Posters

Top Posters Selected for 2018 20th Annual ASIPP Meeting

Abstract winners:

Fellow:
Tied for first:
Patient Pain Satisfaction Scores Are Unchanged by an Opioid Reduction Protocol Utilizing the Tracking of Morphine Equivalent Dose Calculations
Kunj Patel

Depth Assessment using Contralateral Oblique View during Cervical InterlaminarEpidural Steroid Injections
Michael O'Connell

Physician:
First:
Spinal Cord Stimulation at 10 kHz for Treatment of Chronic Upper Limb and Neck Pain
Kasra Amirdelfan MD

Second:
WHISPER: A Multicenter, Prospective Cross-Over Randomized Controlled TrialEvaluating Sub-Perception Spinal Cord Stimulation at ≤ 1.2 kHz
James North, MD

Third:
Amniotic Membrane and Umbilical Cord Particulate for Pain Associated with Knee Osteoarthritis: Preliminary Results of a Single-center, Prospective, Pilot Study
Ramon Castellanos

Alternative Approaches to Intrathecal Pump Implantation in an Obese Patient with Persistent Device Flipping

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Background

Chronic pain affects many patients with various illnesses, including cerebral palsy, stroke, traumatic brain and spinal cord injuries, multiple sclerosis, and malignancy. For some, adequate pain relief requires implantation of an intrathecal drug delivery system (IDDS), a well-established approach for managing a patient's chronic pain using a basal infusion rate with supplementing patient controlled bolus doses using a wireless transmitter [1,2]. The IDDS consists of a drug reservoir within a mechanical pump and a connected catheter that extends into the intrathecal space. Traditionally, the pump is secured in a subcutaneous pocket beneath the abdominal skin.

Complications, including pump migration, are rare, but correlate to IDDS implantation technique and patient comorbidities. Pump migration is rare, but serious, and may require an alternative method of installation. Alternatively, a subfascial pump pocket has been previously considered, especially in patients with the abdominal fascial integrity compromised. In this approach, the pump is placed in the abdominal wall between the fascial layer of the rectus abdominus and the external oblique muscles [3].

Objective

To outline a novel technique and recommend exploration in IDDS implantation.
This technique was employed during the extensive and complicated course of IDDS implantation and revision in an obese adult patient. Using conventional subcutaneous IDDS implantation, our patient suffered from multiple incidents of pump migration and flipping with catheter occlusion. A technique described by Kopell et al., of pocket placement in the subfascial layers did not prove successful. Our novel technique of a submuscular approach to installment was performed, in coordination with the plastic surgery service, yielding successful long-term device securement.

Methods

A 45-year-old morbidly obese female patient, with body mass index of 47 kg/m2, presented to our clinic for low back pain with radiation into her buttocks bilaterally for many years, secondary to multiple motor vehicle accidents and falls. However, 8 months after initial implantation, the patient returned with pain due to catheter occlusion caused by repetitive pump migration and flipping. After five revisions over the next 2 years for identical complications, plastic surgery was consulted to assist with alternate installation techniques.

On examination, the plastic surgeon reported the patient's pump was easily mobile, at times flipping into a vertical position inferior to the ribs. The patient's morbid obesity, with a, allowed for significant mobility of the subcutaneous tissue in the upright position. Based on these findings, the plastic surgeon assisted with subfascial placement, with the approach previously described by Kopell et al, of the pump pocket for improved stability [3].

However, 4 months later, the patient returned with device flipping, which could be attributed to the patient's morbid obesity. The patient was reevaluated by the plastic surgeon, who determined the stability of the device was still likely compromised by the patient's abdominal girth. During the intraoperative period, the skin incision was extended deep to the layers of the implanted device. The pump was readily identified in a large encapsulated cavity, approximately two times the device size. The capsule was removed and new pocket formation was attempted. The fascial layer was partially resected during the capsulectomy, leaving a large open area with no sufficient area to secure the device. At this time, a submuscular placement of the pump pocket was decided (Fig. 1).

Technique

The external oblique muscle was elevated laterally and inferiorly providing a pocket of appropriate size submuscularly approximately 7 to 8 cm anterior and superior to the iliac crest. A pocket was created and sufficient for the device dimensions and included a partial posterior and partial anterior portion of the muscle layers (Fig. 2). The device was positioned and secured with 2-0 braided nonabsorbable sutures to the deeper muscle layer (Fig. 3). Muscle closure was tight over the device and performed using 0 braided absorbable sutures (Fig. 4). Considering the large cavity of the capsulectomy and previous location of the device, figure-of-eight quilting sutures were placed to secure the cavity and minimize the chances of wound opening, seroma formation, and potential repositioning of the implant in the cavity. Prior to tying the quilting sutures, fibrin glue was sprayed over the cavity providing good closure of the tissue. Tying the knots completed the closure of the cavity. Deep tissue over the location of the device and closure of the old pocket continued with interrupted 0 braided absorbable sutures. The remaining fascial, deep dermal, and epidermal layers were closed in a routine fashion (Fig. 5).

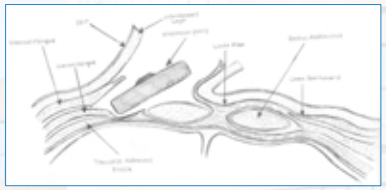

Figure 1. The submuscular pump pocket was between the layers of the external and internal oblique muscles. The external oblique muscle was dissected to be elevated laterally.

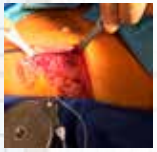

Figure 2. Pocket created with borders of muscle layers posteriorly and anteriorly.

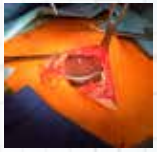

Figure 3. Pump secured with 2-0 braided nonabsorbable sutures to deep muscle.

Figure 4. Superficial muscle layer of pocket closed with 0 braided absorbable sutures.

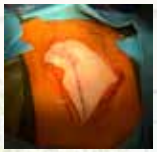

Figure 5. Fascial, deep dermal, and epidermal layers closed in routine fashion.

Results

Device-related events are rare, but can result in surgical revision in up to 49.4% of complications [4]. Appropriate placement of the pump pocket is an important consideration that may help reduce complication rates. Our patient had to undergo multiple revisions due to pump flipping and poor securement to the abdominal fascia. Despite expecting improved outcomes with subfasical implantation, the patient's body habitus prevented this technique from providing adequate pain relief without similar complications. After revising the implantation with a submuscular pump pocket, the device mobility has reduced drastically and appears more stable.

We found the submuscular approach to be promising as the patient has not returned for further revisions or noted any signs of infection. To date, she has not reported any device flipping and has improved control of pain in her lower back. In addition, interrogation and refills have been performed without procedural difficulty or concern for the increased depth of the device.

Discussion

Traditionally, the IDDS device is surgically secured in a subcutaneous pocket in the abdominal wall beneath the skin. Although rare, this technique can result in complications, including pump migration, requiring alternative installation procedures to be devised. Subfascial implantation is an alternative technique that may help minimize these risks; however, this approach is rarely performed in the adult patient population. In this report, an adult patient with repeated incidents of pump migration and catheter coiling underwent subcutaneous and subfascial IDDS implantation with insufficient securement of the device, resulting in persistent flipping and catheter obstruction. This failure was attributed to the patient's large abdominal girth, which permitted extensive pump migration with changes in body position. Subsequently, the device was implanted submuscularly, as described in this poster, to achieve improved pump stability and securement. Since using this technique, the patient has not required any additional surgical revision and has experienced improved pain relief. There are limited reports of these techniques being used in the adult population and this requires more investigation as a routine option for implantation.

Conclusion

Our new technique of submuscular implantation of an IDDS has shown success in this patient. Alternative techniques need to be further developed and researched to establish their efficacy in device securement in select populations. Although the subdermal and subfascial techniques remain a more common technique to use, we need to consider the submuscular technique in a certain set of patients, especially those with a significantly elevated BMI.

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Amniotic Membrane and Umbilical Cord Particulate for Pain Associated with Knee Osteoarthritis: Preliminary Results of a Single-center, Prospective, Pilot Study

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1) StemCell Miami, Miami, FL, USA

Background

Knee osteoarthritis (OA) is a chronic, degenerative disease that is associated with pain and dysfunction that is often debilitating. Traditionally OA is clinically assessed based on visual grading of the joint space narrowing using radiographic images followed by treatment with corticosteroid or hyaluronic acid injection. However recently, attempts have been made to more adequately address underlying etiologies and phenotypic changes of the knee. For instance, MRI can be used to identify subchondral bone features such as subchondral cysts and bone marrow lesion that has been correlated to clinical symptoms and can indicate OA disease progression.

Cryopreserved human umbilical cord (UC) and human amniotic membrane (AM) are both commercially available and have a long history of safe use in a variety of clinical applications due to their known anti-inflammatory, anti-scarring, and pro-regenerative properties. Despite its widespread use, no clinical studies have investigated the use of intra-articular injection of AMUC (FLO) in the knee for resolution of pain and inflammation.

Objective

To evaluate the short-term safety and effectiveness of AMUC in the management of pain in patients with various severities of knee OA.

Methods

This IRB-approved, single-center, prospective, pilot study enrolled 20 adults aged ≥ 18 years diagnosed with knee OA Grades 0 to 4 by MRI based on the presence of bone marrow lesions. Patients were eligible if they had knee pain > 40 mm as determined by the 100mm VAS WOMAC Section A, and had not received another intra-articular injection in the affected knee within 30 days.

Patients that met the eligibility criteria received an ultrasound-guided intra-articular injection of 2 ml preservative free saline pre-mixed with 50 mg AMUC particulate (Clarix FLO). Patients were then monitored at 6-weeks, 12 weeks and 24 weeks post-injection. The primary outcome measure is the change in pain as measured by the WOMAC Section A from the baseline visit. Patients that did not show improvement of >30% reduction in pain received a second injection of AMUC at 6 weeks.

Results

Preliminary data is reported herein from 20 patients (aged 71.0 ± 6.4 years old) that have completed the 6 weeks follow up visit as of February 8, 2018. Their severities were graded by MRI as Grade 0 (n=5), Grade 1 (n=5), Grade 2 (n=6), and Grade 3 (n=4) and presented at the baseline with an average pain score of 75 ± 17 mm. Patients presenting with Grade 3 knee OA had the highest severity of pain (86 mm).

At 6-weeks post-injection, pain significantly decreased to 45 ± 26 mm with an average improvement of 35%. The Patient's Global Assessment of change from baseline to 6 months showed that all 20 patients noted reduction in pain. A total of five, four, and six patients subjectively rated their improvement as "much better", "better", and "a little better", respectively. No adverse events were reported.

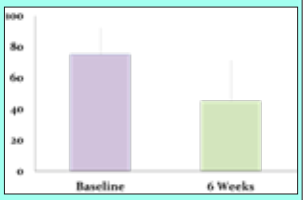

Figure 1. WOMAC A Scores before and 6 weeks after AMUC injection

Figure 2. Illustrative example of Bone Marrow Lesion Grades 0 (A), 1 (B), 2 (C) amd 3 (D)

Conclusion

The preliminary results from this pilot study suggested that intra-articular injection of particulate AMUC improved pain in patients with symptomatic knee OA that presented with a wide range of severities (Grades 0 to 3 by MRI). No adverse events were reported.

Financial Disclosure

This study was supported in part by a research grant from TissueTech, Inc. Miami, FL.

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A Prospective, Randomized, Controlled Trial of High Frequency Spinal Cord Stimulation for the Treatment of Neuropathic Limb Pain from Painful Diabetic Neuropathy: The SENZA-PDN Protocol

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Introduction

Data from the Centers for Disease Control and Prevention (CDC) estimate in the United States there are currently[1]:

- 29 million people living with diabetes
- 86 million people with prediabetes

➢ resulting in $245 billion in annual healthcare costs and lost productivity

Approximately 20% of diabetic patients will develop painful diabetic neuropathy (PDN),[2] a debilitating, progressive chronic pain condition that significantly impacts the patient's health-related quality of life. Current treatments are primarily pharmacological, including anticonvulsants, antidepressants, opiates, and topical agents;[3] however, substantial numbers of PDN patients discontinue medications due to lack of efficacy or intolerable side effects[4] (**Table 1**):

Medication	3 months	6 months	12 months
duloxetine	39%	50%	64%
gabapentin	47%	61%	72%
pregabalin	49%	64%	77%

Table 1: Percentage of patients who discontinue common PDN medications within 3, 6, and 12 months of prescription.

Traditional, low frequency spinal cord stimulation (SCS) has also been applied in this patient population.[5,6] Neither pharmacological treatments nor low frequency SCS has provided significant, long-term pain relief for PDN patients, thus there is a large unmet clinical need in this population. Data from a small, prospective study using high frequency SCS (HF-SCS) at 10 kHz for the treatment of peripheral polyneuropathy suggest that this therapy could provide a new treatment option for PDN (**Figure 1**).[7] In addition to pain relief, 48% of subjects displayed improvements on neurological examination with HF-SCS at 10 kHz treatment.

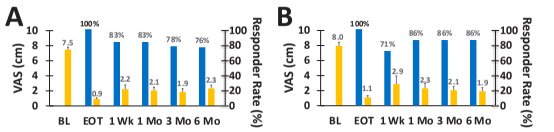

Figure 1: Preliminary observational data for HF-SCS at 10 kHz to treat pain from peripheral polyneuropathy (A, N-18), including subjects with painful diabetic neuropathy (B, N=7). Average VAS scores shown in yellow, responder rates shown in blue.

Materials & Methods

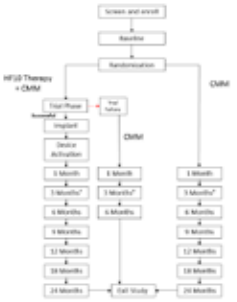

Figure 2: Study flow diagram
†Primary endpoint

Study design

- Prospective, multicenter, randomized, controlled trial
- 216 subjects with PDN randomized 1:1
  - HF-SCS at 10 kHz combined with conventional medical management (CMM)
  - CMM alone
- 24 month follow-up

Key inclusion criteria

1) Diagnosis of PDN for at least 12 mo
2) Pain intensity in the lower limbs of at least 5 out of 10 cm on the visual analog scale (VAS)
3) Appropriate candidate for SCS

Key exclusion criteria

1) Lower limb amputation
2) Large and/or gangrenous ulcers
3) Pain intensity in the upper limbs of at least 3 out of 10 cm on the VAS

Data collection

- Pain VAS
- Neurological assessment
- Health-related quality of life
- Sleep quality
- Patient satisfaction

Primary endpoint

- Compare responder rates (≥ 50% pain relief) and safety rates between treatment groups
- Assessed at 3 months

Several secondary endpoints will also be reported. There may be increased risk with SCS perioperative infections in patients with diabetes.[8] We will quantify the infection rate in this study population and compare it with prior observations of diabetic cohorts. Each clinical site will obtain Institutional Review Board approval and each individual subject will provide written informed consent prior to participating in the study.

Results

Enrollment in the SENZA-PDN study commenced in August, 2017, and is expected to be complete in 2019.

Conclusions

The SENZA-PDN study will be the largest RCT conducted using SCS in subjects with PDN, a growing patient population with unmet clinical needs. This prospective, multicenter study will determine whether HF-SCS at 10 kHz improves clinical outcomes, health-related quality of life, and is a cost-effective treatment for PDN.

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Disclosure

This study is funded by Nevro Corp.

RUSK REHABILITATION

NYU Langone Health

Inflammatory Low Back Pain Mistaken for Chronic Mechanical Low Back Pain: A Case Report

Samantha Mastanduno, D.O., Raj Panchal, D.O., Salvador Portugal, D.O.

Case Report

24-year-old female presented to an outpatient interventional pain management office seeking second opinion regarding chronic, aching right buttock and low back pain for three years. The pain had an insidious onset without any trauma or inciting event which continued to progress and eventually caused the patient to quit her job one month before presentation. Pain worse with immobility, especially at night and early morning.

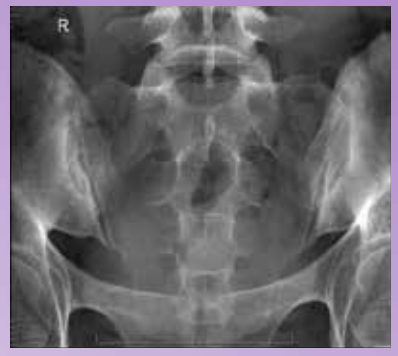
The patient was previously managed by another pain medicine physician who provided the following treatments: physical therapy, meloxicam, hydrocodone and acetaminophen, tramadol, cyclobenzaprine, two sacroiliac joint steroid injections, one sacroiliac joint platelet-rich-plasma injection, and trigger point injections without adequate relief. Patient did not have any red flag signs.

Previous lumbar spine MRI was normal. Physical exam was positive on the right for Fortin' s sign, thigh thrust test, and Patrick' s sign, as well as pain at the end range of lumbar spine flexion and extension. Tests for lumbar radiculopathy were negative. Patient also had positive family history for inflammatory arthropathy and a personal history of psoriasis.

Clinical Course

Sacroiliac joint x-rays and MRI were ordered to assess for possible sacroiliitis. Sacroiliac joint x-rays and MRI revealed bilateral asymmetric sacroiliitis right greater than left which may be seen in the setting of psoriatic and reactive arthritis. Bloodwork revealed positive HLA-B27 and elevated ESR. This patient was also referred to a rheumatologist to further assess possible inflammatory arthropathy. Patient was diagnosed with axial form of psoriatic arthritis and started on adaliumumab.

Imaging



Sacroiliac Joint X-Ray:
Sacroiliac joints: There is loss of the cortical margins along the iliac sides of both sacroiliac joints with mild subchondral sclerosis and irregularity suspicious for bilateral sacroiliitis, right greater than left. These findings can be seen in psoriatic arthritis. The sacral arcuate lines are preserved.

Discussion

Axial spondyloarthritis is a potentially debilitating form of arthritis associated with Low back pain and stiffness for >3 months, Pain worse with immobility, especially at night and early morning, Pain improves with exercise but not with rest, Sacroiliitis seen on diagnostic imaging, HLA-B27 Positive and Age at onset < 45 years. There is also an association with uveitis, psoriasis (as seen in this patient), and inflammatory bowel disease.
Many of the current interventional pain management guidelines do not suggest further additional workup to determine the etiology of sacroiliac joint pain. Misdiagnosis may lead to inappropriate treatment, iatrogenic complications associated with aforementioned treatment, and progression of the rheumatological disease.

Conclusion

When evaluating patients, it is important to consider inflammatory axial spondyloarthropathies as potential causes of sacroiliac joint pain in young adults prior to considering treatment options.

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Cannabidiol in the geriatric population: A novel treatment option for chronic back pain

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INTRODUCTION

The use of cannabinoids in pain medicine is controversial. The disparity in the state and national recommendations makes the decision even more complex. It is currently legalized in some form for medical use in 29 states and the District of Columbia, but it is still listed as a Schedule 1 drug by the Drug Enforcement Agency which defines it as a drug with no currently acceptable medical use and a high potential for abuse. (1) However survey studies has shown that it is being used for various medical conditions including pain, headache, anxiety/depression, muscle spasticity, and arthritis with pain being reported as one of the top reason for its use. (2) Gathering scientific data on cannabis use and translating it to clinically relevant information will likely be a topic of research for decades. In the interim, patients are requesting information about this therapy from clinicians. Here we present a case of a patient who reports significant pain relief from using an oral cannabinoid product consisting of a high percentage of cannabidiol (CBD).

CASE

An 87 year old lady presented to our clinic for evaluation 3 years ago. She had chronic low back pain with L5 radiculopathy. Her pain on initial presentation was rated as 7-10/10 and described as achy and dull in a band like distribution over the lumbar region of her lower back. It also radiated down the posterior aspect of the right thigh During the course of her treatment her pain responded somewhat to epidural steroid injections. She had minimal response to lumbar radiofrequency ablation of right lumbar medial branch nerves for lumbar spondylosis with facet arthropathy. She declined surgical intervention and advanced procedures such as spinal cord stimulator due to fear of complications given her age. Previous trials of other non-opioid pain medications included pregabalin, which caused altered mentation and inability to think clearly. Over 3 years her pain and disability progressively worsened despite the best efforts of a multidisciplinary pain clinic. Her pain had worsened such that she was entirely wheelchair-dependent. However, recently the patient started CBD which was recommended by her daughter who had used this medication in the past with positive results. Patient was ingesting 10-20 mg CBD orally infused in baked goods up to 3 times a day as needed for pain. After one month of taking CBD she presented to our clinic for follow and reported that her pain was significantly controlled with this addition to her prior pain regimen of duloxetine 20mg qday and Tylenol 1000mg BID PRN. Her pain score at last visit was 0/10 with intermittent exacerbations to 4/10 pain which responds well to the use of the CBD edible. There is no worsening of her mentation and she was able to titrate off pregabalin, leading to improvement in mental status.

DISCUSSION

Lumbar facet and sacroiliac joint arthropathy is a very common debilitating pain generator not only for the geriatric population but for a significant portion of the general population. (3,4) In difficult cases refractory to standard conservative and interventional treatment and in patients where surgery and advanced procedures are relatively contraindicated, a trial of therapeutic CBD may lead to improved pain scores and functional status. CBD is an antagonist of the CB1 receptor and an inverse agonist of the CB2 receptor and likely functions as a modulating agent, attenuating the psychotropic side effects of THC in cannabis. (5) However, it also may play a secondary role in pain reduction as CB2 receptors are mainly localized on immune cells and inverse agonism of these receptors has been documented as reducing immune cell migration and decreasing inflammation overall in animal studies.

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TRANS S1 INFRALAMINAR SCARRING TRIANGLE

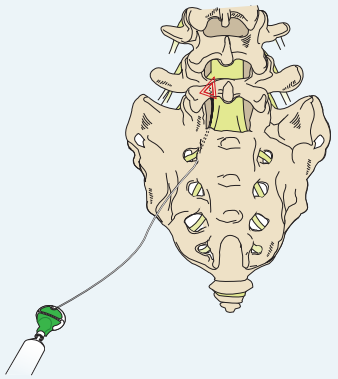
A Step-By-Step Guide

by Gabor B. Racz M.D., DABPM, FIPP, DABIPP

Introduction

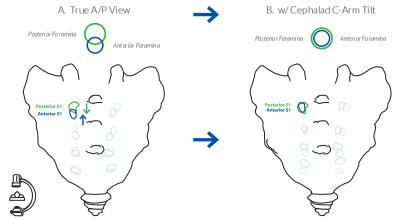
A unique triangular space has been identified by Teske *et al.*, measuring 0.9-1.1 mL on each side.[1] The boundaries are medial to the L5 nerve root, lateral to the S1 nerve root and the base of the triangle is above the disc of L5-S1. This space is large enough to accept the average loose disc fragment. This space tends to collect leaky disc material as a common result of trauma and surgery. Due to the curvature of the sacrum and the formation of dense scarring, regular epidural catheters and scopes have not been able to enter this scarred epidural area. Matsumoto *et al.*, realized that entering from the posterior aspect of the S1 neural foramin with an 18 gauge RX-2™ Coudé® Needle and then rotating it, the curved tip allows for ventral epidural projection of a 21 gauge VERSA-KATH®.[2] The VERSA-KATH® is x-ray visible, and it is also steerable as long as rotation coincides with the advancement of the catheter.

The scarring triangle is located in-between the L5 DRG and the S1 nerve root and above the L5-S1 disc. Dense scarring can present clinically as: ipsilateral back pain (due to the dura and posterior longitudinal ligament adhering together), L5 radiculopathy, numbness and dysesthesia in the lateral calf to the lateral ankle and foot, and weakness on dorsal flexion of the foot. In advanced cases, foot drop may be evident. Opening of the scarring triangle with the recommended volumes can reverse these clinical symptoms. An S2 component will present as radiculopathy along the posterior aspect of the thigh and calf. Stretch-induced ischemia of the involved nerve roots is likely the cause of foot drop and can be reversed following the scarring triangle neuroplasty.



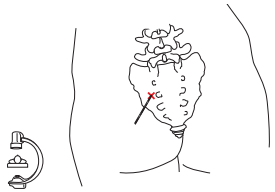
1 Alignment of Neural Foramina Using C-Arm

Place patient in prone position. Fluoroscopically, with a true A/P view (A), the 4 sacral neural foramina will be seen as 8 foramina because of the curvature of the sacrum. The posterior neural foramina will be seen more cephalad while the anterior foramina will be seen more caudal. To align the neural foramina, rotate the c-arm in a cephalad direction until the S1 ventral and dorsal neural foramina line up (B). The 18 gauge needle has a curve near the tip, but one still needs a gentler angle to allow cephalad advancement of the catheter. The starting point will be the lateral side of the S2 posterior neural foramen.



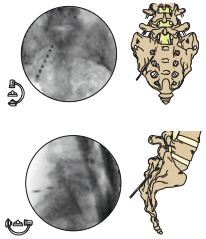
2 RX Coudé® Needle Entry Site and Placement

The needle entry point is from the S2 aiming towards the medial side of S1. Apply topical anesthesia and advance the needle through the skin.



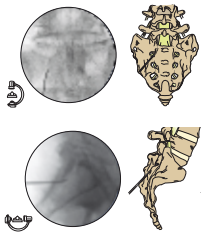
3 RX Coudé® Needle Advancement

Curve the needle down to and contact bone between the S1 and S2 on the sacrum. After contact is made, continue to advance until a penetrative "pop" is felt, indicating foraminal entry.



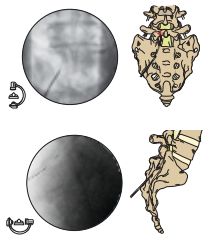
4 Introduction of Blunt Stylet

Remove the original stylet and interlock the atraumatic, blunt stylet. With the aid of lateral fluoroscopic visualization, rotate the needle tip dorsally and medial. Position the c-arm with a cephalad tilt to reduce radiation exposure to the operator's hand, leaving only the needle tip visible.



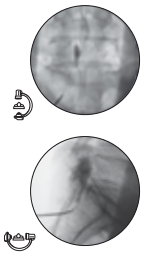
5 Catheter Placement

Advance the stylet ted VERSA-KATH® into the sacral canal under fluoroscopic visualization after removing the second stylet. The catheter needs to cross the L5-S1 disc space and advance into the fibrotic tissue (scar) near the top of the L5 neural foramen. The catheter should not advance medial or lateral inside the imaginary triangle between L5 and S1. For more accurate placement, the VERSA-KATH® can be rotated during advancement.



6 Inject 5-10 mL of OMNIPAQUE™ 240, Followed by 150 Units of Hylenex® Diluted in 10mL of Preservative Free Saline, Bolus of Steroid and Local Anesthetic

1. Connect the Stingray® Connector and inject 5-10 cc of OMNIPAQUE™ 240 within the scarred area. Injection of contrast may require significant pressure for a complete spread due to its viscosity. It will open up the ventral epidural space, slowly crossing over, and spread from L4 down to S2 bilaterally.
2. Inject a mixture of 10 cc of preservative-free saline and 150 units of Hylenex®; this will disperse the contrast. Carefully observe for a potential spread into the subdural and subarachnoid spaces, especially in failed surgery cases where the possibility of a dural tear may exist.
3. Slowly inject a mixture of 10 cc of 0.2% ropivacaine and 40 mg triamcinolone. Ask the patient to move their feet and to report any pain at any time other than during injection. Subdural injectate accumulation in the scarred area may produce bilateral pain and have atypical appearance. If subdural loculation occurs, it can be aspirated with an interlaminar needle placement.
4. After local anesthetic injection, observe the patient for 20-30 minutes and make sure they are able to perform a 90 degree straight leg raise without any evidence of motor block.
5. Infuse 10% NaCl over a 15-minute period. Then flush with local anesthetic or normal saline at completion.
6. If the patient develops a motor block, he or she may need to be admitted into the hospital for observation.
7. A one-time injection into the scarring triangle is effective for a short period of time; however, three repeat injections, 6-8 hours apart, have been reported as more effective for many months to over a year.
8. Instruct the patient to perform neural flossing exercises to the patient for the sciatic area. There are also separate instructions for the upper lumbar area.



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Alternative Approaches to Intrathecal Pump Implantation in an Obese Patient with Persistent Device Flipping

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Background

Chronic pain affects many patients with various illnesses, including cerebral palsy, stroke, traumatic brain and spinal cord injuries, multiple sclerosis, and malignancy. For some, adequate pain relief requires implantation of an intrathecal drug delivery system (IDDS), a well-established approach for managing a patient's chronic pain using a basal infusion rate with supplementing patient controlled bolus doses using a wireless transmitter [1,2]. The IDDS consists of a drug reservoir within a mechanical pump and a connected catheter that extends into the intrathecal space. Traditionally, the pump is secured in a subcutaneous pocket beneath the abdominal skin.

Complications, including pump migration, are rare, but correlate to IDDS implantation technique and patient comorbidities. Pump migration is rare, but serious, and may require an alternative method of installation. Alternatively, a subfascial pump pocket has been previously considered, especially in patients with the abdominal fascial integrity compromised. In this approach, the pump is placed in the abdominal wall between the fascial layer of the rectus abdominus and the external oblique muscles [3].

Objective

To outline a novel technique and recommend exploration in IDDS implantation.
This technique was employed during the extensive and complicated course of IDDS implantation and revision in an obese adult patient. Using conventional subcutaneous IDDS implantation, our patient suffered from multiple incidents of pump migration and flipping with catheter occlusion. A technique described by Kopell et al., of pocket placement in the subfascial layers did not prove successful. Our novel technique of a submuscular approach to installment was performed, in coordination with the plastic surgery service, yielding successful long-term device securement.

Methods

A 45-year-old morbidly obese female patient, with body mass index of 47 kg/m2, presented to our clinic for low back pain with radiation into her buttocks bilaterally for many years, secondary to multiple motor vehicle accidents and falls. However, 8 months after initial implantation, the patient returned with pain due to catheter occlusion caused by repetitive pump migration and flipping. After five revisions over the next 2 years for identical complications, plastic surgery was consulted to assist with alternate installation techniques.

On examination, the plastic surgeon reported the patient's pump was easily mobile, at times flipping into a vertical position inferior to the ribs. The patient's morbid obesity, with a, allowed for significant mobility of the subcutaneous tissue in the upright position. Based on these findings, the plastic surgeon assisted with subfascial placement, with the approach previously described by Kopell et al, of the pump pocket for improved stability [3].

However, 4 months later, the patient returned with device flipping, which could be attributed to the patient's morbid obesity. The patient was reevaluated by the plastic surgeon, who determined the stability of the device was still likely compromised by the patient's abdominal girth. During the intraoperative period, the skin incision was extended deep to the layers of the implanted device. The pump was readily identified in a large encapsulated cavity, approximately two times the device size. The capsule was removed and new pocket formation was attempted. The fascial layer was partially resected during the capsulectomy, leaving a large open area with no sufficient area to secure the device. At this time, a submuscular placement of the pump pocket was decided (Fig. 1).

Technique

The external oblique muscle was elevated laterally and inferiorly providing a pocket of appropriate size submuscularly approximately 7 to 8 cm anterior and superior to the iliac crest. A pocket was created and sufficient for the device dimensions and included a partial posterior and partial anterior portion of the muscle layers (Fig. 2). The device was positioned and secured with 2-0 braided nonabsorbable sutures to the deeper muscle layer (Fig. 3). Muscle closure was tight over the device and performed using 0 braided absorbable sutures (Fig. 4). Considering the large cavity of the capsulectomy and previous location of the device, figure-of-eight quilting sutures were placed to secure the cavity and minimize the chances of wound opening, seroma formation, and potential repositioning of the implant in the cavity. Prior to tying the quilting sutures, fibrin glue was sprayed over the cavity providing good closure of the tissue. Tying the knots completed the closure of the cavity. Deep tissue over the location of the device and closure of the old pocket continued with interrupted 0 braided absorbable sutures. The remaining fascial, deep dermal, and epidermal layers were closed in a routine fashion (Fig. 5).

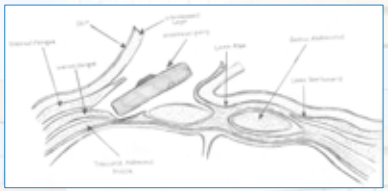

Figure 1. The submuscular pump pocket was between the layers of the external and internal oblique muscles. The external oblique muscle was dissected to be elevated laterally.

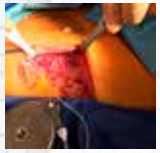

Figure 2. Pocket created with borders of muscle layers posteriorly and anteriorly.

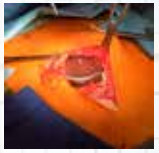

Figure 3. Pump secured with 2-0 braided nonabsorbable sutures to deep muscle.

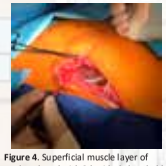

Figure 4. Superficial muscle layer of pocket closed with 0 braided absorbable sutures.

Figure 5. Fascial, deep dermal, and epidermal layers closed in routine fashion.

Results

Device-related events are rare, but can result in surgical revision in up to 49.4% of complications [4]. Appropriate placement of the pump pocket is an important consideration that may help reduce complication rates. Our patient had to undergo multiple revisions due to pump flipping and poor securement to the abdominal fascia. Despite expecting improved outcomes with subfasical implantation, the patient's body habitus prevented this technique from providing adequate pain relief without similar complications. After revising the implantation with a submuscular pump pocket, the device mobility has reduced drastically and appears more stable.

We found the submuscular approach to be promising as the patient has not returned for further revisions or noted any signs of infection. To date, she has not reported any device flipping and has improved control of pain in her lower back. In addition, interrogation and refills have been performed without procedural difficulty or concern for the increased depth of the device.

Discussion

Traditionally, the IDDS device is surgically secured in a subcutaneous pocket in the abdominal wall beneath the skin. Although rare, this technique can result in complications, including pump migration, requiring alternative installation procedures to be devised. Subfascial implantation is an alternative technique that may help minimize these risks; however, this approach is rarely performed in the adult patient population. In this report, an adult patient with repeated incidents of pump migration and catheter coiling underwent subcutaneous and subfascial IDDS implantation with insufficient securement of the device, resulting in persistent flipping and catheter obstruction. This failure was attributed to the patient's large abdominal girth, which permitted extensive pump migration with changes in body position. Subsequently, the device was implanted submuscularly, as described in this poster, to achieve improved pump stability and securement. Since using this technique, the patient has not required any additional surgical revision and has experienced improved pain relief. There are limited reports of these techniques being used in the adult population and this requires more investigation as a routine option for implantation.

Conclusion

Our new technique of submuscular implantation of an IDDS has shown success in this patient. Alternative techniques need to be further developed and researched to establish their efficacy in device securement in select populations. Although the subdermal and subfascial techniques remain a more common technique to use, we need to consider the submuscular technique in a certain set of patients, especially those with a significantly elevated BMI.

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A MULTICENTER, PROSPECTIVE, CLINICAL TRIAL OF HIGH FREQUENCY SPINAL CORD STIMULATION (HF-SCS) AT 10 kHz IN THE TREATMENT OF CHRONIC UPPER LIMB AND NECK* PAIN

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Introduction

Disorders of the cervical spine are frequently disabling and costly[1,2]. When patients do not improve with conservative care, surgical procedures including anterior cervical discectomy with or without fusion are often employed. In a randomized comparison trial of various surgical techniques in patients with cervical radiculopathy secondary to single level pathology, the incidence of arm pain and neck pain was 0-8% and 17-27% respectively at 24 months[3].

Upper limb and neck pain remain difficult-to-treat areas of pain. Traditional SCS has been successfully used to treat upper limb and neck pain[4,5,6]. However, variability in the distribution and intensity of the induced paresthesias as well as obtaining effective coverage of axial neck pain remain limitations. High frequency SCS (HF-SCS) at 10 kHz is a paresthesia-independent therapy that has demonstrated long-term safety and effectiveness in the treatment of chronic, intractable back and leg pain[7,8]. The lack of paresthesia may reduce the positional variation that can compromise neck and upper limb pain relief. The goal of this study is to assess the safety and effectiveness of HF-SCS in the treatment of upper limb and neck pain.

Materials & Methods

- Prospective, multi-center study (ClinicalTrials.gov identifier: NCT02385201)
- Subjects with chronic, intractable neck and/or upper limb pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) enrolled
- Major exclusion criteria: Mechanical instability of the spine, cervical stenosis, significant epidural scarring or symptoms of myelopathy
- Investigative device exemption (IDE) obtained from the US Food and Drug Administration, followed by Institutional Review Board approval
- Each subject implanted with two epidural leads spanning C2-C6 vertebral bodies (Figure 1)
- Subjects with successful trial stimulation (≥40% pain relief) implanted with a Senza system (Nevro Corp., Redwood City, CA)
- Primary safety and effectiveness endpoints (≥50% pain relief) assessed at 3 months post-implant
- Per-protocol-population (PPP) results (mean ± standard deviation)
- Complete results at primary endpoint (3 months) presented

Figure 1: Anterior-posterior and lateral views of cervical lead placements.

Results: Safety

With complete study enrollment

- Neurological deficits: None
- Subjects experiencing paresthesias: None
- Device or procedure related adverse events (AEs): 15
- All AEs resolved without sequelae

Results: Responder Rates and Pain Scores

Subjects	Trial : Implant	3 Months	12 Months
All	47/51 (92%)*	33/42 (79%)	13/15 (87%)
W/ Neck Pain > 5 cm VAS	45/50 (90%)	32/42 (79%)	13/15 (87%)
W/ UL Pain > 5 cm VAS	26/29 (90%)	20/24 (83%)	9/9 (100%)

Table 1. Responder rate as a function of time. *Four subjects (VAS<5 cm) excluded from PPP analyses; one subject withdrew consent soon after implant and was explanted.

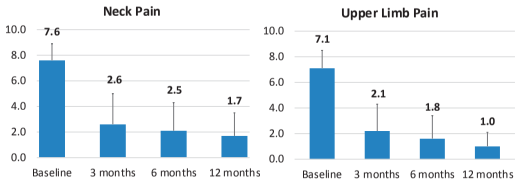
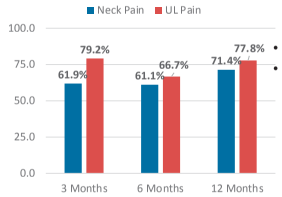


Figure 2: Neck (left) and upper limb (right) pain scores reported in VAS (in cm) as a function of time.

Conflicts of Interest

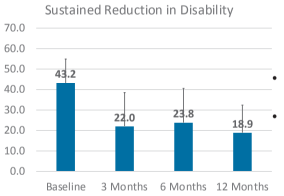
KA: Personal fees from Nevro Corp., Saluda Medical, Medtronic, and St. Jude Medical. Grants from Nevro Corp., Mesoblast, and St. Jude Medical. Scientific advisory board member of Nevro Corp., Mesoblast, Nalu Medical, Biotronik; CY: Personal fees from Boston Scientific, Medtronic, and St. Jude Medical; RV: Grants from Nevro Corp. and Boston Scientific and personal fees from Nevro Corp. and Boston Scientific; RB (Coastal Orthopedics and Pain Medicine): Personal fees (speaking engagements) and research grants from Nevro Corp; TLY: Research grants from Boston Scientific, Nevro Corp., and St. Jude Medical; Consulting agreements with Boston Scientific, Nevro Corp., St. Jude Medical and Neuronano; Officer in Meagan Medical (Chief Medical Officer) and Algos Clinical Development (Director); RB (Millennium Pain Center): Consulting agreement with Medtronic; Research grants and personal fees from Medtronic, Boston Scientific, St. Jude Medical and Nevro Corp.

Results: Remitter



- Defined as a subject with VAS ≤ 2.5 cm
- Nearly two-thirds or greater proportion of subjects deemed neck pain and upper limb pain remitters at all follow-ups

Results: Disability



- Disability assessed by Pain Disability Index (Range: 0-70)
- Lower index score = Less disability

Conclusions

Results from a multicenter, prospective study using high frequency spinal cord stimulation at 10 kHz to treat upper limb and neck pain demonstrate clinically meaningful and sustained pain relief and quality of life improvements over a 12-month period.

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*Investigational only – not on-label or indicated for use

Myofascial Pain Secondary to Cannabinoid Hyperemesis Syndrome: A Case Study

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Background

Marijuana- both medical and recreational- is often used to manage pain and nausea. Some advocate for its use over traditional opioid therapy noting that it may be a safer and more effective alternative for treating chronic pain[1,2]. However, there is emerging evidence that marijuana may have adverse effects on pain and nausea. Activation of cannabinoid receptors inhibits GABAergic synaptic transmission in a number of central nervous system regions. The interneurons stop releasing the inhibitory neurotransmitters GABA and glycine[3]. Without these inhibitory signals, pain signaling to the brain intensifies[3]. This suggests cannabinoids can control the interneurons and potentially facilitate the transition of acute pain into chronic pain.

Moreover, it appears cannabis can not only suppress nausea in certain situations, but also cause it in vulnerable patients. THC activates cannabinoid receptors in the enteric nervous system, which mediate nausea and vomiting[4]. Accumulation of THC in fatty tissues leads to enteric stimulation which can also lead to nausea[4]. Cannabinoid hyperemesis syndrome (CHS) is a disorder characterized by recurrent nausea, vomiting and abdominal pain[5]. It associated with chronic cannabis use. The short-term treatment of CHS is supportive care. Long-term treatment is aimed at discontinuing cannabis use.

Objective

To assess the potential link between myofascial pain affecting the abdominal musculature and marijuana use.

To raise awareness about cannabinoid hyperemesis syndrome in patients with chronic pain who are *not* requesting opioid therapy.

Case Presentation

This is the case of a 22-year-old male who presented with acute on chronic abdominal pain and recurrent vomiting for over two years. He would vomit between one and seven times per day. He had developed multiple trigger points in the rectus abdominis, internal and external obliques, and transverse abdominis muscles.

Diagnostically, the patient had a CT scan of the abdomen/ pelvis, which was unremarkable. He also had an endoscopy that was non-specific. He had multiple evaluations by various gastroenterologists and psychiatrists with no specific cause found for his symptoms.

The patient had previously tried zofran, hydroxyzine, and sertraline without benefit. He reported smoking marijuana on a daily basis to address the pain and nausea.

Over the treatment course, the patient received trigger point injections at the most painful areas. He returned three times over the course of six months to repeat the trigger point injections. It soon became apparent that the vomiting, which had caused the trigger points to form, was secondary to marijuana use. The patient was subsequently referred to a multidisciplinary Addiction Disorders clinic.

The patient experienced > 50% relief of his chronic abdominal pain with a combination of trigger point injections and abstinence from marijuana.

Conclusion

Although many advocates suggest cannabis could be effective for relieving non-malignant chronic pain syndromes such as myofascial pain syndrome, there are some reports that pain may be increased with the use of this drug. To our knowledge, this is the first case in the literature of marijuana discontinuation, in combination with trigger point injections, leading to a greater than 50% improvement in myofascial pain symptoms in the abdomen and pelvis.

Daily forceful vomiting can cause trigger points to form in the abdomen and pelvis. CHS can cause multiple episodes of vomiting per day[5]. Therefore, there may be a link between the two conditions. Patients with myofascial pain syndrome and CHS may present in the pain management office setting. Pain physicians treating patients with unexplained nausea and vomiting as well as abdominal myofascial pain should consider further assessing these patients for recreational drug use. CHS is a potential cause of chronic pain in a minority of patients.

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Medical Management versus 10 kHz Spinal Cord Stimulation and Medical Management for the Treatment of Non-Surgical Back Pain

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Introduction

Low back pain is the leading cause of disability worldwide [1]. Both surgical and conservative treatment modalities have yielded often unsatisfactory results. High frequency spinal cord stimulation (HF-SCS) at 10 kHz is a promising new treatment modality for low back pain for failed back surgery patients [2] as well as in subjects who are not considered candidates for surgery [3, 4]. Not all medical payers reimburse for SCS in the surgery-naive back pain population. Therefore a cost effectiveness comparison, safety and clinical effectiveness with conventional medical management is warranted.

Objectives

The primary endpoint of this post-market study is the percentage of subjects in each group who experience at least 50% reduction in pain intensity (as assessed by VAS) for back pain at 3 months.

Materials & Methods

Based on the outcomes from the previous studies [3,4] and under the guidance of a multidiciplinary steering committee, a post-market randomized controlled trial (RCT), the first of it's kind, has been initiated to assess the safety, clinical effectiveness and cost-effectiveness of conventional medical management (CMM) alone versus CMM plus HF-SCS in subjects with chronic refractory low back pain (with or without leg pain) in patients who are not considered surgical candidates. Potential subjects will first undergo expert surgical evaluation and subsequently determined as non-surgical candidates. Enrolled subjects must have a primary complaint of axial back pain ≥ 5 cm on a visual analog scale (VAS).

Materials & Methods

In addition to VAS multiple secondary and tertiary endpoints will be obtained including functional measures, medication usage, quality of life and detailed health economic analyses. Data at follow-up visits will be compared to the subjects' baseline data with results compared between treatment groups at the respective visits.

Assuming a 60% responder rate in the stimulation group (HF10+CMM) and 36% in the control group (CMM), a sample size of 98 subjects in each group was estimated sufficient to detect a significant difference with a power of 90% and a two-sided type I error of 0.05. Assuming a 10% attrition rate, a total of 108 patients per group will be randomized.

Design

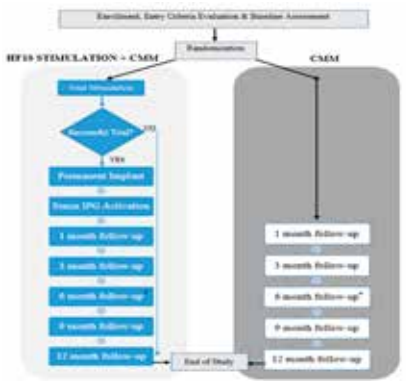

Fig.1: Study flowchart: subjects will be allowed to cross-over at 6 months

Results & Discussion

Evidence from prior studies show the benefit that HF-SCS at 10 kHz can provide to surgery-naïve back pain patients who are not surgical candidates. The goal of this study is to provide rigorous evidence sufficiently acceptable to payers, regulators and clinicians to support earlier consideration of SCS. Detailed efficacy, safety and cost effectiveness data will be presented at future timepoints.

Conclusions

Results will be presented at a future meeting.

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MINIMAL AMPLITUDE IN SPINAL CORD STIMULATION THERAPY USING HIGH DOSE STIMULATION – THE SCS DOSING STUDY

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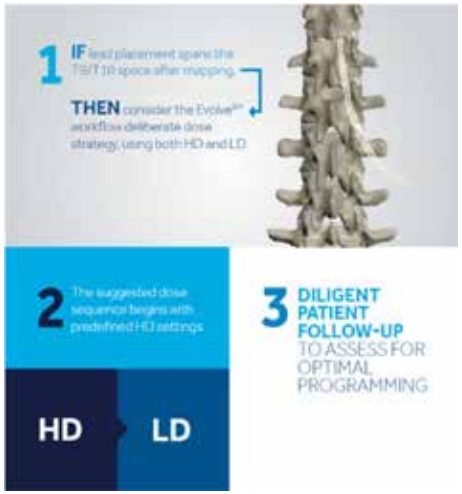
BACKGROUND

The Evolve[SM] workflow offers standardized guidance when treating patients with chronic, intractable back and leg pain with high dose (HD) spinal cord stimulation (SCS) therapy. The dose in the workflow is defined as 90 µs and 1000 Hz, programmed at an amplitude that is comfortable for the patient.

A preliminary multicenter retrospective analysis of data from patients (n = 87) following the Evolve workflow for low back and leg pain showed a responder rate at trial of almost 70%, with these patients having a 75% improvement in pain. In a subset of patients with data out to 3 months postimplant (n = 18), pain relief was sustained, with numeric pain rating scale scores decreasing from 7.47 at baseline to 2.44 at the 3-month follow-up.

While evidence for using a standardized approach to SCS therapy is growing, there is limited literature available regarding the minimum amplitude level needed to produce effective SCS therapy when stimulating at this high dose. This poster will present on the study design of the SCS Dosing Study.



OBJECTIVES

The SCS Dosing Study is a prospective, multi-center, single-blind, post-market feasibility study.

The primary objective is to characterize the minimum amplitude as a percentage of perception threshold that maintains SCS therapy satisfaction when using HD stimulation. The secondary objective is to characterize the minimum amplitude as a percentage of perception threshold that maintains overall pain relief.

METHODS

Eligible subjects who were implanted with a Restore[TM] Sensor[TM] system for the treatment of back and leg pain and using HD stimulation will be enrolled into the study (Figure 1). Subjects with an average overall Visual Analog Scale (VAS) pain score of ≤ 4 based on the baseline pain diary will proceed on with the study. Subjects will receive four different programmed amplitude settings each for approximately two weeks. Subjects will be blinded to the different amplitude settings received. At each follow-up visit, subjects' satisfaction and pain scores (VAS for overall, back, and leg pain in a pain diary) will be collected. Minimal amplitude that maintained the subjects' satisfaction and overall pain score will be summarized.

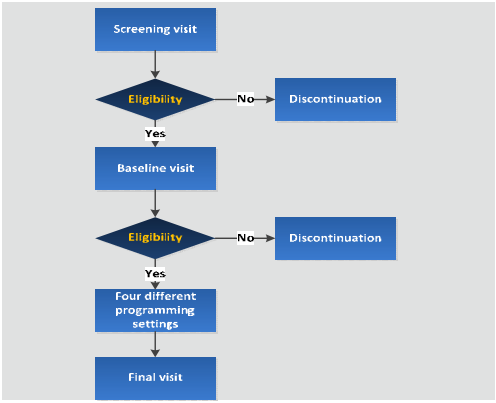


Figure 1 Study Visit Diagram

METHODS (cont.)

Safety will be evaluated by collecting device deficiencies and adverse events related to the implanted SCS system and accessories, as well as the SCS therapy.

At least 60 subjects will be enrolled to make sure at least 40 subjects complete the follow-up visits.

RESULTS

This study is currently recruiting study subjects from 4 active sites in the United States and additional sites are working towards activation.

Figure 2 Activated Study Sites

CONCLUSIONS

The data collected will provide insight into the role of amplitude with HD settings and has the potential to shape future clinical practices of titrating amplitude to an effective dose.

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Disclosure

This study was supported by Medtronic PLC.

Medtronic

Spinal Cord Stimulation at 10 kHz for the Treatment of Chronic Abdominal Pain*: Interim Results from a Multicenter Feasibility Study

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* Investigational only – not on label or indicated for use

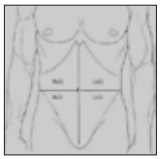
Introduction

- Chronic abdominal pain (CAP): debilitating condition, challenging to treat
- Opioids, sympathetic nerve blocks, and radiofrequency ablation do not resolve pain in many patients
- Traditional spinal cord stimulation has been tried in this patient group; retrospective analysis shows some long term success.[1,2,3,4]
- High frequency cord stimulation (HF-SCS) at 10 kHz spinal has the potential to increase patient satisfaction because of better pain relief outcomes and the absence of stimulation-induced paresthesias.

Study Objectives and Design

- Objective: Study treatment of CAP with HF-SCS (Senza system, Nevro Corp., Redwood City, CA) in a prospective, single arm, multicenter study
- FDA granted an Investigational Device Exemption and institutional review board approval was obtained at four US centers. Participants who met inclusion/exclusion (Fig 1A) signed informed consent.
- Subjects were implanted with a HF-SCS system after a successful temporary trial. Lead placement shown in Fig 1B, plus a subcutaneously implanted stimulator.
- Patient reported pain, symptoms, disability, sleep quality and satisfaction were assessed at Baseline, 1, 3, 6, and 12 months, with "responder rate" defined as the percent of implanted population with ≥50% pain relief.

A.



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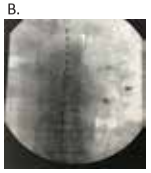


Figure 1 A. Included subjects had abdominal pain between inguinal crease and T 12 rib. B. Epidural leads placed between T4-T9 vertebral levels.

Results: Population

Twenty-three subjects have undergone temporary trial, none having previous SCS. Baseline characteristics are shown in Table 1. Interim results are presented for all implanted subjects. The number of subjects who have reached each study time point is shown in Table 2. Ninety-six percent (22/23) achieved successful pain relief during temporary trial, twenty have been implanted to date, and two are scheduled for implant.

Table 1.

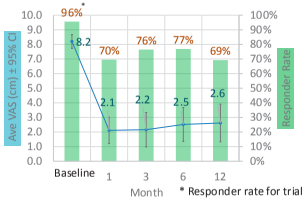
Baseline Characteristics	
Age (yrs)	45± 13
Female n (%)	18 (78)
Years Since Diagnosis	8.5± 8.5
Pain Etiology n (%) *	
Gastroparesis/ Dysmotility	14 (61)
Post-surgical / post-traumatic	7 (30)
Chronic pancreatitis	5 (22)
Abdominal wall pain	2 (9)
* Includes 6 subjects with multiple etiologies	

Table 2.

	Subjects (N)
Baseline	23
EOT	23
Implanted	20
1 week	20
1 Month	18
3 Month	17
6 Month	13
12 Month	13

Results: Outcomes

Figure 2. The average pain relief from baseline to month 12 post implant, and responder rates (bars) are shown.

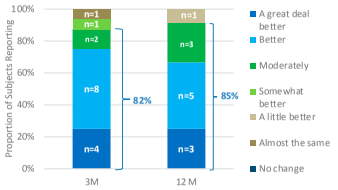


The average abdominal pain intensity was reduced from a baseline of 8.0 cm on the VAS to 2.6 cm at 12 months. The responder rate was 96% at EOT, and 77% and 69% at 6 and 12 months, respectively.

In terms of safety, three serious adverse events were reported: one perioperative due to aspiration that was resolved with antibiotic treatment, and two explants due to infection.

The pain disability index (PDI) showed an average reduction of 30 pts (95%CI 22-37 pts) from baseline, approximately three times the minimal clinically important difference.

Figure 3. Patients rated their global impression of change (PGIC) due to the therapy at 3 and 12 months.



In addition, at least one gastrointestinal symptoms (nausea, vomiting or abdominal bloating) improved in 81% of patients. Sleep quality also improved significantly ($p<0.001$), and PGIC was moderately to a great deal better for 82% and 85% of subjects at 3 and 12 months, respectively.

Conclusions

- Interim results suggest that HF-SCS at 10 kHz may be an effective tool for the treatment of CAP, providing significant pain relief, and improvements gastrointestinal symptoms, disability, and sleep quality.
- HF-SCS at 10 kHz appears to be therapeutic for a range of visceral pathologies.

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Conflicts of Interest

Dr. Kapural reports serving on scientific advisory board for Abbott, Nevro, Saluda, SPR Therapeutics, Neuros, Halyard, receiving consultant fees from Gimer Medical, Best Doctors, Solis Medical, Nalu Medical, Biotronic, and research grants from Stimwave, Nevro, Neuros, Halyard, SPR Therapeutics, Boston Scientific, Medtronic, Saluda.

A Retrospective Case Series on Ultrasound Guided Fragmentation of Calcific Supraspinatus Tendinosis without Lavage

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[1]Division of Physical Medicine and Rehabilitation, McMaster University, Hamilton, Ontario, Canada [2]Michael G. DeGroote School of Medicine, McMaster University, Hamilton, Ontario Canada [3]Division of Radiology, Hamilton General Hospital, McMaster University, Hamilton, Ontario, Canada

BACKGROUND

- Calcific tendinosis of the supraspinatus tendon can be a debilitating form of rotator cuff pathology leading to significant pain and functional loss.[6]
- A non-operative intervention for calcific tendinosis includes ultrasound-guided needle fragmentation of the calcification, with associated lavage where the calcific remnants are suctioned.[6]
- Currently, research on the benefits of needle fragmentation alone without lavage in calcific tendinosis of the rotator cuff is limited.
- Often when the calcification is physically hard for aspiration the lavage step is not possible
- Hence the therapeutic value added by lavage is uncertain and has not been explored

This study aims to explore the efficacy of ultrasound guided needle fragmentation without lavage in managing pain for patients with dense calcification in calcific tendinosis of the supraspinatus tendon.

METHODS: Design and Outcomes

Figure 1: Recruitment of participants and follow up

Study Design

- Retrospective Study
- Patients referred to Dr. H Choudur July 2014 – July 2016 to Hamilton General Hospital Dept. of Radiology
- Enrolled only Fragmentation without lavage

Inclusion Criteria	• Age >18 • Calcific supraspinatus tendinosis as diagnosed on ultrasound • Shoulder pain with reduced horizontal abduction • Pain for >6 months • Documentation of failed conservative management with physiotherapy and Non-Steroidal Anti-Inflammatories
Exclusion Criteria	• Calcific tendinosis in rotator cuff tendons other than supraspinatus tendon • Presence of a tear of the rotator cuff • Calcification >2.5 cm • Previous shoulder surgery • Diagnosis of Frozen Shoulder, Fibromyalgia, or Complex Regional Pain Syndrome • Anticoagulation/Immunosuppressant • Allergic to medication used/Skin infection at site of needle entry • Significant medical co-morbidities requiring daily assistance • Ongoing litigation or compensation claims secondary to shoulder problems
Primary Outcome	• Visual analog pain score (VAS) collected at pre-procedure, 3 weeks, and 3 months post procedure
Secondary Outcomes	• Required surgery • Adverse Events (ADEs) including infection, tendon tears, etc.

Table 1: Inclusion and Exclusion Criteria of this study for recruiting participants, and the Primary and Secondary Outcomes of the Study.

METHODS: Procedure

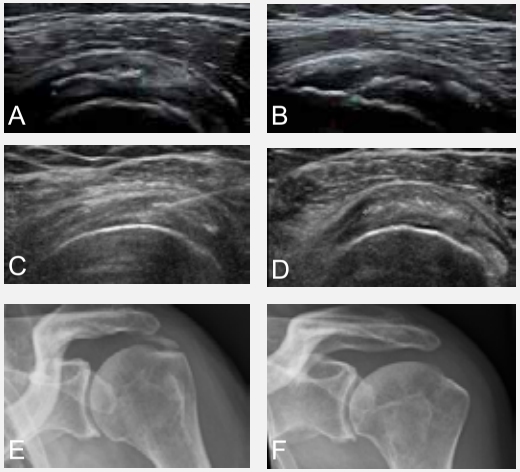

Figure 2: The procedure of the ultrasound guided fragmentation without lavage includes initially ultrasound guided localization of the calcification in the single best plane and a skin mark made to indicate point of needle entry. US images of the calcification in the short (A) and long axis (B) planes of the supraspinatus tendon was obtained and marked as pre-procedure US images. Using local anesthetic and strict aseptic precautions the tip of the 22 gauge needle was advanced into the sub acromial bursa under ultrasound guidance and 2ml of local anesthetic (1% xylocaine) was used. The needle tip was advanced into the supraspinatus tendon (C) and 0.5ml or less of 0.5% sensorcaine was injected into the pseudocapsule around the calcification. Using 15-20 to and fro movements of the needle tip, the calcification was fragmented with the needle tip within the pseudocapsule. The needle tip was then retracted into the subacromial bursa and 3ml of 0.5% sensorcaine and 1ml of steroid (depomedrol 40mg/ml) was injected into the bursa. The needle was then removed. Post procedure US images in the short (D) and long axis planes was then obtained and documented. Radiographs pre-procedure (E) and 3 months post-procedure (F) are seen above.

Results

Figure 3: Pre-procedure mean Visual Analogue Scale (VAS) score on a scale of 0-10, and subsequent reduction 3 weeks and 3 months post-procedure by 4.96 and 4.95 respectively

DISCUSSION

- There was **significant improvement in VAS pain scores** at 3 weeks post-procedure, indicating there was therapeutic effect of ultra-sound guided fragmentation without lavage within 3 weeks.
- This could be due to the physical fragmentation of the calcification, as well as an additional inflammatory response caused by the associated **needle fenestration** of the surrounding tendon. The fragmented calcium was then resorbed by the **neovascularity** within the tendon.
- For appropriate patients where lavage is not feasible, this procedure could be performed as an alternative.
- For those who have hard calcifications, **this procedure is effective in reducing pain**, and clinically is a minimally invasive and a relatively low risk, low cost procedure
- Was an observational study, **limitations** included patient reporting bias and differential loss to follow up
- **Next steps** would include a Single Blinded Randomized Control Trial comparing Fragmentation with no Lavage, Fragmentation with Lavage, and an Ultrasound Guided Subacromial Steroid injection to determine the implications of Lavage and Fragmentation in pain reduction

CONCLUSION

- **Ultrasound guided needle fragmentation for calcific supraspinatus tendinosis may be an efficacious option for treatment when the calcification is dense and not amenable to lavage**
- This may be in part due an additional inflammatory response caused by the fenestration around the calcium which incites neovascularity, that works as a scavenger to remove the fragmented calcium, and also incites tendon healing
- High degree of pain relief at 3 weeks and at 3 months post-procedure

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Successful use of spinal cord stimulator for the treatment of chronic cervicalgia due to spasmodic torticollis.

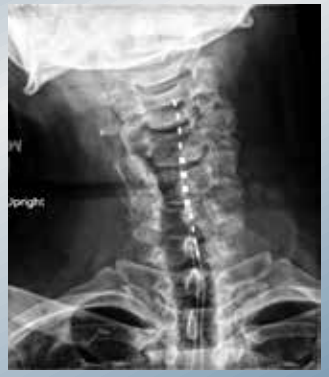
Scott Chamberlain DO, Intikhab Mohsin MD, Yousaf Chowdhry MD, Vishad Sukul MD

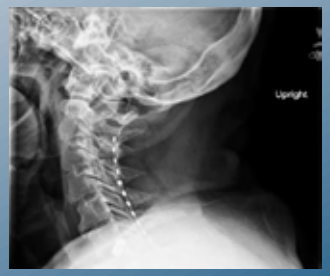
Background:

A 60 year old male presented with chronic right sided neck and arm pain secondary to spasmodic torticollis. The patient had attempted treatment with medications including cyclobenzaprine, amitriptyline, duloxetine, gabapentin, and hydrocodone/APAP with only minimal relief. He had also formerly received some relief with Myobloc injections, however these were no longer benefitting him. On presentation, the patient had severe spasmodic torticollis with his chin touching his chest and rotated to the right. Cervical range of motion was found to be decreased in all directions. Palpation with even minimal pressure produced severe pain which extended from right mid cervical region to the right shoulder. Neurologic exam was significant only for motor strength of 4/5 on the right compared to 5/5 on the left.

Methods:

Because of the patient's severe spasm in the cervical region, positioning would likely be made more difficult for any interventional procedures. After a discussion with the patient, the decision was made to trial a spinal cord stimulator under general anesthesia with intraoperative neuromonitoring and EMG rather than the traditional monitored anesthesia care. A percutaneous dual lead placement was performed using an 8 contact Boston Scientific electrode with the lead being placed at the base of the C2 vertebral body bilaterally. Spinal surgery was involved in the placement of the trial stimulator.





Results: After programming of the spinal cord stimulator, the patient reported that his chronic pain level of 8/10 was reduced to a 3-4/10, a greater than 50% decrease in pain. Because of the successful trial, the patient received a permanent spinal cord stimulator. The patient noted that after placement of the trial, he was able to use his right arm for activities of daily living, such as feeding himself, that he had not been able to do in years due to pain.

Conclusions: We describe the successful treatment of chronic cervicalgia due to dystonia using cervical spinal cord stimulator. The treatment of cervical dystonia is typically based on symptomatic control using medical therapy. In a patient that has failed standard medical therapy, few treatment options exist. Traditionally deep brain stimulator has been used for recalcitrant cervical dystonia. We present the case of successful treatment of cervical dystonia using cervical spinal cord stimulator, a less invasive treatment option for patients failing medical therapy.

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Can Current Spinal Cord Stimulator Placement Guidelines Be Applied to Patients with Chronic Alcoholic Liver Disease?

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Background:

The American Society of Regional Anesthesia (ASRA) provides guidelines regarding neuraxial procedures with respect to coagulation studies in the setting of anti-platelet and anti-coagulation medications.

- Recommend INR ≤ 1.4 for neuraxial interventions.[1]

Case Reports:

- Smith C.C. et al showed paraparesis and epidural hematoma after spinal cord stimulator (SCS) placement in the setting of normal coagulation studies. [2]
- Ladh A. et al revealed spinal hematoma after removal of thoracic epidural catheter s/p laparotomy for resection of a GIST tumor [3]:
  - Pre-operatively:
    - Normal liver function tests and coagulation studies but mildly low albumin levels.
  - Post-operative day 5:
    - Epidural catheter was removed and hours later patient developed sudden loss of sensory and motor function of lower extremities.

Objective:

Should current ASRA guidelines be applied when neuraxial procedures such as SCS placement are being considered in patients with underlying liver disease not on blood thinners?

INR may not be adequate for evaluation in this population!

It is known that in chronic liver disease patients have decreased serum albumin, AST/ALT ratio > 2.0, macrocytic anemia, thrombocytopenia, and elevated INR [4]. We want to shed light on:

1. The risks regarding patients who are being evaluated for placement of SCS in the setting of long-standing liver disease.
2. Alternative ways to assess a patients candidacy who have an underlying coagulopathy for neuraxial interventions whom are not on blood thinners.

Case Report:

A 44-year old male was referred for evaluation of SCS placement for severe diabetic neuropathy of their bilateral lower extremities from mid-calf to his feet not responding to conservative treatment.

- Pain is constant, severe burning and intermittent throbbing with numbness and tingling
- Antalgic wide-based gait, requiring the assistance of a cane
- Worse at night and after prolonged standing/walking

Past Medical History:

- Hypertension
- Smokes ½ ppd for 25 years
- Consumes 10 alcoholic beverages daily, recent abstinence however not in counseling
- Diabetes: Hemoglobin A1C at diagnosis was 9.0, decreased to 5.7

Physical Exam:

- Decreased sensation to soft touch on lateral aspect of b/l lower extremities from mid-calf to the feet
- Strength and reflexes were intact
- Decreased cadence
- Red and dark skin discoloration below mid-calf level
- Atrophy of bilateral gastrocnemius
- EMG: Sensorimotor mixed polyneuropathy and denervation of bilateral gastrocnemius muscles and chronic bilateral L5-S1 radiculopathies

Failed Conservative Treatments:

- Lyrica, Gabapentin, Cymbalta, Amitriptyline, Nucynta
- Lidocaine infusions
- Subcutaneous botulin toxin injections → provided 75% reduction in pain for only 6-7 days

SCS trial evaluation laboratory workup:

Albumin 3.4 – 5.0 g/dL	AST/ALT 15-37/12-78 U/L	Direct bilirubin 0.0 – 0.2 mg/dL	Platelets thousand	PT 10.9 – 13.3 seconds	PTT 22.9 – 36.7 seconds	INR 0.9 – 1.1
2.7	46/28	0.5	127	15.6	37.8	1.5

Not a candidate at this time due to abnormal laboratory values and underlying liver dysfunction

Discussion:

Current pre-operative selection criteria for SCS:

- Normal CBC/Platelets and scrutiny of anti-coagulation therapy
- If concerned of bleeding obtain INR > PT/PTT [5]
  - PT examines speed of extrinsic coagulation pathway which varies. INR normalizes these variations.
    - Why is the standard for measuring coagulation weighted heavily on only a portion of the coagulation pathway?

De Pietri L. et al [6]	Ladha A. et al [3]
TEG in cirrhotic patients prior to liver transplant	**Occurrence of epidural hematoma with initial normal coagulation studies**
79.3% of liver disease patients had abnormal TEG: • Hypocoagulable, slower and less stable clot formation	Short duration of fasting for laparotomy led to: • Nutritional deficiency • Decrease in Vitamin-K factors
Question: *Should TEG, which assess overall clot formation, be used as a more comprehensive assessment rather than PT/INR in patients with underlying liver disease for evaluation of SCS placement?*	**Question:** *Should patients with baseline nutritional deficits (alcoholism) have additional work-up to include pre-albumin, albumin and vitamin-K factor levels for evaluation of wound healing and increased risk of bleeding?*

The question this population brings to light is should the current ASRA guidelines be applied when neuraxial procedures such as spinal cord stimulator placement are being considered?

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Depth Assessment using Contralateral Oblique View during Interlaminar Cervical Epidural Steroid Injections

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Background

- Interlaminar cervical epidural steroid injections (CESI) are common procedures utilized in the treatment of cervical radiculopathy and cervical spinal stenosis.
- Traditional fluoroscopic views include the trajectory view (anterior-posterior) for initial needle placement and safety view (lateral) for needle depth.
- Recent literature has demonstrated that the contralateral oblique (CLO) view provides a more consistent and reliable angle in determining needle depth when compared to the lateral view.
- Despite utilization of CLO safety views, contrast patterns, and loss of resistance techniques, inherent risk of injury remains.
- Additional safety measures must be assessed to provide clinicians with further safeguards to prevent major neurological and medical complications.

Objectives

- To provide a reliable method of gauging needle depth insertion during interlaminar CESI by comparing the distance from skin to epidural space when measured on MRI and when measured intra-operatively.
- Accurate correlations may allow physicians performing interlaminar CESI the ability to decrease overall procedure time and minimize radiation dosage, reduce patient discomfort, and provide an additional safety measure in preventing complications.

Methods

- The study sample included 45 patients with clinically diagnosed cervical radiculopathy or cervical spinal stenosis.
- The distance from skin to epidural space was measured on cervical spine MRI and with the spinal needle intra-operatively. (See Figures 1 and 2)
- Primary analysis assessed how closely the depth measurements correlated, and whether the correlation was influenced by either injection level (ex. C6-C7 or C7-T1), needle tip location (ex. midline vs para-midline), or BMI.

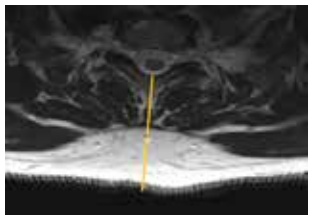

Figure 1: A cervical spine MRI in axial view was obtained for pre-procedural planning. The yellow line indicates the distance measured from the skin to the posterior epidural space

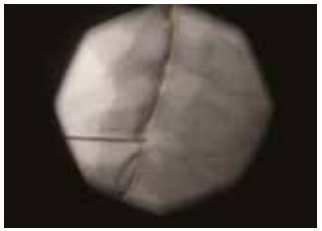

Figure 2: CLO oblique view of Tuohy needle ventral to the spinolaminar line. A mark was placed on the needle at the skin surface. After needle removal, the actual procedural depth was then measured from the needle tip to intra-operative marking

Results

- Significant correlation (r=.975, P < .001) with an average difference of .03mm (STD 2.99mm) was found between MRI and procedural measurements (See Figure 3)
- Neither injection level nor BMI had a significant influence on the difference in depth correlation
- The needle tip location analysis was unable to be performed due to an unbalanced sample size of the midline vs para-midline group.

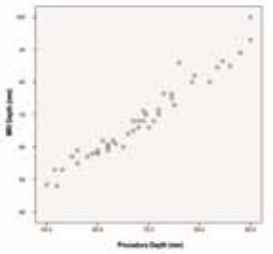

Figure 3: Correlation between MRI Depth and Intra-Operative Depth

Discussion

The close proximity of vital structures within the cervical spine and anatomic variability among patients increases the risk of significant procedural complications. This study showed a strong correlation between pre-procedural MRI and intra-operative measurements. Because the majority of patients undergoing interlaminar CESI will have already obtained an MRI, measuring the distance pre-procedurally is a simple and practical method for physicians to implement. Utilizing this method may also increase the efficiency of the procedure by minimizing usage of safety views, thus decreasing fluoroscopic time and lessening radiation exposure to the patient.

Conclusion

When combined with traditional safety techniques, obtaining pre-procedural MRI depth measurements provides a reliable method in predicting the true needle depth to safely enter the posterior epidural space, improving both the safety and quality of cervical interlaminar epidural steroid injections.

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