MCRR was 7 (range: 2-30). **Conclusions:** In this observational descriptive study, the efficacy of **TP** for Intermediate-2 and High-risk MDS patients has been reported. However, these findings need to be complemented with more statistical data, to have a more accurate picture of azacitidine in community practice.

PSY3  **EFFICACY OF PHENTERLINE MONOTHERAPY, TOPIRAMATE MONOTHERAPY, AND PHENTERLINE/TOPIRAMATE COMBINATION THERAPY ON WEIGHT LOSS: A NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIAL DATA**

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**OBJECTIVES:** Obesity is a major health crisis with vast economic and population-health implications. Effective pharmacological therapies for weight management are desirable, yet few have been approved by the Food and Drug Administration (FDA) since the withdrawal of fenfluramine/phentermine in the late 1990’s. Recently a new product, combination phentermine/topiramate, obtained marketing approval. Both phentermine monotherapy and topiramate monotherapy were previously investigated for weight loss, yet only one study compared this new combination product to its respective components. The goal of the current meta-analysis was to compare the effectiveness of phentermine monotherapy, topiramate monotherapy, and phentermine/topiramate combination therapy in weight reduction treatment. METHODS: Studies were identified from meta-analyses, pharmacological weight loss review articles, and electronic databases including PubMed and ClinicalTrials.gov. Eligible studies were randomized placebo-controlled trials with the objective of weight loss assessment. Data from 6 studies comparing phentermine monotherapy, topiramate monotherapy, and 9 studies of phentermine monotherapy were included for analysis. Pooled analysis of mean percent weight change was performed using a random effects model. Intention-to-treat weight loss was assessed and described overall and in relation to pooled weight loss estimates of subjects receiving control placebo treatment. **RESULTS:** Phentermine/topiramate combination therapy had a mean percent weight loss above placebo of 7.18% (95% CI: -8.22 to -6.14%), a treatment effect larger than the mean percent weight loss above placebo of 4.57% (95% CI: -5.39 to -3.76%) calculated for topiramate monotherapy or the mean percent weight loss above placebo of 5.79% (95% CI: -6.22 to -4.75%) calculated for phentermine monotherapy. **CONCLUSIONS:** Pooled clinical trial data show that phentermine/topiramate combination therapy is more effective than topiramate monotherapy and phentermine monotherapy in reducing weight. Future studies are needed to determine if these controlled trial-derived weight loss results translate to real-world clinical success.

PSY4  **TREATMENT OF NEUROPATHIC PAIN WITH THE CAPSAICIN 8% PATCH QTZENZA®: EVALUATION OF TIME TO RETREATMENT, PATCH USAGE AND PATIENT SATISFACTION**

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**OBJECTIVES:** Pain is an important driver of quality of life and health care resource use, though few treatments are available to effectively treat neuropathic pain. The purpose of this study was to characterise the retreatment interval, patch usage and other factors affecting the use of the capsaicin 8% patch QTZENZA® (QTZ) when used to treat peripheral neuropathic pain in clinical practice. METHODS: Interim data were available from a prospective, observational study of people with neuropathic pain who used QTZ in the United Kingdom (n = 555). QTZ usage and clinical manifestations (p < 0.05) and less postoperative pain which were conducted at baseline (3-7 days before the operation), on the day of surgery, and around 24 hours after surgery. Repeated measures ANCOVA and univariate analysis of covariance were used to examine the data. RESULTS: Children in the experimental group demonstrated no superior result in perioperative anxiety (p < 0.05), but indicated significantly fewer negative emotional manifestations (p < 0.01) and postoperative pain (p < 0.01) as compared with those in the control group. **Conclusions:** The therapeutic play intervention is superior to usual care in reducing negative behaviors and postoperative pain in children undergoing inpatient elective surgery. These findings suggest the need for providing the therapeutic play intervention for school-aged children who are undergoing inpatient elective surgery.

PSY5  **EFFICACY AND SAFETY OF COMBINATION OF PREGABALIN AND AMITRIPTYLINE IN PATIENTS WITH CHRONIC LOW BACK PAIN IN INDIAN POPULATION**

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**OBJECTIVES:** Chronic low back pain (CLBP) with or without radiculopathy is a major expensive, and disabling condition around the globe. Limited safety and efficacy data of various analgesics make difficult in prescribing. Present study aimed at assessing the efficacy and safety of combination therapy of pregabalin and amitriptyline in patients with CLBP in Indian population. **Methods:** A longitudinal prospective observational study was conducted at pain clinic of a public tertiary care hospital. Adult patients suffering from low back pain for >3 months, and who received pregabalin (75-150 mg/day) and amitriptyline (10/25 mg/day) were included in the study. Data collected for baseline and follow-ups of monthly through hospital visits and telephonic contacting until 6 months for VAS, baseline and 6 months for Modified Oswestry low back pain Disability questionnaire (MODQ). Percentage of patients achieved >50% of pain reduction by VAS score (0-100) after six months is the primary endpoint. Safety and improvement in quality of life after six months assessed as secondary endpoint. Analysis done by one way repeated measures anova. **Results:** A total of 198 patients were included in this study with mean age of 44.8±12.4 years, 63% are having BMI >25 kg/m², and duration of pain 30 (12-60) months. Magnetic imaging resonance findings have shown disc bulging (43.9%), disc herniation (12.6%), spondylosis (11.1%) and other problems. Significant reduction in pain was observed p<0.01 on VAS score after 6 months follow up. CLBP & ModOswestry back pain (0-100) scores were 70 (60-90) & 52 (45-60), and after 6 months 52 (55-50) & 48 (24-53), no improvement in quality of life found p=0.08. Dry mouth is being the commonest adverse event [80 (40.4)]. Other adverse events reported were headache, constipation, dizziness and postural hypotension. **Conclusions:** Our results suggest that combination of pregabalin and amitriptyline are efficacious and safe in managing CLBP.

PSY8  **META-ANALYSIS OF EFFECT OF ROMILISTOM FOR IMMUNE IDIOPATHIC THROMBOCYTOPENIA**

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**Objective:** Immune idiopathic thrombocytopenia (IIT) is a rare autoimmune disease characterized by low platelet counts and spontaneous bleeding. Treatment options include corticosteroids, immunoglobulins, and rituximab, with the latter two being the most efficacious. However, their high cost has limited their use. Alternative therapies, such as romilistom, have been explored. **Methods:** A systematic review and meta-analysis were performed to evaluate the efficacy and safety of romilistom in the treatment of IIT. A total of 198 patients were included in this study with mean age of 44.8±12.4 years, 63% are having BMI >25 kg/m², and duration of pain 30 (12-60) months. Magnetic imaging resonance findings have shown disc bulging (43.9%), disc herniation (12.6%), spondylosis (11.1%) and other problems. Significant reduction in pain was observed p<0.01 on VAS score after 6 months follow up. CLBP & ModOswestry low back pain Disability questionnaire (MODQ). Percentage of patients achieved >50% of pain reduction by VAS score (0-100) after six months is the primary endpoint. Safety and improvement in quality of life after six months assessed as secondary endpoint. Analysis done by one way repeated measures anova. **Results:** A total of 198 patients were included in this study with mean age of 44.8±12.4 years, 63% are having BMI >25 kg/m², and duration of pain 30 (12-60) months. Magnetic imaging resonance findings have shown disc bulging (43.9%), disc herniation (12.6%), spondylosis (11.1%) and other problems. Significant reduction in pain was observed p<0.01 on VAS score after 6 months follow up. CLBP & ModOswestry back pain (0-100) scores were 70 (60-90) & 52 (45-60), and after 6 months 52 (55-50) & 48 (24-53), no improvement in quality of life found p=0.08. Dry mouth is being the commonest adverse event [80 (40.4)]. Other adverse events reported were headache, constipation, dizziness and postural hypotension. **Conclusions:** Our results suggest that combination of pregabalin and amitriptyline are efficacious and safe in managing CLBP.
OBJECTIVES: Immune (idiopathic) thrombocytopenia (ITP) is an autoimmune condition characterized by increased platelet destruction and decreased platelet production, resulting in low platelet counts (thrombocytopenia). Romiplostim has shown efficacy in increasing platelet counts. The objective of this study was to conduct meta-analysis and present total evidence for Romiplostim for treatment of ITP. The present meta-analysis was performed using randomized controlled trials (RCTs) evaluating Romiplostim for the treatment of ITP. We included RCTs that compared romiplostim versus placebo for management of ITP, had a treatment duration of at least 12 weeks, were doubleblind (patients and investigators blinded) and reported data on platelet response. A systematic literature search for Externeter trials was undertaken for the databases PubMed, Embase, Biosis, Google Scholar, and Cochrane. Data was collected for the study size, interventions, year, and the two outcomes overall and durable platelet response rate. For meta-analysis, random-effects and fixed-effects models were used to obtain cumulative statistics. RESULTS: Two RCTs with a total of 125 patients were identified. The pooled response rates for Romiplostim versus placebo were 82% (95% CI 75%-89%) and 92% (95% CI 85%-97%), and for durable platelet response rate were 48% (95% CI 26%-71%). The pooled response rates for placebo overall platelet response rate were 7% (95% CI 0%-15%), and for durable platelet response rate were 2% (95% CI 0%-4%). For overall platelet response rate, ICTs with placebo versus Romiplostim was 0.09 (95% CI 0%-4%). For durable platelet response rate, the cumulative relative risk with placebo versus Romiplostim was 0.03 (95% CI 0%-6%). CONCLUSIONS: Meta-analysis shows Romiplostim offers patients with Immune idiopathic thrombocytopenia an effective therapeutic option for increasing platelet counts.

PSY9 INDIRECT TREATMENT COMPARISONS OF OBINUTUZUMAB (GA101) PLUS CHLORAMBUCIL (CLB) VERSUS BENDAMUSTINE AND VERSUS OFATUZUMAB PLUS CLB IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA

OBJECTIVES: Obinutuzumab (GA101) is a novel, glycoengineered, type II CD20 antibody. The monoclonal antibody binds to and internalizes, thus leading to the cell death. We conducted a systematic review of non-randomized and randomized controlled trials (RCTs) to assess the clinical efficacy and safety of pharmacological interventions for previously untreated CLL, manuscripts (Jan 1992 to Mar 2013), abstracts (including hand-searching, Jan 2010 to Mar 2013), and in-progress studies were screened for inclusion. Based on extracted data, a feasibility assessment of quantitative analysis was undertaken. ICTs of G-CLB versus Bend and G-CLB versus Ofat-CLB were derived. The Valsecchi et al. Cochrane profile was used to parameterize the fixed effect network meta-analysis model used a natural logarithm of the hazard ratios (HR) for PFS as the (continuous) outcome variable. RESULTS: Of the 4,819 publications identified, 262 manuscripts and 13 abstracts were selected for detailed evaluation. Following de-duplication of publications, the data set included 28 RCTs (157 publications) and nine non-RCTs (14 publications). ICTs were based on HR and 95% confidence intervals (CIs) reported for G-CLB in the CLL11 trial, for Bend in the Enaust et al. publications, and for Ofat-CLB in the Complement 1 trial. The ICT for G-CLB versus Bend had a HR (95% CI) of 0.53 (0.35-0.77) and the ITC for G-CLB versus Ofat-CLB had a HR (95% CI) of 0.33 (0.22-0.47). CONCLUSIONS: Based on the ITCs of available evidence in this indication, G-CLB is non-inferior to both Bend and Ofat-CLB and may improve PFS rates compared with Bend or Ofat-CLB. How this benefit will translate into overall survival differences will be assessed when the available data are more mature.

PSY10 MEDICAL COMPLICATIONS AND RESOURCE UTILIZATION IN BLOOD TRANSFUSION–DEPENDENT PATIENTS WITH MYELOFIBROSIS BY IRON CHELATION THERAPY USE

OBJECTIVES: To compare incidence of myelofibrosis-related complications and all-cause and MF-related resource utilization (RU) in blood transfusion-dependent (TD) MF patients treated with vs. without iron-chelating therapy (ICT vs. ICT+). METHODS: Two commercial health care claims databases, Truven MarketScan (2000-2012) and PharMetrics (2001-2012), were analyzed. Patients with ≥2 MFC-9 diagnosis codes ≥30 days apart and ≥18 years at first MFC diagnosis were included. First evidence of TD (index date) was defined as ≥3 transfusion events within any 3-month period. Adjusted incidence rate ratios (aIRRs) of MF-related complications and all-cause and MF-related RU in TD ICT vs. ICT+ patients were assessed using Poisson regressions, controlling for baseline comorbidities and MFC-9 related complications. RESULTS: Of the 571 eligible TD MF patients, 103 (18%) were ICT+ and 468 (82%) were ICT-. Mean age was similar between groups [ICT+ 67.2(SD: 10.4 vs. ICT- 64.8(SD: 11.1; p=0.04)]. ICT+ patients were more likely to have received ICT for ≥12 months during the 22 [19.3] vs. 12 [11.6]; ICT+ patients had higher mean Charlson Comorbidity Index (1.81±2 vs. 2.32±1), suggesting a greater burden of comorbidities. Mean number of transfusion events was also similar between groups (2.1±3 vs. 3.1±3; p=0.04) ICT+ patients had lower rates of thrombocytopenia (aIRR: 0.54; p<0.01) and pancytopenia (0.53; p<0.01). Rates of other MF-related complications were similar between groups. ICT+ patients had significantly lower rates of all-cause and MF-related RUs (aIRR: 0.59 vs. 1.06; p=0.03). The objective of this study was to determine the epidemiology of the incidence and prevalence of all-cause and MF-related RUs in ICT+ and ICT- patients. The study was conducted, based on 17 Hematology departments of Hospitals throughout the country. Eligible patients were analyzed concerning the frequency of Serious and Non-Serious Adverse Drug Reactions (SADRs/NSADRs). By definition, a SADR could result in resignation of the significant deterioration of the quality of life, thus could not be classified as a NSADR or might be considered medically important. Any reaction which does not fulfill the above description is a NSADR. Patients were recruited if were ≥18 years old and were alive at the time of their data collection, they have completed at least one evaluation after azacitidine treatment initiation and at least one cycle of azacitidine treatment regardless of the outcome. The study was conducted in accordance with the declaration of Helsinki. RESULTS: During ICT treatment was 50% and 42%, respectively. The most commonly reported SADRs were neutropenia (11.4%), thrombocytopenia (9.1%), pyrexia (8.0%) and constipation (8.0%). Regarding their intensity, 45.7% of NSADRs were grade I, 4.6% were grade II, and 0.6% were grade III. None of the NSADRs resulted in patient hospitalization. The most commonly reported SADRs were thrombocytopenia (13.6%), pyrexia (10.2%), neutropenia (9.1%), febrile neutropenia (4.5%), anaemia and respiratory tract infection (both 4.5%). 48.6% of all SADRs were grade III, while 18% were grade IV. In 20.8% of SADRs no action was taken, 1.4% resulted in permanent discontinuation, while temporary treatment interruption was required for 34.7% of patients. 30.7% of patients experienced any SADRs, required hospitalization. CONCLUSIONS: In this study, the safety and tolerability of azacitidine for intermediate-2 and high risk MS patients was descriptively analyzed based on Greek data. A broader, real life, analysis is needed to reach more decisive conclusions in the local setting.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY13 INCREASING BARIATRIC PROCEDURE VOLUME IN BRITISH COLUMBIA, CANADA: BUDGET IMPACT ANALYSIS OVER 10 YEARS

OBJECTIVES: British Columbia (BC) currently performs around 250 bariatric procedures each year with a significant burden of comorbidities. With BC’s population approaching 87,000 and is increasing at about 1.04% annually. Obese individuals are high volume users of the health care system and bariatric surgery has proven to be an effective intervention for weight loss and for reducing the impact of obesity-related comorbidities. The objective of this study was to determine the epidemiology of the increasing volume of bariatric procedures performed in BC to include 1% of all eligible patients each year. METHODS: A budget impact model accounting only for direct health care costs was created using data from Statistics Canada, peer-reviewed literature, the Canadian Institute for Health Information and case-costing data.