECTIVES: It is known the obesity increases in general population of the Republic of Serbia. The aim of the study was to determine the mean value of the BMI in adults. Data were from 2005 to 2006. Proposed study, conducted in 2007 had been focused on the dietary behavior and consumption of dietary supplement among the adults, as well as gender differences.

METHODS: An observational, prospective study was performed among adults (both, males and females) in form of short questionnaire. The questionnaire included various topics covering the following concepts: personal data, usage and knowledge of dietary supplements and other way for weight loss. A total of 993 adults were included, 224 (22.56%) who used dietary supplements and 769 (77.44%) who didn’t. The study was conducted in public pharmacy setting of three districts of Serbia (Belgrade, Novi Sad and Nis). RESULTS: The mean value of BMI for male was 26.25 and female 23.79, difference was statistically significant. It is showed the BMI values were higher in all age groups of males compared to those of females, except in 60 years of age and older. In both cohorts groups the obesity became clinically significant in population older than 40 years of age. Of 224 examines, only 10% used dietary supplements every day and 12% used it sparingly. The main purpose of their usage is physical appearance (49%), disease prevention (41%) and existing disease (10%). Previously to dietary supplements use the examiners tried to lose weight through diet (35%), exercise (23%), lower food portions without any diet (23%), medication (11%), and 7% did not take any action. CONCLUSIONS: We conclude the outcomes of the proposed study have showed the somewhat awareness and behavior toward obesity in domain of disease prevention and gender difference (males have higher BMI values) exist in the general population of the Republic of Serbia.

**PSY38**

VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE FOR PRESCRIPTION WEIGHT LOSS MEDICATION IN OBESITY; TRIM-WEIGHT

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OBJECTIVES: Obesity is a worldwide pandemic with serious health implications including increased risk of cardiovascular disease and type 2 diabetes. Unfortunately, attempts to develop antiobesity medications have had mixed results due to poor tolerability and adverse events. Furthermore, the absence of a well developed patient reported outcome (PRO) measure assessing the impact of antiobesity medication on functioning and well-being has limited our understanding of treatment impact. This study validated the Treatment Related Impact Measure (TRIM)-Weight, a disease specific PRO measure for assessing these relevant impacts. METHODS: The 43-item TRIM-Weight, developed and debriefed in a previous study according to the 2006 draft FDA guidelines, was validated in this web-based survey in 4 countries (United States, UK, Australia, Canada) for measurement structure and psychometric properties to assess factor structure, reliability, validity for the total score and for each domain. RESULTS: Two hundred and eighty eight respondents completed the survey. Twenty-one of the 43 items were omitted due to redundancy with other items, ceiling effects, poor factor loadings, or poor conceptual fit resulting in a 22 item measure. A five-factor structure was achieved with domains of Daily Life, Weight Management, Treatment Burden, Exposure of Side Effects, and Psychological Health. Internal consistency coefficients of the total score and each subscale ranged between 0.71 and 0.94 and test-retest reliability ranged from 0.75 to 0.86. All pre-specified hypotheses for convergent and the majority for known-groups validity were met. The completion time was estimated to be 3.38 (SD 2.49) minutes. CONCLUSIONS: The development of the TRIM-Weight was conducted according to well-defined scientific principles. The total score, as well as each domain subscale, are a brief, conceptually sound, rigorously developed PRO measure with strong evidence supporting the psychometric properties. Use of the TRIM-Weight in both clinical and research settings can facilitate development of patient-centered treatments resulting in a greater adherence, tolerability, and treatment efficacy.