Top Posters

2022 ASIPP Abstract and Poster Winners

Overall Physician Attending

Provider Specialty Effect on Spine Pain Resource Use/Cost
– Peter Staats, MD

First Place Resident

Examining the Efficacy of TeleHealth in a multidisciplinary Spine Center
– Maria Lyuksyutova, MD

Second Place Resident

The Prediction of Future Opioid Abuse in Patients Who have been Prescribed Opioids
–Alex D. Pham, MD

Overall Medical Student

A Pain in the Neck: A Population Study of Cervical Axial Pain in the COVID-19 Era
–Priya Uppal

Impact of provider specialty on spine pain resource use & costs

Peter S Staats, MD, MBA, National Spine and Pain Centers, Rockville, MD , USA, World Institute of Pain, Winston-Salem, NC USA
Ricardo Vallejo, MD, PhD, National Spine and Pain Centers, Rockville, MD , USA
Nicolas C Gasquet, MPH, Medtronic Neuromodulation, Minneapolis, MN, USA
Christine N Ricker, MA, MBA, Medtronic Neuromodulation, Minneapolis, MN, USA

Background

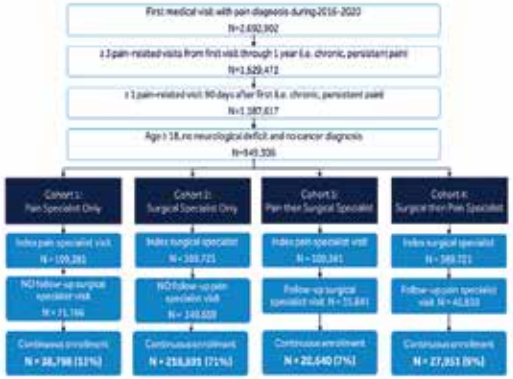
Persistent, or recurring, back pain is one of the leading health care crises in America. This cost burden can result in long-term negative effects on a person's quality of life and overall healthcare costs [1-4]. Patients seeking care for new-onset chronic pain may follow a variety of care pathways.

The aim of this study was to determine how initial pain specialist selection and subsequent care influenced healthcare costs in the first year after a referral for chronic spine pain management.

Methods

- The Optum Clinformatics™ Data Mart database was queried (2016 – 2020) to identify adult patients diagnosed with chronic spine-related pain. This database contains claims for ~50 million patients from a large commercial insurer.

Figure 1. Study Population Inclusion/Exclusion Criteria



- **Key study measures included**: pain-related and all-cause medical resource use, pain-related and total all-cause costs, and opioid prescription fills.

Results

- 306,080 patients were included in the study population–13% of patients saw only a pain specialist (cohort 1), 71% only a surgeon (cohort 2), 7% a pain specialist followed by a surgeon (cohort 3), and 9% of patients initially saw a surgeon and then a pain specialist (cohort 4; Fig1.)
- Patients managed only by a pain specialist experienced fewer pain-related inpatient hospitalizations during the one-year follow-up period, compared to those who only saw a surgeon (P <.0001.)
- Referral to a pain specialist alone was associated with lower resource utilization and per-patient adjusted cost savings of $3,311 (pain-related) and $6,447 (all-cause) compared to patients referred to a surgeon alone (Fig 2., P<.0001)

Figure 2. Adjusted Total Payer and Patient Payments and Cost Differences to Cohort 1

- Fewer patients managed by a pain specialist alone (38.7%) had spine-related imaging visit within 12 months of diagnosis compared to those managed by a surgeon alone (65.3%) or a combination of surgeon and pain specialists (66.6% to 76.7%; P <.0001, Table 1.)
- Significantly fewer patients managed by a pain specialist alone (0.3%) underwent a spinal fusion procedure versus a surgical specialist alone patient (7.4%) or with a pain specialist (7.2% to 9.4%; P <.0001, Table 1.)

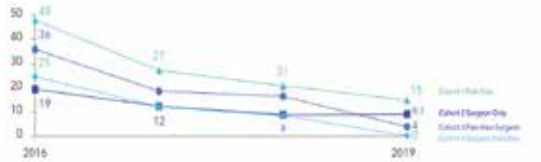
Results cont.

Table 1. Follow-up Imaging Related Visits

	Pain Only	Surgeon Only	Pain then Surgeon	Surgeon then Pain	P-value*
Imaging visit during follow-up (%)	38.7%	65.3%	66.6%	76.7%	<.0001
Spinal Fusion Procedure (%)	0.3%	7.4%	7.2%	9.4%	<.0001
Laminectomy (%)	0.4%	8%	8.1%	9.8%	<.0001

- More patients filled an opioid prescription during follow-up when only managed by a pain specialist (53.4%, 39.7 mg/day Morphine Milligram Equivalent-MME) versus only by a surgeon (41.3%, 14.5 mg/day MME; P<.0001).
- Average daily MME among pain specialist only patients decreased from 48 mg/day for patients treated in 2016 to 15 mg/day in 2019, the largest decrease in MME compared to the other cohorts (Fig 3.)

Figure 3. Opioid use - Average daily MME by index year



Conclusion

- Management through pain specialists alone can lead to significant cost-savings
- Starting with a pain specialist may be a cost-effective option for price-sensitive patients and payers that need to manage overall healthcare expenditures.

The choice regarding pathway should be a decision between the referring physician and the patient, without cost as a primary consideration.

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Examining the efficacy and patient satisfaction of telehealth in a multidisciplinary spine practice

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Background

The use of telehealth (TH) has long been available, but the coronavirus 2019 (COVID-19) pandemic has accelerated the global use of TH due to in-person visit restrictions. However, studies examining the effectiveness, relevance, and satisfaction with this technology for the care of spine patients are limited. In addition, comparing patient satisfaction with care provided by different spine specialists in a multidisciplinary spine practice, consisting of surgical and non-surgical physicians and advanced practice providers, in a TH setting is also limited.

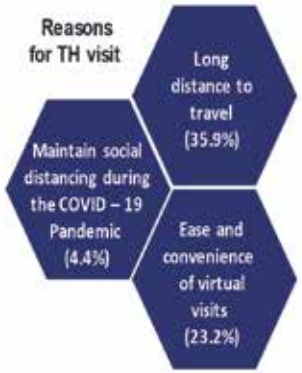
Purpose

To investigate the efficacy and patient satisfaction with telehealth visit administered by non – surgical physicians, surgical physicians, and non-physician providers in a multidisciplinary spine practice. Physician specialists in the study include the following: neurosurgery, orthopedic spine surgery, anesthesiology, and physical medicine and rehabilitation.

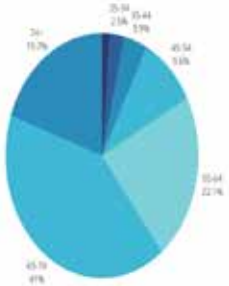
Methods

- The survey study was administered electronically via email from June 1, 2021, to December 2, 2021, to all spine center patients who used TH services in that period. 407 patients responded and completed the survey.
- Survey reviewed patient demographics, visit type, patient satisfaction, and likelihood to recommend.

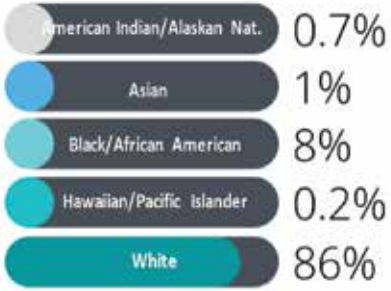
Reasons for TH visit



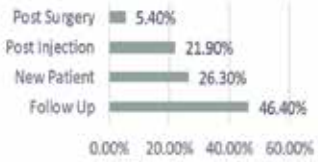
Utilization by Age Group



Telehealth Utilization by Race



Appointment Type



First time TH utilization was 48.6%

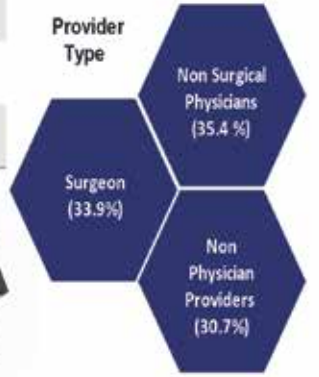
Conclusions

- A large majority of patients believe that TH visits are a successful, informative, and satisfactory choice for receiving care in a multidisciplinary spine center, regardless of provider's specialty or type of visit.
- Special considerations must be noted for populations that may not be served best with TH visits and would benefit more from in-person visits. These considerations include language barriers and limited access or ability to use computer technology.

Ethnicity	Percentage
Hispanic/Latino	6.6
Not Hispanic/Latino	88.7
Would rather not say	4.7

65.6% of respondents identified as female

Provider Type



"94% of patients would recommend a telehealth visit to their friends and/or family"

Reference: Bhuva S, Lankford C, Patel N, Haddas R. Implementation and Patient Satisfaction of Telemedicine in Spine Physical Medicine and Rehabilitation Patients During the COVID-19 Shutdown. Am J Phys Med Rehabil. 2020; 99: 1079-1085.
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LSU Health NEW ORLEANS

Prediction of Future Opioid Abuse in Patients who have been Prescribed Opioids

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LSU Health NEW ORLEANS

Background: One of the greatest threats in medicine today is the abuse of both prescription and non-prescription opioids. Patients are often introduced to these drugs as part of their healthcare before developing Opioid use disorder (OUD). Opioid use disorder is a subset of substance use disorder (SUD), which uses any substance in a problematic pattern that causes physical or social impairments. The DSM-5 uses some criteria to assess for severity of substance use disorder. Problematic behaviors associated with SUD include using a higher dose than what is prescribed, cravings for the medication, increased tolerance, withdrawals, placing strain on relationships or occupation, and an inability to quit despite a desire to do so.

Opioids are a class of highly addictive analgesics with great historical significance in managing both acute and chronic pain. They were prescribed heavily in the 1990s due to a belief that newly developed opioid medications were safe for use and had little risk for addiction. The use of opioids for chronic pain relief resulted in increased tolerance to the medication, which pressured physicians to give higher dosages to maintain adequate analgesia in their patients. In the 2010s, many people suffering from addiction to prescription opioids turned to heroin use, which increased fatal overdoses. Now an incredibly strong synthetic opioid, fentanyl, is becoming more prevalent as a street drug and has greatly increased opioid-related deaths in recent years. The misuse of opioids over the last three decades has had a significant impact on the health care system. The number of deaths attributed to opioid overdose per year has quadrupled from 1999 to 2019 and has almost surpassed 500,000. In 2019, there were over 70,000 deaths due to overdose, with opioids accounting for more than 70% of those. Fourteen thousand of those deaths were associated with prescription opioids. A greater number of people suffered opioid-related overdoses and survived. These individuals had a very high chance of recurrent, potentially fatal overdoses. In a national survey done in 2019, 10.1 million people over 12 years old reported misuses of opioid medications. Prescribed opioids were involved in 9.7 million cases. The financial price of this epidemic has been staggering for the healthcare system and our nation. The economic impact was estimated to be $1.02 trillion in 2017, with a majority of the burden being due to the reduced quality of life with OUD and the value of life lost.

The prevention of future opioid misuse is the most effective and efficient method of reducing the impact of the opioid epidemic on our healthcare system. This involves trying non-opioid forms of pain management first. If opioid medications are necessary, use them for a reduced time with the lowest effective dosages and short duration of action. If a patient does require opioid pain treatment, educating them on the risks of opioid misuse can also reduce problematic outcomes. Other methods of reducing opioid misuse include pain contracts, frequent monitoring of patients using opioids for chronic pain, and intervening with early signs of OUD. One study designed at creating a database that predicted patients at high risk for opioid misuse and using non-opioid forms of medications in these scenarios showed to be very cost-effective; however, because it was not implemented, it could not show an impact on the health or outcomes of these patients.

Methods: Conducted a systemic comprehensive literature search using a collaboration of existing publications involving predicting future opioid abuse in patients who have been prescribed opioids. We present the existing literature in the understanding of predicting future opioid abuse in patients who have been prescribed opioids.

Results: To curb the opioid epidemic, the CDC released a guideline in 2016 detailing the prescription of opioids for patients with chronic pain, recommending a prescription of the lowest effective dose of an immediate-release opioid for acute pain management with a three-day prescription being adequate for treatment. Rarely is a seven-day or greater supply necessary. They also recommended careful consideration of patient risks before increasing the dose to ≥ 50 morphine milligram equivalents (MME) per day or transitioning to extended-release/long-acting opioids, as both are associated with a greater risk of overdose. For post-surgical opioid prescription practices, procedures with rapid recovery, such as simple dental procedures, should only require three days. Procedures with a medium-term recovery period, such as a cesarean section, should generally be prescribed a 7-day supply. More extensive recovery periods for procedures such as knee replacements should be given no more than a 14-day supply. For all cases requiring a longer duration of opioids than recommended, the patient should be re-evaluated and tapered from opioids within six weeks after surgery. While the opioid dispensing rate has declined with these guidelines in place, physicians are still performing high-risk practices as the average number of days for an opioid prescription in 2017 was 18 days with an average daily dose of more than three times the average dose compared to 1999.

➢ **Opioid Use Disorder:** Despite their clinical efficacy for pain management, short and long-acting opioids have displayed a significant potential for abuse. A 2017 systematic review encompassing 38 studies determined opioid misuse in 21% to 29% and opioid abuse in 8% to 12% of U.S. prescribed patients. The number of deaths among these patients has also increased. During 2019, the CDC recorded nearly 70,000 drug overdose deaths, of which 70% were attributed to opioids. The highest per capita death rates were registered in West Virginia, Delaware, and Washington DC. In 2020 all-cause overdose deaths in the United States were higher than any previous twelve-month period and were 38.4% higher than the year prior. During 2020, all but one jurisdiction reported an increase in opioid deaths, with the most significant increases being seen in western states. The CDC determined common factors facing cities with higher opioid prescription rates. These include smaller cities or larger towns, a high percentage of white residents, a higher number of dentists or primary care physicians per capita, more uninsured people, and more residents with arthritis, diabetes, or disability. Synthetic opioids are responsible for 72.9% of opioid deaths due to overdose. Furthermore, the data shows that physicians have become more cautious in prescribing opioids, as represented by a 19% reduction in annual prescribing between 2006 – 2017 The most prominent risk factor for developing opioid abuse disorder is a diagnosis of substance abuse within the prior six months. Other common risk factors include: Young age, High dose prescription, Chronic opioid prescription, Smoking, Nonfunctional status due to pain, Unclear etiology of pain, Psychological disease, Family history of substance abuse, Poor social support.

Conclusion: While opioid drugs carry a great benefit in the relief of pain in both acute and chronic settings, they have the potential to create equal harm in patients. For most of the 20th century, these drugs were reserved for the most severe cancer pain, but we began using them with increased frequency for a wider range of conditions starting in the 1980s. This change in medical practice has snowballed into what is now termed the opioid epidemic. This epidemic continues to take its toll on our population, as we recorded 70,000 deaths due to drug overdose in 2019, with opioids being responsible for 70% of them. We have taken measures to counter this by changing the way we prescribe these drugs and monitoring those with prescriptions, but the numbers are still high. The easiest and safest solution to this is to improve our methods for predicting abuse in our patients, preventing the problem before it occurs. Understanding the risk factors for OUD would allow physicians to either encourage patients to seek alternative treatment or catch the problem before it is too late. The greatest risk factor for OUD is a history of substance abuse. More common risk factors include young age, high prescription dosages, long-term prescriptions, smoking, a nonfunctional status due to pain, an unclear etiology of the pain, psychological disease, a family history of substance abuse, and poor social support. Although they have little clinical efficacy, there are three available screening tools to quantify the risk of OUD: the Screener and Opioid Assessment for Patients in Pain (SOAPP-R), the Opioid Risk Tool (ORT), and the Pain Assessment and Documentation Tool (PADT). These could be used in conjunction with a physician's clinical assessment to better predict abuse.

Although we currently do not have an effective way to predict abuse in patients, perhaps there is still a way to prevent it. The driving force behind addiction is a feeling of euphoria experienced when using a drug. Binding interactions with the mu-opioid receptor have been shown to produce euphoria in human and animal studies. Opioids also play a role in the mesolimbic system by increasing dopamine, resulting in euphoria and dependence. The next big step for ending the opioid epidemic from a pharmacologic standpoint will be to find a way to separate the euphoria from the analgesia. We have used methadone to study this concept and found that the euphoria could be diminished via decreased heterodimerization of the GALR and MOR. With methadone's ability to bind the mu-opioid receptor for a longer duration than morphine, perhaps it will pave the way for a future synthetic opioid to end the opioid epidemic. Whether the solution is found in better prediction or a different pharmacologic approach, strides need to be made to reduce the impact of OUD on the healthcare system and the patient population.

ALBANY MEDICAL CENTER

A Pain in the Neck: A Population Study of Cervical Axial Pain in the COVID-19 Era

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BACKGROUND

The COVID-19 pandemic has dramatically altered the lives of the global population, with disruptions in nearly every aspect of daily life. When looking at patients afflicted by pain, cervical axial pain affects up to 30-50% of working adults in the United States (US) and has several reported causes that may be associated with COVID-19 disruptions.[1]

This study aims to analyze the relationships between positive COVID-19 diagnoses, rates of depression, and neck pain in the adult population.

A questionnaire was created to address these study aims using the Neck Disability Index (NDI) and The Patient Health Questionnaire-9 (PHQ-9). The NDI is a well-established neck pain questionnaire that has been used in small sample sizes internationally; however, it has not been utilized in the US in a large national study.[2,3] The Patient Health Questionnaire-9 (PHQ-9) is a validated and and widely used questionnaire across the US to screen for depression.

METHODS

A questionnaire was made in Qualtrics and distributed via Amazon MTurk, a crowdsourcing platform. Respondents were asked to complete the NDI and the PHQ-9 to assess the severity of functional impairment from their neck pain and depression, respectively.

The NDI has a score range from 0 to 50 points, with higher scores indicating greater neck disability. The PHQ-9 has a score range from 0 to 27 points, with higher scores correlating with more severe depression. Respondents were asked about their COVID-19 status, family members who had COVID-19, and their neck pain following COVID-19. Lastly, respondents were asked questions about their chronic pain conditions, pain interventions that they would be interested in pursuing, and interest in seeing a pain specialist.

Inclusion criteria included respondents 18 years or older who lived in the US. Two Way Analysis of Variance (ANOVAS) with Dunnett's Multiple Comparison Correction, Fisher's Exact Test, and Pearson's Correlation Coefficient were used to compare the mean scores, predict associations, and determine correlations.

STUDY DEMOGRAPHICS

A total of 2,859 responses were included in our analysis. Of the respondents, the majority were Caucasian (56.9%) and male (53.6%); 44.9% were between the ages of 25-34. In this population, 539 respondents (18.9%) were overweight, 442 (15.5%) respondents were obese, and 916 (32.0%) respondents were underweight according to CDC-determined BMI categories. The mean NDI score was 13.05 and the average PHQ-9 score was 9.53

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RESULTS

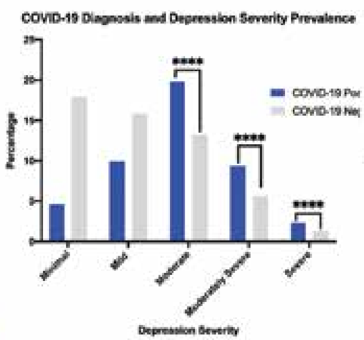

Figure 1: COVID-19 Diagnosis and Depression Severity Prevalence: Among COVID-19 positive respondents, 47% had moderate, 20% had moderately severe, and 5% had severe depression. The prevalence of moderate, moderately severe, and severe depression was significantly greater among COVID-19 positive patients (p<.0001)

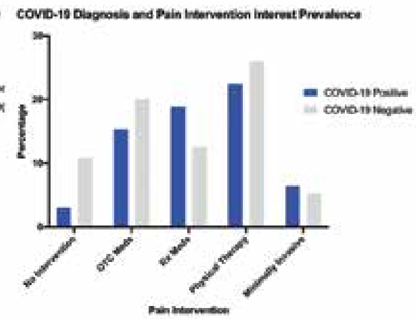

Figure 2: COVID-19 Diagnosis and Pain Intervention Interest Prevalence: When looking at COVID-19 positive respondents, 49% were interested in physical therapy, 41% were interested in prescription medication, 33% were interested in over-the-counter medications, and 14% were interested in minimally invasive procedures; overall, 93% of COVID-19 positive patients were interested in seeking one or more pain interventions

	NDI		PHQ-9		Interest in Pain Specialist		
	Mean	SD	Mean	SD	Mean	SD	N
COVID-19 Negative	11.50	8.14	7.82	5.60	5.29	2.98	1544
COVID-19 Positive	14.88****	7.87	11.55****	4.99	6.88****	2.35	1315
Family members w/o COVID-19	11.75	8.33	7.38	5.64	5.33	2.96	1241
Family members w/ COVID-19	14.07****	8.01	10.79****	5.32	6.60****	2.36	1598

Asterisk (*) indicates level of significance between the results of the COVID-19 positive and negative groups and between families that had or lacked members with COVID-19 positive diagnosis.
* significant at p <0.05, **significant at p <0.005, *** significant at p <0.0005, **** significant at p <0.0001.
Respondents who had a positive COVID-19 diagnosis had associated increase in neck pain with a PPV of [illegible], an NPV of [illegible], a sensitivity of [illegible], and a specificity of [illegible] (p<.0001).
Fisher's exact test was used to determine if there was a significant association between a COVID-19 positive diagnosis and neck pain, depression, and interest in seeing a pain specialist. There was a statistically significant difference between the groups across all variables (two-tailed p<0.0001).
Fisher's exact test was used to determine if there was a significant association between having a family member/family members with COVID-19 and neck pain, depression, and interest in seeing a pain specialist. There was a statistically significant difference between the groups across all variables (two-tailed p<0.0001).

Table 1: NDI and PHQ-9 Scores of COVID-19 Positive vs. COVID-19 Negative Respondents: COVID-19 positive respondents had higher mean NDI and PHQ-9 scores as compared to respondents without COVID-19 (p<.0001). They also reported a greater interest in seeing a pain specialist (p<.0001). Respondents who had a family member with COVID-19 also had higher NDI and PHQ-9 scores; they also demonstrated a greater interest in seeing a pain specialist (p<.0001)

		NDI		PHQ-9		Interest in Pain Specialist		
		Mean	SD	Mean	SD	Mean	SD	N=1315
COVID-19 positive, without reported increased pain following the pandemic	• No increase in screen time	9.89	8.32	6.75	5.45	4.04	3.13	71
	• Increase in screen time	10.93****	7.31	8.60****	5.43	5.93****	2.80	190
COVID-19 positive, with reported increased pain following the pandemic	• No increase in screen time	17.13	7.87	10.81	4.59	5.98	2.43	53
	• Increase in screen time	15.59****	7.08	12.12****	4.41	7.12****	1.80	1001

Asterisk (*) indicates level of significance between the results of the COVID-19 positive respondents and changes in neck pain and screen time.
* significant at p <0.05, **significant at p <0.005, *** significant at p <0.0005, **** significant at p <0.0001.
Respondents who had increased screentime had associated increase in neck pain with a PPV of [illegible], an NPV of [illegible], a sensitivity of [illegible], and a specificity of [illegible] (p<.0001).
Fisher's exact test was used to determine if there was a significant association between screen time and neck pain. There was a statistically significant association between the two variables (two-tailed p < 0.0001).

Table 2: COVID-19 positive respondents, screen time changes, and NDI, PHQ-9, and Pain Specialist Interest: During the pandemic, this same cohort of respondents who self-reported either an increase in neck pain or screen time also had higher NDI and PHQ-9 scores (p<.0001). These respondents also had a greater interest in seeking a pain specialist (p<.0001).

DISCUSSION

The growing interest in axial cervical pain and the evolving changes of the COVID-19 pandemic makes the need to investigate neck pain increasingly important. The results of our study support that neck pain is correlated with depression, a positive COVID-19 diagnosis, and increased screen time.

Predictably, individuals in our study who were COVID-19 positive had worse neck pain and depression scores. One of the explanations for this could be the physical discomfort from prolonged hospital stays as well as stay at home quarantine periods.[4] Another cause of heightened neck pain could be due to physical debility and muscle loss in the hospital.[5]

When looking at depression severity, there were greater proportions of moderate, moderately severe, and severe depression among COVID-19 positive patients. Combined with social isolation, illness stigma, and physical debility, it is reasonable to expect that COVID-19 positive patients demonstrate higher levels of neck pain and more severe depression.[6]

Moreover, respondents who had a family member and or partner who lived in the same household who was COVID-19 positive, also had higher NDI and PHQ-9 scores. The caregiver role that is often assumed by family members during the pandemic has been documented to contribute to higher rates of depressive symptoms due to schedule disruptions, physically taxing care, and prognosis uncertainty.[7]

Notably, increased screen time among COVID-19 positive patients was associated with greater NDI scores. While the daily activities of hospitalized COVID-19 positive patients is variable, it is foreseeable that there are smartphone, tablet, and TV interactions during their hospital course.[8] The repetitive strain and forward head flexion known as 'tech neck' is likely responsible for the increased amount of neck pain due to the reduced cranial vertebral angle leading to greater compressive forces on the facet joints as well as connective tissue strain.[9]

CONCLUSIONS

The present study substantiates the association of depression, a positive COVID-19 diagnosis, and increased screentime with increased neck pain. Consequently, greater emphasis should be placed on screening and risk-stratifying patients for these factors given their growing prevalence in the adult population. Patients should be educated on multimodal treatment options as it relates to their condition. Physical therapy exercises to strengthen neck flexors, head position adjustments, and multidisciplinary referrals for COVID-19 related stressors should be part of an effective treatment plan for axial cervical pain.

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Determining the Efficacy of Autologous Bone Marrow Mesenchymal Stem Cells in the Treatment of Lower Back Pain

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Introduction

- **Lower back pain is the most expensive medical condition in the United States with an annual expenditure of $134.5 billion in 2016.**
- **There has been escalating growth of treatments, including over-the-counter (OTC) medications, structured exercise programs, physical and drug therapy, interventional techniques and surgical interventions**
- The anti-inflammatory, immunomodulatory, and regenerative properties of bone marrow mesenchymal stem cells (BM-MSCs) have not been demonstrated in controlled studies of treating low back pain
- Multiple pain generators have been hypothesized to be responsible in severe spinal degeneration and it is difficult to identify a single pain generator; consequently, resulting in inadequate therapeutic results.

Objective

The study was undertaken to evaluate the effectiveness of autologous bone marrow MSCs in the treatment of chronic low back pain due to severe lumbar spinal degeneration with involvement of multiple structures.

Methods

The treatment group patients received a one-time bone marrow concentrate injection into spinal structures (i.e., discs, facets, spinal nerves, and sacroiliac joints), along with conventional treatment, whereas the control group received conventional treatment with nonsteroid anti-inflammatory drugs, over-the-counter drugs, structured exercise programs, physical therapy, spinal injections and opioids, etc.

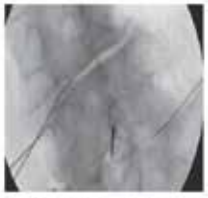

Fig. 1. Needle placement in the posterior iliac crest.

Data Analysis

- Outcomes were assessed utilizing multiple instruments, including the Oswestry Disability Index (ODI), Numeric Rating Scale (NRS-11), EuroQOL 5-Dimensional Questionnaire (EQ-5D-3L), Global Mental Health (GMH), and Global Physical Health (GPH)
- Multiple outcomes were assessed with primary outcomes being minimal clinically important differences (MCID) in ODI scores between the groups and/or a 2-point reduction in pain scores.
- In the study group, total nucleated cells, colony forming units-fibroblast, CD34-positive cell numbers and platelets were also recorded, along with post-procedure magnetic resonance imaging changes. Outcomes were assessed at 1, 3, 6, and 12 months.

	BMA	BMC	Enrichment
TNC (million/ml)	45.5	256.5	5.2
Total TNC/patient (million)	2,376	2,604	0.86
CFU-F frequency (% per TNC)	0.0026%	0.0020%	0.8
CFU-F/ml.	1,220	8,987	6.0
CFU-F/patient	65,000	44,883	0.68
CD34+/ml.	691,675	3,340,824	4.7
% CD34+	1.5	1.2	0.92
Platelet (million/ml.)	214.5	968.8	4.5
Hematocrit (%)	23.4%	24.3%	0.7

Fig. 2 Cell analysis of study BMA and BMC samples for average TNC, CFU-F, CD34+, and platelets, and enrichment factor after centrifugation.

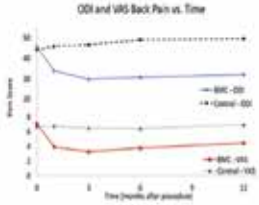

Fig.3 Correlation of ODI scores with CFU-F numbers after one year

Results

- Significant improvement was achieved in functional status measured by ODI, pain relief measured by NRS-11, and other parameters measured by EQ-5D-3L, GMH, and GPH, in the study group relative to the control group at all time periods.
- Significant improvements at 12-month follow-up with 67% of the patients in the study group achieving MCID utilizing ODI when compared to 8% in the control group
- Greater than 2-point pain reduction was seen in 74% of the patients at 3 months, 66% of the patients at 6 months, and 56% of the patients at 12 months. Both MCID and pain relief of 2 points were significantly different compared to the control group. Opioid use decreased in the investigational group, whereas there was a slight increase in the control group

Outcome Data for ODI, NRS-11, EQ-5D-3L,GMS, and GPH scored

Discussion

- The results of this study showed significant improvement in function and pain relief in 67% of the study group, and achieved MCID for ODI at 12 months, when compared to only 8% in the control group
- Pain relief was also seen with a 2-point difference in 56% of patients in the study group at 12 months compared to only 8% in the control group
- The study group also showed reduced opioid usage, ass this is the first of its nature study with BM-MSC injecting multiple structures in one setting in chronic spinal degeneration
- Patients in this study were not stringently selected, the goal was to evaluate this therapy in "real life" challenging patients and patients with severe changes on the MRIs were included if they did not exhibit neurologic deficits

Conclusions

- Autologous bone marrow cell therapy represents an alternative to traditional treatments for low back pain to provide pain relief via multimodal MSC functions of anti-inflammation, immunomodulation, cell recruitment, and remodeling/regeneration
- Stem cell therapy has the potential to slow, halt, or, in some cases, reverse the progression of degenerative discs and joints
- Positive outcomes in this study population, which presented with severe spinal degeneration were likely due in part to the combination of injecting high numbers of progenitor cells/MSCs and by addressing multiple pain generator sites
- It appears that stem cell therapy could be a reasonable option to treat chronic low back refractory to conventional treatment, especially if performed by qualified physicians following the proper guidelines

Author Contributions

The study was designed by SA, KBA, NB, and LM
Statistical analysis was performed by Sagar Vidyasagar Pampati

THE OHIO STATE UNIVERSITY

RCT on DTM™SCS for Intractable Chronic Low Back and Leg Pain

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BACKGROUND

Spinal cord stimulation (SCS) is a treatment for chronic low back pain (LBP) relief. DTM™ SCS is a SCS programming approach inspired from science where electrical signals are multiplexed spatially and temporally. In preclinical studies DTM™ SCS showed the ability of differentially modulating neurons and glial cells to balance interactions perturbed by neuropathic pain.[1] A feasibility study of DTM™ SCS demonstrated a responder rate of 80% for back pain with 85% of subjects preferring DTM™ SCS to conventional SCS therapy[2]. This large randomized controlled trial (RCT) evaluated the efficacy and safety of DTM™ SCS compared to conventional SCS over a 12-month follow-up period.

METHODS

This was a prospective, multicenter, randomized, open-label, post-market study comparing DTM™ SCS programming to conventional SCS in patients suffering from chronic, intractable pain in the low back and legs. The study was IRB approved and registered on clinicaltrials.gov. Subjects that reported Visual Analog Scores (VAS) of ≥5 in low back pain (LBP) with moderate to severe leg pain at Baseline were enrolled.

Informed and consented subjects meeting eligibility criteria were randomized 1:1 to either of the two treatment groups in a parallel assignment. Subjects underwent a SCS trial, per labeling. Subjects that reported ≥50% improvement in LBP relative to baseline during the trial phase were implanted with a rechargeable neurostimulator (Intellis™, Medtronic). Evaluation visits occurred at 1-, 3-, 6-, and 12-months post device activation.

The primary outcome was percentage of responders (subjects with ≥50% LBP relief) to therapy at 3 months after activation of the implanted SCS system. Additional outcomes included changes in leg pain, satisfaction, extent of disability, quality of life, and safety data.

RESULTS

Demographics

A total of 116 subjects completed the trial phase (58 in each arm), 94 subjects were implanted (47 in each arm), 92 subjects completed 3-month visits (46 in each arm), and 79 subjects completed 12-month visits (42 in DTM arm and 37 in control arm). Demographics for all randomized subjects (N=128) are detailed in Table 1.

Table 1. Baseline Demographics (N=128)

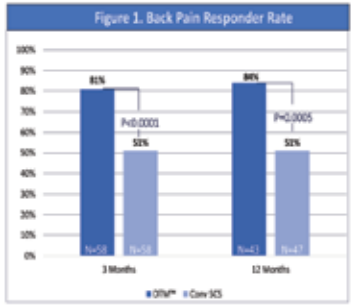
	DTM™ SCS Arm (N=67)	Conventional SCS Arm (N=61)	P-value
Mean Age (SD)	61.28 (12.16)	60.66 (11.77)	0.7675
Sex	50.7% F / 49.3% M	55.7% F / 44.3% M	0.5888
Year of pain onset (SD)	12.64 (13.05)	12.89 (11.25)	0.9106
Mean number of prior surgeries (SD)	1.49 (1.33)	1.41 (1.13)	0.7067
Baseline back pain (SD)	7.25 (1.49)	7.35 (1.26)	0.6707
Baseline leg pain (SD)	6.20 (2.58)	6.58 (2.06)	0.3576

There were no statistically significant differences between the two treatment groups with respect to gender, age, baseline back pain VAS, baseline leg pain VAS, approximate number of years since the onset of symptoms, or the number of previous spine surgeries.

Back Pain Responder Rate

Responder Rate is defined as proportion of subjects who had ≥ 50% pain relief from baseline. The study met the primary endpoint as DTM™ SCS therapy demonstrated non-inferiority to conventional SCS at 3-month (81% and 51%, respectively). Furthermore, DTM™ SCS superiority to conventional SCS was established both at 3- and 12-months (Figure 1).

Figure 1. Back Pain Responder Rate



Profound Back Pain Responder Rate

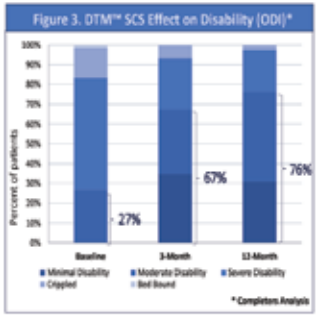
Profound Responder Rate is defined as ≥ 80% pain relief from baseline. Profound back pain responder rate at 12-month was 69% with DTM™ SCS and 35% with conventional SCS.

Figure 2. Back Pain Relief at 12-Months

Change in Oswestry Disability Index (ODI)

76% of subjects had minimal to moderate disability with DTM™ SCS at 12-month visit (Figure 3).

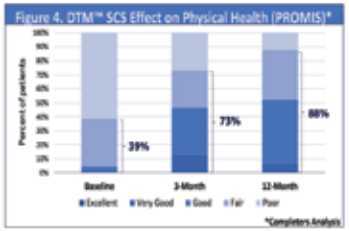
Figure 3. DTM™ SCS Effect on Disability (ODI)*



Change in Physical Health (PROMIS)

88% of subjects communicated their quality of life as being excellent, very good, good, or fair with DTM™ SCS at the 12-month follow-up visit (Figure 4).

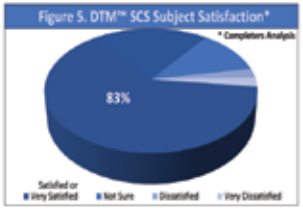
Figure 4. DTM™ SCS Effect on Physical Health (PROMIS)*



Subject Satisfaction

83% of subjects were "Satisfied" or "Very Satisfied" with DTM™ SCS at 12-month follow-up visit (Figure 5).

Figure 5. DTM™ SCS Subject Satisfaction*



CONCLUSIONS

This study demonstrated that DTM™ SCS and conventional SCS can offer LBP relief, however DTM™ SCS provided superior LBP responder rate and benefits in other clinically meaningful outcomes.

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DISCLOSURE

This study was sponsored by Stimgenics, which was acquired by Medtronic.

Viable Disc Allograft Supplementation in Patients With Chronic Low Back Pain (VAST Trial): Interim 24-month Results of an Open-label Extension Study

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Introduction

Chronic lower back pain can be caused by the degeneration of the intervertebral discs. Available treatments have limited effectiveness and durability. Previously reported at 12 months, clinically meaningful improvements in pain and function were achieved in both the investigational allograft and saline groups of the VAST randomized controlled trial (NCT03709901). An open-label extension study is in progress. Here, we report outcomes in patients who completed the 24-month follow-up.

Materials and Methods

The study was conducted in 218 patients with 1- or 2-level degenerative lumbar disc disease and refractory chronic low back pain. At 12 months, patients could continue in an open-label extension study for up to 36 months, with an interim visit at 24 months. In this interim analysis, we assessed mean change from baseline in VAS and ODI scores and categorical responder status. To minimize confounding, we compared these 24-month data with results from prior timepoints in this completer population only.

VIVEX Biologics, Inc. (Miami, FL) sponsored this study and contributed to study design, data monitoring, statistical analysis, and reporting of results and paid for independent data collection, core laboratory, and EDC services. All authors had complete access to data and were provided all analyses requested.

Results

Nine of 12 sites participated in the extension; outcome data were entered for 83 patients at 24 months (allograft-treated, n=70; saline-treated, n=13). The 24-month completer population within each study arm was similar to the intent-to-treat population in age, sex, race, ethnicity, body mass index, and smoking status. In the allograft-treated group, change from baseline in VAS score (mean [95% CI]) at month 24 was -26.4 (-34.29 to -18.41) versus -16.2 (-36.4 to 3.68) in the saline-treated group. Success rates in the allograft-treated group (Figure 1) show that patients continued to have clinically meaningful benefits through 24 months in both pain and function, with 78% of patients reporting a ≥ 10-point ODI improvement and 55% reporting ≥ 30% improvement in VAS at 24 months.

Figure 3. Improvement from baseline in VAS score (A) and proportion of patients with ≥50% reduction in VAS score (B)

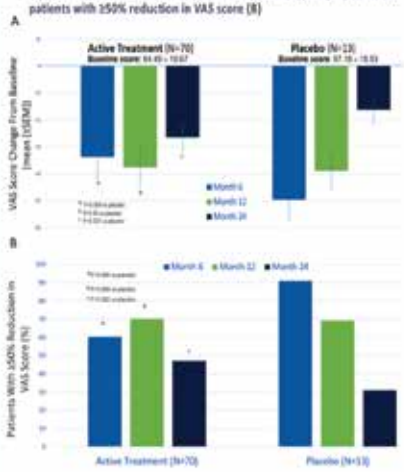

Figure 2A. VAS score (mean ± SD) in treated patients (n=70)

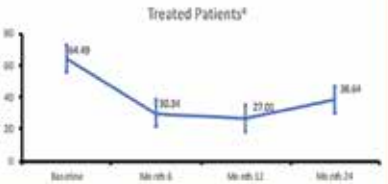

Figure 2B. ODI score (mean ± SD) in treated patients (n=70)

Table 1. Responder rate in change from month 12 to month 24 (completer population)

	Treated[a,b]	Placebo
VAS average back pain		
≥50% reduction	13.6% (9/66)	7.7% (1/13)
Score ≤20 points	39.4% (26/66)	15.4% (2/13)
Oswestry Disability Index		
≥10-point reduction	13.0% (9/69)	0.0% (0/13)
≥15-point reduction	5.8% (4/69)	0.0% (0/13)

Safety

At 24 months, this study has shown that cellular allograft injection has an excellent safety profile. There were fourteen adverse events (AE) reported by 8 (11.3%) of the 71 study participants. Of these, two AEs in 2 patients were treatment-related reporting post-procedural pain and increased low back pain. There were four serious AEs reported by 2 (2.8%) of patients of which none were related to CLBP. There were no adverse events reported in the ten crossover patients.

Discussion

The data presented here may represent the largest long-term data set for a cellular allograft injection therapy for discogenic CLBP. The improvement in pain at 24 months as measured by VAS and ODI is similar to results reported at same time points and endpoints in a study of a single intradiscal injection of STRO-3+ adult allogeneic mesenchymal precursor cells combined with hyaluronic acid[4]. These results are also comparable with those reported in a systemic review and single-arm meta analysis of cell-based therapies for discogenic LBP[5]. Noteworthy limitations include the high rate of study discontinuation after 12 months, and the likelihood that there was selection bias with respect to those who remained in the study.

Conclusion

This interim analysis of an open-label extension of the VAST trial suggests that viable disc tissue allograft might be a beneficial nonsurgical treatment for patients with chronically painful degenerated lumbar discs. The treatment was very well tolerated and there were no safety signals through 24 months. There was durable pain relief seen in treated patients, including some with further improvements between 12 and 24 months. Those patients who were labeled high responders maintain this pain relief at 24 months. Follow-up through 36 months is ongoing.

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Customized Tuned TX: The Future of Spinal Cord Stimulation

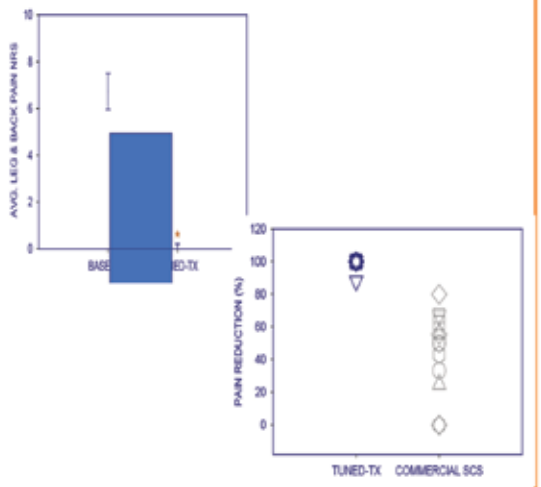
Amol Soin, MD

Introduction

Spinal Cord Stimulation is a modality to treat back and leg pain that has seen significant advancements and increased use over the past 20 years. New modalities, waveforms, and technologies are emerging showing significant advances. ***However, there should be no reason why we would not be able to consistently and predictably drop pain scores down to 0 for patients who suffer from back and leg pain in the right patient***

Methods

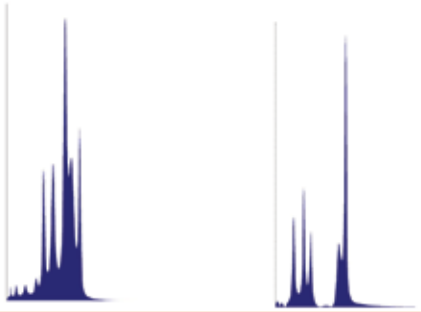
- To test in 20 patients for the first time in humans a new type of spinal cord stimulator that uses aperiodic random electrical signals that is tunes to specific power spectral densities to see if we can get pain scores down close to 0 as possible.



Inclusion Criteria

1. ≥ 18 years of age;
2. Have chronic (defined as at least 6 months duration), intractable neuropathic leg and/or low back pain; any nociceptive pain must be less prominent than the neuropathic pain;
3. Have pain that is unresponsive to conservative treatment options;
4. Has average baseline leg and/or back pain NRS score of at least 6;
5. Be considered by the Investigator as a candidate for implantation of a spinal cord stimulator system;
6. Planning to undergo a SCS trial;
7. Be willing to cooperate with the study requirements including compliance with the study procedures;
8. Reported stable pain (non-escalating) for 30 days prior to signing informed consent;
9. Has stable pain medication use and dosage for 30 days prior to signing informed consent;
10. Be psychologically qualified to receive a spinal cord stimulator as per the clinician's standard clinical practice and does not have clinically relevant psychological condition(s) that would interfere with ability to accurately report outcomes or complete study procedures.

FIGURES Below show sample waveforms:



Results

All subjects responded within 45 minutes of treatment with significant pain reduction

Discussion

1) It is possible to achieve near 0 pain scores using spinal cord stimulation but this requires a completely different paradigm of neuromodulation than one that is used today.

2) This requires using aperiodic random signaling that is specifically tuned by the patient to achieve their desired pain reduction. No other system commercially available uses aperiodic random signaling. What's most interesting is that our data plots of spectral density of stimulation varies significantly from patient to patient.

3) Just like each fingerprint in humans is a unique signature (see Figure 6) , the spectral density for patients with similar pain patterns is also unique and may explain why current conventional stimulation is able to achieve very significant pain reduction but mostly unable to receive near 100% reductions reliably and predictably. Further studies are warranted.

Acknowledgments

Thank you

Allelic Frequency Differences Between Responders and Non-Responders to CBD Oil: A Pharmacogenetic Study

Daniel Roth D.O., Brian Henriksen Ph.D., Yekaterina Afonina D.O.

Hypothesis

Allelic differences exist between CBD oil responders and non-responders

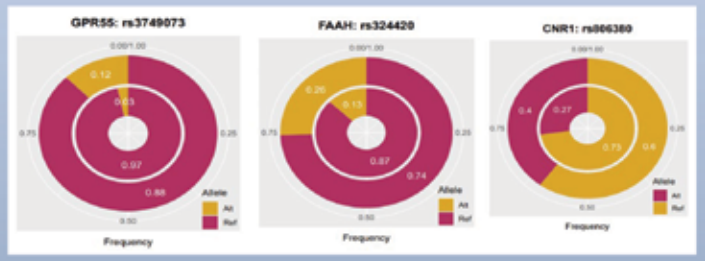
Background

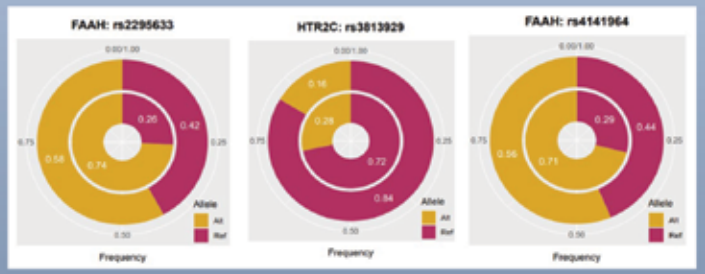
- 2018 Farm Bill legalized the growth, inter-state transport, and sale of hemp derived ingredients containing less than 0.3% THC as well as removed it from the schedule-one list
- The quantity of CBD in the products is not always consistent with the label description
- Possible unsafe manufacturing processes
- CBD known to cause transaminitis in animals studies, has not been replicated in human studies
- FDA currently working on establishing guidelines and encouraging further research
- Currently no way to determine whether or not a patient will receive any benefit from trialing CBD.

Methods

- Buccal swab samples were collected from participants
- DNA was extracted and purified using the Promega Maxwell16 system
- After elution DNA was quantified using Nanodrop 2000
- 76 SNP's were selected, 60 are part of Genemarker's Pharmacogenomics Open Array and 16 SNP's due to their specific involvement in CBD metabolism, transport, and efficacy
- Quality control of genotyping data was performed using TagMan Genotyper software
- IRB approved

Results





Gene Symbol	NCBI SNP Reference	Associations	Responder vs Non-Responder P-value
CNR1	rs806380	Risk of cyclic vomiting syndrome, cannabis dependence	0.095
FAAH	rs2295633	Variability in pain response; PTSD	0.024
FAAH	rs324420	Addiction susceptibility; missense mutation known to affect endocannabinoid levels, though to be involved in hypoalgesia	0.052
FAAH	rs4141964	Variability in pain levels	0.052
GPR55	rs3749073	Binding affinity for endocannabinoids; missense mutation with functional significance	0.049
F5	rs6025		0.098
HTR2c	rs3813929		0.059

Discussion

- Most frequently tested genes for pain showed no difference between our cohorts
- 5 genes involved in CBD metabolism, transport, and receptors, along with 2 genes from Genemarkers PGX Panel did show a significant difference
- CNR1 rs806380 – Previously associated with cannabis dependence, association has not been replicated
- FAAH metabolizes endocannabinoids (ie AEA), CBD inhibits FAAH, resulting in increased activity of AEA. Increased levels of endocannabinoids are associated with analgesic and anti-inflammatory effects
  - Rs32440 – Responders may retain increased levels of endocannabinoids
  - Rs4141964 and rs2295633 associated with variability in pain response in humans
- GPR55 rs3749073 – Alternate Allele results in lower activity and is more abundant in a group of patients diagnosed with anorexia nervosa
- HTR2C rs3813929 has not been extensively studied in response to cannabinoids, however is associated with the risk of antipsychotic induced weight gain
- F5 rs6025, also knowns as Factor V Leiden, a known risk for thrombosis. The connection between this SNP and the function and/or response to cannabinoids has not been studied

Limitations

- Single institution
- MAF data is less reliable/should be considered with care

Conclusion

- Genetic screening resulted in significant allelic differences between CBD responders and non-responders

Clinical Outcomes in a Highly Comorbid Population Using Interspinous Spacers for the Treatment of Lumbar Spinal Stenosis

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BACKGROUND

Indirect Decompression Systems (IDS) or Interspinous Spacers are an option in well-selected patients with impaired physical function who experience relief in flexion from symptoms of leg, buttock and/or groin pain due to lumbar spinal stenosis (LSS). A growing body of published clinical evidence has demonstrated excellent long-term clinical benefit with sustained pain relief, improved quality of life and medication reduction up to 5 years post-implant.[1-3] In addition, this minimally invasive treatment option may be especially appropriate for highly comorbid patients that have not responded to prior conservative care or interventions for function-limiting claudication. Here, we present our experience utilizing this approach in an observational case-series.

METHODS

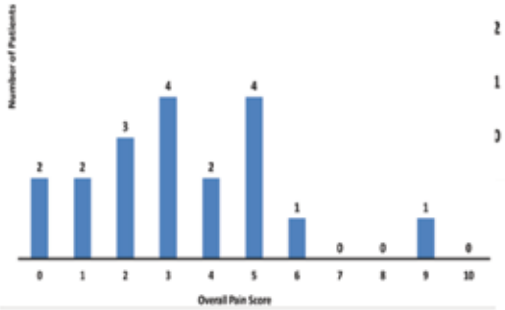
Study Design	Multi-center, observational case-series. Data collected by site personnel only
Study Device	Boston Scientific Superion Indirect Decompression Systems (IDS) 
Patients/Sites	19 patients with multiple co-morbidities who received IDS for Lumbar Spinal Stenosis (LSS)

RESULTS

Baseline Characteristics (n = 19)

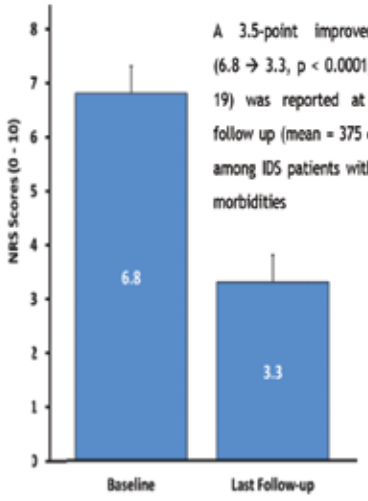
Gender - Females (%)	47.4% (9/19)
Age [Mean (SD)]	71.7 (10.9) years n = 18
Baseline NRS [Mean (SD)]	6.8 (2.2) n = 19
Follow-up [Mean (SD)]	375.3 (453.7) days n = 19
Diagnosis	Lumbar Spinal Stenosis

Distribution of Overall Pain Scores (n = 19)



58% (11 of 19) of IDS patients with co-morbidities reported a pain score of 3 or less at last follow up.

Overall Pain Scores (n = 19)



A 3.5-point improvement (6.8 → 3.3, p < 0.0001, n = 19) was reported at last follow up (mean = 375 days) among IDS patients with co-morbidities

68% (13 of 19) of patients reported a clinically significant* improvement in their overall pain at last follow-up

*≥ 2-point improvement in pain scores (NRS)

CONCLUSIONS

- Lumbar Spinal Stenosis patients with co-morbidities have a higher surgical risk for procedures
- Results from this ongoing real-world observational case-series of patients with other co-morbidities who received IDS for the treatment of their LSS symptoms demonstrated at last follow-up (mean = 375 days):
  - ➢3.5-point improvement in overall pain (6.8 → 3.3, p < 0.0001)
  - ➢68% (13 of 19) of patients reported a clinically significant improvement in their overall pain at last follow-up (i.e., ≥ 2-point improvement)
  - ➢58% (11 of 19) reported a pain score of ≤3
- This preliminary evidence aligns with other published reports.

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DISCLOSURES

Study Sponsored by Boston Scientific.
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AM2022

Algorithms to Identify Nonmedical Opioid Use

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Background: Spinal Cord Stimulation (SCS) has been FDA approved for treatment for a primary indication of neuropathic limb pain that is resistant to more conservative medical therapy. Additional benefits of SCS therapy include reduced narcotic use, improved quality of life, and a greater chance of returning to their work-life. The disorders qualified for treatment include neuropathic, post-surgical, post-amputation, osteodegenerative, and pain related to vascular disease. Some of the most frequently cited conditions for treatment of SCS include failed back surgery syndrome, complex regional pain syndrome (CRPS), and post-herpetic neuralgias. CRPS is a painful neuropathic condition affecting the distal aspect of a limb that may or may not be precipitated through injury. Currently, CRPS is categorized into Type I, characterized by an initiating injury or cause of immobilization, and Type II demonstrated through a known nerve injury.

Although CRPS can be difficult to treat, several clinical studies have reported high success rates of pain relief with SCS as trial insertion and long-term therapy. Furthermore, a recent case report demonstrated thermographic findings in the treatment of Type II CRPS through SCS and clinical reports of 60% to 80% of patients experiencing pain relief for CRPS Type I. Physical evidence of edema, sweat gland abnormalities, or abnormal blood flow to the affected site may be present. Although the pathophysiologic mechanism is not well understood, tissue inflammation, vasomotor dysfunction, central neurologic sensitization, and neuroplasticity are believed to be involved. SCS targets hyperexcitable central neural pathways and efferent sympathetic transmission related to CRPS pain signaling. Despite these successes, some CRPS patients do not experience adequate relief, or pain control diminishes over time. Current studies also suggest that post-herpetic neuralgia can be managed through SCS therapy. PHN produces painful paresthesia along the dermatomal pattern affected by the Herpes Simplex virus, showing persistent resistance to analgesic pharmacotherapy.

Chronic pain related to degenerative spinal disorders and post-back surgery can often remain refractory to conservative measures and require prolonged courses of narcotic medical management. Furthermore, one source reported that 15 to 40% of patients would experience chronic back and limb pain after lumbar surgery. Many of these conditions are suggested to be treated through SCS, including failed back surgery syndrome, post-laminectomy pain, multiple back operations, peripheral causalgia, epidural fibrosis, and arachnoiditis. Vascular etiologies have also been suggested for therapy with SCS, and both inoperable peripheral vascular and inoperable angina-related pain have shown improved pain relief, quality of life, and limb mobility. While many of these painful, difficult to treat conditions, SCS has provided adequate therapy in cases refractory to conservative management and may lead to prolonged pain relief, decreased narcotic requirement, and improved quality of life.

Methods: Conducted a systemic comprehensive literature search using a collaboration of existing publications involving burst spinal cord stimulation in the treatment of chronic pain. We present the existing literature in the understanding of the safety and efficacy of burst spinal cord stimulation in pain management.

Results: Burst SCS was first tested in a 2010 study as a novel stimulation design that could reduce neuropathic pain without paresthesia, a side effect frequently observed from spinal cord stimulation. Twelve patients experiencing neuropathic pain received a spinal cord electrode implant, which administered external stimulation. Patients received traditional tonic stimulation (40 or 50 Hz) and burst stimulation (40-Hz burst with five spikes at 500 Hz/burst) separately. Burst stimulation showed promising results, as the method significantly increased pain suppression, based on the VAS and Megill Short Form score, with fewer patients exhibiting paresthesia symptoms for burst (17%) vs. tonic (92%) stimulation.

A follow-up 2013 study evaluated the efficacy of burst stimulation by comparing testing three stimulation patterns: burst, tonic, and placebo. Fifteen subjects experiencing pain received a lamitrode implant and were administered each stimulation pattern for one week. Pain intensity scores improved for burst SCS (back: 51%, limb: 53%, general: 55%) and tonic SCS (back: 30%, limb: 52%, general: 31%) compared to scores for placebo. Pain now, least, and worst pain improved for burst (Now: 50%, least: 73%, worst: 36%) and tonic stimulation (Now: 26%, least: 46%, worst: 13%). Results showed significant improvement for burst SCS vs placebo. Only burst SCS showed improved outcomes while tonic and placebo exhibited worse outcomes concerning attention to pain and pain changes.

To test the long-term safety efficacy of burst SCS, the SUNBURST was conducted. 100 participants affected by failed back surgery syndrome or radiculopathy were randomized to 12 weeks of tonic followed by 12 weeks of burst stimulation or vice versa. Assessments occurred at 6, 12, 18, and 24 weeks, and then participants would choose their preferred therapy and be assessed every 6 months to 2 years. It was demonstrated that burst stimulation was non-inferior to tonic stimulation ($p < 0.001$). Burst also showed superiority for overall VAS ($p < 0.017$), trunk VAS ($p < 0.013$), and limb VAS ($p < 0.045$). More subjects preferred burst stimulation over tonic stimulation (70.8% vs. 18.8%, $p < 0.001$). After a year, 68.2% of subjects preferred burst stimulation, 23.9% preferred tonic, and 8.0% of subjects had no preference in stimulation.

Using results from the SUNBURST trials, a 2019 study evaluated if burst stimulation was more efficacious than tonic stimulation in decreasing the reported pain. The study revealed a positive correlation for burst amplitude for "worst" and "trunk" pain on the VAS, a positive correlation for the domains of "role physical" "bodily pain, " "general health" for SF36v2, and a positive correlation for scores on the PCS. The results aligned with the original hypothesis that lower burst spinal cord stimulation amplitudes could significantly increase pain suppression in subjects.

A second post hoc analysis conducted on the SUNBURST trial evaluated how tonic and burst stimulation affected the rate of opioid consumption. Subjects had significantly lower opioid consumption at 12 months than baseline (53.94 vs. 79.19 MME, $p = 0.008$). At 12 months, 15.9% of patients originally taking opioids discontinued consumption, while the proportion of patients taking >120 MME/day decreased by 61.7% compared to baseline.

Conclusion: SCS has been FDA-approved for treatment for a primary indication of neuropathic limb pain that is resistant to more conservative medical therapy. Additional benefits of SCS therapy include reduced narcotic use, improved quality of life, and a greater chance of returning to work. The disorders qualified for treatment include neuropathic, post-surgical, post-amputation, osteodegenerative, and pain related to vascular disease. Some of the most frequently cited conditions for treatment of SCS include failed back surgery syndrome, CRPS Type I and Type II, and post-herpetic neuralgias.

➢ SCS targets hyperexcitable central neural pathways and efferent sympathetic transmission related to CRPS pain signaling. Despite these successes, some CRPS patients do not experience adequate relief, or pain control diminishes over time. Current studies also suggest that post-herpetic neuralgia can be managed through SCS therapy. Post-herpetic neuralgia produces painful paresthesia along the dermatomal pattern affected by the Herpes Simplex virus, which has shown persistent resistance to analgesic pharmacotherapy.

➢ While many of these painful, difficult to treat conditions, SCS has provided adequate therapy in cases refractory to conservative management and may lead to prolonged pain relief, decreased narcotic requirement, and improved quality of life. Burst SCS has been shown in available studies to be non-inferior to the traditional SCS, which can cause pain paresthesias in patients who already have chronic pain. Burst SCS does not seem to cause or need the paresthesias seen in traditional SCS, making SCS not tolerable to patients. Moreover, some studies suggest that burst SCS may decrease opioid consumption in patients with chronic pain. This can make burst SCS an extremely useful tool in the battle against chronic pain and the raging opioid epidemic. As of now, more research needs to be performed to further delineate the effectiveness and long-term safety of this device.

Knowledge of Opioid Treatment Patient-Provider Agreement Amongst Providers and Patients

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Background

Patient-provider agreements (PPA) for opioid therapy are documents outlining the expectations and responsibilities of patients and prescribers for the purpose of educating patients, reducing opioid misuse and improving treatment outcomes.[1] Currently, no universal standards for PPAs exist though most enumerate the risks and benefits of opioid therapy, instructions on opioid medication refills, storage and disposal, guidelines for mitigating aberrant drug-related behaviors (ADRB) (such as urine or blood drug screening) and possible consequences for violations.[1] Lack of understanding of the purpose and content of PPAs by patients may limit their effectiveness.

Measures

An anonymous true or false questionnaire was distributed to providers and patients prescribed opioids at an academic pain medicine practice. The questionnaire was designed to cover information presented in the opioid treatment PPA at the practice that included both evidence-based information on opioid treatment as well as protocols purposed for decreasing ADRB. Providers were also asked to identify their role (physician assistants, subspecialty fellows in pain medicine, or attending physicians) and their length of time practicing pain medicine. Patients were also asked if they had read the PPA or if a provider had reviewed it with them. Finally, the length of time a patient had been prescribed opioids from the clinic after initially signing the PPA was recorded.

Questionnaire

Number	True/False	Statement
1	False	It is OK to receive opioid prescriptions from multiple providers, practices, and pharmacies and patients do not have to contact this office prior to filling opioid medications from another provider.
2	True	The doctor will not replace opioids that have been reported to be stolen or lost.
3	True	When taking an opioid medication, risk of death is increased in people with liver or kidney disease, depression, or a sleep disorder.
4	True	Patient must be seen in the practice at least every 3 months.
5	False	Opioid medications can be filled on nights, weekends, or holidays.
6	True	Patients must call or send a message at least 3 business days in advance of when you need a refill.
7	True	Unused medications should be disposed in a state or federally approved drop box or take back program.
8	False	A woman of childbearing age does not need an effective form of birth control while taking opioids.

Outcomes

- The average percent correct on the questionnaire for providers (91.07%) was higher than for patients (76.8%)
- Time exposed to the practice of pain medicine (time spent in practicing for providers and time receiving opioids under medical management for patients) was a poor predictor of percent correct on the questionnaire for both groups ($r^2 = 0.01$ for both providers and patients)
- The majority of patients (8 patients, 72.7%) stated that they had read the opioid agreement and that a provider had reviewed it with them

Conclusion

Improving knowledge of the opioid treatment PPA may help to optimize its role in mitigating opioid misuse and improving treatment outcomes. Guidelines for the formation and implementation of opioid treatment PPA requires further investigation.

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Cleveland Clinic

Sphenopalatine Ganglion Blocks Disrupt the Cycle of Chronic Daily Cluster Headaches

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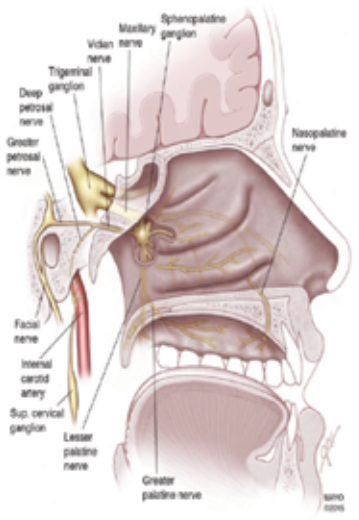
Background

- Cluster headaches cause severe pain that is reportedly worse than the pain associated with childbirth [1].
- The attacks are strictly unilateral with a typical duration of 15-180 minutes, and commonly associated with lacrimation and conjunctival injection [2].
- Typically, the attacks are clustered in daily cycles of only a few months duration [3].
- The individual attacks involve activation of the trigeminal-autonomic reflex [3].
- The sphenopalantine ganglion provides a rational treatment target for trigeminal autonomic cephalagias, due to its role in the trigemino-autonomic reflex [4,5].

Case Presentation

A 71 year old male with no prior history of traumatic brain injury presented to our pain clinic with a history of chronic cluster headaches. The headaches have been present for more than 1 year in duration and almost always occur at night, awakening him from sleep. The headaches are located just below the left eye. The pain is described as throbbing and piercing in character and is associated with lacrimation and conjunctival injection of his left eye. He denies photophobia or sensitivity to sound. Over the time, the headaches have developed from every several nights (episodic) to every night (chronic) and last for approximately one hour in duration. Oxygen provides only temporary relief. He has failed conservative management including NSAIDs, calcium channel blockers, beta blockers, botox, anticonvulsants, triptans, and monoclonal antibodies.



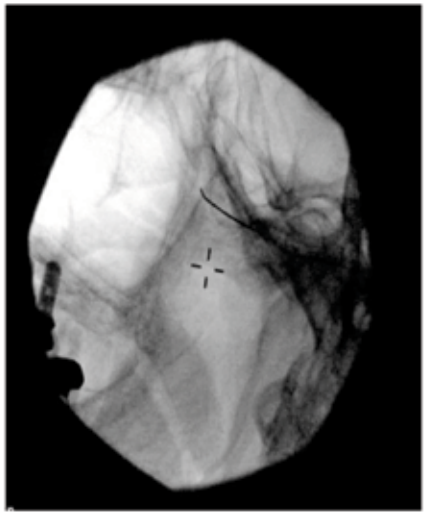


Figure 1. Anatomy of sphenopalantine ganglion and connections. Figure 2. Fluoroscopy guided sphenopalantine ganglion block with lateral image and needle through coronoid notch.

Results and Discussion

A series of three sphenopalatine ganglion blocks, with a combination of local anesthetic and dexamethasone, broke the daily cycle of chronic intractable cluster headaches in a patient who has previously failed medical management. The sphenopalatine ganglion was accessed using a lateral fluoroscopic technique through the coronoid notch. After the series of local anesthetic and steroid blocks, the patient can go 3-4 days without a headache, and sometimes up to 5 days without symptoms. His frequency of cluster headaches was reduced from 100% of nights to approximately 40% of nights. Now, he is able to control his existing cluster headaches with acetaminophen, oxygen, and frovatriptan. The durability of his injections is approximately 60 days in duration.
To date, SPG blocks have largely been used for abortive therapy for acute cluster headache attacks. We demonstrate that they are also helpful in converting chronic into episodic cluster headaches by disrupting the vicious cycle from dysregulated parasympathetic stimulation.

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Symptomatic Pneumocephalus:
A Systematic Review and Analysis

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Introduction

Epidural injections continue to grow as a part of interventional pain, labor analgesia, and multimodal approach to anesthesia practices. Epidural injections are typically safe and reliable but are not without potential complications. Headache is the most common side effect of epidural injection and often originates from inadvertent dural puncture. The incidence of inadvertent dural puncture during epidural injection is upwards of 3.6% (15). Headache after epidural or "wet tap" may be due to post-dural puncture headache (PDH) or pneumocephalus. PDPH after "wet tap" is more common with an incidence of up to 88% (16). A rarer, more elusive diagnosis is symptomatic pneumocephalus which typically presents with a more rapid onset, non-positional headache. It is vital to note the differences in presentation between PDH and pneumocephalus because of the differences in management between the two.

Epidural access utilizing loss-of resistance to air (LORA) is a commonly used technique. This technique vastly increases the risk of pneumocephalus (2). In the event of inadvertent dural puncture during LORA technique, air is entrained into the intrathecal space resulting in some degree of pneumocephalus. Roderick et al. demonstrated that less than 2cc of intrathecal air can lead to symptomatic pneumocephalus (14). Many factors contribute to the degree of symptoms and the presentation of pneumocephalus. It has previously been hypothesized that the amount of intrathecal air correlates with onset and duration of symptoms, however, it remains unclear if this correlation truly exists clinically. Within this report, we present a systematic review and analysis of pneumocephalus following incidental intrathecal injection of air.

Objective

The objective of this review is to assess the clinical significance of the amount of intrathecal air injected during inadvertent dural puncture and its effects on the symptoms onset and duration in cases of pneumocephalus.

Case	Air Injected (ml)	Symptom Onset (minutes)	Symptom Duration (hours)
Han et al (13)	9	60	96
Kim et al. (12)	8	30	24
Jung et al (11)	4	5	120
Kim et al (10)	1	4	504
Nune et al (9)	3	<1	312
Mateo et al (8)	7	<1	0.1
Jagla et al (7)	10	<1	0.5
Guarino et al (6)	2	20	0.25
Kim et al (5)	2	<1	4
Ros et al (4)	3	1	120
Sachdeva et al (3)	3	360	240
Verdun et al (17)	5	15	18
Park et al (18)	1	10	24
Park et al (18)	1	60	22

Table 1. Data collected upon systematic review of literature comparing amount of air injected into intrathecal space to onset and duration of symptoms.

Results

A total of fourteen (n=14) cases among 13 publications were analyzed. When comparing the amount of intrathecal air to the duration of symptoms in patients with symptomatic pneumocephalus, we found no statistically significant correlation $r_s = -0.23$, $p = 0.42$ (Figure 1). When comparing the amount of intrathecal air to the time to onset of symptoms in patients with symptomatic pneumocephalus, we, likewise, found no statistically significant correlation $r_s = -0.13$, $p = 0.65$ (Figure 2). Pearson correlation coefficient was considered as a statistic measure, however, coefficient of determination resulted in nonlinearity between variables. In this systematic review and analysis, we accept the null hypothesis that the amount of intrathecal air injected during inadvertent dural puncture has no effect on symptom onset or symptom duration in cases of symptomatic pneumocephalus.

Conclusion

Symptomatic pneumocephalus has been described with a wide range of clinical presentations. Literature review shows a spectrum of severity, onset, and duration of symptoms associated with pneumocephalus (Table 1). In cases of symptomatic pneumocephalus during epidural injection, headache is the most common symptom and onset is often immediate. However, symptom onset has been reported as late as two days after initial inadvertent dural puncture and intrathecal entrainment of air. Resolution of symptoms has been reported between ten minutes and two weeks after onset. The amount of air injected into the intrathecal space has previously been hypothesized to correlate with onset and duration of symptoms of pneumocephalus, however, we find no statistically significant correlation to support this claim.

These findings are limited to inadvertent dural puncture with LORA during epidural injection and air injectate of less than 10cc (typical loss of resistance syringe). In addition, the symptoms onset/duration in pneumocephalus may be multifactoral. Our data was limited by the number of published case reports that provided the data required for inclusion. Future researchers may investigate correlations between amount of air injected intrathecally and severity of symptoms or occurrence of associated symptoms.

Methodology

Data was collected via literature review. Cases included in this review provided data on the amount of air injected into the intrathecal space during attempted epidural injection, time to onset of symptoms, duration of symptoms, and confirmation of pneumocephalus via CT after attempted epidural injection. Fourteen cases were found which included all of these criteria (Table 1). Cases excluding any one of these data points were excluded. The alpha value was set at 0.05. Statistical analysis was performed using R statistical software. Spearman correlation was used to determine correlation coefficient between amount of intrathecal air injected vs time to onset of symptoms of pneumocephalus and amount of intrathecal air injected vs the duration of symptoms of pneumocephalus.

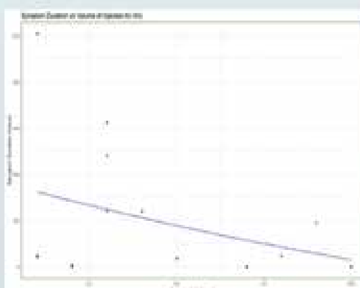

Figure 1. Duration of Symptoms vs Amount of Intrathecal air

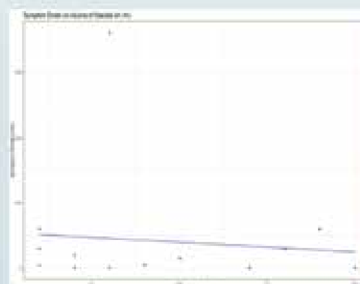

Figure 2. Time to Symptom Onset vs Amount of Intrathecal air

Cited

An Unusual Mimic Of Tarlov Cyst Causing Pain- A Case Report And Literature Review From a Pain Physician Perspective

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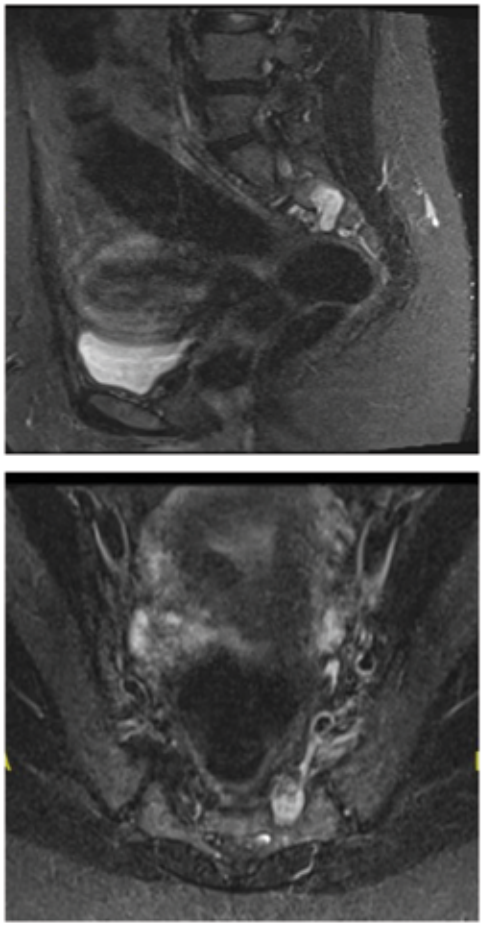
INTRODUCTION

- Tarlov cysts (TC) are defined as CSF-filled saccular lesions located in the extradural space of the spinal canal and are formed within the nerve root sheath at the dorsal root ganglion.
- TC are typically located at the junction of the dorsal ganglion and the posterior nerve root and usually develop between the endoneurium and perineurium of the nerve root. TC are classified as Type 2 Spinal meningeal cysts.
- These cysts are predominantly found in the sacral region but can also be found in the other regions in the spine.
- TC are predominantly seen in females. The prevalence of TC is about 4.6% in the general adult population. About 70% of these cysts are asymptomatic, 17% have additive effects on other pathological entities and only 13% are symptomatic.
- TC are more often seen in patients with connective tissue disorders like Marfan syndrome or Ehlers-Danlos syndrome.
- The cause of TC is not clear. Many theories have been proposed, and the most important ones include TC resulting from: increased hydrostatic and pulsatile pressure in the spinal canal, inflammation of nerve root cysts followed by inoculation of fluid, arachnoidal proliferation along and around the sacral nerve root, breakage of venous drainage in the perineurium and epineurium secondary to hemosiderin deposition after trauma, and developmental or congenital origin.

CASE DESCRIPTION

- 40-year-old female presented to Interventional Pain Clinic with a 2-month history of severe perineal pain and numbness concerning for pudendal neuralgia.
- Other symptoms included urinary retention and constipation.
- MRI of her sacrum done a few weeks prior at the Emergency Department showed features of TC at the S2 level.
- Neurosurgery there referred her to Gynecology who then referred her to Interventional Pain Clinic.
- Physical exam in clinic showed bilateral hip flexion weakness, decreased perineal sensation, and decreased rectal tone.
- She was subsequently referred to neurosurgery emergently who performed sacral laminectomy.
- Intraoperatively she was found to have an epidural tumor that was resected along with a lesion at the S2 nerve root that was biopsied.
- Epidermal lesion was diagnosed as Ewing's sarcoma and S2 lesion was diagnosed as a reactive fluid.
- She was eventually seen by oncology with plans for further staging followed by chemo-radiotherapy.



MRI Sacrum T2 STIR Sagittal (above) and Axial (below)

DISCUSSION

- Misconception exists that TC are asymptomatic and incidental findings.
- However, if the signs/symptoms correlate with the level of the TC then it should be considered in the differential diagnosis.
- Signs/symptoms include pain, weakness, paresthesia, numbness, dyspareunia, coccygodynia, constipation/diarrhea, bladder dysfunction (urinary retention/frequency), cauda equina syndrome, headache.
- MRI is diagnostic modality of choice for TC – appear hypointense on T1-weighted images, hyperintense on T2-weighted images, and show no enhancement with gadolinium contrast.
- Sometimes other cystic lesions (i.e., schwannoma, abscess, etc.) can be misread as TC on MRI, like in our case.
- Red flag symptoms (i.e., neurological deficits, unremitting pain) should prompt further evaluation and need for histopathological diagnosis.
- No consensus exists regarding management of symptomatic TCs.
- Many believe treatment is indicated when TC are >1.5 cm in diameter and/or symptomatic.
- Conservative treatment with PT and medication (analgesics, NSAIDs) is often helpful.
- Epidural steroid injection can be considered if conservative treatment fails.
- In refractory cases, CT-guided percutaneous cyst drainage, tissue adhesive injection into the cyst, or open surgery with sacral laminectomy/laminoplasty followed by microsurgical resection of the wall of the cyst(s) can be considered.
- Lumbo-peritoneal shunt has also been suggested for patients with multiple TCs when it is difficult to determine which one is symptomatic.

CONCLUSION

- TC are often classified as incidental findings; however, they should be considered as the source of a patient's pain when the signs and symptoms correlate with the level of the TC.
- Red flag symptoms should prompt further evaluation and need for histopathological diagnosis as imaging alone can lead to misdiagnosis.
- Treatment options for symptomatic TC vary and range from conservative measures to more invasive surgical modalities.
- Prompt recognition of TC as the culprit of a patient's symptoms is necessary to determine the most appropriate next step in management.

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Repeated fluoroscopic guided Pulsed Radio frequency ablation in the treatment of Pudendal Neuralgia, a case series

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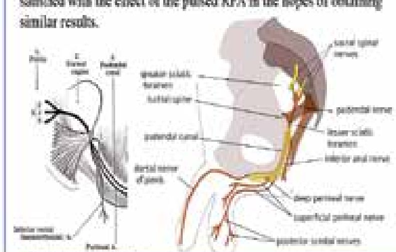
BACKGROUND

Pudendal neuralgia (PN) can be a very debilitating form of pain that impacts 4% of patients suffering from chronic pelvic pain (1). Generally the incidence of this condition is considered a rare event – 1/100,000, however, most physicians treating patients with this condition feel the actual rate of incidence may be significantly higher. Pudendal neuralgia continues to be poorly recognized and poorly treated. Patients with pudendal neuralgia are often presented with disabling pain affecting their daily activities and quality of life. The most common causes of pudendal neuralgia are birth trauma, prolonged sitting on hard surfaces, prolonged straddling (i.e. bikes or horseback), infection, blunt trauma, and following pelvic surgeries. Pudendal neuralgia is mainly a clinical diagnosis based on the five Nantes Criteria (2), including:

1) Pain in the anatomical territory of the pudendal nerve,
2) Pain worsened by sitting,
3) Pain that does not wake the patient from sleep,
4) No objective sensory loss on clinical examination,
5) Positive anesthetic pudendal nerve block.

Treatment of pudendal neuralgia (3) has been multidisciplinary including medications (NSAIDs, antidepressants, anticonvulsants), pelvic floor physical therapy, behavioral modifications, pudendal nerve blocks, pulsed radiofrequency ablation (pRFA), neuromodulation (such as spinal cord stimulation), and finally surgical decompression and release. The rationale of using pulsed RFA is to lower the risk of motor function of the nerve and avoid sexual, bowel, or bladder dysfunction from semi-permanent damage to nerve and neuritis, while still having pain relief from the ablation. Oftentimes patients asked to repeat the procedure as they were satisfied with the effect of the pulsed RFA in the hopes of obtaining similar results.

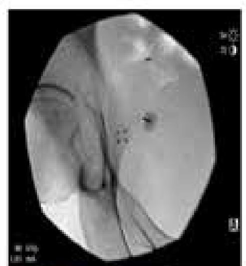


OBJECTIVES

The primary objective of this case series is primarily to demonstrate the efficacy and safety of pulsed RFA for the treatment of pudendal neuralgia. Secondly, this case series will demonstrate the long term effect of repeating the minimally invasive technique on patients symptoms and quality of life. A third objective of this case series is to describe the fluoroscopic guided pulsed RFA technique. Finally, this case series will demonstrate an improvement in the quality of life of patients after repetitive pulsed RFA.

METHODS

Chart review of 6 female patients with pudendal neuralgia who underwent pulsed RFA of the pudendal nerve . Eligible patients for pulsed radiofrequency ablation are those clinically diagnosed with pudendal neuralgia, failed conservative management medications, and had successful 2 pudendal nerve blocks with pain relief more than 50% for several weeks.



TECHNIQUE

After the patient signs the informed consent, the patient is placed in the prone position. Monitors are placed including pulse oximetry, noninvasive blood pressure, and electrocardiogram. The gluteal region is prepared with a sterile solution, and draped in a sterile manner. Intravenous sedation, typically with fentanyl and midazolam, is administered incrementally to allow the patient to remain comfortable and conversant throughout the procedure. The C-arm fluoroscopy is positioned to obtain an optimal ischial spine view in an anteroposterior (AP) view.

The skin entry site is identified and skin anesthesia is achieved using 2 cc of lidocaine 0.5%. Then, a 22-gauge 100mm radiofrequency cannula with a 5 mm straight active tip is slowly advanced towards the ischial spine. Once the needle tip touches the ischial spine, the needle is then slowly walked off medially and downward. A lateral view of the pelvis is then obtained to confirm the correct position. Negative aspiration of blood and fluid is required. The pulsed radiofrequency cannula is then advanced into the needle and sensory and motor stimulation testing is done. Sensory stimulation should produce paresthesia at the anoperineal area with less than 0.5mV with 50 Hz frequency at a 1 msec duration. Motor testing should be negative at voltage less than 1.5mV and 2 Hz. Once testing is complete, 1cc of 2% lidocaine is injected and after 1 minute, pulsed radiofrequency ablation at 42 degrees Celsius for 120 seconds. Once completed, 2cc of 0.5% bupivacaine is injected.

	Average	Median	Range	Std Dev
Age (yrs)	44.50	40.5	26-73	16.40
BMI	26.17	28	19-30	4.31
# of PN pRFA	4.67	5	4-5	0.52
% Pain Relief	82.5%	82.0%	75%-90%	6.89%
Duration of Relief (months)	7.50	6.5	6-12	2.35
VAS Pre-procedure	7.33	8	5-9	1.51
VAS Post-procedure	1.33	1.5	0-3	1.21

RESULTS

From 2017 to 2021, 6 consecutive female patients underwent repeat pudendal nerve pulsed RFA. The patients' age ranged from 26-73 years with an average of 44.5 years old. The patients' BMI ranged from 19 to 30, with an average BMI of 26.2. The patients' number of pulsed RFA performed ranged from 4-5, with an average of 4.7. The patients had a range of 70 to 90% pain relief from each pulsed RFA with an average of 82.5% relief. The duration of relief ranged from 6 to 12 months with an average of 7.5 months. The average time between pulsed RFA was 250 days and ranged from 161 days to 454 days. The mean VAS scores at baseline was 7.33, ranging from 5 to 9 and a standard deviation of 1.51. The mean VAS scores post pulsed RFA was 1.33, ranging from 0 to 3, with a standard deviation of 1.21. This was statistically significant, comparing post pulsed RFA VAS score to baseline VAS score at a P<.0001 using a paired t test.

In person office follow-up or phone follow up was conducted after each pulsed RFA to assess for pain relief, side effects, complications, and quality of life. All patients received bilateral pudendal nerve pulsed RFA. There were no immediate, or long-term procedure related side effects or complications. All patients did promote improvement in their symptoms, including relief of burning sensation, deep pelvic pain and dyspareunia, as well as improvement in quality of life and sexual life. This shows that in this small sample size (n=6), safety is demonstrated as has been shown in other published literature (4).

CONCLUSIONS

Pulsed RFA is a safe and effective minimally invasive technique for longer term management of pain in patients with pudendal neuralgia. Future research to validate the efficacy of repeated fluoroscopic guided pulsed RFA of the pudendal nerve for pudendal neuralgia should be conducted in a carefully selected patient population and well-designed randomized control trials.

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2. [illegible]
3. [illegible]
4. [illegible]
5. [illegible]

Real-World Evaluation of Patients Using an Interspinous Spacer for the Treatment of Lumbar Spinal Stenosis

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6. Piedmont Interventional Pain Center, Salisbury, NC USA 7. Pacific Sports and Spine, Eugene, OR USA 8. Axis Spine Center, Coeur D'Alene, ID USA 9. California Orthopedics and Spine, Novato, CA USA 10. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Indirect Decompression Systems (IDS) or Interspinous Spacers are an option in well-selected patients with impaired physical function who experience relief in flexion from symptoms of leg, buttock and/or groin pain due to lumbar spinal stenosis (LSS). A growing body of published clinical evidence has demonstrated excellent long-term clinical benefit with sustained pain relief, improved quality of life and medication reduction up to 5 years post-implant.[1-3]

Real-world reports demonstrated excellent long-term clinical benefit for patients including leg pain responder rate and pain severity of 75% and 60% respectively at 12 months post operation.[4]

Here, we provide real-world outcomes in patients with severe pain who received an Indirect Decompression System (IDS) for LSS related pain and symptoms as part of an ongoing multi-center observational case series

METHODS

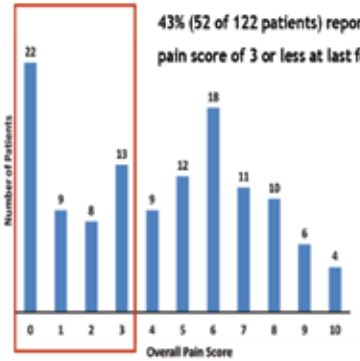
Study Design	Multi-center, observational case-series. Data collected by site personnel only
Study Device	Superion Indirect Decompression System (Boston Scientific) 
Subjects	122 patients with severe pain (8 or above) at 9 centers who received IDS for their Lumbar Spinal Stenosis (LSS)

RESULTS

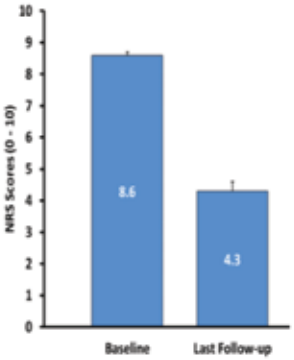
Baseline Characteristics (n = 122)

Gender - Females (%)	65% (79/122)
Age [Mean (SD)]	71.3 (11.6) years n = 118
Baseline NRS [Mean (SD)]	8.6 (0.8) n = 122
Follow up Duration [Mean (SD)]	127 (168) days n = 122
Diagnosis	Lumbar Spinal Stenosis
Gender - Females (%)	65% (79/122)

Distribution of pain scores at last follow-up (n = 122)



Overall Pain Scores (n = 122)



A 4.4-point improvement (8.6 → 4.3, p<0.0001) was reported at last follow-up (mean = 127 days) among patients with severe pain at Baseline (8 or more)

78% (95 of 122) of patients reported a clinically significant* improvement in their overall pain at last follow up

*≥ 2-point improvement in pain scores (NRS)

CONCLUSIONS

- Results from this ongoing real-world observational case-series of severe pain patients (8 or more on NRS) who received an IDS for the treatment of their LSS symptoms demonstrated at last follow up (mean = 127 days):
  - 4.4-point improvement in overall pain (8.6 → 4.3, p < 0.0001)
  - 78% reported a clinically significant improvement in pain (≥ 2-point improvement)
  - 43% reported a pain score of 3 or less
- This preliminary evidence aligns with data from previous reports in the peer-reviewed literature.

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DISCLOSURES

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AM2022


MEDICARE CLAIMS STUDY:
mild® VS. BENCHMARK LSS PROCEDURES
PETER S. STAATS, MD, MBA
mild
OBJECTIVE
To evaluate mild® and benchmark lumbar spinal stenosis (LSS) procedures using real-world Medicare claims data to assess rates of procedure-related harms and subsequent procedures for LSS patients suffering from neurogenic claudication.
METHODS
mild® Procedure (n=1,777)
Spacers without open decompression (n=2,544)
Spacers with open decompression (n=817)
Surgical decompression (n=10,507)
Data was extracted from the Medicare Research Identifiable Files (RIFs) containing all claims for 100% of Medicare beneficiaries during 24-month follow up.
REAL-WORLD DATA
SAFETY
% of patients experiencing at least one harm
EFFICACY
% of patients undergoing at least one subsequent LSS intervention
RESULTS
mild® patients experienced the lowest rate of harms and the lowest rate of subsequent lumbar spine interventions compared to all other cohorts.
PRESENCE OF HARMS (predominately mechanical complications or wound problems)
SUBSEQUENT LUMBAR SPINE INTERVENTION
4.8%
mild® Procedure
26.2%
11.6%
Spacers without open decompression
27.7%
16.0%
Spacers with open decompression
49.7%
11.6%
Surgical decompression
35.0%
2.4-3.3x
MORE HARMS THAN mild®
CONCLUSION
The robust safety profile and lowest rate of subsequent interventions supports mild® as:
THE GOLD STANDARD OF CARE
+
FIRST-LINE THERAPY FOR LSS*

S1 Nerve Root Block Associated with Sacroiliac Joint Injection: A Case Series

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Introduction

Sacroiliac (SI) joint injection is considered a gold standard diagnostic study as well as therapeutic treatment for sacroiliac joint dysfunction. The SI joint injection is commonly performed under fluoroscopic guidance. Although this procedure is relatively safe, there are associated complications including exacerbation of pain, vasovagal reactions, injection site soreness, and facial flushing and/or sweating.

Another common complication is temporary numbness and weakness in the leg. This weakness is likely associated with S1 nerve root blocks and should resolve in a couple of hours after the procedure depending on the type local anesthetic used. There are some theories as to how this occurs, such as defects in the capsule allowing leakage of injectates into the nearby neurovascular bundles.[1]

This case series reveals the path of contrast spread from the SI joint into the S1 posterior neuroforamen.

Methodology

Four patients with history and physical examinations consistent with sacroiliac joint dysfunction underwent SI joint injections under fluoroscopic guidance with cone beam CT imaging capability. (GE Discovery IGS7 with 3D image fusion capability.) (See table)

The procedures details were as follow: The patient was positioned prone. The gantry was rotated to an oblique view until the sacroiliac joint is visualized. The target for the sacroiliac joint was the upper portion of the posterior sacroiliac joint. The needle entry site was sterilized with lidocaine 1%. A 22 G spinal needle was used to advance into the sacroiliac joint under fluoroscopic guidance. 1 mL of contrast was injected through the needle. Cone beam computed tomography (CT) images were acquired to evaluate accuracy of needle placement and contrast spread in the SI joint. Once the needle placement is confirmed, 4 mL of mixture of bupivacaine 0.25% with or without corticosteroid was injected.

The CT images were reviewed to study the contrast spread in the sacroiliac joint and its flow outside of the joint. (Fig. 1)

Results

Patient	History and Physical Exam	Results and Images (Fig. 1)
A	• 64 y/o male • History of lumbar fusion • Pain localized to PSIS • Hx of SI joint injections with mild relief for 2 weeks	Contrast flow was noted in the right sacroiliac joint with spread into in the right S1 posterior neuroforamen
B	• 47 y/o male • Failed conservative management • Received SI joint injections with some relief • Positive Patrick's and Gaenslen's tests • Tenderness to palpation at left PSIS	Contrast flow was noted in the left sacroiliac joint with flow into the left S1 posterior neuroforamen
C	• 60 y/o male • History of spinal stenosis, L4-S1 lumbar fusion • Lower back pain with radiating pain down left leg	Contrast flow was noted in the left sacroiliac joint with flow into the left S1 posterior neuroforamen
D	• 63 y/o female • Chronic low back pain • History of SI joint injection with 6 months of relief • Positive Fortin finger sign	Contrast flow was noted in both sacroiliac joints with flow into the right posterior S1 neuroforamen

Fig 1: Arrows indicating contrast spread tracking from the sacroiliac joint into the posterior S1 neuroforamen

Fig 2: Cone Beam CT (left) demonstrating contrast spread in the left sacroiliac joint tracking into the left posterior S1 neuroforamen. The same axial plane on the lumbar spine MRI (right) demonstrating posterior sacroiliac ligament which corresponds to this contrast track.

Discussion

The sacroiliac joint is secured by intrinsic and extrinsic ligaments. The intrinsic ligaments of the joint connect the ilium to the sacrum. The posterior sacroiliac ligament (PSIL) runs from the posterior superior iliac spine to the various posterior segments of the sacrum.

Comparing MRIs and CT scans, we observed that the contrast follows the PSIL from the SI joint to the sacrum. In figure 2, the cone beam CT demonstrates contrast spread from the right sacroiliac joint to the right posterior S1 neuroforamen. On the same axial plane, the lumbar spine MRI demonstrated the posterior sacroiliac ligament which corresponds to this contrast path.

In this case series we visualized the contrast spread from the SI joint, into the posterior S1 neuroforamen. A lower concentration of local anesthetic should be considered to decrease the risk of a S1 nerve root block. When a diagnostic SI joint injection is required for a SI joint fusion an appropriate evaluation should be considered to rule out SI pathology as a significant pain generator to improve the specificity of this test, and the outcome of SI joint fusion surgeries.

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Novel Treatment of Muscle Tension Dysphonia Secondary to Post-Acute COVID-19 Syndrome Associated with Chronic Cough and Laryngeal Dysfunction

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Introduction

The coronavirus disease 2019 (COVID-19) is a Betacoronavirus, a genus of the coronavirus family. COVID-19 virus is transmitted person-to-person via respiratory droplets from other human sources who are in close contact with each other. It leads to the destruction of alveoli as well as the induction of a cytokine storm, which increases the inflammatory response and can become fatal in some patients with a severe infection and heavy viral load. Post-Acute COVID-19 is a syndrome that is now recognized and characterized by the persistence of clinical symptoms beyond four weeks from the onset of acute symptoms, with a common symptom being a chronic cough. COVID-19 enters the nervous tissue through retrograde and anterograde transport along peripheral nerves and can infect neurons through the TMPRSS2 (transmembrane protease serine 2) and ACE2 (angiotensin I-converting enzyme-2) receptors. The virus can then be transported through the vagus and trigeminal nerves, causing them to become susceptible of developing inflammation from the effects of the virus on the innate immune system. These two nerves are involved in the development of chronic cough in Post-Acute COVID-19 syndrome. One important documented symptom of Post-Acute COVID-19 syndrome that is associated with chronic cough, is muscle tension dysphonia due to laryngeal dysfunction. Muscle tension dysphonia is a common disorder of your voice even if your vocal cords are unharmed. Muscle tension dysphonia commonly occurs after a viral infection, such as COVID-19, due to the virus affecting the nerves that innervate the muscles and the release of inflammatory cells that subsequently cause further dysfunction. When muscle tension dysphonia occurs, there is an imbalance in the normal tension of extrinsic and intrinsic laryngeal musculature relationship, which causes an improper position of the larynx (21). This results in tension on the vocal folds and intrinsic muscles. This tension causes difficulty with phonation, swallowing, and breathing (21). The decreased pressure of breath that could also cause muscle tension dysphonia, can be seen due to respiratory infections that disrupt normal airflow and gas exchange. Muscle tension dysphonia should be suspected in a patient presenting with chronic cough and other laryngeal dysfunction after a COVID-19 infection.

Case Report

We herein report three cases of suspected muscle tension dysphonia secondary to Post-Acute COVID-19 syndrome with associated chronic cough and other laryngeal dysfunction.

Case #1

A 22-year- old African American woman presents to the pain management clinic with complaints of chronic, debilitating cough post-COVID infection and pain in her neck from the cough. Her voice had become deeper, and she was unable to hit the high notes while singing like she once was able to do. She was administered a trigger point injection consisting of 1 cc Bupivacaine in the digastric muscles, mylohyoid muscle, and sternocleidomastoid muscle, bilaterally. Her voice was restored to normal after the injection. She returned to the office one week later, two weeks later, and three weeks later where she received repeated injections in the same trigger points with 1 cc of Bupivacaine, with the addition of dexamethasone. Her cough symptoms improved gradually after each week of injections with complete resolution by the 4th week.

Case #2

A 36-year-old Caucasian female presents to the pain management clinic with complaints of chronic cough post-COVID that was unresponsive to a round of oral steroids from her primary care physician. She experienced extreme pain in her neck from the chronic cough as well as a deepened voice. She was administered a 2 cc trigger point injection consisting of bupivacaine and dexamethasone in the digastric muscles, mylohyoid muscle, and sternocleidomastoid muscle, bilaterally. After the first round of injections, her voice had completely normalized. She returned the following week to receive another round of trigger point injections in the same areas, and afterwards had complete resolution of her cough.

Case #3

A 50-year-old Caucasian male presents to the pain management clinic with severe neck pain secondary to a debilitating, chronic cough post-COVID. He was given a 2 cc trigger point injection of bupivacaine and dexamethasone in the digastric muscles, the mylohyoid muscle, and the sternocleidomastoid muscle, bilaterally. He had partial resolution of his cough and neck pain after the first injection. He returned to the clinic one week, two weeks, and three weeks later to receive further trigger point injections in the same areas. By the final appointment there was complete resolution of his symptoms.

Discussion

The rapid clearance of immune complexes and viral particles is necessary to maintain immune homeostasis and for resolution of inflammation (20). Since recent studies have found decreased alveolar macrophages in bronchoalveolar lavage of patients with severe COVID-19 infection, and due to macrophages role in resolving inflammation in the localized area, it can be postulated that the reduction in alveolar macrophages in these patients can contribute to a prolonged inflammatory response. The prolonged inflammatory response can thus chronically sensitize and alter the responsiveness of afferent vagal nerve fibers of the airway, contributing to hyperactive stimulation of these fibers which could lead to excessive cough reflex. This could be an explanation of the chronic cough experienced by patients with Post-Acute COVID-19 syndrome. Chronic cough can also be thought to occur secondary to muscle tension dysphonia. The TMPRSS2 (transmembrane protease serine 2) and ACE2 (angiotensin I-converting enzyme-2) receptors are found in neurons, which means that the virus can be transported through the vagus and trigeminal nerves; both of which are important for innervating the extrinsic and intrinsic laryngeal muscles. The inflammation and dysfunction of said muscles, along with the inflammation of the vagus nerve and the supposed immune suppression due to alveolar macrophage destruction can all contribute to the development of muscle tension dysphonia with further susceptibility of developing chronic cough that is seen in Post-Acute COVID-19 syndrome. Suppressing the inflammation and treating the pain related symptoms by administration of Bupivacaine and Dexamethasone can sufficiently inactivate trigger points, which could be effective in reducing symptoms caused by Post-Acute COVID-19 syndrome muscle tension dysphonia. Suppressing the inflammation could also aid in stabilizing the immune system homeostasis due to the alveolar macrophage dysfunction and subsequent impaired ability to clear the inflammatory residues in the respiratory system. This is helpful, as the retained inflammatory residues are thought to be partly to blame for the persistent, chronic inflammation even after the virus has cleared from the body. As such, trigger point injections not only may benefit in symptomatic control, but also in potentially eliminating Post-Acute COVID-19 syndrome. Our patients presented with neck pain, voice hoarseness and deepening, and chronic cough after being infected with COVID-19 virus. They each displayed symptoms consistent with muscle tension dysphonia. As a result, they were treated with bupivacaine, a local anesthetic and dexamethasone, a corticosteroid in the areas of muscle tension dysfunction that were contributing to their symptoms. Two of our patients found 100% resolution of cough, pain, and voice changing symptoms after the first trigger point injection. The third patient had at least 50% resolution after the first injection, with complete resolution by the 4th.

Conclusion

The improper balance of muscle tension between the muscles involved in dysphonia in conjunction with the inflammation and hyper-sensitization of the afferent fibers of involved muscles, can make muscle tension dysphonia due to COVID-19 infection a good candidate for trigger point injections. Trigger point injections have been demonstrated to be effective in inactivating trigger points. They are believed to cause a temporary relaxation of the taut muscle cord, which in turn allows for improved perfusion, ATP replenishment to release the actin-myosin chains causing lengthening of the muscle fiber, along with removal of metabolite waste (26). These factors assist in breaking the pain-tension cycle (26). Three of our patients displayed symptoms consistent with muscle tension dysphonia, a documented complication of COVID-19 infection that could persist even after the virus has cleared from the body. The intrinsic and extrinsic muscles of the larynx are innervated by the vagus nerve, and branches of the trigeminal nerve, respectively. Research has found that COVID-19 can potentially inflame the vagus and trigeminal nerves due to the expression of angiotensin-converting enzyme II receptor on neurons. This inflammation can cause dysfunction in the muscles that are innervated by the nerves, resulting in the imbalance of muscle tension and pressure, ultimately making the individual susceptible to developing muscle tension dysphonia. COVID-19 as also been found to irritate, sensitize, and inflame the vagus nerve afferent fibers directly, while also infecting and destroying alveolar macrophages, further contributing to the development of a chronic cough due to unopposed inflammation and sparse immune suppression response. All three patients received multiple rounds of trigger point injections into the sternocleidomastoid muscle, digastric muscles, and mylohyoid muscle, bilaterally. The trigger point injection consisted of bupivacaine and dexamethasone. Two of our patients had complete resolution of their symptoms after the first injection, whereas one of our patients had 50% resolution after the first injection, with complete resolution after the final injection. Physicians should be made aware of this potential side effect, as it is a diagnosis of exclusion and could therefore take time to properly diagnose.

References

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Complications of Spinal Cord Stimulation Trials: A Retrospective Review

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BACKGROUND

- Spinal cord stimulators have been used to target the gate theory of pain since 1967.[1] Typically, prior to proceeding with surgical implantation of the device and electrode leads, an interventionalist will perform a trial of stimulation. The trial lasts about one week and is used assess the patient's response to the intervention.
- Implantation of electrodes in spinal cord stimulation trials is usually performed percutaneously via a translaminar epidural approach. The leads are left external and covered with surgical dressing.
- Overall, the rate of complications associated with spinal cord stimulation has been reported to be 30-40%, with complications divided in to hardware or biological related groups.[2] However, these studies do not distinguish if the complication occurred in a trial or implantation.

Hardware Related	Biological
Lead Migration (15.49%)	Device Related Pain (6.15%)
Lead Fracture/Malfunction (6.37%)	Infection (4.89%)
Battery Failure (1.7%)	Hematoma (0.3%)
	Dural Puncture Headache (0–0.3%)
	Neurologic Damage (0.03%)

Table 1: Reported complications associated with spinal cord stimulation[2]

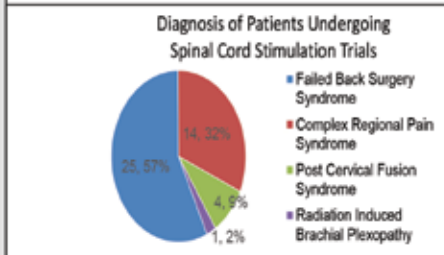
- One previous study mentioned complications specific to spinal cord stimulation trials where 5/707 (0.7%) of subjects experienced lead migration. There were no infections or other hardware related complications reported for.[3] However this study did not provide further details, such as average trial duration.
- There are case reports describing epidural hematoma after lead placement, and after removal, of the percutaneous leads.[4,5]
- To our knowledge this is the first study that is specific to complications associated with spinal cord stimulation trials in the clinical setting.

METHODS

- Ongoing retrospective single center study, IRB approved
- Records were identified using the Current Procedural Terminology code 63650 over a 3 year period from 2018-2021.
  - Percutaneous implantation of neurostimulator electrode array, epidural
- Subjects were included if they are aged over 18 years, and have met clinical criteria for and consented to proceed with spinal cord stimulation.
- Individuals who are not yet adults, pregnant women, or prisoners were excluded.

RESULTS

- ~50% (n=44) of identified cases have been reviewed.
- 54.5% of subjects were male. The most common underlying diagnosis was failed back surgery syndrome (57%).
- On average, the trials lasted 8.1 days.
- One subject (2.3%) reported device related pain at the lead insertion site. There were no other reported complications, including infection or lead migration.



CONCLUSION

- Spinal cord stimulator trials are likely a safe procedure, with a low risk of hardware related or biological complications. This is likely due to the short duration of the trial, which averaged 8.1 days in our retrospective review.
- There is limited published information regarding the rate of complications encountered with spinal cord stimulation trials. One study reported lead migration as the only complication experienced, however this complication was not identified on our review. This may be due to differences in lead anchoring.
- This single center, retrospective study is limited by its design and small subject number.

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DISCLOSURES

None

Pectus Excavatum Intercostal Neuralgia Relief with Peripheral Nerve Stimulation

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Background

- Pectus excavatum, the posterior displacement of the sternum and adjoining ribs into the thoracic cavity, is the most common anterior chest wall deformation[1]
- Incidence: 1 in 40 to 1 in 400 births[1]
- Moderate to severe cases are often associated with chronic sternal and chest wall pain[2]
- In recent years, intercostal nerve cryoablation during surgical correction of the anatomy via the Nuss procedure has been associated with a shorter hospital length of stay, decreased opioid consumption, and longer duration of chest numbness particularly in adults[3]
- Intercostal neuralgia is commonly treated with oral medications and single shot injections; however, pain relief can be unsatisfactory or short-lived
- To date, there are only scant case reports on using spinal cord stimulation and no study on using peripheral nerve stimulation (PNS) to treat intercostal neuralgia from pectus excavatum

- We describe a case in which a 69-year-old woman with a history of chronic chest wall pain secondary to pectus excavatum found pain relief with PNS at the T4 nerve root bilaterally after minimal pain relief with physical therapy, multiple neuropathic agents, and chronic opioids.

Intervention

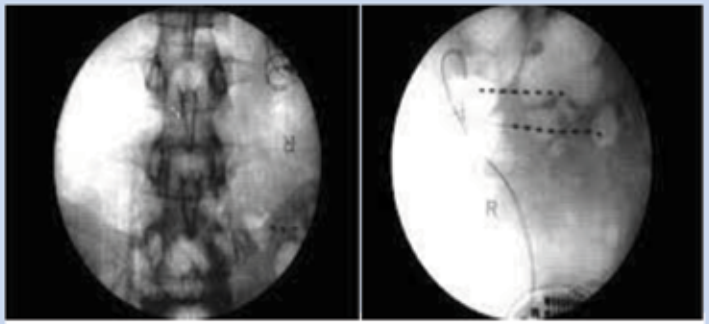
- Ultrasound-guided bilateral single shot intercostal nerve blocks with local anesthetics were performed to diagnose the primary distribution of pain (T4)

- Fluoroscopic-guided bilateral PNS leads were placed at the T4 nerve root

- PNS stimulation therapy for a total of 60 days

- Patient reported better mobility, increased duration of sleep, more independence, decreased oral pain medication consumption, superior quality of life, and improved pain relief during the 60-day stimulation period and persistent pain relief at 1 month follow-up after lead extraction

- Further follow-ups pending



(Left) Posterior-anterior view of the right peripheral nerve stimulator lead placed at the T4 nerve root.
(Right) Lateral view of the bilateral peripheral nerve stimulator lead placement at the T4 nerve root.

Conclusion

- Peripheral nerve stimulation of the T4 nerve root is a safe and viable treatment option for refractory pectus excavatum-associated intercostal neuralgia as part of an opioid-sparing, multimodal treatment regimen

- Long-term sustainability of pain relief after a 60-day stimulation period needs to be further evaluated

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Long term Outcomes with 10kHz Spinal Cord Stimulation for treating Non-surgical Refractory Back Pain: 18-month Results from Multicenter RCT

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Introduction

- What is **non-surgical refractory back pain (NSRBP)**?
  - Pain that is **refractory to conventional medical management (CMM)** – this includes pain medications, anticonvulsants, antidepressants, physical therapy, nerve block therapies, etc.
  - Patient has had **no previous spine surgery**
  - Surgical evaluation indicates **not acceptable candidate for surgery**
- Until recently limited evidence existed for treatment of NSRBP with SCS, most with 10kHz SCS (1)
- An RCT was undertaken to evaluate clinical and cost effectiveness of 10kHz SCS in addition to CMM for NSRBP (2), we present the 18-month results.

Methods

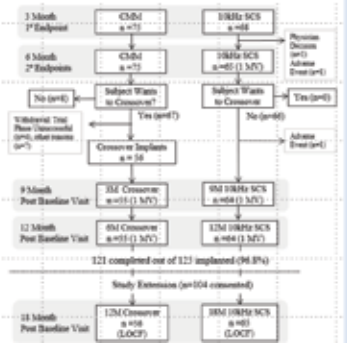
- NSRBP patients were enrolled **if ineligible for surgery based on surgical consultation** (3)
- Subjects were randomized 1:1 to either 10kHz SCS in addition to CMM or CMM alone
- 10kHz SCS group underwent permanent implantation if ≥50% pain relief was achieved during a temporary trial
- Both groups continued with CMM, and had the **option of crossing over at 6 months**(M), if satisfactory pain relief was not achieved
- Subjects had the option of consenting to a study extension which allows for observation of outcomes though 24 M of follow-up
- We present pain relief on visual analog scale (VAS), Oswestry disability index (ODI), and quality of life (EQ-5D-5L). Pain responder was defined as achieving at least 50% pain relief, and remission was defined as a reported VAS score at or below 3 cm for at least 6 M

Results

There were 159 NSRBP patients randomized to either CMM alone (n=75) or to 10kHz SCS in addition to CMM (n=83), with similar baseline characteristics (Table 1).

Table 1. Baseline Characteristics	CMM N=76	10kHz SCS N=83
Age in years, median (range)	58.5 (26.0 to 77.0)	53 (29.0 to 87.0)
Sex (female/male), n	(40/36)	(50/33)
Years since diagnosis of CLBP, median (range)	8.0 (1.0 to 59.0)	8.5 (0.5 to 52.0)
Back Pain VAS		
Mean (SD)	7.2 (1.0)	7.4 (1.2)
Median, Range	7.2 (4.5 to 9.9)	7.6 (4.0 to 10.0)
Baseline Leg Pain Present [1]	45 (59.2%)	52 (62.7%)
Pain Etiology[2] n (%)		
Degenerative disc disease	52 (68.4%)	60 (72.3%)
Internal disc disruption / annular tear	6 (7.9%)	8 (9.6%)
Spondylosis	49 (64.5%)	55 (66.3%)
Lumbar facet-mediated pain	25 (32.9%)	24 (28.9%)
Radiculopathy	35 (46.1%)	34 (41.0%)
Mild/mod spinal stenosis	24 (31.6%)	23 (27.7%)
Spondylolisthesis	9 (11.8%)	7 (8.4%)
Sacroiliac dysfunction	5 (6.6%)	3 (3.6%)
Total Pain Detect Scores		
Mean (SD)		17.8 (6.9)
Median, Range	17.2 (7.4) 17.5 (0.0 to 37.0)	18.0 (1.0 to 33.0)
Non-Surgical Candidate reason, n (%)		
• Patient is not a good surgical candidate based on presentation and underlying pathology	61 (80.3%)	65 (78.3%)
• Patient is a candidate for surgery but declines	10 (13.2%)	11 (13.3%)
• Patient not recommended due to moderate to high surgical risk due to comorbidities or other clinical conditions	5 (6.6%)	6 (7.2%)

Figure 1. Study Flow. 74.7% (56/75) in the CMM arm met the criteria for crossover and were implanted, none wished to crossover from 10kHz SCS arm



Results (cont)

- The primary and secondary endpoints were all met ($p<0.001$)
- Pain relief was not diminished over the 18 M follow-up (Figure 2 and 3.)

Figure 2. Reported pain on VAS was reduced by 5 points following 10kHz SCS implant in both original and crossover groups. Durability to 18 M is shown.

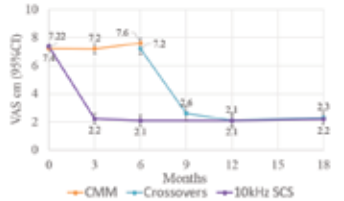


Figure 3. Responder rate, profound responder, and percentage in remission are shown for all implanted (10kHz group only at 18M). Last Observation Carried Forward (LOCF) for 12 and 18 M.

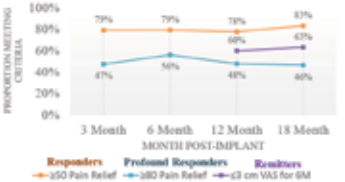
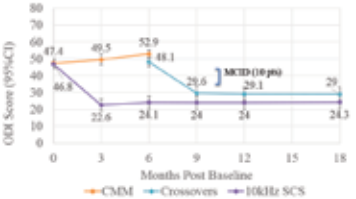


Figure 4. Disability (ODI) reported through 18 months.



Reported quality of life improvements was also durable. No additional study related SAE occurred beyond the 5 reported at 12 months in the combined cohort (all implanted subjects)

Conclusion

- The current study demonstrates that the addition of 10kHz SCS to CMM results in **profound improvements in pain relief, function, and quality of life**
- Even in this hard-to-treat NSRBP population:
  - Who have been **deemed not surgical candidates, and**
  - **Exhausted all available appropriate nonoperative medical management**
- These improvements are achieved with a **safe, reversable therapy**
- Treatment effects show **durability** through 18 month follow-up in this large multicenter study.

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Cooled Radiofrequency Ablation vs. Standard Medical Management for Chronic Sacroiliac Joint Pain: A Multi-Center, Randomized Comparative-Effectiveness Study

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Funding Disclosure: This study was funded by Avanos Medical

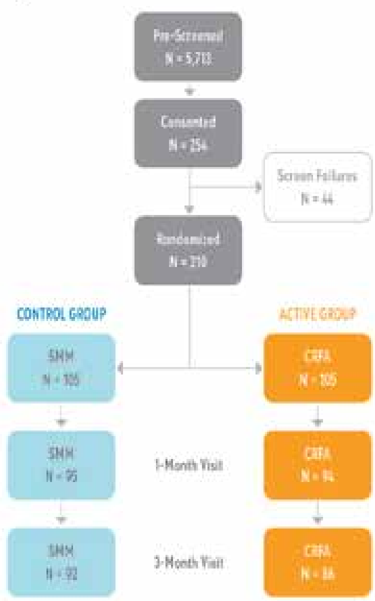
INTRODUCTION

Low back pain (LBP) is one of the leading causes of physician visits and disability in the United States, with a lifetime prevalence rate ranging between 60 and 80%.[1]

Cooled radiofrequency ablation (CRFA) has previously been demonstrated to provide pain relief for pain originating in the sacroiliac joint (SIJ).[2,3]

The objectives of the multi-center, comparative-effectiveness study are to compare CRFA to standard medical management (SMM).

Figure 1. Patient Flowchart



METHODS

This prospective, randomized, controlled, multi-center clinical study was registered in ClinicalTrials.gov (NCT03601949). Protocol, consent forms and recruitment materials were IRB approved.

Selection criteria included adult subjects over the age of 21 diagnosed with chronic SIJ pain lasting at least 3 months.

Other selection criteria included:

- At least 1 positive SIJ provocation test (e.g., thigh thrust, compression or sacral thrust)
- At least 50% pain relief lasting < 3 months from a SIJ injection
- At least 50% pain relief lasting for the expected duration of local anesthetic from a standardized set of lateral branch blocks (LBB)
- Numeric rating scale (NRS) pain score of > 4 over the last 7 days
- Other major sources of low pain were ruled out.

CRFA was performed under fluoroscopic guidance, creating 9 lesions.

Physician-prescribed SMM included pharmacotherapy, physical therapy, lifestyle changes, acupuncture, yoga, chiropractic and therapeutic injections into the SI ligaments or joint cavity.

OUTCOME MEASURES

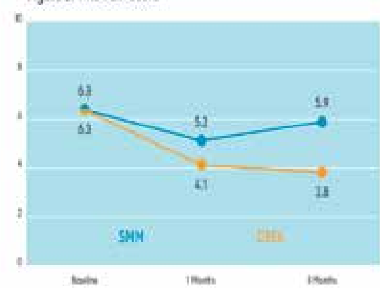
Data collected included numeric rating scale (NRS), Oswestry Disability Index (ODI), 36-item short form survey (SF-36), and EuroQol-5 (EQ-5D-5L).

Responders were defined as participants who had a > 30% decrease in average daily NRS pain score coupled with a rating of at least 5 on PGIC at the month 3 visit.

RESULTS

The CRFA cohort reported a mean reduction in average NRS pain score of 2.5 points at the 3-month timepoint, compared to the 0.4-point decline in the SMM group (p < 0.0001) (Figure 2).

Figure 2. NRS Pain Score



52.3% of subjects in the CRFA cohort were deemed responders, compared to 4.3% of subjects in the SMM cohort (Figure 3).

Figure 3. Percent of Subjects Deemed Responders

Subjects in the CRFA group also reported larger improvements in ODI, SF-36 and EQ-5D-5L compared to the SMM group (Table 1).

Table 1. 3 Month Timepoint Data

		Baseline		3 Months	
		CRFA	SMM	CRFA	SMM
NRS					
	Mean	6.3	6.3	3.8	5.9
	SD	1.4	1.4	2.4	1.7
	P-value	0.9182		<0.0001	
SF-36PF					
	Mean	40.9	36.7	55.8	39.9
	SD	22.7	22.1	24.9	20.1
	P-value	0.2745		<0.0001	
ODI					
	Mean	40.7	43.7	29.2	41.5
	SD	13.8	13.9	15.2	13.6
	P-value	0.2742		<0.0001	
EQ-5D-5L					
	Mean	0.48	0.46	0.68	0.47
	SD	0.27	0.27	0.22	0.29
	P-value	0.5293		<0.0001	
PGIC					
	Improved			65.5%	6.5%
	Not Improved			34.5%	93.5%
	P-value			<0.0001	

CONCLUSION

CRFA is superior to SMM in the management of chronic SIJ pain.

The majority of subjects receiving CRFA reported meaningful improvements in pain, function and quality of life.