Abstracts

2014 Abstract Session Presentations

First Place	Predisposing Risk in Injury Claims Exceeding 1yr: Predictive Assessment using Pharmacogenetics Presenter: Daniel A Schwarz, MD, MROC
Second Place	Reduction of Pain-Related Symptoms with Transcranial Magnetic Stimulation Treatment in Depressed Patients Presenter: David G. Brock, MD
Third Place	New Standardized Approach to Cervical Epidural Injections (Cei): The "Prone Left Contralateral Oblique (Clo) Hanging Drop" Technique Presenter: Sukdeb Datta, MD

FIRST PLACE

Predisposing Risk in Injury Claims Exceeding 1yr: Predictive Assessment using Pharmacogenetics

Presenter: Daniel A Schwarz, MD, MROC

First authot: Brian Meshkin, BA
Co-authors: Daniel A Schwarz, MD, MROC; Andrea M Trescot, MD; Sanford M Silverman, MD;Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Si Van Nguyen, MD; Tobore Onojighofia, MD

Affiliations: President and CEO, Proove Biosciences, Inc. Co-author Affiliations Daniel A. Schwarz, MD, MROC: President, Pain Recovery Specialists, PLLC
Andrea Trescot, MD: Director, the Pain and Headache Center, Anchorage, AK
Sanford M. Silverman, MD, Medical Director, CEO, Comprehensive Pain Medicine, Pompano Beach, FL
Si Van Nguyen, MD: Medical Director, Huntington Beach Hospital, CA
Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Tobore Onojighofia, MD are employees of Proove Biosciences, Inc.

Background: Data from insurers, third-party administrators and pharmacy benefit managers show that the longer a worker's compensation claim stays open; the cost increase becomes more dramatic. Open medical-only claims beyond one year to two years drop from 37% to 21% of claims. However, the average cost jumps from less than $6,875 to $19,888. Those medical-only claims closing between two and three years drops to 13%, while the average cost rises to $36,792.

Objective: To evaluate whether a specific mesolimbic genetic predisposition in chronic pain patients can predict the length of open workers compensation claims in order to guide earlier interventions, thus preventing extended costs and burden of illness.

Methods: Workers compensation patients (n=272) with chronic pain from a workplace injury (146 male, 126 female). The average length of time from the date of injury to the date of service was 71 days (range 0 to 1,278 days). Subjects were genotyped at Proove Medical Laboratory (Irvine, CA) with the Narcotic Risk Profile using TaqMan SNP genotyping assays. A proprietary scoring algorithm, the PRICE score, was calculated to determine elevated risk of a claim extending beyond one-year based on genetic predisposition of three genes: the Dopamine D2 Receptor A1 Allele (rs1800497), Dopamine D4 Receptor (rs3758653) and Catechol-O-Methyltransferase Val158Met (rs4680).

Results: Subjects with a PRICE Score of 3, meaning they had heterozygous or homozygous variations in all three of these genes, were more likely to have a claim extend beyond one year (48.5% PPV). Subjects with a PRICE Score of 2 or 1 had a 63% chance of not having an open claim greater than 1 year (92% sensitivity, 88% specificity).

Conclusions: This PRICE Study suggests that by performing the Narcotic Risk Profile on every workers compensation claim where chronic pain is involved, a clinician and insurer can possibly identify patients who would require more appropriate therapy early in the episode of care during their first year to end the claim. This could also help avoid the dramatic cost escalation that occurs in those 21% of claims that extend beyond one year. This would reduce costs by 58% and provide a 4:1 return on investment to the worker's compensation carrier.

Disclosure: Daniel Schwarz, MD; Andrea Trescot, MD and Sanford Silverman, MD are consultants for Proove Biosciences, Inc and members of their advisory board, respectively.

References

1. Ceniceros, Roberto. "Costs mount quickly as workers comp claims age." Business Insurance, Crain Communications, Inc. Aug. 13, 2012.

SECOND PLACE

Reduction of Pain-Related Symptoms with Transcranial Magnetic Stimulation Treatment in Depressed Patients

Presenter: David G. Brock, MD

Co-authors Mark A. Demitrack, M.D., Karen L. Heart, Angela Waltman, Darlene Lambert-Christie, Seth Zuckerman

Author Affiliations: Neuronetics, Inc

Background: Over 75% of patients with depression experience pain-related symptoms that interfere with their daily activities. The presence of comorbid moderate-to-extreme pain contributes significantly to unfavorable outcomes, poor health-related quality of life and increased cost of treatment of major depression. Transcranial Magnetic Stimulation (TMS) has shown potential benefit as a new treatment option for chronic pain.

Objective: This study was designed to assess change in patient-reported pain outcomes following Transcranial Magnetic Stimulation (TMS) treatment when used for the treatment of Major Depressive Disorder (MDD).

Methods: Two large TMS treatment studies of outpatients with a primary diagnosis of MDD, and persistent symptoms despite prior antidepressant pharmacotherapy. The first, involving 301 medication-free patients with pharmacoresistant major depression were randomized to active or sham TMS in a 6-week controlled trial. The second is an open-label naturalistic study of 307 patients at 42 US based clinical practice sites. The outcome was defined as the change in the bodily pain scores of the Medical Outcomes Study (MOS) 36-Item Short-Form Health Survey (SF-36) from baseline through end of acute treatment.

Results: The SF-36 bodily pain scores improved significantly following acute TMS treatment in both the randomized trial and the open label naturalistic study. In the randomized trial, over 6 weeks, patients receiving active treatment improved from 43.5 to 45.5 ($P = 0.002$) while the sham group change was not significant ($P=0.124$). Patients with pain scores below the median, treated with active TMS, improved a mean 4.5 (SD 8.7) ($P <0.001$) Over the course of acute treatment in the naturalistic trial, patients' bodily pain scores improved from 44.5 to 48.1 ($P < 0.0001$).

Conclusions: TMS shows statistically significant benefits on patient-reported pain outcomes, in both a randomized clinical trial setting and in clinical practice. Patients with more severe pain at baseline experienced a greater improvement in their scores relative to the total population. These data show that the effectiveness of TMS in the treatment of depression is not only disease-specific but also associated with a general improvement in pain.

Disclosure: Employee, Neuronetics, Inc Encore Presentation No.

References

1. Carpenter et al. Transcranial magnetic stimulation (TMS) for major depression: A multisite, naturalistic, observational study of acute treatment outcomes in clinical practice (2012) Depression and Anxiety 29: 587-596.
2. Solvason HB, et al. (2013) Improvement in Quality of Life With Left Prefrontal Transcranial Magnetic Stimulation in Patients With Pharmacoresistant Major Depression: Acute and Six Month Outcomes. Brain Stimul. Nov 4. pii: S1935-861X(13)00343-4. doi: 10.1016/j.brs.2013.10.008. [Epub ahead of print]

THIRD PLACE

New Standardized Approach to Cervical Epidural Injections (Cei): The "Prone Left Contralateral Oblique (Clo) Hanging Drop" Technique

Presenter: Sukdeb Datta, MD

Co-author: Somdatta Gupta, M.D.
Affiliaitons: Datta Endoscopic Back Surgery and Pain Center, Mount Sinai School of Medicine

Background: Cervical epidural steroid injections (CEIs) under fluoroscopic guidance are widely performed for cervical pathology. Current CEI techniques suffer from two critical limitations – safety and efficacy. Firstly, due to the lack of the ligamentum flavum in the midline and the presence of the shoulder shadow on fluoroscopy, conventional lateral "Safety" view fails to accurately depict the anatomy of the cervical epidural space, leading to inadvertent iatrogenic trauma. Secondly, efficacy is limited due to placement lower in the cervical spine and the conventional small volumes of injectate are often insufficient to access wide ranges of pathology at higher cervical levels.

Objective: To describe a new standardized technique for performing a cervical epidural injection along with presentation of results of a series of Cervical Epdural Injections performed using this standardized technique.

Methods: The study group comprised 123 patients (69 M, 54 F) who underwent CEIs between 2012 and 2014. The average age was 46.04 (range24-68) years. Pathology identified was at C2-C3 (n = 26), C3-C4 (n = 60), C4-C5 (n = 70), C5-C6 (n = 85), C6-C7 (n = 67) and C7-T1 (n = 16). 70 patients had disc bulge, 86 had disc herniation (12 right, 14 left, 60 central); 76 had other indications. The patients were placed in a prone position. AP view was used to identify left paramedian needle position at the appropriate level of pathology [Fig.1 (A)]. Next, the fluoroscope was rotated to the contralateral side to open up the neural foramen. A 20 G Tuohy needle was introduced in this view up to the interlaminar line, and the stylet removed. A drop of saline was then placed in the hub of the Tuohy needle and the needle was carefully introduced till a distinct "saline drop" or a change in compliance of the saline was noted in the hub. Contrast was then injected in the CLO view to demonstrate the proper spread [Fig.1 (B and C)], followed by 5 ml of 0.125% bupivacaine or 5 ml 0.1% ropivacaine plus betamethasone, as compared to the conventionally used 1-2 ml of injectate.

Results: Significant pain relief and functional status improvement was demonstrated in 87 patients. The mean pretreatment pain score (NRS) was 7.5 and post-CEI scores was 6.1 at 6 weeks post-treatment. Complications (n = 2) included 1 patient with a definite wet tap, and 1 probable wet tap as evidenced by postoperative headache.

Conclusions: Several key problems in present approaches to CEI include inability to visualize cervical epidural space, specifically on the lateral views; concerns about inadvertent needle placement into the cervical epidural space at inappropriate levels (for example, placing the injectate into T2 area versus anatomically higher-up area of cervical pathology); and appropriate visualization of contrast spread. Additionally, when with the use of a bulky loss of resistance (LOR) syringe to identify the cervical epidural space, the subtle change in compliance of the epidural space is difficult to observe and increases the risk of a dural tap. Although the CLO technique has been described in the cervical epidural space, it has not been standardized or validated(1). We therefore developed our technique to specifically address these issues in a systematic manner. Initial technique utilized a sitting fluoroscopic lateral approach with a hanging drop technique; though this did avoid the shoulder shadow on fluoroscopic imaging as well as the bulky LOR syringe, the disadvantage was the inability to visualize the needle position on the AP view. We therefore modified this technique and changed to a prone CLO approach. The CLO approach builds on the advantages of the lateral view (avoidance of shoulder shadow) and additionally, allows both AP and lateral views. The CLO also allows an accurate hanging drop technique to be used in minute increments: the procedure is started only once the interlaminar line is reached, and stopped once the needle is past the lateral 1/3rd of the foramen on the contralateral view. A quick AP is essential to document that the needle has not traveled obliquely to the opposite side or is too lateral in the cervical "gutter". Even when we did not perceive a distinct "drop" in 10 cases, the contrast spread epidurally in all. The 1 case of wet tap was performed in the lateral position. The 1 case of possible wet tap was performed in the CLO technique where there was a good LOR but the patient had a very muscular shoulder and a very deep skin to foramen distance. 5 ml of injectate is the optimal volume for distribution to achieve optimal spread2. Outcomes with the prone left CLO hanging drop technique are standardized, procedure complications are minimized and higher effectiveness is achieved with the ability to appropriately access target herniation levels.

References

1. Furman, M, Jasper NR, Lin H. Fluoroscopic contralateral oblique view in interlaminar interventions: A technical note. Pain Medicine 2012; 13: 1389-1396.
2. Lee SE, Joe HB, Park JH, Yi IK, Choi YH, Han KR, Kim C. Distribution range of cervical interlaminar epidural injections: a comparative study with .5 mL, 5 mL, and 10 mL of contrast. Pain Physician. 2013 Mar-Apr; 16(2):155-64.

Pain Relief Through Percutaneous Trochanteroplasty in a Patient with Bilateral Trochanteric Myelomatous Lytic Lesions

Presenter: Kyle Silva, DO

Coauthors: Shervin Najafi, MD, Sayed Wahezi, MD
Affiliations: Montefiore Medical Center, Department of Physical Medicine and Rehabilitation, Division of Interventional Spine

Background: : Although osteoplasty has played an important role in the treatment of vertebral compression fractures, it is rarely used to treat painful extra-spinal myelomatous lesions. This case study promotes the use of percutaneous trochanteroplasty as a safe, novel, and minimally invasive, procedure for relieving pain.

Objective: Case: A 67 year old female with medical history of stable IgA lambda multiple myeloma for 5 years, on chronic chemotherapy, who presented with sentinel bilateral greater trochanteric lytic lesions resulting in bilateral hip pain. Her pain was refractory to conservative therapy which included PT, oral opiates and local greater trochanteric injections. On initial examination her bilateral hip pain was 8/10 sharp, achy, and non-radiating. Significant exacerbation of her pain occurred when performing sit to stand transfers and with ambulation as well as side lying. The pain continued to wake the patient frequently throughout the night. She reported 1/2 block walking tolerance secondary to pain. Review of systems were negative for new onset numbness, weakness, or paresthesias. Bone survey displayed multiple greater trochanteric lucencies bilaterally which worsened when compared to a prior bone survey in 2012.

The patient underwent core biopsy of the right greater trochanter lytic lesions with concomitant trochanteroplasty using methylmethacrylate cement. The intended goals were to offer pain relief and fracture prevention. No intra-operative or post-operative complications occurred. Upon one week follow-up the patient reported resolution of her right hip pain. Given the success of her right trochanteroplasty, a left trochanteroplasty was performed two weeks later without complication; this also resulted in substantial left hip pain reduction.

Methods: Under image-intensifier control, a 13 gauge bone biopsy needle was directed into the superior lateral aspect of the greater trochanter. 10cc of methylmethacrylate cement were mixed in sterile fashion. The cement was introduced into a Cook Medical Vertebroplasty Injector System and then allowed to form a toothpaste-like consistency. 2.5cc of cement were then injected into the right greater trochanter under live fluoroscopic guidance. No evidence of vascular or extra-cortical uptake was observed. This procedure was repeated 2 weeks later at the left greater trochanter.

Results: The patient underwent bilateral percutaneous core biopsies of greater trochanteric lytic lesions with concomitant trochanteroplasties. No intra-operative or post-operative complications occurred. The patient reported complete resolution of bilateral hip pain at six month follow up.

Conclusions: Intra-osseous cement has demonstrated efficacy in the treatment of myelomatous pain, especially in the spine. [1,2,3] In select cases, pain caused by extra-spinal myelomatous lytic lesions can be effectively treated by performing percutaneous trochanteroplasty. To our knowledge there has been one prior study by Masala, et al., which evaluates the use of extra-spinal osteoplasty in the setting of multiple myeloma. Masala's results were concordant with the findings in our case study suggesting that percutaneous osteoplasty is a safe and effective option for treating pain secondary to lytic lesions [1].

References:

1. Masala S, Volpi T, Fucci FP, et al. Percutaneous osteoplasty in the treatment of extraspinal painful multiple myeloma lesions. Support Care Cancer 2011;19:957–62.
2.. Mathis JM, Barr JD, Belkoff SM, et al.Percutaneous vertebroplasty: a developing standard of care for vertebral compression fractures. AJNR Am J Neuroradiol 2001;22:373–81.
3. Trumm C, Jakobs T, Pahl A, et al. CT fluoroscopy-guided percutaneous vertebroplasty inpatients with multiple myeloma: analysis of technical results from 44 sessions with 67 vertebrae treated. Diagn Interv Radiol 2012;18:111–20.

TOP 20

From Pain to Relief: Investigating the Application of Stellate Ganglion Block for the Treatment of Post-Traumatic Stress Disorder

Authors: Maryam Navaie, DrPH[1], Morgan S. Keefe, BA[2], Anita H. Hickey, MD[3], Robert N. McLay, MD, PhD[4], Elspeth Cameron Ritchie, MD, MPH[5], and Salahadin Abdi, MD, PhD[6]

Author Affiliations:
[1]Advance Health Solutions, LLC, 2200 Pennsylvania Ave NW, 4th Floor East, Washington, D.C. 20037. [2]Advance Health Solutions, LLC, 4370 La Jolla Village Drive, Suite 400, San Diego, CA 92122. [3]Department of Anesthesiology, United States Naval Hospital Okinawa, PSC 482 Box 173, FPO, AP 96362, Okinawa, Japan. [4]Department of Mental Health, Naval Medical Center San Diego, 34800 Bob Wilson Dr., San Diego, CA 92134. [5]Department of Mental Health, District of Columbia, 64 New York Avenue NE, Room 347, Washington, D.C. 20002. [6]Department of Pain Medicine, Division of Anesthesiology and Critical Care, The University of Texas M.D. Anderson Cancer Center, 1515 Holcombe Blvd., Houston, TX 77030

Background: Studies on post-traumatic stress disorder (PTSD) within the U.S. civilian and military populations have estimated prevalence rates ranging from 7.3% [1] to 40% [2-5], respectively. Among patients seeking treatment for PTSD, chronic pain is often a common co-morbid condition [6,7], especially among active and retired military personnel [8]. Recently, preliminary evidence has been emerging on the use of a common interventional pain management procedure known as stellate ganglion block (SGB) for PTSD. To date however, the evidence has not been aggregated across published cases to examine potential trends that may inform next steps in research and practice.

Objective: The objective of this study was to systematically review all published case reports or series on the use of SGB for PTSD in order to examine clinically significant changes in outcomes. Methods EMBASE, PubMed, PsychINFO and Cochrane databases were reviewed using an iterative keyword search strategy that applied the following criteria: (a) SGB or stellate ganglion block, (b) PTSD, post-traumatic stress disorder or post-traumatic stress, and (c) English language. No date delimiter was applied. The search yielded 12 articles, of which seven were eliminated due to lack of case data, duplicate publications or invalid PTSD outcome measures (i.e., no use of a standardized instrument to measure PTSD symptoms or severity). Twenty-four cases contained within five articles [9-13] were evaluated further. No published randomized or controlled trials of SGB for PTSD were identified in the literature.
Data were extracted on a wide range of metrics including patients' sociodemographic and clinical characteristics, PTSD treatment histories, SGB treatment, and PTSD symptoms as measured by the Post-Traumatic Stress Disorder Checklist - Military Version (PCL-M) [14] or Clinician-Administered Post-Traumatic Stress Disorder Scale (CAPS) [15]. Improvements in PTSD were calculated as the difference in either PCL-M or CAPS scores from pre-SGB 1 to post-SGB after each treatment episode. A change of ≥30% in PTSD scores between pre- and post-SGB were considered clinically meaningful, irrespective of whether assessments were made using the CAPS or the PCL-M [15,16]. SPSS was used to compute effect size by Cohen's d as recommended for a one group pre-post study design [17,18] and to compare mean differences in PTSD scores pre- and post-SGB treatment. $P < 0.05$ denoted statistical significance.

Results: The majority of patients were male (n=21, 88%) and active duty service members (n=14, 58%) or veterans (n=8, 33%) with combat-related PTSD. The patients ranged in age from 29 to 66 years old, averaging 40.5 years (±10.0 SD) across cases. Prior to SGB treatment, patients had received >1 year of unsuccessful psychotherapy, pharmacotherapy, or both. Comorbidity was reported in 87.5% of all published cases. Depression was the most commonly reported comorbid condition (50%), followed by chronic pain (33%), insomnia (29%), alcohol abuse (21%) and suicidal ideation or attempt (21%).
Seventeen patients (71%) received one SGB, however seven (29%) received multiple SGBs. SGB administration was consistent across nearly all patients, with injections of 7cc of 0.5% ropivacaine or bupivacaine. Clinically meaningful improvements were observed in 75% (n=18) of patients after SGB, with statistically significant differences between mean PTSD scores pre- (69.5 ± 26.6) and post-SGB (34.2 ± 32.5) across all cases ($P < 0.001$). The magnitude of the effect size was large (d=1.2). On average, PTSD improved by 50.4% (± 30.9 SD; range: 6.3-98.4) for patients treated with one SGB and 69.0% (± 28.0 SD; range: 9.2-93.5) for patients treated with multiple SGBs]. Patient follow-up time ranged between one to 264 days, with 54% observed for ≤7 days. The average time interval over which improvement was measured was 39.0 days (±62.9) across all cases, 20.2 days (±33.4) for cases with one SGB, and 84.57 days (±93.7) for cases with multiple SGBs. No complications associated with SGB were reported in the cases compiled in this review.

Conclusions: The majority of patients showed clinically meaningful improvements in PTSD symptoms after SGB treatment, with the greatest improvement in patients receiving multiple SGBs. Replication of these preliminary findings in rigorously designed clinical trials is warranted given the potential to improve health and quality of life for patients with PTSD with an interdisciplinary approach to care management by specialists in pain medicine and psychiatry.

References

1. Roberts AL, Gilman SE, Breslau J, Breslau N, Koenen KC. Race/ethnic differences in exposure to traumatic events, development of post-traumatic stress disorder, and treatment-seeking for post-traumatic stress disorder in the United States. Psychological Medicine.

2011; 41(1): 71-83.
2. Harvard School of Medicine. National Comorbidity Survey. Available at http://www.hcp.med.harvard.edu/ncs/publications.php
3. Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. New England Journal of Medicine 2004; 351(1):13-22.
4. Tanielan T, Jaycox LH, eds. Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery. Santa Monica, CA: RAND Corporation; 2008.
5. Vasterling JJ, Proctor SP, Friedman J, Hoge CW, Heeren T, King LA, King DW. PTSD symptom increases in Iraq-deployed soldiers: Comparison with non-deployed soldiers and associations with baseline symptoms, deployment experiences, and postdeployment stress. Journal of Traumatic Stress. 2010; 23(1):41-51.
6. Cyders MA, Burris JL, Carlson CR. Disaggregating the Relationship Between Post Traumatic Stress Disorder Symptom Cluster and Chronic Orofacial Pain: Implications for the Prediction of Health Outcomes with PTSD Symptom Cluster.
7. Palacio C, Krikorian A, Saldarriaga N, et al. Post Traumatic Stress Disorder and Chronic Pain. Techniques in Regional Anesthesia and pain management. 2012;16:190-195.
8. Shipherd SC, Keyes M, Jovanovic TJ, et al. Veterans Seeking Treatment for Posttraumatic Stress Disorder: What about Comorbid Chronic Pain. Journal of Rehabilitation Research and Development. 2007;44(2):153-166.
9. Mulvaney SW, McLean B, de Leeuw J. The use of stellate ganglion block in the treatment of panic/anxiety symptoms with combat-related post-traumatic stress disorder; preliminary results of long-term follow-up: a case series. Pain Pract. 2010;10(4):359–365.
10. Hickey A, Hanling S, Pevney E, Allen R. Stellate Ganglion Block for PTSD. American Journal of Psychiatry 2012; 169(7):760.
11. Lipov EG, Navaie M, Stedje-Larsen ET, Burkhardt K, Smith JC, Sharghi LH, Hickey AH. A novel application of stellate ganglion block: preliminary observations for the treatment of post-traumatic stress disorder. Mil Med. 2012 Feb;177(2):125-7.
12. Lipov EG, Navaie M, Brown PR, Hickey AH, Stedje-Larsen ET, McLay RN. Stellate ganglion block improves refractory post-traumatic stress disorder and associated memory dysfunction: a case report and systematic literature review. Mil Med. 2013 Feb;178(2):e260-4.
13. Alino J, Kosatka D, McLean B, Hirsch K. Efficacy of Stellate Ganglion Block in the Treatment of Anxiety Symptoms from Combat-Related Post-Traumatic Stress Disorder: A Case Series. Military Medicine 2013; 178)4:e473-e476.
14. Weathers FW, Huska JA, Keane TM. PCL-M for DSM-IV. Boston; National Center for PTSD – Behavioral Sciences Division, 1991.
15. Blake DD, Weathers FW, Nagy LM, Kaloupek DG, Gusman FD, Charney DS, Keane TM. The development of a Clinician-Administered PTSD Scale. J Trauma Stress. 1995 Jan;8(1):75-90. Review.
16. National Center for PTSD. Using the PTSD Checklist (PCL). Available at http://www.ptsd.va.gov/professional/pages/assessments/assessment-pdf/pcl-handout.pdf. July 2012.
17. Lipsey MW, Wilson DB. Practical meta-analysis. Thousand Oaks, CA: Sage; 2001.
18. Olive ML, Smith BW. Effect size calculations and single subject designs. Educational Psychology 2005;25:313-324.

Review of Spinal Cord Stimulator Trials by Three Interventional Pain Physicians

First Author Donald E. Jones, M.D.
Co-authors: Philip Jones, B.S., Peter Kroll, M.D., Richard Muench, M.D., Edward Kahn, M.D. Alan D. Kaye, MD, PhD

Author Affiliations :Comprehensive Pain Specialists, Methodist Medical Center Co-author Affiliations

Background: For over 4 decades, spinal cord stimulation has been a valuable tool in the treatment of a number of pain processes. In recent years, improvement in its technology has further increased its effectiveness.

Objective: We wanted to quantify the effectiveness of spinal cord stimulator trials in the hands of three affiliated interventional pain Physicians.

Methods From April 2011 to April 2013, three interventional pain physicians placed spinal cord stimulators and outcomes were measured utilizing chart review, pharmacy database reports, and patient telephone interviews. Data collection included percentage of trials to implants, percentage of pain relief, and changes in pain pill consumption rates.

Results: During the 24 month study period, a total of 273 patients had spinal cord stimulator trials. A total of 160 patients had the permanent device implanted or 59% of the total who received spinal cord stimulator trials. Based on telephone interviews, the average reduction in pain was 43%. Pain pill consumption actually decreased by 15%.

Conclusions: More than half of the patients who were trialed during the study period went on to have a permanent implant. Overall, there was a significant reduction in their pain from baseline. The vast majority of patients with the implant significantly reduced their morphine equivalent of pain pills. Spinal cord stimulation is an effective tool for pain reduction. Additional benefits, including reduction in opioid consumption, were seen in this challenging patient population.

Encore Presentation Case Report: Thoracic epidural hematoma following placement of spinal cord stimulator trial

References

1. Boswell, M.V., Trescot, A.M., Data, S., Shultz, D.M., Hansen, H.C., Abdi, S., Sehgal, N., Shah, R.V., Sing, V., Benyamin, R.M.,Patel, V.B., Buenaventura, R.M., Colson, J.D., Cordner, H.J., Epter, R.S., Jasper, J.F., Dunbar, E.E., Alturi, S.L., Bowman, R.C., Deer, T.R., Swicegood, J.R., Staats, P.S., Smith, H.S., Burton, A.W., Kloth, D.S., Giordano, J., Manchikanti, L. Interventional techniques: evidence based practice guidelines in the management of chronic spinal pain. Pain Physician 2007; 10: 7-111.
2. Yampolsky, C; Helm, S; Bendersky, D; Dorsal Column Stimulation Applications, Surg Neurol Int. 2012; 3(Suppl 4) S275D-S289.
3. North, R.B.; Kidd, D.H.; Olin, J.; Sieracki, J.M.;Farrokhi, F.; Petrucci, L. Cutchis, P.N.; Spinal Cord Stimulators for axial low back pain : a prospective controlled trial comparing dual with single percutaneous electrodes. Spine 2005;30:1412-1419.
4. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery 2006; 58:481-496.
5. Taylor RS, Taylor RJ, Van Buyten JP, Buchser E, North R, Bayliss S. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. J Pain Symptom Manage 2004; 27:370-378.
6. Bradley K. The technology: the anatomy of a spinal cord and nerve root stimulator: the lead and the power source. Pain Med 2006; 7 Suppl 1:S27-S34.
7. Quigley DG, Arnold J, Eldridge PR, Cameron H, McIvor K, Miles JB, Varma TR. Long-term outcome of spinal cord stimulation and hardware complications. Stereotact Funct Neurosurg 2003; 81:50-56.
8. Renard VM, North RB. Prevention of percutaneous electrode migration in spinal cord stimulation by a modification of the standard implantation technique. J Neurosurg Spine 2006; 4:300-303.
9. Eldridge JS, Weingarten TN, Rho RH. Management of cerebral spinal fluid leak complicating spinal cord stimulator implantation. Pain Pract 2006; 6:285-288.

Pulsed Radiofrequency Ablation for Superior Cluneal Nerve Pain

First Author Victor Tseng, DO
Co-authors: Yury Khelemsky, MD
Author Affiliations The Mount Sinai Hospital

Background: The patient had this pain for about a year with worsening over the past 3 months. During the pregnancy she had more pronounced shooting sensations down the right leg. At the time of her initial visit, the shooting symptoms had somewhat resolved but the low back and buttock pain became a burning, deep achy pain.

An MRI Lumbar spine was ordered, showing L4-5 and L5-S1 moderate disc bulges, more prominent on the right, as well as L4-5 facet joint widening bilaterally, right much more than left. Given her symptoms and MRI results, we performed a right L5 transforaminal epidural steroid injection. The injection did not provide any relief and she eventually underwent an L5 laminectomy.

Her pain unfortunately did not resolve completely after the laminectomy. We performed a series of injections over the span of 6 months including lumbar medial branch blocks, a right sacroiliac joint injection, and deep lumbar paraspinal trigger point injections. All of these injections gave her short term equivocal relief, but none provided definitive relief of her pain.

Since most her pain was in the right buttock region near the iliac crest and we ruled out other major causes of pain in this region by various diagnostic blocks, we opted to focus on the superior cluneal nerves. A diagnostic block of the superior cluneal nerves resulted in complete relief of the patient's pain. We then performed a pulsed radiofrequency ablation (PRFA) of the superior cluneal nerve by palpating along the iliac crest and placing the active tip at the area of most tenderness. We used a 22G, 10 cm probe with 10 mm active tip. PRFA was done with a NeuroTherm NT100 Generator; pulse rate of 2 Hz, pulse duration of 20 ms, for 4 minutes, with temperature not exceeding 42°C .

Objective: To make the interventional pain physicians aware that pulsed radiofrequency ablation (PRFA) can be a used as a safe and effective modality to treat superior cluneal nerve pain. Methods Case Presentation

Results: At her follow-up visit, the back pain symptoms completely resolved and she was pleased to be able to carry on her daily activities pain free. Currently, she continues to be pain free 4 months after the procedure.

Conclusions: Superior cluneal nerve entrapment is a rare diagnosis but should be something to consider in the differential, especially if the pain is unilateral along the iliac crest. Using a pulsed radiofrequency ablation technique is a safe and effective

way to treat this diagnosis if the patient had a good response to a diagnostic block.

References

1. De Andres Ares J, Diaz L. Superior Cluneal Nerve Entrapment by Adipose Tumor, an Odd Type of Low Back Pain. Pain Practice. 12 (Sup 1):74, Feb 2012.
2. Talu G, Cimen A, Ozyalcin N, Erdine S. An Uncommon Cause of Low–back Pain: Superior Cluneal Nerve Entrapment. European Journal of Pain. 10 (Sup 1):S109, Sept 2006.
3. Talu G, Ozyalcin S, Talu U. Superior Cluneal Nerve Entrapment. Reg Anesth Pain Med. 2000 Nov-Dec;25(6):648-50.
4. Tubbs R, Levin M, Loukas M. Anatomy and Landmarks for the Superior and Middle Cluneal Nerves: Application to Posterior Iliac Crest Harvest and Entrapment Syndromes. Journal or Neurosurgery Spine. 13(3):356-9, Sept 2010.
5. West M, Wu H. Pulsed radiofrequency ablation for residual and phantom limb pain. Pain Practice. 10(5):485-91, Sept 2010.

Pulsed Radiofrequency Treatment for Chronic Lumbar Radicular Pain: Review of evidence from Randomized Controlled Trials (Update)

First Author: Vasanth Kattalai Kailasam MD1.,
Co-authors: Taghogho Agarin MD2., Aniefiok Agarin1 MD.,
Author Affiliations:
1Harlem Hospital Center, Columbia University College of Physicians & Surgeons, New York, NY
2Manchester Memorial Hospital, Manchester, CT

Background: The annual prevalence of low back pain described as radiating to leg in the general population, is reported to be between 9.9% and 25%. Also, the point prevalence (4.6–13.4%) and lifetime prevalence (1.2–43%) are very high [1]. Pulsed Radiofrequency treatment (PRF), since its first introduction in 1996 has been an effective tool for managing regional pain. The use of PRF to the Dorsal Root Ganglion (DRG) in cervical radicular pain is reported to be compelling [2]. Though the mechanism by which PFR exerts analgesia is still unclear [3], it has been documented to significantly reduce Chronic Lumbar Radicular pain (CLR) in the literature, in turn improve quality of life. Here we review the evidence from available Randomized Controlled Trials (RCT).

Objective: To determine the efficacy of Pulsed Radiofrequency Treatment (PRF) in management of Chronic Lumbar Radicular Pain (CLR). Methods We systematically searched randomized articles published since 1996 for clinical studies on PRF for CLR. We searched the Google Scholar, MEDLINE (PubMed), Cocharne Database and EMBASE database, using the free text terms: pulsed radiofrequency, lumbar radicular pain, radio frequency, radiation, isothermal radiofrequency, and combination of these. Out of 13 filtered articles, we identified 2 as RCT. We excluded published observational studies, case reports, case series, reviews and audits.

Results: In the first study, patients with lumbosacral pain were randomized into two groups. Group one was managed with PRF and second was treated with PRF and then Continuous Radiofrequency (CRF) to maximum tolerated temperature. The study reported their result as no significant difference in the percentage of successful response rate or in the average decline in VAS between the two groups. By the eighth month after either of the procedure, the vast majority of patients had returned to their baseline pain intensity. T The average pain relief duration was 3.18 (± 2.81) months in those treated with PRF and 4.39 (± 3.5) months in those treated with both CRF and PRF [4]. But the study was not an efficacy trial.

In the second study, patients were randomized to a placebo group (needle placement) or a treatment group (PRF at 42°C for 120 seconds to the Dorsal Root Ganglion). Patients were followed up for 3 months post procedure. Outcomes with regard to pain, Oswestry Disability Index score (ODI), and side effects were analyzed on an intention-to-treat basis. At 4 weeks and 3 months, the mean VAS score showed a small but no significant decrease in the PRF group compared with the placebo group. Compared with placebo, the decrease in pain scores was consistent throughout follow-up and was more pronounced at 3 months (3 months -0.75 (-3.12, 1.63) ***P*** - 0.524) than at 4 weeks (4 weeks -0.61 (-2.68, 1.46) ***P*** - 0.552). The ODI also decreased in both groups. Similar to VAS scores, the decrease in ODI was more obvious in the PRF group than in the placebo group. Five of 16 (31%) patients had a 50% decrease in pain score in the PRF group compared with three of 14 (20%) in the placebo group. Limitations include insufficient power and heterogeneous sample [3].

Conclusions: Paucity of literature showing randomized trials remains a limitation.Out of 2 studies one shows no difference between PRF verses PRF and CRF treated patients. The second study shows significant improvement in pain compared to placebo group. Additional randomized controlled trials with large sample size and follow ups are required to validate the efficacy of PRF. Utility in patients with pain unresponsive to epidural steroids or patients who are not a candidate for more invasive analgesic methods deserves future evaluation and research.

References

1. Van Boxem K, Cheng J, Patijn J, van Kleef M, Lataster A, Mekhail N, Van Zundert J. Pain Pract. 2010 Jul-Aug;10(4):339-58. doi: 10.1111/j.1533-2500.2010.00370.x. Epub 2010 May 17. Review.
2. Chua NH, Vissers KC, Sluijter ME. Pulsed radiofrequency treatment in interventional pain management: mechanisms and potential indications-a review. Acta Neurochir (Wien). 2011 Apr;153(4):763-71. doi: 10.1007/s00701-010-0881-5. Epub 2010 Nov 30. Review.
3. Shanthanna H, Chan P, McChesney J, Thabane L, Paul J. Pulsed radiofrequency treatment of the lumbar dorsal root ganglion in patients with chronic lumbar radicular pain: a randomized, placebo-controlled pilot study. J Pain Res. 2014 Jan 10;7:47-55. doi: 10.2147/JPR.S55749. eCollection 2014.
4. Simopoulos TT, Kraemer J, Nagda JV, Aner M, Bajwa ZH. Response to pulsed and continuous radiofrequency lesioning of the dorsal root ganglion and segmental nerves in patients with chronic lumbar radicular pain.Pain Physician. 2008 Mar-Apr;11(2):137-44.

Multi-Center Study to Evaluate Accuracy of the Medication Efficacy Differentiation (MED) Scale to Predict Hydrocodone Efficacy versus the Pain VAS Score

First Author Brian Meshkin, BA
Co-authors: Daniel A Schwarz, MD, MROC; Andrea M Trescot, MD; Sanford M Silverman, MD;Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Si Van Nguyen, MD; Tobore Onojighofia, MD

Author Affiliations President and CEO of Proove Biosciences, Inc Co-author Affiliations Daniel A. Schwarz, MD, MROC: President, Pain Recovery Specialists, PLLC; Andrea Trescot, MD: Director, the Pain and Headache Center, Anchorage, AK
Sanford M. Silverman, MD, Medical Director, CEO, Comprehensive Pain Medicine, Pompano Beach, FL
Si Van Nguyen, MD: Medical Director, Huntington Beach Hospital, CA
Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Tobore Onojighofia, MD are employees of Proove Biosciences, Inc.

Background: Hydrocodone is the most widely prescribed opioid analgesic. We are lacking metrics to assess the analgesic response to these medications. We propose using the Medication Efficacy Differentiation (MED) Scale to evaluate the degree of therapeutic efficacy. As a substitute for prospective or longitudinal measurements of effectiveness, the MED Scale provides a retrospective assessment and insights into the degree of medication usefulness.

Objective: The objective of the study is to validate the Medication Efficacy Differentiation (MED) Scale among chronic non-cancer pain patients taking hydrocodone, by comparing the MED scale values to the Pain Visual Analog Scale (VAS). Methods Across 23 clinical sites in the United States, investigators completed a MED Scale on 313 patients taking prescription hydrocodone for analgesia. Physicians gauge patient response on a scale of 0 to 5, where 0 = no response, 1 = very poor response, 2 = poor response, 3 = indeterminate response, 4 = good response, and 5 = very good response. We excluded subjects taking hydromorphone and other daily DEA schedule II opioids in addition to hydrocodone. Patients were divided into 2 groups by MED: poor responders had a score of 0 to 3 while good responders had scores 4 or 5. Pain VAS (Scale 0-10) was also recorded for each study subject to estimate the level of pain perception. Low pain VAS was set at less than or equal to 6 and a high VAS was greater than 6. A chi-squared statistical analysis test was performed using SAS JMP software.

Results: Statistical significance was found for the inverse relationship between the Pain VAS and the Medication Efficacy Differentiation (MED) Scale for Hydrocodone (p=0.001). (Sensitivity = 81% (95% CI), PPV= 36.5% (95% CI), NPV 82.3% (95% CI), OR= 2.68 (95% CI). Poor responders that had high intensity on pain VAS were 82% true positives, while good responders with high intensity in pain VAS were 64% true positive.

Conclusions: This validation study suggests the MED Scale may be a reliable assessment of therapeutic efficacy for chronic pain patients treated with hydrocodone, when they are poor responders. Good responders to Hydrocodone, were still likely to report higher intensity on the Pain VAS. However, there may be a biased response, in order for patients to insure they obtain their analgesic medication. Further research is required on whether the MED Scale can correlate with the degree of efficacy in good responders, as well as its ability to predict efficacy for other analgesic and pharmaceutical agents.

Disclosure: Daniel Schwarz, MD; Andrea Trescot, MD and Sanford Silverman, MD are consultants for Proove Biosciences, Inc and members of their advisory board, respectively.

Analgesia Perception of Prescription Opioids with Chronic Pain: Comparing Genotype to Pain VAS

First Author Brian Meshkin, BA
Co-authors: Daniel A Schwarz, MD, MROC; Andrea M Trescot, MD; Sanford M Silverman, MD;Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Si Van Nguyen, MD; Tobore Onojighofia, MD

Author Affiliations President and CEO, Proove Biosciences, Inc. Co-author Affiliations Daniel A. Schwarz, MD, MROC: President, Pain Recovery Specialists, PLLC
Andrea Trescot, MD: Director, the Pain and Headache Center, Anchorage, AK
Sanford M. Silverman, MD, Medical Director, CEO, Comprehensive Pain Medicine, Pompano Beach, FL
Si Van Nguyen, MD: Medical Director, Huntington Beach Hospital, CA
Bilikis Akindele, MD; John Hubbard, RPT; Derrick Holman, MD; Tobore Onojighofia, MD are employees of Proove Biosciences, Inc.

Background: Various studies have explored modalities for Objectively evaluating pain perception in the Central Nervous System, including functional MRI and genotype. In this study, we evaluated the prevalence of specific mesolimbic gene variants from our proprietary practice-based evidence database to conduct a cross-sectional analysis of genotype vs Pain visual analog scale (VAS).

Objective: To evaluate whether genotype, or SNP variations can help Objectively stratify patient perception of pain among chronic pain patients taking narcotics. Methods 2,721 subjects (1,584 women and 1,137 men) from 48 Clinic sites across the United States were enrolled in this IRB-approved cross-sectional study. Subjects diagnosed with chronic pain and currently taking prescription opioid pain medications were genotyped using Real-Time quantitative Polymerase Chain Reaction using TaqMan Assay (LifeTechnologies, Carlsbad, CA). The following single nucleotide polymorphisms (SNPs) were evaluated: COMT (Val158Met), DRD2 (A1 allele)), DRD1 and OPRK1 All 2721 patients completed a Pain VAS rating their perception of pain on a scale from 0 to 10. Subjects with no pain (Pain VAS) were excluded from the study. Low pain perception was defined as a score of 1, 2 or 3 (n=249, 9.2%); Moderate pain perception score of 4, 5, or 6 (n=1259, 46.2%) and High pain perception score of 7, 8, 9 or 10 (n=1,213, 44.6%). A multinomial logistic regression analysis was performed using SPSS (V 22, IBM, Armonk, NY).

Results: Statistical significance was found among all four variants The DRD1 variant is more prevalent in the low pain perception population compared to high pain perception population [p<0.043, OR 1.334 (95% CI); PPV 84.44% (95% CI Among subjects with a moderate pain perception) the COMT and OPRK1 variants were more prevalent compared to those with high pain perception COMT: P < 0.007, OR 1.25 (95% CI PPV: 52.41% (95% CI) OPRK: P < 0.032, OR 1.19 (95% CI) PPV 51.09% (95% CI: Among subjects with a high pain perception, the DRD2 variant was more prevalent compared to subjects with moderate pain perception [p<0.041, OR 1.25, PPV 52.61% (95% CI)]

Conclusions: This retrospective analysis provides a potential genotypic analysis to stratify pain perception, and a more Objective method to define subjective Pain VAS perceptions.

Disclosure: Daniel Schwarz, MD; Andrea Trescot, MD and Sanford Silverman, MD are consultants for Proove Biosciences, Inc and members of their advisory board, respectively.

Discontinuation of Systemic Opioid Usage After Implantation of Intrathecal Drug Delivery System reduces Expenditures

First Author David Caraway
Co-authors:John Hatheway, Guy David, Candace Gunnarsson, Jennifer Hinnenthal, Robert Spencer and Michael Saulino
Author Affiliations St. Mary's Regional Medical Center Pain Relief Center, Huntington, WV

Background: A concentrated form of morphine specifically developed to be administered intrathecally by implanted pump was approved by the FDA in 1991. The expectation of this "new" treatment for severe pain was "relief …without the peaks and valleys of pain sometimes associated with capsules, pills, and intravenous injections." In the 20+ years since approval, intrathecal drug delivery, as a route of administration for pain medications, has varied in clinical practice between an alternate route and an adjuvant route of delivery.

Objective: To compare healthcare utilization and expenditures for pain patients discontinuing systemic opioid use after Intrathecal Drug Delivery System (IDD) Implant vs. those continuing with systemic opioid use as an adjuvant to intrathecal delivery. Methods METHODS: Using claims data from the Truven Health MarketScan® Commercial and Medicare Supplemental Databases, we identified patients for inclusion if the following criteria were met: (1) a record of a complete IDD Implantation on the same service date; (2) a record of opioid usage prior to implantation; and (3) 12 months pre and 13 months post-implant

continuous health plan and pharmacy enrollment. The one month time period after implant served as a "blanking period". Records of patients discontinuing systemic opioids were evaluated at the following time points: 1st, 90th, 120th, and 180th day post blanking period; records of these patients, defined as the "treatment group", were analyzed cross-sectionally. Multivariable models were developed to investigate the effect of discontinuing systemic opioids on healthcare utilization and expenditures.

Results: A total of 401 patients met the final inclusion criteria. A total of 12% of patients discontinued systemic opioids within the blanking period (one month following implant), 39% discontinued during the year post-blanking period, and the remaining 49% continued systemic opioid use for the entire study period. Multivariable results indicate that discontinuing systemic opioids within 90, 120, or 180 days post blanking period versus continuing systemic opioid in addition to intrathecal delivery is associated with a reduction of $3,388 to as much as $4,465 and a reduction of $4,689 to as much as $5,571 when drug expenditures are added to the model. These reductions were seen in inpatient and outpatient expenditures over the study period. No effect was found for inpatient ER admissions or hospitalizations.

Conclusions: We find evidence that discontinuation of systemic opioid usage after IDD implantation results in significantly lower inpatient, outpatient and drug expenditures.

Disclosure: David Caraway has consulted with or received research support from Medtronic, Inc., Spinal Modulation, Inc., Nevro, Inc., and Biones, Inc.
John Hatheway, has consulted with or been on speaker bureau for Insys Pharmaceuticals and Medtronic, Inc.
Guy David is an academic affiliate to S2 Statistical Solutions, which is a paid consultant to Medtronic Inc.
Candace Gunnarsson is an employee of S2 Statistical Solutions, which is a paid consultant to Medtronic Inc.
Jennifer Hinnenthal and Robert Spencer are employees of Medtronic, Inc which is the study sponsor.
Michael Saulino has consulted with or been on speaker bureau for Medtronic, Inc., Jazz and Mallinckodt.

Infusion System Flow Rate Error and Pump Delivery Accuracy: What Physicians Need to Know

First Author Robert Spencer, MS, MBA
Co-authors: Sally McCarville, MS, Maria Breitenfeldt, PhD; Linda Page, PharmD

Author Affiliations Medtronic Neuromodulation

Background: Assessment of infusion accuracy for implantable pumps is an area of clinician and patient interest to ensure effective, reliable and safe therapy delivery. Instances of pump over or under-infusion can cause patient morbidity and in extreme cases mortality. Physicians educate patients, caregivers and family members to recognize the signs and symptoms associated with intrathecal drug therapy overdose, underdose or withdrawal, but physicians must also understand the inherent variability of pump delivery and utilize this information to evaluate whether discrepancies in retrieved volume at refill is cause for concern.

Objective: The objective of this work is to provide insight into the methods by which pump accuracy can be determined, and provide examples as to how that information could be used in the clinical setting. This work will incorporate data from multiple sources, including bench assessment, clinical studies, and a real-world infusion system registry. Methods Assessment of infusion system accuracy is done from device manufacturing through the point of anticipated need for replacement. Presented in this poster are methods of assessment at each point in the product life-cycle, with expected variations, the source(s) of those variations, and the means by which to conclude additional assessment is warranted.

Results: The SynchroMed II Infusion device is labeled with an accuracy specification of +/-14.5 %; however, many clinicians find this device specification to be of limited value in the practice setting. Variability is expected from any infusion devices due to a multiplicity of factors including care setting, syringe error, technique, device over- or under- infusing, and other mitigating factors. Safe and effective management of patients with infusion devices includes implementation of refill best practices coupled with the close following of any patients who present with significant volume discrepancies. Data will be presented to showcase various means of measuring accuracy and to provide clinicians with perspective on how to assess whether discrepancies in medication delivery are normal variations or represent potential safety issues with infusion system function.

Conclusions: Refill to refill, device to device, and patient to patient variations in pump flow rate accuracy are to be expected. These variations have several causes, and an understanding of these potential causes is needed for the selection of a specific product for implant, as well as ongoing troubleshooting after implant.

Disclosure: All authors are employees of Medtronic, Inc.
Encore Presentation North American Neuromodulation Society 2014

Overview of a Clinical Program on Intrathecal Morphine Sulfate for Chronic, Nonmalignant Pain

First Author David Caraway, MD, PhD
Co-authors: Timothy Deer, MD, DABPM
Eric Grigsby, MD, Robert M Levy, MD PhD, Mark Wallace, MD, Robert Spencer, MS MBA, Linda Page, PharmD
Author Affiliations Center for Pain Relief Tri-State, Huntington WV; Medtronic Inc, Minneapolis MN;
Center for Pain Relief, Charleston WV; Napa Pain Institute, Napa CA;
Unv of Florida, Jacksonville FL; Unv of California, San Diego, CA

Background: A concentrated form of morphine specifically developed to be administered intrathecally by implanted pump was approved by FDA in 1991. The expectation of this "new" treatment for severe pain was "relief …without the peaks and valleys of pain sometimes associated with capsules, pills, and intravenous injections." Medtronic business and market analysis indicates that fewer than 5% of eligible pain patients receive intrathecal pain therapy, in spite of existing, albeit limited, evidence supporting safety, efficacy and cost effectiveness. With current concerns over complications associated with systemic opioid use, including misuse, diversion, abuse and addiction, the need for medical evidence supporting this treatment modality as an alternate route of delivering pain medications has never been greater.

Objective: Presented here is an overview of a clinical program intended to provide intrathecal morphine with the medical evidence needed to fully support its approved indication for chronic, non-malignant pain. Methods Medtronic Neuromodulation and medical experts in pain medicine outlined this clinical program. The penultimate goal of the program is a large, randomized, controlled clinical trial (RCT) providing the Level 1 medical evidence needed for intrathecal morphine. To properly design this study, initial pre-clinical work studying drug distribution within the IT space, dosing and drug-delivery variables, and areas of risk (ie, inflammatory mass) mitigation is underway or in development. In addition, clinical studies are being developed and initiated to evaluate various methods of therapy utilization as an alternate route of delivering pain medications (ie, complete discontinuation of systemic opioid use and conversion to IT morphine, bolus dosing versus continuous infusion, optimal dosing parameters, etc.).

Results: The results from individual studies within this program will all serve to bolster the medical evidence supporting intrathecal morphine. In addition, results from each study will benefit the development of the large RCT, aiding in the identification of dosing and delivery parameters and study endpoints.

Conclusions: Intrathecal morphine has been an approved, but underutilized therapy for chronic pain for more than 20 years. Upon completion of this clinical program, results will ideally increase adoption of this therapy, reduce the use of and complications with systemic opioid use, provide guidance around optimal clinical and economic application of intrathecal morphine, and address the needs of what has been identified as a large population of undertreated patients.

Disclosure: Drs. Caraway, Deer, Grigsby, Levy, and Wallace are consultants for Medtronic, Inc
Robert Spencer and Linda Page are employees of Medtronic, Inc

Research support is provided by Medtronic, which also manufactures the SynchroMed Infusion System Encore Presentation North American Neuromodulation Society, December 2014

Randomized Controlled Trial of Interspinous Spacers for Lumbar Spinal Stenosis: 2-year Outcomes

First Author Thomas R Haley, DO1
Co-authors: David L. Lichten, MD1; Larry E Miller, PhD2,3; Jon E Block, PhD3
Author Affiliations: 1 Performance Spine and Sports Physicians, Pottstown, PA; Performance Spine and Sports Physicians, Pottstown, PA; 2 Miller Scientific Consulting, Inc., Arden, NC; 3 The Jon Block Group, San Francisco, CA

Background: Degenerative lumbar spinal stenosis (LSS) with severe intermittent neurogenic claudication symptoms is treated with decompressive laminectomy, with or without fusion. Interspinous spacers may serve as an alternative to open surgery in patients with moderate LSS resistant to nonsurgical treatments.

Objective: To evaluate the 2-year clinical outcomes in patients treated with the Superion or X-STOP interspinous spacer for intermittent neurogenic claudication secondary to radiographically confirmed moderate LSS. Methods This multicenter, prospective, randomized, controlled, investigational device exemption trial randomly allocated patients to treatment with the Superion or X-STOP interspinous spacer. All patients with a minimum of 2-year follow-up were included in this report (Superion 101, X-STOP 91). Main outcomes included Condition-specific Zurich Claudication Questionnaire (ZCQ), back function with Oswestry Disability Index (ODI), and back and leg pain severity with visual analogue scale (VAS). Clinical success was defined as a

minimum 20-point improvement for back and leg pain severity and a minimum 15 percentage point improvement for ODI.

Results: ZCQ symptom severity and physical function scores improved 34%-36% in both groups through 2 years (all p<0.001). ZCQ patient satisfaction scores at 2 years were 1.8±0.9 with Superion and 1.6±0.8 with X-STOP. Back pain severity decreased from 57±27 mm to 22±27 mm in the Superion group (p<0.001) and from 55±25 mm to 23±25 mm with X-STOP (p<0.001). Leg pain decreased from 64±26 mm to 16±26 mm with Superion (p<0.001) and from 62±26 mm to 20±22 mm with X-STOP (p<0.001). Back and leg pain clinical success rates were comparable (back pain: Superion, 66%; X-STOP, 62%: leg pain: Superion, 79%; X-STOP, 75%). Back function similarly improved with Superion (38±13% to 20±18%; P < 0.001) vs. X-STOP (39±12% to 20±16%; P < 0.001). Back function success rates were 59% for Superion and 60% for X-STOP. No significant between-group differences were noted for any outcome at 2 years.

Conclusions: Treatment with the Superion or X-STOP interspinous spacer results in promising 2-year outcomes in patients with intermittent neurogenic claudication secondary to moderate LSS

Disclosure: Drs. Miller and Block are independent clinical trials consultants and were remunerated by the sponsor to assist in developing the text of the abstract.

The Effects of Gastroretentive Gabapentin (Gralise®) on Spinal Stenosis Patients with Radicular Pain

First Author: Alan D. Kaye, MD, PhD Professor and Chair, LSU New Orleans, Dept of Anesthesiology
Co-authors: Franklin Bueno-Rivera, MS, MS--medical student, University of Indiana
Bonnie Katalenich, MPH--statistician, Tulane Medical Center
Carol Stell, RN--research nurse, Tulane Medical Center
Aaron J. Kaye, BS (expected)-Stanford University
Mary E. Fox, BS-LSU, Research Associate
Henry Liu, MD--Associate Professor, Tulane Medical Center Dept of Anesthesiology
Charles Fox, MD--Professor and Chair, LSU Shreveport, Dept of Anesthesiology
Frank Rosinia, MD--Professor and Chair, Tulane Medical Center, Dept of Anesthesiology

Background: The health and efficacy profiles of Gralise® in the treatment of pain from spinal stenosis and radicular symptomatology have not been measured. A review of the current literature indicates that no studies exist that evaluate the safety and efficacy profiles of Gralise® in the treatment of pain from spinal stenosis and radicular symptomatology.

Objective: Our study is aimed at determining whether Gralise® is a safe and effective pharmacotherapy for the pain from spinal stenosis and radicular symptomatology.

Study design: A 4 week prospective open label single arm and single center study of patients with MRI diagnosis of spinal stenosis with radicular pain.

Methods: The primary measure of efficacy was a change in average daily pain (ADP) score from baseline to completion of Gralise® therapy for 4 weeks. The secondary efficacy endpoints were the subjects' Patients' Global Impression of Change Scale (PGIC), the clinician's Clinical Global Impression of Change Scale (CGI) reports, and the Medical Outcomes Study (MOS) sleep scale of improvement from baseline to completing 4 weeks of Gralise® therapy. The safety and tolerability were evaluated by the incidence of adverse events reported while on Gralise® therapy.

Setting: The study was performed at the Clinical Research Facilities at a medical school in the period from December 1, 2012 to August 30, 2013.

Results: Thirty-five patients achieved an efficacy point of 1-week Gralise® medication treatment. 27 of 35(77.2%) patients completed all 5 visits. The PGIC noted a significant positive change in: (1) activity limitations; (2) symptoms; (3) emotions and overall quality of life when related to their condition from first visit as well as improved degree of change when related to their condition from first to last visit. The MOS sleep scale and sleep diaries noted a significant increase of hours slept on average (an increase in over one hour per night-5.8 hours versus 6.86 hours) from the beginning of the study to the end. The CGI noted a majority of 10 out of 27 with marked significant therapeutic effect with no side effects. The ADP rating from pain intensity scale and pain diaries noted significant improvement of lesser levels of pain experienced (P = .5907 and P = .8547 respectively). No significant adverse effects were noted in the study.

Conclusions: Gralise® demonstrated moderate efficacy with reduced pain intensity and increased sleep and was well tolerated in spinal stenosis patients with radicular symptoms.

Digital Subtraction Angiography is Superior to Real-Time Fluoroscopy for Detection of Intravascular Penetration Prior to Epidural Steroid Injections: A Meta-Analysis

First Author Ognjen Visnjevac, MD
Co-authors: Sina Farid Davarai, MD
Nader Djalal Nader, MD, PhD Presenter Ognjen Visnjevac, MD
Author Affiliations Dept. of Anesthesiology and Pain Medicine, State University of New York: Buffalo Program; Dept. of Anesthesiology and Pain Medicine, State University of New York: Buffalo Program

Background: Neurological injury is a rare but highly morbid complication of epidural steroid injections (ESI), generally thought to arise from neurovascular compromise following intravascular steroid injection or vascular spasm. (1) The most common preventative measure taken by interventional pain physicians is the use of real-time fluoroscopy (RTF) to avoid intravascular penetration. In 2002, it was proposed that digital subtraction angiography (DSA) may be useful for interventional pain physicians performing. (2) Since then, several prospective studies have compared the sensitivity of DSA to RTF for detection of intravascular injection. (3-6)

Objective: As DSA is not currently an official "gold standard," a meta-analysis of was performed to compare the efficacy of DSA versus RTF for detection of intravascular penetration. Methods Using the keywords "digital subtraction angiography epidural," "digital subtraction fluoroscopy epidural," and "digital subtraction fluoroscopy pain" the Cochrane, EMBASE and MEDLINE databases were searched for published prospective reports comparing the sensitivity of DSA to RTF in the same individuals without change in needle position between comparative imaging. Retrospective studies and prospective studies comparing DSA to RTF individually in separate groups of patients were excluded. Search was not restricted by year or publication or language. Search results yielded 48 reports and three published paper were analyzed, per inclusion and exclusion criteria. Each of the studies utilized the transforaminal approach for ESI. Review manager software (Rev Man 5) was used for the analysis (7). Pooled estimate of odds ratios with 95% confidence interval using a random effect model was conducted.

Results: A total of 1041 ESI's were performed at cervical, lumbar, and sacral levels with an overall intravascular event detection of 117 by RTF and 148 by DSA. DSA was shown to have a statistically significant favorable odds ratio over RTF for detection of intravascular penetration during ESI (OR 1.32, 95% C.I. 1.01-1.71, $P = 0.04$).

Conclusions: DSA was shown to have a greater than 30% improvement (OR 1.32) for detection of intravascular penetration with ESI when compared to RTF. Although this supports advocacy for the use of this technology, it also suggests that there is an approximately 30% "missed-events" rate when using RTF for ESI. This incidence of missed-events is significantly greater than the generally reported cumulative rates of complications (approximately 1%), which in and of themselves are generally minor complications of which neurological injury is a small subset (8,9). As of yet, it is unclear what the determinants of this disparity of missed-event to complication rate are. Along with particular steroid size, intravenous, rather than intraarterial, injection of steroid is likely to play a significant factor in this apparent disparity as the analyzed studies did not report arterial injection (1). Furthermore, DSA is not a perfect technique either, as there have been reports of devastating injury following negative DSA imaging (10). Considering the discrepancies between missed-event rates and complications, along with reports of false-negative DSA imaging resulting in devastating neurological injury, it would be inappropriate to recommend DSA as a "gold standard" imaging technique for ESI at this time.

Disclosure: None of the authors have any financial conflicts of interest or other conflicts of interest pertinent to this study.

References

1. Glaser SE, Shah RV. Root cause analysis of paraplegia following transforaminal epidural steroid injections: The "unsafe" triangle. Pain Physician 2010;13(3):237-244.
2. Jasper JF. Is digital subtraction flouroscopy a useful tool for the interventional pain physician? Pain Physician 2002;5(1):36-39.
3. El Abd O, Amadera JE, Pimentel DC, Pimentel TS. Intravascular flow detection during transforaminal epidural injections: a prospective assessment. Pain Physician 2014;17(1):21-7.
4. Kim YH, Park HJ, Moon DE. Rates of lumbosacral transforaminal injections interpreted as intravascular: fluoroscopy alone or with digital subtraction. Anaesthesia. 2013 Nov;68(11):1120-3
5. Lee MH, Yang KS, Kim YH, Jung HD, Lim SJ, Moon DE. Accuracy of live fluoroscopy to detect intravascular injection during lumbar transforaminal epidural injections. Korean J Pain. 2010 Mar;23(1):18-23.
6. McLean JP1, Sigler JD, Plastaras CT, Garvan CW, Rittenberg JD. The rate of detection of intravascular injection in cervical transforaminal epidural steroid injections with and without digital subtraction angiography. PM R. 2009 Jul;1(7):636-42.
7. Review Manager (RevMan) [Computer program]. Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008.
8. McGrath JM1, Schaefer MP, Malkamaki DM. Incidence and characteristics of complications from epidural steroid injections. Pain Med. 2011 May;12(5):726-31.

9. Malhotra G, Abbasi A, Rhee M. Complications of transforaminal cervical epidural steroid injections. Spine (Phile Pa 1976) 2009;34(7)731-9.
10. Chang Chien GC, Candido KD, Knezevic NN. Digital subtraction angiography does not reliably prevent paraplegia associated with lumbar transforaminal epidural steroid injection. Pain Physician. 2012 Nov-Dec;15(6):515-23.

Ozone and Steroids Injection Compared to Either Treatment Alone in the Management of Lumbar Disc Herniation: A Review of Randomized Trials.

First Author Aniefiok Agarin MD.

Co-authors: Taghogho Agarin MD, MBA, MPH, Vasanth Kattalai MD.
Author Affiliations Harlem Hospital/ Columbia University, New York; Manchester Memorial Hospital, Connecticut.
Vasanth Kattalai MD - Harlem Hospital/ Columbia Hospital, New York.

Background: Lumbar Disc Herniation (LDH) occurs in about 2% of the general population. For most patients, the condition resolves with conservative management over a period of a few months. For others who do not resolve, the gold standard approach is microsurgical discectomy and to a lesser extent percutaneous discectomy which is effective in about 80- 90% of cases. Ozone therapy via intradiscal or intraforaminal access has been shown to be a minimally invasive effective treatment method for LDH with rare published complication rates in the literature which could be used before surgical intervention for cases that fail conservative management. We review the use of ozone therapy and steroids in management of LDH.

Objective: To review the effect of ozone therapy and steroid injection for treatment of LDH, in published randomized studies. Methods Using key words like ozone therapy, lumbar disc herniation, percutaneous discectomy, in Pub Med and Google scholar we identified over 50 articles that discussed the effectiveness of ozone therapy most of which were prospective studies. We chose only two articles which were randomized and compared ozone therapy, steroids and anesthetics in varying combinations for review. We excluded all prospective studies and all studies that examined the use of ozone therapy for other causes of low back pain other than LDH.

Results: One study randomized 600 patients into 2 groups of 300 each. The first group received intradiscal and preganglionic ozone injection, while the other received ozone, a costicosteroid and an anesthetic. The outcome in the latter group was excellent 78.3% of the time compared to 70.3% of the time when patients were assessed at 6 months using the modified MacNab criteria. In the second study, Gallucci et al randomized 159 patients to two groups, 77 patients had a steroid and an anesthetic, while 82 patients had the same treatment, but had ozone therapy in addition. Using scores from the Oswestry Low back pain questionnaire, the later group had 74% resolution of symptoms at 6 months compared to 34% in the former.

Conclusions: Ozone and Steroid Combination is superior to Ozone alone or Steroid alone in the treatment of LDH. More randomized studies are needed to validate or disprove the above.

Disclosure: None

References

1. Gallucci M, Limbucci N, Zugaro L, et al. Sciatica: treatment with intradiscal and intraforaminal injections of steroids and oxygen-ozone versus steroid only. Radiology 2007;242:907-13.
2. Andreula CF., Simonetti L, Desanti F; Aguti R; Rici R, Leonardi M. Minimally Invasive oxygen-Ozone Therapy for Lumbar Disc Herniation. Am J Neuroradiol 2003 May; 24(5); 996-1000