

in pre-pubertal children with idiopathic GH Deficiency (GHD) and Turner Syndrome (TS). The long-term prediction of height was validated in new cohorts of pre-pubertal children with GHD (n= 664) or TS (n=607) from KIGS. **RESULTS:** When height was simulated from GH start in GHD, the predicted mean (SD) gain after 4 years was 30.4 (3.4) cm; the observed height gain was 30.0 (5.0) cm. In TS the corresponding predicted and observed mean gains were 27.2 (2.2) and 26.5 (3.8) cm. CONCLUSIONS: Sequential application of annual KIGS growth prediction models permits accurate simulation of height development during the first four years of GH treatment in GHD and TS and is applicable for patient groups from GH start. Long-term growth simulation helps managing patient's expectations and facilitates an individualised, cost effective growth hormone (GH) therapy in children.

STUDYING HETEROGENEITY IN TREATMENT RESPONSE IN WOMEN WITH IDIOPATHIC MENORRHAGIA TREATED WITH LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM (LNG-IUS): APPLICATION OF INNOVATIVE METHODS TO IDENTIFY DIFFERENTIAL RESPONSE

Stull DE^1 , Houghton K^1 , <u>Filonenko A^2 </u>, Wittrup-jensen K^2

¹United BioSource Corporation (formerly), London, UK, ²Bayer Schering Pharma, Berlin, Germany **OBJECTIVES:** To establish whether there are subsets of women with idiopathic menorrhagia who experience differential health-related quality of life (HRQL) benefits with LNG-IUS treatment, and which factors could be attributed to those differences. METHODS: Data for women with idiopathic menorrhagia residing in India, Russia and Turkey were derived from a prospective, 12-month observational study. Latent profile analysis (LPA) was used to identify unknown subgroups of differential responders on the Mental Component Summary (MCS) of the SF-36v2. Post hoc analyses were performed to characterize identified subgroups using baseline and 12 month data. RESULTS: Overall improvement in MCS scores from baseline to 12 months was 8.4 points. LPA analyses revealed two distinct subsets of patients: one smaller subset (30% of the sample) showed a smaller improvement (2.3 points) than the improvement overall and are thus referred to as 'partialresponders.' A larger subgroup (70% of the sample) was identified with a much greater improvement (11.3 points) than that overall, thus referred to as 'responders'. Post hoc analyses revealed statistically significant differences between MCS responders and partial-responders: significantly greater proportion of MCS responders had university-level education, were more likely to reside in India or Russia and be employed, reported 'none' or 'light' bleeding intensity while on treatment, reported greater patient and physician satisfaction with treatment, and had higher 12-month haemoglobin levels. CONCLUSIONS: Understanding of heterogeneity of treatment response is critical for routine clinical practice. Application of LPA identified two distinct subgroups of women showing differential response to HRQL from LNG-IUS treatment. All women showed a statistically significant improvement in HRQL as measured by the MCS, although this improvement was greater for a large subset of women in the sample. Country-level differences in treatment effect on mental HRQL may be subject to cultural or health care practice

Systemic Disorders/Conditions - Clinical Outcomes Studies

TOLERABILITY OF ORAL LONG-ACTING OPIOIDS IN THE TREATMENT OF CHRONIC PAIN: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS Nalysnyk L^1 , Kavanagh S^2 , Xu Y^1 , Mercaldi K^3 , Martin A^1 , Merchant S^4

³United BioSource Corporation, Lexington, MA, USA, ³Ianssen Global Services, Beerse, Belgium, ³United BioSource Corporation, Bethesda, MD, USA, ⁴Janssen Global Services, LLC, Raritan, NJ,

OBJECTIVES: To evaluate the tolerability of oral long-acting opioids (LAOs) in patients treated for chronic pain. Opioid analgesia is the mainstay of treatment for moderate to severe chronic pain. While highly effective in relieving pain, it is limited by adverse events (AEs), especially gastrointestinal and central nervous system events. AEs may result in additional treatment costs and discontinuation of therapy, compromising pain management. METHODS: A systematic review of English-language literature published through February 2009 was performed. Random $ized\ controlled\ trials\ comparing\ commonly\ used\ or al\ schedule\ II\ LAOs\ with\ placebo$ or another opioid were included. Data on pain measures and pre-specified AEs (nausea, vomiting, somnolence, constipation, headache, pruritus, and dry mouth) were collected from each study. For descriptive statistics, treatment-arm data on tapentadol, oxycodone, oxymorphone, morphine, hydromorphone, and placebo were pooled across trials. Direct and indirect meta-analyses were performed to compare AE rates of individual LAOs with placebo and with tapentadol. RESULTS: Seventy-one published studies met the inclusion criteria. Tapentadol was associated with the lowest incidence of AEs across the 5 LAOs, with the exception of headache and dry mouth. The AE incidences for tapentadol, oxycodone, oxymorphone, morphine, hydromorphone, and placebo were: nausea: 19.5%, 32.5%, 38.8%, 29.7%, 33.5%, and 8.4%, respectively; vomiting: 7.9%, 16.1%, 19.9%, 15.5%, 15.1%, and2.4%; somnolence: 10.2%, 24.8%, 18.3%, 33.6%, 50.4%, and 3.7%; constipation: 14.1%, 34.7%, 26.9%, 43.2%, 27.6%, and 6.1%; headache: 13.3%, 11.3%, 9.7%, 3.8%, 5.7%, and 10.4%; pruritus: 5.2%, 16.6%, 15.7%, 20.1%, 20.8%, and 1.5%; and dry mouth: 6.8%, 11.8%, 10.0%, 31.4%, and 2.6% (placebo), with no data for hydromorphone. Indirect meta-analyses further revealed a significantly favorable tolerability profile of tapentadol when compared to oxycodone, oxymorphone, and morphine. CONCLUSIONS: Opioid-associated AEs are common, but the incidence varied across the LAOs reviewed. Indirect meta-analyses suggest that tapentadol has a better tolerability profile than other LAOs.

COEXISTENCE OF IMMUNO-MEDIATED INFLAMMATORY DISEASES: AN ANALYSIS OF THE QUEBEC ADMINISTRATIVE HEALTH DATABASES

<u>Lachaine</u> J¹, Beauchemin C¹, Martel MJ², Parison D³

¹University of Montreal, Montreal, QC, Canada, ²Abbott Laboratories, St-Laurent, QC, Canada, ³Abbott Canada, St-Laurent, QC, Canada

OBJECTIVES: Immuno-mediated inflammatory diseases (IMIDs) may coexist within the same patient. Anti-TNFs have been shown to be effective at treating IMIDs. The present study aimed at evaluating the prevalence of the coexistence of selected IMIDs and other comorbidities, characterizing the patient population and assessing the use of anti-TNFs from a populational standpoint. $\textbf{METHODS:} \ A \ co$ hort of patients who had received at least one diagnosis of rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, psoriasis (Ps), Crohn's disease (CD), ulcerative colitis, or uveitis, between January 2005 and December 2009, was randomly selected from the Régie de l'assurance-maladie du Québec (RAMQ) databases. The coexistence and temporality of the above diagnoses as well as other predefined chronic conditions were assessed. Characterization and stratification according to demographics and anti-TNF use (use or no-use) were also performed. RESULTS: A total of 80,566 patients who had at least one diagnosis of an IMID were included in this cohort. The study population was on average 53.6 years old (SD: 21.3 years) and was in majority female (60,1%). Most common primary diagnoses were RA (33.4%), Ps (33.8%) and CD (22.8%) while 3.9% of patients had received at least one prescription of an anti-TNF medication. In this population, 9.1% of patients presented with one coexisting IMID diagnosis and 1.4% with 2 or more coexisting diagnoses. Among patients who had used an anti-TNF, 27.9% had one coexisting IMID diagnosis and 9.1% had 2 or more coexisting diagnoses. Other chronic comorbidities were found in 82.8% of patients. The most frequent comorbidities were hypertension (37.2%), cardiovascular diseases (22.4%), diabetes (16.7%) and osteoporosis (15.7%). CONCLUSIONS: Coexisting IMID diagnoses and comorbidities are often present in patients with IMID and greatly contribute to the burden of disease.

THE POTENTIAL IMPACT OF OBESITY DEGREE ON DIABETES, HEART ATTACK, HYPERTENSION, CHRONIC ANXIETY AND DEPRESSION IN ADULT SPANISH

<u>Espallardo O</u>¹, Busutil R¹, Ribaric G², Lopez-belmonte M¹ ¹Johnson & Johnson Medical, Madrid, Madrid, Spain, ²Ethicon Endo-Surgery (Europe) GmbH, Hamburg, Hamburg, Germany

OBJECTIVES: Obesity is considered a major Public Health issue in most developed countries nowadays for its wide spread across population groups, as well as its contribution to the development of chronic diseases. Our objective was to estimate and better understand the impact of progressively increasing Body Mass Index (BMI) on diagnosed Diabetes, Heart Attack (HA), Hypertension, Chronic Anxiety (CA) and Chronic Depression (CD) in adult population. METHODS: Retrospective analysis of the Spanish 2009 European Health Survey System data base was conducted. Data from population under 18 years old or with BMI under 18.5 or with not reported BMI were excluded. Sample size of 19,880 adults (89.6% of the initial sample) was available for analysis. A logistic regression model was constructed for each of the five dependent variables. Age groups were divided by quartiles. BMI groups were "18.5-24.9", "25-29.9", "30-34.9" (g3) and "35 or more" (g4). RESULTS: Diabetes prevalence was 7.7%; (OR adjusted for g3:2.3; 95% CI: 2.0-2.7; OR_g4: 4.2; CI:3.4-5.3), Hypertension prevalence was 23.6%; (OR_g3: 3.4; CI:3.0-3.8; OR_g4: 5.8; CI: 4.8-6.9), HA prevalence was 2.8%; (OR_g3: 1.7; CI: 1.3-2.1; OR_g4: 1.6; CI: 1.1-2.5), CA prevalence was 8.2%; (OR_g3: 1.6; CI: 1.3–1.8; OR_g4: 2.3; CI: 1.8–2.9), CD prevalence was 7.9%; (OR_g3: 1.7; CI: 1.4-2.0; OR_g4: 2.7; CI: 2.2-3.4). All the stated OR reached statistical significance (p < 0.05 for OR_g4 in HA and p < 0.001 for all the rest of them). CONCLUSIONS: The results show how the risk of the examined comorbidities largely increases in those patients with BMI>35. Considering its potential economical impact on Public Health, it would be required to design and implement effective strategies aimed at the early detection of subjects at risk and the provision of adequate treatment, as well as to establish suitable preventive programmes.

PSV4

COMPARISON OF INFLIXIMAB AND USTEKIMUMAB FOR TREATMENT OF MODERATE TO SEVERE PSORIASIS: A MIXED TREATMENT META-ANALYSIS

 $\overline{\text{Fan}}$ T¹, Bennett H², Smith N¹, Marin M², Sen S¹ $\overline{\text{Merck}}$ & Co., Inc., Whitehouse Station, NJ, USA, ²OptumInsight, Burlington, ON, Canada

OBJECTIVES: No direct comparisons have been made between infliximab and ustekinumab in the treatment of moderate to severe psoriasis. A mixed treatment comparative (MTC) meta-analysis was conducted to compare the relative efficacy of infliximab and ustekinumab for the treatment of moderate to severe plague psoriasis. METHODS: Randomized clinical trials that included infliximab, 5 mg/kg, ustekinumab 45 mg or ustekinumab 90 mg in the treatment arm and reported PASI 75 and PASI 90 endpoints were identified from a systematic literature search. The log odds ratio (log OR) was used as the treatment effect measure using both fixedeffects and random-effects MTC models. Six trials meeting the inclusion criteria were included in the mixed treatment networks to estimate relative efficacy. RESULTS: The pooled odds ratio of achieving PASI 75 was 164.4 (95% (CI): 78.3 -330.1) for infliximab, 77.9 (95% CI: 49.3 - 121.1) for ustekinumab 90 mg and 59.8 (95% CI: 37.9 - 92.3) for ustekinumab 45 mg compared to placebo. Pairwise comparison suggested that infliximab is significantly better than and ustekinumab 45 mg to achieve PASI 75 (p < 0.05). Pooled odds ratio of achieving PASI 90 was 172.6 (95% CI: 46.7 - 525.2) for infliximab, 79.6 (95% CI: 39.2 - 155.2) for ustekinumab 90 mg and 65.5 (95% CI: (32.1 - 127.8) for ustekinumab 45 mg. Similarly, there was a statistically significant difference between infliximab and ustekinumab 45 mg in attaining PASI