

Abstracts

 **2016 Abstract Session Presentations**

- | | |
|--------------|---|
| First Place | Innervation of the Anterior Capsule of the Human Knee: Implications for Radiofrequency Ablation
Dr. Jeff Petersohn |
| Second Place | Multicenter Randomized Controlled Pivotal Trial Comparing 10 kHz and Traditional Spinal Cord Stimulation: 24-month Results
Ramsin Benyamin, MD |
| Third Place | Sustained Effectiveness of Intrathecal Ziconotide Use as the First Agent in Pump in Patients With Severe Chronic Pain
Dr. Richard Rauck |

Abstracts appear in their orgiinally submitted form. No alterations or edits have been completed.

FIRST PLACE

INNERVATION OF THE ANTERIOR CAPSULE OF THE HUMAN KNEE: IMPLICATIONS FOR RADIOFREQUENCY ABLATION

Authors: Carlo D. Franco, MD, Asokumar Buvanendran, MD, Jeffrey D. Petersohn, MD, Robert D. Menzies, MD, and Linda Pham Menzies, MD

Presenter: Jeffrey D. Petersohn, MD

Author Affiliations: Department of Anesthesiology and Pain Management, Rush University Medical Center; Department of Anesthesiology and Pain Management, JHS Hospital of Cook County, Chicago, IL; Department of Anesthesiology, Drexel University College of Medicine, Philadelphia, PA; and JPS Sports Medicine and Orthopedics, Arlington, TX.

Background and Objectives: Chronic knee pain is common in all age groups. Some patients who fail conservative therapy benefit from radiofrequency neurotomy. Knowledge of the anatomy is critical to ensure a successful outcome. The purpose of this study was to reanalyze the innervation to the anterior knee capsule from the perspective of the interventional pain practitioner.

Methods: The study included a comprehensive literature review followed by dissection of 8 human knees to identify the primary capsular innervation of the anterior knee joint. Photographs and measurements were obtained for each relevant nerve branch. Stainless-steel wires were placed along the course of each primary innervation, and radiographs were obtained.

Results: Literature review revealed a lack of consensus on the number and origin of nerve branches innervating the anterior knee capsule. All dissections revealed the following 6 nerves: superolateral branch from the vastus lateralis, superomedial branch from the vastus medialis, middle branch from the vastus intermedius, inferolateral (recurrent) branch from the common peroneal nerve, inferomedial branch from the saphenous nerve, and a lateral articular nerve branch from the common peroneal nerve. Nerve branches showed variable proximal trajectories but constant distal points of contact with femur and tibia. The inferolateral peroneal nerve branch was found to be too close to the common peroneal nerve, making it inappropriate for radiofrequency neurotomy.

Conclusions: The innervation of the anterior capsule of the knee joint seems to follow a constant pattern making at least 3 of these nerves accessible to percutaneous ablation. To optimize clinical outcome, well-aligned radiographs are critical to guide lesion placement.

SECOND PLACE

MULTICENTER RANDOMIZED CONTROLLED PIVOTAL TRIAL COMPARING 10 KHZ AND TRADITIONAL SPINAL CORD STIMULATION: 24-MONTH RESULTS

Authors: Leonardo Kapural MD, PhD, Cong Yu, MD(1), Matthew W. Doust, MD(2), Bradford E. Gliner, MS(3), Ricardo Vallejo, MD, PhD(4), B. Todd Sitzman, MD, MPH(5), Kasra Amirdelfan, MD(6), Donna M. Morgan, MD(7), Thomas L. Yearwood, MD, PhD(8), Richard Bundschu, MD(9), Thomas Yang, MD(1), Ramsin Benyamin, MD(4), Abram H. Burgher, MD(2)

Presenter: Ramsin Benyamin, MD

Author Affiliations: Center for Clinical Research and Carolina's Pain Institute at Brookstown, Wake Forest Baptist Health, Winston-Salem, NC; (1) Swedish Pain Center, Seattle, WA; (2) The Pain Center of Arizona and HOPE Research Institute, Phoenix, AZ; (3) Clinical and Regulatory Affairs, Nevro Corp., Menlo Park, CA; (4) Millennium Pain Center, Bloomington, IL; (5) Advanced Pain Therapy, PLLC, Hattiesburg, MS; (6) IPM Medical Group, Inc., Walnut Creek, CA; (7) Pain Consultants of Oregon, Eugene, OR; (8) Comprehensive Pain & Rehabilitation, Pascagoula, MS; (9) Coastal Orthopedics and Pain Medicine, Bradenton, FL

Introduction: Effective pain relief with spinal cord stimulation (SCS) has historically been linked with paresthesias overlapping chronically painful areas (Schultz, et al., 2012) (Parker, Karantonis, Single, Obradovic, & Cousins, 2012). However, recent innovation has introduced paresthesia-free 10 kHz stimulation (HF10 Therapy), shifting focus to improved patient outcomes. Twelve month results comparing the two therapies have been reported elsewhere (Kapural, et al., 2015). This study compared HF10 Therapy to traditional low frequency (~50 Hz) SCS for the treatment of chronic back and leg pain, with 24-month efficacy outcomes reported.

Methods: A randomized controlled pivotal trial was conducted across 11 comprehensive pain treatment centers (ClinicalTrials.gov NCT01609972). Subjects had visual analog scale (VAS) scores of ≥ 5.0 of 10.0 cm for both back and leg pain. Subjects were randomly assigned (1:1) to receive HF10 Therapy or traditional low frequency SCS. The primary endpoint was responder rate, defined as $\geq 50\%$ pain reduction.

Results: 198 subjects were randomized to receive a short-term trial SCS system (101 HF10 Therapy, 97 traditional SCS). 171 subjects (90 HF10 Therapy, 81 traditional SCS) successfully completed the trial and were implanted. Subjects averaged 54.9 ± 12.9 years of age, 13.6 ± 11.3 years since diagnosis, 86.6% had previous back surgery, 88.3% were taking opioid analgesics. At 24 months, back pain decreased to a greater degree with HF10 Therapy ($7.5 \text{ cm} \pm 1.3 \text{ cm}$ at baseline to $2.4 \text{ cm} \pm 2.3 \text{ cm}$, or 66.9%) than traditional SCS ($7.8 \text{ cm} \pm 1.2 \text{ cm}$ at baseline to $4.5 \text{ cm} \pm .9 \text{ cm}$, or 41.1%, $p < 0.001$). Similarly, leg pain decreased to a greater degree with HF10 Therapy ($7.1 \text{ cm} \pm 1.5 \text{ cm}$ at baseline to $2.4 \text{ cm} \pm 2.3 \text{ cm}$ or 65.1%) than traditional SCS ($7.6 \text{ cm} \pm 1.4 \text{ cm}$ at baseline to $3.9 \text{ cm} \pm 2.8 \text{ cm}$ or 46.0%, $p = 0.002$). More subjects were responders to HF10 Therapy than traditional SCS (Back pain: 55% versus 49.3%, $p < 0.001$; Leg pain: 72.9% versus 49.3%, $p < 0.001$).

Conclusion: This study demonstrates the long-term superiority of HF10 Therapy over traditional SCS in treating both back and leg pain. The advantages of HF10 Therapy are anticipated to substantially impact the management of patients with chronic pain.

References:

1. Schultz D, Webster L, Kosek P, Dar U, Tan Y, & Sun, M. (2012). Sensor-Driven Position-Adaptive Spinal Cord Stimulation for Chronic Pain. *Pain Physician*, 15(1):1-12.
2. Parker J, Karantonis D, Single P, Obradovic M, & Cousins MJ. (2012). Compound action potentials recorded in the human spinal cord during neurostimulation for pain relief. *Pain*, 153(3):593-601.
3. Mosby. *Mosby's Medical Dictionary*. 8th Edition; 2009.

THIRD PLACE

SUSTAINED EFFECTIVENESS OF INTRATHECAL ZICONOTIDE USE AS THE FIRST AGENT IN PUMP IN PATIENTS WITH SEVERE CHRONIC PAIN

Authors: Timothy Deer, MD, Michael F. Saulino, MD, PhD; Philip Kim, MD; Mark Wallace, MD; I-Zu Huang, MD; Fannie Mori, MS; Geertrui F. Vanhove, MD, PhD; Gladstone McDowell, MD

Presenter: Richard Rauck, MD

Author Affiliations: Timothy Deer, MD, The Center for Pain Relief, Charleston, Michael F. Saulino, MD, PhD, Moss-Rehab, Elkins Park, PA; Philip Kim, MD, Center for Interventional Pain and Spine, LLC, Newark, DE; Mark Wallace, MD, University of California, San Diego, La Jolla, CA; I-Zu Huang, MD, Jazz Pharmaceuticals, Palo Alto, CA; Fannie Mori, MS, Jazz Pharmaceuticals, Palo Alto, CA; Geertrui F. Vanhove, MD, PhD, Jazz Pharmaceuticals, Palo Alto, CA; Gladstone McDowell, MD, Integrated Pain Solutions, Columbus, OH

Introduction: The Patient Registry of Intrathecal Ziconotide Management (PRIZM) is evaluating short-term and long-term effectiveness, safety, and patient-reported outcomes associated with the use of intrathecal ziconotide in the clinical practice

Methods: PRIZM is an ongoing, open-label, long-term, multicenter, observational study of adult patients with severe chronic pain who meet ziconotide prescribing information criteria and initiate ziconotide as the sole agent in the pump. Enrollment in this study has closed; however, patients may remain in the study for up to 18 months if they continue to receive ziconotide. An interim subset analysis (data as of July 10, 2015) of ziconotide use as the first versus second-or-later intrathecal agent in pump reports change from baseline over time (month 3, 6, 9, and 12) in "average pain for the past 24 hours" with an 11-point Numeric Pain Rating Scale (NPRS; primary efficacy endpoint).

Results: Enrollment has closed at 93 patients; data are available for these patients in this interim analysis. Sixty-one patients were eligible for 12-month efficacy analysis; 30 patients were still active in the study at month 12 and 21 had NPRS scores at all data collection timepoints in this analysis (baseline and months 3, 6, 9, and 12); 13 of 21 patients (61.9%) received ziconotide as the first agent in pump (FIP+), whereas 8 (38.1%) did not (FIP-). Mean (SD) baseline NPRS scores were 7.4 (1.3) and 8.3 (1.2) in FIP+ and FIP- patients, respectively. Mean percentage change (SE) in NPRS scores for FIP+ and FIP- patients were -19.2 (7.9)% and -12.2 (7.8)% at month 3, -30.8 (7.2)% and -4.3 (4.0)% at month 6, -22.8 (9.3)% and -22.3 (7.4)% at month 9, and -32.7 (9.7)% and -5.4 (11.4)% at month 12, respectively. The most common adverse events (AEs; in $\geq 10\%$ of patients overall) were peripheral edema (38.5% vs 0%; FIP+ vs FIP- patients, respectively), amnesia (30.8% vs 12.5%), auditory hallucination (30.8% vs 25.0%), nausea (30.8% vs 0%), balance disorder (23.1% vs 12.5%), headache (23.1% vs 0%), memory impairment (23.1% vs 12.5%), urinary tract infection (23.1% vs 0%), confusional state (15.4% vs 25.0%), diarrhea (15.4% vs 12.5%), dizziness (15.4% vs 12.5%), and pruritus (15.4% vs 12.5%).

Conclusion: In this small interim subset analysis of the PRIZM database with a limited number of patients with NPRS scores available for all data collection timepoints up to 12 months, the data suggest that there may be a greater sustained treatment response for up to 12 months when ziconotide was initiated as first-line intrathecal therapy versus second-or-later agent in the pump. The AE profile of ziconotide was consistent with the prescribing information.

Funding support provided by Jazz Pharmaceuticals.

Acknowledgment: The authors thank Douglas Milikien, MS (former contract employee for Jazz Pharmaceuticals), for his contributions to the development of the abstract.

References:

1. Schmidtko A, et al. *Lancet*. 2010;375(9725):1569-1577.
2. Prialt (ziconotide) solution, intrathecal infusion [package insert]. Jazz Pharmaceuticals, Inc.: Palo Alto, CA; 2013.
3. Kress HG, et al. *Pain Pract*. 2009;9(5):338-347.
4. Lawson EF, Wallace MS. *Curr Pain Headache Rep*. 2010;14(1):8-16.
5. Staats PS, et al. *JAMA*. 2004;291(1):63-70.
6. Wallace MS, et al. *Neuromodulation*. 2006;9(2):75-86.
7. Rauck RL, et al. *J Pain Symptom Manage*. 2006;31(5):393-406.
8. Deer TR, et al. *Pain Physician*. 2009;12(4):E291-E296.
9. Raffaelli W, et al. *Pain Physician*. 2011;14(1):15-24.
10. Dupoirion D, et al. *Pain Physician*. 2012;15(5):395-403.

WHISPER: A PROSPECTIVE MULTICENTER TRIAL EVALUATING THE USE OF SUBPERCEPTION SCS AT ≤ 1.2 KHZ

First Author: James North, M.D.

Co-authors: Daniel Campbell, Ph.D., Nitzan Mekel-Bobrov, Ph.D.

Presenter: James North, M.D.

Author Affiliations: Carolinas Pain Institute, Winston-Salem, North Carolina; Boston Scientific Corporation, Valencia, California

Introduction: Spinal Cord Stimulation (SCS) has relied on understanding that dorsal column stimulation-induced paresthesia must be generated around an area of pain to achieve pain relief. However, studies suggest that effective pain relief may be obtained by employing stimulation without paresthesia (1). These studies have focused on high rate (~10kHz) and burst stimulation programs. However, concerns have been voiced regarding potential for significant charging burden and decreased time before IPG replacement due to frequent recharging (2, 3). Exploratory research on subperception SCS (SPSCS) at ≤ 1.2 kHz suggests that effective pain relief can be achieved at relatively low rates with appropriate patient selection.

Methods: This multi-center, randomized, controlled, crossover, openlabel study (WHISPER Study, Boston Scientific Corporation) with a group-sequential design is currently on-going. The primary endpoint evaluates the proportion of subjects with greater than 50% reduction in overall pain intensity with the use of subperception settings as compared with traditional SCS settings with no increase in baseline average daily medication intake used to treat pain. Other assessments include percent pain relief, low back pain intensity, and quality of life. Key inclusion criteria include the use of Precision SCS for at least 6 months and a 30% improvement in overall pain intensity with its use. Subjects with significant cognitive impairment that may confound study results will be excluded. A total of 146 subjects at up to 25 sites will be included in this study.

Results: The accompanying report provides details of the study design, demographics, and other preliminary data from the study. The study is currently ongoing.

Conclusion: This study will report the outcomes in subjects with chronic pain of the trunk and/or limbs when using a spinal cord stimulator (SCS) system at subperception amplitude with commercially available parameters. This is particularly relevant in those who prefer no paresthesia with use of their SCS system while receiving effective pain control.

References:

1. North RB., Ewend MG., Lawton MT., and Piantadosi S. "Spinal cord stimulation for chronic, intractable pain: superiority of "multi-channel" devices", *Pain*. 1991 Feb;44(2):119-30.
2. De Ridder D., Vanneste S., Plazier M., van der Loo E., Menovsky T. Burst spinal cord stimulation: toward paresthesia-free pain suppression. *Neurosurgery*. 2010 May;66(5): 986-90.
3. Al-Kaisy A., Van Buyten JP, Smet I., Palmisani S., Pang D., Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med*. 2014 Mar;15(3):347-54.
4. Buchser E., Comment on: Van Buyten JP, et al., High-frequency spinal cord stimulation for the treatment of chronic back pain patients: results of a prospective multicenter European clinical study. *Neuromodulation*. 2013 Jan-Feb;16(1):59-65.
5. Gulve A., Comment on: Tiede J. et al., Novel Spinal Cord Stimulation Parameters in Patients with Predominant Back Pain. *Neuromodulation*. 2013 Jul-Aug;16(4):370-5.

6. North JM, Hong J, Cho PY. Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation (SCS) In Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial (RCT). Neuromodulation (in press).

REAL WORLD EVIDENCE OF CLINICAL OUTCOMES OF MULTIMODAL SPINAL CORD STIMULATION: A PROSPECTIVE GLOBAL REGISTRY STUDY

Authors: Eric Loudermilk (1); Daniel Roth (2), Channing Willoughby (3), Randall P. Brewer (4), Anthony Berg (5), Matthew McCarty (6), Joseph N. Atallah (7), Stephen G. Smith (8), Richard Rauck (9), Joseph C. Hegarty (10), Gregory Phillips (11), Nameer Haider (12), Jeff B. Phelps (13), T. Matthew Crooks (14), Melinda Lawrence (15), Louis Bojrab (16), Chong Kim (17), Shakil Ahmed (18), Albert Lee (19), James Brennan (20), Lee T. Snook (21), Kamyar Assil (22), Ryder Gwinn (23), Annu Navani (24), Mayank Gupta (25), Praveen Mambalam (26), Abel Murillo (27), Louis Raso (28), Carroll M. McLeod (29), Andrew Trobridge (30), Joshua Rosenow (31), Medhat F. Mikhael (32), Mahendra Sanapati (33), Kenneth Candido (34), Milind Deogaonkar (35), James North (36), Kristen Lechleiter (37), Dat Huynh (37), Roshini Jain (37), Nitzan Mekel-Bobrov (37)

Presenter: Anthony Berg

Author Affiliations: 1. Piedmont Comprehensive Pain Management Group, Anderson, SC, United States. 2. Summit Pain Management, Fort Wayne, IN, United States. 3. Channel Research, Pawley's Island, SC, United States. 4. Willis Knighton River Cities Clinical Research Center, Shreveport, LA, United States. 5. Spine Team Texas, Rockwell, TX, United States. 6. Balcones Pain Consultants, Austin, TX, United States. 7. University of Toledo, Toledo, OH, United States. 8. Midwest Pain Center, Bridgeton, MO, United States. 9. The Center for Clinical Research, Winston-Salem, NC, United States. 10. Orthopedic Research Foundation, Savannah, GA, United States. 11. NeuroSpine Institute, Eugene, OR, United States. 12. Spine and Skeletal Pain Medicine, Utica, NY, United States. 13. Spine Works Institute, North Richland Hills, TX, United States. 14. Atlantis Global Research Institute, Youngtown, AZ, United States. 15. Case Western Reserve University, Cleveland, OH, United States. 16. Forest Health Medical Center, Ypsilanti, MI, United States. 17. West Virginia University, Morgantown, WV, United States. 18. Weill Cornell Medical College, New York, NY, United States. 19. Tallahassee Neurological Clinic, Tallahassee, FL, United States. 20. Florence Neurosurgery and Spine, Florence, SC, United States. 21. Metropolitan Pain Management Consultants, Sacramento, CA, United States. 22. Conejo Pain Specialists Medical Group, Thousand Oaks, CA, United States. 23. Swedish Neuroscience Institute, Seattle, WA, United States. 24. Comprehensive Pain Management Center, Campbell, CA, United States. 25. Advanced Pain Treatment Center, Edgewood, KY, United States. 26. Washington Center for Pain Management, Bellevue, WA, United States. 27. Advanced Medical Pain Management and Research, Miami Gardens, FL, United States. 28. Jupiter Interventional Pain, Jupiter, FL, United States. 29. Jackson Anesthesia Pain Center, Jackson, MS, United States. 30. American Health Network of Indiana, Muncie, IN, United States. 31. Northwestern University Feinberg School of Medicine, Chicago, IL, United States. 32. Pain Medicine Associates, Fountain Valley, CA, United States. 33. Global Scientific Innovations, Evansville, IN, United States. 34. Chicago Anesthesia Pain Specialists, Chicago, IL, United States. 35. Ohio State University Wexner Medical Center, Columbus, OH, United States. 36. Carolinas Pain Institute, Winston-Salem, NC, United States. 37. Boston Scientific Corporation, Valencia, CA, United States.

Objectives: Different treatment modalities in Spinal Cord Stimulation (SCS) are now available including standard rate, 1K, burst, anode intensification, 10K, Multiple Independent Current Control (MICC), etc. On the other hand, identification and analysis of clinically-relevant patient sub-populations using these different modalities, via mining large datasets ("Big Data") of real world evidence (RWE) and implementation of advanced analytics, have not yet been conducted. We report here the largest SCS study of its kind designed to investigate real-world, "multimodal" SCS.

Methods: This is a prospective, multi-center, global registry study (RELIEF Registry, Boston Scientific) enrolling up to 4800 subjects at up to 150 centers. All subjects undergo a trial for pain with a commercially-approved neurostimulator and followed up to 36-months. To date, programming parameters and waveform usage among 800 patients have been collected.

Results: Analyzed subjects used a large number of programs/waveforms from 0-30 days post-implant (10-11 programs) but stabilize by 6 months post-implant (2-3 programs). Most subjects utilized the standard SCS waveform (62.6%) compared to others (1k, anode intensification, burst). Seventy-two percent of subjects utilized multimodal SCS versus single mode (28%). Of these, approximately 90% of subjects use at least 2 modes (~10% use 3 or more) with most using a combination of 1 kilohertz and standard rate programs (29%).

Conclusion: This study collects and analyzes a large dataset of RWE. Subjects have so far been found to use multiple modalities/waveforms long-term, using a variety of options at different times each day. This initial observation underscores the clinical-relevance of a single device capable of multimodal SCS.

IMPLEMENTING POPULATION MANAGEMENT IN A PAIN SPECIALTY PRACTICE

First Author: Barbara Koschak, APNP, DNP,
Co-authors: David A. Bryce, MD FIPP ABIPP, J. Timothy Harrington, MD

Presenter: David A. Bryce, M.D.

Author Affiliations: Department of Physical Medicine and Rehabilitation University of Wisconsin Medical Foundation, Madison, WI.; Clinical Faculty University of Wisconsin School of Medicine and Public Health; Advanced Pain Management, Madison, WI.; Professor of Medicine, Retired, University of Wisconsin School of Medicine and Public Health; Harrington Consulting LLC, Madison, WI.

Background: Population management provides a promising new approach to caring for people with chronic conditions. It manages the entire population of patients, and individuals within this context. Analytic registries are used for monitoring and improving the effectiveness and outcomes of care, implementing protocols, and supporting care teams.

Objective: To test the feasibility and impacts of implementing population management in a pain management specialty practice.

Study Design: An 18-month observational cohort study including all new patients referred for pain management.

Setting: A private, interventional pain management practice staffed by a physician-nurse practitioner team within the Middle Western United States (Advanced Pain Management)

Methods: A population registry was developed to enroll all new patients and to track their progress through a 6-month cycle of care. Patient demographics, referral sources, standardized measures of pain and function, and treatments were collected at baseline and during scheduled follow up visits. Measures included patient-derived pain rated on a 0-10 visual analogue scale (VAS), the Oswestry Disability Index, the morphine equivalent daily dose (MEDD), and a provider-derived global score (PGS). The PGS is collected on a 0-10 VAS with controlled (0-1), Low (1.1- 4), Moderate (4.1-7), and High (7.1-10) segments to reflect the pain level, functional status, and drug use reported by each patient. The registry was used to track individual patient's management, to assess care processes, to determine outcomes for patients completing a 6-month cycle of care, and to analyze subsets within the population.

Results: Six hundred sixteen new patients were successfully enrolled over the initial 18 months of registry use. Only 247 (40%) completed a 6-month cycle of care. A 30% no-show rate was documented for follow-up appointments with major reasons including lack of insurance coverage and patient decisions to avoid recommended care. Remaining patients were returned to their referring physician for continuing management within 6 months. MEDD at baseline was a strong predictor of loss to follow-up. Of the 247 patients completing a 6-month cycle of care, 56% improved in 1 or more measures of pain, function, and their PGS.

Limitations: Six-month assessments were not available on patients who did not complete a full cycle of care.

Conclusions: A pain population registry provided new understandings of our patient population and practice performance that in turn produced positive impacts on our effectiveness and efficiency. Defining a 6-month cycle of care facilitated better analysis of practice processes and patient outcomes. Physician appointments became increasingly focused on interventional management and nurse practitioner appointments on medical management and care coordination. A protocol to follow up with no-show patients was developed, and initial management of patients with high baseline MEDD levels was focused on establishing a drug management

program. Referring physicians were educated in opioid management to reduce drug abuse-related referrals and subsequent no-shows. The PGS shows promise for improving the monitoring and management of chronic pain populations. A need for system level and inter-disciplinary cooperation to better manage this chronic pain population was documented.

REFERENCES:

1. Committee on Quality of Health Care in America. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. 2001. Washington, DC. National Academy Press.
2. Great Health Care: Making It Happen Editors JT Harrington and ED Newman. 2011. New York. Springer USA. Berwick DM. Broadening the view of evidence-based medicine. *Qual Saf Health Care* 2005;14:315-6.
3. Baily MA, Bottrell M, Lynn J, Jennings B. A Hastings Center special report: the ethics of using QI methods to improve health care quality and safety. *Hastings Center Report*. Jul-Aug 2006.

THE EMERGING THERAPEUTIC ROLES OF KAPPA OPIOID AGONISTS

First Author: Mark R Jones

Co-authors: Alan David Kaye (1), Aaron J. Kaye (2), Richard D. Urman(3)

Presenter and Contact Person: Mark R Jones

First Author Affiliations: Tulane University School of Medicine, Senior Medical Student; Department of Anesthesiology, LSU School of Medicine, Research Associate

Co-author Affiliations: (1) Professor and Chairman, Department of Anesthesiology, LSU School of Medicine; (2) Medical Student, Medical University of South Carolina; (3) Associate Professor, Harvard Medical School, Department of Anesthesiology Perioperative and Pain Medicine, Brigham and Women's Hospital

The current practice of mu-opioid receptor agonists such as morphine as the primary means of acute and chronic pain relief has several dangerous consequences that limit their effectiveness, including respiratory depression, gastrointestinal motility inhibition, addiction, tolerance, and abuse. Several other opioid receptors, notably the k-opioid receptor (KOP), have long been known to play a role in pain relief.

Recent discoveries and advancements in laboratory techniques have allowed significant developments of KOP agonists as potential novel therapies for pain relief and other pathological processes. These drugs exhibit none of the classic opioid adverse effects and have displayed pronounced analgesia in several different scenarios. New formulations since 2014 have unveiled increased oral bioavailability, exceptional peripheral vs central selectivity, and a positive safety profile.

Continued refinements of established k-opioid agonist formulations have virtually eliminated the centrally mediated side effects of dysphoria and sedation that limited the applicability of previous KOP agonists.

Further research is required to better elucidate the potential of these compounds in pain management, as well as in the mediation or modulation of other complex pathophysiological processes as therapeutic agents.

References:

1. Feng Y, He X, Yang Y, et al. Current research on opioid receptor function. *Curr Drug Targets*. 2012;13(2):230-246.
2. Filizola M, Devi LA. Grand opening of structure-guided design for novel opioids. *Trends Pharmacol Sci*. 2013;34(1):6-12.
3. Obara I, et al. Local peripheral opioid effects and expression of opioid genes in the spinal cord and dorsal root ganglia in neuropathic and inflammatory pain. *Pain*. 2009;141:283-291.

WHOSE URINE IS IT? A NEW APPROACH TO EXPOSE OTHER HUMAN AND SYNTHETIC URINE SUBSTITUTION IN OUTPATIENT MEDICATION/SOBRIETY MONITORING.

First Author: Matt McCarty MD

Co-authors: Keqin Gregg, PhD: Shawn Lunney, Wenjing Guo, Robert Rhodes, Cynthia Harris, Paul Samilpa, Lyndsey Langley, Archana Subramanya, Dillon McCarty, Kyle Ames,

Presenter and Contact Person: Matt McCarty, MD

First Author Affiliations: Matt McCarty MD Owner/Founder/Medical Director of Genotox Labs

Co-author Affiliations: Keqin Gregg PhD Genetics labs supervisor, Genotox Labs; Shawn Lunney, COO, Genotox Labs; Wenjing Guo, Genetic Analyst- Genotox Labs; Robert Rhodes, Research Analyst- Genotox Labs; Cynthia Harris, Balcones Pain Consultants Lab Manager; Paul Samilpa, Genetics Analyst- Genotox Labs; Lyndsey Langley, Genetics Analyst, Genotox Labs; Archana Subramanya, Genetics Analyst- Genotox Labs; Dillon McCarty, MSIII AUC Medical School; Kyle Ames, Research Analyst- Genotox Labs

Urine as a sample for drug screening and confirmation remains the gold standard in sobriety, medication monitoring and return to work programs across the country. Sample validity measures of pH, temperature, specific gravity and creatinine have long been relied upon for sample authenticity. Unfortunately innovations in drug testing validity measures have not kept up with the creativity used to cheat a drug test. In fact, a simple internet search of "how to cheat a drug test" produces over 2.5 million results ranging from instruction blogs on how to cheat current validity tests using assorted chemicals, to wearable devices and even the "fool proof method" of using substitute or synthetic urine. It is not hard to imagine the health and economic impact of UDS cheating on both the individual and society at large can be devastating.

Although federal and state programs use witnessed sample collection, medical and many sobriety monitoring locations rely on unwitnessed collection. Unwitnessed collection creates an increased opportunity for circumvention. In fact a VA outpatient study in an opioid dependent population converting from unwitnessed to witnessed sample collection documented a 16% increase in appropriate positives for prescribed medication (4). With the advent of precision medicine and new PCR instrumentation, the idea was developed that genetic matching of sample to urine donor could eliminate the need for a witnessed sample collection environment.

It is widely understood in forensic circles that obtaining adequate dna from urine as a sample is difficult. A new patent pending validity method developed by a toxicology lab in Austin Texas using biomarkers matching the donor's buccal cells and urine cellular dna as well as spectrophotometric analysis has been developed. This method was validated in a recent previous study⁵. The current study was conducted to validate the accuracy and practical utility of the test in a clinical setting. A double-blind study with randomized introduction of known control samples at 11 medication/sobriety monitoring sites in Texas was conducted from June-December 2015. Novella Clinical and Compass IRB approved and monitored each site's participation to ensure protocol compliance and proper voluntary patient consent. Once informed of the nature of the study, only 48% patients at each site consented to participate. A total of 900 urine and buccal swab pair samples were collected and processed.

Among the 900 samples, 171 were introduced in accordance with the randomization schedule as controls. 166 of these (call rate 97%) control samples yielded enough genetic material to complete the test. The other 5 samples had insufficient genetic material leading to difficulty in making a call and were not included in the final analysis. The final results including; 82/82 (100%) matched, 67/67 (100%) substituted or mismatched and 17/17 (100%) synthetic samples were all accurately identified by the newly developed lab method.

The results demonstrate 100% specificity and 100% sensitivity. Out of the 729 non-randomized samples, 36 were indeterminate due to insufficient DNA (call rate 95.1%.) Of the 693 successfully tested samples, 11 were substituted samples (1.6%). Since all participants of the study were informed of the purpose and functionality of the test and approximately only half participated it is possible that the , the natural "cheater" rate in this sample population is greater than 1.6%. In conclusion, this test is a proven method to help doctors identify urine drug test "cheaters" who submit substitute human or synthetic urine samples in medication monitoring or sobriety programs.

REFERENCES:

1. <http://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-asam.pdf>
2. Gombos, J. (1999). Chapter 10: Substitution. . In J. Gombos, In *Fooling the Bladder Cops: The Complete Drug Testing Guide*. online posting.
3. Mallya, A. et al. (2013). Witnessed versus unwitnessed random urine tests in the treatment of opioid dependence *Am J Addict.*, 22, 175-7.

SURVEY AFTER PARTICIPATION IN BRIEF COMPUTERIZED MINDFULNESSBASED INTERVENTIONS (CMBI) IN A CHRONIC PAIN POPULATION INDICATES HIGH ACCEPTANCE AND INTEREST IN INCREASED USE OF THESE THERAPIES

First Author: William Longton

Co-authors: Ruben Kalra, Richard Shinaman, Presenter William Longton, MD,

Presenter and Contact Person: William Longton, MD

Author Affiliations: WellBrain, Inc., Pain Medicine Consultants, Inc

Despite over 100 million Americans suffering from chronic pain, and medical costs climbing beyond \$635 billion dollars per year, the penetration of low-cost mindfulness therapies into chronic pain populations has been limited. An unfortunate preconception among health care providers is that patients with chronic pain are only interested in opiate therapy.

It is been well established that mindfulness-based interventions relieve chronic pain of various etiologies when practiced for up to 8 weeks in structured settings, and attenuate experimental pain, even in a setting using only four daily 20 minute guided meditation sessions. Mindfulness meditation related pain relief is associated with the activation of brain regions involved in the cognitive modulation of pain which are distinct from brain regions activated by sham meditation or placebo effects. Mind-body therapies are clearly beneficial in the treatment of chronic pain and insomnia. Meditation is used by approximately 8% of US adults, however it is estimated that less than 10% of patients experiencing chronic musculoskeletal pain currently use any form of mind-body therapy. Multiple reasons for low utilization of mindfulness-based interventions (MBI) may include perceived lack of efficacy by patients or physicians not familiar with mindfulness techniques, out of pocket costs not covered by insurance, and lack of providers with expertise in teaching MBI.

In the setting of low adoption rate among patients with chronic pain, increased use of MBI would potentially result in cost-savings even with modest increases in adoption rates of the therapy. To determine whether patients would be more likely to practice MBI after a brief exposure to a computerized MBI (CMBI) as a pain management therapy, we conducted a study on a random sample of 232 chronic pain patients (average duration of pain 10 years, average morphine equivalent 46 mg/day) from a single private practice setting who underwent a five minute session of digitally guided mindfulness instruction using open awareness meditation. A short survey was administered afterward to determine the immediate effects of the therapy as well as assess patient interest in CMBI therapies.

Following the computerized mindfulness intervention, patients were queried 1) regarding likelihood of using CMBI if it were doctor-prescribed and if customized to their pain condition, 2) whether they would be likely to recommend CMBI to a friend, 3) whether they thought it had the potential to reduce the amount of pain medication they were taking, and 4) whether they thought that reducing medication quantity was important. They were also queried in un-blinded fashion about pain relief and mental relief immediately following the intervention.

Our findings indicate that patients with chronic pain are very likely to use a doctor prescribed CMBI therapy, and would prefer the CMBI be doctor prescribed and customized. The patients reported that they believe that CMBI therapy may help them reduce the need for prescription medications. There was a modest correlation indicating that the willingness to follow the doctor's recommendation and recommend meditation to a friend increased with age (5-10% of observed variability). There was a modest negative correlation indicating that patients consuming larger amounts of opioids judged that dose reduction was less important. Some patient sex differences were noted. The general willingness to follow a doctor's recommendation and recommend medita-

tion to a friend found more support among women than men.

Finally, our results, although obtained in un-blinded and not controlled fashion, suggest that the effect size for pain relief and mental relief following a brief CBMI was about 30%. This indicates that the intervention may be clinically meaningful even in a single short session. This treatment effect may be consistent with mechanisms that facilitate relaxation responses, which would be interpreted as analgesic.

Conclusion: A random survey of patients experiencing chronic pain revealed that a majority of these patients were interested in using CMBI as a means of treating the chronic pain -especially if customized to their pain condition, would refer the therapy to their friends, and believe that it could help them reduce their prescription drugs. We conclude that CMBI as an ongoing pain management therapy has the potential for high adoption rate given the reported interest level among patients experiencing chronic pain following a brief CMBI therapy in the office. Additionally such brief interventions may be a means of providing brief levels of physical and mental pain relief, even if the mechanism is predominantly via a relaxation response. Overall the goal is to engage the vast population of chronic pain patients in mindfulness practice, given the benefits that have been recognized since the ground-breaking work of Zinn, et al in the 1980s. CMBI therapies that are easily accessible should be further developed and refined and tested and then hopefully utilized for the treatment of chronic pain conditions.

References:

1. Kabat-Zinn, J *Gen Hosp Psychiatry*. 1982 Apr;4(1):33-47
2. Zeidan, F *The Journal of Neuroscience*, November 18, 2015 • 35(46):15307–15325 • 15307
3. NIH Consensus Statement: Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia. Available at: http://odp.od.nih.gov/consensus/ta/017/017_statement.htm. Accessed 5/8/02.
4. Wolsko, PM *J Gen Intern Med*. 2004 Jan; 19(1): 43–50.
5. Tindle, HA *Complement Ther Med*. 2005 Sep; 13(3): 155–164.
6. Sobel, DS, *JAMA*.2000;284:1705.
7. Beary JF, Benson H (1974) . *Psychosom Med* 36:115–120.
8. Physician Perceptions on Opioid Therapy for Chronic Pain A Report on Prescribing Practices and the Role of Continuing Education on Opioids. Boston University School of Medicine <https://www.scopeofpain.com/toolkit/documents/whitepaper.pdf>
9. Goyal, M, Haythornethwaite, J Is it time to make mind-body approaches available for chronic low back pain? *JAMA*, 2016, 315(12): 1236-1237

ZICONOTIDE AS A FIRST-LINE INTRATHECAL MONOTHERAPY

First Author: Julia Prusik BS

Co-authors: Charles Argoff, MD; Julie G Pilitsis MD, PhD

Presenter and Contact Person: Julie Pilitsis, MD, PhD

Author Affiliations: Department of Neurosurgery, Albany Medical Center, Albany; NY and Center for Neuroscience and Neuropharmacology, Albany Medical College, Albany NY; Department of Neurology, Albany Medical Center, Albany, NY

Background: Ziconotide intrathecal drug therapy (IDT) has been demonstrated to have fewer and less serious associated adverse effects compared to morphine. Further, tolerance and acute withdrawal have not been documented. Little is known, however, about its use as a first line monotherapy.

Objective: We aim to demonstrate that ziconotide can be used as a first-line monotherapy, and to create an algorithm for initial dosing.

Methods: We retrospectively reviewed demographics, dosing, and outcomes at 3 months and latest follow-up (mean 12.9 months post-operatively (7.0-22.6)) of 16 patients between 2012 and 2015 utilizing ziconotide as a first-line agent monotherapy in IDT.

Results: Of our 16 patients, one was explanted during the first three months and excluded from further analysis. The mean age of the remaining patients was 57.3 years (range 43-80). There were 6 men and 9 women. Six patients were diagnosed with neuropathic pain, 5 patients with failed back surgery syndrome (FBSS), and 3 with complex regional pain syndrome type 1 CRPS). Four of these patients were receiving short acting narcotics, 8 were taking long acting narcotics, and 3 were opioid naïve at baseline. Analysis of outcomes revealed 8 responders and 7 non-responders. Responders were characterized by having 40% or greater improvement in visual analog scale scores (VAS) (n=7), activities of daily living (ADLs) (n=7), or both (n=6) at 3 month follow-up. Their VAS (mean + SEM) were 8.0 +0.64 at baseline, 5.0+0.95 at 3 months and 4±3.6 at most recent follow-up (mean 12.9 months post-operatively (7.0-22.6)).

There were no differences between groups in terms of age, gender, diagnosis, prior back surgery, prior spinal cord stimulation or current opioid use. The initial ziconotide dose in 12 patients was 1.13 mcg per day (range for others 0.6-1.4) Following initial dosing, visits 2 to 5 were at 2-3 weeks, 6 weeks, 8 weeks, 9 weeks, and 10 weeks respectively. Titration doses were 1.39 mcg (range 0.7-1.7) at visit 2 and 1.61 mcg (0.6-2.2) at visit 3. For patients that did not respond, titrations at following visits ranged from 2.02 to 2.66 (range= 1.2- 3.8mcg). Dizziness occurred in 2 patients which resolved with dose reduction. Transient urinary retention was experienced in one patient. No serious adverse events occurred at the 3 month time point. No psychological or withdrawal symptoms occurred.

Discussion: We demonstrate that ziconotide used as a firstline monotherapy is safe and efficacious short term at 3 month follow-up. Fifty-three percent of our patients had outcomes of > 40% improvement in VAS or ADLs, despite many having failed multiple other interventions including high-dose systemic opioids, spinal cord stimulation and/or back surgery.

SUBJECT SATISFACTION WITH PARESTHESIA-FREE 10 KHZ AND PARESTHESIA-BASED LOW-FREQUENCY SPINAL CORD STIMULATION SYSTEMS

First Author: Kasra Amirdelfan

Co-authors: Leonardo Kapural, MD, PhD (1), Cong Yu, MD (2), Matthew W. Doust, MD (3),
Bradford E. Gliner, MS (4), Ricardo Vallejo, MD, PhD(5), B. Todd Sitzman, MD, MPH (6),
Donna M. Morgan, MD (7), Thomas L. Yearwood, MD, PhD (8), Richard Bundschu, MD (9),
Thomas Yang, MD (2), Ramsin Benyamin, MD (5), Abram H. Burgher, MD (3)

Presenter and Contact Person: Ricardo Vallejo, MD

First Author Affiliations: IPM Medical Group, Inc., Walnut Creek, CA

Co-author Affiliations: (1) Center for Clinical Research and Carolina's Pain Institute at Brookstown, Wake Forest Baptist Health, Winston-Salem, NC; (2) Swedish Pain Center, Seattle, WA, USA; (3) The Pain Center of Arizona and HOPE Research Institute, Phoenix, AZ; (4) Clinical and Regulatory Affairs, Nevro Corp., Menlo Park, CA; (5) Millennium Pain Center, Bloomington, IL; (6) Advanced Pain Therapy, PLLC, Hattiesburg, MS; (7) Pain Consultants of Oregon, Eugene, OR; (8) Comprehensive Pain & Rehabilitation, Pascagoula, MS; (9) Coastal Orthopedics and Pain Medicine, Bradenton, FL.

Introduction: The SENZA-RCT study demonstrated the superior effectiveness of paresthesia-free 10 kHz stimulation to traditional paresthesia-based low-frequency spinal cord stimulation (SCS) for the treatment of chronic back and leg pain over a 24 month follow-up period. This abstract reports on the comparative satisfaction of study subjects with the use of their SCS device system.

Methods: SENZA-RCT subjects who received SCS therapy through 24 months were provided a questionnaire regarding the interactive components of their device system: the charger and the patient remote control. Satisfaction responses were according to a 5-point Likert scale ranging from "Very Satisfied" to "Very Dissatisfied".

Results: 55 of 80 (68.8%) subjects treated with 10 kHz and 40 of 57 (70.2%) subjects treated with low-frequency SCS (LF-SCS) through 24 months completed the survey. For 10 kHz, the most frequent charging interval was once per day, compared with once per week or less often for LF-SCS. The most frequent charging duration was 0.5-1.0 hours for 10 kHz, compared with a relatively even distribution of charging times between 0.5 hours and >3 hours for low-frequency SCS. Patient satisfaction is summarized in Table 1. As figure 1 shows, 74.5% of 10 kHz SCS subjects reported using their remote control to adjust therapy settings compared with 87.5% of LF-SCS subjects, $p=0.193$ (Question 1). Of subjects using their remote control, 0.0% of 10 kHz SCS reported using it at least once per day compared with 40.5% of LF-SCS subjects, $p<0.001$ (Question 2). 38.2% of 10 kHz SCS subjects reported bringing their remote control with them when leaving home compared with 85.0% of LF-SCS subjects, $p<0.001$.

Conclusion: Overall, subjects treated with paresthesia-free 10 kHz SCS were more satisfied with charging their device systems than subjects treated with traditional low-frequency SCS. Subjects with 10 kHz SCS rely on their patient remotes less than subjects with traditional low-frequency SCS. These observations might be related to the superior pain relief with 10 kHz stimulation while not causing paresthesias, thus reducing patient attention to pain as well as therapy application.

References:

1. Kapural et al. Multicenter Randomized Controlled Pivotal Trial Comparing 10 kHz and Traditional Spinal Cord Stimulation: 24-month Results. 19th Annual Meeting – North American Neuromodulation Society (NANS). Las Vegas, NV. Dec. 10-13, 2015.
2. Sitzman et al. Long-term Outcomes of Predominant Leg Pain and Predominant Back Pain Cohorts from a Multicentre Randomized Controlled Pivotal Trial (SENZARCT) Comparing 10 kHz High Frequency and Traditional Low Frequency Spinal Cord Stimulation. 19th Annual Meeting – North American Neuromodulation Society (NANS). Las Vegas, NV. Dec. 10-13, 2015.

PAIN PERCEPTION IN PATIENTS WITH PRIMARY PSYCHOTIC DISORDER

First Author: Qasim Raza MD

Co-authors: Vasanth Kattalai-Kailasam MD, Ihuoma Nwakanma MD, Claricio Decastro MD

Presenter and Contact Person: Qasim Raza, MD

Author Affiliations: None

Introduction: Pain, a subjective phenomenon, causes strong emotional response either as a first degree experience or observing other in pain. Schizophrenia is marked by gross distortion from reality, disturbances in thinking, feeling and behavior. It has long been postulated that patients with schizophrenia have alteration in pain perception, some suggesting for decreased pain perception in schizophrenia, others for increased pain sensitivity, while there are also reports stating no differences between healthy controls and schizophrenic patients. The purpose of this review is to analyze available information regarding pain manifestations in the context of schizophrenia, so as to evaluate and quantify the phenomenon to get better management for this disorder and to possibly raise hopes of higher life quality in patients suffering from schizophrenia.

Method: Literature searching PubMed, Google Scholar, EBSCO CINAHL and Medline Literature from 2000 to 2015. Preference was given to literature which utilized standardized tools for assessing perception and severity of pain and had a control group.

Results: 1. Most of the studies concluded that pain perception is impaired in majority of patients with schizophrenia. 2. Some studies found that patient with schizophrenia had an increased sensitivity to pain. 3. Only a few studies were not able to find any difference in pain perception.

Conclusion: Vast majority of patient with schizophrenia have impairment in pain perception. Although some patient can have increased sensitivity to painful stimuli. Management of schizophrenia patient with painful condition should be individualized. Paucity of literature showing randomized trials remains a limitation. Pain perception in patients with primary psychotic disorder deserves future evaluation and research for creation of evidence based management protocol.

References:

1. Kishi T. A cross-sectional survey to investigate the prevalence of pain in Japanese patients with major depressive disorder and schizophrenia. *Compr Psychiatry*. 2015 May;59:91-7. doi: 10.1016/j.comppsy.2015.02.004. Epub 2015 Feb 17.
2. Birgenheir DG. Pain conditions among veterans with schizophrenia or bipolar disorder. *Gen Hosp Psychiatry*. 2013 Sep-Oct;35(5):480-4. doi: 10.1016/j.genhosppsy.2013.03.019. Epub 2013 Apr 29.
3. Wojakiewicz A. Alteration of pain recognition in schizophrenia. *Eur J Pain*. 2013 Oct;17(9):1385-92. doi: 10.1002/j.1532-2149.2013.00310.x. Epub 2013 Mar 25.
4. Boettger MK. Increased cold and heat pain thresholds influence the thermal grill illusion in schizophrenia. *Eur J Pain*. 2013 Feb;17(2):200-9. doi: 10.1002/j.1532-2149.2012.00188.x. Epub 2012 Jul 2.
5. Levesque M. Pain perception in schizophrenia: evidence of a specific pain response profile. *Pain Med*. 2012 Dec;13(12):1571-9. doi: 10.1111/j.1526-4637.2012.01505.x. Epub 2012 Nov 21.
6. De La Fuente-Sandoval C. Neural response to experimental heat pain in stable patients with schizophrenia. *J Psychiatry Res*. 2012 Jan;46(1):128-34. doi: 10.1016/j.jpsychires.2011.09.008. Epub 2011 Sep 28.
7. Martins MJ. Sensitivity to expressions of pain in schizophrenia patients. *Psychiatry Res*. 2011 Sep 30;189(2):180-4. doi: 10.1016/j.psychres.2011.03.007. Epub 2011 Apr 5.
8. De La Fuente-Sandoval C. Functional magnetic resonance imaging response to experimental pain in drug-free

- patients with schizophrenia. *Psychiatry Res.* 2010 Aug 30;183(2):99-104. doi: 10.1016/j.psychresns.2010.05.003. Epub 2010 Jul 6.
9. Urban-Kowalczyk M. Pain perception in schizophrenia: influence of neuropeptides, cognitive disorders, and negative symptoms. *Neuropsychiatry Dis Treat.* 2015 Aug 6;11:2023-31. doi: 10.2147/NDT.S87666. eCollection 2015.
 10. Potvin S. Pain perception in schizophrenia: no changes in diffuse noxious inhibitory controls (DNIC) but a lack of pain sensitization. *J Psychiatry Res.* 2008 Oct;42(12):1010-6. Epub 2008 Feb 21.
 11. Blumensohn R. Pain perception in patients with schizophrenia. *J Nerv Ment Dis.* 2002 Jul;190(7):481-3.
 12. EARLE A. The blood pressure response to pain and emotion in schizophrenia.
 13. Robert H. Dwrkin. Affective deficits and pain insensitivity in schizophrenia
 14. Jochum T. Influence of antipsychotic medication on pain perception in schizophrenia. *Psychiatry Res.* 2006 Jun 15;142(2-3):151-6. Epub 2006 Apr 24.

EVALUATION AND TREATMENT OF SACROILIAC JOINT PAIN IN PATIENT WITH HISTORY OF VERTEBRAL COMPRESSIONS FRACTURES: A CASE SERIES

Authors: Steve M. Aydin, Peter Shupper, MD, Kevin Trinh, MD

Presenter: Peter Shupper, MD

Contact Person: Steve M. Aydin

Author Affiliations: Hofstra-Northwell Health School of Medicine, Manhasset, NY; Manhattan Spine & Pain Medicine Rutgers-NJMS/Kessler Institute for Rehabilitation, Newark, NJ

Background: Vertebral Compression fractures in the spine are a common occurrence, and are extremely disabling in patients. Many times, a patient will go undiagnosed with compression fracture, likely due to patterns of pain and other referred pain patterns. Many times, patient will present with sacroiliac joint pain dysfunction, muscle spasms, etc. Chronic SI joint pain is common in patients with compression fractures, likely due to changes in spine alignment, biomechanics and center of gravity shifts.

Objective: Here we present a retrospective case series of patients, who presented to an office setting with chronic lower lumbar pain and were diagnosed with sacroiliac joint dysfunction on physical exam, with the presence of vertebral compression fractures diagnosed on imaging.

Methods: Patients were evaluated with physical exam, as well as imaging. SI joint dysfunction was done with finding three of five tests; hip/thigh thrust, Fortin's finger palpation, FABer test, Gaenslen test, and PSIS/SI joint compression. Patients were treated with therapeutic as well as diagnostic sacroiliac joint injections. Each patient underwent treatment of SI joint injection twice, with a month of time in between. After two rounds of SI joint injections with live fluoroscopy, as well as conservative treatment of the compression fractures, patients were evaluated and treated with kyphoplasty. Following kyphoplasty, patients were followed up at 1 week and 1 month. Pain scores percentages were assessed for each patient, as well as physical exam for SI joint dysfunction.

Results: Here we present five patients, with multiple levels of compression fractures, ranging from T11 to L3. Each patient underwent conservative treatment for the compression fractures, as well as diagnostic and therapeutic sacroiliac joint injection twice, with SI joint pain improvement from a range of 1 day to 2 months. Following this, each patient was taken for 2 level kyphoplasty. The levels done were those which were most acute on MRI imaging. Following kyphoplasty, each patient was seen at 1 week and 1 month. SI joint pain was evaluated with subjective percentage of improvement, and had a range of 30% to 90% improvement at the 1 week and 1 month marks. The average improvement in SI joint pain following kyphoplasty was 59% overall for both 1 week and 1 month.

Conclusion: With the presence of a vertebral compression fracture, patients will develop compensator mechanisms in gait, ambulation, and movement due to the pain and posture. Most commonly a compression fracture occurs between the levels of T11 to L2, and can alter the center of gravity of a patient, in turn causing an impact on the kinetic chain movement. Very often we focus on the fracture pain, muscular pain, and the facet mediated pain. However, further consideration needs to be given to the sacroiliac joint and pain being mediated from this region..

References:

1. Genant, H.K., et al., Interim report and recommendations of the World Health Organization Task-Force for Osteoporosis. *Osteoporos Int*, 1999. 10(4): p. 259-64.
2. Vogt, T.M., et al., Vertebral fracture prevalence among women screened for the Fracture Intervention Trial and a simple clinical tool to screen for undiagnosed vertebral fractures. Fracture Intervention Trial Research Group. *Mayo Clin Proc*, 2000. 75(9): p. 888-96.
3. Gibson, J.E., T.K. Pilgram, and L.A. Gilula, Response of nonmidline pain to percutaneous vertebroplasty. *AJR Am J Roentgenol*, 2006. 187(4): p. 869-72.
4. Yuan, H.A., C.W. Brown, and F.M. Phillips, Osteoporotic spinal deformity: a biomechanical rationale for the clinical consequences and treatment of vertebral body compression fractures. *J Spinal Disord Tech*, 2004. 17(3): p. 236-42.
5. Jean, L., Influence of age and sagittal balance of the spine on the value of the pelvic incidence. *Eur Spine J*, 2014. 23(7): p. 1394-9.

REPEATED PLATELET RICH PLASMA INJECTION IN A PATIENT WITH CHRONIC TIBIALIS ANTERIOR TENDON PAIN

Authors: Steve M. Aydin, DO, Tom Lione, DO and Eduino Chen, MD

Presenter: Tom Loine, DO

Author Affiliation: Hofstra - Northwell Health School of Medicine, Manhasset, NY

Background: Ankle pain is a common complaint in patients, and can often develop from a sprain or trauma. Most times the pain will improve with conservative management. In some cases, surgical intervention is used to treat issues with instability and/or tendon/ligament rupture. Over the last decade, the advent of regenerative medicine has worked its way into the armamentarium of practicing physicians, and has certainly become a treatment option that patients are pursuing and requesting prior to more invasive interventions, as well as after surgical interventions have not resolved their problems.

Objective: Platelet Rich Plasma has become a main component of regenerative medicine. We present an approach to treating a chronic tibialis anterior tendon/muscle pain with PRP. A patient with a series of three PRP injections, who present with pain over the ankle and the TA tendon, and had little success with conventional treatments. Our goal is to demonstrate that subsequent PRP injection may be done, with significant improvement with each repeated injection. And to demonstrate PRP should be in the algorithm of treating anterior ankle pain.

Method: Patient had had previous surgical intervention, as well as steroid injection along the painful region. Patient underwent a pre screen of a CBC with platelet count to confirm adequate level of platelets and rule out thrombocytopenia. Blood draw with an 18g needle, with the first 5cc of blood disregarded, and then aspiration continued to 40cc of venous blood. This was done under sterile technique. Aspiration was done with 5cc of dextrose citrate to act as anticoagulant. Then this was placed into a centrifuge using the Arteriocyte system for 19 minutes. Each syringe have a starting volume of 45cc of venous blood (40cc) mixed with the dextrose citrate (5cc). A total volume of PRP obtained was 4cc. Then injection of PRP was done under live ultrasound with sterile technique along the insertion of the tibialis anterior tendon and tibialis muscle distally. This was done without local anesthetic or other agents, to avoid an acidic or basic environment, and allow for optimal effect of the PRP injectate. This was done with 25g 1.5 inch needles and 5cc syringe. Patient avoided taking aspirin, steroids, or non-steroidal-anti-inflammatory medications for 2 weeks prior to the procedure. As well as for three weeks after the procedure. Each patient was seen on follow up at 3 week and 6 weeks. No complications were noted in any of the patient. Patient underwent PRP a total of 4 times. Each 3 month apart from the other. Each time patient underwent PRP a reduction in pain and pain medication was noted. Patient was given the option to repeat PRP, if he felt as though it was helpful.

Results: Patient had PRP and was followed up at the 3 week and 6 week post injection period. The first round of PRP to the region was a 25% reduction in pain. Patient also had reduction in opioid medication. Total opioids used by patient was 50mg of oxycodone in a day. Following 3 months after first PRP injection, patient reduced to 40mg in a day. Patient underwent three more rounds of PRP with 3 months inbetween each injection. Follow up was at 3 week and 6 weeks after each PRP injection. After 4 rounds patient had 75% improvement in pain, and is only using a total of 15 mg oxycodone in a total day.

Conclusions: Platelet rich plasma injection has become very novel in the medical world. However, its use needs to be limited and specific to each problem. Here we demonstrate its use in one area, and one tendon/muscle region. PRP certainly has a role in the use of chronic tendon and muscle pain. Specifically in the tibialis anterior tendon/muscle. The use of PRP for TA pain has shown to reduce pain in this patient. We demonstrate that repeated PRP injection has had effective reduction in pain as well as opioid medication consumption, in an otherwise chronic pain issue for a patient that was given no other treatment options. PRP has a role in the multimodal approach to the chronic pain patient, as well as helping to reduce the dependence and escalation of pain medication.

PLATELET RICH PLASMA TREATMENT FOR MEDIAL MENISCAL TEAR IN THE KNEE: A DIRECT VISUALIZATION AND CATHETER PLACEMENT TECHNIQUE

Steve M. Aydin, DO, Edurado Chen, MD & Tom Lione, DO

Presenter: Edurado Chen, MD

Contact Person: Steve M. Aydin

Author Affiliation: Hofstra - Northwell Health School of Medicine, Manhasset, NY

Background: Knee pain is one of the most common joint complaints patients will seek medical attention for. Many times work up will involve x-ray, and MRI. Patients with medial pain with an audible pop or click, there are concern regarding a meniscal tear. With the recent attention to regenerative medicine, patients and physicians have considered platelet rich plasma injections for these problems. PRP is an injection of autologous blood which concentrates the level of platelets \geq four fold. This is done through an aspiration and centrifuged process. Unfortunately, the use of PRP has not been standardized in preparation or with use and placement. Injection on the medial side of the knee in a blind fashion, with x-ray guidance, and/or ultrasound guidance has been used in PRP treatment. Here we discuss the use of direct visualization with arthroscopy for the treatment of medial meniscal tear along with a catheter placement technique.

Objective: Platelet Rich Plasma has become a main component of regenerative medicine. As a vast world of products and approaches develops in regenerative medicine, we try to present an approach to treating a medial meniscal pain due to tear with PRP. We present a technique where we can directly visualize the placement of the regenerative product in a non-operative room setting. Many cases of PRP have been done in conjunction with arthroscopy during surgical intervention. Our goal is to present an in-office technique using direct arthroscopy visualization of the tear, and placement of the PRP directly with a catheter system, over blind PRP injection.

Methods: Patient was evaluated and treated for meniscal injury of the medial meniscus. This was confirmed on MRI as well as physical exam. Pain noted on medial aspect of the knee, and an audible click was noted with ambulation. Patient had undergone steroid injection once 2 years prior to current evaluation, and PRP injection with blind technique 6 months prior. Steroid injection gave 1 year of relief, with return of symptoms. Patient has 25% improvement with previous PRP injection.

Patient underwent a pre screen of a CBC with platelet count to confirm adequate level of platelets and rule out thrombocytopenia. A blood draw with an 18g needle, with discard of the first 5cc, and then aspiration continued to 50cc of venous blood. This was done under sterile technique. Aspiration was done with 5cc of dextrose citrate to act as anticoagulant. Then this was placed into a centrifuge using the Arteriocyte system for 19 minutes. Syringe having a starting volume of 50cc of venous blood mixed with the dextrose citrate (5cc). A total volume of PRP obtained was 4cc. Then the joint region of the knee was sterilely prepared, and gowned in sterile fashion. Then the skin was anesthetized on the lateral and medial inferior compartment of the knee. Then the 14g needle for the arthroscope (MiEye system) was placed. This was done on the lateral inferior region of the knee. Local anesthetic of 0.5% lidocaine 5cc injected into the joint for anesthesia. Then an 18g curved tuohy needle was placed into the joint under live ultrasound guidance into the medial compartment. Once needle confirmation was done with direct camera visualization, a 21g rach catheter was advanced into the joint. The camera was used to visualize the meniscal medial tear. Then the catheter was advanced live, with camera visualization. Once the catheter tip was placed over and on the medial meniscal tear, injection of 2 cc of PRP was done, and confirmed to be on the meniscus and into the area of the torn tissue

Results: The patient was given post op instructions. No complications were noted. Patient was followed up at 3 and 6 week intervals. The patient indicated 90% improvement in pain and function, as well as noted remarkable improvement in pain, mobility, as well as less catching/clicking sensation.

Conclusion: Platelet rich plasma injection has become very novel in the medical world. However, its use needs to be limited and specific to each problem. Here we demonstrate its use in a more targeted and specific placement area along the medial meniscus and direct visualization. It is important that we understand the goal of PRP and that targeting the dysfunction tissue is paramount. Needle image guided techniques have advanced with fluoroscope and ultrasound machines, however the use of a catheter along with an in-office arthroscopy system can further excel placement of the PRP product, and document its placement visually.

AYURVEDA AND INTERVENTIONAL PAIN MANAGEMENT: EXPLORING NEW HORIZONS

First Author: Hari Prabhakar, MD, MSc, MIHM

Co-authors: Mahesh M. Mathpati, BAMS, MSc, Lucy L. Chen, MD

Presenter and Contact Person: Hari Prabhakar, MD, MSc, MIHM

First Author Affiliations: MGH Center for Pain Medicine, Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital, Boston, MA

Co-author Affiliations: MGH Center for Pain Medicine, Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital, Boston, MA; Institute of Ayurveda and Integrative Medicine, Foundation for Revitalization of Local Health Traditions Initiative, Bangalore, India

Introduction: Complementary and alternative medicine (CAM) has been an important and popular source of pain management strategies in the framework of integrative medicine. Literature and clinical practice involving CAM interventional pain techniques have predominantly focused on use of Traditional Chinese Medicine (TCM), namely acupuncture. In this exploratory study, we aimed to investigate the potential of Ayurveda, India's oldest traditional medical system, as a valuable source of interventional pain strategies, given Ayurveda's significant contributions to surgical technique to treat a variety of conditions. (1,2)

Methods: We conducted a review of the seminal Ayurvedic texts with an emphasis on exploring the notion of pain in Ayurveda, along with examination of pain strategies with interventional components used historically in Ayurveda. We coupled this with a PubMed/Google Scholar review of existing studies of Ayurvedic interventional strategies for pain management (2003-2015). We focused on identifying Ayurvedic interventional pain techniques with hopes of investigating avenues for further research, refinement, and integration to suit contemporary interventional pain practice.

Results: Through examination of the primary Ayurvedic texts, namely Sushruta Samhita and Charaka Samhita, we identified four major interventional pain practices that have historically been used to treat a variety of painful conditions. These include Agnikarma (cauterization therapy), Suchika Voron (regional injection of venom), Shastra Visrevana/Siravedhana Karma (catheterization therapy), and Marmapuncture/Suchi Bharana (placement of needles into designated "energy" points, similar to acupuncture). While a review of the literature demonstrated a paucity of studies with limited sample size, as compared to the substantive body of academic literature on Traditional Chinese Medicine in pain management, we did identify 12 studies that validate the use of these interventional techniques in improving sciatic pain, arthritic pain, spondylosis, and adhesive capsulitis (Table 1). Most notable and statistically significant ($P < .05$) findings are the use of Agnikarma in improving sciatic and arthritic pain and the use of Suchika Voron to improve symptoms of adhesive capsulitis (based on bee venom acupuncture data) and to modulate inflammatory markers in arthritic conditions. No studies were found validating the use of Marmapuncture/Suchi Bharana in alleviating pain. Agnikarma, Suchika Voron, and Marmapuncture appear to have plausible mechanisms of action in terms of neuroablation, endorphin release and inhibition of pain pathways, and modulation of inflammatory mediators. The potential mechanisms of Shastra Visrevana/Siravedhana Karma are not clear in the literature and appear to show a mild benefit in the limited studies available.

Conclusion: As a system with over 30 terms for pain and a large compendium of surgical/interventional procedures, Ayurveda offers several interventional pain techniques including Agnikarma, Marmapuncture/Suchi Bharana, Suchika Voron, and Shastra Visrevana/Siravedhana Karma which are worthy of further study, adaptation, and potential integration into contemporary pain practice. As demonstrated, many of these procedures appear to be grounded in widely accepted mechanisms of pain inhibition. While these techniques have been used for

centuries, there is a relative paucity of clinical and safety data as compared to the body of evidence collected on TCM interventional pain strategies such as acupuncture. For example, we found no research literature on Marmapuncture/Suchi Bharana. As such, in combination with existing but limited in vivo studies, further animal studies and prospective clinical trials with larger sample sizes may be of benefit, in addition to further studies defining mechanism of pain reduction in these Ayurvedic interventional techniques.

References:

1. Jethava NG, Dudhamal TS, Gupta SK. Role of Agnikarma in Sandhigata Vata (osteoarthritis of knee joint). *Ayu* 2015 Jan-Mar;36(1):23-28.
2. Kalpitha E, Ahalya S. A Comparative Study On the Efficacy of Agnikarma and Siravyadha In The Management of Gridharasi (Sciatica). *Ayushdhara* 2015;2(1):53-63.
3. Vaneet Kumar J, Dudhamal TS, Gupta SK, Mahanta V. A comparative clinical study of Siravedha and Agnikarma in management of Gridhrasi (sciatica). *Ayu* 2014 Jul-Sep;35(3):270-276.
4. Bakhshi B, Gupta SK, Rajagopala M, Bhuyan C. A comparative study of Agni karma with Lauha, Tamra and PanchadhatuShalaka in Gridhrasi (Sciatica). *Ayu* 2010 Apr;31(2):240-244.
5. Bali Y, Vijayasarathi R, Ebnezar J, Venkatesh B. Efficacy of Agnikarma over the padakanistakam (little toe) and Katibasti in Gridhrasi: A comparative study. *Int J Ayurveda Res* 2010 Oct;1(4):223-230.
6. Sehgal U, Manjusha R, Dwivedi R, Narayan B. Role of Agnikarma & Ajamodadivati in the Management of Sandhigata Vata w.s.r. to Cervical Spondylosis. *Ayu* 2009;30(3):345-349.
7. Shekokar A, Borkar K. Role of Agnikarma in the management of chronic plantar fasciitis. *Int J Ayu Med* 2013;4(421-425).
8. Nagnath S. Critical Appraisal of Agnikarma and its Therapeutic Effects. *Int Res J Pharm* 2013;4(5):75-77.
9. Joshi S. *Marma Science and Principles of Marma Therapy*. 1st ed. Delhi: Vani Publications; 2010.
10. Kawakita K, Okada K. Acupuncture therapy: mechanism of action, efficacy, and safety: a potential intervention for psychogenic disorders? *Biopsychosoc Med* 2014 Jan 20;8(1):4-0759-8-4.
11. Sonal C, Pankaj K. Role of Agnikarma and Rakta Mokshana Karma in Gridhrasi WSR to Sciatica. *IJSR* 2014;3(3):359-362.
12. Nipate SS, Hurali PB, Ghaisas MM. Evaluation of anti-inflammatory, anti-nociceptive, and anti-arthritis activities of Indian Apis dorsata bee venom in experimental animals: biochemical, histological, and radiological assessment. *Immunopharmacol Immunotoxicol* 2015 Apr;37(2):171-184.
13. Gomes A, Bhattacharya S, Chakraborty M, Bhattacharjee P, Mishra R, Gomes A. Anti-arthritis activity of Indian monocellate cobra (*Naja kaouthia*) venom on adjuvant induced arthritis. *Toxicon* 2010 Feb-Mar;55(2-3):670-673.
14. Park YC, Koh PS, Seo BK, Lee JW, Cho NS, Park HS, et al. Long-term effectiveness of bee venom acupuncture and physiotherapy in the treatment of adhesive capsulitis: a one year follow-up analysis of a previous randomized controlled trial. *J Altern Complement Med* 2014 Dec;20(12):919-924.
15. Koh PS, Seo BK, Cho NS, Park HS, Park DS, Baek YH. Clinical effectiveness of bee venom acupuncture and physiotherapy in the treatment of adhesive capsulitis: a randomized controlled trial. *J Shoulder Elbow Surg* 2013 Aug;22(8):1053-1062.
16. Lee MS, Pittler MH, Shin BC, Kong JC, Ernst E. Bee venom acupuncture for musculoskeletal pain: a review. *J Pain* 2008 Apr;9(4):289-297.

REAL WORLD DISABILITY AND PRODUCTIVITY OUTCOMES FOLLOWING SPINAL CORD STIMULATION

Authors: Robert Frey, M.D.¹, Rajni Jutla, M.D.², Nitzan Mekel-Bobrov, Ph.D.³

Presenter: Robert Frey

Contact Person: Nitzan Mekel-Bobrov

Author Affiliations: 1. Pacific Pain Management, Ventura, CA, United States; 2. Mind Your Body Institute, Seattle, WA, United States; 3. Boston Scientific Corporation, Valencia, CA, United States

Objectives: Successful spinal cord stimulation (SCS) therapy in patients with chronic pain may not only improve pain intensity but may also reduce disability and increase activities of daily living (ADL). A recently introduced SCS paradigm using a 3-dimensional algorithm to customize stimulation (Neural Targeting SCS) has enabled SCS treatment of pain areas which have historically been challenging, such as low-back pain. This has potentially opened up new possibilities for functional improvement in patients suffering from predominant back pain. We undertook a large observational study to characterize real world disability and functional outcomes using Neural Targeting SCS out to 2 years post implant.

Methods: LUMINA is a multi-center, consecutive, observational study assessing 100 subjects using Precision Spectra SCS (Boston Scientific Corporation) for chronic, intractable pain of the low back and/or legs out to 2 years post-implant. The majority of subjects in this sub-study (72%) reported severe pain at baseline. In addition, 62% percent of subjects reported only experiencing low back pain at baseline.

Results: To date, significant reductions in Oswestry Disability Index (ODI) scores and Numeric Rating Scale (NRS) scores, with increases in walking tolerance and an approximately 90% satisfaction rate, have been observed. Relative to baseline, these reductions include a 21.3 point decrease in mean ODI score, a 51% increase in mean walking time, and a 3.3 point drop in mean NRS score.

Conclusion: In subjects with moderate or severe low back and/or leg pain, Neural Targeting SCS provided reduced disability (as measured by ODI and walking tolerance), reduced pain intensity (as measured by NRS), and produced generally high satisfaction rates.

LONG-TERM OUTCOMES OF NEURAL TARGETING SPINAL CORD STIMULATION: FINAL RESULTS OF THE LUMINA STUDY

First Author: Salim Hayek M.D., Ph.D.

Co-authors: Elias Veizi¹, James North², T. Brent Chafin³, Thomas L. Yearwood⁴, Louis Raso⁵, Robert Frey⁶, Kevin Cairns⁷, Anthony Berg⁸, John Brendel⁹, Nameer Haider¹⁰, Matthew McCarty¹¹, Henry Vucetic¹², Alden Sherman¹³, Lilly Chen¹³, Nitzan Mekel-Bobrov¹³

Presenter: Salim Hayek M.D., Ph.D.

Contact Person: Nitzan Mekel-Bobrov

Author Affiliations: 1. University Hospitals - Case Western Reserve Medical Center, Cleveland, OH; 2. Carolinas Pain Institute, Winston-Salem, NC; 3. Roanoke-Chowan Hospital, Roanoke, NC; 4. Comprehensive Pain and Rehabilitation, Pascagoula, MS; 5. Jupiter Pain Clinic, Jupiter, FL; 6. Pacific Pain Management, Ventura, CA; 7. Florida Spine Specialists, Fort Lauderdale, FL; 8. Spine Team Texas, Rockwall, TX; 9. Interventional Pain Specialists of Wisconsin, Rice Lake, WI; 10. Comprehensive Pain Clinic, Utica, NY; 11. Balcones Pain Consultants, Austin, TX; 12. Spine and Pain Institute, Akron, OH; 13. Boston Scientific Corporation, Valencia, CA

Objectives: A recently introduced Spinal Cord Stimulation (SCS) paradigm uses a 3-dimensional algorithm to customize stimulation (Neural Targeting SCS). We undertook a large observational study to characterize the real world outcomes of Neural Targeting SCS in the treatment of leg pain only, leg plus back pain, and predominant back pain.

Methods: LUMINA is a multi-center, consecutive, observational study of 213 trialed subjects (63% Female, 37% Male) treated out to 2 years post-implant using the Precision Spectra system (Boston Scientific Corporation). Only "on label" treatment for low back and leg pain was required. Pain intensity was measured on a 0-10 numerical rating scale – NRS. Responder Rates ($\geq 50\%$ pain reduction) at 24 months were calculated. Responder rates using a previous generation system (non-Neural Targeting SCS) versus those using Neural Targeting SCS were determined.

Results: The mean overall pain reduction in all subjects and a subset of subjects classified as "severe" (NRS >8.0) decreased 4.2 and 5.3 points from baseline (7.17 and 8.75), respectively. All subjects (and "severe" subset) reporting only low back pain displayed a decrease in mean low back pain of 4.1 and 5.6 points from baseline (7.21 and 8.60), respectively. Responder rates were greater than 70% for overall and low back pain. Compared to a previous generation SCS system, statistically significant increases in response rates were observed using Neural Targeting SCS.

Conclusion: This large observational study showed long-term highly effective real world overall and low-back pain relief out to 2 years using Neural Targeting SCS.

TREATMENT OF METASTATIC DISEASE AT C2 USING ANTEROLATERAL KYPHOPLASTY USING AN OSTEOTOME

First Author: Corey Reeves M.D.

Co-authors: Enrique Galang M.D., Devang Padalia M.D., Lawrence, Kelleher MD, Nam Tran M.D. Ph.D.

Presenter and Contact Person: Corey Reeves M.D.

First Author Affiliations: USF College of Medicine Physical Medicine and Rehabilitation Resident

Co-author Affiliations: Moffitt Cancer Center, Departments of Interventional Pain and Neurosurgery; USF College of Medicine Physical Medicine and Rehabilitation, Resident and Pain Fellowship.

Background: Treatment of metastatic disease involving C2 vertebrae remains challenging. This is in part due to the complex anatomy and the biomechanical stresses at the cranial-cervical junction. Treatment goals include pain control and spinal stabilization. A variety of treatments and surgical approaches have been reported with no consensus on the optimal treatment algorithm. The potential benefit of surgical intervention has to be weighed against the limited life expectancy and generalized poor health of the patient. The benefits and outcomes of less invasive procedures like kyphoplasty have been previously demonstrated; however, the optimal approach and long term outcomes have yet to be defined.

Objective: To discuss the outcomes and benefits of anterolateral kyphoplasty technique performed on three patients with malignant lesions of the C2 vertebral body.

Methods: Patient Sample: Three patients with malignant plasmacytomas of C2 secondary to multiple myeloma from 3/2014 to 1/2015 for whom nonoperative treatment was unsuccessful. Intervention included kyphoplasty of the C2 vertebrae via anterolateral approach using an articulating osteotome for guided cannulation prior to injection of polymethyl methacrylate. Pain reduction measured by visual analog scale, Karnofsky performance status, postoperative complications, postoperative stability, and postoperative imaging studies.

Results: Three patients with metastatic multiple myeloma underwent successful C2 kyphoplasty using an anterolateral approach requiring a small incision. The indications for this procedure included pain, fracture, and instability at C2. The three patients had no intraoperative complications. One patient did develop dysphagia which resolved over the course of one year. All patients had notable durable reduction of reported pain. All patients experienced pain relief within 5-10 days. T-test analysis of preoperative and postoperative VAS scores demonstrated improved average of $8.33 \pm .58$ to 1.67 ± 1.58 at 8-10 months ($p < 0.002$). Karnofsky performance status respectively improved respectively from 76.7 ± 5.77 to 90 ± 10.00 postoperatively ($p < 0.06$). During the follow-up period of up to 14 months there was no evidence of C2 fracture or impaired stability in any of the three patients that underwent this procedure.

Limitations: Sample size of three patients, needs validation in other malignancies.

Conclusions: Anterolateral kyphoplasty for tumors of the C2 vertebra should be considered in patients who have failed conservative treatment and are poor surgical candidates for open stabilization. Anterolateral kyphoplasty can result in pain reduction and improved cervical stability while having a low complication rate.

Disclosure: Nam Tran MD- Speaker and instructor for Dfine kyphoplasty and STAR systems. Encore Presentation n/a.

VALUE OF EXAMINATION UNDER FLUOROSCOPY FOR THE ASSESSMENT OF SACROILIAC JOINT DYSFUNCTION

First Author: Jonathan P. Eskander, MD

Co-authors: Juan G. Ripoll, MD1, Frank Calixto, MD1, Burton D Beakley, MD1, Jeffrey T. Baker, MD2, Patrick J. Healy, MD2, O. H. Gunduz, MD3, Lizheng Shi, PhD4, Jaimie A. Clodfelter, DO3, Jinan Liu, MHA4, Alan D. Kaye, MD, PhD5, and Sanjay Sharma MD2

Presenter and Contact Person: Burton D Beakley

Author Affiliations: Department of Anesthesiology, Tulane School of Medicine, New Orleans, LA; Department of Anesthesiology, Southeast Louisiana Veterans Health Care System, New Orleans, LA; PM&R, Southeast Louisiana Veterans Health Care System, New Orleans, LA; Research(WOC), Southeast Louisiana Veterans Health Care System, New Orleans, LA; Department of Anesthesiology, LSU School of Medicine, New Orleans, LA

Background: Pain emanating from the sacroiliac (SI) joint can have variable radiation patterns. Single physical examination tests for SI joint pain are inconsistent with multiple tests increasing both sensitivity and specificity.

Objective: To evaluate the use of fluoroscopy in the diagnosis of SI joint pain.

Study Design: Prospective double blind comparison study

Setting: Pain clinic and radiology setting in urban Veterans Administration (VA) in New Orleans, Louisiana.

Methods: 22 adult male patients at a southeast United States VA interventional pain clinic presented with unilateral low back pain of more than 2 months duration were randomly chosen for this study. Patients who have had back surgery were excluded from the study. Each patient was subjected to a (Gapping) test, Patrick's (FABERE) test, and Gaenslen's test. A second blinded physician placed each patient prone under fluoroscopic guidance, asking each patient to point to the most painful area. Pain was provoked by applying pressure with the heel of the palm in that area to determine the point of maximum tenderness. The area was marked with a radioopaque object and was placed on the mark with a fluoroscopic picture taken. A site within 1 cm of the SI joint was considered as a positive test. This was followed by a diagnostic injection under fluoroscopy with 1 cc 2% Lidocaine. A positive result was considered as more than 2 hours of greater than 75% reduction in pain. Then, in 2-3 days this was followed by a therapeutic injection under fluoroscopy with 1 cc 0.5% bupivacaine and 40 mg methylprednisolone.

Results: Each patient was reassessed after 6 weeks. The sensitivity and specificity in addition to the positive and negative predictive values were determined for both the conventional examinations as well as the examination under fluoroscopy. Finally, a receiver operating characteristic (ROC) curve was constructed to evaluate test performance. The sensitivity and specificity of the fluoroscopic examination were 0.82 and 0.80 respectively; Positive predictive value and negative predictive value were 0.93 and 0.57 respectively. The area under ROC curve was 0.812 which is considered a "good" test; however the area under ROC for the conventional examination were between 0.52 -0.58 which is considered "poor to fail".

Limitations: Variation in anatomy of the SI joint, small sample size.

Conclusions: In conclusion, the fluoroscopic penny test is a valuable addition to an interventional pain physician's armament for diagnosis of sacroiliac joint pain. Most commonly, sacroiliac joint pain may be misinterpreted as facetogenic pain and visa versa. The fluoroscopic penny test, combined with physical exam maneuvers,

may help the diagnostician obtain an accurate diagnosis by helping to rule out alternative diagnosis such as facetogenic pain, iliolumbar syndrome and superior cluneal nerve entrapment. Drawbacks of this techniques include increased, albeit, minimal exposure to ionizing radiation for both the patient and fluoroscope operator. Based on our studies, however, the penny test is the most sensitive and specific maneuver for sacroiliac joint dysfunction.

References:

1. Deyo RA, Mirza SK, Martin BI. Back pain prevalence and visit rates: estimates from US national surveys, 2002. *Spine*. 2006; 31:2724—2727
2. Rupert MP, Lee M, Manchikanti L, Datta S, Cohen SP. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. *Pain Physician* 2009; 12:399-418.
3. Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: A comprehensive review of epidemiology, diagnosis and treatment. *Expert Rev Neurother* 2013; 13:99-116.
4. Chou LH, Slipman CW, Bhagia SM, Tsaur L, Bhat AL, Isaac Z, Gilchrist R, El Abd OH, Lenrow D. Inciting events initiating injection-proven sacroiliac joint syndrome. *Pain Med* 2004; 5:26-32.
5. Mazza DB. Diagnosing SI joint disorders—provocative testing. YouTube® video 2011;6:50. www.youtube.com/watch?v=ukDJ_OxOuBY

