Spinal Cord Stimulation in Diabetic Neuropathy and Ischemic Limb Pain

Richard M. Vaglienti MD,MBA,FASA
Director WVU Center for Integrative Pain Management

vaglientir@hsc.wvu.edu

WVUMedicine

No Disclosures to Report

Overview of Diabetes

- 415 million diabetics worldwide; 642 million by 2040
- 10% prevalence worldwide
- Diabetic neuropathy most common complication
- Diabetic neuropathy (DN) is the greatest source of morbidity and mortality
- DN results in 50-75% of non traumatic amputation
- Diabetic foot ulcers lead to 85% of amputations

PDN and Self Care

- Diabetes-related self care activities related to better outcomes
- DN associated with poor adherence to self care and depression
- Depression is associated with decreased glucose monitoring, poor adherence to diet and exercise and missing medication doses
- Negative feedback loops develop among these 3 factors

Patient Preference and Adherence
2016;10: 1169-1175

PDN and Fall Risk

- Severity of DN directly related to level of loss of balance
- Balance impairment is greatest in descending stairs
- Balance derangement correlated to falls
- Falls are associated with 19 Billion USD of healthcare cost (ca.2000)
- Falls lead to wrist and hip fractures
- Hip fractures resulted in 8.7 billion USD in 2000

PLoS One. 2016;11(4)

Diagnosis and Treatment of Diabetic Neuropathy

- ADA Clinical Compendia 2022
- 50 % lifetime prevalence
- Prevalence increases with time
- Can occur in newly diagnosed patients
- Early injury to C fibers (unmyelinated) lead to burning, stinging and dysesthesia.
- Later A fibers (myelinated) affected leading to loss of sensation and proprioception
- Glycemic control alone cannot prevent PDN

Pathophysiology

- Creation of reactive oxygen species (ROS) due to altered metabolism
- Altered lipid and glucose metabolism injure mitochondria leading to inflammation, apoptosis (programmed cell death) of neurons and axonal damage
- Axons farthest from cell body most vulnerable i.e. feet and lower leg

Diagnosis

TABLE 1 Symptoms and Clinical Signs of Diabetic Peripheral Neuropathy

	Symptoms	Function	Signs on examination (clinically diagnostic)

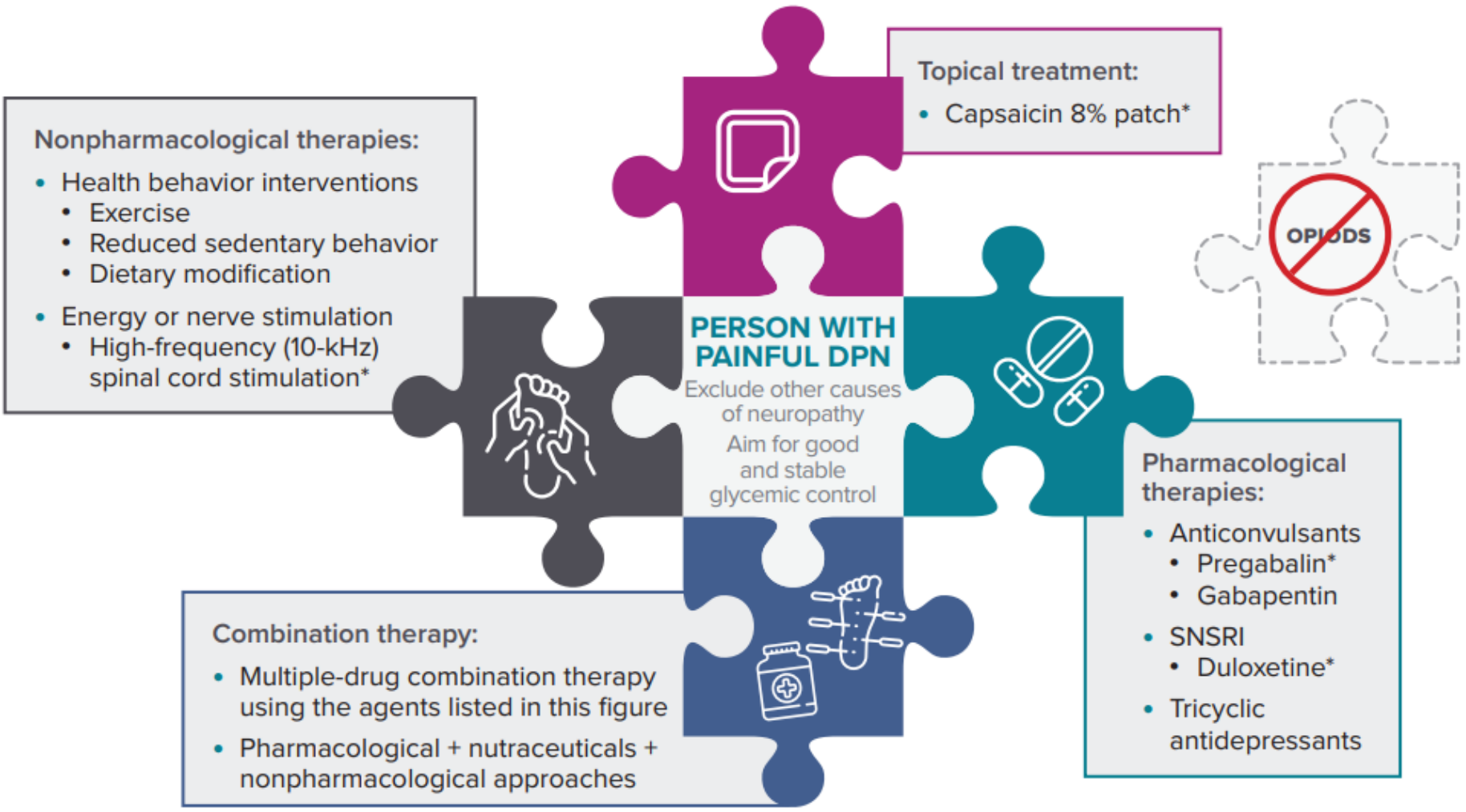
Large, Myelinated Nerve Fibers	• Numbness
	• Tingling
	• Poor balance
		• Pressure
		• Balance
			• Ankle reflexes:
			  • Reduced
			  • Absent
			• Vibration perception:*
			  • Reduced
			  • Absent
			• 10-g monofilament sensation:*
			  • Reduced
			  • Absent
			• Proprioception:
			  • Impaired

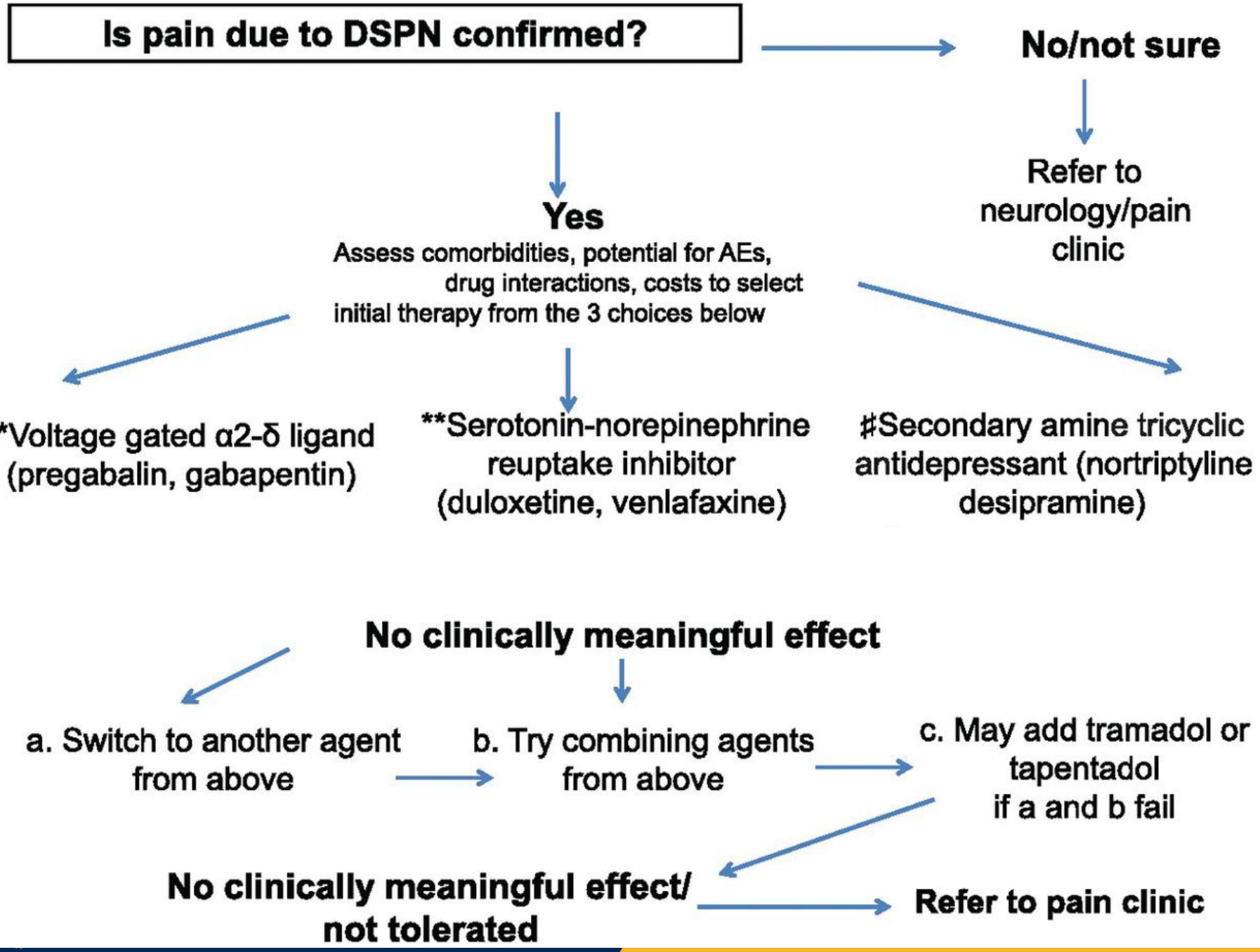
Small Nerve Fibers	• Pain:
	  • Burning
	  • Electric shocks
	  • Stabbing
	• Hyperalgesia
	• Allodynia
		• Nociception
		• Protective sensation
			• Thermal (cold/hot) discrimination:*
			  • Reduced
			  • Absent
			• Pinprick sensation:*
			  • Reduced
			  • Absent

**Document impairment/loss in symmetrical, distal-to-proximal pattern.*

Treatment Recommendations Summary

- Assess Patient
- Complete pain resolution is unlikely : setting expectations
- Assess mood and sleep
- Four classes of oral medications have demonstrated evidence of pain reduction in meta-analyses: TCAs, SNRIs, Gabapentinoids, and sodium channel blockers(Lamotrigine).
- Opioids not recommended : Tapentadol(Nucynta) is FDA approved for PDN
- Combination therapy works better

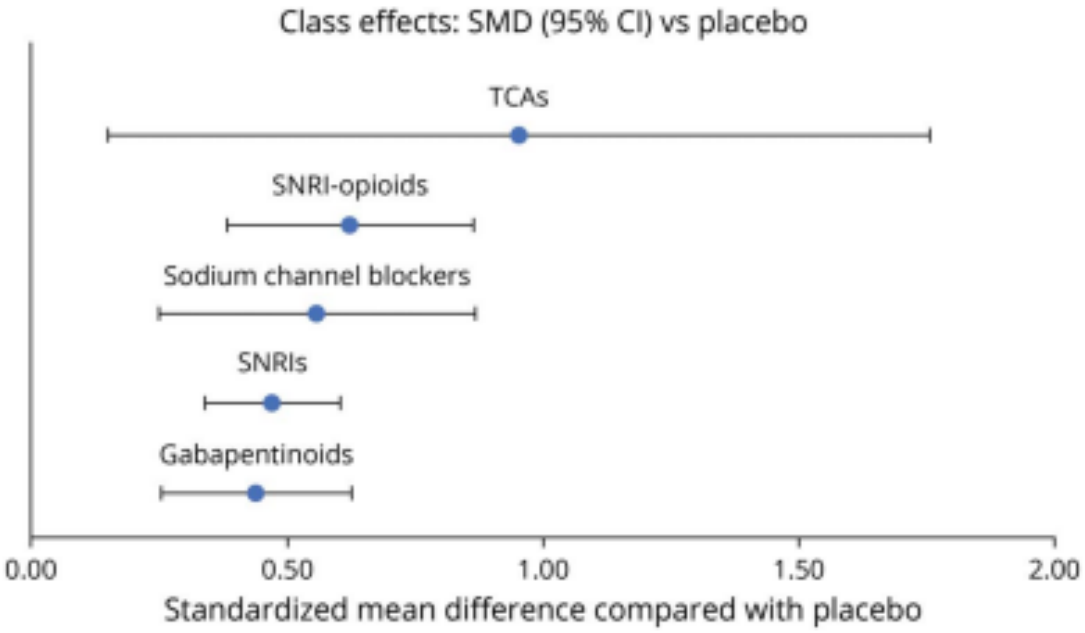

Topical treatment:
• Capsaicin 8% patch*
OPIOIDS
Nonpharmacological therapies:
• Health behavior interventions
• Exercise
• Reduced sedentary behavior
• Dietary modification
• Energy or nerve stimulation
• High-frequency (10-kHz) spinal cord stimulation*
PERSON WITH PAINFUL DPN
Exclude other causes of neuropathy
Aim for good and stable glycemic control
Pharmacological therapies:
• Anticonvulsants
• Pregabalin*
• Gabapentin
• SNSRI
• Duloxetine*
• Tricyclic antidepressants
Combination therapy:
• Multiple-drug combination therapy using the agents listed in this figure
• Pharmacological + nutraceuticals + nonpharmacological approaches


Is pain due to DSPN confirmed?
No/not sure
Refer to neurology/pain clinic
Yes
Assess comorbidities, potential for AEs, drug interactions, costs to select initial therapy from the 3 choices below
*Voltage gated α2-δ ligand (pregabalin, gabapentin)
**Serotonin-norepinephrine reuptake inhibitor (duloxetine, venlafaxine)
♯Secondary amine tricyclic antidepressant (nortriptyline desipramine)
No clinically meaningful effect
a. Switch to another agent from above
b. Try combining agents from above
c. May add tramadol or tapentadol if a and b fail
No clinically meaningful effect/ not tolerated
Refer to pain clinic

Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary Report of the AAN Guideline Subcommittee

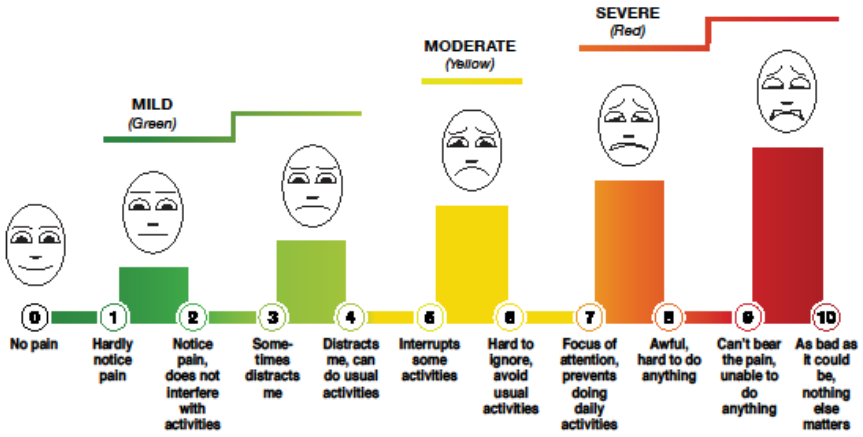
- Neurology® 2022;98:31-43.
- Gabapentinoids are probably more likely than placebo to improve pain
- Duloxetine is probably more likely than placebo to improve pain
- Amitriptyline is possibly more likely than placebo to improve pain
- Valproic acid is possibly more likely than placebo to improve pain
- Tapentadol is possibly more likely than placebo to improve pain
- Topicals

Figure Class Effects for the Most Well-Studied Oral Treatments of Painful Diabetic Polyneuropathy



The effects of different oral medication classes on painful diabetic neuropathy including gabapentinoids, serotonin-norepinephrine reuptake inhibitors (SNRIs), sodium channel blockers, SNRI/opioid dual mechanism agents, and tricyclic antidepressants (TCAs). CI = confidence interval; SMD = standardized mean difference.

Defense and Veterans Pain Rating Scale



v2.1

DVPRS Supplemental Questions

For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not interfere — *Completely interferes*

2. Circle the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not interfere — *Completely interferes*

3. Circle the one number that describes how, during the past 24 hours, pain has affected your MOOD:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not affect — *Completely affects*

4. Circle the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not contribute — *Contributes a great deal*

*Reference for pain interference: Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 23(2): 129-138, 1994. v 2.1

What is Spinal Cord Stimulation?

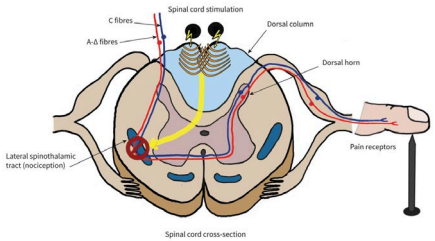
- Neuromodulation – the alteration of nerve activity through targeted delivery of a stimulus, such as **electrical stimulation** or chemical agents

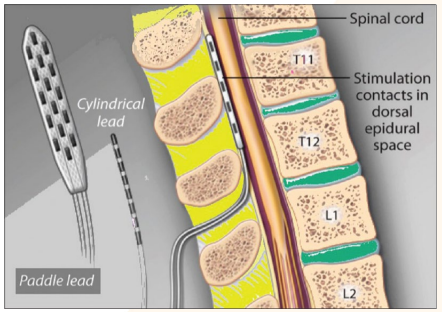
Leads

Pulse Generators

What is Spinal Cord Stimulation?

- Gate theory of Pain
  - Melzack and Wall in 1965





- In 1967 Norman Shealy implanted a monopolar SCS intrathecally near the dorsal column.

The Evolution of Spinal Cord Stimulation

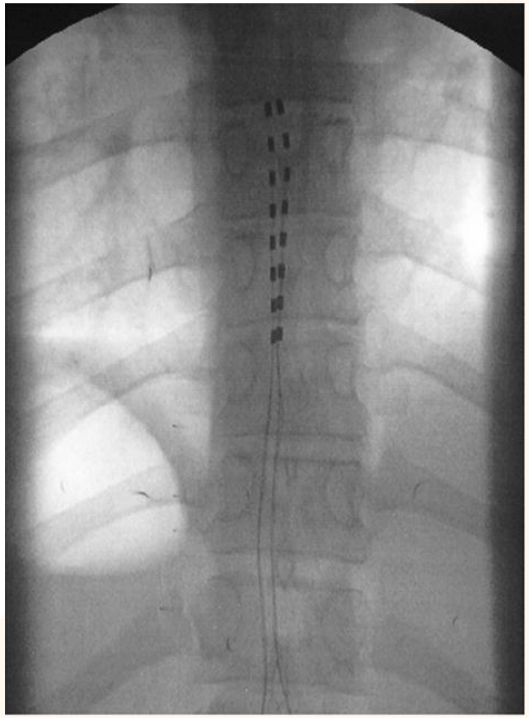
- Technical advances
  - Lead configuration, IPG size, Battery life, Rechargeable, MRI compatibility
- Understanding Multiple mechanisms of action
  - Supraspinal pathway activation, Sympatholytic Effect, Glial cell activation
  - Neurochemical changes, Targeting pathways other than Dorsal Columns
- Stimulation waveforms
  - Tonic stimulation
  - Non-paresthesia modes – High frequency, burst stimulation, Differential targeted multiplex
- Estimated 50,000 SCS were placed in 2017

WVU Selection Process

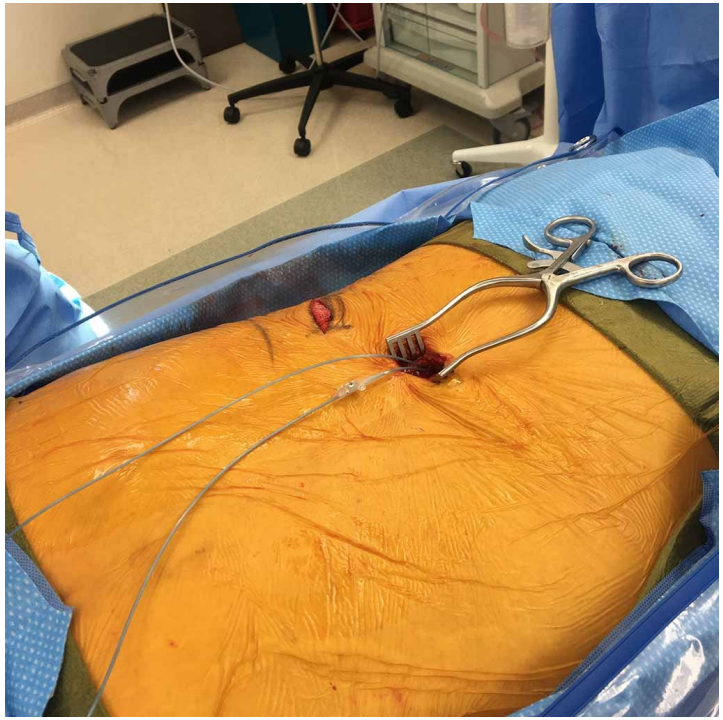
- Initial Consult with Pain Specialist
- MRI of Lumbar and Thoracic: as needed
- Behavioral medicine: insurance requirement
  - Psychology evaluation – R/O: Personality D/O, untreated bi-polar, depression, anxiety
- SCS education class

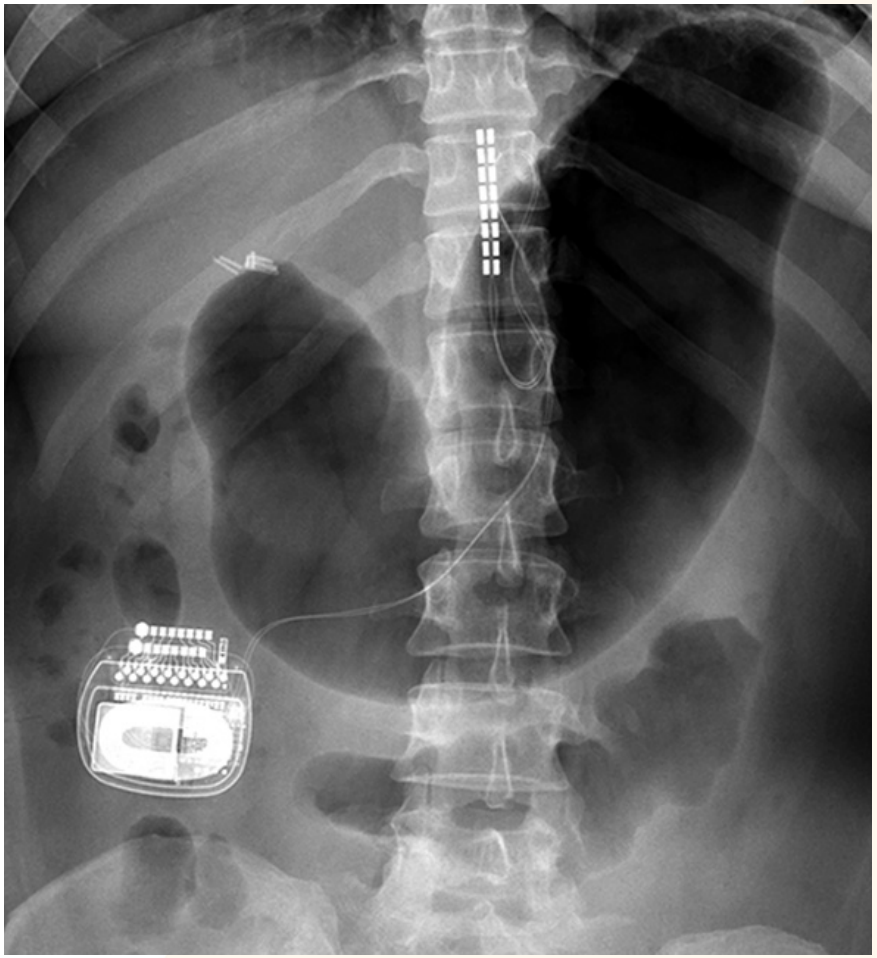
Trial


Omnia
Patient: AAAA-1234
Device: IPG 12345
100%
Connected
P1 2.1mA
Stop Stimulation
Lead Type
Perc.
Top Lead
T8
Program History
Patient Remote
Summary
P1
P2
P3
P4
P5
Select a waveform to begin:
HF10
PD
Pulse Dosing
Frequency Pairing
Burst10k
LF
Traditional Stimulation
Device Selection
Patient Information
Visit Details
Programs
Reports
Paresthesia Testing
Additional Settings
Impedance
Auto-Align
Omnia



SCS implant





Four Systems FDA approved for PDN

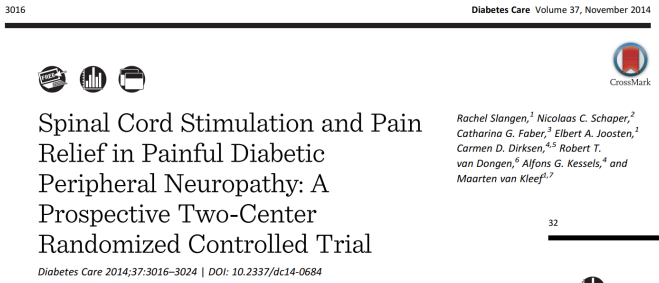
- NEVRO: first to market, 10k Hz frequency(patented), not perceptible to patient
- MEDTRONIC: Tonic stimulation, under 1000Hz, patient feels it, must not be perceived as uncomfortable to succeed. DTM: differential target multiplex not perceptible
- ABBOTT: Burst pattern stimulation
- BOSTON SCIENTIFIC: Tonic stimulation
- Bottom Line: all work
- Non tonic seems to be better

Contraindications and Complications

- Complications
  - Device related complications – more common
    - Lead migration 10-25%
    - Lead malfunction 0-10%
  - Biologic complications
    - Pain over incision site 1-12%
    - Infection - 4-10%
    - Serious neurological injury – 0.3%
- Contraindications
  - Inability to control device
  - Major ongoing psychiatric disorder
  - Unacceptable surgical risk: WVU criteria BMI >40 and HgbA1c >9, other medical comorbidities

Clinical Evidence

- Two multicenter randomized control trials done in 2014
- Both with peer-reviewed publications and inclusion in systematic reviews with meta-analyses
- 5 year follow up data

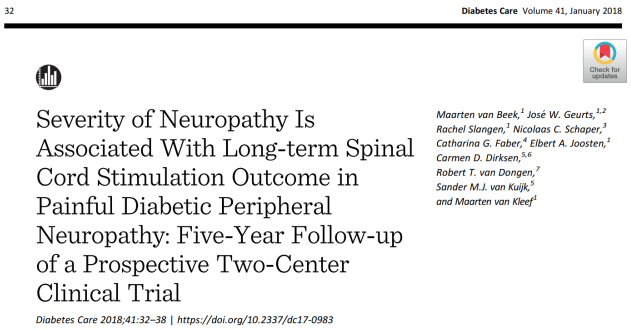


3016 Diabetes Care Volume 37, November 2014

Spinal Cord Stimulation and Pain Relief in Painful Diabetic Peripheral Neuropathy: A Prospective Two-Center Randomized Controlled Trial

Rachel Slangen,[1] Nicolaas C. Schaper,[2] Catharina G. Faber,[3] Elbert A. Joosten,[1] Carmen D. Dirksen,[4,5] Robert T. van Dongen,[6] Alfons G. Kessels,[4] and Maarten van Kleef[1,7]

Diabetes Care 2014;37:3016–3024 | DOI: 10.2337/dc14-0684



32 Diabetes Care Volume 41, January 2018

Severity of Neuropathy Is Associated With Long-term Spinal Cord Stimulation Outcome in Painful Diabetic Peripheral Neuropathy: Five-Year Follow-up of a Prospective Two-Center Clinical Trial

Maarten van Beek,[1] José W. Geurts,[1,2] Rachel Slangen,[1] Nicolaas C. Schaper,[3] Catharina G. Faber,[4] Elbert A. Joosten,[1] Carmen D. Dirksen,[5,6] Robert T. van Dongen,[7] Sander M.J. van Kuijk,[5] and Maarten van Kleef[1]

Diabetes Care 2018;41:32–38 | https://doi.org/10.2337/dc17-0983

PAIN® 155 (2014) 2426–2431

www.elsevier.com/locate/pain

Clinical note

Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial

Cecile C. de Vos [a,b,c,*], Kaare Meier [d], Paul Brocades Zaalberg [e], Harold J.A. Nijhuis [f], Wim Duyvendak [g], Jan Vesper [h], Thomas P. Enggaard [i], Mathieu W.P.M. Lenders [a,c]

WVUMedicine

The Results: *Slangen, et al. Diabetes Care*
and van Beek M, et al. Diabetes Care

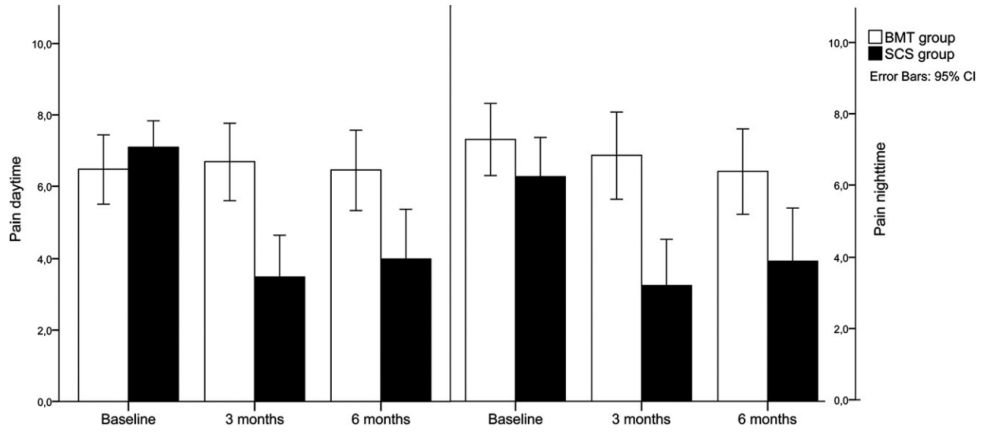
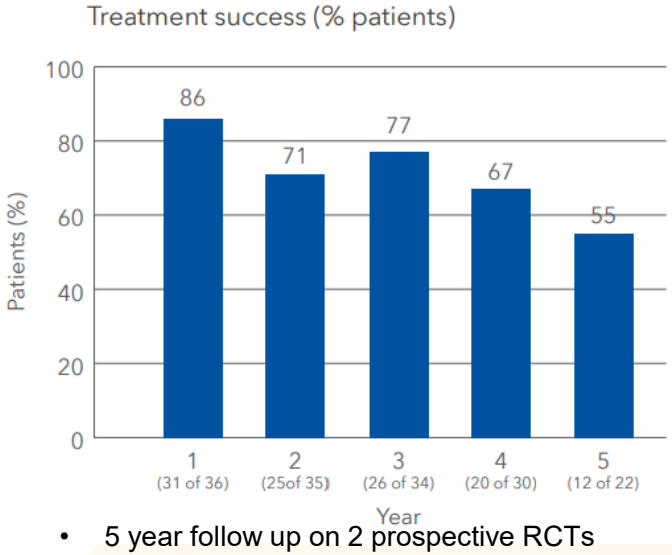


Figure 2—Mean pain scores at daytime and nighttime. ITT analysis.

- Daytime NRS decreased by 3.1 compared to no change (p <0.001)
- Nighttime NRS decreased by 2.4 points compared to 0.9 points (p < 0.003)



- 5 year follow up on 2 prospective RCTs
- Treatment success is at least 50% pain relief or at least "much improved" on the PGIC scale (global impression of change)

The Results: *de Vos et al. PAIN*

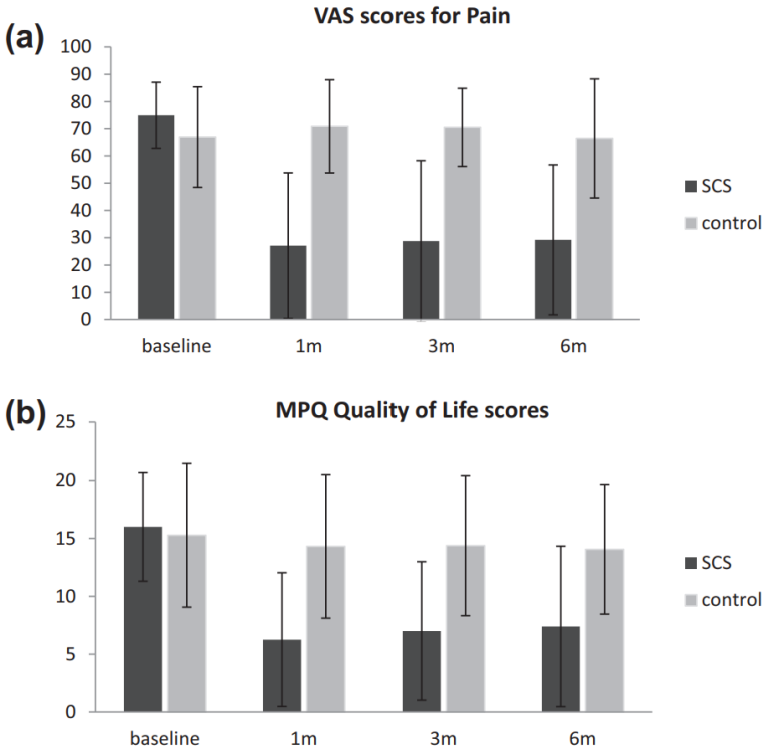


Fig. 1. (a) Average pain scores for the SCS treatment group (dark grey) and control group (light grey) at baseline and after 1, 3, and 6 months of treatment; high score corresponds with severe pain. (b) Average McGill Pain Questionnaire Quality of Life scores; high score corresponds with severely disturbed daily activities and sleep. Error bars represent standard deviation.

Table 2
Outcome measures for study groups at baseline and after 6 months of treatment (intention-to-treat analysis).

Characteristic	SCS		Control	
	Baseline (n = 40)	6 mo (n = 40)	Baseline (n = 20)	6 mo (n = 20)
Pain				
Mean VAS (SD)	73 (16)	31 (28)***	67 (18)	67 (21)^^^
Absolute VAS reduction (SD)		42 (31)		0 (20)^^^
Relative VAS reduction (SD)		55% (41)		0% (47)^^^
>50% pain reduction n (%)		25 (60%)		1 (5%)^^^
MPQ mean NWC-T (SD)	13 (5)	8 (7)***	13 (3)	13 (4)^^
MPQ mean PRI-T (SD)	27(13)	15 (14)***	24 (9)	26 (10)^^
Analgesics				
MQS, mean (SD)	10.6 (9.7)	7.7 (8.7)***	9.2 (7.8)	10.1 (8.2)
Opioids, n (%)	18 (45%)	15 (38%)	11 (55%)	11 (55%)
NSAIDs, n (%)	6 (15%)	3 (8%)	2 (10%)	2 (10%)
Antidepressants n (%)	14 (35%)	13 (33%)	9 (45%)	8 (40%)
Anticonvulsants n (%)	23 (58%)	18 (45%)	7 (35%)	7 (35%)
Acetaminophen n (%)	12 (30%)	7(18%)	6 (30%)	6 (30%)
No analgesics n (%)	6 (15%)	9 (23%)	3 (15%)	1 (5%)
Quality of life				
MPQ QoL score, average (SD)	16 (5)	8 (7)***	15 (6)	14 (6)^^^
EQ5D self-reported health, average (SD)	50 (19)	61 (22)*	46 (17)	41 (20)^^
PGIC pain reduction, n (%)		29 (73%)		3 (17%)^^^
Satisfaction with treatment		8/10		4/10^^^

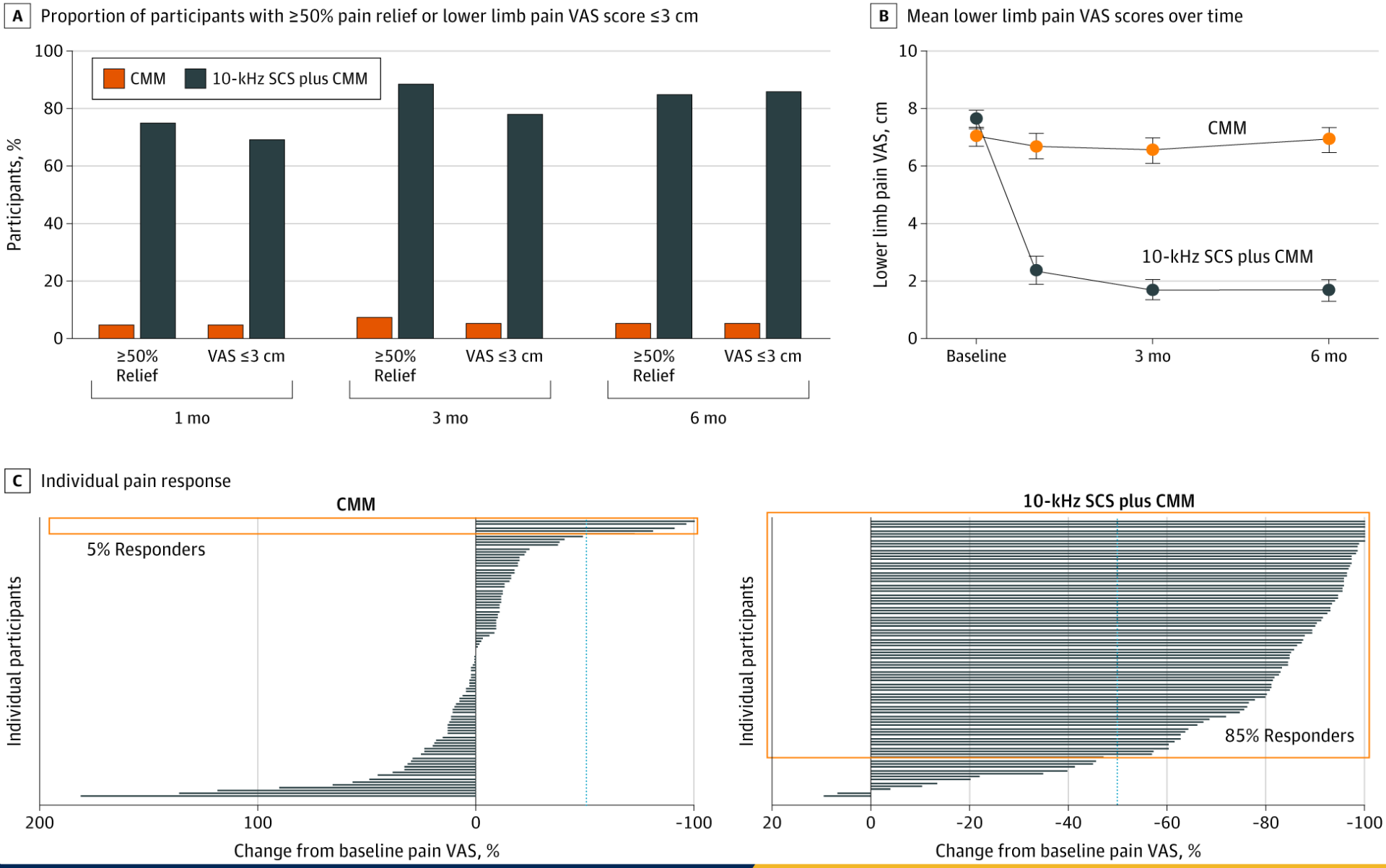
SCS, spinal cord stimulation; VAS, visual analog scale; NWC-T, McGill Pain Questionnaire; PRI-T, pain rating index; NSAID, nonsteroidal anti-inflammatory drug; MPQ, McGill Pain Questionnaire; MQS, Medication Quantification Scale III; QoL, quality of life; EQ5D, EuroQoL 5D; PGIC, patient global impression of change.
*P < .05, ***P < .001 (significant treatment effect within a group); ^^P < .01, and ^^^P < .001 (significant treatment effect between groups).

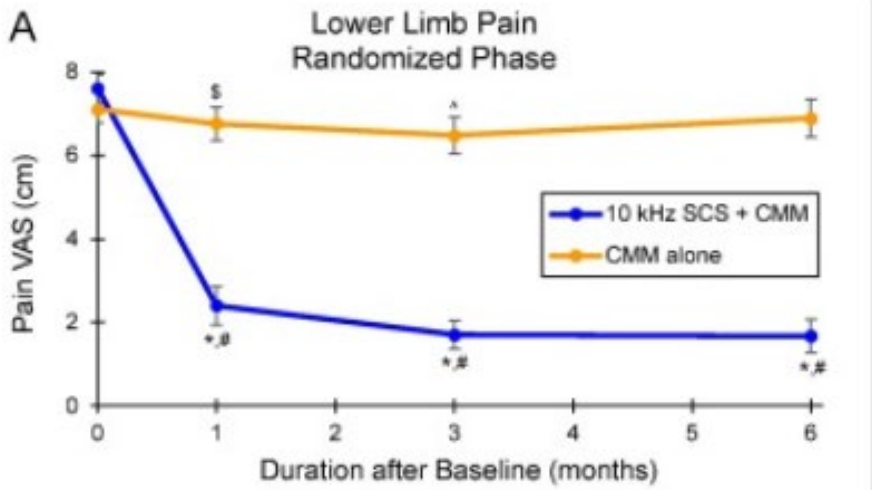
Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy A Randomized Clinical Trial

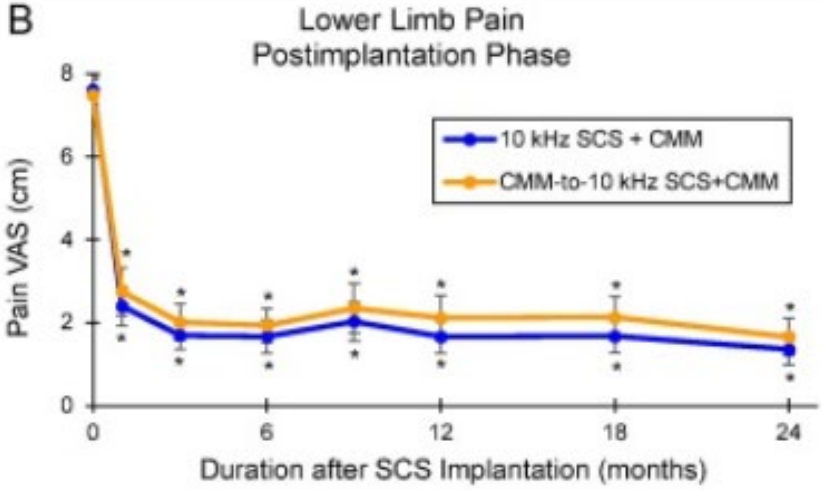
JAMA Neurol. 2021;78(6):687-698

- Inclusion criteria
  - Lower limb pain at least 50 mm
  - Over 12 months of pain
  - Pain refractory to gabapentin or pregabalin and at least 1 other class analgesic
- Exclusion criteria
  - HbA1c >10%
  - BMI > 45
  - Daily MME >120
  - Upper limb pain >30 mm
  - Contraindications to SCS

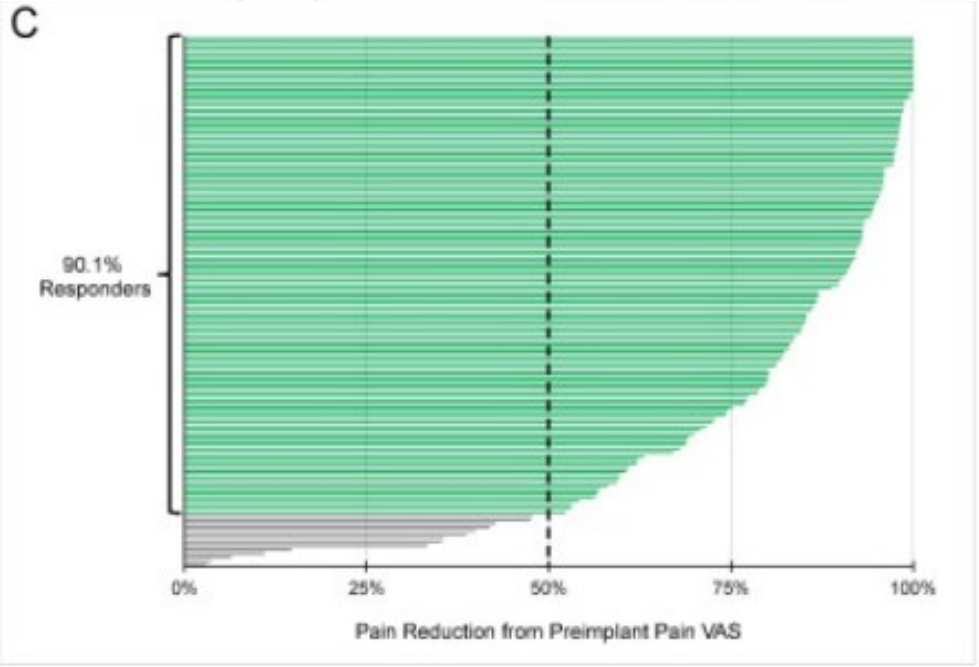
- 216 randomized
- 103 CMM 113 SCS
- 6 trial failures
- 76 of 93 in CMM group elected to crossover
- Pain improved
- QOL improved
- Improved neurological assessment over 6 months


A
Proportion of participants with ≥50% pain relief or lower limb pain VAS score ≤3 cm
CMM
10-kHz SCS plus CMM
Participants, %
100
80
60
40
20
0
≥50% Relief
VAS ≤3 cm
≥50% Relief
VAS ≤3 cm
≥50% Relief
VAS ≤3 cm
1 mo
3 mo
6 mo
B
Mean lower limb pain VAS scores over time
Lower limb pain VAS, cm
10
8
6
4
2
0
CMM
10-kHz SCS plus CMM
Baseline
3 mo
6 mo
C
Individual pain response
CMM
5% Responders
Individual participants
200
100
0
-100
Change from baseline pain VAS, %
10-kHz SCS plus CMM
Individual participants
85% Responders
20
0
-20
-40
-60
-80
-100
Change from baseline pain VAS, %





Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: **24-Month results** of a randomized controlled trial



DN 4 Questions

Interview questions for the patient:
Question 1: Does your pain have one or more of the following characteristics?

	Yes (1)	No (0)
1. Burning		
2. Cold is painful		
3. Electric shocks		

Question 2: Is the pain associated with one or more of the following symptoms in the same area?

	Yes (1)	No (0)
4. Tingling		
5. Pins and needles		
6. Numbness		
7. Itching		

Examination of the patient:
Question 3: Is the pain located in an area where the physical examination had one or both of the following characteristics?

	Yes (1)	No (0)
8. Hypoaesthesia to touch		
9. Hypoaesthesia to pinprick		

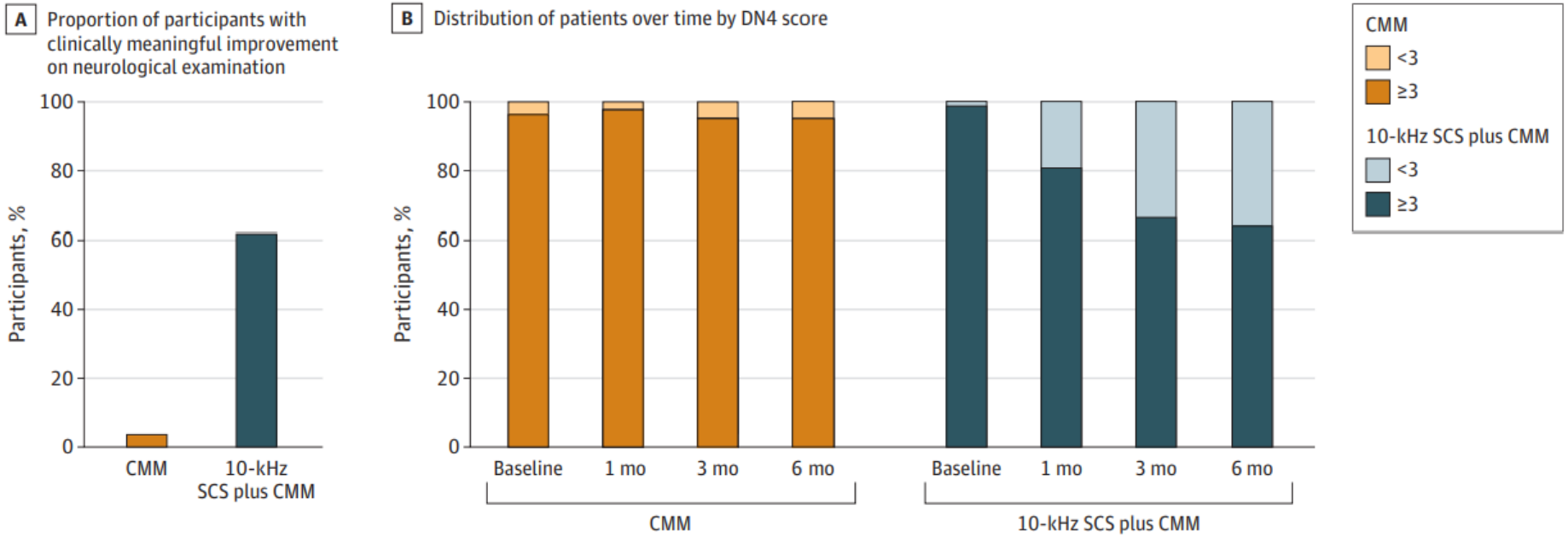
Hypoaesthesia: decreased sensitivity

Question 4: In the painful area, can the pain be caused or increased by:

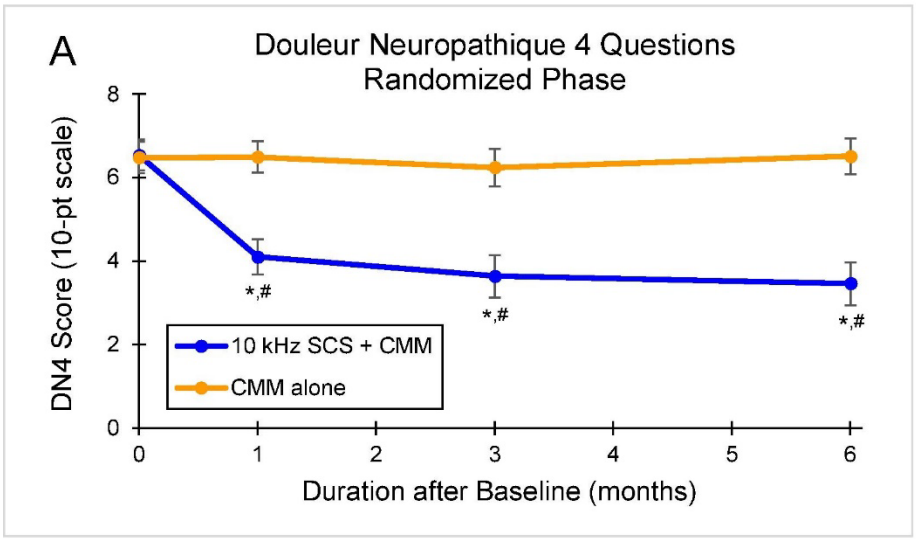
	Yes (1)	No (0)
10. Brushing		
Total score =		

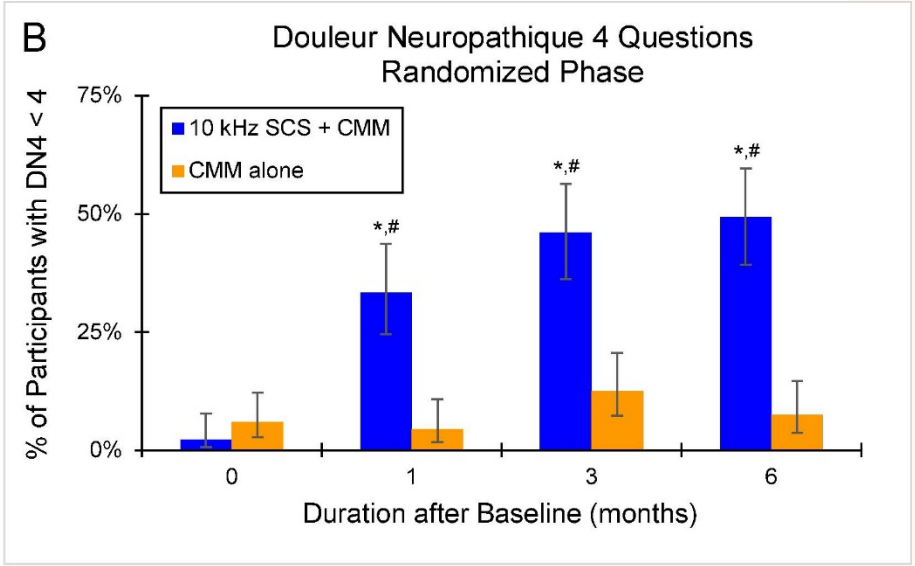
Total score ≥ 4: 90% probability of neuropathic pain.

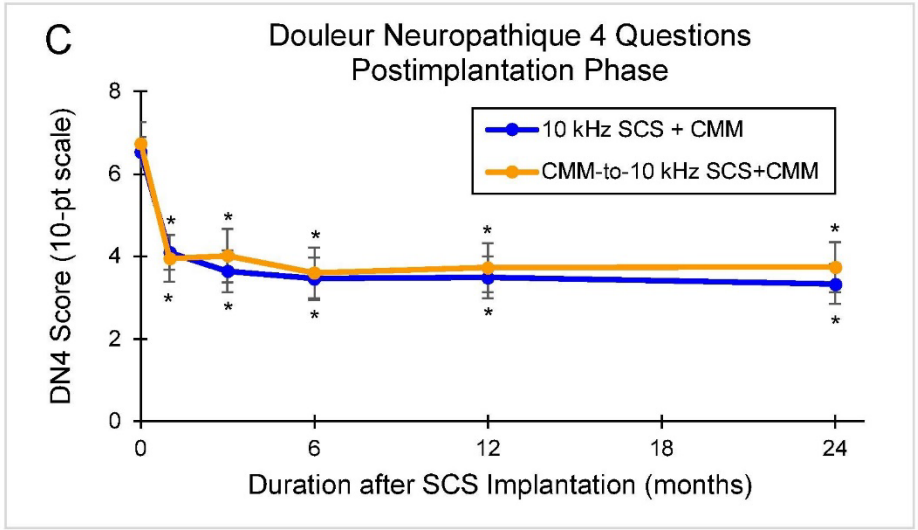
Figure 3. Changes in Neurological Assessment and Quality of Pain

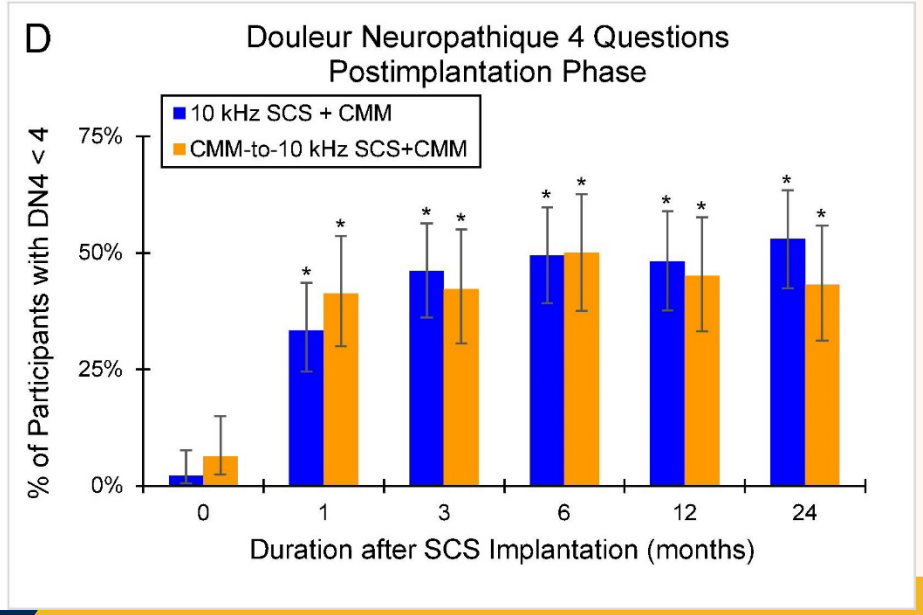


- Investigators documented improvement in neurological exam in 62% of the SCS group at 6 months
- DN4 score decreased with SCS from an average of 6.5 to 3.5 (Score > 4 = likely neuropathy)

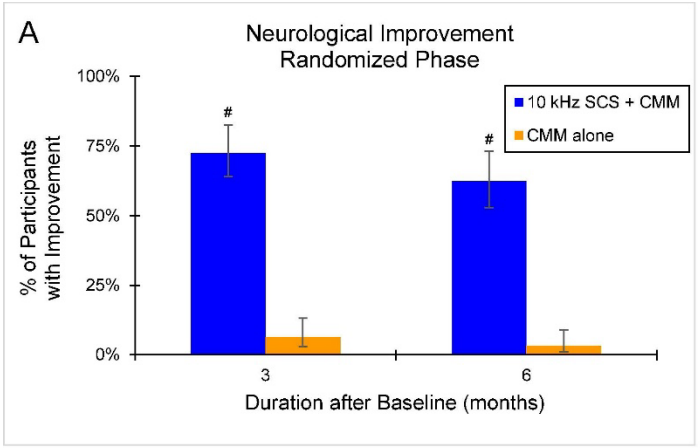

A
Douleur Neuropathique 4 Questions
Randomized Phase
DN4 Score (10-pt scale)
Duration after Baseline (months)
10 kHz SCS + CMM
CMM alone
*,#

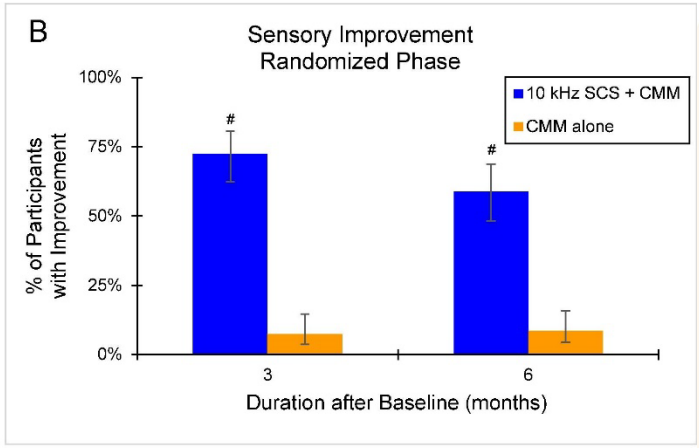

B
Douleur Neuropathique 4 Questions
Randomized Phase
% of Participants with DN4 < 4
Duration after Baseline (months)
10 kHz SCS + CMM
CMM alone
*,#

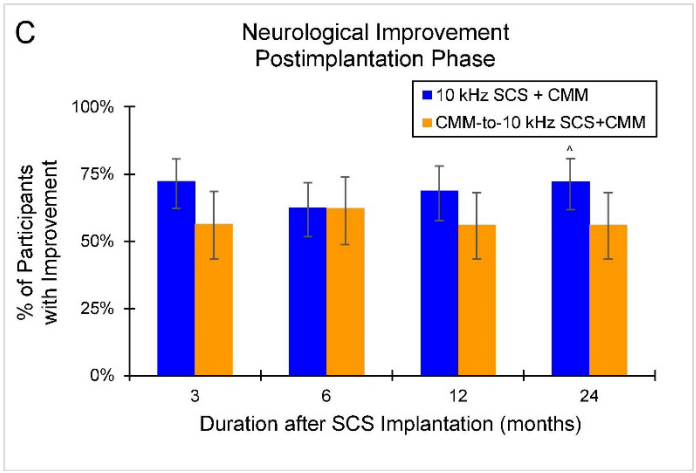

C
Douleur Neuropathique 4 Questions
Postimplantation Phase
DN4 Score (10-pt scale)
Duration after SCS Implantation (months)
10 kHz SCS + CMM
CMM-to-10 kHz SCS+CMM
*

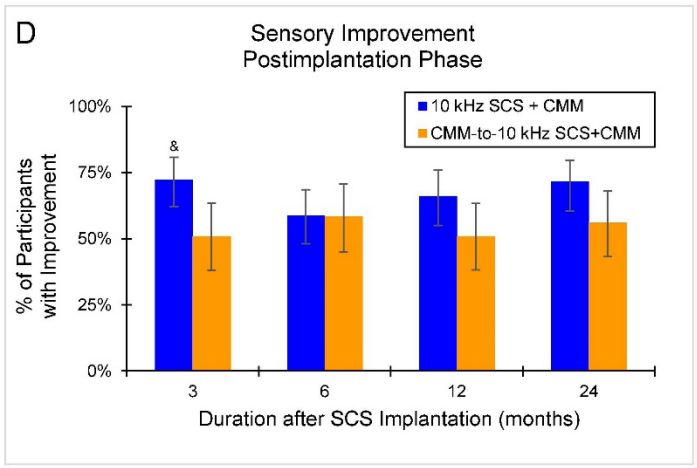

D
Douleur Neuropathique 4 Questions
Postimplantation Phase
% of Participants with DN4 < 4
Duration after SCS Implantation (months)
10 kHz SCS + CMM
CMM-to-10 kHz SCS+CMM
*

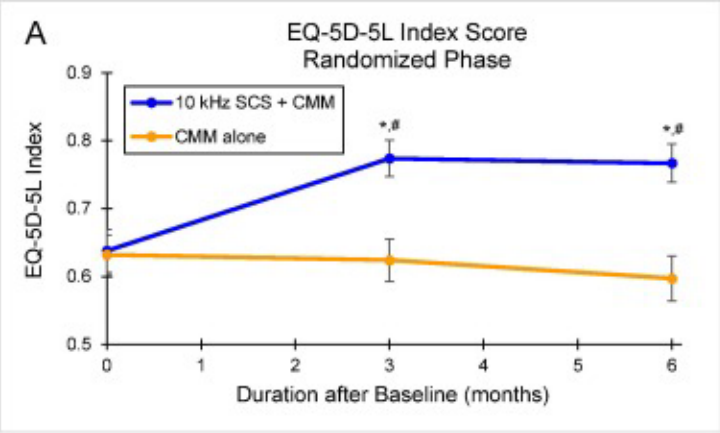
Neurologic Improvement Sensory, Motor or Reflex

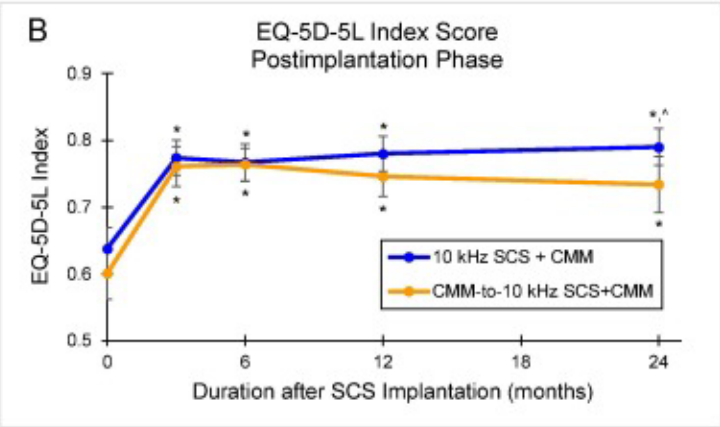


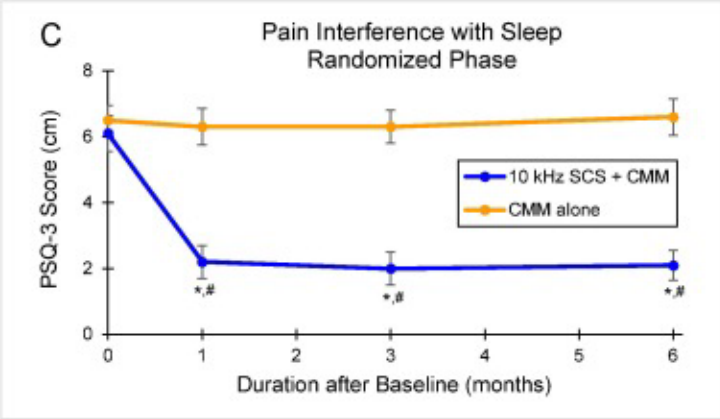


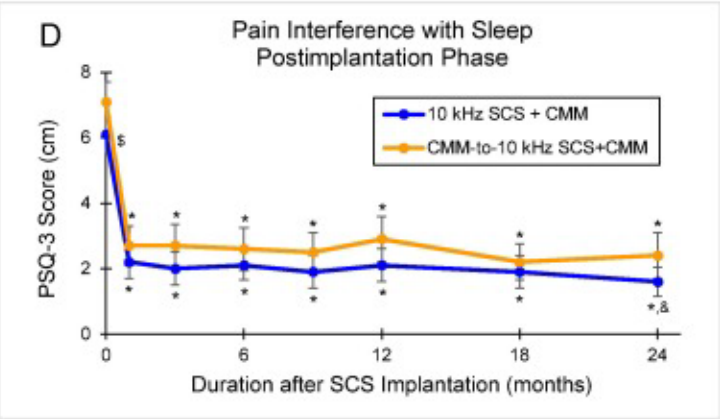












Other Clinical Factors

62% improvement in sleep interference

Improvement in Quality-of-Life P>.001

WVUMedicine

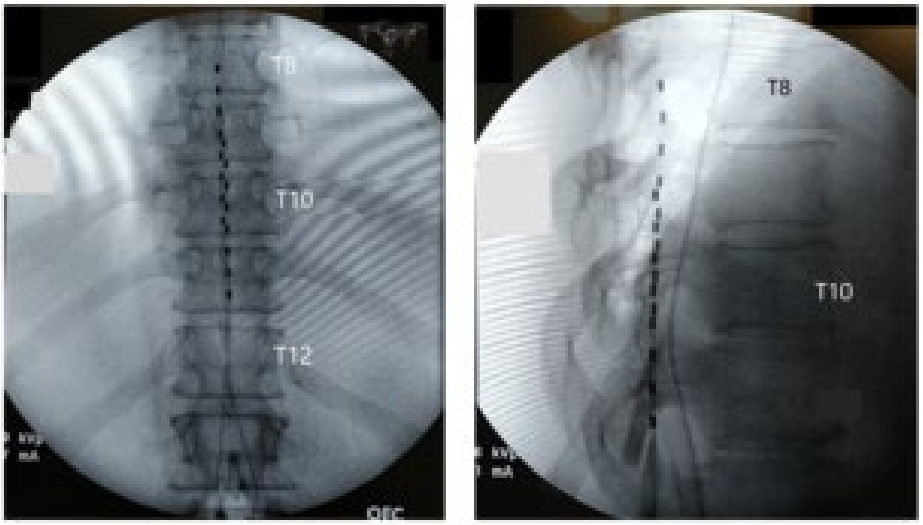
eTable 3. Summary of study-related adverse events

	CMM n = 103	10 kHz SCS + CMM n = 113
Total study-related AEs, n (# of subjects, %)	None reported	18 (14, 12.4%)
Rated as Serious AEs	-	2 (2, 1.8%)
Study-related AEs by type		
Infection	-	3 (3, 2.7%)
Wound dehiscence	-	2 (2, 1.8%)
Impaired healing	-	1 (1, 0.9%)
Device extrusion	-	1 (1, 0.9%)
Incision site pain	-	1 (1, 0.9%)
IPG site discomfort	-	1 (1, 0.9%)
Lead migration	-	1 (1, 0.9%)
Contact dermatitis	-	1 (1, 0.9%)
Urticaria	-	1 (1, 0.9%)
Radiculopathy	-	1 (1, 0.9%)
Uncomfortable stimulation	-	1 (1, 0.9%)
Gastroesophageal reflux	-	1 (1, 0.9%)
Myalgia	-	1 (1, 0.9%)
Arthralgia	-	1 (1, 0.9%)
Hyporeflexia	-	1 (1, 0.9%)

eTable 3: Summary of study-related adverse events (AEs). IPG: implantable pulse generator.

WVUMedicine

eFigure 2. Spinal cord stimulation lead placement



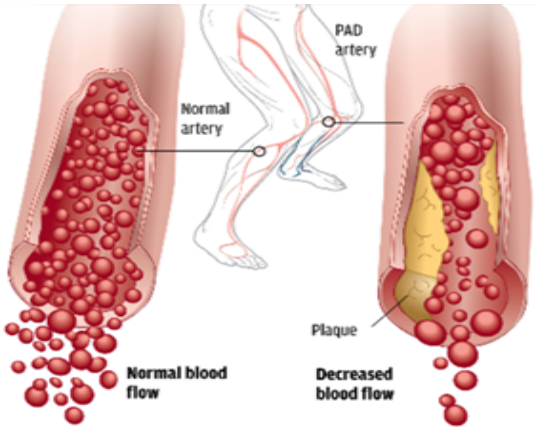
eFigure 2: Typical placement of stimulation electrodes along midline T8-T11 vertebral levels shown in anterior-posterior (left) and lateral (right) x-rays.

SCS IN LIMB ISCHEMIA

Chronic-Critical Limb Ischemia

Mortality rate up to 25% within one year of diagnosis and over 50% at 5 years[1].

Currently limited treatment options for CLI: **revascularization or amputation.** No approved drugs for treatment.

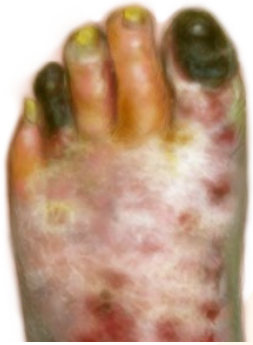


Age and diabetes are two significant risk factors for PAD and CLI. Increasing trends for both.

CLI associated with **high risk** of cardiovascular events, including **myocardial infarction, stroke and death.**

Source:
1. The Sage Group LLC

UP TO **30%**
Amputation Rate
By 1 year post-diagnosis



UP TO **25%**
Mortality Rate

Diagnosis

Table 1. Noninvasive Vascular Testing in Chronic Limb-Threatening Ischemia.*

Test	Description	Normal Findings	Findings Consistent with Chronic Limb-Threatening Ischemia	Advantages	Limitations
Ankle pressure and ankle–brachial index	Systolic blood pressures are measured with the use of limb cuffs at the ankle (dorsalis pedis and posterior tibial arteries) and with a Doppler probe.	Ankle–brachial index >0.9	Ankle pressure <70 mm Hg for tissue loss and <50 mm Hg for ischemic pain while at rest; ankle–brachial index <0.5	Widely available; simple to perform; inexpensive	May be falsely elevated or normal in patients with calcified tibial arteries (e.g., those with diabetes, renal failure, or advanced age)
Toe pressure and toe–brachial index	Systolic pressure in the toe (usually the first toe) is obtained with the use of a small occlusive cuff, and distal flow is measured with a flow sensor.	Toe–brachial index >0.75	Toe pressure <50 mm Hg for tissue loss and <30 mm Hg for ischemic pain while at rest; toe–brachial index <0.3	Simple to perform; inexpensive; useful in patients with noncompressible tibial arteries (and unreliable ankle pressures)	Toe cuffs not universally available; digital arteries may also be noncompressible in certain patients (e.g., those with diabetes, renal failure, or advanced age)
Pulse-volume recordings	Changes in limb volume with the cardiac cycle are recorded with the use of limb cuffs connected to a plethysmograph.	High-amplitude waveforms with dicrotic notch	Low-amplitude waveforms at the ankle and foot	Useful in patients with poorly compressible or noncompressible arteries	Not widely available; subjective; qualitative and may be abnormal with severe cardiac insufficiency
Doppler waveforms	Continuous-wave Doppler flow at the ankle (dorsalis pedis and posterior tibial arteries) is evaluated.	Triphasic or biphasic Doppler waveforms	Monophasic, low-amplitude waveforms at the ankle	Widely available; simple to perform; useful in patients with poorly compressible or noncompressible arteries	Subjective and qualitative
Transcutaneous oximetry	Measurement of $TcPo_2$ is performed in the distal limb with the use of electrodes and compared with a reference value (chest).	$TcPo_2$ >60 mm Hg	$TcPo_2$ <40 mm Hg for tissue loss and <20 mm Hg for ischemic pain while at rest	Helpful in assessing perfusion and healing potential; not affected by arterial calcification	Dependent on multiple factors (e.g., ambient and skin temperature, edema, obesity, and hyperkeratosis)

* To calculate the ankle–brachial index to assess the degree of ischemia, divide the highest ankle pressure by the highest brachial pressure. To calculate the toe–brachial index, divide the toe pressure by the brachial pressure. $TcPo_2$ denotes transcutaneous oxygen pressure.

Results

Spinal cord stimulation for non-reconstructable chronic critical leg ischemia
Cochrane Database Systematic Review
2013 Feb 28

- Limb salvage at 12 months was significantly higher in the SCS groups with a number needed to treat (NNT) of 9.
- In the SCS groups significant pain relief was more prominent and fewer analgesics were used.
- More patients improved to Fontaine stage II in the SCS groups compared to the conservative only groups. (NNT=3)
- No significantly different effect on ulcer healing was observed
- The patients receiving conservative treatment alone had a higher incidence of G.I. bleeding, dizziness, and nausea.

Proposed Mechanism

- One of these proposed possibilities is that SCS causes release of Nitric oxide (NO) (vasodilator) within the vascular system.

- Modulation of the sympathetic nervous system has also been postulated as a possible mechanism.

Conclusion

- CLI – Cost over 200 billion a year and is responsible for over 58000 deaths
- Spinal Cord stimulations can be a helpful modality in non-operable or failed operative vascular disease for treating pain, improving healing of skin ulcerations and possible limb salvage.
- The earlier referral is important since TcPO2 <20 mmHG result in poorer outcomes
- Cost effectiveness
  - SCS + CMM is more expensive over 20 years than CMM
  - SCS + CMM therapy more than doubled the quality-adjusted life year (QALY) for those patients.

Questions ?

Vaglientir@hsc.wvu.edu
Office: 304-598-6216
Cell: 304-282-0801