

MCR was 7 [range: 2-30]. **CONCLUSIONS:** In this observational descriptive study, the efficacy of azacitidine 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 PHENTERMINE MONOTHERAPY, TOPIRAMATE MONOTHERAPY, AND PHENTERMINE/TOPIRAMATE COMBINATION THERAPY ON WEIGHT LOSS: A NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIAL DATA

Thompson JA¹, Heaton PC¹, Kelton CM²

¹University of Cincinnati, Cincinnati, OH, USA, ²University of Cincinnati College of Business, Cincinnati, OH, USA

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 this 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 published 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 of combination phentermine/topiramate, 10 studies of 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. Intervention-induced 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 -6.82 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 to assess the effectiveness of phentermine/topiramate combination therapy are merited 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 QUTENZA™: EVALUATION OF TIME TO RETREATMENT, PATCH USAGE AND PAIN ALLEVIATION

Chambers C¹, Poole CD², Berni E³, Odeyemi I¹, Thomas R³, Currie CJ²

¹Astellas Pharma Europe Ltd, Chertsey, UK, ²Cardiff University, Cardiff, UK, ³Pharmatelligence, Cardiff, UK

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 clinical effectiveness of the capsaicin 8% patch 'Qutenza' (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 treated with QTZ throughout Europe (n=340); the ASCEND study. The Numeric Pain Rating Scale (NPRS) recorded pain on an integer scale between 0 (no pain) and 10 (worst imaginable pain). Time to retreatment was evaluated using the Kaplan-Meier method, accounting for right-censored observations. Change in pain severity was evaluated using independent sample and paired samples t-tests. **RESULTS:** At baseline, the mean NPRS was 6.82 (SD 1.89). At eight weeks following first treatment, 43.8% of patients achieved a 30% reduction and 24.2% a 50% reduction. In this analysis, 105 (30.9%) patients were retreated with QTZ at least once, of which 26 (7.7%) had two re-treatments, and 5 (1.5%) had three or more re-treatments. There was no difference in baseline NPRS between those that progressed to receiving multiple treatments and those treated once (mean NPRS=6.87 vs. 6.67 units respectively (p=0.355)). Mean NPRS prior to the second application was 5.66 (2.09; p<0.001), and 5.19 (2.38; p= 0.010) prior to subsequent applications. The mean number of patches used at the first, second and third applications was 1.18 (0.81), 1.16 (0.75), and 1.19 (1.07), respectively (p=0.115, p=0.214). The median time from first to second treatment was 22 weeks (95% CI 17-27), and from second to third a further 21 weeks (95% CI 16-26). **CONCLUSIONS:** This study shows that capsaicin 8% patch use and retreatment intervals are stable across successive treatments suggesting consistent efficacy.

PSY5

COMPARABILITY OF TRIAL POPULATIONS IN NETWORK META-ANALYSES ASSESSING BIOLOGIC TREATMENTS IN MODERATE TO SEVERE PLAQUE PSORIASIS

Smiechowski B, Chen M, Vieira MC

Mapi, Boston, MA, USA

OBJECTIVES: To assess the comparability of the trials included in network meta-analyses (NMAs) comparing biologic treatments in moderate to severe plaque psoriasis (PsO). **METHODS:** A systematic literature review identified two recently published NMAs. The definition of 'moderate to severe' psoriasis adopted by one of the NMAs was "having an inadequate response to topical treatments alone and either having received prior systemic therapy or being candidate for such therapy".

The second NMA did not report the definition used; instead, the eligibility criteria were defined in terms of the treatments assessed in the randomized controlled trials (RCTs). The eligibility criteria adopted in each RCT and the resulting patient population characteristics were collected in order to assess comparability among the trials in each NMA. **RESULTS:** The RCTs selected in each of the NMAs adopted diverse eligibility criteria based on body surface area (BSA), psoriasis area and severity index (PASI) score and exposure or failure to previous therapies. Although many of the trials adopted eligibility criteria that aligned with clinical guideline definitions of moderate to severe PsO as BSA above 10% and PASI above 10, the resulting 'moderate to severe' populations showed wide variation in their baseline characteristics. Analogous differences in placebo responses were observed. For example, baseline PASI scores ranged from 14 to 23, while the proportion of patients with a 75% reduction in the PASI scores at 12 weeks varied from 2% to 18% among the trials in each NMA. **CONCLUSIONS:** The current definitions of 'moderate to severe' PsO do not seem enough to guarantee similarity in severity across trials, which may lead to imbalance in the distribution of potential effect modifiers across comparisons, and consequent bias in the NMA estimates. In the absence of better characterization of the patient population, adjusting for baseline risk is advisable.

PSY6

THE EFFECTIVENESS OF A THERAPEUTIC PLAY INTERVENTION ON CHILDREN'S PERIOPERATIVE ANXIETY AND POSTOPERATIVE PAIN: A RANDOMIZED CONTROLLED TRIAL

He HG¹, Zhu L¹, Saw SK¹, LiamLWJ², LiHCW³, ChanWCS¹

¹National University of Singapore, Singapore, Singapore, ²KK Women's and Children's Hospital, Singapore, Singapore, ³The University of Hong Kong, Hong Kong, China

OBJECTIVES: Children undergoing surgery often experience anxiety, exhibit negative behaviors and suffer postoperative pain. Previous studies showed inconsistent findings in the effects of therapeutic play intervention on children's perioperative anxiety, negative behaviors and postoperative pain. This study aimed to examine the effectiveness of a therapeutic play intervention on perioperative anxiety, negative emotional manifestation and postoperative pain in children undergoing inpatient elective surgery. **METHODS:** A randomized controlled trial with two-group pre- and post-tests study design was conducted. A total of 106 eligible children (6-14 years old) were recruited and randomly allocated to either a control group (receiving routine care) (n = 53) or an experimental group (receiving one-hour therapeutic play intervention in addition to routine care) (n = 53). Outcome measures included children's anxiety, emotional manifestation and 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 analyse 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 less 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 of providing the therapeutic play intervention for school-aged children who are undergoing inpatient elective surgery.

PSY7

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

Kanukula R¹, Bansal D², Ghai B³

¹National Institute of Pharmaceutical Education and Research, Punjab, India, ²National Institute of Pharmaceutical Education and Research, Punjab, India, ³Post Graduate Institute of Medical Education and Research, Chandigarh, Chandigarh, India

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 Ostwery 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 >25kg/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. VAS&MODQ baseline median (IQR) scores found to be 75(60-90)&52(40-60), and after 6 months 35(20-50)&41(24-53), no improvement in quality of life found p=0.08. Dry mouth is being the commonest adverse event [in 80 (40.4)]. Other adverse events reported are 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 EFFICACY OF ROMIPLOSTIM FOR IMMUNE IDIOPATHIC THROMBOCYTOPENIA

Aggarwal S, Topaloglu H

Novel Health Strategies, Bethesda, MD, USA