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Anatomic Lead Placement Without Paresthesia Mapping Provides Effective and Predictable Therapy During the Trial Evaluation Period: Results From the Prospective, Multicenter, Randomized, DELIVERY Study

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Objective: The purpose of this study was to compare the trial success rate between anatomic lead placement (AP) and paresthesia-mapped (PM) lead placement techniques for spinal cord stimulation (SCS) using a nonlinear burst stimulation pattern.

Materials and Methods: Eligible patients with back and/or leg pain with a Numeric Rating Scale (NRS) score of ≥6 who had not undergone previous SCS were enrolled in the study. A total of 270 patients were randomized in a 1:1 ratio to each treatment arm. In the AP group, one lead tip was placed at the mid-body of T8, and the other at the superior endplate of T9. In the PM group, physicians confirmed coverage of the patient's primary pain location. Trial success was a composite of the following: ≥50% patient-reported pain relief at the end of the minimum three-day trial period, physician's recommendation, and patient's interest in a permanent implant.

Results: Trial success for AP vs. PM groups was equivalent to 84.4% and 82.3%, respectively. Physicians who performed both techniques preferred AP technique (70% vs. 30%). Procedure times for placement of two leads were 31% shorter in the AP group ($p < 0.0001$). Decrease in the mean NRS pain score was similar between groups (53.2%, AP group; 53.8%, PM group, $p = 0.79$). Trial success for patients who went on to an extended trial with tonic stimulation was 50% (5/10) vs. 79% (11/14) for AP group and PM group, respectively ($p = 0.2$). A total of 13 adverse events were observed (4.5%), most commonly lead migrations and pain around implant site, with no difference between groups.

Conclusions: When using a nonlinear burst stimulation pattern, anatomic or PM lead placement technique may be used. Non-responders to subthreshold stimulation had a higher conversion rate when a PM technique was used. AP resulted in shorter procedure times with a similar safety profile and was strongly preferred by trialing physicians.

Keywords: Burst stimulation therapy, chronic pain, intraoperative paresthesia testing, lead placement, spinal cord stimulation

Conflict of Interest: Jason Pope serves as a paid consultant for Abbott, Flowonix, Jazz Pharmaceuticals, Medtronic, Nevro, and Saluda. Stefan Schu serves as a paid consultant for Abbott. Dawood Sayed serves as a paid consultant for Abbott, Flowonix, Merit, Vertiflex, Nevro, and SPR. Ahmed Raslan serves as a paid consultant for Abbott. Ganesan Baranidharan serves as a paid consultant for Abbott, Nevro, Boston Scientific, and Nalu. Robert Heros serves as a paid consultant for Abbott. Bram Blomme and Robyn Capobianco are the employees of Abbott (formerly St. Jude Medical). Timothy Deer serves as a paid consultant for Abbott, Axonics, Bioness, Flowonix, Mainstay, Nalu, Saluda, SpineThera, Vertiflex, and Vertos.

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INTRODUCTION

Spinal cord stimulation (SCS) has been successfully used for the treatment of chronic pain for the past five decades (1). It has been shown to increase the quality of life for patients with chronic pain, reduce medication use, and achieve significant cost savings over time compared with conventional medical pain management (2). SCS has been used to treat a variety of neuropathic pain conditions including failed back surgery syndrome (3,4), complex regional pain syndrome (5–7), phantom limb pain (8), ischemic limb pain (9), refractory unilateral limb pain syndrome (10), postherpetic neuralgia (11), and acute herpes zoster pain (11). Typically, candidates for SCS therapy are those who have failed other treatment options and have reached the end of the traditional treatment continuum.

Conventional SCS uses a tonic waveform that delivers repetitive pulses at constant amplitude, pulse width, and frequency. During tonic stimulation, effective pain relief has been dependent on stimulation-induced paresthesia that overlaps with areas of chronic pain (12,13). BurstDR (nonlinear burst) (Abbott, Plano, TX, USA) is a stimulation design that delivers a burst packet of closely spaced monopolar spike discharges with a nonlinear accumulation of charge during the bursting phase followed by a quiescence phase where there is a passive charge balance (14,15). The amplitudes used for nonlinear burst stimulation therapy are much lower than those for tonic stimulation. When compared to tonic stimulation, burst stimulation therapy is associated with a reduction of paresthesia or no paresthesia. This stimulation design has been shown to be more effective than tonic stimulation for the treatment of neuropathic pain in several studies (16–22).

SCS treatment most commonly involves a short-term evaluation period called a "trial," which may last from 3 to 30 days depending on patient satisfaction, payor requirements, and the physician's discretion. The standard of care for a "successful" trial evaluation includes, but is not limited to, the patient's assessment of at least 50% pain relief and willingness to have the system permanently implanted. At present, trial leads for a burst SCS system are placed using intraoperative paresthesia mapping. Briefly, paresthesia tonic stimulation parameters are used intraoperatively to elicit feedback from patients to confirm that leads are properly localized over the area of the spinal cord concordant with the location of the patient's primary pain complaint. After the leads are placed, the clinician programs the stimulation parameters to provide the maximum level of pain relief switching from conventional tonic to burst stimulation therapy. Herein, we report the results of a randomized, controlled, prospective, multicenter study evaluating anatomic vs. paresthesia-mapped (PM) lead placement for burst therapy during the trial evaluation period (DELIVERY). The DELIVERY study was set out to demonstrate whether there was any difference in trial success rates if the lead was placed with intraoperative testing (PM) or placed using anatomic landmarks without conventional tonic-based paresthesia mapping.

In different settings, anatomic placement of leads has shown to produce equivalent clinical outcomes compared with more provocative techniques. In deep brain stimulation (DBS) of the subthalamic nucleus (STN) for Parkinson disease, anatomic placement of the DBS lead into the STN vs. microelectrode recording to confirm functional placement resulted in no significant difference in the reduction of clinical symptoms or medication dosage (23). Additionally, for successful cardiac resynchronization therapy (CRT), a spatial and electrical separation of the right and left ventricular electrodes is essential. In patients undergoing CRT, Oddone et al. investigated the optimization of coronary sinus (CS) lead placement targeted to the myocardial segments of the latest electrical activation as guided by measuring the electrical conduction delay between the right ventricular (RV) and CS lead during RV pacing (right-to-left delay). The authors concluded that this technique does not provide additional clinical benefits compared with anatomic placement in basal or midventricular positions of the posterior and lateral walls (24).

The primary endpoint of this study was to demonstrate that the trial success rate with anatomic lead placement (AP) is noninferior to the trial success rate with PM lead placement for the burst stimulation therapy trial evaluation period. In addition, physician's preference for lead placement technique, procedural characteristics, and patient's reported outcomes were collected.

MATERIALS AND METHODS

DELIVERY is a prospective, multicenter, randomized study that was conducted at 23 sites in the United States, Europe, and Australia (ClinicalTrials.gov registration NCT03277378). All sites obtained the Institutional Review Board/Ethics Committee approval before the study commenced.

Patients (≥18 years) with chronic, intractable pain of the trunk and/or lower limbs recommended by a physician for SCS therapy were recruited for this study. Eligible patients had a baseline score on the Numeric Rating Scale (NRS) ≥6 over the past 24 hours for "average overall pain" in the area(s) of chronic pain to be treated with SCS, and a pain profile indicating lead placement from T7 to T10 to achieve coverage of the primary site of pain. Patients with an existing SCS system, previously failed SCS, or had a primary diagnosis of peripheral vascular disease, angina pectoris, or chronic migraine were excluded from the study.

Randomization occurred at the end of the baseline visit or just prior to surgery for the trial system implant visit. Randomization assignment was communicated to the site via randomization application available in the Electronic Data Capture Site Portal. The treating staff had no advance knowledge of the next assignment before the next patient was identified.

Procedures

After providing written informed consent, enrolled patients were randomized in a 1:1 ratio using random permuted blocks of varying length, stratified by site.

The operative conditions and patient preparation were allowed based on the routine for the participating investigator. Similarly, physicians were permitted to use either one or two trial or permanent leads as per their routine. In the PM group, physicians confirmed coverage of the patient's primary pain location using intraoperative testing. In the AP group, specific lead placement guidelines were provided. When using one lead, the tip was placed at the superior endplate of T9. When using two leads, one lead was placed at the mid-body of T8 and the second was placed at the superior endplate of T9. The lead position was confirmed using fluoroscopy. Outside of the United States (OUS), permanent leads are frequently used during the trial procedure for a "staged" trial. This staged trial procedure includes the additional steps of anchoring the leads to the fascia and tunneling the lead(s) to accommodate future implantation of the pulse generator. The leads are then connected to extensions that are externalized for the duration of the trial period. If the trial is a success, the extensions are removed, and the leads are connected to an implantable pulse generator.

Nonlinear burst stimulation therapy parameters were configured using the clinician programmer and delivered using an external

pulse generator (Abbott). The burst stimulation design consisted of a monopolar burst at 500 Hz delivered in groups of five pulses, repeated at a 40 Hz frequency, with a 1 ms pulse width. After burst mode was enabled, the amplitude was slowly ramped upwards by 0.05 mA until the patient experienced any sensation (e.g., pressure, heat) and then slowly decreased until the sensation disappeared. This amplitude was subsequently reduced by 40% and set as the target amplitude. The maximum amplitude for the Patient Controller settings was adjusted to the lowest possible value that was still above the target amplitude. Stimulation cycling was then enabled to improve battery longevity. Cycling began with stimulation on for 30 sec and off for 90 sec. If further optimization was needed to maintain therapeutic efficacy, the on/off durations were reduced (e.g., 15 sec on, 45 sec off; 5 sec on, 15 sec off). In the AP group, if after 3 days the patient was not responding, reprogramming was allowed using the standard protocol and experience.

All patients underwent a minimum three-day stimulation trial and were evaluated for success at the end of three to five days (length of trial period). Those who were considered a trial success exited the study. Those who were not considered a trial success were offered an extended trial evaluation period, utilizing tonic stimulation for an additional three or more days. Patients who refused exited the study and continued their treatment as per the physician's routine.

Study Endpoints

The primary endpoint for this study was the trial success rate at the end of the initial trial evaluation period using a composite of the following: ≥50% of the patients reported pain relief at the end of the initial trial period, the physician's recommendation, and the patient's interest in placement of a permanent system. The NRS score was past 24 hours average overall pain specific to the area(s) of chronic pain being treated. The secondary endpoint was physician's preference based on the following question: "Considering your patient's experience and outcomes and your experience with both lead placement techniques, which technique do you prefer?" (only for physicians who performed both techniques during the study).

The descriptive endpoints of this study comprised procedural characteristics including the total procedure time (room-in to room-out), lead placement time (needle-in to needle-out), and intraoperative fluoroscopy exposure time for each randomized group, stratified by the number of leads (one or two), trial lead type (trial vs. "staged trial"), and geographical area (US and OUS sites).

Therapy satisfaction was measured by asking the following question: "Please indicate the subject's overall level of satisfaction with the therapy". Patients could choose from "Very satisfied/Satisfied/Neither satisfied or dissatisfied/Dissatisfied/Very dissatisfied". The number of patients who answered "satisfied" and "very satisfied" were grouped and expressed as a percentage of the total number of patients.

All adverse events (AEs), including all adverse device effects (ADE), were collected for the duration of the study. ADEs were defined as nonserious AEs related to study device.

Statistics

The analysis for the primary endpoint was a noninferiority test of the difference in trial to permanent conversion rate (i.e., trial

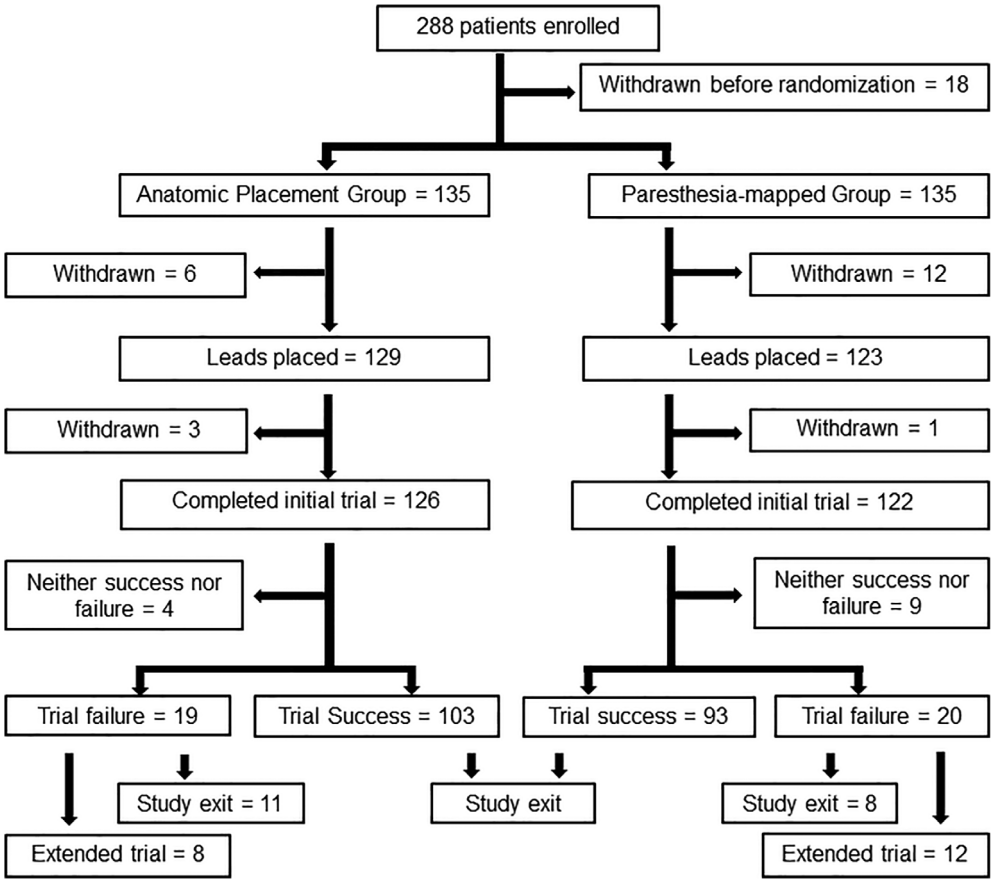

Figure 1. Disposition of patients.

Table 1. Patient Demographics and Baseline Characteristics.

	All randomized patients (*N* = 270)	AP group (*N* = 135)	PM group (*N* = 135)
Age (year)			
Mean ± SD	62.8 ± 13.5	61.8 ± 13.2	63.9 ± 13.8
Range (minimum, maximum)	(25, 89)	(31, 86)	(25, 89)
Gender, % (*n*/*N*)			
Female	61.1% (165/270)	57.8% (78/135)	64.4% (87/135)
Male	38.9% (105/270)	42.2% (57/135)	35.6% (48/135)
Race—United States and Australia only, % (*n*/*N*)			
Black or African American	3.4% (8/232)	4.3% (5/116)	2.6% (3/116)
Native Hawaiian or Other Pacific Islander	0.9% (2/232)	0.9% (1/116)	0.9% (1/116)
White	86.6% (201/232)	88.8% (103/116)	84.5% (98/116)
Other	9.1% (21/232)	6.0% (7/116)	12.1% (14/116)
Years of having chronic pain			
Mean ± SD	11.46 ± 11.48	12.23 ± 11.83	10.69 ± 11.11
Range (minimum, maximum)	(0.08, 60.00)	(0.33, 58.08)	(0.08, 60.00)
Pain diagnosis, % (*n*/*N*)*			
Causalgia	2.6% (7/265)	2.3% (3/132)	3.0% (4/133)
Failed back surgery syndrome	46.8% (124/265)	47.0% (62/132)	45.9% (61/133)
Lumbosacral plexus disorders	0.8% (2/265)	0.8% (1/132)	1.5% (2/133)
Radiculopathy	42.3% (112/265)	43.2% (57/132)	41.4% (55/133)
Intervertebral disk disorder With/without radiculopathy	7.5% (20/265)	6.1% (8/132)	9.0% (12/133)
Complex regional pain syndrome	2.3% (6/265)	3.0% (4/132)	1.5% (2/133)
Other	18.1% (48/265)	17.4% (23/132)	18.8% (25/133)

*A patient might have up to two pain diagnoses.

success rate) between anatomic and PM lead placement. The noninferiority margin was set at 15% with a significance level of 0.05. A sample size of 115 patients for each arm to achieve 80% power to show noninferiority between anatomic and PM lead placement was estimated (PASS 13 [NCSS, LLC]).

RESULTS

Between September 2017 and August 2018, 288 patients at 23 investigational sites were enrolled (Fig. 1, Table 1). The average age was 63 ± 14 years and 61% of the patients were female. Patients had experienced pain for an average of 11.5 ± 11.5 years at the time of study enrollment. Demographics and baseline characteristics were statistically comparable between the two randomized arms (all $p > 0.05$). Figure 1 shows the disposition of the patients. A total of 252 patients had one or two lead(s) placed (200, US and 52, OUS). The total population who completed the trial evaluable period consisted of 126 and 122 patients in the AP and PM groups, respectively. Table 2 summarizes the vertebral levels of lead placement in the PM group. Trial success was achieved in 84% (103/122) of the anatomic and in 82% (93/113) of the PM lead placement group. The trial success rate of patients implanted with one lead was 79.1% (34/43). A total of 13 patients (4, AP and 9, PM) did not meet the conditions required for trial success or trial failure and were therefore excluded from the primary endpoint analysis. A total of 39 patients did not meet the definition of trial success and were offered an extended trial; 8 in the AP group and 12 in the PM group completed the extended trial, and 19 exited the study (Fig. 1).

Table 2. Vertebral Levels of Lead Placement for Leads 1 and 2 in the Paresthesia-Mapped Group.

Vertebral level	Lead 1 (*N* = 123)	Lead 2 (*N* = 98)
T7-T8; *n* (%)	6 (4.9)	6 (6.1)
T7-T9; *n* (%)	25 (20.3)	19 (19.4)
T8-T9; *n* (%)	41 (33.3)	32 (32.7)
T8-T10; *n* (%)	29 (23.6)	29 (29.6)
T8; *n* (%)	2 (1.6)	0 (0.0)
T9-T10; *n* (%)	13 (10.6)	8 (8.2)
T9; *n* (%)	1 (0.8)	0 (0.0)
T9-T11; *n* (%)	3 (2.4)	2 (2.0)
T10-T11; *n* (%)	2 (1.6)	0 (0.0)
T10-T12; *n* (%)	1 (0.8)	2 (2.0)

The estimated difference between the trial success rates for the AP and PM groups was 2.1% (95% lower confidence bound: −6.1%), which is less than the prespecified noninferiority margin of −15%. Therefore, the primary endpoint was met ($p = 0.0003$). The individual independent criteria for permanent implant trial success also did not differ between the groups (Fig. 2). The trial success rate for patients who went on to extended trial with tonic stimulation was higher in the PM group (79% [11/14] vs. 50% [5/10] AP) although this was not significant ($p = 0.2$). Importantly, among physicians who performed both implant procedures, preference was higher for the AP technique (70% vs. 30%).

For patients with a trial success, the mean (SD) reduction in pain, as measured on NRS, was not different between groups: 4.2 (±2.8) and 4.3 (±2.7) point reduction ($p = 0.79$) for AP and PM groups, respectively (Fig. 3). Furthermore, there was no association of patient satisfaction with lead implant technique: 83% (105/126) of the patients in the AP and 82% (99/121) of the patients in the PM group ($p = 0.38$) were satisfied or very satisfied with the therapy.

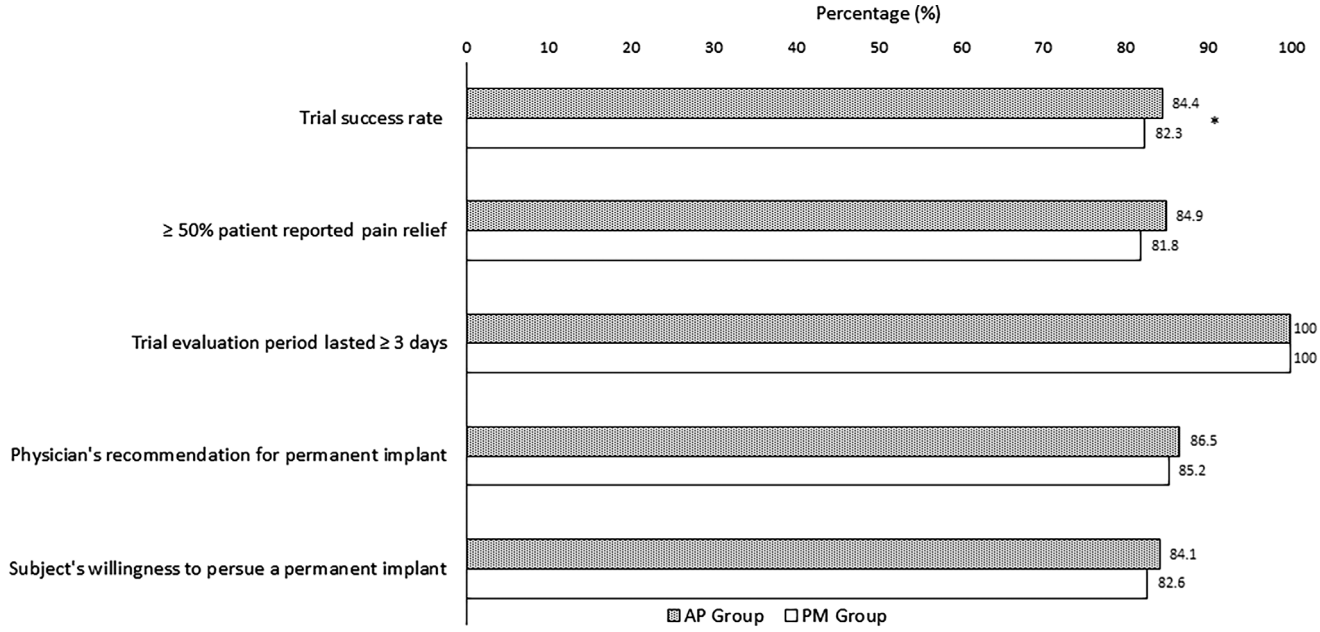

Figure 2. Trial success rate and independent criteria for permanent implant of each lead placement technique.

US sites predominantly used two trial leads (n = 189). This contrasts with sites outside of the United States; both trial and permanent leads were used to a similar extent (permanent leads were used during staged trials).

Intraoperative Characteristics

There was a significant difference in procedure times between lead placement groups. When two trial leads were used, the lead placement time (needle-in to needle-out) was 31% shorter for AP compared with PM technique: 14 $\pm$ 9 min, 21 $\pm$ 11 min, respectively ($p < 0.0001$). Furthermore, the total procedure time (room-in to room-out) was 12% shorter for AP compared with PM technique: 40 $\pm$ 12 min, 46 $\pm$ 14 min, respectively ($p = 0.004$). In contrast, a total of 24 trials with a single trial lead were performed (11, AP and 13, PM) with no significant difference in procedure time between groups (Table 3). A total of 25 staged trials were performed: 6 using two permanent leads and 19 using a single permanent lead. As expected, total procedure times were longer with permanent lead placement. There was no significant difference in procedure time by group except for lead placement time when one permanent lead was used (12 $\pm$ 9 min, AP vs. 23 $\pm$ 12 min, PM; $p = 0.04$) (Table 4). No difference in intraoperative fluoroscopy time was observed between the groups.

A total of 13 AEs were reported; there was no difference by group. One nondevice-related serious AE occurred in the AP group (permanent lead); a patient was hospitalized for acute hemiplegic symptoms on the right side. There were two device-related serious AEs. In the AP group (trial lead), one patient suffered spinal cord compression. As per the investigator, this event was unresolvable; the patient's leads were removed. One patient in the PM group (permanent lead) reported feeling stimulation in unwanted places. The lead placement was revised, and the patient recovered without sequelae. Of the 13 AEs, 10 were

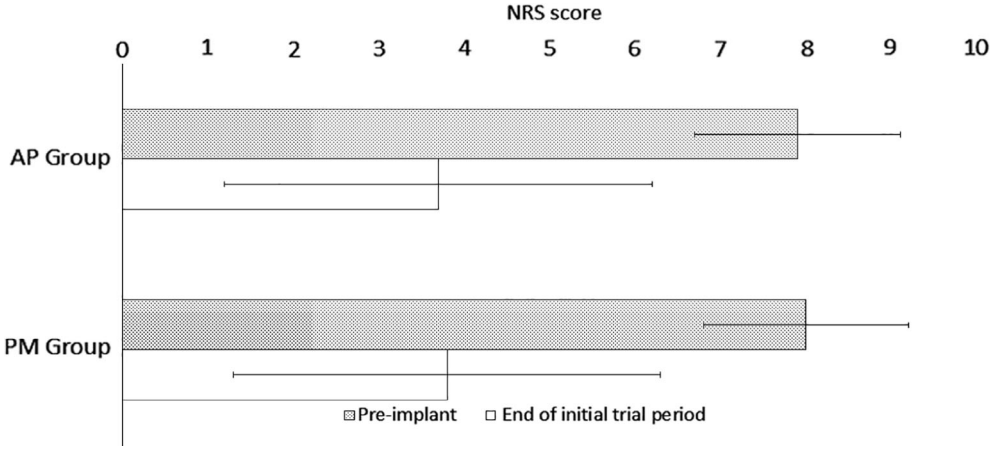

Figure 3. Change in NRS score by the randomization group for patients who completed the initial trial evaluation period. NRS, Numeric Rating Scale.

Table 3. Intraoperative Characteristics for Each Technique Using One or Two Trial Leads in US and OUS Sites.

	One trial lead (N = 24)			Two trial leads (N = 203)		
	AP group (n = 11)	PM group (n = 13)	p value*	AP group (n = 106)	PM group (n = 97)	p value*
Total procedure time (room-in to room-out)						
Mean ± SD	45.0 ± 13.6	49.8 ± 17.6	0.462	40.4 ± 12.3	45.9 ± 14.1	0.004
Range (minimum, maximum)	(20, 64)	(25, 90)		(15, 74)	(17, 90)	
Lead placement time (needle-in to needle-out)						
Mean ± SD	21.2 ± 15.2	26.2 ± 14.9	0.423	14.3 ± 8.5	20.6 ± 10.6	<0.0001
Range (minimum, maximum)	(3, 52)	(8, 59)		(3, 47)	(2, 60)	
Fluoroscopy time						
Mean ± SD	3.59 ± 2.42	3.40 ± 2.41	0.851	1.65 ± 1.13	1.79 ± 1.3	0.398
Range (minimum, maximum)	(1.15, 7.15)	(1.15, 8.12)		(0.28, 6.55)	(0.05, 5.87)	

*t-test.

considered ADEs. These ADEs included hematoma (n = 1; AP group; permanent lead), cerebrospinal fluid leakage (n = 1; PM group; trial lead), new leg pain on walking instead of original dysesthetic sensation (n = 1; PM group; permanent lead), persistent pain at lead site (n = 2; one in each group; one trial and one permanent lead), and unpleasant sensations or motor disturbances (n = 1; PM group; trial lead). All resolved without sequelae. Additionally, there were four (trial) lead migrations (two in each group); two were reprogrammed. The other two were considered meaningful lead migrations, defined as a lead migration resulting in the inability to program for therapeutic response.

DISCUSSION

The DELIVERY study showed that there was no difference in trial success rates between AP and PM techniques when nonlinear burst therapy was applied during the trial evaluation period. This is also the first study to show trial success rates, which were >80%, with this type of stimulation design as patients in the SUNBURST study had to undergo a successful tonic trial before they were randomized to burst or tonic stimulation mode (15). Furthermore, physicians who performed both implant techniques preferred AP over PM placement of leads (70% vs. 30%, respectively).

Our study showed that AP resulted in 31% shorter lead placement times when two percutaneous trial leads were placed. Total procedure times for conventional SCS trials range from 30 to 105 min (25–27). The point estimate for anatomic and PM trial lead placement (two trial leads) in our study was 40 and 46 min, respectively. A minority of trials (n = 24) used a single trial lead, and these trials showed longer procedure times. Over a third of these procedures were accompanied by technical difficulties; the physician indicated that lead placement was moderately to extremely difficult or that the (second) lead could not be placed. Outside of the United States, permanent leads are frequently used for a staged trial. Due to the additional steps of lead anchoring and tunneling, procedure times are longer than trials using temporary leads, on average 92 min for two permanent leads in the PM group. In our study, an equal amount of temporary trial and staged trial procedures were performed at OUS sites. Lead placement in both randomized groups did not seem to influence fluoroscopy time. Importantly, with these data, we establish a more streamlined and time-efficient technique through an anatomic approach, but we also wish to highlight the variable nature of procedure times due to differences in local practice and difficulties due to anatomy.

The other descriptive analyses indicated that there were no differences in patient's outcomes between groups. Both changes in NRS pain score and patient satisfaction did not vary between groups; >80% of patients were satisfied to very satisfied with the therapy. There was no difference in AEs between the two groups. Furthermore, by using only anatomical imaging references, there is no need to reduce sedation and/or analgesia during the procedure to gain the patient's cooperation for accurate reporting; a valid consideration when patient reporting may be compromised by anesthesia or medications, anxiety, acute discomfort, and/or surgical positioning. Moreover, non-awake surgery has been associated

Table 4. Intraoperative Characteristics for Each Technique Using One or Two Permanent Leads in OUS Sites.

	One permanent lead (N = 19)			Two permanent leads (N = 6)		
	AP group (n = 9)	PM group (n = 10)	p value*	AP group (n = 3)	PM group (n = 3)	p value*
Total procedure time (room-in to room-out)						
Mean ± SD	59.6 ± 16.2	68.6 ± 19.7	0.287	56.0 ± 4.6	92.3 ± 23.7	0.113
Range (minimum, maximum)	(38, 78)	(35, 90)		(51, 60)	(66, 112)	
Lead placement time (needle-in to needle-out)						
Mean ± SD	11.6 ± 9.4	22.6 ± 12.2	0.040	19.3 ± 5.1	27.3 ± 6.5	0.174
Range (minimum, maximum)	(3, 33)	(7, 48)		(15, 25)	(21, 34)	
Fluoroscopy time						
Mean ± SD	2.12 ± 0.88	2.83 ± 1.64	0.250	5.96 ± 3.09	4.93 ± 4.45	0.761
Range (minimum, maximum)	(1.23, 4.15)	(1.10, 6.00)		(3.68, 9.48)	(2.23, 10.07)	

*t-test.

with fewer failures and reoperations (28). Since both placement methods are equally effective, physicians have the option to use the technique that is most appropriate for the patient.

Sustainability of therapy is always the centerpiece in device selection and implementation for chronic disease states (29). Although there was no statistical difference between the trial to permanent conversion for the AP and PM groups, there was a considerable difference between these groups for the extended trial. Patients who failed a paresthesia-free trial were markedly more likely to achieve success when a PM lead placement technique was used; however, this is a small portion (9%) of patients in the current study. This may represent, for a small subset of patients, the importance of paresthesia inducing waveforms, which has been suggested in many studies (15,30,31).

Study Limitations

There are limitations to this study that may affect the interpretation of the results. First, our study was designed to collect data during the initial trial period only. A prospective, randomized, double-blinded, crossover study (CRISP) to compare the efficacy of burst therapy AP vs. PM is currently ongoing to meet this caveat; data up to three-month postpermanent implant will be collected. Results are expected by the end of this year. Second, as suggested above, although anatomic placement of leads eliminates the need for intraoperative paresthesia testing, it may not provide adequate paresthesia coverage for patients wishing to periodically use a paresthesia-based stimulation design.

CONCLUSIONS

This study shows that leads placed using an anatomical approach at T8 and T9 result in equivalent SCS trial success when compared with leads placed using paresthesia mapping. Furthermore, the anatomic technique resulted in shorter, more predictable lead placement times and greater physician preference, without affecting patient satisfaction or clinical outcomes.

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Authorship Statement

Jason Pope contributed to the conception and design of the clinical trial and to the acquisition of the data and assisted with data interpretation and manuscript preparation. Stefan Schu, Ahmed Raslan, Ganesan Baranidharan, and Robert Heros contributed to the acquisition of the data and assisted with document preparation. Dawood Sayed contributed to the acquisition of the data, design of the clinical trial, and document preparation. Bram Blomme contributed to the analysis and interpretation of the data and document preparation. Robyn Capobianco contributed to the study conduct, analysis and interpretation of the data, and document preparation. Timothy Deer contributed to the conception and design of the clinical trial, analysis and interpretation of the data, and document preparation. All authors reviewed and approved the final manuscript for submission.

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