Top Posters

2023 ASIPP Abstract and Poster Winners

Overall Winner Physician Attending

ECAP-Based SCS for the Treatment of Chronic Pain: Evoke Study 36-month Outcomes
– Sean Li, MD

Overall Winner Trainee

Efficacy of PENG Blockade I the Relief of Chronic Shoulder Pain
– Lisbeth Esther Godinez Ortiz, MD

Overall Winner Medical Student

Off-Label Use of Antibiotic Impregnated Beads to Salvage an Infected Intrathecal Baclofen Pump in a Complicated Cerebral Palsy Patient
–Elishama Michel

Overall Winner Research Scientist

Cervical Sympathetic Block and Ketamine Infusion in TBI/PTSD
–Eugene Lipov, MD

ECAP-Based SCS for the Treatment of Chronic Pain: EVOKE Study 36-Month Outcomes

Sean Li, MD[1], Peter Staats, MD, MBA[2], Nagy Mekhail, MD, PhD[3] on behalf of the EVOKE Study Group

[1] Premier Pain Centers, Shrewsbury, NJ. [2]National Pain and Spine Centers. [3]Cleveland Clinic

Introduction

Utilization of objective neurophysiological measures to guide clinicians in providing optimal spinal cord stimulation (SCS) for chronic pain patients is a novel concept to neuromodulation. An innovative SCS system delivers evoked-compound action potentials (ECAPs)-based therapy that enables real-time measurement of continuous, objective, in-vivo neurophysiological data to 1) Guide programming and confirm activation of the intended target (i.e., ECAP-guided programming); and 2) Deliver closed-loop therapy to maintain accurate and consistent neural activation on every stimulus (i.e., ECAP-controlled closed-loop SCS).

Methods

The EVOKE RCT evaluates ECAP-based SCS therapy to treat chronic back and leg pain (NCT02924129)[1]. Patients were randomized to open-loop (OL) or ECAP-controlled closed-loop (CL) stimulation; both treatment groups received ECAP-guided programming and continuous ECAP measurement during home use. Following the 24-month visit[1], patients were offered a self-selected crossover for up to 3-months before continuing to the 36-month visit. Patient-reported outcomes collected included pain intensity (VAS), physical (ODI) function, emotional (POMS) function, sleep quality (PSQI), and quality of life (EQ-5D). Objective neurophysiological data, including spinal cord activation and neural accuracy, were measured.

Crossover Results

Fig. 1: Self-Selected Blinded Crossover Decision at 24 Months.

CL patients crossed over primarily due to curiosity. OL patients crossed over for better pain relief. 89% (68/76) of subjects who were exposed to CL remained in CL (5 OL that crossed to CL crossed back to OL, 3 CL crossed and stayed in OL).

ITT Results

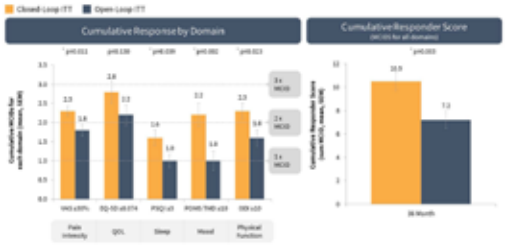

Fig. 2: Depth of Outcome Domains and Cumulative Response for All Domains.

When looking at Minimally Clinically Important Difference (MCID) as a threshold for demonstrating clinical benefit, CL patients averaged >2 MCIDS in each of the patient-reported outcome domains at 36-months. In addition, CL patients had a statistically greater cumulative response than OL patients on average for all domains at 36-months.

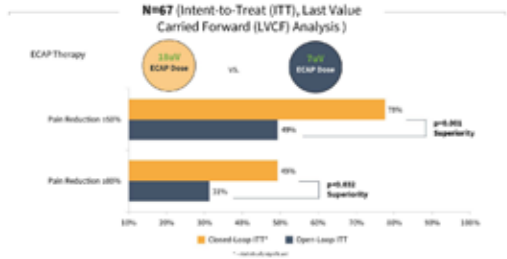

Fig. 3: EVOKE 36 Month Responder and High Responder Rates
Intent-to-Treat (ITT), Last Value Carried Forward (LVCF) Analysis

A significantly greater proportion of CL patients had ≥50% and ≥80% reduction in overall back and leg pain than OL patients at 36 months.

Objective Neurophysiological Measures

While system utilization was similar between groups (p=0.263), CL patients had statistically greater spinal cord activation (p=0.049) and therapy delivered with statistically greater neural accuracy (p<0.001) compared to OL patients at 36-months.

FINANCIAL SUPPORT : This study was conducted with support from Saluda Medical.

Implanted Closed-loop Results

Outcomes for closed-loop patients who were in their randomization assignment (i.e., not in crossover treatment assignment) at 36 months (n=41) are presented below. There were zero explants due to loss of efficacy at 36 months. These results demonstrate sustained clinically meaningful improvements in all domains in patients randomized to closed-loop through 36-months follow-up.

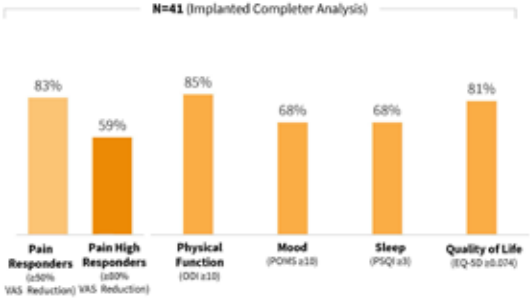

Fig. 4: EVOKE 36 Month Pure Closed-loop Multimodal Responder Rates in Pain , Physical Function, Mood, Sleep and Quality of Life
Implanted Completer Analysis

Conclusion

The EVOKE study demonstrates that ECAP-guided programming and ECAP-controlled closed-loop neural activation resulted in sustained clinically meaningful improvements in multiple domains for patients with chronic refractory back and/or leg pain. ECAP-based therapy provides a transparent, objective approach to SCS by which therapy can be monitored and adjusted to improve patients' lives. Presentation of objective physiologic evidence that produced the reported clinical effect is paramount in increasing transparency and replication in future SCS studies.

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ASIPP 2023 — MARCH 16–18, 2023 — NATIONAL HARBOR, MD

saluda MEDICAL

EFFICACY OF PENG BLOCKADE IN THE RELIEF OF CHRONIC SHOULDER PAIN

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BACKGROUND

Shoulder pain has a prevalence of 18-26% in adults. Some of the treatment options are surgery, analgesic treatment, or interventional pain management. The pericapsular blockade of a nerve group (PENG), originally described for hip pain approach, has been used as an anesthetic technique and postoperative analgesic in shoulder surgeries.

In a study carried out in ten embalmed cadavers where a PENG shoulder approach was performed, the observed pattern corresponded to a pericapsular distribution and the articular branches that innervate the glenohumeral joint were reached. Currently, there are a few studies about the PENG approach in chronic painful shoulder.

OBJECTIVE

Describe the evolution of pain in patients undergoing PENG blockade in chronic shoulder pain.

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METHODS

A retrospective, analytical and observational study was carried out, in which PENG technique was used in the management of chronic shoulder pain in patients without shoulder surgery. Patients over 18 years of age, who had not had shoulder surgery in at least 2 years prior to the procedure, with chronic non-malignant shoulder pain of more than 6 months of evolution and who had accepted the procedure were included. The patient's records were obtained in the period from January 2022 to January 2023. Using ultrasound, the tip of the needle was placed between the deltoid muscle and the subscapularis tendon and 14 ml of 0.2% ropivacaine and 1 ml of 40 mg methylprednisolone were injected.

After the procedure, the visual analogue scale (VAS) was analyzed at the first hour, 24 hours, 48 hours, 1 week, 2 weeks and 1 month.

GRAPHIC 1. Visual analogue scale (VAS) at the first hour, 24 hours, 48 hours, 1 week, 2 weeks and 1 month after the procedure.

RESULTS

A total of 10 patients with shoulder pain were included. The average age was 75 years with a standard deviation of 3 years, 40% were women and 60% men. At least 80% of the individuals were admitted with a diagnosis of painful shoulder syndrome secondary to supraspinous ligament rupture, 20% with shoulder osteoarthritis, 70% had an injury to the right shoulder, 20% both shoulders and the rest had an injury in the left shoulder.

The mean baseline pain reported was 8 on a VAS. A statistically significant decrease in pain was observed at 24 hours, 48 hours and 1 week after PENG approach compared to the initial VAS (p=0.030, p=0.021, p=0.012 respectively). After 2 weeks the average maximum pain recorded was 3 on the VAS, this being a 62% reduction at 1 month compared to baseline pain.

CONCLUSION

The use of PENG block in the management of shoulder pain showed a statistically significant pain reduction during the first week, subsequently the pain reduction was greater than 60%. No adverse events were reported in the follow-up. Further studies with a longer follow-up time are necessary.

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Tufts School of Medicine
South Shore Health
Off-Label Use of Antibiotic Impregnated Beads to Salvage an Infected Intrathecal Baclofen Pump in a Complicated Cerebral Palsy Patient
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Tufts University School of Medicine & South Shore Hospital
Background
Intrathecal baclofen (ITB) pumps are surgically implantable devices that deliver medication directly to the spinal cord at exponentially lower doses than their oral equivalents. Patients with painful contractures as a result of cerebral palsy (CP) or various forms of brain injury often require high oral doses of muscle relaxants for symptom management.
Targeted delivery of baclofen via ITB pumps are beneficial for management as they avoid the unwanted, systemic side effects of baclofen. ITB pumps have been shown to reduce spasticity, improve contracture prevention and enhance functional abilities in this population[10,11].
Despite these benefits, ITB pumps come with high risk as those patients are often frail, difficult to provide proper hygiene to and poor wound healers. Among the many potential device complications[12], infections can be devastating as they are difficult to treat and many place the patient's life at risk.
Removal of the entire ITB pump system is most reliable way to ensure infections are cured; however, this compromises patient quality of life by reducing the ability to provide proper hygiene, manage symptoms, triggering potential baclofen withdrawal, and reducing the potential for pump reimplantation. Many pain specialists will attempt to save infected pumps however the literature on pump salvage techniques remains quite limited[8,18].
Antibiotic impregnated Beads (AIB) come in several forms. One such AIB is comprised of an absorbable calcium sulfate carrier designed to be mixed with one or more antibiotics of the surgeon's choice in order to manage bone or soft tissue infections[22]. This case study describes the off-label use of AIBs as a novel strategy for ITB pump salvage.
Objective
The objective of this case is to highlight a challenging ITB pump patient and the potential for off-label use of antibiotic impregnated beads for pump salvage.
Case Report
Medical History
31-year-old wheelchair-bound man with a history of urinary incontinence requiring condom catheter, scoliosis with spinal fusion from T3 to pelvis and quadriplegic cerebral palsy with spasticity treated with an ITB pump since 2014. For this patient, the pump was essential for his pain management and quality of life.
Patient's pump was surgically exchanged in October of 2021 due to impending end of battery life. Four months after successful replacement, the pump eroded through his poorly-healed incisional scar. The contaminated pump was then urgently removed and a new pump was implanted on the contralateral side of his abdomen requiring catheter revision through a midline back incision.
Two weeks later, the posterior incision was secondarily infected with gram-negative, urinary bacteria necessitating debridement and washout.
Intervention
Given his comorbidities and spinal fusion, ITB pump removal would have been terminal so a decision was made instead to salvage the pump using all resources available; this included inserting AIBs impregnated with Gentamycin and Vancomycin.
Post operative course was complicated by recurrent wound dehiscence, multiple surgical take-backs with AIB replacement, and ultimately the involvement of the plastic surgery service for wound vac and rostional black flap placement to cover the catheter site.
Methods
A literature review was conducted on ITB pump salvage techniques on PubMed. Keywords used in the search included "intrathecal baclofen pump infections" and "intrathecal baclofen pump salvage". Results were limited to papers published since the year 2000.
Results
138 publications were reviewed but the majority focused on prevention of ITB pump infections.
Only twelve publications were found to be related to pump salvage techniques. Published techniques were limited to systemic antibiotic use[2,8,14,20], intra-reservoir administration of antibiotics[15,21], usage of antibiotic impregnated collagen fleece[18], hyperbaric oxygen therapy[8], muscle flaps[3], and debridement with washout and/or pump removal[7,15,17].
To date, there has been no documentation of the use of AIBs as a method to salvage ITB pumps from infection.
Since the implementation of AIBs, all follow up clinic visits for this patient by December 2022 revealed appropriate wound healing of surgical scars without any signs or symptoms of infection.
Figure 1.
In-situ implantation of antibiotic-impregnated beads (AIBs), as a local antibiotic delivery system
Polymer
Antibiotic
Conclusions
We demonstrate successful implementation of off-label use of antibiotic beads (AIBs).
Given excellent post-operative course of the patient, off-label use of AIBs may therefore be an effective measure at salvaging ITB pumps during moments of infection.
Use of these beads may significantly reduce the incidence of pump removal and help patients maintain their quality of life.
Disclosures
There are no financial relationships between co-authors of this abstract and medical or device manufacturers to report.
References

Cervical Sympathetic Block and Ketamine Infusion in TBI/PTSD

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Introduction

- The co-occurrence of post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI) symptoms is particularly prevalent in the special operations forces (SOF) community, who also often present a unique pattern of interrelated medical and psychological conditions.
- Currently available treatments demonstrate limited efficacy in addressing the unique neuropsychiatric symptoms in SOF members and veterans.
- Evidence has shown that subanesthetic ketamine infusion (sKI) improves function following TBI and may show immediate improvements of PTSD symptoms lasting 1–2 weeks.
- Cervical sympathetic blockade (CSB) involves a combination of C6 and C4 ganglion injections and has also reported high efficacy as a PTSD treatment.
- We noticed that the efficacy of combined CSB and sKI in PTSD and TBI appears greater than the impact of the individual treatments.
- Possible mechanisms of action for this synergy may involve modulation of the apoptotic protein BAX, sympathetic storming through regulation of catecholamine levels, and regulation of norepinephrine levels. (**Figure 1**)

Objectives

- This case series aims to report on the combined efficacy of bilateral CSB and four sKI in a cohort of five SOF patients diagnosed with PTSD and comorbid TBI, with a 6 month follow-up.

Methods

- The initial ketamine infusion was performed by using racemic ketamine hydrochloride (0.5 mg/kg), administered intravenously over 45 minutes. The infusions on day 2 and 3 were performed with mild elevations of the dose. On day 4, CSB was performed under ultrasound guidance on the right side, with 8 cc of 0.5% bupivicaine. This was repeated at the 4th cervical level, with 4 cc of 0.5% bupivacaine.
- The patients' PTSD symptoms were evaluated using the PTSD Checklist (PCL-5) at baseline and 6 month after the treatment. This 20-item self-report measure yields a total symptom severity score out of 80. For reference, a PCL-5 score drop by 10 points is considered clinically significant to demonstrate the success of a PTSD intervention.

Results

- Five patients with TBI and PTSD were included in this cohort.
- CSB combined with four sKI showed prolonged benefits in treating PTSD as measured by PCL-5, with an average reduction of 28 points at the 6 month follow-up (**Table 1**).
- For reference, the longest follow-up published to date using sympathetic blockage to treat PTSD treatment has been 8 weeks.
- In addition, TBI symptoms such as memory function and mood stabilization were improved per the patients' self-report.
- We acknowledge that this is a limited case report, with a lack of validated assessment of TBI symptoms, and a small number of patients included.

Figure 1. Proposed mechanism of action

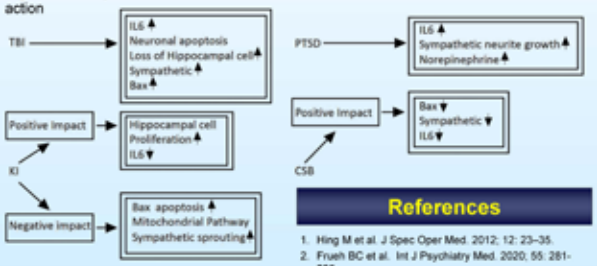

Table 1. Baseline demographic data and change in the pain score over 24 month follow-up

PATIENT	Pre-Treatment	6 Months Post Treatment	CHANGE (IN POINTS)	CHANGE (IN %)
1	54	17	37	69%
2	50	34	16	32%
3	45	21	24	53%
4	33	10	23	70%
5	41	3	38	93%
AVERAGE	**45**	**17**	**28**	**63%**

Conclusions

- CSB combined with sKI can markedly reduce symptoms of PTSD, with an effect lasting over 6 months in an SOF cohort.
- This combined intervention also appears to improve TBI symptoms.
- Considering the high rate of PTSD and TBI comorbidity in the SOF community, a more formal study of this innovation is warranted.

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Comparing Radiofrequency Ablation Lesion Sizes Generated Using a Bifurcated Cannula to a Standard Cannula

Jennifer Lee[1], Alden Sherman[2], Roshini Jain[2]

1. Evergreen Health Medical Group, Kirkland, WA USA 2. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

In patients with axial spine pain or joint pain, thermal Radiofrequency (tRF) ablation can be used to achieve significant pain relief and improved quality of life. The extent of pain relief as well as the duration of benefit is often directly correlated to the size of the lesion.[1]

Multiple methods to enhance the size of the lesion have been studied. These include- higher temperatures, larger cannulas, increased size of active tip, lesion time, and others like fluid modulation.[1] In this study, we sought to examine the impact of a newer bifurcated cannula on lesion sizes when compared to a standard curved cannula.

METHODS

Study Design	Ex vivo analysis of lesion sizes generated comparing a bifurcated cannula with a standard cannula
Study Device	• G4 radiofrequency generator (Boston Scientific) • Bifurcated cannula: Sidekick™2 (Boston Scientific) • Standard cannula: Curved Sharp Cannula (Boston Scientific)
Cannula Configurations	Each cannula was used in following configurations: • 18G, 10cm long, 10mm tip • 20G, 10cm long and 10mm tip.
Procedure	Monopolar tRF lesions were generated using the G4 radiofrequency generator (Boston Scientific) by placing the electrodes between two boneless pork chops at body temperature (37°C ±2°C) at 0° and 90° orientations. The orientation is defined by the plane in which both the electrode shaft and the bent tip of the cannula lie. The temperature and duration settings were 80°C and 2 minutes respectively, and the lesions were repeated using eight cannulas for each configuration.
Assessments	Radial and axial lesion sizes measured visually using a scale.

RESULTS

Cannula Type & Tip Size	RF Lesion Size* Major Axis (mm)	Minor Axis (mm)	Vertical Axis (mm)	Ellipsoid Volume (mm3)
Standard 20 ga/10 mm	11.1 ± .34	5.1 ± .35	5.5 ± .53	179 ± 25
Sidekick 2 Cannula 20 ga/10 mm	11.4 ± .51	7.9 ± .35	7.6 ± .44	392 ± 38 (+119%)

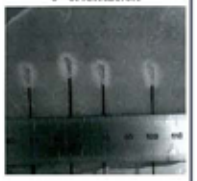
- **The 20G/10mm standard configuration generated a lesion size of 179 ± 25 mm³ (Mean ± STD)**
- **The 20G/10mm bifurcated configuration generated a lesion size of 392 ± 38 mm³ (+119%)**

Cannula Type & Tip Size	RF Lesion Size* Major Axis (mm)	Minor Axis (mm)	Vertical Axis (mm)	Ellipsoid Volume (mm3)
Standard 18 ga/10 mm	15.1 ± .35	8.9 ± .35	9.0 ± .00	633 ± 31
Sidekick 2 Cannula 18 ga/10 mm	15.1 ± .28	11.1 ± .35	10.9 ± .00	881 ± 28 (+39%)

- **For the 18G/10mm standard configuration, the lesion size was 633 ± 31 mm³**
- **The 18G/10mm bifurcated configuration generated a lesion size of 881 ± 28 mm³ (+39%)**

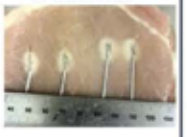
20 ga Standard 0° orientation

20 ga Sidekick 0° orientation



18 ga Standard 0° orientation

18 ga Sidekick 0° orientation



*Mean ± SD (n=8) extent of color change in porcine muscle ex vivo at 37°C, set temperature 80°C, set time 2:00, monopolar RF, Boston Scientific G4 Generator. Ellipsoidal volume Vestimated from cross-sectional measurements. Ex vivo lesions may differ from clinical lesions.

CONCLUSIONS

- Bifurcated cannulas allow for larger lesions to be generated without using a larger gauge needle, which might allow for clinicians to achieve better results without significantly modifying their interventional tRF approach.
- In addition to larger lesions, clinical guidelines recommend the use of parallel approach over perpendicular to maximize the utilization of the active tip to provide an effective large lesion[1]
- The evidence derived from this ex vivo study needs to be further reproduced in clinical studies.

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DISCLOSURE

Study sponsored by Boston Scientific. Roshini Jain, Courtney Johnson, and Ashley Armacost are employees of Boston Scientific. Dr. Lee has consulting agreement with Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
THE VOICE OF INTERVENTIONAL PAIN

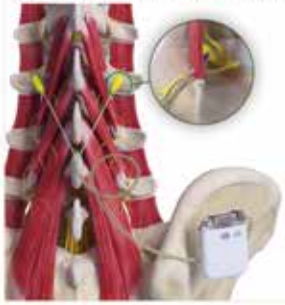
ASIPP 2023
—MARCH 16-18, 2023—
NATIONAL HARBOR, MD

Four-Year Effectiveness of Restorative Neurostimulation in Patients with Chronic Mechanical Low Back Pain

Chris Gilligan on behalf of the ReActiv8-B study group. Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA.

ASIPP 2023

Introduction: Restorative Neurostimulation targets non-surgical chronic low back pain (CLBP) associated with multifidus dysfunction. A pivotal randomized sham-controlled trial (NCT02577354) established effectiveness, 4-year durability and safety of this therapy.[1,2,3]



- Rehabilitative treatment aimed at restoring neuromuscular control of lumbar spine stability
- Stimulates the L2 medial branch 2x daily for 30 minutes to elicit episodic multifidus contractions

Override inhibition

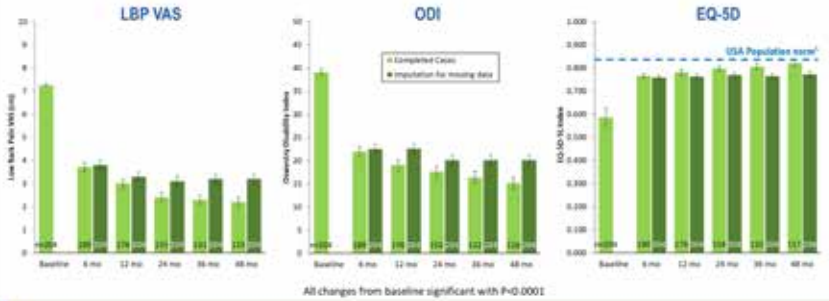
Elicit proprioception

Reactivate muscle control

Restore functional spine stability

Reduce pain

Objective: Evaluate durability of treatment effectiveness of restorative neurostimulation in patients with CLBP associated with multifidus dysfunction.
Methods: Four-year open label analysis with imputation for missing data (N=204) using mixed model repeated measures for continuous variables.
Overall results: Baseline mean age 47±9 years; backpain duration 14±11 years; LBP on 97±8% of days; VAS 7.3, ODI 39 and EQ-5D 0.585;



All changes from baseline significant with P<0.0001

Compelling long-term effectiveness

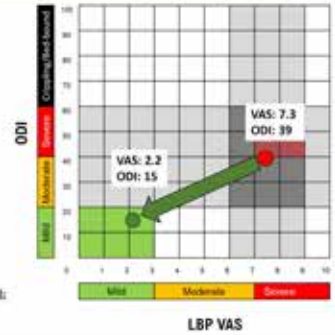
- Average VAS improved from 7.3 to 2.2
- Average ODI improved from 39 to 15
- **73%** with ≥50% improvement in LBP VAS
- **63%** with ≥20-point improvement in ODI
- **79%** with ≥50% improvement in VAS and/or ODI
- **56%** with ≥50% improvement in VAS **and** ODI
- **91%** were "Definitely satisfied" with the treatment

Voluntary opioid reduction

70% of patients on opioids at baseline voluntarily have eliminated (46%) or reduced (24%) opioid consumption

Safety

- Favorable safety profile compared to other implantable neurostimuli
- No lead migrations



Conclusions:

- Restorative Neurostimulation is a safe, effective and durable treatment for patients with refractory disabling mechanical CLBP
- Intention-to-treat analysis instills confidence in outcomes
- No lead migrations have been observed
- Progressive improvements and durability in pain and functional capacity are consistent with the restorative mechanism of action

References:

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Disclosures:

ReActiv8-B trial is funded by Mainstay Medical. CG reports payment to his institution, personal fees and stock-options received from Mainstay, personal fees from Mainstay, Saluda, Persica, Eli Lilly, Iliad, research funded by Sollis, expert witness testimony fees, and serving as Editor in Chief of Pain Practice;

SCS for Painful Diabetic Peripheral Neuropathy: A History of Evidence

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INTRODUCTION

Diabetic peripheral neuropathy (DPN) is the most common neuropathic syndrome seen in patients with diabetes. Roughly 30% of the diabetes patient population experience painful DPN symptoms including bilateral stabbing or burning pain in addition to numbness in the feet and lower legs[1]. Traditionally painful DPN symptoms have been treated with conventional medical management (CMM) including glycemic control, general risk factor management, as well as pharmaceutical agents. These treatment approaches are often unsuccessful in the long-term[1]. Spinal cord stimulation (SCS) has been demonstrated as an effective treatment for painful DPN of the lower extremities with multiple publications dating back to 1996 showing benefits of SCS for pain relief and improved Quality of Life (QoL) in DPN patients (Figure 1)[2-18].

METHODS

A systematic literature review of the robust body of evidence for SCS in the treatment of painful DPN was conducted. Publications were selected for inclusion by two independent reviewers using defined selection criteria. Selection criteria included:

- Publication must include data on a distinctly identifiable diabetic population
- Publication must include data from studies on SCS to treat DPN with quantifiable information regarding pain reduction, probability of treatment success, or quality of life (QoL) improvements
- Meta-analyses were included if report synthesized new data based on prospective studies

RESULTS

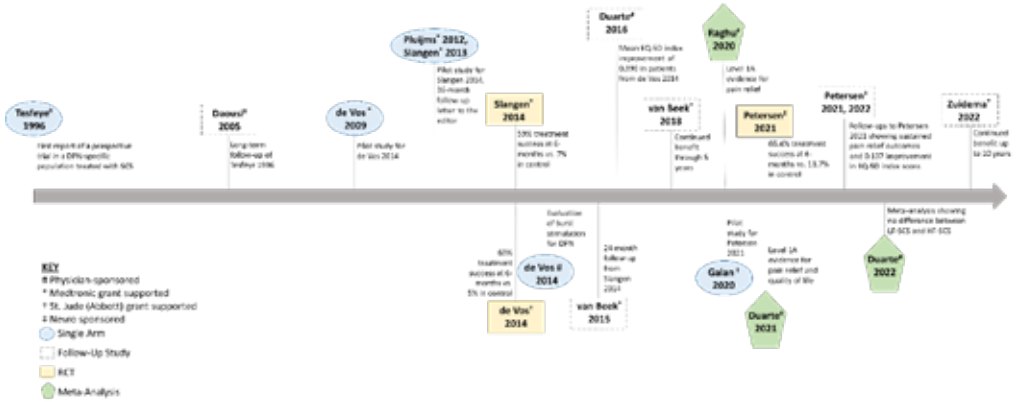
SCS was first documented as an effective treatment for DPN in 3 single-arm studies published between 1996 - 2012[2,4,5], 1 of which was followed-up to 36 months[18], and another to 7-years[3]. These studies paved the way for 2 RCTs published in 2014[6,7], 1 of which was followed-up to 10-years in 3 publications[8,10,20], and another[7] was followed-up with analyses on QoL[9] and an evaluation of the effects of burst SCS[17]. Three meta-analyses were published between 2020-2022[11,12,19]. A post-hoc analysis of a multi-center single-arm study on high frequency (10kHz) SCS to treat DPN was published in 2020[13] and followed by an RCT published in 2021[14] with additional 1-year follow-up[15,16]. Collectively these studies demonstrate SCS as an effective therapy for patients with DPN by reducing pain and increasing QoL.

DISCLOSURE

This study was supported by Medtronic.

RESULTS

Figure 1. Key studies of SCS for the treatment of painful DPN. Studies were selected by two independent reviewers according to defined selection criteria. Treatment success, defined as ≥50% pain relief or ≥50% pain relief and/or PGIC of Much Better or Very Much Better, is listed per randomized controlled trial (RCT) by Intention to Treat (ITT) analysis.



DISCUSSION

This review of a large body of evidence shows a decades-long history of the effectiveness of SCS for symptom relief in patients suffering from painful DPN. Future research on the effectiveness of new waveforms and novel methods of energy delivery to the spinal cord are needed. The study of outcomes in addition to pain relief is also needed, which may better illustrate the breadth of effects of SCS therapy on the underlying disease factors. Increasing awareness of the current evidence is essential to increasing therapy adoption by expanding payer support and influencing referring health care provider behavior.

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Multiple RCTs with consistent outcomes demonstrate SCS an effective treatment for painful Diabetic Peripheral Neuropathy

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INTRODUCTION

Diabetic peripheral neuropathy (DPN) is the most common neuropathic syndrome seen in patients with diabetes. DPN symptoms can include stabbing or burning pain eventually progressing to numbness in the lower extremities resulting in loss of protective sensation. Traditionally, pain associated with DPN has been pharmacologically treated with gabapentin/pregabalin, tricyclic antidepressants, and serotonin-norepinephrine reuptake inhibitors[1]. These treatment approaches are often unsuccessful in the long-term, with many painful DPN patients abandoning initial prescription analgesics within months[1]. Spinal Cord Stimulation (SCS) has been examined in 3 randomized controlled trials (RCTs)[2,3,4] comparing SCS to conventional medical management (CMM).

METHODS

Three RCTs[2,3,4] comparing SCS to CMM for the treatment of painful DPN were compared and contrasted by primary outcome measures, primary endpoint duration, intervention, demographics, treatment-effect-size and quality-of-life outcomes based on the intention-to-treat principle (Table 1).

Two RCTs[2,3] using traditional SCS programming were independently designed, conducted and reported, with industry grant support, in western Europe. One RCT[4] using high frequency SCS programming was industry-sponsored and conducted in the United States. Primary outcome measures included a composite primary endpoint where patients could be identified as treatment responders by reduction in pain diary scores or Patient Global Impression of Change, ≥50% reduction in VAS measurement for pain, and a compound primary endpoint of ≥50% reduction in pain score and no neurologic decline. EQ-5D questionnaires were used to assess Quality of Life. Primary endpoint duration was 6 months in two studies[2,3] and 3 months in one study[4].

RESULTS

All three studies included mostly patients with Type 2 diabetes (Table 1).

Treatment effect size is a published way to look at the effect of an intervention for DPN, used by the American Academy of Neurology (AAN)[10]. A difference >20% is considered a large treatment effect. The difference in treatment effect size between SCS and control groups for the primary endpoint in the Intention-to-Treat populations ranged from 52% to 58% (Table 1, Figure 1).

Improvement in EQ-5D Quality of Life (QoL) index scores at 6 months ranged from 0.124 to 0.380, with an average (SE) improvement from baseline of 0.28 (0.07) at 6-months and 0.24 (0.09) at 12-months (Figure 1). The studies of traditional SCS[2,3,6] show greater and sustained improvement in QoL than the study of high frequency SCS[7] (Figure 2).

RESULTS

Table 1. Study Design and Treatment Effect

	Slangen et al (2014)[2]	de Vos et al (2014)[3]	Petersen et al (2021)[4]; Clinical Summary[5]
Study Logistics and Design			
Sponsor	Maastricht University Medical Center (NCT01162993)*	Medisch Spectrum Twente (ISRCTN03269533)**	Nevro
Study Device Manufacturer	Medtronic	St. Jude/Abbott	Nevro
Number of Centers (Countries)	2 (Netherlands)	7 (Netherlands, Denmark, Belgium, Germany)	18 (United States)
Design	RCT	RCT	RCT
SCS Programming Comparator	Traditional SCS Best medical treatment	Traditional SCS Best medical therapy	10 kHz SCS Conventional medical management
Primary endpoint (months)	6	6	3
Population	Refractory DPN	Refractory DPN	Refractory DPN
Sample Size	36	60	216
% Subjects with Type 2 Diabetes	Control arm = 93 SCS arm = 86	Control arm = 75 SCS arm = 75	Control arm = 97.1 SCS arm = 92.9
Mean (SD) HbA_{1c} % at Baseline	Control arm = 8.4 (2.7) SCS arm = 8.3 (2.0)	NA	Control arm = 7.4 (1.2) SCS arm = 7.3 (1.1)
Study Outcomes			
Primary Endpoint Definition (all randomized subjects; ie, ITT):	≥ 50% pain reduction during daytime or nighttime or a score of ≥ 6 on a 7-point Likert scale of the PGIC scale for pain and sleep	> 50% pain reduction	≥ 50% pain relief without a meaningful worsening of baseline neurological deficits
SCS Responder Rate	59%	63%†	66.4%††
Control Responder Rate	7%	5%	11.7%††
Treatment Effect Size‡	**52%**	**58%**	**55%**

ITT = intention-to-treat, PGIC = Patient Global Impression of Change
*Support (grant) was provided by Medtronic. Medtronic was not involved in data analysis/interpretation or manuscript writing.
**Support (grant) was sponsored by St. Jude Medical. St. Jude Medical was not involved in data analysis/interpretation or manuscript writing.
†Number calculated using the number of patients randomized to the SCS study group (n = 40) and the number of patients in the SCS study group with > 50% pain reduction (n = 25) at 6 months. The publication itself† (Table 2) reported a "> 50% pain reduction in (%)" of "25 (80%)" for the SCS study group (n = 40; randomized patients) at 6 months.
††Primary endpoint ITT responder rate as reported in the Nevro Clinical Summary and FDA Summary of Safety and Effectiveness Data. Petersen et al (2021) reported SCS and control responder rates of 79% and 5%, respectively ("ITT population with known status").
‡Treatment effect size = SCS responder rate - control responder rate
‡‡EQ-5D values represent the baseline and follow-up scores on a scale of 0 to 1, with 1 = perfect health.

Figure 1. QoL Improvements in 3 RCTs

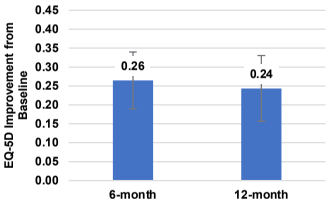
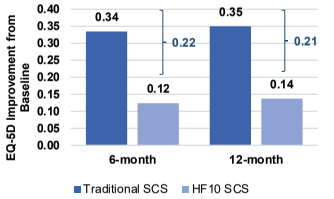


Figure 2. QoL Improvements by Waveform



DISCUSSION

Three RCTs[2,3,4] have all shown SCS as effective over CMM for treating DPN pain symptoms. The variety of primary endpoints were all meaningful measures of reduction in pain symptoms and ranged from pragmatic measures to measures that included neurological deterioration, though very few subjects regressed. Multiple RCTs have clearly established effectiveness of SCS therapy for the treatment of painful DPN. Patients from 1 study[4] have been followed-up to 18 months[8] and patients in another[2] up to 10 years[9] with similar outcomes, demonstrating long-term benefits of SCS for patients with painful DPN.

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DISCLOSURE

This study was supported by Medtronic.

Significant Pain Relief and Treatment Satisfaction Following Radiofrequency Ablation - Prospective, Multicenter study (RAPID)

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BACKGROUND

Patients suffering with chronic pain typically undergo a variety of treatment approaches including medications, physical therapy, and surgery. Notably however, a recent meta-analysis of 96 randomized trials involving over 26,000 subjects with chronic pain demonstrated that use of opioid drugs was not associated with significant improvements in pain and physical function, nor associated with outcomes that were significantly better than that achieved using conventional treatments (i.e., antidepressants, nonsteroidal anti-inflammatory drugs, anticonvulsants, cannabinoids, or usual care).[1]

Radiofrequency ablation (RFA) is minimally invasive, outpatient treatment that has been demonstrated to alleviate pain, improve function, decrease healthcare utilization, and eliminate the need for opiates.[2-6] Additionally, RFA has been progressing as a key approach to managing chronic pain.

Here, we assess patients treated with RFA for chronic pain as part of a prospectively-enrolled multicenter, international study.

METHODS

Study Design	Multicenter, Prospective, International Outcomes Study with consecutive enrollment
Study Device	Commercially-approved RFA Systems (Boston Scientific, USA)
Cohort	269 enrolled patients at 13 sites; 261 patients with RFA procedure completed

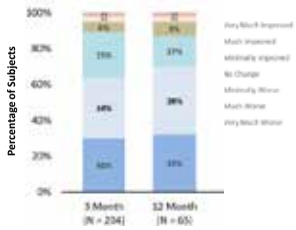
RESULTS

Baseline Characteristics (n = 269)

Gender - Females (%)	56.3% (n = 148/269)
Age (years) [Mean (SD)]	61.7 ± 12.4 years (n = 263)
Pain Duration (years) [Mean (SD)]	13.1 ± 12.9 years (n = 260)
Baseline Targeted Pain Score [Mean (SD)]	6.7 ± 1.8 (n = 241)
Number of Study RF Procedures [Mean (SD)]	1.7 ± 0.8 procedures (n = 264)
Regions treated with RF (with initial procedure completed)	Lumbar - 74.2% (n = 190/261)
	Cervical - 23.8% (n = 61/261)
	Sacroiliac - 23.1% (n = 59/261)
	Hip - 10.6% (n = 27/261)
	Knee - 14.8% (n = 38/261)
Follow-up Duration [Mean (SD)]	200 ± 137 days (n = 261)

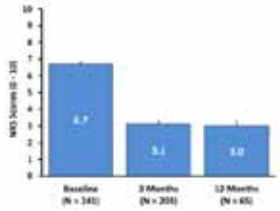
Targeted Pain is the area of pain intended to be treated with RF

Patient Satisfaction (PGIC) post-procedure



Over 80% of patients reported improvement (very much, much, or minimally improved) up to 12-months post-procedure

Targeted Pain Scores up to 1-year post-procedure



Responder Rates (Targeted Pain) post-procedure

At 12-months post-procedure:

- Significant improvement ($p<0.0001$) in pain scores was noted.
  - 3.5-point improvement (6.7 → 3.1) at 3-months and sustained long-term (Δ = 3.2-point improvement)
- High Responder rates were noted

CONCLUSIONS

- Preliminary clinical data from this prospective, multicenter, real-world outcomes radiofrequency ablation (RFA) study of 269 enrolled patients (261 patients with initial RFA procedure complete) shows significant improvement in pain scores up to 12-months post-procedure.
- High responder rates and high patient satisfaction was noted during long term follow up.
  - 87% reported very much, much or minimally improved at 12-month post-procedure follow-up.

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DISCLOSURES

Study sponsored by Boston Scientific. Drs. Atallah and Provenzano have consulting agreements with Boston Scientific. Roshini Jain, Nilesh Patel, and Lily Chen are current employees of Boston Scientific. Kristen Lechleiter was previously an employee of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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ASIPP 2023
—MARCH 16-18, 2023—
NATIONAL HARBOR, MD

Improving Access to SCS Care and Treatment Efficiency using Digital Patient and Clinician Applications

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BACKGROUND

Chronic Pain affects over 20 Million people in the USA, yet conventional pain therapies often fail to alleviate pain and improve function. A limited number of patients have access to care provided by qualified pain physicians. Additionally, their care may not be delivered in an efficient and maintenance of long-term pain relief is often challenging. Digital applications (apps) and tools have the potential to improve access to care, efficient delivery of therapy, and maintain relief long-term. For instance, recent published data has shown a positive correlation between patient engagement and improved trial outcomes in Spinal Cord Stimulation (SCS) by utilizing a novel real-time tracking application (Lee 2022). A suite of digital tools and solutions have been developed to identify bottlenecks in patient care, increase throughput of pre-authorization processes, enhance patient engagement during trials, and uncover clinic-specific insights into the efficiency of care delivery for patients. These new technologies therefore offer the promise of addressing inefficiencies and removing hurdles that restrict patient access to therapy.

Here, we describe our initial appraisal of these newly-available digital tools and comparatively assess their use relative to SCS trial-to-permanent implant conversion rate and trial-to-permanent implant duration.

METHODS

This is a quantitative assessment of a new digital health suite (part of Cognita Practice Optimization, Boston Scientific, Valencia, CA)

- mySCS App: A patient-facing real-time tracking application allowing tracking of outcomes and patient-specific goals during trial
  - Data was sourced from a real-world, retrospective evaluation of SCS trial cases with ≥90 days elapsing from trial start date to assess T2P conversion rates.
- Cognita QuickView: A novel clinic portal to track the patient journey
  - Pilot centers included those utilizing the portal for a period of at least 6 months with at least 10 cases (trial or perm) since using the portal. Baseline T2P durations and T2P conversion rates were defined as an average of 2020 calendar year data for each pilot physician in each center.

mySCS app interface

Cognita QuickView portal interface

RESULTS

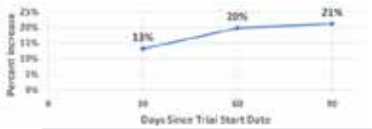
Cohort Patient Demographics

A cohort of 15,053 SCS trials were analyzed.

	Patients without App (n=4,639)	Patients with App (n=10,414)
Gender (%F)	52.9	55.3
Age (Mean ± SD)	66.9 ± 13.8	60.4 ± 14.0

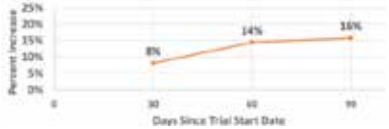
Age data was unavailable for 3 patients, and gender was unknown for 6.

Change in Trial-to-Perm Conversion Rate for Patients with Trial App vs. without Trial App.



Patients who used the trial app (n=10,414) were 20% more likely to get the permanent implant within 60 days than patients without the app (n=4,639).

Change in Trial-to-Perm Conversion Rate for *Successful trial* Patients with Trial App vs. without Trial App.



Successful trial patients who used the trial app were 14% more likely to get the permanent implant within 60-days than successful trial patients without the app.

RESULTS: FASTER PERMANENT IMPLANT FOLLOWING TRIAL USING CLINIC PORTAL

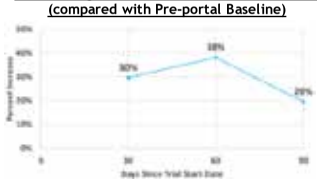
A cohort of 11 pilot centers were analyzed spanning 462 cases since onboarding and 433 cases as baseline.

Pilot centers (n = 11) implanted patients on average 20-days faster after implementing the clinic portal in their practice.

Centers that used the clinic portal (n = 11) had a 38% increase in their Trial-to-Perm conversion rate within 60-days compared to their pre-portal baseline on average.

- Digital health platform (web application): Cognita QuickView [Boston Scientific, Valencia, CA]
- Pilot centers included those utilizing the portal for a period of at least 6 months with at least 10 cases (trial or perm) since using the portal.
- Baseline T2P durations and T2P conversion rates were defined as an average of 2020 calendar year data for each pilot physician in each center.

Mean Change in Trial-to-Perm Conversion Rate (compared with Pre-portal Baseline)



CONCLUSIONS

The development and implementation of new digital health technologies is an important aspect for enabling improved accessibility and delivery of relevant healthcare to patients in need.

- Preliminary evaluation of such new digital tools suggests that with use, improvements can be effectively achieved by Increasing the likelihood that patients a permanent implant within 90 days
- Decreasing the average trial-to-permanent implant duration

These initial results represent promising early evidence in care acceleration for chronic pain patients seeking SCS therapy. Further studies are needed.

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DISCLOSURES

Dr. Vucetic has a consulting agreement with Boston Scientific. Nicholas Kellerman, and Roshini Jain are employees of Boston Scientific.

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ASIPP 2023
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NATIONAL HARBOR, MD

Real-World Outcomes Using Spinal Cord Stimulation for Treatment of Chronic Back Pain with No Prior Back Surgery

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1. Carolinas Pain Institute, Winston-Salem, NC USA 2. Boston Scientific, Division of Neuromodulation, Valencia, CA USA

BACKGROUND

Chronic intractable low back pain (i.e., back pain persisting for at least 6-months) refractory to treatment is complex and dynamic. A recent meta-analysis of 96 randomized trials involving over 26,000 subjects with chronic pain demonstrated that use of opioid drugs was not associated with significant improvements in pain and physical function, nor associated with outcomes that were significantly better than that achieved using conventional treatments (i.e., antidepressants, nonsteroidal anti-inflammatory drugs, anticonvulsants, cannabinoids, or usual care).[1] Hence, an approach that includes non-opioid therapies such as neuromodulation for the management of pain has been recommended (HHS 2019 Best Practices report and 2022 CDC guidelines).[2, 3]

Previously published studies support the use of Spinal Cord Stimulation (SCS), a reversible treatment option, prior to back surgery.[4-6] However, these studies have not yet evaluated SCS systems that can provide multiple neurostimulative approaches that can be selectively used per patient.

Here, we outcomes in real-world patients with no prior back surgery who used various SCS systems capable of customizable neuromodulatory approaches.

METHODS

Real-world data with use of a commercially-available Boston Scientific SCS systems in the treatment of pain was collected among patients with no prior back surgery

1. RELIEF Prospective, multicenter registry
2. Retrospective, observational case-series

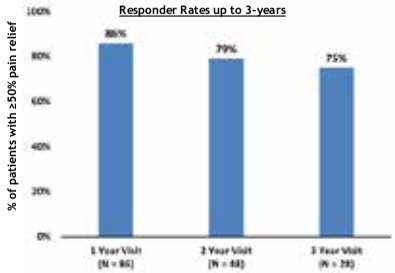
RESULTS

A total of 262 real-world participants were identified
- Prospective, multicenter registry: 108
- Retrospective, observational case series: 154

Baseline Characteristics (n = 262)

	Prospective Registry (n = 108)	Observational Case-Series (n = 154)
Gender - Females (%)	63% (68/108)	61% (90/148)
Age [Mean (SD)] n	60.4 (13.4) yrs. n = 108	59.5 (14.4) n = 137
Baseline NRS [Mean (SD)] n	7.2 (1.8) n = 60	7.4 (1.9) n = 154
Follow-up duration [Mean (SD)] n	Ongoing up to 3-years	375.6 days (507.4) n = 154

Prospective Multicenter Registry (n=108)

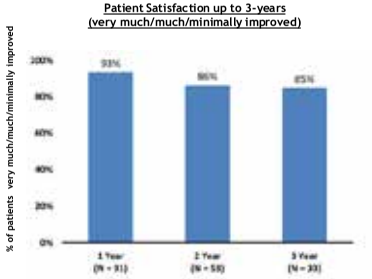


≥75% responder rate (% of patients with 50% or more pain relief) reported up to 3-year follow-up

Observational Case Series (n=154)

At last follow-up (mean = 375.6 days)
- 47% of patients reported a pain score of 3 or less
- A mean 3.4-point improvement (7.4 → 4.1, p<0.0001) was noted among all patients (n = 154)

Prospective Multicenter Registry (n=108)



High Satisfaction with ≥85% of patients reporting improvement (very much/much/minimally) up to 3-year follow-up

CONCLUSIONS

- Results from two ongoing, real-world, multicenter, studies (consecutive patients) demonstrate a durable and significant improvement in pain and satisfaction suggesting that SCS may be an option for chronic pain in patients with no history of prior back surgery.
- High responder rates (≥75%) and high satisfaction (≥85% of patients reporting improvement) were reported up to 3-years indicated sustained efficacy.
- Additional studies of chronic pain patients with no history of prior back surgery who are implanted with SCS systems equipped with advanced, technological capabilities are now needed.

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DISCLOSURES

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AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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ASIPP 2023
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NATIONAL HARBOR, MD

Comparing SCS and Conventional Medical Management in Patients with No Prior Back Surgery (SOLIS RCT)

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10. Goodman Campbell Brain and Spine, St. Vincent Health, Indianapolis, IN USA 11. Delaware Valley Pain and Spine Institute, Trevose, PA USA 12. Ochsner Health System, New Orleans, LA USA 13. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Use of Spinal Cord Stimulation (SCS) as a treatment for chronic pain has been historically designated for patients who have had at least one prior spinal surgery. Considering the opioid drug crisis and the often-mixed clinical success of conservative treatment approaches and invasive back surgery procedures, there is growing interest in utilizing SCS in chronic pain patients who have not yet undergone previous surgical intervention.[1-4]

Recent SCS devices offer substantially more novel technological capabilities and neurostimulative approaches than older-generational SCS systems. Correspondingly, interventional treatment approaches capable of multimodal therapeutic strategies are now actively recommended by pain care advocates.[5,6]

Here, we describe our clinical assessment of SCS in patients with no prior history of surgery implanted with a device capable of customizable programming engaging multiple mechanisms of action in a prospective, multicenter, randomized controlled trial (RCT) compared with Conventional Medical Management (CMM).

METHODS

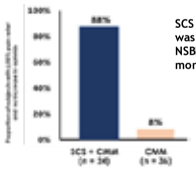
Study Design	Prospective, multicenter, parallel group design RCT (NCT04676022)
Study Device	WaveWriter SCS Systems, Boston Scientific • Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting, Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC) • Combination therapy
Cohort	Non-Surgical Back Pain (NSBP)
Study Arms	Experimental: Spinal Cord Stimulation (SCS) Control: Conventional Medical Management (CMM)
Primary Endpoint	Proportion of subjects with ≥50% reduction in average overall pain with no increase in baseline opioid medications at 3-months (SCS vs. CMM)

RESULTS

Baseline Characteristics (n = 60 treatment activated subjects)

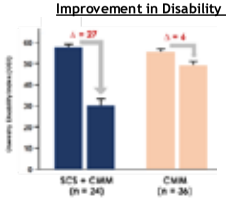
Age (yrs.) - Mean (SD) n	59.8 (11.2) 60
Gender (Female) - % (n/N)	56.7% (34/60)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Lumbosacral Radiculopathy	65%
Lumbar Spinal Stenosis	50%
Lumbar Facet Arthropathy	35%
Average Overall Pain (VRS) - Mean (SD) n	7.5 (0.8) 60
Average Low Back Pain (VRS) - Mean (SD) n	7.7 (0.8) 60
Disability (Oswestry Disability Index [ODI] - Mean (SD) n)	56.2 (9.2) 60
Duration of low back pain (yrs.) - Mean (SD) n	16.2 (13.0) 60

Primary Endpoint Analysis (3-months post-activation)



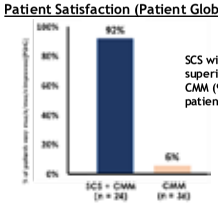
SCS with multiple modalities was superior to CMM in treating NSBP patients (p<0.0001) at 3 months

Improvement in Disability (Oswestry Disability Index)



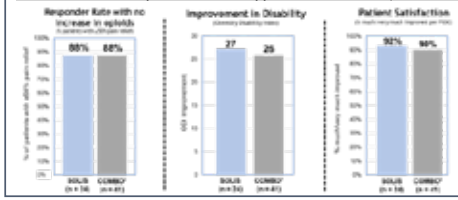
SCS with multiple modalities demonstrated superiority in improving functional outcomes compared to CMM (27-point vs. 6-point ODI improvement) at 3-months.

Patient Satisfaction (Patient Global Impression of Change)



SCS with multiple modalities had superior outcomes compared to CMM (92% vs. 6%, p<0.0001) in patient satisfaction at 3-months.

NSBP outcomes compared with SCS-approved indications (SOLIS vs. COMBO RCT: 3 months)



SOLIS RCT (NSBP) outcomes are consistent with COMBO RCT (current "on-label" indications) outcomes at 3-months[7]

NOTE: Boston Scientific SCS Systems are not approved for sale in the US to treat non-surgical back pain (NSBP) patients

CONCLUSIONS

- The SOLIS RCT (multicenter, prospective, parallel-group study) met its primary endpoint (p<0.0001) and secondary endpoints based on a pre-specified cohort of 60 subjects.
- SCS with multiple modalities is an effective treatment for Non-surgical back pain (NSBP) demonstrating superior outcomes compared with CMM in patients with no prior back surgery.
- At 3-months:
  - Higher responder rate w/o increase in opioids (88% vs 8%)
  - Significant improvement in disability (27-point vs. 6-point improvement)
  - Higher Satisfaction (92% vs. 6% reporting very much/much improved)
- SOLIS RCT NSBP outcomes are consistent with RCT outcomes in patients with currently-approved "on-label" chronic pain indications[7]

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DISCLOSURES

Sponsored by Boston Scientific. Dr. North has a consulting agreement with Boston Scientific. Lilly Chen and Roshini Jain are employees of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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ASIPP 2023
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Outcomes of a Large, Multicenter, Real-world Study Using An SCS System Engaging Surround Inhibition

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BACKGROUND

Given the established subjective and varying nature of the experience of pain, providing those implanted with a Spinal Cord Stimulation (SCS) device with multiple and selectable neurostimulative programming options (that can be optimized for the individual) is increasingly recognized as an important aspect for enabling the most efficient and effective treatment for chronic pain.[1-3]

A recently launched, commercially-available SCS device capable of full-body MRI can provide (within a single device) an array of paresthesia-based and sub-perception-based neurostimulation modalities that enagage multiple mechanisms of action including fast-acting sub-perception therapy (FAST), Combination therapy and other advanced waveforms/field shapes.

In this report, we describe our real-world, observational experience and patient-outcomes using this new SCS system for use in the treatment of chronic pain.

METHODS

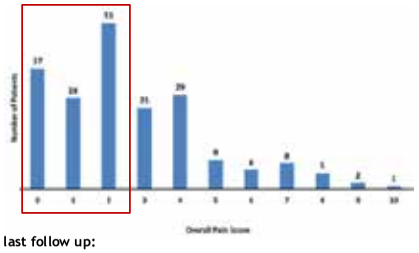
Study Design	Multicenter, Consecutive, Observational, Case-Series. Data collected by site personnel only.
Study Device	SCS System (WaveWriter Alpha, Boston Scientific): • Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting, Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	201 patients diagnosed with chronic pain

RESULTS

Baseline Characteristics (n = 201)

Gender - Females (%)	51.8% (104/201)
Age [Mean (SD)]	65.7 (12.6) years n = 199
Pain Location (%)	Low Back Pain (90.1%)
	Low Back and Legs (90.6%)
Baseline NRS [Mean (SD)]	7.7 (1.7) n = 201
Follow-up duration [Mean (SD)]	91 (122) days n = 201

Distribution of Overall Pain Scores at Last Follow Up (n = 201)



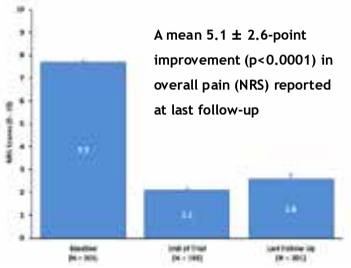
At last follow up:

- 59% (119 of 201) reported a pain score of 2 or less
- 18% (37 of 201) of subjects reported pain free (NRS = 0)

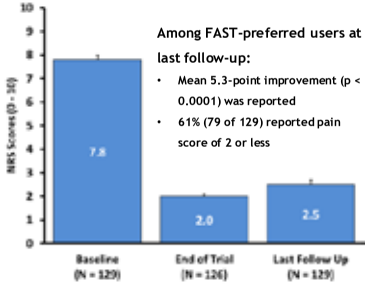
At last follow up, 129 of 201 (64%) preferred FAST as their preferred program of choice

Follow up Ongoing

Overall NRS Pain Scores at Last Follow-up (n = 201)



A mean 5.1 ± 2.6-point improvement (p<0.0001) in overall pain (NRS) reported at last follow-up



Among FAST-preferred users at last follow-up:

- Mean 5.3-point improvement (p < 0.0001) was reported
- 61% (79 of 129) reported pain score of 2 or less

CONCLUSIONS

- Preliminary data from this multicenter, real-world, observational, case-series demonstrate significant improvement of chronic pain in patients with a new SCS system capable of providing multiple paresthesia-based and sub-perception-based modalities that engage multiple mechanisms of action.
- At last follow up, of 201 patients,
  - 59% reported a pain score of 2 or less
  - 18% reported being pain free
- Most patients (64%) preferred FAST as their preferred therapeutic modality of choice to treat their chronic pain (129 of 201) and reported a 5.3-point NRS score improvement with 61% (79 of 129) being pain free (NRS = 0).

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DISCLOSURES

Study sponsored by Boston Scientific. Drs. Ferro, Leier, Wilson and Newton have consulting agreements with Boston Scientific.
Yu Pei and Roshini Jain are employees of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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Three-year Outcomes of a Large, Multicenter, Real-world Study Utilizing an SCS System with Combination Therapy

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BACKGROUND

Single-modality Spinal Cord Stimulation (SCS) approaches are currently available to patients.1-4 However, these approaches are typically only available via separate commercially-available SCS devices. Systems capable of providing multiple therapeutic neurostimulation modalities and adjustable programming options are now thought to be key for personalizing therapy to identify the best, patient-specific course of treatment and may help avoid surgical revision and/or explant.

In this report, we present long-term real-world outcomes from multiple centers using an SCS system designed to provide patients with an enhanced capability for customizing their SCS treatment by offering several modalities including combination therapy (simultaneous delivery of modalities) that engages multiple mechanisms of action.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series - All data collected by site personnel
Study Device	Multiple Waveform SCS system (Spectra WaveWriter, Boston Scientific) with following capabilities: • Engage multiple mechanisms of action • Combination Therapy (sequential or simultaneous neurostimulation) • Multiple waveforms and field shapes
Cohort	420 patients diagnosed with chronic pain
Key Inclusion Criteria	Chronic Pain Patients implanted with SCS

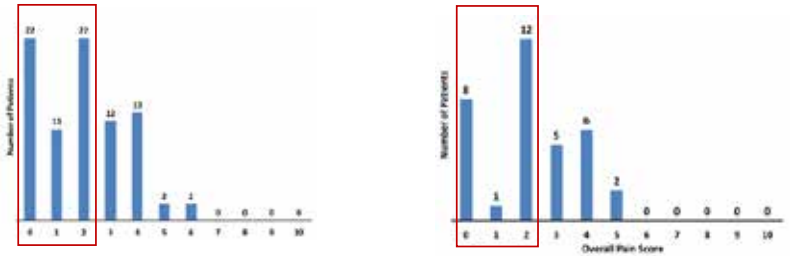
RESULTS

Baseline Characteristics (n = 420)

Gender - Females (%)	53.1% (217/409)
Age [Mean (SD)]	66.2 (13.4) years n = 417
Pain Location (%)	Low Back Pain (67.9%)
	Low Back and Legs (85.7%)
Baseline NRS [Mean (SD)]	7.2 (1.8) n = 420
Follow-Up Duration [Mean (SD)]	371 (393) days n = 420

Overall Pain Scores at Baseline and up to 3-years

Overall Pain Scores at 2-year and 3-year follow-up



During long-term follow-up, ≥60% reported a pain score of 2 or less and nearly a quarter of all patients were pain free (NRS = 0)

Follow-up Ongoing

CONCLUSIONS

- Results from this large, multicenter, real-world observational cohort demonstrated sustained significant improvement in overall pain with the use of an SCS system capable of engaging multiple mechanisms of action, providing combination therapy, and multiple waveforms
- This evidence aligns with that of previous studies indicating the practical value of providing various SCS-based programming options to patients[5-10]
- At long-term follow-up (up to 3-years):
  - ➢A mean 5.0 ± 2.4-point improvement (p<0.0001) in overall pain at 2-years (n = 84) and sustained up to 3-years
  - ➢≥60% reported a pain score of 2 or less and nearly a quarter of all patients were pain free (NRS = 0)

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DISCLOSURES

Study sponsored by Boston Scientific. Drs. North, Pyles, Washabaugh, Berg, and Waghmarae have consulting agreements with Boston Scientific. Yu Pei and Roshini Jain are employees of Boston Scientific.

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NATIONAL HARBOR, MD

Real-World Incidence of Reoperation Rates with Interspinous Spacers for Lumbar Spinal Stenosis

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BACKGROUND

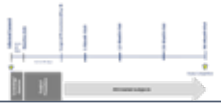
The substantial rise over the last few decades in the number of surgical procedures for Lumbar Spinal Stenosis (LSS) has in turn lead to more patients undergoing reoperation as a result of intraoperative or post-operative complications.[1-4]

The use of Indirect Decompression Systems (IDS) or interspinous spacers in patients with moderate Lumbar Spinal Stenosis (LSS) has been increasingly adopted over the past few years, per the inherent minimally-invasive nature of the IDS procedure. Moreover, clinical outcomes with the use of IDS in a randomized controlled trial with long-term follow-up to 5-years indicated high overall improvement and low reoperation rate with the use of interspinous spacers.[5]

Here, we report reoperation rates derived from a real-world, prospective, multicenter study of patients using an Indirect Decompression System (IDS) for LSS.

METHODS

Design	Prospective, Multi-center, Global Outcomes Study
Device	Superion Indirect Decompression System (Boston Scientific)
Eligibility Criteria	KEY INCLUSION CRITERIA: - Study candidate is scheduled to receive commercially approved Boston Scientific Indirect Decompression Systems, per local Instructions for Use (IFU) KEY EXCLUSION CRITERIA: - Currently diagnosed with cognitive impairment, or exhibits any characteristic, that would limit study candidate's ability to assess pain relief or to complete study assessments in the opinion of the investigator.



RESULTS

A total of 131 patients provided consent and 100 patients (63 *de novo*, 37 previously implanted) completed their implant.

Baseline Characteristics (all patients) n = 128*

Gender - Males (%)	51.6% (66/128)
Age [Mean (SD)]	73.0 (8.74) years n = 128
Diagnosis	Moderate Lumbar Spinal Stenosis

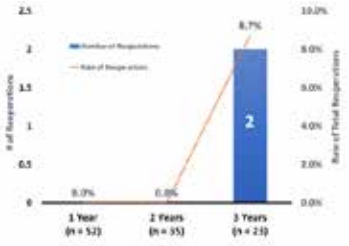
***Data not available for 3 patients**

Success Rates

98%
of patients without reoperations

Of all implanted patients, 2% (2 of 100) underwent reoperation

Reoperation Rate over each year



- Of the 100 implanted subjects:
  - 52 completed 1-year visit
  - 35 completed 2-year visit
  - 23 completed 3-year visit
- No reoperations were reported up to 2-years post-implant.
- 2 reoperations occurred during Year 3

Reoperation is defined as a subsequent procedure following initial implant of the IDS, including replacement and/or removal.

CONCLUSIONS

- Clinical results from this real-world, multicenter prospective study demonstrate high success rate with use of Indirect Decompression Systems (IDS) for treating LSS
  - 98% of patients (n = 100) did not require any reoperation and/or removal following initial implant
  - No surgical reoperations/removals were reported in Year 1 and Year 2.
  - 2 of 23 implanted patients required reoperation/removal in Year 3.
- These results demonstrate a marked reduction in reoperation rates compared with previously published IDE data and may be attributed to improved physician experience, training and/or adjustments in surgical techniques.[5]

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DISCLOSURES

Study sponsored by Boston Scientific. Lily Chen, Holly Kaufman and Roshini Jain are employees of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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Rapid Onset of Analgesia During Trial Period Utilizing Fast-Acting Sub-Perception Therapy SCS

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BACKGROUND

Sub-perception Spinal Cord Stimulation (SCS) offers patients an opportunity to obtain pain relief without paresthesia. Onset of maximum pain relief using traditional sub-perception techniques (e.g., 1-10 kHz) can take up to several hours and even days to occur (unlike conventional paresthesia-based SCS), thereby prolonging and potentially compromising therapy optimization.[1-3]

Newly uncovered low frequency-based (90 Hz) Fast-Acting Sub-Perception Therapy (FAST)-SCS is now often observed to provide pain relief below threshold of perception within seconds to minutes – a characteristic more analogous to traditional paresthesia-dependent SCS.[4,5] Obtaining a quick response to sub-perception therapies, especially during SCS trials is crucial as it has the potential to determine expected response and provide customized therapies for effective pain relief.

Here, we assessed the effectiveness and onset time of FAST-SCS during trial period in a multicenter observational case-series.

METHODS

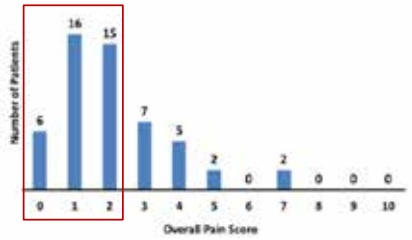
Study Design	Multicenter, Consecutive, Observational, Case-Series Data collected by site personnel only.
Study Device	SCS System (WaveWriter Alpha, Boston Scientific) • Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting, • Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	53 patients diagnosed with chronic pain who underwent a trial with FAST-SCS only

RESULTS

Baseline Characteristics (n = 53)

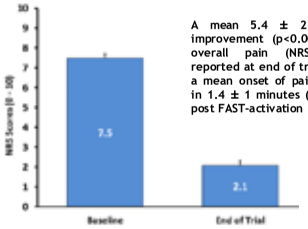
Gender - Females (%)	64.1% (34/53)
Age [Mean (SD)]	65.6 (12.1) years n = 53
Pain Location (%)	Low Back and Legs (96.2%)
	Low Back (94.3%)
Baseline NRS [Mean (SD)]	7.5 (1.7) n = 53
Trial Duration [Mean (SD)]	5.5 (1.7) days n = 53

Distribution of Overall Pain Scores at End of Trial with FAST-SCS* (n = 53)



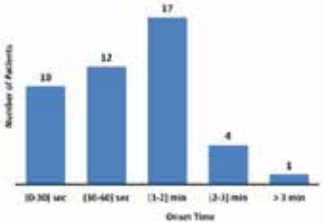
70% (37 of 53) reported a pain score ≤2 at End of Trial with the use of FAST-SCS therapy

Overall Pain (NRS) at End of Trial* (n = 53)



A mean 5.4 ± 2.3-point improvement (p<0.0001) in overall pain (NRS) was reported at end of trial with a mean onset of pain relief in 1.4 ± 1 minutes (n = 44) post FAST-activation

Distribution of Onset of Pain Relief with FAST-SCS[Y] (n = 44)



89% (39 of 44) of patients reported pain relief in ≤2 minutes following activation of FAST-SCS therapy.

*End of Trial Pain Scores: NRS or PPR converted to NRS
[Y]Onset data not provided for 9 patients

CONCLUSIONS

- Preliminary data from this ongoing, multicenter observational case series where a cohort of 53 patients underwent a trial with FAST-SCS demonstrates:
  - Significant pain relief (>5-point NRS score reduction) with a fast onset of pain relief (mean = 1.4 minutes, n = 44)
  - 70% of patients reported a pain score of 2 or less at end of trial with FAST-SCS
  - 89% reported pain relief in ≤2-minutes following FAST-SCS activation
- Results are similar to outcomes previously presented from ongoing prospective study[6]
- The success of utilizing fast-onset therapies during trials allows physicians and patients to determine if they are responder and customize therapy in a quick and efficient manner.

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DISCLOSURES

Study sponsored by Boston Scientific. Yu Pei and Roshini Jain are employees of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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Significant Pain Relief Using an SCS System Delivering Novel, Fast-Acting Sub-Perception Therapy

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BACKGROUND

Treating chronic pain using Spinal Cord Stimulation (SCS) now commonly incorporates use of various sub-perception neurostimulative modalities.[1-3] Recent work has shown that sub-perception SCS for use in treating chronic pain can be successfully applied using a range of stimulation parameters that require substantially reduced energy demands as well as optimization of neural dose (adjustment of amplitude and pulse-width) in order to achieve effective and equivalent pain relief across frequencies.[4,5]

Fast-Acting Sub-Perception Therapy (FAST) is a new SCS method developed in part from the knowledge gleaned in these earlier studies that also exploits the feeling of paresthesia as a marker for precise targeting of sub-perception stimulation.[6]

Here, we report our experience using FAST-SCS with or without the use of a custom field shape programming algorithm during the trial period and after permanent implantation in a single-center, observational case-series.

METHODS

Study Design	Single-center, observational case-series Data collected by site personnel only
Study Device	Spinal Cord Stimulation *(SCS) System (WaveWriter Alpha, WaveWriter, Precision Spectra, Boston Scientific): Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting • Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	• 128 chronic pain patients considered for SCS

RESULTS

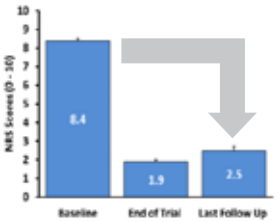
Baseline Characteristics (n = 128)

Gender - Females (%)	64.1% (82/128)
Age [Mean (SD)]	66.5 (12.4) years
Pain Location (%) (may have multiple pain locations)	Low Back and Legs (88.3%)
	Foot (2.3%)
	Legs (43%)
Baseline NRS [Mean (SD)]	8.5 (1.2) n = 128

128 patients underwent a temporary trial at a single center from July 2020 - September 2022:

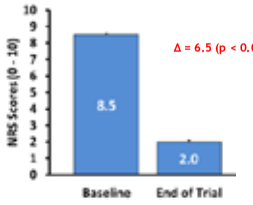
- **All patients received fast-acting sub-perception during the trial (alone or in combination with customized field shape programming).**
- **Of these 128 patients, 116 (91%) were FAST-SCS responders (≥50% pain relief) at end of trial***

Overall Pain Scores at Last Follow-Up (n = 108†)



- A 6.0-point improvement (8.4 → 2.5, p < 0.0001) was reported at last follow-up (mean = 107 days) using novel fast-acting sub-perception therapy (FAST) alone or in combination with customized field programming in majority of patients.
- At 3-months (n = 30), a 7-point improvement (8.4 → 1.5, p < 0.0001) was noted

Overall Pain Scores at End of Trial (n = 116, FAST Responders)



A mean 6.5-point improvement (8.5 → 2.0, p<0.0001) was reported at End of Trial compared with Baseline in FAST responders (n = 116)

Distribution of Overall Pain Scores at Last Follow-Up (n = 108†)

At last follow-up:

- **59% (60 of 101) patients reported pain score of 2 or less**
- **14% (15 of 101) were pain free (pain score = 0)**

*Pain relief calculated using Percent Pain Relief (PPR) or change in pain scores as available.
†108 patients who have undergone a permanent IPG implant as time of data collection. Seven patients did not provide pain score.

CONCLUSIONS

- Computational modeling from the Grill lab suggests that FAST-SCS activates dorsal column axons and inhibits dorsal horn projection neurons[7]
- Published data demonstrates that Fast-Acting Sub-Perception Therapy (FAST) can provide significant pain relief within minutes of activation.[6]
- Results from this single-center, real-world, observational case series demonstrates that significant chronic pain relief (6-NRS points) may be achieved using fast-acting sub-perception therapy (FAST) alone or in combination with customized field programming following permanent implant.
- The use of FAST either alone or in combination with customized field shape programming has potential to provide significant improvement in overall pain.

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DISCLOSURES

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Yu Pei and Roshini Jain are employees of Boston Scientific.

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Optimizing Outcomes and Patient Ease-of-use Through Automated Dose Management of Fast-Acting Sub-Perception Therapy

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BACKGROUND

Treatment of chronic pain using contemporary Spinal Cord Stimulation (SCS) devices now routinely involves the personalized delivery of therapy via application of highly customized neurostimulative settings and approaches per the specific preference and clinical response of each patient. As such, there is a large compendium of published studies that report positive clinical outcomes in patients with access to multiple SCS-based chronic pain treatment options within a single device.[1-5] Individualized automation of SCS programming (i.e., preset, automatic modulation of neurostimulative programming according to one's schedule/activities/other) is yet another, more recently-introduced "customizable" feature provided on commercially-available SCS-systems that some patients do elect to utilize.

Here, we present preliminary outcomes of Fast-Acting Sub-perception (FAST) implemented with a dosing regimen (FAST AutoDose) depending on patients' preference and activity, as part of a multicenter observational case series.

METHODS

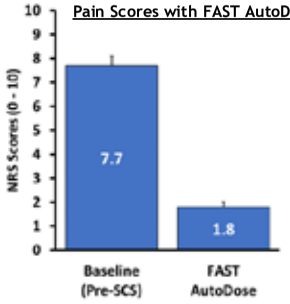
Study Design	Multicenter, Consecutive, Observational, Case-Series Data collected by site personnel only.
Study Device	Spinal Cord Stimulation *(SCS) System (WaveWriter Alpha, WaveWriter, Precision Spectra, Boston Scientific): Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting • Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	• 128 chronic pain patients considered for SCS

RESULTS

Baseline Characteristics (n = 12)

Gender - Males (%)	33% (4/12)
Age [Mean (SD)]	61.0 (13.3) years n = 11
Pain Location (%)	Low Back Pain (100%)
	Low Back and Legs (100%)
Baseline NRS [Mean (SD)]	7.7 (1.4) n = 12

Pain Scores with FAST AutoDose (n = 12)



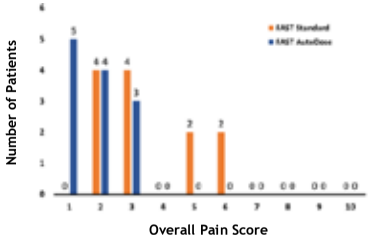
A 5.9-point improvement (7.7 → 1.8) was noted with FAST AutoDose as compared with Baseline (p < 0.0001)

*Patients with pain score ≥5

All patients received FAST Therapy followed by FAST AutoDose for up to 1-2 weeks

FAST AutoDose:
Schedules a proactive stimulation bolus within specified intervals to simplify the patient experience and reduce the potential of habituation.

Distribution of Overall Pain Scores with FAST Standard and FAST AutoDose (n = 12)



- All patients (12 of 12) using FAST AutoDose reported an overall pain score ≤3 compared with 67% (8 of 12) of patients using FAST Standard
- Using FAST AutoDose, FAST Standard non-responders* (n = 4) reduced their overall pain by a mean of 3 points

CONCLUSIONS

- Preliminary results from this multicenter observational case series demonstrates that FAST AutoDose provides significant improvement in overall pain
  - A 5.9-point improvement with FAST AutoDose (7.7 → 1.8, n = 12)
  - All patients (12 of 12) using FAST AutoDose reported an overall pain score ≤3
  - Using FAST AutoDose, FAST Standard non-responders (n = 4) reduced their overall pain by a mean of 3-points
- FAST AutoDose seeks to simplify therapy for patients by automating neural dosing for simplified therapy while providing improvement in pain scores.

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DISCLOSURES

Study sponsored by Boston Scientific. Dr. Ferro has a consulting agreement with Boston Scientific. Yu Pei and Roshini Jain are employees of Boston Scientific.

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Treatment of Pain Using Cervical Radiofrequency Ablation: Outcomes from an International, Prospective Multicenter Study (RAPID)

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BACKGROUND

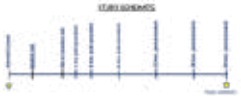
Chronic axial neck pain with or without headache and/or upper extremity pain is increasingly noted as a source of enduring disability and medical costs, and one of the leading causes of healthcare burden[1]. Several clinical studies, including RCTs and observational studies have demonstrated positive outcomes using radiofrequency ablative (RFA) techniques for a range of chronic neck pain indications.[2-6] Further, a recent meta-analysis of 20 previously published studies showed that evidence collectively published supports the use of therapeutic radiofrequency (RF) techniques for the effective management of chronic neck pain.[7]

In light of the on-going opioid epidemic and the need to provide better care to chronic pain patients, recent guidelines (HHS 2019 Best Practices report and 2022 CDC guidelines) have highlighted the need to incorporate interventional techniques including neuromodulation and RF.[8-9] Thus it is important to continually assess and document clinical effectiveness of contemporary RF devices in real-world patients with chronic neck pain, headaches and proximal upper extremity pain.

We conducted an assessment of patients diagnosed with chronic cervical facet joint pain who were treated with RFA as part of a prospectively-enrolled, real-world, multicenter, international study.

METHODS

Study Design	Multicenter, Prospective, International Outcomes Study with consecutive enrollment
Study Device	Commercially-approved RFA Systems (Boston Scientific, Marlborough, MA USA)
Cohort	61 patients with cervical facet joint pain



RESULTS

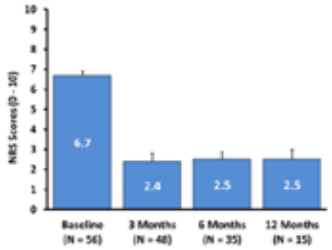
A total of 61-enrolled subjects with cervical facet joint pain in the prospective, multicenter, real-world study received radiofrequency treatment.

Baseline Characteristics (n = 61)

Gender - Females (%)	61% (n = 39)
Age (years) [Mean (SD)]	60.6 ± 11 years (n = 64)
Pain Duration (years) [Mean (SD)]	15.2 ± 13.5 years (n = 64)
Baseline Targeted Pain Score [Mean (SD)]	6.7 ± 1.7 (n = 56)

Targeted Pain is the area of pain intended to be treated with RF

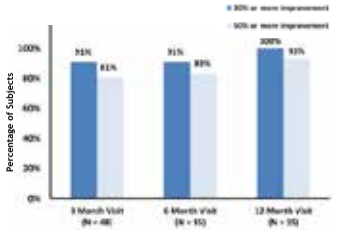
Targeted Pain Scores up to 1-year post procedure



At 12-months post-procedure, significant improvement (p<0.0001) in pain scores was noted.

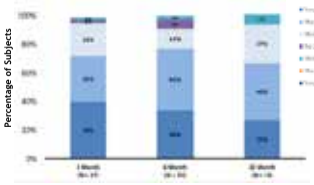
- 4.0-point NRS score improvement (6.7 → 2.4) at 3-months and sustained long-term

Responder Rates (Targeted Pain) post-procedure



High responder rates (>80%) among patients receiving RF for cervical pain up to 12-months post-procedure

Patient Satisfaction (PGIC) post-procedure



Over 90% of patients (cervical RFA) reported improvement (very much, much, or minimally improved) up to 12-months post-procedure

CONCLUSIONS

- Treating cervical facet joint pain with radiofrequency ablation can result in significant pain relief and over all satisfaction and these results are consistent with published reports (Hurley et al., 2022, Manchikanti et al., 2022)
- Preliminary sub-analysis from an ongoing, prospective, multicenter, real-world outcomes RF study of 61 patients with cervical pain shows significant improvement in pain scores up to 12-months post-procedure.
  - 4-point NRS pain score improvement (6.7 → 2.4) a 3-months and sustained up to 12-month post-procedure
  - High responder rates (>80%)
  - Over 90% of patients assessed reported improvement (i.e., very much, much or minimally improved)

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DISCLOSURES

Study sponsored by Boston Scientific.
Roshini Jain, Nilesh Patel and Lilly Chen are employees of Boston Scientific.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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ASIPP 2023
—MARCH 16-18, 2023—
NATIONAL HARBOR, MD

Pain Relief Using an Interspinous Spacer for Treatment of Lumbar Spinal Stenosis Among Patients with Severe Pain

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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] 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 (8-10/10 on Numerical Rating Scale) who received an Indirect Decompression System (IDS) for LSS related pain and symptoms as part of an ongoing multicenter 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) 
Cohort	• 157 patients with severe pain (8 or above) at 10 centers who received IDS

RESULTS

Baseline Characteristics (n = 157)

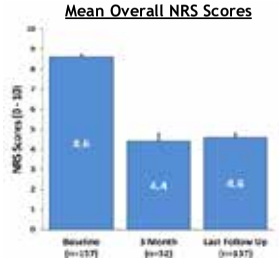
Gender - Females (%)	59.9% (94/157)
Age [Mean (SD)]	72.1 (11.4) years n = 151
Baseline NRS [Mean (SD)]	8.6 (0.8) n = 157
Follow-up duration [Mean (SD)]	200 (306) days n = 157
Diagnosis	Lumbar Spinal Stenosis

Distribution of Leg Pain Scores (NRS) at Last Follow-Up

At last follow-up:

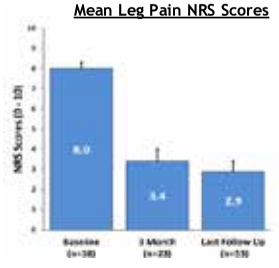
- **58% (31 of 53) reported a leg pain score of 2 or less**
- **43% (23 of 53) of patients reported pain free (NRS = 0)**

Mean Overall NRS Scores



A mean 4.1 ± 3.1-point improvement (p<0.0001) in overall pain (NRS) reported at last follow-up (mean = 200 days) among patients with severe pain at Baseline (8 or more)

Mean Leg Pain NRS Scores



A mean 4.2-point improvement (8.0 → 2.9, p<0.0001) was reported at last follow-up (mean = 200 days) among patients with severe pain at Baseline (8 or more)

CONCLUSIONS

- Results from this ongoing, real-world, observational case-series of severe pain patients (8 or more on NRS), who received an IDS for treatment of LSS symptoms, demonstrated the following at last follow up (mean = 200 days):
  - 4.1-point improvement in overall pain (8.6 → 4.6, p<0.0001)
  - 4.2-point improvement in leg pain (8.0 → 2.9, p<0.0001)
  - 58% reported a leg pain score of 2 or less
  - 43% of patients reported no leg pain (NRS = 0)
- This preliminary evidence aligns with reports in peer-reviewed literature.

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DISCLOSURES

Study Sponsored by Boston Scientific.
Holly Kaufman, Yu Pei and Roshini Jain are employees of Boston Scientific.

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Modified Epidural Adhesiolysis—A Case Series

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Background

Epidural fibrosis (EF) is the development of non-physiologic scar tissue within the epidural space due to local inflammation provoked by tissue trauma (1). Such trauma is often associated with surgical procedures, with studies reporting that the likelihood of developing some degree of EF following lumbar surgery is as high as 91% (2). For this reason, the presence of EF is thought to be a major risk factor for the development of failed back surgery or post laminectomy syndrome.

EF can also occur following infection, annular tearing, hematoma formation, and disc herniation (3, 4). The presence of EF within the lumbar region of a patient's spine can render the spinal cord, cauda equina, and nerve roots more susceptible to entrapment, compression, and tension—each of which can potentially contribute to low back and radicular pain in the lower extremities. It has also been hypothesized that EF can alter the vascular supply to the nerve root which can result in ischemic injury (5). Finally, it is thought that EF can limit the spread of medications within the epidural space intended to treat the very pain that it can produce, limiting the efficacy of procedures such as transforaminal and interlaminar epidural steroid injections (6).

In 1989, Racz and Holubec proposed an epidural adhesiolysis protocol to treat pain caused by the development of EF in the lumbar region (7). Since then, several different modifications to this protocol have been proposed (8, 9, 10, 11, 12, 13, 14, 15, 16). This presentation describes a small series of patients with evidence of EF who underwent treatment with a modified epidural adhesiolysis protocol after failing to have significant relief from previous interventions.

Cases

Patient Characteristics

Patient 1: 73 year old male who had onset of low back pain while doing mechanic work under a car ultimately leading to a L2-4 Posterior Lumbar Interbody Fusion (PLIF).

Patient 2: 50 year old male with a history of chronic low back pain from a parachuting accident. His baseline symptoms include radicular pain down his lateral leg to the dorsal aspect of his foot.

Patient 3: 48 year old male with chronic radicular low back pain exacerbated by forward flexion since a 30 foot fall. He underwent 3 microdiscectomy surgeries and ultimately an L5-S1 fusion.

MRI Findings

Patient 1: degenerative changes status post laminectomy and posterior fusion from L2 to L4 as well as bilateral foraminal stenosis at L5/S1 compressing the L5 nerve roots bilaterally

Patient 2: mild central canal stenosis at L4/5 with neuroforaminal stenosis most pronounced at L5-S1 with associated modic type II changes at L5-S1

Patient 3: postsurgical changes from the laminectomy as well as bilateral neuroforaminal narrowing at L5-S1

Previous Interventions

Patient 1: several L5/S1 interlaminar epidural steroid injections (ILESI) with no significant benefit from the initial injection and some overall benefit from subsequent injections

Patient 2: several ILESI with over 50% relief temporarily for 3-8 weeks. Also underwent bilateral medial branch blocks with 50% relief for about 2 weeks followed by multiple RFAs with 50% relief for about 2 months

Patient 3: two unsuccessful spinal cord stimulator trials after surgical intervention

Protocol

-patient prone on fluoroscopic table
-low back and posterior sacral area prepped with chlorhexidine gluconate 2% and isopropyl alcohol 70% antiseptic solution and draped in sterile fashion
-sacrum and sacral hiatus identified using fluoroscopy with C-arm in the lateral view
-5 mL of 1% lidocaine injected into skin and subcutaneous tissues over the sacral hiatus entry point
-16-gauge 3.5-inch epidural needle placed through the sacral hiatus, into the caudal canal
-after negative aspiration, 4 mL of non-ionic, water-soluble contrast injected in lateral and AP views to visualize contrast spread in the epidural space
-19-gauge 14-inch radiopaque epidural catheter advanced through the epidural needle to the targeted lumbar epidural space under fluoroscopic guidance
-after negative aspiration for CSF and blood, another 2 mL of contrast injected through the catheter into the epidural space to confirm placement
-4-5 ml of preservative-free 0.2% ropivacaine injected as a test dose
-after approximately 5 minutes, a motor test is performed to confirm no significant blockade
-injection of the remaining solutions in the following sequence:
1) 4-7 mL of 600-1000 units hyaluronidase in preservative-free normal saline
2) 4 mL of steroid (6 mg betamethasone or 10 mg dexamethasone) in 0.2% ropivacaine
3) 4 mL mixture of 0.2% ropivacaine/10% saline in 1:1 ratio
4) 3-6 mL mixture of 6 mg betamethasone/0.2% ropivacaine/10% saline in 1:1:1 or 1:2:3 ratio
-Post-injection fluoroscopy to demonstrate appropriate washout of contrast
-catheter and needle removed
-patients' backs cleaned and bandages applied at the needle puncture sites
-patients monitored for 20 minutes post-procedure

Results

Patient 1: modified epidural adhesiolysis twice after failing multiple ILESI for low back pain. The first procedure directed to the left L5 lateral recess provided greater than 50% reduction in symptoms sustained over 4 months. The subsequent second procedure, aimed at the right inferior L5-S1 disc, provided greater than 50% reduction in pain over the course of 14 months

Patient 2: after many unsuccessful ILESI and RFAs, underwent modified epidural adhesiolysis a total of 4 times. Other than the 2nd procedure, the patient reported significant pain relief of >50% sustained well over 3 months, stating the procedure was the "best one yet"

Patient 3: after 2 SCS trials, underwent a total of 31 modified epidural adhesiolysis procedures aimed at the right and left L5-S1 disc each providing 50-80% pain relief that lasted at least 3 months

Patients' Treatment Response

	Pre-procedure pain level (10 point scale)	Degree of pain relief	Duration of pain relief
Patient 1	8	> 50%	≥ 3 months
Patient 2	8-10	> 50%	≥ 3 months
Patient 3	8-10	> 50%	≥ 3 months

Discussion

Epidural adhesiolysis has been described for treatment of post laminectomy syndrome and failed back syndrome. The medications utilized are thought to break down scar tissue and decrease swelling in the epidural space. The traditional method outlined in the table below consists of a series of injections over 2 days in an inpatient setting.

The modified epidural adhesiolysis procedure is an adaptation completed in a 30-60 minute outpatient visit. The series of medications administered is critical, although the volumes administered may vary based on observed contrast spread and patient experience. Specifically the first injectate of 0.2% ropivacaine serves as a test dose to detect intrathecal spread, as well as to help with patient comfort and tolerance of subsequent injectates. For post laminectomy syndrome and failed back syndrome, larger volumes of solutions are favored based on patient tolerance. However, if patients experience significant pressure during slow administration, then volume may be limited. For discogenic pain, smaller volumes may be favored for targeted drug delivery at the specific disc level, particularly if contrast is observed to spread at the target level. However, if the catheter cannot be advanced to the target level, then larger volumes may be used to allow spread of medications to the target level.

EF can develop after surgery, infection, hematoma, annular tearing, or disc herniation. One of the proposed benefits of advancing an epidural catheter via a caudal approach is the potential to access the ventral epidural space. This case series also explores potential efficacy for vertebrogenic pain, as evidenced by Modic changes on MRI. Our patients had low back pain with radicular symptoms and risk factors for development of EF. Although they did not experience relief after having an epidural steroid injection, they had significant pain relief after the modified epidural adhesiolysis procedure.

Traditional	Modified
Day 1	
	0.2% ropivacaine 4-5 mL
Hyaluronidase 1500 units in PFNS	Hyaluronidase 600-1000 units in PFNS
Local anesthetic/steroid 10 mL	Local anesthetic/steroid 4 mL
Wait 30-50 mins	0.2% ropivacaine/10% saline 4 mL (1:1)
10% saline 10 mL inf over 15-30 min	Steroid/0.2% rop/10% saline 3-6 mL (1:1:1 or 1:2:3)
Day 2	
0.2% ropivacaine 10 mL	
10% saline 10 mL inf over 15-30 min	
Wait 4-6 hours	
0.2% ropivacaine 10 mL	
10% saline 10 mL inf over 15-30 min	

Conclusion

The therapeutic effects experienced by these 3 patients from the modified epidural adhesiolysis procedure warrant further studies with larger sample sizes to illustrate the potential benefits of this procedure, especially in patients with prior trauma and/or surgeries. Studies blinding both patients and outcome assessors in those with radicular pain symptoms could objectively compare this adhesiolysis procedure to epidural injections and would be beneficial in establishing its efficacy. Future studies comparing the original adhesiolysis procedure with the modified version could also illustrate the cost-savings and efficiency benefit of this unique protocol.

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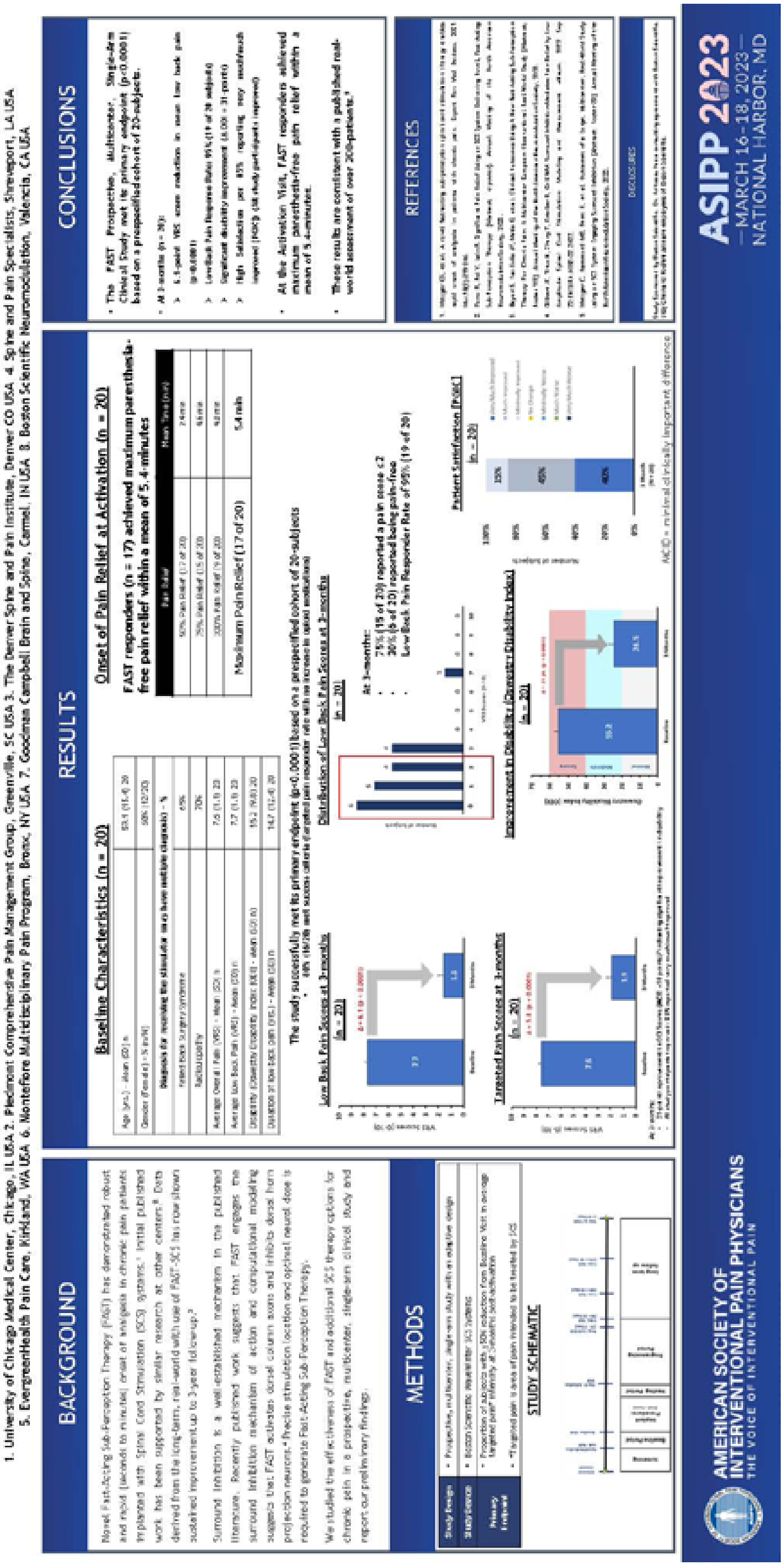
Clinical Outcomes of a Novel, Fast-Acting Sub-Perception SCS Therapy Engaging Surround Inhibition (FAST Prospective Study)
Magdalena Anitescu[1], Eric Loudermilk[2], Drew Trainor[3], John Noles[4], Jennifer Lee[5], Sayed Wahezi[6], Derron Wilson[7], Lilly Chen[8], Roshini Jain[8]
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5. EvergreenHealth Pain Care, Kirkland, WA USA 6. Montefiore Multidisciplinary Pain Program, Bronx, NY USA 7. Goodman Campbell Brain and Spine, Carmel, IN USA 8. Boston Scientific Neuromodulation, Valencia, CA USA
BACKGROUND
METHODS
STUDY SCHEMATIC
RESULTS
Baseline Characteristics (n = 20)
Onset of Pain Relief at Activation (n = 20)
FAST responders (n = 17) achieved maximum paresthesia-free pain relief within a mean of 5.4-minutes
Maximum Pain Relief (17 of 20)
5.4 min
The study successfully met its primary endpoint (p<0.0001) based on a prespecified cohort of 20-subjects
Low Back Pain Scores at 3-months
Distribution of Low Back Pain Scores at 3-months
At 3-months:
75% (15 of 20) reported a pain score ≤2
30% (6 of 20) reported being pain-free
Low Back Pain Responder Rate of 95% (19 of 20)
Targeted Pain Scores at 3-months
Improvement in Disability (Oswestry Disability Index)
Patient Satisfaction (PGIC)
MCID = minimal clinically important difference
CONCLUSIONS
REFERENCES
DISCLOSURES
AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
THE VOICE OF INTERVENTIONAL PAIN
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Spinal cord stimulator for chronic pain from transverse myelitis in a patient with hemodialysis

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UTRGV School of Medicine

SOUTH TEXAS HEALTH SYSTEM McALLEN

Background

- **Transverse myelitis** is a rare neurologic disease from acute inflammatory changes due to various causes resulting in spinal cord injury.
  - **More than 60 percent of patients** with transverse myelitis suffer from sequelae such as motor and sensory deficits, autonomic dysfunction, and chronic pain[1].
  - ***Chronic pain*** significantly affects the quality of life of **around 40 percent of patients**[2].
- Conservative management consists of antiepileptics with antidepressants.
  - Opioids also have a limited role in pain management[2].
  - Pain management with medication is complicated in a patient with **end-stage renal disease** due to significant physiochemical changes[3].
    - It makes *side effects of TCA, and opioids more prevalent* because of their decreased and variable clearance[4].
- Because of the neuropathic nature of the pain, a **spinal cord stimulator** is a viable option for those with failed conservative management[5].
- The authors experienced successful outcomes in pain management for a patient on hemodialysis with chronic pain as sequelae from transverse myelitis by application spinal cord stimulator.

Patient Presentation

- A 55-year-old paraplegic female had chronic neuropathic pain in her mid and lower back radiating to bilateral lower extremities.
- Her symptoms developed 15 years ago when she had transverse myelitis after a spider bite.
- ***Chronic pain with bilateral lower extremity weakness, and hypoesthesia under T12*** remained.
- Her diabetes has worsened since she became wheelchair-bound, and dependent on hemodialysis due to end-stage renal disease from diabetic nephropathy.
- It had impeded her medical treatment for chronic pain, deteriorated her quality of life, and provoked mood changes with adjustment disorder.
- She tried various classes of opioids but suffered from side effects such as dyspnea, intractable nausea, and vomits.
- She only tolerates gabapentin 300mg, amitriptyline 25mg, and oxycodone 10mg daily.
- Several epidural steroid injections only relieved the pain for a few days without lasting effect.

Intervention and Outcome

- On a trial of a spinal cord stimulator, lasting pain relief was achieved.
- The permanent spinal cord stimulator was implanted five weeks later.
- Incision, dissection and introduction of leads to epidural space were done on T10 level due to adhesion and stenosis on T11/12
- Two leads placed on the level of T7 and T8
- **Postoperative VAS score showed significant improvement *(8-10/10 to 0-2/10)* with reduced use of analgesics.**

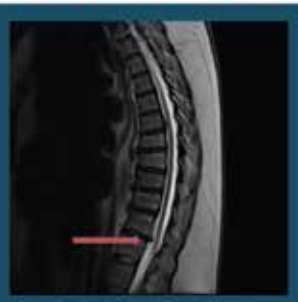

Figure 1. Central canal stenosis with fibrosis on T11/12 is shown on preoperative thoracic spine MRI

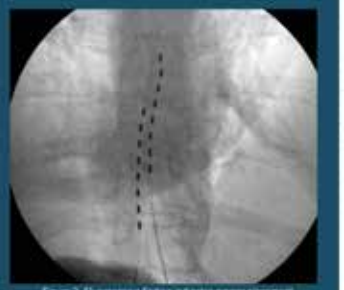

Figure 2. Fluoroscopic finding indicates proper placement of spinal cord stimulator leads on T7 and T8

Discussion

- A patient with comorbidities that limit conservative management can be a good candidate for a spinal cord stimulator implant.
- Despite variable results of spinal cord stimulation in neuropathic pain of transverse myelitis[6,7], recent case reports show successful outcomes with careful patient selection[8,9].
- The authors suggest considering spinal cord stimulation early in the chronic pain management plan in the patient with chronic kidney disease
  - to minimize the side effects of medical treatment and optimize pain control for quality of life

Conclusion

- **A spinal cord stimulator is a feasible treatment option in chronic pain management for a patient with sequelae of transverse myelitis, particularly with end-stage renal disease.**

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The UTRGV IRB has determined this case report as "not research"

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Effect of Restorative Neurostimulation on Major Drivers of Chronic Low Back Pain Economic Impact

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Introduction

Chronic low back pain (CLBP) has significant economic and social consequences.

Pain impact is an important construct that correlates with both functional and economic outcomes.

High impact pain has been defined by the US Department of Health and Human Services (HHS)[1] as

- pain that has been present on most days for six months or more
- is associated with substantial restriction of participation in
  - work,
  - social,
  - and self-care activities

When applied to specifically CLBP, high impact pain patients are more likely to be frequent users of high-cost healthcare resources, reporting substantially higher average pain intensity, and describing higher pain-related interference with life and work-related activities.[2]

Therapies that deliver durable benefit in both pain and dysfunction reduce downstream direct and indirect healthcare costs. Restorative neurostimulation is a therapy that is applied to CLPB patients that have failed conservative management and have few viable therapeutic options remaining.[3]

Objective

Analysis of patients to establish whether the long-term clinical benefit also results in an improvement in the major drivers of economic impact of long-standing CLBP.

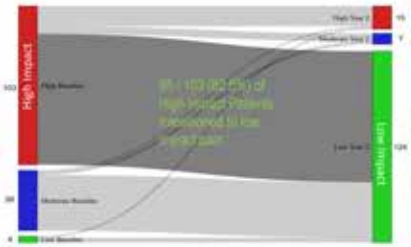
Methods

A cohort of 146 patients with complete data were included in this analysis from the patients completing 2 year follow-up and stratified patients to high, medium, and low impact CLBP. Indirect drivers such as work performance were collected through questionnaires.

Results – Pain Impact

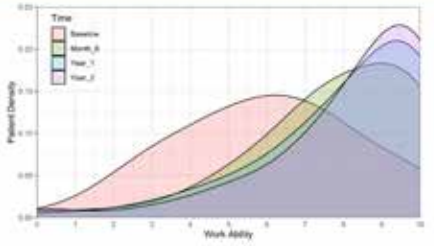
Following two years of therapy 124 (84.9%) of all patients were in the low impact pain class. Of the 103 patients with high impact pain at baseline, 85 (82.5%) reported low impact pain, 5 (4.8%) transitioned to a moderate pain class and only 13 (12.6%) remained unchanged.

142 / 146 (97%) of Patients were high or moderate impact at baseline



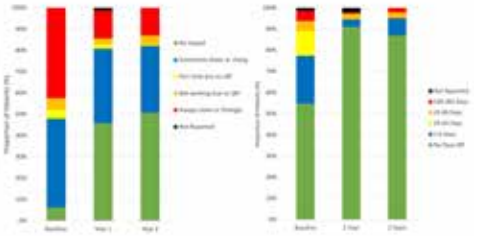
Results – Presentism

Work performance was assessed as "ability to do your work at its best" on a 10-point numerical rating scale. Mean score at baseline 6.0±0.2 improved to 7.8±0.2, 8.1±0.2 and 8.3±0.2 at 6 months, 1 and 2 years, respectively. The proportion of patients rating their work ability as a 9 or10 was 87/146 (60%) at 2 years compared to 21/146 (14%) at baseline.



Results – Work Problems

At baseline, 9/146 (6.2%) of patients reported no work problems due to CLBP. This improved to 67/146 (45.9%) and further to 50.1% after 1 and 2 years of therapy respectively.



Conclusions

There is a disproportionate distribution of healthcare resource utilization between mildly and highly impacted patients. Restorative neurostimulation is one therapeutic option that should reduce healthcare consumption over the long term in line with meaningful and durable symptom relief and transition from the high impact pain category.

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Disclosures

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ORTHOINDY

Emerging Evidence for the Application of Restorative Neurostimulation in an Aging Population

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BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Introduction

- Low back pain prevalence in the ageing population is high despite their underrepresentation in the literature.[1]
- Data on the Medicare population shows that eligible patients are still major consumers of LBP interventions. [2,3]
- In 2016 CMS reported over 2.4 million facet joint related procedures
- Only approximately 1 million were primary procedures.

The high proportion of repeat interventions (~60%) underscores the high burden on healthcare resources and the need for more effective and durable interventions in this population

Restorative Neurostimulation is an effective and durable therapy for chronic mechanical low back pain

Aim

To examine the evidence of clinical benefit of restorative neurostimulation in an older patient population

Method

Data from three clinical studies was aggregated.

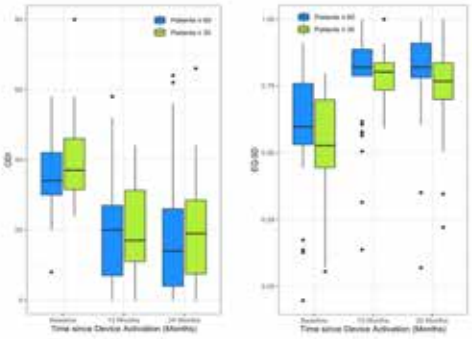
- ReActiv8 B [4]
  - prospectively followed 204 patients in the US, UK Europe and Australia,
- ReActiv8-C [5]
  - prospectively followed 87 patients in Germany
- ReActiv8-PMCF [6]
  - prospectively followed 42 patients in the UK.

To examine the effect of age we identified two cohorts with complete data at 2 years

- Older population ≥ 60 (n= 33)
- Younger population ≤ 35 years old (n=29)

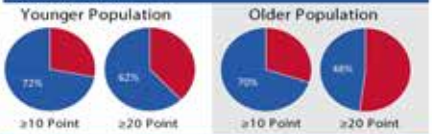
Results

Statistically significant improvements in disability (ODI) and quality of life (EQ-5D-5L) were seen at all assessment time points compared to baseline but not between cohorts.

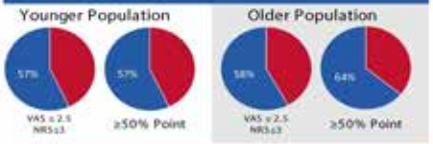


- Profound benefit achieved in both disability and pain irrespective of age
- In patients over 60 years 58% were pain remitters by 2 years
- All outcomes were not statistically different between groups but significant from baseline

ODI Improvement



Pain Improvement



Conclusion

This aggregate analysis combining outcome data from three independent studies provides insight into the performance of restorative neurostimulation in a population over 60. Patients derived significant and clinically meaningful benefit in disability, health related quality of life and pain. This supports the use of restorative neurostimulation in a well selected older population

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THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

Association Between Smoking Status and Opioid Dose in Prescriptions Written For Breast Cancer Related Pain.

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INTRODUCTION

- Current smoking is prevalent in the cancer population and is important cause of variation in cancer related pain intensity and expression.
- The prevalence of poorly controlled cancer pain and the associations between smoking, chronic pain, and opioid utilization patterns in the noncancer population have been previously described.
- However, little is known about the relationships between smoking status and outpatient opioid utilization patterns in patients with cancer.
- We assessed the association between smoking status and high risk opioid prescribing behaviors as described by the CDC guidelines for opioid prescribing prescribing opioid to patients with breast cancer related pain.

METHODS

- Cross sectional analysis of the prescribing patterns of oncologists prescribing opioids for breast cancer related pain from March 15, 2015 to March 15, 2017
- The University of Mississippi Medical Center (UMMC) Patient Cohort Explorer deidentified database was used to assess opioid prescriptions written in the outpatient setting by oncologist at UMMC for breast cancer related pain
- Adjusting for smoking status, age, race, insurance status, and stage of disease,, multivariable logistic regression was used to predict the likelihood of prescriptions written for two CDC opioid guideline specific outcome measures: prescriptions written for ≥ 50 MME and prescriptions written for ≥ 90 MME

RESULTS

- The sample consisted of 577 opioid prescriptions that were written in the outpatient by oncologist to females ages 18 years and older for breast cancer related pain.
- 19.6% of the prescriptions were written to current smokers, 21.3% to former smokers, and 58.1% to nonsmokers.
- Nonsmoking status predicted an increased odds of receiving a prescription ≥ 50 MME (OR=1.98, 95% CI: 1.08-3.60, p=0.030) and ≥ 90 MME (OR=6.29, 95% CI: 1.38-28.58, p=0.017) compared to current smokers.
- Nonsmoking status predicted an increased odds of receiving a prescription ≥ 90 MME (OR=4.29, 95% CI: 1.43-12.92, p=0.009) compared to former smokers

DISCUSSION

- Prior studies assessing the relationship between smoking and opioid utilization patterns in cancer populations have found no difference based on smoking status.
- However, this study shows that non-smoking status is associated with an increased odds of a prescription being written by an oncologist for ≥ 50 MME and ≥ 90 MME for breast cancer related pain relative to current smokers.
- The limitations of this study include our sample being drawn from a single institution and only included a single cancer population, which impacts generalizability. Also, our data was drawn from secondary data not intended for the purposes of our study, which limits the inclusion of other variables that could potentially confound the results.

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Dual System Trial with DRG and SCS for Chronic Pain

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Introduction

Spinal cord stimulator (SCS) implant is a minimally invasive interventional treatment for chronic neuropathic pain. The dorsal root ganglion (DRG) stimulator system is similar; however, it focuses on nerve roots and their respective dermatomes. While the SCS targets the dorsal column or epidural space in a general area, the DRG stimulator can target a specific nerve with more precision.[1]

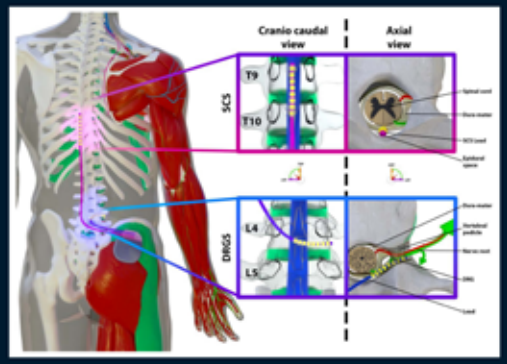

Figure 1: The differences in implantation of a spinal cord stimulator compared to a dorsal root ganglion stimulator as depicted in an illustration.[2]

Case Description

Our patient was a 59-year-old female with a history of NASH on the liver transplant list, cholangitis requiring multiple stents and revisions, hepatocellular carcinoma s/p TACE, and multiple ERCPs. She presented with left lower extremity pain and chronic right abdominal pain secondary to gross distension due to liver failure, both of which were limiting her functional ADLs. She had also been on extended-release narcotic therapy while awaiting a liver transplant. The patient consented to a left-sided SCS trial to target the pelvic and hip girdle pain, and a right-sided DRG stimulator trial for the abdominal and pelvic pain components. Here, we present a case of a neuromodulation trial with simultaneous SCS and DRG stimulator techniques.

Methods

The objective was to compare neuromodulation techniques in the treatment of poorly-controlled chronic pain, and it was accomplished by the following methods. The leads were inserted using complete procedural sterile technique, including betadine followed by chlorhexidine skin preparation. The trial was performed with fluoroscopic guidance under general anesthesia and SSEPs/MEPs/EEGs were used for neuromonitoring. The left-sided SCS lead was placed to the top of T7 via epidural access obtained at T12-L1 level. The two right-sided DRG leads were placed via access from a contralateral level one interspace below the eventual destination in T5 and T9. There were no intraoperative or postoperative complications. The leads are present in the accompanying images (Figure #2).

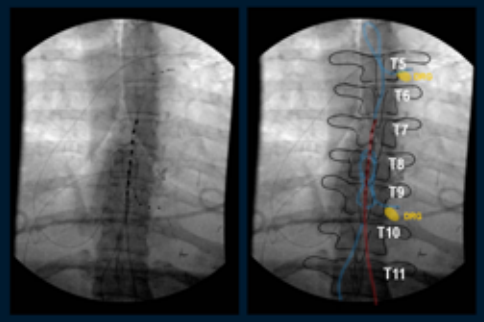

Figure 2. (left) SCS lead placed at top of T7, and DRG leads placed at T5 and T9. (right) Labeled overlay of leads.

Results

Patient was seen in clinic three days post-insertion of SCS and DRG systems.

Patient reported 100% pain relief in the lower abdomen, pelvic girdle, and the left lower extremity, and less impressive relief in the RUQ and right flank.

For the trial period, the patient reported improved functional ambulation.

Discussion

The clinical use of neuromodulation techniques continues to evolve in interventional pain management. While SCS neuromodulation can target a generalized area of pain, the DRG neuromodulation can be used in treatment of more focal neuropathic pain.[3] This patient preferred the SCS system and will present for implant in the next few weeks. Successful treatment with either modality requires appropriate lead placement with no migration, disconnection, or damage.[4] We are interested in allowing patients to make their own decision to help us guide their therapy when considering the differences in SCS and DRG stimulator systems. While SCS systems have many years of evidence, DRG stimulator systems are a newer modality. The field of pain medicine will benefit from comparative studies of SCS versus DRG stimulation.

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Mass General Brigham

A Stim without a Rose: Neurological Recovery post-SCS Explant

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Background

Spinal cord stimulation (SCS), first developed in the 1960's, has become widespread in the United States with over 25,000 neuromodulation devices implanted to date[1]. While the exact mechanism of action of neuromodulation is not fully understood, postulated explanations include cortical down-regulation of pain signals and activation of islet cell dendrites, amongst others[2]. Studies have shown significant efficacy of SCS devices including sustained results after two years in 74% of postlaminectomy syndrome patients and 95% of complex regional pain syndrome (CRPS) patients after five years. However, there are a number of complications that can stem from SCS trials and implantation, including lead migration, lead fracture, implantable permanent generator migration or failure, and infection[2,3].

We present a case of a patient who developed profound lower-extremity sensory and motor deficits after permanent SCS placement despite straightforward SCS implantation and a prior SCS trial being highly successful. No abnormalities were found on initial imaging after SCS placement, so the entire SCS system was removed and intravenous steroids given for 24 hours with the patient's sensory and motor function returning immediately postoperatively without subsequent recurrence. Follow-up imaging showed no explanation for the patient's transient symptoms.

Case Presentation

PREOP

- 38F with NKDA and history of depression, anorexia nervosa, headaches, and CRPS Type I.
- Constant sharp, burning pain that started at her left ankle and foot with radiation up to her left leg and hip. Pain started after being struck by a cart at work.
- Physical exam = left ankle swelling + allodynia; strength and ROM limited by pain.
- Multiple lumbar sympathetic blocks as well as ketamine infusions = marginal relief.
- SCS trial = 75% relief of pain + improvement in sleep and functional capacity.

INTRAOP

- SCS implantation procedure proceeded smoothly. Epidural space was accessed at the L1-L2 bilaterally.
- Leads to mid-T8 on right and mid-T9 on left, respectively.
- Bupivacaine around the incision sites for post-op analgesia; closed in three layers + dermabond, steri-strips, Telfa, and Tegaderm.

PACU

- Upon awakening, severe upper lumbar back pain near the midline incision site without radiation.
- Bladder scan = 460mL of urine → I&O cath.
- Bandages removed. Area without fluctuance, dehiscence, drainage, skin discoloration, rash, etc..
- Thoracolumbar X-ray = no abnormality. Physical exam findings unchanged from baseline at that time.
- Analgesia = 100mcg fentanyl + 30mg of ketamine intra-op. PACU = 200mcg fentanyl + 3mg hydromorphone, minimal effect.

PRESENTATION

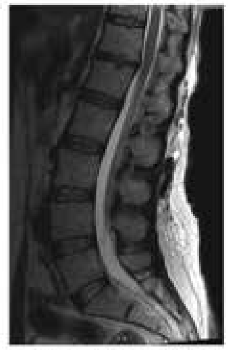
- Lumbar back pain worsened
- Sensory deficits developed and progressed → insensate in BL lower extremities, including in area of prior allodynia
- Motor weakness with 1/5 plantarflexion on the right and 0/5 elsewhere in BL lower extremities.
- DTR = significantly diminished.
- Upper extremity sensation and motor strength unaffected.
- Concern for epidural hematoma. Thoracic + Lumbar MRI would take too long = Thoracic + Lumbar CT → revealed no evidence of postoperative complication.

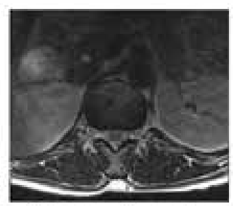
TREATMENT

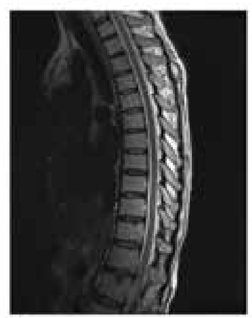
- Unable to pinpoint the reason for progressive sensory and motor deficit → gave dexamethasone 10mg IV.
- Return to OR for complete SCS system removal
- Intraop = no significant bleeding, tissue damage, or necrosis. System removed, irrigated, closed in same way as before.

POSTOP

- Pain improved. DTR, motor, and sensory function returned, including baseline allodynia.
- Admitted overnight for observation + Dexamethasone 10mg Q6H x24H
- Thoracic and Lumbar MRI = small Schmorl's nodes at T11, T12, and L1 + expected postoperative gas in soft tissue.
- Spine Surgery recommended no further tx. Neurology recommended physical exam trending as outpatient.
- Further SCS implantation deferred. 2-week postop = no sequelae, pain at baseline.







Discussion

In a study looking at over 52,000 percutaneous spinal cord stimulators, the estimated rate of spinal cord injury was exceptionally low at 0.45%; risk factors included diagnosis of thoracic stenosis or cervical stenosis within one year, diagnosis of osteoporosis within one year, low-molecular weight heparin (LMWH) administration within 30 days, and male sex[4]. Our patient did not develop thoracic stenosis or osteoporosis, is female, and received no LMWH within 30 days prior to or following the SCS implantation. Another study of over 8,000 patients showed slightly higher overall spinal cord injury in percutaneous SCS implantation at 2.35% with a spinal hematoma incidence of 0.75%[5].

Case reports have detailed paralysis following intramedullary placement of SCS leads and needle penetration into the lower cervical spinal cord, both leading to permanent quadriplegia[3]. Epidural hematoma has resulted in partial paraparesis - American Spine Injury Association (ASIA) D - and complete neurological injury graded as ASIA A; thoracic spinal stenosis has led to partial paresis - ASIA C, and spinal cord contusion has led to more mild partial paresis - ASIA D[6]. Imaging showed no evidence of any of these conditions in our patient, and she had a full return to her baseline status.

Functional neurological disorder (FND) is a consideration, but this diagnosis is not clear-cut in this situation. While motor weakness is often acute-onset in FND, it is typically unilateral[7]. Pain may occur alongside FND, but FND does not explain the presence of pain; our patient's acute pain exacerbation with subsequent resolution after explant would not readily fit with the diagnosis of a FND[7]. Contact allergy to the SCS leads was proposed as a possible mechanism, but this seems unlikely to have resolved so rapidly, and the SCS leads are made from titanium and the incidence of titanium allergy is thought to be low, but the precise number is currently unknown[8]. Definitive testing to establish a diagnosis of titanium hypersensitivity is not available[8].

Conclusion

There is no definitive disorder or condition that fully explains our patient's postoperative pain, motor, sensory, and reflex abnormalities with spontaneous improvement after device explantation. There was no evidence for spinal cord injury, spinal cord contusion, epidural hematoma, FND, or implant alloy hypersensitivity. While MRI-imperceptible spinal cord contusion is most likely of these, hypersensitivity and FND cannot be fully excluded, and other etiologies could exist which have yet to be elucidated. After review of the literature, no cases with similar findings were discovered.

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Approaches to Patients with Chronic Visceral Pain

A Systematic Review of Literature

Anand S. Patil DO; Ahish Chitneni DO; Nimisha Halder BS; Mayank Gupta MD

Objective

To asses various management approaches to chronic visceral pain by measuring pain score and effects on opioid consumption levels

Background

- Visceral pain symptoms: diffuse, dull and poorly localized abdominal pain with occasional nausea and vomiting[1]
- No identifiable abnormality within GI system
- Hypothesize that preganglionic sympathetic fibers are overactive and causing symptoms[2]

PubMed Search

1. (Analgesic drugs) and (visceral pain)
2. (Nerve block) and (visceral pain)
3. (Spinal cord stimulation) and (visceral pain)

Raw Results

1. n = 210
2. n = 34
3. n = 45

Visceral Pain Specific

1. n = 19
2. n = 12
3. n = 16

Analgesic Drugs

Opioids

- *Addictive*
- *Sedating*
- *Narcotic Bowel Syndrome: Abdominal pain due to narcotics*

Nonsteroidal Anti-inflammatory

- *Nonspecific*
- *Stomach ulcers*
- *Renal problems*
- *Antiplatelet effects*

Tricyclic Antidepressants

- *Imipramine can decrease esophageal pain[3]*
- *Beneficial in treatment of Irritable Bowel Syndrome[4]*
- *Functional dyspepsia patients taking amitriptyline 3X more likely to report pain relief[5]*
- *TCAs correlated with positive pain control in patients with neuropathic pain[6]*
- *Side effects of dry mouth, constipation or dizziness in 33% of users of TCA[7]*

Anesthetic Nerve Blocks

Celiac Plexus

- *Two studies show decreased opioid dependence after block[8,9]*
- *Two studies show decreased VAS pain scores[10,11]*
- *Block effects last 8 weeks to 6 months[12,13]*

Splanchnic Nerve

- *Longer lasting compared to Celiac Plexus Block[14]*
- *Easier to target thoracic splanchnic[15]*
- *Larger pain score reduction than Celiac Plexus block[16]*
- *Uncertain decrease in opioid usage: decreased in one study but not another[17,18]*

Transversus Abdominus Plane

- *One case report of patient having reduced pain scores and decreased opioid consumption[19]*
- *Known to lower pain scores up to 24hrs after surgery but limited longevity in chronic pain[20]*
- *Difficult in obese patients[21,22]*

Spinal Cord Stimulation

- *Generally implantation of leads covering T4-T8 region*
- *Good long standing pain relief, indefinite depending on stimulation[23,24]*
- *9 case reports specifically studying reduction in pain scores[25]*
- *1 case report of reduction in pain in patient with chronic pancreatitis[26]*
- *Prospective, single-arm study showing efficacy of 10-kHz spinal cord stimulation in patients with intractable chronic visceral pain over a 12-month follow-up period[27]*
- *Can tailor stimulation to individual needs*
- *Lead migration can be a potential complication*

Conclusion

Among the multiple approaches to managing chronic visceral pain, spinal cord stimulation implantation emerges as a beneficial therapeutic due to long term reductions in pain scores and opioid usage

Mass General Brigham

COVID Vaccination: A Real Pain in the Neck?

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Background

Severe acute respiratory syndrome coronavirus (COVID-19) led to over 800,000 deaths within one year[1]. The creation and administration of a vaccine against COVID-19 decreased the spread, morbidity, and mortality related to the COVID-19 pandemic[2]. While generally safe, the CDC reported rare adverse events including anaphylaxis, thrombosis with thrombocytopenia, Guillain-Barre Syndrome, and myocarditis/pericarditis[3].

We describe new-onset cervical radicular pain in three patients shortly after COVID-19 vaccination, suggesting that vaccine administration may have played a role in neural coct inflammation or irritation.

Case 1 (Pfizer)

A 35-year-old male with a past medical history of anxiety and GERD presented to the pain clinic with new-onset left cervical radicular symptoms after receiving his first COVID vaccine in his left arm. He initially felt tingling at the injection site with radiation to his fingertips starting immediately after inoculation. He later described dull, achy radiating pain that started in the neck and traveled to the trapezius, posterior arm, and down to his thenar eminence. His pain was rated in severity up to 7 out of 10 on a visual analog scale (VAS) and was accompanied by numbness and tingling but was not associated with any weakness or limited range of motion.

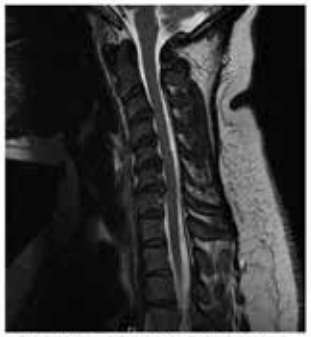
Physical exam was reassuring at the initial clinic visit, and an unremarkable left shoulder X-ray ruled out bony pathology of the shoulder. A two-week course of celecoxib provided mild pain relief. The differential diagnosis primarily focused on peripheral nerve injury versus cervical radiculitis.

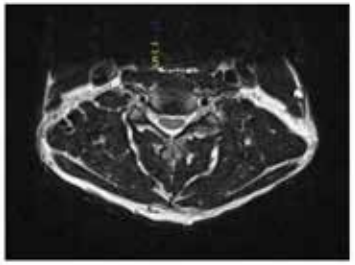
Further diagnostic workup including electromyography and cervical magnetic resonance imaging (MRI) were considered had symptoms persisted, but the cervical radicular symptoms gradually improved and had completely resolved within four months of vaccination. At one-year follow-up, his cervical radicular symptoms had not returned. No additional therapeutics were required beyond celecoxib and expectant management.

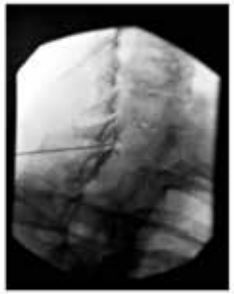
Case 2 (Moderna)

A 38-year-old female with a past medical history of anxiety, vasovagal syncope, and diverticulitis presented with acute-onset, shooting left arm pain ranging in severity from 6 to 10/10 starting two days after receiving a COVID booster vaccination in her left deltoid. The pain originated in the posterior neck and radiated to the left trapezius and posterior upper arm and forearm, into the 2nd and 3rd fingers, and occasionally into the thumb. Physical exam revealed tenderness to palpation in the left trapezius, left posterior neck, and pain with cervical facet loading; Spurling test was negative bilaterally. Cervical magnetic resonance imaging (MRI) demonstrated multilevel cervical spondylosis with mild vertebral canal narrowing and mild to moderate right neuroforaminal narrowing at C3-4.

The patient received trigger point injections at an urgent care with temporary improvement in symptoms, and she was also started on valacyclovir and gabapentin given suspicion for shingles, but never developed a rash suggestive of shingles. Upon evaluation at the pain clinic, her gabapentin dose was increased to 600mg TID while meloxicam 15mg daily, acetaminophen 1000mg twice daily, and a steroid dose pack were prescribed. A subsequent C6-C7 left paramedian interlaminar epidural steroid injection led to complete resolution of pain and numbness. She was tapered off gabapentin and other analgesic medications without return of her symptoms.







Case 3 (Pfizer)

A 57-year-old male with a history of HTN, HLD, syncope, cholecystectomy, left ring finger fracture repair, and left shoulder arthroscopy years prior presented with new-onset burning, pins-and-needles left posterior scapula pain moving to the left shoulder, arm, and into the second and third fingers. The pain ranged in severity from 6-8/10. The pain started after receiving COVID vaccination in the left deltoid. The patient participated in physical therapy and used naprowen 500mg twice daily for symptom relief. He also had received a left subacromial bursa injection prior to presentation to Pain Management.

A cervical MRI revealed moderate to severe spinal stenosis with left-sided spinal cord compression at C6-7 and moderate to severe bilateral C6-C7 neuroforaminal stenosis. Physical exam showed no gross sensory or motor deficits. A C7-T1 interlaminar epidural steroid injection (ESI) provided 70% relief of his radicular symptoms with a repeat 3 months later providing similar relief. Though offered surgical consultation due to concordant findings on advanced imaging with his symptoms, he has preferred to continue with conservative management.

Discussion

With COVID-19 infecting over half a billion people and leading to over 6 million deaths by May 2022, the once-novel illness seems to have ingrained itself as a permanent fixture in modern society[1]. Due to COVID infection resulting in varied neurological presentations and effects, (including long-COVID syndrome), documentation of worsening lumbosacral pain is not entirely unsurprising and can be found documented in the literature[4].

However, there is limited previous literature showing new or exacerbated symptoms of cervical radicular pain with vaccination against COVID-19. This case series shows that COVID-19 vaccination may lead to a manifestation of symptoms that correlate with radiological findings such as in Case 3. At the same time, it simultaneously evidences both a transient pain exacerbation without correlating imaging that resolved spontaneously with conservative management (Case 1), and new-onset radicular pain out-of-proportion compared to imaging findings that improved after a single epidural steroid injection (Case 2).

Conclusion

The mechanism of action behind the exacerbation of cervical and thoracic radicular symptoms cannot be fully described at this time, and larger prospective studies are needed to investigate the possible causal association between the COVID-19 vaccine and cervical radiculitis.

There is no apparent difference between Pfizer and Moderna vaccines based on our case series.

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Radiofrequency ablation of the thoracic descending branch of the posterior rami - an effective intervention for thoracic facet joint pain

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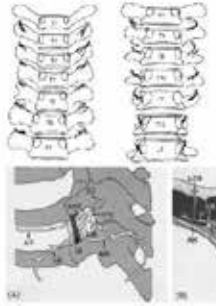
Objective

To investigate whether RFA of the descending branches rather than medial branches of the posterior ramus can relief thoracic facet joint pain.

Introduction

Thoracic spine pain is believed to have a comparable prevalence to that of neck and low back pain in the general population [1,2], but treatment of thoracic facet joint pain has not been well studied[2]. In the cervical and lumbar spine, the facet joint is innervated by the medial branch (MB) of dorsal rami. However, in the thoracic spine, the descending branch (DB), the first branch of the posterior ramus at the junction of superior articular process (SAP) and transverse process (TP) innervates the facet joint capsule 3.



Left: Location of MBs, traditionally

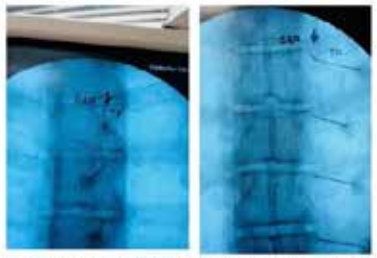
Left: location of the DB

The MBs are located as above and is the spot where MBBs and MBB RFAs are performed, if possible. Of note, MBBs on T5-8, cannot be performed due to the location of nerve on the TP, but when DB are targeted, RFAs can be performed. We hypothesize that performing radiofrequency ablation (RFA) on the DB rather than the classically taught MB would provide relief of thoracic facet joint pain.

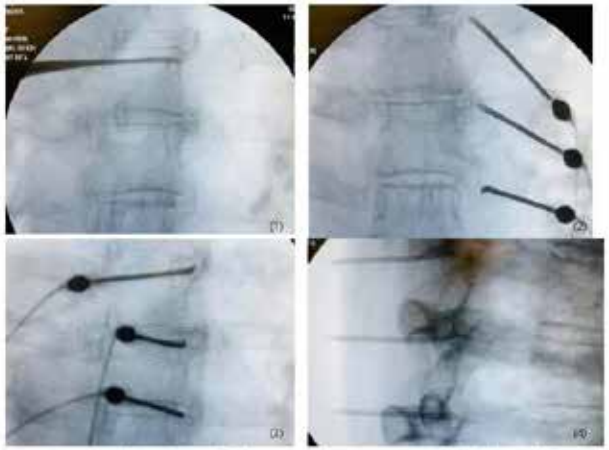
Case Presentation

Our patient is a 57-year-old female who presented with non-radiating mid-thoracic back pain for four months. The patient failed to improve with conservative therapy (physical therapy and oral medications) for several months. Imaging studies included chest and thoracic spine X-rays followed by a non-contrast CT Chest revealed nonspecific spondylosis. Two consecutive DB nerve blocks were performed instead of a standard MB block. Bilateral fluoroscopic-guided T4-6 DB nerve blocks were performed with 0.5ml of 2% lidocaine and 2 weeks later, 0.5% Bupivacaine. These injections yielded temporary pain resolution by at least 80%. She then underwent RFA of bilateral DB nerve of the posterior ramus, which provided complete pain relief for at least 6 months.

Method



The DB is at the junction of the SAP root and the TP. The above are AP and oblique views.



The above picture is RFA of right-sided T 5,6 levels, after squared the targets T5/6, T4/5 and T5/6 levels of intervertebral disc (patch (1). The C-arm was rotated 15 degrees oblique ipsilaterally (2 and 3). The important thing is the RFA electrode tip is in the bony junction of SAP and TP and does not to cross the top of the junction as it may erroneously or potentially advanced to deep into the neuroforamen and injure the underlying blood vessels, nerves or even into the intervertebral disc. Another view for safety is done (4).

After local anesthetic skin wheal was raised and an anesthesia track made all the way down to the bony junction of SAP and TP, an 18 gauge 10cm length with 10mm exposed tip of RFA electrode (Boston Scientific) was introduced down to the same bony targets. After injection of 0.5ml of 2%lidocaine, RFA lesioning was carried out with 85 degrees of centigrade for 90 seconds(RFA machine, Cosman G4 radiofrequency generator). Only one lesion was made, the 16 gauge of electrode typically burns about 4mm in diameter and therefore, it will adequately burn the ascending branches.

Results

The patient had about 75% relief of thoracic facet joint pain up to a year after RFA. The left- sided thoracic pain returned about one year later, but again, initially fully resolved after a repeat DB RFA.

Conclusion

This is the first case report on RFA of descending branch of the posterior ramus in the thoracic spine would provide effective and long-term pain relief for the thoracic facet joint pain. This RFA approach should be studied, ideally in a randomized fashion on a large enough patient population in order to confirm the clinical efficacy of this approach.

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Center for Advanced Pain Management and Rehabilitation

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Refractory Multifactorial Anterior Thigh Pain and Application of Peripheral Nerve Stimulation

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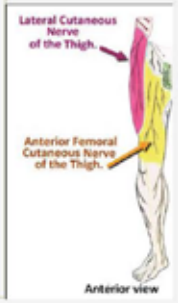
Introduction

- Evaluation of anterior thigh pain is often difficult due to overlapping sensory territories and anatomical variability that can obscure the correct target pain generator.
- Anterior femoral cutaneous nerve (AFCN) neuropathy can masquerade as meralgia paresthetica arising from the LFCN, genitofemoral neuropathy, or inguinodynia
- The AFCN is also prone to neuropathy caused by trauma or surgeries of the hip and knee



Case Description

- 83-year-old Veteran with chronic refractory anterior thigh pain following surgery on her left hip in 12/2020
- She underwent radiofrequency ablation (RFA) of nerves in L4-L5, as well as LFCN RFA, and genicular RFA throughout 2022
- She continued to have deep anterior thigh and medial knee pain which prevented ambulation
- An AFCN RFA was performed 8/22 and she reported immediate pain relief lasting <1 month
- temporary femoral peripheral nerve stimulation was discussed as the next best treatment option

Discussion

- Neuromodulation targets the CNS via deep brain stimulation or spinal cord stimulation (SCS). These require constant stimulation over time and often target larger distribution.
- Newer technologies target specific nerve signal disruption in the peripheral nervous system (PNS) via lead placement directly onto the targeted nerve.
- The SPR system has been studied for pain of the low back, shoulder, post-amputation, and chronic and acute post-operative pain. Cleared for use up to 60 days.
- Benefits:
  - It has low complications as compared to more invasive treatments like SCS or surgery.
  - Temporary (60 days or fewer)
  - Shorter administration times
  - No radiation exposure

- US-guidance should be considered the first-line option
- Techniques will differ in needle approach and position based on the targeted nerve, impacting clinical considerations and associated risks
- The SPR sytem is a versatile treatment that can isolate a specific pain generator instead of larger distribution involvement
- Can help reduce overall medication needs, especially opiates and other
- Result of modulating central plasticity to enable significant and sustained pain relief
- Potential for long term benefit via CNS downregulation

Results

- The SPR was implanted with 0/10 pain immediately after the procedure
- At 10 days follow-up, she reported 2/10 pain at rest with reduced pain in the groin, thigh, and knee
- 50% pain improvement with better quality of life
- >70% improvement of pain at 30 days post

Conclusion

This case demonstrates the challenges of distinguishing specific pain generators from other more common masqueraders. SPR allows targeting large, mixed nerves to improve pain at multiple joints without loss of function, as RFA would cause. Our results emphasize the therapeutic utility of this modality for more specific PNS stimulation.

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Herpetic Trigeminal Neuralgia Masquerading as Migraine Headache

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VA U.S. Department of Veterans Affairs

VCU

Introduction

- Headaches make up approximately 3% of all ED visits, thus Postherpetic Trigeminal Neuralgia (PTN) less likely to be diagnosed and appropriately treated
- PTN causes tingling and neurological abnormalities, often presenting as severe headache with a stabbing or burning sensation before a rash manifests along CN V distribution
- Prevalence is relatively low with 4-13 in 100,000 cases reported annually
- 60% involve the mandibular or maxillary branches

Case Description

- 62-year-old veteran with a C4-5 ACDF (2012) complicated by chronic cervicalgia and spasms
- Severe refractory headaches diagnosed and treated as migraines since 2020
- Headaches refractory to oral medications and Botox injections
- Referred to Pain Clinic for trigger point and occipital blocks with suboptimal outcomes.
- Returned in acute pain crisis, revealing a history consistent with a Zoster infection at initial onset
- Underwent CN V block via the pterygopalatine fossa followed by pRFA with success

Discussion

- Patients may be unable to accurately characterize or even localize their pain
- Patients with refractory pain may visit several pain providers to achieve pain relief increasing the risk of polypharmacy.
- A broad differential and adaptive treatment plan is crucial for patients not responding to conventional treatment.
- Reviewing the history is crucial at each visit to ensure critical details weren't missed.
- In the case of our veteran, PTN was suspected, but unconfirmed
- An ultrasound guided diagnostic nerve block to the trigeminal nerve was performed to support the diagnosis and validate proceeding with a minimally invasive treatment such as pulsed radiofrequency ablation (pRFA).

Results

- A diagnostic trigeminal (V2) block through the pterygoid fossa was performed and provided 90% relief, confirming our diagnosis
- A pRFA of CN V via the pterygopalatine fossa was performed with 0/10 pain immediately after,
- He reported continuing relief for several weeks
- This new diagnosis allowed for other providers to more accurately target the pain generator reducing polypharmacy and inappropriate medications

Conclusion

This case report emphasizes the importance of obtaining a detailed history, assessment of prior treatments, to develop appropriate future interventions. In this case study we correctly identify the etiology of post-herpetic trigeminal neuralgia in a veteran with multifactorial chronic headaches and successfully incorporated ultrasound guidance to deliver both diagnostic nerve blocks and pRF to the trigeminal ganglion with positive outcomes.

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Facet Joint PRP an approach to Failed Back Surgery Syndrome

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Background

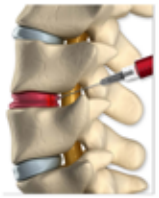
- For patients impacted by failed back surgery syndrome (FBSS), conservative methods including NSAIDs and physical therapy for their back pain are often ineffective, requiring escalation to interventional measures.
- Failed epidural and facet cortisone injections often lead to more invasive procedures such as radiofrequency ablation and neuromodulatory therapies such as SCS
- Orthobiologics have comparable outcomes to ESI with minimal long term side effects.

Case Description

- A 40 year old veteran presented with a history of L5/S1 laminectomy and refractory low back pain with chronic left lower extremity numbness.
- Repeated transforaminal epidural steroid injections (ESIs) provided short term relief; thus, he was scheduled for a SCS trial. Prior to the SCS trial, intra & periarticular PRP injections to L4/L5, L5/S1 facet joints were performed.

Objective

To explore the successful application of PRP for radicular and axial low back pain following failed ESIs in lieu of escalation to implantable devices..



Methods

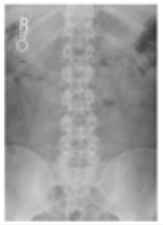
- During PRP injection, using AP fluoroscopic imaging, lumbar vertebral bodies and sacrum were identified.
- Oblique fluoroscopic view identified the left L4/5 joint space.
- Subcutaneous tissue was anesthetized with 1cc lidocaine 1%. A 22G 3.5" spinal needle was directed to the facet joint/capsule under fluoroscopic visualization.
- The technique was repeated at the left L5/S1, right L4/5 and facet joints.
- 0.75ml of PRP and 0.25ml 2% lidocaine per joint were injected in and around the facet capsule
- At the 10-month post-procedural follow-up, he reported further gradual return of sensation to his left leg with sustained back pain relief.

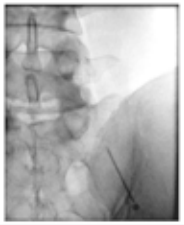
Results

- Following facet joint PRP injections there was improvement in axial and radicular pain.
- At one-month post-procedural follow up there was 70% resolution of low back pain in addition to complete resolution of radicular pain and improvement in leg numbness.
- Thereafter, he reported 90% sustained relief at his six-month post-procedural follow up; injection was repeated at this visit.

Conclusion

- FBSS is generally limited to conservative measures, corticosteroid injections, radiofrequency ablation and implantable devices.
- PRP can provide similar benefits to other interventional treatments with reduced long term side effects.
- This case demonstrates the potential for PRP to have improvement in chronic radicular symptoms.





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When the Hardware Looks Screwy

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Background

Lumbar pedicle screws are key elements involved in spinal fusion. Optimally placed screws that penetrate the central portion of the pedicles are crucial to ensuring adequate fusion. One potential complication is lateral placement of pedicle screws which penetrate lateral to the vertebral body, breaching the lateral pedicle wall or the vertebral cortex. In the case of suboptimal screw fixation, there is an increased risk for pseudoarthrosis and persistent pain.

Clinical Presentation

Our patient presented for evaluation of chronic low back pain with a history of L4-5 transpedicular fusion three years prior which was complicated by hardware infection with MRSA and required open washout, wound vac, and intravenous vancomycin followed by a prolonged course of oral doxycycline. At our visit, the patient was experiencing progressively worsening axial low back pain which was worse with extension and side bending and with midline lower lumbar tenderness to palpation. MRI of his lumbar spine from over one year prior revealed transitional lumbosacral anatomy with a sacralized L5 vertebra and demonstrated the L4-5 fusion with the left L4 pedicle screw entering the pedicle and exiting lateral to the vertebral body. There was also evident grade 2 spondylolisthesis of L4 on L5. CT scan of the lumbar spine again showed the poor placement of the pedicle screw breaching the lateral wall of the pedicle and also showed a halo phenomenon around this screw, suggesting micro motion and potential non-union.

Workup

Because of his history of hardware infection and the suboptimal pedicle screw placement with concern for instability, MRI with and without contrast of his lumbar spine was ordered with accompanying flexion and extension x-rays.

Imaging

T2 weighted MRI (left) shows left L4 pedicle screw breaching the lateral wall of the pedicle. CT scan (right) demonstrates a halo phenomenon around the left pedicle screw, suggesting non-union.

Discussion

MRI of the lumbar spine with and without contrast showed no change in the fusion hardware with bilateral transpedicular screws. It also showed no abnormally enhancing mass lesion, abscess, discitis, or osteomyelitis.

Discussion (continued)

Although the flexion and extension x-rays did not show dynamic instability in the L4-5 segment, this exam has less sensitivity with lower lumbar segments which is the case in this patient with a sacralized L5 vertebra serving functionally as an S1 vertebra. Aside from imaging, it is difficult to determine clinically whether this patient's pain stems from persistent pseudoarthrosis or from worsening spondylosis. He was therefore referred back to neurosurgery for consideration of surgical revision before offering further pain interventions.

Conclusion

Literature review indicates that improper placement of pedicle screws is a rare occurrence but can result in pseudoarthrosis and instability which can lead to persistent pain. Our patient's history was also complicated by hardware infection which is an independent risk factor for hardware failure and non-union. This case highlights the importance of investigating the less common causes of pain around fused lumbar segments. Interestingly, neither the breached pedicle screw nor the halo phenomenon on the CT scan were mentioned in the report of any of the available images. This serves as a reminder of the importance of reading the images of every scan and not to rely on the report alone.

MANAGEMENT OF A PATIENT WITH POSSIBLE SUPERIOR MESENTERIC ARTERY SYNDROME

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INTRODUCTION

Superior mesenteric artery (SMA) syndrome is an unusual cause of duodenal obstruction. The syndrome is characterized by compression of the third portion of the duodenum due to narrowing of the space between the superior mesenteric artery and aorta and is primarily attributed to loss of the intervening mesenteric fat pad. Patients with SMA syndrome can present with considerable postprandial pain. Diagnosis can be difficult as the condition is not common, and symptoms can be non-specific. Treatment can range from conservative modalities such as gastric decompression, dietary modifications, and electrolyte abnormality correction to more invasive surgical interventions. Celiac plexus blocks, which are commonly used to help manage abdominal pain due to malignancy, may be useful in the management of SMA syndrome.

CELIAC PLEXUS

The celiac plexus block aims to target the afferent nociceptive fibers and can be used as both a diagnostic technique and a therapeutic tool for managing intraabdominal pain. The major indication for celiac plexus block is abdominal pain that is nonresponsive to analgesic interventions; often these patients are nonresponsive to high-dose opioid therapies. Conditions in which celiac plexus blocks may be useful include intractable intraabdominal pain, including pain related to malignant or benign neoplasms involving the pancreas or other retroperitoneal organs, biliary tree, or other abdominal organs. The celiac plexus is comprised of a network of nerve fibers and individual ganglia located near the anterolateral surface of the aorta at the T12/L1 vertebral level (See Figure 1). Presynaptic sympathetic fibers travel from the thoracic sympathetic chain toward the celiac ganglia, traversing over the anterolateral aspect of the inferior thoracic vertebrae as the greater (T5-T9), lesser (T10-T11), and least (T12) splanchnic nerves.

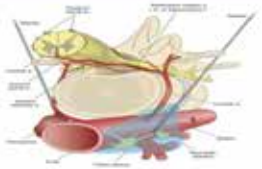

Figure 1. Cartoon Image of the Celiac Plexus

CASE REPORT DETAILS

29-year-old male with past medical history of Crohn's Disease complicated by terminal ileitis status post ileocecectomy complicated by chronic abdominal pain. Patient experiences significant postprandial pain.. He had lost considerable amount of weight due to this intractable pain. He had been managed conservatively with diet modifications as well as pain medication, including oxycodone, but the pain relief was inadequate. He was evaluated by a general surgeon for possible superior mesenteric artery syndrome, but the evaluation, including CT imaging (See Figure 2), did not show clinically significant obstruction and no surgical intervention was recommended although his aortomesenteric angle is reduced to 11 degrees. He presented to our outpatient chronic pain clinic for evaluation of this chronic abdominal pain. He was offered celiac plexus block for management of this pain.

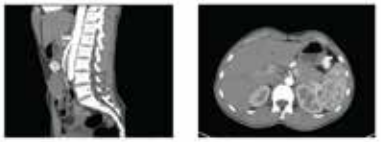

Figure 2. Patient's Abdominal CT imaging

CELIAC PLEXUS BLOCK

Due to a lack of efficacy with conservation management with continued pain and weight loss, the patient consented to undergo a bilateral celiac plexus block with ropivacaine 0.5% and dexamethasone 10mg. The fluoroscopic images from this block are found in Figure 3.

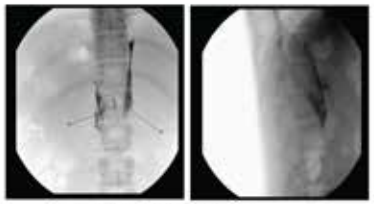

Figure 3. Celiac Plexus Block #1

Two months after the first block, the patient underwent a second block due to return of symptoms. See Figure 4 for fluoroscopic images of block #2.

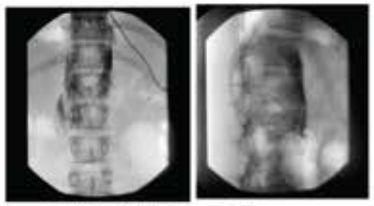

Figure 4. Celiac Plexus Block #2

DISCUSSION

SMA can be a challenging diagnosis to confirm and can be equally as challenging to treat. In this case, the patient was not deemed a candidate for surgical intervention as his surgical team did not see radiographic evidence of significant superior mesenteric artery occlusion. The patient failed conversative treatment and experienced significant weight loss due to his postprandial pain. The first celiac plexus block worked extremely well for this patient. He gained 20 lbs. of weight with an 80% reduction in pain. The patient reported feeling well for nearly two months, but his symptoms returned. He underwent a second celiac plexus block at L1 but, unfortunately, the patient did not get the same degree of relief with this second block. These cases can be challenging to manage especially when the diagnosis is inconclusive, like in our case. Additional options for this patient include peripheral nerve blocks, such as a transversus abdominis plane block, which the patient was offered, however, has yet to undergo.

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Trigger Point Injection of the Pterygoid Muscles for Persistent Idiopathic Facial Pain: A Case Report

Boston University School of Medicine

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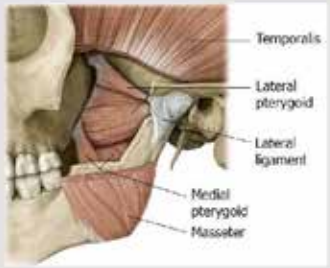
Introduction

- Atypical facial pain or persistent idiopathic facial pain is described as a chronic facial pain in the distribution of the trigeminal nerve in the absence of neurologic deficit or other clear etiology.
- It is a challenging diagnosis of exclusion, with limited known effective treatment options. A variety of treatments have been attempted, with variable success. There remains no gold standard for treatment of this difficult to diagnose disorder.
- We describe a patient with unilateral atypical facial pain in a V2 and V3 distribution that was challenging to diagnose at first, but then successfully treated with trigger point injection.



Case Description and Presentation

- A 78-year-old female developed toothache and pain localized to the tragus of the left ear two years prior to presentation to our pain clinic. The patient's dentist extracted the tooth, in hopes of alleviating her symptoms, but shortly after the tooth extraction, the patient's pain got worse. The patient began to experience a combination of sharp pain and aching extending from the left tragus to the tip of her nose and pain along the left mandible. Brain MRI reported the left superior cerebellar artery potentially abutting the superior aspect of the left cisternal trigeminal nerve, and the patient was diagnosed with trigeminal neuralgia.
- Carbamazepine, gabapentin, and tricyclic antidepressants slightly improved the patient's pain, but she continued to describe her symptoms as very distressing.
- When the patient presented to our pain clinic, she continued to describe the pain as a sharp sensation, exacerbated by brushing teeth, chewing, talking, and direct palpation around the pterygoid plate.
- The description of her pain was lacking the typical trigeminal neuralgia presentation, such as "electrical shock" sensation or pain induced by facial touch/cold temperature. On physical examination, her oropharynx was negative for otalgia. No audible clicking or pain of the temporomandibular joints was elicited with opening, closing and lateral excursions.

Procedure and Methods

- The patient was offered trigger point injections, which the patient consented to. At the start of the procedure, the patient was reporting 7/10 pain on NRS.
- For the procedure, the patient received a left lateral and medial pterygoid injection using 40mg Depomedrol mixed with 3mL of 0.25% Bupivacaine, confirmed by direct intraoral palpation of the left lateral pterygoid muscles, duplicating and exacerbating patient's typical pain symptoms.
- Ten minutes post-procedure, the patient had no pain, 0/10 on NRS. The patient did not sustain any loss of sensation over the V2 or V3 distribution of the trigeminal nerve. At follow up 3 months later, she continued to report greater than a 50% decrease in intensity of pain and significant improvement in her quality of life. Furthermore, the patient was able to discontinue gabapentin.

Results

At follow up 3 months later, she continued to report greater than a 50% decrease in intensity of pain and significant improvement in her quality of life. Furthermore, the patient was able to discontinue gabapentin.

Conclusions

Atypical facial pain continues to be a poorly understood pathology that can significantly diminish the quality of life of those that are affected. Up to 26% of people may experience facial pain during their lifetime. Standardizing diagnostic and treatment approaches will help improve treatment efficacy for patients. Trigger point injections could be an effective treatment for those afflicted with atypical facial pain.

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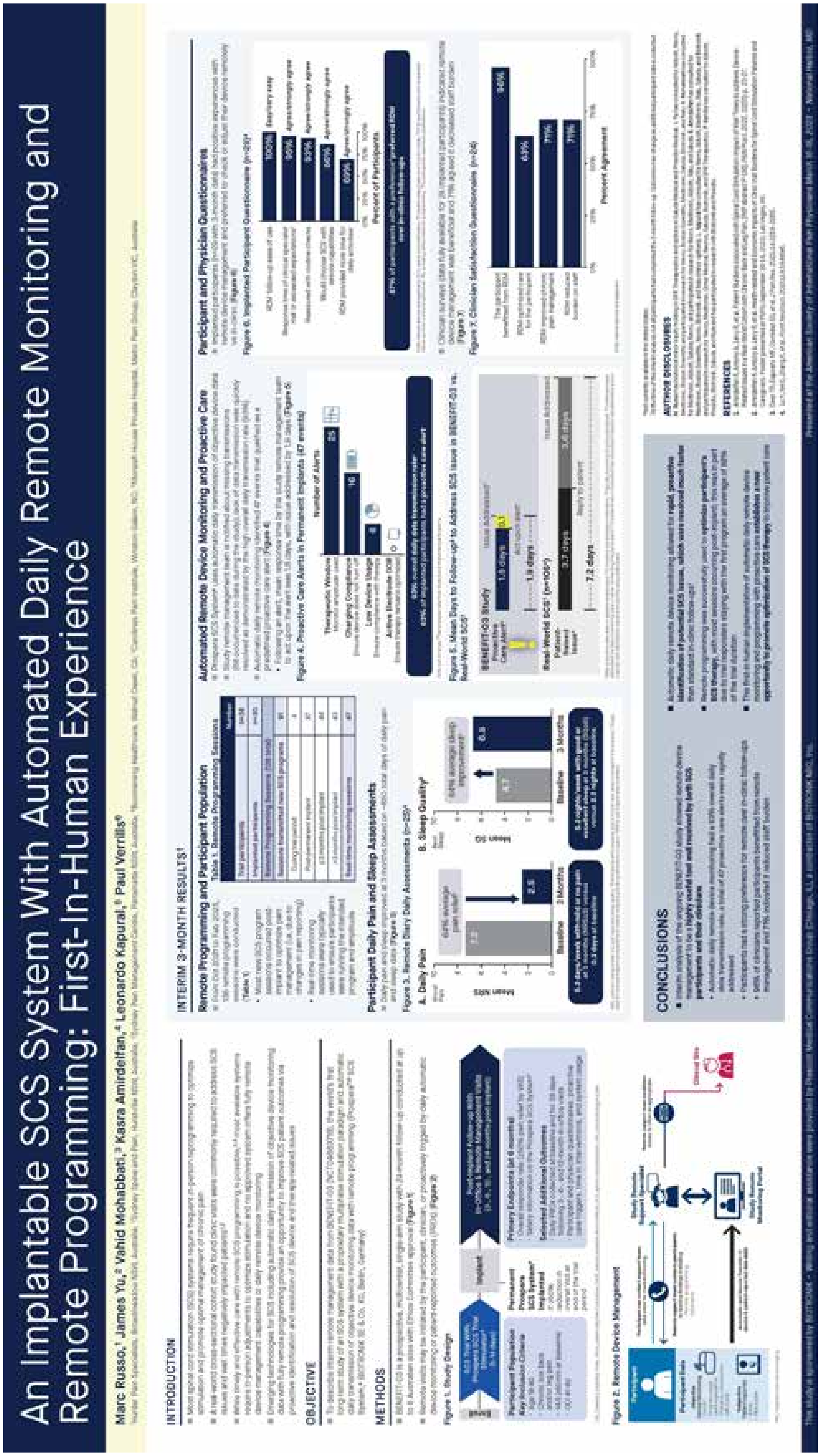
An Implantable SCS System With Automated Daily Remote Monitoring and Remote Programming: First-In-Human Experience
Marc Russo, James Yu, Vahid Mohabbati, Kasra Amirdelfan, Leonardo Kapural, Paul Verrills
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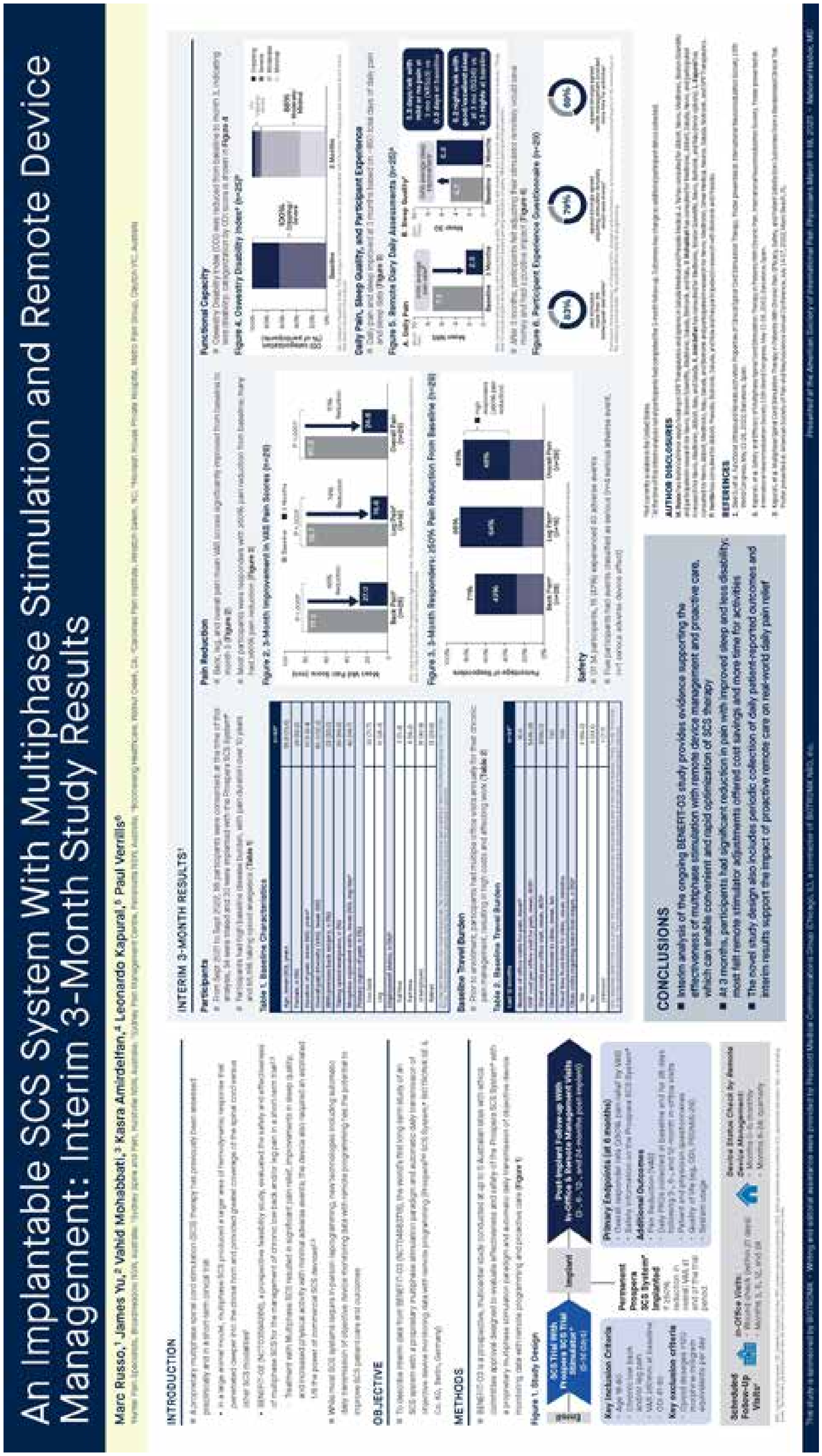
An Implantable SCS System With Multiphase Stimulation and Remote Device Management: Interim 3-Month Study Results
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Interim analysis of the ongoing BENEFIT-03 study provides evidence supporting the effectiveness of multiphase stimulation with remote device management and proactive care, which can enable convenient and rapid optimization of SCS therapy
At 3 months, participants had significant reduction in pain with improved sleep and less disability; most felt remote stimulator adjustments offered cost savings and more time for activities
The novel study design also includes periodic collection of daily patient-reported outcomes and interim results support the impact of proactive remote care on real-world daily pain relief
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Newly Naïve: Re-Sensitization to Opioid Therapy Following an Episodic Withdrawal Secondary to Iatrogenic Damage to an Intrathecal Morphine Pain Pump

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Joseph A. McGuire, MD[1]; Kristin E. Davis, MD[1]; Violet Shackleford, MD[1]; Athanasios Tzaras, MD[1]; Richard M. Vaglienti, MD[1]

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Introduction

- Intrathecal drug delivery systems have been safely used for decades and can treat a wide variety of pain and neurological conditions.
- Complications, which can be fatal if unrecognized, include pump failure or pump malfunction leading to under- or over-delivery of medication, or intrathecal catheter-related complications, such as migration, occlusion, disconnection, or laceration. [1]
- Patients undergoing withdrawal from intrathecal opioids normally require significant symptomatic supportive care and a taper and can have tolerance and hyperalgesia if previously treated for an extended period.
- Preemptively treated with higher doses of opioid medication than their opioid naïve counterparts would receive when experiencing acute pain episodes.
- The mechanism behind development of tolerance to opioid medication is still unknown, and very little is known about the reversal of tolerance following an extended period of opioid therapy. [2]
- This report highlights an interesting clinical phenomenon of re-sensitization to opioid therapy and elimination of tolerance following an episodic withdrawal secondary to an iatrogenic injury to an intrathecal catheter during routine operation.
- This phenomenon has been reported before in rat models [3], however, very little research has been done in humans due to the severity of symptoms that arise during withdrawal and the ethical considerations that must be considered.

Case Presentation

- 49-year-old female with chronic low back pain and lumbar post-laminectomy syndrome and previous placement of intrathecal morphine pump presented with new radicular leg pain consistent with L4 radiculopathy
- Right L4 transforaminal nerve block provided complete relief of pain for 48 hours, so patient subsequently underwent right lateral lumbar interbody fusion with instrumentation, allograft posterior percutaneous screw removal, and new percutaneous screws at L4-L5 three months later
- At the time, her intrathecal pump was running at a dose of 5.004mg per day with a basal rate of 2.754mg and a flex rate of 0.750mg per hour over three intervals (MME of 1,501.2; Figure 1).
- During the procedure, the subcutaneous pain pump catheter was inadvertently transected. Neurosurgery was unable to repair the pump due to equipment compatibility issues
- Pain management recommended clamping the catheter at the side most proximal to the intrathecal inlet to prevent a CSF leak while still allowing for subcutaneous infusion of morphine, however, both sides of the catheter had already been clamped before the recommendation was relayed to the surgical team
- Patient was started on acetaminophen, gabapentin, extended-release morphine sulfate, morphine, and oxycodone for pain management, but experienced severe pain over the next three days

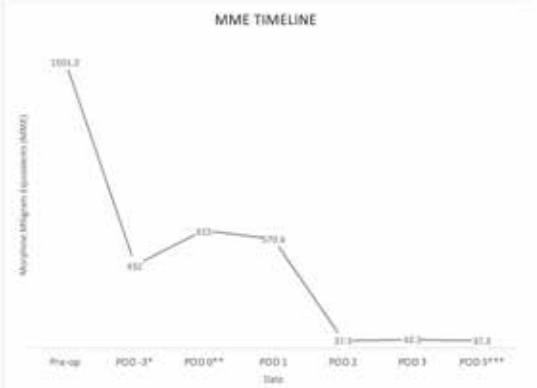

Figure 1. Morphine Milligram Equivalent (MME) Timeline. The MME total the patient was receiving is illustrated. Post-operative days (POD) are relative to the day of operative repair of the intrathecal pump. * - POD -3: Day the catheters were severed during right lateral lumbar interbody fusion. ** - POD 0: Day of intrathecal pump repair. *** - POD 5: Day of patient discharge from the hospital.

- Catheter was replaced by pain management, and patient received a one-time bolus of 0.05 mg morphine and a basal rate of 1.999 mg morphine per day
- Patient was noted to be difficult to arouse and received 2 doses of naloxone, transferred to ICU with concern for opioid overdose
- Intrathecal pump rate was subsequently decreased to a rate of 0.962mg per day and then to a minimal infusion rate of 0.125mg per day
- Patient experienced confusion and somnolence despite remaining on minimal infusion rate and required naloxone on postop days 2 and 3
- Patient's mental status gradually improved and she was later discharged
- Intrathecal morphine concentration was decreased, and patient was programmed with a daily dose of 0.125mg morphine per day for sustained pain control, which she reported sustained pain control during follow-up

Discussion/Conclusion

- To our knowledge, this is the first reported case wherein the patient appears to become opioid naïve rapidly following withdrawal. In fact, the patient is noted to have had a total MME reduction of 97.5% during the entirety of her course from presentation to discharge (Figure 1).
- Another similar case has been reported wherein the patient was noted to be less opioid tolerant and subsequently overdosed, however the patient remained tolerant to oral and IV opioids. [4]
- Mechanisms of rapid re-sensitization have been proposed from rat model studies [3] but remain a challenge to study in human subjects due to ethical concerns surrounding an acute withdrawal event.
- In conclusion, there is much more research needed to further describe tolerance to opioid medications in humans. Here we report an interesting case of re-sensitization following a withdrawal episode secondary to an iatrogenic injury to an intrathecal catheter. This case also highlights the importance of a multidisciplinary approach to patient care.

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Catheter Avulsion due to Twiddler's Syndrome of an Intrathecal Ziconotide Pump: Report and Review of the Literature

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Introduction

- First described in 1968, Twiddler's Syndrome (TS) originally referred to a rare complication of implantable cardiac pacemaker devices that involved the spinning of the pacemaker's leads in an anatomical space, subsequently leading to dysfunction [1].
- This has now been widely reported in pacemakers and implantable cardioverter defibrillators [2].
- Variations of the syndrome have also been described with the manipulation of other devices, including chemotherapy infusion pumps [3], deep brain stimulators [4–6], and spinal cord stimulators [2,7–9].
- While TS in intrathecal drug delivery (IDD) systems has been reported several times, the incidence appears to be very rare [10–14].

Case Presentation

- 42-year-old female with history of low back, abdominal, hip, and flank pain and renal cell carcinoma
- Refractory pain to conservative therapy, candidate for intrathecal ziconotide
- Underwent implantation of IDD with no complications
- Six months later, patient had new onset increasing abdominal pain and requested an increase in medication administration
- Basal rate increased to 0.147 mcg/hr from 0.125 mcg/hr, but patient continued to complain of increased pain
- Patient reported pump reservoir moving in her abdominal wall
- Scheduled for revision of intrathecal pump pocket and catheter due to Twiddler's syndrome
- Intraoperatively, discovered complete disconnection between tubing and medication reservoir with multiple twists in the catheter (Figure 1, Figure 2) which was repaired without issue
- Procedure was tolerated with no complications
- Post-operative follow-up two weeks later showed patient's pain was well-managed

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Figure 1. Intrathecal drug delivery catheter shown tangled on the surgical field

Figure 2. Intrathecal drug delivery pump disconnected completely from the catheter system.

Discussion/Conclusion

- TS occurs when a patient manipulates or twists the drug pump, often unknowingly, causing the device to malfunction.
- This can lead to several problems, including underdose, pump failure, displacement, or infection [15].
- Patients with psychiatric co-morbidities are at high risk of voluntarily manipulating the pump, and previous literature has called for pre-placement evaluation [16].
- Additionally, individuals with loose or thin subcutaneous tissue seem to be at higher risk for device loosening within its anatomical space, allowing for movement and subsequent TS.
- Because of this, children, elderly, and obese individuals are at a higher risk of TS development [11].
- Theoretically, those with connective tissue disorders or severe nutritional deficiencies may also be at a higher risk.
- The presentation of TS would be similar to that of other catheter-related IDD complications, most likely leading to sudden termination of drug delivery to the intrathecal space [15]. Diagnosis is achieved through a combination of clinical suspicion from withdrawal symptoms and radiological evidence. Withdrawal symptoms will vary widely depending on the substance that was being infused into the intrathecal space.
- Other reported cases have been in patients receiving intrathecal opioids [10,11,13,14] and baclofen [12]. Due to this, their presentations were more clearly withdrawal rather than an overall decrease in drug efficacy and increased pain that we describe here. Ziconotide, which this patient was receiving, poses a slightly more challenging clinical picture, as it can be discontinued abruptly without withdrawal effects [15,17].
- In conclusion, although infrequent, Twiddler's Syndrome of pain pumps can cause avulsion of the catheters, inadequate drug supply, as well as drug withdrawal in rare circumstances.
- It should be considered in patients with subjective feelings of device movement, a new onset decline in therapeutic efficacy, or withdrawal symptoms.

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Early Outcomes from a Randomized Control Trial for the Treatment of Peripheral Neuralgia

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Introduction

Peripheral nerve stimulation (PNS) is a well-established method for the treatment of chronic intractable pain. We are reporting the updated results of the first large PNS randomized clinical trial (RCT), COMFORT Study, involving a battery-free system with a micro-implantable pulse generator (Nalu Medical, Inc. Carlsbad, CA).

Methods

The COMFORT Study is a post-market, open-label, minimal risk, multicenter RCT designed to align with standard of care procedures for PNS. Up to 150 subjects will be randomized to the active and control arms in a 2:1 ratio, per protocol. Subjects who are eligible, consented, and prescribed PNS therapy to treat chronic pain in the shoulder, knee, low back and foot will be considered for study participation. Subjects randomized to Control Arm will receive conventional medical management (CMM), while those randomized to the Active Arm will receive a PNS implant with CMM.. Subjects will be followed in both arms at -1, -3, -6 and 12-months from randomization and device activation, respectively. Control Arm subjects may cross over to the Active Arm at 3-months Outcomes related to pain relief, satisfaction, functional outcomes and safety will be collected and reported. IRB approval was received prior to study activities.

Results

To-date, complete 3-month data is available on 16 active and 12 control subjects. Numeric Rating Scores (NRS) for pain showed an average pain reduction of 69% ± 31% in the active arm vs 7% ± 21% in the control arm. The mean pain score improved from 7.5 ± 1.32 at baseline, to 2.19 ± 1.94 at 3-months, in the Active Arm. In the Control Arm, the mean score changed from 7.42 ± 1.5 at baseline to 6.75 ± 1.6 at 3-months (Figure 1). The responder rate (50% or greater improvement) in the Active Arm was 81% (13/16) and 0% in the Control Arm. Oswestry Disability Index data shows functional improvements with 57% of Active Arm subjects reporting improvement vs. 3% of the Control Arm subjects. Patient Global Impression of Change (PGIC) data shows that 94% (15/16) of subjects in the active arm reported improved PGIC vs 16% (2/12) in Control arm; 75% (9/12) of control arms subjects reported no change over time vs 0% of active arm subjects (Figure 2). No serious adverse events or unanticipated device effects have been reported to-date. There have been no reports of pocket pain.

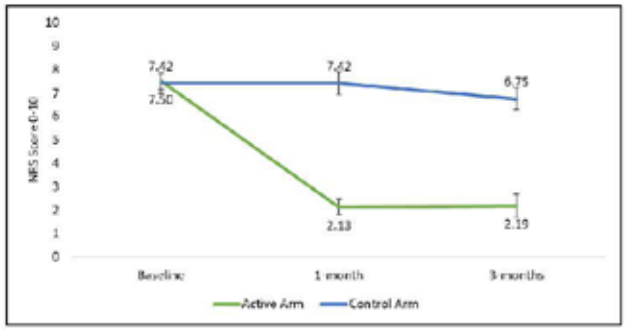

Figure 1: Pain relief in both study arms with 69% improvement in the active arm and 7% in the control arm

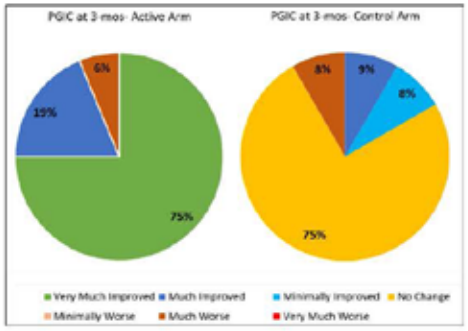

Figure 2: 94% of patients in the active arm showed improvement per PGIC compared to 16% of patients in the control arm.

Conclusions

Early results from this ongoing study, demonstrate that patients receiving PNS therapy along with conventional medical management (CMM) realize significantly better pain relief and functional improvement than patients receiving CMM alone. We look forward to reporting additional data as the study progresses.

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Lumbar Epidural Hematoma after Neuraxial Pain Procedure in a Myeloma Patient with Chronic Low Back Pain from Spondylosis and Myelomatous Lesions

Wilkinson, AJ; Osborne, AT; Kovitz, CA, Chai, T; Huh, BK

UTHealth Houston

Case Description

An 84-year-old female with multiple myeloma and lumbar spondylosis, was admitted for severe low back pain and difficulty walking. She stated on admission that she underwent a lumbar "nerve ablation" procedure by a local pain doctor the week prior.

Lumbar Spine Magnetic Resonance Imaging (MRI) demonstrated a dorsal epidural hematoma at L2, resulting in several central spinal canal stenosis (Figure)

The patient then underwent an emergency evacuation of the epidural hematoma via L2-L4 laminectomy by the Neurosurgery service, without any complications. Postoperatively, she reported significant improvement in her pain and regained the ability to walk at baseline with her walker.

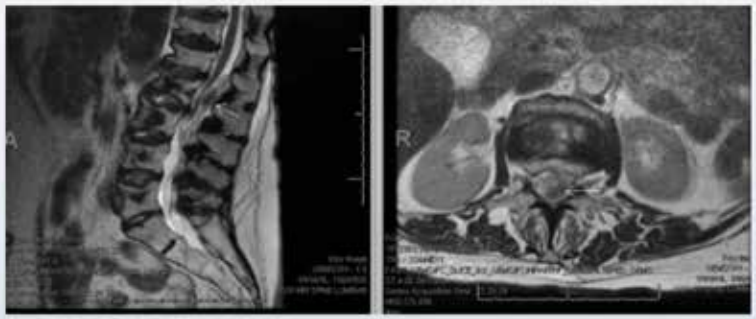

Figure: MRI Lumbar Spine T2 sequence in both sagittal (LEFT) and transverse (RIGHT) sections showing the location of the epidural hematoma.

Discussion

The incidence of any general neuraxial blockade (GNB) complication is estimated to be between 1/1000 and 1/1,000,000. Spinal epidural hematoma (SHE) resulting from neuraxial procedures is a rare complication seen in pain management with an estimated prevalence of SEH is 1:200,000 after a spinal block and 1:150,000 after an epidural block for all patients. This patient stated that she underwent a lumbar "nerve ablation" procedure, and therefore it is unclear as to what specific procedure was done; however, SEH after nerve ablation procedures appears have been described in the literature.

The American Society of Regional Anesthesia's (ASRA) guidelines for avoiding neurological damage in neuraxial procedures identifies the importance of proper imaging and documentation of patient-specific anatomy, avoidance of conditions that lead to increased bleeding, principally concurrent use of anticoagulants or imminent use of anticoagulants, use of proper sterile technique, avoidance of overdosing of local anesthetic during the procedure, and that the procedures be done in a setting capable of necessary resuscitation in the event of serious complications.

Conclusions

Preventing neurologic and hematologic complications in patients undergoing neuraxial procedures remains a top priority within the field of interventional pain management. Even in low-risk patients undergoing low-risk procedures, there is still a chance of potentially devastating complications such as the formation of a spinal epidural hematoma resulting in neurologic injury

Complex Regional Pain Syndrome Masquerading as Cellulitis

Lenny Rostomian, Tristian Medina, Behnum Habibi
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Introduction

- Complex regional pain syndrome(CRPS) is a rare but debilitating condition that should always be considered when evaluating patients with persistent and regionally restricted pain.

Background

- CRPS is characterized by continuous regional pain that is disproportionate to the underlying injury with abnormal sensory, vasomotor, sudomotor, and/or trophic findings.
- CRPS can broken down into two subtypes:
  - -Type 1: Without evidence of peripheral nerve injury.
  - -Type 2: With evidence of peripheral nerve injury.
- The current causative etiology is unknown, however suggested mechanisms include inflammatory responses and changes in pain perception/processing involving the peripheral and central nervous systems.
- The diagnosis of CRPS is a clinical one and can be made utilizing the Budapest Criteria[1]
  - -The patient must have persistent pain that is out of proportion to the inciting etiology.
  - -The patient must have at least one symptom in three of the following categories: sensory, vasomotor, sudomotor, and/or trophic.
  - -The patient must have at least one physical exam finding in two of the following categories: sensory, vasomotor, sudomotor, and/or trophic.
- Triple phase bone scans and radiographs have been used as adjunctive testing to confirm diagnosis.

Case

- A 71 year old female presented for evaluation by PM&R for several months of right lower extremity allodynia, dysthesia, swelling, erythema, and skin breakdown.
- Her symptoms began three months prior to admission after an electrodiagnostic evaluation. She was hospitalized twice for concern for cellulitis and underwent multiple courses of antibiotics. Duplex and CT imaging of the affected limb during these hospitalizations were negative.
- When her symptoms did not resolve after a 30 day course of antibiotics, there was concern for possible CRPS type 1. She under a triple phase nuclear medicine bone scan that showed increased radiotracer uptake in the right leg on angiographic and blood pool images.
- She was referred for evaluation by PM&R and underwent a right lumbar sympathetic block. On follow up she had a 60% reduction in her pain and an 80% reduction in limb erythema. On two month follow up she continued to experience significant relief.

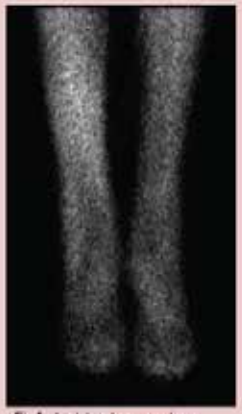

Fig 2: A triple phase nuclear medicine bone scan showing increased radiotracer uptake in the right leg on angiographic and blood pool images.

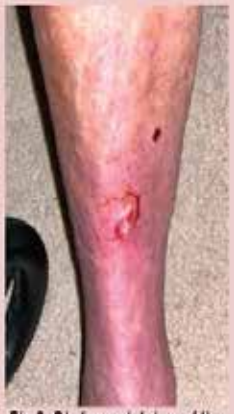

Fig 3: Photograph taken of the right lower limb at follow up appointment with infectious disease.

Discussion and Conclusion

- CRPS is a painful condition that is generally a diagnosis of exclusion.
- There is no gold standard for diagnosis but clinicians can utilize the Budapest Criteria and adjunctive imaging to make the diagnosis.
- Once the diagnosis is made initial treatment involves physical/occupational therapy with concomitant pharmacotherapy[1].
- Should this fail, a sympathetic nerve block can be performed at the region of the relevant sympathetic ganglia[2].

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Temple University Health System

Combination Spinal Cord Stimulator and Dorsal Root Ganglion Stimulator Trials for Cancer-Related Pain: A Case Series

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[1]MD Anderson Cancer Center

Introduction

- Neuromodulation techniques, such as spinal cord stimulation (SCS) and dorsal root ganglion stimulation (DRGS), are emerging treatment options to treat cancer-related pain[1]
- Patients with a history of cancer treatment (e.g., surgery and radiation) often present multiple sources of pain pathology that preclude certain applications of SCS or DRGS[2]
- This case series examines the use of combination SCS/DRGS trials to compare efficacy between modalities and patient preference within the cancer population.

Case Description

- **4 patients** (from Nov.-Dec. 2022) presented with symptoms of chronic low back pain and lower extremity radiculopathy.
- **Patient 1**: 41F, hx of myxopapillary ependymoma at L1, resection (L1 laminectomy), and radiation therapy; Low back pain, groin pain, lumbosacral polyradiculopathy
- **Patient 2**: 71M, hx of extra-skeletal myxoid chondrosarcoma of Right gluteus/posterior thigh; RLE pain after radical resection and radiation, drop foot
- **Patient 3**: 65F, hx of chronic kidney disease, Reynaud's syndrome, and recurrent ovarian cancer; chronic low back pain, Left lower extremity radiculopathy
- **Patient 4**: 47F, hx of T8 spinal cord glioma resection, chemoradiation for leptomeningeal disease, dextroscoliosis of T-spine; cancer-related post laminectomy LBP, LLE radic.

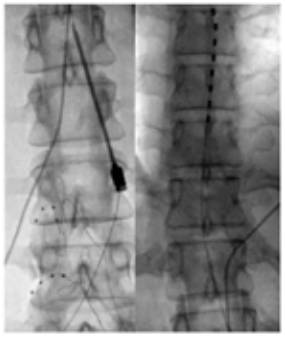
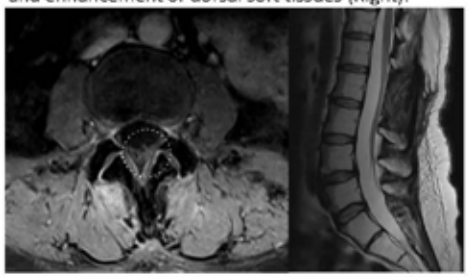


Figure 1. Dorsal root ganglion stimulator leads placed at Left L3 and L4 neural foramen (Left Image); Spinal cord stimulator lead advanced up to superior endplate of T8, placed to the right of midline (Right Image).

Figure 2. Axial lumbar MRI showing treatment-related enhancement of nerve roots at L1 (Left); Sagittal thoracolumbar MRI showing L1 laminectomy and enhancement of dorsal soft tissues (Right).



Methods

- **Retro review** of **4 patients** who received a **dual SCS/DRGS trial** to treat axial LBP and radiculopathy. Patients blinded; 3 days DRGS then 3 days SCS; after 1-week trial, patients asked for preference
- **Patient 1**: SCS (T8) for RLE pain from herniated disc; DRGS (L3/4) for L1/2 inguinal neuralgia from L2 lami, ependymoma resection
- **Patient 2**: SCS trial (T8, 2 leads) followed by DRGS trial (Right L5 and S1) one month later
- **Patient 3**: SCS trial (Right T7) for LBP; DRGS trial (Left L2, L4) for lower extremity pain from spinal stenosis at L4/5
- **Patient 4**: SCS trial (Left T9); DRGS (Right S1 foramen) for altered thoracic anatomy after spinal cord glioma resection, radiation, lami

Results

- After combo trial, **3/4 patients preferred SCS** over DRG.
- **Patient 1**: SCS trial captured groin pain that DRGS did not cover.
- **Patient 2**: DRGS trial better targeted dorsal foot neuropathy.
- **Patient 3**: SCS trial provided higher degree of back/leg pain relief; most noticeable after lead removal
- **Patient 4**: SCS trial improved pain relief and overall quality of life

Conclusion

- Combination SCS/DRGS trials can help identify which neuromodulation technique is more effective for patients with symptoms of both axial low back pain and radiculopathy.
- Patients with complex spine anatomy, especially due to radiation and laminectomy, may benefit from dual SCS/DRGS trials

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The Role of Stellate Ganglion Blocks for the Treatment of Ventricular Arrhythmias: A Case Report

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Introduction: The stellate ganglion is a collection of neuronal cell bodies formed at the inferior cervical and upper thoracic ganglia which provides sympathetic output to the myocardium, upper extremity, neck and face. Stellate ganglion blocks (SGB) are most performed for the treatment of sympathetically mediated pain such as chronic regional pain syndrome. However, they are also utilized for the treatment of post-traumatic stress disorder, migraines and cardiac arrhythmias (1-2). The following case describes the use of an ultrasound guided SGB for the treatment of persistent ventricular tachycardia.

Case Report: The patient is a 62-year-old male with a history of ischemic cardiomyopathy with a left ventricular ejection fraction of 25-30% and an automatic implantable cardioverter defibrillator (AICD) that was admitted to the critical care unit for complications status post a planned ventricular ablation. Throughout the hospitalization, the patient had persistent sustained runs of ventricular tachycardia refractory to oral sotalol, lidocaine drip and multiple cardioversion attempts. Patient was deemed a poor surgical candidate for sympathectomy by cardiothoracic surgery due to extensive comorbidities. Pain management service performed an ultrasound guided left sided stellate ganglion block at bedside.

Utilizing a high frequency linear probe, the C6 vertebral level along with the carotid artery and longus colli muscle were identified under ultrasound guidance. A stimuplex needle was then advanced in a direct in-plane approach until the tip of the needle was visualized between the carotid artery and longus colli muscle. An injectate consisting of 5 milliliters of 1% lidocaine was then deposited without any complications.

Within twenty-four hours of the SGB, episodes of ventricular tachycardia resolved, and the patient was successfully transitioned from intravenous to oral antiarrhythmic medications. The patient's AICD was interrogated three weeks later without any recordings of ventricular tachycardia.

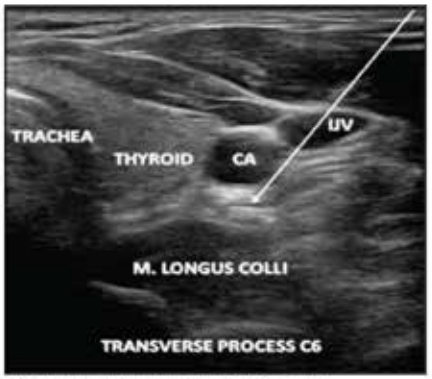

Figure 1: Needle trajectory for an ultrasound guided Stellate Ganglion Block.
Gurgun, Maged, et al. "Stellate Ganglion Block For the Treatment of Hot Flashes in Patients with Breast Cancer: A Literature Review." The Orthopedic Journal, vol. 15, no. 2, 2023, pp. 252-60.

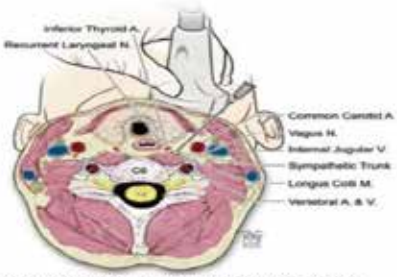

Figure 2: Illustration showing the position of the ultrasound probe and the needle when performing a Stellate Ganglion Block with the oblique approach.
Sarwar, Samer et al. "Ultrasound-guided stellate ganglion block successfully prevented esophageal puncture." Pain physician 10.6 (2007): 747-52.
*Images do not reflect the condition of the patient and are for illustration purposes only

Discussion: There is growing evidence highlighting the efficacy and safety of SGB in treating ventricular arrhythmias refractory to conventional treatment modalities in patients with ischemic and non-ischemic cardiomyopathy (3-4). One study shows that patients with electrical storm treated with sympathetic blockade had a significantly lower one-week mortality rate than the patients treated by standard advanced cardiac life support protocols (5). SGB can be performed blindly using anatomical landmarks, under ultrasound or fluoroscopic guidance (6). Although the stellate ganglion lies near major vessels, this procedure is relatively safe. Rates for serious complications such as hematoma formation and intravascular injections are relatively low (6). Duration of ventricular arrhythmia suppression with SGB is generally short term and may last from several hours to several days (7,8). This specific case is interesting as it produced more sustained relief for three weeks. This case report highlights that SGB is an efficacious and relatively safe intervention to treat refractory ventricular tachyarrhythmias. SGB is an appropriate alternative to treat patients who have failed conventional treatment modalities, are not good surgical candidates for more invasive procedures, or it can be used as a bridge to a definite treatment.

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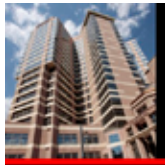

Efficacy of Peripheral Nerve Stimulation in Neurofibromatosis Type 1: A Case Report

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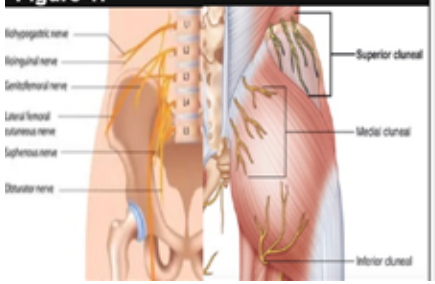
Introduction

Neurofibromatosis Type 1 (NF1) is a neurogenetic disorder characterized by a heightened predisposition to development of benign and malignant tumors ranging from cutaneous neurofibromas (NF) to complex plexiform NF[1]. Accompanying symptoms may include skin disfiguration, airway obstruction or nerve compression leading to pain and quality of life (QOL) impairment. Treatment options for pain control are limited and can lead to a significant impact on QOL metrics such as sleep. Beyond medications or surgical interventions, a paucity of data exists on alternative treatment options for pain management.

Neuromodulation is an evolving neurotechnology field involved in modulating pain pathways in the central or peripheral nervous system. Specifically, peripheral nerve stimulation (PNS), can address uncontrolled neuropathic pain when standard of care analgesics fail and with a higher specificity or when surgery is not indicated.

Figure 1:

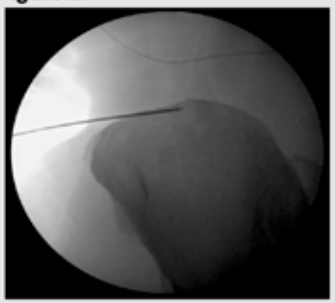


Case Report

A 54-year-old male with NF1 presented as a referral from surgical oncology for left lower quadrant abdominal and left low back pain. He has a history of nerve sheath tumor excision in the left chest wall, arising from the intercostal nerve branch at T8 and excision of multiple cutaneous NF at the left flank region. His pain was refractory to neuropathic agents gabapentin, and duloxetine and negatively impacted his QOL due to sleep impairment. He was referred for evaluation of PNS to address his acute on chronic pain till additional medical records were obtained by the surgical oncology team for definitive surgical intervention.

After evaluation, his pain was consistent with localized neuropathic pain in distribution of left iliohypogastric/ilioinguinal and cluneal nerves and he underwent percutaneous PNS placement. Fluoroscopy and ultrasound was utilized to guide and confirm placement of stimulator leads along the cluneal nerve and ilioinguinal nerve respectively. No complications occurred with the procedure. During his one month follow up, the patient reported over 50% pain relief in addition to cutting down use of as needed analgesics by 80%. Additionally, 80% improvement in sleep was reported at one month follow-up.

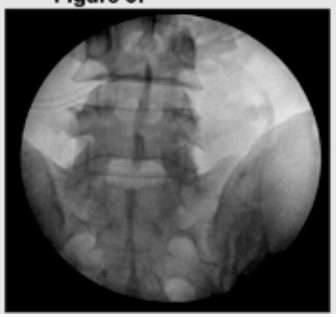
Figure 2:



Discussion

NF1 has a lifelong disease course with up to 50% of patients reporting significant pain and discomfort[3]. Definitive management of painful or suspected malignant NF is surgical removal however recurrence is not uncommon. This can be a lengthy process as the oncology team waits for accurate estimation of tumor burden and a shared decision-making process with the patient. In the interim, options are limited for pain control when medications fail and adds to their morbidity. PNS can help to address this gap in treatment and offers patients a temporary, minimally invasive intervention. MRI surveillance can be a barrier to certain neuromodulation interventions in oncology. However, with temporary PNS placement up to 3 months and co-ordination with the oncology team, this can be a feasible option for short term relief till definitive surgery. In addition, with research focusing on therapeutic drugs to control the growth and limit volume of peripheral nerve tumors, additional non-surgical interventions to manage pain can play an increasing role in symptom burden and compliance with medication regimen.

Figure 3:



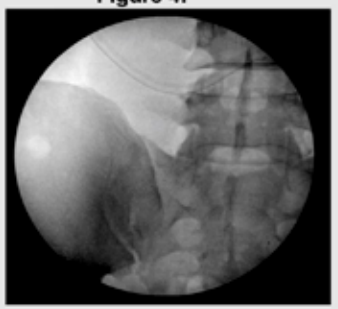
Conclusion

Additionally, numerous case studies report on NF1-related pain in the abdomen, mid-scapular, ribs, lower back, epigastric, ocular, craniofacial, neck, temporomandibular and maxillary, distal thigh and leg, pelvic, perineal and urethral areas which are anatomical regions that can be managed by PNS when surgery is not indicated or medication management fails.

On the contrary, these patients are prone to developing additional neurofibromas and pain does not always follow the distribution of a structural lesion making PNS not a routine viable intervention.

However, limited literature exists on acute pain management beyond medication and surgical interventions for patients with NF1. With appropriate patient selection, PNS can be a minimally invasive alternative that can provide notable relief in pain and improvements in QOL.

Figure 4:



Celiac Plexus Block for Painful Diabetic Gastroparesis

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1. University of Cincinnati Department of Physical Medicine and Rehabilitation, 2. University of Cincinnati Department of Anesthesiology, Division of Pain Management

University of CINCINNATI

Background

Diabetic gastroparesis (DG) is described as delayed gastric emptying without evidence of obstruction causing various symptoms including nausea, vomiting, loss of appetite, weight loss and abdominal pain [1]. Persistent hyperglycemia, autonomic neuropathy, and gastrointestinal tract neuromuscular inflammation all play a role in the pathogenesis of this syndrome [2]. There are a variety of dietary, medical, and surgical interventions that can be applied to treatments depending on severity [2]. Due to widespread innervation of the gastrointestinal tract by the celiac plexus, patients who fail conservative medical management undergo celiac plexus block (CPB) with good success.

Case Presentation

35-year-old male with diabetes and DG presented to our clinic with intractable nausea, vomiting, and abdominal pain with subsequent 240-lb weight loss. Diabetes is well controlled with A1c of 5.6 mg/dL. He underwent numerous treatments such as dietary modification, medication management, pyloric botox injections, and pyloromyotomy which improved his nausea and vomiting. His abdominal pain, however, persisted.

His upper abdominal pain was described as 8/10 on the numeric rating scale, constant, cramping in nature, and worse after eating. Initial celiac plexus block under transendoscopic ultrasound-guidance was performed using a total of 30 mL 0.5% bupivacaine and 160 mg methylprednisolone which gave 100% pain relief for 3 weeks. Repeat block under fluoroscopic guidance was done using a total volume of 8 ml of 40mg triamcinolone and 0.25% bupivacaine which resulted in 100% pain relief for 3 months (Figure 1 & 2). The patient came back for repeat procedure 10 months later but the procedure was denied by insurance despite multiple appeals due to non-coverage.

Objective

To describe a case of painful diabetic gastroparesis effectively treated with CPB

Methods

This is a case report devoid of any identifiable information.

Discussion

Located in the epigastrium anterior to the crura of the diaphragm and body of the first lumbar vertebra, the celiac plexus receives sympathetic input from the greater, lesser, and least splanchnic nerves and also contains parasympathetic contribution from the vagus nerve. [3]. CPB is well described for treatment of a variety of causes of chronic abdominal pain [4] and multiple techniques and approaches have been described. It induces gastric motility by blocking sympathetic nerve fibers leading to an overflow of parasympathetic activity. In a case report, celiac plexus neurolysis with alcohol resulted in profound pain relief for a patient with DG [5]. Reported most common adverse events with CPB include transient and local pain, orthostatic hypotension, and diarrhea [6].

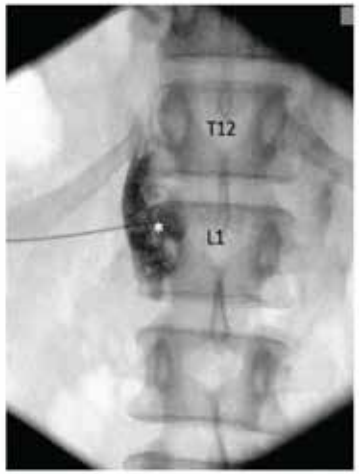

Fig. 1 Left Posterior Para-Aortic Approach CPB
* = Needle Tip with Surrounding Contrast

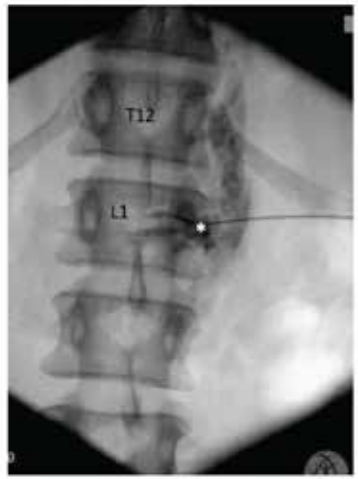

Fig. 2 Right Posterior Para-Aortic Approach CPB
* = Needle Tip with Surrounding Contrast

Conclusions

Celiac plexus block is a safe and effective procedure for painful, symptomatic DG. Although CPB provided the most profound, longest lasting relief compared to a number of other treatments, the patient's insurance denied repeat blocks. This procedure has been well described for treatment of visceral abdominal pain and therefore DG should be included as an indication.

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Does blood sugar really matter? A retrospective analysis of diabetes, perioperative glucose, and surgical site infections in neuromodulation

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Background

Although well documented in other surgical fields, the effects of diabetes mellitus (DM) and associated factors on neuromodulatory surgical site infections are yet unclear. Select studies that have included DM as a risk factor for infection have had mixed results (1-5) and none have reported specific factors reflecting diabetic control, such as HbA1c or insulin use.

Objective

To explore the effects of DM, HbA1c, and related variables as primary risk factors for the development of postoperative surgical site infection following neuromodulation procedures.

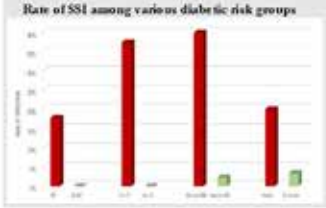
Methods

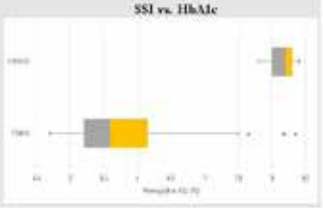
Patients who underwent procedures involving a neurostimulator or intrathecal pump from May 2019 to September 2022 at a single tertiary care center were identified after IRB approval was obtained. Patients were followed for at least three months to assess for postoperative or device-related infections. Patients' demographics, clinical characteristics, and surgical outcomes were summarized through descriptive statistics. Wilcoxon rank sum test was used to compare location parameters of continuous distributions between patient groups. Fisher's exact test was used to evaluate the association between two categorical variables.

Results

A total of 195 qualifying procedures involving 123 unique patients were included in the analysis. Procedures included trials, implants, revisions, and explants of spinal cord stimulators (SCS), dorsal root ganglion stimulators (DRG), intrathecal pumps (ITP), and peripheral nerve stimulators (PNS). Patient age ranged from 19 to 88 years with a median of 60.0 years. 48% of patients were male and 52% were female. Median BMI was 29.0 kg/m^2 with a minimum of 15.5 kg/m^2 and maximum of 54.0 kg/m^2.

Five cases (2.6%) developed a postoperative infection. These included three ITP implants, one SCS explant, and one SCS trial. All patients (100%) who developed postoperative infections had DM. The rate of postoperative infection was significantly higher among patients with DM (17.9%) compared to patients without DM (0%, p=0.0005). The rate of infection was significantly higher among the cases with high A1c (>=7%) compared to the cases with lower A1c (23.1% versus 0%, p=0.0012). The rate of postoperative infection was significantly higher (40%) among the cases with high perioperative glucose (≥200 mg/dl) compared to the cases with lower perioperative glucose (2.3%, p=0.0101). While the rate of postoperative infection for patients who were on insulin was higher (20%) than for those who were not (3.4%), this difference did not reach statistical significance (p=0.1903).





Conclusion

Elevated HbA1c, elevated perioperative glucose levels, and preexisting diabetes mellitus may all contribute to increased risk of postoperative surgical site infections in patients undergoing procedures involving a neurostimulator or intrathecal pump.

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Case Report and Clinical Review of an elusive case of Thoracic Outlet Syndrome

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INTRODUCTION

Clinically, the thoracic outlet comprises the brachial plexus roots and the subclavian artery as they traverse between the anterior and middle scalene muscles to supply the upper extremities [7]. When pressure increases, these structures may be impinged, resulting in Thoracic Outlet Syndrome (TOS) [7]. This can lead to a constellation of vague symptoms including pain, pallor, swelling, paresthesia and weakness. TOS is classified based on its pathophysiology as neurogenic (nTOS), venous (vTOS), and arterial (aTOS). Around 90% of cases are attributable to nTOS [7]. The etiology is frequently related to fibrotic bands, spasticity or hypertrophy of the anterior and middle scalenes. Other less common causes include space occupying lesions, anatomical variants, cranial nerve XI palsies, trauma, and transient positional compression [5].

Diagnosis of TOS is largely clinical, but imaging can provide supportive evidence. Modalities such as X-Ray, Ultrasound, CT, and the most detailed and specific, MRI, are useful to assess anatomical structures [4]. Although MRI's have low sensitivity, they can help guide decision-making regarding TOS procedures [3]. EMGs are often noncontributory or normal, but nTOS can show an axonal loss pattern in the lower trunk of the brachial plexus. They can also help evaluate the severity and progression of TOS over time [6, 9]. Despite the variety of tests, there is no standardized workup to guide the diagnosis of TOS [2,8]. Initially, treatment is conservative with patient education, activity modification, and physical therapy [6]. In cases with unrevealing imaging and refractory symptoms, an interventional approach with a scalene block can be diagnostic and therapeutic [8]. Scalene injections can help guide localization for potential surgical interventions [10]. Of the different types of TOS, nTOS is the most responsive to surgery [1,6].

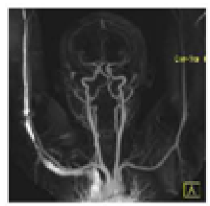
METHODS

Case Report and Clinical Review.

CASE PRESENTATION

A 19-year-old female college swimmer with no significant past medical history who presented with complaints of left shoulder pain. She had suffered an anterior subluxation of the left shoulder with immediate self-reduction. She was treated conservatively but had minimal improvement and developed intermittent anterior left shoulder pain, mainly during abduction. She had episodes of arm numbness in multiple nerve distributions and discoloration (Figure 2). Despite thorough musculoskeletal and vascular workup, only an arterial duplex demonstrated increased velocity with arm abduction. Although the case was concerning for neurogenic or arterial TOS, arterial compression was not evident on MR angiogram or diagnostic angiogram (Figure 1). She was referred to a Pain Interventionist for diagnosis and treatment. A left scalene block provided diagnostic information but failed to provide significant long-term improvement. The patient deferred an additional injection, and opted for surgery through a first rib resection, which is pending.

FIGURE



1) Diagnostic Angiogram.

2) Skin discoloration of the LUE.

OBJECTIVE

This case report presents a complex diagnostic case of TOS. We performed a clinical and interventional management review of 10 other existing publications that elaborate on diagnosis and treatment of TOS.

CONCLUSION

TOS often presents with vague symptoms, which can make for a challenging diagnostic process. While this case is yet to determine whether the TOS is neurogenic or vascular, further research is needed to objectively validate diagnostic approaches to TOS.

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Percutaneous Peripheral Nerve Stimulation for the Treatment of Phantom Limb Pain Following Traumatic Amputation: A Case Report

UAMS

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OBJECTIVE

To explore the efficacy of percutaneous peripheral nerve stimulation for phantom limb pain with an implanted device

BACKGROUND

After amputation, a patient can experience pain that can be divided into two categories – residual limb pain (RLP) and phantom limb pain (PLP). PLP is the perception of pain or discomfort from a limb that is no longer there and RLP which is pain that originates from the site of the amputation. RLP is most common in the early period after an amputation and usually resolves as the amputation site heals and is usually due to some underlying cause – nerve entrapment, neuroma formation, surgical trauma, ischemia, skin breakdown, or infection. 95% of patients report experiencing some amputation pain – 79.9% report phantom pain and 67.7% report RLP. The etiology of PLP is unclear with multiple theories that have been debated. The only agreement is that it is multi-factorial and is thought to include both peripheral and central nervous system components. PLP should be diagnosed after other causes for pain are ruled out. It is important to distinguish between PLP and RLP as their treatments can differ. There are many treatments that have been tried for PLP including: NSAIDs/acetaminophen, opioids, antidepressants, anticonvulsants, NMDA receptor agonists (ketamine and dextromethorphan), B-blockers, topical analgesics, botox type B, local anesthetics, TENs, mirror therapy, SCS, virtual and augmented reality as an advanced form of mirror therapy. "Although up to 70% of patients have phantom limb pain after amputation, there is little evidence from randomized trials to guide clinicians with treatment" (Halbert).

Peripheral nerve stimulation (PNS) has been used since the late 1960s to treat neuropathic pain of the extremities that is resistant to other modalities. Percutaneous peripheral nerve stimulation is an analgesic technique involving the percutaneous implantation of a lead followed by the delivery of electric current using an external pulse generator. Ultrasound-guided percutaneous peripheral nerve stimulation was first reported *in situ* by Huntoon and Burgher in 2009 using an epidural neurostimulation electrode for the treatment of neuropathic pain and have since been mostly used for chronic pain conditions (Ilfeld).

CASE

Middle aged person who sustained a traumatic above knee amputation who developed severe phantom limb pain of the lower extremity. Phantom limb pain was poorly controlled with opioid analgesics. A single percutaneous lead was implanted under ultrasound guidance targeting the sciatic nerve using an in-plane transgluteal approach. Patient reported 50% relief during period of percutaneous implantation as well as an accelerated rehabilitative course with regards to prosthetic use.

METHODS

Relief of pain measured via:

- Subjective pain scores on scale 1-10
- Patient Enjoyment of Life and General Activity scale (PEG) scores
- Pain disability index: self-report instrument that has been used to assess the degree to which chronic pain interferes with various daily activities
- Current Opioid Misuse Measure (COMM) scale: brief patient self-assessment to monitor chronic pain patients on opioid therapy
- Screener and Opioid Assessment for Patients with Pain: a tool for clinicians to help determine how much monitoring a patient on long term opioid therapy might require

"A) Fine-wire coiled percutaneous peripheral nerve stimulation leads were implanted and (B) connected to external, body-mounted stimulators. A stimulating needle was used to identify the optimal lead location remote from the targeted (C) femoral and (D) sciatic nerves. FA, femoral artery; FI, fascia iliaca; FL, fascia lata; FN, femoral nerve; GI, gluteus; II, iliopsoas; IT, ischial tuberosity; SN, sciatic nerve." (Image and description from Gilmore).

"A, a preloaded, small-diameter (0.2 mm), open-coiled, helical electrical lead with an anchoring wire preloaded within the 12.5-cm, 20-g insertion needle and a small-diameter (0.2 mm), open-coiled, helical electrical lead with an anchoring wire B. a stimulator small enough to be simply adhered to the skin during use" (image from Ilfeld)

RESULTS

Scale	1 month Pre-implantation	1 month Post-implantation
Subjective Pain scale	7-8/10	3-4/10
Pain disability index	53	31
PEG	9	5.3
COMM	6	2
SOAPP	4	2

CONCLUSION

Chronic pain in the amputee population is an important barrier that will need to be addressed to promote functional recovery and optimize rehabilitative therapy. The case report demonstrates the ongoing potential and benefit of percutaneous peripheral nerve stimulation as treatment that promotes recovery while also being opioid sparing and the need for further research to evaluate this as a treatment option for PLP.

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Micro-dosed Intravenous Buprenorphine Induction for Opioid Use Disorder

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Introduction

Suboxone (Buprenorphine/Naloxone) is the standard first line treatment for opioid use disorder (OUD) but its induction process can be quite challenging. Transitioning from illicit opioid use to maintenance Suboxone carries the risk of precipitated withdrawals, the fear and risk of which can be a strong deterrent for most patients. Various society Guidelines recommend tapering and discontinuing opioids for at least 36-72 hours prior to initiating Suboxone. Buprenorphine micro-dosing using the sublingual formulation, is an alternative approach used mostly in the outpatient setting. Using IV Buprenorphine as an alternative to sublingual buprenorphine, in one third dosing, allows for more rapid induction which can be especially valuable in the hospital setting. Furthermore, in-patient initiation of buprenorphine for opioid use disorder is associated with better long term treatment adherence and lower chances of relapse.(1) The objective of this case is to present three cases that were successfully transitioned to Suboxone maintenance with the use of IV buprenorphine.

Methods

Using IV formulation of Buprenorphine micro-dosing we could successfully induce patients. We chose half hourly rapid induction of low dose buprenorphine at 0.3mg/ml. Patients were monitored on COWS protocol. Comfort medications for withdrawal including gabapentin, Clonidine, Zofran, hydroxyzine were provided.

Case Report

CASE	INDUCTION	MAINTENANCE	DISCHARGE
A 21-year-old male with a medical history of type 1 Diabetes, OUD, Intravenous drug use (IVDU), multiple unintentional overdoses, and repeated admissions for diabetic ketoacidosis (DKA) was admitted again with DKA. The patient had a remote history of being on Methadone but with poor compliance and intermittent periods of relapses. The patient's recent most relapse was 3-4 months prior to this admission and the last heroin and fentanyl use was within 24 hours of hospital admission.	IV Buprenorphine, 0.3 mg/ml, half hourly for 3 doses. The following day patient was initiated on sublingual Suboxone.	2mg of Suboxone and the dose was titrated up gradually to a final dose of 24mg.	Suboxone 24/6mg morning, mirtazapine 15mg nightly and Gabapentin 300mg TID.
A 39-year-old male with OUD and IVDU was admitted for increasing low back and bilateral lower extremity intractable pain with an L4-S1 posterior compressive epidural abscess. The patient underwent L4-5 laminectomy and evacuation of epidural abscess. The patient had recently relapsed on fentanyl prior to admission. Prior to relapse, he was taking prescribed suboxone 12 mg daily for at least 3 months.	Patient was started on sublingual Suboxone the same day following IV buprenorphine induction	Titrated to 12mg	suboxone 12 mg (8mg morning and 4 mg nightly)
A 58-year-old male with a past medical history of T1DM, unspecified cardiac disease, opiate use disorder, and Hepatitis C presented as a transfer from outside hospital due to concern for bowel ischemia and acute liver failure. She was found to have septic shock and DKA. Additionally, the patient underwent traumatic intubation and developed dysphagia, hoarseness, and loss of vocal cord function bilaterally. A PEG tube was placed initially, later replaced with a G tube. The patient had difficulty with treating pain throughout the admission and was maintained on IV Dilaudid and Oxycodone for pain.	Patient received X 3 doses of 0.3 mg IV Buprenorphine every 30 mins. Three additional PRN doses of 0.3 mg IV Buprenorphine were given 4 and 9 hrs. after the induction for ongoing pain.	Patient was then initiated on sublingual suboxone 8mg BID the following morning.	suboxone 8 mg Q8H for better pain coverage
34-year-old female with a history of OUD, amphetamine use disorder, HCV, admitted with 10-15% TBSA burns to the abdomen and thighs and underwent multiple debridement's. Patient was reportedly high on heroin and fell asleep next to a sterno burner and awoke with clothes on fire. Patient required high doses of full-agonist opioids throughout admission. Patient's pain regimen included Tylenol, Oxycodone prn, gabapentin, Robaxin/methocarbamol, hydroxyzine prn, PRN IV hydromorphone for dressing changes.	2 doses of IV Buprenorphine 0.3 mg that were spaced by about eight hours.	Patient was then initiated on sublingual suboxone 8mg BID the following morning.	suboxone 8 mg q8H the following day

Conclusions

Intravenous Buprenorphine micro-dosing is an innovative method that can be used in hospitals to initiate suboxone induction while minimizing and bypassing the risk of precipitated withdrawals.

Results

We present 4 cases of successful in-hospital Suboxone induction using the approach of micro-dosing with IV buprenorphine. Both patients were transitioned to Suboxone without precipitated withdrawal symptoms during the process. One strength of this approach is the speed of induction. Traditional Suboxone micro-dosing usually takes up to 2 weeks. While in our method we could successfully transition in 2 days.
Our study adds to the existing evidence on in-hospital micro dosing of IV Buprenorphine for initiating rapid induction. Further studies are needed to improve and standardize the approach of short induction protocol methods using IV Buprenorphine. Research on outcomes after initiation and in long-term are needed in these patients.

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Stellate Ganglion Block in the Treatment of PTSD

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Introduction

•PTSD is defined by 4 clusters of symptoms:
•(1) Intrusive re-experiencing of a traumatic event
•(2) Avoidance of trauma-related stimuli.
•(3) Negative changes in mood and cognition.
•(4) Persistent physiological arousal and reactivity.
•Diagnosis of PTSD requires that the symptoms significantly impair functioning and last for at least one month.
•Treatments include medication management, psychotherapy, or a combination of the two.
•Pharmacotherapy typically consists of SSRIs and SNRIs. If unsuccessful, treatment may expand to mood stabilizers, anticonvulsants, antipsychotics, and prazosin for reduction of nightmares/hyperarousal symptoms.
•Stellate ganglion nerve blocks may be a safe and viable treatment option for PTSD refractory to med management and psychotherapy alone.

Methods

Case based on a patient seen in outpatient pain clinic at University of Louisville in 2022. Literature review performed.

Case Report

•46-year-old male with a history of TBI and multiple psychiatric disorders including ADD, PTSD, Bipolar, and Depression, presented to the pain clinic with worsening anxiety and chronic headaches.
•The patient's anxiety began 30 years ago and worsened in the past fifteen years after a TBI. He has been admitted to psychiatric facilities and undergone treatment for substance abuse multiple times. He continues to follow up with a psychologist.
•He notes frequent headaches as well and was referred from PM&R clinic for further evaluation. His pain on evaluation was 6/10, interfering with his quality of life and activities of daily living.
•Medical management included Clonazepam 0.5 mg TID, Gabapentin 400 mg QHS, Lamotrigine 25 mg BID, Paroxetine 40 mg Daily, Prazosin 2 mg QHS, Celecoxib 200 mg BID.
•Left Stellate Ganglion Block (SGB) was administered under ultrasound guidance. Injectate included a total of 5 ml of 0.5% lidocaine with 10 mg Dexamethasone and 100 mcg clonidine. This was repeated on the right side 4 weeks later.
•The patient had >80% relief of headache and 100% relief of his PTSD symptoms for 2-3 months.

Conclusions

•The stellate ganglion is connected to regions of the brain that are abnormally activated in PTSD, such as the amygdala.
•SGB for PTSD has been recommended for use as an adjuvant in individuals who have not fully responded to conventional therapies.
•SGB is thought to inhibit sympathetic nervous system firing and decrease excitatory neurotransmitter levels.
•SGB provides patients with adequate pain relief and has been shown to reduce symptoms associated with PTSD significantly.
•Other innovative treatments for PTSD are being investigated as alternative options for refractory PTSD. These include Ketamine, MDMA-assisted psychotherapy, and cranial electrical stimulation.

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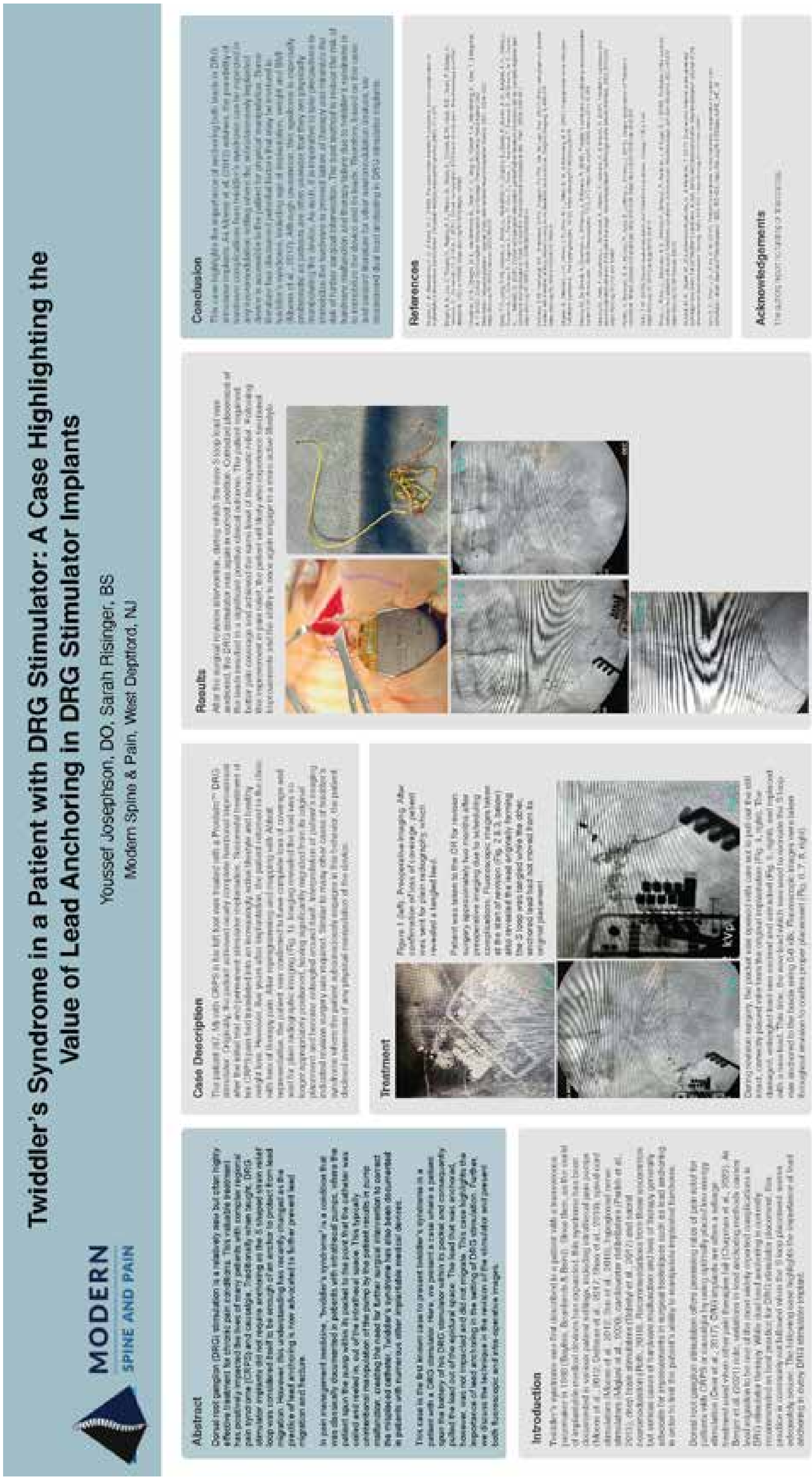
MODERN
SPINE AND PAIN
Twiddler's Syndrome in a Patient with DRG Stimulator: A Case Highlighting the Value of Lead Anchoring in DRG Stimulator Implants
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Modern Spine & Pain, West Deptford, NJ
Abstract
Introduction
Case Description
Treatment
Results
Conclusion
References
Acknowledgements

Personalized 10kHz SCS therapy delivered by mobile app yields high patient satisfaction

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Introduction

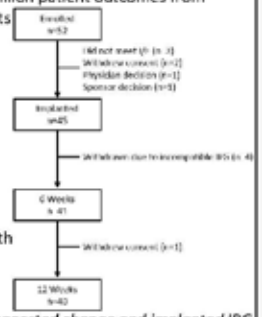
- The safety and efficacy of high frequency (10 kHz) spinal cord stimulation (SCS) for patients suffering with chronic pain following failed back surgery [1, 2], as well as non-surgical refractory back pain [3], painful diabetic neuropathy [4], among others [5, 6, 7] has been established.
- Currently, SCS therapy optimization requires scheduled visits in clinic or via telehealth, phone calls, and treatment algorithms that require human intervention.

The objective was to evaluate the usability of a mobile app designed to optimize 10 kHz therapy and personalize it based on subject-reported data.

Methods

- Study type: 12-week, prospective, multi-center, design validation study
- Therapy optimization algorithm contained in a mobile application based on >20 million patient outcomes from >80,000 commercial patients
- Daily surveys collected, including: Pain relief, pain score, changed in pain medication, and activity
- Algorithm recommendation suggests:

Changes in stimulation parameters (e.g., location, amplitude)* **OR** Continued treatment with the existing program.



**Patient is prompted to accept suggested change and implanted IPG is reprogrammed through the app/IPG interface.*

Mobile app provides a digital alternative to personalize and optimize SCS therapy for patients

Demographics and Primary Study Endpoint Results

Demographic and Baseline Characteristics

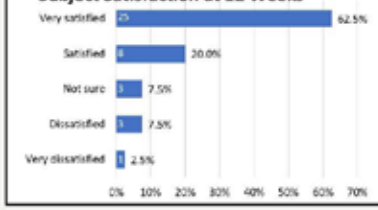
	N = 40
Age in years	
Mean (SD)	57.4 (14.4)
Median (Range)	60 (22, 80)
Sex	
Male, n (%)	17 (42.5%)
Female, n (%)	23 (57.5%)

Primary study endpoint: the proportion of implanted subjects who have tested up to 3 programs as guided by the mobile app.

All 40 subjects (100%) met the primary endpoint at 12 weeks.

Results: Patient Satisfaction

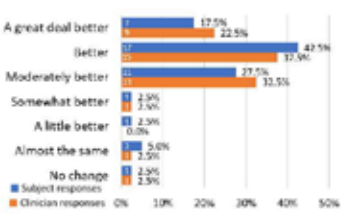
Subject Satisfaction at 12 Weeks



82.5% (33/40) of patients reported being "satisfied" or "very satisfied"

Results: Global Impression of Change

Global Impression of Change Score at 12 Weeks



87.5% (35/40) of subjects and 92.5% (37/40) of clinicians reported patients were "Moderately better," "Better," or "A great deal better"

Safety outcomes: 2 AEs related to implant procedure, none related to use of mobile app.

Conclusions

- Greater than 80% of subjects were satisfied with their pain treatment and felt their quality of life was "better" or "a great deal better".
- No subjects elected to transition to the physical remote and most described the mobile app as easy to use and they were satisfied with their treatment.
- The results of this study confirm that 10 kHz SCS therapy delivered by a mobile app yields high patient satisfaction.
- This mobile app affords a digital alternative to personalize and optimize SCS therapy for patients.

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Caudal Epidural Steroid Injections with Paracoccygeal Injections for Management of Postpartum Coccydynia, a case series

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Introduction

We present two cases of postpartum coccydynia where administering caudal epidural steroid injection (ESI) in combination with paracoccygeal injections resulted in substantial pain relief and improvement in activities of daily life (ADL).

The prevalence of coccydynia is five times higher in women compared to men, likely due to the straining of coccygeal ligaments or even fractures of the coccyx experienced during childbirth.(1,2)

Cases

Both patients developed coccydynia after vaginal birth. They presented to our clinic after non-invasive treatments provided little pain relief. Treatment involved caudal ESI with triamcinolone 60 mg mixed with 6 mL of saline under fluoroscopic guidance as well as paracoccygeal injections under fluoroscopic guidance with 40 mg triamcinolone and 8 mL 0.25% bupivacaine. (figures 1,2)

Both patients reported significant pain relief after the procedures.

Discussion and conclusion

Caudal ESI with paracoccygeal injections is an effective treatment option for unresponsive postpartum coccydynia.

Possible side effects when using corticosteroid injections include skin and soft tissue atrophy at the injection site and calcifications within the coccygeal disc. (3,4)

Our findings demonstrate that administering caudal ESI in combination with paracoccygeal injections can be an effective treatment option for unresponsive postpartum coccydynia.

Figure 1. Fluoroscopic dye injected near coccyx for caudal epidural steroid injections.

Figure 2. Fluoroscopic dye injected near coccyx for paracoccygeal steroid injections.

References

American Society of Interventional Pain Physicians
2023 ASIPP® ANNUAL MEETING

Gabapentin ER for the Treatment of Persistent Post Herpetic Neuralgia (PHN)

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INTRODUCTION:

We present a 64-year-old active female patient who enjoys travelling around the country in an RV with her husband. She presented with complaints of right sided post herpetic neuralgia following a T4 dermatome. The patient has been under the care of our pain team for over 6 months. She underwent multiple interventions including antiviral medication, gabapentin, Salonpas patch, tramadol, Tylenol, naprowen, lidocaine 5% patches, and acupuncture with insufficient relief of her symptoms.

Patient has also undergone T4-5, T5-6, T6-7, T7-8 & T10-11 paravertebral nerve blocks without relief of her pain. Patient had some pain relief after right intercostal nerve block, in combination with gabapentin, anti-depressants, and lidocaine patches. This intervention resulted in the relief of pain for a few weeks after which she returned seeking another treatment plan.

We have no reason to believe that she has an altered mental status or that she is drug-seeking.

OBJECTIVE:

As the patient is an active female who would like to return to her normal daily activity, our objective was to find a treatment plan for her to reduce the need for long-term multifaceted intervention with minimal side effects.

METHODS:

After performing a review of various publication and consulting with the care team it was determined that a protocol of gabapentin ER would be the next step in her treatment plan. The literature review suggested that extended-release gabapentin formulation, that is FDA approved for PHN, with a titration would be an appropriate next step.

The suggested schedule begins with 300 mg on day 1; 600 mg on day 2; 900 mg on days 3 to 6; 1,200 mg on days 7 to 10; 1,500 mg on days 11 to 14; and 1,800 mg on day 15 and thereafter. We followed the suggested dosing and determined that once she reached 600 mg 3 times daily with a total dosage of 1800 mg/day, patient had complete relief of her pain symptoms.

Although the mechanism of action of gabapentin ER is not know it has been found to be beneficial in treating a variety of neuropathic pain symptoms. Current studies suggest that gabapentin may block the calcium channel alpha(2)delta (a2d)-1 receptor in the brain. Therefore, the therapeutic effect of gabapentin could be attributed to prevention of new synapse formations as it inhibits the protein-modulated receptor responsible for excitatory synapse formation.

RESULTS:

Patient has been pain-free for the past 6 months while using gabapentin ER.

She has returned to her active lifestyle and is in the process of being tapered off the medication.

CONCLUSIONS:

Gabapentin ER provided adequate pain control for post herpetic neuralgia that did not respond to regular gabapentin nor to other intervention modalities including blocks.

This result may be due to the constant medication blood level, needed to inhibit synapse formation, with the ER form of the medication.

DISCLOSURES:

This is a medically challenging case and IRB approval is not mandatory according to Nuvance Health Policy.

Patient informed consent was obtained, and no identifiable patient information is contained within this case report.

No personal nor financial disclosure to report.

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Combining Contemporary SCS Paradigms with Evoked Compound Action Potential Sensing

Ricardo Vallejo, MD, PhD[1], Krishnan Chakravarthy, MD, PhD[2], David Dinsmoor, MS[3], Juan Hincapie, PhD[3]

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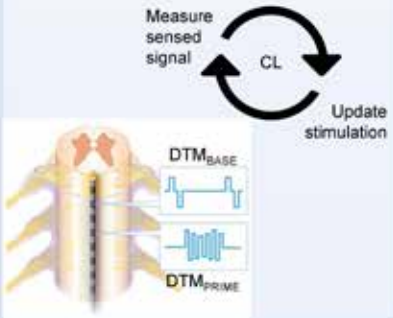
Introduction

- Recent advances in SCS have focused on:
  - Bioinformatics-informed DTM-SCS[1], which has demonstrated superior pain relief, and
  - Closed-loop (CL) SCS with the evoked compound action potential (ECAP) as a feedback signal to compensate for physiologic variability.[2]
- Simultaneous application of both approaches may allow for a new generation of neural responsive SCS that **blends a science-based methodology for pain management with real-time CL control for biophysical variation.**
- In this study, CL DTM-SCS was explored to determine control characteristics of the system in the clinical setting.



Methods

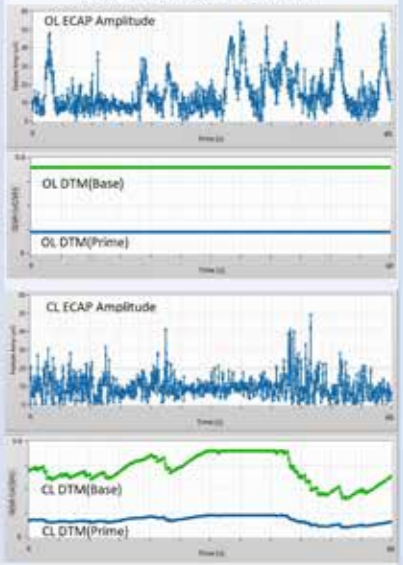
- Included here are a sample of 10 subjects who underwent a DTM SCS trial using dual percutaneous 1x8 leads placed near T9.
- Following the trials, the leads were connected to an investigational neurostimulation system capable of recording ECAPs and delivering a novel CL DTM-SCS pattern.
- The control policy parameters and nominal charge/phase (Q/ph) of DTM$_{BASE}$—one component of the DTM waveform, also used to elicit the ECAP—was selected to optimize comfort and mitigate variability in neural activation over a range of aggressor activities, such as a back arch.
- The Q/ph of the priming component of DTM, DTM$_{PRIME}$, was programmed relative to DTM$_{BASE}$.
- The subjects were then asked to re-perform the aggressor activities while the system was operated in both the open-loop (OL) and CL configurations.
- ECAP variability in both configurations was calculated to assess the capability of CL DTM-SCS to control neural activation versus OL DTM-SCS.

Results

- Across subjects, average ECAP variability—and presumably variability in neural activation with the DTM SCS—was reduced by 51% ($p<0.001$) in the CL arm (3.5 µV) versus the OL arm (7.1 µV).

- Across subjects, average ECAP variability—and presumably variability in neural activation with the DTM SCS—was reduced by 51% ($p<0.001$) in the CL arm (3.5 µV) versus the OL arm (7.1 µV).

Fig 1. OL vs. CL ECAP Amplitudes, DTM$_{BASE}$, and DTM$_{PRIME}$ over aggressor activities.



Discussion

- These results demonstrate the technical feasibility of CL DTM-SCS on conventional 1x8 leads.
- The CL DTM-SCS system limited ECAP amplitude variability by about a half versus OL across typical aggressor activities.
- Potential benefits of this approach may include a more durable therapy and consistent outcomes, as well as broader SCS programming customized for the patient.
- Further study is needed to characterize the chronic utility and associated clinical benefits of these methods.
- CL DTM-SCS has promise as the natural evolution of the paresthesia-centric, CL-SCS systems described by others.[3]

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Contact Information

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Case Report: Use of Peripheral Nerve Stimulation for Treatment of Pain from Vertebral Plana Fracture

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AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
THE VOICE OF INTERVENTIONAL PAIN MANAGEMENT

Introduction

We present a case of an 80 year old female with complex cardiac history s/p post stent placement as well as multiple other comorbidities presenting for acute on chronic low back pain. Endorsed recent fall at home after which she experienced sharp 9 out of 10 pain that did not radiate down her legs. Pain was described as constant, dull, achy and worsened by any type of movement. Physical exam limited by pain however did reveal positive facet loading as well as paraspinal tenderness. Pain was successfully treated with peripheral nerve stimulation (PNS)

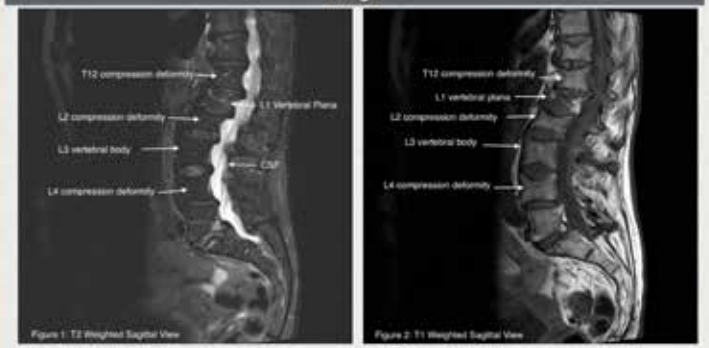
Materials & Methods

T12-L2, and L4 compression deformities most significant at L1 demonstrating a near complete vertebral plana. Patient was initially started on acetaminophen-codeine 300-30 mg PO TID PRN for severe pain. Several interventional techniques were discussed however she "did not want steroids" for facet injections and rejected vertebral augmentation because she did not want to undergo anesthesia given her cardiac history. Peripheral Nerve stimulation was discussed to be completed under local to which the patient agreed. Two electrode peripheral nerve stimulators (PNS) with SPRINT® were placed at L3 bilaterally to stimulate the multifidi muscles. After the electrode placement the patient scaled her pain as 7/10 intensity. One week post procedure, the patient endorsed improvement in her pain which was scaled 5/10 accompanied by a decreased use of Tylenol-codeine to once a day. At the 1-month and 2-month follow-ups, pain scores were reported at 4/10 and 3/10, respectively with no usage of Tylenol-codeine. PNS electrodes were removed after 60 days, per FDA guidance

Results

At the 3-month follow-up after electrode removal she continued to have pain scored at 3/10 and reported continued cessation of pain medication. This relief was continued through the 6 month follow up.

Image



MRI imaging of Vertebral Plana

Discussion

Plana fractures are a severe form of compression injuries with unique treatment obstacles. The flattening of the vertebrae makes is a contraindication to percutaneous augmentation techniques due greatly increased risk of bone cement extravasation into spinal canal

Discussion (cont.)

as well as recurrent pain and fracture of adjacent vertebrae. Additionally, many of the elderly patients with compression fractures are poor candidates for anesthesia and may not tolerate prone positioning for extended periods of time for procedures. This highlights the need for new, minimally invasive techniques to treat fracture pain. PNS has been used successfully in treating other types of pain including trauma, phantom limb, OA, and peripheral nerve pain, among others. The mechanism of action of PNS involves a combination of the gate control theory of pain and modulation of neurotransmitters. This mechanism of action is similar to that of SCS and more research is needed to into PNS as a less invasive option to treat acute and chronic pain due to pars plana fractures

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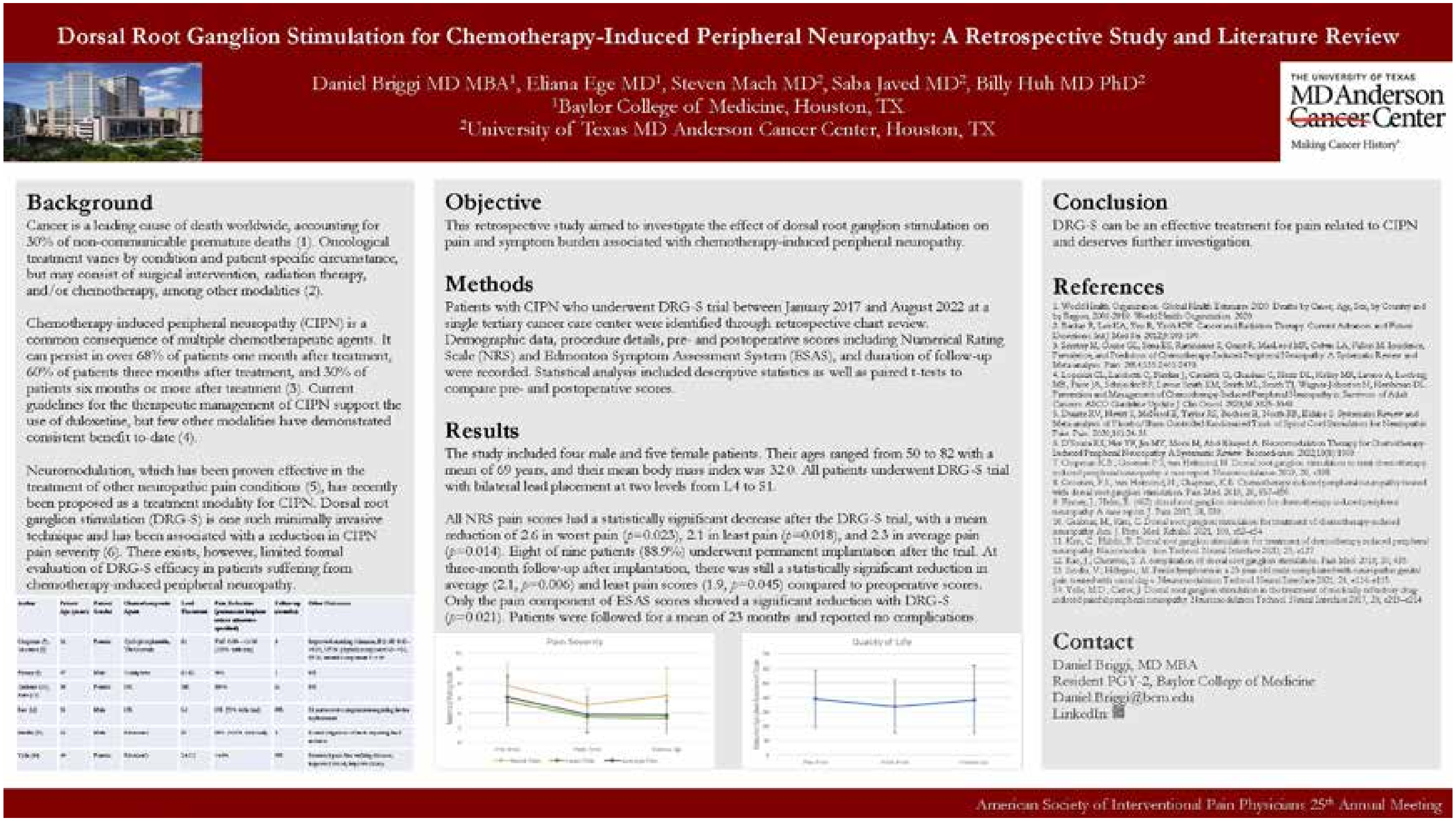
Dorsal Root Ganglion Stimulation for Chemotherapy-Induced Peripheral Neuropathy: A Retrospective Study and Literature Review
Daniel Briggi MD MBA[1], Eliana Ege MD[1], Steven Mach MD[2], Saba Javed MD[2], Billy Huh MD PhD[2]
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THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History
Background
Cancer is a leading cause of death worldwide, accounting for 30% of non-communicable premature deaths (1). Oncological treatment varies by condition and patient-specific circumstance, but may consist of surgical intervention, radiation therapy, and/or chemotherapy, among other modalities (2).
Chemotherapy-induced peripheral neuropathy (CIPN) is a common consequence of multiple chemotherapeutic agents. It can persist in over 68% of patients one month after treatment, 60% of patients three months after treatment, and 30% of patients six months or more after treatment (3). Current guidelines for the therapeutic management of CIPN support the use of duloxetine, but few other modalities have demonstrated consistent benefit to-date (4).
Neuromodulation, which has been proven effective in the treatment of other neuropathic pain conditions (5), has recently been proposed as a treatment modality for CIPN. Dorsal root ganglion stimulation (DRG-S) is one such minimally invasive technique and has been associated with a reduction in CIPN pain severity (6). There exists, however, limited formal evaluation of DRG-S efficacy in patients suffering from chemotherapy-induced peripheral neuropathy.
Objective
This retrospective study aimed to investigate the effect of dorsal root ganglion stimulation on pain and symptom burden associated with chemotherapy-induced peripheral neuropathy.
Methods
Patients with CIPN who underwent DRG-S trial between January 2017 and August 2022 at a single tertiary cancer care center were identified through retrospective chart review. Demographic data, procedure details, pre- and postoperative scores including Numerical Rating Scale (NRS) and Edmonton Symptom Assessment System (ESAS), and duration of follow-up were recorded. Statistical analysis included descriptive statistics as well as paired t-tests to compare pre- and postoperative scores.
Results
The study included four male and five female patients. Their ages ranged from 50 to 82 with a mean of 69 years, and their mean body mass index was 32.0. All patients underwent DRG-S trial with bilateral lead placement at two levels from L4 to S1.
All NRS pain scores had a statistically significant decrease after the DRG-S trial, with a mean reduction of 2.6 in worst pain (p=0.023), 2.1 in least pain (p=0.018), and 2.3 in average pain (p=0.014). Eight of nine patients (88.9%) underwent permanent implantation after the trial. At three-month follow-up after implantation, there was still a statistically significant reduction in average (2.1, p=0.006) and least pain scores (1.9, p=0.045) compared to preoperative scores. Only the pain component of ESAS scores showed a significant reduction with DRG-S (p=0.021). Patients were followed for a mean of 23 months and reported no complications.
Pain Severity
Quality of Life
Conclusion
DRG-S can be an effective treatment for pain related to CIPN and deserves further investigation.
References
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American Society of Interventional Pain Physicians 25th Annual Meeting

Unprovoked Shoulder Pain Found to be Melorheostosis: A 1:1,000,000 Diagnosis

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INTRODUCTION

- Melorheostosis (melo) is a benign sclerosing bone dysplasia and a rare cause of chronic musculoskeletal pain.
- The estimated prevalence of melo is approximately 1/1,100,000; half of these patients develop symptoms before the age of 20.[1,4]
- Asymmetric joint contractures, pain, soft tissue fibrosis and hyperpigmented patches of skin overlying the site of pathologic bone are common clinical presentations.

CASE DESCRIPTION

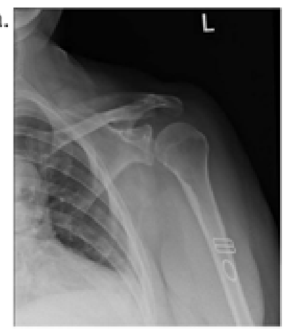
- A 67-year-old female presented with a 3-week history of left neck and shoulder pain radiating into the forearm. In the last five days, she had worsening pain over her left shoulder without any inciting events. Her pain was further exacerbated in LLR position.
- Physical exam was remarkable for TTP of left shoulder and trapezius. Shoulder special testing was negative.
- Shoulder XR: No acute fractures or dislocation of the glenohumeral joint. Flowing lobulated cortical thickening along the medial aspect of the proximal humeral meta-diaphysis suggestive of endosteal melo.
- Cervical MRI: Degenerative changes with up to moderate bilateral C5-6 and left C4-5 foraminal stenosis.
- No surgical intervention was deemed necessary as her left shoulder pain was controlled medically on follow-up with Neurosurgery.
- Based on imaging and clinical presentation, patient was diagnosed with endosteal melo.

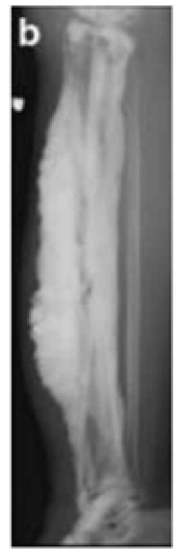
Subject	VAF Affected Bone	VAF Unaffected Bone	VAF Blood
melo4	10.10%	0.00%	0.00%
melo9	17.19%	0.00%	0.00%
melo19	30.86%	.99% (seq. error)	0.00%
melo10	12.07%	0.00%	0.00%
melo2	6.09%	0.00%	0.00%
melo6	3.12%	0.00%	0.00%
melo16	1.04%	0.00%	0.00%
melo18	25.21%	0.00%	0.00%

2018 NIH Study Results
- 8/15 patients with Melo had mutations in MAP2K1 gene of affected bones
- High level of correlation ($R = 0.96$ or >, $p < 0.003$) between WES, PCR, and Amplicon testing (latter two unshown).

(a.) L Shoulder XR AP view exhibiting endosteal Melo in our patient with medial cortical thickening along proximal humeral meta-diaphysis contrasting with classic "dripping candle wax" seen in the more common MAP2K1(+) Melo **(b.)**[2]

a.





DISCUSSION

- Melo's sporadic occurrence, localized distribution, and lack of reports exhibiting inheritance suggests somatic mosaicism as the genetic mechanism [2].
- The MAP2K1 gene disrupts the regulation of bone cell proliferation through overactivation of MEK1 proteins leading to hyperostosis of cortical bone [2].
- In the much less common endosteal melo-variant, the SMAD3 gene is known for stimulating osteoblast differentiation and mineralization [5].
- Some differentials include other benign bone dysplasias like osteopoikilosis (OPK) and osteoid osteomas. Rarely, melo, may coexist with OPK which is an AD disease with symmetric distribution[2].
- If pain persists, surgical removal of hyperostotic bone can be considered following skeletal maturity.

CONCLUSION

- Melo is an uncommon differential for musculoskeletal pain that is largely dependent on radiographic findings.
- While MEK inhibitors are used for the treatment of certain melanomas, there are currently no definitive treatments for melo thus management is aimed at symptom control.

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

Metastatic Melanoma of the Cervical Spine Presenting as C5 Radiculopathy

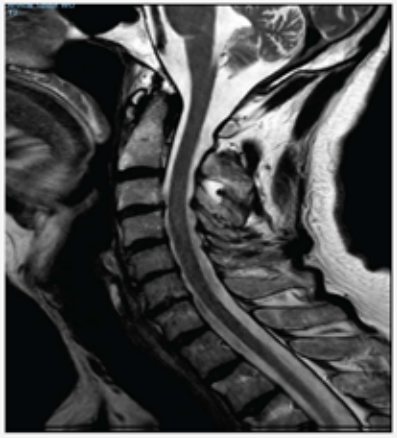
Eric Xu DO, Michael Downing DO, William Ward MD
University of Miami at Holy Cross Hospital, Fort Lauderdale, Florida

Introduction

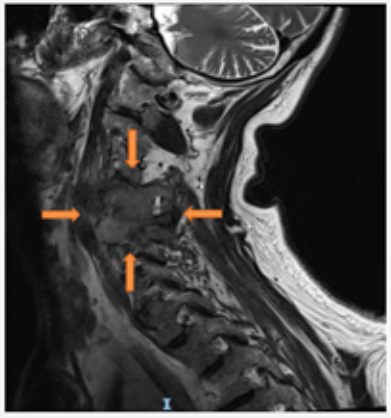
Metastatic melanoma of the spine with an unknown primary site **(MUP)** is rare, with an estimated prevalence of just 2.4%[1]. Prognosis is poor given its rapid clinical progression, with an estimated survival period of 6-months[2]. Treatment is controversial due to unclear survival benefits, but options include chemotherapy, radiation, and surgery.

Case Description

- 79-year-old male with no significant PMHx presented with a two-month history of **left-sided neck and shoulder pain.**
- His neck pain was characterized as "stabbing" and radiated to his left upper arm with intermittent numbness.
- Pain increased with turning his neck or use of the left upper extremity.
- **Physical examination** – 1/4 biceps reflex, 3/5 muscle strength at deltoid m. with notable deltoid m. atrophy.
- **Cervical X-ray and MRI** at initial evaluation only significant for age-related degenerative changes.
- **Initial treatment** included a combination of oral prednisone, gabapentin, and PT/OT with minimal relief. A C3-5 medial branch block also done and provided minimal relief.
- Given the patient's poor response to treatment, **repeat imaging** of his cervical spine was ordered (**just 2-months later** from his initial imaging).



Magnetic resonance imaging from 3/19/22 showed multilevel disc disease and facet arthropathy.



Magnetic resonance imaging from 5/19/22 showed a large left enhancing mass extending from C3-6 and a smaller right mass spanning from C3-5.

Results

- **CT-head/neck** demonstrated left paraspinal soft tissue mass measuring 4.3 x 3.6 x 4.7 cm extending from C3-C6 with significant vertebral destruction and epidural involvement. There was also involvement of the foramina transversarium at C4-5 and C5-6 and neural foramina at those levels.
- **Repeat MRI** showed similar results as CT, with left vertebral artery encasement. A smaller but similar mass spanning from C3-C5 on the right with vertebral artery encasement was also found.
- **Biopsy** of the left paraspinal mass was completed revealing metastatic malignant melanoma, but a primary site was never identified.
- The patient was referred to oncology and started on **nivolumab** with improvement in his radicular symptoms.

Discussion

MUP disguised as cervical radiculopathy is incredibly rare. This pathology must be considered in patients with **treatment-resistant radiculopathy.** Prompt diagnosis is crucial as to not delay oncologic and/or surgical intervention.

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A Randomized, Double-Blind Study of the Effects of a Sustained Release Formulation of Sodium Nitrite (SR-nitrite) on Patients with Diabetic Neuropathy

Amol Soin, MD

INTRODUCTION

To evaluate the safety and efficacy of 40 and 80 mg, BID, of an oral sustained release formulation of sodium nitrite (SR-nitrite) in patients suffering from diabetic neuropathy, and to determine whether SR-nitrite would reduce the frequency of headaches reported previously by subjects receiving the same doses of an immediate release formulation.

Methods: Twenty-four patients were randomized to 40 mg or 80 mg SR-nitrite or placebo twice daily for 12 weeks. The primary objective was to determine whether headaches would be reduced using SR-nitrite. The primary efficacy endpoint was the mean difference in the change of the Neuropathic Pain Symptom Inventory (NPSI) pain score from baseline to that reported after 12 weeks of treatment. Secondary endpoints included changes from baseline for the Brief Pain Inventory (BPI) Scale, the RAND 36 questionnaire, Short Form McGill Questionnaire, daily patient reported score for neuropathic pain, changes in HbA1c, PulseOx and quantitative sensory testing.

RESULTS

Results: The number of subjects reporting adverse events and the number of adverse events did not change with dose. There were no reports of treatment-related headaches. Although no significant differences were identified in patient responses to the questionnaires, a trend was observed. In the NPSI assessment, patients in the 40 mg and 80 mg dose group reported a 12.7% and 22.0% reduction in pain, respectively, compared to an 8.4% reduction by patients in the placebo group. A trend was also observed with the BPI total severity score. However, the 40 mg dosing group reported the greatest reduction in pain using the McGill Pain index and via patient logs of daily pain scores, where the mean of pain scores reported by subjects in the 40 mg group dropped by day 41 and generally stayed lower than the mean of scores reported by subjects in either of the other two groups. Patients in the 80 mg SR-nitrite group had an improvement in both Nerve Sensory Conductance and Nerve Sensory Velocity. No changes were observed in HbA1c levels or PulseOx.

CONCLUSIONS

Sustained release sodium nitrite prevents the prevalent reports of headaches by patients treated with an immediate release formulation of sodium nitrite. In a previous study of patients with peripheral arterial disease (PAD), 40 mg BID treatment led to a statistically significant reduction in reported pain, similar trends were observed at the end of the trial period for most of the pain questionnaires used in the study. The 80 mg BID treatment had the more pronounced affect on bioactivity (quantitative sensory testing), which was similar to the PAD study, where this dose group had the greatest improvement in FMD (AU: spell out FMD). The ability to alleviate pain with BID treatment of SR-nitrite offers promise for a new non-addictive, non-sedating treatment of chronic pain and warrants further study.

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In Vitro Study of Development of a BiPhasic Low Dose Naltrexone Tablet (2mg) To Treat Complex Regional Pain Syndrome

Amol Soin, MD

INTRODUCTION

We attempted to conduct an invitro study to create a novel biphasic formulation of naltrexone with a immediate release shell and a extended release core.

Methods: Pictured here you can see our methods of formulating the tablets and our final embodiment as well as the dissolution curves

B12 R1032-01-107 Coated Tablets

Appearance: Off-white/slight beige hue with a matte gloss finish
Average weight: 62.52 mg
Diameter: ~4mm
Hardness: 11 kP

Spray Coating

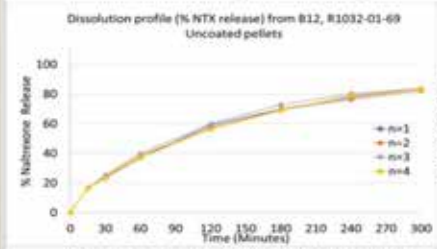
CONCLUSIONS

Conclusions

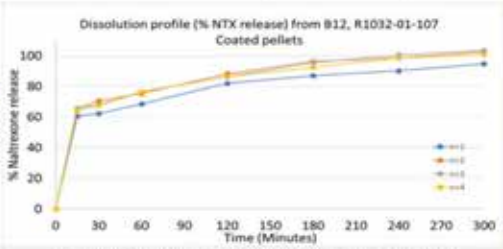
- The uncoated tablets (core) show a sustained release over a period of 5 hours.
- The coated tablets (coat + core), show a burst at 15 min (first time point tested) followed by a steady release over a period of 3 hours
- 1mg from the coat is released instantaneously whereas the total drug load of the tablet (2mg) is released by 3 hours
- The release from the uncoated tablets is monophasic whereas from that of the coated tablets is biphasic
- This formulation meets the target release profile

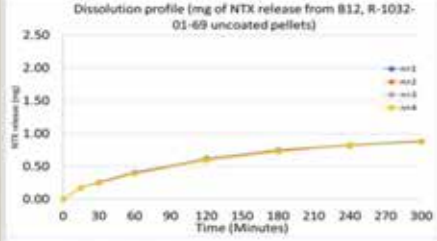
Dissolution of Tablets from prepared from B12

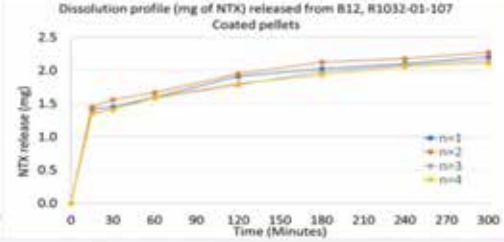
Blend 12 Uncoated (R1032-01-69)



Blend 12 Coated (R1032-01-107)







Ultrasound guidance to avoid C1-C2 Vertebral Artery Anomaly

Rakesh Dara, DO PGY-2, Shounuck Patel, DO

Case Presentation

Our patient is a 24 year old college football player who presented to us with cervical pain, facetogenic in nature, due to repetitive stress and trauma to the area. After careful review of the patient's imaging and presenting signs and symptoms the decision was made to treat the C1-C6 Zygapophyseal facet joints bilaterally with a combination of PRP and Stem cell therapy for an optimal long term management and prevention of the pain.

During the procedure we found that at the C1-C2 area we were unable to find a safe entry point into the joint space with just use of fluoroscopy (x ray guided?) There fore we grabbed the Doppler ultrasound and at the left C1-C2 area we found a high riding vertebral artery. With the use of this modality we were able to safely avoid this anatomical anomaly and successfully bathe the C1-C2 zygaopophyseal facet joint space with PRP/stem cell lystate.

Objectives and Methods

- Our objective was to discern and shed light on the positive prognostic value of Ultrasound in conjunction with fluoroscopy during cervical procedures. Specifically in regards to potential adverse events related to vertebral artery anatomic anomalies.
- Injections were done with patient prone → with Fluoro and Duplex Ultrasound. The optimal target was the junction of the lateral one third and medial two thirds of the C1-2 joint. This was to minimize excessive laterality (due to vertebral artery) or mediality due to the risk of epidural/dural entry.

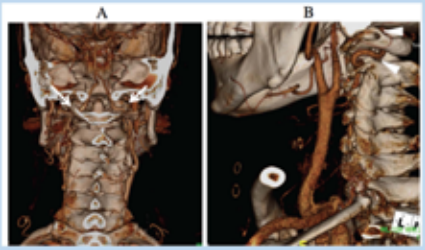
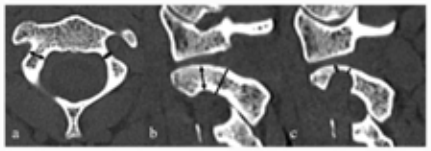


Fig. 2



a Exemplary measurements of C2 pedicle width. Normal width on the right side. Narrow pedicle on the left side. b Normal C2 isthmus height (solid line) and C2 internal height (arrow line). c A side with a high-riding vertebral artery. Short C2 isthmus height (solid line). Short C2 internal height (arrow line)

Type of variation	Total number of subjects (incidence %)	Bilateral/ right/left	Male/female	Simultaneous variations
Persistent first intersegmental artery (FIA)	7 (1.8 %)	1/3/3	5/2	1 with HRVA
VA fenestration (FEN)	5 (1.3 %)	0/2/3	3/2	1 with HRVA
C1/2 origin PICA (PICA)	5 (1.3 %)	0/3/2	4/1	
High-riding VA (HRVA)	39 (10.1 %)	10/14/15	30/9	1 with FIA, 1 with FEN
Ponticulus posticus (PP)	24 (6.2 %)	1/10/13	13/11	1 with FIA

Table 1 Vascular and osseous anomalies at C1/2 diagnosed by 3D CTA among 387 normal subjects

Discussion

The Cranio-vertebral junction can be complicated and the Vertebral artery course can have anatomical variations. The normal course of the five curves (segments) can be appreciated to the left. Variations are often overlooked and can be appreciated in normal patients and often has a predilection for ethnicity as well. Different variations include a persistent first intersegmental artery, fenestration of the VA above and below C1 and a HRVA.

- A HRVA has been defined as a C2 isthmus height of <5 mm and/or internal height of <2 mm measured 3 mm lateral to the border of the spinal canal. HRVA and narrow C2 pedicles pose a great risk of injuring the vessel during interventional procedures or transarticular screw placements.
- A study conducted with close to 1000 randomized subjects found that nearly 20% had variations and of those with HRVA, 30% were bilateral.
- A study performed in Eastern Europe on 511 patients with a mean age of 63.6 revealed 24.1% with a HRVA (6% bilaterally), a nearby PICA branch in 4% and a PP in 14%
- Another study used on a Japanese population revealed significant presence of anomalies as well (refer to Table 1)

Results and Conclusion

In a perfect world we would use CT angiography consistently to screen individuals for vertebral artery anatomical variations prior to any interventional procedure. However this is not always feasible. There is sufficient literature present revealing the presence and prevalence of vertebral artery anomalies. Adverse events associated with damage to the vertebral artery can be as severe as strokes, coma and even death. The use of diagnostic ultrasound during these procedures provides nothing but positive prognostic value as it can aid in avoiding nicking and damage to the vertebral artery, especially in cases of a high riding vertebral artery in our case of the young football player

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Unique Approach to MILD Procedure with Spinal Cord Stimulator In Situ

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Introduction:

There is a paucity of data regarding the intricacies of a minimally invasive lumbar decompression (MILD) procedure in a patient with a prior history of spinal cord stimulator (SCS) placement in which the indwelling SCS hinders access to the ligamentum flavum. Here we describe a MILD procedure in a patient with a history of SCS placement with hardware that prevented access via the traditional entry point. By utilizing intraoperative fluoroscopy and an alternative entry, the patient was able to undergo successful MILD.

Case Description:

Our patient is a 72 year old male with a past medical history of L3-S1 laminectomy who suffered from lumbar spinal stenosis and post-laminectomy syndrome. He underwent SCS implant with Boston Scientific in 2020 that was reprogrammed multiple times, however continued to have debilitating pain. The patient's radicular pain was described as 8/10 in severity, sharp, radiating down the right thigh and ankle, constant, relieved with bending forward. He was evaluated by neurosurgery and was deemed not a surgical candidate. The patient was scheduled for MILD at L1-L2, L2-L3 under MAC. Intraoperatively, under AP fluoroscopy, it was noted that the patient's SCS wire was in the trajectory of the normal pathway of the trochar to gain access to the superior aspect of the inferior lamina. This warranted an alternative approach, utilizing a more acute angle of entry to the desired interspace to avoid the overlying SCS wires.

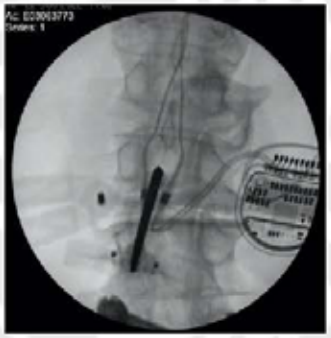

Figure 1: AP with trochar inserted, visualization of SCS and overlying wires

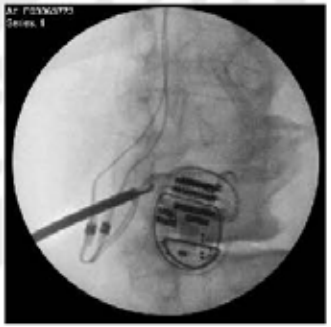

Figure 2 contralateral oblique view demonstrating our trajectory in relation to SCS

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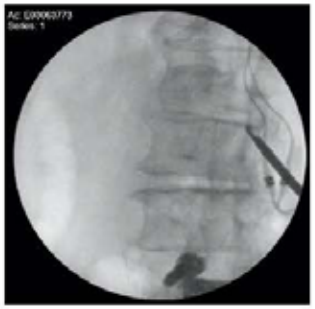

Figure 3: Ipsilateral oblique view

Results:

The patient underwent a successful MILD utilizing an alternative approach with no complications and SCS hardware still intact. Post-operatively he reported significant functional improvement and was able to ambulate twice as far without significant pain.

Discussion:

In a traditional MILD, the interspace below the desired area to decompress is utilized to gain access to the ligamentum flavum. Due to the overlying SCS hardware, this specific case required a more acute angle of entry than that of a traditional MILD. In addition, the SCS generator was overlying the target interlaminar level in the contralateral oblique view, making it difficult to visualize the ventral interlaminar line. This required angle adjustments intraoperatively to effectively visualize the target. This case may be used as a reference point for future physicians who encounter similar obstacles of the MILD procedure in the intraoperative setting. Furthermore, this case may guide providers in the adequate preoperative assessment and planning of the MILD procedures in patients with hardware that may hinder access to the ligamentum flavum.

Using Quantitative Motion Analytics as Inclusion Criteria for Spinal Cord Stimulators (SCS)

ASIPP 25th Annual Meeting 2023

GLADSTONE C. MCDOWELL, II MD
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INTRODUCTION

Spinal cord stimulation (SCS) is a non-pharmaceutical, effective, technological advancement for the treatment of pain associated with the trunk and extremities as supported by of clinical experience and studies. Qualifying the proper patient for the procedure is critical to optimize success and minimize the failure rate, which is not optimal for the patient and the payer.

Currently much of the inclusion/exclusion criteria depend upon patient self-report, subjective patient assessment tools and clinician observation. Published reports suggest a reduction in efficacy over time and the development of "tolerance," which may lead to explantation of the device. Accumulating evidence suggests a significant relationship between pain level and functional performance.

OBJECTIVES

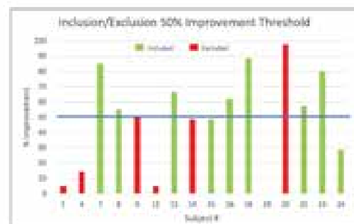
1) Examine functional motion analytics retrospectively to identify the correlation between quantitative motion anlaytics with clinician and insurer threshold for proceeding with implantation;

2) Use quantitative motion analytics to obtain objective functional measurement pre-SCS implantation to compare to patient's self-reported pain level.

MATERIALS & METHODS

- BioMech Lab™, a sensor-based motion analytics platform, was used to assess quantitative functional motion (gait and balance) pre-Senza Spinal Cord Stimulator (SCS) implantation phase;
- 25 participants, male and female, 18 years of age or older, who were considering a Senza® Spinal Cord Stimulator system (Nevro Corp.) to help treat chronic pain were studied after appropriate consent;
- The evaluations were performed immediately pre-trial visit, and on the seven-day post-trial visit;
- Six gait metrics were evaluated and the BioMech Lab Functional Gait Index™ (FGI) was calculated;
- The balance score was determined measuring deviation in various positions;
- A functional improvement threshold of 50% was selected to emulate the 50% pain relief required for insurance carrier approval.

GAIT BALANCE



Graph I: Functional motion analytics as inclusion criteria

RESULTS

- 16 Subjects were assessed during the pre-implantation (trial) phase;
- Nine subjects were selected for implantation;
- Seven of the nine subjects demonstrated functional scores that supported inclusion for implantation (78% correlation);
- Of the seven excluded patients six had functional improvement that was below acceptable levels (86% correlation with physician concern with equivocal pain score).

CONCLUSIONS

- Quantitative motion analytics performed on patients diagnosed with chronic back and/or leg pain can be used as inclusion criteria to support implantation of a Senza® HFX Lumbar Spinal Cord Stimulator system;
- BioMech Lab gait and balance analyses provide additional, objective, and actionable metrics augmenting traditional subjective pre- and post-surgical assessment protocols;
- When clinicians are presented with objective data regarding patient function as compared to borderline subjective scores, they may more accurately select patients who will successfully respond long-term to the Senza® HFX Lumbar Spinal Cord Stimulator System.

Serotonin Syndrome in a Patient with Co-Morbid Cerebral Palsy and Metastatic Adenoid Cystic Carcinoma

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THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Making Cancer History®

Introduction

- Occurs when the use of serotonergic medications and the subsequent activation of peripheral and central postsynaptic 5HT-1A and 5HT-2A receptors.
- Most typical presentation: mental status changes, neuromuscular hyperactivity, and autonomic hyperactivity
- Diagnosis of exclusion, without a specific diagnostic test.
- Past medical history, physical exam, home medication review (including supplements and illicit substances), and timing of the onset of symptoms remain the most important pieces
- Certain medical conditions, such as cerebral palsy (CP) are accompanied with a higher prevalence of medical co-morbidities that rely on serotonergic drugs for their management
- Necessitates the need for a meticulous and individualized approach to the management of their pain complaints with both medications and interventions that involve local administration of medications

Presence of serotonergic agent and any one of the following:
Spontaneous clonus
Inducible clonus and agitation or diaphoresis
Ocular clonus and agitation or diaphoresis
Tremor and hyper-reflexia
Hypertonic and temperature >38 C and ocular or inducible clonus

Table 1: Hunter Serotonin Toxicity Criteria (HSTC)

Scan for abstract and references

Case Report

- 58-year-old female with CP, history of metastatic adenoid cystic carcinoma to the T12 vertebra and adjustment disorder with anxiety who presented to the emergency department with acute on chronic pain and muscle spasms in her lower back. Her pain was multifactorial with components of neuropathic, nociceptive and somatic pain but overall controlled.
- At baseline, pain was improved with generalized movement of the lower extremities but worsened with lying flat. Due to upcoming MRI – for surveillance imaging, she was advised to take additional hydrocodone, muscle relaxant (Flexeril and/or baclofen or cyclobenzaprine).
- Neuropathic pain was responding to gabapentin however dosing was limited due to risk of serotonin syndrome with escalating doses.
- **Presentation:** Pain radiated to left anterior thigh, progressively worsened over the past week, and associated with increased spasticity in bilateral shoulders and lower extremities. On examination, she had hyperreflexia in bilateral lower extremities and tachycardia. Her symptoms were refractory to her home regimen of gabapentin, hydrocodone, cyclobenzaprine and tizanidine. She was initiated on IV dilaudid, titrated on her tizanidine and scheduled for a left sided sacro-iliac joint injection.
- After medication management and her local sacro-iliac joint injection, she experienced 50%-75% relief in her pain and was able to ambulate and be safely discharged back to the community. It was also theorized that other medications, not commonly associated with serotonergic drugs may have also contributed to her presentation due to imbalances in serotonergic activity in patients with CP.

Discussion

- Patients with CP experience changes in their muscle tone and activity due to spasticity and muscle spasms.
- These conditions heavily rely on medications such as baclofen and cyclobenzaprine which can produce effects on serotonin receptors.
- These patients are also at risk for mood disorders that are best managed by selective serotonin re-uptake inhibitors such as duloxetine which also act on serotonin receptors.
- Necessitates the need for pain physicians to individualize their pain management approach as they may have heightened sensitivity to serotonin activity or additive effects of serotonin.
- Early detection, a multi-disciplinary approach, prompt recognition, and successful titration of medications leads to improved patient morbidity and mortality through avoidance of this phenomenon.

Conclusion

- Patients with CP experience changes in their muscle tone and activity due to spasticity and muscle spasms.
- CP patients heavily rely on medications such as baclofen and cyclobenzaprine which can produce effects on serotonin receptors.
- At risk for mood disorders that are best managed by SSRI's. such as duloxetine which also act on serotonin receptors.
- Necessitates the need to individualize their pain management approach due to likely heightened sensitivity to serotonin activity or additive effects of serotonin.
- Early detection, a multi-disciplinary approach, prompt recognition, and successful titration of medications leads to improved patient morbidity and mortality through avoidance of this phenomenon.

Symptom Severity	Management
Mild	Discontinue offending agents
	Supportive treatment (to include cooling measures)
	Consider benzodiazepine (diazepam) for mild agitation, fever, hypertension
Moderate (hyperthermia >40 C, agitation, hypervigilance)	All of above + consider 5HT antagonist (cyproheptadine)
	Admission for close monitoring
Severe (Hyperthermia > 41.1 C, hemodynamic instability, muscle rigidity)	All of above
	Anti-hypertensives
	Possible intubation, sedation ICU admission

Table 2: Treatment of Serotonin Syndrome Based on Disease Severity

Comparison of the Oswestry Disability Index (ODI) with a Digitally Measured Functional Gait Index (FGI)

ASIPP 25th Annual Meeting 2023

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INTRODUCTION

Spinal cord stimulation (SCS) is an effective treatment for pain of the trunk and extremities as supported by clinical experience and studies. The currently acceptable standard to indicate therapeutic benefit and enable insurance coverage is achieving at least a 50% reduction in pain during the trial using subjective patient scales including the Oswestry Disability Index (ODI) and the Numeric Pain Intensity (NPI) Scale.

Some centers choose 5-7 day trials, and in others, extended trials are required to confirm benefit. Published reports suggest a reduction in efficacy over time and the development of "tolerance." Accumulating evidence suggests a significant relationship between pain level and functional performance.

OBJECTIVES

1) Use quantitative motion analytics to obtain longitudinal, objective, functional measurements pre/post-SCS implantation;
2) Examine the correlation between objective functional measurements and patients ODI scores; and
3) Assess the efficacy of the treatment over a three-month period using objective motion analytics.

MATERIALS & METHODS

- BioMech Lab, a sensor-based motion analytics platform, was used to assess quantitative functional motion (gait and balance) pre- and post-Senza Spinal Cord Stimulator (SCS) trials and implantation phases;
- 25 participants, male and female, 18 years of age or older, who are considering or have received a Senza® Spinal Cord Stimulator (SCS) system (Nevro Corp.) to help treat chronic pain were studied after appropriate consent;
- The evaluations were performed immediately pre-trial visit, and on the 7-day post-trial visit, 4-, 8- and 12-weeks post-implant;
- Six gait metrics were evaluated and the BioMech Lab Functional Gait Index™ (FGI) was calculated;
- The balance score was determined measuring deviation in various positions;
- Statistical significance was determined using simple linear regression.

Graph 1: The relationship between average ODI and FGI scores over the study period

RESULTS

- Subjects that successfully completed the three-month study experienced functional improvement (positive change) for the following parameters: Balance 12%, Gait 14%, NPI 32 %, ODI 35%;
- A significant correlation between patients' average Functional Gait Index (FGI) and average ODI scores across the three-month study period (r2 = 0.06).

CONCLUSIONS

- Patients diagnosed with chronic back and/or leg pain who received a Senza® Spinal Cord Stimulator (SCS) system and completed the three-month protocol had a significant and measurable improvement in functional motion (gait and balance) ***suggesting a lack of tolerance to treatment;***
- BioMech Lab gait and balance analyses provide additional, objective, and actionable metrics augmenting traditional subjective pre- and post surgical assessment protocols;
- Functional improvement for gait and balance agreed with their change in ODI score and perception of pain improvement;
- When patients were presented with objective data regarding their improvement, they may more accurately report the efficacy of the treatment with the Senza® HFX Lumbar Spinal Cord Stimulator System, supporting the conclusion that digital measurements can be used to supplement patient subjective assessment tools.

Tropical Spastic Paraparesis: A Case of Lower Back Pain & Disability

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SUNY Downstate Health Sciences University - Department of Orthopedic Surgery and Rehabilitation Medicine (Brooklyn, NY)

Background

Tropical Spastic Paraparesis, also known as HTLV-1-associated myelopathy, is characterized by inflammatory damage to the brain and spinal cord. HTLV-1 virus is endemic in the Caribbean, Japan, and Africa, affecting people most frequently 30-50 years of age. Prognosis is poor, with progression to wheelchair confinement. Clinical features include lower extremity weakness, spasticity, back pain, bowel/bladder dysfunction, and sensory changes. Diagnostic testing includes imaging, CSF and serum testing, and PCR. MRI imaging of the brain and spinal cord may be normal or have subcortical and periventricular white matter lesions, and atrophy of the cervical and/or thoracic cord. Current treatment is limited to symptom management. There is some reported evidence of delay of disease severity and progression with corticosteroids, plasmapheresis, and exclusive monoclonal antibody therapies.

Case Presentation

A 57-year-old male with a past medical history of type 2 diabetes mellitus presented with lower back pain, lower extremity weakness and sensory changes, gait instability, and increased lower extremity (LE) tone. Patient was discharged, work-up for myelopathy resulted positive for HTLV-½ antibodies, and the patient was lost to follow-up. A few months later, he presented with worsened symptoms, and new urinary incontinence and erectile dysfunction. He received steroids and IVIG with minimal improvement. Gabapentin and baclofen provided some symptomatic relief. On examination, he had increased bilateral LE tone with 2/5 strength with hyperreflexia and decreased sensation T4 downwards to light touch, pin prick, and vibration.

Discussion/Results

MRI brain showed small foci of signal abnormality and enhancement of white matter; MRI spine showed signal abnormalities in long segments of thoracic spine, and some abnormalities in cervical spine. Within a year, he developed major depressive disorder and became wheelchair-bound. Patient was referred from sports medicine to physical therapy and was evaluated by PM&R/pain management for evaluation of worsening lower back pain where he presented with lower back pain 8-10/10 intensity, sharp, radiating to medial thighs and abdomen, worsened with prolonged sitting, and improved with lying flat. Functional decline was present, requiring extensive assistance with activities of daily living. On examination, the patient was found to have limited range of motion of the lumbar spine due to pain, positive slump test, normal upper extremity strength, and LE strength 0-2/5 throughout. Patient was recommended for physical therapy, and MRI lumbar spine for evaluation of possible lumbosacral radiculopathy.

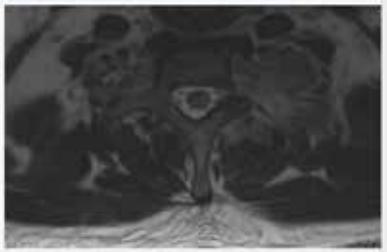

Figure 1 – Transverse view of CT Thoracic Spine

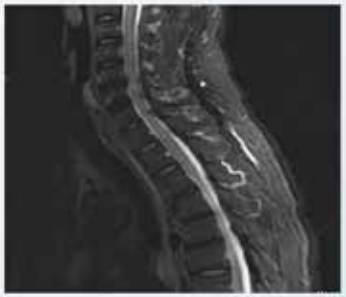

Figure 2 – Sagittal view of CT Thoracic Spine

Conclusion

Tropical Spastic Paraparesis is characterized by slow onset of progressive weakness and spasticity in the lower extremities, bladder and bowel changes, and back pain. The holistic pain clinician should be aware of this disease entity and medical management should include patient education, pain control, spasticity management, psychotherapy, knowledge about wheelchair-user injuries, and adaptations to minimize disability.

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Dynamic Stimulation (DS) Can Enhance Pain Coverage of Acute Spinal Cord Stimulation

Jessica Block[1], Eric Loudermilk[2], Robert Frey[3], Changfang Zhu[1], Kristen Lechleiter[1,*], Michael Moffitt[1], Rosana Esteller[1]

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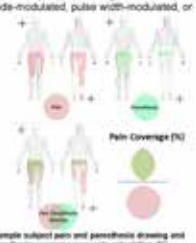
BACKGROUND

Spinal Cord Stimulation (SCS) for chronic pain management typically uses static stimulation (SS), also referred to as tonic pulse-trains, where the amplitude, pulse width, and rate of stimulation remain the same across time. Several SCS therapies, including both paresthesia-based that typically evoke "tingling" sensations and fast-acting paresthesia-free, are dependent on precise paresthesia-pain overlap. A recent publication demonstrates dynamic stimulation (DS) (where at least one stimulation parameter is constantly varying) can improve efficacy of SCS in a preclinical rodent model[1]. Given the acute nature of this study, we could not assess pain relief, instead, we evaluated the hypothesis that dynamic stimulation may improve pain coverage by measuring pain-paresthesia overlap in subjects experiencing acute static and dynamic SCS

METHODS

N = 35 subjects who were undergoing an on-label percutaneous SCS temporary trial (Boston Scientific, Valencia, CA) were enrolled in a prospective study at two centers in the U.S. (NCT02988713). A commercial external stimulus generator (STG4004, Multi-Channel Systems, Germany) was used to generate static and dynamic stimulation sequences. The dynamic stimulation (DS) waveforms consisted of amplitude-modulated, pulse width-modulated, or rate-modulated pulse-trains. A bipole electrode configuration was used without multiple independent current control (MICC) optimization. This same configuration was used for Dynamic Stimulation. *Subjects received a few static and numerous dynamic stimulation options for comparison in a blinded fashion. Other SCS parameters including electrode configuration were held constant. Subjects provided multiple assessments including pain drawings, paresthesia drawings, and preference rankings.



Example subject pain and paresthesia drawing and paresthesia coverage over pain calculation (%)

The demographics for subjects who reported a pain drawing and at least one paresthesia drawing for both SS and DS (n=31) are as follows:

Gender – Females (%)	58.1% (18/31)
Age – Mean (Range)	62.0 (19-85) yrs, n=31
Years of Chronic Pain Mean (STD)	16.3 (10.9) yrs, n=30*
Baseline pain score Mean (STD)	Overall 7.5 (1.6), n=31 Leg 5.9 (2.9), n=31 Low back 7.9 (1.8), n=31

*One subject did not report their baseline

[1] Kiyama, Suguru, et al. "Sub-paresthesia spinal cord stimulation reverses thermal hyperalgesia and modulates low frequency EEG in a rat model of neuropathic pain." Scientific reports 8.1 (2018): 1-7

RESULTS

Out of the n=19 subjects that completed preference rankings for at least one DS and one SS, 53% (n=10/19) of subjects ranked DS highest and 21% (n=4/19) ranked SS highest despite no optimization of the dynamic stimulation settings for electrodes or baseline parameters

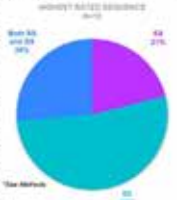


Figure 1: Highest Rated Stimulation Sequence in N=19 Subjects that completed preference rankings for at least one DS and one SS. Patients compared DS and SS stimulation in multiple pairwise comparisons. Those comparisons were compiled and the option with the highest rank is reported here. DS alone was the highest rated sequence in 53% of subjects, 26% of subjects ranked both DS and SS equally, and 21% ranking SS alone highest.

Conceptual examples of Static Stimulation and Dynamic Stimulation

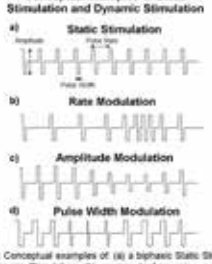


Figure 2: Conceptual examples of: (a) a biphasic Static Stimulation and (b-d) Dynamic Stimulation. (b) represents frequency modulation: the pulse frequency is varied over time, while the pulse amplitude and width are kept constant between pulses. (c) represents amplitude modulation: the pulse amplitude is varied over time, while the pulse width and frequency are kept constant. (d) represents pulse width modulation: the pulse width is varied over time, while the pulse amplitude and frequency are kept constant.

68% of patients (n=21/31) reported better pain-paresthesia concordance with Dynamic Stimulation

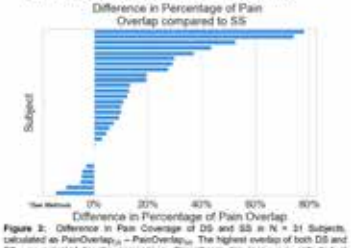


Figure 3: Difference in Pain Coverage of DS and SS in N = 31 Subjects, calculated as $PainOverlap_{DS} - PainOverlap_{SS}$. The highest overlap of both DS and SS was selected for the comparison. Paresthesia drawings were collected at amplitudes where the patient reported a "medium, but comfortable" sensation for both DS and SS. Positive values indicate a larger overlap of pain for DS stimulation and negative values indicate a larger overlap of pain for SS stimulation.

45% (n=14/31) patients reported the highest level of DS pain-paresthesia overlap with rate modulated with a sinewave (Rsin) and rate modulated with a Poisson function (Rpoi)

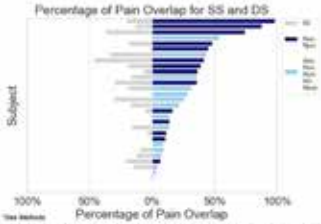


Figure 4: Percent Pain Overlap observed in individual subjects (n = 31) for both SS (left) and DS (right). Pain coverage for Rsin and Rpoi are emphasized. 14/31 patients (45.2%) reported the high level of DS pain-paresthesia overlap with Rsin and Rpoi

Increase in pain-paresthesia coverage of rate modulated DS (Rpoi and Rsin) trends with increased modulation depth

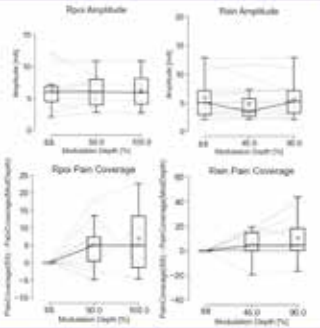


Figure 5: In-subject comparisons of Test Amplitude and Normalized Paresthesia-Pain Coverage with respect to the Modulation Depth for Rpoi (n=12) and Rsin (n=19). Each gray line is a single subject, the dark black line represents the trend along the medians, and the white circles mark the mean of each distribution. Static Stimulation corresponds to zero Modulation Depth so it is represented as "SS" on the axis for the 0%. The Test Amplitudes for each rate-modulated sequence were minimally affected by variation in the Modulation Depth (top). Other SCS parameters including electrode configuration were held constant. Interestingly, both Rpoi and Rsin, showed a slight positive trend in Paresthesia-Pain Overlap with increasing Modulation Depth (bottom), not observed in the other DS sequences (data not shown). This suggests a better pain coverage with these rate modulation sequences independently of a change in test amplitude.

CONCLUSIONS

We showed that SCS using DS has the potential to improve pain coverage (enhanced pain-paresthesia overlap), a key step to achieving optimal pain relief for many SCS therapies, despite not including optimization of the electrode configuration to achieve paresthesia (with either dynamic stimulation or single frequency settings) in the study. In addition, DS allows to cover more area while maintaining comfortable stimulation levels for more patients than SS. Rate modulated sequences (Rsin and Rpoi) show positive trends in Paresthesia-Pain Overlap while increasing Modulation Depth while maintaining relatively constant Test Amplitudes. Future hypotheses may test whether the results are even more pronounced when optimized configurations are used. Further, the improvement of pain coverage provided by rate modulated (Rsin and Rpoi) DS aligns with the DS pattern that achieved the best pain outcomes in a preclinical rodent model[1]. Thus, future chronic studies are warranted to evaluate DS therapy efficacy.

DISCLOSURES

Block J, Zhu C, Moffitt M, Esteller R are full-time, salaried employees of Boston Scientific. *Lechleiter K completed the work presented here while a full-time, salaried employee of Boston Scientific and is now a full-time, salaried employee of Xilis Inc., Durham, NC, USA

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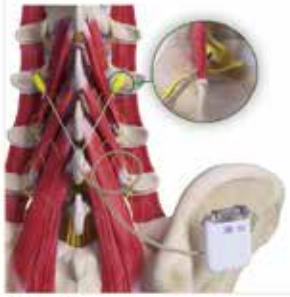
Restorative Neurostimulation Effectiveness in Patients with Chronic Low Back Pain and Spine Pathologies Not Indicated for Surgery

Meredith Langhorst[1] and William Klemme[2] on behalf of the ReActiv8-B study group. [1] *OrthoIndy, Indianapolis, IN, USA;* [2] *Uniformed Services University of the Health Sciences, Bethesda, MD*

Introduction: Restorative Neurostimulation targets non-surgical chronic low back pain (CLBP) associated with multifidus dysfunction. A pivotal randomized sham-controlled trial (NCT02577354) established effectiveness, 3-year durability and safety of this therapy.[1,2,3]



- Rehabilitative treatment aimed at restoring neuromuscular control of lumbar spine stability
- Stimulates the L2 medial branch 2x daily for 30 minutes to elicit episodic multifidus contractions

Override inhibition

Elicit proprioception

Reactivate muscle control

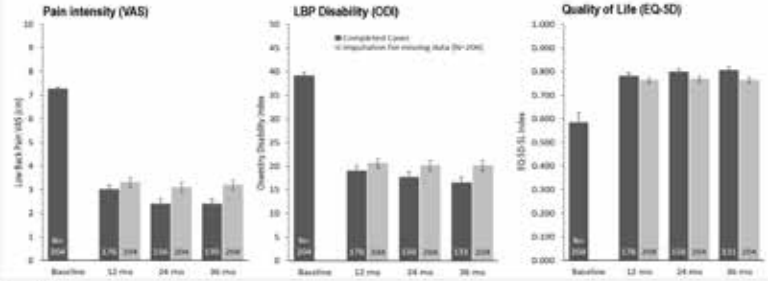
Restore functional spine stability

Reduce pain

Objective: Evaluate prognostic value of non-surgical spine pathologies on treatment effectiveness and durability.

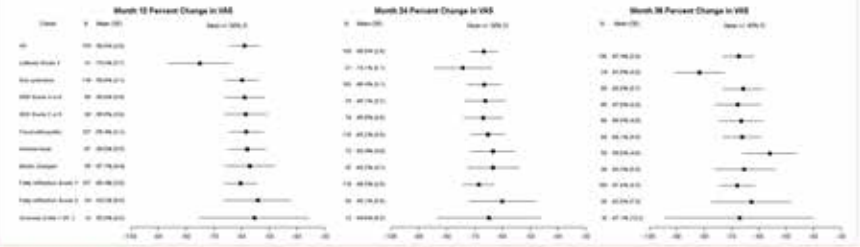
Methods: Non-surgical spinal pathologies identified and graded by expert MRI reviewer and sub-analysis performed.

Overall results: N=204; Age 47±9 years; backpain duration 14±11 years; LBP on 97±8% of days. Longitudinal outcomes:



Sub-analysis results:

- Improvements in pain (VAS) and other outcomes are equally substantial and durable as results of the total study population.
- Participants with stable grade-1 listhetic segments at baseline (n=36/204) showed more rapid improvements than those without this diagnosis.
- At 1 year, differences were statistically significant and clinically relevant for CLBP VAS (p=0.004), ODI (p=0.03) and EQ-5D (p=0.01).



Conclusions:

- Restorative neurostimulation is an effective and durable treatment for patients with CLBP associated with multifidus dysfunction.
- Effectiveness and durability is equivalent in non-surgical spine pathologies.
- Early and vigorous response in a sub-cohort with stable grade-1 listhetic segments is consistent with treatment-induced functional stabilization and is hypothesis generating for future studies in this subpopulation.

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Disclosures:

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ORTHOINDY

Baseline Measures and Temporary Trial Predict 2 Year 10kHz SCS Outcomes in Nonsurgical Refractory Back Pain Patients

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Introduction

Spinal cord stimulation (SCS) has been shown to be effective in treating persistent back and leg pain post spine surgery.[1] But patients with non-surgical back pain need a treatment option when conventional medical management (CMM) cannot relieve their pain. Non-surgical refractory back pain (NSRBP) is defined as patients with chronic refractory back pain who have not had previous spine surgery and are not candidates for spine surgery based on a consultation with a spine surgeon. A recent randomized clinical trial demonstrated superior efficacy and cost-effectiveness with 10kHz SCS over CMM alone in this NSRBP patient group.[2]

Objective

Despite the good success rate, cost-effectiveness, and good safety profile of SCS3, there is a significant upfront cost and therefore an ongoing effort to find baseline characteristics that can predict therapeutic response with SCS.4,5 We report on analysis examining the association between pre-implant patient characteristics and 24-month outcomes from this multicenter NSRBP RCT.

Methods

- NSRBP patients, as defined above, were consented and enrolled if ineligible for surgery based on surgical consultation, as described by Patel et al.[6]
- Subjects were randomized 1:1 to either 10kHz SCS plus CMM or CMM alone (**Table 1**).
- Subjects randomized to 10 kHz SCS underwent permanent implantation if ≥50% pain relief was achieved during a temporary trial. The pain relief achieved at the end of trial was recorded.
- Trial endpoints included proportion of subjects in each group achieving ≥50% pain relief compared to baseline (Responders), pain relief on the visual analog scale (VAS), Oswestry Disability Index (ODI), and quality of life (EQ-5D-5L). Patients who consented to a study extension were followed to 24 months (24M).
- Analysis was based on 24M outcomes for all 125 implanted patients (original = 69 and crossover arm n = 56) with last observation carried forward used for missing data.
- Linear regression analysis was performed to assess baseline parameters that were associated with both Pain Relief and ODI improvement at 24 month (**Table 2**). Multivariate regression with a backward stepwise procedure was used to determine the parameters that made up the multivariate model.

Table 1. Population Demographics of randomized patients.

	CMM (n = 76)	10kHz SCS+CMM (n=83)
Age, mean (SD), year	56.2 (11.6)	54.5 (12.1)
Female (%)	40 (52.6%)	50 (60.2%)
Years since diagnosis	11.9 (11.8)	11.4 (10.0)
Back Pain VAS, mean (SD)	7.3 (1.0)	7.4 (1.1)
Baseline Leg Pain Present[1]	45 (59.2%)	52 (62.7%)
Pain Etiology[2]	n (%)	n (%)
degenerative disc disease	49 (64.5%)	60 (72.3.7%)
spondylosis	39 (51.3%)	47 (56.6%)
radiculopathy	35 (46.1%)	34 (41.0%)
lumbar facet-mediated	25 (32.9%)	24 (28.9)
mild / moderate spinal stenosis	24 (31.6%)	23 (27.7%)
spondylolisthesis	9 (11.8%)	7 (8.4%)
internal disc disruption / annular tear	6 (7.9%)	8 (9.6%)
sacroiliac dysfunction	5 (6.7%)	3 (3.6%)

[1]Subjects with a left or right lower limb baseline pain score greater or equal to 5 are included only
[2]Subject may have more than one etiology

Pain and Functional Improvement at 24 months in Nonsurgical Back Pain Patients Across a Variety of Clinical Characteristics

Results

- There were 159 patients randomized with similar baseline characteristics (**Table 1**). All primary and secondary study endpoints were met (p<0.001)[2].
- Pain and Functional outcomes through 24 months are shown (**Fig 1, 2**), with an 81.6% responder rate at 24M
- A total of 6/125 (4.8%) explants occurred during 24-month follow-up, three due to dissatisfaction with therapy, and three to infection (two of which were replaced).

Figure 1: Pain Relief and Responder Rate over 24 Months

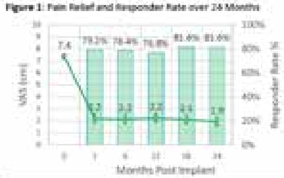
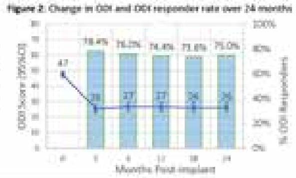


Figure 2: Change in ODI and ODI responder rate over 24 months



Baseline Characteristic	VAS Change p	ODI Change p
Sex (1: Female, 0: Male)	0.014*	0.24
Age	0.18	0.004*
Nonsurgical candidate due to presentation and underlying pathology (1: not acceptable surgical candidate due to pathology, 0: not surgical candidate due to comorbidities or refusing surgery)	0.57	0.99
Obesity (1: BMI ≥30 kg/m2, 0: BMI<30kg/m2)	0.52	0.77
PHQ-9	0.95	0.45
Years Since Diagnosis (1: ≥4 yrs, 0:0–3 yrs)	0.39	0.28
Degenerative Disc Disease and/or internal disc disruption/annular tear (1:yes, 0:no)	0.41	0.56
Spondylosis and/or Lumbar facet-mediated pain (1:yes, 0:no)	0.44	0.18
Radiculopathy (1:yes, 0:no)	0.44	0.36
Mild/moderate spinal stenosis (1:yes, 0:no)	0.58	0.87
Spondylolisthesis (1:yes, 0:no)	0.79	0.90
Sacroiliac dysfunction (1:yes, 0:no)	0.45	0.98
Neuropathic Pain (1: PainDetect ≥19, 0: PainDetect <19)	0.048*	0.003*
Nociceptive Pain (1: PainDetect ≤12, 0: PainDetect >12)	0.35	0.17
Pain Detect Score	0.009*	0.009*
Baseline ODI Score	0.52	0.021*
Baseline VAS (cm)	0.0002*	0.95
Change in VAS at end of trial	<0.0001*	0.23

Table 2. Univariate Binary Logistic Regression with point change in VAS and ODI at 24 Months. Significant relationships highlighted.

* statistically significant p-value at the 0.05 level.

Abbreviations: ODI: Oswestry Disability Index, PHQ-9: Patient Health Questionnaire – 9 item, EoT_PainRelief: Percent Pain Relief at End of Trial, yrs: years, r: Pearson Correlation coefficient, p2 tailed significance.

Results: Multivariate Analysis

Predictors of Pain Relief

Table 3: Multivariate Linear Regression Results to Predict Pain Relief (pt change in VAS) at 24M.

Predictors of Response		p-value
Change in VAS at EoT	Higher pain relief EoT = more pain relief [illegible]	<0.0001*
Sex (Male)	Males had less pain relief than females [illegible]	0.022*
PainDetect Total Score	Higher Pain Detect Score = more pain relief [illegible]	0.039*

Abbrev: PR: pain relief, EoT: end of trial.

Predictors of Functional Improvement

Table 4: Multivariate Linear Regression Results to Predict Change in ODI at 24 Months

Predictors of Response	ODI Change	p-value
Age	Older = less ODI improvement [illegible]	0.002*
PHQ-9	Higher depression = less ODI improvement [illegible]	0.009*
Baseline ODI	Higher baseline ODI = more ODI improvement [illegible]	0.009*
Neuropathic (PainDetect ≥ 19)	Neuropathic Pain = more ODI improvement [illegible]	0.01*
Baseline VAS	Higher baseline VAS = less ODI improvement [illegible]	0.025*
Change in VAS at EoT	Higher PR EoT = more ODI improvement [illegible]	0.024*
Radiculopathy	Radiculopathy = less ODI improvement [illegible]	0.039*

- Change in VAS at end of Trial was the strongest predictor of pain relief (**Fig. 4**), and Age predicted less disability improvement (**Fig 5**) in the multivariate models.

Figure 4: Change in VAS at End of Trial is positively associated with change in VAS at 24 M

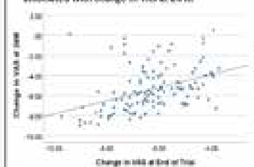
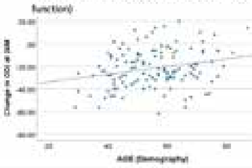


Figure 5: Age is negatively associated with improvement in ODI at 24 M (lower ODI = better function)



Conclusions

- End of trial pain relief had predictive value for both outcomes suggesting that the magnitude of pain relief obtained in trial can inform the therapeutic effect that will be obtained with permanent implant.
- The negative association of functional improvement with age may be explained by additional comorbidities in elderly patients that limit function.
- Higher PainDetect Scores were weakly correlated with higher pain relief and disability improvement.
- But overall, the percentage of variability in outcome explained by the models was low, suggesting that good 24-month outcomes, with a low explant rate for inefficacy (2.4%), can be achieved with this therapy in a wide clinical population.

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