1. **Tetrodotoxin for Chemotherapy Induced Neuropathic Pain**
   
   a. **Presenter:** Samuel Goldlust, MD
   
   b. **Authors:** Samuel Goldlust, MD; Mehran Kavoosi, BSc; Walter Korz, HCA; and Kenneth Deck, MD
   
   c. **Background:** Tetrodotoxin (TTX) is a small molecule that blocks voltage-gated sodium channels involved in pain signaling.
   
   d. **Objective:** A phase 2 randomized, double-blind, dose-finding, placebo controlled, multicenter trial is ongoing to evaluate TTX as a treatment for chemotherapy induced neuropathic pain (CINP). Here we report completed dose optimization results, the objective of which was to identify up to two dosing schemes for further study.
   
   e. **Methods:** Subjects with taxane or platinum induced CINP were randomized to one of five cohorts: placebo twice daily (b.i.d.), TTX 7.5 µg b.i.d., TTX 15 µg b.i.d., TTX 30 µg daily (q.d.), or TTX 30 µg b.i.d. TTX or placebo was injected subcutaneously for four consecutive days. The TTX 30 µg q.d. cohort also received a daily placebo to maintain blinding. The primary efficacy endpoint was assessed using the numerical pain rating scale. The secondary endpoints were assessed using the EORTC CINP 20 and SF-36 questionnaires, as well as the patient’s global impression of change.
   
   f. **Results:** 125 patients (77 women) were randomized, with 125 in the intent to treat population and 107 in the per protocol population. The mean change from baseline pain score was greatest in the TTX 30 µg q.d. (-1.7 ± 2.3) and TTX 30 µg b.i.d. (-1.5 ± 1.8) cohorts for week 4 post-treatment, the primary efficacy endpoint. The same pattern was demonstrated for weeks 1-3. Analysis of ≥30% improvement in 10-day average pain scores at any time point demonstrated that the TTX 30 µg b.i.d. cohort had the largest number of responders (15/26; 57.7%) compared to placebo (8/25; 32.0%) (P = 0.027). The TTX 30 µg b.i.d. and 15 µg b.i.d. cohorts showed the largest improvements in the EORTC CINP 20 questionnaire, SF-36 values, and overall global impression of change. Statistical significance was not required or expected using the predefined endpoints for dose optimization. Oral paresthesia was the most frequently reported AE (37/125; 29.6%), followed by oral hypoesthesia (31/125; 24.8%). Most AEs were mild to moderate (grade 1 and 2). There
were four grade 3 AEs (paresthesia, pain, viral upper respiratory infection, hypertension) and no grade 4 AEs reported. Three patients experienced SAEs, two unrelated and one unlikely related to TTX.

g. **Conclusions:** The TTX 30 µg b.i.d. dosing regimen is well tolerated with promising early efficacy data to merit further study. Continued clinical development is planned.

h. **References:** n/a

i. **Disclosure:** This study was supported by WEX Pharmaceuticals Inc.

2. **Fibromyalgia Clinical Trial Analysis from 2004 to 2014**

a. **Presenter:** Elan Lutinger, PharmD, RPh

b. **Author:** Elan Lutinger, PharmD, RPh

c. **Background:** Fibromyalgia was first recognized in the 1970s, but the medical community has been reluctant to accept it as a true disorder. Chronic widespread pain is the hallmark but there are associated symptoms (1). Ten to 11% of the population is estimated to suffer from widespread pain, while only .5-4.0% may have fibromyalgia (2), an incidence of about 5 million Americans.

d. **Objective:** The purpose of this evaluation is to determine the quantity of initiated and successfully completed industry clinical trials in fibromyalgia, from 2004–2014, separated by clinical trial phase and initiation year. In order to design efficacious and safe clinical trials in the future, data about past successful and unsuccessful trials are necessary.

e. **Methods:** Clinical trials were included in the analysis if they met all of the following criteria: were industry-sponsored; were comprised of ≥ five clinical sites; ≥ one clinical site in the United States; and involved ≥ one oral medication treatment arm. After trials were excluded for failing to meet the inclusion criteria, ongoing, terminated, and completed trials were then separated. The completed trials were then divided into those which: had indeterminate results; did not meet their primary efficacy endpoint; and met their primary efficacy endpoint. Finally, the data were separated by year of trial initiation and clinical trial phase.

f. **Results:** A total of 106 total clinical trials were included in this analysis. Of these, 54 were excluded for failing to meet one or more of the pre-specified criteria and 52 clinical trials will be included in the analysis. Five were still ongoing at the time of this publication, 10 were terminated, and 37 were completed. Of these 37 completed trials, the
majority (75.68%) was completed successfully. The year 2006 saw the greatest number of trials initiated (11) and both 2014 and 2012 saw the least number (1). The mean number of clinical trial sites per clinical trial for the former was 34.42 and 58.68 for the latter.

g. **Conclusions:** Of the 52 clinical trials that this analysis examined, 28 (53.85%) met their primary efficacy endpoint. The period of 2005-2006 was a watershed, with 50% of successfully completed trials, which met this study’s inclusion criteria, initiated during this period. When the data for the number of trial sites were evaluated, it was shown that there were more sites per successful clinical trial than there were in unsuccessfully completed, terminated, or unknown outcome clinical trials.

h. **References:**

i. **Disclosure:** n/a

3. **Efficacy of Radio Frequency Nerve Ablation (RFNA) in Trigeminal Neuralgia and its Comparison with Injection Triamcinolone: A Randomized Controlled Trial**
   a. **Presenter:** Qurat ul Ain BDS, RDS
   b. **Author:** Shahzad Anwar MBBS, DOM; Qurat ul Ain BDS, RDS; Waqas A Chaudhry MBBS, MD, MSc; Ehsan ul Haq Rafiq, MBBS, MCPS; and Faiza Shahzad MBBS, FCPS1, RMP
   c. **Background:** Trigeminal neuralgia (TN) is a neuropathic pain condition affecting the face. It has a significant impact on the quality of life and physical function of patients.
   d. **Objective:** To evaluate the efficacy and safety of radio frequency in patients suffering from TN.
   e. **Methods:** A randomized controlled trial (RCT) was opted and a total of 116 patients were chosen using non-probability purposive sampling technique. Pain was graded by using a patient-friendly Visual Analogue Score (VAS), scoring from 0 to 10. Patients were randomly separated into two groups, one receiving radio frequency (A) group (n = 60) and the other control (B) group (n = 56)
matched by age and severity of symptoms. Group A received thermal radio frequency ablations of the affected branches followed by injection of triamcinolone (40 mg) at the site of lesion.

f. **Results:** The average pain score in patients who received radio frequency was 7.65 ± .91 before treatment, whereas after treatment it was 2.31 ± .98. The mean pain score in patients who were given injection triamcinolone before starting the treatment was 7.47 ± .71 and after treatment, it was 6.23 ± .98. The mean score for daily life activities in subjects who received radio frequency was 9.56 ± 2.37 before treatment, while after treatment it was 7.56 ± 1.54. The average score for daily life activities in patients who were given injection triamcinolone before starting the treatment was 9.05 ± 1.93 and after treatment, it was 8.11 ± 1.71. Average depression and anxiety score in patients receiving radio frequency was 9.29 ± 2.28 before treatment, whereas after treatment it was found to be 7.42 ± 1.91. Similarly, the mean depression and anxiety score in patients who were given injection triamcinolone before starting the treatment was 9.38 ± 2.21 and after treatment, it was 8.38 ± 2.14.

g. **Conclusions:** The mean score in our study reveals that radio frequency shows much better outcomes in improvement of pain relief, depression, anxiety, and daily life activities compared to injection triamcinolone in patients suffering from trigeminal neuralgia.

h. **References:**
4. Safety and Efficacy of Ultrasound Guided Percutaneous Needle Tenotomy Procedure in Treating Chronic Refractory Tendon Pain

   a. Presenter: Sunny R. Kim, MD, FAAPMR
   b. Author: Sunny R. Kim, MD, FAAPMR
   c. Background: Chronic tendon pain afflicts millions of patients a year and remains a difficult condition to treat. In the chronic phase, antiinflammatory and physical therapy approaches often fail due to the development of painful disorganized collagen fibrosis within the tendon interfering with the normal healing process. Minimally invasive ultrasonic percutaneous tenotomy approaches in removing the painful collagen matrix have been shown to be effective in treating this pain and allow for normal tissue healing to take place.
   d. Objective: To assess the safety and efficacy of ultrasonic percutaneous tenotomy in treating chronic refractory tendon pain.
   e. Methods: Forty-four patients suffering from chronic refractory tendon pain on average lasting 26 months were treated with minimally invasive ultrasonic percutaneous tenotomy by a single operator. The procedures were performed in an outpatient hospital same day setting under local anesthesia through a small stab incision. Pain scores and Patient Global Impression of Change (PGIC) were measured before and after the procedure at two weeks. In all cases, patients had failed initial course of physical therapy, antiinflammatory medications, and corticosteroid injections. Conditions treated by diagnostic groups were as follows: patella tendonosis 8, medial/lateral epicondylitis 15, Achilles tendonosis 7, plantar fasciosis, 14. Patients with severe immunocompromised states and end stage medical co-morbidities were excluded.
f. **Results:** At two weeks 93% of patients reported a significant improvement in pain scores. The average improvement in pain scores was 3.7. The average PGIC was 59%. No complications (hematoma, infection, nerve damage, or tendon rupture) were observed.

g. **Conclusions:** Ultrasonic percutaneous tenotomoy is a safe and effective minimally invasive outpatient procedure for treating chronic refractory tendon pain. The minimally invasive approach is an attractive alternative for patients who might otherwise undergo more risky open surgical tenotomies which often require longer recovery times.

h. **References:** n/a
i. **Disclosure:** n/a

5. **Correlation of RBC Magnesium Levels and IGF-1 Levels in Fibromyalgia Syndrome**
   a. **Presenter:** Thomas J. Romano, MD, PhD
   b. **Author:** Thomas J. Romano, MD, PhD
   c. **Background:** Low levels of RBC Mg and IGF-1 have been described separately in Fibromyalgia (FM).
   d. **Objective:** To determine if a correlation exists between levels of RBC Mg and IGF-1 in FM.
   e. **Methods:** Sixty FM patients had levels of RBC Mg and IGF-1 measured simultaneously.
   f. **Results:** The mean RBC Mg level was 4.49 mg/dl, which was significantly lower than the mean of 5.5 mg/dl measured in controls, which was also the laboratory standard ($z = 6; P = .001$). Mean IGF-1 level was 159 ng/dl, much lower than the expected mean of 235 ng/dl calculated based on patients’ ages since IGF-1 levels are age-dependent. A correlation coefficient of .48 was calculated with a test statistic of 1.97.
   g. **Conclusions:** Since there was a positive correlation between RBC Mg levels and IGF-1 levels, clinicians who discover one such co-morbidity would be helped in managing the patient by checking for the other. FM can be very difficult to treat. Discovering one or more co-morbidities can aid in optimizing treatment for FM patients.
   h. **References:** n/a
   i. **Disclosure:** n/a

6. **Stereological Evaluation Of Sacral Canal and Age-Related Volumetric Changes and Clinical Effects**
   a. **Presenter:** Mahmut Talha Kaner, MD
b. **Author:** Ozan Alkoc, PhD; Tuncay Kaner, MD; Mahmut Talha Kaner, MD; and Veli Caglar, PhD

c. **Background:** The sacrum constitutes the rear upper wall of the pelvis and it articulates with lateral os coxae, below the cocyx and above the fifth lumbar vertebra. Foramen of joined vertebrae merge and forms sacral canal. Anatomical structures and volume of sacral canal has high clinical importance during caudal epidural block (CEB) and the cause of unsuccessful CEB might depend on anatomic basis.

d. **Objective:** The purpose of this study is to investigate the volume of sacral canal in adults, to compare the changes depending on the age and sex of individuals, and to search of its clinical effects.

e. **Methods:** In our study, we examined the range of sacral canal volume by using Cavalieri principle from stereological techniques. We could not find any study that shows the use of stereological method to measure the sacral canal. CT of 60 adults (30 male and 30 female) were used for volumetric estimation of sacral canal. Participants were selected to get equal representation of gender and age, which separated two groups to be under and above the age of 50. During the measurement of sacral canal, data obtained after counting was entered to the above formula previously designed Microsoft Excel spreadsheet for automatic calculation of results. Patient data were analyzed by using Student-t test and regression analysis. A possibility of .05 or less was considered statistically significant.

f. **Results:** Patients' ages ranged from 18 to 89 with an average of 51.43 ± 17.78 years. There were 29 patients (48.3%) under and 31 patients (51.7%) above the age of 50. In all cases, stereologic measurements of the sacrum channel was found statistically significant according to age differences ($P < .05$). Stereological measurements were found significantly high in the patients who were under the age of 50. Negative correlation was found between age of the patients and stereological measurements of sacral canal ($r = -.280, P = .030; P < .05$). In male patients, there was no statistically significant difference between the stereological measurements of sacral canal according to age groups ($P > .05$). In female patients, there was also no statistically significant difference between the stereological measurements of sacral canal according to age groups ($P > .05$).
g. **Conclusions:** We found that there is a statistically significant difference in the volume of the sacral canal in all cases depending on age (above or below 50 years) but there was no statistically significant difference according to gender.

h. **References:**
1) İnsan Anatomisi, Mustafa Sarsılmaz, Akademi yayınları sy. 54-55. 2014. İstanbul.

i. **Disclosure:** n/a

7. **Appropriate Spinal Vertebral Level for Lumbar Sympathetic Ganglion Block**

   a. **Presenter:** Juyeon Park, MD, MHM
   b. **Authors:** Juyeon Park, MD, MHM; Jong Min Sun; Jee-Won Ahn, Jong Bum Choi; Youn-Woo Lee
   c. **Background:** Lumbar sympathetic ganglion block (LSGB) is targeted to reduce pain, swelling, sweating, and to improve blood flow in the lower extremity by blocking the sympathetic nerves. There are numerous variations in both the location and number of the lumbar sympathetic ganglia.
   d. **Objective:** To assess the appropriate level of lumbar vertebra where the lumbar sympathetic ganglia principally aggregate.
   e. **Methods:** Sixty consecutive patients, 30 female and 30 male, underwent LSGB either on the left (26 patients) or the right side (34). The primary site of needle entry was randomly selected between L3 (30 patients) and L4 (30) vertebrae. Less than 2 mL of radio opaque dye was injected with caution not to traverse one vertebral body level. The same volume of a mixture of 2% lidocaine and radio opaque dye was injected subsequently. The procedure was considered responsive when skin
temperature of either the sole or dorsum of the foot increased more than 1°C within five minutes. When determined as unresponsive, the procedure was repeated in other vertebral levels sequentially. The space between the upper border of the sacrum (point 0) to the upper border of the L3 (point 12) was divided into 12 segments to allow numerical description of the spread of radio opaque dye.

f. **Results:** The median spread of radio opaque dye was 6.7 (middle 1/3 of L4 body level). The value was significantly different between female and male patients [7.5 (upper 1/3 of L4) and 5.9 (lower 1/3 of L4), respectively] (P = .002). However, there was no significant difference between Lt.- and Rt.- sided LSGB patients [6.3 (middle 1/3 of L4) and 7.1 (upper 1/3 of L4), respectively] (P = .203). The spread of radio opaque dye did not correlate with height or BMI. There were no serious complications on three-month follow-up after neurolytic blocks.

g. **Conclusions:** The results demonstrate that presumably, the lumbar sympathetic ganglia aggregate at the L4 vertebral body level. In male patients, the lumbar sympathetic ganglion aggregated at a lower level (lower 1/3 of L4) compared to that in female patients (upper 1/3 of L4).

h. **References:**

i. **Disclosure:** n/a

9. **Isolated Urate Arthropathy in a Lumbar Facet Joint of a Patient with No History of Hyperuricemia**
   a. **Presenter:** Mehran Rahbar, MD.
   b. **Author:** Mehran Rahbar, MD.
   c. **Background:** The report of gout and pseudogout of the spine is rare. To our knowledge, a total of 10 cases of symptomatic gouty facet cysts have been reported in the literature. In the reported cases, the clinical presentation had been related to the compression of neural elements due to tophaceous material rather than facet joint pain. Therefore, the diagnosis of a gouty cyst of a facet joint has almost always been achieved by histological examination of a specimen obtained during surgical decompression.
   d. **Objective:** To describe the clinical, imaging and laboratory findings in a patient with lumbar facet pain with highly concentrated urate crystals in one facet joint fluid without tophus and the response to facet intra-articular steroid injection.
e. **Methods:** An 82-year-old white male was referred to our clinic for the treatment of his chronic low back pain. The clinical evaluation identified the location of his pain generator in the posterior elements of the lumbar spine, specifically in his facet joints at L4-5 segments. MRI study of the lumbar spine revealed multilevel facet arthropathy, with slight increase in T2 signal within the right L4-5 and L3-4 facet joints. The patient was scheduled for examination under fluoroscopy and facet intra-articular steroid injections. Following the insertion of the spinal needle into the facet joints, the aspiration of the synovial fluid from each joint was attempted. The left L4-5 joint contained significant amount of cloudy synovial fluid with reduced viscosity. The fluid was submitted to the laboratory for analysis. The result returned positive for monosodium urate crystals. Subsequently, serum urate level was analyzed. It was within normal limits (3.1 mg/DL).

f. **Results:** The patient responded well to the injection of 20 mg of methylprednisone into the joint. However, his low back pain recurred after about 18 months. The examination of the facet joint revealed clear fluid on the left and very cloudy fluid on the right at L4-L5 level.

g. **Conclusions:** Isolated facet urate arthropathy in the absence of systemic hyperuricemia, gouty arthritis in other joints or tophaceous materials in the facet joints has not been reported. Lumbar facetogenic pain only localizes the pain generator in the lumbar facet joints. It does not indicate the nature of joint pain. The examination of synovial fluid aspirated before the injection of the joint can provide valuable information in regard to the nature of the pain generator.

h. **References:**

**Disclosure:** n/a

**10. Cross-Linked Hyaluronic Acid: A Paradigm Shift in the Treatment of Neuropathic Pain**

a. **Presenter:** John A. Campa III, MD
b. **Author:** John A. Campa III, MD
c. **Background:** Persistent neuropathic pain presents a special challenge to the clinician as current treatment regimens routinely include opioids, antineuropathic adjuvants, and nerve blocks, which provide at best, modest pain control, and are hindered by dose limiting side effects. Hence, a method of treatment that is safe, provides prolonged, significant relief, without side effects, dose limitations, and not affecting cardiovascular stability, would be ideal. While the literature describes the use of cross-linked hyaluronic acid as a dermal filler, we believe our study is the first to assess its safety and efficacy in the treatment of neuropathic pain.
d. **Objective:** The aim of this study is to assess the safety and efficacy of cross-linked hyaluronic acid in the treatment of neuropathic pain.
e. **Methods:** Thirty-four-month retrospective chart review; 15 patients (7 female/8 male); Average: pain duration—66 mos. (4-200); Age—51yrs. (22-85). Twenty-two separate neuropathic pain syndromes underwent targeted, neural matrix antinociception injection of cross-linked hyaluronic acid. Pain locations: face, 1 (5%); spine: cervical, 1 (5%); thoracic, 3 (14%); lumbosacral, 2 (9%); shoulder, 1 (5%); elbow, 2 (9%); wrist, 2 (9%); thigh, 1 (5%); feet, 9 (41%).
f. **Results:** Average: Dose given—0.15 cc (0.05-0.2); time to relief—24 hrs. (0-48); relief duration—7.7 mos. (2.5-18); pain score—1.5/10 (0-3.5); untoward effects: 0; results assessed by degree/duration of pain relief from single injection.
g. **Conclusions:** We conclude that targeted, neural matrix antinociception injection of cross-linked hyaluronic acid is a safe and effective method of treating neuropathic pain. Its routine use should be considered early in the treatment of this patient group. Additional study is required to elucidate underlying mechanisms and refinement of the injectate.

h. **References:**


4) Allergan, Inc, Juvéderm Gel, package insert.

5) Lim, L. Executive Summary Dermal Filler Devices, Public Advisory Committee Meeting. FDA. 2008; Nov 18:1-41.

6) Medicis Aesthetics Inc, Restylane Gel, package insert.


i. **Disclosure:** n/a

**11. Ultrasonographic Assessment in Carpal Tunnel Syndrome: Clinical and Electrodiagnostic Correlations**

a. **Presenter:** Fatma Ayşen Akıncı Tan, MD

b. **Authors:** Serdar Can Güven, MD; Levent Özçakar, MD; Murat Kara, MD; Bayram Kaymak, MD; and Fatma Ayşen Akıncı Tan, MD

c. **Background:** Electrodiagnostic studies (EDS) are accepted as the gold standard in the diagnosis of carpal tunnel syndrome (CTS). Herewith, ultrasound (US) evaluation can be used to morphologically confirm the diagnosis and also to uncover possible causative factors. Although nerve swelling (proximal to the carpal tunnel) has been found to correlate with the clinical and EDS findings, the results are contradictory.

d. **Objective:** To study the relationship between US measurements, EDS, and clinical findings in CTS.

e. **Methods:** Clinically and electrodiagnostically diagnosed patients with idiopathic CTS (38 F, 2 M, aged 18-65 years) were evaluated. Patients with severe CTS were excluded. Median nerve distal motor and sensory latencies and distal sensory nerve conduction velocities were recorded. Median nerve CSA at
proximal carpal tunnel were measured by US. Symptom and functional status were evaluated with Boston carpal tunnel questionnaire symptom and function scale, and pain intensity with visual analogue scale. Provocative tests (Tinel, Phalen and carpal compression tests) were also applied. Static and dynamic two-point discrimination and Semmes-Weinstein monofilament tests were performed. Medial abduction and opposition strengths of the thumb were evaluated by manual muscle testing.

f. **Results:** Forty hands (23 dominant and 17 nondominant) of 28 patients (16 unilateral, 12 bilateral) were analyzed. Mean symptom duration was 73.9 months. Mean distal median motor and sensory latencies, and distal sensory nerve velocity were 4.6 ms, 3.9 ms and 41.6 m/sec, respectively. Mean median nerve CSA was 12.80 mm². Correlation analyses yielded positive correlations between cross-sectional area (CSA) and Boston symptom scale ($r = .491$, $P = .001$).

g. **Conclusions:** In patients with CTS, morphological changes of the median nerve seem to better correlate with the symptom severity.

h. **References:** n/a

i. **Disclosure:** n/a

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12. **Treatment of Pain Due to Osteoarthritis with Duloxetine**

a. **Presenter:** Li Yue, MD

b. **Authors:** Guochun Wang, MD; Li Yue, MD; Chia-Ning Wang, PhD; Héctor Dueñas, MD; Vladimir Skljarevski, MD; and Madelaine Wohlreich, MD

c. **Background:** The current treatment options used to manage pain due to osteoarthritis (OA) are associated with limited efficacy and/or safety concerns, augmenting the need for alternative treatment options. Duloxetine has been approved to treat pain associated with diabetic peripheral neuropathic pain, fibromyalgia, and chronic musculoskeletal pain in many countries.

d. **Objective:** We assessed efficacy and safety of duloxetine (60 mg, once daily) during a 13-week treatment period in Chinese patients with chronic pain due to OA.

e. **Methods:** The primary efficacy measure in this phase 3, multicenter, randomized, double-blind, parallel, placebo-controlled clinical trial was assessment of the reduction of pain severity by the Brief Pain Inventory (BPI) 24-hour average pain rating. Male or female outpatients ≥ 40 years of age who met clinical and radiographic criteria for the diagnosis of OA with rating ≥ 4 on the BPI 24-hour average pain item were enrolled in the study. A mixed-effects model repeated measures approach and analysis of covariance were used to analyze efficacy measures.

f. **Results:** Of 407 patients randomized (duloxetine: $n = 205$; placebo: $n = 202$), 166 (81.0%) patients from the duloxetine group and 176
(87.1%) patients from the placebo group completed the 13-week treatment phase. Most patients were female (76.4%); mean (standard deviation) age was 60.5 (8.31) years. Duloxetine-treated patients reported significant pain reduction on the BPI 24-hour average pain rating throughout the 13-week treatment phase (least-squares mean change at endpoint, duloxetine: -2.23; placebo: -1.73; \( P = .001 \)). A significant treatment difference favoring duloxetine over placebo was also observed in most secondary efficacy measures: 30% response rate (63.4% vs. 49.7%; \( P = 0.008 \)), Patient Global Impressions of Improvement (2.73 vs. 3.09; \( P < .001 \)), Western Ontario McMaster Universities Arthritis Index total score (-13.58 vs. -10.09; \( P = .001 \)), and Clinical Global Impressions of Severity (-.81 vs. -.53; \( P < .001 \)). No deaths or suicide-related events were reported in either group. The overall incidence of treatment-emergent adverse events was 60.8% in duloxetine-treated patients and 41.9% in placebo-treated patients \( (P < .001) \). For adverse events occurring in \( \geq 10\% \) of patients, duloxetine-treated patients, compared with placebo, experienced significantly higher rates of dry mouth (15.6% vs. 5.6%; \( P = .002 \)), somnolence (14.1% vs. 5.1%; \( P = .003 \)), nausea (12.1% vs. 2.5%; \( P < .001 \)), and constipation (10.6% vs. 2.5%; \( P = .002 \)).

**g. Conclusions:** This study demonstrated the efficacy of duloxetine across multiple measures in Chinese patients with chronic pain due to OA. The safety profile of duloxetine demonstrated in this study was similar to that found in previous duloxetine trials.

**h. References:** n/a

**i. Disclosure:** This study was funded by Eli Lilly and Company.

### 13. Polycystic Ovarian Syndrome, Headache, Temporomandibular Disorder

**a. Presenter:** T.J. Hanson, MD

**b. Author:** T.J. Hanson, MD; and Rand Redfern, DDS

**c. Background:** A recently published article in the *Journal of Maxillofacial Surgery* reported that 76% of 50 patients diagnosed with polycystic ovarian syndrome (PCOS) had symptoms of TMD and headache, where only 24% of a cohort group without PCOS had TMD symptoms. The clinical evaluation was performed and there were no imaging studies.

**d. Objective:** To advise the medical and dental communities regarding the relationship of headaches, temporomandibular disorders (TMD), and PCOS.

**e. Methods:** Three case studies, including clinical examination, CT, and MRI are presented.

**f. Results:** Three young women were referred to the clinic for evaluation of anterior temporal and retrobulbar headaches, musculoskeletal, head, and neck pain. The clinical digital examination was consistent with findings associated with TMD
with myofascial pain (as per J. Travell's work). Computerized
tomography and MRI scans revealed degeneration of the
intracapsular tissues and articular cartilage in the head of the
mandibular condyle. The patients were treated medically for
their PCOS. An intraoral orthopedic appliance was used to
unload the TMJs, decrease muscular hyperactivity, and decrease
the musculoskeletal symptoms, including headache. The orthotic
also allowed for stabilization of the temporomandibular joints.
The patients’ pain level improved from an average of 10/10 to
2/10 for the three cases. The articular cartilage and TMJ
fibrocartilage is affected by the hormonal imbalance in PCOS
resulting inflammation. Additionally, load changes impact the
biomechanical relationships of the joint, which can contribute to
muscular hyperactivity with adaptation to dimensional change.

g. Conclusions: When clinicals are presented with headache and
TMD symptoms in young women, PCOS needs to be considered.
Preventative dental measures need to be implemented to treat
headaches and prevent degeneration of the TMJs and help
protect from potential lifelong sequelae, which can include pain
and future extensive dental treatments.

h. References:

1) Soydan SS, Deniz K, Uckan S, Una I AD, Tutunca NB. Is the incidence of temporomandibular
52(9):822-826.
2) Warren MP, Fried JL. Temporomandibular
disorders and hormones in women. Cells Tissues
3) Travell JG Simons DG. Myofascial Pain and
The Upper Half of Body. Lippincott, Williams, and
Wilkins.

i. Disclosure: n/a

Spinal Cord Stimulation

a. Presenter: Nathaniel Ellens, MS-I
b. Author: Nathaniel R. Ellens, MS-I; Laura M. Muncie, PA-C;
and John S. Winestone, MD

c. Background: Spinal cord stimulation, a neuromodulatory
technology involving the administration of therapeutic doses
of electrical stimulation to the spinal cord, is a surgical
technique currently used to treat chronic pain disorders.
Stimulation of the dorsal columns has been shown to reduce
the perception of pain, with common accompaniment of
paresthesia coverage in associated dermatomes. At the C1-2
level, paddle lead placement provides effective cervical stimulation to ameliorate upper extremity and sometimes lower extremity symptoms. Due to intraoperative safety concerns and patient comfort, this procedure must be performed under general endotracheal anesthesia (GETA) rather than the traditional awake or semi-conscious state used when this procedure is performed at the thoracic level. As a result, patients are unable to provide direct feedback, and an additional monitoring mechanism may be useful in confirming proper stimulator placement. Somatosensory evoked potential collision testing (SSEP) is an accepted monitoring tool that has been used in the subaxial spine when performing cervical spinal cord stimulation in a multistage surgical procedure carried out over three days. However, for the use of SSEP monitoring in single stage, C1-2 placement of spinal cord stimulators has not been evaluated.

d. **Objective:** To support the use of somatosensory evoked potential (SSEP) diminution data to assist with laterality and paresthesia coverage when performing single-stage placement of C1-2 penta leads under general anesthesia.

e. **Methods:** Case series of six patients with complex regional pain syndrome undergoing GETA for posterior C1 and C2 laminotomies and placement of C1-2 penta leads. Fluoroscopy and direct visualization were used to obtain proper anatomic midline placement. Median nerve and posterior tibial nerve SSEPs were obtained for patients complaining of upper and lower extremity pain, respectively.

f. **Results:** Following placement of the stimulators, a reduction in SSEP amplitude ranging from 5% to 87% was observed, confirming inhibition of dorsal column conduction. No new post-operative deficits occurred in any of the patients and no additional significant changes were observed in the SSEP traces other than the transient changes observed while conducting the collision studies. Reliable SSEP blocking, indicating paresthesia coverage, was observed in every case.

g. **Conclusions:** This study evaluated the intraoperative placement and post-operative efficacy of spinal cord paddle lead stimulation placement at C1-2 using SSEP collision studies as an intraoperative guide. SSEP feedback provides the opportunity to adjust paddle lead placement intraoperatively to ensure that a patient will achieve clinically relevant post-operative paresthesia coverage. The results suggest that SSEP feedback is safe and may enhance the efficacy of chronic pain treatment. Due to our limited sample size and short follow-up period, further studies may be necessary to confirm these findings.

h. **References:**
   1) Whitworth LA, Feler CA. C1-2 Sublaminar insertion of


i. **Disclosure:** n/a

15. **Gait-Synchronous Muscle Stimulation for Patellofemoral Pain**

a. **Presenter:** Dhruv Gupta, MSc.

b. **Authors:** Dhruv Gupta, MSc; Larry Kirn; Jody Jensen, PhD; and Lisa Griffin, PhD

c. **Background:** Knee pain afflicts 25% of Americans. Patellofemoral pain syndrome (PFPS) is a common non-radiologic knee pathology, with 2.23 a times higher rate in females. The primary cause of PFPS is imbalanced quadriceps control involving a delayed onset time of the vastus medialis (VM) compared to the vastus lateralis (VL), which may lead to patella maltracking.

d. **Objective:** Our purpose is to determine if neuromuscular electrical stimulation (NMES), which simultaneously activates the VM and VL at the start of the swing phase, will influence the control of these muscles in comparison to gait cycles performed without stimulation.

e. **Methods:** Five women with PFPS performed four six-minute walk tests with 10-minute rests in between. The first was a baseline test. The second was performed with a device placed around the knee that housed an electrical stimulator which was turned off. During the third walk test, the stimulator was turned on (91 Hz) from toe off to heel strike at a tolerable level which elicited visible muscle contraction. The fourth test was identical to the second. Surface acoustic myography (AMG) microphones were placed over the VM and VL and onset times were measures as a percent of stride length with respect to toe-off as determined by VICON motion capture. Onset times and total AMG area (iAMG) were averaged for all strides during the middle four minutes of all walk
tests. iAMG for all trials were normalized to those of the first walk test. Hierarchical linear modelling was used for statistical analysis with factors walk test and muscle group for onset times and iAMG.

f. Results: In the test before stimulation, mean onset times for VM (28.65 ± 0.07%) were later (P < .01) than those for VL (23.28 ± .04%). In the test with gait-synchronous stimulation, there was no difference (P = .79) between the onset times of VM (25.37 ± .05%) and VL (25.03 ± .06%). In the test following the stimulation test, there was no difference (P = .67) between the VM (23.21 ± .06%) and VL (22.68 ± .05%) onset times and VM onset times were earlier than before the stimulation (P < .01). The VM iAMG remained higher than that of the VL for all trials (P < .01).

g. Conclusions: The results of this study demonstrate that NMES, which simultaneously activates the VM and VL during the gait swing phase, can improve the lag in VM onset time experienced by patients with PFPS during voluntary walking muscle activity.

h. References: n/a

i. Disclosure: This study was supported by Articulate Labs Inc.


a. Presenter: Namratha Prabhu, MD
b. Authors: Namratha Prabhu, MD; and Uzma Parvez, MD
c. Background: Chronic back pain is a common health issue among adults, and has a negative impact on the quality of life for many individuals. Many structures in the lower back contribute to the generation of pain, one being the facet joint. Inflammation or injury to these joints can lead to the development of lumbar facet syndrome. Long-term treatment of lumbar facet syndrome includes radiofrequency ablation (RFA).

d. Objective: To present a case of lumbar facet syndrome that was treated with both conventional percutaneous RFA and endoscopic RFA and to compare the effectiveness of both techniques on long-term pain relief and patient satisfaction.

e. Methods: A 69-year-old female presented with a history of lower back pain since 2007. Her symptoms and physical exam were consistent with lumbar facet syndrome. She tried several therapeutic interventions for pain relief, including medical management, physical therapy, medial branch blocks, radiofrequency ablations, lumbar epidural steroid injections, and sacroiliac joint injections with recurrence of pain in 2013. She underwent a medial branch conventional RFA at the L3, L4, and L5 levels on the left side and an endoscopic medial branch rhizotomy at the L3, L4, and L5 levels on the right side in 2013.

f. Results: The endoscopic method resulted in similar results of pain relief in comparison to the conventional method. There was no significant difference in the outcome between the two
techniques. Our patient had complete pain relief with conventional RFA for at least 15 months, but then started experiencing occasional spasms on that side, which were relieved with cyclobenzaprine. The patient has been completely symptom free for over 21 months on the side where she had undergone endoscopic RFA. Her pain score on the Visual Analog Scale has been zero during the follow up visits for these time periods.

**g. Conclusions:** Both conventional RFA and endoscopic RFA have similar effects in long-term pain relief. An advantage with the endoscopic approach is direct visualization of the nerves, but disadvantages include longer duration, increased cost, need for prolonged anesthesia, and lengthened recovery due to incisions. It also results in scars that can be cosmetically undesirable. Considering the advantages and disadvantages of the endoscopic versus conventional fluoroscopically guided RFA and based on the comparable outcomes in pain relief and patient satisfaction, the conventional fluoroscopic medial branch RFA is a preferable technique.

**h. Reference:**

**i. Disclosure:** n/a

**17. Risk of Diversion and Loss of Hydrocodone Extended-Release Tablets Formulated with Abuse-Deterrence Technology: Randomized, Double-Blind, Placebo-Controlled Study in Patients With Chronic Low Back Pain**

**a. Presenter:** Richard Malamut, MD

**b. Authors:** Martin E. Hale, MD; Thomas R. Zimmerman, Jr., MD; Eli Eyal, MSc; and Richard Malamut, MD

**c. Background:** Increasing rates of emergency department visits and deaths ascribed to misuse of prescription opioids have led to development of abuse-deterrent formulations of these medications. Hydrocodone extended-release (ER) is a single-agent (i.e., acetaminophen and ibuprofen free) opioid that was developed with CIMA® Abuse-Deterrence Technology (ADT) platform to lower the potential for misuse or manipulation for abuse by crushing or by alcohol extraction while maintaining extended-release properties.

**d. Objective:** To assess the abuse characteristics of hydrocodone ER in a 12-week, phase 3, randomized, double-blind, placebo-controlled, randomized-withdrawal study.

**e. Methods:** Eligible patients aged 18–80 years had a ≥ three-month history of moderate to severe chronic low back pain. In an open-label treatment period, hydrocodone ER was titrated to an analgesic dose that provided optimal pain relief without unacceptable adverse events. Patients were then randomized to
12-week double-blind treatment with their analgesic dose of hydrocodone ER (30-90 mg) or matching placebo every 12 hours; a stepwise, double-blind tapering schedule implemented during the first two weeks (i.e., randomized-withdrawal period) reduced the risk of withdrawal effects in patients randomized to placebo. Rescue medication (hydrocodone immediate release/acetaminophen 5/325 mg tablets) was permitted with limits. Signs and symptoms of opiate withdrawal were measured using the Subjective Opiate Withdrawal Scale (SOWS) and Clinical Opiate Withdrawal Scale (COWS) for the first four weeks of double-blind treatment. Study drug diversion and loss were also monitored.

f. **Results:** The SOWS showed that 59%–68% of hydrocodone ER patients and 52%–65% of placebo patients rated withdrawal symptoms as normal (i.e., no withdrawal), and the COWS showed that clinicians rated withdrawal symptoms in 87%–95% of hydrocodone ER patients and 82%–93% of placebo patients as normal. Rates of study drug or rescue medication diversion and loss were low. Diversion occurred at an overall rate of ≤ 2%; six patients reported diversion of hydrocodone ER, six reported diversion of rescue medication, and one reported diversion of placebo. Study drug loss occurred at an overall rate of ≤ 4%; 20 patients reported loss of study drug.

g. **Conclusions:** After randomized-withdrawal of hydrocodone ER, withdrawal symptoms were reported as absent or mild in most patients. The low rates of study drug diversion and loss support the potential abuse-deterrence properties of hydrocodone ER formulated with an ADT platform.

h. **References:** n/a

i. **Disclosure:** This study was sponsored by Teva Branded Pharmaceutical Products, Inc. (Frazer, PA, USA).

18. **Hydrocodone Extended-Release Tablets Formulated With an Abuse-Deterrence Technology Platform for Treatment of Moderate to Severe Pain: Efficacy and Safety in Patients With Chronic Low Back Pain**

a. **Presenter:** Richard Malamut, MD

b. **Authors:** Martin E. Hale, MD; Thomas R. Zimmerman, Jr., MD; Eli Eyal, MSc; and Richard Malamut, MD

c. **Background:** The US Food and Drug Administration identified development of abuse-deterrent opioids as a high public priority. The current phase 3 study was conducted to evaluate a new single-agent (i.e., acetaminophen and ibuprofen free) formulation of hydrocodone extended-release (ER) tablet formulated with a CIMA® Abuse-Deterrence Technology (ADT) platform.
d. **Objective:** To assess the efficacy and safety of hydrocodone ER formulated with an ADT platform in patients with moderate to severe chronic low back pain.

e. **Methods:** Patients aged 18–80 years with a ≥ three-month history of moderate to severe back pain identified an optimal analgesic dose of hydrocodone ER (i.e., dose that provided stable pain relief without unacceptable adverse events [AEs]) during an open-label titration period. Those who achieved an analgesic dose were randomized to receive hydrocodone ER every 12 hours at their identified dose (30-90 mg) or matching placebo in a 12-week, double-blind, placebo-controlled, randomized-withdrawal treatment period. The primary efficacy measure was change from baseline to week 12 in weekly average of daily worst pain intensity (WPI) scores. Secondary efficacy measures included change from baseline to week 12 in average pain intensity (API) scores and proportion of patients with loss of efficacy leading to study discontinuation.

f. **Results:** During open-label treatment, 371 patients identified an optimal analgesic dose of hydrocodone ER and were randomized to double-blind treatment. Significantly higher changes from baseline to week 12 (indicating worsening pain) were seen in the weekly average of daily WPI scores in the placebo group vs. the hydrocodone ER group: least squares (LS) mean change (standard error [SE]) .74 (.15) vs. .11 (.14); \( P < .001 \). Significantly higher changes from baseline to week 12 were also seen in API scores in the placebo group vs. hydrocodone ER group: LS mean change (SE) .55 (.14) vs. –.03 (.12); \( P < .001 \). The proportion of patients with loss of efficacy leading to discontinuation was lower with hydrocodone ER vs. placebo (23% vs. 30%; hazard ratio [95% confidence interval] 0.68 [.45, 1.01]; \( P = .059 \)). Common AEs with hydrocodone ER during double-blind treatment were constipation (14%) and nausea (10%).

g. **Conclusions:** Hydrocodone ER, formulated with ADT, was significantly more effective than placebo in relieving chronic low back pain. The safety profile was consistent with that of hydrocodone and other opioid analgesics.

h. **References:** n/a

i. **Disclosure:** This study was sponsored by Teva Branded Pharmaceutical Products, Inc. (Frazer, PA, USA).

19. **Evaluation of the Relative Intranasal Abuse Potential of a Hydrocodone Extended-Release Tablet Formulated with Abuse-Deterrence Technology in Nondependent, Recreational Opioid Users**

a. **Presenter:** Richard Malamut, MD
b. **Authors:** Mary Bond MS, MBA; Kerri A. Schoedel, PhD; Laura Rabinovich-Guilatt, PhD; Maciej Gasior, MD, PhD; Richard Malamut MD; Yuju Ma MS; and Lynn R. Webster, MD

c. **Background:** The two most common routes of administration in the abuse of immediate-release hydrocodone products are oral and intranasal (i.e., snorting). A single-agent (i.e., acetaminophen and ibuprofen free) hydrocodone extended-release (ER) tablet was developed with CIMA® Abuse-Deterrence Technology to provide resistance against rapid release of hydrocodone when tablets are manipulated or taken with alcohol, potentially reducing abuse liability when misused or abused.

d. **Objective:** To assess the relative abuse potential of manipulated (milled) intranasal hydrocodone ER in healthy, nondependent adults with a history of recreational and intranasal opioid use.

e. **Methods:** Subjects were randomized (1:1) to receive intranasal placebo powder and intranasal hydrocodone active pharmaceutical ingredient (API) powder 45 mg to identify those subjects able to tolerate the 45-mg dose of intranasal hydrocodone API and discriminate effects of hydrocodone from those of placebo. Eligible subjects were randomized into a double-blind, five-period, crossover treatment phase to assess abuse potential. Subjects received each of the following separated by a ≥ seven-day washout: intranasal milled hydrocodone ER 45 mg, intranasal hydrocodone API 45 mg (surrogate for immediate-release hydrocodone), intact oral hydrocodone ER 45 mg, intranasal milled Zohydro ER 45 mg (hydrocodone ER capsule commercially available at time of study), and placebo. Coprimary pharmacodynamic endpoints included maximum effect ($E_{max}$) for “at the moment” drug liking and $E_{max}$ for end-of-day/next-day Overall Drug Liking, both scored on a 100-point bipolar visual analog scale (VAS).

f. **Results:** Thirty-four patients were evaluable for pharmacodynamic assessments performed through 48 hours after administration of study medication. $E_{max}$ for “at the moment” drug liking was significantly ($P = .004$) lower for hydrocodone ER vs. hydrocodone API and Zohydro ER (72.8 vs. 80.2 and 83.2, respectively) and significantly ($P < .001$) higher vs. oral hydrocodone ER (57.3) and placebo (58.6). $E_{max}$ for end-of-day/next-day Overall Drug Liking VAS was also significantly ($P = .004$) lower for hydrocodone ER vs. hydrocodone API and Zohydro ER (68.5 vs. 77.1 and 79.8, respectively) and significantly ($P \leq .001$) higher vs. oral hydrocodone ER (57.8) and placebo (57.7). Outcomes for secondary measures were generally consistent with the coprimary pharmacodynamics results. No new safety signals were observed.

g. **Conclusions:** Abuse potential following intranasal administration, one of the two most common routes of abuse, was significantly lower with hydrocodone ER than with hydrocodone API and the non–abuse-deterrent opioid product Zohydro ER. When
hydrocodone ER was administered intact orally, as intended, liking scores were comparable to placebo.

h. References: n/a

i. Disclosure: This study was sponsored by Teva Branded Pharmaceutical Products R&D, Inc. (Frazer, PA, USA).

20. How Common is Attention Deficit Disorder (ADD) in Chronic Pain Patients?

a. Presenter: Forest Tennant MD, DrPH

b. Author: Forest Tennant MD, DrPH

c. Background: Chronic pain patients frequently complain about poor concentration ability and memory loss. Some are notoriously noncompliant with therapeutic instructions and studies on centralized pain patients show that most have hyperarousal of the autonomic nervous system, loss of inhibition of descending pain pathways, and catecholamine deficiencies. Given these physiologic disturbances, ADD should be a common comorbidity.

d. Objective: To determine if ADD is a common comorbidity in chronic pain patients that may warrant treatment.

e. Methods: A 16 item questionnaire was given to 45 consecutive chronic pain patients who routinely attended their treatment clinic in May, 2015. Questions were selected from symptoms reported in the adult ADD literature. They were directed at whether the patient had deficiencies in: concentration, attention, distractibility, impulsivity, reading and retention, coordination, temper, and short-term memory. A positive answer to 5 or more questions was considered to indicate the presence of ADD.

f. Results: Seventeen (37.8%) of the 45 patients answered five or more questions in a positive manner indicating the presence of ADD.

g. Conclusions: In this pilot study a significant percentage of chronic pain patients reported classical symptoms of ADD. This finding may explain some of the poor functions in activities of daily living and non-compliance with therapeutic instructions frequently observed in chronic pain patients. Recognition of ADD in chronic pain patients and its treatment may enhance chronic pain management, and this issue needs to be a subject of future investigation.

h. References:


i. Disclosure: This study was supported by the Tennant Foundation.
21. Which Chronic Back Pain Patients have Arachnoiditis?
   a. **Presenter:** Forest Tennant MD, DrPH
   b. **Author:** Forest Tennant MD, DrPH
   c. **Background:** Low back pain is the most common problem that brings a patient to pain treatment. While the cause of low back pain in the majority of cases is degenerative in nature, an unknown, but definite percentage, have arachnoiditis. This condition, which appears to be increasing in incidence, can be catastrophic in that it is an inflammatory, progressive process that may cause severe, disabling pain, lower extremity paralysis, bowel and bladder dysfunction, sexual inability, and a systemic autoimmune disorder. Although previously thought to be a hopeless disease, recent reports show significant improvement and recovery in patients who receive specialized pain and neurogenic management.
   d. **Objective:** To provide a short, simple, clinical interview that pain practitioners can use to identify the lower back pain patient who requires a diagnostic evaluation for the presence of arachnoiditis.
   e. **Methods:** A 21-item questionnaire was given to 26 patients with Arachnoiditis, which was documented by magnetic resonance imaging (MRI). Specific questions were selected from a review of the literature and clinical observations of patients. Questions were directed at the presence of positional pain, bowel and bladder function, physical dysfunctions, character of the pain, and symptoms indicative of cerebrospinal fluid obstruction.
   f. **Results:** Remarkably all 26 patients reported that their pain was constant and that: (1) severe pain occurred with standing too long, which caused the patient to sit or lie down; and (2) jerking or tremors in their legs. At least 23 of 26 (88.5%) patients reported: (1) intense episodes of heat and sweating; (2) difficulty with initiation of urination and/or defecation, and; (3) episodes of blurred vision. All patients had undergone a wide variety of spinal surgeries and procedures.
   g. **Conclusions:** Since arachnoiditis is increasing in incidence and perhaps the most catastrophic, disabling pain condition, it is essential that every back pain patient be quizzed for symptoms of arachnoiditis. A patient should be suspected to have arachnoiditis if they have a typical clinical profile which consists of inability to stand long without severe pain, tremors, or jerking in the legs, intense episodes of heat and sweating, difficulty initiating urination or defecation, and episodic blurred vision.
   h. **References:**

i. Disclosure: This study was supported by the Tennant Foundation.

22. Function and Serum Levels in High Dose Oxycodone Patients

a. Presenter: Forest Tennant MD, DrPH
b. Authors: Forest Tennant MD, DrPH; Lloyd Costello, MD; Martin J. Porcelli, DO; and Scott Guess, PharmD

c. Background: Some severe intractable pain patients have found that high and ultra-high dosages of oxycodone provide excellent pain control, allow normal physical and mental function, and permit a good quality of life. Daily dosages may transcend into high (100 to 1000 mg) dosages and even ultra-high (over 1000 mg) of daily morphine equivalence. Patients who take ultra-high oxycodone dosages have not been studied or evaluated.

d. Objective: To determine if some intractable pain patients can function with ultra-high oxycodone dosages and high blood levels.

e. Methods: Seventeen chronic pain patients who have maintained on daily ultra-high, oxycodone dosages for at least five years have been referred to us for evaluation and management. Daily oxycodone dosages range from 875 to 3500 mg a day (1000 to 4200 mg of morphine equivalence). Patients have been evaluated by history and physical, hormone profile, pharmacogenetic testing, inflammatory markers, and family reports of pain severity and necessity of ultra-high oxycodone dosages. Serum levels of oxycodone have been periodically assessed, and patients have been encouraged but not required to reduce their daily dosages or change opioids.

f. Results: All patients have severe, central, intractable, painful conditions such as chronic regional pain syndrome (CRPS), post-encephalitis headache, and adhesive arachnoiditis. Serum levels of oxycodone have ranged from 86 to 831 ng/ml. Physical measures including blood pressure, pulse rate, mental alertness, sedation, and ambulation have been routinely monitored and found to be normal. Nine (52.9%) patients hold full-time jobs and 15 (88.2%) are able to drive a car. There has been no evidence of drug diversion, abuse, or other aberrant behavior. Oxycodone dosages have remained rather static without escalation, and no patient desires to withdraw or change treatment as they claim they have good pain control and a good quality of life. The only biologic complication we have detected is some hormone suppression, particularly testosterone,
pregnenolone, and cortisol. Thirteen (76.4%) patients demonstrate at least one and six have 2 cytochrome P450 abnormalities. Three patients have genetic diseases.

g. **Conclusions:** Some severe, intractable pain patients appear to safely and effectively maintain with ultra-high dosages of oxycodone. They appear to mentally and physically function, have a good quality of life, and do not wish to change or reduce their daily oxycodone dosage. At this time we see no objective clinical reason to force a change and recommend that these patients be scientifically studied and treated in specialty settings.

h. **References:** n/a

i. **Disclosure:** This study was supported by the Tennant Foundation.

### 23. Hormone Abnormalities in Buprenorphine/Naloxone Patients

a. **Presenter:** Forest Tennant MD, DrPH

b. **Authors:** Anastasia Jandes, MD, Pharm.D and Forest Tennant MD, DrPH

c. **Background:** Buprenorphine/naloxone is a relatively new, outpatient treatment for patients with opioid dependence. Buprenorphine is an antagonist/agonist compound with partial mu opioid agonist with ceiling effects and known analgesic effects. Consequently, patients with opioid dependence and/or chronic pain may benefit from it. To date, there have been no endocrine evaluations of patients maintained with buprenorphine/naloxone.

d. **Objective:** To determine if buprenorphine/naloxone patients have hormone abnormalities that may benefit from therapeutic interventions.

e. **Methods:** Forty-eight (48) adult patients with opioid dependence maintained on buprenorphine/naloxone therapy were serum tested with a hormone profile consisting of adrenocorticotropicin (ACTH), cortisol, dehydroepiandrosterone-S (DHEA-S), Vitamin D, progesterone, and testosterone. (ETHOS®, Cincinnati) Blood samples were taken mid-day. There were 20 (42%) females and 28 (58%) males.

f. **Results:** Forty-seven (47) of 48 patients had one or more hormone abnormalities. Every hormone tested showed some abnormalities. Three (3) patients revealed significant pituitary-adrenal-gonadal insufficiency defined as a low serum ACTH plus low levels of two adrenal or gonadal hormones. Eight (8) patients had low cortisol, three (3) of which clinically warranted treatment with hydrocortisone, and one (1) of which was below 1.5 mcg/dl. Twenty-one (21) patients had low gonadal hormone levels. Thirty-four (34) patients had low vitamin D levels, which represented 71% of the patients sampled.
g. **Conclusions:** The hormone levels detected in these patients strongly suggest a need for therapeutic interventions in some patients, however, the specific cause of these abnormalities is generally unclear. High levels may represent out-of-control pain or stress, and low levels may represent long-term pain, stress, neuroinflammation, or opioid suppression among other causes. It is unknown if, but speculated that, therapeutic intervention may improve patient retention, abstinence, pain relief, function, and weaning. Opioid-dependent patients maintained on buprenorphine/naloxone show a high prevalence of hormone abnormalities. Some hormone levels were significantly lowered, but it is unknown what clinical benefits may result with hormone replacement or other therapeutic intervention.

h. **References:** n/a

i. **Disclosure:** N/a

24. **Can a Holistic Wellness Model Help Patients Reduce Their Need for Pain Medication?**
   
a. **Presenter:** Veena Prasad, MA, MBA
   
b. **Authors:** Veena Prasad, MA, MBA; Adriana Dyurich, MS; and A.R.S Prasad, Ph.D., M.D.
   
c. **Background:** Research has shown that a holistic approach to chronic pain is effective in reducing consumption of pain medication. Currently there is an emphasis on reducing opiate prescription for chronic pain. There are several existing approaches for multimodal pain management but there is a lack of a comprehensive model to help patients identify the areas where they need help and improvement. A 360 degrees wellness model incorporating all domains of life, including psychological, physical, and spiritual, will be tested among patients as an aid for chronic pain management. This study explores relationships between psychological, physical, and spiritual dimensions that play a role on the overall wellness of clients with chronic pain.
   
d. **Objective:** To explore if our wellness model can help patients continue to live successfully with chronic pain. The objective is to help patients look at their overall life over focusing on pain.
   
e. **Methods:** Our model will be presented to patients with chronic pain. We will help them identify those areas that need attention. The intervention will involve psychoeducation, coaching, and relaxation techniques and, most importantly, psychological flexibility based on cognitive behavioral therapy (CBT).
   
f. **Results:** This model will be applied to patients who are on medication. Outcome will be measured based on pain management and life quality by developing appropriate and valid instruments to test the effectiveness of this model.
   
g. **Conclusions:** A wellness model will be used to encourage healthy and improved holistic living, to help patients to make
changes in life. By helping patients identify the areas of their life that they can modify, the intervention aims to help them live a plentiful life, paying less attention to pain, and reducing their dependency on pain medication.

h. **References:**

i. **Disclosure:**

25. **A Meta-Analytic Review of the Adverse Events of Long-Term Use of Opioids for Chronic Non-Cancer Pain**

a. **Presenter:** Matthew Pelcowitz BA, MSc (in progress)
b. **Authors:** Matthew Pelcowitz BA, MSc; and (in progress), Andrea Furlan MD, PhD
c. **Background:** Opioids are considered one of the most effective analgesics with well-established therapeutic benefits. In 2011, a systematic review identified 62 randomized trials demonstrating the benefits of opioids for chronic non-cancer pain (CNCP) (1). However, knowledge on opioid-related adverse events is limited, in part due to the historical propensity for scientific literature to emphasize therapeutic benefits and minimize alternative adverse health outcomes (2). More recently, researchers have identified the need to report the adverse events of medical interventions. This is especially true for prescription opioids, widely prescribed drugs that can cause many adverse events (3).

d. **Objective:** This meta-analytic review will focus on opioids, widely prescribed drugs that cause numerous adverse events. In doing so, this review will assess the paucity in the literature on adverse events and surmise the literature’s current state.

e. **Methods:** Studies for the current project were acquired from major databases, including: MEDLINE, EMBASE, CINAHL, PsycINFO, Central and Business Source Premier using a comprehensive search strategy. The initial search retrieved 16,288 studies; 72 studies, which were either RCTs (six studies), controlled observational studies (27 studies), or non-controlled observational studies (39 studies), met inclusion criteria, and were included in the meta-analytic review. Included studies were assessed on risk of bias, measured with a comprehensive assessment tool derived from a previous systematic review, quality of reporting, measured using McHarm, and overall prevalence of adverse events.

f. **Results:** Anticipated results include less risk of bias and better quality of reporting for RCTS compared to other study designs. Additionally, the prevalence of adverse events is expected to be less in RCTs. This may be due to the more rigorous
methodology employed from RCTS. However, the limited sample of RCTs may have influenced findings.

g. **Conclusions:** Overall, both risk of bias and quality of reporting was poor across study design. Future studies are encouraged to utilize tools, such as Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) to improve methodologies and reporting of adverse events.

h. **References:**

i. **Disclosure:** n/a

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26. **Evolution of the Tolerability of Switching Patients on Chronic Full Opioid Agonist Therapy to BEMA® Buprenorphine**

a. **Presenter:** Daniel Gruener, MD

b. **Authors:** Lynn Webster, MD; Daniel Gruener, MD; Todd Kirby, PhD; Qinfang Xiang, PhD; Evan Tzanis; and Andrew Finn, PharmD

c. **Background:** Buprenorphine is a partial mu-agonist with poor oral bioavailability, requiring transmucosal, transdermal, or parenteral administration for analgesia. BEMA® Buprenorphine (BB) is a mucoadhesive film designed for buccal delivery, currently being investigated for use in moderate-to-severe pain. Due to its partial agonist activity and high affinity for μ-opioid receptors, there is a potential for buprenorphine to precipitate withdrawal in patients who are already on full agonist opioids. Accordingly, current practice is to taper a patient’s around-the-clock (ATC) opioid to a 30 mg morphine sulfate equivalent (MSE) dose before switching to buprenorphine.

d. **Objective:** To determine whether patients with chronic pain receiving 80-220 mg oral MSE of an ATC full opioid agonist could be safely transitioned to BEMA Buprenorphine at approximately 50% of their oral MSE dose without inducing opioid withdrawal or sacrificing analgesic efficacy.

e. **Methods:** This was a randomized, double-blind, double-dummy, active-controlled, two-period crossover study in patients 18-60 years old receiving ATC full opioid agonist therapy (morphine sulfate or oxycodone) and confirmed to be opioid dependent by naloxone challenge. Study doses were substituted at the time of the regular
dose schedule for each patient. The primary endpoint was the proportion of subjects with a maximum Clinical Opiate Withdrawal Scale (COWS) score ≥ 13 (significant withdrawal) or were rescued due to withdrawal symptoms.

f. **Results:** Thirty-five subjects (31 on 80–160 mg and four on 161–220 mg MSE per day) were evaluable for opioid withdrawal status. Only one of 35 patients during BB treatment and two during 50% full mu-agonist treatment experienced significant withdrawal. In addition, the mean maximum COWS scores were similar between BB and full agonist treatments (mean [SD] 4.6 [3.15] and 5.3 [4.42], respectively; \( P = .79 \)) and there was no significant difference in pain ratings between the two treatments in the 80-160 mg group. The most frequent adverse events (AEs) with BB were headache (19%), vomiting (13%), nausea, diarrhea, and drug withdrawal syndrome (each 9%); with full agonist treatment the most frequent AEs were headache (16%), drug withdrawal syndrome (13%), and nausea (6%).

g. **Conclusions:** The results demonstrate that in this study, chronic pain patients treated with ATC full opioid agonist therapy can be switched to BEMA.

h. **References:**

i. **Disclosure:** Study supported by Endo Pharmaceuticals Inc.

27. **Safety and Efficacy of Oxycodone DETERx: Results of a Randomized, Double-blind, Placebo-Controlled Phase III Study**

a. **Presenter:** Ernest A. Kopecky, PhD, MBA

b. **Authors:** Ernest A. Kopecky, PhD, MBA; Alison B. Fleming, PhD; Ravi. K. Varanasi, MPharm; Melinda O’Connor, BA; and Said Saim, PhD

c. **Background:** Chronic pain and abuse of prescription opioids are public health crises in the United States. Extended-release (ER) opioid analgesics offer advantages in the treatment of chronic pain, e.g., lower peak-trough fluctuations, reduced dosing frequency. However, these analgesics have become a target for abuse due to the large quantity of opioid in the formulation. To mitigate nonmedical use, abuse-deterrent (AD) ER products are being developed. Unfortunately, the majority of AD products are hard-to-crush tablets, creating an unmet need for patients with chronic pain and dysphagia (CPD). Oxycodone DETERx (Xtampza ER; herein DETERx) is a microsphere-in-capsule (DETERx drug delivery platform), ER, AD formulation that offers dosing flexibility by enabling sprinkling onto soft foods or administration via enteral tube.

d. **Objective:** To evaluate the efficacy and safety of DETERx compared with placebo in subjects with moderate-to-severe chronic low back pain (CLBP), requiring continuous around-the-clock (ATC) opioid analgesia.
e. **Methods:** This was a multicenter, double-blind, enriched-enrollment, randomized-withdrawal, placebo-controlled study that enrolled opioid-experienced and opioid-naïve subjects. Key inclusion criteria: males, females, 18-75 years, six-month history of mechanical CLBP, pain $\geq 5$ and $\leq 9$ (on 11-point pain intensity-numerical rating scale). Rescue medication: acetaminophen. Patients who achieved a stable, effective dose of DETERx in titration were randomized into the 12-week, double-blind maintenance phase. Primary efficacy endpoint was the change in average pain intensity from randomization baseline to week 12. Secondary endpoints included Patient Global Impression of Change (PGIC), responder analysis, total amount of rescue medication, and time-to-exit. Safety assessments: adverse events, vital signs, clinical laboratory values, physical examination.

f. **Results:** Three hundred eighty-nine subjects were randomized; 193 subjects to DETERx and 196 to placebo. Change (worsening) in average pain score was higher for placebo subjects ($P < .0001$). Multiple sensitivity analyses supported the primary analysis result ($P \leq .0002$). DETERx demonstrated greater improvement in pain intensity than placebo by week 2 ($P = .0105$), which was sustained through week 12 ($P = 0002$). PGIC was greater for DETERx ($P = .0040$). Approximately 50% of subjects had $\geq 30\%$ reduction in pain ($P = .0013$). Time-to-exit (all causes) was longer for subjects in the DETERx group than placebo ($P = .0090$). More subjects discontinued on placebo due to lack-of-efficacy ($P < .0001$). Mean amount of rescue medication (mg) was numerically higher for placebo. DETERx was well-tolerated in the study. Most common treatment-related AEs for DETERx were nausea, headache, and constipation. Results from clinical laboratory assessments and physical examination were similar between the DETERx and placebo groups.

g. **Conclusions:** Oxycodone DETERx was safe and effective in the reduction of pain intensity in subjects with moderate-to-severe CLBP requiring continuous ATC opioid analgesia.

h. **References:** n/a

i. **Disclosure:** Studies presented here were supported by Collegium Pharmaceutical, Inc.

28. **A Study to Validate Findings of a Randomized Clinical Trial on the Use of Biofeedback Stimulation Technology to Manage Pain in Chronic Pain Patients**

a. **Presenter:** Rob Gussenhoven, PharmD

b. **Authors:** Rob Gussenhoven, PharmD; and Tino Unlap, PhD

c. **Background:** Electrostimulation devices (ESDs) were first used to treat shock and as morphine substitute for pain management in wounded soldiers and have undergone a number of improvements including refining the emitted wave form to access C-fibers, and to a
lesser extent A-fibers, to stimulate the release of neuropeptides that blunt pain perception in cortical centers of the brain. One of the next generation biostimulation devices developed by Avazzia, the Biofeedback Electrical Stimulation Technology (BEST™), has been used to manage pain in chronic pain patients.

d. **Objective:** To validate the findings of a registered clinical trial conducted overseas on the efficacy of using biofeedback stimulation technology for pain management.

e. **Methods:** Preliminary Study: Patients with a variety of chronic pain were treated with BEST™ in a randomized clinical trial in Malaysia. Pain level, pain severity, and pain interference were recorded before, immediately after, and 24 hours post-treatment. Patients were first treated with an electrode emitting a frequency of 30-300 hz by gliding the electrode across the area of pain until resistance was reduced (five minutes) followed by treatment using a self-adhesive pad at a frequency of 30 hz for 20 minutes. Current Study: Patients with chronic pain are treated with Avazzia’s BEST™ using the treatment paradigm used in the preliminary study administered once a week for 4 weeks. Using an IRB-approved BPI survey that we have used, pain severity, the most recent 24 hour pain, and physical and emotional quality of life (QoL) metrics will be measured before and at one and four weeks post-treatment. Adverse events will also be recorded. The significance of the treatment will be determined by comparing baseline with week 1 and week 4 values using Analysis of Variance (ANOVA). P values ≤ .05 will indicate significance.

f. **Results:** Preliminary Study: The results showed that pain level decreased from 62 to 22 ± 19 (P < .001), pain severity decreased from 5.4 to 2.45 ± 1.58 (P < .005), and pain interference decreased from 4.9 to 2.2 ± 1.3 (P < .001) after 24 hours of treatment. The study also reported no adverse events. Current Study: Using the BPI survey, our study should demonstrate the utility of BEST™ as a therapy to reduce severity of pain, most recent 24 hour pain, and improve physical and emotional QoL.

g. **Conclusions:** This study should validate the preliminary findings that BEST™ is an effective therapy to manage chronic pain in chronic pain patients.

h. **References:**

i. **Disclosure:** n/a

29. **Diverse Opioid Pathways in Chronic Pain Recovery**
   a. **Presenter:** Bruce Singer, PsyD
   b. **Authors:** Seddon Savage, MD; Brent Moore PhD; Bruce Singer PsyD; Seth Resnick, MD; Michael Brennan, MD; Michael Fortin, DPT; Tiffany Nienstedt, MS; and Sigurd Ackerman, MD
c. **Background:** While some patients with chronic pain experience effective analgesia with opioid therapy, over time other patients experience loss of analgesia, declining function, persistent side effects, mood changes, increasing pain, escalating dose requirements, and/or diverse types of opioid misuse that ultimately result in declining well-being. A patient’s distress in such contexts may reflect diverse issues including:
- Ineffective pain management due to tolerance, hyperalgesia, opioid non-responsiveness, or inappropriate dosing
- The presence of unaddressed, co-occurring symptoms that facilitate pain such as depression, anxiety, intrusive memories, sleep disturbance, or others
- Opioid-induced distress related to active opioid misuse or addiction
- A combination of these

d. **Objective:** To address chronic pain in patients who have not responded favorably to opioid therapy, the Chronic Pain & Recovery Center (CPRC) at Silver Hill Hospital (SHH) is guided by the following understandings:
- Chronic pain, like other chronic medical conditions, often has complex biopsychosocial contributors and benefits from a strong foundation in self-management.
- Distress occurring in the treatment of chronic pain with opioids can reflect diverse drivers, therefore opioid management must be tailored to the individual and the causes of distress; no single approach is effective in addressing the needs of all patients.
- Outcomes of treatment based on these guidelines are presented.

e. **Methods:** Patients

*Admission criteria and process*
All patients have one or more pain diagnoses. Many have co-occurring psychiatric or addictive disorders. Treatment costs are covered by the individual, workers compensation, the Veterans Administration, or through SHH scholarships covering 75% of cost.
Patients are admitted to the program by two routes:
- On an non-urgent, elective basis following outpatient evaluation by the CPRC team.
- On transfer from inpatient psychiatric admission for acute mental health or addiction issues with chronic pain; evaluated by the CPRC team once stable.

*Patient Characteristics*
Table 1 indicates the numbers of common pain diagnoses and psychiatric and substance abuse disorders in the first 154 patients admitted to the program.

**Table 1**

**Pain Diagnoses** *

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculoskeletal- Axial</td>
<td>95</td>
</tr>
<tr>
<td>Musculoskeletal-oint/limb</td>
<td>34</td>
</tr>
<tr>
<td>Neuropathic (non-facial)</td>
<td>18</td>
</tr>
</tbody>
</table>
Headache 15
Abdominal 9
Facial 5
Genital 2
Other 15

Psychiatric and Substance Abuse Diagnoses*
Depressive disorder or state 114 *
Anxiety disorder or state 79
PTSD 10
Bipolar disorder 4
Opioid use disorder 72
Sedative hypnotic use disorder 45
Alcohol use disorder 35

*Patients could be diagnosed with more than one pain or psychiatric disorder

Payer sources were 54% self-pay, 30% workers compensation, 2% Veterans Administration, and 14% scholarship.

Treatment
Program format and goals
The CPRC is a minimum four-week, residential program with a maximum census of eight patients. The program focuses on acquisition of self-management skills with goals to reduce pain, improve coping with residual pain, increase function, effectively treat co-occurring disorders (mental health or addiction), reduce medication reliance, and enhance overall quality of life. Patients engage in therapeutic activities 12 to 14 hours a day. Treatment is primarily group-based with individual counseling sessions with a psychologist a minimum of twice weekly and medical/psychiatric appointments from one to five times a week as indicated. Core treatment approaches include:
• Cognitive behavioral therapy (CBT) integrated with acceptance and commitment therapy (ACT) tailored to comprehensively address pain, mood, and substance disorders
• Mindfulness strategies including meditation, body awareness, gratefulness
• Physical therapy tailored to individual condition
  o Land-based exercise (aerobic, stretch, strengthening)
  o Aquatic exercise
• Goal setting and process groups
• Education on pain, mood, substance use, sleep hygiene, nutrition, and related topics
Patients also participate in
• 12-step groups including Chronic Pain Anonymous, AA, NA
• Movement groups including yoga, Tai Chi, Chi Gong
• Art therapy
• Family program
• 12-month step down aftercare and telephone support follow-up is offered

Medication management
All patients using opioids without favorable response or with negative consequences are educated about ways in which opioids can contribute to distress and are encouraged to taper off on a trial basis. Decisions regarding ongoing management of opioids are made with the patient based on their response to taper. Common management approaches include:
• Opioid taper with continued cessation (with or without naltrexone)
• Transition to opioid agonist maintenance therapy for opioid addiction (buprenorphine/naloxone or methadone maintenance)
• Rotation to an alternative opioid at lower doses for analgesia
• Lower dose therapy using the admission opioid for analgesia
Psychiatric medications are adjusted as indicated to treat co-occurring psychiatric issues. Non-opioid medications for pain are introduced or adjusted as indicated.

f. Results: One hundred eighteen of the first 136 patients admitted completed treatment and had assessment data analyzed. Clinical outcomes for pain, pain interference, mood, catastrophizing are indicated in the adjacent graphs. Data indicates significant reductions in mean pain and pain interference with enjoyment of life and with activity. Anxiety and depression scores significantly reduced, as did scores from the pain catastrophizing measures. Data available at three and six months after initiation of treatment on a smaller group of 18 patients who participated in aftercare suggest that these improvements persisted.

Opioid use data is available on 154 patients who completed treatment and indicates the following:
• 79% of 154 (122) patients admitted to CPRC were using opioids on admission.
• 63% of those admitted on opioids (77) no longer used opioids at discharge
  o 3 of these were on the depot naltrexone to support recovery from opioid addiction.
• 18% (22) were transitioned to opioid agonist therapy (OAT) for treatment of opioid addiction.
  o 20 on buprenorphine/naloxone
  o 2 on methadone with referral to methadone maintenance
• 19% (23) were on lower dose opioid prescriptions for pain, most rotated to a different opioid with a mean dose reduction of greater than 75% morphine equivalents.
• One patient with history overuse of prescribed opioids and relapsing alcoholism (in part driven by pain) who was not on opioids at admission, was prescribed buprenorphine/nx for pain.
• One patient's admission opioids were unchanged on discharge. Opioid use data at six months post discharge based on self report and urine drug screens on 19 patients in aftercare (see Table 2) indicate maintenance of discharge opioid status for all but one patient.

g. Conclusions: From treatment intake to discharge, all measures of pain, pain interference, and measures of psychiatric functioning (anxiety and depression) showed significant clinical improvement. For participants in the aftercare program, improvements appear to be retained for the pain measures. There is some indication that anxiety and depression scores at later follow-up may be returning toward baseline.

Importantly, these clinical improvements occurred in the context of reduction or elimination of opioid use for pain. Opioid management generally followed these principles:

• Patients were transitioned to OAT for addiction or taken off opioids and prescribed depot naltrexone if they were determined to have moderate to severe opioid use disorder (OUD).
  o OAT was prescribed to patients with histories of relapsing opioid addiction, high levels of craving or other variables indicating strong potential for relapse or opioid-associated harm.
  o Naltrexone was considered in patients with recent onset addiction, no history of prior addiction or addiction treatment, and/or those who declined OAT.

• Patients were tapered and discharged off opioids without naltrexone if
  • Opioids were ineffective for pain but they had no co-occurring opioid use disorder
  • They had misused opioids targeting relief of pain or other symptoms/distress but were not judged to have triggered addiction (absent craving, history of relapses, past opioid addiction, or other indicators) or
  • They were identified as having moderate to severe OUD but declined OAT or naltrexone.

• Opioids were continued or resumed for analgesia if no major OUD was identified and impairing pain persisted during or after opioid taper and interfered with function and/or program engagement despite introduction of self-management strategies and use of non-opioid analgesic approaches

• In this treatment population for whom opioid analgesic therapy was previously unsuccessful or associated with misuse or harm, upward titration of opioids for pain was not identified as useful.

Limitations and further study:
The study is limited to patients in residential treatment for chronic pain, and may not generalize to other populations. In addition, although standardized assessment measures were used, all assessments were based on self-report. Finally, both clinical and opioid use follow-up data is limited to patients who actively
participated in an aftercare program, so the persistence of clinical improvement in patients with less support following discharge is unknown.

Future evaluations will include:

• Analysis of the relationship of opioid management strategies implemented and their association with different pain types, mental health diagnoses, and other patient variables.

• How opioid use changes over time post-treatment to determine the long-term effectiveness of different opioid management options for different patients.

• Examination of which ongoing self-management practices (exercise, cognitive awareness, meditation, etc.) at what intensity of practice are associated with best clinical outcomes.

These outcomes suggest that intensive residential engagement in self-management can improve chronic pain, function, and quality of life at the same time reliance on opioids is reduced. Opioid management strategies associated with positive pain treatment outcomes vary according to patient clinical variables and may include:

• Opioid cessation (with or without naltrexone)
• Transition to opioid agonist treatment for opioid addiction
• Opioid rotation and reduction in equivalent opioid dose
• Reduction in dose of current opioid
**Clinical Outcomes**

**Opioid Outcomes**

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**Table 2. Opioid Status 6 months post treatment. (N=19)**

<table>
<thead>
<tr>
<th>Discharge status</th>
<th>Status at 6 mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>No opioids</td>
<td>13</td>
</tr>
<tr>
<td>OAT for addiction</td>
<td>6</td>
</tr>
</tbody>
</table>

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**h. References:** n/a

**i. Disclosure:** n/a
30. **Intrapelvic Obturator Internus Muscle Injections: A Novel Fluoroscopic Technique**

a. **Presenter:** Michael P. Zaccagnino, MD

b. **Authors:** Assia Valovska, MD; Michael P. Zaccagnino, MD; Michael J. Weaver, MD; Valovski I, MD; Alan D. Kaye, MD, PhD; and Richard D. Urman, MD, MBA

c. **Background:** The obturator internus (OI) muscle is important in adult chronic noninfectious pelvic, perineal, gluteal, and retrotrochanteric pain syndromes. Evaluation and management of these patients’ pain can be challenging with clinicians advocating the use of injections to assist in the diagnosis and treatment of OI-related pathologies.

d. **Objective:** The purpose of this two-case series is to describe a novel fluoroscopic-guided contrast controlled transpectineal approach to intrapelvic OI injections.

e. **Methods:** Case Report No. 1: At presentation, the patient was a 27-year-old female with complaints of a 1.5 year history of chronic pelvic floor pain located deep and left of the pubic symphysis with some radiation to the hip. In the past the patient had trialed numerous medications as well as received a ganglion impar block, pubic symphysis injection, and an intravaginal botulinum toxin A injection with little benefit. Case Report No. 2: At presentation, the patient was a 53-year-old male with complaints of a five-week history of sharp constant right-sided perineal, testicular, and penile pain. Prior injections included two pudendal nerve blocks with no relief. Injection Technique: Each patient was placed in supine position. Fluoroscopy was used to optimally visualize the OF in the outlet view of the pelvis. With a transpectineal approach, a 22-gauge 3.5 inch spinal needle was inserted perpendicular to the skin slightly radial from the center of the OF at the 6 o’clock position. Fluoroscopy was then used to square the OF for needle depth visualization by placing the C-arm in the inlet view of the pelvis and lining up the superior and inferior pubic rami until they overlapped. The needle was then advanced 2-3 mm beyond the posterior edge of OF. While in the inlet view, needle placement was evaluated by injecting 1 mL of iohexol and visualizing the presence of the presumed intrapelvic OI contrast pattern. This contrast pattern was additionally evaluated in the AP view and the outlet/obturator oblique Judet view of the pelvis. Finally, 40 mg methylprednisolone in 4 mL 0.25% bupivacaine was injected.

f. **Results:** Case Report No. 1: The average pre- and postprocedural visual analog pain scale scores were 5 out of 10 and 2 out of 10, respectively, with a self-reported 75% pain reduction. Case Report No. 2: The average pre- and
postprocedural visual analog scale scores were 8 out of 10 and 1 out of 10, respectively, with a self-reported 90% pain reduction.

g. **Conclusions:** In summary, the OI muscle is gaining importance in adult chronic noninfectious pelvic, perineal, gluteal, and retrotrochanteric pain syndromes. This two-case series described a novel fluoroscopic-guided contrast controlled transpectineal approach to intrapelvic OI injections with positive results. The utilization of multiple standard fluoroscopic pelvic views enabled accurate needle depth within the pelvic cavity thereby permitting the bulk of the OI to be injected in a controlled and safe fashion.

h. **References:** n/a

i. **Disclosure:** n/a

31. High Health Care Utilizers in Diabetic Peripheral Neuropathy

a. **Presenter:** Alesia Sadosky, PhD

b. **Authors:** Birol Emir PhD; Patrick Hlavacek, MPH; Maria de los Angeles Resa, MA; Alesia Sadosky, PhD, MPH; Andrea Alexander, MBA; Bruce Parsons, MD, PhD; Andrew G. Clair, PhD; Elizabeth T. Masters, MS, MPH; Stuart L. Silverman, MD; and John Markman, MD

c. **Background:** High utilizers of health care resources disproportionately account for a large share of health care costs. Diabetic peripheral neuropathy (DPN) is characterized by a spectrum of resource utilization and costs.

d. **Objective:** To use electronic health records to identify DPN patients with high resource use and costs.

e. **Methods:** Data were from the Humedica electronic health record and integrated Optum claims databases, consisting of de-identified records including demographics, diagnoses, inpatient/outpatient encounters, medications, procedures, and lab results. Records are linked through an Optum-generated identifier, allowing access to medical and pharmacy claims and costs. Patients were ≥ 18 years; associated with an integrated delivery network; with DPN diagnosis (ICD-9 codes 250.6 or 357.2; index event) between July 1, 2007, and December 31, 2014; and continuously enrolled six months pre- and 12 months post-index. Exclusion criteria were cancer; transplantation; residency in a nursing inpatient facility; or diagnoses associated with non-diabetic neuropathy six months pre-index. QRMIX partitioned high utilizers for the 12-months post-index by classifying patients into low, medium, and high health care cost groups adjusted for demographics characteristics. QRMIX, a finite mixture model that allows for heterogeneity of covariate effects across the distribution of outcomes, partitions data into a specified number of clusters through quantile regression (Willke et al. "A Comparison and Integration of Quantile Regression and
Finite Mixture Modeling," presented at Joint Statistical Meeting 2014, Boston, MA). Random Forest modeling or Least Absolute Shrinkage and Selection Operator regression will be used to determine the variables best predictive of high resource use.

f. **Results:** A total of 4,221 patients meeting inclusion criteria were partitioned into three cost clusters; low (n = 876; Cluster 1), moderate (n = 1,848; Cluster 2), and high costs (n = 1,497; Cluster 3), with total costs the sum of emergency room, inpatient, office, outpatient, and prescriptions filled costs. Median (interquartile range) health care resource costs per patient for 12-months post-index were $2,187 ($1,380-$2,953) for Cluster 1, $7,440 ($5,468-$9,980) for Cluster 2, and $27,010 ($18,853-$46,943) for Cluster 3; maximum costs were $4,908, $15,961, and $618,505, respectively. Mean age was similar across clusters (67.1-67.9 years), and patients were primarily female 51.7%-52.5%) and Caucasian (77.8%-79.0%). We will also explore how health care resources and baseline characteristics vary across the clusters.

g. **Conclusions:** This study identified three cost clusters for characterizing variables predictive of high health care resource utilization, with selection of the cost clusters based on optimized and robust statistical methods. Such information may help develop management strategies that could potentially improve outcomes and reduce healthcare costs.

h. **References:** n/a

i. **Disclosure:** Supported by Pfizer Inc.

32. **Differentiating Chronic Pain Types**

a. **Presenter:** Alesia Sadosky, PhD

b. **Authors:** Samuel Whipple, BS; Alesia Sadosky PhD; Marina Brodsky PhD; Jack Mardekian PhD; Michael J Asmus PharmD; Sean Donevan PhD; Daniel Krichbaum PharmD; Rozelle Hegeman-Dingle PharmD; Karin Coyne PhD MPH; Brooke Currie MPH; Elie Mulhem MD; and J. Bruce Hillenberg PhD

c. **Background:** Designed for primary care, the electronic Chronic Pain Questions (eCPQ) are completed by patients to document chronic pain presence, severity, characteristics, and interference with activities, sleep, and mood. The eCPQ also includes ID Pain, a validated screening tool for neuropathic pain (NeP), a pain map of 33 body areas, and two final items that assess pain’s effect on memory and patient’s sensitivity to sensory stimuli. When combined with other elements, these two final items may suggest the presence of sensory hypersensitivity (SH) conditions like fibromyalgia. The eCPQ was psychometrically validated in 395 patients at two primary care clinics.
d. **Objective:** To compare eCPQ responses between NeP and non-NeP patients (defined by ID Pain scores), and to examine responses to the two final eCPQ items.

e. **Methods:** Primary care patients were recruited to participate in the eCPQ validation. Among those who self-reported chronic pain, patients scoring ≥3 (range 1-5) on the ID Pain component of the eCPQ were classified as NeP and compared against non-NeP (scoring < 3). Separately, patients scoring ≥5 (range 0-10) on the two final eCPQ items were compared to those scoring < 5 on at least one.

f. **Results:** Among 208 chronic pain patients (1 missing ID Pain score), 39 (18.8%) were potential NeP candidates and 168 (80.8%) were non-NeP based on ID Pain. 56.4% of NeP patients reported severe pain (7+ on a 0-10 numeric rating scale), compared with 35.1% of non-NeP patients (p=0.0152). Marked interference with daily activities, sleep, and mood (defined as scores ≥ the mean on each item) was observed in 61.5% of NeP, compared with 28.6% of non-NeP (P = .0001). Respectively, the groups reported pain in an average of 3.0 and 1.8 body areas (P = .0342). 29 chronic pain patients (13.9%) endorsed the two final eCPQ items by scoring ≥ 5. 177 (85.1%) scored <5, and 2 had missing responses. 65.5% of patients that endorsed the two items reported their pain as severe, compared with 35.0% of those that did not endorse (P = .0021). Marked interference was observed in 72.4% of endorsers and 28.2% of non-endorsers (P < .0001). On the pain map, average scores were 3.9 and 1.7, respectively (P = .0004).

g. **Conclusions:** Chronic pain patients with possible NeP had more severe and widespread pain, and greater interference with daily activities, sleep, and mood. Similarly, scores ≥ 5 on the two eCPQ items relating to potential SH identified a group of patients scoring higher on the eCPQ pain severity scale, body map, and interference questions.

h. **References:** n/a

i. **Disclosure:** This study was supported by Pfizer, Inc.

33. **Prevalence of Self-Reported Chronic Pain in Primary Care**

a. **Presenter:** Michael J. Asmus PharmD

b. **Authors:** Michael J. Asmus PharmD; Elie Mulhem MD; J Bruce Hillenberg PhD; Sean Donevan PhD; Daniel Krichbaum PharmD; Samuel Whipple; Joseph C Cappelleri PhD; Rozelle Hegeman-Dingle PharmD; Karin Coyne PhD MPH; Brooke Currie MPH; and Alesia Sadosky PhD

c. **Background:** Primary care clinics do not routinely screen for the presence of chronic pain. The electronic Chronic Pain Questions (eCPQ) comprise a 14-item validated instrument developed to screen for chronic pain and monitor patient outcomes. The eCPQ was fully integrated into the electronic
medical record (EMR) of two primary care clinics. The aim of the eCPQ is to assist primary care physicians to efficiently assess, manage and monitor chronic pain patients. The eCPQ includes items to identify the presence of chronic pain; assess the intensity, location, and type of pain; and evaluate pain interference with function, sleep, and mood.

d. **Objective:** As part of a psychometric validation of the eCPQ, we report the prevalence and descriptive analysis of self-reported chronic pain in a cohort of routine consecutive patients seen at two southeastern Michigan primary care clinics.

e. **Methods:** All men and women aged ≥18 years who arrived at the two primary care clinics over one month in the fall of 2014 were invited to participate in the eCPQ validation study. Clinic staff verbally administered the eCPQ to patients and recorded their answers directly into the EMR prior to patients seeing their physician. The results were available for review by the physician during the patient-physician consultation. Study participants also completed a battery of ancillary health outcome measures after the clinic visit for the psychometric validation of the eCPQ (reported elsewhere).

f. **Results:** Over half (52.7%; 208 of 395) of the primary care cohort self-reported chronic pain. The mean (± SD) age of chronic pain patients was 46.6 ± 15.9 years (vs 39.6 ± 16.6 years for subjects without chronic pain), 65.9% were Caucasian, 66.4% were female, 48.1% were employed full- or part-time, and 14.5% were on disability. Thirty-nine (18.8%) patients self-reporting chronic pain rated their pain as mild (0-3 on 0-10 NRS), 41.5% (n = 86) rated their pain as moderate (4-6 on 0-10 NRS), and 39.6% (n = 82) rated their pain as severe (7-10 on 0-10 NRS). Three of 39 (7.7%) patients with mild pain, 14 of 86 patients (16.3%) in the moderate group, and 22 of 82 (26.8%) in the severe pain group had possible neuropathic pain.

g. **Conclusions:** In this cohort of primary care patients, the prevalence (52.7%) of self-reported chronic pain was higher than expected and much greater than the ~30% suggested by the 2011 Institute of Medicine Report (*Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*).

h. **References:** n/a

i. **Disclosure:** This study was supported by Pfizer, Inc.

34. **Quantum Mechanics Regenerates Nerves Destroyed by Neuropathy**

   a. **Presenter:** Peter M. Carney, MD, FAANS
   
   b. **Authors:** Peter M. Carney, MD, FAANS; Robert Odell, MD, PhD; Steve Kreisher, PA; and Lisa A. Galloway, MD
   
   c. **Background:** Combined Electrochemical Therapy (CET)\(^1\) uses the principles of quantum theory (mechanics)\(^2\) to help more
patients with peripheral neuropathy (PN) than does pharmacology.\textsuperscript{3,4}

d. **Objective:** To show that Combined Electrochemical Therapy (CET) will regenerate nerves

e. **Methods:** Forty-one patients who received CET at three different clinics had Epidermal Nerve Fiber Density (ENFD) biopsies done before and three to 10 months after CET. Their pre and post CET clinical responses and the anatomic changes in their biopsy results were compared.

f. **Results:** Clinical: The average patient had a 5.6 VAS point reduction and 34 patients (83%) reduced their VAS by 50% or more. Adverse Side Effects: None. Anatomical: Thirty (73%) had some increase in their ENFD. Twenty-five (61%) had a greater than a 25% increase in their ENFD. Fifteen (37%) had a 100% or greater increase in their ENFD and one patient went from having no fibers on her initial biopsy to a normal amount six months after treatment. Case Example: 65-year-old female with diabetic peripheral neuropathy had 16 CETs in 3 ½ months.

Pre CET: VAS = 9 Post CET: VAS = 2

<table>
<thead>
<tr>
<th>Pre CET Biopsy</th>
<th>Post CET Biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/14/2013</td>
<td>05/13/2014</td>
</tr>
<tr>
<td>0.0 nerves/mm (&gt;3.0/mm)</td>
<td>3.4 nerves/mm (&gt;3.0/mm)</td>
</tr>
<tr>
<td>VAS: Decreased by 77%</td>
<td>ENFD increased from 0/mm to 3.4/mm.</td>
</tr>
</tbody>
</table>

**g. Conclusions:** **CLINICAL:** The patients in this study who received CET reduced their average VAS score 133% better than patients receiving pregabalin ($P = > .00006$);\textsuperscript{4} were 113% more likely to reduce their pain by at least 50% than patients receiving pregabalin ($P = > .003$);\textsuperscript{4} and had no adverse side effects as compared to the 38% of pregabalin treated patients who had at least one adverse side effect.\textsuperscript{4} **ANATOMICAL:** Clear and convincing biopsy pictures show that 30 of 41 patients (73%) had some regrowth in nerves damaged or destroyed by neuropathy, and one patient went from having no fibers on her original biopsy to a normal number six months after finishing her treatment. These impressive clinical and anatomic results raise two important questions:

1.) When will CET become available to help the millions who suffer daily from PN?

2.) How does combining electromagnetic energy fields with injections of local anesthetics cause nerves to regenerate?

**h. References:**
1) Odell RH, Jr., Sorgnard, RE. *Practical Pain Manage.* 2011;June52-68.

i. **Disclosure:** n/a

35. **Touching Lives with ECHO: A case report from Ontario, Canada**

a. **Presenter:** Andrea D. Furlan, MD, PhD

b. **Authorss:** Jane Zhao, MSc; Sara Lavoratore, BSc; Lindsay Wall, PhD; Kednapa Thavorn, PhD; Leslie Carlin, PhD; Paul Taenzer, PhD; Ruth Dubin, MD PhD; Andrea D. Furlan, MD, PhD

c. **Background:** ECHO Ontario Chronic Pain and Opioid Stewardship is the first replication of the ECHO model in Canada (1). ECHO aims to build capacity and provide support for chronic pain management in remote and underserved areas. During each ECHO session, a brief didactic is given and patient cases are discussed in a hub and spoke model. Project ECHO has a goal “to touch 1 billion people by 2025” defined on three levels: 1) primary touch, a patient case presented at ECHO; 2) secondary touch, a patient treated by ECHO spoke; and 3) tertiary touch where a clinical population is affected by system improvements due to ECHO.

d. **Objective:** 1) To present a case to demonstrate the “secondary touch” of the ECHO model in Ontario; and 2) to report preliminary health economics analyses for this case.

e. **Methods:** A 63-year-old Caucasian woman was referred to an ECHO spoke for a fentanyl wean. The patient had been on 100 mcg/hr fentanyl patch for chronic pain since 2002. She complained that her shortness of breath was bothersome and was being followed by respirology for the past year due to a significant decline in her respiratory status. The patient was also referred for inpatient pulmonary rehabilitation. She is retired and her pain interferes with her activities of daily living (ADLs).

f. **Results:** Since April 2015, the ECHO spoke tapered her fentanyl patch from 100 mcg/hour to 25 mcg/hour. The patient’s pain remained the same and there was no decline in her ADLs. The patient was doing so well she was refused for inpatient admission to pulmonary rehab. This ECHO spoke regularly attended ECHO Ontario clinic sessions and attributed the successful narcotic taper directly to the knowledge she gained from attendance in ECHO. This ECHO spoke has also become
the point of referral at her community health center for narcotic
tapers.
g. **Conclusions:** This case report demonstrates how the ECHO
model can have impact beyond patient cases directly presented
during ECHO sessions. The knowledge this ECHO spoke gained
and applied from ECHO clearly benefited this patient. Potential
cost-savings associated with participating in ECHO will be
presented.
h. **Reference:**
       Ontario Chronic Pain & Opioid Stewardship: Providing
       access and building capacity for primary care
       providers in underserviced, rural, and remote
i. **Disclosure:** This study was supported by the Ontario Ministry of
   Health and Long-Term Care (MOHLTC) and CIHR.

36. **Pulsed Radiofrequency Treatment (PRF) of the Dorsal
    Root Ganglion at T11-T12 for the Treatment of Intractable
    Groin Pain**
   a. **Presenter:** Jeremy M. Epstein, MD
   b. **Authors:** Jeremy M. Epstein, MD; and Netsere Tesfayohannes,
      MD, ABA, ABAP
   c. **Background:** Ilioinguinal neuritis and genitofemoral
      neuralgia can cause significant pelvic and groin pain.
      Commonly, these nerves can be injured during
      inguinal hernia repair, pelvic surgery, trauma, or
      nerve compression from a tumor. PRF delivers
      alternating electrical current to a selective nerve
      without significant destruction or heating of the
      nerve. Typically, electrode temperatures are
      maintained < 43 degrees Celsius, thus preventing
      neural coagulation.
   d. **Objective:** To present a case of an adult male with
      intractable right-sided groin pain following a
      laparoscopic inguinal hernia repair who failed
      conservative management and was successfully
      treated with a fluoroscopic-guided PRF of the dorsal
      root ganglion at T11-T12.
   e. **Methods:** A 56-year-old male without prior history
      of chronic pain complaints and a past medical history
      of well-controlled hypertension presented with right-
      sided groin pain status post laparoscopic inguinal
      hernia repair with ongoing debilitating pain
      refractory to conservative pain management.
Moreover, the intractable pain interfered with his daily functioning, meaningful social interactions, ability to maintain gainful employment, and sexual intimacy with his wife. Standard medical interventions failed, including the use of membrane stabilizers (pregabalin, gabapentin), NSAIDS, and opioids. Furthermore, a variety of opioids with escalating doses were employed thereby causing excessive drowsiness, thus preventing retention of meaningful employment. Repeated evaluation by the surgical team failed to produce any surgical solution for the patient’s complaint. On presentation to our clinic, the patient was diagnosed with severe ilioinguinal neuritis and genitofemoral neuralgia. A peripheral nerve block was employed providing temporary relief for the patient’s groin pain. After failing to maintain long-lasting pain relief from a peripheral nerve block the patient underwent a selective nerve block at T11-T12, which provided short-lived relief for two weeks. Subsequently, he successfully underwent a PRF of the dorsal root ganglia at T11-T12 at 42 degrees Celsius for four minutes at each level.

f. **Results:** The patient obtained greater than 90% pain relief, which was maintained with amitriptyline 10mg po QHS with full return to normal activities.

g. **Conclusions:** The use of pulse radiofrequency ablation (RFA) represents an effective, inexpensive, precise, and relatively noninvasive mechanism to treat intractable ilioinguinal neuritis and genitofemoral neuralgia. PRF’s mechanism is currently unclear, but it is thought to be due to neuromodulation without a histological lesion on the target nerve. Future research into the mechanism of pain relief is needed. Moreover, prospective trials with long-term follow-up and comparison to other treatment modalities should be investigated. Future investigations can help reduce the unnecessary implantation of spinal cord stimulators, thus reducing healthcare expenditures.

h. **Reference:**


i. **Disclosure:** n/a
37. The Evaluation of Abuse and Dependence Potential of CNS-active Drugs: A Review of Evolving Methodology and Regulatory Requirements

a. **Presenter:** Talar Hopyan, PhD

b. **Authors:** Beatrice Setnik, PhD; Talar Hopyan, PhD; C.Psych and Pierre Geoffroy, MDCM, MSc, FCFP

c. **Background:** The evaluation of abuse and dependence potential of drugs is a critical safety evaluation required by regulatory agencies in order to appropriately schedule drugs and mitigate risks. Such evaluations are typically conducted while a drug is being developed and applies to drugs that affect the central nervous system, are chemically or pharmacologically similar to other drugs with known abuse potential, or produce psychoactive effects such as sedation, euphoria, and mood changes. The methodological approach to evaluate abuse and dependence potential of a drug continues to evolve and is a composite of various data including the chemistry, preclinical pharmacology, clinical data, and available post-marketing data. Specific clinical studies that are commonly included in such evaluations include human abuse potential studies and assessment of withdrawal after abrupt drug discontinuation, the latter of which may be included as part of patient trials or under some circumstances as a separate study in healthy volunteers.

d. **Objective:** The purpose of this poster is to: 1) review the evolving regulatory guidelines for abuse and dependence potential evaluation, 2) identify key properties of a drug that may render the need for an evaluation of abuse and dependence potential, 3) outline the types of studies and data required to assess abuse and dependence potential, 4) highlight the relevant data required to inform human abuse potential study design and the timing of such studies, and 5) identify the key adverse events of interest that are critical in the evaluation of abuse and dependence potential.

e. **Methods:** N/A as poster is theoretical in nature.

f. **Results:** N/A as poster is theoretical in nature.

g. **Conclusions:** Studies examining human abuse potential require an understanding of the pharmacology of the drug, including identification of therapeutic doses, prior to commencement. In addition to such studies, safety data collected across a clinical program are evaluated for specific events related to abuse, misuse, dependence, overdose, drug diversion, and withdrawal. Evaluation of such events may pose challenges and be limited by data collection methods.

h. **References:** n/a

i. **Disclosure:** n/a
37. Alternative Method of Retrocrural Approach During Celiac Plexus Block Using a Bent Tip Needle

a. **Presenter:** Juyeon Park, MD

b. **Author:** Jee-Won Ahn, MD; Jong Bum Choi, MD; and Youn-Woo Lee, MD

c. **Background:** Celiac plexus block (CPB) and neurolysis are effective in treating refractory upper abdominal visceral pain caused by hepatic, gastric, or pancreatic cancer.

d. **Objective:** To determine safe ranges of oblique angle, skin entry point, and needle length while performing CPB by reviewing computed tomography (CT) scans and to evaluate the usefulness of a 10° bent tip needle during CPB.

e. **Methods:** CT scans of 60 CPB patients were reviewed. Image of the uppermost margin of L2 vertebral body was used to measure minimal and maximal oblique angles and distances from midline to skin entry point. The imaginary trajectory distance of the needle was calculated by three-dimensional measurement. The actual distance from midline to entry point (GF/G’F) was also measured while using a 10° bent tip needle under 20° oblique fluoroscopic view.

f. **Results:** The safety range of oblique angle was 26.4-34.2° and 27.7-36.0° on the right and left, respectively. The distance from midline to skin entry point was 6.1-7.6 cm on the right and 6.3-7.6 cm on the left. The trajectory distance of the needle at minimal angle was 9.6-11.6 cm on the right and 9.5-11.5 cm on the left. GF/G’F was 5.1-6.5 cm and 5.0-6.4 cm on the right and left, respectively. All imaginary parameters were correlated with BMI except for GF/G’F. All complications were mild and transient.

g. **Conclusions:** Safety range of angles and distances in CPB using a straight needle was identified. Furthermore, a bent tip needle was safely and effectively utilized in performing CPB under 20° oblique fluoroscopic view, within smaller parameter ranges.

h. **References:**


i. **Disclosure:** n/a

38. **Decreased Pain Following use of a Topical Analgesic: Interim Results from the Optimizing Patient**
**Experience and Response to Topical Analgesics (OPERA) Observational Study**

j. **Presenter:** Jeffrey Gudin, MD  
a. **Author:** Michael Brennan, MD, Jeffrey Gudin, MD, Edmund Harris, MD, Peter Hurwitz, Derek Dietze, Christopher Viereck, PhD  
b. **Background:** As many as 40% of patients treated for chronic pain do not attain adequate analgesia. Additionally, many pain therapies, including opioids are associated with significant side effects. Evaluation of opioid-sparing treatments including topical compounded formulations is critical to identification of alternative and safer approaches to the treatment of pain.  
c. **Objective:** This pre-planned interim analysis of an observational study (IRB-approved, informed consent) involving 16 sites, evaluated the efficacy of a topical analgesic formulation in reducing pain in adult patients experiencing either neurologic or musculoskeletal pain, using the BPI (Short Form).  
d. **Methods:** Following IRB approval and patient consent, data were collected beginning in 2014 via paper surveys completed by study participants from 16 physicians treating patients with chronic pain. Survey 1 (at first patient visit before topical analgesic use) included questions regarding primary pain complaint/symptoms and location, the BPI Short Form, and current medication usage. Survey 3 (at third patient visit—approximately 90 days since starting topical analgesic use) included all Survey 1 questions, plus questions related to use of the topical analgesic and side effects. Statistically significant differences between Survey 1 and Survey 3 results calculated using McNemar and Wilcoxon tests. Alpha set at .05.  
e. **Results:** Paired data from 78 adult patients (51 F, 27 M) were included in this analysis. Reductions in pain following a mean of 105±43 days treatment with the topical analgesic were found for 10/11 BPI items. BPI Severity score decreased by 24% (from 4.6 to 3.5/10; P<.001). BPI Interference score decreased by 35% (from 4.8 to 3.1/10; P<.001). 97% reported no side effects, 1 reported rash, and 1 reported an “other” side effect. Neither of the 2 side effects reported was a serious adverse event.  
f. **Conclusions:** Results from this interim analysis suggest that the topical analgesics used in this study may reduce BPI scores for adult patients with neuropathic and musculoskeletal pain. The topical analgesics were safe and well-tolerated. Results justify continuation of the OPERA trial. Note: Results will be updated, incorporating data from a larger pool of patients completing Surveys 1 to 3.  
g. **References:** Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011.
h. **Disclosure:** This study was supported by Advantage Medical and Pharmacy, Advantage Medical Infusion, Annie's Apothecary, Boothwyn Pharmacy and Cypress Compounding Pharmacy.