Top Posters Selected for 2017 19th Annual ASIPP Meeting

First Place Abstract Presentation
Dr. Richard North
Multicolumn Spinal Cord Stimulation for Predominant Back Pain in Failed Back Surgery Syndrom Patients: An International Multicenter Randomized Trial (PROMISE Study)

2nd Place Abstract Presentation
Gladstone C. McDowell, II MD
Effectiveness and Safety of Intrathecal Ziconotide as teh First Agent in Pump for Adult Patients with Severe Chronic Pain

Fellow Award
Christian Estrada
Performing a Transforaminal Epidural in a Patient with an Implanted DRG Nerve Stimulator

Resident Award
Ken Ehrhardt
New Treatment of Lower Back Pain with Matrix Metalloproteinases
Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: an international multicenter randomized trial (PROMISE study)

Philippe Rigoard1,2*, Mehul J. Desai3,4, Rod S. Taylor5, Lieven Annemans6, Mary Jo Johnson7, Ye Tan7, Carine Van den Abeele8, Richard North9,10

On behalf of the PROMISE Study Group

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Background
Spinal cord stimulation (SCS) has been shown to be an effective treatment for failed back surgery syndrome (FBSS) with predominant radicular pain. Case series (Rigoard 2012 & 2014) support SCS for predominant low back pain (LBP), but until now we lack direct randomized controlled trial (RCT) evidence in this population.

Objective
PROMISE, this multicenter, prospective, randomized, open-label, parallel-group study, was designed to assess the clinical effectiveness of SCS in FBSS patients with predominant LBP.

Methods
Eligible subjects were randomized 1:1 to optimal medical management alone (OMM group) or SCS plus OMM (SCS group). SCS group patients underwent trial stimulation, and if they achieved adequate LBP relief, a permanent pacemaker was implanted. Evaluations occurred at 1, 3, and 6 months, after which patients could change treatment groups and continue follow-up until 12 months.

The primary outcome was the proportion of subjects with ≥ 50% reduction in LBP based on a diary of numerical pain rating scale (NPRS) scores. Secondary outcomes included change in LBP intensity, leg pain intensity, functional disability (Oswestry Disability Index, ODI) and health-related quality of life (Short-Form Health Survey, Physical Component Summary, SF-36-PCS).

Results
Of 278 participants enrolled in 28 centers in Canada, Colombia, Europe, and the United States, 218 were randomized (110 to SCS group and 108 to OMM group). In intention-to-treat (ITT) analysis at 6 months, there were significantly more responders in the SCS group compared to the OMM group (55 participants, 15.4% versus 5, 4.6%, p=0.036, Figure 2). The SCS group responder rates varied from 0 to 30% across sites.

Secondary outcomes at 6 months improved significantly (p<0.001) for all measures in the SCS group, and the difference between groups was significant (all p<0.001) in favor of the SCS group (Figure 3). The OMM group did not improve by any measure at 6 months except the SF-36-PCS (p=0.03).

At 6 months, 2/80 (2.5%) of the SCS group opted to cease therapy, and 73/106 (68.9%) of OMM subjects requested crossover to SCS. Of the 68 continuing on SCS and with 12 months data, 18 (26.5%) were LBP responders.

In the SCS group, 102 were trialed, of which 18 (17.6%) experienced device/therapy related complications through 6 months. Among these, 12 (11.8%) required surgical intervention.

Conclusion
In this international multicenter RCT, adding SCS with a multicolumn lead to OMM provided significant improvements in pain relief, health-related quality of life, and function compared with OMM alone in a traditionally difficult to treat patient population of FBSS patients with predominant back pain. These improvements were sustained in the SCS group at 12 months.

Disclosures
MJJ, CV, TT: Medtronic employees. All others or their employers: industry consultancy, grants, and/or equity. Detailed disclosure on request.

Acknowledgments
PROMISE Study Group: Prof. Rigoard; Prof. R. Basu; Prof. Desai; Dr. Kumar; Rod Taylor; Prof. Annemans; Prof. Mulder; John Phillips; Dr. Van der Linden; Dr. Guiraud; Dr. M. Arakawa; Dr. Llorente; Dr. Jaramillo; Dr. Eif; Dr. Yepes; Dr. Lopez; Dr. Van Haeverbeek; Dr. Hoozemans; Dr. Barcella; Dr. Eschekiran; Dr. Piron; Dr. Roser; Dr. Garda; Dr. P. Claeys; Dr. L. P. Hart; Dr. North.
Effectiveness and Safety of Intrathecal Ziconotide as the First Agent in Pump for Adult Patients With Severe Chronic Pain: Primary and Secondary Outcomes

Gladstone McDowell, MD; Mark Wallace, MD; Timothy Deer, MD; Philip Kim, MD; Eric Grigsby, MD; I-Zu Huang, MD; Robert Ryan, MS; Michael F. Saulino, MD, PhD

Background: Intrathecal (IT) ziconotide (PumpZiconotide) was approved in the United States for the management of severe chronic pain in adult patients for whom intrathecal (IT) therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

Methods: The safety and efficacy of PumpZiconotide were assessed in the open-label, randomized, controlled, multicenter, investigator-initiated study by the primary endpoint of mean percentage change from baseline to Week 12 in “average pain for the past 24 hours” as rated by the patient on a 0–10 numeric pain rating scale (NPRS) (0 = no pain; 10 = moderate pain). The IT ziconotide dosing was adapted to maintain a mean plasma concentration of 8–20 ng/mL over 24 hours.

Results: As of July 5, 2016, 93 treated patients had data entered and were included in the analysis. Of those patients, 42 patients were classified as treatment responders at month 12. The most common prespecified primary diagnoses were lumbar radiculopathy (17.6%), complex regional pain syndrome (11.8%), low back pain (11.8%), central pain syndrome (11.8%), and thoracic radiculopathy (11.8%). Treatment response defined as ≥2 unit reduction in NPRS score from baseline was reported by 48.4% of patients with ziconotide first in pump and 23.1% of patients with ziconotide not first in pump (p = 0.0092). Patients who had ziconotide first in pump had a longer duration of pain than patients who had ziconotide not first in pump (p = 0.0037).

Conclusions: In this study, IT ziconotide efficacy was observed when it was titrated in an initial dose of 150 mcg/day. The most common adverse events observed were nausea (34.1%), vomiting (21.4%), and device-related laboratory results (9.5%). A significant number of patients also experienced adverse events not related to ziconotide, including psychiatric disorders, suicidal ideation, mental status changes, pain worsening at the injection site, and device-related laboratory results (9.5%).

References:
Introduction
The dorsal root ganglion (DRG) is a nerve structure that processes and filters pain information from the periphery to the central nervous system. Stimulating the DRG is a type of neuromodulation that offers a meaningful option for patients suffering from chronic intractable pain in the lower limbs who are currently underserved by traditional spinal cord stimulation. The ACCURATE study provided evidence of the safety and efficacy of DRG stimulation in CRPS patients. As the number of patients with CRPS being treated with DRG stimulation rises, there will be a subset of patients with concurrent radicular low back pain.

Case
Patient is a 49-year-old man with a past medical history of chronic low back pain with radiculopathy and bilateral foot deformities s/p multiple surgeries secondary to a previous dancing career. He subsequently developed severe burning pain in the plantar aspect of both feet associated with a growing inability to walk, affecting his ADLs. Fulfilling the Budapest criteria, he was diagnosed with CRPS. After failing multiple conservative therapies, he underwent bilateral L5 and right S1 DRG stimulator implantation. Afterwards, the patient reported complete resolution of the burning sensation in the bottom of his feet.

Months later, the patient complained of sharp low back and radicular pain down bilateral legs posteriorly in an L5 nerve root distribution. This pain was not covered by the DRG stimulator. Due to a known displaced intervertebral disc causing bilateral neural foraminal stenosis at L5-S1, the decision was made to proceed with bilateral L5-S1 transforaminal epidural steroid injections with special care taken to avoid the radiopaque DRG leads.

Discussion
Our treatment plan was based on the idea that the DRG leads were irritating the nerve roots exiting an already stenotic foramen. Performing an epidural via the transforaminal approach in a patient with DRG leads at the same level can provide unique challenges. Before prepping the skin, we took several fluoroscopic images to map out the locations of the stimulator as well as the DRG leads. During the procedure, the ideal oblique angle of the fluoroscopic beam had to be readjusted because the DRG lead was in the way. This was particularly a problem when accessing the right foramen.

The needle placement was slightly more lateral than ideal. However, we were still able to access the epidural space safely.

Other options considered were an interlaminar epidural as well as a caudal approach. These two options are technically less difficult. However, the location of the injectate would offer a less efficacious treatment given that the painful condition involved the nerve roots.

After a systematic review of the literature, we were unable to find other case reports where a transforaminal epidural was done at the same level as DRG leads. Contraindications to epidural injections from the manufacturer were not found. Close proximity of the needle to the leads would risk direct lead damage. The manufacturer does warn of the use of radiofrequency (RF) ablation since it may cause interference with the stimulator. Also, if the patient was wearing a trial neurostimulator, we would have postponed the epidural injection because the cleaning agents used to sterilize the skin may cause corrosion and affect the outcome of the trial.

Conclusion
DRG stimulation provides targeted pain relief in patients with debilitating CRPS. As this treatment modality gains popularity as an alternative to opioid therapy, there will be a larger subset of these patients with chronic radicular low back pain. Transforaminal epidural steroid injection remains a treatment option for radicular back pain in patients with implanted DRG leads. One however must consider the increased level of difficulty in placing the needles and risk of possible direct damage to the leads.

References
New Treatment of Lower Back Pain with Matrix Metalloproteinases

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Background:
The prevalence of chronic lower back pain (CLBP) is increasing in today’s society. Current treatment of lower back pain is effective in less than fifty percent of patients after one year. Matrix metalloproteinases (MMPs) are a family of proteolytic enzymes that participate in the degradation of matrix components such as glycoproteins, proteoglycans, and collagen. MMP-3 degrades the protein core of proteoglycans and small noncollagenous proteins. Their activity is inhibited by tissue inhibitors of metalloproteinases (TIMPs). It has been hypothesized that the dysbalance of MMPs and TIMPs leads to disc degeneration.

Objective:
This review investigates Matrix Metalloproteinases as a new treatment for lower back pain and disc herniation.

Methods:
An extensive literature search utilizing PUBMED, focused on matrix metalloproteinases as a treatment for CLBP.

Results:
Limited studies have been completed at present. Bachmeier et al. took 37 lumbar specimens obtained during surgical procedures, including lumbar discectomies and interbody fusions. A quantitative molecular analysis of the mRNA expression for MMPs and TIMPs was performed using RT-PCR. The researchers found that MMP-3 mRNA levels were consistently upregulated in samples with histological evidence for disc degeneration. Interestingly, TIMP-1 was also upregulated. The authors concluded that MMP-3 plays a key role in the degenerative cascade leading to symptomatic disc herniation. In another study, Haro et al. conducted an extensive study to examine the role of MMPs in the treatment of herniated discs. Administration of rh MMP-7 and chymopapain into canine herniated discs resulted in a decrease in protruded disc mass as seen by MRI and myelography. Histologically, rh MMP-7 destroyed the nucleus pulposus, but an intact nucleus area and annulus fibrosus remained. In contrast, chymopapain showed degradation though the NP and AF. The authors concluded that rh MMP-7 shows the greatest promise for the treatment of herniated discs.

Conclusion:
Further research and innovation is needed to implement these methods into practice and assess clinical significance. The current evidence suggests that matrix metalloproteinases are promising new agents for the treatment of CLBP and in particular herniated discs.

References:
Opioid overdose causes up to 18,000 deaths in the USA each year. Once opioids are dispensed there are no checks or balances to prevent abuse. Abuse deterrent mechanisms can prevent iv or intranasal use but not oral ingestion (commonest form of abuse) of multiple doses or selling of opioids. Currently available medication dispensers allow for preprogrammed dispensing of medication doses at preprogrammed intervals however without actual monitoring of medication ingestion the patient can just remove one dose at a time, save all the pills in a bottle and then subsequently abuse or divert them all.

Goal is to develop of abuse resistant medication dispensers which

1) Allow the patient to access only one dose of medication at a fixed preprogrammed dosing interval
2) Allow electronic monitoring of actual ingestion of the drug by the patient
3) Are tamper resistant
4) Deter medication from being administered by any other route than prescribed
5) Prevent access to dispensed medications by anyone other than the patient
6) Allow for deactivation of the remaining unused medication once a specified interval has passed and the medication is no longer medically necessary

We describe a Medication dispenser which includes 3 main components

1) A portable battery operated, reusable tamper resistant medication dispenser that allows only a preprogrammed dose of the medication to be dispensed only at preprogrammed interval upon activation using biometric identification sensors.

2) A refillable liquid reservoir attached to the bottom of the medication dispenser into which the medication is dispensed

3) A smartphone and camera based monitoring system which records actual consumption of the medication infused liquid from the liquid reservoir by the patient

4) The medication in p8, pellet or liquid form, is contained in the medication chamber, which is boiled with accesses only to a pharmacist for medication refill and disposal.

A smart phone integrated with the device acts as the primary ECU. Tamper sensors including break/tripwire sensors, shock sensors, and temperature sensors detect any attempts at breaking, perforating or tampering. The medication is in liquid form and an electronically controlled pump when activated allows for a fixed preprogrammed volume of the medication solution to be dispensed at the preprogrammed interval.

The medication can be specially formulated by addition of gelling and thickening agents to prevent intravenous administration of the dispensed medication. Also orally inactive opioid antagonists such as naloxone can be added to the opioid medication to prevent intravenous usage.

The medication is dispensed directly into a refillable liquid reservoir permanently attached to the bottom or side of the medication dispenser. This reservoir has float switches and has to be filled with at least a fixed predetermined volume of any potable opaque liquid such as milk, Ensure, protein shake or nutritional supplement etc before the medication is dispensed into the reservoir and the patient drinks the liquid mixed with the medication directly by sucking from the outlet port of the liquid reservoir. The reservoir float switch monitors filling and emptying of the reservoir and prevents dispensing of the medicine into the reservoir until the reservoir is filled with a specified amount of liquid and subsequently emptied after the medication has been dispensed to prevent multiple doses of medication being dispensed into the reservoir.

When tampering is detected the medications are immediately rendered unfit for misuse or abuse by electronically activated pyrotechnic charge causing release of denaturing/neutralizing chemicals into the medication chamber.

The tamper resistant medication dispenser can be programmed to activate the medication deactivating mechanisms at the end of a specified interval when the medical necessity for the prescribed medications is over, such as 2 weeks after surgery when severe pain should have resolved and the remaining unused medications in the medication chamber can be deactivated and rendered unfit for abuse and misuse.
REAL WORLD UTILIZATION OF MULTIPLE SPINAL CORD STIMULATION WAVEFORMS IN CHRONIC PAIN PATIENTS
Anthony Berg1, Dat Huynh2, Roshini Jain2
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BACKGROUND
Chronic pain disorders can be inherently complex and significantly differ in presentation and etiology from patient to patient. Therefore, customizing spinal cord stimulation therapy offers the prospect of addressing patient variability by tailoring disease treatment to each patient. The recent availability of different treatment modalities in Spinal Cord Stimulation (SCS) such as standard rate, 1 kHz, burst, anode intensification, Multiple Independent Current Control (MICC), and anatomically-guided (3D) Neural Targeting SCS now allows for the potential real world, clinical application of highly customized SCS therapy. To begin to understand how patients utilize different modalities when empowered with different targeting and waveform options using a single SCS device, we first embarked on a device utilization study. In this specific analysis, the usage of multiple stimulation waveforms is examined in 250 chronic pain patients.

METHODS
Study Design
Retrospective, multicenter, real-world device utilization

Study Device
Precision Spectra SCS system (Boston Scientific) equipped with MICC and Anatomically-Guided (3D) Neural Targeting and the following available waveform programming options:
- Standard rate
- 1 kHz
- Burst stimulation
- Anode Intensification
- Combinations of all the above

Sample Size
250 patients with chronic pain

Analyzed Patients
Group 1: used standard rate programs exclusively
Group 2: used advanced waveforms and field shapes either exclusively or in combination with standard rate programs

RESULTS

Proportion showing usage of each waveform (based on ≥ 20% of total device usage)

Distribution of waveform usage (N = 144)

Mean number of programs used in past 30 days

Patients try ~6 different programs around the time of implant and will level to ~3-4 different programs after about 180 days

CONCLUSIONS

- This analysis demonstrates patients used multiple waveforms/programs long-term and at different times each day.
- This strongly suggests the need for a device capable of providing several options to each patient based on their individual needs, thereby customizing SCS therapy.
- Future data, advanced analytics, and assessment of outcomes will drive further understanding of the impact of providing such options on patient lives.
Outpatient Thoracic Endoscopic Discectomy with or without foraminotomy - Case Series

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Background
- Surgical management of thoracic disc herniations is a challenge.
- Due to poor outcomes with thoracic discectomy, posterior lateral and lateral approaches have been developed.
- All approaches have high morbidity. Most approaches need hospitalization and extensive post-operative rehabilitation.
- With thoracic disc herniations, any approach medially carries risk of spinal cord injury or dural tears.
- Additional thoracic disc herniations at T6 lowest carry a risk of "watershed area" of tension to avoid supply yielding neurologic complications in common.

Case 1 Thoracic Endoscopic Discectomy T12-L1 without foraminotomy
- 31 y/o white female with right sided thoracic pain after ski accident.
- MRI: T10-11 superiorly extruded component; T11-12 left sided disc herniation; T12-L1 right sided disc herniation with adhesions to thecal sac and mild flattening of cord.
- Initial surgical option anterior thoracic discectomy and fusion with thoracotomy.
- Failed conservative care, epidural injections, thoracic facet blocks and thoracic radiofrequency ablation.
- Thoracic discogram: concordant pain at T12-L1.
- Preoperative planning: Review of MRI and CT discogram and access planning (Figure 3).
- Endoscopic discectomy at T12-L1 via posterolateral approach on right side. 18 G 10 inch needle into disc (Figure 4), indigo carmine contrast into disc.
- Gentle insert, needle removed, blunt dilator advanced under fluoroscopic control into postero lateral disc.
- Endoscope inserted through 9 mm sheath.
- Surgical decompression carried out with microforcps and radiofrequency ablation.
- Complete dissection carried out with good visualization of exiting nerve.

Case 2: Thoracic Endoscopic Discectomy T6-T7 with foraminotomy
- 34 y/o female, T6-7 disc herniation with failed conservative care and urinary urgency, discogram positive concordant pain.
- 5 cm to right of midline incision, serial dilatation to inferior aspect of the foramen posterior to the rib and inferior aspect of the foramen and into the disc space.
- Second dilator passed, inner two stabilized.
- First of three trephines used to resect a portion of the superior articular process and initiate the foraminotomy. Trephine removed and third dilator passed.
- Cannula passed over the four dilators and discectomy initiated. Bioforce radiofrequency used to shrink disc.
- Pulsating periosteal fat noted indicating adequate decompression.
- Patient released home same day, no chest tube needed, blood loss less than 150 ml

Case 1: T12-L1 ENDOISCOPIC DISCECTOMY WITHOUT FORAMINOTOMY

Figure 2: T12-L1 herniation to right. Soft herniation with thecal sac adhesions. Also note the blood vessel in the trajectory for the access. Modified approach planning to avoid medial approach and contact with the thecal sac. C. Preoperative planning identified an area 7.5 cm to the right of the midline and at an angle of 40 degrees to avoid the blood vessel and at a safe area to avoid injury to the thecal sac.

Figure 3. A) Anatomy and B) Thoracoscopic with needle insertion. C. Under direct visualization over the guide wire in AP and coronal view.

Figure 5. After complete removal of the herniated disc fragment at T11-T12, the decompressed pulsating dura and PLL complex can be seen.

CASE 2: T6-7 ENDOISCOPIC DISCECTOMY WITH FORAMINOTOMY

Figure 7. A) Sagittal view showing the T6-7 herniation. B) Axial view: T6-7 right paracentral disc herniation with flattening of the hemicord.

Figure 8. T6-7 DISCECTOMY WITH FORAMINOTOMY

STEPS: A) AP View. Needle placement 5 cm from midline. B) Lateral View C) Posterior discectomy commencement with tube placement D) Endoscope working tube placed after foraminotomy.

Figure 9. A) Initiation of discectomy with endoscopy. Indigo carmine stained disc at bottom of image. B) Completion of discectomy with pulsating dura and PLL visible clearly.

Discussion
- Analytic features in thoracic disc herniations are complex. Thoracic spine kyphosis, spinal stenosis and foraminitis (when present) need to be assessed.
- Surgical approaches can’t avoid surgery’s inherent stress and potential perioperative complications (bleeding) and insertion of chest tubes.
- The spinal cord diameter to canal diameter ratio is higher in thoracic area compared to lumbar and cervical area leaving less room for spinal cord in case of stenosis.
- Thoracic spinal cord vulnerable to ischemic injury (“watershed zone”) may lead to ischemia or dural sac tears.
- Thoracic endoscopic discectomy (TVED) can be an attractive option, however, pulmonary compromise is frequent.
- Conventional posterior or posterolateral approaches: Need for hospitalization, possibility of extensive post-operative rehabilitation, high morbidity.
- Review of literature

- Natural history not well defined. Thus, indications and optimal type of surgery controversial. 75% occur below T8 and commonest level is T11-12.
- Approaches include laminectomy, transpedicular (with or without foraminotomy), mini-open transpedicular, transfacet pedicle sparing approaches, costotransversectomy, transthoracic transpleural approach (2011, Diverin et al): Minimal invasive anterolateral thoracoscopic approach in 78 patients - intercostal vessel in the trajectory for the access. Modified approach planning to avoid medial approach and access planning (Figure 3).
- Transfacet pedicle sparing approach (2010, Jho et al): thoracoscopic transpleural approach, 72 patients, follow up 2 years, decompression, no further surgery.
- Thoracic and Lumbar (2002): Video assisted thoracic surgery, 100 patients with intercostal nerve sparing, no atelectasis, 96% pain relief.
- Thoracic and Lumbar (2009): Endoscopic discectomy, 100 patients, 68% pain relief, 100% satisfaction.
- Thoracic and Lumbar (2011): Endoscopic discectomy, 14 patients, thoracic facet blockade, 100% pain relief.
- Thoracic and Lumbar (2010): Endoscopic discectomy, 14 patients, thoracic facet blockade, 100% pain relief.
- 18 G 10 inch needle into disc (Figure 4), indigo carmine contrast into disc.

Thoracic Endoscopic Discectomy “Pearls”
- Thoracic discectomy absolutely essential, planning level of surgery.
- Review of MRI and CT discogram to identify that that plain film showed a window between 5 and 9 cm from midline ideal access point.
- First of three trephines used to resect a portion of the superior articular process and initiate the foraminotomy. Trephine removed and third dilator passed.
- Cannula passed over the four dilators and discectomy initiated. Bioforce radiofrequency used to shrink disc.
- Pulsating periosteal fat noted indicating adequate decompression.
- Patient released home same day, no chest tube needed, blood loss less than 150 ml

Conclusion
- Thoracic discectomy endoscopic approach feasible in an outpatient setting with proper planning.
- Though infrequent, necessary guidelines for better outcomes.
- Endoscopic approach to thoracic herniations can be performed with or without foraminotomy.
- Better access tools availability and knowledge will lead to use of this approach more in the future.
- Long term follow up results great with neither fusion / stabilization needed.

- Outpatient thoracic endoscopic discectomy under local anesthesia and epidural needle placement.
- No hospitalization needed.
- Postoperative pain makes return to normal activities quick.
- Several patients have described the procedure as non-traumatic.
- Pain management is usually done at home, no chest tube needed.
- Admitted to floor after 12 hours and discharged home after 24 hours.
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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Background

Disorders of the cervical spine are frequently disabling and costly1,2. 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 months3.

Upper limb and neck pain remain difficult-to-treat areas of pain. Traditional SCS has been successfully used to treat upper limb and neck pain4,5. However, variability in the distribution and intensity of the induced paresthesia 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 pain6. 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.

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, following by Institutional Review Board approval
- Each subject implanted with two epidural leads spanning C3-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

Results: Etiologies

<table>
<thead>
<tr>
<th>Pain Etiology</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>Chronic intractable</td>
<td>26</td>
</tr>
<tr>
<td>upper limb and neck pain only</td>
<td>12</td>
</tr>
</tbody>
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Results: Safety

- No neurological deficits
- None of the subjects reported experiencing paresthesia
- Two device-related adverse events: Muscle spasm in neck/shoulder, Malaise
- Both resolved with reprogramming

Conclusions

Preliminary results from a multicenter, prospective study using high frequency spinal cord stimulation at 10 kHz to treat upper limb and neck pain are promising with outcomes similar to SENZA RCT results for back and leg pain.

References


Results: Responder Rates

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Trial Months</th>
<th>3 Months (Primary)</th>
</tr>
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<tbody>
<tr>
<td>All</td>
<td>36/38 (95%)</td>
<td>19/20 (97%)</td>
</tr>
<tr>
<td>With Neck Pain</td>
<td>36/38 (95%)</td>
<td>19/20 (97%)</td>
</tr>
<tr>
<td>With Upper Limb Pain</td>
<td>18/19 (95%)</td>
<td>10/12 (83%)</td>
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Results: Pain Scores and Percentage Pain Relief

<table>
<thead>
<tr>
<th>Pain Area</th>
<th>Scores</th>
<th>3 Months</th>
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</thead>
<tbody>
<tr>
<td>Neck Pain</td>
<td>7.5 60%</td>
<td>7.0 67%</td>
</tr>
<tr>
<td>Upper Limb Pain</td>
<td>8.0 70%</td>
<td>7.0 67%</td>
</tr>
</tbody>
</table>

Figure 2: Neck (left) and upper limb (right) pain as a function of time. VAS scores shown in blue, percentage pain relief shown green. *p<0.001.

Results: Disability

- Disability assessed by Pain Disability Index (PDI) (Range 0-70)
- Lower index score = less disability
- Minimal clinically important difference (MCID): 8.5-9.9
- Proportion of subjects reporting a MCID: 66.7%

Conflict of Interest

KA: Personal fees from Nevro Corp., Saluda Medical, Medtronic, and St. Jude Medical. Grants from Nevro Corp., Medtronic, and St. Jude Medical. Scientific advisory board member of Nevro Corp. MA, MB, EA, CV, BB, DV, TN, and SN: Members of the research team for pain management and/or hardware and/or software development and/or pain management. JA: Members of the research team for pain management and/or hardware and/or software development and/or pain management. RC: Presidential speaker for Nevro Corp., Medtronic, and St. Jude Medical. Member of the research team for pain management and/or hardware and/or software development and/or pain management. JK: Member of the research team for pain management and/or hardware and/or software development and/or pain management. JK, MH, MM, JC, and MF: Members of the research team for pain management and/or hardware and/or software development and/or pain management. YS: Member of the research team for pain management and/or hardware and/or software development and/or pain management. HS: Member of the research team for pain management and/or hardware and/or software development and/or pain management. AB, AV, and SB: Members of the research team for pain management and/or hardware and/or software development and/or pain management. SN and RY: Researcher and/or member of the research team for pain management and/or hardware and/or software development and/or pain management. RV, BZ, and BZ: Employees of Medtronic, Inc. SN: Member of the research team for pain management and/or hardware and/or software development and/or pain management. RV, BZ, and BZ: Employees of Medtronic, Inc. SN: Member of the research team for pain management and/or hardware and/or software development and/or pain management. RV, BZ, and BZ: Employees of Medtronic, Inc. SN: Member of the research team for pain management and/or hardware and/or software development and/or pain management.
Valve Gated Pump Used in Intrathecal Drug Delivery System Shows Reduced Dosage Escalation as Compared to Peristaltic-based Systems: A 24-Month Retrospective Study

Daniel R. Kloster, M.D., Interventional Pain Management Specialist, LLC, Overland Park, KS

Introduction

Minimizing dose escalation observed in chronic intractable pain patients implanted with programmable intrathecal (IT) drug delivery systems (IDDS) is critical for therapy efficacy. Dose escalation can be managed by dosing algorithms including micro-dosing and low-dose drug delivery, as clinical data suggests. Current implantable drug delivery platforms rely on either peristaltic- or valve gated-based systems. Thus, it was of interest to determine what difference in dose escalation, if any, existed between these two platforms in this patient population. Our retrospective analysis of patient records from a single center evaluated type of IDDS and drug dosage, as well as change in medication. Since baclofen, hydromorphone, and morphine were the most common analgesics recorded, their IT dosages were of particular interest. Available data were evaluated at 3, 6, 12, and 24 months post-implant.

Inclusion Criteria

Inclusion Criteria for Analysis

Age ≥ 18 yrs

Chronic intractable pain who were nonsurgical candidates and/or experienced intolerable side effects to oral analgesics

Enrolled with either peristaltic or valve gated pump

IDDS Implant Date

June 2009 to June 2016

Results

Table: Medications Administered Over 24 Months

<table>
<thead>
<tr>
<th>Medication</th>
<th>Peristaltic</th>
<th>Valve Gated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baclofen</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clonidine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clonidine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Morphine</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Prialt</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Total Mean Dosage Administered (mg) Over 24 Months

<table>
<thead>
<tr>
<th>Medication</th>
<th>Peristaltic</th>
<th>Valve Gated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baclofen</td>
<td>5.12</td>
<td>5.12</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>57.1</td>
<td>5.7</td>
</tr>
<tr>
<td>Clonidine</td>
<td>22.2</td>
<td>22.2</td>
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<tr>
<td>Hydromorphone</td>
<td>31.0</td>
<td>31.0</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>22.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Clonidine</td>
<td>22.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>31.0</td>
<td>31.0</td>
</tr>
<tr>
<td>Morphine</td>
<td>1.35</td>
<td>1.35</td>
</tr>
<tr>
<td>Prialt</td>
<td>0.01</td>
<td>--</td>
</tr>
</tbody>
</table>

Mean Dosage (mg ±SD) Over Time

<table>
<thead>
<tr>
<th>Period</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bup.</td>
<td>2.95 ±0.79</td>
<td>2.35 ±0.41</td>
<td>2.35 ±0.34</td>
<td></td>
</tr>
<tr>
<td>Hyd.</td>
<td>1.47 ±0.46</td>
<td>1.98 ±0.83</td>
<td>1.48 ±1.33</td>
<td></td>
</tr>
<tr>
<td>Morph.</td>
<td>2.18 ±3.13</td>
<td>2.35 ±1.48</td>
<td>2.18 ±1.33</td>
<td></td>
</tr>
<tr>
<td>Prialt</td>
<td>1.01 ±0.72</td>
<td>1.04 ±0.72</td>
<td>1.01 ±0.72</td>
<td></td>
</tr>
</tbody>
</table>

Results

Post-Implant Mean Percent Change in Dosage From Previous Month

<table>
<thead>
<tr>
<th>Medication</th>
<th>Peristaltic</th>
<th>Valve Gated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baclofen</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clonidine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Clonidine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Morphine</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Prialt</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Discussion

Dose escalation observed in the peristaltic pump may be due to patients worsening pain as they approach the refill date. The peristaltic system decreases delivery of the medication as pressure diminishes with lower volumes. This results in a clinical picture of worsening pain, and decisions are made to escalate the pump. Conversely, the valve gated system allows constant delivery of the medication even as the volume diminishes toward the refill date. We believe this results in fewer upward adjustments in the pump because the patient’s pain score is stable regardless of the volume of medication in the pump.

IT pharmacotherapy with a valve gated IDDS may be a safe and effective option for this population upon further evaluation of the therapy in a prospective clinical trial of appropriately powered sample size.

Conclusion

This retrospective review of real world cases has demonstrated over a two-fold and twenty-fold percent decrease in use of bupivacaine and hydromorphone respectively, with a concomitant decrease in morphine delivered after a 24-month period via a valve gated-based drug infusion system versus a peristaltic drug infusion system. Though four patients from the valve-gated group have not completed the 24-month post-implant period, the overall trend suggests a lower IT dosage to alleviate nociception, particularly after 3 months post-implant.

Acknowledgements

This study was supported (partially) by Flowonix, Inc.

1. The content of this poster includes data from the abstract as well as additional data analyzed post abstract submission.
Epidural Steroid Injection with Racz Catheter Placement for Cervical Radiculopathy, is that Contrast in the Vertebral Artery: A Case Series

Yuriy O. Ivanov DO, Steve M. Aydin DO
Dept. of PM&R – Montefiore Medical Center, Hofstra Northwell School of Medicine

Background
Two patients with history of anterior cervical discectomy and fusion with a bone graft at C5-6 level were seen in the office five years after the original surgery. They presented with radicular signs and symptoms and new disc herniation at C2-3/C3-4 above the fusion.

Case Description
Cervical epidural steroid injection with a Racz catheter was performed in order to reach the disc levels above the fusion and to lyse potential adhesions. Catheter was placed at the C6-7 level under live fluoroscopic guidance and brought to the C2-3/C3-4 where contrast was injected.

Case (continued)
The contrast spread pattern showed vertebral artery spread, however it persisted and did not disappear as typical vascular flow. It appeared to be outlining the vertebral artery, likely due to the catheter tip being in the vertebral foramen. To minimize any complications the catheter was repositioned and after confirmation with new contrast spread injections were performed.

Discussion
Cervical epidural steroid injection (ESI) is a widely used treatment for both cervical radiculopathy and failed spine syndrome. The two major types of cervical ESI are intralaminar and transforaminal. Intralaminar is utilized to address diffuse symptoms and is deemed a fairly safe approach. Transforaminal is performed to directly treat a single nerve root; however it is associated with increased complications due to proximity of vascular structures in the cervical spine.

Discussion (continued)
Epidural injections with catheter placement are considered by some to be more effective than nonselective ESI. They can produce adhesiolysis of scar tissue and provide selective block in the epidural space closer to the dorsal root ganglion.

Images

Patient 1 Racz vertebral foramen contrast spread

Patient 2 Racz vertebral foramen contrast spread

References
Scrambler Therapy for Chemotherapy Induced Peripheral Neuropathy – A Case Series

Siddarth Thakur, MD, Salahadin Abdi, MD, PhD

Introduction

Chemotherapy induced peripheral neuropathy (CIPN) is a common and disabling side effect that impacts many patients undergoing treatment with antineoplastic agents. The incidence of CIPN has been reported as high as 90% with some chemotherapeutic drugs. As demonstrated by the results of our case series, Scrambler Therapy is a viable option for the treatment of CIPN. We demonstrated marked improvement in pain in our small group of patients. Our results are inline with previous studies of Scrambler Therapy (4).

Methods

After obtaining approval from the Institutional Review Board at the University of Texas MD Anderson Cancer Center, patients were enrolled in a pilot study. Enrollment was limited to patients who had documented chemotherapy induced peripheral neuropathy. The patients underwent Scrambler Therapy at our comprehensive cancer center outpatient pain clinic. Each patient underwent 7-10 treatment sessions (45 minutes). At each session, 8-10 electrodes were utilized through 4-5 channels, and applied optimized to provide maximum pain relief (ideally, eliminate pain). The level of stimulation was adjusted based on patients comfort and level of pain relief. Electrode placement and stimulation was optimized to provide maximum pain relief (ideally, eliminate pain). The increase in level of activity is key for patients to improve their quality of life and regain function lost due to CIPN.

Results

All patients reported improvements in the quality of their sleep. All patients reported increased in the level of activity they were able to tolerate. For example, one patient reported improved ambulation and balance, and expressed great excitement in being able to cook a Thanksgiving meal. Four patients were able to decrease their medication use. Remarkably, all patients demonstrated improved sensation to light touch on physical examination (Figure 3a,b). No patients suffered from an adverse event.

Discussion

Additionally, we have noted truly remarkable results from the treatment of pain in our small group of patients with chemotherapy induced peripheral neuropathy. The patients underwent Scrambler Therapy at our comprehensive cancer center outpatient pain clinic. Each patient underwent 7-10 treatment sessions (45 minutes). At each session, 8-10 electrodes were utilized through 4-5 channels, and applied optimized to provide maximum pain relief (ideally, eliminate pain). The level of stimulation was adjusted based on patients comfort and level of pain relief. Electrode placement and stimulation was optimized to provide maximum pain relief (ideally, eliminate pain). The increase in level of activity is key for patients to improve their quality of life and regain function lost due to CIPN. Further, we noted improvement in their post-treatment. For example, one patient reported improved ambulation and balance, and expressed great excitement in being able to cook a Thanksgiving meal. Four patients were able to decrease their medication use. Remarkably, all patients demonstrated improved sensation to light touch on physical examination (Figure 3a,b). No patients suffered from an adverse event.

Conclusions

Scrambler Therapy is an effective and non-invasive technique for the treatment of pain associated with chemotherapy related peripheral neuropathy. The patients underwent Scrambler Therapy at our comprehensive cancer center outpatient pain clinic. Each patient underwent 7-10 treatment sessions (45 minutes). At each session, 8-10 electrodes were utilized through 4-5 channels, and applied optimized to provide maximum pain relief (ideally, eliminate pain). The level of stimulation was adjusted based on patients comfort and level of pain relief. Electrode placement and stimulation was optimized to provide maximum pain relief (ideally, eliminate pain). The increase in level of activity is key for patients to improve their quality of life and regain function lost due to CIPN. Further, we noted improvement in their post-treatment. For example, one patient reported improved ambulation and balance, and expressed great excitement in being able to cook a Thanksgiving meal. Four patients were able to decrease their medication use. Remarkably, all patients demonstrated improved sensation to light touch on physical examination (Figure 3a,b). No patients suffered from an adverse event.

References

Introduction

Ziconotide is an intrathecally delivered, nonpeptide analgesic agent approved in the United States for the management of severe chronic pain in adult patients for whom intrathecal (IT) therapy is warranted and who are intolerant of or refractory to other treatments, such as systemic opioids, adjunctive therapies, or IT morphine.

- The efficacy of IT ziconotide for the treatment of severe chronic pain was established in randomized, double-blind, placebo-controlled trials.
- The Patient Registry of Intrathecal Ziconotide Management (PRIZM) evaluates efficacy and safety associated with IT ziconotide therapy in current clinical practice.

Objectives

To evaluate the time to first response during treatment with IT ziconotide.

Methods

PRIZM was a prospective, open-label, long-term, multicenter, observational study evaluating IT ziconotide compared with the clinical practice setting.

- The study was designed as a single-arm study of patients with severe chronic pain (as defined in the prescribing information).
- The study was enrolled in adults aged 18 or older who were intolerant of or refractory to other treatments, such as systemic analgesics, adjunctive therapies, or IT morphine, and initiated IT ziconotide as the sole agent (or polypharmacy).
- Patients were followed for up to 18 months as long as they continued to receive IT ziconotide.

The primary efficacy outcome was a measure of PRIZM using the 11-point Numeric Pain Rating Scale (NPRS) as perceived by investigators.

- Secondary outcomes included time to first response, as assessed by the PGIC, was 3.5 months (95% confidence interval, 3.0-3.9).
- The analysis population included patients who completed at least 12 weeks of treatment with IT ziconotide (evaluable patients).

The authors report receiving research grants from Alfred Mann Foundation (EG, MW), Boston Scientific (EG), CNS SPR Therapeutics (EG), St. Jude Medical, Inc. (TD), Tenex Health, Inc. (EG), Vertos Medical, Inc. (MS, MW, PK, TD); serving on the advisory board for Axonics Modulation Technologies (TD), Bioness, Inc (TD), Ethos Laboratories (TD), Medtronic, Inc. (EG); receiving a consultancy fee or honorarium from Jazz Pharmaceuticals (MS), Medtronic, Inc. (MS), and SPR Therapeutics (MS); receiving fees for participation in review activities for Jazz Pharmaceuticals (EG); receiving a consultancy fee from Jazz Pharmaceuticals, Inc. (TD).

Results

- For all 75 patients, 90% had data entered into the PRIZM database.
- At the blinded population’s end point, it had closed 99 patients.
- The mean age of the evaluable patients was 56.1 years, and the mean duration of pain was 10.0 years (median 6.0 years, minimum 0.4 years, maximum 55.0 years).
- On the PGIC, 71 patients (94.7%) responded positively to intervention of treatment with IT ziconotide.
- The most common adverse events were nausea, confusional state, auditory hallucination, and dizziness.

Conclusions

- In this interim PRIZM analysis, median time to first response, as assessed by the PGIC, was 3.5 months.
- However, the first PGIC assessment occurred at the month 3 visit, potentially missing improvement that occurred earlier in treatment.
- On the PGIC, a positive response to ziconotide treatment was reported by 55.8% of patients at month 6 and 85.2% of patients at month 12.
- The most common adverse events were nausea, confusional state, auditory hallucination, and dizziness.

Table 1: Patient Demographic and Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Evaluable Patients (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (M/F)</td>
<td>45/30</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>56.1 (13.9)</td>
</tr>
<tr>
<td>Pain etiology, n (%)</td>
<td>72 (96.0)</td>
</tr>
<tr>
<td>Pain severity (NPRS scores)</td>
<td>Median (min, max)</td>
</tr>
<tr>
<td>Duration of pain, y</td>
<td>Median (min, max)</td>
</tr>
<tr>
<td>Ever tried IT ziconotide, n (%)</td>
<td>63 (84.0)</td>
</tr>
<tr>
<td>Posters (%)</td>
<td>Neuropathic (48.0)</td>
</tr>
</tbody>
</table>

Table 2: Adverse Events Occurring in ≥10% of Patients

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No Change</th>
<th>Somewhat better</th>
<th>Better</th>
<th>Marked improvement</th>
<th>No change</th>
<th>Marked improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>19 (25.3)</td>
<td>3 (4.0)</td>
<td>1 (1.3)</td>
<td>1 (1.3)</td>
<td>3 (4.0)</td>
<td>3 (4.0)</td>
</tr>
<tr>
<td>Headache</td>
<td>11 (14.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>8 (10.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Memory Impairment</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Headache</td>
<td>11 (14.7)</td>
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<td>Memory Impairment</td>
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<td>Memory Impairment</td>
<td>1 (1.3)</td>
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<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

*This table includes adverse events that were coded using MedDRA (version 16.0) as of July 5, 2016.

Figure 1: Patient Global Impression of Change (Evaluable Population)

Figure 2: Time to Response on the Patient Global Impression of Change (Evaluable Population)

PRIZM = Patient Registry of Intrathecal Ziconotide Management; NPRS = Numeric Pain Rating Scale; SD = standard deviation.

REFERENCES

3. JAMA SUPPORT
## Background

Patient reported outcomes (PROs) are becoming increasingly important to determine the value delivered in patient care. PROMIS has been well validated in the spine literature. It assesses independent domains utilizing computer adaptive testing (CAT) and item-response theory (IRT), with outcomes reported as t-scores. Single-level and multilevel transforaminal epidural injections (TFESIs) have not previously been compared using PROMIS outcome measures.

## Objective

To compare single-level and multilevel TFESI outcomes utilizing the PROMIS domains: Physical Function, Pain Interference, and Depression.

## Methods

A single-center prospectively collected database was searched by CPT codes 64483 and 64484 to identify patients who underwent single-level or multilevel TFESIs respectively. Patients who had follow-up between 91-150 days since the date of their final injection were selected. The MCID was calculated for both single-level and multilevel injections for each PROMIS domain using the distributive method, defined as ½ the standard deviation of the change. The single-level (SL) and multilevel (ML) groups were then compared using PROMIS domain scores for Physical Function (PF), Pain Interference (PI), and Depression (D).

## Results

A total of 266 patients were identified (168 SL, 98 ML). There were 126 male (78 SL, 48 ML), 140 female (90 SL, 50 ML), p=0.688. The mean age (years) was 54.6 (SL), 58.1 (ML), p=0.066. The mean follow-up was 117 days (SL), 121 days (ML), p=0.076.

The baseline PROMIS scores were: PF 36.3 (SL), 37.5 (ML), p=0.111; PI 65.4 (SL), 64.5 (ML), p=0.244; D 52.3 (SL), 51.9 (ML), p=0.723. The change in PROMIS scores were: PF 0.8 (SL), 2.8 (ML), p=0.037; PI -2.4 (SL), -4.7 (ML), p=0.041; D -0.4 (SL), -2.3 (ML), p=0.061. The PROMIS MCID values were: PF 3.6 (SL), 3.8 (ML); PI -4.4 (SL), -4.0 (ML); D -4.2 (SL), -3.9 (ML). The percentage of patients who met MCID were: PF 25.0% (SL), 38.8% (ML), p=0.018; PI 34.5% (SL), 48.0% (ML), p=0.031; D 28.0% (SL), 30.6% (ML), p=0.647.

## Conclusion

At 3-5 month follow-up, multilevel TFESIs demonstrated significantly greater improvement in PROMIS Physical Function and Pain Interference domains compared to single-level injections. Additionally, multilevel injections had a greater proportion of patients who achieved MCID for both Physical Function and Pain Interference domains.

## Figures

- Figure 1. Comparison of mean change in PROMIS domain scores for single and multilevel TFESIs.
- Figure 2. Comparison of percentage of patients who met MCID by PROMIS domain for single and multilevel TFESIs.

## References

5. Singh JR, Cardozo E, Christelisa GC. The clinical efficacy for two-level transforaminal epidural steroid injections. PMR. Sept 2016. [Epub ahead of print].
Background

- Opiates are important for pain management during acute rehabilitation stays and have an effect on participation in therapy, but they are potentially overprescribed and have many adverse effects.
- Due to the increased use of opioids in our nation and the risks associated with opioid use, this study aims to decrease the opioid burden among patients admitted to Emory Rehab Hospital.

Methods

- Pre-intervention: We reviewed patients admitted to ERH in March-April 2016, and calculated the Morphine Equivalent Dose (MED) based on admission med reconciliation and again at discharge.
- The following interventions were done at the start of April, and we repeated the MED calculations in April-May 2016:
  - Informational lecture delivered to house staff/attendings how to use MEDs
  - Posted MED charts of common orders in clinical work areas
  - Pharmacist calculated MEDs weekly and emailed medical team to show weekly trends.
- The pharmacist calculated MEDs weekly and emailed medical team to show weekly trends.

Results

Demographics

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td>38</td>
<td>53</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td><strong>Age (SD)</strong></td>
<td>59.3 ± 16.2</td>
<td>59.6 ± 15.1</td>
</tr>
<tr>
<td><strong>LOS (SD)</strong></td>
<td>13.6 ± 6.1</td>
<td>11.9 ± 5.3</td>
</tr>
<tr>
<td><strong>BMI (SD)</strong></td>
<td>29.1 ± 8.9</td>
<td>27.5 ± 6.6</td>
</tr>
</tbody>
</table>

Admitting Diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stroke</strong></td>
<td>20</td>
<td>31</td>
</tr>
<tr>
<td><strong>Brain Injury</strong></td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td><strong>SCI</strong></td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td><strong>Amputation</strong></td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>Debility</strong></td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td><strong>Other Ortho</strong></td>
<td>11</td>
<td>7</td>
</tr>
</tbody>
</table>

Morphine Equivalent Dose

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Avg Admission MED</strong></td>
<td>32.6</td>
<td>41.2</td>
</tr>
<tr>
<td><strong>Avg Discharge MED</strong></td>
<td>26.7</td>
<td>29.6</td>
</tr>
<tr>
<td><strong>Change</strong></td>
<td>9.5</td>
<td>11.6</td>
</tr>
</tbody>
</table>

Summary and Conclusions

Opiate burdens can be significantly decreased in the acute rehabilitation setting by following the MED calculations throughout the length of stay and with periodic reminders from the pharmacist.

Given these results, we recommend the use of MED as a patient care tool.

Future directions could include implementing automatic MED calculations into the EMR, and utilizing MED in other clinical settings.

Thank you to ERH and Select Medical.
Establishing PROMIS Minimal Clinically Important Difference (MCID) Values after Single-level and Multilevel Transforaminal Epidural Steroid Injections

Nicole Strong DO, Benjamin Strong MD, Rajeev Patel MD, David Speach MD, John Orsini MD, David Mitten MD, Christopher DaSilva, Clifford Everett MD, MPH

University of Rochester Medical Center, Rochester, NY

Background

Patient reported outcomes (PROs) are becoming increasingly important to determine the value delivered in patient care. PROMIS has been well validated across the orthopaedic and spine literature. It assesses independent domains utilizing computer adaptive testing (CAT) and item-response theory (IRT), with outcomes reported as t-scores. There remains an absence of published minimal clinically important difference (MCID) values for use after interventional spine procedures.

Objective

To establish PROMIS MCID values for single-level and multilevel transforaminal epidural steroid injections (TFESIs) at 1-3, 3-5, and 5-7 month follow-up periods.

Methods

A single-center prospectively collected database was searched by CPT code 64483 “single level injection”. Patients with the additional CPT code 64484 “multilevel injection”, were then separated, which resulted in the two cohorts of: single-level only injections and multilevel injections. Patients were further subdivided into three groups: 30-90, 91-150, and 151-210 day follow-up since the date of their last injection. Baseline PROMIS scores: Physical Function (PF), Pain Interference (PI), Depression (D) were compared to PROMIS scores at final follow-up. The MCID was calculated for each PROMIS domain by the distributive method as 0.5 of the standard deviation of the change. The percentage of patients who achieved the MCID in each PROMIS domain was then calculated.

Results

<table>
<thead>
<tr>
<th>Group (mo)</th>
<th>Total Patients</th>
<th>Men</th>
<th>Women</th>
<th>Mean Age (years)</th>
<th>Mean Follow-up (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>161</td>
<td>82</td>
<td>79</td>
<td>58.6</td>
<td>60</td>
</tr>
<tr>
<td>3-5</td>
<td>98</td>
<td>48</td>
<td>50</td>
<td>58.1</td>
<td>121</td>
</tr>
<tr>
<td>5-7</td>
<td>45</td>
<td>27</td>
<td>18</td>
<td>55.2</td>
<td>179</td>
</tr>
</tbody>
</table>

Table 1: Baseline demographics for single-level TFESIs separated into groups by time of follow-up

<table>
<thead>
<tr>
<th>Group (mo)</th>
<th>Total Patients</th>
<th>Men</th>
<th>Women</th>
<th>Mean Age (years)</th>
<th>Mean Follow-up (days)</th>
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</thead>
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<td>5-7</td>
<td>45</td>
<td>27</td>
<td>18</td>
<td>55.2</td>
<td>179</td>
</tr>
</tbody>
</table>

Table 2: Baseline demographics for multilevel TFESIs separated into groups by time of follow-up

Conclusion

MCID values were calculated for PROMIS domains (PF, PI, D) following single-level and multilevel TFESIs at 1-3, 3-5, and 5-7 month follow-up. Combined results after TFESIs indicated the PROMIS MCID for Physical Function ranged between 3.6 and 4.2, Pain Interference between -3.7 and -4.4, Depression between -3.4 and -4.6. This analysis provides a benchmark to understand what is meaningful improvement when using PROMIS as a patient reported outcome measure following interventional spine procedures.

Resources

Management of Cerebrospinal Fluid Leak After Implantation of Dorsal Root Ganglion Stimulator
Kathryn J Flavin M.D., Zahidul Huq M.D., Dennis Patin, M.D.
Department of Anesthesiology, University of Miami Hospital/Jackson Memorial Hospital, Miami, FL

Introduction
Spinal cord stimulation (SCS) has been a treatment modality for chronic pain management since 1967. Neuromodulation has evolved significantly over the last 50 years in terms of targets, equipment, and therapy. During the last five years, the dorsal root ganglion (DRG) has emerged as a viable target.

DRG stimulation has become an effective treatment modality for chronic pain of areas that are difficult to cover with conventional SCS. As with any procedure, this therapy has unique risks and potential complications. Management of DRG related complications can be compared to those experienced during conventional SCS. Dural puncture and cerebrospinal fluid (CSF) leak are rare complications of SCS. The incidence and management of such complications in DRG stimulation is not well studied.

Case Presentation
A 56 year old woman presented with a 10 year history of neuropathic pain of bilateral lower extremities which was biopsy proven to be small fiber neuropathy. She had sub-optimal results with conservative therapy and expressed strong dislike for opioid medications. She had failed a course of epidural injections, underwent a successful trial of conventional SCS, and proceeded to permanent implantation. However, over the next year, she developed worsening pain of bilateral feet and was deemed an appropriate candidate for DRG stimulation. She underwent successful trial followed by permanent implantation of St. Jude Medical 4 contact leads at bilateral L4 and L5. In the recovery room she exhibited left foot weakness which was attributed to difficulty with lead placement in left L5 foramen. She was administered intravenous dexamethasone and was discharged without issue. On post-operative day three, the patient showed interval resolution of her weakness.

Then, nine days following implantation, she reported positional headache, generator site tenderness, and generator site swelling which fluctuated with position. She was advised to go to the emergency room where evaluation revealed a tense pocket. Oral antibiotics were initiated, blood cultures obtained, and sterile aspiration produced 80 mL of CSF. Two days later, she underwent epidural blood patch under fluoroscopic guidance with administration of 15 mL autologous blood which resulted in immediate relief of symptoms. She was advised to remain flat until her next follow up where she reported continued resolution of symptoms.

Epidural blood patch under fluoroscopic guidance:

Conclusion:
The technical aspects of the DRG stimulator implantation and management of complications parallel conventional SCS. Dural puncture and CSF leak is a known but infrequent complication of SCS implantation. In this patient, difficulty with placing leads during trial and permanent implantation with subsequent transient post-procedural motor weakness may have prompted greater suspicion for dural injury and CSF leak. Due to similarity in mechanisms of injury, it is not surprising that the patient responded to a epidural blood patch.

There is a fair amount of literature regarding management of this complication following SCS implantation, but there is a lack of such literature for DRG implantation. As DRG stimulation becomes more popular, there should be continued effort to track the incidence of complications and their respective management.

References:
Spinal Cord Stimulation (SCS) Trial Outcomes after Conversion to a Multiple Waveform SCS System

Nameer Haider1, Nathan Miller2, Christopher Gilmore3, Gregory Moore4, Rick Paicius5, Eduardo Garcia6, Kirk E. Harum7, Dwight Lingham8, Kristen Lechleiter9, Amarpreet Bains9, Roshini Jain9

BACKGROUND
SCS trial outcomes can have a significant effect on patients’ decision to proceed with permanent implantation. SCS trial failures can result sometimes from inadequate optimization of programming and/or lead placement. Enabling patients to experience multiple stimulation frequencies and waveforms using a single device (Multiple Waveform SCS) within a trial thus offers the potential for a more definitive identification of neurostimulative approaches optimally suited to each individual, which in turn may allow for better trial outcomes and successful permanent implantation. We therefore chose to investigate the effect of utilizing a system capable of providing multiple waveforms during a trial. We describe, here, the outcomes of an ongoing study of a cohort of patients who, after enduring a trial failure using a system designed to achieve pain relief with stimulation held constant at 10 kHz only, were switched to an SCS system capable of delivering multiple stimulation waveforms.

METHODS

Study Design
Multicenter, observational study

Study Device (Trial Neurostimulator):
Senza (Nervus Corporation):
- 10 kHz subperception
Precision Spectra (Boston Scientific):
- Anatomically-aided (3D) Neural Targeting algorithm
- Multiple Independent Current Control (MICC)
- Standard rate
- 1 kHz
- Anode intensification
- Burst stimulation
- Combinations of all the above

Available Programs/Waveforms

Sample size
N = 20 (14 with NRS or % pain relief scores)

Follow-up
SCS Trial Phase Only

Key Inclusion
Failed Trial Using Trial Neurostimulator at 10 kHz

RESULTS

Patient Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age (Range)</th>
<th>Baseline NRS [Mean (SD)]</th>
<th>Pain Location (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 (20)</td>
<td>33 - 81 yrs</td>
<td>8.00 (2.28)</td>
<td>Low back and Legs 50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low Back only (40%)</td>
</tr>
</tbody>
</table>

Previous Back Surgeries

<table>
<thead>
<tr>
<th>Number of Surgeries</th>
<th>Percent of Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>20%</td>
</tr>
<tr>
<td>1</td>
<td>40%</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>10%</td>
</tr>
</tbody>
</table>

50% of Patients Converted to Higher Pain Relief Categories

In 14 patients who failed an SCS trial using 10 kHz and had NRS or Percent Pain Relief (PPR) scores available, 50% (n = 7) reported ≥50% improvement in pain relief as measured by PPR using a Multiple Waveform SCS System (Fig. 1).

65% of Patients preferred Multiple Waveform SCS

Figure 1: Patient Outcomes following SCS trials (Percent Pain Relief)

Circles (○) represent 10 kHz trial outcomes. Arrowheads (Δ) represent Multiple Waveform SCS trial outcomes. Pain Percent Relief scores were available for n = 14 patients only.

Figure 2: Patient Preference (n = 20)

65% of Patients preferred Multiple Waveform SCS

CONCLUSIONS

- In 14 patients who failed an SCS trial using 10 kHz and had NRS or Percent Pain Relief (PPR) scores available, 50% (n = 7) reported ≥50% improvement in pain relief as measured by PPR using a Multiple Waveform SCS System (Fig. 1).
- Of the 6 patients where NRS or PPR scores were not available, 3 patients preferred Multiple Waveform SCS and 3 did not have a preference.
- Of all 20 patients in cohort, 65% (n=13) who failed a trial with 10 kHz stimulation preferred Multiple Waveform SCS (Fig. 2).
- These preliminary data support the concept that a system capable of multiple SCS waveforms offers the potential to salvage failed 10 kHz trials and achieve positive outcomes. Further study is needed.

*FBSS is counted as 1 surgery
Longitudinal Study of Pain Area Changes and Paresthesia Coverage in Neuropathic Pain Patients

Amarpreet Bains, Matthew McDonald, Sherry Lin

Boston Scientific Corporation, Valencia, CA USA

PROJECT FUNDING: BOSTON SCIENTIFIC

BACKGROUND

Spinal cord stimulation (SCS) often loses effectiveness in chronic pain treatment over time (Hayek et al., 2015; Kemler et al., 2006; Kumar et al., 1998; Sears et al., 2011). This may be partially driven by the appearance of new pain areas that are not covered by paresthesia. However, high-resolution assessment of pain area locations is limited by the fact that many different locations are often grouped in the same category. For instance, “low back pain” may refer to many different points or regions within the lower back. Here, we sought to quantify the extent to which pain patterns change over time at a fine resolution. In addition, as a metric of therapy effectiveness, we evaluated paresthesia coverage of these changing pain patterns.

METHODS

Study Design
- Multicenter, observational

Study Device
- Any commercially approved Boston SCS system

Sample Size
- 71 implanted patients from Baseline to 6 Months; 51 implanted patients from 6 to 12 Months

Number of Sites
- 72 sites

Follow Up Duration
- Up to 12 months after trial implant

Key Inclusion
- Pain in lower body (torso, back, or legs, including regions 15-23 or 36-47 in Figure 1)
- Additional pain could occur elsewhere

Study Assessments
- Pain drawings at Baseline, 6 and 12 Months, showing pain with stimulator off
- Paresthesia drawings at 6 and 12 Months
- Overlap of pain areas and pain freedom at Baseline to 6 Months and 6 to 12 Months

RESULTS

Appearance and Disappearance of Pain Over Time

Figure 2. a) Percent of pain pixels that disappeared from first to second time point. b) Percent of pain pixels at second time point that newly appeared since first time point. Left: Baseline to 6 Months. Right: 6 to 12 Months.

For 50% of patients at each follow-up time point, >24% of their pain was new since previous time point.

Figure 3. Change in number of discrete pain areas from Baseline to 6 Months (top) or 6 to 12 Months (bottom).

66.2% of patients showed a change in the number of pain areas from Baseline to 6 Months.

60.8% of patients showed a change in the number of pain areas from 6 to 12 Months.

Paresthesia Coverage of New Pain in Lower Body

Figure 5. Paresthesia coverage of new pain developed in the lower body by 6 Months (left) or 12 Months (right). Pain was assessed with stimulator off.

50% of patients had >64% coverage of new pain pixels in the lower body (indicated for SCS) at 6 or 12 Months

CONCLUSIONS

- Pain patterns change considerably over time after implantation of an SCS system
- Areas of pain change size over time; amount of new pain was not equal to amount of disappeared pain from either Baseline to 6 Months or 6 to 12 Months
- Additional pain could occur elsewhere
- Pain pixels at second time point were not equal to pain pixels at first time point
- Pain in lower body (low back or legs, including regions 15-23 or 36-47 in Figure 1)
- Pain patterns change considerably over time at a fine resolution. In addition, as a metric of therapy effectiveness, we evaluated paresthesia coverage of these changing pain patterns.

REFERENCES


Peripheral neuropathy is caused by damage to peripheral nerves, resulting in pain, numbness, and/or weakness. Damage may affect small (myelinated Aδ and unmyelinated C) fibers along with injury to large myelinated fibers. Traditional SCS has been used to treat pain from peripheral polyneuropathy with limited long-term success\(^1\). Patients describe paresthesia-elicited sensations as “annoying” and “irritating”.\(^4\) High frequency SCS (HF-SCS) at 10 kHz stimulation is a paresthesia-independent therapy that has demonstrated long-term safety and effectiveness in the treatment of chronic, intractable back and leg pain\(^6,7\). The goal of this prospective, multi-center study is to assess the safety and effectiveness of the Senza system in the treatment of chronic intractable pain from peripheral polyneuropathy.

Key Inclusion/Exclusion Criteria

- Inclusion: Subjects with chronic, intractable pain of \(\geq\) 5 cm (on a 0-10 cm visual analog scale [VAS]) of the upper or the lower limb from peripheral polyneuropathy
- Exclusion: Subjects with mononeuropathies, significant stenosis, epidural scarring or symptoms of myelopathy

Trial and Implant

- Subjects trialed with two epidural leads spanning C2-C6 or T8-T11 vertebral bodies for upper limb pain and lower limb pain, respectively (Figure 1).
- After successful trial stimulation (\(\geq\) 40% pain relief) implanted with a Senza system (Nevro Corp., Redwood City, CA).
- Primary safety and effectiveness endpoints (\(\geq\) 50% pain relief) at 3 months post-implant.
- Stimulation: 10 kHz, 30 µs, individualized current amplitude.

Statistics

- Data reported for 26 (Baseline) and 16 subjects (1 month).
- Mean ± standard deviation.
- Significance assessed at p<0.05.
- Permanent implant data reported.

Safety

- Three procedure-related AEs
- Implant site infection (1) and implant site extravasation (2)
- All AEs resolved.

Conclusions:

The trial-to-implant ratio of 84% is similar to, if not better than, the reported values in the literature (63%-82%)\(^1\)\(^-\)\(^3\). However, preliminary results for HF-SCS at 1 month follow-up demonstrate better outcomes than that reported with traditional SCS. Preliminary results from a multicenter, prospective study using high frequency spinal cord stimulation at 10 kHz to treat chronic intractable pain from peripheral polyneuropathy are promising with outcomes similar to SENZA-RCT results for chronic back and leg pain.

References: