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Retrospective Review

Spinal Cord Stimulation Tolerance and Treatment by Waveform Conversion Using Externalized Trialing: A Retrospective Review

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Conflict of interest: Dr. Wahezi receives research funding from Boston Scientific, Abbott, and Vertos. He is also a consultant for Boston Scientific. Dr. Wahezi also holds neuromodulation patents 11,964,153; 12,138,454; 12,138,455; 12,191,034. Dr. Petersen has received research funding from Mainstay, Medtronic, Nalu, Neuros Medical, Nevro Corp, ReNeuron, SPR, Surgical Information Systems, and Saluda, as well as personal fees from Abbott Neuromodulation, Biotronik, Medtronic Neuromodulation, Nalu, Neuros

Background: Spinal cord stimulation is utilized in the management of a variety of pain states. Commonly, implanted stimulator systems lose their efficacy, resulting in explantation of the devices. Strategies beyond repositioning the leads have evolved in recent years. Replacing generators to deliver a new electrical signaling is known as "salvage" or "rescue" therapy.

Objectives: To assess the impact of testing multiple pulse generator systems during a salvage trial on clinical outcomes and cost-effectiveness in patients with failed primary SCS devices.

Study Design: Retrospective chart review.

Setting: An academic health care institution.

Methods: We retrospectively reviewed the charts of patients who were treated from 2016 to 2019, had previously been implanted with spinal cord stimulation (SCS) systems, and had subsequently undergone a salvage trial in the operating room. In all cases, the original SCS generator was explanted while the existing epidural lead array was preserved and connected to percutaneous extension leads. Those leads were externalized and attached to an alternative stimulation system. Patients underwent a one-week externalized trial with individualized parameter optimization. They then returned to the operating room for either permanent implantation or system removal. Data on changes in visual analog scale (VAS) scores, percent coverage, potential morphine equivalent daily dose (PMEDD), and trial outcomes were collected.

Results: We reviewed 20 serially treated patients who had been previously implanted with SCS systems and subsequently undergone a salvage trial in the operating room. The present investigation found, in a subgroup analysis of patients, that gender may play a role in the complexity of waveform selection. Average age was slightly higher in the multiple trial group (55.4 years versus 49.6 years), and both groups had comparable BMI values (32.6 versus 32.16). Patients in the multiple-trial group tended to proceed to salvage therapy sooner (3.5 years versus 4.9 years, $P < 0.001$). In summary, proprietary electrical signaling platform cycling seems to be an effective strategy for SCS salvage. Pre-trialing may improve implantation outcomes, and larger studies are warranted to develop best practice strategies for these chronic pain patients.

Limitations: Limitations include a small sample size, variability in follow-up timing, inconsistent reporting of clinical data, and the absence of standardized functional and quality-of-life outcome measures.

Conclusion: Emerging stimulation paradigms such as burst and high-frequency stimulation present promising alternatives for patients with ineffective SCS systems. In cases wherein the existing device cannot support these modalities, an IPG externalization trial may serve as a low-risk strategy to potentially rescue and optimize therapy.

Key words: Spinal cord stimulation, electrical signaling, pain processing, chronic pain, salvage therapy, rescue therapy

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Spinal cord stimulation (SCS) is a standard treatment for the management of chronic pain that uses electrical signaling (ES) to alter pain processing. Several SCS generators exist, each of which has its own proprietary electrical signaling (PES) platforms to modulate different spinal cord (SC) pathways (1). However, the efficacy of ES can diminish over time, with studies indicating that approximately 30-40% of patients implanted with SCS generators lose significant therapeutic benefits within one to 5 years after the implantation. In such cases, salvage therapy, including generator replacement or lead revision, is considered. Literature suggests that around 10-20% of patients with implanted SCS devices eventually proceed to salvage interventions (2,3). Some generators have the capability to apply several types of ES; for those, reprogramming to a different ES may salvage therapy (4). However, when reprogramming fails, patients may need to have their systems replaced for the purpose of trying an ES provided by a different generator.

To reiterate, the strategy of replacing generators to deliver a new ES is known as "salvage" or "rescue" therapy. This procedure is usually effected by the surgical placement of a different generator, with or without lead revision. Most often, salvage generators are placed without the trialing of PES for potential efficacy. The present investigation evaluated whether testing multiple PES during a salvage trial could help optimize out comes and healthcare costs, since most insurance plans cover only one trial prior to the de novo implantation. Here, we describe a novel technique for pre-surgical trialing of generator revision in 20 patients who did not respond to the PES of their original device.

Methods

This study was conducted with a waiver of informed consent and approval from the University of Arkansas for Medical Sciences Institutional Review Board (IRB). All patient records and data were anonymized and de-identified prior to analysis. We reviewed 20 patients who had been serially treated from 2016 to 2019 with previously implanted SCS systems and subsequently undergone a salvage trial in the operating room. Patients were included if they no longer responded to their PES—with cessation of response defined as failure to achieve at least a 50% reduction in pain compared to the pre-procedure scores or the persistent reporting of pain scores above 6 on the Visual Analog Scale (VAS) during the preceding year—and if they failed at least 3 reprogramming attempts within a one-year period.

Procedure

In each case, the patient's existing SCS generator was explanted. The existing epidural lead array was preserved and connected to percutaneous extension leads, which were then externalized and connected to an alternative stimulation system for approximately one week. Stimulation parameters were optimized based on individual response. This approach allowed the trialing of different neuromodulation paradigms without requiring new lead placement. Following the trial period, patients returned to the operating room for either the permanent implantation of a new system or complete removal of the system, depending on the trial outcomes.

Data Collection and Outcome Measures

Retrospective data collected from electronic medical records comprised the following:

- Pain scores: pre- and post-trial VAS pain scores
- Opioid use: changes in potential morphine equivalent daily dosage (PMEDD)
- Pain coverage: Patient-reported percentage of overall pain relief experienced during the trial period. Numeric pain scores like the VAS measure pain intensity, whereas pain coverage represents the patient's reported percentage of pain relief, allowing assessment of both the severity of pain and the extent of relief provided by the treatment.
- Trial outcomes: the proportion of patients proceeding to permanent implantation vs. explantation

Outcome measures were analyzed to assess the effectiveness of the salvage trial in restoring SCS.

Results

Twenty patients (mean age: 51.65 years; range: 32–88) were included in the analysis, comprising 16 women and 4 men (Table 1). All patients underwent an externalization trial between 2016 and 2019 due to decreased PES efficacy. Data on the longevity of the prior devices was available for 16 patients, revealing a mean duration of 4.48 years (median: 2 years) before salvage therapy. Salvage therapy was successful in 95% of patients.

The primary diagnoses included chronic pain syndrome (n = 18), failed back surgery syndrome (n = 10), lumbosacral radiculopathy (n = 11), complex regional pain syndrome (n = 2), and spinal cord injury neuropathic pain (n = 1) (Fig. 1). Some patients had a single diagnosis, while others presented with multiple concurrent conditions. The time to salvage surgery was also compared among patients with different diagnoses; however, no statistically significant differences were observed between the groups in terms of time to surgery, pain scores, or PMEDD.

Among the 11 patients whose VAS data were available, clinically meaningful improvement was observed in 7 individuals, who experienced some degree of pain reduction. The mean pre-salvage pain score decreased from 6.59 (SD 1.56) to 5.32 (SD 1.93) after the procedure, resulting in a mean reduction of 1.27 (SD 1.49, range: -1 to 4). A paired t-test showed this decrease to be statistically significant ($P = 0.018$), indicating a meaningful reduction in pain following the procedure (Fig. 2, Table 2). Before the salvage therapy, those patients' mean PMEDD was 107.1, whereas their post-salvage mean PMEDD was 103.6 (Table 2). Three patients reduced their PMEDD, while 4 increased their dosage. No significant correlation was observed among PMEDD, VAS, and percentage of pain coverage. On average, patients reported a 44% subjective reduction in pain, along with overall satisfaction with the change in therapy strategy. All patients were previously unresponsive to variations of subparesthesia or tonic-based ES and transitioned to systems with different PES.

Among the 20 patients, 6 underwent salvage using a new IPG from the same manufacturer with different PES, while 14 received alternative systems that also offered new PES. Seven patients required more than one PES trial (Tables 3a, 3b). All patients were previously unresponsive to variations of subparesthesia or tonic-based ES and transitioned to systems with different PES.

BMI appeared to influence outcomes (Table 4). The mean BMI of the 20 patients was 32.3 kg/m² (95% CI: 29.5–35.1). There was no statistically significant difference in VAS pain score reduction between patients with

Table 1. *Study demographics.*

Variable	Value
Study Design	Retrospective
Study Interval	2016-2019
Sample Size	20
Male	4
Female	16
Age	51.7 years (32-88)
BMI	32.31 (95% CI: 29.5–35.1)
Time to Salvage	4.5 (0.75-15) years
Psychiatric Medication Use	16/20 (80%)

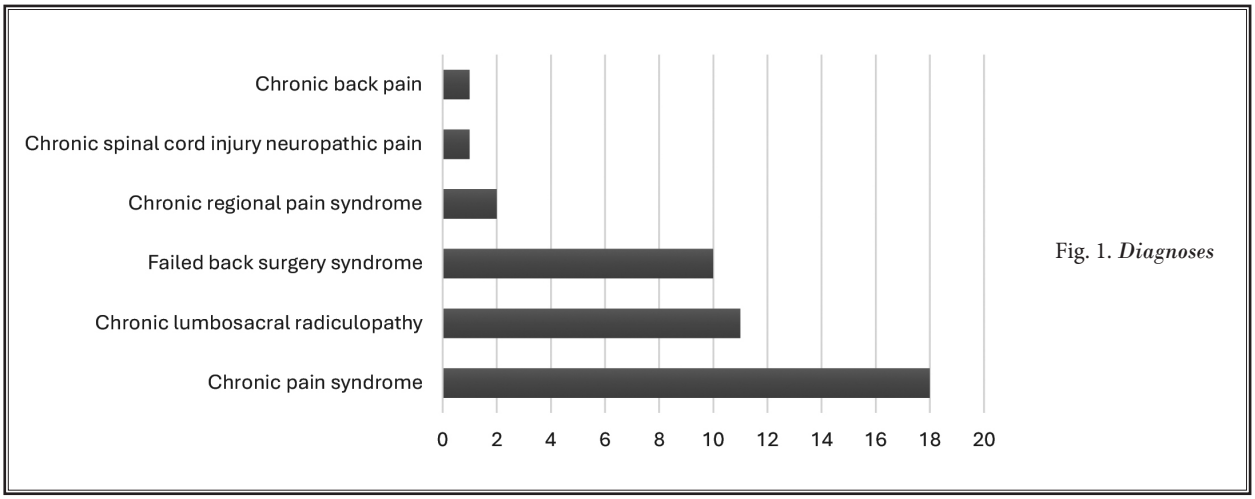

Fig. 1. *Diagnoses*

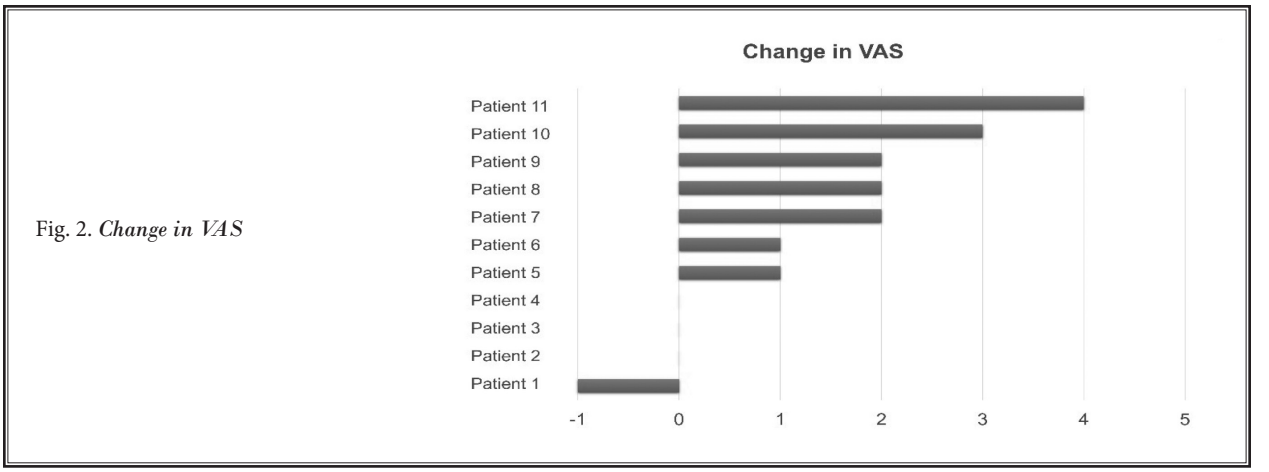

Fig. 2. *Change in VAS*

Table 2. *Primary outcomes*.

Results (n)	
Decrease in VAS (11)	1.3
Decrease in PMEDD (12)	3.6
Improvement in Pain Coverage (7)	44%
Trials Leading to Implanting Trial Generator	19/20 (95%)

a BMI under 30 (n = 6; 2.33 ± 1.70) and those with a BMI over 30 (n = 14; 0.88 ± 1.05). Similarly, those with a BMI under 30 demonstrated a larger reduction in PMEDD scores (4.28 ± 32.41) than did patients with higher BMI, who showed no change, but this difference was also not statistically significant (t(13) = -0.49, $P = 0.630$).

Subgroup Analysis

Among the 20 patients, 7 underwent multiple externalization trials before final system implantation, while 13 patients had a single trial (Table 4a). A comparative analysis between these 2 subgroups is summarized in Table 4. Notably, none of the patients in the multiple-trial group were male, whereas 4 out of 13 patients (31%) in the single-trial group were. The average age was slightly higher in the multiple trial group (55.4 vs. 49.6 years), and both groups had comparable BMI values (32.6 vs. 32.16).

Patients in the multiple-trial group tended to proceed to salvage therapy sooner (mean: 3.5 years vs. 4.9 years, $P < 0.001$). Although the use of psychiatric medications was higher in the multiple-trial group (86% vs. 77%), this difference was not statistically significant ($P = 1.0$). Complete explantation of the prior system was rare in both groups. All patients across both subgroups received systems with a different waveform, and the majority had a change in manufacturer as well (Table 5).

Notably, the single-trial group demonstrated a greater mean reduction in VAS scores (1.57 vs. 0.75, $P < 0.001$) and experienced a decrease in PMEDD, while the multiple-trial group showed an increase (+18.75 vs. –4.03, $P < 0.001$). These findings suggest that patients requiring only one externalization trial may achieve more favorable pain and opioid reduction outcomes following salvage therapy (Table 5).

Discussion

The field of SCS has made considerable progress in the last decade, since each device manufacturer has developed new stimulation patterns that have demonstrated superior clinical efficacy to previous platforms. Despite the superior clinical outcomes, device explantation rates caused by waveform tolerance increase over time, with approximately 5% at one year, 18% at 5 years, and up to 22% at 7 years after the implantation (5,6). Overall, 10-30% of patients with SCS have their devices removed or replaced due to waveform tolerance (1,7,8). The median time to device removal is generally around 4 to 5 years (5,6). Here, we studied a cohort of patients whose waveforms failed to provide long-term benefits. Their IPGs were surgically removed, and the existing leads were connected to a trialing system that delivered a different electrotherapy.

Patients were offered multiple different waveform therapies during the trial and then implanted with a new IPG if it provided them with clinical benefits. There were no statistically significant differences among any of the patients in terms of their time between the diagnoses of their conditions and the receiving of surgery. Neither did the patients' pain scores, pain diagnosis, or PMEDD show statistically significant differences from one another. Main pain scores decreased from 6.59 to

5.3 after waveform switching. Mean PMEDD decreased from 107.1 to 103.6. There was no significant correlation observed among PMEDD, VAS, and percent pain coverage.

On average, patients reported a 44% subjective reduction in pain along with overall satisfaction with the change in waveform therapy. Six patients underwent salvage therapy using a new IPG from the same manufacturer with different waveform applications; 14 received IPGs from different manufacturers. In addition, BMI appeared to influence outcomes. The mean BMI of the 20 patients was 32.3 kg/m² (95% CI: 29.5–35.1). Patients with a BMI under 30 (n = 6) showed a greater mean reduction in VAS pain scores (2.33 ± 1.70) than did those with a BMI over 30 (n = 14; 0.88 ± 1.05), although this difference did not reach statistical significance (t(6.71) = 1.95, *P* = 0.094). Similarly, those with a BMI under 30 demonstrated a larger reduction in PMEDD scores (4.28 ± 32.41) than did patients with a higher BMI, who showed no change, but this difference was also not statistically significant (t(13) = -0.49, *P* = 0.630). Larger trials need to be performed to validate our findings.

The present investigation found the subgroup analysis of patients who required multiple trialing systems to be particularly interesting. All patients in this cohort were female, suggesting that gender may play a role in the complexity of waveform selection. Average

Table 3a. *IPG salvage trial results.*

Results (n)	
Complete explantation of old system	1/20 (5%)
Different manufacturer implanted	14/20 (70%)
IPG—different waveform selected	20/20 (100%)
IPG—one-waveform trial	13/20 (65%)
IPG—2-waveform trial	7/20 (35%)

Table 4. *BMI comparison.*

	BMI < 30, n = 6	**BMI > 30, n = 14**
Decrease in VAS	2.33 ± 1.70 (n = 3)	0.88 ± 1.05 (n = 8)
Decrease in PMEDD	0.00 ± 0.00 (n = 2)	4.28 ± 32.41 (n = 10)
Pain Red Coverage	50 (n = 2)	41 (n = 5)

Table 3b. *Systems and waveforms.*

	Systems				
	Initial Manufacturer	**Initial System**	**Alternate System Trialed but Not Kept**	**Final Manufacturer**	**Final System**
1	Medtronic	Rechargeable		Nevro	Senza®
2	Abbott/St. Jude	Proclaim™ 5 (conventional)		Abbott/St. Jude	Proclaim™ 7–Burst
3	Medtronic	RestoreUltra®	Boston Scientific—WaveWriter™	Abbott/St. Jude	Proclaim™ 7–Burst
4	Boston Scientific	Spectra™	Medtronic—Intellis™	Abbott/St. Jude	Proclaim™ 5
5	Medtronic	RestoreUltra®		Medtronic	Intellis™
6	Abbott/St. Jude	Eon Mini™		Abbott/St. Jude	Proclaim™ 7— Burst
7	Medtronic	RestoreSensor™		Nevro	Senza®
8	Boston Scientific	Spectra™	Nevro—Senza™	Medtronic	Intellis™
9	Boston Scientific		Abbott/St. Jude— Proclaim™ 7	Nevro	Senza®
10	Boston Scientific	Precision™	Nevro—Senza®	Boston Scientific	WaveWriter™
11	Boston Scientific			Abbott/St. Jude	Proclaim™ 7—Burst
12	Medtronic	RestoreUltra®		Medtronic	Intellis™
13	Medtronic	Intellis™	Nevro—Senza®	Medtronic	RestoreSensor®
14	Boston Scientific	Spectra™		Abbott/St. Jude	Proclaim™ 7—Burst
15	Boston Scientific	Montage™		Abbott/St. Jude	Proclaim™ 7—Burst
16	Medtronic	RestoreUltra®		Abbott/St. Jude	Proclaim™ 7—Burst
17	Nevro	Senza®		Abbott/St. Jude	Proclaim™ 5—Burst
18	Boston Scientific	Infinion™/WaveWriter™	Medtronic— RestoreUltra®	Nevro	Senza®
19	Boston Scientific	Montage™		Nevro	Senza® II
20	Boston Scientific	Spectra™		Abbott/St. Jude	Proclaim™ 7—Burst

Table 5. *Single-trial group vs. multiple-trial group.*

Variable	Multiple-Trial	Single-Trial
Sample Size	7	13
Men	0	4
Women	7	9
Age	55.4 (42-68)	49.6 (32-88)
BMI	32.6	32.16
Time to Salvage	3.5 (0.75-10) years	4.9 (1-15) years
Psychiatric Medication Use	6/7 (86%)	10/13 (77%)
Complete Explantation of Old System	0/7 (0%)	1/13 (7.7%)
IPG—Different Manufacturer	5/7 (71%)	9/13 (69%)
IPG—Different Waveform	7/7 (100%)	13/13 (100%)
Decrease in VAS	0.75	1.57
Decrease in PMEDD	18.75	-4.03
Diagnosis	CPS (5), CLR (4), FBSS (3), CRPS (1), spinal cord injury—neuropathic pain (1), chronic back pain (1)	CPS (13), CLR (7), FBSS (7), CRPS (1), chronic back pain (1)

age was slightly higher in the multiple-trial group (55.4 years versus 49.6 years), and both groups had comparable BMI values (32.6 versus 32.16). Furthermore, patients in the multiple-trial group tended to proceed to salvage therapy sooner (meaning 3.5 years versus 4.9 years, $P < 0.001$).

Use of psychiatric medication among patients did not demonstrate statistical significance when comparing the multiple-trial cohort to the single-trial cohort. The single-trial group also demonstrated a statistically significant greater mean reduction in VAS scores (1.57 versus 0.75). Therefore, female gender, earlier tolerance to initial waveform therapy, and older age seem to predict poorer response to waveform switching. Though this information is compelling, we submit that larger trials must be performed to validate the clinical value of this information.

All patients in the study were previously unresponsive to variations of subparesthesia or tonic-based ES prior to waveform switching. In our SCS cohort, switching to a new waveform was preferred by 19 out of 20 patients in this study, suggesting that waveform alteration was an important clinical tool to improve SCS tolerance. Evidence suggests tolerance with sustained PES (3,9,10). Therefore, varying PES may offer an opportunity to restore benefits. We maintain that preoperative trialing should be considered in salvage surgery, as such trialing is during de novo implantation. Though our method allows for the opportunity to verify patient benefits and trial multiple systems prior to the implantation of a new device, we caution against trials longer than 7 days due to a higher infection risk (11). Nearly all patients in this series experienced meaningful symptom relief with revised PES and proceeded to permanent implantation. Although reduction in opioid usage (PMEDD) was modest, it highlights the potential for PES cycling as an opioid-sparing model.

Limitations

Limitations to this study include the small sample size, retrospective design, lack of functional outcomes, and lack of a comparative group. While several prior reports have demonstrated benefits from cycling PES in salvage scenarios (12,13), the novelty of our approach lies in the pre-trialing of PES options to guide re-implantation decisions. Personalization of SCS therapy remains the goal, although no currently available device appears to deliver ES options to each patient. Future advancements in cross-platform software compatibility may help address this limitation (10). In the interim, surgical pre-trialing of salvage units may be an alternative option.

SCS is an essential part of chronic pain treatment, and recent advancements will reshape our field. However, waveform tolerance which develops as a consequence of monotherapy may prohibit payors from continuing to fund these procedures, as device exchanges prior to IPG end of life reduces the cost benefit of the hardware. Therefore, an app or cloud-based system for waveform sharing which allows uploading of a new waveform may be a way to offer most SCS therapies to a patient without surgery (1,10). There is considerable proprietary, and payor, hurdles that need to be addressed before this innovation is available. However, it may be an elegant solution to a prevalent problem.

Conclusion

PES cycling seems to be an effective strategy for SCS salvage, and pre-trialing may improve implantation outcomes.

Author Contributions

Dr. Sayed Emal Wahezi, MD, is responsible for the overall content as guarantor. He accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

SK: Conceptualization, manuscript writing, editing, review.
UY: Methodology, analysis, original draft preparation, writing, editing,
EAP: Conceptualization, design and data collection, methodology, writing - original draft preparation.
HBC: Manuscript preparation, editing, review.
ADK: Conceptualization, writing, editing, supervision

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