Interventional

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Experimental Efficacy and Safety Study on a NEW Navigatable Percutaneous Disc Decompression Device (L'DISQ)—Histologic Evaluation and Thermo-Mapping in Human Cadaver Spines
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Objective: To assess the efficacy and safety of L'DISQ based on an intraoperative C-arm fluoroscopic evaluation, temperature measurements, and a postoperative histological study of discs and adjacent vital spinal structures. Methods: Intradiscal procedures were performed on six fresh human cadaver spine specimens using the L'DISQ spine wand. Using a standard clinical protocol (posterior-lateral technique), a needle was inserted into the target disc space under fluoroscopic guidance. 1) Accurate guidance of the needle tip to the posterior annulus of the disc was achieved by intra-operative C-arm fluoroscopy. 2) Thermocouple probes were positioned at the segmental nerve and the posterior longitudinal ligament (PLL) of human cadaveric discs. Temperatures were recorded continuously during the procedure. Temperatures were also recorded at various distances from the wand tip in the nucleus pulposus and annulus fibrosus during the procedure. 3) Light microscopic evaluation was performed to examine the histology of the intervertebral disc and neural tissues (T12-Sacrum) from treated spinal segments. Results: 1) Using intermittent C-arm fluoroscopy, the tip of wand can be guided to the posterolateral or postero-central annulus. 2) The temperature did not exceed 13.25±0.84 (?degrees) above initial temperature at any location, indicating that denaturation of adjacent neural tissue did not occur. 3) Histopathologic examination demonstrated decompression of the nucleus pulposus without thermal damage to the surrounding neural tissues. Conclusions: We successfully developed a percutaneous disc decompression device with a navigatable tip which can access the posterolateral and postero-central annulus. Using radiofrequency energy, we achieved volumetric removal of the target disc tissue without overt thermal or structural damage to adjacent neural tissues. Further clinical studies are needed to confirm the safety and effectiveness of this promising technology.


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Sciatic and Suprascapular Nerve Block Are Effective for Back and Neck/Shoulder Pain
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Objective: To assess the effectiveness and safety of sciatic and suprascapular nerve block when added to therapeutic modalities in non-surgical back and neck/shoulder pain. Methods: We retrospectively reviewed charts of 81 adult patients with lower back pain and 56 patients with neck/shoulder pain who presented to our center between March, 2006 and March, 2008. Sixty patients with back pain had received sciatic block. The 21 who declined served as controls. Thirty-seven patients with neck/shoulder pain had agreed to suprascapular block. Nineteen who declined were controls. Age/sex distributions were similar in both groups. One investigator performed modalities on all patients to achieve best therapeutic result, regardless of injection status. Patients completed VAS scores before treatment (VAS 0), and at one (VAS 1) and four weeks (VAS 4) after treatment. A single investigator performed bilateral nerve blocks at VAS 0 using bupivaine 0.5% + depo-medrol.

Results: Patients receiving sciatic nerve block plus modalities had similar mean VAS scores to modalities alone at zero and one week, but statistically better VAS at four weeks. Suprascapular nerve block reduced mean VAS significantly at both one and four weeks. Two patients undergoing sciatic nerve block developed transient leg weakness. Suprascapular nerve block produced no complications. Conclusions: 1) Sciatic nerve block is safe and effective when added to a rehabilitation regimen for non-surgical low back pain. 2) Suprascapular nerve block is similarly safe and effective for neck and shoulder pain.


Funding: None

Table 1. Sciatic Nerve Block for Low Back Pain

<table>
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<tr>
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<th>VAS 0 ±s.d.</th>
<th>VAS 1 ±s.d.</th>
<th>VAS 4 ±s.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injected</td>
<td>6.6 ± 2.1</td>
<td>3.3 ± 1.2</td>
<td>1.9 ± 0.7</td>
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<tr>
<td>Control</td>
<td>5.5 ± 1.4</td>
<td>3.8 ± 1.4</td>
<td>3.5 ± 2.1</td>
</tr>
<tr>
<td>p-value</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&lt;0.001</td>
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</table>

Table 2. Suprascapular Nerve Block for Neck/Shoulder Pain

<table>
<thead>
<tr>
<th></th>
<th>VAS 0 ±s.d.</th>
<th>3</th>
<th>VAS 4 ±s.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injected</td>
<td>6.9 ± 1.4</td>
<td>1.2 ± 0.7</td>
<td>0.8 ± 0.7</td>
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<tr>
<td>Control</td>
<td>6.3 ± 2.1</td>
<td>4.3 ± 0.8</td>
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<tr>
<td>p-value</td>
<td>&gt;0.05</td>
<td>&lt;0.0001</td>
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</table>
Sphenopalatine Ganglion Block in Traumatic Trigeminal Neuralgia and the Outcome to Radiosurgical Ablation

Christopher Zarembinski, MD, zar65@sbcglobal.net1, Steven Graff-Radford, DDS1, Ajay K. Ananda, MD2 and Behrooz Hakimian, MD3, (1) The Pain Center, Cedars-Sinai Medical Center, Los Angeles, CA, (2) Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, CA, (3) Samuel Oshin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA

Introduction: Neuropathic trigeminal pain has responded to sympathetic blockade. Sphenopalatine ganglion block may offer a better outcome compared to stellate ganglion block. This forms the basis for radiosurgical ablation of the sphenopalatine ganglion. Methods: Patients diagnosed with traumatic trigeminal neuralgia were treated with stellate ganglion block. If they responded, a second block was performed. If they did not have relief greater than three months, they were given a sphenopalatine ganglion block. This was repeated if there was a greater than 60% reduction in pain. Those patients who had two positive responses to sphenopalatine ganglion block were offered Gamma knife ablation, using 90 Gy delivered through two 8 mm superimposed ports. Results: Twenty six patients were diagnosed with traumatic trigeminal neuralgia. There were 17 females (65.3%) and 9 males (34.6%). Pain was localized to V1 in 42.3%, V2 in 42.3% and V3 in 42.3%. Seventeen patients underwent stellate ganglion blocks. Twelve out of these 17 patients (70.5%) responded to the first block and 12/17 (70.5%) responded to the second block. The longest duration of relief was 4 months. Average duration of relief was 36 hours. Sphenopalatine ganglion blocks were performed on the 12 that responded to stellate ganglion blocks as well as 14 additional patients. All 12 patients who responded to stellate blocks also responded to two sphenopalatine ganglion blocks, and 8 of the additional 14 responded as well, with a total of 20 out of 26 responding (76.9%) to sphenopalatine ganglion blocks. Eleven patients who responded to sphenopalatine blocks underwent Gamma knife ablation. Nine out of these eleven had more than 60% reduction in pain at 6 months follow-up. Conclusion: Sphenopalatine ganglion block provides as much relief for traumatic trigeminal neuralgia as stellate ganglion block. Patients who respond to two sphenopalatine ganglion blocks have a favorable outcome to radiosurgical ablation.

References: none

Funding: None

Chronic Assessment of Relative Percutaneous Lead “Micro-Migration”

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Background: Lead migration is the dominant complication in spinal cord stimulation (SCS). Typically, lead migration is reported only if it ultimately requires lead revision. We prospectively quantified the actual amount of lead migration in patients who did not require revision. Methods: From our own practices, chronic pain patients implanted with an SCS system (PrecisionTM implantable pulse generator and two LinearTM octopolar leads, parallel positioned in the mid-low thoracic region [T7-T9]) were enrolled. All subject provided informed consent per IRB-approved protocol. With the patient in a prone (during IPG implant) and supine (2, 4, 12, and 26 weeks post-IPG implant) posture, the C-arm was positioned in AP and lateral orientations and fluoroscopic images were taken, printed, and digitally scanned. Using imaging software, AP fluoros were analyzed for relative electrode positions. The relative, one-dimensional stagger between the two leads was estimated at each visit. Migration was defined as the relative difference in stagger in mm between the implant lead position and that measured at follow-up. Results: Eight patients with a mean follow-up time of 24 ± 5 weeks and one patient with 2 weeks follow-up were studied. The eight patients demonstrated a mean relative stagger migration of 2.4 ± 2.1 mm over the entire follow up period. Most relative migration appeared at the 2-week follow-up.
period. After this, there was no follow-up visit in which migration was more or less likely to be observed. In the ninth patient, at the 2-week follow-up, multi-vertebral migration of one lead was observed, approximately 45mm caudal to the other lead. This patient was not revised, however, since paresthesia coverage was still concordant with pain. Conclusion: Most successful SCS patients with dual parallel leads experience a mean relative “micro-migration” of approximately 2-3 mm of stagger between their leads, equivalent to one typical SCS contact offset.


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A Severe Case of Complex Regional Pain Syndrome Type I Managed with Spinal Cord Stimulation
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Complex regional pain syndrome (CRPS) I formerly known as RSD is a condition that usually affects the extremities. Spinal cord stimulation is usually reserved for refractory cases. The clinician's lack of familiarity with the disease or delay in the appropriate management of this condition may cause unnecessary suffering to the patient. We report of a 24 y/o female who developed CRPS I after a shoulder injury from playing softball. The patient was diagnosed with a subluxation of the right shoulder. She continued to have chronic burning pain despite physical therapy. After her shoulder surgery, the patient noted increased pain and significant burning sensation over the right upper extremity. The patient was referred to our clinic for sympathetic blocks. On examination, the patient had skin breakdown and contracture of the right upper extremity. The patient had experienced temporary relief with the blocks. It took 7 months to have an SCS system (Boston Scientific-BS) implanted on the patient for control of her symptoms in the right upper extremity due to insurance delay. Three months after the implant, the patient developed similar symptoms in her lower extremities. Despite aggressive rehabilitation, the patient's symptoms worsened. The patient then underwent a second SCS implant (BS) for control of her symptoms in the lower extremity. Subsequently, the patient was losing coverage of her painful areas and was charging both pulse generators twice a day. A decision was then made to change both systems. During explant of the thoracic paddle lead it was noted that the contacts of the BS have come loose and came off its attachment. With her new system (ANS), the patient's lesions have healed, her pain has decreased significantly, she charges every 3-4 weeks and she ambulates without the use of a wheelchair. Early consideration of spinal cord stimulation may be warranted to prevent progression CRPS.


Funding: None
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Ultrasound Guidance to Locate Main Port and Catheter Access Port of an Intrathecal Drug Delivery System: A Case Report
Maya Therattil, MD, mtheratt@montefiore.org, Rao Ali, MD, Moo-Yeon Oh-Park, MD, Binod Prasad Shah, MD and Yumei Wang, MD, Department of Rehabilitation Medicine, Montefiore Medical Center, NY, Bronx, NY

45 year old lady with syringomyelia and severe spasticity requiring intrathecal baclofen for management of spasticity. The patient had an intrathecal drug delivery system for 6 years. She had multiple revision surgeries due to pump and catheter complications and was also obese. There was prominent scarring and keloid formation in the suture area on the abdominal wall. Both the physiatrist and the neurosurgeon found it difficult to access the main port and the catheter access port for doing diagnostic studies. We used the portable ultrasound equipment which is readily available in our clinic setting for musculoskeletal diagnostic purposes and injection procedures, to detect and mark the area on the skin above it with cross bars prior to accessing the port using sterile technique. A similar technique was used to access the catheter port also. This is a very easy technique to use in patients and does not require advanced expertise of the use of an ultrasound machine. This technique was used successfully multiple times in this patient and in other patients in whom the use of the template was insufficient for pinpointing the the port for access. The easiness of use and the need not to use a sterile technique while marking the area makes this approach user friendly in any patient setting where a portable ultrasound machine is available. It saves the patient from repeated trauma and other imaging techniques to find the location of the ports.

Funding: None

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Chinese Scalp Acupuncture Reduces Pain and Restores Function in Injured Combatants Diagnosed with Complex Regional Pain Syndrome of the Upper Extremity
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Introduction/Statement of the Problem: Complex Regional Pain Syndrome (CRPS) can result from accidental trauma or after surgery to an extremity. Recalcitrant to conventional treatment, it is often very difficult to manage effectively. If not recognized and treated early, CRPS can cause significant dysfunction and result in extreme debilitation. Symptoms attributed to CRPS include constant neuropathic pain in an extremity, allodynia, sudomotor changes and decreased range of motion. It can occur with (CRPS Type II) or without (CRPS Type I) nerve injury. A number of soldiers sustaining upper extremity injuries during combat have manifested this symptomatology.

Materials and Methods: Fourteen subjects were diagnosed with CRPS in various stages of recovery after sustaining upper extremity injuries during military operations. After failing aggressive medication management and occupational therapy, Chinese Scalp Acupuncture (CSA) was utilized once to twice a week for one to four weeks. Results: CSA resulted in improvement in the Pain Visual Analog Scale by reducing allodynia by more than 50% in fourteen consecutive soldiers with upper extremity pain. Pain relief often occurred within 20 minutes of beginning treatment. Additionally, decreased sensory changes and improved extremity function were noted on physical exam and therapy assessments. Notably, the
reduction in pain, functional improvement, and normalization of sensation have been fully maintained between treatments in all but one patient. To date, the treatment response has been sustained for as much as twelve weeks with no return of allodynia or decrement in function. **Conclusions:** Chinese Scalp Acupuncture effectively provided lasting pain reduction, improved function and sensation in this small group of combatants with upper extremity CRPS. It is a novel method of treatment that warrants further research.


**Funding:** None

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**Benchmark and Comparative Testing of a Newly Released SCS Lead Anchoring System**

*Sudeep Dutta, sudeep.dutta@ans-medical.com, Vikram Gaonkar and Todd Stirman, Advanced Neuromodulation Systems, Inc. ®, Plano, TX*

**Introduction:** Lead migrations and lead fractures are some of the most common causes of revisions of SCS systems. These complications can be mostly attributed to anchors and anchoring technique. ANS has developed the CinchTM anchor to address these issues and frustrations associated with anchoring.

**Materials and Methods:** The Cinch anchor is made of silicone and has a titanium retention sleeve designed to enhance holding strength and prevent migrations. It is entirely radiopaque for easy identification and has an extended distal strain relief design to prevent lead breakage and migration.

Several benchmark tests were performed on the Cinch anchor including: Anchor retention force test, anchor flex test, lead insertion into anchor buckling test, and sliding force test and distal lead movement during anchor installation. Comparative testing between the Cinch anchor and the Medtronic Titan anchor system was also performed. **Results:** To Be Presented. **Conclusion:** The Cinch anchor, in benchmark testing, has shown to be stronger and more durable than the current ANS anchor systems that are available on the market.

**References:** N/A

**Funding:** This work was supported by Advanced Neuromodulation Systems, Inc.

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**CAUDAL Approach for Percutaneous Spinal Cord Stimulator Implantation**

*Nameer Haider, M.D., DABPM, drhaider@killpain.com¹ and Rao Ali, MD², (1) PM&R, Pain Medicine, Medical Director:SPINAL & SKELETAL PAIN MEDICINE, Utica, NY, (2) Department of Rehabilitation Medicine, Montefiore Medical Center, NY, Bronx, NY*

Spinal cord stimulation has been used for thirty years to diminish pain in patients. It is a pain treatment modality focused on reducing the intensity, duration, and frequency with which pain is felt. Currently spinal cord stimulation is an extremely effective treatment for numerous painful conditions including Failed back syndrome [1], Reflex sympathetic dystrophy [2], Chronic intractable pelvic pain [6]. The mechanism of action involves more than inhibition of pain pathways in the dorsal horn nuclei [13] and exact mechanism of action is not yet fully understood. Placement of electrodes used in spinal cord stimulation differs depending on the type of pain being treated. For pain in the lower extremities and lower back, the stimulator electrode implant is generally placed between T8 and L1 levels. Sacral stimulation is used to treat conditions including pelvic pain, rectal pain, interstitial cystitis and vulvodynia [14]. Previously both retrograde and sacral transforaminal approaches have been described [15]. Currently percutaneous spinal cord stimulation lead(s) are placed either by anterograde approach
i.e. to approach from caudal to cephalic direction or by retrograde approach (figure 1), which means to approach from cephalic to caudal direction (e.g. to implant electrode between S1 and S3, approach from L1 level). Placement of sacral paddle leads may also be performed laminotomy of the os sacrum. Placement of stimulator electrodes for pelvic, sacral, vulvar and vaginal pain is generally between S1 and S4 levels. Previously, placement of percutaneous spinal cord stimulating leads into the sacrum had only been described using the retrograde and transforaminal approaches. We describe a novel approach for both trial and permanent stimulation of the sacral nerve roots using entry at the sacral hiatus and navigating the lead in a cephalad direction which we call the Caudal Approach for sacral stimulation.


Funding: None

110 Intractable Vulvodynia Treated with Spinal Cord Stimulation: A Case Report
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A 50-year-old woman presented with 6-year history of pelvic and vaginal pain, status post vaginal hysterectomy in 2000 and was diagnosed with Vulvodynia. The Patient had been seen by multiple practitioners including a gynecologist, rheumatologist, neurologist and pain physician and had tried bed rest, physical therapy, muscle relaxants, narcotics, and membrane stabilizers without any significant relief. Fluoroscopic guided Ganglion Impar sympathetic blockade was performed 5 times but the pain improved only temporarily. Eventually a trial of spinal cord stimulation was performed. Prior to stimulation, her numeric pain intensity was rated as 9/10 on the verbal analogue scale. Four days after procedure the pain was reduced to 4/10 and after one week the pain had resolved. The patient went on to have permanent stimulation. Patient is being followed up on regular basis and since permanent implantation of the spinal cord stimulator; Pt had no episode of vulvodynia or any other complication related to the procedure. Further investigation is needed to determine the efficacy of spinal cord stimulation in Pelvic pain.


Funding: None

111 A Cost-Utility Analysis of Rechargeable Spinal Cord Stimulation for the Relief of Chronic Back and Leg Pain
Cheryl D. Monroe, MPH, cheryl.monroe@ans-medical.com and Stephanie Washburn, Clinical Research, Advanced Neuromodulation Systems, Inc.®, Plano, TX
Introduction: Spinal cord stimulation (SCS) is becoming increasingly popular to treat chronic pain. These systems can be expensive, making it imperative to analyze the associated costs and benefits. In this cost-utility analysis, costs are compared against the health effects of the treatment in terms of
quality-adjusted life-years (QALYs) gained. QALYs are widely used because they are a useful outcome measure that combines patient-perceived health-related quality of life (QOL), patient preference (utility), and survival. The use of QALYs is especially important for assessment of SCS treatment, since improvements are in quality of life not survival. Materials and Methods: Patient demographics, healthcare utilization and prescription information were retrospectively collected from the medical records of 21 patients currently enrolled in 2 ongoing studies investigating the effectiveness of a rechargeable IPG for the treatment of chronic back pain with or without leg pain. The total cost of office visits and procedures related to patient pain, including the price of the SCS system, were totaled for the year prior to and after implantation using 2007 Medicare reimbursement rates. Average wholesale price was used to calculate medication costs and patient-perceived health-related QOL was measured using the SF-36. Results: The mean cost per QALY gained was $27,274.64 over the 10 year life of the IPG. Subgroup analysis revealed that patients diagnosed with Failed Back Surgery Syndrome (FBSS) showed more improvement in utility scores than patients diagnosed with radiculopathy. Also, patients who received a 3 lead system showed more improvement in utility scores than those who received a 2 lead system. However, neither of these differences was statistically significant. Conclusion: These results suggest that SCS is a cost-effective treatment for chronic back and leg pain. Additional research with a larger patient sample is warranted to further investigate the subgroup results found in this study.

References: None

Funding: This work was supported by Advanced Neuromodulation Systems, Inc. through ANS-sponsored clinical studies.

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Ultrasound Guidance for Occipital Nerve Stimulator Placement

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Background: Occipital nerve stimulation is an emerging treatment for refractory occipital neuralgia and other refractory headache disorders. The potential of this therapy is promising, given the limited alternative treatment options for these conditions. Ultrasound technologies have been increasingly utilized in regional anesthesia and pain medicine for optimal catheter placement. Objective: To report the utilization of compact ultrasound to assist in optimal placement of the occipital stimulation leads. Initial reports of occipital lead placement utilized manual palpation of the lead along with the assistance of fluoroscopy. However, precise depth of lead placement is difficult with palpation of the subcutaneous lead and use of fluoroscopy. Precise depth of lead placement is important given recent a report of lead erosion. Placement of lead too deeply may traumatize the paracervical muscles, potentially compromising the trial process. Design: Technical report. Methods: Case review IRB# 08-005920. Results: We utilized a high-frequency compact ultrasound probe (GE LOGIQ e with 12L-RS probe, 5-13 MHz broadband, multifrequency) to visualize the soft-tissues of the sub-occipital region. We were able to clearly delineate the epidermis, dermis, subcutaneous fatty layer, and the suboccipital connective tissue layers of the trapezius and sternocleidomastoid muscles. We were able to clearly visualize the stimulator lead needle for optimal lead placement. Conclusions: With ultrasound guidance, we were able to place the stimulating lead in the connective tissue layer below the subcutaneous fat while avoiding trauma to the paracervical muscles. Placement in this connective tissue location may also help to minimize lead migration, which has been reported to be a potential complication with occipital systems.

An Evaluation of Demographic Factors and Their Relationship to Trial Success or Failure
Brandy Castaño, brandy.castano@ans-medical.com and Cheryl Monroe, Advanced Neuromodulation Systems, Inc.®, Plano, TX

Introduction: Before spinal cord stimulation (SCS) implantation, a trial is generally conducted. During a trial, temporary leads are implanted and attached to an external stimulator system. Usually, if a patient achieves at least 50% pain relief, and paresthesia coverage is adequate and agreeable, the trial is deemed a success and permanent implantation proceeds. Understanding the factors involved in trial failure is important to identify good candidates for SCS treatment. This analysis was done to investigate if there was a relationship between demographic factors and trial failure.

Materials and Methods: Data presented is from two completed, IRB-approved studies with identical protocols. Trial success was determined by the investigator according to standard procedures. Associations and differences between trial success and demographic characteristics were explored using a Fisher's exact test for categorical variables or a t-test for continuous variables.

Results: Based on our results the overall trial success rate for all patients was 83.2%. There was an association between gender and trial outcome (Fisher's Exact Test, p<0.001). The relative risk of trial failure for males versus females is 4.2. Therefore, men are 4 times more likely to fail an SCS trial than women. There was no statistical difference in race, diagnosis, age, length of chronic pain, VAS pain score, or previous treatments used between trial successes and trial failures. All factors were again evaluated among males only. No factor yielded a statistically significant result. However, male patients who had successful trials averaged 9.9 years of chronic pain while those who had failed trials averaged 6.9 years of chronic pain. This result was not statistically significant (t-test, p=0.239).

Conclusion: These results suggest males are more likely to fail a trial than females though reasons are not understood. Additional research with a larger patient sample is needed to further explore the subgroup outcomes.

References: N/A

Funding: This work was supported by Advanced Neuromodulation Systems, Inc. through ANS-sponsored clinical studies.

Adhesiolysis and Targeted Steroid/Local Anesthetic Injection During Epiduroscopy Alleviates Pain and Reduces Sensory Nerve Dysfunction in Patients with Chronic Sciatica
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Introduction: Recently, epiduroscopy has been shown to offer significant diagnostic and therapeutic interventions for patients with chronic low back pain and sciatica. Although previous studies have shown that adhesiolysis in epidural space and targeted steroid injection during epiduroscopy is useful for pain relief in these patients, there are currently very few studies that show the effect of these procedures on sensory nerve function. The present study was carried out to evaluate the effect of adhesiolysis followed by the injection of steroid and local anesthetic during epiduroscopy on sensory nerve function, pain, and functional disability in patients with chronic sciatica.

Material and Methods: After institutional approval was obtained along with written informed consent, epidural adhesiolysis using epiduroscopy followed by the injection of steroid and local anesthetic were scheduled in 19 patients with chronic sciatica refractory to lumbar epidural block. Sensory nerve function in the legs was tested with a series of 2000-Hz (Aβ-fiber), 250-Hz (Aδ-fiber) and 5-Hz (C-fiber) stimuli, using the current perception threshold (CPT), and CPT values and intensity of pain and Roland Morris Disability Questionnaire (RMDQ) scores were assessed before and 1 and 3 months after the epiduroscopy.

Results: At all frequencies, the CPT values in the affected legs of patients before the epiduroscopy were significantly
higher than those in the unaffected legs. Epidural adhesiolysis was successfully performed in 16 out of the 19 patients. In these patients, the CPT values at 2000 and 250 Hz, and pain and RMDQ scores 1 and 3 months after the epiduroscopy were significantly lower than those before the epiduroscopy, while the CPT value at 5 Hz did change. Conclusions: Epidural adhesiolysis followed by the injection of steroid and local anesthetic during epiduroscopy alleviated pain, functional disability, and reduced dysfunction of Aβ and Aδ fibers in patients with chronic sciatica.

References: None

Funding: None

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An Evaluation of Lead Migration in Published Literature and Eight Clinical Research Studies
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Background: Spinal Cord Stimulation (SCS) is a safe and effective treatment for chronic intractable pain. One of the most common complications reported in the literature is lead migration. Lead migration rates in the literature as well as completed and on-going studies was calculated to evaluate this common complication. Methods: For the literature review, the following keywords were used in conjunction with the term “pain” to search PubMed and the journal Neuromodulation: electrical stimulation, spinal cord stimulation, neurostimulation, and neural stimulation. Only articles published in English since January 1981 and those using human subjects were included. Incidence rate is calculated as the number of events out of the total sample. Incidence represents the likelihood or risk that a patient will experience a lead migration, regardless of if they have previously experienced one. An analysis of lead migration rates reported in the literature over time was also conducted to evaluate how the complication rate has changed as technology and technique improves. Data from four completed studies and four on-going studies were analyzed to further evaluate lead migration rates. All studies were IRB approved and all patients signed informed consent prior to enrolling in the studies. Results: A total of 67 articles that reported on 4,634 patients were included in the literature analysis. The literature review found the overall incidence of lead migrations to be 13.5%. Additional results are to be presented. References: 1. Cameron, T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. 2004. J.Neurosurg: Spine, 100(3):254-267.

Funding: This work was supported by Advanced Neuromodulation Systems, Inc. through ANS-sponsored clinical studies.

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Epidural Contrast Flow Patterns of Transforaminal Epidural Steroid Injections Stratified by Final Needle Tip Position
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Introduction: Transforaminal epidural steroid injections (TFESIs) were developed for targeted non-operative therapies for disc-related pain. TFESIs are thought to deliver injectate to the postulated site of pathology in the anterior epidural space. Anterior epidural contrast flow has been demonstrated in 75–100% of TFESIs (1,2,3). No studies to date have evaluated final needle-tip position in TFESI as a marker for subsequent contrast spread. We hypothesize that final needle-tip position will be the primary determinant of subsequent contrast flow. Materials and Methods: Following approval by the IRB of the George Washington University, 84 TFESIs were retrospectively identified. Inclusion criteria: Lumbosacral radiculopathy Lumbar degenerative disk Lumbar herniated disk. Exclusion criteria: Lumbosacral stenosis Lumbar spondylolisthesis Incomplete data. Final needle-tip position was assessed in 2 planes by a blinded examiner: AP and lateral. In the lateral view, the neural foramina were divided into 4 quadrants [superior-posterior (SP), superior-anterior (SA), inferior-posterior (IP), inferior-anterior
(IA)) and final needle-tip position was marked. The presence of anterior and posterior contrast flow, as well as the number of levels of anterior flow was noted. Results: Under AP view all TFESIs were lateral to the “6 o'clock” of the pedicle. No IA or IP placements were observed. 41/84 (48.8%) had SA placement and 43/84 (51.2%) had SP placement. Significantly greater anterior flow was seen in 40/41 (97.6%) with SA placement vs. 28/43 (65.1%) with SP placement (p <0.0001). Posterior flow was statistically greater in the SP group (p<0.00001) and was observed in 17/41 (41.5%) with SA vs. 39/43 (90.7%) with SP placement. Conclusions: Superior-anterior placement of final needle tip position showed statistically significant greater anterior contrast flow. Although follow-up studies are needed to determine if this placement translates into greater clinical efficacy, anterior delivery of injectate is not reliable or consistent without appropriate needle placement.


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117 An Evaluation of the Effect of Pulse Width on Efficacy Measures in Spinal Cord Stimulation for Chronic Pain

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Introduction: There has been little examination in the literature of pulse width settings in relation to spinal cord stimulation efficacy for chronic pain. Some work has been published on the strength duration curve and calculation of the chronaxie, but this has not been related to SCS efficacy measures. Materials and Methods: Data is presented from two sources: A completed clinical research study conducted with patients implanted with a conventional implantable pulse generator (IPG) and an ongoing, IRB-approved, clinical research study conducted with patients implanted with a rechargeable IPG. Mean pulse width for each patient at each visit was calculated using the patients 1 or 2 favorite programs. For each patient visit, measures of pain relief, patient satisfaction, and quality of life were available. Analysis of variance was used to determine if there was any difference in average pulse width between patients with varying levels of pain relief, satisfaction, and quality of life. Also, the relationship between pulse width and patient reported percent pain relief was explored using Pearson correlation. Results: The mean pulse width for patients with the conventional IPG (cIPG) was 274.3µs and 351.4µs for patients with the rechargeable IPG (rIPG). Analysis of variance found no significant difference in PW among patients who reported varying levels of satisfaction, pain relief, and improvements in quality of life. There was no trend observed of increasing pulse width in increasing satisfaction, quality of life, or pain relief. In addition, Pearson correlation was not significant for either population, with r = 0.045 for cIPG.
patients and $r = 0.143$ for rIPG patients. **Conclusion:** Pulse width settings do not appear to have any effect or relationship to efficacy measures among patients with both conventional IPGs and rechargeable IPGs.

**References:** N/A

**Funding:** This work was supported by Advanced Neuromodulation Systems, Inc. through ANS-sponsored clinical studies.

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**A Retrospective Evaluation and Data Collection Study to Evaluate Patients Implanted with A Rechargeable Implantable Pulse Generator (IPG) and A 3-Column 16-Contact Paddle Lead**

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**Background:** The Lamitrode™ Tripole 16C (Advanced Neuromodulation Systems, Inc.®) is a type of paddle lead specifically designed to capture elusive back pain without producing the unpleasant and often painful sensation associated with stimulation of the dorsal roots. This is accomplished using special programming commonly referred to as a transverse tripole configuration in which three aligned electrodes are programmed such that the negative field is surrounded by two positive fields (i.e. + - +). Transverse tripole stimulation was conceptualized by Holsheimer (1996) who theorized that it would confine the negative energy field to the dorsal columns, eliminating unwanted stimulation of the dorsal roots and allowing for a higher stimulation threshold. Clinical studies have since substantiated Holsheimer’s theory and are currently used in practice by SCS programmers at ANS. However, ANS has not systematically evaluated the clinical efficacy of transverse tripole stimulation in patients implanted with the Lamitrode Tripole 16C paddle lead.

**Methods:** This was a retrospective, single-center, one visit data collection study. A maximum of 20 established patients previously implanted with an ANS Eon™ Implantable Pulse Generator (IPG) and the Lamitrode Tripole 16C Paddle Lead were evaluated. Patients signed informed consent prior to study related data collection. Patients provided demographic information, device and program data, and information about current pain and satisfaction with SCS. Retrospective information prior to (and following) device implantation, including pain location and severity, was collected from the patient's medical record. If this information was not available, patients were asked to recall this information to the best of their ability. Patients were also asked to identify the paresthesia coverage for their current optimal stimulation program. The following parameters were evaluated: Pain Scales (0-10), battery recharging information (Eon patients only), patient satisfaction and quality of life, programming information, stimulation coverage, and additional physician visits.

**Results:** Results will be presented.

**References:** N/A

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**A Review of Articles Published on Spinal Cord Stimulation Treatment for Chronic Pain Since 2001**

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**Background:** The number of studies published on spinal cord stimulation (SCS) for treatment of chronic pain has increased substantially over the past 5 years. Given the increasing acceptance of SCS, it is necessary to review these articles to assess efficacy and safety. **Methods:** The following keywords were used in conjunction with the term “pain” to search PubMed and the journal Neuromodulation: electrical stimulation, spinal cord stimulation, neurostimulation, and neural stimulation. Only articles published in English since January 1981 using human subjects were included. Selection Criteria were as follows:
patients had pain in the trunk and/or limbs, means, percentages, and/or statistics were reported, the study examined SCS efficacy, pain measures included VAS, > 50% reduction on a numeric rating scale, narcotic consumption or a comparison to a relevant control group, and the number of patients was stated. 

Results: Of 1,196 articles identified, 84 met inclusion/exclusion criteria. A total of 4,584 patients were evaluated for a mean follow-up period of 29.9 months. Outcome measures and definition of success varied. Some studies reported the percentage of patients that achieved >50% pain reduction. Others dichotomized patient-reported pain relief and reported number of patients in each category. Patient-perceived results were also used to conclude success. To simplify our analysis, we have grouped and only report the percentage of patients that fall into one of these standards for success. Done this way, an overall success rate of 68.5% was observed. In addition, of 917 patients requiring analgesics prior to treatment, 56.3% were able to decrease consumption. A total of 67 articles that reported on 4,634 patients were included in the safety analysis. There were a total of 2,118 complications reported among these patients. The most common complication was lead migration with an incidence rate of 13.5% followed by lead breakage with an incidence rate of 7.6%.

References: N/A

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Spinal Cord Stimulation (SCS) Complications and Surgical Hurdles—Experiences in a Neurosurgery and Pain Management Private Practice Setting

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Introduction/Goals: In contrast with ablative pain surgery (1), the reversibility of neuromodulation with SCS has made this technique a valuable treatment option for intractable chronic pain. Despite standardized techniques (2) procedural difficulties and hurdles need to be addressed not infrequently. Materials and Methods: Pre-, intra- and post-operative clinical and imaging information was collected concurrently from 04/2005 to 08/2008 and retrospectively reviewed focusing on surgical challenges. Surgical technique modifications to avoid electrode migration and mechanical wire complications including specific electrode anchoring and wire routing techniques will be illustrated. Results: Final SCS implants [Medtronic (N=20); Advanced Bionics (N=5)] were performed in 25 patients including 11 surgical trials [failed back surgery syndrome (N=15), complex regional pain syndrome (N=5), diabetic polynueuropathy (N=2), thoracic discogenic pain (N=1), and idiopathic lumbar radiculopathy (N=2)] following standard clinical, imaging and pain psychology evaluation. Including revisions and complication-related additional procedures 44 surgical procedures were performed in 27 patients (11 M vs. 14 F; average age 50.9 years; range 28 – 76 years). Implant level was localized over T8-T10 in 25 procedures, T11-T12 in 4 procedures, T12-L1 in 2 procedures and cervical in 1 patient. Only one SCS insertion was done in general anesthesia. Inadequate patient cooperation was a problem in 3 cases during wake-up testing. Three patients complained intensely about local implant site discomfort: one unit required removal, and one necessitated repositioning. One infected and one functioning but therapeutically ineffective unit each was explanted; unsatisfactory SCS results could be improved in 2 patients by surgical repositioning. Up to the present no mechanical failures were encountered. Conclusions: A few SCS patients will have surgery-related difficulties (3) but for the majority of carefully selected patients SCS implant is a satisfactory treatment option. Attention to detail will help prevent complications and careful observation allows their timely detection.


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Multi-Center Evaluation of Drug Delivery Accuracy with the Prometra® Intrathecal Infusion Pump

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Introduction: Accuracy of drug delivery is an important therapeutic component when treating pain patients with an implantable pump. The Prometra pump utilizes a number of design elements aimed at improving accuracy. During a prospective, multi-center FDA approved clinical study (Prometra's Utilization in Mitigating Pain, or PUMP), accuracy of the Prometra programmable pump was evaluated.

Materials and Methods: The PUMP study was a prospective open-label evaluation of the Prometra pump system (InSet Technologies, Mt. Olive, NJ) to treat chronic pain with MSO4. IRB approval was obtained at seven clinical sites, and 110 patients (age: 56 ± 13, gender: 51F) were enrolled after giving informed consent. Data was collected in three phases: baseline (pre-implant), monthly follow-up for the first 6-months post-implant and then quarterly. Refill accuracy was calculated by dividing the measured delivered volume by expected delivered volume. Data were tabulated by an independent third party (inVentiv Clinical Solutions, The Woodlands, TX). Results: After a total of 35,838 device-days of follow-up (mean 10.7 months, range 0.4-16.0 months) and 753 refill procedures, accuracy of drug delivery was 97.5% ± 0.53*. 214 (35%) refill procedures were measured to be between 99% and 101%. There were no significant accuracy differences among programmed flow rates (range: 0-1.5 ml/day).

Mean accuracy at the first (one-month) visit (92.5% ± 1.05%*) was significantly (p<.0001) lower than months 2-14 (98.4% ± 0.59%*). *Data presented as mean ± standard error. Conclusions: The Prometra pump was observed to be accurate and consistent over time and over a wide range of flow rates. As expected, due to a learning curve, the first post-implant visit accuracy was lower than subsequent measurements.


Funding: Investigators for the PUMP study were compensated for clinical administrative costs

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Targeted Epidural Steroid Injection via Radiopaque Catheter for the Treatment of High Level Cervical Radicular Pain

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Introduction: Delivering corticosteroid to high level cervical nerve root or disc pathology may be challenging. Cervical transforaminal epidural steroid injections are performed for the treatment of radicular pain. Multiple recent case reports have raised safety concerns regarding neurological deficits after these injections.1,2,3 Critical arteries located in the posterior aspect of the intervertebral foramen may be vulnerable to intravascular particle injection or injury during the transforaminal approach. Conventional injections below C7 level may not achieve significant medication spread in the higher
cervical levels. They may be insufficient to address high cervical anterior epidural pathology i.e. herniated disc or radiculopathy.

**Methods:** Two consecutive patients with cervical radiculopathy and correlating MRI pathology were studied. In the prone position an 18G gauge introducer needle was placed into the thoracic epidural space under fluoroscopic guidance and using loss of resistance to saline. A 21 gauge spring coiled radiopaque epidural catheter with a slightly bent stylette was advanced at the anterior epidural space to the level of lesion. X-ray contrast material confirmed placement and epidural spread. After negative aspiration triamcinolone 80mg with Lidocaine 30mg in 5ml solution was injected and catheter and needle were removed together. The technique may be performed in multiple levels or bilaterally with repositioning the catheter to the desired area.

**Results:** Both patients had extended pain relief. One patient receives semi-annual treatments and is now working full time. The other patient had marked relief until his previously scheduled decompressive surgery two months later.

**Conclusion:** Our experience suggests that fluoroscopically guided, selective epidural steroid injection via radiopaque catheter is a safe and clinically effective procedure, avoiding the dangerous injection into radicular and vertebral arteries, in the management of high level cervical radicular pain. Larger studies should be conducted to evaluate the effectiveness of this technique over the conventional interlaminal epidural steroid injection.

**References:**

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**126 Ultrasound-Guided Permanent Implantation of Peripheral Nerve Stimulation (PNS) System:**

**Original Cases and Outcomes**

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**Background and Objectives:** Peripheral nerve stimulation (PNS) is utilized in the treatment of peripheral neuropathic pain resistant to conservative treatment. PNS electrode placement required an open surgical approach in the past. Recently, ultrasound guidance for percutaneous electrode placement was studied in an anatomical model (1,2). We report the first case series of patients who underwent PNS implantation with ultrasound-guided PNS electrode placement.

**Methods:** After institutional review board (IRB) approval, the medical records of five patients who underwent percutaneous ultrasound-guided peripheral nerve stimulation electrode trial and/or permanent implantation were retrospectively studied. Bilateral radial nerve implants were placed in one patient. In the remaining patients, unilateral radial nerve, unilateral ulnar nerve, unilateral median nerve, and unilateral tibial nerve stimulation electrode(s) were placed utilizing a 14-7 MHz high frequency linear transducer.

**Results:** Patient #1 had one episode of lead migration of a radial electrode requiring revision and placement of a second electrode. Patient #2 had two perpendicular radial nerve leads placed bilaterally. Patient #3 had median nerve stimulation trial via percutaneous placement resulting in excellent paresthesia coverage but no analgesia. The lead was later removed without incision being made. Patient #4 had a tibial nerve electrode placed. Patient #5 had dual lead ulnar nerve placement. All but patient #3 underwent permanent implantation of a pulse generator in addition to electrodes as described above.

**Conclusions:** Ultrasound imaging facilitated peripheral nerve electrode placement in 5 patients. The single patient who did not experience analgesia
despite paresthesia coverage avoided surgical incision. The other 4 patients had sustained analgesia, with dual lead placement required in upper extremity patients. An ultrasound-guided, minimally invasive approach allows a trial of stimulation prior to permanent implantation and may reduce unnecessary incision and explantation in some patients. Longitudinal study of outcomes and prospective trials are needed to substantiate this treatment.


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Complete Resolution of Complex Regional Pain Syndrome Type I Using Spinal Cord Stimulation: Where Is the Neural Switch?
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Introduction: Complex regional pain syndrome type I (CRPSI) is a neuropathic pain disorder of unclear etiology. 1, 2 It commonly follows a trivial injury and is characterized by spontaneous pain manifesting regionally that is disproportionate to the inciting event. Associated CRPSI signs and symptoms include allodynia, hyperalgesia, edema, sudomotor, vasomotor abnormalities, and trophic changes. 3, 4 Although multiple modalities exist to treat CRPSI, significant disability, diminishments in quality of life, and reductions in overall health often accompany the syndrome. A CRPSI case where spinal cord stimulation (SCS) was used for pain management with complete resolution of symptoms one month following implantation such that stimulation was discontinued is presented. Case Report: A 57 year old male in good health suddenly developed severe [VAPS=9; verbal analog pain scale (VAPS) 0 = no pain, 10 = worst pain imaginable] deep throbbing right foot pain. He denied an inciting event. Physical examination revealed an antalgic gait, swelling, erythema, increased sweating, dysesthesia, and allodynia. A diagnosis of CRPSI was made based upon clinical presentation and IASP diagnostic criteria. He was treated with gabapentin, nortriptyline and methadone, and responded transiently to lumbar sympathetic blocks. Following successful SCS trial and permanent implantation he experienced complete symptom resolution within 2 months. All oral medications were discontinued and the SCS was turned off. He remained symptom-free and was able to return to full-time employment. Discussion: The pathophysiology of CRPS remains elusive with no scientifically validated cure. However, for this patient the CRPSI signs and symptoms completely resolved following SCS implantation raising the question as to where the neural switches are located. The pathophysiological model implicates an interaction between the CNS and peripheral nervous systems is the most plausible explanation for the SCS to effect a complete “cure” through reorganization of the disordered “neural switches,” further study is necessary. References: Bibliography: 1. Stanton-Hicks M, Baron R, et al. Complex Regional Pain Syndrome: guidelines for therapy. Clin J Pain 1998; 14:155-166 2. Janig W, Baron R. Complex regional pain syndrome is a disease of the central nervous system.Clin Auton Res 2002; 12: 150-164. 3. Stanton – Hicks M, Janig W, Hassenbusch S, et al. Reflex sympathetic dystrophy: changing concepts and taxonomy. Pain 1995; 63: 127-133. 4. Harden RN, Bruehl S, Stanton-Hicks M et al. Complex regional pain syndrome: are the IASP diagnostic criteria valid and sufficiently comprehensive? Pain.1999; 81(1-2):147-154.

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Peripheral Field Stimulation in a Patient with Chronic Low Back Pain: A Case Report

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Setting: Outpatient Pain Clinic. Patient: 74 year-old male with failed back syndrome and chronic low back pain responding to the placement of a peripheral stimulating electrode placed along the sacroiliac joint. Description: The patient failed conservative management and underwent multiple surgeries and procedures since 1994. In our clinic, a combination of interventional and conservative treatments, including a spinal cord stimulator trial, did not provide relief. After this failed, the electrode was placed along the sacroiliac joint, which alleviated the patient's low back pain. Discussion: Although controversial, the sacroiliac joint, a true synovial joint, has been implicated as a cause for chronic low back pain. However, assessing for sacroiliac pain can present a challenge as there are many other potential pain generators and the clinical and diagnostic work-up may not suggest sacroiliac etiology. In the treatment for those suffering from chronic low back pain, spinal cord stimulators are being increasingly used. Common indications for SCS implantation include the treatment of neuropathic pain and axial back pain when conservative measures have failed. Peripheral nerve stimulation involves placing an electrode along the course of a specific painful peripheral nerve. It has been published in the literature for chronic pain related to headache. The sacroiliac joint is innervated by multiple lumbosacral roots, and thus a peripheral nerve stimulator will not be able to course a specific nerve. Conclusion: There are no known studies in the literature in the use of peripheral field stimulation to treat sacroiliac joint pain. In this case report, we present a male who has successfully responded to peripheral stimulation of the sacroiliac joint after a trial of a spinal cord stimulator was not able to alleviate his pain. Future studies are needed to determine if peripheral stimulation of the sacroiliac joint will be a useful treatment of sacroiliac pain. References: Selection of Spinal Cord Stimulation Candidates for the Treatment of Chronic Pain. 2008. Pain Medicine. 9: S82-S92. Funding: None

Cervical Spinal Cord Stimulation: A Useful Intervention in a Patient Suffering from Mitochondrial Complex IV Disease with Diffuse Limb Pain

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Introduction: Mitochondrial diseases are complex disorders that affect multiple systems and as such can have varied phenotypic presentation1. Neuropathic pain is a common feature of mitochondrial disorders, as a result of degenerative nerve changes. Muscle aches and abdominal pain/dysmotility are also common features. Each of the four complexes of the mitochondrial respiratory chain can be affected but most common are complex II and complex IV defects2. The case presented here is an exception due to the rarity of adult presentation and slow progression of this form of the disease and the response of the diffuse neuropathic pain to a novel technique of spinal cord stimulation (SCS) in cervical epidural space with resultant four-limb coverage3. Purpose: To report successful management of diffuse neuropathic pain affecting upper and lower extremities as a result of mitochondrial complex IV disease presenting in adult life. Methods: Case Report. Authors have complied with HIPAA and have obtained signed authorization. Results: A 47 year old female was diagnosed with mitochondrial degenerative disorder, complex IV, by means of muscle biopsy 6 years ago. Initial presentation was that of chronic abdominal pain and motility problems. A year ago patient developed diffuse neuropathic-like pain in all her extremities. After failing conservative medical management, cervical SCS was implemented with very good results. Her pain scores improved from 7/10 to 10/10 to reporting 1/10 to 2/10. Her functional
capacity was dramatically improved as demonstrated by improvement of the Pain Disability Index (PDI) score from 60/60 before the intervention to 8/60 two months post intervention. Consumption of opioids decreased dramatically. Discussion: We have previously described successful 4-limb neurostimulation with cervical neuroelectrodes. This technique proved useful in this case of diffuse neuropathic pain associated with mitochondrial disorder. To the best of our knowledge, no reports of successful SCS exist in cases of mitochondrial disorders.


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Cerebrospinal Fluid Aspiration from a Cervical Zygapophysial Joint
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Case Report: A 62-year-old female with an 8-month history of neck pain following a motor vehicle accident presented for evaluation. Her cervical spine MRI showed left C3-C4 facet arthropathy with marrow edema and mild facet synovitis. The cervical spinal cord was normal with no syrinx or other noted abnormality of the meninges. We proceeded with a left C3-C4 facet injection. Fluoroscopy was used to visualize the left C3-C4 facet joint from a lateral approach. Following local analgesia a 25-gauge, 1.5 inch needle was passed under intermittent fluoroscopy into the posterior lateral aspect of the left C3-C4 facet using a direct lateral approach. At this point, aspiration revealed 2 mL of clear fluid. The needle was removed from the joint, repositioned slightly and again advanced into the joint. Once again aspiration revealed 2 mL of clear fluid. An anterior-posterior fluoroscopy image demonstrated appropriate needle tip placement within the lateral aspect of the left C3-C4 joint. Next 1 mL of Omnipaque was injected under direct fluoroscopic visualization which revealed a myelographic appearance. Thus, the needle was withdrawn and the procedure was terminated. The patient's case was reviewed at our institution's multidisciplinary spine conference - the consensus being that the procedure was performed in a correct manner and the antecedent cervical MRI provided no clues regarding the pathophysiology that allowed CSF to be aspirated from the joint. Conclusion: During the performance of cervical facet injections due vigilance must be exercised to avoid complications. Regardless, physical anomalies may exist that could cause inadvertent iatrogenic injury if not recognized. The authors recommend strict adherence to a systematic procedural approach.1


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Facet Joint Synovitis: A Possible Etiology of Corticosteroid Responsive Z-Joint Mediated Pain
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Background: The pathology of z-joint mediated lower back pain remains unknown. These joints can be affected by inflammatory arthritides, osteoarthritis, capsular inflammation, etc. ISIS Guidelines state that lumbar medial branch blocks (MBB) should replace intra-articular injections when diagnosing lumbar z-joint mediated pain. MBB are not therapeutic. Although intra-articular injections are not supported as the preferred diagnostic block, the therapeutic role of intra-articular injections with corticosteroids remains uncertain. No previous study has looked for a correlation between z-joint synovitis and symptomatic relief from an intra-articular corticosteroid injection. Methods: This
retrospective cohort study analyzed symptomatic relief of patients who underwent z-joint corticosteroid injections for lower back pain. Synovitis, measured by joint aspiration, at the time of injection was documented in the procedure note. Pre-procedure pain scores were documented for all patients using a visual analog scale (VAS). Post-procedure VAS scores were obtained at the follow-up visit (~two weeks after injection). All fluoroscopically guided lumbar z-joint corticosteroid injections, performed by one interventionalist, in 2005 at a large academic institution were reviewed (n=99). Results: Of 99 patients, 9 had documented synovitis. 68 patients in the non-synovitis group either did not have pre- or post- VAS scores documented. Three of the patients with synovitis either did not have pre- or post- VAS scores. In total, 28 patients charts were complete (non-synovitis, n=22; synovitis, n=6). There was no statistical difference between the two groups baseline VAS scores (p=0.13). There was no statistical difference in the average change in VAS scores between the two groups (p=0.735), although VAS scores improved in both groups. Conclusion: This study failed to show a difference between improvements in pain scores for the patients who had z-joint synovitis versus those who did not. Failure to show a difference when a difference is actually there could have occurred due to incomplete data. A prospective study is recommended.


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Successful Treatment of Refractory Pudendal Neuralgia with Pulsed Radiofrequency
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Pudendal neuralgia (PN) involves severe, sharp pain along the course of the pudendal nerve. Current therapies include medical management, nerve blocks, decompression surgery, and neuromodulation. The ideal management for PN has not been determined. We present a case of a female with 1.5 years of sharp, burning pain of the left gluteal and perineal regions. She could not sit for longer than 10-15 minutes. Sacroiliac joint, epidural, and piriformis injections did not improve her pain. She had tried physical therapy, occupational therapy, message, and acupuncture but the pain persisted. Medication treatment with oxycodone-acetaminophen, extended release morphine sulfate, amitriptyline, and gabapentin provided only minor relief and she had failed other multianalgesic therapy. She had been unable to work at her desk job for over a year. She had a positive response to 2 diagnostic pudendal nerve blocks with lidocaine that provided pain relief for several hours. This patient elected to undergo pulsed radiofrequency (PRF) of the left pudendal nerve in hopes of achieving a longer duration and improved pain relief. PRF was carried out at a frequency of 2 Hz and a pulse width of 20 milliseconds for duration of 120 seconds at 42 degrees Celsius. After the procedure she reported tolerating sitting for 4-5 hours. At 5 months follow up she felt motivated to return to work. At one and a half years after the procedure she is only taking oxycodone-acetaminophen for pain relief and still has good sitting tolerance. To our knowledge PRF for the treatment of PN has not been reported elsewhere in the literature. PRF is a relatively new procedure. Current literature suggests that PRF delivers an electromagnetic field, which modifies neuro-cellular function without cellular destruction. We conclude
that PRF of pudendal nerve offers promise as a potential treatment of PN that is refractory to conservative therapy.


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Peripheral Nerve Stimulation of the Genitofemoral/ilioinguinal Nerve: A Novel Technique
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Background and Purpose: Genitofemoral and ilioinguinal neuralgias are painful peripheral neuropathies that can occur commonly following lower abdominal surgeries. Treatment of these conditions is often difficult and at times requires application of neuromodulation techniques. Purpose: To report successful coverage of the genitofemoral and ilioinguinal nerves through placement of a percutaneous cylindrical octapolar neuroelectrode. Study Design. Case Report. Authors have complied with HIPAA. Results: Two male patients with presented with refractory ilioinguinal/genitofemoral neuralgias following inguinal herniorrhaphies had failed conservative medical management with limited response to medications and nerve blocks. One patient also underwent spinal cord stimulation with partial coverage (above the inguinal ligament) of the painful area. Prior reported neurostimulation techniques involved subcutaneous peripheral field stimulation around the scar area1. This technique was attempted in both patients during neurostimulation trial, however, paresthesiae were not obtained in the skin of the upper and medial part of the thigh, the root of the penis and the scrotum. The needles were then directed deep toward the pubic tubercle and the lead was threaded. In both cases, the lead appeared to follow the path of the ilioinguinal/genital branch of the genitofemoral nerve2. Patients had successful trials and subsequently underwent permanent implantation of the peripheral nerve stimulators. No complications occurred.

Discussion: We here describe a simple method of peripheral nerve stimulation of the ilioinguinal and genitofemoral nerves. The technique may be further refined by combining ultrasonography with fluoroscopy.


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Is it Possible That Paresthesia of Spinal Cord Stimulation Is Concentrated on Only Severe Painful Region in Unilateral Pain?
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Introduction: Spinal cord stimulation (SCS) is a therapeutic method applied in a variety of chronic pain states. An important requirement for the success of SCS therapy is that the paresthesia generated by electrical stimulation of the spinal cord must cover the entire painful area. So far, we have tried to treat unilateral pain by single electrode SCS. However, we have encountered some cases that the paresthesia covered the painful area in part or the paresthesia covered not only severe painful area but also slight or no pain region. Patients expected the paresthesia to cover whole painful area and more in the severe painful area, otherwise it was regarded as discomfort. Purpose: To concentrate the paresthesia on only limited painful region. Materials and Methods: Ten cases of unilateral pain caused by postherpetic neuralgia (PHN) or persistent acute herpes zoster pain. Two parallel quadripolar electrode arrays were placed on unilateral side at a small distance from each other (1-2mm) with the tips of each array placed with staggering the electrodes. Results: In all cases the paresthesia covered the whole painful area and were concentrated to severe painful area not a wide range. The paresthesia from an electrode array located to inter side covered proximal area in the painful region and one located to outer side covered distal area. Conclusions: The electrical field has a limited extent in tripolar stimulation, further in “guarded cathode” stimulation (+, -, +). In our hypothesis, this limited extent is more concentrated by using “double guarded cathode” stimulation to form a triangle overlapped by two guarded cathode stimulation. There have been no reports that the idea of the formation of triangle overlapped by two triangles produced by two guarded cathode of SCS to limit the electrical field. We will introduce this technique as a new approach for SCS therapy.


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135 Variations of the Artery of Adamkiewicz and Its Clinical Implications for Interventional Pain Management: A Preliminary Cadaveric Dissection Study Report
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Introduction: The artery of Adamkiewicz (AoA) typically originates from one of the left thoracolumbar segmental arteries to supply the lower spinal cord, and is of enormous clinical importance. Its damage or injection with particulate steroids has been reported to result in anterior cord syndrome. This study's goal was to investigate variations in branching of the AoA in order to enhance awareness among clinicians. Methods: The blood supply of the anterior spinal cord blood was investigated via anterior dissection of 29 ethnically diverse cadavers. The AoA level and side of origin, length, and the presence of secondary and tertiary radicular arteries were documented. (Fig.1) Results: All AoAs originated from T9 to L3 spinal levels (Fig.2). Seven (24.13%) had a lumbar origin. Right-sided AoAs occurred in 6 cadavers (20.69%) and had a suggestive gender and ethnic distribution. Four of 15 (26%) females, but only 2 of 12 males (14.29%) had right-sided AoAs. One of 10 (10%) African American, 1 of 6 (16.67%) Hispanic, and 4 of 13 (30.77%) Caucasian cadavers exhibited this condition. Secondary radicular arteries were also identified in nine cadavers (8 thoracic, 1 lumbar), and a tertiary anterior radicular artery was identified in two cadavers (1 thoracic, 1 lumbar). A statistically significant correlation (r=0.84 p<.0001, Fig.3) was found between the length of the AoA and its level of origin (T9-L3) with AoA length increasing cranial to caudal. Conclusion: The AoA arose from a thoracic segmental artery in 75.86% of cases (N = 29). Additional anterior radicular arteries occurred in 37.93% of cases. AoAs originating in the lumbar spinal levels were significantly longer than those originating in the thoracic
levels. This unexpected relationship between spinal level and length is unreported. Suggested gender and ethnic differences in AoA location deserve further research to expand the sample size and to establish statistical significance.


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Fig. 1 Artery of Adamkiewicz Originating at the Left T10 Intervertebral Foramen
Fig. 2 Left and Right Artery of Adamkiewicz Occurrence

Fig. 3 Artery of Adamkiewicz length and spinal level correlation
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Suboccipital Decompression: A Retrospective Analysis of a Novel Technique for the Treatment of Occipital Neuralgia
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Introduction: Occipital neuralgia is a common cause of headache that remains a treatment challenge. There are reports that occipital neuralgia responds well to greater and lesser occipital nerve blocks. However, patients rarely receive lasting relief from these injections and often fail conservative management. Currently, there are no studies investigating fluoroscopic guided injections into the suboccipital compartment for treatment of occipital neuralgia. We performed a retrospective study of 29 patients with confirmed occipital neuralgia diagnosed by physical exam. We investigated whether this injection can provide both temporary and sustained pain relief, decreased analgesic use, and improved quality of life.

Methods and Materials: (IRB# L08-028) Patients were placed prone with neck in flexion. The nuchal line was identified under fluoroscopy; skin was entered 2 cm lateral to the midline nuchal ridge. A 22G 1 1/2 inch blunt needle was advanced towards the arch of C1 and needle position was confirmed on lateral view. Contrast agent was injected to verify correct needle placement and 10 mL of local anesthetics/steroids was injected. Results: The pretreatment NRS pain scores decreased from 7.9/10 to 0.8/10 immediately post-treatment. Fifteen of 29 patients received more than one treatment (M=1.7). Analgesic use decreased in 14 of 25 patients (56%). ADLs improved in 15 of 25 patients (60%). Pain was decreased greater than 50% of baseline at each follow-up interval, with follow-up NRS M=3/10 remaining significantly lower than pre treatment, t (28) = 9.9 (p < 0.0000000027). Treatment effects were not significantly related to gender or age. Conclusion: Blockade of either the greater, lesser and/or third occipital nerves in the suboccipital compartment via suboccipital decompression was effective in reducing NRS pain score by greater than 50% at 4, 12 and 24 week follow-up. Additionally, analgesic consumption and ADLs improved. This study supports suboccipital decompression in treating occipital neuralgia.


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Greater Occipital Nerve Block: A Useful Tool in Chronic Daily Headache
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Many patients with chronic daily headaches (CDH) report features of more than one type of primary headache. Despite a favorable experience with a variety of headache types, there is little evidence existing about the effects of greater occipital nerve (GON) block in treatment of intractable CDH. Moreover, the underlying mechanism of action is not yet understood. We retrospectively describe 46 patients with CDH who had failed pharmacological therapies. Demographic data, headache history and features were documented. The diagnoses were based on the International headache Society – ICHD 2 classification. Of the 46 patients; 16 had migraine, 3 had tension-type, 1 had cluster headache and the other 26 had multiple component headache. Patients received bilateral GONB (1.0 cc of 0.75 % bupivacaine and 6 mg betamethasone, each side), which was repeated depending upon response. We evaluated headache intensity (10-point visual analog scale) and frequency before and after treatment. Follow up period ranged between 1 to 16 months. When compared to the values before treatment, the mean number of headaches per week reduced from 4.9 +/- 2.4 to 2.4 +/- 2.7 ((P < 0.001), mean headache intensity reduced from 7.4 +/- 1.7 to 3.5 +/- 2.3 (P < 0.003). The response rate did not differ between headache types. Tenderness over the GON was strongly predictive of outcome, and medication overuse component did not. The mean time for response initiation was 77 +/- 128.1 hours and the response lasted for 123.6 +/- 97 days. Twelve (33%) patients reported soreness and 8 (17.3%) reported an increase in headache intensity for a short (< 24 hrs) period. Our results show that the GON block is a useful therapeutic tool in the treatment of intractable CDH regardless of different components of headache types and is generally well tolerated. We hypothesize that the underlying mechanism of action involves a common pathway of central sensitization.

References:

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Use of Intraoral Cryoneuroablation for the Treatment of Intractable Posterior Tongue Pain in a Patient with Glossopharyngeal Neuralgia

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Introduction: The glossopharyngeal nerve is a mixed motor and sensory nerve that provides sensation to the middle ear, posterior third of the tongue, pharynx, and the palatine tonsils. Neuralgia involving this nerve can be severely debilitating. Treatment options are often limited to topical anesthetics and adjuvant medications, all with potential side effects. Radiofrequency ablation or chemical neuroablation risk neuromas, neuritis and motor blockade. The traditional interventional approach enters at the styloid process. The size of the cryoneuroablation probe may make this approach undesirable. Damage to the carotid artery, vagus, hypoglossal, and spinal accessory nerves can occur at the entry site, as can unsightly hypopigmentation and frostbite. We present a case of a 75 year old male with a six year history of posterior left tongue pain described as intermittent, lancinating, and burning. Multiple procedures including sphenopalantine ganglion blocks failed to provide relief. A diagnostic glossopharyngeal nerve block via the intraoral approach provided 3 hours of 100% pain relief. Cryoneuroablation via the same route was then performed.

Materials and Methods: The patient was placed in the supine position with his tongue retracted medially. The left inferior tonsillar pillar was anesthetized, a 14-gauge angiocatheter was advanced approximately 3mm. A 1.4 mm cryoneuroablation probe was inserted, sensory stimulation was achieved at 0.4 V. Stimulation was consistent with the
distribution of the patient's pain. Cryoneuroablation was performed with two three-minute cycles.

**Results:** Pain was decreased >95% immediately following the procedure. On follow up, the patient reported >75% sustained relief for six weeks. Pain relief continued at >50% for three months. The patient's pain then returned to baseline. **Conclusions:** Intraoral glossopharyngeal cryoneuroablation is a viable alternative for treating glossopharyngeal neuralgia. This approach provides a selective localization of the glossopharyngeal nerve and avoids unwanted neuroablation of surrounding nerves compared to the extraoral approach.


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**Sacroiliac Joint Complex Pain Syndrome: A Comparative Pilot, Prospective Cohort Study of Conventional Radiofrequency Versus Cooled Radiofrequency "SInergy"**

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**Introduction:** Sacroiliac joint (SIJ) pain syndrome is a complex pain condition affecting patients with axial lower back pain, exhibiting a prevalence between 15% to 25%1,2. The aim of this pilot study is:1) To compare the effectiveness of conventional (RF) verses cooled (RF) "SInergy" treatment for (SIJ) complex pain syndromes and 2) To stimulate and generate further research into the diagnosis and treatment modalities of this challenging and complex pain disorder3,4. **Method:** Four patients suffering presumably with a diagnosis of (SIJ) complex pain syndrome were enrolled. All patients were treated first with conventional (RF) targeting the nerve branches responsible for the posterior innervation of the (SIJ) and nearby complex structures including: denervation of the dorsal medial branches of L4, dorsal branches of L5 and lateral branches of S1,S2,S3. Assessment of the pre and post innervation changes in pain scores (VAS), pain diagrams, provocative testing, reduction of opioids and adjuvants. Consumption and Oswestry disability scores and quality of life scores were done. **Results:** 3 patients experienced significant pain reduction (>75% VAS) and pain relieve for longer periods (>1 year), when exposed to SInergy.1 patient exhibited good pain relief (>50% VAS), who previously failed to respond to conventional RF. Improvements in the quality of life scoring evidenced by SF-36, and disability scores (Owestery) were also achieved in addition to significant reduction of opioid consumption, in the Synergy treated group. **Conclusions:** SInergy denervation of SIJ can significantly reduce pain scores VAS, opioids, and adjuvant consumption. Improved quality of life predictors and disability scores are shown when compared to conventional RF. This is due to the generation of large volume lesions due to cooling the tissue adjacent to the electrodes, allowing for greater heat dissipation, producing consistency in the lesion size and shape. Randomized controlled trials are needed to further evaluate its efficacy.

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An Alternative Technique to the Piriformis Injection
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Introduction: It has been estimated that 10% of sciatica is due to piriformis syndrome. Injection of local anesthetic and steroid is a common treatment. However, these injections can be limited in patients with contrast allergy. In cases of known allergy, the injection can be performed without fluoroscopy; however this decreases the effectiveness of the block. Materials and Methods: (IRB#L09-001) We conducted a retrospective study of ten patients where air, rather than contrast dye, was used for piriformis injection. Patients were placed prone; the target site was identified via fluoroscopy at the superior junction of the femoral head/acetabulum and midway between the greater trochanter and sacrum in an AP view. A 22G 3 ½ inch spinal needle was placed in a co-axial view and the needle was advanced until it entered the piriformis muscle. Two milliliters of air were injected to visually confirm an air myogram, followed by injection of contrast dye to re-confirm correct placement. Six milliliters of local anesthetic and steroid were injected. Results: In all cases, air effectively delineated the piriformis muscle, confirmed by contrast dye injection. Pain scores decreased following all procedures, pre-median 7.5 (3-10 range) and post-median 0.5 (0-4 range). All patients reported increased activities of daily living at 1, 3 and 6 months. No complications were noted. Conclusion: This is the first case series described, demonstrating that air can act as a contrast agent to correctly delineate the piriformis muscle. This technique offers several advantages. The risk of allergic reaction to contrast dye is eliminated. Air does not obscure the view of the piriformis muscle, which may occur after multiple failed injections of radiocontrast dye. The use of air for localization of the piriformis muscle may be a safe and effective alternative to the use of traditional radiocontrast dyes and reduces cost.
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Cooled Radiofrequency Denervation "Sinergy", as a Novel Treatment of Sacroiliac Joint Complex Pain Syndrome, a Pilot Study
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Introduction: Sacroiliac joint pain syndrome is a complex pain condition exhibited by 15% to 25% of patients with chronic axial lower back pain. Prevalence studies are complicated by diagnostic methodology, non validated provocative tests, physical examination findings with interpersonal differences, pain history of subjective bias and insensitive radiological testing. Although the most common standard method to diagnose the sacroiliac joint as a pain generator is the intra-articular injection of anaesthetics with steroids, but its validity remains unproven. The Aim of this pilot study is: 1) Asses the efficacy of Sinergy in treating the sacroiliac joint pain by cooled radiofrequency
denervation, 2) To stimulate further research into this challenging and complex disorder. **Material and Methods:** 4 patients were selected for this prospective case series pilot study, with presumptive diagnosis of Sacroiliac joint complex pain syndrome, by history and physical examination, then underwent to 2 different arthrographically confirmed trials of local anaesthetic/steroids sacroiliac joint injections. All had >80% reduction in pain scores (VAS). All 4 patients underwent COOLED RF(SINERGY), denervation of the Dorsal medial nerve branch of L4, dorsal nerve branch of L5, and lateral nerve branches of S1, S2 and S3. Assessments of pre and post denervation changes in (VAS) pain scores, pain diagrams, physical examination, opioid consumption, BPI and quality of life scores.

**Results:** 3 patients experienced excellent (>75% reduction VAS) pain relief, 1 patient had good (>50% reduction VAS) pain relief. Also improved quality of life scores and opioids reduction.

**Conclusion:** This study is the first step in suggest that COOLED Radiofrequency denervation "SINERGY" of the sacroiliac joint can reduce pain, opioids and adjuvants consumption and improve functional quality of life predictors in selected patients with sacroiliac joint complex pain syndromes. Sinergy appears to be an effective treatment for this challenging pain condition. RCTs are needed to further evaluate its effectiveness.

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### 142 Epidural Steroid Injections: Variations in Techniques Taught Among US Pain Fellowship Programs

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**Introduction:** Epidural steroid injections (ESIs) are among the most common procedures performed by pain physicians and not without risk (1,2). Surprisingly, there is no standard on how to perform these injections and research on this topic is limited (3). To compare the currently taught techniques, we surveyed attendings at all the US intervention pain programs.

**Methods:** Ninety-two pain fellowships were identified using the frieda database. After IRB approval, a 21-question survey was distributed to the programs via mail, fax, and email, with follow-ups by phone and email. **Results:** The current response rate is 50%. We found a wide range of volumes used for cervical (2-10cc with mean 4.3 +/- 1.3 (mode 5)), lumbar (2-10cc with mean 6.6 +/-2.4 (mode 10)) and caudal (3-30cc with mean 10.6 +/- 4.6 (mode 10)) ESIs. The four most common steroids used were depomedrol, celestone, decadron and kenalog. Their use for different ESIs was as follows: cervical: depomedrol 39.4%, celestone 12.1%, decadron 15.2%, kenalog 33.3%; lumbar: depomedrol 55%, celestone 3%, decadron 5%, kenalog 37%; caudal: depomedrol 55.1%, celestone 2.2%, decadron 3.4%, kenalog 39.3%. The ranges of doses used per ESI were 40-120mg for depomedrol, 6-15 mg for celestone, 4-12 mg for decadron and 10-80 mg for kenalog. The maximum amount of steroids used in a 12 month period for the two most common steroids used was depomedrol ranging from 120-720mg/year with mean 327.2+/− 110.3 (mode 240) and kenalog ranging from 120-480mg/year with mean of 281 +/- 94.8 (mode 320). Transforminal ESIs in the cervical area were performed by 34.40% of physicians surveyed compared to transforminal ESIs in the lumbar area which were performed by 96.30%. **Conclusion:** The great variety of techniques taught for ESIs
reflects the lacking of a best standard for these common performed procedures and further research is needed.


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Spinal Cord Stimulator Failure After Static Magnetic Therapy

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Introduction: Spinal cord stimulation has been demonstrated to have therapeutic pain-relieving effects in a number of painful syndromes including post-laminectomy syndrome with a chronic radicular component. We report a complication in a patient who had a permanent spinal cord stimulator (SCS) placed for lumbar post-laminectomy syndrome followed by implanted pulse generator (IPG) failure due to the use of static magnetic therapy. This case highlights the importance of patient education regarding SCS and the potential for failure of the IPG component with static magnet therapy. Case Report: Our patient was a 72-year-old female with a history of lumbar post-laminectomy syndrome with chronic bilateral lower extremity radiculopathy. After a discussion regarding the risks and benefits of SCS the patient underwent a single percutaneous lead trial with dorsal column placement over the T9 vertebrae. The patient had a successful trial with approximately 90% coverage of her chronic radicular pain however this modality did not cover her entire axial lumbar pain. The patient elected to have a permanent SCS implanted which was without incident. Despite the best efforts of the pain physician and staff in attempting to educate the patient, she sought alternative therapies to treat her chronic axial lumbar pain including acupuncture, herbal remedies, chiropractic manipulation and magnetic therapy. Approximately one month after initiating static magnetic therapy with a waist belt, her SCS stopped functioning and she returned to the pain clinic for interrogation of the IPG. This revealed over 1500 resets and an error message. The IPG was replaced and the SCS function was restored. Conclusion: This case emphasizes the need for extensive formal patient education regarding SCS and its potential interaction with other complementary modalities especially static magnetic therapy.


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Intra-Arterial Injection of Steroids. Evaluation of CNS Injury Using a Rodent Model

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Introduction: Transforaminal epidural steroid injections (TF-ESI’s) are used to treat radicular pain. This approach is associated with complications including stroke, and death (1,2). While the mechanism is unknown, the leading hypothesis is that injection of particulate steroids leads to microembolisation (3). To characterize the nature of steroid induced injury, a rodent model was employed. Methods: After IRB approval, Wistar rats were anesthetized and ventilated. The internal carotid artery was dissection and its
branches ligated. The external carotid artery was ligated, mobilized and cannulated. Five groups were tested: Depo-Medrol (40mg/mL, n=11), Depo-medrol carrier (N=6), Solumedrol (n=8), Decadron (4mg/mL, n=8) and normal saline (n=7). Drugs, in a total volume of 50 µL, were injected into the ICA via the ECA cannula at 25uL/min. The animals were sacrificed on POD 3. The extent of CNS injury was quantitated by image analysis of coronal sections. In separate groups, the extent of injury to the BBB was determined by Evan's blue dye leakage 2h after drug injection. Results: Evaluation demonstrated 8 of 11 animals in the Depo-Medrol, 8 of 8 in the solumedrol group, and 3 of 6 animals in the Depo-Medrol carrier groups had cerebral hemorrhage; no lesions were identified in the dexamethasone and saline control groups (p<0.01). There was Evan's blue leakage detected in the Depo-Medrol and Solumedrol but not the Decadron or saline groups. Conclusion: This study presents the first in vivo evaluation of intra-arterial steroid injections. The data demonstrate Depo-Medrol, as well as its non-particulate carrier and Solumedrol, can produce significant injury to the blood brain barrier when injected intra-arterially. These results suggest that Depo-Medrol induced injury is produced not only by particulate obstruction of the cerebral microvasculature, but also by its non-particulate carrier or methylprednisolone.

References: None

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Cooled Radiofrequency (RF) of Dorsal Ramus of L5 for Denervation of the Sacroiliac Joint: Technical Report

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Introduction: Sacroilitis is a common cause of chronic low back pain(1). RF denervation of SI joint has positive long-term outcome (2-4). Posterior innervation of SI joint consists of L5 dorsal ramus (DRL5) and S1 through S3 lateral branches with great variability (1). Novel cooled RF electrode may overcome these difficulties by creating larger lesions. While cooled RF lesion was used at S1, S2 and S3 level, it was not for DRL5 (fear of damage to L5 (2-4). For the same reason a conventional RF was used(2). Such approach results in prolonged procedural time and additional costs. Methods: Electronic chart review was conducted on 92 consecutive RF procedures. Data collected included age, sex, years of pain, BMI, post-procedural pain, numbness, weakness and other complications. Results: Of 92 procedures 78 were completed using cooled electrode for sacral lateral branches and DRL5. Of 78 procedures completed using cooled RF to DRL5, 21 were reported to be of high difficulty and 17 with poor visualization (bowel gas). Still, there were no major complications related to the procedure. Three patients reported increased pain: two from the conventional RF of DRL5 group and one from the cooled RF group. All of the pains were transient and returned to the baseline within 6 weeks. There were two patients experiencing localized numbness over the upper medial quadrant of the buttock, both in cooled RF group. There was no reported weakness of the lower extremity. Two patients complained of increased lower back pain and two of prolonged itching. Discussion: The cooled RF may be used for lesioning of the L5 dorsal rami. We could not observe radicular or any other complications when cooled RF was used for DR L5 denervation. To examine an actual frequency of any complication larger follow up registries are needed.

Cooled radiofrequency (RF) system for the treatment of chronic pain from sacroiliitis: the first case-series. In press, Pain Practice

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146 Occipital Nerve Stimulation with Self-Anchoring Leads for the Management of Refractory Chronic Migraine Headache
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Introduction: Occipital nerve stimulators (ONS) has shown efficacy in the management of intractable chronic migraine.1 However, the incidence of migration of the leads is significant. In one review it was found to be 60% one year post-implant, and 100% three year post-implant.2 On the other hand, the incidence of migration of the tined leads used for sacral neuromodulation is about 3%.3 Therefore, we were interested to examine the efficacy and safety of using tined leads for ONS. Methods: 12 patients with medically refractory chronic migraine who underwent ONS using a tined lead were identified. The data collected included: demographic variables; baseline and post-implant headache frequency, severity, Headache Impact Test 6 (HIT-6), pain disability index (PDI). All patients underwent a 7-day percutaneous stimulation trial with a regular Octad lead prior to permanent placement of the self-anchoring lead from Medtronic Inc.® Leads were placed at the C1 level and tunneled to the implantable pulse generators (IPG) in the flank, or the infraclavicular region. Results: The data were analyzed for 12 patients (10 females and 2 males) with a mean age of 37 (range 25-56). Nine patients had bilateral and three had unilateral lead placement. The mean follow up period was 13 months (range 6-18). Headache frequency (30 days) improved from a mean of 28 days (baseline) to 16; headache severity (0-10) from 8.2 to 4.7; HIT-6 improved from 72 to 59; PDI improved from 58.3 to 23.8. One patient had 3-mm lead migration forwards with little change in stimulation pattern; however without loss of efficacy. Discussion: The results of this study suggest a role for the self-anchoring lead in ONS in the treatment of medically refractory migraine headaches. There were significant reductions in headache frequency, severity, HIT-6, and PDI with ONS. None of 12 patients required a surgical revision for lead migration for a mean follow up period of 13 months.


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148 Peripheral Nerve Field Stimulation (PNFS) for Treatment of Postlaminectomy Syndrome in Patients with Implanted Intrathecal Pain Pumps
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Introduction: Postlaminectomy syndrome has been reported in 10-40% of the patients following the back surgery [1]. Patients with postlaminectomy syndrome continue to experience low back and leg pain despite conventional treatments. Control of axial low back pain is difficult to achieve with SCS or intrathecal pump. Despite intraspinal therapy for treatment of postlaminectomy syndrome some patients continue to complain low back pain despite complete control of the pain in extremities. Peripheral nerve stimulation has been used to treat patients with injuries to a specific nerve [2], including application to occipital [3], ilioinguinal, supraorbital, and trigeminal neuralgia. PNFS utilizes percutaneous placement
of leads in the area of pain and direct stimulation of the region of affected nerves. **Methods:** In 2007, 12 patients with postlaminectomy syndrome who had previously implanted intrathecal pain pumps underwent PNFS implant. The patients aged between 53 to 90 years, including 8 males and 4 females. The patients continued with intractable axial low back pain despite utilization of different intrathecal medications. After a successful trial of two 8-electrode percutaneous leads positioned in the subcutaneous tissue in the area of greatest pain in the lumbar region, all 12 patients reported >50% improvement in low back pain. **Results:** After final implantation all patients reported significant pain relief (>80% reduction in VAS) with permanent stimulator. All patients were able to decrease or discontinue use of pain medications including intrathecal drugs. Patients also reported other positive outcomes including improved functional status, the ability to return to social activities. Five patients with intrathecal pumps who had good pain control by using PNFS underwent removal of intrathecal devices. **Conclusion:** Peripheral nerve field stimulation appears to be effective, safe and less invasive treatment for patients who exhausted traditional and even advanced treatments like spinal cord stimulation or intrathecal pumps. **References:** 1. Devulder J, De Laat M, Van Bastelaere M, Rolly G. Spinal cord stimulation: a valuable treatment for chronic failed back surgery patients. J Pain Symptom Manage 1997;13:296-301. 2. Novak CB, Mackinnon SE. Outcome following implantation of a peripheral nerve stimulator in patients with chronic nerve pain. Plast Reconstr Surg 2000;105:1967-1972. 3. Slavin KV, Nersesyan H, Wess C. Peripheral neurostimulation for treatment of intractable occipital neuralgia. Neurosurgery 2006;58:112-119. **Funding:** None

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Ultrasound-Guided Lateral Atlanto-Axial Joint Injection for the Treatment of Cervicogenic Headache
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**Introduction:** The lateral atlanto-axial joint(AA joint) is a common cause of cervicogenic headache. The only means of establishing a definite diagnosis is a diagnostic block with intra-articular injection of local anesthetic. **Method:** The procedure was performed with ultrasonography as the primary imaging tool, and with fluoroscopic confirmation. With the patient in the prone position, ultrasound examination was performed using a curved array transducer(C2-5, Philips HD11-XL). A longitudinal midline scan is obtained by applying the transducer vertically in the midline over the cervical spinous processes and C1-2 level is identified (C1 arch lacks a spinous process). Then the transducer is moved laterally till the C1-2 joint(AA joint) appears in the image, more laterally one can easily see the vertebral artery. A 22-gauge blunt-tip needle is introduced just caudal to the transducer and advanced in-plane under real-time ultrasound guidance to target the AA joint just medial to the vertebral artery. Alternatively, once the C1-2 level is identified by the longitudinal midline scan, the transverse axial view is obtained and the procedure is carried out by inserting the needle out-of-plane between the vertebral artery laterally and the C2 DRG medially. **Results:** AP and lateral fluoroscopic images verified correct needle position. Contrast agent injected under real-time fluoroscopy showed the needle tip to be intra-articular. Then 1 ml 0.5% Bupivacaine and 10 mg Kenalog were injected and the patient reported complete pain relief in 30 minutes. **Discussion:** Atlanto-axial joint injection has the potential for serious complications. The vertebral artery lies laterally and the C2 DRG and nerve root cross the posterior aspect of the middle of the joint. Our case report shows the feasibility of using ultrasound imaging to guide AA joint injections. Ultrasound allows visualization of soft tissues, nerves and vessels which has the potential to improve safety by decreasing the incidence of injury or injection into nearby structures. **References:** 1- Narouze S, Casanova J, Mekhail N. The longitudinal effectiveness of lateral atlantoaxial intra-articular steroid injection in the management of cervicogenic headache. Pain Medicine 2007;8:184-188.
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Safety Guidelines for RF Neurotomy in Patients with DBS
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Introduction: We present a case of a patient with severe Parkinson’s Disease (with two Medtronic Soletra® implantable neurostimulators) who underwent spinal nerve dorsal rami medial branch radiofrequency (RF) neurotomy without apparent complication. Methods: Subject: 67 year old male with intractable back pain due to advanced lumbar spondylosis. History of advanced Parkinson’s Disease requiring deep brain stimulators (DBS) with one of the neurostimulator batteries located in the left abdominal wall. History of minimal / short term response to numerous prior corticosteroid injection therapies including epidural steroids, facet injections, sacroiliac injections, trochanteric bursa, and trigger point injections. Pain predominantly axial, low lumbar. Average daily pain intensity 8/10. Lumbar CT confirmed multilevel advance facet arthropathy, and degenerative disc disease, with acquired central and neuroforaminal stenosis. Intervention: Radiofrequency neurotomy left L4-5 & L5-S1 joints using an 18 gauge 10cm cannula with 10mm, angled, active tip. Heating to 80°C for 90 seconds. Six weeks later, radiofrequency neurotomy right L3-4, L4-5 & L5-S1 joints using an 18 gauge 10cm cannula with 10mm, angled, active tip. Heating to 80°C for 90 seconds. Results: Left sided back pain was relieved 70% at 6 months. Right sided back pain was relieved 70% at 4.5 months. The patient did not report any atypical symptoms during the procedure. Discussion: There are several theoretical concerns when using RF therapies in patients with neurostimulators. Our patient did not experience any known adverse events during or subsequent to the procedure. This poster will present our proposed safety guidelines for using RF neurotomy in patients with DBS. Conclusions: Radiofrequency facet nerve ablation was performed in a patient with two deep brain stimulators with a satisfactory clinical outcome, and no adverse sequela. Additional study is warranted regarding the safety and compatibility of of DBS and RF interventions.
References: None
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Efficacy of Vertebroplasty and Kyphoplasty in Treatment of Severe Planar Vertebral Compression Fracture
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Vertebal compression fractures cause significant spinal pain in patients. Vertebroplasty and kyphoplasty have been used to treat vertebral compression fractures in many circumstances with good pain relief and low incidence of complications (1). However, little in the literature has been devoted to the utilization of vertebroplasty and kyphoplasty for patients with vertebral fractures with malignancy, especially with those with severe planar vertebral compression fractures. A planar fracture is defined as one where the vertebral body has been compressed by at least 70% of its original height (2). In our study, all of the patients who had received vertebroplasty and kyphoplasty at MD Anderson Cancer Pain Center were reviewed retrospectively for the past 3 years. A total of 371 kyphoplasty and vertebroplasty patients were reviewed. Thirty patients with planar compression fractures were identified by MRI review. There were 16 men and 14 women and average age was 65 years of age. In this patient population, multiple cancers were represented such as multiple myeloma, renal cell carcinoma, small cell lung carcinoma, esophageal and B cell lymphoma. Only two complications were noted in two patients with localized hematoma at needle insertion sites. Twenty nine out of the thirty patients had
substantial pain relief with the procedure with the average reduction of average pain score of 57%. Average pain score was 7.5 preoperatively, and 3.4 was the average postoperative pain score. With consideration of pain relief, all of our patients have complicated pain histories with multiple sites of pain and metastatic lesions and other problems may have contributed to overall pain scores. Our retrospective analysis illustrates good pain relief with few complications in this patient population. Overall, this study demonstrates that vertebroplasty and kyphoplasty can be utilized safely in patients with severely compressed vertebral fractures.


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Peripheral Nerve Field Stimulation for Treatment of Pain Related to Spine Deformities
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Introduction: Patients with spine deformity often have chronic intractable pain. Deformity in the cervical spine, hyperlordosis or sway neck deformity, or deformity in the thoracolumbar spine, kyphoscoliosis, may require surgical intervention to straighten and stabilize the spine. Despite surgery, pain may continue. Use of PNFS may be beneficial to treat pain associated with these conditions. PNFS has been used to treat patients with injuries to a specific nerve,1 including application to occipital,2 ilioinguinal,3 supraorbital, and trigeminal neuralgia. PNFS utilizes percutaneous placement of leads in the area of pain and direct stimulation of the region of affected nerves.

Methods: A 63 year-old female with kyphoscoliosis of the thoracic and lumbar spine had previously failed conservative therapies, injections and two surgical fusions. She underwent successful trial of two 8-electrode percutaneous leads positioned in the subcutaneous tissue in the area of greatest pain in the paraspinal areas of the lumbar region. Two weeks later the patient underwent implantation of four 4-electrode permanent and RestoreULTRA (Medtronic Inc., Minneapolis, MN) rechargeable generator. An 81 year-old female with swan neck deformity of the cervical spine and chronic neck and shoulder pain had previously failed conservative therapies and injections. She underwent successful trial of two 8-electrode percutaneous leads positioned in the subcutaneous tissue in the area of greatest pain in the paraspinal areas of the cervical region. Three weeks later the patient underwent implantation of two permanent 8-electrode leads and RestorePrime (Medtronic Inc., Minneapolis, MN) non-rechargeable generator. Results: After final implantation both patients reported almost 100% pain relief with permanent stimulator. The first patient was able to decrease use of pain medications and the second patient was able to discontinue use of pain medications. Conclusion: PNFS appears to afford good pain relief for patients who exhausted traditional and surgical interventions for chronic pain related to spinal deformities.


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Efficacy of Interventional Pain Management in Pediatric Cancer Patients
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Pediatric cancers can cause significant pain in young patients, which can be challenging to treat. Oral and intravenous medications are the mainstays of pediatric cancer pain treatment. Despite progress in pediatric cancer therapy, about 25% of these patients will have progressive disease and go on to die from their cancer (1). Interventional pain procedures can be used for treatment of pediatric cancer pain refractory to medication therapy. In this study, all pediatric patients who received interventional pain treatment were reviewed retrospectively for the past 2 years. A total of 58 patients (n=58) were identified, with a wide range of pediatric cancer diagnoses, including osteosarcoma, Ewing's sarcoma, lymphoma, germ cell tumor, soft tissue sarcoma, Wilms' and neuroendocrine tumors. Pain procedures were classified into 5 categories: neural blockade (n=24), neurolytic blocks (n=13), intrathecal therapy (n=12), neurostimulation therapy (n=5), and vertebral augmentation (n=4). Neural blockade includes neural plexus and individual nerve blocks. Neurolytic blocks include destruction of the nerves or nerve plexus involved in cancer process. Intrathecal therapy involves placement of intraspinal catheter to infuse medication for pain blockade at spinal cord level. Neurostimulation therapy includes spinal cord and peripheral nerve stimulation. Vertebral augmentation includes vertebroplasty and kyphoplasty for treatment of vertebral compression fractures from metastatic lesions. There were 32 female and 26 male patients. Average age was 14.2 years, with age range from 4 to 18 years. All patients experienced significant pain relief with 68.7% reduction of pain scores and 65.0% decrease in opioid consumption. The average pain score pre-procedure was 8.3 and post-procedure was 2.6. The average pre-procedure morphine equivalent daily dose (MEDD) was 326, and post-procedure MEDD was 114. Complications from these procedures included 2 cases of post-dural puncture headaches from intrathecal therapy. This retrospective study shows that interventional pain management has a role in helping pediatric cancer patients.


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Peripheral Nerve Stimulation (PNS) for Treatment of Intractable Headaches Associated with Lyme Disease

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Introduction: Lyme disease is a bacterial infection caused by Borrelia burgdorferi. It affects various body systems including the nervous system. The patients may multiple pain areas and intractable neuropathic pain despite conventional treatments. Control of headaches associated with Lyme disease is challenging despite numerous treatment modalities available in the field of pain management. Peripheral nerve stimulation (PNS) has been used to treat patients with injuries to a specific nerve,1 including application to occipital,2 ilioinguinal,3 supraorbital, and trigeminal neuralgia. Recently this type of treatment is utilized to control headaches. Materials and Methods: A 29 year-old male with Lyme disease and 8 year history of chronic joint pain and intractable diffuse headaches had previously failed conservative therapy and had minimal pain relief after multiple nerve blocks. Seven years earlier he underwent surgery for incidentally found Chiari malformation which made his headaches even worse. The patient had successful PNS trial with percutaneous placement of two 8-electrode leads positioned in left and right occipital region. During the 2 day PNS trial the patients reported greater than 90% improvement in pain. Two weeks later he underwent implantation with permanent leads and RestoreULTRA (Medtronic Inc., Minneapolis, MN) rechargeable generator. Stimulator parameters programmed with amplitude 1.5 volts, pulse width 450 microseconds, and frequency 30 Hz. Results: After final implantation the patient reported complete elimination of headaches with permanent stimulator. The patient was able to decrease
and discontinue use of pain medications. He also reported other positive outcomes including the ability to return occupational activities and improved family relationships. **Conclusion:** Peripheral nerve stimulation appears to be a therapeutic alternative for patients with chronic intractable headaches who in the past exhausted all available treatments. This technique is a relatively easy to perform, effective, and safe procedure. The therapy is reversible should patients lose its pain-alleviating effect or headaches resolve.


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**Occipital Nerve Stimulation (ONS) for Treatment of Intractable Migraine Headache: 3-Month Results from the ONSTIM Feasibility Study**

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**Introduction:** Despite aggressive medical therapy, 3-14% of patients with episodic migraine develop chronic migraine characterized by headache >15 days per month. Intractable chronic migraine (ICM) is a severely disabling illness. ONS for ICM has the potential to serve a large unmet medical need if proven safe and effective. **Materials and Methods:** A multi-center, prospective, randomized, single-blind, controlled feasibility study (IRB approved) was conducted to obtain preliminary safety and efficacy of ONS for treatment of ICM. Subjects who met ICHD-II criteria received diagnostic Occipital Nerve Block (ONB). ONB responders were randomized 2:1:1 to Adjustable Stimulation (AS), Preset Stimulation (PS), or Medical Management (MM). The first 8 who failed ONB formed an Ancillary Group (AG) and were offered ONS. Three-month objectives included reduction in headache days/month, decrease in overall pain intensity (0-10 scale), and responder rate (>50% drop in headache days/month or >3-point drop in overall pain intensity from baseline) based on daily electronic diary data. Adverse events were evaluated. **Results:** 110 subjects were enrolled from 9 centers, 75 were assigned to a treatment group (AS=33, PS=17, MM=17, AG=8), of which, 66 subjects completed diary data during 3-month follow-up (AS=28, PS=16, MM=17, AG=5). At 3 months, percent reduction in headache days/month was 27.0±44.8% (AS), 8.8±28.6% (PS) (p=0.132), 4.4±19.1% (MM) (p=0.058), 39.9±51.0% (AG) (p=0.566) (p-values for comparison to AS group). Reduction in overall pain intensity was 1.5±1.6 (AS), 0.5±1.3 (PS) (p=0.076), 0.6±1.0 (MM) (p=0.092), and 1.9±3.5 (AG) (p=0.503). Responder rate was 39% (AS), 6% (PS) (p=0.032), 0% (MM) (p=0.003), and 40% (AG) (p=1.000). No unanticipated adverse device events occurred. Lead migration occurred in 12 of 51 (24%) subjects.

**Conclusions:** This is the first reported controlled trial evaluating ONS for ICM. Based on responder rate, ONS may be a promising treatment for ICM and ONB may not be predictive of response to ONS.

**References:** None

**Funding:** Study Sponsored by Medtronic, Inc.
156 Ultrasound-Guided T2 Sympathetic Block with the Anterior Approach  
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Introduction: We report a novel technique of ultrasound-guided blockade of the sympathetic chain at T2 using the anterior approach. Some postganglionic fibers originating from T2/T3 sympathetic ganglion bypass the stellate ganglion and pass directly to the upper extremity (the nerve of Kuntz) that may be present in up to 60% of cases, and this explains the nonspecificity of stellate ganglion block. Methods: An informed consent was obtained from a patient with left upper extremity CRPS. The patient was positioned in the supine position with the neck extended. A 3-12 MHz linear array probe (HD11-XL, Philips) was applied transversely at the root of the neck. C7 was identified with its characteristic transverse process as well as its relation to the vertebral artery. By moving the probe caudally T1 will appear in the image, and then after a caudal tilt, one can identify T2. A 22-G blunt needle is inserted out of plane and advanced so that the needle tip will lie lateral to the longus coli tendon. Caution must be exercised to avoid the vertebral artery as it lies anterior to the sympathetic chain at this level. Needle position was rechecked with fluoroscopy. 5 ml of Bupivacaine 0.25% were injected under the paravertebral fascia with spread of the LA from C6-T3. Results: 5 minutes after the procedure, the patient developed Horner's syndrome and the temperature at the fingers rose 5 degrees. The patient didn't develop RLN palsy and pain dropped from 8 to 2 (scale of 0-10). Discussion: We described an ultrasound-guided technique to block T2 sympathetic ganglion with the anterior approach that should provide a complete sympathetic block to the upper extremity. Ultrasonography may improve the safety of the procedure by direct visualization of the related anatomical structures and accordingly the risk of inferior thyroid artery, vertebral artery, esophagus or pleura injury may be minimized.  
Funding: None  

157 Sphenopalatine Ganglion Stimulation for the Acute Treatment of Intractable Migraine  
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Introduction: We report preliminary results of a novel acute treatment for intractable migraine. The sphenopalatine ganglion (SPG) has sensorimotor and autonomic (sympathetic, parasympathetic) components and is involved in migraine pathophysiology. Methods: The study was IRB approved. Six consecutive patients with medically refractory chronic migraine headache with known triggers were recruited in this pilot study. The sphenopalatine fossa was accessed with a 20-gauge needle using the infrazygomatic approach under fluoroscopic guidance. All patients underwent temporary electric stimulation of the SPG with a Medtronic 3057 test stimulation lead after induction of full-blown migraine. Stimulation with different settings was carried out for ≤ 60 minutes, then the lead was removed. All patients had unilateral lead placement. Data collected included: demographic variables; baseline, post-induction and post-stimulation headache severity; duration and stimulation parameters; and procedure complications. Results: Data were analyzed for the first 6 patients (all females). Patients had migraines for a mean of 20y. Two patients had complete abolition of their induced headaches (3 attacks each) within a mean of 3 min of SPG stimulation (range 1-4 min). The stimulation settings were: mean amplitude of 1.2V (range 0.9-1.8 V), pulse rate of 57 Hz (range 50-120 Hz), and mean pulse width of 394 ms (range 300-700 ms). In 2 other patients headache severity reduced 2.5 and 3 points/10
respectively after 20 min of stimulation. Two patients experienced no headache relief. Discussion: This study suggests a role for SPG stimulation in the treatment of medically refractory migraine headaches. Complete headache abolition in 2 patients was achieved within minutes of SPG stimulation; 2 other patients had >2.5 point reduction in headache severity. In the 2 patients with no headache relief, posterior nasal paraesthesias were not obtained during stimulation, possibly indicating suboptimal lead placement; furthermore those patients had medication overuse headache.


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Dorsal Nerve of the Penis Electric Stimulation for Intractable Penile Pain
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Introduction: Post-surgical neuropathic pain is an underrated complication that can be extremely disabling (1). Multiple treatment modalities have been studied with mostly disappointing results. We report a case of intractable penile pain following varicocele repair who obtained excellent pain relief following peripheral stimulation. Case presentation: We report on a 20 year old male who presented to our pain clinic with constant pain at the tip of the penis and burning pain on micturition as well as intermittent sharp pain in the left groin. The left groin pain started first and a few months later he developed burning pain at the head of his penis/foreskin with "any friction" following varicocele surgery in 2005. Gabapentin, amitryptaline, clonazepam, duloxetine and narcotics all provided minimal relief. He had also received nerve blocks, epidural anesthetic infusion with ropivacaine in combination with intravenous ketamine and topical capsaicin, and even a surgical neurectomy of the ilioinguinal nerve with temporary relief only. After successful trial, the patient underwent a permanent implant of 2 peripheral nerve stimulation leads, one placed above and parallel to the inguinal ligament to cover the ilioinguinal nerve and the second placed across the root of the penis just below the symphysis pubis across the dorsal nerve of the penis. The patient obtained adequate coverage with good pain relief and was weaned off his medications. Discussion: Post-surgical neuropathic pain is common. Our patient had neuropathic pain involving the glans penis supplied by the dorsal nerve of the penis that was intractable and had failed all other treatment modalities. While the effective use of peripheral stimulation for post-surgical inguinodynia has been reported (2), this is the first report of its effectiveness in treating intractable penile pain. Thus, peripheral stimulation can be an effective modality for treating intractable penile pain.


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Minutes of Recharge Per Week to Maintain Pain Therapy for the Restore Neurostimulator
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Introduction: In recent years, rechargeable neurostimulator implants for treatment of neurological disorders have increased. As with any new technology, it's important for the efficacy of the technology
to be measured over time. Recharge effectiveness is influenced partly by the patient since the patient must properly locate and maintain good coupling between the external recharge antenna and implanted neurostimulator over an extended period of time. Additionally, the system must be able to transfer energy efficiently once good coupling has been achieved. This analysis evaluates the time required to recharge weekly to maintain pain therapy. Materials and Methods: Quantitative data collected by the implanted device was analyzed from 24 pain patients indicated for SCS who had been implanted from between 6 and 12 months. The data collected included: 1) the amount of energy the patient used over 1 week's time, and 2) how quickly the user put energy back into the device. Energy needs are influenced by such factors as device programming, device usage, and the devices' ability to efficiently manage the energy and deliver the desired therapy. From these parameters, time needed to recharge per week was calculated by the following equation: Energy needed per week / Recharge energy transmitted per minute = Minutes recharging per week. Results: Analysis of data collected from 24 pain patients from 7 different clinics implanted with the Restore Rechargeable Neurostimulator for an average 268 days (min 180/max 379 days) demonstrated the median patient needs to recharge 38 minutes per week. Recharge times ranged from 16 minutes to 245 minutes per week to maintain therapy. Conclusions: The Restore rechargeable stimulator provides an excellent alternative to traditional primary cell, non-rechargeable neurostimulators. The additional burden of recharging is minimized by having an efficient use of energy delivered and an efficient method of replenishing energy into the neurostimulator.

References: None
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Closed Loop Feedback from the Implanted Device Aids Patients in Achieving Optimal Charge Rates During a Transcutaneous Recharge Session

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Introduction: Charging a neurostimulator battery is based on inductive coupling, which has low efficiency and long session times. The efficiency depends on how well the external transmitter is located over the implant's center. A simple “GO/NO GO” indication for acceptable location could be used. However, the threshold to define acceptable performance may be poor given the desire to have a reasonable “GO” area and the fact performance falls off rapidly away from the center. Alternatively, a system could indicate levels of “coupling” performance to guide the patient to the region for achieving optimal charge rates. Methods: This investigation compares two feedback mechanisms by relating actual recharge times achieved by patients using a coupling display with expected performance of a Go/No Go system; optimum recharge rates are compared. The probability of achieving any given charge rate is the ratio of area that achieves that rate to total area within the “GO” area. This probability is based on randomly placing the antenna within the area that satisfies the GO/NO GO criteria without guidance. Clinical data will be shown for a system that gives location feedback via telemetry by displaying 8 levels of charge rate. Results: 38 patients were implanted with a rechargeable system that uses an external recharger displaying levels of coupling effectiveness calculated from telemetry data. Clinical data was recorded on all recharge sessions performed by patients for one year. This resulted in 449 recharge sessions lasting >10 minutes. Median of these sessions achieved an average charge rate >75% of the maximum rate. The probability of achieving at least this rate in a GO/NO GO system is 27%. Conclusion: The location aid provided to patients by a system that indicates 8 accurate coupling levels can nearly double recharge performance (recharge rate), thereby nearly halving the time needed to recharge the neurostimulator.

References: None
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Preference for Voltage or Current Stimulation Pulse Trains Is Not Consistent in Patients Undergoing Spinal Cord Stimulation (SCS) Trial

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Introduction: Commercially available SCS devices control the energy delivered to neural tissue through constant voltage (CV) or constant current (CC) stimulation in order to cause the sensation of paresthesia. This study aimed to determine 1) if initially indicated preference for CV or CC corresponded with the outcome of a randomized trial and, 2) whether patients could correctly identify identical and different pulse trains. Materials and Methods: In this IRB-approved multicenter feasibility study, 14 patients received stimulation alternating between CV and CC and specified whether they preferred either sensation. Subsequently, each patient also received 20 randomly presented pairs of 15-second pulse trains. Patients identified whether the two pulse trains were the same or different, and if they preferred the first or second train. Patients were blinded to the type of stimulation presented. Results: Initially, nine patients responded that pulses felt the same when alternating between CV and CC, while four preferred current and one preferred voltage. However, during blinded and randomized pulse trains, the preferences became less clear. Two patients with initial CC and CV preferences, respectively, actually preferred more of the opposite pulse type. Two patients initially choosing CC were not able to consistently identify pulse pairs. Only one patient having a preference at the start (CC) was able to correctly choose CC pulses during the randomized study. Overall, few patients consistently identified when “same” and “different” pulses were being presented. Only three patients performed above average by indicating that at least 6/10 pulses were the same and 7/10 pulses were different. Of these patients, two preferred voltage, while one preferred current. Conclusion: Few patients displayed a strong preference for either CV or CC. When a preference was initially indicated (5/14), in only one case did the blinded, randomized portion of the study support the patient's perceived stimulation preference. References: None

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Radiofrequency Ablation Within the 1ST Intercoccygeal Disc for Coccygodynia: A Case Report

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Introduction: Interventional procedures for coccygodynia are limited. This is a case report of long-term improvement following radiofrequency ablation (RFA) within the 1st intercoccygeal disc. Case Presentation: A 44 year old female presented with a one year history of coccygodynia following a fall. Examination under fluoroscopy localized her pain at the disc in between the 1st and 2nd coccygeal vertebrae. Provocation with needle entry reproduced the patient's pain and the 1st intercoccygeal disc was injected with 40 mg of methylprednisolone. This gave her excellent relief for about 3 weeks. The procedure was repeated at 4 weeks, providing her with the same response. The decision was then made to proceed with RFA. After inserting a 22 gauge 5mm active-tip RFA needle into the midline of the disc using fluoroscopy, her symptoms were reproduced in response to stimulation at 50 Hz with 0.9 volts (and stimulation at 2 Hz with 2 volts did not result in any motor stimulation). RFA was then carried out at 70 degrees Celsius for 80 seconds followed by injection of 20 mg methylprednisolone. Her NRS pain score decreased from 9/10 to 3/10 following the RFA. At about the 6 month mark, it was noted that the patient had gradual recurrence of her pain. A repeat RFA procedure is planned. Overall, she had about 70% pain relief for about 6 months. Discussion: There is evidence that intercoccygeal discs are a source
of coccygodynia. Immunohistochemistry has shown mechanoreceptors in intercoccygeal discs and coccygeal discography has been shown to reproduce coccygeal pain. In fact, intercoccygeal disc injection is described as a therapeutic option in the literature. Since various RFA techniques have been used for intervertebral discogenic pain, the decision was make to attempt RFA at the 1st intercoccygeal disc with resultant significant long-term improvement.


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Botulinum Toxin Type B (BoNT-B) Effects on Pain in Cervical Dystonia: Results of Placebo- and Comparator-Controlled Studies
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Introduction/Statement of the problem: The study objective is to evaluate the effect of BoNT-B on pain in CD using TWSTRS-Pain scale (TWSTRS-PS).

Materials and Methods: Response rates (RRs) and mean improvements (MIs) on TWSTRS-PS from 3 large controlled trials were reviewed. AN072-301 enrolled botulinum toxin type-A (BoNT-A) responsive subjects randomized to placebo, BoNT-B 5,000U, and 10,000U; AN072-302 BoNT-A resistant subjects to placebo and BoNT-B 10,000U; AN072-042 BoNT naïve subjects to BoNT-A 150U and BoNT-B 10,000U group. Responders were defined as >20% TWSTRS-PS improvement at week 4 vs baseline.

Results: In AN072-301, RR differences at Week 4 were -43% (95% CI: -64%, -22%) for placebo vs. BoNT-B 5,000U, and -36% (95% CI: -57%, -14%) for placebo vs. BoNT-B 10,000U. MI differences were -3.2 (-4.9, -1.4), and -3.8 (-5.8, -1.9). In AN072-302, RR and MI differences for placebo vs. BoNT 10,000U were -30% (-50%, -10%) and -3.5 (-5.0, -2.0). In AN072-402, RR and MI differences for BoNT-A 150U vs. BoNT-B 10,000U were -23% (-42%, -3%) and -0.8 (-2.0, 0.4). Conclusions: Subjects treated with BoNT-B 5,000U to 10,000U in placebo-controlled studies were more likely to meet responder criteria and showed larger MI compared to placebo. Toxin-naïve subjects treated with BoNT-B 10,000U demonstrated a statistically significantly higher RR and a larger MI than the BoNT-A 150U group.


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Multi-Center Evaluation of Efficacy of Morphine Sulfate Infusion via the Prometra® Intrathecal Infusion Pump

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Introduction: Improvement in function and decrease in pain levels are important goals when treating pain patients with an implantable programmable intrathecal pump. During a prospective, multi-center FDA approved clinical study (PUMP), efficacy was evaluated. Materials And Methods: The PUMP study was a prospective open-label evaluation of the Prometra pump system (InSet Technologies, Mt. Olive, NJ) to treat chronic pain with MSO4. After obtaining IRB approval at seven clinical sites, 110 patients (age: 56 ± 13, gender: 51F) were enrolled after giving informed consent. Baseline data are collected pre-implant and follow-up is monthly for the first 6-months post-implant and then every three months. Subjects completed visual analog scales (VAS), numeric rating scales (NRS – scale of 1 to 10), and Oswestry Disability Indexes (ODI) at baseline, monthly for the first six months, and finally at twelve months post-implant. Results: After a total of 35,838 device-days of follow-up (mean 10.7 months, range 0.4-16.0 months) and eighty-one subjects had completed at least six months of follow-up; sixteen subjects had completed at least 12 months of follow-up. Statistically significant improvements (improvement in function, decrease in pain scores) from baseline were reported at each visit during the first six months for each of the questionnaires (VAS, NRS, and ODI). At the six-month visit, mean VAS improvement was 26% (p<0.0001), mean NRS raw improvement was 2 points (p<0.0001), and mean ODI improvement was 9% (p=0.0014). Improvements from baseline were also reported at the 12-month visit for at least 60% of the subjects completing twelve months. Conclusions: Results show that intrathecal morphine sulfate therapy via the Prometra pump is effective in significantly improving function and decreasing pain. Effectiveness was consistent through six months post-implant, and shows trends towards remaining consistent through twelve months and afterwards.


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A Prospective, Randomized, Multi-Centered Crossover Study to Evaluate Constant Current Versus Constant Voltage Trial Stimulation Systems: Patient Perceived Differences

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Background: Electrical stimulation can be applied to the spinal cord using either constant current (CC) or constant voltage (CV) power source. A CC source adjusts voltage in response to changes in impedance to maintain current. A CV source does not adjust voltage and current may change as impedance changes. Both systems produce paresthesia and have been shown effective in clinical trials. However, it has been suggested that patients prefer constant current over constant voltage. This study compares patient preference for the stimulation sensation elicited by CC and CV systems. Methods: This study is an IRB approved, prospective, randomized, double blinded, multi-centered, crossover study during a 6-day stimulation trial period. Patients were randomized into 2 treatment groups; Group A received constant voltage and Group B received constant current. Patients completed baseline evaluation prior to trial implantation. Patients returned 1 day post-operatively for randomization and received
programming. Three days later, patients were evaluated and crossed over into the alternate treatment group. The same programs, including electrode configuration, pulse width and frequency, were used throughout the study. Six days post-operatively, patients returned for the final evaluation, including patient well being, pain, satisfaction/QOL, stimulation sensation and preference. Results: Thirteen patients have completed the study. Nine patients (69.2%) preferred CC stimulation after experiencing both treatments. During CV stimulation, 7 patients (53.8%) were satisfied or very satisfied and 6 patients (46.2%) were unsatisfied or very unsatisfied. During CC stimulation, 12 patients (92.3%) were satisfied or very satisfied and only 1 patient (7.7%) was unsatisfied. The mean reported pain relief was 59.6% for CV and 63.5% for CC. The only descriptor for stimulation sensation used more often to describe CC over CV was “soothing.” This descriptor was also associated with patient satisfaction. References: 1. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. J Neurosurg (Spine 3) 2004 March; 100:254-67.

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Lumbar Inter Facet Fusion: A Retrospective Analysis of a Novel Technique
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Purpose: Patients with spinal instability and mechanical pain are often considered candidates for fusion with invasive instrumentation. Far less complicated operative strategies targeting the facet joint have been biomechanically shown to increase stability. This study was undertaken to report the clinical results of a simple posterior facet fusion technique using a novel cortical allograft bone dowel (TruFUSE®).

Methods: A retrospective review of 81 cases treated with posterior facet fusion was conducted. Fusions were performed in 2 patients as a stand alone procedure, 66 after decompression, and 13 as an augmentation to anterior interbody fusion. Multiple levels were fused in 34 patients. Cortical allograft bone dowels were used to stabilize the lumbar facet joints. The technique is performed open or percutaneously. A drill guide with spatula prongs for centering is inserted into the facet expanding the joint and tightening the joint capsule. The guide is angled along the plane of the joint and drilling is performed. Impaction of the Morse tapered cortical allograft dowel is then carried out.

Results: Pain levels decreased significantly with good to excellent outcomes noted in 90% of patients by six weeks. Fewer than 5% of patients following up at three months continued to complain of severe pain. 96% reported fair to excellent results. There were 3 cases of dowel back out > 75%, only one of which required revision due to recurrence of symptoms. Conclusions: Minimally invasive posterior facet fusion can easily augment a wide variety of lumbar surgical procedures and also be used as a stand alone procedure. A high level of good to excellent outcome, with significant reduction in back pain and rapid improvement in activity was seen. Interfacet fusion provides the advantage of simplicity, safety, diminished operating time, low complication rate, and clinical results comparable to more invasive instrumentation.

References: Dr. Ehud Mendel, Professor of Neurosurgery, Ohio State University. Columbus Ohio Dr. Frank Vrionis, Associate Professor of Neurosurgery, Moffitt Cancer Center. Tampa Florida

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CT-Guided, Anterior Scalene Botulinum Toxin Injection for Thoracic Outlet Syndrome
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Introduction: Blockade of the scalene muscles produces temporary improvement in patients with thoracic outlet syndrome (TOS). Further, local anesthetic injection to the scalene muscles is helpful in predicting which patients may benefit from surgical decompression. Botox injection into the scalene muscles has been shown to provide more durable relief than anesthetic blockade. This study was undertaken to assess pain relief following Botox injection into the anterior scalene muscle under CT-guidance for the treatment of TOS. Methods: This is a prospective, observational study that includes 18 patients. Patients rated their baseline pain score from 0 (No pain) to 5 (Excruciating). Each patient underwent a CT-guided anterior scalene local anesthetic injection with 1cc of 0.25% bupivacaine. Patients then underwent CT-guided anterior scalene injection with 20 units of Botox. Lastly, patients completed the SFMPQ and a Botox side effect questionnaire at 1, 2 and 3 months post-Botox injection and rated their pain improvement and duration of relief. Results: A total of 18 patients were selected for the study. At time of submission, 16 of 18 patients were at the 3 month post-Botox injection time interval. Preliminary data are available for 12 of 16 patients (75%). The mean pain score prior to intervention was 4.25. In 9 of 12 patients (75%) there was more than a 50% reduction in symptoms following the Botox. The mean duration of relief in these 9 patients was 2.2 months, with a range of 0.5 months to 3 months of relief. Only 1 of 12 patients (8%) reported no relief following Botox injection. The mean pain score at 3 months was 3.1. No patient reported any significant adverse effects from the Botox injection. Conclusion: A single, CT-guided Botox injection into the anterior scalene muscle is a safe and effective, though temporary intervention in patients awaiting surgical correction for TOS. References: References: 1. Ann Vasc Surg. 1998;12:260-264. 2. Ann Vasc Surg. 2000;14(4):365-9. Funding: None

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A Multi Modality Treatment Regimen for CRPS1 of Upper Extremity
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A multi modality treatment regimen for CRPS1 OF UPPER EXTREMITY
Introduction: CRPS 1 is a perplexing condition for which various treatments have been tried and discarded. We present the consistent success of a combination therapy of medication, stellate and continuous brachial plexus block, repeated dry needling and physiotherapy of extremity muscles in 41 patients with CRPS1 of upper extremity. Methods: 41 patients, 18 men and 23 women with documented clinical, radiological and bone scan features of CRPS1 underwent image guided placement of a stimulating catheter into the infraclavicular brachial plexus after a single shot image guided stellate ganglion block with Triamcinolone. The catheter was subcutaneously tunneled away and connected to a continuous PCA infusion pump to deliver a background infusion of 2-4 ml/hr of 0.125% bupivacaine with a 5-7 ml bolus dose prior to Physiotherapy. The infusion was continued for the next 25-40 days. Daily physiotherapy and twice weekly dry needling of the specific musculature of neck, shoulder girdle, extremity and the small muscles of the hand was done for the next 25-40 days on an outpatient basis. They also received Amitriptyline 25 mg at night. Results: 38 patients with the catheter for 3-5 weeks along with dry needling and physiotherapy became pain free, recovered complete hand function and have maintained an active lifestyle for the past 1-5 years. Complications:3 patients had catheter extrusion at 5-12 days. They had no rest pain but had a recurrence of swelling, stiffness and pain on physiotherapy. 2 had catheter reinsertion but one refused and was lost to follow up. Conclusion: Complete reversal of CRPS1 was possible with a combination therapy: medication, prolonged continuous plexus block over a period of 3-5 weeks for sustained suppression of the sensory and autonomic symptoms, dry needling and physiotherapy to reverse the motor symptoms. References: CRPS: Current Diagnosis and Therapy. Progress in Pain Management Research, Vol. 32. 2005 Peter R. Wilson, Michael Stanton-Hicks, and R. Norman Harden (Editors) J. Schmidt. Treatment of Complex Regional Pain Type I in Stroke Using Dry Trigger Point Blocks: A Pilot Study. Archives of
Muscles as a Treatable Pain Source in Patients with Failed Back Surgery Syndrome
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Introduction: Failed Back Surgery Syndrome (FBSS) is broadly defined as persistence of chronic back/leg pain after surgery. Of patients undergoing spine surgery for the relief of back pain, 40-51% are unsuccessful with an annual incidence of 80,000 FBSS/year nationally. From 1990-2006, the incidence of lumbar fusion surgeries rose 400%. Based on a 2008 literature review from The American Journal of Medicine, no controlled studies/accepted treatment guidelines for FBSS exist. Current treatment methods include medication, physical therapy, additional surgery, and spinal cord stimulation. In the majority of cases, care is palliative. Of those treatment modalities, spinal cord stimulators and additional surgery average 50% pain reduction in 37.5% and 11.5% of patients, respectively. As nearly 90% of the LS spine MRIs are read as abnormal prior to surgery, it is no wonder the presence of abnormalities on imaging post-operatively would justify further interventions to correct the putative pain generator. Muscles as a primary source of pain are generally overlooked in published guidelines for back pain evaluation/treatment and in the pain management community standard of care.

Methods: A retrospective review was conducted of 40 patients with FBSS who presented to a comprehensive pain treatment center with chronic low back and/or sciatic pain. We found 85% had painful muscles on examination. 18 patients received the suggested muscle injection comprehensive protocol. Patients were assessed with the Brief Pain Inventory and Beck Depression Scale.

Results: 13 patients reported at least an 85% pain and depression reduction on the last day of treatment, with a 64% reduction in 11 patients at an averaged 5 month follow-up.

Conclusion: Muscles as a treatable pain source are overlooked in a growing, poorly treated population of chronic pain patients. Our results suggest proper muscle evaluation and treatment protocols may offer significant, lasting relief to FBSS patients.

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Psychosocial / Rehabilitation

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One Intact Hand Is the Window on the Other Phantom Hand
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After amputation, most patients experience a phenomenon known as a phantom limb (PL). A variety of PL experiences appear to be associated with neural plasticity within the CNS. However, due to the subjective nature of PL experiences, there was no definitive way to assess PL experiences and we had to rely on patients' direct reports about their PL experiences. Here, we were able to obtain patients' indirect responses to PL experiences, for a more objective evaluation. First, we conducted a study with normals and 19 non-PL patients experiencing pathological pain in one hand. We took digital photographs of their affected and unaffected hands, altered the sizes of the images digitally, and then asked each subject to choose the image that most closely matched the actual size of their own hands (from a series of images presented on a video screen). Subjective size perceptions of the hands were homologous, regardless of the pathological condition of one hand (Pearson's correlation: \(p<0.0001\), \(R^2=0.78\); Figure A). Next, we used the same method for 9 patients with a phantom hand. The intact hand size perception was linearly correlated with phantom hand size perception (Linear regression analysis: \(p<0.03\), \(R^2=0.53\); Figure B). Thus, without requiring a subjective description about PL, the patients' evaluation of the intact hand size precisely but indirectly indicated whether the PL was perceived to be telescoped, normal or swollen. More objective evaluation of PL phenomenon, proposed here, would be a clue to disentangle the neural mechanisms involved.


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A Randomized Controlled Evaluation of a New Muscle Pain Detection Device (MPDD) to Diagnose Muscle Pain as the Source of Back and/or Neck Pain in Patients

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Introduction: Manual pressure (MP) to identify Trigger Points (TrPs) by determining low pressure pain threshold has low inter-rater reliability and may lack validity since it is done on inactive muscles. Muscle pain is generally experienced with activity. To elicit a muscle contraction and mimic movement that “causes” pain, a Muscle Pain Detection Device (MPDD) has been developed. A selected muscle is stimulated and painful muscles are precisely detected, allowing distinctions between primary and referred muscle pain [in our nomenclature, Muscle Pain Amenable to Injection vs. TrPs] as well as distinguishing other functional muscle pain thought to cause myofascial pain syndrome. MPDD could provide a valid, reliable assessment of muscle pain which is frequently ignored/mistreated.

Methods: An IRB approved double-blind, randomized controlled study of the MPDD (20 patients) vs. MP (20 patients) control to identify which muscle(s) was the source of pain in 40 subjects presenting to the NYU Pain Management Center with a minimum 3 month history of back pain. Patients were unaware of their diagnostic group. Subjects were injected in 1-3 sites identified via MP or MPDD by a separate physician blinded from the method of detection. Prior to, and following treatment at one week and one month, the patients are given a physical exam and administered Oswestry and VAS pain questionnaires by a blinded evaluator.

Results: The MPDD group reported statistically significant improvement in pain, mood and Oswestry scores at 1 week and one month (P < 0.001 - 0.004). The control reported no statistical improvements except for the Oswestry scores at 1 week. Moreover, the MPDD group reported 82.5% pain relief at 1 month, compared to 53.2% in the control (P < 0.001).

Conclusion: Using the MPDD appears to be more valid and reliable than palpation to identify muscles causing regional pain that could benefit from muscle injections.

References: none

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Muscles as a Treatable Pain Source in Patients with Failed Back Surgery Syndrome

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Introduction: Failed Back Surgery Syndrome (FBSS) is broadly defined as persistence of chronic back/leg pain after surgery. Of patients undergoing spine surgery for the relief of back pain, 40-51% are unsuccessful with an annual incidence of 80,000 FBSS/year nationally. From 1990-2006, the incidence of lumbar fusion surgeries rose 400%. Based on a 2008 literature review from The American Journal of Medicine, no controlled studies/accepted treatment guidelines for FBSS exist. Current treatment methods include medication, physical therapy, additional surgery, and spinal cord stimulation. In the majority of cases, care is palliative. Of those treatment modalities, spinal cord stimulators and additional surgery average 50% pain reduction in 37.5% and 11.5% of patients, respectively. As nearly 90% of the LS spine MRIs are read as abnormal prior to surgery, it is no wonder the presence of abnormalities on imaging post-operatively would justify further interventions to correct the putative pain generator.

Muscles as a primary source of pain are generally overlooked in published guidelines for back pain evaluation/treatment and in the pain management community standard of care.

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Results: 13 patients reported at least an 85% pain and depression reduction on the last day of treatment, with a 64% reduction in 11 patients at an averaged 5 month follow-up. Conclusion: Muscles as a treatable pain source are overlooked in a growing, poorly treated population of chronic pain patients. Our results suggest proper muscle evaluation and treatment protocols may offer significant, lasting relief to FBSS patients.


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Pilot Study: Effectiveness & Safety of Non-Surgical Spinal Decompression

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Introduction: Back pain is one of the most frequent reasons that patients visit primary care physicians, a common reason for time taken off from work or short-term disability, the fifth most frequent reason for hospital admission, and one of the top five reasons for surgery. Methods: The protocol used to recruit subjects received IRB approval prior to enrolling the first subject. 20 patients with chronic LBP based on diagnoses of musculoskeletal or mechanical LBP, herniated discs, bulging or protruding discs, degenerative disc, pain from failed back surgery (> 6 mos), posterior facet syndrome or sciatica underwent a series of 20 DRX treatments (28 mins each) for 6 wks with 5 sessions the 1st wk tapering to 2 session/wk. The multimodal protocol included ice after DRX sessions, lumbar stretching exercises, and adjunct analgesics PRN. Assessments of pain, analgesic use, functionality, satisfaction, ADL and safety were collected. Results: 18 evaluable subjects had a change in mean VRS pain score from 6.4
(n=18) (0=no pain 10=worst pain) at baseline that decreased to 3.1 at wk 2 (n=18, p<0.001) and 0.8 at wk 6 (n=17, p<0.001). 16 out of 18 (88.9%) of the patients reported an improvement in pain. Oswestry Disability Index (ODI) score documented improved function in ADL (23.7 improving to 5.5, p<0.001). On a 0-10 scale, patients rated DRX9000™ treatment 8.1. No patient required additional invasive therapies. No adverse events related to DRX9000 treatment occurred. Conclusion: Overall, patients' pain improved after DRX treatment, requiring fewer analgesics, with better function. There were no safety issues identified with the multimodal treatment routine. Non-treatment or control groups were not included making efficacy outcome versus placebo or spontaneous recovery difficult to determine. Randomized double-blinded or comparative long-term outcome trials are needed to further prove the efficacy of the DRX9000 for the routine treatment of chronic LBP.

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A Biopsychosocial Approach to Pain Management

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Chronic pain effects between 11-44% of adults in North America and involves significant financial and social costs. Pharmacologic interventions, such as non-steroidal anti-inflammatory drugs, muscle relaxants and opioids, are first line interventions. Medications can be effective for acute pain, but are often partially effective for moderate to severe chronic pain, and may have a plethora of side effects. A multidisciplinary approach is often necessary for complicated and chronic pain syndromes. We reviewed the literature to determine the level of evidence for psychosocial techniques alone or in combination with pharmacological interventions in the treatment of pain. Exercise, biofeedback, relaxation techniques, various psychotherapies and other modalities used as pain reduction techniques were reviewed. The strongest evidence favors a comprehensive approach to pain management, particularly with Cognitive Behavioral Therapy (CBT). CBT has been shown to improve mood, decrease pain, improve fatigue and sleeplessness, as well as increase physical functioning and stress management. CBT helps patients examine their maladaptive cognitions and behaviors and develop appropriate coping skills. Treatment of patients' co-morbid medical and psychiatric disorders is crucial to success in treating pain, as anxiety and depression have been shown to exacerbate pain syndromes. Combinations of education, Operant Behavioral Therapy (OBT), self hypnosis and exercise are techniques with evidence of efficacy. OBT uses conditioning of behaviors through positive and negative reinforcement. OBT and CBT focus on factors that exacerbate and maintain suffering in chronic pain. The strength of the alliance between patient and provider is associated with improvements in pain. The evidence for psychosocial interventions are similar to that of a pharmacological-only approach to pain. In conclusion, psychosocial treatments combined with pharmacotherapy are effective in treating chronic pain, and in particular, CBT. More research is needed to allow for more specific recommendations for various chronic pain syndromes.


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Pain Control During Wound Care for Combat-Related Burn Injuries Using Custom Articulated Arm Mounted Virtual Reality Goggles
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Introduction: We describe the first two cases where virtual reality was added to pain medications to reduce excessive pain during wound care of combat-related burn injuries. Results: Patient 1 suffered 3rd degree burns on 32% of his body, including his right hand, during a roadside bomb attack. The nurse administered wound care to half of the right hand during VR and the other half of the same hand during no VR (treatment order randomized). using a unique custom articulated arm mounted VR goggle system. Three 0-10 visual analog scale (VAS) pain scores for each of the two treatment conditions served as the primary variables. The patient reported less pain when distracted with VR (e.g., "time spent thinking about pain" dropped from 100% during no VR to 15% during VR, "pain unpleasantness" ratings dropped from “moderate” (6/10) to “mild” (4/10). Wound care during VR was "pretty fun" (8/10) vs. "no fun at all" (0/10) during no VR. Patient 1 reported no reduction in worst pain during VR. Patient 2 suffered 2nd and 3rd degree burns when his vehicle was hit by a grenade. During his wound care debridement, "time spent thinking about pain" was 100% (all the time) with no VR and 0 (no time) during VR. His "pain unpleasantness" ratings dropped from "severe" (7/10) to "none". Worst pain dropped from "severe" (8/10) to mild pain (2/10). He also endorsed that fun increased from "no fun at all" (0/10) with no VR to "extremely fun" (10/10) during VR. Conclusions: Although preliminary, using a within-subjects experimental design, the present study provided evidence that immersive VR can be an effective adjunctive non-pharmacologic analgesic for reducing cognitive pain and the sensory component of pain of soldiers during wound care of combat-related burn. These results are similar to findings in civilian burn patients (1).


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Successful Treatment of Co-morbid Chronic Pain and Major Depression with Eclectic/Integrative Psychotherapy and Pharmacotherapy: A Case Report
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Patients with co-occurring chronic pain and depression are common and often challenging to treat. Chronic pain is a disorder with multi-factorial origins, which include the original physical injury, but is also associated with abuse, “victimization”, childhood neglect and a range of psychosocial stressors. Various medications, such as anti-depressants, anti-epileptics, non-steroidal anti-inflammatories, muscle relaxants and opioids, are commonly used as first line interventions. Medications alone can be effective, but a multidisciplinary approach which includes psychotherapy is often necessary. Cognitive Behavioral Therapy (CBT) has been shown to improve mood, decrease pain, improve fatigue and insomnia, as well as increase physical functioning and stress management. Deconstructive Dynamic Psychotherapy (DDP, Gregory et. al.) has shown to be an effective treatment for the core symptoms of borderline personality disorder (BPD). We suggest in this article that similar “core” symptoms in BPD can also arise in patients
who are attempting to cope with chronic pain, including unstable self image, feelings of emptiness, fear of abandonment, intense interpersonal relationships, and reactivity of mood leading to episodes of depression, anxiety and possibly intense anger. We present a case of a 54 year old female patient with comorbid chronic pain and depression who improved significantly after treatment in the outpatient psychiatry clinic with medication management and eclectic psychotherapy. Combined CBT, DDP and supportive therapy techniques were utilized in this patient's care. The case history and treatment, including specific psychotherapeutic interventions, are described.


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A Longitudinal Study of the Efficacy of an Interdisciplinary Pain Rehabilitation Program with Opioid Withdrawal for Patients with Fibromyalgia: Comparison of Treatment Outcomes Based on Opioid Use Status at Admission

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Introduction: Use of opioids for chronic noncancer pain is controversial and the longitudinal efficacy of interdisciplinary pain rehabilitation programs (IPRPs) that incorporate opioid withdrawal requires further investigation [1, 2]. We test the hypothesis that patients with fibromyalgia and longstanding opioid use who undergo opioid withdrawal in the course of rehabilitative treatment will experience significant and sustained improvement in pain and functioning similar to patients who were not taking opioids. Methods: A longitudinal design study compared 80 consecutive patients with fibromyalgia admitted to the Mayo Clinic Pain Rehabilitation Center at admission, discharge and 6-months posttreatment by opioid status at admission. Measures of pain severity, depression, psychosocial functioning, health status, and pain catastrophizing were used to assess between- and within-group differences. Treatment involved a 3-week interdisciplinary pain rehabilitation program focused on functional restoration. This study was approved by the Mayo Foundation Institutional Review Board. Results: Of the patients with fibromyalgia, 41.3% were taking opioids daily at admission. The mean daily morphine equivalence was 100.0 mg/day (SD=134 mg). Mean years of opioid therapy was 5.1 years (SD=4.9). The majority of patients (90%) completed rehabilitation and 71% of patients who completed the program returned questionnaires six months posttreatment. On admission, fibromyalgia patients taking opioids reported significantly greater pain catastrophizing (P=.008) than the non-opioid group but both groups reported significant pain, poor functioning and high depression. Significant improvement was found on all outcome variables following treatment (P<.001) and 6-months posttreatment (P<.001) regardless of opioid status at admission. There were no differences between the opioid and non-opioid groups upon discharge from the program or at 6-months following treatment. Conclusion: Patients with fibromyalgia, including those with long history of opioid use, can experience significant and sustained improvement in pain severity and functioning following interdisciplinary rehabilitative treatment that incorporates opioid withdrawal.

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Repetitive Transcranial Magnetic Stimulation Relieved Thalamic Pain Due to Stroke in 10 Drug Resistant Patients

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Objective: Repetitive transcranial magnetic stimulation (rTMS) of the cerebral motor cortex has been studied as a non-invasive tool used to produce analgesic effects in chronic pain syndromes(1). The efficacy of rTMS was evaluated in patients with chronic pain.

Methods: Ten patients suffering from intractable pain secondary to thalamic stroke underwent a trial therapy of rTMS. The patients, 8 males and 2 females with an average age of 66.8, were applied a figure-of-8 coil over the motor cortex for 10Hz stimulations (lasting 5 seconds) administered 20 times at 30 second intervals daily for 10 days. The set intensity of the stimulus corresponded to 90% of the motor threshold of the adductor pollicis of the painful side. Pain was scored using the visual analogue scale (VAS) before, after 10 day treatment and 1 month following the treatment.

Results: At baseline, the average VAS was 8 for all patients. After the 10 day treatment the VAS was 3 and one month after the VAS was 4. The percent of pain reduction was 60% at the conclusion of the treatment sessions and 50% a month following the treatment. There were only two minor and transient side effects that were reported during the stimulation period, which were headache and local scalp irritation. The results of the study were consistent with descending modulation within the brainstem, triggered by the motor corticothalamic output confirming that motor cortex rTMS was able to induce analgesic effects(2).

Conclusion: These preliminary results were encouraging and should suggest the possible use of rTMS as a treatment of intractable chronic pain. Further longer trials are justified.


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Translational

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Apoptosis of the GABAergic Interneurons in the Dorsal Horn of the Chronic Post-Ischemic Pain Model
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Introduction: It was well known that the GABAergic inhibitory interneuronal system has an important role in the modulation of the noxious stimulation transmitted from the primary afferent input. Some studies revealed that the role of GABA inhibitory interneuronal system in the modulation of the pain transmission and the changes of the GABAergic interneurons in the neuropathic pain. Now this study was focused on the apoptosis of the GABAergic interneuron that assumed to attribute to the neuropathic pain.

Materials and Methods: Male Sprague-Dawley rats weighing 290-310g were used. CPIP model was made by placing a tourniquet on the left hindpaw of rats. The tourniquet maintained for 3 hours, then released to allow reperfusion. Thirty minutes before reperfusion, N-acetyl-L-cystein (NAC group) or normal saline (control group) was injected. Mechanical allodynia and cold allodynia were measured. Also, the release of cytochrome c into the cytosol was measured through the western blot or immunohistochemistry in the spinal cord.

Results: Mechanical and cold allodynia was developed and the number of GABA interneuron was reduced in the control group. The cytochrome c of the GABA interneuron was released into the cytosol and the amount release was reduced with the NAC administration.

Conclusions: In a CPIP neuropathic pain model, the GABA interneuron in the Rexed laminae ±, II showed releases of the cytochrome c into the cytosol that is known as the process of the apoptosis and the N-acetyl-L-cystein was able to prevent the process.


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GTP Cyclohydrolase Polymorphisms Are Associated with Individual Differences in Capsaicin Pain Ratings
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Introduction: Though it is clear that genomic variability plays an integral role in accounting for individual differences in pain sensibility, controversy exists over which genes are involved. In this study, we evaluated single nucleotide polymorphisms (SNP) in the GTP cyclohydrolase (GCH1) gene for their association with ratings of pain produced by topical capsaicin. Materials and Methods: This study involved human subject volunteers and was IRB-approved. We analyzed the association of five GCH1 SNPs with ratings of pain induced by high-concentration topical capsaicin applied to the skin of 39 healthy subjects.

Results: The uncommon variants of multiple GCH1 polymorphisms were associated with lower capsaicin pain ratings. When combined, three of the five GCH1 SNPs accounted for 35% of the inter-individual variance in pain ratings.

Conclusions: We conclude that SNPs of the GCH1 gene profoundly affect ratings of pain induced by capsaicin. Given the variability in prior findings, the downstream effects of GCH1 on pain responses may vary across pain induction modalities.

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Prevention and Reversal of Morphine Tolerance by the Analgesic Neurosteroid Alphadolone
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Introduction: Alfadolone is a neurosteroid that causes antinociception in rats and analgesia in human subjects without sedation by interaction with spinal cord GABA_ receptors. This study investigated whether alphadolone could affect morphine tolerance. Materials and Methods: Morphine tolerance was induced in rats with subcutaneous (sc) sustained-release morphine emulsion (M-SR; 125 mg/kg/day). Tolerance was assessed by a blinded observer using tail flick latency (TFL) response to intraperitoneal (ip) injection of immediate release morphine (M-IR 6.25 mg/kg) given before and after this treatment. 55 rats, given M-SR as above were divided into three groups: group A received 1.0 ml sc emulsion containing vehicle with no drug added; groups B and C received alphadolone (250 mg/kg alphadolone acetate) and alfaxalone (80 mg/kg alfaxalone) respectively as sc emulsions injected at the same time as the M-SR. Results: The TFL response [%MPE] to M-IR was reduced from 89.6 ± 2.5 pre-treatment to 20.3 ± 4.8 after M-SR treatment (mean ± SEM; p < 0.001, one way ANOVA) [figure 1]. Coadministration of alphadolone sustained release emulsion (250 mg/kg/day) with the M-SR caused no sedation and prevented the occurrence of morphine tolerance. The TFL response to M-IR (6.25 mg/kg) given to morphine tolerant rats was 29 ± 8 %MPE whereas the TFL was 78.6 ± 9.8 %MPE when immediate release alphadolone (10 mg/kg ip) was injected at the same time as M-IR to tolerant rats (p < 0.001 one way ANOVA) [figure 1]. Alfaxalone treatment caused sedation and no effects on morphine tolerance. Conclusions: We conclude that the analgesic neurosteroid alphadolone can prevent morphine tolerance and that it can also restore normal antinociceptive responses to morphine in rats with established morphine tolerance. The lack of sedation suggests clinical utility in human pain states requiring morphine.


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CNSB004 [leconotide] Causes Antinociception Without Side Effects When Given Intravenously: A Comparison with Ziconotide in a Rat Model of Diabetic Neuropathic Pain

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Introduction: Leconotide [CVID, AM336, CNSB004] is an omega conopeptide that selectively blocks voltage sensitive calcium channels. It was developed for intrathecal applications like ziconotide. Intravenous administration [iv] of leconotide is less toxic than ziconotide¹. This study compared the antinociceptive potencies of leconotide and ziconotide given iv alone and in combinations with a KCNQ potassium channel opener flupirtine [intraperitoneally; ip], in a rat model of diabetic neuropathic pain.

Methods: 322 rats were given streptozotocin [STZ; 150mg/kg ip] to cause diabetic neuropathy and hyperalgesia². All subsequent experiments were performed on these rats with ≥30% hyperalgesia to noxious heat³ measured by an observer unaware of the treatment given to each rat. 112 such rats were given injections of each conopeptide iv alone and in combinations with flupirtine ip as well as saline controls and placed in an open field activity monitor to define the maximum non-sedating doses and dose combinations. A range of doses up to the maximum non-sedating doses and dose combinations were then given to 210 rats with hyperalgesia. Dose response and 3D surface plots were constructed.

Results: The maximum non-sedating dose of leconotide [2 mg/kg iv] caused 51.7% reversal of hyperalgesia compared with 0.4% reversal for the highest non-sedating dose of ziconotide [0.02 mg/kg iv; p<0.001, one-way ANOVA; figure 1]. Leconotide caused dose related antinociceptive effects that were potentiated by coadministration with flupirtine which was ineffective when given alone in this model [figure 1]. Leconotide [0.02 mg/kg] and flupirtine [2.5 mg/kg] given alone caused 25.3 ± 7.6 and 8 ± 8% reversal of hyperalgesia when given alone but in combination they caused 59.5 ± 11.2% reversal of hyperalgesia [p<0.01; one-way ANOVA]. Conclusion: These results suggest that CNSB004 [leconotide] could have wider clinical applications than ziconotide because antinociception can be achieved with leconotide without the necessity for intrathecal administration.

Funding: All funding for this project was provided by CNSBio Pty Ltd who have the intellectual property and commercialisation rights to leconotide.

182 Antinociceptive Effects of the Neurosteroid Analgesic Alfadolone in Carrageenan Induced Paw Inflammation in Rats
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Introduction: GABA attenuates the hyperalgesic response produced by carrageenan injection in the hind paw in rats. Therefore positive modulation of GABAₐ receptors may also reverse hyperalgesia in carrageenan-induced inflammation. Alfadolone is a pregnanedione neurosteroid analgesic that has been shown to produce antinociceptive effects by interaction with GABAₐ receptors in the spinal cord. This study investigated the antinociceptive effects of alfadolone injected intraperitoneally (ip) alone and in combinations with three opioids (fentanyl, morphine and oxycodone) using a rat inflammatory pain model.

Methods: Maximum non-sedating doses of each drug were determined using a rotarod and open field activity monitor. Carrageenan was injected into the hind paw of rats to cause inflammation and then nociceptive thresholds were measured using paw pressure withdrawal latencies as described by Randall and Sellito. Dose response curves were plotted for the antinociceptive effects of non-sedating doses of alfadolone and each opioid given alone and in combinations. Results: The maximum non-sedating doses of fentanyl, morphine, oxycodone and alfadolone were 20μg, 3.2mg, 1.0mg and 10mg ip respectively. Alfadolone caused dose-dependent antinociception when given alone, the highest non-sedating dose (10mg/kg) causing 60% reversal of carrageenan-induced hyperalgesia [figure 1]. Each opioid also caused dose-dependent antinociceptive effects when given alone. The co-administration of alfadolone did not increase the antinociceptive effects of morphine and oxycodone. By contrast, the combination of fentanyl with alfadolone caused greater antinociceptive effects than by the administration of either drug alone. Fentanyl 20μg alone caused a 56.5% effect but there was 100% reversal of carrageenan-induced hyperalgesia when fentanyl was administered with 0.1mg/kg alfadolone, a dose that was ineffective when given alone. Conclusion: We conclude that alfadolone is an effective antinociceptive agent in carrageenan induced paw inflammation. Furthermore coadministration of alfadolone with fentanyl, but not morphine or oxycodone leads to a marked increase in the antinociception produced.

Expression of Interleukin-8 in DRG and Dorsal Horn in a Neuropathic Pain Model Induced by Lumbar Disc Herniation

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Participation of chemokines in painful degenerative disc disease and pain modulation has been demonstrated. The aim of this study is to investigate the pain-related behaviors and the sequential changes of interleukin-8(IL-8) expression in the dorsal root ganglion (DRG) and dorsal horn (DH) in a rat model of lumbar disc herniation. SD rats (male, 200-250g, n=90) were used for rat model of lumbar disc herniation. After laminectomy, autologous nucleus pulposus was implanted on the left L5 nerve root proximal to the DRG without mechanical compression. Mechanical allodynia and thermal hyperalgesia were assessed. The plantar surfaces of both hindpaw were tested on 2 days before surgery, and on 1, 5, 10, 20, 30 and 60 days postoperatively. After extraction of total RNA and synthesis of cDNA from L5 DRG and DH tissues, real time PCR assay was performed. Mechanical allodynia in ipsilateral hindpaw developed 1 day after surgery and lasted until 60 days. Five days after surgery, thermal hyperalgesia was developed and peaked at 10 days postoperative on the ipsilateral hindpaw (p<0.01) and then gradually recovered after 50 days (p<0.05). The mRNA level of IL-8 in DRG was...
peaked at 10 days after surgery and then gradually returned to basal level until 30 days (p<0.05). The expression of IL-8 in the spinal DH was not significantly increased until 60 days after surgery. Lumbar disc herniation induces predominantly mechanical allodynia rather than thermal hyperalgesia and upregulates the expression of IL-8 in the DRG, followed by increase in DH. In comparison to the other substances upregulated earlier to neuropathic pain state, upregulation of IL-8 was delayed relatively. It would reflect that IL-8 is associated with maintaining chronic radicular neuropathic pain induced by lumbar disc herniation.


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Antinociceptive Effects of CNSB002, a Novel Sodium Channel Blocker: Investigations of Drug Effects When Given Alone and in Combinations with Morphine in Rat Models of Inflammatory and Neuropathic Pain

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Introduction: CNSB002 [1 - (2 - (4-chlorophenyl) -2- hydroxy) ethyl -4- (3, 5-bis(1, 1- dimethyl) -4- hydroxyphenyl) methylpiperazine] is a novel agent incorporating antioxidant and Na+ channel blocking properties¹². This study set out to characterise any antinociception caused by this compound and also investigate possible interactions with morphine. Methods: Studies were performed on 508 male Wistar rats. The maximum non-sedating doses were determined for CNSB002 and morphine given alone and in combinations intraperitoneally (ip) using an open field activity monitor. Dose response curves for non-sedating doses of both drugs given alone and in combinations were constructed for antinociceptive effects using paw withdrawal from noxious heat in two models of hyperalgesia: carrageenan-induced paw inflammation and streptozotocin–induced diabetic neuropathy⁴. Results: The maximum non-sedating dose of morphine was 3.2 mg/kg and for CNSB002 10.0 mg/kg. The maximum non-sedating dose combination was 5.0 mg/kg CNSB002 with morphine 3.2 mg/kg. CNSB002 given alone caused dose-related antinociceptive effects in carrageenan-induced paw inflammation (35.0 ± 10.3 % reversal)
of hyperalgesia; 10.0 mg/kg) and diabetic neuropathy (26.7 ± 6.0 % reversal of hyperalgesia; 10.0 mg/kg) [figure 1]. Morphine (3.2 mg/kg) caused 23.5 ± 7.6 % and 29.2 ± 4.1 % reversal of hyperalgesia in the inflammatory and neuropathic models respectively. When administered in combination with 5 mg/kg CNSB002, morphine (3.2 mg/kg) antinociception increased significantly to 72.8 ± 11.9 % in the inflammatory pain model and 53.3 ± 6.1 % in the diabetic neuropathy model (p<0.01; one way ANOVA). Conclusions: The sodium-channel blocker CNSB002 causes antinociception in rat models of inflammatory and neuropathic pain. The maximum antinociceptive effect achievable with non-sedating doses may be increased significantly when the drug is used in combination with morphine. The antinociceptive effect of the combination also exceeds the maximum antinociceptive effect that could be achieved with morphine given alone at the highest non-sedating dose.


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The Impact of CYP2D6 Genetic Polymorphisms, Smoking and Other Factors on Postoperative Pain
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Background: Several reports have shown that CYP2D6 appears to act at the critical step of the morphine biosynthetic pathway in various tissues such as: brain, liver and human peripheral monocytes (1). Other studies have observed a relationship between smoking and a decrease in analgesic efficacy in the postoperative period (2). This present study assessed the association between CYP2D6 genetic polymorphisms, smoking, other variables, and pain response after surgery.

Methods: IRB approval and signed informed consent were obtained. Pain scores in PACU, ethnic origin, age, BMI, smoking, surgical duration, procedure class and other variables were evaluated in female patients undergoing a standardized general anesthetic. DNA was extracted from blood in all patients and was genotyped by the Amplichip® (Roche) to determine the specific CYP2D6 genotypes.

Results: Two hundred thirty six patients were enrolled. After adjusting for all variables, patients who were poor metabolizers (PM) had significantly higher pain scores than intermediate and extensive metabolizers (IM and EM) (p-values 0.004 and 0.012 respectively). The pain scores in smoking patients were higher than in the non-smoking patients (P=0.034). A positive correlation between pain scores and surgical time was also noted (regression coefficient beta ± SE is 0.007± 0.003, p=0.005).

Discussion: Recently, the presence of an endogenous morphine pathway and its relationship to pain sensitivity has drawn the attention of researchers (1). It appears that endogenous morphine compounds are released in response to surgical, pathogenic and psychological stress. Other studies have reported that exposure to cigarette smoke correlates with increased pain sensitivity in human subjects (3). Our current study suggests that poor metabolizers of CYP2D6, which may have an impact on endogenous morphine production, cigarette smoking and longer surgical duration are three INDEPENDENT factors that are associated with increased pain scores in postoperative patients.


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Novel Opioid-Nicotinic Hybrid Drug for Pain
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Introduction: Adequate treatment of chronic pain remains a critical health issue. Currently available drugs have limitations in regards to side effects and/or limited efficacy, especially for neuropathic pain states. We have been examining the effect of combining drugs with known analgesic activities in an effort to produce compound(s) with potentially synergistic analgesic activity, efficacy in mixed pain states and reduced side effects. In the present study we have synthesized a hybrid single entity drug consisting of an opioid (codeine) and a nicotinic agonist (S-nornicotine). So called hybrid drugs have both pharmacodynamic and pharmacokinetic advantages.

Objective: A novel hybrid drug, consisting of
codeine and S-nornicotine (1:1) connected via a covalent chemical linker, as well as codeine and S-nornicotine alone were characterized in rodent models of nociceptive (tail-flick test) and neuropathic (chronic constriction nerve injury, CCI) pain [Bennet and Xie, 1988]. Method: Drugs were administered via the oral route (PO) in Sprague-Dawley male rats. Antinociception and antihyperalgesia were assessed as an increase in tail-flick latency and paw-withdrawal threshold [Randal and Selitto, 1957] in uninjured and CCI rats, respectively. Results: The antihyperalgesic potency of the hybrid drug was significantly greater compared to its constituents, codeine and S-nornicotine alone [ED50 = 3.5 (2.7-4.7), 13.5 (7.8-23.4), 16.9 (7.2-39.5) mg/kg, respectively; CCI]. Similar findings were observed regarding the antinociceptive effect of the hybrid drug [ED50 = 8.9 (6.0-13.0), 18.6 (9.3-30.1), 18.6 (11.0-31.4) mg/kg, respectively; the tail-flick test]. No gross behavioral or motor effects were observed at the highest dose of hybrid-drug tested. Conclusion: Enhanced and prolonged responses were produced by a codeine-S-nornicotine hybrid drug in rodent models of nociceptive and neuropathic pain. These preclinical findings suggest that an opioid-nicotinic hybrid drug may have efficacy and an acceptable therapeutic index for treatment of mixed pain states. References: Bennett G, Xie Y. Pain 1988; 33:87-107 Randal I, Selitto J. Arch Int Pharmacody Ther 1957; 111:409-419

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Pharmacological

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Serum Levels of Opioids in Patients with Sickle Cell Disease Treated in the Day Unit

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Introduction: A major issue in the management of sickle cell painful crises in the emergency room is waiting several hours for treatment of pain. An advantage of the sickle cell day unit is the prompt and aggressive treatment of pain. Patients in the day unit receive large amounts of opioids over a short period. There has been concern that patients leaving the day unit may have serum opioid levels that are within the toxic range. In order to clarify this issue, we determined the serum opioid levels of a convenient sample of patients before discharge from the unit.

Methods: After thorough assessment of admitted patients, treatment was initiated with intravenous hydration and a loading dose of hydromorphone followed by assessment within 30 minutes. After the initial assessment patients were medicated with 25-75% of the loading dose of hydromorphone depending on the level of pain relief and sedation. Vital signs were assessed every 30 minutes. Serum levels of hydromorphone were drawn 15 minutes after the last dose and were determined by high pressure liquid chromatography/tandem mass spectrometry.

Results: The serum level of hydromorphone ranged from 11 to 104 ng/ml with mean ± SD = 45.8 ± 32.70, N = 6 (toxic range >49 ng/ml). The total amount of hydromorphone given varied between 14 and 64mg with a mean ± SD of 39.3 ± 18.89. Treated patients showed no signs of respiratory depression, sedation, or changes in the mental status.

Conclusion: The data indicate that the serum levels of hydromorphone were within an acceptable safe range. Moreover a high level of serum hydromorphone in the absence of side effects indicates tolerance to this opioid. Monitoring serum levels of opioids may be of value in documenting tolerance in certain patients and confirming the safety of high serum opioid levels in certain individuals.


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Do Transdermal Opioids Reduce Healthcare Use in a Rural Pain Population?

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Introduction: Persistent (non cancer) pain is on the increase as the population grows older and degenerative musculoskeletal changes increase. This burden of pain must be effectively treated to enable physical independence to continue. Healthcare access in rural areas is limited by resources and distance. The aim of this pilot study is to compare the healthcare use of subjects with transdermal (TD) or oral controlled release (OCR) opioids for persistent (non cancer) pain. Opioids are increasingly being used for the treatment of disabling pain(1), as their long term safety profile is predictable. The usual choice is from a wide variety of oral controlled release preparations. Since 2006 transdermal preparations(2,3) have become more widely available in Australia. Many doctors and patients find them a satisfactory alternative when problems arise with oral opioid dosing(4). This study aims to find out if transdermal opioids should have a wider role in the treatment of persistent pain, particularly in rural areas like North West Tasmania.

Materials and Methods: Approval was obtained from the Tasmanian Scientific Research Advisory Committee (#H0009695) to recruit subjects from medical practices and hospital clinics in North West Tasmania. The number, type, and purpose of all health care contacts, together with the time and cost (including travel) associated, were recorded in a monthly diary. Data collected was analysed using Stata 10 statistical package(5). Results: The initial data (152 subjects - 656 subject...
months) shows little difference in healthcare use between the two opioid groups (TD v OCR), with a wide variation in time and cost components due to distance travelled. Conclusion: Persistent pain is a multifactorial chronic disease state with many reasons for seeking healthcare. This initial data from North West Tasmania indicates that subjects using transdermal or oral controlled release opioids are equivalent in their healthcare use.


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190 Ketamine PCA for Managing Opioid-Induced Hyperalgesia
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Introduction: Opioids have become a cornerstone therapy for treating severe acute and chronic pain. The use of opioids may act as a double-edged sword by developing analgesia or opioid induced hyperalgesia (OIH). There is increasing evidence suggesting that the activation of the N-methyl-D-aspartate (NMDA) receptors is one of the underlying mechanisms for OIH. Thus, Ketamine which is a noncompetitive NMDA receptor antagonist can be beneficial for the use of reducing hyperalgesia in chronic opioid-treated patients. A Case Description: A 34-year-old African-American female with a longstanding history of sickle cell disease continues to experience excruciating, intractable pain despite high consumption of opioids. Her home pain regimen includes Oxycontin 240 mg every 8 hours, Fentanyl patch 225 mcg every 72 hours, and a patient controlled infusion of Fentanyl through her Port-A Cath (25 mcg per hour continuously/ bolus of 120 mcg every 15 minutes). Patient had developed profound sedation and respiratory depression. Because of these medical complications and patient's worsening pain despite escalation of opioids, we weaned patient off of her opioids by using Ketamine PCA.

Results: The first four days, patient was placed on Ketamine 10mg bolus with a lock out every 20 minutes. On the fifth day it was 10mg with a 30 minute lockout, and the subsequent day the lock out was every hour. By the seventh day, Ketamine was discontinued, and the patient was off all opioids. Ketamine yielded reduction in doses of opioids and subjectively improved pain control. Per medical staff, patient appeared to be more alert and interactive. Discussion/Conclusion: We report successful treatment of opioid-resistant pain with the administration of Ketamine. Paradoxical abnormal pain can be alleviated with Ketamine, which offers a promising therapeutic option in the treatment of opioid induced hyperalgesia. Well-controlled studies are needed to examine the efficacy and safety of this medication.


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Should Remifentanil Be Avoided in Opioid Dependent Patients?
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Intraoperative remifentanil has been reported to precipitate acute postoperative tolerance and hyperalgesia in opioid naïve patients, however its effects in patients with chronic pain is unclear[1-3]. We observed clinically significant acute opioid tolerance and hyperalgesia which was produced by the use of intraoperative remifentanil in a chronic pain patient. Case Report. A 39-year-old woman with chronic neck pain and spinal stenosis presented for elective anterior cervical discectomy with fusion. Her pain was controlled with combination of oxycodone, extended release oxycodone, and acetaminophen. After smooth intravenous induction with propofol she was intubated. Her chosen anesthetics included intravenous fentanyl for induction and emergence, a remifentanil drip 0.1 mcg/kg/min and propofol drip intraoperatively, with consideration of evoked muscle potential testing during the procedure and family history of malignant hyperthermia in a first degree relative. There was an uneventful intraoperative course. She was extubated in the operating room, and transferred to the post-anesthesia care unit (PACU). On arrival to the PACU she was screaming, complaining of intolerable pain. Rescue analgesia was provided with multiple doses of hydromorphone, however effective pain control was difficult to establish. On the next day her pain score was 5 out of 10, which was compatible with her pre-admission pain level. She was discharged from the hospital in the morning of postoperative day two with her pain being adequately controlled with her same pre-admission medications and dosages. This case demonstrates that given its short analgesic duration and risk of hyperalgesia, remifentanil should be avoided in this and probably in most opioid dependent patients. Its use may interfere with treatment goals and become a burden to the patient and hospital alike. In the case where remifentanil use could not be avoided, we recommended that a long lasting opioid be added preemptively to help deter the development of acute tolerance and hyperalgesia.


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Determination of the Effective Dose of Alfentanil on Human Experimental Pain Using the Sequential Up-Down Method
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Introduction: Human experimental pain models permit the ethical and controlled study of the response to painful stimuli. The sequential up-down method offers the advantage over traditional dose-response curves in determining the median effective dose (ED50) of analgesics in that many fewer volunteers are needed (1). To test this method, we aimed to determine the median effective dose of alfentanil for male and female volunteers using an intradermal capsaicin pain model. Methods: After IRB approval, two groups (male and female) of volunteers were enrolled in this prospective, randomized, placebo-controlled crossover trial. Following intradermal capsaicin injection into the forearm, each subject underwent 2 intravenous infusions, one alfentanil and one placebo. The effective dose for alfentanil
was defined as the plasma concentration that resulted in at least 30% reduction of pain. In case of effective pain reduction, the next volunteer received a ‘step down' (lower concentration), and for inadequate pain reduction, the next volunteer received a ‘step up' (higher concentration). Based on preclinical studies, the starting plasma concentration was chosen at 37.5 ng/ml and each step adjustment at 12.5 ng/ml. (2) The endpoint of this study was defined as 7 opposite direction step adjustments in each group. Results: 10 females and 17 males were needed to achieve the 7 step adjustments. A statistically significant difference was found in the analgesic requirements between males and females. The median effective dose of alfentanil that produced a 30% reduction in spontaneous pain scores in females was 62.4 ng/ml vs 28.1 ng/ml in males. Conclusion: The Up-down method appears to be an efficient method to estimate the ED50 of alfentanil for experimental pain in fewer then 20 subjects for each gender group studied. Validation of this effective paradigm will enable future studies of analgesics in human experimental pain.

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The Addictive Qualities of Cannabinoid Medication Studied in a Randomized, Controlled, Crossover Trial for Pain
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Objective: Many cannabinoid medications are approved in North America or in Phase III trials, such as Marinol (dronabinol), nabilone, or Sativex. Little is known about their abuse potential when used for pain management. The 49-item Addiction Research Center Inventory (ARCI) is the gold-standard, self-rated measure for determining the abuse liability of substances.[1] Elevated scores on its 5 subscales are highly correlated to the likelihood that a substance will be abused: MBG=morphine effects, euphoria; PCAG=phenobarb/ETOH effects, sedation; LSD= somatic dysphoria; BG=Benzedrine effects, intellectual energy; A=amphetamine effects. We hypothesized that when used for pain, dronabinol has psychoactive effects in a dose response relationship, whose peak effects are comparable to smoking marijuana.

Methods: With IRB/consent approval, this was an RCT of single dose placebo, 10 or 20 mg dronabinol in 30 chronic noncancer pain patients taking opioids, not using marijuana, nor significantly depressed or anxious.[2] Hourly, for 8 hours during 3 monitored sessions subjects completed the ARCI. Comparison sample was the ARCI ratings in a study population with no pain (N=20), monitored every 30 minutes after smoking a 1.99% THC (low) and a 3.51% (high strength) marijuana cigarette.[3]

Analysis was done with repeated measures ANCOVA. Results: Average age=43.5 years, 53% female, 67% had LBP>5 years, baseline pain=6.9/10. The 10 and 20 mg dronabinol doses had significantly elevated scores on 4 subscales vs. placebo over time: MBG, PCAG, BG, A (p<.05). Average daily morphine use, TOTPAR, age, gender, and baseline pain level were not significant covariates. ARCI peak effects at 2 hours were similar to peak effects of smoked marijuana at 30 minutes (p=.80, 10 mg=low, 20 mg=high strength). Conclusions: In pain patients dronabinol has significant abuse liability (patients got stoned) and a projected likelihood of addiction similar to smoking marijuana. These risks must be considered in decisions to prescribe cannabinoids for pain.


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Suboxone for Pain Management in Patients with Gastric Bypass: Two Case Reports

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Introduction: Increased rates of obesity have prompted increased gastric bypass surgeries which typically bypasses the duodenum. Morphine is absorbed in the duodenum, potentially making treatment with morphine ineffective. Other opioids are also thought to have significant absorption in the duodenum. Treating chronic pain patients who have had gastric bypass may therefore be a challenge. Using medications with transdermal or sublingual delivery may significantly improve analgesia. We present two cases in which patients with a history of gastric bypass surgery failed oral and transdermal medications. In both cases, treatment with Suboxone successfully reduced pain.

Materials and Methods: In Case #1, the patient had chronic pelvic pain. She failed numerous opioids, anti-convulsants, anti-depressants and fentanyl patches. Before initiation of Suboxone, her pain level was 8/10 VAS. In Case #2, the patient had a history of pelvic and myofascial pain. She, too, tried and failed numerous medications including opioids, anti-convulsants, fentanyl and lidoderm patches. In this case, the patient responded to pregabalin, baclofen and opioids before her bypass surgery; however, post-operatively, these same medications did not control her pain. She was started on Suboxone.

Results: After starting Suboxone, both patients had rapid improvement in pain control. Over the following 10 months, Patient #1 reported up to a 30% (VAS 5/10) improvement in her pain and continues to be maintained on Suboxone. In Case #2, pain level dropped from 8/10 to 0/10 immediately after initiation. Over the next 10 months, the patient continued to report an increased activity level, participation in ADLs and quality of life.

Conclusion: For patients who have undergone gastric bypass surgery, the ability to adequately absorb oral pain medications may be impaired, leading to inadequate pain control when using oral medications as the primary method of treatment. In these cases, treatment with Suboxone, which is absorbed sublingually, could be considered.


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Opioid Dose Evaluation for Breakthrough Pain and Its Proportionality to the Total Daily Opioid Dose in Cancer Patients with Chronic Opioid Use

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Introduction: Prospective trials evaluated optimal dosing of intravenous morphine and oral transmucosal fentanyl for breakthrough pain treatment but very few have evaluated oxycodone or hydromorphone.

Objective: This retrospective chart review evaluated the dosage of various opioids used to treat breakthrough pain.

Methods: After Institutional Review Board approval, patients admitted to the adult oncology service with an average of 1 to 4 episodes of breakthrough pain daily on chronic opioids were
studied. Patients were excluded for having neuropathic, spasm or bone pain. Outcomes measured included changes in pain score for each episode at the onset of pain, 30 minutes and 2 hours after opioid administration. Episodes treated with < 10%, 10 to 20% and > 20% of the total daily opioid requirement were labeled as group A, B, and C. Results: 859 episodes of breakthrough pain were recorded. Groups A, B, and C received IV opioids and 30 minutes after treatment had decrease in pain scores of 46%, 54.9%, and 47.2%. Pain reductions reported > 2 hours post treatment with IV opioids were 25%, 37.5%, and 29.5% for groups A, B, and C. Groups A, B, and C received oral opioids and 30 minutes after treatment had decrease in pain scores of 41.3%, 43% and 48.3%. Pain reductions reported > 2 hours post treatment with oral opioids were 27%, 36.9%, and 53.2% for groups A, B, and C. Conclusion: Reductions of > 33% in pain scores at 30 minutes post-dose were independent of dosing or route of administration. Successful reductions of > 33% in pain scores at > 2 hours post-dose were dependent on dosing and route of administration. Patients receiving greater then 10 % of their total daily opioid requirement achieved initial and sustained pain reductions of > 33 % for 2 hours using IV and oral routes of administration.


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Extended-Release Tramadol: A Review of Health Outcomes Data
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Objective: To compile patient reported outcomes such as pain, pain-related sleep disturbances and physical functioning on extended-release (ER) tramadol versus placebo. Methods: A literature review was conducted, using PUBMED, to capture original articles published from 1/1997-3/2008. Key study search criteria included: adults 18+ years, chronic pain, and treatment with once-daily extended-release tramadol. Results: Fifteen studies were included for this review. Significant improvements versus placebo, in pain, pain-related sleep disturbances, physical function and joint stiffness, for patients with chronic pain due to osteoarthritis (OA) or low back pain, were reported. In these conditions, clinically meaningful improvements in pain (defined as 30% or 30-mm pain reduction from baseline), pain-related sleep disturbances (defined as ≥ 16-mm sleep improvement from baseline) and physical functioning (defined as at least a 10 points improvement in Western Ontario McMaster Universities [WOMAC] OA Index Physical Functioning subscale) were observed. In patients with chronic pain due to OA, clinically meaningful pain improvement attained from tramadol ER therapy was associated with significant and clinically meaningful improvements in pain-related sleep disturbances and physical functioning. Even modest pain improvement (i.e.15-29% improvement in pain) corresponded to a significant improvement in pain-related sleep disturbances and physical functioning as well. The most commonly reported adverse events were related to gastrointestinal system and central nervous system, however most events were mild to moderate in severity and were resolved during therapy. Conclusion: This compiled outcomes review suggests that the once-daily tramadol ER can be a safe and effective treatment alternative in moderate to moderately-severe chronic persistent pain relative to placebo. Head to head studies with active comparators are needed to demonstrate the potential benefit of once-daily tramadol ER against other persistent pain treatments.
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Long-Term 12-Month Open-Label Safety of Remoxy® in Patients with Moderate-to-Severe Chronic Pain
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Introduction: Pain is undertreated, at least in part because of concerns regarding the misuse and abuse of opioid analgesics. Controlled-release formulations may be manipulated to dose dump the active molecule, resulting in a serious public health problem. Remoxy is a controlled-release oxycodone formulation designed to resist the most common forms of physical and chemical manipulation and extraction. The long-term safety of Remoxy was evaluated over 12 months in an open-label trial.

Materials and Methods: Patients (N=828) with moderate-to-severe chronic pain (low back or hip/knee osteoarthritis) were enrolled and 824 patients received Remoxy doses ranging from 5 to 80 mg BID, titrated as needed. Adverse events were collected, and safety was assessed. This study was approved by an IRB. Results: The number of patients who continued to receive Remoxy at 3, 6, and 12 months was 562, 469, and 381, respectively. Mean exposure time was 220.8 days, mean maximum daily dose was 33.4 mg BID, and mean final daily dose was 32.1 mg BID. The most common adverse events (AEs; ≥10% of patients) were constipation, diarrhea, nausea, vomiting, dizziness, headache, somnolence, and insomnia; 21% of patients discontinued treatment due to AEs. AEs reported most frequently during the first 6 months of treatment were similar to those reported through 12 months. No clinically meaningful effects on vital signs, laboratory tests, physical examinations, or electrocardiograms were observed. Pain intensity was significantly reduced from baseline throughout the 12-month study.

Conclusion: Remoxy was shown to be safe and well-tolerated, and demonstrated a significant reduction in pain intensity associated with its long-term use.


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The Effect of Intravenous Midazolam on Post Traumatic Stress Disorder Development in Burned Soldiers
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Introduction: Midazolam, a short-acting benzodiazepine, is often used pre-operatively for amnesia and anxiolysis. Subsequently, patients often do not recall events which occurred while they were sedated (1). Recent work has potentially identified retrograde facilitation of memory as an additional side effect (2). PTSD is based on memory of a traumatic event and ~17% of uninjured soldiers have symptoms consistent with PTSD (3). Predisposing factors for PTSD include experiencing a traumatic event and threat to one's physical integrity (4). Severity and duration of pain associated with the trauma itself are other variables. This study investigated prevalence of PTSD in burned service-members receiving...
midazolam to determine if there is a correlation with enhanced memory. **Methods:** After IRB approval, the charts of soldiers burned in OEF/OIF (2003-2008) admitted to the military burn center were reviewed to determine if screened for PTSD with the PTSD CheckList-Military (PCL-M). Variables assessed were the number of surgeries, the anesthetic regime, total body surface area burned (TBSA), and injury severity score (ISS). Statistical analysis included the chi-squared test. **Results:** The military burn center received 603 burned soldiers from OIF/OEF. Of those 370 burned soldiers completed the PCL-M. During surgery, 142 received midazolam and 69 did not. The prevalence of PTSD was higher in soldiers receiving midazolam as compared to those who did not (29% vs 25%) (p=0.481). Midazolam patients had similar TBSA and ISS. Midazolam patients had similar scores on questions related to memory on the PCL-M. **Conclusion:** Patients receiving midazolam did not have an altered prevalence of PTSD. Patients receiving midazolam had similar injuries and underwent similar numbers of surgeries. Prior data has shown that injury severity and TBSA are not associated with PTSD development in burned soldiers. Intra-operative midazolam is not associated with increased PTSD development or with increased intensity of memory of the traumatic event.

**References:**

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**A Case of Spinal Myoclonus with Radiculopathy Following Spine Surgery**

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Despite adequate surgery a number of patients have a return of back pain and radiculopathy of the legs following operation. Herein, a case of spinal myoclonus with radiculopathy after spine surgery, is described. A 51 year old woman with bilateral radiculopathy with urinary incontinence was diagnosed with a cauda equina syndrome with spinal stenosis. The patient was underwent emergency operation for posterior decompression and internal fixation from L2 to S1 level. Immediately after surgery, the patient continued to experience intermittent myoclonic movement with severe shooting pain of her legs despite being given pharmacological treatments, such as benzodiazepines, opioids, NSAIDs, gabapentin. The patient was found to have sudden, brief, bilateral involuntary muscle contraction on the lower extremities. The patient was consulted to our pain clinic. She underwent a caudal block with 2 times in 4 days. However, she reported only limited pain relief for 3 to 4 hours. She was then prescribed phenytoin 300 mg intravenously in a day; her myoclonic movement was gradually subsided after 1 week of receiving phenytoin. Sixty days later she was discharged without long term sequelae.

**References:**

**Funding:** None
Compliance and Adherence to Duloxetine Among Commercially Insured Patients with Diabetic Neuropathic Pain


Objective: This retrospective cohort study utilized claims data to assess the use of duloxetine over one-year among elderly patients with diabetic neuropathic pain (DNP) and Medicare supplemental coverage.

Methods: We assessed pharmacy records for duloxetine among over-65 diabetic patients between 10/1/2004 and 12/31/2005 with first claim denoted as the “index date”. All individuals selected had: 1) 1+ diabetic neuropathy diagnosis and pain medication dispensed in the 12 months pre-index period; 2) initial dose of duloxetine of 30 or 60 milligrams; and 3) at least 30 days available of duloxetine. Two cohorts of patients were constructed for individuals with a starting duloxetine dose of 30 (“Dulox30”) and 60 (“Dulox60”) milligrams, respectively. Utilization of duloxetine was assessed over follow-up in terms of adherence and compliance, as well as dose titration. Multivariate regressions were performed to adjust for potential differences in demographic and clinical characteristics.

Results: 182 Dulox30 and 383 Dulox60 patients were identified. Dulox30 patients were 2 years older (76 versus 74 years, p<0.01) and less likely males (40% versus 45%, p<0.01). 95% of patients were dispensed duloxetine by a specialist and each group had about 4 unique pain medications dispensed in the prior year. History of chronic lower back pain was higher among Dulox60 patients (41% versus 35%, p<0.01). Over the 12-month follow-up period, the mean proportion of days with duloxetine was numerically lower among Dulox30 patients (0.53 versus 0.55, p=0.58) and discontinuation was similar between cohorts. Controlling for demographic and clinical differences, Dulox30 patients were 5.6 times (95% confidence interval: 3.6 to 9.0) more likely to have an increase in dosing, which occurred much earlier (an adjusted 73 days, p<0.01) relative to Dulox60 patients. Conclusion: These findings indicate that there are important implications in terms of whether and when DNP patients have an increase in duloxetine dosing.

References: None

Funding: Eli Lilly and Company, Inc.

Healthcare Resource Use and Costs Among Patients with Diabetic Neuropathic Pain in the One-Year Following Duloxetine Therapy: Is Initial Dosing a Significant Factor?


Objective: This study examines factors associated with healthcare costs among working age patients with diabetic neuropathic pain (DNP) who are undergoing duloxetine therapy. Methods: Using a retrospective cohort design and claims data, we assessed the predictors of total healthcare costs over a one-year follow-up period for patients (18-64 years) with 30+ days of available duloxetine therapy between 10/1/2004 and 12/31/2005. The index date was defined as the first observed pharmacy claim for duloxetine. All individuals selected had 1+ diabetic neuropathy diagnosis and pain medication dispensed in the 12 months pre-index. Two cohorts of patients were constructed for individuals with a starting duloxetine dose of 30 (“Dulox30”) and 60 (“Dulox60”) milligrams, respectively. Baseline demographic and clinical characteristics were assessed for each cohort, as was prior use of pain medications.
Resource utilization and expenditures were evaluated over 12-months following index. Multivariate linear regression was performed to assess whether initial dose of duloxetine was correlated with healthcare costs, controlling for demographic and clinical characteristics. *Results:* We identified 196 Dulox30 patients and 655 Dulox60 patients. The Dulox30 and Dulox60 groups were similar by age (55.0 vs 54.2, p=0.16), and gender (59.2% vs. 58.4% female, p=0.85). A higher proportion of patients in Dulox30 group had 4+ diabetes-related complications (26.5% vs 18.4%, p<0.01) and a Charlson Comorbidity score >1 (23.0% vs 17.6%, p=0.03) relative to those in the Dulox60 group. Prior use of antidepressants was greater among Dulox60 patients whereas Dulox30 patients were more likely to receive oxycodone and hydrocodone (all p<0.01). After adjusting for patient characteristics, patients in both cohorts had similar total healthcare costs (p=0.95). Factors associated with increased costs included advancing age, prior pain-related hospitalizations, insulin therapy, diabetes-related complications, and other chronic comorbidities. *Conclusion:* These findings indicate that one-year healthcare costs were similar for DNP patients receiving duloxetine therapy, regardless of initial dose.

References: None

Funding: Eli Lilly and Company, Inc

**203 How Does Average Daily Dose of Duloxetine Affect Adherence and Healthcare Cost in Patients with Diabetic Neuropathic Pain?**

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*Introduction:* We assessed the correlation between duloxetine dosing, adherence of therapy, and healthcare costs among commercially insured patients with diabetic neuropathic pain (DNP). *Methods:* Using administrative claims data, we examined the association between average daily dose of duloxetine, adherence to duloxetine therapy and healthcare costs over one-year follow-up for under-age-65 commercially insured patients who were dispensed duloxetine between 4/1/2005 and 12/31/2005. All patients selected had at least 1 diabetic neuropathy diagnosis and 1 pain medication dispensed in the 12 months prior to start of duloxetine therapy. High adherence was defined as a medication possession ratio (MPR) for duloxetine of ≥0.80 over one-year follow-up. Multivariate regression models were applied to examine the association between average daily dose and adherence, and adherence and healthcare cost. *Results:* Of the 497 identified patients, 58.7% were females and the average age was 54.7 years. Patients on average had 2 diabetes-related complications, and the mean Charlson Comorbidity score was 0.8. Fourteen percent of patients had an average daily dose ≤30mg, 18% between 31mg and 59mg, 54% 60mg, and 13% >60mg. Thirty percent of those identified had "high" adherence to duloxetine therapy over follow-up. Controlling for demographic and clinical characteristics, patients with a higher average daily dose (>30mg) were more likely to adhere to duloxetine therapy in comparison to patients whose average daily dose was ≤30mg (31-59mg: Odds Ratio [OR] = 3.5, 95% Confidence Interval (CI): 1.6-7.7; 60mg: OR=2.1, 95% CI: 1.1-4.3; >60mg: OR=4.2, 95% CI 1.9-9.6). Further analysis revealed that patients with high adherence had approximately $11,000 lower healthcare cost over the one-year follow-up (p=0.04). *Conclusion:* On average, DNP patients who were dispensed a higher dose of duloxetine over one-year follow-up were more adherent to therapy. Patients with high adherence (MPR ≥0.80) were also associated with lower healthcare expenditures.


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Long-Term Safety, Tolerability, and Effectiveness of Duloxetine in the Treatment of Fibromyalgia
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Background: Fibromyalgia is characterized by widespread body pain and allodynia. Studies show duloxetine, a serotonin and norepinephrine reuptake inhibitor, to be a safe, efficacious treatment for fibromyalgia. Materials and Methods: Results reported from 6-month extension phases of 2 randomized, double-blind, placebo-controlled clinical trials having 6-month acute phases. Study 1 (N=278) patients received duloxetine 120 mg/day after 28 weeks on placebo or duloxetine 60 or 120 mg/day. Study 2 (N=204) patients taking placebo titrated to duloxetine 60 mg/day after 27 weeks, while duloxetine patients remained on their current dose of 60 or 120 mg/day. Safety and tolerability were assessed via discontinuation rates, treatment-emergent adverse events (TEAEs), and changes in vital signs and laboratory measures. Efficacy measures included Brief Pain Inventory (BPI) average pain severity score, Patient Global Impressions-Improvement (PGI-I), and SF-36. Results: In Studies 1 and 2, 56.1% and 68.6% of patients completed the extension phase, with most discontinuations due to adverse events (AEs) found in patients titrating from placebo to duloxetine. The most commonly reported discontinuation-emergent AEs were dizziness, pain and nausea. The most common TEAEs in both Studies 1 and 2 were nausea and dry mouth. No significant within-group changes occurred in blood pressure. Significant within-group mean increases in pulse rate occurred in patients titrating from placebo to duloxetine (placebo/duloxetine) in both studies. Small, statistically significant mean changes (not clinically relevant) occurred in chemistry and hematology analytes. Most treatment groups showed small mean change improvements in the BPI, while both placebo/duloxetine groups showed significant improvement on the PGI-I, SF-36 and most other efficacy and health outcome measures. Conclusion: Findings substantiate a positive risk/benefit profile for duloxetine in treatment of fibromyalgia, with efficacy maintained for up to one year.

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Comparisons of the Efficacy and Safety of Duloxetine for the Treatment of Fibromyalgia in Patients With vs. Without Major Depressive Disorder (MDD)
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Background: Fibromyalgia and MDD are often co-morbid conditions. Objective: Determine whether co-morbid MDD influenced efficacy and safety of duloxetine in treating fibromyalgia. Methods: Post-hoc analysis using pooled data from 4 double-blind, placebo-controlled studies of patients with American College of Rheumatology-defined primary fibromyalgia with or without MDD. Patients were randomized to duloxetine [60 or 120 mg/d (N=797)] or placebo (N=535) for 3 months. Efficacy measures included Brief Pain Inventory average pain score [BPI], 17-item Hamilton Depression Rating Scale [HAMD17], Fibromyalgia Impact Questionnaire [FIQ], and Patient’s/Clinician’s Global Impressions of Improvement/Severity [PGI-I and CGI-S] scales. Results: Baseline: 26% of patients met diagnostic criteria for MDD; endpoint (3 months or last observation), duloxetine showed significantly
(P<.05) greater improvement vs. placebo on BPI, FIQ, CGI-S and PGI-I in patients with and without co-morbid MDD. The effect of duloxetine efficacy measures was consistent across fibromyalgia patients with or without MDD (P>.1 for treatment-by-strata interaction). Similarly, BPI 30% and 50% response rates were significantly greater for duloxetine compared with placebo (P<.001) within each subgroup (with and without co-morbid MDD). Effect of duloxetine on BPI response rates was consistent across fibromyalgia patients with or without MDD (P>.1 for treatment-by-strata interaction). Similarly, BPI 30% and 50% response rates were significantly greater for duloxetine compared with placebo (P<.001) within each subgroup (with and without co-morbid MDD). Safety profile of duloxetine vs. placebo regarding serious adverse events, or discontinuation due to adverse events was similar for fibromyalgia patients with vs. without MDD (P>.1 treatment-by-strata interaction). Conclusions: Duloxetine was equally effective in reducing pain and other symptoms in fibromyalgia patients with or without MDD and demonstrated a similar safety profile for both groups. For fibromyalgia patients with co-morbid MDD, duloxetine treated group showed a significantly greater improvement in depressive symptoms compared with placebo.

References: None

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Efficacy and Safety of Duloxetine 60 mg to 120 mg Once Daily in Patients with CLBP
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Purpose: Chronic low back pain (CLBP) is a common musculoskeletal disorder of complex and not fully understood pathophysiology. By modulating pain inhibitory pathways, duloxetine has been shown to be efficacious in reducing pain associated with diabetic peripheral neuropathy and fibromyalgia. This study was designed to assess the efficacy of duloxetine in the reduction of CLBP.

Methods: Adult patients with a history of non-neuropathic CLBP for >6 months with a weekly mean 24-hour average pain score ≥4 at baseline (0-10 scale) and without major depressive disorder were treated with duloxetine 60-120 mg once daily for 13 weeks in a randomized placebo-controlled trial. After 7 weeks of duloxetine treatment, patients reporting <30% pain reduction (nonresponders) had their dose increased to 120 mg. Responders continued on 60 mg. The primary objective was the reduction of the Brief Pain Inventory (BPI) 24-hour average pain score. Secondary measures included RMDQ-24, PGI-I, BPI-S and BPI-I, diary-based weekly mean of the 24-hour average pain score, CGI-S, and response rates. Health outcomes, safety, and tolerability were also assessed.

Results: Compared with placebo-treated patients, duloxetine-treated patients had significantly greater reduction in BPI 24-hour average pain scores from baseline (P = .004 at week 13) and in the diary-based weekly mean of 24-hour average pain scores (P = .001 at week 13). Also compared with placebo group, duloxetine group significantly improved on PGI-I, RMDQ-24, BPI-S and BPI-I, diary-based night pain and worst pain, CGI-S, response rates, and SF-36. Significantly more patients in duloxetine group discontinued due to adverse events (P = .047). Most common treatment-emergent adverse events (≥5%) in duloxetine group included nausea, dry mouth, fatigue, diarrhea, hyperhidrosis, dizziness, and constipation.

Conclusion: Compared with placebo, duloxetine 60-120mg once daily significantly reduced pain, improved functioning, and was well tolerated in patients with CLBP.

References: None

Funding: Eli Lilly and Company
207 Duloxetine 60 to 120 mg Once Daily Versus Placebo in the Treatment of Patients with Osteoarthritis Knee Pain

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Introduction: Reduction of pain is crucial to the management of osteoarthritis (OA) as it is a common cause of disability in OA patients.1 Duloxetine is efficacious in treating diabetic peripheral neuropathic pain and fibromyalgia.1,2,3 In this study, duloxetine (60-120 mg once daily) was evaluated in the treatment of OA knee pain. Methods: This was a 13-week, randomized, double-blind, placebo-controlled trial in patients meeting American College of Rheumatology clinical and radiographic criteria for OA of the knee, with pain for ≥14 days of each month for 3 months before study entry and a mean 24-hour average pain score of ≥4. Patients were randomized to duloxetine (N=128) or placebo (N=128) and stratified by nonsteroidal anti-inflammatory use. At week 7, patients (33/128) who did not respond to 60-mg dose (≤30% reduction in pain) increased their dose to 120 mg. The primary efficacy outcome was Brief Pain Inventory (BPI) 24-hour average pain, analyzed using a mixed-effects repeated measures approach. Secondary outcomes included Patient's Global Impressions-Improvement (PGI-I), Western Ontario and McMaster Universities (WOMAC) pain and physical functioning, Clinical Global Impressions-Severity (CGI-S), BPI-Severity and -Interference, and weekly 24-hour average pain. Tolerability was also assessed. Results: Compared with placebo-treated patients, duloxetine-treated patients had significantly greater reductions from baseline on the primary outcome, BPI average pain, from visit 3 through visit 5 (P<0.001). Compared with placebo, duloxetine significantly reduced the WOMAC total scores (P=0.044), weekly 24-hour average pain (P=0.008), and CGI-S (P=0.009). The PGI-I was improved significantly in duloxetine treated patients from visit 3 through visit 5 (P≤0.05). Frequency of nausea, constipation, and hyperhidrosis were significantly higher in duloxetine group compared with placebo (P<0.05). Significantly more duloxetine-treated patients discontinued due to adverse events (P=0.002).

Conclusions: Compared with placebo, duloxetine treatment effectively reduced the pain and improved function in patients with OA knee pain; it was well tolerated.


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208 Response Profile of Patients with Fibromyalgia Treated with Duloxetine

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Introduction: Understanding the time course of improvement on medication may help clinicians make more informed treatment management decisions. This study examined the time course for minimally clinically significant improvement in pain severity during the initial 12 weeks of treatment in patients with fibromyalgia taking duloxetine. Materials and Methods: Four double-blind, placebo-controlled trials of duloxetine in patients with fibromyalgia were pooled. Across all studies, 797 patients received duloxetine 60-mg/day or 120-mg/day and 535 patients received placebo. Each site's Institutional Review Board approved the protocol, and patients provided written informed consent before study procedures were initiated. Clinically significant treatment response (defined as a 30% reduction in pain severity on the 24-hour average pain severity of the Brief Pain Inventory scale) was assessed by week to determine
the percentage of responders. **Results:** At endpoint, the percentages of patients with 30% improvement on average pain from baseline were 46.9% for duloxetine 60-mg-, 48.6% for duloxetine 120-mg- and 32.1% for placebo-treated patients (P<.001). The probabilities of achieving response at weeks 1, 2, 4, 8, and 12 among duloxetine 60-mg treated patients were 27%, 44%, 45%, 47%, and 49% respectively, and among duloxetine 120-mg treated patients were 35%, 43%, 53%, 53%, and 51% respectively (P<.01 vs. placebo at each week). Among patients who did not respond by weeks 1, 2, 4 and 8, the percentages of duloxetine 60-mg-treated patients who achieved a response by the endpoint of the study were 36.9%, 29.8%, 28.9%, and 26.9% respectively. **Conclusions:** Duloxetine-treated patients with fibromyalgia had significantly higher rates of treatment response compared with placebo-treated patients from week 1 through the end of the study. While the greatest likelihood of response occurred within the first 2 weeks on duloxetine 60-mg, more than 25% of the nonresponders at week 8 achieved a clinically significant response at the end of study. **References:** Arnold LM, Lu Y, Crofford LJ, et al. A double-blind, multicenter trial comparing duloxetine with placebo in the treatment of fibromyalgia patients with or without major depressive disorder. Arthritis Rheum 2004;50:2974-84. Arnold LM, Rosen A, Pritchett YL, et al. A randomized, double-blind, placebo-controlled trial of duloxetine in the treatment of women with fibromyalgia with or without major depressive disorder. Pain 2005;119:5-15. Russell IJ, Mease PJ, Smith TR, et al. Efficacy and safety of duloxetine for treatment of fibromyalgia in patients with or without major depressive disorder: Results from a 6-month, randomized, double-blind, placebo-controlled fixed-dose trial. Pain 2008;136:432-44.

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Milnacipran for the Treatment of Fibromyalgia Syndrome: A European Multicenter, Double-Blind, Placebo-Controlled Trial

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**Introduction:** Milnacipran, a dual reuptake inhibitor of norepinephrine and serotonin, has previously demonstrated efficacy in the treatment of fibromyalgia syndrome (FMS) in the US. This study investigated the efficacy and safety of milnacipran in treating FMS in a European population.¹-³

**Methods:** 83 sites across 13 European countries randomized a total of 884 fibromyalgia patients to placebo (n=449) or milnacipran 200 mg/day (n=435) for 16 weeks. The primary analysis used a sequential testing procedure involving a composite response criterion (pain VAS + Global Patient Improvement of Change, PGIC, both recorded on an eDiary), and then the change in the Fibromyalgia Impact Questionnaire (FIQ) total score (eDiary). Fibromyalgia composite responders were defined as individuals concurrently having ≥30% improvement from baseline in pain and a rating of "very much improved" or "much improved" on the PGIC. The study protocol was approved by each center's Institutional Review Board; patients gave written, informed consent. **Results:** At 16 weeks, milnacipran 200 mg/d, compared to placebo, resulted in a significant increase in both the primary efficacy composite criterion (P=.0003) and in the FIQ total score (P=.015). Secondary analyses revealed that the 200 mg daily dose of milnacipran led to statistically significant improvements on multiple domains at the 3-month endpoint as compared to placebo: pain scores on eDiary (p≤.001), Brief Pain Inventory (BPI) Pain Interference (p<.05), SF-36 (Mental and Physical components, p<.01 and p<.05 respectively), Multidimensional Fatigue Inventory (MFI) total score (p<.01), FIQ Physical function subscore (p<.05) and Multiple Ability Self-Report Questionnaire cognition complaints total score (MASQ, p<.05), non-
refreshing sleep (eDiary, p<.01). Milnacipran was well tolerated with the majority of adverse events (AEs) reported (nausea, hyperhidrosis and headaches) being mild to moderate in severity. **Conclusions:** These findings confirm, on all relevant parameters, that milnacipran 200mg/d is an effective and safe treatment for the multiple symptoms of FMS


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**XP13512/GSK1838262 Treats the Pain Associated with Restless Legs Syndrome**

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**Introduction:** Although not a criterion for diagnosis, pain associated with Restless Legs Syndrome (RLS) symptoms is reported by 59% of patients, with 19% reporting pain as their most troublesome symptom. XP13512/GSK1838262 is a non-dopaminergic treatment under investigation for RLS.

**Methods:** A 12-week, double-blind trial (PIVOT RLS 1 — Patient Improvements in Vital Outcomes following Treatment for RLS) randomized patients with moderate-to-severe RLS to XP13512 1200mg (n=114) or placebo (n=108) once-daily at 5pm with food. Local/regional IRBs approved the protocol. Co-primary endpoints were change from baseline in International Restless Legs Scale (IRLS) total score and proportion of responders (rated ‘very much’ or ‘much’ improved) on the investigator-rated Clinical Global Impression-Improvement (CGI-I) scale at Week 12 LOCF. Patients recorded ‘pain associated with RLS symptoms’ in the last 24 hours on an 11-point RLS pain scale (0=no pain, 10=most intense pain imaginable) every morning for 7 days prior to baseline and Week 12. Patients with neurologic disease or movement disorder were excluded.

**Results:** XP13512 significantly improved mean IRLS total score versus placebo at Week 12 LOCF (adjusted mean treatment difference: −4.0; 95%CI: −6.2, −1.9; p=0.0003) and significantly more patients were CGI-I responders (76.1% versus 38.9%; adjusted odds ratio [AOR]: 5.1; 95%CI: 2.8, 9.2; p<0.0001). Overall, 51% of patients reported baseline average daily pain scores ≥4. XP13512 significantly reduced mean (SD) pain scores versus placebo for patients with baseline pain scores ≥4 (−3.7 (2.2) versus −1.9 (2.4); treatment difference: −1.7; 95%CI: −2.6, −0.9; p<0.0001) at Week 12 LOCF. Significantly more XP13512 patients with baseline pain ≥4 reported ≥50% pain reduction versus placebo (75% versus 33%; AOR: 6.9; 95%CI: 2.9, 16.5; p<0.0001; post-hoc). Most frequently reported XP13512 adverse events were somnolence, dizziness, and headache.

**Conclusions:** XP13512 1200mg once-daily significantly improves RLS symptoms in all patients, and reduces pain associated with RLS compared with placebo.

References: None

**Funding:** Research funding for design and conduct of this study; collection, management, analysis, and interpretation of the data were sponsored by XenoPort, Inc., Santa Clara, CA, USA.
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The Effect of Different Cmax/Tmax Ratios on Euphoria Following Oral Oxycodone Dosing in Opioid-Experienced, Non-Dependent, Recreational Drug Users
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Introduction: The continuing problem of nonmedical use of oxycodone (1) creates a need to better understand how euphoria predicts misuse liability. This study evaluates the relation of pharmacokinetic (PK) to pharmacodynamic (PD) effects following oral oxycodone. Materials and Methods: This randomized, double-blind, placebo-controlled, crossover study contains two cohorts, each consisting of 25-30 opioid experienced, non-dependent, recreational drug users. All subjects will undergo a naloxone challenge and screening for the ability to discriminate between oxycodone and placebo. Qualifying subjects proceed to the double-blind abuse liability phase. Subjects in cohort 1 will receive one treatment per day on 5 consecutive days: 40 mg oral oxycodone solution + placebo capsule; 40 mg oral oxycodone in a capsule (tablet crushed) + placebo oral solution; 80 mg oral oxycodone in a capsule (tablet intact) + placebo oral solution; and placebo oral solution + placebo capsule. Subjects in cohort 2 will receive one treatment per day on 4 consecutive days: 20 mg oral oxycodone solution, 40 mg oral oxycodone solution, 80 mg oral oxycodone solution, and placebo oral solution. The primary PD endpoints are the Drug Effects Questionnaire (DEQ) questions, “Do you like the drug?” and “How high are you now?” Primary PK endpoints include Tmax, Cmax, and AUC at various time points to be calculated via plasma samples and compared to PD effects. Secondary PD and safety effects will be measured. IRB approval will be obtained before study commencement. Results: Analysis is pending. Conclusions: The relationship of the Cmax/Tmax ratio to euphoria is explored. The clinical implications are linked to whether a shortened/prolonged Tmax increases/decreases the likeability of opioids when the Cmax is constant. Likewise, it is observed whether high/low Cmax increases/decreases the likeability of opioids when Tmax is constant.

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Long-Term Effectiveness and Tolerability of Oxymorphone Extended Release in Cancer Patients
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Introduction: Oxymorphone extended release (OPANA® ER) is a long-acting oral opioid with demonstrated efficacy for the management of chronic moderate to severe pain in randomized controlled trials (RCTs).1-3 This is a combined subset analysis of cancer patients from 2 double-blind RCTs of oxymorphone ER for moderate to severe pain who enrolled in a 1- to 2-year open-label study following completion of the RCT. The objective of this analysis was to evaluate long-term effectiveness and tolerability of oxymorphone ER in cancer patients. Materials: Patients entering the open-label period continued treatment with oxymorphone ER every 12 hours at the dose determined in the previous RCT, starting at the lowest dose received in RCT. Dose adjustments were permitted as needed. Oxymorphone immediate release was available for breakthrough pain. Pain intensity on the 100-mm Visual Analog Scale (VAS; 0 = no pain, 100 = worst pain imaginable), patients' ratings of study medication, and adverse events (AEs) were recorded. Results: Of the 80 patients who entered the combined studies, 26 completed 1 year. Of the patients who discontinued, 25 did so because of AEs and 2 because of lack of efficacy. The mean age (SD) at the start of the open-label period was 57.0 (12.7) years and 41% were
women. Throughout the study, patient pain was well controlled with little change from baseline: the mean (SD) average pain intensity on the VAS ranged from 25.7 (20.9) mm to 40.3 (30.9) mm. After 1 year, 96.2% of patients rated oxymorphone ER as Excellent (30.8%), Very Good (42.3%), or Good (23.1%). The most common AEs were nausea (n=11), concomitant disease progression (n=10), pyrexia (n=7) and fatigue (n=7). Conclusions: In this small group of cancer patients, effective, tolerable pain control was achieved with oxymorphone ER every 12 hours. Pain relief was maintained for 1–2 years of treatment.


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Local Efficacy of Diclofenac Topical Gel in Knee Osteoarthritis
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Introduction: Topical diclofenac sodium gel (DSG) provides effective analgesia for knee osteoarthritis (OA). A study was analyzed to determine if DSG applied to 1 knee affected the contralateral knee. Methods: Patients with mild to moderate unilateral symptoms of knee OA for ≥6 months requiring treatment with NSAIDs or acetaminophen and no OA pain in the contralateral knee for ≥12 months were randomized to apply DSG or vehicle to only the symptomatic knee qid. Pain and function were assessed on each knee using an abridged Western Ontario McMaster Universities (WOMAC) Osteoarthritis Index (2 questions apiece from pain and function indices, scale=0—8) at baseline and through 12 weeks. Changes from baseline were described by simple summary statistics. Informed consent and Institutional Review Board approval were obtained. Results: Baseline mean (SD) abridged WOMAC pain and function scores, respectively, were 4.9 (1.0) and 4.4 (1.4) in the DSG-treated knee, 0.3 (0.5) and 0.3 (0.7) in the untreated contralateral knee, 5.1 (1.2) and 4.3 (1.6) in the placebo-treated knee, and 0.3 (0.5) and 0.3 (0.6) in the untreated contralateral knee. The treated knee improved more in the DSG group (n=127) than the placebo (n=119) group, whereas the untreated contralateral knee worsened slightly in both groups. Mean (SD) changes at 12 weeks vs baseline for WOMAC scores for pain and function, respectively, were 2.4 (1.7) and 2.1 (1.9) in the DSG-treated knee, −0.3 (0.9) and 0.2 (1.3) in the untreated contralateral knee, 1.9 (2.0) and 1.3 (2.0) in the placebo-treated knee, and −0.5 (1.2) and −0.6 (1.5) in the untreated contralateral knee. Conclusions: DSG improved measures of pain and function in the knee with mild to moderate symptoms of OA. The lack of impact of DSG from the treated knee on the untreated contralateral knee demonstrates that DSG exerts a local effect on the treated knee.


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Nasal Absorption and Absolute Bioavailability of Intranasal Ketamine Hydrochloride in Healthy Adult Volunteers

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Introduction: A proprietary formulation enabling safe and effective intranasal (IN) delivery of ketamine is under clinical investigation for the treatment of acute pain. Rapid analgesia is observed following IN ketamine administration(1-3), and this may be due to rapid absorption from the nasal mucosa. The objectives of this study were to quantify the percentage of total ketamine exposure that is contributed by absorption from the nasal mucosa after administration of IN ketamine and to determine the absolute bioavailability of IN ketamine.

Methods: Healthy volunteers received IN ketamine hydrochloride 30mg (with and without activated charcoal) and intravenous (IV) ketamine hydrochloride 30mg in an open-label, randomized, single-dose, cross-over, pharmacokinetic study. Blood samples for ketamine and norketamine analysis were collected through 48 hours post-dose. There was a 48-hour washout between treatments. The protocol and informed consent were approved by an independent IRB.

Results: Twenty-seven subjects were randomized, and twenty-five completed all treatments. The median time to maximum plasma ketamine concentration following IN ketamine was 30 minutes. The areas-under-the-curve (AUCinf) following IN ketamine, IN ketamine+charcoal, and IV ketamine was 168±40, 122±35, and 404±81 ng•h/ml, respectively. The geometric mean ratios of AUCinf for IN ketamine to IV ketamine and IN ketamine+charcoal to IN ketamine are 41.6% and 72%, respectively. Pilot work showed that activated charcoal blocked 75% of oral ketamine absorption. The most frequently reported (≥10% of subjects) treatment-emergent adverse events for IN ketamine alone were dizziness, dysgeusia, and euphoric mood; and diarrhea, abdominal pain, dizziness, headache, nausea, and vomiting for IN ketamine+charcoal.

Conclusions: IN ketamine may offer a safe and non-invasive analgesic to treat acute pain. IN ketamine is rapidly absorbed from the nasal mucosa. The absolute bioavailability of IN ketamine is 42%, of which 26% (62% of the total absorbed dose) and 16% (38% of the total absorbed dose) are due to nasal mucosa and oral absorption, respectively.


Funding: This study was sponsored by Javelin Pharmaceuticals, Inc.
were approved by a regional IRB. Results: Study 1 (Linearity): Mean C_{max} values for BEMA™ Fentanyl doses of 200, 600, and 1200µg were 0.38, 1.16, and 2.19ng/mL, and corresponding values for mean AUC_{inf} were 3.46, 11.72, and 20.43ng•hr/mL, respectively. Study 2 (Consistency): Two single 600µg doses of BEMA™ Fentanyl administered 3 days apart in Periods 1 and 2 produced nearly identical mean C_{max} (1.08 and 1.01ng/mL) and AUC_{0-12} (6.3 and 6.2ng•hr/mL). Three days later, application of three 600µg doses of BEMA™ Fentanyl at 1-hour intervals in Period 3 produced a proportional increase in peak plasma concentration and exposure compared to a single dose (Period 3, 1800µg [3x600µg]: mean C_{max} 3.31ng/mL, AUC_{inf} 30.31ng•hr/mL vs. Period 1, 600µg: mean C_{max} 1.08ng/mL, AUC_{inf} 9.14ng•hr/mL). Study 3 (Predictability): Application of one 800µg dose unit compared to four 200µg dose units produced identical C_{max} (1.33ng/mL) and nearly identical AUC_{last} (11.4 vs. 11.7ng•hr/mL). Conclusions: Fentanyl plasma concentrations and exposure across the 200-1200µg BEMA™ Fentanyl dose range were linear. Fentanyl exposure from BEMA™ Fentanyl was also highly consistent from dose to dose. Fentanyl C_{max} and AUC following 1x800µg and 4x200µg dose units were bioequivalent, which supports the recommended titration process for BEMA™ Fentanyl. The predictability and consistency of dosing with BEMA™ Fentanyl can be attributed to the proportional relationship between the fentanyl dose and the film's surface area.


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A 10-Year Evaluation of Chronic Pain Patients Treated with High Dose Opioids
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Introduction/Statement of Problem: There are essentially no reports on the outcomes of chronic pain patients treated with opioids for over about three years. Materials and Methods: Twenty-four (24) adult patients with severe, intractable pain who had been treated in Los Angeles County with at least one long and one short-acting opioid for at least 10 years were evaluated. In June, 2008 these patients were evaluated by chart review and their completion of a 19-point questionnaire that inquired about: (1) pain reduction; (2) activities and functions; (3) medical complications; (4) potency and stability of opioid dosage; and (5) use of dietary supplements and exercises. Results: Twenty-Two (22) of 24 (83.3%) patients believe their pain has decreased over time, and 22 of 24 (83.3%) believe their opioids still provide the same relief as when they started treatment. All patients reported one or more activities or functions that they can now do that they couldn’t do prior to opioid treatment. A majority reported they can get out of bed everyday, shop or visit friends, take a trip in a car, or take walks. A significant, but less than a majority, report they can now dress without assistance, drive a car, attend church, have normal sexual relations, garden, or care for a pet. Opioid dosages have remained rather constant. No medical complications of opioid treatment have been detected except testosterone suppression in some patients. All patients report the use of dietary supplements and stretching exercises. Conclusions: Since the majority of patients reported that their opioid regimen was still effective, dosage was stable, pain had decreased, and activities and functions had improved, long-term opioid therapy should continue to be provided and evaluated.


**Funding:** None

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**Long-Term Opioid Therapy May Suppress Adrenal Corticosteroids**

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**Introduction/Statement:** While it is known that opioid treatment may initially normalize serum cortisol concentration in severe, chronic pain patients, it is unknown if long-term opioid therapy may suppress adrenal gland corticosteroids. There are animal and short-term human studies that suggest opioids may reduce adrenal production and secretion of corticosteroids, but there are no reports in chronic pain patients who take opioids for extended periods that corticosteroid suppression may actually occur.

**Materials and Methods:** Twenty-five (25) severe, intractable pain patients who were treated with a long and short-acting opioid for at least three years submitted an 8:00AM, fasting blood specimen. All these subjects were known to have had normal cortisol and pregnenolone serum concentrations in their first year of opioid treatment. The blood specimen was analyzed for the corticosteroids, pregnenolone, and cortisol. **Results:** Five (5) patients showed a deficiency of either cortisol or pregnenolone. One of these patients demonstrated both deficiencies. Two (2; 8.0%) patients demonstrated serum cortisol concentrations under 4mcg/dl, and 4 (16.0%) demonstrated serum pregnenolone concentrations under 10ng/dl. On the day of sampling one patient had a blood pressure of 99/75mm/Hg and had severe nausea, anorexia, and fatigue. Another reported severe fatigue, weakness, and inability to ambulate during the previous week. Both responded to corticoid replacement. No other patients demonstrated overt signs and symptoms of adrenal insufficiency or any recent change in pain control. **Conclusions:** While it is known that testosterone suppression may occur with long-term opioid therapy, this is the first report that corticosteroid suppression may also occur. The incidence of this occurrence or whether it is dose-related is unknown, but corticosteroid deficiency may interfere with opioid analgesia, impair immune protection, and even be fatal. Due to this seriousness, periodic corticosteroid screening is recommended during long-term opioid treatment.


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**Effects of Benzodiazepine Use on Treatment Outcomes of Multidisciplinary Pain Rehabilitation**

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**Introduction:** Benzodiazepine (BNZ) use is common among patients with chronic pain. However, the effects of BNZ use on treatment outcomes have not been previously investigated. The primary aim of this study was to determine the effects of BNZ use on treatment outcomes of multidisciplinary pain rehabilitation (MPR) including baseline opioid use. **Methods:** A retrospective, repeated measures design was used to assess pre- and posttreatment outcomes based on BNZ use in a consecutive series of patients admitted to a 3-week, outpatient MPR program from September 2003 through February 2007. **Outcome**
NGX-4010, a High-Concentration Capsaicin Patch, in Painful Diabetic Neuropathy (PDN)

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Introduction: NGX-4010 is a high-concentration capsaicin dermal patch (capsaicin, 8%) which has been demonstrated to significantly reduce pain in patients with postherpetic neuralgia (PHN) and HIV-distal sensory polyneuropathy (HIV-DSP).1,3 The efficacy, safety, and tolerability of NGX-4010 in patients with PDN is assessed in the current study. Materials and Methods: This randomized, open-label, multicenter 12-week trial included patients with PDN with moderate-to-severe pain in both feet (average Numeric Pain Rating Scale [NPRS] score of 3 to 8 inclusive). Patients received pretreatment with 1 of 3 topical anesthetics (LMX4®, Topicaine®, or Betacaine®) followed by a single NGX-4010 treatment applied for 60 or 90 minutes. The primary efficacy variable was percentage change in mean NPRS scores for “average pain for the past 24 hours” from Baseline during Weeks 2 to 12. Safety and tolerability measures included continuous monitoring of adverse events (AEs) and periodic assessments of clinical laboratory parameters, vital signs, physical examination, electrocardiograms, dermal assessments, neurologic/sensory assessments, and rescue pain medication usage. The study was conducted in accordance with the ethical principles originating from the Declaration of Helsinki and in accordance with Good Clinical Practice (GCP) guidelines. Results: 91 patients with PDN received treatment and were included in this analysis. NGX-4010–treated patients achieved a mean decrease of 32% in NPRS scores from Baseline during Weeks 2 to 12, and 48% of patients were classified as responders (having a ≥ 30% decrease from Baseline in NPRS score). AEs were generally mild or moderate in severity; the most common treatment-related events were application site burning and application site pain. Efficacy was similar for the 60- or 90-minute NGX-4010 treatments. Conclusions: A single 60- or 90-minute treatment with NGX-4010 was associated with a reduction in pain for 12 weeks in patients with PDN. The primary adverse events were local application site reactions.

References: None

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Long-Term Safety of NGX-4010, a High-Concentration Capsaicin Patch, for the Treatment of Neuropathic Pain in Patients with Painful HIV-Distal Sensory Polyneuropathy (HIV-DSP) or Postherpetic Neuralgia (PHN)

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Introduction: Significant medical need exists for effective and tolerable agents for peripheral neuropathic pain. We assessed the safety of repeated applications of NGX-4010, a high-concentration capsaicin dermal patch (capsaicin, 8%), over 1 year in patients with moderate-to-severe PHN or HIV-DSP.

Methods: This open-label, multicenter study enrolled patients who had successfully completed a previous NGX-4010 study and had a pain level appropriate for further treatment. Eligible patients had not been treated with NGX-4010 within 12 weeks of study initiation. A 60-minute topical, local anesthetic pretreatment (4% lidocaine) was followed by a single 60-minute (PHN and HIV-DSP subjects) or 90-minute (HIV-DSP subjects) treatment with NGX-4010. Patients could receive up to 3 additional treatments at intervals of ≥ 12 weeks. This study was conducted in accordance with the ethical principles from the Declaration of Helsinki, and Good Clinical Practice (GCP) guidelines.

Results: 106 enrolled patients received a total of 293 NGX-4010 treatments. The most common treatment-emergent adverse events (AEs) were application site erythema (96% and 75%), pain (67% and 73%), and edema (11% and 4%), in patients with PHN or HIV-DSP, respectively. Adverse events were generally transient and mild to moderate. Small, transient changes in blood pressure noted during the treatment procedure appeared to be associated with treatment-related changes in pain. No evidence of neurologic adverse effects was observed at the end of the study period. No relationship between the number of exposures and the occurrence of AEs, dermal assessment scores, or the numerical pain rating score on the day of treatment were noted, suggesting no cumulative toxicity with repeated treatments.

Conclusions: Up to four repeated treatments with NGX-4010 over 48 weeks were generally well tolerated. Treatment was associated with local application site reactions and transient changes in blood pressure. No evidence of neurologic adverse effects or cumulative toxicity was noted.

References: None

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Lyrica for Chronic Abdominal Visceral Pain

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Introduction: Chronic abdominal pain is a difficult condition to treat. We present the efficacy of oral pregabalin with the presumption that this is a visceral neuropathic condition. Methods: 12 patients, 4 men and 8 women with abdominal pain associated with chronic pancreatitis(2), abdominal surgery (8) and abdominal tuberculosis(2). Where pain was associated with surgery it was doubtful whether the pain had been the cause or effect. 2 patients had 1 surgery and others had up to 7 laparotomies. The visual analogue scores (VAS) varied between 4-10 at the time of presentation. All of them were on analgesics (proxyvon / tramadol / Morphine and antispasmodics, hyoscine, cyclopam). The patients were given amitryptyline 10mg HS in addition to their analgesic/antispasmodic. They were given a prescription for pregabalin 14 capsules (lyrica75mg® Pfizer) with instructions to start pregabalin only if their pain continued to be > 6 at any time during the day or after one week of amitryptyline if they had VAS > 6.

Results: 8 patients started pregabalin 1HS after 2days. After 2 days all of them reported up to
50% relief but asked for an increase to 75mg pregabalin twice a day. 4 patients started pregabalin after a week. At 15 days with amitryptyline and pregabalin All the patients reported relief of up to 1-2 VAS throughout the day. Discussion: In India patients pay for the medication. Pregabalin is very expensive compared to amitryptyline. We depended on this to make sure that pregabalin was indeed necessary before the patients used it. All the patients in this study showed a distinct benefit only after pregabalin with VAS reducing from 6 to 1-2. Amitryptyline appeared to be marginally useful Conclusion: Chronic abdominal pain a visceral neuropathic condition appears to be sensitive to therapy with a combination of amitryptyline and oral pregabalin.


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The Effect of Milnacipran on Tenderness in Fibromyalgia: A Psychophysical and fMRI Analysis

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Introduction: Milnacipran, a dual reuptake inhibitor of norepinephrine and serotonin, has previously demonstrated efficacy in the treatment of fibromyalgia syndrome (FMS) in the US 1-2. The present study evaluated tenderness and spontaneous pain in FMS. Methods: 92 female FMS patients participated in a 13-week, multicenter, randomised placebo-controlled trial assessing the effect of milnacipran 200 mg/d compared to placebo. Pressure-evoked pain response (S-R) to multiple pressure stimuli of suprathreshold pain intensities randomly applied to the left thumb was established using visual analog scale assessments at baseline and endpoint. Brain activity was assessed by functional Magnetic Resonance Imaging (fMRI) during repeated painful pressure stimuli. The treatment effects of milnacipran or placebo were quantified by a second, post-treatment assessment of subjective ratings of pressure pain and fMRI analysis at baseline and endpoint. The study protocol was approved by each center’s Institutional Review Board; patients gave written, informed consent. Results: Treatment with milnacipran reduced pain-evoked tenderness in comparison to placebo, an effect that approached significance for all patients (p = 0.11). Baseline fMRI analysis showed significant pressure-evoked brain activity in primary (S1),and secondary (S2) somatosensory cortex, insular and cingulate cortex, cerebellum, thalamus, and amygdala. fMRI analyses revealed significantly increased brain activity following milnacipran treatment in multiple brain regions including the S1, caudatus nucleus, anterior insula, anterior and posterior cingulum and amygdala. In contrast, placebo treatment increased activity only in a parietal region and mid insular cortex. A statistical comparison between the effects of milnacipran and placebo showed increased activity in a large region of posterior cingulate/precuneus (p<0.05). Milnacipran was well tolerated. Conclusions: Treatment with Milnacipran, reduces tenderness and alters activity evoked by painful pressure in brain regions known to be involved with pain.
modulation. The specific effects of milnacipran may provide important information for further development of pharmacological treatment solutions in patients with fibromyalgia.


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Analgesic Efficacy Outcomes from a 12-Month Open-Label Safety Study of Morphine Sulfate Plus Sequestered Naltrexone HCl Extended-Release Capsules (ALO-01) in Patients with Chronic, Moderate-to-Severe, Non-Malignant Pain

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Introduction: Increased non-medical opioid use has created need for products with reduced abuse-liability. An investigational formulation, ALO-01 (EMBEDA™, morphine sulfate extended-release with sequestered naltrexone hydrochloride) capsules has been developed (not approved or commercially available at time of abstract). When intact ALO-01 pellets are administered orally as-intended, morphine is available for systemic-absorption while naltrexone is to remain sequestered. When ALO-01 is tampered with (crushed/chewed), sequestered naltrexone is released with intention of mitigating morphine-induced euphoria. Here we report predefined secondary analgesic efficacy-outcomes from a 12-month open-label study assessing safety of ALO-01 in patients with chronic, moderate-to-severe, non-malignant pain.

Methods: Patients in this IRB-approved multicenter-study had chronic (≥3mos), moderate-to-severe, non-malignant pain. ALO-01 dose was titrated (starting dose: opioid-naive patients, 20mg q12h; opioid-experienced, morphine-equivalent of 50-75% of prior week's requirement). Investigators could adjust dose and dosing-frequency (q24h, q12h) as needed throughout study. Safety (primary outcome) was assessed via adverse events, laboratory results, and withdrawal symptoms. Analgesic efficacy was assessed using pain-intensity score (0=no pain; 10=worst pain) on 4 items (worst, least, average, and current pain) from Brief Pain Inventory Short Form.2 patient global-assessment-of-study-drug (1=poor, 5=excellent), and rescue-medication (acetaminophen) usage.

Results: Four-hundred-sixty-five patients received ≥1 dose. Mean±SD baseline pain-scores: worst pain, 7.5±1.5; least, 4.5±2.0; average, 6.0±1.7; current, 5.9±2.1. Efficacy results are reported for patients remaining in study at each visit. Mean decrease from baseline was significant for all 4 scores at each visit after week-1 (p<0.0001). Pain-scores generally improved from baseline until week-28, then remained stable. At each visit from 3 months (n=253) to study-end (n=162), ≥90% of patients reported good-to-excellent global-assessment of study-drug. Acetaminophen-dose generally decreased to week-16, then remained stable. Most common adverse events were constipation (31.8%), nausea (25.2%), headache (12.0%), vomiting (11.8%). Conclusions: Results provide supporting evidence for long-term persistence of analgesic effectiveness of ALO-01 in patients with chronic, moderate-to-severe, non-malignant pain.

The Safety and Efficacy of Oral Diclofenac Liquid Filled Soft Gelatin Capsule in Patients with Postsurgical Dental Pain

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Introduction: Diclofenac potassium liquid filled soft gelatin capsule (DPSGC) is an investigational oral formulation that uses ProSorb® technology to facilitate rapid and consistent absorption compared with immediate-release diclofenac potassium tablets, potentially decreasing time to analgesic onset. The safety and efficacy of DPSGC was assessed in adult patients with pain following third molar extraction in 2 multicenter, randomized, parallel-group, double blind, placebo-controlled studies.

Methods: Patients experiencing a requisite level of pain (at least 50 mm out of 100 mm on a visual analog scale within 4 hours after surgery) were randomized to receive single doses of DPSGC 25 mg, 50 mg, 100 mg, or placebo. Pain intensity and relief were assessed for 6 hours following dosing. Efficacy endpoints included summed pain intensity difference (SPID3 and SPID6) and total pain relief (TOTPAR3 and TOTPAR6) over 3 and 6 hours, and median time to onset of perceptible and meaningful pain relief (2-stopwatch method). Safety and tolerability were evaluated for 6 hours following dosing. This study was approved by local institutional review boards.

Results: 265 and 249 patients were enrolled. In both studies, SPID and TOTPAR scores were significantly improved for patients in all DPSGC groups compared with placebo (P < .0001) and displayed a general dose response trend. The median times to onset of perceptible pain relief for the lowest dose group (DPSGC 25 mg) were 22 and 25 min for Study 1 and 2, respectively (P ≤ .002 vs placebo) and times to meaningful relief were 45 and 52 min (P < .0001 vs placebo). Adverse event rates were similar across all treatment groups ranging from 7.9% to 13.2%.

Conclusions: DPSGC offered significant pain relief compared with placebo. These data show DPSGC was well tolerated and efficacious in patients requiring pain relief following third molar extraction.

References: None

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Improvement in Functional Status with Carisoprodol 250-mg Tablets in Patients with Acute Lower Back Spasm: A Randomized, Double-Blind, Placebo-Controlled Trial

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Introduction/Statement of problem: It is generally accepted that returning patients to acceptable functional status as quickly as possible following acute musculoskeletal injuries is a key component of effective treatment. In a clinical study of a low-dose carisoprodol treatment regimen, the Roland Morris Disability Questionnaire (RMDQ) was used to assess functional status in patients with lower back spasm.

Materials and Methods: The study was an IRB-approved, multicenter, double-blind, placebo-controlled trial in patients 18 to 65 years of age. The study consisted of a baseline screening, during which patients were evaluated for inclusion/exclusion criterion, and a 7-day double-blind treatment period. All patients had moderate-to-severe back pain as determined by the investigator. Patients were randomly assigned to treatment with carisoprodol 250-mg tablets or matching placebo tablets four times daily. RMDQ was measured at baseline and at study days 3 and 7.

Results: A total of 269 patients...
treated with carisoprodol 250-mg tablets and 278 patients treated with placebo were analyzed for efficacy. The mean RMDQ score at baseline was 10.4 in the carisoprodol group and 10.3 in the placebo group (severity scale: 1 to 24, with 24 being maximum disability). The mean change from baseline was 3.5 with carisoprodol compared to 1.6 with placebo on day 3, and 6.3 compared to 4.0 on day 7 (P<.001 on both days). The percentage of patients with a minimum detectable improvement in the RMDQ score also was significantly greater (P<.001) in the carisoprodol group than in the placebo group. Eight (2.9%) patients in the carisoprodol group and 5 (1.8%) patients in the placebo group discontinued due to an adverse event. Conclusions: This study demonstrated that carisoprodol 250-mg tablets four times daily improved functional status compared to placebo and was well tolerated in patients with acute, muscle spasm of the lower back.

References: None

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Dual Opioid Treatment of Acute Postoperative Pain: A Double-Blind, Placebo-Controlled Study

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Introduction: Enhanced analgesia has been demonstrated in studies of coadministered opioids with different receptor-binding properties. This study examined the safety and efficacy of flexible doses of a 3:2-mg fixed ratio of immediate-release morphine plus oxycodone (Q8003). Methods: Patients undergoing unilateral bunionectomy were evaluated in a randomized, double-blind, placebo-controlled, ascending-cohort, dose-response study. Doses included 3/2 mg, 6/4 mg, 12/8 mg, and 18/12 mg administered over 48 hours (pm) with at least 1-2 hours between doses. Safety measures included incidence of reported adverse events (AEs), AE severity, SpO2 and respiration rate, and patient-rated opioid-related AEs. The primary efficacy endpoint was the sum of the 48-hr pain intensity differences (SPID48) from baseline. IRB approval and informed consent were obtained. Results: A total of 256 patients participated (Q8003, n=196 across doses; placebo, n=60). The mean number of study medication doses ranged from 11.6 (3/2 mg) to 5.2 (18/12 mg), and the mean dose mg/6h of study medication ranged from 6/4 (3/2 mg) to 15/10 (12/8 mg). The most commonly reported AEs were nausea (38%-65% range across doses), vomiting (23%-51%), and dizziness (8%-25%). Sedation was seen in 1 patient (18/12-mg group) and somnolence ranged from 2%-8%. Euphoria was not observed. Most AEs were mild-to-moderate in severity and decreased over time in all dose groups. Patient-rated AEs also declined over time. Changes in respiration rate and SpO2 were minimal. Overall, 5% of patients (13/256) discontinued due to AEs, including 1 patient in the placebo group. Compared to placebo, Q8003 was significantly more effective in providing pain relief across the dose range (P=0.0065). Conclusion: This study showed that Q8003 was generally safe and effective in the relief of acute postoperative pain. The low levels of somnolence and respiratory depression warrant further investigation.


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Terazosin (HYTRIN) for Complex Regional Pain Syndrome: A Case Report
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Introduction: The treatment algorithm for patients with Complex Regional Pain Syndrome (CRPS) often begins with sympathetic blockade and can proceed to spinal cord stimulation (SCS). Frequently overlooked in sympathetically-responsive CRPS is the role of oral α1-adrenergic antagonists.
Case Presentation: A 33 year old female presented ten years ago with left lower extremity (LLE) pain, status post multiple ankle injuries. In addition, she presented with allodynia, burning, warmth, and atrophic skin changes. Gabapentin was started and lumbar sympathetic blocks were performed with significant temperature increases and analgesia. Terazosin was initiated at 1 mg daily and increased 1 mg weekly over twelve months to 5 mg four times daily. Despite steady progress, it was felt that SCS would accelerate recovery. After a successful trial, a SCS was implanted with marked improvement over several months. After achieving complete pain relief, she stopped using the SCS and requested its removal. She continued gabapentin and terazosin and no longer required follow-up visits. Approximately two years ago she developed Postural Orthostatic Tachycardia Syndrome (POTS). Her cardiologist and neurologist weaned the terazosin, with resolution of POTS. During the weaning process, burning pain returned in the LLE with new pain on the right. Her exam remained normal. She returned to the pain clinic and failed subsequent SCS trial. For 2 years multiple anti-convulsants and anti-depressants failed to provide analgesia. After consultation with her physicians, terazosin was restarted. Her pain improved almost immediately, and was tolerable within 25% of her previous maximum dose.
Discussion: While anti-convulsants and anti-depressants are the mainstay of oral pharmacologic treatment of CRPS, often overlooked are the potentially beneficial effects of α1-adrenergic antagonists. Oral α1-adrenergic antagonists are used primarily for refractory hypertension and benign prostatic hyperplasia. This case report is an example of the use of an α1-adrenergic antagonist in the successful treatment of CRPS.
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Safety and Tolerability of Long-Term Extended-Release Hydrocodone/Acetaminophen in Patients with Moderate-to-Severe Noncancer Pain by Prior Opioid Use
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Introduction: Twice daily 12-hour extended-release hydrocodone 15mg/acetaminophen 500mg(HC/APAP CR) showed efficacy for treatment of moderate-to-severe noncancer pain in a previously reported long-term (56-week), open-label study. This report evaluates safety and efficacy of HC/APAP CR by patients' prior opioid use. Methods: 431 patients with moderate-to-severe noncancer
pain (osteoarthritis/OA or chronic low back pain/CLBP) were recruited from 74 US sites. In the titration period, patients took 1 tablet HC/APAP CR once daily for 3 days followed by 1 tablet twice daily for 4 days. During maintenance, patients took 2 tablets HC/APAP CR twice daily for 56 weeks. Following the maintenance period, patients had their medication tapered over one week. Patients were permitted rescue medication (acetaminophen) up to three times per week. Safety was assessed by adverse event (AE), vital sign and laboratory assessment and efficacy was evaluated by an 11-point pain-intensity scale. Results: 291 of the 431 (68%) patients entering the study were opioid experienced (had taken opioids in the last month to treat OA or CLBP) and 140 (32%) were opioid naïve. Overall AE rates were significantly higher in opioid naïve patients (92%) compared with opioid experienced patients (83%; p=0.012) and the most common AEs were nausea (39% and 19% for naïve and experienced patients, respectively) and dizziness (11% and 5%). A larger percentage of opioid naïve patients discontinued the study primarily due to AEs (32%) compared with opioid experienced patients (23%). At final evaluation, the opioid naïve patient group had greater mean percent improvements in pain intensity from baseline (-33.8) compared with the opioid experienced patient group (-29.7); these differences were not statistically significant (p=0.435). Conclusions: In this long-term study, AE rates were significantly higher in the opioid naïve group compared with the opioid experienced group and similar efficacy was observed for opioid experienced and opioid naïve patients receiving HC/APAP CR.


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Efficacy and Safety Evaluation of 12 Weeks Extended-Release Hydrocodone/Acetaminophen Treatment in Patients with Chronic Low Back Pain (CLBP) by Prior Opioid Use
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Introduction: Twice daily 12-hour extended-release hydrocodone 15mg/acetaminophen 500mg (HC/APAP CR) demonstrated superior efficacy compared with placebo for the treatment of moderate-to-severe chronic low back pain (CLBP) in a previously reported 12-week randomized, double-blind, placebo-controlled, withdrawal trial. This report evaluates the efficacy and safety of HC/APAP CR by prior opioid use. Methods: Opioid experienced patients [had taken opioids for CLBP in the last month; 302 of 770 (39%)] and opioid naïve patients [had not taken opioids in the last month; 468 of 770(61%)] with CLBP were enrolled at 62 U.S. sites. Study periods were: Washout/Screening, 3-week Active-Drug Open-Label(OL), 12-week Double-Blind(DB) in which patients were randomized to placebo, 1- or 2-tablets HC/APAP CR twice daily, and Taper/Follow-up. The primary efficacy endpoint was mean change from DB-baseline to final evaluation in Subject's Assessment of CLBP Intensity (visual analog scale;0-100). Safety was evaluated by adverse-event (AE), vital sign and laboratory assessment. Results: 209/302(69%) opioid experienced and 302/468(65%) opioid naïve patients completed the OL period and were randomized to the DB period. For the primary endpoint, both opioid experienced and naïve patient groups receiving HC/APAP CR had smaller mean increases from DB-baseline compared with placebo; this difference was statistically significant for the 2-tablet groups (p≤0.03). There were no statistically significant differences (p=0.467) for the primary endpoint between opioid experienced and naïve patients receiving either placebo, 1-tablet HC/APAP CR or 2-tablets HC/APAP CR. There were no significant differences (p>0.05) in overall adverse event rates across treatment groups for either opioid experienced [placebo(51%), 1-tablet HC/APAP CR(43%) or 2-tablets HC/APAP CR(52%)] or opioid naïve patients [placebo(42%), 1-tablet HC/APAP CR(45%) or 2-tablets HC/APAP CR(53%)].
Conclusions: In this study, HC/APAP CR was efficacious for the treatment of moderate-to-severe CLBP and the efficacy and safety profiles were similar for opioid experienced and opioid naïve patients. References: Codding C, Levinsky D, Hale M, Thomas J, Lockhart E, Best A, Jain R. Analgesic efficacy and safety of controlled-release hydrocodone and acetaminophen tablets, dosed twice daily, for moderate-to-severe mechanical chronic low back pain: A randomized, double-blind, placebo-controlled withdrawal trial. J Pain 2008: 9 (4); Suppl 2; p 38

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**Correspondence of the Pharmacokinetics and Efficacy of Once-Daily Cyclobenzaprine Extended-Release**

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**Introduction:** Steady state (C\text{SS}) represents maximum exposure and is typically reached after five half-lives. A potential association between systemic exposure with once-daily cyclobenzaprine extended-release (CER) 15 and 30mg and clinically observed effects on days 4 and 8 was examined. Materials and Methods: This retrospective analysis utilized multiple-dose pharmacokinetic data from a single phase I study of 36 healthy volunteers and pooled efficacy data from two double-blind, placebo-controlled studies of 504 patients with acute muscle spasm. Occurrence of C\text{SS} for CER and percent C\text{SS} at day 4 were determined. Efficacy assessments (e.g., medication helpfulness, clinical global assessment, local pain relief) following CER administration at days 4 and 8 are presented. All protocols were IRB-approved; patients provided written informed consent. Results: C\text{SS} for CER was achieved by day 7, with approximately 90% C\text{SS} by day 4. Improvements across several efficacy measures were observed on days 4 and 8 for CER 15 and 30mg. Response distributions for medication helpfulness were significantly different for CER 15 and 30mg compared with placebo (P<0.025). On days 4 and 8, approximately 15% more patients receiving CER 15mg (56.0% and 67.5%, respectively) reported “good” to “excellent” responses compared with placebo (40.0% and 52.6%, respectively). Similarly, there were differences in response distributions for local pain relief. On days 4 and 8, approximately 15% more patients receiving CER 15mg (63.8% and 81.2%, respectively) experienced “some” to “complete” relief compared with placebo (51.7% and 65.5%, respectively). There were no significant differences in response distributions versus placebo for the physician's clinical global assessment on days 4 or 8. Conclusions: Following multiple-dose administration with CER, 90% of C\text{SS} was achieved by day 4; this corresponded with efficacy in medication helpfulness and relief of local pain.

References: not applicable

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**Timing of Effect of Diclofenac Epolamine Topical Patch 1.3% (FELECTOR® Patch) in the Treatment of Pain Due to Osteoarthritis of the Knee**

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**Introduction:** Oral non-steroidal anti-inflammatory drugs (NSAIDs) provide effective analgesia for patients with osteoarthritis (OA), but their use is associated with gastrointestinal and cardiovascular side effects.1 Topical NSAIDs have low systemic absorption and provide analgesia, potentially avoiding the risks associated with oral NSAIDs.1 Diclofenac epolamine topical patch 1.3% (DETP), the first topical NSAID patch approved in the United States, is indicated for the treatment of acute pain due to minor
strains, sprains, and contusions.2 This post-hoc analysis reports the timing of effect in a trial of DETP in patients with knee-OA.3 Methods: Data were analyzed on the intent-to-treat population from a randomized, double-blind, placebo-controlled, Ethics Committee-approved trial conducted in Europe in 1991 in patients with radiologically confirmed symptomatic knee-OA and Visual Analog Scale (VAS) pain-scores >40mm (0mm=no pain, 100mm=intolerable pain).3 Following a 7-day washout from analgesics and NSAIDs (rescue acetaminophen ≤2 g/d allowed), 155 patients had been randomized to DETP (n=78) or placebo patch (PP; n=77) twice daily for 15 days. Acetaminophen use was permitted only on days 4-15. Efficacy was assessed by patient-reported VAS pain-scores before and at appointed times after patch application. Results: A statistically significant difference in median reduction from baseline VAS pain-scores favoring DETP over PP was observed as early as 1 hour after application of the first patch (p=0.013) and maintained through day 15. Median reductions in VAS pain-scores of 30% at day-2 and 50% at day-7 were observed with DETP vs a 30% reduction at day-6 with PP. After 15 days of treatment, median reductions in VAS pain-scores were 70% with DETP vs 38% with PP. Conclusions: DETP was effective in treating pain due to knee-OA, had a rapid onset of action, and had tolerability comparable to PP. DETP may offer an alternative to existing therapies in providing analgesia to patients with symptomatic knee-OA.


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Remoxy® Controls Moderate-to-Severe Osteoarthritis Pain: A Phase 3, Multi-Center, Randomized Controlled Study

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Introduction: Pain is undertreated, at least in part because of concerns regarding the misuse and abuse of opioid analgesics. Controlled-release formulations may be manipulated to dose dump the active molecule, resulting in a serious public health problem. This Phase III study was conducted to analyze the safety and analgesic efficacy of Remoxy, a controlled-release formulation of oxycodone designed to resist common methods of physical and chemical manipulation and extraction, including crushing, snorting, heating, freezing, and dissolution in alcohol. Materials and Methods: Prior to entering a 12-week double-blind treatment period, patients with moderate-to-severe pain due to osteoarthritis (OA) of the hip or knee were randomized to receive Remoxy BID (N=205) or placebo (N=207). During weeks 1 to 4, patients were allowed to titrate their total daily dose of medication (range 10-80 mg) to accommodate individual differences. After week 4, the dose was fixed. This study was approved by an IRB. Results: Patients on Remoxy reported significantly lower pain intensity scores over the 12-week treatment period, evidenced by the primary endpoint, area under the curve for change in pain intensity (p=0.007). Patients receiving Remoxy also reported significantly better scores on Global Assessment (p=0.007), Quality of Analgesia (p=0.004), pain sub-scales of the WOMAC™ Osteoarthritis Index (p=0.023), and other secondary endpoints. The most frequent adverse events were common and expected opioid-related side effects. Thirty-six percent of patients receiving placebo and 34% receiving Remoxy dropped out of the study. Conclusions: Remoxy was shown to be a safe and well-tolerated treatment for moderate-to-severe pain associated with OA of the hip or knee, and demonstrated a significant reduction in pain intensity relative to placebo.

References: None

Funding: Pain Therapeutics, Inc. & King Pharmaceuticals, Inc.
Absorption of Oxycodone from Remoxy® When Coadministered with Alcohol in Healthy Volunteers: A Phase I, Single-Center, 4-Way Crossover Pharmacokinetic Study

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Introduction: Pain is undertreated, at least in part because of concerns regarding the misuse and abuse of opioid analgesics. Controlled-release formulations may be manipulated to dose dump the active molecule, resulting in a serious public health problem. Prescription opioids may be combined with alcohol, either deliberately in an attempt to facilitate euphoria or by individuals unaware of the potential adverse results. Some controlled-release opioid formulations dose-dump when combined with alcohol, which can have serious adverse consequences. This study demonstrates the effects of alcohol coadministration on the pharmacokinetics of Remoxy, a controlled-release oxycodone formulation designed to resist the most common methods of physical and chemical manipulation and extraction.

Materials and Methods: Thirty-seven subjects were enrolled in this study. In each treatment session, subjects swallowed a single Remoxy 40-mg capsule with 240 mL of either plain water or either 4%, 20%, or 40% ethanol. This study was approved by an IRB. Results: The oxycodone C\text{max} after ingesting Remoxy was 45.3 ng/mL with water alone, versus 45.0, 39.0, and 49.7 ng/mL with 4%, 20% and 40% ethanol, respectively. The shape of the plasma concentration time curve was not affected by ethanol. There was no effect on total exposure; the ratios for AUC\text{inf} of water co-ingestion to ethanol co-ingestion were 1.00, 1.06, and 1.14, with respective increasing concentrations of ethanol. Conclusions: These results demonstrate that Remoxy maintains a controlled-release profile when combined with up to and including 40% ethanol and does not dose dump.

References: None

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Epidemiology / Health Policy / Education

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Survey of Preferences for Deep Sedation during Painful Adult Oncology Procedures
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Introduction: Diagnostic and therapeutic procedures in oncology patients such as bone marrow biopsy/aspiration (BMB/A) and lumbar puncture (LP) with intrathecal medication administration are painful. In adults, these procedures are often performed in a conscious patient with a combination of local/topical anesthetics, analgesics, and moderate sedatives. In children and adolescent teens, these procedures are almost always performed under deep sedation (with the patient unconscious). While patient cooperation is more easily achieved with adults, pain elimination/reduction is a priority for both adults and children. The purpose of this study is to survey adult oncology patients on their preference of whether to have these painful procedures performed under deep sedation in an unconscious state.

Background: Until recently, midazolam sedation was routinely used in our institution for bone marrow aspirates and lumbar punctures in children with cancer. It has been perceived by many doctors and nurses as being well tolerated by children and their families. Aim: To compare the efficacy of inhalational general anaesthesia and midazolam sedation for these procedures. Methods: A total of 96 children with neoplastic disorders, who received either inhalational general anaesthesia with sevoflurane, nitrous oxide, and oxygen (GA) or sedation with oral or nasal midazolam (SED) as part of their routine preparation for procedures were studied. The experiences of these children were examined during their current procedure and during their first ever procedure. Main outcome measures were the degree of physical restraint used on the child, and the levels of distress and pain experienced by the child during the current procedure and during the first procedure. The family's preference for future procedures was also determined. Results: During 102 procedures under GA, restraint was needed on four occasions (4%) when the anaesthetic mask was first applied, minimal pain was reported, and children were reported as distressed about 25% of the time. During 80 SED procedures, restraint was required in 94%, firm restraint was required in 66%, the child could not be restrained in 14%, median pain score was 6 (scale 0 (no pain) to 6 (maximum pain)), and 90% of the parents reported distress in their child. Ninety per cent of families wanted GA for future procedures. Many families reported dissatisfaction with the sedation regime and raised concerns about the restraint used on their child.

Methods: Oncology patients from a single oncologist study investigator were sent informational letters requesting study participation consent. For those who consented, a telephone interview was conducted regarding the patients' previous experience with painful procedures (BMB/A and/or LP) and whether they would prefer to have had these procedures performed under deep sedation, given the necessary information required for informed consent. This study was reviewed by the Human Subjects IRB of Hawaii Pacific Health and approved as carried out. Results: 17 patients consented to the interview, of which six patients stated that they would like to undergo deep sedation for these procedures such that they would be unconscious and not have any awareness or recall of the pain during the procedure. The remaining 11 patients were satisfied with having these painful procedures performed as they had been conducted without deep sedation. Conclusion: The current practice of deep sedation for painful procedures in pediatric oncology patients is preferred by some adult oncology patients as well.

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Post-Partum Headache: An Unusual and Evolving Case
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Background: CVT and dural puncture headache are important diagnostic considerations in women with postpartum headache. Dural puncture headaches usually begin within the first week after delivery and occur in approximately half of patients with accidental dural puncture. Typically, dural puncture headaches are postural. CVT is the most common cause of stroke peripartum, most often occurring in the second and third weeks post-delivery. Definitive diagnosis requires the presence of seizures, focal neurologic deficit, or increased ICP. We report a case of CVT in a patient with persistent postpartum headache. Methods: Case report. Results: On postpartum day one, a 22-year-old primigravida reported a postural headache. During labor an epidural catheter was placed. Her headache was initially severe and had a significant postural quality. There were no other neurologic symptoms. On the fifth postpartum day, she underwent an epidural blood patch, without relief. She continued to have a severe postural headache, and the blood patch procedure was repeated seven days later. She experienced almost immediate relief. One day later, she noticed double vision and a left-sided facial droop. A headache recurred. Exam revealed a right abducens nerve palsy. MR venogram demonstrated left temporal and parietal occipital cortical venous thromboses and subocclusive thrombus in the left transverse sinus. Lumbar puncture revealed an elevated opening pressure. The patient was anticoagulated and treated with acetazolamide. Her symptoms improved. Two weeks later, exam revealed only papilledema. Conclusions: CVT is a rare cause of postpartum headache, and is difficult to diagnose in the setting of post-dural-puncture headache. Multiple factors in pregnancy increase blood viscosity and may predispose to CVT. Dural puncture may add to the risk of postpartum CVT; several mechanisms are proposed. CVT should be considered in patients with postpartum dural puncture headaches, especially if the postural character of the headache resolves or new neurologic symptoms occur. References: references to follow with poster presentation
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Roland-Morris Questionnaire as an Outcome Measure for Low Back Pain and Radiculopathy Management at a University Interventional Pain Practice
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Background and Purpose: Functional outcome measurement has become a necessity in today's practice of medicine1. The Roland-Morris Disability Questionnaire (RMQ)2 is a validated tool for functional evaluation of chronic low back pain and radiculopathy 3. The objective of this study is to assess the effect of implementing the RMQ in our academic interventional pain practice. Methods and Outcomes: New patients presenting to the interventional pain clinic with chronic low back and/or leg pain were prospectively enrolled. Outcome measures tracked included: 1) RMQ at baseline and at 3 months, 6 months and 1 year; 2) Pain intensity scores (VAS) recorded separately for back and leg. Results: 288 patients with low back pain and/or leg pain were screened and enrolled. At three months, the data collection rate was 90% leaving 259 patients for analysis (27 with only leg pain, 67 with only back pain and 165 with back and leg pain). There were 49 (17%) patients with RMQ scores ≤8 that showed a
change in score at 3 months of 1.2±2.05 (mean change ± SD). Patients with baseline RMQ scores of 8-18 (148 patients, 57%) there was a dramatic improvement in score of 7.7±3.4. Patients with RMQ scores of 18-24, (67 patients, 26%) had a change of 5.7±3.7 at three months post intervention. There was an improvement in reported VAS scores in all three groups with an average of 35±44 mm for back and 28±37 mm for leg pain. Conclusion: The use of RMQ in the setting of interventional pain practice is easy to implement and is a valuable instrument to assess treatment outcome efficacy. In the short term (3 months), patients with RMQ scores 8-18 (moderate dysfunction) have the most dramatic improvement in functional status in response to interventional approaches.


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Longitudinal Experience of a Nationally Representative Sample of the U.S. Population 18 Years and Older: The Importance of Co-Morbid Major Depression, Alcohol and Drug Abuse

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The National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) was conducted by the National Institute of Alcohol Abuse and Alcoholism in 2000-2001 (Wave1) and 2004-2005 (Wave2) to obtain longitudinal epidemiologic data on substance use and DSM-IV disorders. The inclusion of the SF-12 pain question, “How much did pain interfere with your normal work” in the Wave1 and 2 in-person interviews enabled examination of the prognostic importance of co-morbid major depression, alcoholism and illicit drug abuse on pain severity, stability and change in a nationally representative sample of 34,853 U.S. residents over age 18 with Waves1&2 interviews. Longitudinally, the sample reported the following: 48.4%-no pain interference; 16.1 %-new pain interference at Wave2; 13.6%-recovered pain interference at Wave2; and 22.0%-persistent pain interference. Statistically significant associations (P=<.00) were observed between pain severity and age(older), gender(female), recent diagnosed major depression, alcoholism and drug abuse. Logistic regressions compared pain groups: no pain interference vs new pain interference; no pain interference vs persistent pain interference; and recovered pain interference vs pain interference non-recovery. Not unexpectedly, after adjustment for confounders, a diagnosis of major depression increased the likelihood of new pain interference, persistent pain interference, and pain interference non recovery. Drug abuse history also increased an individual's risk of new pain interference, persistent pain interference, and pain interference non-recovery (OR=1.3; OR=1.7; OR=1.2 respectively). As well, alcoholism history increased the risk of persistent pain interference (OR=1.5) and interference non-recovery (OR=1.2). These findings from the first longitudinal, prospective study of such a large community sample of adults with pain confirm the importance of screening, evaluating and managing substance abuse, depression and pain together when developing cost-effective health programs for communities.

Complex Regional Pain Syndrome: Demographics, Comorbidities and Treatment Outcomes in Patients at University Interdisciplinary CRPS Clinic

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Background: CRPS is a complex disease that involves dysfunction of peripheral and central nervous system. While CRPS is often associated with other autonomic disorders, there has been no formal exploration of the incidence of comorbid disorders in CRPS. Further more a multidisciplinary approach is believed to yield the best results in treatment outcome. For that purpose the objective of this study is to examine the demographics and comorbidities of patients with CRPS UHCMC CRPS interdisciplinary clinic.

Methods: Cohorts were identified from the Ohio Dysautonomia Survey (ODYSA) database. Demographic data and coexisting medical conditions were compared. In a cohort of 34 patients of UHCMC CRPS clinic, demographics and characteristics were examined by analyzing responses to WHY-MPI and BDI-II. This study has been approved by IRB.

Results: 46 patients meeting criteria for CRPS and 61 controls were identified. Patients with CRPS were less likely to have functional dyspepsia than controls (7% vs. 39%, P < 0.0002). CRPS patients were more likely to have fibromyalgia (67% vs. 36%, P = 0.0026), chronic fatigue syndrome (16% vs. 0%, P = 0.0019), and interstitial cystitis (32% vs. 9%, P = 0.0129) compared to controls. In cohort of 34 of CRPS patients 90% had previous trauma or surgery, 20 patients have only LE involvement, 5 UE involvement, 3 U&LE involvement while 8 patient have bilateral involvement of extremities. Almost 24% of the patients had moderate BDI-II scores while 12% had high BDI scores indicating severe depression. In a subpopulation of 16 patients, only 9 had a positive response to sympathetic block while 7 had no relief despite a technically successful block.

Conclusions: Chronic fatigue syndrome, fibromyalgia, and interstitial cystitis often occur as comorbid conditions in patients with CRPS. Only a portion (59%) of the CRPS patients has sympathetically maintained pain.


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Pain Disparities: Comparisons Between Black and White Elders

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Objective: To examine disparities in the experience of pain between black and white community-dwelling adults and examine associations with other health and quality of life variables.

Methods: A secondary analysis of data from the Quality of Life, Health and Valuation of Life by Elders (QOLE) research study was performed. The data was organized to examine differences in the experience of pain between white [N=297] and black [N=295] older adults. Descriptive, univariate, and multivariate analyses were used to quantify disparities in pain and related factors, using selected variables collected from the baseline sample of the QOLE survey study.

Results: Black participants reported greater pain

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and functional limits. The prevalence of certain common conditions associated with pain was higher among blacks. Pain and functional limits attributed to most conditions were more highly correlated among blacks as compared to whites. For blacks with multiple conditions, pains attributed to such conditions were more strongly correlated than among whites. A multivariate analysis showed that self-rated health, reported depressive symptoms, and the interaction between race and number of reported health conditions were important predictors for functional limits among those reporting arthritis and pain, with blacks showing increased odds of functional impairments as number of conditions increased, as compared to whites. **Conclusions:** The experience of pain differs between black and white older community-dwelling adults, with blacks reporting greater pain and limits. The greater prevalence of chronic disease among blacks may impact racial disparities in pain and functional limit measures. **References:** Bates MS, Edwards WT, & Anderson, KO. “Ethnocultural Influences on Variation in Chronic Pain Perception.” Pain 52(1993): 101-112. Green CR, Anderson KO, Baker TA, Campbell LC, Decker S, Fillingim RB, et al. “The Unequal Burden of Pain: Confronting Racial and Ethnic Disparities in Pain.” Pain Medicine 4(2003): 277-294. Reyes-Gibby CC, Aday LU, Todd KH, Cleeland CS, & Anderson KO. "Pain in Aging Community-Dwelling Adults in the United States: Non-Hispanic Whites, Non-Hispanic Blacks, and Hispanics." The Journal of Pain 8(2007): 75-84. **Funding:** None

### 249 Controlled Substance Agreements: The Patient's Perspective

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**Introduction:** Controlled substance agreements are widely used by healthcare providers who prescribe opioid medications. Little empirical research supports their effectiveness in increasing patient adherence, education, or legal protection for providers. **Research Question:** How do patients receiving long-term opioid treatment characterize the controlled substance agreement process? **Method:** This quantitative, non-probability study studied patients with chronic pain receiving long-term opioid treatment in private medical practices. Watson's Theory of Human Caring provided the framework to explore patients' perceptions with a modified version of the Caring Behaviors Inventory. **Results:** The majority of respondents viewed the American Academy of Pain Medicine's sample Controlled Substance Agreements as a caring health care activity by providers. Patients with higher educational levels had lower total care scores on the modified Caring Behaviors Instrument. The controlled substance agreement studied ranked highest in being honest with patients and demonstrating professional knowledge to the study patients but lowest in expressing hopefulness. **Conclusion:** The Theory of Human Caring by Watson provided a useful theoretical framework to actualize and quantify patient-centered care. Research patients receiving long-term opioids for chronic, non-malignant pain perceived the American Academy of Pain Medicine's controlled substance agreement as a caring healthcare document. **References:** Wolf, Z. R., Giardino, E. R., Osborne, P. A., & Ambrose, M. S. (1994). Dimensions of nursing care. Image: Journal of Nursing Scholarship, 26(2), 107-111. Quinn, J. F., Smith, M. S., Ritenbaugh, C., Swanson, K., & Watson, J. (2003). Research guidelines for assessing the impact of the healing relationship in clinical nursing. Alternative Therapies, 9(30) A65-A79. Arnold, R. M., Han, P. K., & Seltzer, D. (2006). Opioid contracts in chronic nonmalignant pain management: objectives and uncertainties. American Journal of Medicine, 119, 292-296. **Funding:** None
Catastrophizing About Pain is Associated with Enhanced Pro-Inflammatory Pain Responses
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Introduction: Pain-related catastrophizing consists of a set of negative cognitive and emotional processes including magnification of pain-related symptoms, rumination about pain, feelings of helplessness when in pain, and pessimism about pain-related outcomes. Catastrophizing appears to exert its deleterious effects on pain via multiple physiological pathways, and there are reasonable grounds for suspecting that catastrophizing may interact with pain-related inflammatory processes, though this particular hypothesis has not been tested in a laboratory study.

Materials and Methods: This study involved human subject volunteers and was IRB-approved. Forty-two generally healthy adults underwent a series of psychophysical pain testing procedures assessing responses to noxious mechanical and thermal stimuli. None of the tests were tissue-damaging, but all resulted in moderate-to-severe ratings of pain intensity. Catastrophizing was measured at multiple time points during the pain induction procedures. Blood samples were taken at baseline and then at several time points from the end of the procedures to 1 hour post-testing. Samples were assayed for plasma levels of cortisol, a classical “stress hormone”, and interleukin-6 (IL-6), a pro-inflammatory cytokine.

Results: Both cortisol and IL-6 increased from baseline during the post-testing period, with cortisol returning to baseline by 1 hour post-testing and IL-6 remaining elevated. Catastrophizing was unrelated to cortisol reactivity (p> .10), but was strongly related to IL-6 reactivity (p< .01), with higher levels of catastrophizing predicting greater IL-6 reactivity to pain.

Conclusions: Collectively, these findings suggest that cognitive and emotional responses during the experience of pain can shape pro-inflammatory immune system responses to noxious stimulation. This pathway may represent one important mechanism by which catastrophizing and other psychosocial factors can shape the experience of both acute and chronic pain in a variety of settings.


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and injured from improvised explosive devices (58.9%) and gunshot (21.4%). Recall of mean average and worst pain scores (± standard deviations) during transport and at LRMC are presented (Table 1). Average percent pain relief achieved during transport was 45% ± 30%, and 65% ± 20% while at LRMC. Participants with CPNB catheters placed at LRMC reported significantly less average pain (p=0.039), and less pain right now (p=0.024) compared to soldiers without CPNBs. High average and worst pain scores were inversely correlated with pain relief during transport (p=0.01), and positively correlated with increased anxiety, distress, and worry during transport (p=0.05). Conclusions: Our findings underscore the value of early aggressive pain management after major combat injuries. Increased pain was associated with increased anxiety, distress, and worry during transport. Regional anesthesia techniques while at LRMC contributed to better pain outcomes. Table 1.


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A Qualitative Analysis of Perceptions and Experiences Following Battlefield Injury and Evacuation: A Survey of Casualties from the Iraq and Afghanistan Wars

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Introduction: Little is known about the early experiences of soldiers sustaining major battlefield injuries in Iraq and Afghanistan during flight evacuation from combat support hospitals to Landstuhl Regional Medical Center (LRMC), Germany. This study employed qualitative methods to elucidate concerns, fears and worries, and perceptions of pain control in transport. Materials and Methods: Using a semi-structured interview method, 110 wounded soldiers at LRMC from Iraq and Afghanistan July 2007 to February 2008 responded to open-ended statements to elicit information on their greatest and least concerns in transport LRMC, and how pain control could have been improved. Data were compiled, categorized, coded, and validated with content analysis techniques. The Walter Reed Army Medical Center Human use Committee approved this investigation. Results: The sample predominantly male (99.1%) and Caucasian (78.6%) sustained injuries primarily from improvised explosive devices (58.9%) and gunshot (21.4%). While responses were brief, powerful insights were gained into their thoughts and awareness. Numerous cluster themes emerged from the analysis of responses including: “Concerns” for both self and others; “Communication of the unknown” wanting a sense of location, knowing what to expect, and being informed; “Fear” of injury, pain and helplessness; “Physiological Concerns,” characterized by basic needs and symptom experiences; and, “Dignity” described by feelings of helplessness. “Making the experience better” was defined by issues around “pain medication,” “comfort measures,” “communication,” and complimentary expressions of “confidence in care providers.” Conclusions: These findings show the importance of addressing perceived priorities of care including
interventions to ensure adequate pain control, information support, and communication during air evacuation. Qualitative studies are essential to understand areas within the current rapid evacuation system requiring change. Our results have led to a greater appreciation of the stressors encountered by combat casualties that may contribute to post-traumatic stress disorder, increased pain, and depression, among other undesirable medical conditions.

References: No references

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An Unusual Presentation of Ankle Pain Secondary to Saphenous Neuropathy, Following an Ankle Surgery: A Case Report
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A 43-year-old male presented with left ankle pain for the last 7 years. The patient had a history of bimalleolar fracture in the left ankle and underwent open reduction and internal fixation in 2001. Since then, he had chronic left ankle pain without a clear diagnosis. The patient stated that the pain was relieved with ankle inversion and exacerbated with ankle eversion. Physical examination revealed Achilles tendon tightness with dorsiflexion restricted to 5 degree and plantar flexion 10 degree, beyond neutral position. Manual muscle testing revealed 4+/5 in dorsiflexion, plantar flexion, inversion, and eversion of the left ankle. Sensations were intact in the left lower extremity but the patient reported exquisite tenderness in several points on the anteromedial aspect of the left lower leg. Tinel sign was positive along the left saphenous nerve distribution from the mid shin to the medial malleolus. Ultrasound of the left lower leg failed to reveal any visible lesion such as a neuroma or lipoma. We used a rubber eraser on the end of a pencil to pinpoint the tender points. After five tender points were isolated, about 1.5ml of 1% lidocaine was injected into the most proximal points of tenderness for diagnostic purposes. The patient's pain was instantaneously decreased from 9/10 to 3/10 on VAS. The patient was clinically diagnosed with left saphenous nerve entrapment secondary to scar tissue adhesion and referred to physical therapy focusing on scar tissue release and mobilization and Achilles tendon stretching.


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Back Pain and Functional Brown-Sequard Syndrome: A Case Report
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We describe a case of a 52-year-old male who presented with new onset of left lower extremity weakness, right lower extremity numbness and several hours of difficulty ambulating. He was in his usual state of health until 3 days prior when he developed left upper back pain, throbbing, non-radiating and involving the entire left hemithorax. He had no history of trauma, injury or other significant condition. On the third day his left leg was weak and the right leg was numb. He had one episode of urinary incontinence. He was evaluated at that time in the Emergency Department. Physical examination revealed 4/5-muscle power in left lower extremity and decrease light touch, pin prick and temperature sensations in the right lower extremity. The sensory level was noted to be T8 level on right side.
Proprioception was diminished on the left side. Deep tendon reflexes were 1+ with down going plantar response bilaterally. No saddle anesthesia or dysmetria was noted. Gait was slow and unsteady. He was unable to walk on heels or toes. The CT scans of chest/abdomen/pelvis and head ruled out aortic dissection and brain pathology. The MRI of cervical/thoracic/lumbar spine with and without gadolinium were negative for spinal cord pathology, tumors, vascular or demyelinating lesions. There was no evidence of psychiatric disease, malingering or secondary gain. Infectious and inflammatory causes were ruled out by extensive laboratory testing. The clinical diagnosis of incomplete Brown-Sequard Syndrome was suggested. The patient responded to rehabilitation intervention with improvement in ambulation and muscle strength. There were no other changes from the previous examination noted.


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Nutraceutical Use in a University Rheumatology Clinic
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Introduction: Nutraceuticals, defined as foods or food supplements to prevent or treat disease, are commonly used by arthritis patients. Objective: We performed a study to determine the frequency of nutraceutical use & characteristics of users in an outpatient rheumatology clinic. Methods: After proper IRB approval was obtained regarding this study, an anonymous questionnaire was given to rheumatology patients for three months during their clinic visits. The questionnaire gathered data about patient demographics, diagnosis, supplements used, and source(s) of information for the supplement. Five hundred randomly selected records of the same patient population were reviewed for recorded supplement use. Results were analyzed with frequency tables & chi square analysis. Results: Four hundred twenty three anonymous questionnaires were analyzed and 34% reported nutraceutical use. In contrast, 500 randomly-selected records found only 11.4% had nutritional supplements listed with medications (p<0.001). There was no statistical difference in use of supplements by gender or ethnic group. There was a statistical difference in nutraceutical use comparing age groups of < 45 years (22.8%), 45-65 years (41.4%), and >65 years (32.3%)(p=0.0025). More than one supplement was reported by 59% of nutraceutical users by questionnaire, but only 32% of reviewed charts recorded more than one per user. Forty-six different supplements were reported taken. The primary source of information about supplements that patients listed was advice from a friend (p=0.0001). Conclusion: Middle-aged, college-educated individuals were more likely to take nutraceuticals than younger or older less-educated patients. Comparison of anonymous questionnaires to randomly selected records suggests that physicians may be unaware of supplement use and thus potential side-effects or medication interactions.

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Educational Needs Analysis Regarding Co-Morbid Pain and Substance Abuse
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Introduction/Statement of the Problem: Successful treatment modalities for patients with co-morbid pain and substance abuse problems have been developed. However, the practice community is ill-equipped to incorporate such evidence-based recommendations or strong clinical consensus opinions due to a lack of knowledge and training in this area. Materials and Methods: Using funding from NIDA, this project is surveying and interviewing primary care physicians (PCPs), primary care residents, and nurse practitioners (NPs), to determine educational needs and learning preferences. We also inquired about interest in an educational experience involving Internet-based Standardized Patients (SPs) to mirror the challenges and variability of interviewing live patients. Exempt research determined by the Clinical Tools' IRB involved opt-in subjects who were contacted by email about participating in online surveys (n=9 for each group). Results: Each group prioritized training need as follows: 1) treating patients in recovery, 2) treating patients actively using substances, 3) treating patients at risk for substance abuse. With respect to conventional online, case-based educational courses, each group preferred a format using multiple short cases (>75%). They differed slightly in terms of how to best integrate cases and factual content but all preferred interactive questions/answer pairs on every page. The majority of each group expressed interest in learning by interviewing a virtual SP. For the SP experience, a chat-based interview was preferred to a video-based interview. Practicing physicians want very flexible hours and quick response time. Residents and NPs are more willing to wait for a response. Conclusions: PCPs, residents and NPs identify a need to learn more about co-morbid substance abuse and pain. They are interested in online education solutions, especially those that employ multiple cases as the learning modality and interactive questions. They are willing to engage with virtual SP via chat. References: Mitchell AM, Dewey CM. Chronic pain in patients with substance abuse disorder: general guidelines and an approach to treatment. Postgrad Med. 2008;120(1):75-9

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Non-Illlicit Drug Poisoning Deaths in Utah: How Are Legitimate Prescriptions Involved?
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Statement of the problem: Fatalities related to prescription drugs, primarily opioids, increased twenty one-fold in Utah between 1997 and 2005. Materials and Methods: We used a combined deterministic and probabilistic algorithm to link Utah's controlled substance prescription registry to the death certificate and medical examiner databases to examine non-illicit poisonings at an individual level. The goal of this IRB approved analysis was to determine the proportion of non-illicit poisoning decedents that had legitimate access to drug at the time of and within the year prior to death. Death certificates were linked to the prescription registry for the years 1999–2004, the most recent year for which
Complete prescription data were available. Decedents with a primary cause of death code for poisoning by narcotics were selected. Suicides, homicides, and deaths with any mention of illicit drugs were excluded. **Results:** Among the 734 decedents identified, 47% had an active prescription for an opioid drug at the time of death, and 75% had filled such a prescription during the year prior to death. We found no evidence of a previous opioid prescription for only 15% of the non-illicit drug poisoning decedents. The average age at death was 41 years with no difference by prescription status. Among a subset of decedents for whom we had medical examiner data, 40% had an active prescription at death for all drug(s) identified as a cause of death by the medical examiner. Analysis is ongoing, and results complete through 2007 are anticipated by November, 2008. **Conclusions:** The large fraction of decedents with valid prescriptions suggests that interventions need to consider patient safety concerns such as existence of multiple active prescriptions in addition to drug diversion to prevent fatal poisonings.

**References:** No citations in abstract. Analysis of routinely collected data.

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### Identifying Practice Patterns Among Physiatrists Treating a Commerically-Insured Population

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**Introduction:** The majority of patients receiving care from physiatrists are treated for pain. The challenge in treating the pain population is that a cause is often unknown and there are no best practices for treating most chronic pain. This situation can lead to excessive variability in the treatment approaches for the pain patient among physiatrists. **Material and Methods:** A data set consisting of medical claims from 8,229 commercilly insured patients treated by 202 physiatrists across multiple health plans and geographic regions in 2006 was analyzed. Patient utilization of office visits, electromyography (EMG) and nerve conduction velocity (CV), translaminar and transforminal ESI, facet joint injections, trigger point injections, and bursa injections were analyzed to determine patient prevalence for each procedure, as well as average frequency, intensity and duration. These were then compared to provider expectations. **Results:** Within a 12-month period, 54% of patients had more than one date of service, which was lower than expected. As expected, the most common procedure received by patients was EMG and CV (24% of patients), followed by transforminal ESI (8.6%), translaminar ESI (7.6%), facet joint injections (5.9%) and trigger point injections (5.8%). The frequency of care was greatest for trigger point injections (1.75 visits/patient) and intensity of care was highest for facet joint injections (1.96 injections/visit). Care duration beyond 3 months for each of these procedures was greater than expected, affecting between 12%-17% of each patient group. **Conclusions:** Medical claims data is an underutilized resource for measuring care provided by a physiatrist. Patient medical care utilization and individual practice patterns can be compared to outcomes that would be expected in a typical physiatric practice. This information can then be compared across populations to identify and manage treatment variability among similar patient groups.


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Outcomes of a Community-Based Pain Management Program

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We investigated outcomes of a community-based, rehabilitative pain program. Health-related quality of life (HRQOL) has not been previously reported as the principal outcome measure in a community-based, non-university pain program. HRQOL may be a more important outcome variable than traditional ones currently measured. Furthermore, results from community-based programs may be more generalizable than university-based programs. Subjects included all outpatients at SMDC Health System Pain Management Program, Duluth, Minnesota, 2000 - 2007. All chronic pain diagnoses were included, but patients under age 18 or those failing to return for treatment after initial assessment excluded. The rehabilitative program was 8 to 16-weeks. Study variables included Brief Pain Inventory (BPI), Functional Assessment (FX-13) scores, Beck Depression Inventory (BDI), SF-36 Health Survey (HRQOL), daily hours active & asleep, drugs, oral morphine equivalent dose, substance use behaviors, and pain program participation (dose intensity). Analysis included paired samples t-test and Spearman's correlations. Our IRB approved the study. 265 patients had complete data and were analyzed for this report. Subjects were in program 8.5 weeks (mean), range 1-16, with primary pain diagnosis: back, 59%, fibromyalgia, 18%, neuropathic pain, 8%, arthritis, 6%, and other pains, 9%. The sample was 58% female, between 18-69 years of age (mean 44.1), 28% employed, 51% married, 8.1 years of pain, and 13.0 years education. Program participation improved primary outcomes: SF36-PCS and MCS mean scores increased 3.1 and 5.8 respectively (both P<0.001). Secondary outcomes all improved in desired directions: BPI pain intensity scores (4), BPI- interference function scores (7), BPI-CPI score, FX-13 score, daily hours asleep and active, and BDI score (all p-values <0.001). This community-based rehabilitative pain program significantly improved patients’ HRQOL as measured by the SF-36 and all other outcomes. Further research is needed to fully understand the value of community-based pain programs, treatment dose-effect, and use of these innovative outcome measures.

References: None

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Characteristics and Impact of Breakthrough Pain (BTP) in Noncancer and Cancer-Related Chronic Pain Managed by Clinicians Who Are Not Pain Specialists

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Introduction: To evaluate and compare the characteristics and impact of BTP in populations with noncancer and cancer-related chronic pain, we surveyed 177 patients undergoing treatment at 18 sites by physicians who were not pain specialists. Eligible patients were receiving chronic opioid therapy and had controlled baseline pain. Methods: Patients completed the Brief Pain Inventory (BPI)1 and the Brief Battery for Health Assessment 2 (BBHI 2)2, and were later surveyed by telephone3. Results: Thirty-three percent of cancer patients (26/78) and 49% of noncancer patients (48/99) reported BTP—temporary flares of severe or excruciating pain. Median number of episodes per day was 1 for both cancer (range <1 to 4) and noncancer patients (range <1 to 5). Median time to maximum intensity was 1 minute (range 0 to 60) in cancer patients and 2 minutes (range 0 to 180) in noncancer patients; 64% of cancer patients and 55% of noncancer patients reached maximum pain intensity within 5 minutes. Median duration of BTP was 45 minutes (range 5 to 360) in cancer patients and 60 minutes (range 5 to 620) in noncancer patients. The onset of BTP could not be predicted by 69% of the cancer patients and 39% of the
noncancer patients. Compared to those without BTP, both cancer patients (p=.004) and noncancer patients (p=.019) patients with BTP had increased pain interference in function, as measured by the BPI. On the BBHI 2, BTP was associated with increased somatic complaints (p=.036 cancer and p=.024 noncancer) and pain complaints (p=.037 and .037); among noncancer patients, BTP also was associated with increased difficulties with functioning (p=.023), depression (p=.039), and decreased quality of life (p=.004). Conclusions: These data demonstrate fundamental similarities in the phenomenology of BTP in populations with and without cancer, and support an association between BTP and poor patient outcomes in both populations.


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Introduction: Postherpetic neuralgia (PHN) demonstrates various clinical features, including pain, allodynia, and sensory deficit. The implicated pathophysiologic mechanisms involved in PHN remain controversial. This study was carried out to clarify the roles of peripheral sensory nerves in the production of allodynia and ongoing pain. Material and Methods: After institutional approval was obtained along with written informed consent, sixteen patients with thoracic PHN (seven men, nine women) were studied. The intensities of ongoing pain and dynamic allodynia were assessed using a numeric rating scale (0-10, with 0 = no pain, 10 = worst pain imaginable). Assessment of sensory nerve function was performed by a series of 2000-Hz (Aβ-fiber), 250-Hz (Aδ-fiber) and 5-Hz (C-fiber) stimuli using current perception threshold (CPT) testing. These measurements were made in ipsilateral and contralateral area. Results: CPTs at all frequencies in the ipsilateral area were significantly higher than those in the contralateral area. There were significant and inverse correlations between the intensity of allodynia and CPTs at all frequencies. No correlation was found between the intensity of ongoing pain and CPTs at any frequency. There was no correlation between the intensity of ongoing pain and the intensity of dynamic allodynia. Conclusions: The intensity of dynamic allodynia in postherpetic neuralgia correlates with the preserved functions of Aβ, Aδ, and C fibers. In contrast, the intensity of ongoing pain does not correlate with either the preserved function of C fibers or the intensity of dynamic allodynia. Therefore, it is suggested that postherpetic neuralgia might be a pain syndrome including both peripheral and central mechanisms.

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Pain Management Strategies of Osteoarthritis Patients in a Medicaid Population: 30 Months of Treatment
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Background: Common problems in the management of osteoarthritis (OA) pain include inadequate pain relief, insufficient duration of relief, sleep loss, and consequences that arise from these problems. The
The purpose of this study was to examine OA treatment patterns including medication use and cost. 

**Methods:** A longitudinal retrospective cohort study was implemented using South Carolina Medicaid data from January 2001 - June 2005. Patients were selected in 2001 and 2002 and followed for 10 quarters from study initiation. Study included continuously eligible patients who were 18 years of age or older, had at least two OA diagnoses in a year, and in the follow-up period had at least one pain-related prescription, had no evidence of cancer, organ transplant, HIV/AIDS, and no nursing home use. Mean utilization and cost were estimated, in a mixed model analysis of variance, for all nine therapeutic categories of study drugs and covariates for age, gender, and time (Q1 – Q10) including interactions. 

**Results:** Study patients (n=3,113) were older (mean age = 62.0 years), mostly female (83.4%), and typically African-American (57.4%). The most common comorbidities were hypertension and myocardial infarct. Obesity, drug, alcohol and substance abuse also were common. Results show substantial shifts in drug therapy over time. For example, 13.8% had no drug use in Q1 but by Q10 prevalence had risen to 54.0%. Similarly, 13.8% used narcotics in Q1 and 18.5% were users in Q10. Drug utilization models showed declining NSAID and COX-2 use, while all other drug use, except antidepressants, increased. Utilization by women was generally higher than men with the exception of narcotic use. 

**Conclusions:** Two prominent patterns of OA treatment over the study period were discontinuation of drug therapy, and an increasing number of patients using narcotic therapy. Whether the change in utilization is due to mis-management or episodic drug therapy is not known. 

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**Linguistic Validation of Six Patient-Reported Outcomes Questionnaires Into Twelve Languages for Patients with Fibromyalgia**

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**Introduction:** Fibromyalgia’s complex symptomatology means that different instruments need to be used for assessing the patients’ perception of this constellation of physical and psychological symptoms and their impact on its daily life. Six questionnaires (Multidimensional Fatigue Inventory MFI, Multiple Ability Self-report Questionnaire MASQ, State-Trait Anxiety Inventory STAI, Fibromyalgia Impact Questionnaire FIQ, Beck Depression Inventory-II BDI-II, and Patient Global Impression of Change PGIC) were validated into twelve languages in order to use them in international studies. 

**Material and Methods:** The standardised linguistic validation process followed includes the following steps: forward translation, backward translation, review of the version by a clinician and comprehension tests on subjects in the target country. 

**Results:** Regardless of the instruments and dimensions studied, the same validation issues arose: i) an issue that is strictly related to translation, for example, the word “things” was translated as “something”; ii) literal translation is possible but culturally irrelevant, for example the expression “to walk several blocks”, which is a totally abstract concept in Europe, was translated as “to walk for more than one kilometre”; iii) the translation needs to be reformulated or the tense needs to be changed for idiomatic reasons. For example, the present perfect does not exist in German, and so the present simple was used in the first version. The imperfect was eventually used with adverbs such as “lately”. 

**Conclusions:** Linguistic validation, completed according to a recognised and rigorous method, allows for the wide-scale use of these patient-reported outcomes instruments in international studies. 


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**Public Opinion Survey Regarding Prescription Pain Medication**

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**Introduction:** In Utah, a public opinion survey was conducted in order to understand perceptions and awareness about use and misuse of prescription opioids to provide a baseline for an education campaign.

**Methods:** A statewide, randomized telephone survey was conducted among Utah residents age 18 and older. 413 interviews were completed. **Results:** Prescription pain medication was perceived as dangerous by 32% of respondents, with the largest perceived dangers being the possibility of addiction (48%), abuse/misuse (21%), and overdose (12%). When asked if they felt that prescription pain medications prescribed by a doctor are considered safe, nearly ¾ of respondents (73%) said “YES”. Regarding misuse, 93% of respondents felt that prescription pain medications are misused, while 55% knew someone personally who has misused or abused a prescription pain medication. Of respondents, 53% felt that people do not take their prescription pain medication exactly as prescribed. Most individuals (58%) felt that sharing prescription pain medications with family, friends or loved ones was “VERY DANGEROUS”. Among respondents, 17% admitted to having shared their prescription pain medications with others for whom they were not prescribed. Similarly, 19% have taken prescription pain medication not prescribed to them, despite 89% of respondents feeling that it is wrong to take prescription pain medications not prescribed to them. Regarding perceived risk of death, 37% of respondents thought it was likely that people die from using prescription pain medications. When asked where they obtain information about prescription pain medications, the majority referred to their doctors (67%) and pharmacists (39%) for information. **Conclusions:** Although prescription pain medications are not perceived as dangerous (particularly when prescribed by a doctor) the majority of Utahns recognize that they can be dangerous when shared. The results of this survey served to direct the efforts of Utah’s educational campaign by targeting areas of misperceptions.

**References:** The Public Opinion Survey Research Report was compiled by Vanguard Media in conjunction with the Utah Department of Health Prescription Pain Medication Program.

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**Utah's Education Campaign for Prescription Opioids**

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**Introduction:** In 2007, the Utah Department of Health began a program to educate providers, patients, and the general public about safe use of prescription opioids. This program was developed under legislative mandate in response to the increase in deaths in Utah related to prescription opioids.

**Methods:** Providers: Academic detailing (small group, one-on-one presentations) will be implemented during 2008-2009. Despite being time and labor intensive, this approach is proven to have the most impact on provider behavior change. Large group presentations and webinars will also be done throughout the state. Evaluations will be done to assess the extent of behavior change attributable to each of these interventions. Patients and general public: A statewide media campaign has been launched
under the name “Use Only As Directed”. The campaign highlights 6 key messages for safe use of opioids. Materials developed include a TV and Radio spot, bookmarks, pamphlets and posters (for doctor's offices and pharmacies). The impact of the various media tools is being monitored in order to see the overall impact the media campaign has had during 2008. Collaboration Methods: Utah has convened a steering committee and advisory committee with over 100 participants representing the partners and stakeholders involved in this important issue. The advisory committee is divided further into work groups that meet on the topics of: patient and community education, provider behavior change, guideline recommendations, guideline tools, and data/research. Conclusion: Utah is using a multi-pronged approach to prescription opioid education, reaching out to physicians, patients, and the general public in order to increase knowledge about potential dangers of prescription pain medication. Many lessons have been learned during the content development as well as from the distribution of the materials. By collaborating with local and state organizations, the materials have been well-accepted and dispersed throughout the state.

References: the website can be seen at www.useonlyasdirected.org

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Dual Crisis Resource Management/Crisis Management Sessions for Pain Clinic Staff

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Introduction: Crisis Management (CM) of complications during everyday pain procedures requires not only practice and reflection of clinical decision-making algorithms, but also good teamwork and communication using Crisis Resource Management (CRM) principles. This CRM/CM Pain Clinic program was developed to build teamwork and leadership skills and to provide a clinical care review and hands-on practice of both for a multidisciplinary staff. Materials And Methods: In the first year of the program (2005), a CRM session was offered to a clinical group that included residents, fellows, nurses, radiology technicians, and office staff. A CM session occurred one week later. Since 2005, the training has continued with annual CM and biyearly CRM sessions. Evaluations were completed after sessions. Results: Participants have completed four sessions since 2005. Trainees rated the value of the courses at a high level, ranging from 8.6 ± 1.273 to 9.2 ± 1.053, with self-perceived benefits noted. These evaluations have been overwhelmingly positive, acknowledging a growing confidence in CM and CRM behaviors in Pain Clinic staff. Discussion: This Pain Clinic staff is comprised of a tightly knit group of experienced staff. Equipment familiarity, medication administration, and emergency response behaviors require recurrent training for optimal patient safety. This training is particularly beneficial for team building since group influences and staff perceptions can have a great impact on the culture of safety in a patient care unit. An appreciation for each others' roles and challenges has added to the overall team approach by providing insight into the most important behavioral aspects of best practice. Office staff, nurses, and physicians have all expressed appreciation for this training. The Penn State Hershey Simulation Center is committed to expanding this highly valued program for other clinical practice groups.

A Meta-Analysis of Spasticity and Pain: Implications for Botulinum Toxin Treatment
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Introduction/Statement of the problem: Relief from spasticity may be associated with decreased pain, but neither the association, nor mechanisms of pain relief are fully understood. The objective of this study is to determine the relationship between changes in pain and spasticity via meta-analysis. This analysis may provide a better understanding of the relationship between reduction in spasticity and relief of pain. Materials and Methods: A PubMed search was completed using ‘spasticity’, ’humans’, ’randomized controlled trials’, and ‘English’ as search terms. The studies selected included effect sizes, or sufficient information for effect sizes to be calculated using Cohen's d. An analysis was performed on the effect size of reduction in spasticity or pain using a mixed-effect model and Pearson's r. Results: From 243 spasticity studies identified in the initial search, 7 fulfilled criteria; 3 studies used botulinum toxin, 2 cannabinol, and 1 each baclofen and tizanidine. Mean effect sizes were 0.49 (SD=0.41) and 0.31 (SD=0.31) for decreases in spasticity and pain, respectively. The difference in effect size between spasticity and pain was insignificant (P=.106). Pearson's r was 0.49 (P=.072) between decreases in spasticity and pain. Conclusions: Treatment of spasticity resulted in a similar effect size for reduction in spasticity and pain. There was also a trend that suggests correlation between change reduction for spasticity and pain.


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Database Analysis to Estimate Medical and Pharmacotherapy Resource Utilization and Costs of Fibromyalgia Prior to and Following Diagnosis in the United Kingdom Primary Care Setting
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Objective: To describe the medical and pharmacotherapy resource utilization and costs of fibromyalgia (FM) preceding and following diagnosis in the United Kingdom (UK) primary care setting. Methods: Resource utilization data were obtained from the GPRD. General practitioner (GP) visit costing data were obtained from the Personal Social Services Research Unit's Health and Social Care Unit. The primary source for pharmacotherapy costs was the British National Formulary (BNF), or, if unavailable in the BNF, the National Health Service Prescription Pricing Authority. The analysis compared resource utilization and costs for the one-year pre– and one-year post–diagnosis periods. Results: A total of 5,444 FM patients, mean age 48.5 years, were included; approximately 83% were women. In the pre–diagnosis period, 95.7% of patients had a GP visit, with an average of 12.1 visits; in the post–diagnosis period, 98.5% of patients had a GP visit, with an average of 13.1 GP visits (P<0.001). Arthralgia and back pain were the most common GP visit reasons in both periods. A similar percentage of patients had specialist
referrals in the pre– (53.1%) and post– (53.3%) diagnosis periods (not statistically significant [NS]); hospital referrals in these periods also were similar (2% vs. 2.4%; NS). Nonsteroidal anti inflammatory drugs, systemic corticosteroids, centrally acting analgesics, and tricyclic antidepressants (TCAs) were the most commonly prescribed pharmacotherapy categories. Utilization was higher in the post– than in the pre–diagnosis period, particularly for TCAs (31.1% vs. 55.9%; P<0.001). Patients incurred a total of ≤377 in GP visits (≤288) and pharmacotherapies (≤88) in the pre–diagnosis period; and a total of ≤442 in GP visits (≤323) and pharmacotherapies (≤119) in the post–diagnosis period (P<0.001 for all comparisons; totals exclude diagnosis GP visit). Conclusions: Medical and pharmacotherapy resource utilization increase in the year following an FM diagnosis, with corresponding cost increases.


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A Prospective Evaluation of the Prevalence of Sleep-Disordered Breathing in Patients on Stable Treatment for Chronic Pain

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Background: Opioid and non-opioid medications can lessen effective control of the upper airway during sleep. Opioids’ acute effects are well known (1), but how a chronic, stable pain-management regime impacts sleep and breathing is not well understood. Prevalence and severity of sleep-disordered breathing were assessed in patients undergoing chronic pain management. Methods: Participants with no history of sleep-disordered breathing, on stable pain management for ≥ 6 months, and with no medication changes within 30 days of providing written, informed consent were recruited. Each participant underwent a full-night, in-laboratory polysomnography (PSG), which was scored by an independent, blinded reviewer. Results: Of 74 participants, 54 (74%) were female. Age was 45 ± 10 (mean ± standard deviation), and body mass index was 29.8 ± 6.4 Kg/M2. On a scale of 0-21, the Epworth Sleepiness Scale was 10 ± 5.3 and the Pittsburgh Sleep Quality Index Global score was 12.3 ± 3.9. At initial assessment, participants averaged a subjective pain rating of 6.9 ± 1.3 on a visual analog scale of 0-10 and an Oswey Pain Score of 22.9 ± 7.1. PSG results are as follows: Variable Results (Mean ± SD) Total Sleep Time (minutes) 358.5 ± 63.6, Sleep Efficiency (%) 79.6 ± 11.8, Arousal Index (events/ hour of sleep) 20.3 ± 10.7, Apnea Hypopnea Index (events/ hour of sleep) 16.8 ± 22.7, Central Apnea Index (events/ hour of sleep) 3.5 ± 12.5, Hypopnea Index (events/ hour of sleep) 10.9 ± 14.2 % TST < 90% 28.3 ± 36.3, Time Below 90% (minutes) 100.2 ± 137.9, Lowest Arterial Saturation 83.4 ± 6.2. Conclusions: Patients with moderate pain on chronic stable doses of pain medications may experience moderate-to-severe sleep-disordered breathing with significant arterial desaturation that may be related to hypoventilation. Subjective symptoms suggesting sleep-disordered breathing may or may not be present.


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The Prevalence of Chronic Pain in a Large Representative National Sample

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Background: Disparities in the pain experience interfering with successful aging are well established.
Few studies examining successful aging provide adequate information about chronic pain impacting
quality of life. This study looked at the prevalence and overall impact of pain in a large nationally
representative sample. Methods: This secondary data analysis utilizes the national comorbidities study
replication, a nationally representative sample, executed between 2001 and 2003. Pain questions
referred to back/neck pain, headaches, arthritis and “other chronic pain.” Additive and “any pain”
variables were created, as was “age of first chronic pain.” Socio-demographic information was used to
describe people with chronic pain. In addition, various functioning measures were compared between
people with and without chronic pain. Results: Participants (n=9282) were 45% male, 57% married, and
65% employed. Their mean age and mean education was 44.7±17.5 and 13.3±2.5 years respectively.
The sample was 72% white, 13% black, 10% latino, 2% asian and 3% “other.” Overall, 60% of the
sample had experienced frequent or chronic pain, women more so than men (64% vs. 43%, p<.001), and
Asians less so than other ethnic groups while “other ethnic groups” has more pain. After adding controls
for age, sex, education, and body mass index (BMI) only “other” remains significantly different.
Although people with pain had worked for more years (largely because they are older) they worked
fewer weeks in the last year (33.8 vs 40.6 weeks, p<.001) and have higher disability rates and physical
and mental health troubles. Conclusions: Pain is extremely common and accompanying pain is a series
of difficulties in functioning and health. There were not substantial racial differences, though women
suffer a higher pain burden. These findings suggest an increased burden of pain for an increasingly
aging and diverse society. Thus, increased efforts are needed to optimize pain management to enhance
successful aging.

References: green CR, baker TA, smith EM, sato Y: The effect of race in older adults presenting for
chronic pain management: A comparative study of african and caucasian americans. The Journal of
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Headaches in Veterans Returning from Iraq/Afghanistan: Relation to Trauma and Combat-
Related Injury

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Introduction: Psychological stress may mediate a headache disorder (1). A recent study found that post
traumatic stress disorder (ptsd) was significantly more prevalent in patients with chronic migraine
headaches than in patients with episodic migraines, suggesting that PTSD may be a risk factor for
headache chronicification (2). Additionally, some studies indicate a relationship between PTSD, combat
injuries such as traumatic brain injury (TBI), and headaches (3), while others have found a relationship
between TBI and PTSD only. We aimed to examine the relationship between PTSD, combat-related
injury, TBI, and headaches in operation enduring freedom and operation iraqi freedom (OEF/OIF)
veterans. Methods: After IRB approval, 343 male and female OEF/OIF veterans registering for care at
the VA san diego healthcare system completed a battery of self-report standardized questionnaires
between March and October 2006. Data consisted of demographic, military, in-theater, psychiatric, and
health-related variables. Results: PTSD and injury during combat were independent predictors of self-
reported headaches. Individuals who endorsed PTSD were 4 times (95% confidence interval: 2.15-8.01;
p < 0.001) more likely to report headaches than veterans without PTSD. Individuals injured during combat were nearly 3 times (95% confidence interval: 1.38-5.62; p = 0.004) more likely to report headaches compared to veterans who did not report injury during combat. Self-reported depression (odds ratio: 1.68; 95% confidence interval: 0.95-2.99) and head injury (odds ratio: 0.43; 95% confidence interval: 0.17-1.14) did not significantly contribute to the risk for headaches. Follow-up analyses demonstrated that PTSD and injury during combat could be differentially related to tension and migraine headaches. **Conclusion**: These results highlight the potential health consequences of trauma exposure and point to a complex relationship between physical and psychological trauma and headaches. The findings have implications for a comprehensive approach to interventions that would include psychosocial as well as medical components.

**References**: None

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**Reduction of Opioid and Ilicit Drug Abuse After Initiation of State Electronic Prescription Monitoring Program**

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**Introduction**: Noncompliance in medical practice is a major problem. Noncompliance in pain management practice is a potential disaster. Noncompliance for prescription opiates takes two basic forms: uncontrolled over use (addiction) and diversion. It is incumbent for all opiate prescribers to detect addiction for the sake of the patient and to detect diverters for the sake of society. It is estimated that over 4.4 million Americans currently use a prescription pain reliever for non-medical purposes. Until this year, physicians had limited ability to screen patients for opiate misuse. Urine drug screens (UDS) provide a quick reference point for compliance and an opportunity to discuss the complexity of opiate pain reliever and a means for the detection of illicit drug use. With the advent of electronic prescription monitoring programs (Inspect Program of Indiana), physicians in some states have a new powerful tool to oversee compliance.

**Methods**: With IRB approval and patient consent two groups of 125 consecutive patients in an interventional chronic pain practice were compared for opiate compliance: group 1, before and group 2, after the availability of Inspect (January, 2008) an electronic prescription monitoring for Schedule II and III drugs.

**Results**: Prior to Inspect, 33% of group 1 had an abnormality detected by UDS, and six months after its initiation group 2 had an abnormality rate that fell to 11%. In group 2, the Inspect report identified 16% of patients who had an opiate abuse, as defined as a patient receiving unsanctioned controlled substances from any source other than WPC. Age and primary insurance coverage (young, Medicaid) but not sex, were correlated with higher abnormal UDS and opioid abuse. There were no abnormal UDS or Inspect reports for Medicare patients over age 65.

**Conclusion**: Electronic prescription monitoring is a valuable tool for the detection of addiction and diversion of opiates.


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Introduction: Neuropathic pain (NeuP) commonly affects the back and legs and is associated with severe disability and psychological illness. It is unclear how patients with predominantly NeuP due to failed back surgery syndrome (FBSS) compare to patients with other chronic pain conditions. The current study presents data on characteristics associated with FBSS patients compared to those with complex regional pain syndrome, rheumatoid and osteoarthritis, and fibromyalgia, which are more commonly known chronic painful conditions.

Materials and Methods: Data on FBSS patients were obtained from the 100 patients recruited in the PROCESS study. Patient characteristics collected at baseline included age, sex, previous surgeries, time since last surgery, employment, primary source of pain, severity of back and leg pain (VAS), health-related quality of life (HRQoL), level of disability, medication and non-drug therapies. A literature search was performed to obtain similar information on the 4 other chronic pain populations identified.

Results: At baseline, patients in the PROCESS Study had a similar age and gender profile compared to other conditions. Back pain severity was similar across conditions, but PROCESS patients suffered from greater leg pain and had lower HRQoL. PROCESS patients commonly took opioids, while antidepressants and NSAIDs were more often used for other conditions. Prior to baseline, 87% of patients had tried at least 4 different treatment modalities.

Conclusions: Patients suffering from chronic pain of neuropathic origin following FBSS, often fail to obtain adequate relief with conventional therapies and suffer greater pain compared to patients with other chronic pain conditions. Alternative treatments such as SCS should be considered earlier in the treatment continuum.

References: None

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Prevalence of Chronic Pain in Patients Seeking Medical Treatment in Southeast Asia
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Introduction: Chronic pain is a common reason for seeking medical care. It impacts negatively on a person's quality of life and costs the healthcare industry millions of dollars in expenditure. A recent survey showed that the prevalence of chronic pain is as high as 11% in US and 19% in Europe.(1,2) However, there are no existing data on the prevalence of chronic pain in Asia. The objective was to determine the prevalence of pain in Southeast Asian countries from both a physician and a patient viewpoint.

Methods: The Pain Management Survey was conducted by an independent research company in Malaysia, Philippines, Singapore and Thailand. Data was collected via face-to-face semi-structured questionnaires with physicians and patients. Patients were recruited via physicians and interviewed.

Results: The demographic similarities amongst the various countries reveal similar trends in pain prevalence in Southeast Asia. Prevalence of chronic pain of at least one-year duration ranged from 40-77%. The commonest types of pain encountered were gouty arthritis, low back pain, osteoarthritis and rheumatoid arthritis. 18-25% of patients felt that their pain conditions impacted upon their activities of daily living to a large extent. 12-29% of patients felt that their pain affected their quality of life significantly. The incidence of migraine/headache is significantly higher in Singapore and Malaysia.

Conclusion: This survey showed a high prevalence of pain in Southeast Asia of between 40-77% based on patients' self-reporting. Similar to trends in other countries, the commonest chronic pain condition is low back pain. Chronic pain has a significant negative impact on daily activities and quality of life in almost 30% of patients.


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Chronic Pain Management by Physicians in Southeast Asia
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Introduction: The prevalence of chronic pain is as high as 11% in US and 19% in Europe in recent studies. Similarly, our preliminary survey in Southeast Asian countries demonstrated a high chronic pain prevalence of between 40-77% based on patients' self-reporting. The aim of our study was to review how pain was assessed, managed and treated from both a physician and a patient viewpoint. Method: The Pain Management Survey was conducted by an independent research company in Malaysia, Philippines, Singapore and Thailand. Data was collected via face-to-face semi-structured questionnaires with physicians and patients. Patients were recruited via physicians and interviewed. Results: Doctors across all 4 participating countries preferred a combination of pharmacological and non-pharmacological methods of pain management. None of the physicians interviewed recommended solely non-pharmacological therapy to their patients. Common non-pharmacological interventions include exercise, physical therapy and weight management. The use of food supplements was also more prevalent in Singapore and Malaysia. More doctors in Singapore and Malaysia initiated pharmacological treatment than doctors in Philippines and Thailand. Common analgesics prescribed included paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs) and cyclo-oxygenase type-2 inhibitors (Coxibs). More than 50% of patients in Singapore and Philippines had tried or were aware of the various pharmacological options (NSAIDs and Coxibs) available for pain management. This contrasted greatly to that in Thailand and Malaysia, where only one-third of patients were aware. Efficacy, cost and side effect profile were the 3 most important considerations for GPs when considering which drug to prescribe for pain. Conclusion: Patients with chronic pain frequently seek treatment only when pain becomes unbearable or when it has affected their daily activities. In general, physicians discuss treatment options well with patients, including efficacy, side effects as well as costs of medications. NSAIDs and COXIBs are commonly prescribed by all physicians.


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A Healthcare Claims Database Analysis to Estimate the Prevalence of Chronic Opioid Use in Adult Patients in the United States
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Objective: To obtain an estimate of the prevalence of adult opioid-tolerant patients within the US. Methods: Wolters Kluwer Health's Source Lx data repository contains healthcare claims and prescription data from physician practices, pharmacies, and hospitals. All 50 US states are represented in this analysis of 2007 data. For the sole purpose of this analysis, patients taking opioids on a daily basis were identified as those with over a 90-day supply of opioid; opioid-tolerant patients were those daily basis patients taking at least 60 mg of morphine equivalents per day. Results: In the overall sample, 54.7 million adult patients had prescription claim data in 2007. 14.3 million adult patients had at least one prescription for an opioid. 1.8 million patients were taking opioids on a daily basis, representing 3.2% of the sample. 737,100 patients met the definition of opioid tolerance, accounting for approximately 1.3% of the sample. Projected to the 74-85% of the US Adult population (225 million) who had at least one prescription, there are approximately 2.2-2.6 million opioid-tolerant adult patients. In the group of patients with at least one prescription for an opioid during 2007, the most common opioids were hydrocodone products at 63%, oxycodone products at 24%, propoxyphene products at 14%, and tramadol products at 13%. In the subgroup of patients classified as opioid tolerant, the most common
medications were oxycodone products at 35%, propoxyphene products at 22%, tramadol products at 18%, morphine products at 12%, methadone products at 9%, and hydrocodone products at 9%.

**Conclusion**: Analysis of a large healthcare claims database provided a projected estimate of 2.2-2.6 million opioid-tolerant adult patients in the US in 2007. The overall profile of opioid medication use within the subgroup of opioid-tolerant patients was different from that in the overall group of patients with at least one prescription for opioids.

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**Relationship Between Quality of Life, Disability and Pain in Patients with Failed Back Surgery Syndrome**

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**Introduction**: Neuropathic pain patients experience poor health-related quality of life (HRQoL). However, little is known about the impact of pain and functional disability on HRQoL. Research to date has focused on disease-specific outcome measures rather than generic measures such as Short Form 36 (SF-36) or EuroQol 5D (EQ-5D). This study investigates the relationship between pain, disability and generic HRQoL based on data from a recent randomized controlled trial of neuropathic pain patients with failed back surgery syndrome (FBSS).

**Materials and Methods**: Using data from the multinational PROCESS trial, we quantified the relationship between generic HRQoL, using the SF 36 and EQ 5D, and disease specific outcome measures, using the Oswestry Disability Index (ODI) and leg and back pain visual analogue scale (VAS), in neuropathic pain patients with FBSS.

**Results**: In our sample of 100 FBSS patients, at baseline, generic HRQoL was univariately consistently associated with disease specific outcome measures: ODI (correlation coefficient: -0.462 to -0.638) and leg pain VAS (correlation coefficient: -0.165 to -0.436). In multilevel regression analysis using both baseline and follow up data, baseline HRQoL and ODI were found to be significant predictors of generic HRQoL (all p<0.001). Leg pain was predictive of EQ-5D and the SF-36 physical component summary score (both p<0.001) but not of its mental component summary score (p=0.201). Baseline socio demographic characteristics (age and gender), clinical history (time since last back surgery and number of back surgeries), location of pain and intensity of back pain were not predictive of generic HRQoL (all p>0.213).

**Conclusion**: Pain and disability are correlated with generic HRQoL in this population of neuropathic pain patients. Further prospective studies are needed to explore the association in the change in pain and disability versus HRQoL in this population.


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