Top 25 Posters

2019 ASIPP Abstract and Poster Winners

Physicians

First Place
Single Center Experience of MILD Procedure
– Navdeep Jassal

Second Place
Dural Puncture, Epidural Blood Patch, and Chronic Low Back Pain
– Ivan Urits

Third Place
Therapeutic Window for SCS using ECAPS (Evoke Study)
– Corey Hunter

Resident/Fellow Section

First Place
Socioeconomic Disparties in the Utilization of Spinal Cord Stimulator Implants in Chronic Pain Patients
– Mark Jones

Second Place
Dorsal Root Ganglion Stimulation as a Method to Treat Chronic Abdominal Pain
– Ajex Yang

Third Place
Spinal Cord Stimulation for Cancer-Related Pain
– Saiyun Hou

Single Center Experience of MILD Procedure Evaluating Opioid and Pain Reduction at Follow-up

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University of South Florida School of Medicine – Department of Neurology/Interventional Pain Medicine

Background

Lumbar spinal stenosis (LSS) patients suffering from neurogenic claudication are initially treated with conservative care which generally involves physical therapy, home exercise programs, epidural steroid injections (ESIs) and analgesics, including opioids. Once patients have failed conservative care, a next treatment option is the MILD procedure which provides minimally invasive lumbar decompression by removing small amounts of laminar bone and hypertrophic ligamentum flavum (HLF), thereby restoring space in the central canal. MILD has been shown to be safe and effective through long-term follow-up (1).

Objective

To evaluate pain relief and opioid reduction achieved by patients treated with MILD at a single center.

Methods

A retrospective chart review of consecutive patients treated with MILD at a single center was conducted to evaluate pain reduction. All patients were diagnosed with neurogenic claudication with HLF as a contributing factor. Patient demographics along with severity of LSS and three additional pre-identified presenting comorbidities were collected including facet hypertrophy, foraminal narrowing, and degenerative disc. Opioid use and patient reported Visual Analog Scale (VAS) were evaluated for change from baseline to follow-up.

Table 1: Baseline Clinical Data

CHARACTERISTIC	N = 33
AGE (YEARS)	77.9
GENDER	
Male	40% (13)
Female	60% (15)
CENTRAL STENOSIS SEVERITY	
Moderate	15.2% (5)
Moderate/Severe	42.4% (14)
Severe	42.4% (14)
COMORBIDITIES	
Hypertrophic ligamentum flavum	100% (33)
Facet hypertrophy	100% (33)
Foraminal stenosis	81.8% (27)
Degenerative Disc	100% (33)

Results

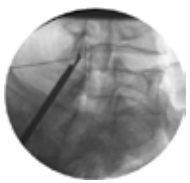
Thirty-three patients were treated with MILD at Florida Pain Medicine by Navdeep Singh Jassal, MD. These patients were treated consecutively between February 2018 and January 2019. All patients had previously failed conservative care including at least one ESI. Forty percent of patients were male, and age ranged from 66 to 91 with a mean of 77.9 years. All patients presented with HLF, facet hypertrophy and degenerative disc, and 82% presented with foraminal stenosis. All patients had moderate/severe central stenosis. (Table 1.) Twenty patients were treated at one level and 13 patients were treated at two levels. All patients were treated bilaterally at each treatment level. Average procedure time was 25 minutes for one level and 45 minutes for two levels. There were no device or procedure-related adverse events reported. Follow-up ranged from three to six months post MILD treatment, with follow-up monthly. Six-month follow-up was available for 20 patients. This patient cohort reported an average 64% reduction in opioid use and a 72% improvement in VAS following treatment with the MILD procedure. To date, 28 patients have received no subsequent interventions, 4 received ESI and one received RF Ablation, however these therapies were not intended for treatment of neurogenic claudication symptoms.

1Staats PS, Chafin TB, Golovac S, Kim CK, Li S, Richardson WB, Vallejo R, Wahezi SE, Washabaugh EP 3rd, Benyamin RM, for the MIDAS ENCORE Investigators. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MIDAS ENCORE. *Reg Anesth Pain Med*. 2018;43:789–794.

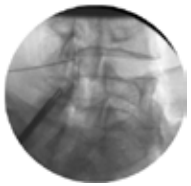
Conclusion

A single-center retrospective chart review of 33 patients treated with MILD demonstrated significant pain relief related to both opioid reduction, as well as VAS. These patients presented with moderate to severe central stenosis, and multiple spinal comorbidities. The results for this patient group are in line with prior reports of the safety and efficacy of MILD for treatment of LSS patients with multiple spinal comorbidities suffering from symptoms of neurogenic claudication (1).

It is important to note that all patients received at least one ESI prior to MILD and experienced either short term relief, or no relief at all from the ESI treatment. The treatment algorithm for neurogenic claudication patients is under evaluation at our institution to potentially include the use of ESIs only for (i) patients requiring epidurogram diagnostic evaluation, or (ii) patients also suffering from radicular pain. Otherwise, appropriate neurogenic claudication patients with HLF and multiple other spinal comorbidities will be treated with MILD following conservative care that does not include the use of ESIs.



Small portions of laminar bone removed using a bone rongeur



Hypertrophic ligamentum flavum de-bulked using a tissue sculpter

MODULATION OF THE NEUROGLIA INTERACTION USING DTM-SCS

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INTRODUCTION

Glia constitute the majority of cells in the spinal cord and play a vital role in regulation of synaptic transmission, neuron repair, and protection. Glia activation and potentiation are essential in development and maintenance of chronic neuropathic pain (NP). Glia responds to electrical stimuli, therefore is plausible to treat NP with spinal cord stimulation (SCS) using waveforms combined in a multiplexed manner to differentially target glia and neurons. This study evaluates the efficacy of differential-target multiplexed (DTM-SCS) approach in providing pain relief and compared it to low-rate (LR) SCS and high-rate (HR) SCS.

MATERIALS AND METHODS

Procedures were approved by the IACUC at Illinois Wesleyan University. Male Sprague-Dawley rats, implanted with a four-contact cylindrical mini-lead, received the spared nerve injury (SNI) NP model (n=10-13/group). DTM-SCS (proprietary signals), LR-SCS (50Hz, 150µs) or HR-SCS (1200Hz, 50µs) was applied continuously for 48h at 70% motor threshold. Naïve rats (n=9) were also evaluated. Pain behavior (mechanical and thermal hypersensitivity) was assessed before SNI, and before and after SCS. Spinal cord tissues adjacent to lead were subjected to RNA-sequencing. Weighted gene co-expression network analysis (WGCNA) and gene ontology enrichment analysis (GOEA) identified biological processes affected by SNI and SCS. Statistical analysis (SPSS) was performed. $p<0.05$ was considered significant.

RESULTS

DTM-SCS relieved mechanical hypersensitivity significantly better than HR-SCS and LR-SCS. DTM-SCS significantly relieved hypersensitivity to thermal stimuli, while neither HR-SCS nor LR-SCS reduced it significantly. WGCNA and GOEA indicate that SNI significantly affected expression of genes in biological processes such as regulation of immune system, ion transmembrane transport, and signal transduction. Although all SCS modalities modulated the expression of different genes towards levels in naïve animals, DTM-SCS modulated significantly more processes than HR-SCS and LR-SCS.

RESULTS (continued..)

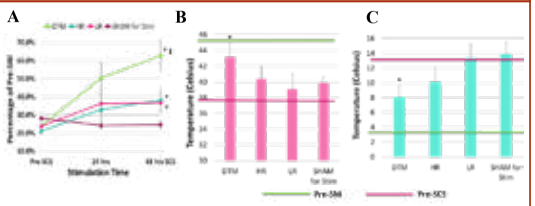

Figure 1. Mean mechanical withdrawal threshold (A) and mean thermal (hot (B) and cold (C)) threshold for DTM-SCS, LR-SCS, HR-SCS and Sham. * represents $p<0.05$ vs pre-SCS; ǂ represents $p<0.05$ vs LR-SCS and HR-SCS.

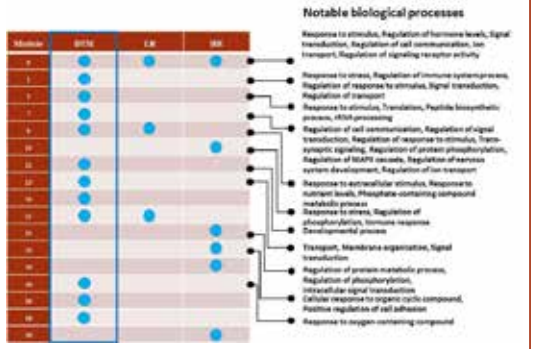

Figure 2. Relevant significantly enriched biological processes GOs for modules with expression patterns significantly affected by SNI (vs Naïve) and reversed significantly by SCS.

RESULTS (continued..)

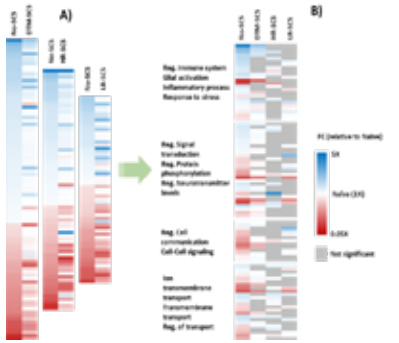

Figure 3. A) Heat maps illustrating the most significantly changed gene expressions due to injury (No-SCS) and the effect of treatments (DTM, HR, or LR) relative to gene expression in naïve animals. B) Heat map of genes regrouped in terms of involvement in relevant biological processes. Gray indicates therapy did not produce a significant change. White indicates that therapy modulated expression back to levels of naïve animals.

DISCUSSION AND CONCLUSION

DTM-SCS provided better relief of pain behavior than HR-SCS and LR-SCS. DTM-SCS significantly affected glial-mediated immune response, cell-to-cell communication, and neurotransmission that are central to homeostasis of neuroglial interaction, thus to chronic pain. DTM-SCS modulated expression of genes in these processes towards naïve levels more effectively than LR-SCS or HR-SCS.

In conclusion, clinical efficacy of DTM-SCS for pain relief may involve a mode of action in which the homeostasis of neuroglial interactions is normalized.

ACKNOWLEDGEMENT: The authors would like to thank Stimgenics LLC, Bloomington, Illinois, USA for funding.

Therapeutic Window for SCS Using ECAPs (Evoked Compound Action Potentials)

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Introduction

Spinal cord stimulation (SCS) is an established treatment for chronic pain; however, long-term success remains suboptimal [1,2]. Current SCS therapies are fixed-output and do not account for large variation in electrical field strength due to changes in distance between the electrode and spinal cord (SC) [3]. The data for this poster are reported from two prospective studies: Evoke and Avalon.

Materials & Methods

In Avalon, 50 subjects were implanted and programmed in closed-loop; in Evoke, 134 subjects were randomized into open-loop (OL-SCS) or closed-loop (CL-SCS). ECAPs, a measure of SC activation, are recorded following each stimulation pulse in both groups (Figure 1). Each subject's therapeutic window (TW) is determined individually as the ECAP amplitude range between sensation perception threshold and discomfort (Figure 2). Without a measure of SC activation (eg, ECAPs), TW can only be based on perception of intensity; however, stimulation can produce variable SC activation (ECAP amplitude) as the electrode to SC distance varies, e.g. with changes in posture (Figure 2).

Results

In the Evoke Study, each subjects' TW was determined in the clinic, along with the clinician prescribed level. There was no statistical difference between the two groups' TWs (Figure 3); however, CL-SCS subjects spent significantly more time in the TW despite having equivalent therapeutic ranges (Figure 4). Long-term data, from the Avalon Study, showed a similar percentage of stimuli in the TW (83%-97%; Figure 5).

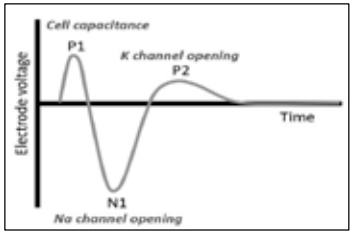

Figure 1: Schematic representation of an ECAP. ECAPs have a well-defined shape with 3 peaks: 2 positive and 1 negative, labelled P1, N1, and P2, in order of appearance. The first P1 peak stems from capacitive coupling between the inside and outside of the fibers. The N1 and P2 peaks result from ionic flow (sodium [Na+] and potassium [K+]) in and out of the fibers that form the well-known compound action potential.

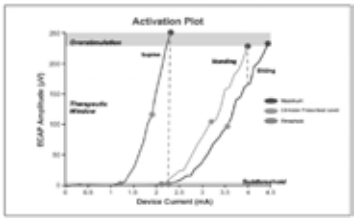

Figure 2: SC activation plots taken from a single Evoke Study patient. This shows variation in activation based on output current (mA) in 3 different postures.

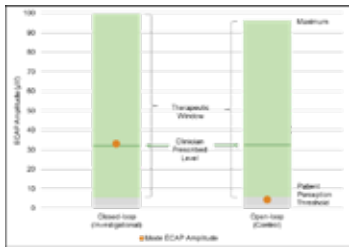

Figure 3: SC activation plot from the total cohort in the Evoke Study. Both cohorts have equivalent TW but OL-SCS runs the device closer to threshold and the CL-SCS group runs it near the in-clinic level.

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

CAUTION - The Evoke™SCS system is an investigational device. Limited by United States law to investigational use.

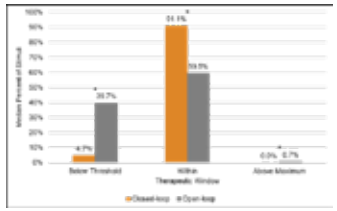

Figure 4: Comparison of CL-SCS (investigational) and OL-SCS (control) in the Evoke Study at 3 months.

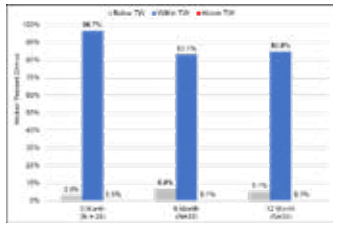

Figure 5: Median percent stimuli below, within, and above the TW from the 3-month to 12-month visits in the Avalon study.

Discussion & Conclusions

TW can be individually defined by ECAP amplitudes (measure of SC activation), removing the need to rely on subjective reports of intensity, which can vary over time and with movement.

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Socioeconomic disparities in the utilization of Spinal Cord Stimulator Implants in chronic pain patients.

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INTRODUCTION

- Pain has economic, health, social, psychological, and quality of life implications.
- Ethnicity and socioeconomic status (SES) have been shown to significantly impact the level of treatment of an individual's pain. Racial minorities have been shown to experience greater burdens of pain due to undertreatment.
- Physicians may contribute to these disparities due to limited self-awareness, cultural beliefs, stigmas and stereotypes regarding minority groups or ethnic groups.

AIM OF STUDY

- This aim of this study was to investigate if health insurance or racial status disparities exists in the use of spinal cord stimulators for the treatment of FBSS and CRPS in the United States.

METHODS

- Chronic pain patients with a discharge diagnosis of FBSS and CRPS were identified with the National Inpatient Sample (NIS) database.
- Patients who had received SCS implants were identified using the International Classification of Diseases, Ninth and Tenth Revision procedure codes.
- Our primary outcome compared the rate of SCS utilization by race/ethnicity (White, Black, Hispanic, and Asian/Pacific Islander), income quartile, and insurance status (Medicare, Medicaid, self-pay, and private).
- Multivariate logistic regression was used to determine the variables associated with utilization of SCS implants. We adjusted for age, sex, charlson comorbidity index and median household income.

RESULTS

Table 1: Demographics for inpatients with FBSS and CRPS from 2011 to 2015

Variable	All Patients	Patients without SCS implant	Patient with SCS implant	t-statistic/ chi-square	P value
All Patients, n (%)	40,858	39,772 (97.3)	1,086 (2.7)		
Age, mean (SD) (year)	57.4 (14.4)	57.4 (14.4)	56.4 (15.1)	2.2	0.03
Age categories, n (%)					
<45	7,482 (18.3)	7,227 (96.6)	255 (3.4)	23.9	<0.001
45 – 64	20,057 (49.1)	19,584 (97.6)	473 (2.4)		
65 – 84	12,357 (30.3)	12,022 (97.3)	335 (2.7)		
> 84	958 (2.3)	936 (97.7)	22 (2.3)		
Female, n (%)	25,734 (63.0)	25,059 (97.4)	675 (2.6)	0.25	0.61
Income quartiles, n (%)*					
0 – 25	9,097 (22.7)	8,878 (97.6)	219 (2.4)	5.3	0.15
26 – 50	10,150 (25.3)	9,888(97.4)	262 (2.6)		
51 – 75	10,768 (26.8)	10,476 (97.3)	292 (2.7)		
76 – 100	10,120 (25.2)	9,824 (97.1)	296 (2.9)		
Charlson comorbidity index (CCI), mean (SD)	1.1 (1.5)	1.1 (1.5)	0.6 (1.0)	16.0	<0.001
Comorbidities, n (%)					
Acute Myocardial Infarction	2,257 (5.5)	2,213 (98.0)	44 (2.0)	4.6	0.031
Congestive Heart Failure	2,792 (6.8)	2,774 (99.4)	18 (0.6)	46.9	<0.001
Peripheral Vascular Disease	1,455 (3.6)	1,442 (99.1)	13 (0.9)	18.2	<0.001
Cerebrovascular Disease	1,724 (4.2)	1,706 (99.0)	18 (1.0)	18.1	<0.001
*COPD**	10,681 (26.1)	10,472 (98.0)	209 (2.0)	27.5	<0.001
Rheumatoid Disease	1,835 (4.5)	1,793 (97.7)	42 (2.3)	1.0	0.31
Diabetes	6,712 (16.4)	6,530 (97.3)	182 (2.7)	0.09	0.77
Diabetes with Complications	1,838 (4.5)	1,818 (98.9)	20 (1.1)	18.3	<0.001
Renal Disease	3,033 (7.4)	2,998 (98.9)	35 (1.1)	28.6	<0.001
Race, n (%)					
White	33,297 (86.3)	32,439 (97.4)	858 (2.6)	7.9	0.05
Black	2,900 (7.5)	2,812 (97.0)	88 (3.0)		
Hispanic	2,880 (5.4)	2,810 (96.6)	70 (3.4)		
Asian/Pacific Islander	315 (0.8)	310 (98.4)	5 (1.6)		
Insurance status, n (%)					
Medicare	22,761 (55.8)	22,212 (97.6)	549 (2.4)	72.5	<0.001
Medicaid	3,465 (8.5)	3,418 (98.6)	47 (1.4)		
Private	13,702 (33.6)	13,223 (96.5)	479 (3.5)		
Self-Pay	857 (2.1)	847 (98.8)	10 (1.2)		

* Median household income quartiles based on patient zip code.
a Bed size categorization using Agency for Healthcare Research and Quality methods based on number of hospital beds, hospital's location, and teaching status.
* COPD: Chronic Obstructive Pulmonary Disease

Table 2: Multivariable Logistic Regression of the association between Race and Insurance Status, and Spinal Cord Stimulator Implant from 2011 to 2015 controlling for age, sex, CCI* and median household income.

Independent Variables	Spinal Cord Stimulator Implant		
	OR	95 % CI	P - value
Race			
White (ref)	Ref	Ref	Ref
Black	1.41	1.12-1.77	0.003
Hispanic	1.41	1.10-1.81	0.007
Asian/Pacific Islander	0.65	0.27-1.57	0.34
Insurance status			
Medicare (ref)	Ref	Ref	Ref
Medicaid	0.50	0.36-0.70	<0.001
Private	1.24	1.08-1.43	0.003
Self-Pay	0.45	0.24-0.85	0.014
Age	1.00	0.99-1.00	0.84
Female	0.97	0.86-1.11	0.70
CCI*	0.73	0.69-0.78	<0.001
Income quartiles			
0 – 25 (ref)	Ref	Ref	Ref
26 – 50	1.07	0.88-1.30	0.488
51 – 75	1.11	0.92-1.34	0.272
76 – 100	1.12	0.93-1.35	0.244

* Charlson comorbidity index (CCI)

CONCLUSIONS

- Our study suggests that socioeconomic disparities exist in the utilization of spinal cord stimulators amongst hospitalized patients with CRPS and FBSS the United States.

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Thoracic and Upper Lumbar Dorsal Root Ganglion Stimulation Lead Migration and Anchoring Technique

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Abstract

Introduction
As most of the dorsal root ganglion neurostimulation (DRG-SCS) leads are placed in the lumbar spine to treat a variety of chronic pain syndromes, the accepted practice of securing the lead in the lumbar foramen is achieved by forming an 'S' tension loop with the lead inside the epidural space. Tension loop placement reduced the need for the placement of an anchor during permanent implant and a tunneled epidural catheter technique is often used to get the leads to the pocket rather than an incision and anchoring (1). This technique is optimal for less mobile segments of the lumbar spine however as utility of DRG SCS expands to upper lumbar/thoracic regions, concerns regarding migration of leads with a larger distance to travel to the generator and in more mobile parts of the lumbar spine have arisen.

Objective
To identify migration risk using certain implantation techniques of dorsal root ganglion stimulation at the upper lumbar and lower thoracic regions and to present our DRG-SCS lead anchoring technique to maximize the infrapedicular lead positional stability.

Results
Two recent papers for the placement of L2 DRG leads for low back pain showed lead migration in 4/12 and 4/15 implants (2,3). Our practice has recently performed two case series of 17 patients each, which had 31 separate patients (3 overlap); we experienced a total of 5 lead migrations out of 31 implants at the T12 level, all of which required revision (4). All migrations were found to be retrograde into the epidural space and one lead migrated out of the epidural space completely. Our implant technique was modified to make a midline incision with anchoring of the leads in the midline. Over 6 months (14 implants) no migrations have been noted as of yet with the anchoring technique. Of the total 13 migrations only one patient did not wish to have the stimulator revised.

Clinical Results

Figure 1. Example of DRG lead that pulled back into the pocket from the T12 epidural space in a 34 year old patient. All leads in the upper levels were found to have migrated back into the epidural space.

Figure 2.Initial implant technique used. Multiple S loops were placed and a tunneled epidural catheter technique was used to without anchors placed or a midline incision.

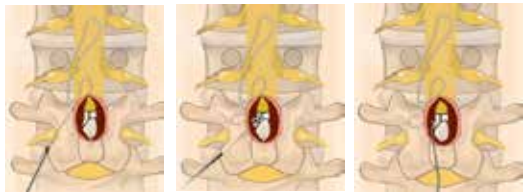
Study	Lead locations	Total leads	Total Implants	Migrations
Kallewaard et al. (2)	L2	30	15	4
Huygen et al. (3)	L2,L3	29	12	4
Chapman et al. (4)	T12, L1	52	17	3
Chapman/ Patel (unpublished)	T12,S1	42	14	2
TOTAL		152	58	13

Anchoring technique

A relevant migration rate was noted by both Kallewaard et al. (2,4) and our studies and implant techniques were subsequently modified. Multiple factors may play a role in causing migration including the distance travelled from the upper lumbar/lower thoracic spine to generator site, the rotational torque of the thoracolumbar junction, and the improved pain control and degree of disability in these patients leading to more activity.

Our group uses a 3 cm incision in the midline (right) after the leads were placed in the usual fashion using 'S' loops. After dissection to the fascia and hemostasis is obtained, the tuohy needle is taken back to the skin and the tuohy needle is advanced to drive the lead into the incision (Figure). Once the lead is in the incision, forceps are used to pull the free end of the lead through the tuohy needle and into the incision site. The tuohy needle is then removed. The Abbot DRG anchor is then placed around the lead and anchored to the fascia with 2.0 Ethibond sutures. This is repeated on the contralateral side if needed, and leads from the level above or below can be driven into the midline incision and anchored if needed. Tunneling to the pocket is performed in the usual fashion with the tunneling device.

The Kallewaard group now anchors leads using the traditional Abbot DC-SCS anchors with individual incisions at the lead site.



3-cm midline single incision approach:

Figure A. Incision made after leads and S loops placed. Dissection made to fascia.
Figure B. Tuohy needle used to drive lead to midline incision.
Figure C. Lead pulled into midline incision from pocket and anchor placed in pocket using Abbott DRG lead anchors.

Discussion

- DRG neurostimulation at the upper lumbar and lower thoracic spine is proving to be an effective therapy to reduce pain for RSD/CRPS as well as truncal pain syndromes including axial low back pain. An increased rate of migration, 13 out of 58 implants in leads between the T12-L3 levels, may be secondary to increased truncal mobility, longer distance from the epidural space lead entry to the pocket, an increase in function and disability leading to more activity, as well as other potential reasons. In our 31 patients, initially the same technique was used for all implantations, which included 'S' loops, no anchor or incision, and tunneled epidural catheter technique to tunnel leads to the pocket. After our first noted migration we changed the technique to using 'S' loops in the epidural space, making a small midline incision, driving the leads to the incision, and anchoring leads with anchors provided in the DRG lead kit (described). As our results are at 9 months thus far with zero migrations, it appears anchoring upper lumbar and lower thoracic DRG leads may be vital to decrease the odds of migration either using the described technique or a two incision technique over the lead puncture sites. The improvements in migration rates with anchoring are consistent with those found by the Kallewaard group.

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Spinal Cord Stimulation for Cancer-Related Pain

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

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Introduction

10% to 15% of patients with cancer-related pain fail to achieve acceptable pain relief with oral analgesics or in combination with alternative interventional pain procedure (1). Treatment of these intractable cancer-related pain syndrome can be challenging and difficult, placing a heavy burden on public health with related high expenditure. The compounding effects of pain and its treatment with other common cancer symptoms such as fatigue, weakness, dyspnea, constipation, nausea, and impaired cognition magnifies the negative effect of cancer pain. Spinal cord stimulation (SCS) has been recognized in non-cancer pain as having the potential for long-term effectiveness with minimal side effects observed clinically (2). Although the mechanism of cancer pain is not yet fully understood, altered peripheral nociception and central sensitization involving the level of spinal cord have critical roles in cancer pain. The objective of this study to evaluate the efficacy of SCS for the treatment of cancer related pain.

Methods

A numeric rating scale (NRS) was used for pain intensity, quality of life was evaluated using the Edmonton Symptom Assessment System (ESAS), and opioids consumption with morphine equivalent daily dose (MEDD) at baseline, visit 1 (within 2-3 month follow-up), visit 2 (within 4 to 6 months follow-up), visit 3 (within 7-9 months follow-up) and visit 4 (within 10-12 months follow-up). The adverse events were recorded. The inclusion criteria were cancer related pain (including metastatic disease), cancer treatment induced pain, poor pain control or intolerable side effects with opioid therapy, and ≥4 on a numeric rating scale (NRS) of pain that ranged from 0 to 10. (Fig 1). In addition, the following demographic, clinical variables were recorded for analysis: age, sex, psychiatric comorbidities, smoking history, cancer pain type including primary cancer pain, and surgery related pain, chemoradiation therapy induced pain.

Each patient underwent a successful trial for 5-7 days in duration of percutaneous placement of two 8 electrode epidural leads after passing a psychological evaluation for an implantable device. During the SCS trial, all the patients reported greater than 50% improvement in pain. Two to four weeks later, the patients underwent implantation with permanent leads and implantable pulse generator. (Figure 2).

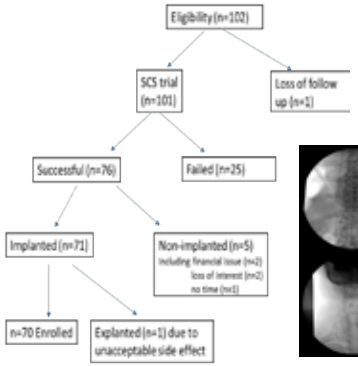

Figure 1. Subject flow chart (2000-2013)

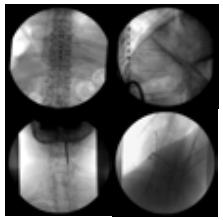

Figure 2. SCS implantation

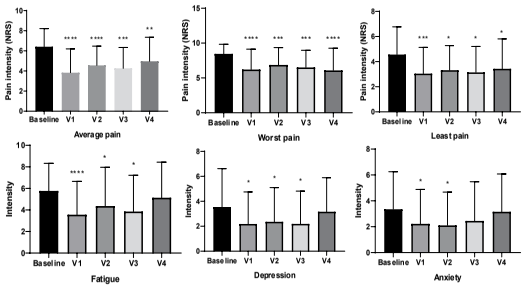

Figure 3

Results:

NRS average pain score significantly reduced from 6.4 to 3.8 at visit 1 ($p<0.0001$) then down to 4.6 at visit 2 ($p<0.0001$), 4.3 at visit 3 ($p<0.001$) and 5.0 at visit 4 ($p<0.01$). Similarly, worst pain reduced significantly from 8.5 to 6.2 at visit 1 ($p<0.0001$), then 6.9 at visit 2 ($p<0.001$), 6.5 at visit 3 ($p<0.001$) and 6.1 at visit 4 ($p<0.0001$). Least pain score significantly improved at visit 1 to 4 compared to the baseline. Fatigue score significantly decreased from 5.8 to 3.6 at visit 1 ($p<0.0001$), then up to 4.4 at visit 2 ($p<0.05$), and 3.9 at visit 3 ($p<0.05$). Depression, anxiety and fatigue score significantly improved at visit 1-3(Fig.3) Patients' age, gender, cancer pain type, psychiatric comorbidities were found not to be associated with the effectiveness of SCS. But patients with no h/o smoking, and high baseline pain score more likely had positive outcome at visit 1.There was a 22% decrease in opioids consumption in MEDD, though not statistically significant. Three patients had lead migration, three had infection, two developed loss of coverage, one had IPG allergy, and one had IPG pain. Overall adverse effects with SCS were mild and well-tolerated.

Discussion

Within the cancer microenvironment, cancer and immune cells produce and secrete mediators that activate and sensitize primary afferent nociceptors. Cancer pain is often regarded as a mixed pain mechanism (3) . It has been estimated that approximately 15% to 40% of chronic cancer pain has a neuropathic pain component, which responds well to SCS therapy (4). Effective SCS can significantly relief pain, reduce the need for increasing doses of systemic opioids and improve quality of life by reducing the opioid-induced side-effects. Therefore, the further prospective controlled study is warranted.

Conclusion

SCS can be effectively used for treating cancer-related pain, irrespective of patients' age, gender, cancer pain type and psychiatric comorbidities. But nonsmoking patients with high baseline pain score may improve treatment outcomes for SCS in short-term follow-up.

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Dural Puncture, Epidural Blood Patch, and Chronic Low Back Pain

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Background

Post dural puncture headache (PDPH) is a low cerebral spinal fluid (CSF) headache that is a relatively common complication in the setting of inadvertent dural puncture (DP) during epidural analgesia. PDPH is thought to be related to low intracranial pressure that leads to sagging of the brain, cerebral blood vessel dilation, and dural tension. Epidural blood patch (EBP) is the standard of care for PDPH recalcitrant to conservative measures.

Little research has been done to establish long-term effects and safety of DP or EBP. The aim of this study is to examine the association of chronic low back pain in patients who experienced a PDPH following labor analgesia and were treated with an EBP.

Methods

This case-control study was approved by the hospital institutional review board (Committee on Clinical Investigations). Hospital ICD-9-CM procedure codes were queried to identify patients who underwent labor epidural analgesia at Beth Israel Deaconess Medical Center (BIDMC) during the period extending from January 1, 2003 to December 31, 2013. Cases were defined as patients who underwent these procedures and underwent a subsequent epidural blood patch (EBP). Once these cases were identified, a matched control group was created using the following variables: index procedure, age at the time of intervention (+/- 10 years), and date of intervention occurring (+/- 6 months). Thus, the two groups were matched in all attributes but only one group had an inadvertent dural puncture requiring an epidural blood patch.

The patients were then contacted privately via telephone and invited to participate in a survey after informed consent. The telephone interview consisted of a series of questions pertaining to low back pain. The primary outcome was chronic low back pain (LBP), defined as lasting greater than 6 months in duration. Secondary outcomes included low back pain lasting fewer than 6 months (LBP<6), LBP frequency, LBP intensity, and LBP quality, effects of LBP on activities of daily living, treatments sought for LBP, and a history of diagnostic MRI for evaluation of the LBP.

Results

	EBP (N=74)	Non-EBP (N=72)	P Value
Sex (Female)	74 (100)	72 (100)	1.0
Race (Caucasian)	57 (77)	52 (72)	0.5
Mean age at spinal procedure (SD)	32.3 (4.3)	32.1 (4.2)	0.8
Mean years since spinal procedure (SD)	8.8 (3.0)	9.2 (3.2)	0.4
Preexisting LBP	7 (9)	2 (3)	0.2*

Table 1: Demographic summary of all patients who underwent an obstetric labor intervention ie; epidural for labor analgesia, spinal for cesarean delivery, combined spinal and epidural for labor analgesia, all N (%) unless otherwise noted, *Fisher's exact.

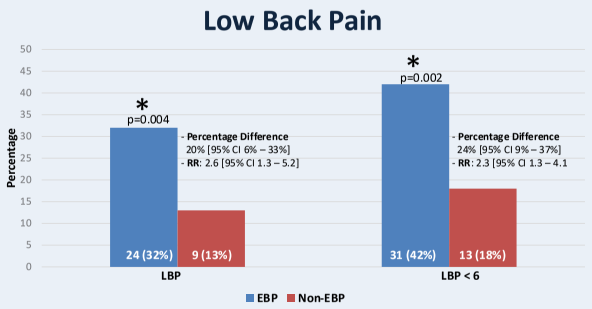

Table 2: Prevalence of low back pain in patients who underwent an obstetric labor intervention ie; epidural for labor analgesia, spinal for cesarean delivery, combined spinal and epidural for labor analgesia. Abbreviations: LBP < 6 - combined low back or low back and leg pain lasting less than 6 months; LBP - combined low back or low back and leg pain lasting greater than 6 months; * denotes statistical significance.

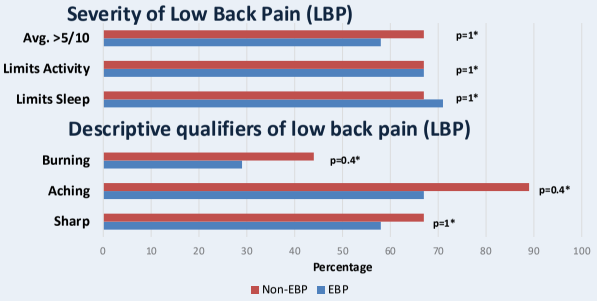

Table 3: Prevalence of pain severity markers in patients reporting low back or combined low back and leg pain lasting greater than 6 months. * denotes Fishers Exact.

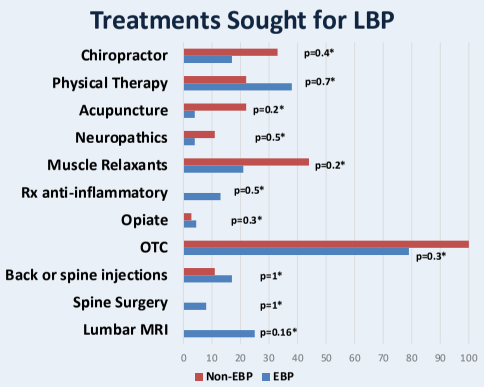

Table 4: Prevalence of treatments trialed by patients reporting low back or combined low back and leg pain lasting greater than 6 months (%) unless otherwise noted. * denotes Fishers Exact.

Limitations

Those inherent to a retrospective cohort study. Retrospective study design and limited patient data preclude a guarantee that both groups were adequately matched. Unmeasured variables may increase the risk for confounding. Small sample sizes used in the secondary-outcome analysis may have underpowered the respective results. The possibility of recall and attributional bias is increased . We are unable to make conclusions regarding causality of either DP or EBP and LBP independently.

Conclusion

Our findings suggest an association between DP, EBP, and subsequent LBP in parturients undergoing neuraxial analgesia. Though correlates have been drawn, a mechanism by which either DP or EBP may cause LBP remains unclear. Further long-term prospective studies are needed to confirm the findings of this study, to elucidate the relative risk of chronic LBP following DP or EBP, and to ascertain causality of LBP.

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Early Clinical Experience with a New Spinal Cord Stimulation Lead for Multi-Site Pain

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BACKGROUND

Chronic pain patients often report experiencing pain derived from multiple anatomical locations or dermatomes. Recent developments in Spinal Cord Stimulation (SCS) such as new neural targeting technologies and advancements in lead designs may be used to better treat patients with multi-site pain.

In this report, we present early clinical outcomes/experience using a newly available lead with a longer span covering over 3 vertebral levels and minimal spacing between electrodes (versus other traditional linear designs) used as part of an SCS system for treating chronic pain.

METHODS

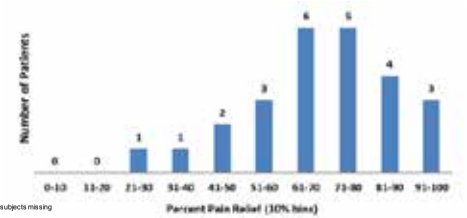
Study Design	Multicenter, Consecutive, Observational, Case-series (n = 32)
Study Device	Multiple Waveform SCS system (Precision and Precision Spectra, Boston Scientific) with following capabilities: • 16-contact lead with 1 mm spacing between electrodes (Infinion CX, Boston Scientific) • Multiple Independent Current Control (MICC) • Anatomically-Guided (3D) Neural Targeting (Precision Spectra) • Multiple available waveforms and/or field shapes
Follow-up Duration	67.1 (89.4) days post-implant [Mean (SD)]
Key Inclusion	Real-World Chronic Pain Patient Cohort

RESULTS

Baseline Demographics (n = 32)

Gender - Females (%)	50% (15/30)
Age [Mean (SD)]	59.2 (11.9) yrs. n = 31
Pain Location (n = 32)	Back and Leg(s) – 56.2%
	Lower Limb(s) – 25%
Baseline NRS [Mean (SD)]	8.3 (1.7) n = 32
Follow-up duration [Mean (SD)]	67.1 (89.4) days post-implant, n = 32

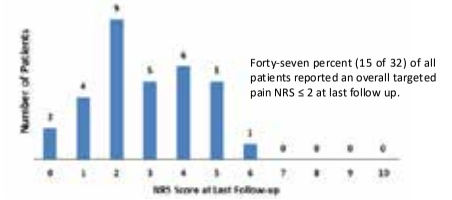
Distribution of Percent Pain Relief at Last Follow-up (n = 26*)



*6 subjects missing

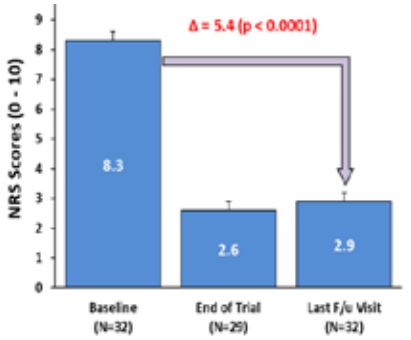
- Fifty percent (13 of 26) of patients reported 71 - 100% improvement in overall pain at last follow-up
- Eighty-five percent (22 of 26) of patients reported greater than 50% improvement at last follow-up

Distribution of Overall Pain Scores at Last Follow-up (n = 32)



Forty-seven percent (15 of 32) of all patients reported an overall targeted pain NRS ≤ 2 at last follow up.

Change in Overall Pain Scores (NRS) at Last Follow up (n = 32)



A statistically significant improvement in overall pain (8.3→2.9) was reported at last follow up (5.4 point improvement, p < 0.0001).

CONCLUSIONS

- A 16-electrode lead with minimal contact spacing and longer vertebral span offers the possibility to improve patient outcomes, target multiple sites of pain, and mitigate the loss of analgesia or need for revision due to lead migration.
- In this small, multicenter, real-world cohort of 32 patients with chronic pain, a statistically significant improvement in overall pain (p < 0.0001) was reported at last follow-up (mean = 67 days post-implant).
  – A similar trend observed in subset (n=9) who completed 3-month visit
- 85% of patients reported >50% improvement at last follow-up

EFFECT OF SCS WAVEFORMS ON PAIN BEHAVIOR AND GENE EXPRESSION

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INTRODUCTION

Spinal cord stimulation (SCS) has emerged as an alternative to address the increased prevalence of chronic pain and mitigate the impact of opioid crisis. Its exact mechanism of action is unclear. This study investigates the effects of phase polarity and recharge balance on behavior and gene expression, to elucidate the mechanism by which variable waveforms induce analgesic effects in a neuropathic pain rat model. We hypothesized that differing waveforms will result in diverse behavioral and transcriptomics expression due to unique mechanisms of action.

MATERIALS AND METHODS

Rats were implanted with a four-contact cylindrical mini-lead and randomly assigned to two control (no-pain and pain model) and five test groups featuring monophasic, as well as charge-unbalanced and charge-balanced biphasic SCS waveforms. Mechanical and cold allodynia were assessed to measure efficacy. The ipsilateral dorsal quadrant of spinal cord adjacent to the lead was harvested post-stimulation and processed to determine gene expression via Real-Time Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR). Gene expression, SCS intensity (mA), and behavioral score as percent of baseline (BSPB) were statistically analyzed and used to generate correlograms using R-Studio. Statistical analysis was performed using SPSS22.0 and $p<0.05$ was considered significant.

RESULTS

As expected, BSPB was significantly lower for the pain model group compared to the no-pain group. BSPB was significantly improved post-stim compared to pre-stim using Cathodic, Anodic, Symmetric Biphasic or Asymmetric Biphasic 1:2 waveforms, however, BSPB was not restored to Sham levels (Figure 1). RT-PCR analysis showed that eight genes demonstrated a significant difference between the pain model and SCS waveforms, and between waveforms (Table 1). Anodic content correlates with fold change for some genes (Figure 2). Correlograms reveal a linear correlation between regulation of expression of a given gene in relation to mA, BSPB, or other genes (Figure 3).

RESULTS (continued..)

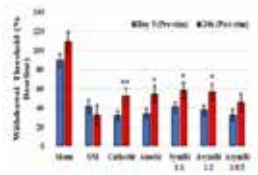

Figure 1. Behavioral response to injury and subsequent SCS. Means ± SEM of BSBP values at day 5 (blue bars) and after 24h SCS (red bars). Data demonstrated a significant difference between Day 5 (pre-stim) and 24h (post-stim). *, represents $p<0.05$ and **, represents $p<0.01$.

	Cathodic	AsymBi 1:0.5	SymBi 1:1	AsymBi 1:2	Anodic
Aif1	0.85	0.62	0.45*#	0.45*#	0.38*#
Bag3	0.68	0.84	0.59	0.69	0.76
Cd68	0.87	0.62	0.49	0.61	0.40
Cd74	0.82	0.51	0.39*	0.50*	0.36*#
C1qb	0.87	0.61	0.33*#	0.42	0.30*#
Calb1	0.90	0.64	0.94	0.95	1.02
Cxcl16	0.76	0.5*	0.45*	0.52	0.44*#
Gabbr1	0.88	0.96	0.88	0.87	0.76
Gfap	1.06	0.97	0.67	0.67	0.71
Gs	0.78	0.84	0.66	0.71	0.75
Hmox1	0.72	0.57	0.39	0.48	0.49
Mt2a	1.23	0.92	0.43#	0.47#	0.57#
S100a4	0.79	0.68	0.56	0.66	0.40
Slc7a11	0.87	0.85	0.73	0.72	0.71
Tspo	0.48*	0.46*	0.29*	0.30*	0.27*
Il1β	0.68	0.52	0.31	0.41	0.34
Il10	1.49	1.57	1.12	1.24	1.38
Il6r	0.55	0.55	0.39	0.43	0.33
Nadsyn1	0.69	0.71	0.54*	0.70	0.60*
Timp1	0.64	0.48	0.27*#	0.43	0.28*#
Txn2	0.85	0.97	0.79	0.85	0.70

Table 1. RT qPCR gene expression represented as average fold change from SNI levels. Anodic content in the waveform increases from left to right. $p<0.05$ was considered significant. * represents significance vs SNI, and # represents significance vs Cathodic.

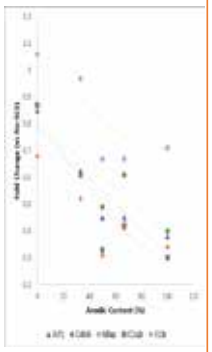

Figure 2. Linear correlations between the anodic content of the waveform and gene expression.

RESULTS (continued..)

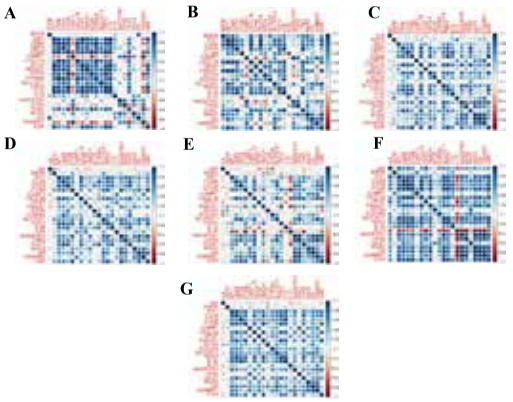

Figure 3. Correlograms illustrating relationships between gene expression, SCS Current (mA), and Behavioral Score as % of Baseline (BSPB). A: Sham, B: No-SCS (SNI), C: biphasic symmetric SCS, D: monophasic cathodic SCS, E: monophasic anodic SCS, F: asymmetric biphasic SCS 1:2, G: asymmetric biphasic 1:0.5.

CONCLUSION

Our results exhibit that specific SCS waveforms differentially modulate several key transcriptional pathways that are relevant in chronic pain conditions. These results have significant implications for SCS: whether to move beyond traditional paradigm of neuronal activation to focus also on modulating immune-driven processes.

ACKNOWLEDGEMENT: The authors would like to thank Millennium Pain Center, Bloomington, Illinois, USA for the funding.

Platelet Rich Plasma for the Treatment of Low Back Pain

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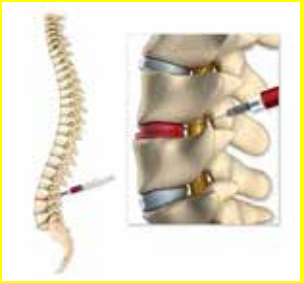
Background:
Back pain is a growing problem worldwide, incurring enormous economic costs and disability. The global prevalence of low back pain is 9.4%, and prevalence within the United States is as high as 13.1%. Expenditures associated with spinal surgery reached $34 billion in 2008, nearly an eight-fold increase from the costs ten years prior. Patients with chronic pain often limit their social contacts and leisure activities; moreover, have a three to four time greater risk of developing depression than the average population. The etiology of low back pain is unidentifiable in nearly 85% of instances. Known causes however include structural injury or malformations of ligaments, vertebral periosteum, facet joints, blood vessels, spinal nerve roots, and other structures. Spinal stenosis is the narrowing of the central spinal canal or the lateral recesses and is a common cause of back pain. Neuroforaminal stenosis is also possible and involves the narrowing of the opening in the spinal column through which the spinal nerves exit. Symptoms can also stem from aberrant neurologic pain, which results in neuropathic low back pain. Nociceptors are activated when inflammatory mediators are released at the original injury site and allow for transmission of afferent signals to the spinal cord and initiation of neurogenic inflammation, which results in peripheral sensitization. Typically, nociception results in pain perception however in certain instances they can occur independently such as in traumas. Aberrant functioning of these processes can result in abnormal perception of pain.

Methods:
Regenerative cellular modalities aim to restore anatomical function in degenerative conditions which may cause low back pain. Platelet rich plasma (PRP) consists of an increased concentration of autologous platelets suspended in a small amount of plasma. PRP can be administered via injection or topically and is prepared using various techniques. We used recent PubMed publications to gather evidence supporting PRP treatment in chronic pain states.

Results:
While a unifying mechanism of action is not well understood, biochemical and cellular changes involved in inflammation and mechanical structure have been detected in both *in vitro* and *in vivo* studies. At a higher level, PRP injection research utilizing animal models and patient data have provided insights into pain relief, chondroprotection, and factors that impact the therapy's efficacy. Recently, a small number of studies have promoted PRP injection as a relatively safe means of treating patients with degenerative disc disease who have failed other means of managing their lower back pain. A small number of prospective trials have suggested there may be some benefit to using PRP injection in the treatment of pain or functional decline caused by facet joint arthropathy. Facet Joint Syndrome (FJS) is a frequent cause of LBP and results from damage to the joint leading to osteoarthritis. A small number of prospective trials have been published recently which suggest there may be some benefit to using PRP injection in the treatment of pain or functional decline caused by FJS. Wu et al. assessed the efficacy of PRP injections in the treatment of back pain with clinical signs of FJS and imaging indicative of degenerative changes in facet joints. PRP was administered by intra-articular injection into facet joint under fluoroscopy. VAS showed continued decrease at 3-month follow-up. In 2017, Singla et al. released the results of an RCT comparing steroid injections to PRP injections for SIJ pain with promising short-term results. Forty patients diagnosed with SIJ pathology on x-ray, MRI, or nuclear scan with 3 or more provocative tests were randomized into either steroid or PRP groups. The steroid group received an ultrasound-guided intraarticular injection of methylprednisolone while the PRP group received an ultrasound-guided injection of autologous, filtered (leukocyte-free) PRP. At 6-weeks and the 3-months, the PRP group had significantly more improvement in VAS, MODQ, and both the physical and mental health component scores of the SF-12. The most notable difference was at 3 months, at which point 25% of patients in the steroid group reported being pain-free as compared to 90% of patients in the PRP group.

Conclusion:
Despite considerable advances in recent decades, low back pain remains highly prevalent and difficult to treat. Platelet rich plasma may be a safe and effective therapy for patients with chronic low back pains secondary to degenerative conditions of the spine and low back. Limited small studies have demonstrated PRP to be beneficial in application to degenerative disc disease, sacroiliac joint related pain, and facet joint arthropathy. Further large clinical trials are required however to better assess safety and efficacy of this treatment in the future.



References(image): https://www.globenewswire.com/news-release/2017/04/05/954805/0/en/Platelet-Rich-Plasma-PRP-Therapy-Offers-Pain-Relief-for-Low-Back-Pain.html

10 kHz SCS for the Treatment of Chronic Pain of the Upper Extremities : A Post-Market Observational Study

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Introduction

Chronic upper extremity pain (UEP) has complex etiologies and is often disabling. Low-frequency spinal cord stimulation (SCS) offers only limited symptom relief and the variability in sensory paresthesia with movement of upper extremities compromises the performance. In contrast, high frequency SCS (HF-SCS) at 10 kHz provides pain relief without any paresthesia and has demonstrated superiority over traditional SCS for the treatment of back and leg pain[1,2]. The objective of this prospective, multi-center, post-market observational study was to gain additional safety and effectiveness data of HF-SCS at 10 kHz for the treatment of chronic UEP.

Methods

Main Inclusion Criteria:

- UEP related to cervical spine and/or of neuropathic origin refractory to conservative therapy for at least 3 months
- Appropriate candidate for surgical procedures
- Stable Neurological status and pain medication

Major Exclusion Criteria:

- Pain in other areas (e.g. fibromyalgia, chronic headache)
- Mechanical spine instability and significant cervical stenosis

Subjects' effectiveness outcomes and safety were assessed for 12 months.

Primary endpoint:

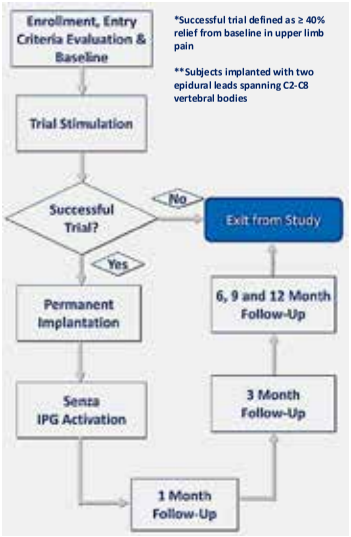
- Responder rate (Percentage of subjects experiencing ≥50% pain relief from baseline).

Secondary endpoints:

- Pain Disability Index (PDI), upper limb functioning (Disability of Arm, Shoulder and Hand; QuickDASH), Global Assessment of Functioning (GAF), sleep (PSQ3), subject satisfaction..

Results

Figure 1: Study flow diagram



A total of 42 subjects (27 Female, Median age: 47 [27-70]) with significant upper extremity pain (Visual analog scale [VAS] ≥ 5 cm at baseline) underwent a trial of SCS at 10 kHz at 6 centers (US-5; UK-1)

Main diagnoses at baseline were radiculopathy, spondylosis, and degenerative disc disease. All subjects had upper limb pain at baseline, while some had concomitant shoulder or neck pain.

Results (contd.)

Safety:

No neurological deficits.

5 additional surgeries (3 total system explant, 1 IPG repositioning, 1 lead explant only)

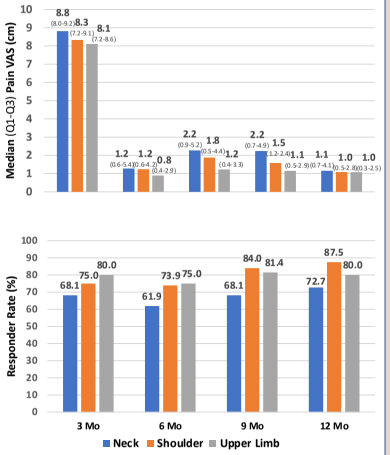
Study-related AEs (2 moderate, 6 mild): 6 procedure-related, and 2 stimulation/therapy.

Trial success: 38/42 (90.4% success rate)

Permanent implant: 33 (5 withdrew consent)

Summary of results at 12 months:

- VAS scores showed a meaningful decrease from baseline.
- Responder rates at 12 months for neck, shoulder, and upper limb pain were respectively 72.7%, 87.5%, and 80%.



Results (contd.)

- Reduction in disability and improvement in functioning and sleep was substantial.
- 86.6% of subjects were satisfied/very satisfied with 10 kHz SCS.

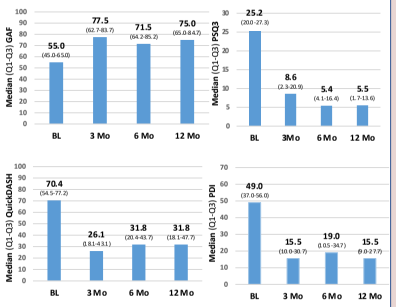


Figure 2: Assessments (BL through 12 months)

Conclusions

This study provides evidence that HF-SCS at 10 kHz produces sustained and substantial pain relief in subjects with chronic UEP. Moreover, clinically meaningful improvement in functioning and sleep, and decrease in disability were observed. These results thus validate that SCS at 10 kHz is an effective and paresthesia-free treatment for chronic intractable pain of the upper extremities.

References

1. Kapural L et al. Anesthesiology. 2015 Oct;123(4):851-60
2. Kapural L., et al. Neurosurgery. 2016 Nov;79(5):667-677

*-In the U.S, treatment of neck pain is investigational only and not on-label or indicated for use. However, as several UEP subjects presented with neck pain, this data was documented as an observational endpoint.

10 kHz-SCS therapy for chronic pain, effects on opioid usage: Post hoc analysis of data from two prospective studies

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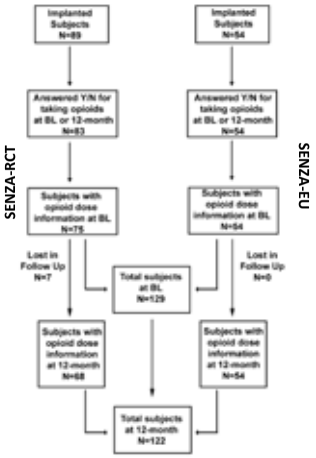
INTRODUCTION

Chronic pain, including chronic low back and leg pain are prominent causes of disability worldwide. While patient management aims to reduce pain and improve daily function, prescription of opioids remains widespread despite significant adverse effects and lack of efficacy for chronic pain. The aim of the study was to test the efficacy of 10 kHz spinal cord stimulation (10 kHz SCS) in reducing opioid dose in chronic low back pain and/or leg pain patients taking daily dose of >90 MME opioids.

METHODS

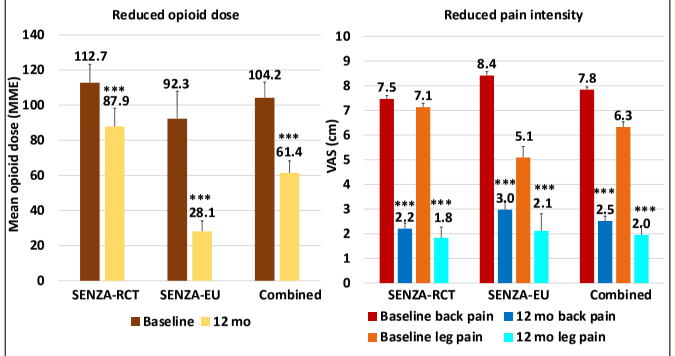
This study pooled data from two large prospective trials on 10 kHz SCS in subjects with chronic low back pain and/or leg pain and performed post hoc analysis on changes in opioid dosage 12 months post 10 kHz-SCS treatment [1,2]. Patient-reported back and leg pain using the visual analog scale (VAS) and opioid dose (milligrams morphine equivalent/day, MME/day) were compared at 12 months post-10 kHz-SCS therapy to baseline.

Flow chart of subjects included in the analysis

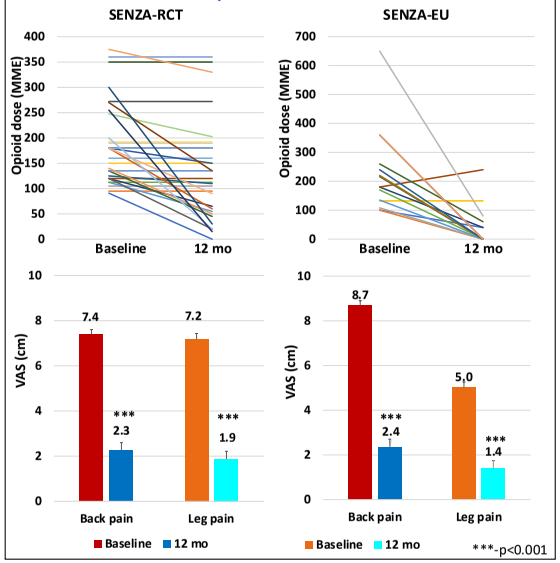


RESULTS

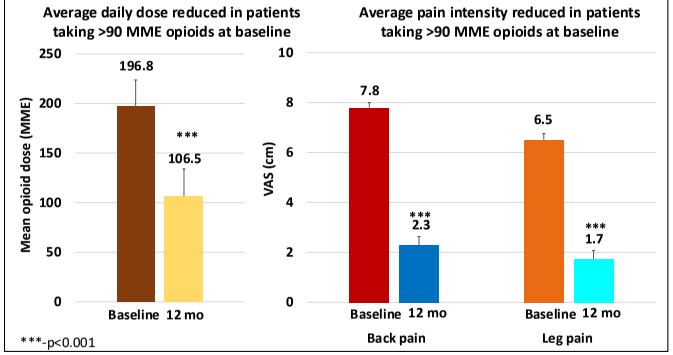
1. Reduction in opioid dose as well as pain intensity in both studies



2. Mean pain intensity reduced in subjects taking high (>90 MME) baseline opioid doses in both studies



3. Reduced dosage in subjects taking high (>90 MME) baseline opioid doses paralleled by reduced pain intensity in combined data set



CONCLUSIONS

Current analysis demonstrates the benefits of 10 kHz-SCS therapy and offers an evidence based, non-pharmaceutical alternative to opioid therapy and/or an adjunctive therapy to facilitate opioid dose reduction whilst delivering significant pain relief.

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A Case of Steroid Injection - Induced Hypokalemic Periodic Paralysis

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OBJECTIVE

We report a patient who presented to St. Vincent Hospital Emergency Department with bilateral upper and lower muscle weakness after receiving a Lidocaine-Betamethasone epidural injection for pain and was diagnosed with hypokalemic periodic paralysis.

INTRODUCTION

Hypokalemic periodic paralysis is a rare disease that presents with acute onset of transient muscle weakness. In addition to the autosomal dominant genetic form of hypokalemic periodic paralysis, it can be precipitated by stress, infection, glucose infusion, metabolic alkalosis, intrinsic renal diseases, medications and endocrine diseases. Although steroid injections have also been reported to induce hypokalemic periodic paralysis, there are rare cases published in the literature[1, 2]. Consent was obtained from patient.

HISTORY PRESENT ILLNESS

The patient was a 42-year-old female with past medical history of hypertension, cervical and lumbar radiculopathy presenting to the emergency department complaining of acute onset bilateral upper and lower extremity weakness. She was involved in a motor vehicle accident in the remote past and received a C 6-7 & L 4-5 epidural injection of 8 milligrams of Lidocaine - Betamethasone for pain management 24 hours prior to presentation. She was unable to move her arms or legs and was unable to void. She denied any numbness, tingling, saddle paresthesia, dizziness, fevers, chills, nausea or vomiting. Patient also denied any shortness of breath and had no trouble swallowing.

Nabih Diab Twitter

St. Vincent IM Twitter

St. Vincent IM Instagram

PHYSICAL EXAMINATION

The patient was alert and oriented to person, place and time. She appeared anxious. No skin abnormalities were seen. Pupils were Equal, Round, Reactive to Light and Accommodation. Chest was clear to auscultation. Cardiac examination revealed a regular rate and rhythm without any murmurs or gallops. Abdominal examination noted a non distended, non tender abdomen with no rebound tenderness or guarding. Low extremities pulses were strong bilaterally and there was no sign of edema. Her neurological exam revealed 1/5 muscle strength in the proximal and distal muscles of the upper and lower extremities. Sensory examination was normal. No Babinski sign was present. Reflexes were diminished. We were unable to assess the patient's gait. The remainder of her physical exam was unremarkable.

ADMISSION WORK-UP

Our patient's vital signs were within normal limits upon presentation. Complete blood count showed a leukocytosis of 14.9.Comprehensive metabolic panel revealed an abnormally low potassium level of 2.3 but a normal magnesium level of 2.4. Electrocardiogram showed sinus rhythm with T wave flattening. TSH level and Free T4 were within normal limits at 0.36 and 0.9 respectively. CPK level was within normal limits as well. Brain and Spine MRI was normal.

MANAGEMENT

Despite potassium repletion with 60 mEq oral and 80 mEq IV on admission day, patient's potassium dropped to 1.9. Over the next 24 hours, the patient received a total of 180 mEq of IV potassium and 50 mEq of oral potassium which increased the patient's potassium level to 4.1. Once the potassium level was corrected, the weakness resolved, and the patient went back to her baseline muscle strength. The patient was discharged home with instructions to follow-up with primary care and nephrology.

DISCUSSION

Patients with hypokalemic periodic paralysis generally have a family history of the disorder. Among the most common non-genetic causes for hypokalemia are diuretic use and GI losses from vomiting or diarrhea[3]. It can be also be precipitated by stress, infection, glucose infusion, metabolic alkalosis, intrinsic renal diseases and endocrine diseases. The prevalence of hypokalemia induced by steroid injections is extremely rare. The mechanism of hypokalemic periodic paralysis by steroid injection has not been clearly explained but it may be due to the Na–K pump in skeletal muscle or due to its insulin or glucose increasing effects[4]. In cases where the causes of hypokalemia are not evident, assessment of 24 hours renal potassium and creatinine excretion is advised. Urine potassium-creatinine ratio reflects renal potassium wasting. In our scenario, urine potassium-creatinine ratio wasn't a good indicator because such cases require immediate potassium repletion which will alter the results. Renal potassium wasting syndromes such as Bartter, Gettleman's or renal tubular acidosis will be investigated by outpatient nephrology.

CONCLUSION

Only a few cases of periodic hypokalemic paralysis induced by steroid injections have been reported in the literature therefore the importance of prompt treatment cannot be overstated. We recommend pain interventionists such as Interventional Radiologists, Anesthesiologists and Physical Medicine and Rehabilitation physicians to check for history of familial hypokalemic paralysis or episodes of hypokalemia and weakness status post steroid injection prior to performing these procedures.

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A Multicenter Real-World Review of 10 kHz SCS Outcomes for Treatment of Chronic Trunk and/or Limb Pain

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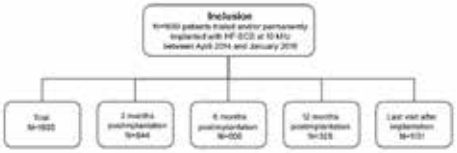
INTRODUCTION

High-frequency spinal cord stimulation (HF-SCS) at 10 kHz has proven to be efficacious in the treatment of chronic back and leg pain in a randomized, controlled, trial (SENZA-RCT)[1,2]. However, large observational studies have yet to be published. Therefore, we performed a real-world, multicenter, retrospective, review of therapy efficacy in 1,660 patients with chronic trunk and/or limb pain.

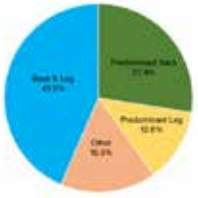
METHODS

Data were collected in a real-world environment and retrospectively sourced from a global database. Included patients were trialed and/or permanently implanted with HF-SCS at 10 kHz between April 2014 and January 2018. We evaluated responder rates at 3, 6, and 12 months post-implantation. Response was defined as ≥50% pain relief from baseline. A last visit analysis included responder rate along with overall change in function, sleep, quality of life, and medication intake versus baseline.

Patient Inclusion Flowchart

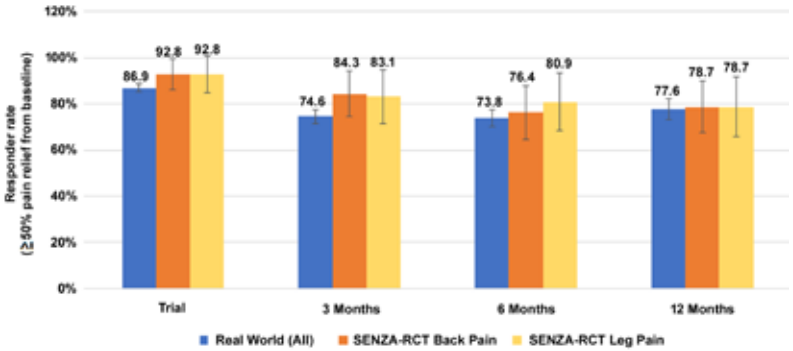


Patient Demographics by Pain



RESULTS

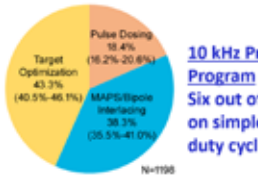
Responder Rates in SENZA-RCT & Real World Analysis (± 95% CI)



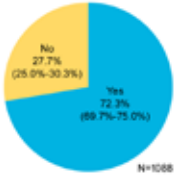
Low Real World Explant Rates

Reason for explant	n (%)
	N = 1,290
Infection	22 (1.7%)
Loss of efficacy	15 (1.2%)
Other reasons	11 (0.8%)
Total	48 (3.7%)

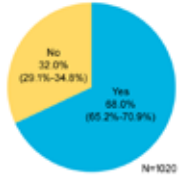
Improved Function and Sleep & Reduced Medication (± 95% CI)



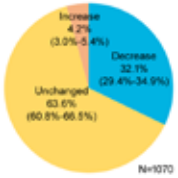
10 kHz Preferred Program
Six out of ten patients on simple bipole or duty cycling programs



Improvement in Function
Seven out of ten patients reported functional improvements



Sleep Improvement
Approximately seven out of ten patients reported sleep improvement



Medication Change
Three out of ten patients decreased medication usage

CONCLUSIONS

- Sustained and effective pain relief was experienced by >70% of HF-SCS at 10 kHz treated patients, consistent with the findings of a previously published randomized, controlled, trial.
- Our review provides complementary evidence to support the treatment of chronic back and leg pain with this therapy.

REFERENCES

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A Multimodal Approach to Pain Management for Patients with Chronic Back Pain

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Background:
Chronic non-cancer related back pain is often a frustrating and difficult problem to manage for many patients. In addition to the ubiquitous nature of pain in healthcare, total pain costs the United States are estimated to cost over $200 billion yearly. Due to the complex nature of pain and a shortage of specialists, pharmacologic treatment has been a controversial but mainstay treatment for many years. As a result chronic non-cancer related back pain poses a significant public health issue worsened by the widespread use of narcotics. Interdisciplinary or multimodal pain management strategies are becoming increasingly more common with some data suggesting a positive impact. The interdisciplinary pain management program at the VA hospital is a multimodal, coordinated approach to treating severe chronic back pain. The program accepts patients who have had pharmacological and nonpharmacological therapies and have experienced minimal relief. The intractable painful conditions are further complicated by coexisting mental health problems like depression, post-traumatic stress disorder (PTSD), traumatic brain injury, addiction, and opioid tolerance. This program has treatment regimen benefits from a multidisciplinary approach to chronic pain, based on a biopsychosocial model. This model implements a three-pronged tactic wherein the biological problems are treated using the conventional medical therapies along with psychological therapies as well as a look into the social factors that may be contributing to chronic non-cancer back pain.

Methods:
This prospective comparison study addressed the efficacy of a multimodal approach by an interdisciplinary pain management team at a VA hospital in the southeastern United States. The team consisted of a primary care provider, interventional pain management specialist, clinical psychologist, physical therapist, and a yoga instructor. A total of 32 adult patients (20 men, 12 women) between the ages of 28 to 69 years, taking opiates for chronic back pain for more than three-months in duration and after failed interventional pain management modalities were enrolled for the study. All patients agreed to enter an eight-week interdisciplinary pain program primarily consisting of interventional pain management, cognitive behavioral therapy, physical therapy, and yoga. All patients were evaluated before and after the eighth-week program and again approximately one year later. It should be noted that those who required continued interventional pain management continued visiting the pain clinic every 3-6 months. POQ-VA (Pain Outcomes Questionnaire for Veterans) score and a patient satisfaction survey (5 questions assessing overall satisfaction, staff kindness, staff skills, appointment ease, and if the patient would recommend program to others) were used to evaluate patient outcomes.

Results:
The results of this investigation suggest that enrolled patients benefitted from lower and sustained pain scores as well as generally high satisfaction with the interdisciplinary program. All POQ pain scores and satisfaction survey scores ranged from 0-10. The mean pain score prior to the eight-week program was 7.31 +/- 1.47, immediately after the eight-week program mean pain score was 4.7 +/- 2.33, and finally after one year mean pain score was 6.16 +/- 1.93. Using R-statistical software package, a student's t-test reveals a p-value of 0.008 for POQ pain score reduction immediately after the eight-week program. One year later, the mean POQ pain scores decreased from the baseline mean with a calculated p-value of 0.01. This data suggests at one year after the interdisciplinary program intervention, veterans with chronic pain experience sustained reduction in the perception of pain. A larger patient size may be needed to comment further on improved functionality per the POQ criteria. The mean overall satisfaction score given to the eight-week program was 7.28 out of 10. All 32 patients enrolled stated they would recommend the interdisciplinary program to a friend. Of note, the only component of the POQ survey to demonstrate statistical significance was the pain score. Furthermore, resource utilization was drastically reduced from 19 unscheduled visits prior the start of the eight-week program to only one unscheduled visit for chronic pain within one year after completion of the program.

Conclusion:
Although at our institution, accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF), patients with chronic pain who failed pharmacologic and interventional pain management are candidates for the interdisciplinary pain program. Initially a nurse administers the VA's POQ. These are a set of questions that translate to a score and a percentile. The percentile compares to the patient with the rest of the nation's VA population. The higher the score or the percentile, the higher the impairment. A downward trend is desirable and certain areas of impairment that are not improving are identified and approached. Goals are set at the beginning of the therapy and the patient is educated about realistic expectations. The POQ questionnaire demonstrated a significantly significant reduction in pain scores and a reduction in emergency room and urgent care clinic visits. Additionally patients demonstrated a high level of satisfaction with the interdisciplinary pain program versus traditional methods of pain management.

References(image): https://www.dailykos.com/stories/2019/1/17/1827087/-Do-you-have-chronic-back-pain-If-so-how-have-you-treated-it

A Prospective, Multi-Site, Clinical Trial of the High-frequency Spinal Cord Stimulation at 10 kHz (HF-SCS) System in the Treatment of Chronic Pelvic Pain

Jordan Tate, MD, MPH[1]; Thomas Stauss, MD[2]; Sean Li, MD[3]; Jeyakumar Subbaroyan PhD[4]

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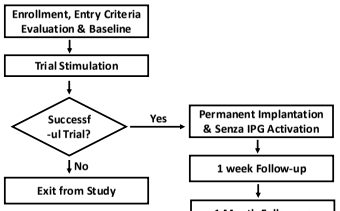
Introduction

Chronic pelvic pain (CPP) is known to disproportionately affect women and have multiple causes such as traumatic injury and post-surgical changes. Standard-of-care treatments often fail to resolve the pain, leaving CPP patients with long term disabilities. High-frequency SCS (HF-SCS) at 10 kHz has been previously shown to provide long-term relief for chronic low back and leg pain patients[1,2]. The objective of this study is to assess effectiveness of the HF-SCS at 10 kHz in the treatment of chronic intractable pelvic pain.

Methods

In this multicenter, prospective study, subjects clinically diagnosed with chronic pelvic pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) refractory to conservative therapy for ≥3 months were enrolled following IRB approval. Significant spinal stenosis, epidural scarring or symptoms of myelopathy and other progressive neurological diseases were causes for exclusion. Subjects were implanted with two epidural leads spanning appropriate vertebral bodies as determined by the location of pain and were implanted with a Senza system (Nevro Corp., Redwood City, CA) if they had successful trial stimulation (≥50% pain relief). Safety and effectiveness endpoints were captured up to 12 months post-implant. Interim 3-month results are presented as mean ± 95% CI in the permanent implant population.

STUDY FLOWCHART



REPRESENTATIVE X-RAY SHOWING LEAD PLACEMENT

Results

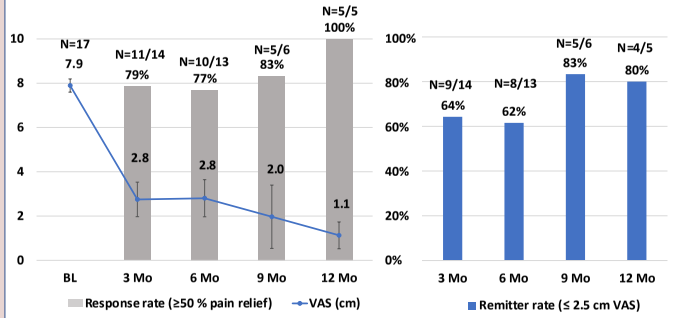
Patient characteristics

- Trialed: 21
  - Female: 19/21 (90%)
  - Median age: 49.3 years
- Trial success: 19/21 (90%)
- Etiology
  - Post Surgical complications: 11 (48%)
  - Pregnancy associated complications: 6 (26%)
  - Painful bladder syndrome: 6 (26%)

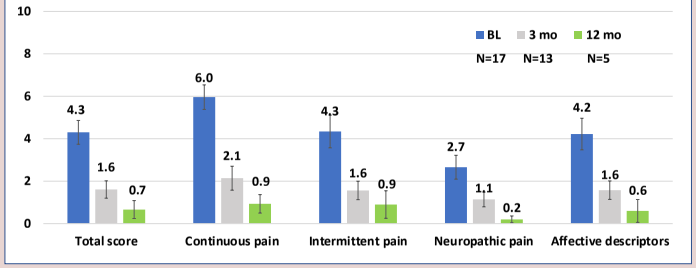
Safety

- No neurological deficits
- Six (6) device or procedure related adverse events (AEs)
- All AEs resolved without sequelae

SUSTAINED PAIN RELIEF, RESPONDER AND REMITTER RATES

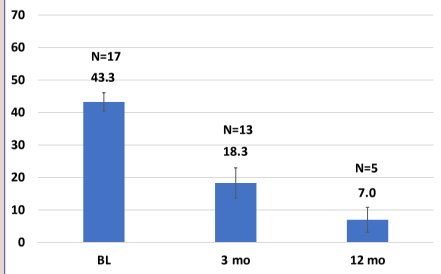


SUSTAINED REDUCTION IN ALL COMPONENTS OF PAIN INTERFERENCE (McGILL PAIN QUESTIONNAIRE, SF-MPQ-2)

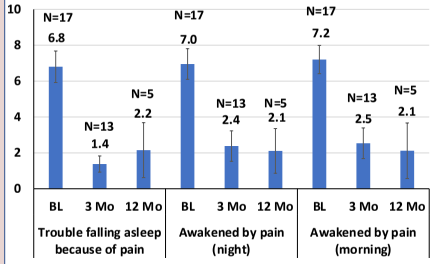


Results (contd.)

SUSTAINED REDUCTION IN DISABILITY (PAIN DISABILITY INDEX, PDI)



SUSTAINED IMPROVEMENTS IN SLEEP



Conclusions

Interim study results show HF-SCS 10 kHz could potentially provide clinically meaningful pain relief to the patients with CPP, a condition that is traditionally difficult to treat.

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AWAKE REAL-TIME MONITORING DURING CRYOABLATION FOR TUMOURS INVOLVING THE CENTRAL CANAL (ARCTIC) FOR PAIN PALLIATION

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Introduction

Vertebral metastases with epidural extension are challenging to treat, and have been regarded as a contraindication to vertebroplasty and ablation due risk of damaging surrounding neuronal structures (1). Recent studies have shown feasibility of vertebroplasty with and without ablation for such lesions (2-5). We report our protocol and experience with cryoablation and cementoplasty for metastases involving the central canal.

Methods

We conducted retrospective review of all patients with tumours involving the spinal canal treated with cryoablation followed by cementoplasty for palliative pain relief from June 2018 to March 2019.

Procedural protocol: Procedures were conducted under conscious sedation to allow for direct monitoring of sensorimotor function during ablation. Transpedicular bone access was achieved using a power drill (Arrow® OnControl®, Teleflex, Pennsylvania, USA). At least 1 freeze-thaw cycle was conducted for each lesion (Galil Medical, Yokneam, Israel). CT screening of the ice ball was done every 5 minutes (Figure 1). Hand-injection of saline-contrast into the epidural space was done for thermoprotection. If the patient experienced focal neurological deficit, ablation was stopped and active thawing commenced. Cementoplasty (Kyphon® Cement Delivery System, Medtronic, Dublin, Ireland) of the ablated cavity was performed during the same setting.

End points: Pre-, peri- and post-procedure pain and functional scores were measured using the visual analogue scale and modified Oswestry Disability Index respectively. Follow-up imaging was analysed for local tumour control when available.

Statistical analysis: Friedman ANOVA and Dunn-Bonferroni post-hoc testing; median scores and interquartile ranges were reported.

Results

Patient and lesion characteristics (refer to Table 1): 7 consecutive patients (3 men, 4 women) of median age 69.0 (49.0-71.0) years with vertebral metastases at 9 levels (5 thoracic levels, 4 lumbar levels) were included.

Procedural outcomes: Technical success was achieved at all levels. 1 patient with pre-existing cauda equina compression developed unilateral foot drop (1 major complication, 14.3%). Asymptomatic cement extrusion occurred in 4 patients (4 minor complications, 57.1%). 3 non-procedure-related deaths occured during follow up.

Clinical outcomes (refer to Table 2): Compared to the pre-procedure scores, usual pain scores, worst pain scores and functional scores showed statistically significant improvements in both the peri-procedural and post-procedural periods.

Follow up imaging: Available in 3 patients. There was local tumour control in all individuals. Re-growth of previously eroded bone was observed in 2 patients (Figure 2).

Discussion

Of the ablative techniques, we believe cryoablation is ideal for lesions involving the central canal as the iceball margin can be monitored on imaging. Additionally, foregoing general anaesthesia in favour of conscious sedation allows direct monitor the patient's neurological status as a precaution against non-target ablation without the use of invasive electrophysiological monitoring. Ablation creates a necrotic cavity for the cement, which may help prevent cement leakage (6).

We had 1 major complication whereby a patient with pre-existing cauda equina compression developed unilateral foot drop following ARCTIC; more data will be needed to see if cauda equina compression is an absolute contraindication.

Table 1. Patient demographics, lesion characteristics and treatment histories

	Age	Sex	Primary cancer	Lesion	Canal stenosis	Prior therapy	Subsequent therapy
1	33	F	Sarcoma	L3 VB	Severe	Chemo, EBRT, L3 foraminal block	Nil
2	68	F	Colon adenoCA	L4 VB	Moderate	Hemi-colectomy, adjuvant chemo	Nil
3	69	M	Lung adenoCA	T9 VB	Severe	Nil (newly diagnosed)	Adjuvant chemo, EBRT
4	70	M	HCC	T11 VB	Mild	Hemi-hepatectomy, TACE, immunotherapy	Nil
5	49	F	Lung adenoCA	T7 VB	Moderate	Nil (newly diagnosed)	Adjuvant chemo, EBRT
6	72	M	RCC	T10 VB, T11 VB, L1 VB & pedicles	Severe (all levels)	Chemo, EBRT, embolization, cryoablation, RFA	Nil
7	71	F	HCC	L3 VB & pedicles	Cauda equina compression	Hepatic TACE, RFA, EBRT	L3 laminec-tomy, EBRT

AdenoCA= Adenocarcinoma; EBRT= External beam radiotherapy; HCC= Hepatocellular carcinoma; RCC= Renal cell carcinoma; RFA= Radiofrequency ablation; TACE= Transarterial chemoembolization; VB= Vertebral body.

Table 2. Median pain and functional scores

	Pre-procedure	Peri-procedure	Post-procedure	$\chi^2(2)$	p=
Usual pain	7.0 (5.8-8.5)*	2.5 (1.5-3.5)	1 (0-3.0)*	10.2	0.006
Worst pain	9.5 (7.8-10.0)*	3.5 (2.8-7.8)	3.0 (1.5-4.3)*	7.5	0.023
Function	60.5 (51.0-73.5)*	54.0 (46.0-59.5)	34.0 (17.0-44.5)*	11.6	0.003

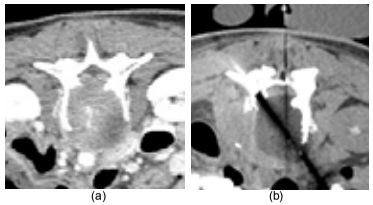
* Statistically significant differences on post-hoc testing for the following pairs: pre and post usual pain scores (p=0.012); pre and post worst pain scores (p=0.042); pre and post functional scores (p=0.003).

Conclusion

ARCTIC shows promise for rapid and sustained pain relief in these difficult to treat lesions. The procedure shows potential as a viable option for palliation, complementary to radiotherapy and surgery.

Figure 1. Cryoablation prior to cementoplasty.

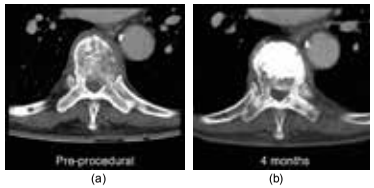
(a) Pre-procedural contrast-enhanced CT shows metastasis at L3 with soft tissue component within the epidural space.
(b) Intra-procedural CT shows the low attenuation ice ball extending into the anterior epidural space to cover the entire tumor.



(a) (b)

Figure 2. Cortical restoration following cryo-ablation and cementoplasty.

(a) CT shows cortical destruction of the anterior central canal at T9.
(b) Post-procedural CT at 4 months shows good local tumor control and regrowth of the anterior central canal cortex.



(a) (b)

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Cannabidiol: A Retrospective Review of Patient Outcomes for Pain, Sleep, Anxiety, Depression and Function

Daniel Roth D.O. M.B.A. M.S., Rene Alonzo M.D., Hari Ailinani M.D., Tom Straub P.A.-C., Brian Henriksen Ph.D.

Hypothesis

Patients who use cannabidiol (CBD Oil) notice improvements in the following clinical metrics: Pain, Sleep, Anxiety, Depression or Function.

Background

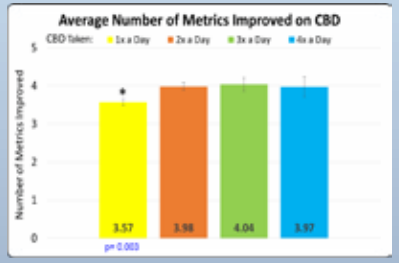
- Cannabidiol (CBD) oil is becoming increasing popular in the US.
- 2018's Federal Farm Bill has further extended the protections for research and consumption by removing cannabis containing less than 0.3% THC by dry weight from the Controlled Substances Act.
- Clinical Studies: wide variety of applications and benefits with no serious adverse effects in safety testing.
- CBD works on the endocannabinoid system directly via CB1 and CB2 receptor agonism and indirectly via allosteric modulation of other receptors.
- CBD is non-psychotropic but psychoactive

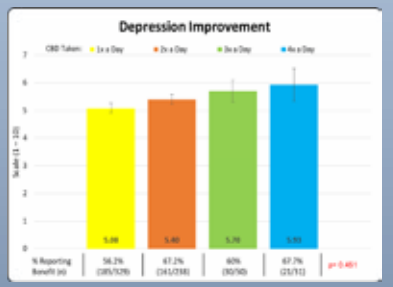
METHODS

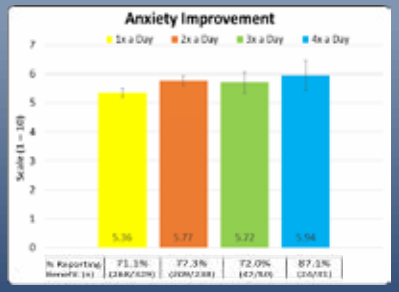
- Setting: large multidisciplinary pain practice.
- Retrospective Chart Review (N=648)
- Inclusion Criteria: patients currently using an orally administered CBD oil product.
- Exclusion Criteria: all patients not on or have never taken CBD
- Questionnaire administered and data collected.
- Likert scale data measured if improvement in each metric were experienced.
- Cohort data analysis was based on daily consumption frequency.

CBD Use:	1x a Day	2x a Day	3x a Day	4x a Day
Average (Days)	95 ± 6	129 ± 9	126 ± 16	200 ± 39
Side Effects:	**1x a Day**	**2x a Day**	**3x a Day**	**4x a Day**
% Yes (n)	7.3% (24/329)	7.6% (18/238)	10% (5/50)	9.7% (3/31)

Results







Discussion

- These data support existing lab and clinical data with regards to the metrics examined.
- Clinical research needed for high quality data, specifically placebo controlled, blinded, crossover studies.
- The adverse events reported in pre-clinical and epidiolex studies appear much safer than the current drugs on market for pain and anxiety.

Conclusion

- Our findings show CBD oil provided a significant improvement in at least 4 out of 5 metrics.
- Once daily frequency appears sufficient to provide improvement in all metrics.
- Greater pain improvement was seen with 4 times daily frequency, which likely relates to greater milligram strength dosing.
- Response rates appears to be similar to those of other current first line treatments for depression and anxiety.
- Liver transaminase levels remained within normal limits throughout all dosing frequency ranges.
- Side effects were mild ranging from 7.3-10% incidence with the most common being somnolence. No severe adverse events noted.

Limitations

- Recall biased results based on patient reported data.
- Unassessed if participants were on other concomitant treatments.
- Study limited by unknown total milligram consumption, only frequency of dosing assessed.

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Chronic Pain Practices: An Evaluation of Positive and Negative Online Patient Reviews

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Background:
Online reviews are an important component of a healthcare organization's identity. According to the latest consumer report, 84% of patients turn to review sites to find a doctor and 80% of consumers trust online reviews as much as personal recommendations. In spite of these trends, the role of online ratings in healthcare provision is still poorly understood and attitudes vary greatly on their viability as a quality metric in medicine. A 2017 survey of patients and physicians by Holliday et al. revealed that physicians place substantially more trust in health system patient experience surveys than in third-party websites. Conversely, patients reported the inverse, placing more trust in online ratings. Still, aggregate data taken from multiple web-based rating sources have shed light on several themes common to positive and to negative reviews. Provider empathy and demeanor, facility cleanliness, and logistical burden placed on patients (e.g., waiting times) are prominent in literature. Despite poor physician confidence in online feedback, there is growing evidence that aggregated online ratings may predict a subset of hospital outcomes. An analysis of the Choices Web NHS (National Health Service) service demonstrated positive patient reviews were negatively correlated with mortality and readmission rates, while revealing that even medically, irrelevant impressions of hospital cleanliness were significantly correlated with low MRSA infection rates. Further obscuring the mechanistic relationship between patient feedback and objective provider quality is the heterogeneity with which web reviews can predict outcomes across clinical sites and specialties.

Methods:
This retrospective study evaluated patient-generated reviews of chronic pain physicians from two online platforms - Yelp and Healthgrades - between the September 1st, 2018 through November 1st, 2018. Ninety chronic pain physicians were randomly selected from four diverse geographical cities in the United States: New York (New York) Houston (Texas), Chicago (Illinois), and Seattle (Washington). Primary outcome was defined as high and low rating scores. Secondary outcome was the proportion of positive and negative attributes (patient, physician, procedure, and administrative attributes) that was associated with high and low rating scores.

Results:
Themes that emerged from the positive and negative reviews were similar in content but opposite in valence. Patient- specific themes included pain improvement, mood, and physical activity. Physician-specific themes included knowledge and competency, helpful, compassion, temperament, communication abilities, and time spent with patient. Ninety chronic pain physicians were randomly identified from four diverse cities across the United States. From these chronic pain physicians, 1,627 reviews were extracted from Yelp and Healthgrade combined. Of this total review, 1296 (79.7%) were high scoring and (331) 20.3% were low scoring. Amongst the high scoring physicians group (79.9%), 77.1% scored a 5 and 2.8% scored a 4 overall. The low scoring physician group consisted of who 17.3% received a score of 2 and 3.0% who received a score of 1. Yelp online platform reported a significantly higher proportion of low rating scores compared to healthgrade ratings (33% vs 13%; $p < 0.0001$). On the opposite spectrum, however, Yelp online platform reported a significantly lower proportion of high rating scores compared to scores from healthgrade (66% vs 85%; $p<0.0001$). The proportion of positive characteristics observed with high score ratings were mostly physician related attributes (63.5%). The proportion of positive characteristics observed with high rating physicians consisted of physician related attributes such as: knowledgeable (39.1%), helpful (38.9%), caring (26.9%), respectful (26.0%), and a good listener (17.9%). There was also a high proportion of courtesy and helpful characteristics amongst the administrative attribute (31.1%). Regarding the low rating scores, the proportion of negative characteristics observed were administrative attributes such as: lack of courtesy/help (32.9%), insurance/billing (29.6%), lack of clear communication with staff (17.5%), prolonged waiting time (16.0%), and poor coordination of care (14.8%). Physician related attribute include: disrespectful (31.7%), and unhelpful (24.2%).

Conclusion:
A review of online platforms evaluating pain physicians from several chronic pain practices identified a range of positive and negative factors that affect patient experiences. These online platforms can serve as a useful tool that provide timely data for chronic pain physicians to gain more insight into the quality of care perceived by patients, thereby aiding providers to improve on ways to optimize patient-care experiences and encounters.

References(image): https://www.cedars-sinai.org/newsroom/data-from-online-physician-review-sites-may-be-skewed-and-misleading-to-consumers-new-study-finds/

Depression Trends in Chronic Pain Patients: An Analysis of the Nationwide Inpatient Sample

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Background:
Chronic pain is a major public health issue which affects the lives of many worldwide and creates significant cost burden to the healthcare system. In a 2011 study of the United States, chronic pain was found to affect over 100 million adults and incur up to $635 million in costs annually. In many cases, chronic pain may exist in the absence of clear physical pathology. Ultimately the physical symptoms of chronic pain can impact every aspect of a patient's life and have been shown to correlate with reduced quality of life, decreased enjoyment of life activities, anxiety, and decreased quality of sleep. Not surprisingly, as these symptoms are significant components of depression, chronic pain has been found to be a major factor for depression. In a large international study, patients with chronic pain were 2.3 times as likely to have associated mood disorders. Moreover, in patients seeking treatment at pain medicine institutions, the prevalence of depression can be as high as 50%. Individually, pain and depression are important comorbidities that severely affect patient disability and outcomes. Moreover, the combination of both seems to have a synergistic influence. Interestingly, symptoms of pain and depression correlate well and demonstrate a positive association in depression compared to changes in pain scores. In light of this, it is difficult to interpret a causative association, as pain was found to persist despite improvements in symptoms of depression. Gaining a better understanding of the association between chronic pain and depression is important and may help lead to improved patient treatment and outcomes.

Methods:
Much of literature that has studied the correlation between chronic pain and depression has been done so via surveys of the general population and in the community setting. In the present investigation, we assess the rate of comorbid depression and chronic pain in the inpatient population. Patients were identified from the National Inpatient Sample (NIS) database using *International Classification of Diseases, Ninth and Tenth Revision* diagnosis codes for chronic pain and co-morbid depression from years 2011-2015. The NIS is one of the Healthcare Cost and Utilization Projects databases that is sponsored by the Agency for Healthcare Research and Quality (AHRQ). This database is considered the largest all-payer inpatient care database in the US that has been used in multiple instances to analyze national trends in outcomes, quality, charges, access and health care utilization based on data extracted from 7-8 million hospital stays. These hospital stays represent approximately 20% of the US community hospitals, defined as all academic medical centers, general specialty hospitals, non-federal, and short-term medical centers. The NIS is publicly available and contains no personal identifying information. Hence, this study was exempt from institutional review board approval. In our analysis, we included chemical dependency treatment facilities, long term acute care hospitals, short term rehabilitation facilities, and psychiatric hospitals. Hospitals within a given stratum have similar statistical probability of sample selection regardless of appearance in prior sample.

Results:
Between 2011 to 2015, an estimated 9.3 million patients with chronic pain were identified. Of this cohort 2.2 million patients (22.9%) were diagnosed with co-morbid depression. The estimated number of patients with depression varied from 399,865 (22.6%) in 2011 to 421,490 (23.1%) in 2015 (P=0.13). From 2011 to 2015, there was a significant upward trend of depression amongst blacks (8.1 ± 0.42% to 9.7 ± 0.27%), patients aged 65 – 84 years (29.0 ± 0.39% to 32.4 ± 0.23%), Medicare insured patients (56.1 ± 0.54% to 58.5 ± 0.29%), Medicaid insured patients (14.7 ± 0.4% to 17.1 ± 0.24%), and patients from ZIP code areas with lowest annual household income (29.2 ± 1.3% to 32.0 ± 0.59%). Amongst depressed patients, the adjusted total hospitalization cost increased from $43,584 in 2011 to $49,923 in 2015 ($P$<.001) with average length of hospital stay stable around 5.05 ± 0.02 days. Most patients were discharged home or with self-care compared to short term facility (57.9 ± 0.14% vs 2.0 ± 0.03%).

Conclusion:
Depression poses a major health concern for chronic pain patients. This retrospective analysis of NIS data, from 2011 to 2015, demonstrates that patients identified as white, female, and 45 - 65 years of age constitute the largest proportion of affected individuals. White patients also experienced the greatest reduction in depression from 2011 to 2015, which may suggest disparities in treatment availability and targeting. Further, despite relative consistency in patient hospitalization, length of stay, rates of provider interventional procedures, and discharge pathways, costs related to depression grew significantly over this period. With approximately 22.9% of adults with depression, dramatic improvements are needed in the safety of provider practices, patient education, counseling, and depression treatment availability.

References(image): https://www.psychologytoday.com/us/blog/the-crime-and-justice-doctor/201810/depression-among-men-its-time-erase-the-stigma

Non-Surgical Candidate Secondary to Severe Pulmonary Hypertension Undergoing Successful Water-Cooled Radiofrequency Ablation for Severe Hip Osteoarthritis

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Case Description

61-year-old female with a history of severe idiopathic pulmonary hypertension treated with an epoprostenol pump who was referred to our pain clinic with severe left hip pain with radiation into the left groin. Pain was described as sharp in nature and rated 10/10 in intensity. Pain was made worse with ambulation and sitting for a long period of time and made slightly better with tramadol. Patient was mostly wheelchair-bound on initial evaluation with a very poor quality of life with limited ability to only ambulate from her bed to the bathroom. Her exam demonstrated limited left internal hip rotation with positive FADIR's and Patrick's test with pain radiating into the left groin. Patient was able to manage to ambulate a few steps with an antalgic gait pattern before having to sit back down in her wheelchair.

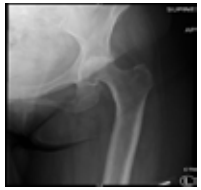
Workup

Further workup with left hip MRI demonstrated severe osteoarthritis, femoral head edema, and labral tear. Patient was then referred to orthopedics who recommended a left total hip arthroplasty. Case was subsequently reviewed at the anesthesia preoperative clinic and it was determined that she was not a surgical candidate given her severe pulmonary hypertension.

Initial Treatment

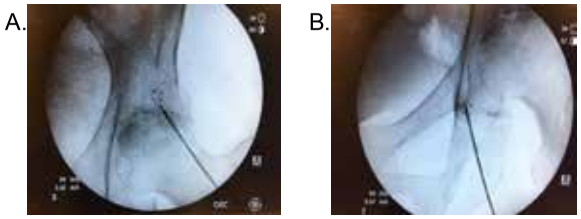
She was referred back to our pain clinic and instructed to explore non-operative options. The patient underwent a left hip intraarticular steroid injection with complete improvement in symptoms initially secondary to the local anesthetic effect of the injection but failed to respond to the steroid medication. She was subsequently hospitalized for pain control but failed aggressive medication management including opioids. She returned back to our clinic desperate for an alternative interventional procedure given she was still in tremendous pain and still unable to be cleared for surgery.

AP X-Ray of Left Hip



AP View of Left Hip Demonstrating Severe Osteoarthritis.

Fluoroscopic Images for Water-Cooled Radiofrequency Ablation of the Hip



Needle placement targeting femoral (A) and obturator (B) articular sensory branches.

Interventional Management

Patient underwent successful diagnostic left hip articular branch blocks with 0.5% bupivacaine and called our clinic the following day reporting nearly 100% pain relief prior to the block wearing off.

One month after the diagnostic left hip articular branch blocks the patient returned to our clinic and successfully underwent left hip water-cooled radiofrequency ablation with combined ultrasound and fluoroscopy guidance.

Results

Patient obtained nearly 1.5 months of pain relief of her left hip from the water-cooled radiofrequency ablation prior to pain returning. Chemoneurolysis with 6% phenol to the left femoral and obturator sensory branches was performed on follow up visit to further help ameliorate her symptoms given she remained a non-surgical candidate.

Conclusions

Water-cooled radiofrequency ablation to the lateral articular femoral and obturator sensory branches of the hip appears to be a safe and effective procedure for patients with intractable hip joint pain who are unable to receive surgical intervention due to their medical co-morbidities.[1,2,3] There is limited evidence for chemoneurolysis of the hip with phenol but it remains a potential treatment option as well.[4] Further studies including randomized controlled studies are needed to better ascertain the true effects of neurolytic interventional techniques within this patient population.

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Rates and Co-occurrences of Psychological Risk Factors Among Chronic Pain Patients

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Background

- The *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes* reports more than 11.5 million Americans, aged 12 or older, reported misusing prescription opioids in 2013 (CDC, 2018).
- In 2016, there were more than 63,600 drug overdose deaths in the United States (CDC, 2017).
- There are many factors affecting the recovery of an orthopedic procedure, however psychological factors appear to play a significant role in perceived patient outcomes (Flanigan, 2015; Rosenberger, 2006).
- Unfortunately, potential risk factors are not always identified until after the procedure is performed.
- Patients may have to be referred to a pain management specialist who can address potential causes for their postsurgical pain issues, including but not limited to psychological disorders or unhealthy lifestyle choices.

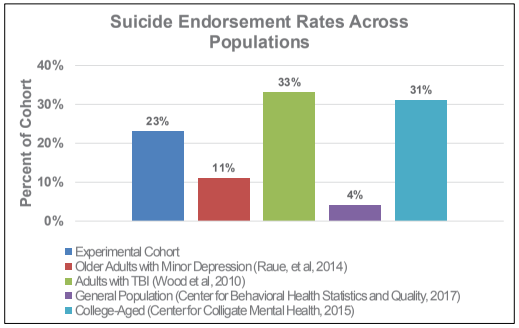
Objectives

- To quantify the incidence of depression, resiliency, suicidality and substance abuse in a chronic pain cohort under the care of a pain management specialist.
- To help identify at-risk patients and expand efforts to improve clinical outcomes.
- To compare chronic experimental pain cohort to previously reported pain and back pain cohorts

Methods

- A convenience sample of pain management patients were recruited from a large, private orthopedic clinic in Tallahassee, Florida.
- A psychological measurement battery was completed by patients prior to their initial clinical evaluation, which included the Connor-Davidson Resilience Scale (CD-RISC-10), Avoidance Endurance Questionnaire (AEQ), and the Center for Epidemiologic Studies Depression Scale (CES-D).
- The CD-RISC-10 is a 10-item version of the full evaluation to assess resiliency (score range 0-40) which comprises items 1, 4, 6, 7, 8, 11, 14, 16, 17, 19 from the original scale.
- The AEQ is a 49-item reliable measure to assess the pattern of fear-avoidance and endurance-related behaviors in responses to pain.
- The CES-D is a 20-item screening test for depression and depressive disorder.
- Florida State University's Institutional Review Board approved this study and all participants provided written informed consent.

Results



- Our experimental cohort consisted of chronic pain patients seeking pain management care (n=30)
- Raue et al., 2014 included older adults (60+ years old) with diagnosed minor depression from primary care practices (n=1,202).
- Wood et al., 2010 sampled middle aged (range) traumatic brain injury patients and demographically matched controls (n=179).
- Center for Behavioral Health Statistics and Quality, 2017 sampled 67,500 through interviews, distributed across three age groups, young adults and older adults included used for comparison (n=50,625).
- The Center for Colligate Mental Health (2015) used college-aged patient data from more than 140 counseling centers (n=82,383).

Participant Demographics (n=30)

Age (years)	59.6 ± 17.4
Sex (# of participants)	16 M; 14 F
Previous Mental Health Diagnosis	30%
Current Smokers	17%
Alcohol Use	47%
Reported Cannabis Drug Use	20%
Previous Surgical Complications	20%

Assessment Reponses

Avoidance-Endurance Questionnaire (AEQ)	**Grade 4 Low Back Pain** (Hasenbring et al., 2009)	**Experimental Group**
Anxiety / Depression	2.7 ± 1.2	2.0 ± 1.3
Help- / Hopelessness	2.5 ± 1.3	1.8 ± 1.3
Catastrophizing thoughts	0.8 ± 1.0	1.0 ± 1.2
Avoidance - Social	3.0 ± 1.4	2.0 ± 1.5
Avoidance - Physical	4.5 ± 1.1	3.5 ± 1.4
Positive mood	3.1 ± 1.1	3.8 ± 1.3
Thought Suppression	3.2 ± 1.3	2.6 ± 1.5
Behavioral endurance	2.8 ± 0.9	3.3 ± 0.8
	Primary Care (Klinkman et al., 1997)	**Experimental Group**
Center of Epidemiological Studies-Depression (CES-D) w/ score of ≥16	11%	27%
	Random Digit Dial (Davidson, 2003)	**Experimental Group**
Connor-Davidson Resilience Scale (CD-RISC-10)	32.1 ± 5.8	30.4 ± 8.8

Discussion

- Results from our pilot study demonstrate that our chronic pain cohort reported depressive symptoms at a higher rate than the national average.
- The cohort also fell in the lower 50%tile for resiliency. When combined, it appears that rates of psychological distress, health risk behaviors and difficulties with resiliency are relatively high in this sample of chronic pain patients.
- Interventions that include integrative, interdisciplinary treatment plans could improve the rate at which chronic pain patients experience meaningful improvement in quality of life.

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The Utilization of Mu-Opioid Receptor Biased Agonists: Oliceridine, an Opioid Analgesic with Reduced Adverse Effects

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INTRODUCTION

Prescription opioids are widely used for the treatment of acute, moderate-to-severe pain. Although they are extremely efficacious in alleviating pain, current opioid treatments induce a wide variety of adverse side effects, such as gastrointestinal dysfunction, nausea, vomiting, constipation, sedation, hypercapnia and respiratory suppression[1]. The use of prescription opioids are also limited by their potential to lead to addiction and abuse. In addition to experiencing these adverse events, patients can develop tolerance to opioids, leading to repeated dosing regimens and dose escalation, which can further the risk of tolerance

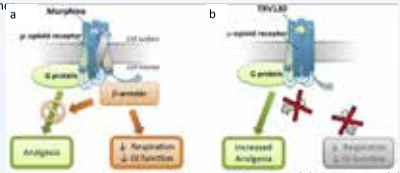

Figure 1. MOR activation upon binding to morphine **(a)**, and TRV130 **(b)**, and downstream molecular pathways[2].

Opioids induce analgesia by binding to opioid receptors expressed in the nociceptive neural circuitry in the periphery and central nervous system, mainly the spinal cord[3]. Morphine, which is one of the most common and efficacious analgesic therapy, is an agonist for the mu-opioid receptor (MOR). Based on the agonist binding, MORs can elicit different intracellular responses; mainly by the G-protein pathway, which elicits the analgesic response, and by beta-arrestin2 pathway, which leads to the adverse events[4].

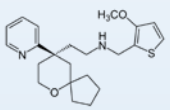

Figure 2. Molecular structure of TRV130[5].

In the search of MOR agonists with high analgesic efficacy with limited adverse events to address the unmet need, Oliceridine (TRV130) was found to be a "biased ligand", selectively activating MOR and causing it to preferentially couple with the downstream G-protein, while limiting beta-arrestin2 recruitment compared to morphine[5]. Also, reduced MOR internalization with TRV130 treatment has been associated with tolerance resistance and the potential of reducing abuse liability[6].

RESULTS

The efficacy, safety, dose-dependency and side effects of Oliceridine were measured in clinical trials including treatment on healthy controls and patients following abdominoplasty and bunionectomy[7,8]. In these studies, anti-nociception and onset of action of different Oliceridine doses were compared to placebo and morphine treatments.

Pharmacokinetics and Pain Relief

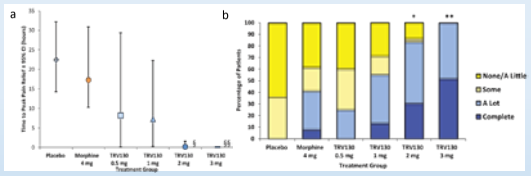

Figure 3. Pain relief in post-bunionectomy patients after various treatments[7]. **(a)** Peak categorical pain relief after the first dose of medication (*, P=0.0005 vs morphine 4 mg; **, P < 0.0001 vs morphine 4 mg). **(b)** The median time to achieve peak categorical pain relief in the 48-hour treatment period (§, P < 0.05 vs morphine 4 mg; §§, P < 0.01 vs morphine 4 mg).

Analgesic Efficacy

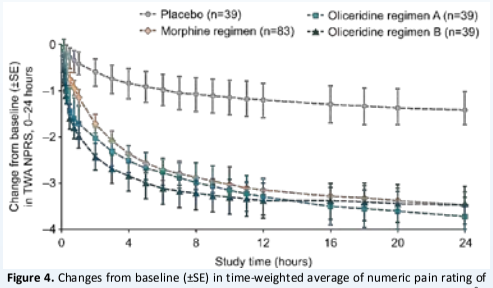

Figure 4. Changes from baseline (±SE) in time-weighted average of numeric pain rating of post-abdominoplasty patients from 0 to 24 hours by treatment group[8]. Loading/patient-controlled demand doses (mg/mg): Oliceridine regimen A, 1.5/0.10; regimen B, 1.5/0.35; morphine, 4.0/1.0. (*P*≈0.0001, Regimen A versus placebo; *P*≈0.0005, Regimen B versus placebo; *P*<0.0001, morphine versus placebo).

The results from the efficacy studies in humans showed that Oliceridine has a faster onset of anti-nociception, inducing quicker meaningful relief in patients. Additionally, patients with Oliceridine treatment reported higher categorical pain relief, compared to morphine treated patients. Although Oliceridine is selective for G-protein coupling of MOR unlike morphine, the analgesic effects of Oliceridine and morphine were at a similar level.

Hypercapnia and Respiratory Distress

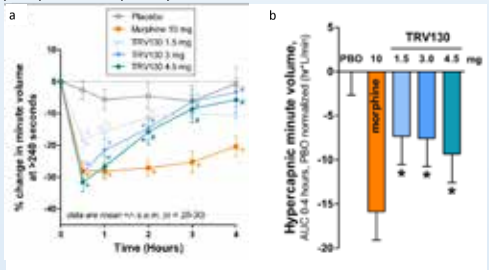

Figure 5. Duration and magnitude of depressed ventilatory response to hypercapnia in healthy volunteers[2]. **(a)** Mean effect of TRV130 (1.5, 3, and 4.5 mg) compared to morphine (10 mg) and placebo on change in minute volume during the fifth of 5 minutes of inspired 5% CO2, measured for 4 hours after intravenous bolus dosing for 28 to 30 subjects (*,P < 0.05 vs placebo, and #,P < 0.05 vs morphine). **(b)** Total hypoventilation, the area under the placebo-corrected curve, for change in minute volume (*P < 0.05 for TRV130 response less than morphine).

All different dose regimens of Oliceridine have been shown to produce a reduction in respiratory drive similar to morphine. In addition, the same levels of respiratory depression were observed when Oliceridine was administered 8-fold over the analgesic dose of morphine[9]. The duration of the respiratory suppression was significantly lower in Oliceridine treatments compared to morphine, which had persistent respiratory drive reduction through 4 hours post-dose.

Adverse Events and Tolerance

	Placebo (n=39)	Oliceridine		Morphine regimen (n=83)
		Regimen A (n=39)	Regimen B (n=39)	
TEAEs in ≥10% of patients				
Patients with ≥1 TEAE	24 (62%) [48]	26 (67%) [54]	32 (82%) [67]	78 (94%) [238]
Gastrointestinal disorders				
Nausea	7 (18%) [7]	16 (41%) [17]	18 (46%) [18]	60 (72%) [63]
Vomiting	3 (8%) [3]	6 (15%) [6]	6 (15%) [6]	35 (42%) [35]
Nervous system disorders				
Headache	5 (13%) [5]	6 (15%) [6]	6 (15%) [6]	14 (17%) [14]
Dizziness	1 (3%) [1]	1 (3%) [1]	4 (10%) [4]	7 (8%) [7]
Somnolence	0	0	2 (5%) [2]	10 (12%) [10]
Vascular disorders				
Hypotension	1 (3%) [1]	6 (15%) [6]	3 (8%) [3]	7 (8%) [7]
Phlebitis	4 (10%) [4]	0	2 (5%) [2]	1 (1%) [1]
Respiratory, thoracic, and mediastinal disorders				
Hyperventilation	4 (10%) [5]	4 (10%) [4]	11 (31%) [12]	34 (41%) [34]
Respiratory depression	0 (0) [0]	2 (8%) [2]	0 (0) [0]	9 (11%) [10]

Table 1. Adverse events in post-abdominoplasty patient following treatment[8]. Data are number of patients (%) [number of events]. Loading/demand doses (mg/mg): Oliceridine regimen A, 1.5/0.10; Regimen B, 1.5/0.35; morphine, 4.0/1.0.

The safety studies showed that under Oliceridine treatment, there were incidences of adverse events in patients, including gastrointestinal dysfunction and nervous system disorders. Compared to morphine, opioid-induced gastrointestinal dysfunction was significantly lower in Oliceridine treated patients, measured by incidence of vomiting, and nausea in humans, and by colonic motility assays in mice.

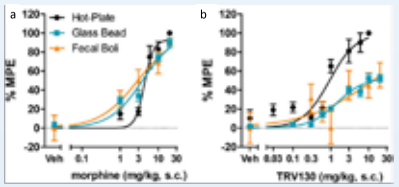

Figure 6. Gastrointestinal dysfunction in mice[2]. Mice were injected s.c. with morphine **(a)** or TRV130 **(b)**, and were subjected a glass bead colonic motility assay, or a 4-hour fecal boli accumulation assay.

Studies measuring tolerance report that anti-nociception and analgesia is retained with repeated Oliceridine administration, indicating a lower chance of tolerance. Oliceridine has been shown to reversibly bind to MOR, and its residence time on the receptor was reported as short in presence of Nolaxone, allowing a rescue function in case of an overdose[2].

CONCLUSION

Oliceridine is a novel, biased MOR agonist that can selectively promote G-protein coupling while not activating the beta-arrestin2 pathways. With its selective mechanism of action Oliceridine has shown to induce analgesia with lessened adverse events, such as respiratory depression and gastrointestinal dysfunction relative to morphine. Although it's a biased MOR agonist, Oliceridine did not show improved analgesic efficacy compared to morphine, which was due to its reduced binding affinity to MOR compared to morphine, making Oliceridine susceptible to competition. Overall, future studies must be done in order to get a better grasp on analgesic efficacy and long term side effects on a wider variety of patients.

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Thoracolumbar Injury Classification and Severity Score (TLICS) in the Management of Osteoporotic Compression Fractures

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INTRODUCTION

- Osteoporotic Vertebral Compression Fractures are an important cause of morbidity and mortality in the elderly; most of these are managed non-operatively.
- A simple and reliable decision making tool that can be deployed by the primary team in the management of these patient is lacking.
- Thoracolumbar injury classification and severity score (TLICS) is an easy to use tool to guide decision making for traumatic spine fractures. In this study we report our experience using TLICS score to guide decision making in osteoporotic compression fractures.

AIM OF STUDY

- In this study we report our experience using TLICS score to guide decision making in osteoporotic compression fractures.

METHODS

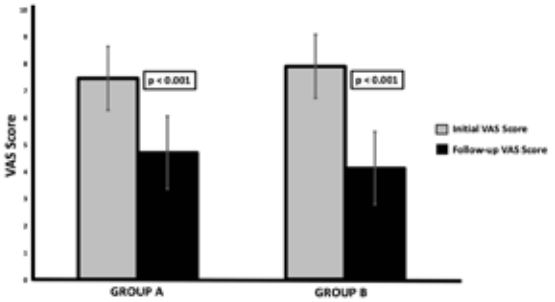
- Patients with osteoporotic vertebral compression fractures, who underwent vertebral augmentation between 2012 and 2017, were identified, and charts were reviewed.
- TLICS score was determined from patient notes and MRI of the patient at the time of initial presentation.
- Patients with incomplete data or imaging were excluded from the study.
- All patients had at least a three month follow up notes. Charts and imaging were analyzed for any spine surgical procedures and neurological stability.

TABLES & FIGURES

Table 1. Patient-Level characteristics by TLICS Scores

Patient Characteristics	Group A TLICS Score	Group B TLICS Score	P - value
Total number of Patients (%, n)	70.69 (41)	29.31 (17)	n/a
Age (mean, SD)	72.22 ± 11.03	75.12 ± 9.94	0.353
Gender (%, n)	78.05 (32)	76.47 (13)	0.896
Ethnicity (% White)	96.77 (30)	100 (15)	0.482
Initial Brace (%, n)	34.15 (14)	23.53 (4)	0.426
Initial VAS score	7.44 ± 2.71	7.89 ± 2.39	0.588
Location of Spine Augmentation (%, n)			0.314
- Thoracic region	61.54 (24)	47.06 (8)	
- Lumbar region	38.46 (15)	52.94 (9)	

Figure 1: Comparison of initial and follow-up pain scores amongst TLICS Scores



RESULTS

- Sixty patients were identified for this retrospective chary review. Forty one patients had a TLICS score of 1 (compression without retropulsion), seventeen patients had a TLICS score of 2 (compression with retropulsion) and 2 patients had a TLICS score of 4.
- All patients with TLICS score of 1 and 2 were managed conservatively not requiring surgical referral or stabilization.
- Of the 2 patients with a TLICS score of 4, and receiving surgical evaluation, one patient underwent surgical stabilization and the second patient was managed non-operatively.
- All patients remained neurologically intact.

CONCLUSIONS

- Atraumatic, or low trauma, osteoporotic thoracolumbar vertebral compression fractures are associated with a low TLICS score of 1 and 2.
- TLICS score is useful in guiding decision making, regarding need for surgical referral, and accurately predicted both; the need for surgical stabilization and neurological stability.
- No difference in outcomes in regards to the degree of pain relief was seen between TLICS 1 (no retropulsion) and TLICS 2 (with retropulsion).

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Utilization of Patient-Reported Outcomes (PRO) in Non-Cancer Chronic Pain Randomized Controlled Studies

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Introduction

Patient-Reported Outcomes (PRO) are validated questionnaires that evaluate patients' symptoms, functioning and quality of life. PRO guide the selection of therapeutic choices, disease management practices, reimbursement decisions and health policies. Despite its utility, application of PRO in non-cancer chronic pain research is variable. Approximately 116 million adults in the United States suffer from non-cancer chronic pain commonly treated with opioids. In the setting of rising opioid overdoses and deaths, healthcare providers are tasked with identifying and implementing alternative treatment strategies which evidently necessitates PRO use.

- Objective 1: report the prevalence of PRO use in non-cancer chronic pain randomized controlled studies
- Objective 2: determine compliance to guidelines for PRO use as outlined by the SPIRIT-PRO (Standard Protocol Items: Recommendations for Interventional Trials) committee

Methods

- Advanced search function in Pubmed was used to search for and identify randomized controlled studies in non-cancer chronic pain published between 2015 and 2017
- Exclusions: trials involving children and cancer-related pain
- Publications manually reviewed for: type and use of PRO, journal name/impact factor, patient diagnosis, type of intervention, study duration, hypothesis, primary and secondary outcomes, follow-up period, number of study subjects, and conclusions.
- A random sampling of 5 studies were selected from each year and evaluated for adherence to SPIRIT-PRO guidelines.

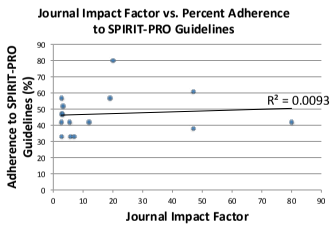
Results

336 non-cancer chronic pain randomized controlled studies published between 2015-2017 were identified of which 71% utilized a PRO. 15 studies were randomly analyzed.

Most Commonly Utilized PRO:
35 PRO were identified of which the Numeric Rating Scale (NRS) was most commonly used followed by the Oswestry Disability Index (ODI), by 5 and 4 studies respectively

Most Commonly Adhered-to Spirit PRO Guideline:
Providing a health-related quality of life data collection schedule by 14 studies followed by utilizing PRO as a primary or secondary outcome and providing a CONSORT flow diagram by 13 studies each

Most Commonly Excluded SPIRIT-PRO Guideline:
Discussion of clinical significance of PRO findings and discussion of PRO in context of other trial outcomes by 13 studies each



No association found between journal impact factor and adherence to SPIRIT-PRO guidelines

Study	PRO listed as abstract outcome	Hypothesis relevant to PRO	Mode of PRO administration	Rationale for PRO choice	Evidence of PRO reliability	HRQL data collection schedule provided	PRO is primary/ secondary outcome	Statistics for each PRO hypothesis	Statistics for missing data	Reason for missing data explained	Sample size based on PRO	Statistics for primary/ secondary outcomes	CONSORT flow diagram	Baseline PRO scores described in Table	PRO limitations explicitly discussed	Generalizability related to PRO discussed	Clinical significance of PRO findings discussed	PRO discussed in context of other trial outcomes	PRO mentioned in conclusion	Impact factor	Percent adherence to guidelines
Altman, '15	Y	N	Y	N	N	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	N	N	N	2.8	47%
Bair, '15	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	20	80%
Filardo, '15	Y	N	N	N	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	N	N	N	5.7	33%
Fransen, '15	N	N	Y	Y	Y	Y	Y	Y	N	Y	N	Y	Y	N	N	N	N	N	N	12	42%
Hunt, '15	Y	Y	Y	N	N	Y	N	N	N	N	N	N	N	Y	Y	Y	N	Y	Y	2.7	42%
Added, '16	N	N	N	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	N	N	N	N	N	2.8	33%
Baron, '16	Y	N	Y	Y	N	Y	Y	N	Y	Y	N	Y	N	Y	Y	Y	N	N	Y	2.8	57%
Cherkin, '16	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	N	N	47	61%
Gimbel, '16	N	N	N	N	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N	N	N	Y	5.5	42%
Hedlund, '16	Y	N	N	N	N	N	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	3.2	52%
Allen, '17	Y	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	N	N	39	57%
Cambron, '17	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	Y	Y	N	N	N	N	Y	3.1	47%
Juch, '17	N	N	N	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	N	N	N	N	N	47	38%
Sanga, '17	Y	N	N	Y	Y	Y	Y	N	N	Y	N	N	Y	N	N	N	N	N	N	6.9	33%
Taylor, '17	N	N	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	N	80	42%

Table 1. Adherence to SPIRIT-PRO Guidelines

Of the randomly analyzed 15 studies that utilized a PRO adherence to SPIRIT-PRO guidelines was 47.1% ± 12.8%

Conclusion

Use of PRO in non-cancer chronic pain randomized controlled trials is widespread, however, standardization of type of PRO used and adherence to SPIRIT-PRO guidelines is currently limited. There is a need for consensus among researchers regarding the selection, use and reporting of PRO.

References

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