### (348) Prediction of pain response by severity of sleep interference in neuropathic pain

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Identification of baseline patient characteristics that predict therapeutic response to a particular drug may help guide treatment selection when choosing among multiple options. This post-hoc analysis examined the relationship between severity of sleep interference scores at baseline and magnitude of pregabalin-mediated pain reduction at endpoint in patients with painful diabetic peripheral neuropathy (DPN) or post-herpetic neuralgia (PHN). Data were pooled from 15 randomized, double-blind, placebo-controlled trials of pregabalin for the treatment of DPN or PHN and grouped according to diagnosis. Trial duration ranged from 5-13 weeks and included 4,126 patients. Severity of sleep interference was based on an 11-point Daily Sleep Interference scale and characterized as mild (<4), moderate (4-7), or severe (>7). Pain scores were based on an 11-point scale and derived from patients' daily pain diaries. Change in mean pain score at endpoint was analyzed for each cohort using an analysis of covariance interaction model. Among DPN patients, pain reduction at endpoint was significantly greater for those receiving pregabalin and greater pain reduction occurred in patients with more severe sleep interference. Improvements over placebo of -0.51 (P=0.0011), -0.73 (P<0.0001), and -1.14 (P<0.0001) were observed in patients with mild, moderate, or severe sleep disturbance, respectively. Likewise, among PHN patients, pain reduction at endpoint was significantly greater for those receiving pregabalin and greater pain reduction occurred in patients with severe sleep disturbance. Improvements over placebo of -0.99 (P<0.0001), -0.98 (P<0.0001), and -1.55 (P<0.0001) were observed in patients with mild, moderate, or severe sleep disturbance, respectively. These findings suggest that patients with DPN or PHN who present severe levels of sleep disturbance at baseline are likely to exhibit the greatest pain reduction in response to treatment with pregabalin. Funded by Pfizer Inc.

### (349) Examining the time-to-improvement of sleep disturbance in patients with painful diabetic peripheral neuropathy and post-herpetic neuralgia

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Pregabalin has been shown as a safe and effective treatment for neuropathic pain associated with painful diabetic peripheral neuropathy (DPN), and post-herpetic neuralgia (PHN). Sleep disturbance is commonly reported in these conditions and may contribute to pain severity and influence response to therapy. This post-hoc analysis examined time to improvement in sleep, as measured by a reduction in sleep interference scores, in patients from 15 placebo-controlled trials of pregabalin for the treatment of DPN or PHN (N=4,220). Pregabalin treatment arms (n=28) included 75-, 150-, 300- or 600 mg/day (fixed or flexible) for DPN and 150-, 300-, or 600 mg/day (fixed) for PHN. Daily sleep interference scores were based on an 11-point numeric rating scale and were analyzed using analysis of covariance in the intention-to-treat populations. The time-to-onset (TTO) for reduction in sleep interference scores was calculated for all pregabalin treatment arms that demonstrated a statistically significant reduction in sleep interference scores at endpoint compared to placebo. TTO was defined as the first day sleep interference scores for that particular day, and the following day, were significantly lower than placebo. In these trials, 23 pregabalin treatment arms achieved a significant reduction in sleep interference scores at endpoint compared to placebo. In 21 of these 23 arms (91.3%), the TTO for reduction in sleep interference scores occurred within the first 3 days of treatment. These findings demonstrate that statistically significant and sustained improvement in sleep occurs rapidly in patients with DPN or PHN in response to treatment with pregabalin, usually by the end of 3 days of treatment. This is consistent with the 2-day TTO for pain reduction that has been reported for patients treated with pregabalin. This study was funded by Pfizer Inc.

## *F05 Cancer Pain - Opioids*

### (350) Pros and cons of a new one-day type of transdermal fentanyl tape

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Cancer is one of major diseases in Japan. Approximately 580,000 patients are diagnosed with cancer annually and more than 320,000 patients died of cancer. Most of those patients are suffered with severe pain and need around-the-clock narcotic pain relief. Since the booklet of WHO guidelines about cancer pain relief was published, various kinds of narcotic analgesics were used in patients with cancer pain. In the 1990s, 3-day type of transdermal fentanyl patch was introduced and is currently the most widely used in cancer pain treatments. In June 2010, a new one-day type of transdermal fentanyl citrate tape, so-called Daily Fentos® Tape, was introduced in Japan and is getting to be popular. We administered Daily Fentos® Tape to more than 100 patients with cancer pain at Saga Medical School Hospital and have analyzed these cases. We showed a couple of cases as follows: (Case 1) A 36-year-old woman, cervical cancer with peritoneal metastasis, was administered Durotep® MT 42mg/72-hour and morphine solution 40-160mg/day. Her morphine consumption was especially increased during 48-72 hours after the attachment of Durotep® MT. She was successfully converted from Durotep® MT to Daily Fentos® 20mg/day. (Case 2) A 70-year-old woman, cervical cancer with lung and liver metastasis, was administered Durotep® MT 12.6mg/72-hour and morphine solution 20-40mg/day. She felt severe sleepiness. She was gradually converted to Daily Fentos® 2mg/day with morphine solution 20mg/day. (Case 3) A 56-year-old man, multiple myeloma with multiple bone metastasis, was administered Durotep® MT 42mg/48-hour and oxycodone 120mg/day. He was successfully converted from Durotep® MT to Daily Fentos® 20mg/day. In conclusion, the clinical advantages of Daily Fentos® are as follows: 1) to exert stable analgesic effects; 2) to evaluate pain and adverse reactions every 24 hours; 3) to take a hot bath and shower; 4) to better cost-effectiveness, and so on.

### (351) The effectiveness of TENS for head and neck cancer pain and function: a randomized and placebo-controlled double blind pilot study

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Approximately 30,000 people are diagnosed with head and neck cancer (HNC) annually, with many requiring radiation as part of their treatment regimen. The majority develop severely painful, radiation-induced oral mucositis that impairs function and leads to feeding tubes, hospitalization, and treatment delays. While pharmacologic medications provide some relief, many report inadequate analgesia and side effects. Transcutaneous electrical nerve stimulation (TENS) is a safe, non-pharmacologic intervention; it decreases pain, analgesic intake, and improves function, yet no studies examined TENS effectiveness for HNC pain. Our aim was to examine the efficacy of TENS for pain and function in HNC patients. A randomized, double-blinded crossover design was used in weeks 3-7 of radiation therapy, with every patient receiving: Active TENS (AT), Placebo TENS (PT) and No TENS (NT) over the temporomandibular joint and upper cervical region. Pain (McGill Pain Questionnaire [MPQ], pressure pain thresholds, 0-10 VAS resting and function) and function (swallowing, mouth opening, tongue movement, speaking) were assessed before and after TENS. Preliminary results from 11 participants (59.7$\pm$10.6yrs, 9M) indicated that average baseline pain ratings were 2.7 (range 0-7.8cm). Participants rated mouth opening and swallowing as most painful. AT significantly decreased resting pain on the MPQ (-2.4$\pm$2.1 vs. -0.1$\pm$0.5, p=0.004) and VAS (-1.3$\pm$1.1 vs. 0.1$\pm$0.7, p=0.006) when compared to PT or NT. There was no significant difference in AT or PT outcomes. Function pain, pressure pain thresholds, and function were not affected by AT vs. PT or NT. Pain during function correlated with poorer oral function (r's=-0.17 to 0.55). These preliminary results suggest a single TENS treatment significantly reduces radiation-induced pain, and thus may be a viable option for HNC pain management. Funding: American Pain Society Future Leaders in Pain; Midwest Pain Society; University of Iowa Interdisciplinary Pain Research Program T32 NS045549-07.