

Abstracts



2015 Abstract Session Presentations

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

FIRST PLACE

A Prospective, Randomized, Multi-Center, Open-Label Clinical Trial Comparing Intradiscal Biacuplasty to Conventional Medical Management for Discogenic Lumbar Back Pain

Presenter Mehul J Desai MD MPH

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Background Current therapeutic options for chronic low back pain (LBP) of discogenic origin are limited. This prospective, randomized cross-over study compared physician-prescribed conventional medical management (CMM, n = 34), including pharmacological management, physical therapy, interventional options and/or lifestyle changes, to CMM + intradiscal biacuplasty (IDB, n = 29), a minimally invasive technique that utilizes cooled radiofrequency to ablate nociceptive ingrowth, the hallmark of internal disc disruption leading to discogenic LBP.

Objective: We endeavored to evaluate the efficacy of intradiscal biacuplasty compared to conventional medical management for the treatment of lumbar discogenic pain.

Methods: Visual analog pain scale (VAS), SF36-physical functioning (SF36-PF), Oswestry Disability Index (ODI), Beck's Depression Inventory (BDI), patients' global impression of change (PGIC), and health-related quality of life (EQ-5D VAS) assessment tools were compared at 1-, 3-, and 6- months.

Results: The two groups were statistically homogeneous at baseline regarding demographics, body mass indices, and assessment scores. In the IDB + CMM cohort, no major complications occurred, the mean VAS score reduction exceeded that in the CMM cohort (-2.4 vs. -0.56; p = 0.02), and the proportion of treatment responders (2-point or 30% decrease in the VAS) was substantially greater than in the CMM cohort (50% vs. 18%). Large differences in mean SF36-PF, ODI, and PGIC score changes (p < 0.05/outcome) favored IDB + CMM, and changes in the BDI and EQ-5D VAS scores showed greater trends of improved health in the IDB + CMM group. Differences in opioid use between groups were not statistically significant.

Conclusion: Superior performance of the IDB + CMM treatment with respect to all study outcomes suggests that IDB is a more effective treatment for discogenic LBP than CMM.

Disclosures: All study investigators, except Dr. Creamer, are consultants for Halyard Health, Inc. (formerly Kimberly-Clark Health Care), but no direct compensation was given to any of the investigators or their respective staffs.

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SECOND PLACE

Emerging Evidence for the Clinical Benefit of More than Two Leads and 16 Contacts in Spinal Cord Stimulation for Chronic Pain

Presenter: Jacob Barkely

Co-authors: Sherry Lin PhD, Nitzan Mekel-Bobrov PhD , Henry Vucetic MD

Affiliations: The Spine and Pain Institute; Cleveland,OH . Boston Scientific Corporation; Valencia, CA

Background: Over the past several years, spinal cord stimulation (SCS) technology has advanced with increasingly sophisticated systems designed to provide greater pain relief for a greater number of patients. One such advancement is the introduction of a new current-controlled system. Using an anatomically- guided neural targeting algorithm, the system can use up to 32 independently controlled contacts and up to four leads. In their last medical coverage policies for SCS, several payors stated that there was insufficient evidence to support the effectiveness of an SCS system with more than two leads and more than a total of 16 contacts. Since then, evidence has been emerging for the added clinical value of this technological feature.

Objective: In this presentation, we will review the current state of evidence for the clinical benefit of more than two leads and 16 contacts, based on the recently emerging data from multiple clinical studies and large-scale public databases.

Methods: This review includes patient-level data from three independent sources: 1) a two-year, multi-center observational study of clinical outcomes in 213 patients; 2) a one-year within-patient controlled study comparing patients' outcomes with a two- lead/16-contact SCS system to the four-lead/32-contact system post-replacement in 14 patients; 3) a prospectively defined study of a large-scale health claims database, analyzing post-implant outcomes as a factor of lead/contact number in over 10,000 patients.

Results: Results from the three studies reviewed in this paper will include leg and back pain intensities on a 0-10 numerical rating scale (NRS), Beck anxiety inventory, objective physical activity from an accelerometer device and in-office mobility test, health resource utilization, and medication reduction.

Conclusion: With the rapid advances in SCS technology seen over the past several years, there will be growing demand for clinical evidence supporting the benefit of these technological innovations. This evidence will be critical in not only providers' decisions in how they treat their patients, but in payors' coverage decisions as well. The availability of clinical data is an ever-evolving process, particularly in the case of newly introduced technologies. Consequently, ongoing systematic reviews of the current state of clinical evidence for various technological features is essential.

Disclosure: Drs. Lin and Mekel-Bobrov are employees of Boston Scientific Corporation; Dr. Vucetic is a consultant for Boston Scientific Corporation

THIRD PLACE

Singe Center Prospective Clinical Series evaluating Targeted-Radiofrequency Ablation in the Treatment of Painful Spine Metasases

Presenter: Dawood Sayed, MD

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Background: Pain relief from spine metastases treated with radiation can be protracted with limited response rates. (1). Targeted- radiofrequency ablation (t-RFA) has been reported as safe and effective in retrospective studies. (2,3.)

Objective: We report findings of a prospective single center clinical series evaluating t-RFA in the treatment of painful spine metastases.

Methods: From Jan 2014 - Sept 2014, 13 patients with painful spine metastases were prospectively enrolled and treated with t-RFA at our center. Cement augmentation was performed in all patients. Inclusion criteria: pain in a thoracolumbar vertebral body concordant to the metastatic lesion. Patients were evaluated at baseline, prior to discharge, day 3, 7, 30, and 90. Following validated scales were used at each interval: Numerical Pain Rating Scale (NPRS), Oswestry Disability Index (ODI), Functional Assessment of Cancer Therapy-7 (FACT-G7) and Quality of Life (FACT BP).

Results: 13 patients (9 M/4F, Age Mean 57.8 ± 12.9 , 100% white) underwent treatment. Primary cancers 6 renal, 2 breast, 1 lung, 1 liver, 1 thyroid, 1, 1. of either 1 level (10 patients; 77%) or 2 levels (3 patients; 23%). Of the 16 levels 5 (31%) were thoracic and 11(69%) were Lumbar. Technical success was 100% (mean time 53 min, 14-133). There was improvement in pain, disability and quality of life from baseline to all intervals (day 3 n=12, 7 n=12, 30 n=12, 90 n=11): NPRS changes from baseline were -0.9, -1.9, -2.0, -2.1 (last 3 p<0.05), ODI changes from baseline were -2.6, -0.6, -1.8, and -7.5. FACT G7 changes: 3.5, 4.5, 2.6, 3.9(p<0.05 except for 30 day), FACT changes: 9.2, 7.8, 7.0, 10.6 (all p<0.01) No major adverse events were reported.

Conclusions: t-RFA is safe and clinical benefit can be detected in a small patient set in pain and quality of life but not in disability in patients with spine metastases.

Disclosure: Teaching Faculty for DFINE and Medtronic

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Characteristics associated with patients discharged from pain clinic

Presenter: Omar Syed, MD

Co-authors: Nathanael Leo, BS May Chin, MD

Background: According to the Center for Disease Control, the United States is currently experiencing a “growing deadly epidemic of prescription painkiller abuse”. Despite the potential for abuse and misuse, prescription painkillers such as opioids are commonly used to treat chronic pain. Patients enrolled in treatment at pain clinics are closely monitored and are often required to abide by the terms of an opioid agreement. At the GW Spine and Pain Clinic, patients are dismissed from the clinic if they (1) test negative for prescribed medications, (2) test positive for psychoactive medications not prescribed, or (3) test positive for illicit drugs. Pain clinic providers are more closely monitoring their patients for abuse and misuse: however there is limited information available regarding which patients are most at risk for noncompliance. Patient demographic factors such as young age and unemployment as well as self-reported history of alcohol or cocaine abuse have been associated with noncompliance among patients prescribed opioids for the treatment of chronic pain. Our primary objective is to examine whether certain patient characteristics, with respect to medical and psychiatric comorbidities, put patients at risk for dismissal from the clinic

Objective: The purpose of our study was to evaluate patient characteristics associated with noncompliance and dismissal from outpatient pain clinic. We reviewed the following data for each subject: age, sex, race, employment status, body mass index, co-morbidities, specialty of referring physician, surgical history, and medications. The co-morbidities were further subdivided into medical and psychiatric afflictions including but not limited to: diabetes mellitus, sarcoidosis, neuropathic pain, lower back pain, abdominal pain, depression, and post-traumatic stress disorder.

Methods: With IRB approval we reviewed charts of patients seen at the GW Spine and Pain Center from 03/01/13 through 03/01/14. We identified 40 subjects dismissed from clinic. We randomly selected 40 patients seen during this time period as control. We looked at age, sex, race, employment status, BMI, co-morbidities, specialty of referring physicians, surgical history and medications prescribed. Univariate associations with discharge status were examined using chi-square or Fisher's Exact test, or independent-groups t-tests. A multivariate model was tested using logistic regression, including all predictors with univariate $p < .20$. A backward elimination approach was used, with variables dropped if $p > .20$. Using the final regression model, a risk score was calculated for each subject, and from these scores an ordinal risk level was created using cut-points at the 10th, 25th, 50th, 75th, and 90th percentiles.

The mean age for patients in the sample was 51.1 ± 11.4 and 60% were female. 44% had private health insurance, 24% had Medicare, 29% had Medicaid, and 3% had no insurance. 60% were African American, 26% Caucasian, and 3% Hispanic. 34% were employed or retired, while the rest were on disability or unemployed. Variables that were significantly associated with discharge status included employment, smoking, drug abuse, and low back pain. Patients on disability or unemployed were more likely to be discharged than those who were employed or retired ($p = .016$). Those who smoked had an odds of being discharged 7 times higher than those who did not (OR 7.37 [2.68-20.27], $p < .0001$). Patients with current or former illicit drug use had an odds of being discharged 6 times higher than those with no such history (OR 6.43 [1.91-21.64], $p = .0012$). Those with low back pain had an odds of discharge 4 times higher than those without this type of pain (OR 4.46 [1.71- 11.60], $p = .0017$).

The final multivariate model predicting discharge was significant ($p < .0001$) with strong effect size (Somers' D = .81, $R^2 = .47$), and strong prediction accuracy ($c = .91$). Significant independent predictors included Referral Source (GW Emergency Room, General Surgery, Hematology-Oncology, Hepatology/PCP, Neurology, Neurosurgery, and Orthopedics were considered high-risk) and Low Back Pain, but smoker, Employed or Retired, Private Insurance, and Drug Abuse also contributed to the model, with $p < .20$.

Results: Based on the regression results, the model for calculating an individual patient's risk of being discharged was:
 $\text{Risk} = 1.25 + .5775 * \text{smoker} + 1.2044 * \text{LowBackPain} - .5947 * \text{EmpRetire} - .6431 * \text{PrivateIns} + .6469 * \text{drugs} + 1.28 * \text{ReferSource}$.
 Risk scores were categorized into 6 levels based on the cut-points shown in Table 2. Since those in groups 5 and 6 both had 100% probability of discharge, these groups were combined. The likelihood of discharge in the lowest risk group ($n = 6$) was 0%. The likelihood in the highest risk group was 100% ($n = 19$). Risk groups 2 through 4 ($n = 45$) had a linear increase in the likelihood of discharge from 12% to 33% to 57%.

Conclusions: Physicians and health care providers who manage patients with chronic pain are often faced with the balancing act of optimizing pain control with opioid analgesics on one hand and preventing opioid abuse on the other. Identifying patient characteristics that correlate with higher risk of aberrant behavior and subsequent dismissal may be helpful in planning pain management strategies that emphasize a multimodal approach using non pharmacological analgesics, physical rehabilitation and interventional techniques

Encore Presentation: CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers--United States, 1999-2008. MMWR 2011; 60:1-6

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Cooled Radiofrequency Ablation in the Management of Sacroiliac Joint Pain – A Systematic Review.

Presenter: Justin Hare DO & Vinod Muniswamy MD, MPH

Co-authors: Vinod K Muniswamy, MD, MPH, Oscar O Ortiz, MD and Sara S Salles, DO

Affiliations: University of Kentucky, Physical Medicine and Rehabilitation

Background: Sacroiliac region pain accounts for a large percentage of chronic axial low back pain and has been shown to negatively impact an individual's functional ability and quality of life. Sacroiliac pain worsens with age due to degenerative changes within the joint. It has been very challenging to manage in the past due to the lack of effective and long lasting treatment options. Conservative treatments, such as lifestyle changes, physical therapy, bracing, anti-inflammatory medications, manual medicine options, steroid injections, and surgical fusion have shown variable degrees of success. Radiofrequency ablation was introduced in 2001 shifting the focus of treatment to more ablative strategies similarly used for facetogenic pain. Several studies have demonstrated the variability of the sacral nerve anatomy, creating concerns about RFA capturing the variability of sacral lateral nerve branches to maximize pain relief.

Cooled Radiofrequency (RF) ablation or neurotomy has been recently introduced as an option to treat sacroiliac joint pain. CRFA is used to create larger lesions and overcome the challenges created by the anatomic variations of the lateral branches of the sacral nerves. This concept in theory would result in more reliable and consistent outcomes by creating a bigger ablative lesion. Some studies in the literature suggest that this technique has the potential to be a viable option in alleviating sacroiliac joint pain. Our goal is to assess the available literature and efficacy of this new treatment approach to a historical difficult area of pain to manage.

Objective The objective of this systematic review is to investigate the efficacy of cooled Radiofrequency ablation to L5 posterior ramus and lateral sacral branches for the treatment of sacroiliac joint pain, particularly its impact on function, pain, and quality of life.

This systematic review included literature searches of PubMed, Cochrane and Clinical trials from January 2008 to January 2015. The Cochrane review Criteria and Newcastle Ottawa Scale criteria were used for quality assessment and clinical relevance of the literature. The level of evidence was classified as good, fair and poor based on the quality of the study. The primary outcomes measured were pain control, functional improvement and quality of life.

Results: Initial search revealed 39 studies that had the potential for consideration. Of those, 17 studies were identified to match the criteria. 10 studies met the inclusion criteria. Of them, 1 systematic review, 2 randomized control trial (RCT), 7 nonrandomized study were analyzed. We determined that 3 of the 10 studies was of good quality, 2 were of moderate quality and the remainder of poor quality. Most of the studies demonstrated >50% pain relief.

Conclusion: Based on our review, cooled RFA could be considered as an alternate method for pain relief in sacroiliac joint pain and is an effective and safe choice with minimal side effects. However, there is need for further good quality randomized control studies to further investigate this topic.

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Genetics and Drug Response: Study on the Role of Genetics in Individual Variations in Response to Gabapentin use

Presenter: Tobore Onojighofia MD, MPH

Co-authors: Brian Meshkin, Bilikis Akindele MD, Dan Schwarz MD, John Hubbard.

Affiliations: Proove Biosciences, Johns Hopkins University. Co-author Affiliations Proove Biosciences

Background: Gabapentin is used for the treatment of neuropathic pain arising from diabetic neuropathy, post-herpetic neuralgia, central neuropathic pain etc. Although genetic factors are believed to account for between 20 to 95% of the observed variation in drug response between individuals, the role of genetics in response to Gabapentin use is not clearly or fully understood.

Objective The objective of this study is to determine the role of genetics in observed individual variations in response to Gabapentin use. 69 subjects currently taking Gabapentin across 10 clinical research sites in the US. The effect of the Gabapentin was recorded using the (MED) Scale (A scale of 0-5 to measure efficacy of a drug). Subjects were matched for age, race and gender and were divided into 2 groups by their MED score:

Methods: poor responders had a score of 0 to 2 while good responders had scores 4 or 5. (28 poor responders and 41 good responders). Subjects with a score of 3 on the scale were excluded from the study. Subjects were genotyped using Taqman® SNP Genotyping Assays (Life Technologies, Carlsbad, CA). It consists of a panel of 12 single nucleotide polymorphisms (SNPs) in genes encoding for proteins expressed in the mesolimbic reward pathway. These genes include: 5HT2a, 5-HTTL, COMT, ANKK1/DRD2, DRD1, DRD4, DAT, DBH, MTHFR, OPRK1, GABA-A receptor gamma2, and OPRM1.

Results: A cross tab analysis using IBM SPSS v21 found significant association between only COMT Val108/158Met (Rs4680) and gabapentin response. (COMT: Dominant Model (G/G vs. G/A-A/A) Pearson chi-square $p=0.009$, Two sided fisher's exact 0.018). Logistic regression found G/A & A/A variations to be more associated with good response to gabapentin while G/G genotype was found to be associated with poor response. $p=0.012$, OR 4.66. (95% CI 1.4 -15.5).

Conclusions: This study suggests that genetic variations may play a role in observed differences in response to Gabapentin usage. Findings in this study will hopefully help further illuminate the role of genetics in drug response as well as guide a more comprehensive pharmacological approach.

Disclosure: The Study was funded by Proove Biosciences.

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Spine surgery in opioid tolerant patients – prevalence and patterns of opioid use in the year after surgery

Presenter Padma Gulur, MD

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Background: Back pain and neck pain are amongst the most common chronic conditions in our population (1,2). Patients often undergo spinal surgery as a means of treating back and neck pain when conservative measures do not produce lasting results.

Concurrently, opioid treatment for spinal pain is increasing significantly (3). As a result, many patients presenting for spinal surgery are also on opioid therapy. There has been increasing concern that those on significant amounts of opioids at the time of their spinal surgery experience poorer outcomes (4, 5). Additionally, major spine surgery can result in significant pain in the postoperative period. Studies have shown that there is increasing opioid use in patients who have undergone spinal surgery (6).

Objective: The purpose of our study is to understand the prevalence and patterns of opioid use after spine surgery, with a focus on opioid tolerant patients at the time of surgery.

Methods: We performed a retrospective cohort review on patients undergoing spinal surgery, with pain as the primary indication, from January to June 2013 at Massachusetts General Hospital. Opioid tolerant patients were compared to control for opioid use preoperatively, at discharge and at 6 months to a year post-surgery.

We excluded those undergoing surgery for tumors or cancer, who were undergoing repeat operations for complications, and those who died shortly after surgery.

Results 626 spinal surgery patients met our inclusion and exclusion criteria. Of these, 84 patients were identified as the opioid tolerant cohort with 542 patients as our control group. At six months to one year postoperatively, 28% of the control patients, compared to 71% of opioid tolerant patients, continued on opioid therapy ($p < 0.01$). Of the 84 opioid tolerant patients, at discharge, 22 were not using any opioids, 38 had decreased use, 22 were on higher doses and 2 were using the same dose of opioids they were on preoperatively.

Conclusion: Our study reveals that the majority of patients on opioids preoperatively were on decreased to no opioids postoperatively. This may indicate that spinal surgery helps to alleviate back pain in many patients.

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Transcranial Magnetic Stimulation in Alleviating Headaches Associated with Traumatic Brain Injury- A case series

Presenter: Robert N. McLay, MD PhD

Co-authors: Albert Leung, M.D., Amir Fallah, B.S. Shivshil Shukla, B.S., Lisa Lin, M.D. Alice Tsia, D.O., David Song, M.D. Gregory Polston, M.D., Roland Lee, M.D.

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Background: Conventional pharmacological treatments have not shown to be effective in alleviating debilitating headaches that occur after mild traumatic brain injury (MTBI-HA). New options are needed. Repetitive transcranial magnetic stimulation (rTMS) utilizes a basic electromagnetic coupling principle in which a rapid discharge of electric current is converted into dynamic magnetic flux allowing the induction of a localized current in the brain for neuromodulation. rTMS has been used as a treatment for other types of headaches, but evidence for MTBI-HA is still sparse.

Objective: We report results from a case series of patients with MTBI-HA who received rTMS treatment.

Methods: Six male patients (average age of 50) with MTBI-HA gave informed consent to receiving rTMS treatment. rTMS was delivered to specific areas of cortices over a two-month period. Patients' average intensities of lingering constant headaches (defined as duration of headache lasting more than 48 hours), and the average frequency (number of severe headache episodes per day), intensity (0-10 pain scale) and duration (hours) of headache exacerbations were assessed pre and post the rTMS treatment protocol.

Results: Average pre and post-rTMS constant headache scores (\pm SD) on the pain scale were 5.50(\pm 1.38) and 2.67(\pm 1.75) respectively with an average post-rTMS headache intensity reduction of 53.05(\pm 19.90)%. The average headache exacerbation frequency (episodes per week) was reduced by 78.97(\pm 19.88) % with two patients reporting complete cessation of severe headache episode. For those(N=4) with persistent headache exacerbations, the average duration and intensity of these exacerbations were reduced by 50.0% and 31.7% respectively.

Conclusion: MTBI-HA is often treatment-resistant, but in this case series, patients were found to have improvements in severity, frequency, and duration of their headaches after rTMS. Randomized controlled studies are required in further validating the efficacy of this treatment modality.

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Anatomic Classification-based Surgical approaches to Lumbar Disc pathology.

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Background: Currently, there are several surgical approaches to the herniated lumbar disc including open posterior approach, and minimally invasive approaches including interlaminar, tubular muscle splitting, endoscopic and percutaneous approaches^{1,2,3,4,5,6,7,8}. Although approaches to lumbar disc herniation have been rapidly evolving over the last several years, at this time, there is no disc treatment-based classification to guide surgical approaches to the morphologic and topographic variations in the disc pathology. The absence of such standardized approach has given rise to the current situation where it is difficult to compare outcomes of the different approaches. Also, the lack of a standardized classification of the disc pathology makes it difficult to support or reject published claims of the superiority of a given approach over the others.

Objective: To present surgical approach strategies based on treatment-based lumbar disc classification.

Methods: MIS Treatment-based Classification of intervertebral disc pathology is used to determine the approach to be used. After exhaustive non-operative measures have been applied, the patient is evaluated for surgical intervention. The pre-operative images including MRI or CT-Myelogram is used to determine the topography, and the morphology of the disc lesion. In the case of tranforaminal endoscopic approach, the portal site, the angle of instrumentation, and the plane of instrumentation is determined based on the pathology. The Disc Surgical Approach Chart is constructed based the data obtained from the imaging study.

Results: Based on the morphologic and topographic classification of the disc pathology a three-column table is constructed. Column 1 stratifies the morphology of the disc pathology. The column identifies intra-annular (contained) versus extra-annular (prolapsed) disc herniation, as well as a degenerate versus an otherwise normal disc which is ruptured. Column 2 identifies the topography of the herniation – central, para-central and intra-extraforaminal herniation. The column also identifies displacement of the extruded fragment – retroannular or migration of the fragment – retro-annular, cranial, caudal or retro-dural. Column 3 prioritizes the strategy for the surgical approach to a given pattern of the disc morphology and topography, based on the ease of access, minimization of complication and surgical trauma.

Conclusion: The Anatomic Treatment-based Classification of disc pathology helps the surgeon determine the best surgical approach to the disc pathology pre-operatively. Such classification minimizes risk of complications, and helps standardize treatment approaches so that outcome studies of the various available techniques can be compared in a credible fashion.

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Anatomic Treatment-based Classification of Diseased Lumbar Spinal Motion-segment.

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Background: Multiple minimally invasive spine approaches and techniques have been developed in recent years. While the disease processes affecting the spinal motion-segment have remained largely the same, surgical treatment options have changed radically and not necessarily in an organized fashion. This is inevitable given the rapid evolution of the technology. The current diagnostic techniques, also evolving, have helped us appreciate the disease pathoanatomy in minute details. A comprehensive classification method accounting for all anatomical participants in the spinal motion-segment pathology, tailored to treatment options, is necessary. Out of many valid options, a spine surgeon should be able to choose a single surgical approach that is most appropriate for the pathoanatomy of his/her patient's disease. We feel that our classification system will help the spine surgeon make that important decision consistently, with minimal risk of overlooking a significant lesion, or disrupting a structure which is not a participant in the disease process.

Objective: To develop a comprehensive, treatment-orientated classification of degenerative lumbar spinal motion-segment disease.

Methods Contributors to spinal motion-segment disease - intervertebral disc, facet joint, ligamentum flavum and mal-alignment were identified. The degrees of abnormalities in each of these entities were coded, and the codes were entered in a matrix from which the possible combinations of pathologic processes were generated. To test the usefulness of the classification system in clinical practice, inter- and intra-observe reliability test was performed on the system. The combined codes so created will be used in a software application along with, clinically relevant patient attributes, and attributes of available surgical options to prioritize surgical management.

A retrospective study of the 57 lumbar MRI films was carried out to determine the frequency of the occurrence of various combinations of the motion-segment disease.

Results: This classification presents 494 possible combinations of the spinal motion-segment disease. Many of the combinations are only theoretical possibilities without clinical significance. The retrospective study of the MRI films of the lumbar spine revealed 33.3% as normal motion-segments; D1A0L0F0 representing 8.8% of the study revealed a bulging disc and normal facet, alignment and facet joint. D2A0L0F2 represented 6.9% and this combination revealed intra-annular disc herniation, normal alignment, mildly thickened ligamentum flavum, and hypertrophied superior articular process of the facet joint. D1A0L1F3 representing 6.4% revealed bulging disc, mildly hypertrophic ligamentum and hypertrophied facet joint.

For inter-observer agreement study, the Cohen's Kappa was used. Inter-observer agreement was Kappa = 0.792 (SE of Kappa = 0.140, 95% C.I. [0.518, 1.065])

Conclusions: A treatment-orientated, standardized classification of spinal motion-segment disease is necessary in light of current multiple treatment options and availability of sophisticated pre-operative imaging techniques. Such a classification will allow standardization of treatment options for various combinations of the pathological processes. With the emergence of new technologies, surgical options can be upgraded based on a standardized classification. This in turn will help minimize confusion for those who want to learn, and facilitate growth in the minimally invasive technology. Software needs to be developed to handle the massive combination possibilities and treatment options, for ease of use by surgeons.

Disclosure:

Osman:

1. Royalty from Zimmer Spine for spinal device.
2. Consultant for Biomet

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Combined Ultrasound and Fluoroscopically Guided Cooled Radiofrequency ablation (RFA) for the Treatment of Chronic Pain from Hip Avascular Necrosis: The First Case Report

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Background: Chronic hip pain can be secondary to coxarthrosis, as well as from a variety of other conditions. Many patients have chronic intractable pain that persists after multimodal therapy including: intra-articular injections, physical/occupational therapy, psychological intervention and the use of pain medications. There is a large population of patients with hip pain who are not optimal surgical candidates secondary to multiple comorbidities. RFA provides a minimally invasive and effective treatment option that is relatively safe, cost effective, and provides moderately long term relief.

Objective: To present the indications, procedural technique, and benefits with ultrasound guided cooled RFA of the femoral and obturator nerves as a viable treatment option for patients with intractable hip pain. Pulsed and continuous RFA have been reported in the literature for treatment of non-operable hip pain, however, cooled RFA has not. To the authors' knowledge, this is the first reported case of ultrasound guided cooled RFA of the femoral and obturator nerve sensory branches.

Methods: A 90-year-old male with history of CVA, osteoporosis and OA presents to interventional pain management clinic for chronic, progressive right hip pain for over 2 years.. He was referred from an orthopedist as he was not a surgical candidate given his poor baseline functionality and active comorbidities. He rated his pain as intractable and disabling, and it was refractory to all conservative management including pain medications, physical therapy, and intra-articular hip steroid injections. Upon review of the patient's presentation, pattern of referred pain, and lack of response to IA injection, a decision was made to attempt diagnostic blocks of articular branches of the femoral and obturator nerves. The patient reported 100% pain relief for approximately three hours with subsequent return to baseline. As the patient displayed a favorable response to diagnostic femoral/obturator nerve blocks, he was subsequently scheduled for cooled RF lesioning of the sensory branches of the femoral and obturator nerves to achieve long- term relief of his intractable and inoperable hip pain. First, we performed the obturator nerve branches to the femoral head using medial approach. The femoral neurovascular bundle was identified with ultrasound 5MHz transducer at the level of pectineus origin in the coronal plane. A 17G 5-inch radiofrequency needle was introduced between the femoral vein and pectineus muscle until the tip of the needle touched the most inferior portion of the acetabulum. The fluoroscopic image was taken to confirm the needle location immediately inferior to the teardrop line. Motor stimulation at 2 Hz, up to 2V, was made to exclude stimulation of the motor branch near the electrode. After 2ml of 1% lidocaine was instilled, cooled RFA was performed at 60°C for two minutes and thirty seconds. Then, the needle was re-directed to create the second lesion slightly to the first lesion for broad coverage of articular branches of the obturator nerve. The second needle was then advanced to the inferior anterior iliac spine near the anterolateral margin of the hip joint by anteroposterior approach. Motor test was performed to exclude femoral nerve stimulation. After 2 cc of 1% lidocaine, cooled RFA was performed.

Results: The patient reported immediate pain relief post procedure, with no complications. Upon 1 day post procedure follow up, the patient still reported 90% pain relief, and reported very

Conclusions: mild soreness at site of needle insertion. The patient's pain response will continue to be followed up to determine efficacy of procedure. Percutaneous radiofrequency lesioning of the sensory branches of the femoral and obturator nerves can provide a unique treatment option for a wide spectrum of patient's with intractable hip pain. Typically, patients with end stage hip osteoarthritis have the best chance of long term pain relief after THA (2). However, there are few alternative treatment options discussed in the literature for patients who are unable to undergo this procedure. A significant advantage of performing cooled RFA is the ability to create a larger lesion more distal to the needle tip. This provides additional benefit that allows for needle position that runs parallel to the obturator nerve rather than perpendicular, provides optimal positioning for nerve denervation (1)(7)(13). In our case, the obturator nerve was approached using ultrasound guidance to avoid injuring the femoral neurovascular bundle. However, a medial to lateral approach was instituted rather than the conventionally reported lateral to medial method of needle advancement. The advantage of placing the needle medial to lateral in this case is that needle trajectory is shorter, and there is less risk of injuring the femoral nerve, which is typically resides laterally. Given the variable presentation of localized and referred pain patterns seen in hip OA, it is of the utmost importance to perform diagnostic blocks to correctly identify patients who may respond positively to radiofrequency ablation Cooled RF lesioning provides a more efficient nerve ablation by creating a larger lesion circumference that can account for anatomic variation that is more practical for everyday practice (13)(14). of them. Comprehensive knowledge and understanding of the nearby anatomic structures and pain generating mechanisms are fundamental to correct diagnosis.

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Comparison of Clinical Outcomes Associated with Interlaminar and Transforaminal Lumbar Epidural Injections

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Background: Interlaminar and transforaminal epidural injections are commonly employed for treatment of low back pain. To date there is a limited amount of data that compares clinical outcomes between these two techniques

Objective: The goal of this study is to assess the clinical outcomes associated with both interlaminar and transforaminal epidural injections used for a variety of low back pain diagnoses and pain syndromes.

Methods: A retrospective study was conducted at Michigan Pain Consultants, an interdisciplinary community based pain medicine practice in West Michigan. The data was collected using the patient reported Pain Health Assessment (PHA) within the PRISM™ Care Management System. PHA data is routinely gathered from chronic pain patients in the practice using IRB approved language in the consent forms. 1,913 patients who were administered interlaminar and/or transforaminal epidural injections between 1/1/2011 –7/31/2014 were studied. Outcomes were compared between the two epidural treatments including functional lower body impairment, percent relief, quality of life, patient satisfaction, and pain levels. To assess if there were differences in these outcomes, a mixed model with repeated measures was used to compare treatments over time, as well as account for patients who were administered more than one treatment. The alpha level was set at 0.05 and all possible covariates including specific diagnosis, medications, physical therapy, and possible interactions were considered in the models.

Results: There were no significant differences between interlaminar and transforaminal epidural injection outcomes in functional lower body impairment, quality of life, patient satisfaction, or pain levels. There was evidence that percent relief differed between groups and an increase in the number of treatments elicited an overall better response within both treatment groups.

Conclusions: Interlaminar and Transforaminal lumbar epidural injections are both effective in treatment of low back pain. Repeated treatment results in better outcomes for both groups.

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Design of the MIDAS ENCORE Study

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Background: Lumbar spinal stenosis (LSS) is a common cause of back pain that mostly affects the Medicare population. Epidural steroid injections (ESIs) are commonly used for the treatment of symptomatic LSS.i,ii,iii,iv,v ESIs are generally administered after failure of other conservative treatment modalities such as physical therapy, home exercise programs, and analgesics. Minimally invasive lumbar decompression (MILD®) is a procedure that offers a non-surgical option for LSS patients presenting with neurogenic claudication and symptoms refractory to conservative therapies. MILD is performed percutaneously through a small 6-gauge port using fluoroscopic-guidance, under local anesthesia and moderate sedation, and leaves no implants behind. A prospective cohort study^{vi} demonstrated the long-term efficacy of MILD. A previous randomized controlled trial^{vii} comparing MILD vs ESIs showed outcomes that were superior for MILD, but the study did not target long term effects and did not have sufficient statistical power.

Objective: The primary objective of this Coverage with Evidence Development (CED) study is to compare patient outcomes following treatment with either MILD or ESIs in patients with symptomatic LSS exhibiting neurogenic claudication and having a verified ligamentum flavum hypertrophy as a contributing factor. CED is a model whereby Center for Medicare and Medicaid Services (CMS) covers products and services on the condition that they are provided in the context of an approved clinical trial. viii

Methods MiDAS ENCORE is a prospective, multi-center, randomized controlled, CED study being conducted in the US. Key inclusion criteria include: age 65 or older and a Medicare beneficiary; symptoms of neurogenic claudication for at least 3 months, failure to or poorly responded to physical therapy, home exercise, and oral analgesics; symptomatic diagnosis of LSS with neurogenic claudication and radiologic evidence of ligamentum flavum >2.5mm; ODI ≥ 31 ; NPRS ≥ 5 ; no prior surgery; and less than Grade III spondylolisthesis. Approximately 150 patients will be enrolled in each treatment arm, for a total of 300 patients.

Results: The primary efficacy endpoint is statistical superiority of the proportion of ODI Responders from baseline to follow-up in the MILD group versus the ESI group. ODI Responders are defined as those patients achieving the validated Minimal Important Change of ≥ 10 point improvement in ODI score from baseline to follow-up as a clinically significant efficacy threshold. ix,x Secondary efficacy endpoints include evaluation of the proportion of ZCQ and NPRS patients achieving MIC from baseline to one year follow-up. The primary safety endpoint is the incidence of device and/or procedure related adverse events.

Conclusions: This randomized controlled study will provide high-quality scientific evidence supporting treatment decisions for LSS patients suffering from symptoms of neurogenic claudication. In addition, the results of this CED study will be provided to CMS to support determination of coverage.

Disclosure: Drs. Benyamin and Staats are the principle Investigators for the study.

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Genicular Nerve Radiofrequency Neurotomy in the Management of Chronic Post-Amputation Pain

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Background: Chronic post-amputation pain afflicts up to 90% of amputees, yet its underlying mechanism remains poorly elucidated and optimal therapy has yet to be established. Patients tend to experience a combination of stump pain, phantom

pain and phantom sensation. The contribution from varying degrees of peripheral, central, and psychological pain mediators further complicate the treatment of this syndrome. While prior reports have suggested a possible role for sympathetic blockade and continuous peripheral nerve blockade, the efficacy of single shot peripheral blocks and the use of radiofrequency ablative techniques have not been investigated for the treatment of chronic post-amputation limb pain.

Objective: To investigate the role of articular genicular nerve block and radiofrequency ablation as a peripheral target in the treatment of chronic post-amputation pain.

Case Report: A 53-year-old male presents to the pain clinic with chronic post-amputation pain of the left lower extremity. Medical history is significant for hypertension, aorto-iliac occlusive disease, and multiple gunshot wounds to the abdomen and bilateral lower extremities, resulting in a right above-the-knee amputation and a left below-the-knee amputation. The patient reported debilitating pain of the left lower extremity, rated 7-9/10, worst at the medial and lateral aspects of the knee, radiating distally. The patient's quality of life was significantly hampered by his inability to tolerate a prosthesis. Prior attempts at multimodality pain management included physical therapy, transcutaneous electrical nerve stimulation (TENS), topical lidocaine, and medical management with gabapentin, baclofen, non-steroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants (TCAs), and opioids. Additionally, the patient underwent evaluation and treatment by vascular surgery and plastic surgery, including bilateral common iliac artery angioplasty and left common iliac artery stent placement. These procedures resulted in further exacerbation of the patient's left lower extremity pain syndrome and prompted consideration of stump revision as a last resort for pain relief.

Methods: The superior medial (SM) and superior lateral (SL) genicular nerves are located at the periosteal area at the junction of the shaft of the femur and bilateral epicondyles. The inferior medial (IM) genicular nerve is located at the junction of the shaft of the tibia and the medial epicondyle. Genicular nerve blocks were performed with fluoroscopy guidance. A 22-gauge, 3.5 inch needle was used to administer 2 mL of lidocaine 2% to each target. The patient reported near complete resolution of his pain to 0-2/10. At the four-week follow up visit, the patient reported return of his symptoms. The procedure was repeated with 2 mL of bupivacaine 0.5% at each of the three targets. Again the patient experienced pain levels reduced to 0-2/10. At six-weeks the decision was made to perform cooled radiofrequency ablation of the genicular nerves. At each of the three target sites, a 10 cm, 20-gauge needle electrode was placed and radiofrequency ablation was performed at 60 degrees Celsius for 150 seconds.

Results: The patient reported significant alleviation of his left lower extremity pain immediately following the diagnostic genicular nerve blocks with both lidocaine and bupivacaine. Radiofrequency ablation of the genicular nerves resulted in sustained analgesia with pain scores in the same subjective range as the diagnostic blocks with local anesthetic.

Discussion: Genicular nerve blocks are a potential treatment modality in the management of chronic post-amputation pain of the lower extremity. At the time of this case report, 5 weeks have passed since the radiofrequency ablation was performed; our patient continues to experience prolonged analgesia resulting in comfortable use of his prosthesis. This case suggests that therapies targeting the peripherally mediated component of post-amputation pain may hold great promise. Further investigation is warranted to determine the long-term effects of radiofrequency ablation and its applicability to pain associated with other sites of amputation.

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Effectiveness of Spinal Cord Stimulation, A Prospective Study

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Background: Spinal cord stimulation (SCS) has been used for over forty years and the progression of associated technologies have resulted in a valuable treatment option for managing intractable pain.

Objectives: The purpose of this study was to evaluate the effectiveness of pain reduction and activities of daily living (ADL) changes in patients with permanent spinal cord stimulator (PSCS) and without (n.PSCS) over an 18 month period.

Method: A total of 346 patients over a period of 18 months were evaluated. SCS trial success, pain intensity, ADL, and side effects investigated. Pain intensity was recorded by Visual Analog Scale (VAS). Pain differences and ADL changes were evaluated. Of the initial 346 patients, 264 (76.3%) were available for follow-up, 152 with PSCS (58%) and 112 without. The average follow-up duration for all patients was 8.1 months. A total of 146 and 136 patients completed pain reduction and ADL surveys, respectively. A one-way Kruskal-Wallis test was applied for analysis of variance. Mann-Whitney U-tests with a Bonferroni correction were applied for post-hoc, pairwise analyses.

Results: Of the remaining 264 patients, 75% reported pain reduction $\geq 50\%$. The averaged post-implant PSCS VAS score (6.1) was significantly lower (p -value < 0.0083) than the baseline for both of the groups, PSCS (7.0) and n.PSCS (7.1), and the averaged n.PSCS VAS (7.0). The averaged pain reduction in the PSCS group (50.9%) was significantly greater than the n.PSCS (32.9%), p -value < 0.0001 . On average, the ADL increase was significantly greater ($p = 0.0014$) for PSCS patients (43.6%) than n.PSCS (30.1%).

Conclusion: The present investigation demonstrates that permanent SCS is a compelling treatment with benefits that may concurrently improve with technological advancements.

Extra-articular Sacroiliac Joint Injection Technique for Sacroiliac Joint Pain

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Background: In many patients with sacroiliac joint dysfunction and pain, there may be significant extra-articular sources of pain in the sacroiliac region based on innervation of the posterior sacral region and on the biomechanics of the posterior sacroiliac ligaments. The lateral branches of the S1-3 spinal nerves and the posterior sacroiliac ligaments are two potential extra-articular sources that could act as pain generators. Sacroiliac joint pain has traditionally been treated with diagnostic and therapeutic intra-articular sacroiliac joint injections at the inferior portion of the joint. However, this technique may not be optimal for targeting these extra-articular pain generators especially in the superior and mid portions of the joint. Furthermore, many patients diagnosed with sacroiliac joint dysfunction and pain do not have significant intra-articular pathology causing their pain so extra-articular injections may be more beneficial for them.

Objective: To describe an extra-articular sacroiliac joint injection technique for the diagnosis and treatment of sacroiliac joint pain.

Methods: Based on a literature review performed on PubMed for sacroiliac joint injection techniques, this is the first description of an extra-articular sacroiliac joint injection technique that targets the superior, mid, and inferior portions of the sacroiliac joint with one needle entry point. The sacroiliac joint is first identified in anterior-posterior view, then contralateral oblique is utilized so that the mid portion of the sacroiliac joint is seen without obstruction from the posterior superior iliac spine. Slight cranial tilt can also be used to elongate the joint on fluoroscopy. A 22-gauge, 3-1/2 inch spinal needle is directed towards the mid portion of the sacroiliac joint just medial to the joint line co-axial to the fluoroscopy beam until bony contact is made. After medication is injected, the needle is then withdrawn slightly and redirected towards the superior one third of the joint just medial to the joint line until bony contact is made. Less contralateral oblique can be utilized with fluoroscopy for the superior aspect of the joint. After medication is injected again, the needle is withdrawn slightly and redirected towards the inferior one third of the joint just medial to the joint line until bony contact is made. An AP view helps to better visualize the inferior portion of the joint. 3ml of a

mixture of local anesthetic and steroid are injected at each portion just medial to the joint.

Results Successful injection technique targets the lateral branches of S1-S3, the posterior sacroiliac ligaments, and superior, mid, and inferior peri-articular portions of the joint with only one needle entry point.

Conclusions: This extra-articular sacroiliac joint injection technique may target potential pain generators including the lateral branches of S1-S3 and posterior sacroiliac ligaments in addition to the superior and mid portions of the sacroiliac joint more effectively than the traditional inferior intra-articular joint injection. Further studies are needed to confirm the efficacy of this technique.

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Intractable Hiccups after Placement of Esophageal Stent in Esophageal Squamous Cell Carcinoma: A Case Report

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Background: Singultus, commonly referred to as hiccups, are a common and often transient involuntary, intermittent and spasmodic contraction of the muscles of the diaphragm and intercostals. The three categories of hiccups are based on duration: A "bout" is an episode lasting up to 48 hours, "persistent" hiccups continue from 48 hours up to one month, and "intractable" hiccups continue for longer than one month. Exact pathophysiology is unknown; however, it is known that afferent and efferent limbs of the phrenic and vagus nerve through a central mediator is known to make up the typical "hiccup reflex." Often hiccups are caused by a multitude of factors including central nervous system disorders, vagus and phrenic nerve irritation, gastrointestinal diseases, thoracic abnormalities, cardiovascular disorders, toxic-metabolic abnormalities, post-op complications, medications and/or psychogenic causes. Reports have been made that gastrointestinal carcinomas have led to intractable hiccups as a complication. The pathophysiology of this is poorly understood, however could be related to irritation of the phrenic nerve from primary tumor, irritation from tumor metastasis, or unintended side effect of therapeutic modalities such as stenting causing esophageal dilatation. Pharmacologic treatments such as proton pump inhibitors, typical antipsychotics, and dopamine antagonists are useful; in some instances, interventional regional anesthesia is a viable therapeutic option. Ultrasound guided phrenic nerve blocks have been shown to be effective for treatment of intractable hiccups. Here we present an interesting case where phrenic nerve block was utilized and successful in treating intractable hiccups in a patient with esophageal squamous cell carcinoma.

Objective To use a phrenic nerve block in treating intractable hiccups in a patient with esophageal squamous cell carcinoma.

Methods case report

Results; a 75 year old gentleman who presented to his gastroenterologist with complaints of dysphagia to solid foods. EGD confirmed an esophageal mass in the distal segment. Subsequent biopsy of the mass revealed squamous cell carcinoma, and EUS did not reveal metastasis to surrounding structures. The patient received esophageal stenting and ultimately PEG tube placement for severe dysphagia. He then developed a case of intractable hiccups, and thus pain management was consulted for a phrenic nerve block for relief. The phrenic nerve is an essential structure that is paramount to diaphragmatic function. Arising from the ventral rami of third and fifth cervical nerve roots, it courses via the prevertebral fascia anteriorly to the anterior scalene muscle before it descends into the thorax where it terminates and innervates the diaphragm. Under ultrasound guidance, the interscalene groove can serve as a landmark where regional techniques can be implemented for therapeutic nerve blocks. Once the interscalene groove is identified, the ultrasound probe should be directed lateral until the phrenic nerve bundle is identified. A 22 gauge Stimuplex needle can be introduced into the vicinity of the phrenic nerve to elicit transient diaphragmatic contractures.

Once identified, local anesthetic with steroids can be placed as a therapeutic modality. In our case, the patient had left phrenic nerve block that provided him with 50% improvement in the hiccup and pain related to the hiccups followed by right sided block three days later that provided him with complete relief of hiccups Follow up with the patient two and four weeks later showed complete alleviation of his hiccups.

Conclusions: Intractable hiccups are known complications of esophageal carcinoma and ultrasound-guided phrenic nerve block offers a plausible treatment modality for symptomatic long term care. This is case is unique because it is mainly done due to mechanical related pain due to esophageal stent.

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Intrathecal Ziconotide as an alternative to treat chronic intractable diabetic neuropathic pain.

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Background Chronic pain continues to pose substantial and growing challenges for patients, caregivers, health care professionals, and health care systems. By the time a patient with severe refractory pain sees a pain specialist for evaluation and management, that patient has likely tried and failed several non pharmacologic and pharmacologic approaches to pain treatment.¹ Although relegated to one of the interventions of “last resort”, intrathecal drug delivery can be useful for improving pain control, optimizing patient functionality, and minimizing the use of systemic pain medications in appropriately selected patients.² Due to its clinical and logistical requirements, however, intrathecal drug delivery may fit poorly into the classic pain clinic/interventional model and may be perceived as a “critical mass” intervention that is feasible only for large practices that have specialized staff and appropriate office resources.^{3,4} Potentially, intrathecal drug delivery may be more readily adopted into larger practices that can commit the necessary staff and resources to support patients’ needs through the trialing, initiation, monitoring, maintenance, and troubleshooting phases of this therapy. Currently, two agents – morphine and ziconotide – are approved by the United States Food and Drug Administration for long-term intrathecal delivery.⁶ Neuropathic pain resulting from disease or injury of the peripheral and central nervous system is a common chronic pain condition caused by a variety of etiologies. For example the prevalence of painful diabetic neuropathy is 11% to 16% among the type II and type I diabetes population. Trigeminal neuralgia is 2.1 to 4.7 cases per 100,000 persons, whereas pain from post herpetic neuralgia occurs approximately 34 cases per 100,000 persons in a general population.⁶ Although the risk is higher in developing neuropathic pain such as post herpetic neuralgia in elderly subjects than the younger, age, gender, employment and education are not considered to be determinant factors leading to neuropathic pain conditions.⁶ Despite an extensive effort in preclinical and clinical studies, treatment of neuropathic pain remains difficult largely due to the lack of effective pharmaco-therapies to achieve adequate pain control.^{7,8} Several factors can influence the outcome of clinical neuropathic pain management, including multilayer, complex mechanisms of neuropathic pain, psychological and psychiatric comorbidities such as depression and anxiety and a subjective nature of pain complaints and lack of objective assessment tools with a poor correlation between pain severity and the underlying pathological conditions.⁸ Therefore clinical management of neuropathic pain can be a challenge to the pain practitioner. We present a case of intractable diabetic peripheral neuropathy successfully treated with Intrathecal (IT) Ziconotide

Objective To provide evidence that IT Ziconotide is an option for the treatment of intractable diabetic neuropathy

Methods Case Report

Results : IT ziconotide provided significant relief of pain in the patient presented in this case report.

Conclusions: Clinical evidence supports the view that IT drug delivery has a defined role as an option for appropriate patients with refractory chronic pain. Health care providers considering IT drug delivery, as a treatment for their patients should ensure that their practices are positioned to meet the challenges of IT drug delivery and can fully accommodate all aspects of IT drug delivery. Recognition and use of important patient selection criteria, including treatment history, diagnosis, pathology, and age, along with cognitive, psychological, or socioeconomic status, can help guide and improve the successful management of chronic pain with IT therapy.⁸ Ziconotide was approved by the United States Food and Drug Administration (FDA) for intrathecal use only in patients with severe pain who are refractory to other options including intrathecal morphine. Ziconotide is considered a potent and selective N-type voltage sensitive calcium channel blocker. Since it is only approved for IT use, an implanted IT infusion system is required for long-term treatment. Ziconotide has shown efficacy across multiple types of pain etiologies.^{9,10} The efficacy and safety profiles of Ziconotide monotherapy have been assessed in three double-blind, placebo-controlled trials of 457 patients with severe chronic pain, and safety has been assessed in 1,254 patients overall, and the findings have been supported by published case series in which Ziconotide was administered as a monotherapy or in combination with other agents, including opioids.^{9,10,11} This experience documents clinically meaningful reductions in chronic pain, as well as improvements in functional capacity and reductions in systemic opioid usage in patients with refractory malignant or nonmalignant pain states.^{9,10} With respect to its safety profile, ziconotide has a narrow therapeutic window, which requires careful titration to determine the lowest possible dose for each patient that is therapeutic and sufficiently well tolerated. A high starting dose and/or rapid dose titration can result in adverse effects, including psychological/psychiatric abnormalities.^{11,12} Cognitive impairment involving mental slowing, confusion, difficulty concentrating, memory impairment, and impaired verbal expression, as well as new-onset psychosis and changes in consciousness are also possible.¹¹ Ziconotide is contraindicated in patients with a history of psychosis, hypersensitivity, or those with general contraindications to IT therapy. Current recommendations for IT Ziconotide treatment highlight the benefits of a slow titration plan to minimize the risk of psychiatric complications.¹² Adverse effects reported with Ziconotide include dizziness, gait abnormalities, headache, diplopia, urinary retention, nystagmus, speech disorder, nausea, nervousness, and somnolence.¹³ The concomitant use of Ziconotide in patients taking antiepileptics, neuroleptics, sedatives, or diuretics may increase the risk of depressed levels of consciousness, and concomitant use with drugs that depress central nervous system activity may increase the risk of adverse effects, such as dizziness and confusion.¹³ These side effects need to be seriously considered during the treatment. Despite its side effects, Ziconotide may have a unique therapeutic role in chronic pain patients who are rendered tolerant to other treatment options including opioids. IT Ziconotide can be an appropriate choice for patients with severe chronic, refractory nociceptive, neuropathic, or mixed neuropathic/nociceptive pain. It provides documented efficacy as a monotherapy, it may be effective in combination with other medications to reduce pain intensity and improve functionality, and it may reduce the need for systemic opioids.¹⁴ Ziconotide also provides the pain specialist with an important alternative to morphine, to avoid opioid-related respiratory depression in patients with lung disease/compromised respiratory reserve or peripheral edema, and in patients with opioid resistance who require high doses or rapidly escalating doses, or who develop opioid-induced hyperalgesia. Unlike morphine and other opioids, Ziconotide is not associated with issues of tolerance, withdrawal, or granulomas, which can have major deleterious effects.

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L5 Dorsal Root Ganglion Pulsed Radiofrequency for Treatment of Leg Pain from CRPS

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Background: 45 year old Iraq war veteran presented to the Manhattan VA with LLE pain following a tibial plateau fracture. His pain was described as "coolness and numbness that often felt like a garden rake being scraped across the skin". It was episodic with average VAS 6/10. After ruling out other likely causes, it was clinically diagnosed as CRPS. EMG showed axonal neuropathy of left saphenous nerve. He underwent a diagnostic and then therapeutic lumbar plexus block at L2-3 and received excellent pain relief. However, patient had erectile dysfunction within a few days after the procedure and a multidisciplinary pain meeting was held to assess the benefits vs. risk of continuing lumbar plexus blocks. And although it was felt that it is an unlikely complication from this interventional procedure, he was managed with oral oxcarbamazepine without much relief. Patient refused SCS trial placement. He was seen again after exacerbation of his pain to 9/10. We re-examined him and confirmed that most of his pain was in L5 distribution and planned a pulsed radiofrequency of L5 DRG, instead of injecting local anesthetic. Patient had excellent relief from this procedure for 4 months and the same procedure was repeated at 7 months. His VAS at 7 months was 1/10 and activity improved to a level where he was able to ambulate and work full time as a nurse. We present this case to report that pulsed radiofrequency is an alternative treatment for pain from CRPS when neurolysis, blockade with LA and SCS is not an option.

Discussion: Pulsed radiofrequency (PRF) treatment uses intermittent administration of high frequency current, thus avoiding temperature rise above the critical level of 42°C which results in neurolysis (vs 67°C with conventional RF ablation). Since its introduction in 1998 no neurological complications were reported. It is also comfortable for the patient. This is a patient who responded well to pulsed RF of L5 DRG and we determine that sympathetically mediated lower extremity pain can be successfully treated with this modality, especially when options are limited. Pulsed radiofrequency is gaining more popularity for these reasons. It is a more economically viable option and no device needs to be placed inside the body. It requires less physician and O.R. time and less exposure to fluoroscopy. However one reason it may not be practiced widely is because many insurance carriers do not pay for this treatment.

MIS Treatment-based Classification of intervertebral disc pathology

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Background: Several minimally invasive spine approaches and techniques have been developed in recent years. While the disease processes affecting the spinal motion-segment have remained largely the same, the emerging technologies have changed treatment options radically and not necessarily in an organized fashion. The current diagnostic techniques, also evolving, have helped us appreciate the disease pathoanatomy in minute details. A comprehensive classification method accounting for all anatomical variations in the disc disease, tailored to treatment options, is necessary. Such a classification will allow the surgeon to choose the most appropriate surgical option in a consistent fashion. We feel this classification system will help the spine surgeon make that important decision consistently, with minimal risk of leaving behind a significant lesion or disrupting an otherwise normal structure of spinal motion-segment. Furthermore, the authors feel such a comprehensive classification will help

surgeons and other care-givers to standardize treatment approaches to the various presentations of disc disease, and apply the evolving technology in an organized fashion.

Objective To develop a comprehensive, treatment-orientated classification of the lumbar disc disease.

Materials and Methods: The literature was reviewed for the classification of disc disease. The morphology of the disc disease, the location of the disc lesion, and the symptom- complex produced by the disc lesion are identified and graded as shown in Table 1 and Table 2, respectively. The features so identified and graded are placed in a matrix as shown in Table 3. Combinations of the anatomical features and symptoms are then computed as shown in the matrix. The MRI database held in the office was studied to determine the most frequent combinations of the disc disease and symptom complex.

Results: 494 combinations were obtained. Many of the combinations are theoretical possibilities with no clinical relevance. The clinically relevant combinations are quite many. Most of the combinations in the first and second rows of Table 2 relate to radicular symptoms and are amenable to endoscopic transforaminal decompression alone. The combinations in the fourth and fifth rows have significant axial pain components and variable radicular symptoms. These most likely would need decompression and stabilization of the spine using minimally invasive, hybrid MIS and open, or open surgical approach depending on the grading of the other elements of the spinal motion-segment.

Conclusions: With new techniques emerging, it is difficult to determine what is the most effective, least traumatic, and cost effective approach treat the herniated disc. Furthermore, disc herniation is not a monolithic entity, but has many configurations, and topographic peculiarities, which need specific strategic considerations for effect surgical interventions. It is imperative to have a universal, anatomic treatment-based classification based on the most sophisticated imaging studies. This will allow comparison of the various surgical approaches. The authors are in the process of developing software application which will provide utilization of the most comprehensive clinical data, and the classification to present the most appropriate surgical options in a hierarchical fashion.

Disclosure

1. Royalty from Zimmer Spine for spine implant
2. Consultant with Biomet

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Platelet Rich Plasma (PRP) versus Hyaluronic Acid (HA) for knee Joint Pathology: Review of Evidence from Randomized Controlled Studies.

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Background: Osteoarthritis is the most common joint disease in adults. Knee osteoarthritis is the most common osteoarthritis and occurs in 6% of adults and 40% of people over 70 years of age (1). It ranks among the top 10 leading causes of disability worldwide. As the mean life expectancy increases, and people live longer, age related degenerative articular cartilage and knee osteoarthritis continue to rise. Treating these conditions can sometimes be challenging because regenerative healing is limited by vascular and nerve supply.

Traditionally, intra-articular injections of steroids have been used but only short term benefit for pain and function is the norm. In patients where they are effective, their use can be limited because of other risks like osteopenia and osteoporosis. Intra-articular hyaluronic acid has been shown to also provide benefit in many studies, though effective it can be costly (2). In the last few years there is burgeoning evidence for the use of autologous platelet rich plasma in the treatment of various knee pathologies.

Objective: To compare Platelet Rich Plasma Therapy and Hyaluronic Acid in the treatment of knee osteoarthritis.

Method: We searched Google Scholar, MEDLINE, for randomized articles published between 2010 and 2015 that compared the efficacy of PRP and Hyaluronic acid in the treatment of knee pathologies. Of 1710 filtered articles, we identified eight randomized studies for review.

Results: We identified eight randomized studies with a combination of 954 randomized participants (444 randomized to HA and 510 to PRP). All studies showed statistically significant pain relief at 6 months from baseline. Seven of the eight studies showed PRP was significantly better than HA with varying degree of significance ranging from p value of <0.05 to <0.001. One study showed no statistically significant difference between HA and PRP. The different studies used varying measures of response including the Western Ontario and McMaster (WOMAC), Visual Analogue Scale (VAS), Euro Qol VAS, International Knee Documentation Committee (IKDC), Knee Society Scoring System (KSSS), Knee Injury and Osteoarthritis Outcome Score (KOOS), Tegner and SF-36.

Conclusion: Overall PRP is an effective treatment for Osteoarthritis of the knee, with a majority of studies showing it to be more effective than HA in osteoarthritis treatment at 6 months. Additional randomized controlled trials with large sample size and follow ups are required to further validate the efficacy of PRP.

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Retrospective Analysis of 33 Headache Patients Treated by Series of Transnasal Sphenopalatine Ganglion Blockade with Tx360

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Background: Management of various forms of headaches is still a challenging problem in medical clinics. Only 21% of migraine patients were satisfied or very satisfied with their current care (1). Many in the medical community suspect that some headaches are a form of automatic dysfunction (2), perhaps an RpSD or "Reflex PARA-Sympathic Dystrophy." If so, just like treating Reflex Sympathetic Dystrophy (RSD), then repetitive PARA-sympathetic nerve blocks may provide a long term solution to headache sufferers. The sphenopalatine ganglion (SPG) is a small heart shaped structure that resides within the pterygopalatine fossa covered by only 1mm thick mucous membrane. Access to this structure can be gained via a small area of mucosa just posterior and superior to the tail of the middle turbinate on the lateral nasal wall. The SPG is a bilateral cranial PARA-sympathetic nerve center and it has important role in various pain syndromes (3). An FDA cleared device, Tx360R, makes this access possible in an easy, accurate, and non-traumatic fashion. This technology allows repetitive nerve blocks with ease.

Objective: The purpose of this retrospective analysis is to evaluate the efficacy of repetitive Sphenopalatine Ganglion blocks in treating various types of headaches.

Methods: Retrospective data was examined from 33 patients treated with a series of Sphenopalatine Ganglion (SPG) Blocks over an 18 month period. Only patients with diagnoses of Chronic Daily Migraines, Cluster Headaches, Post-Concussion Headaches, and Atypical Facial Pain were chosen. Patients with symptoms of strong occipital and/or cervical components were excluded. SPG blocks were done bilaterally to maximize autonomic modulation benefits. Each SPG nerve block was performed with the Tx360R with 0.3cc of 0.5% bupivacaine delivered to each side (total of 0.6cc). The number of blocks ranges from 4 to 19 times, at the interval of 2 to 4 times per week. SPG blocks were stopped once patients reported a duration of satisfactory pain relief for over 72 hours with at least 50% of reduction in VAS. Patients' age ranged from 18 to 80 years, with average age of 46.4 years. There were 13 male patients, 20 female patients; the diagnoses included were 4 Cluster headache patients, 4 Atypical Facial Pain patients, 3 Post-Concussion headache patients, and 22 Chronic Migraine headache patients. Patients were followed up to 6 months. Failure of treatment was defined as less than 50% improvement in VAS lasting to 6 months.

The initial presenting VAS ranged from 3 to 10 with average of 7.64 per patient. After treatment VAS ranged from 1 to 10 with average of 1.94 per patient. This was nearly a 75% reduction in headache intensity. An average of 10 SPG blocks were performed per patient. One patient from the group of 4 atypical pain patients failed treatment, and two patients from the 22

Chronic Migraine group failed treatment. The failed atypical facial pain patient is currently seeking a neurosurgical solution. The two failed migraine headache patients have chosen to continue to receive more treatments. For these two migraine patients, even though the pain relief was less than 50%, both subjects noted a significant improvement in their work and daily function. Overall, 90.91% of patients responded positively with the series of Sphenopalatine Ganglion Blocks (30 out of 33). No significant side-effects nor complications were observed.

Conclusions: Repetitive Sphenopalatine Ganglion blocks utilizing a total 0.6cc of 0.5% bupivacaine delivered bilaterally through a Tx360R device produced a 75% long-term decrease in VAS with patients suffering from various forms of headaches. These results suggest that a theory of neuromodulation with repetitive SPG nerve block may be valid; the results show that this may be an efficacious treatment for many types of the headache patients.

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Study to Calculate Risk of Undifferentiated Abdominal Pain by Incorporating Genetic and Phenotypic Risk Factors.

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Background: Annually, 5 to 10% of emergency department patients complain of abdominal pain. Of these complaints, 25% are diagnosed with undifferentiated abdominal pain (UAP) (Guertler et. al, 1995). While prior studies have evaluated the diagnosis and treatment of UAP, the role of genetics in the risk of UAP continues to be elusive.

Objective: The objective of this study is to determine the predictability of UAP by using a comprehensive scoring algorithm that incorporates single nucleotide polymorphisms (SNP's) affecting neurochemistry of the mesolimbic reward system and phenotypic risk factors.

Methods: 46 subjects were selected from a pain clinic in Baltimore, MD. Of this population, 22 suffered from UAP and 24 subjects were used as controls. Subjects were genotyped using TaqMan SNP genotyping assays. A scoring algorithm, the Undifferentiated Abdominal Pain Risk Index (UAPRI) score was calculated to predict risk of undifferentiated abdominal pain. The UAPRI is a scale of 0-13 that predicts risk of UAP by incorporating both genetic and phenotypic risk factors (3 SNPs and Age). <7 indicates low risk of UAP while 7 and greater indicates high risk of UAP.

Results: A cross tab analysis using IBM SPSS found a significant association between UAP and a UAPRI score greater than or equal to 7. (Pearson Chi-Square = <0.05), Fishers Exact= <0.05, Sensitivity= 63.64% (95% CI: 40.67% to 82.76 %), Specificity= 91.67% (95% CI: 72.96 % to 98.73 %), PPV 87.50% (95% CI: 61.62 % to 98.08 %), NPV 73.33% (95% CI: 54.11% to 87.69%), PLR =7.64 (95% CI: 1.95 to 29.87), NLR= 0.40 (95% CI: 0.23 to 0.70).

Conclusion: This study suggests that a UAPRI score of greater than or equal to 7 may be an effective cutoff to predict risk of UAP. The knowledge of the genetic and phenotypic factors incorporated in the UAPRI could help physicians evaluate diagnostic and therapeutic solutions.

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Study to Comprehensively Calculate Risk of Aberrant behavior to Opioids by Incorporating Genetic and Phenotypic Risk Factors in Pain Patients

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Background: According to the CDC, nearly three out of four prescription drug overdoses are caused by prescription opioid pain relievers. The misuse and abuse of prescription opioid pain relievers was responsible for more than 475,000 emergency department visits in 2009, a number that nearly doubled in just five years. A recent study estimated that in 2006 the total cost in the United States of nonmedical use of prescription opioids was \$53.4 billion (Hansen et al. (2011)). Thus, it has become extremely important to be able to effectively predict a patient's risk of aberrant behavior if given opioid pain relievers.

Objective The objective of this study is to determine the predictability of aberrant behavior to opioids (misuse, abuse, dependence and addiction) by using a comprehensive scoring algorithm that incorporates single nucleotide polymorphisms affecting neurochemistry of the mesolimbic reward system and phenotypic risk factors.

Methods: 162 pain subjects randomly selected from five clinical sites in the US. 80 diagnosed with Opioid drug dependence (ODD, ICD code 304.01) and 82 controls. Subjects were genotyped using TaqMan SNP genotyping assays (Life Technologies, Carlsbad, CA). A scoring algorithm, the Opioid Risk Index (ORI) score was calculated to predict risk of aberrant behavior to opioid pain relievers. The ORI is a scale of 0- 52 that predicts risk of aberrant behavior to opioid pain relievers by incorporating both genetics and phenotypic risk factors (11 SNPs and personal history of alcohol abuse, personal history of prescription drug abuse, personal history of illicit drug abuse, Age and Depression). <13 indicates low risk of aberrant behavior while 13 and greater indicates high risk of aberrant behavior.

Results: A cross tab analysis using IBM SPSS found a significant association between ODD and a NRI score of greater than or equal to 13. (Pearson Chi-Square = <0.05), Fishers Exact= <0.05, Sensitivity= 80.00 % (95% CI: 69.56 % to 88.11 %) Specificity= 93.90 % (95% CI: 86.33 % to 97.97 %), PPV 92.75 % (95% CI: 83.88 % to 97.58 %), NPV 82.80 % (95% CI: 73.57 % to 89.83 %), PLR =13.12 (95% CI: 5.57 to 30.89) NLR= 0.21 (95% CI: 0.14 to 0.33). Low (0-11), Moderate (12-23) and High risk (24 and greater) groups were calculated for the ORI by comparing it to the ORT (Opioid risk tool). The results were much better for the low, moderate and high risk groups derived from the ORI compared to same groups in the ORT.

Conclusions: This study suggests that an ORI score of greater than or equal to 13 is a good cutoff to predict risk of aberrant behavior to opioid pain relievers. The ORI is also a useful tool to effectively stratify patients with risk of abusing opioids into low, moderate and high risk groups. In addition, the study showed that the ORI test may be a more robust test to help clinicians predict a patient's likelihood of aberrant behavior if given opioid pain relievers compared to the ORT test (current gold standard). It could therefore be employed before commencement or during therapy with opioid pain relievers to stem the tide of prescription opioid misuse/abuse.

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Systematic Review of Radiofrequency Ablation of Genicular Nerve in the Management of Chronic Knee Pain Due to Osteoarthritis.

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Background: Chronic knee pain due to osteoarthritis (OA) impairs function and quality of life. Conservative treatments, such as physical therapy, bracing, anti-inflammatory medications, steroid injections, and viscosupplementation are effective for symptom control in mild to moderate osteoarthritis. For severe OA, or refractory joint pain, knee arthroplasty is an excellent option; however, in patients with medical contraindications for surgery, treatment options are very limited. Radiofrequency (RF) ablation or neurotomy has historically been used in some chronic pain conditions such as trigeminal neuralgia, cancer and spinal pain. Some reports in the literature suggest that this technique has potential to be a viable option to alleviating knee pain in patients

with refractory knee pain secondary to OA. However, the available literature substantiating its use is relatively scarce.

Objective: The objective of this systematic review is to investigate the efficacy of RF ablation to genicular nerves for the treatment of chronic knee pain due to osteoarthritis, particularly its impact on function, pain, and quality of life.

Methods: This systematic review included literature searches of PubMed, Cochrane, Clinical trials, Google Scholar and EMBASE from January 2000 to January 2015. The Cochrane review criteria and Newcastle-Ottawa Scale criteria were used for quality assessment and clinical relevance of the literature. The level of evidence was classified as good, fair and poor based on quality. The primary outcomes measured were pain control, functional improvement and quality of life.

Results: Thirty two studies were identified. Eight studies met the inclusion criteria. There was one randomized control trial (RCT), one non randomized control study, five prospective studies and one retrospective study. We determined that 1 of the 8 studies was of good quality, 3 of the 8 were of moderate quality and the rest of poor quality. All the studies favor the use RF ablation for the treatment of knee OA. A meta- analysis using random effects method (Hedges Estimator), including nonrandomized studies, reveals a significant improvement on pain and function with this intervention (p value <0.05).

Conclusions: Based on our review, RFA is an effective and safe choice for refractory knee pain due to chronic osteoarthritis. However, there is need for more good quality RCTs.

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Transcutaneous Electrical Nerve Stimulation (TENS) trial as a possible substitute for percutaneous ONS trial as a predictor of outcomes of implanted Occipital Nerve Stimulator.

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Background Headache pain is a significant problem in modern society. The WHO's;S Stover et al studied Headache populations worldwide. The prevalence for any type of headache was found to be 47%, Tension Type Headache 38%, Migraine 10 and 3% for Chronic Daily Headache. Lifetime prevalence has been estimated to be as high as 66% for headache, 46% for TTH and 14% for migraine. In 21-30 year olds the 5 year incidence of new migraine was found to be 8.4 %. Eighty percent of subjects with migraine reported pain levels from severe to very severe levels. (4) Needless to say there is a substantial need to reduce suffering in this large population. Direct costs of migraines stem from frequent visit to clinics and emergency departments. (5) An 18-month study of 2672 patients, half of which were migraine sufferers, revealed that migraine patients required 19,971 medical visits for migraines issues compared to 13,072 medical visits for the other half of the group that had no migraines. Another study found that 24% of migraine patients required at least one emergency department visit in the past 6 months compared to 15% of non-migraines patients (4). Studies conducted in the US have estimated that the yearly cost of treatment of migraines patients was roughly \$100 per migraine patient per year and a total population cost in the U.S. to be above \$1 billion per year (6). [A study of the U.S. workforce during a two week period found that the loss of productivity work time due to common painful conditions was estimated to affect 13% of the total workforce.] Headache was the most common painful condition estimated at 5.4% followed by back pain 3.2%, arthritis pain 2% and other musculoskeletal pain 2%. Lost work production time for common painful conditions was estimated to be \$61.2 billion per year. Headache patients lost an average of 3.5 hours per week of productivity time. [We estimated that \$ 25.4 billion was lost in productivity for employees with headache]. (7). Treatment of headache Treatment of chronic and disabling headaches continues to be a challenge. Neuro-modulation is one of the most exciting technologies for management of intractable headaches. Occipital Nerve Stimulation (ONS) involves the electrical stimulation on the greater occipital nerves (GON) in order to block pin signals from reaching the cervico-trigeminal complex. The evidence continues to expand to provide evidence that the ONS is an effective treatment for

intractable cephalgias. The proposed mechanism of action is central inhibition of the Cervical-Trigeminal Complex. Unfortunately the cost can be prohibitive. The protocol involves an outpatient ONS trial period where the leads are percutaneous placed over one or both occipital nerves. These leads are connected to an external pulse generator unit that provides a therapeutic electrical current. During the following 7 days patients evaluate their level of reduced pain and stimulation tolerability. The criterion for a successful trial is a reduction of average pain level equal to or more than 50% on a Numerical Rating Scale. Once this has been achieved for a minimum of two days then we have an indication to proceed with permanent implantation. If this single criterion is not met we understand that the complexity of pain calls for other metrics therefore we strongly consider other criteria. These include the increased ability to carry out daily activities, decreased intake of analgesics and overall perception of satisfaction with the modality. Overall care of the pain patients calls for evaluating the risks to the patient's health as well as the monetary cost of a trial. The main risks of an ONS are infection, hematoma and nerve injury. The cost of a trial is a considerable expensive undertaking. Utilizing modalities that reduce this cost and risk should be explored which brings us to Transcutaneous Electrical Neuro-Stimulation. A search of journals for TENS produced a wealth of information concerning its use for acute and chronic painful conditions. (1) As a result its use continues to be controversial. (2)(3) The first TENS unit was patented in the United States in 1974 (4) by Burton C (Jan 1974) interestingly enough he utilized TENS to test the tolerability of electrical stimulation prior to implanting dorsal column electrodes. Although its use was intended as a trial to predict tolerance to the implanted electrodes the patients had received such excellent relief that many did not return for implant. Specifically a TENS trial is non-invasive method which employs two or more pads or electrodes that transmit an electrical current from an electrical generator. The stimulation is placed on the skin over a targeted nerve for the treatment of pain. TENS generators are mostly battery-operated for portability and can be adjusted to vary the pulse width, frequency and intensity to provide a current that is effective in reducing pain as well as not bothersome for the patient.

Case Series: In this case study series we evaluated whether TENS can be used as an inexpensive and safer alternative predictor of ONS implant success compared to the traditional percutaneous ONS trial. The following is a case series describing candidates for ONS trial based on a history of intractable headaches. These patients were referred to the Moffitt Cancer Center and Research institute Interventional Pain clinic from the clinics at the University of South Florida Headache and Pain clinic. After consulting with the Ethics Committee of the hospital and obtaining approval, all headache patients who had considered invasive treatments were offered an Occipital Nerve Transcutaneous Neurostimulation trial utilizing a TENS. We explained the research nature of the procedure and reassured the patient that choosing to participate in this case series would not have any impact on the original plan to proceed with a formal trial. Seven out of eight patients agreed to the initial TENS unit trial. The Department of physical therapy was recruited to provide the proper placement of the TENS unit. We purposefully provided the same physician and physical therapist at each visit in order to provide consistency and familiarity. The TENS placement procedure required having direct access to the skin surface over the bilateral greater occipital nerves therefore the area was shaved and contact was made with the bare skin. The leads were then connected to the TENS unit pulse generator and properly adjusted in regards to pulse width, frequency and intensity to achieve reduction of their headache pain. The process of adjustment of a TENS unit utilizes sensory level pulses which are of high frequency (>50 Hz) which facilitates the avoidance of motor contractions which are usually produced by low frequencies (<10 Hz). Amplitude is adjusted until the stimulation was perceived at the base of the occiput and with increasing amplitude to incrementally reach to the crown of the head. Amplitude adjustment is limited by higher levels uncomfortable stimulation. The range of amplitudes needed varies from 0-100 Mili-Amps. Prior to discharge home the patient was educated on the safe and optimal use and adjustment of the TENS unit. They were advised to return to their daily activities for the trial period of 7 days.

Objective: To determine if a TENS unit can be used alternative to percutaneous ONS trial for predicting successful Occipital Nerve Stimulator (ONS) implant therefore reducing the cost and risk of a trial
Methods Eight patients with a history of uncontrolled chronic headache were selected to have a trial period utilizing a TENS unit applied to the occipital nerves.

Results: A TENS unit trial was not able to accurately predict the outcomes for an implanted ONS

Case #1 (TENS positive/ONS trial positive)++

Case#2 (TENS negative/ONS trial negative) - -

Case #3 (TENS Positive/ONS trial positive/ONS permanent positive)+++

Case #4 (TENS Positive/ONS trial positive/ONS permanent positive)+++

Case #5 (TENS Negative/ONS trial negative) - -

Case#6 (TENS Negative/ONS trial positive/ONS permanent positive)-++

Case #7 (TENS Negative/ONS trial positive/ONS permanent positive)-++

Conclusions: Occipital nerve stimulation has been successful in the treatment of Occipital neuralgia. Tension, Migraine and Cluster headaches. In this study our goal was to evaluate an alternative means of predicting the success of an ONS trial and thereafter a permanent implant of ONS unit. Our second goal if our first was successful was to provide an alternative that would provide reduced cost and risk to ONS trial. In this case review series seven of eight subjects agreed to trial a TENS unit

in addition to ONS trial and possible permanent implants. Five of the seven subjects had consistent responses to a TENS unit trial and ONS trial and subsequent ONS implant. Two of the subjects were predictors of successful ONS trial and successful permanent implant of ONS. Two of the subjects were not predictors of successful ONS trial and successful permanent implant of ONS. Another two subjects were good predictors of ONS trial failure and failure of ONS implant. Overall a TENS unit was only able to predict approximately 66.66% of the outcomes. Given that the other two subjects which had a negative response to TENS and positive response to ONS trial and permanent implant leads us to a definite conclusion that in on a larger scale many subjects that fail TENS would likely benefit from a permanent ONS implant. In light of this information we would be failing to provide effective relief for headache patient by using a TENS unit as a predictor of success. It would be prudent to examine the critical factors that could influence a failure of TENS trial in light of a successful ONS trial and implant. Reviewing the literature provided some answers. In one study it was revealed that the factors in failure of a TENS unit in treating pain were found to be poor methodological quality in studies and implementation of the TENS unit. They found that one of the most effective methods used to test TENS unit success or failure in treating pain depended on accurately documenting the time, intensity and duration of TENS utilization and time link this with pain scores. (7) Another study that emphasized that the precise placement similar to acupuncture of the electrical stimulator pads or electrodes was important in the efficacy of the occipital nerve stimulator. (8). The mechanism of action of the TENS unit and Spinal cord stimulators should be similar in order to achieve a high correlation in utilizing TENS unit trials to predict ONS implants. Unfortunately the majority of literature investigates Spinal Cord Stimulator implants. We can extrapolate the use of SCS implant outcomes to better understand ONS implants given that there may be similar mechanisms of action. The following is a brief review of mechanism of actions of each. A TENS unit utilizes an electric field to directly affect pain transmission. A TENS unit affects the dorsal horn pain pathways and we take the liberty to extrapolate to the trigeminal-cervical pathway of pain transmission. The purported mechanism includes modulating the gating mechanisms at the dorsal horn system to decrease pain transmission to the brain and stimulation of endogenous neurotransmitters and opioids. Cutaneous nerve fibers are stimulated using surface electrodes emitting a mild electrical current. The stimulation can vary by type of current, amplitude, pulse width, and frequency. Duration of the treatment and length of each treatment can vary widely, with some protocols calling for continuous treatment. High-frequency low-intensity stimulation patterns are better tolerated and result in immediate analgesia, while low-frequency, high-intensity patterns cause more discomfort and result in longer-lasting analgesia. Interferential current therapy (ICT) uses electrical current like TENS, but combines two different high-frequency pulses so that their interference patterns creates a low-frequency stimulation. The high-frequency stimulation penetrates skin better than low-frequency stimulation, but the treatment results in the longer-lasting effect of low-frequency stimulation (8). In comparison of TENS unit to Spinal Cord Stimulation (SCS) mechanisms we understand that there is a substantial overlap in the mechanisms of action. SCS mechanism of action was at first believed to involve gate control theory when Melzack and Wall proposed their theory in 1965. The basis of this theory is thought that non-painful stimulation of large myelinated AB fibers could impede painful stimuli carried by C-fibers and lightly myelinated since that time it has become clear that the mechanisms of action are more complex (9). Mechanism of action of neurostimulation gate exists in the dorsal horn of the spinal cord which modulates the transmission of neural activity pain signals. The idea proposed that the gate was opened when the balance favored the small afferent fiber activity and less large afferent contributor activity originating in the peripheral nervous system. In contrast the gate closed when the major balance contributor was the large fiber input. This theory was extended with the use of SCS which would allow external elective closing of the gate providing reduction or elimination of painful stimuli directed toward the spinal cord and onto the brain. As with most early theories they tend to gain complexity as research reveals the reality of molecular and electrical signaling. (9)

In summary, in our case series we attempted to describe a novel approach to determining successful occipital nerve stimulation prior to implantation. Our results show that TENS is not a predictor of successful neurostimulation of occipital nerves. The purpose of this case series is to also provide information in regards to the decreased cost and risk of TENS unit as an alternative to invasive ONS trial. In comparison of the cost of SCS/ONS and TENS unit the following information has been obtained. For example excellent evidence exists in RCTs that supports the cost effectiveness of SCS in the treatment of Failed Back Surgery Syndrome (FBSS) and Chronic Regional Pain Syndrome (CRPS). The cost in treating each FBSS in the U.S. prior to 2009 was \$31,530 up to \$48,357 for SCS trial and implantation. (2) The cost of a TENS unit ranges from \$89.99 up to \$849.99 (8). Another retailer quotes a cost range of \$21.95 up to \$539.95. (9). Utilizing a TENS unit will substantially reduce complications rates given that the TENS unit is not invasive. We have only data of complications of spinal cord stimulator divided into three categories of complications. These have been extrapolated to the peripheral ONS trial period which has less severe complications compared to spinal cord stimulator trial and implantation. Surgical complications include hematoma, seroma, infection and erosion. Device complications include hardware malfunction, migration, and pain at trial/ implant site, allergic response, and reoperation. Stimulation-induced complications include undesirable change in stimulation, (discomfort, jolting, shocking), loss of pain relief and adjacent area stimulation. Data from SCS trials-implantations reveal that reported peri-operative infections were 5% of cases with a range of (0-12%) found over 20 years of data with no life threatening infections. (5). Hemorrhage or neurologic injury was reported to be up to 9% of cases. Device related complications are the most prominent concerns when trials and implants are employed which are noted to be as much as 30% of cases. (4) Electrode migration was a significant concern at 24% of device-related complications and loss of coverage of the intended area of treatment. Reoperation for revision or replacement was reported to be 5% cases. (11) In one study 3% reported discomfort or loss of pain relief. Oakley studied 126 subjects during two

years after implantation and found that 20% stopped stimulation and subsequently had their stimulator removed. The reasons for removal of the stimulator system include disease progression 55%, loss of pain relief with appropriate coverage of painful area 41% and painful hardware at the implant site 0.08%. Overall the evidence for the use of a TENS unit trial to predict the success or failure of an implanted ONS is good. Overall use of TENS in this manner would most likely reduce the cost and risks of subjecting patients to an ONS invasive trial for treatment of headaches. More research is required to in a larger number of subjects with appropriate application of statistical methods to quantify the exact numbers that will benefit from such as trial. Also more research is required to provide for a head to head comparison of TENS versus ONS trials to qualify and quantify the cost and complications. We believe this case series is a first step in the right direction in providing patients with less risky and cost effective alternatives in treatments of their chronic pain secondary to headache.

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