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Spinal Cord Stimulation Trialing: Is Trialing Predictive of Short, Intermediate, and Long-term Pain Outcomes?

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Introduction

Increased attention has surrounded spinal cord stimulation's (SCS) long-term effectiveness and methods to improve patient selection. SCS trialing is utilized to identify patients that would benefit from an SCS implant and is commonly assessed by documentation of pain relief ≥ 50%, which was reinforced by government agencies (e.g., FDA). (1) Post trial patient-reported percent improvement in pain scale has been significantly associated with greater odds of experiencing ≥50% improvement at the last follow-up compared to calculated percent improvement in pain scale.(2) However, the overall utility, reporting protocols, and evidence surrounding the long-term prognostic value of trialing has been questioned, which is problematic because an SCS trial costs $10,900 on average in US Medicare dollars. (3) Previous studies demonstrated that an SCS screening trial may have some diagnostic utility but lacks cost-effectiveness and patient outcome benefits when compared to a no-screening trial and direct to permanent SCS implantation strategy.(2) A trial-to-implant ratio of roughly 82%, further questions the utility of a SCS trial as it is only able to exclude a small cohort of patients.(4) The purpose of this study is to analyze the influence of SCS trial reported pain results to accurately predict short, intermediate, and long-term pain outcomes, as well as to identify possible patient-specific confounding variables.

Materials and Methods

Following IRB approval, a retrospective review identified 123 SCS implant patients with a minimum follow-up of 6-months (Table 1). Pain scores (PS) and patient-reported percent pain reduction (PR-PPR) were collected for the latest follow-up for 1–6- (short), 9–15- (intermediate), and 18–24- (long-term) month ranges that contained a PS and PR-PPR. Reduction in PS (ΔPS) from each time period compared to pre-trial values was utilized to determine calculated percent pain reduction (C-PPR). Data on patient-specific factors are depicted in Table 1. Linear regressions were conducted for each method at each time period to determine the predictive ability of trial pain relief on implant pain relief. Confidence intervals (CIs) of the slope coefficients assessed strength of association between post-trial value and implant value for each technique by time period. Covariates with the highest correlation with each method at each time point were utilized in bi-directional, stepwise multiple regression to identify Akaike information

criterion (AIC)-selected covariates that improved prognostic ability.

Results/Case Report

All trial pain reporting techniques significantly predicted short-, intermediate-, and long-term implant pain reduction outcomes, except for the PR-PPR intermediate time point, with minimal change in prognostic capabilities up to 24 months (Figure 1). While 95% CIs for slopes overlapped for all models (Table 2), and overall predictive ability was low (R2: 0.03 – 0.40), ΔPS was better than PR-PPR and C-PPR in predicting short, intermediate, and long-term pain outcomes (Figure 1). Few covariates contributed explanatory power to the models (Table 3). Increased opioid use significantly reduced the association of post-trial PR-PPR and PR-PPR for the intermediate- and long-term time points (Table 3).

Discussion

Although all pain measurement techniques were predictive of implant pain outcomes, their predictive abilities were limited, with at best providing 40% of the information required to make an accurate prediction. This study questions the prognostic capabilities of patient-reported pain outcomes in predicting SCS implant outcomes. In addition, the findings presented here differ from a prior study that observed that post-trial PR-PPR was the most useful pain measure predictor of long-term outcomes.(5) Further research is needed on the development of prognostic techniques to assist decision-making for implantation.

References

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Disclosures

Yes

Tables / Images

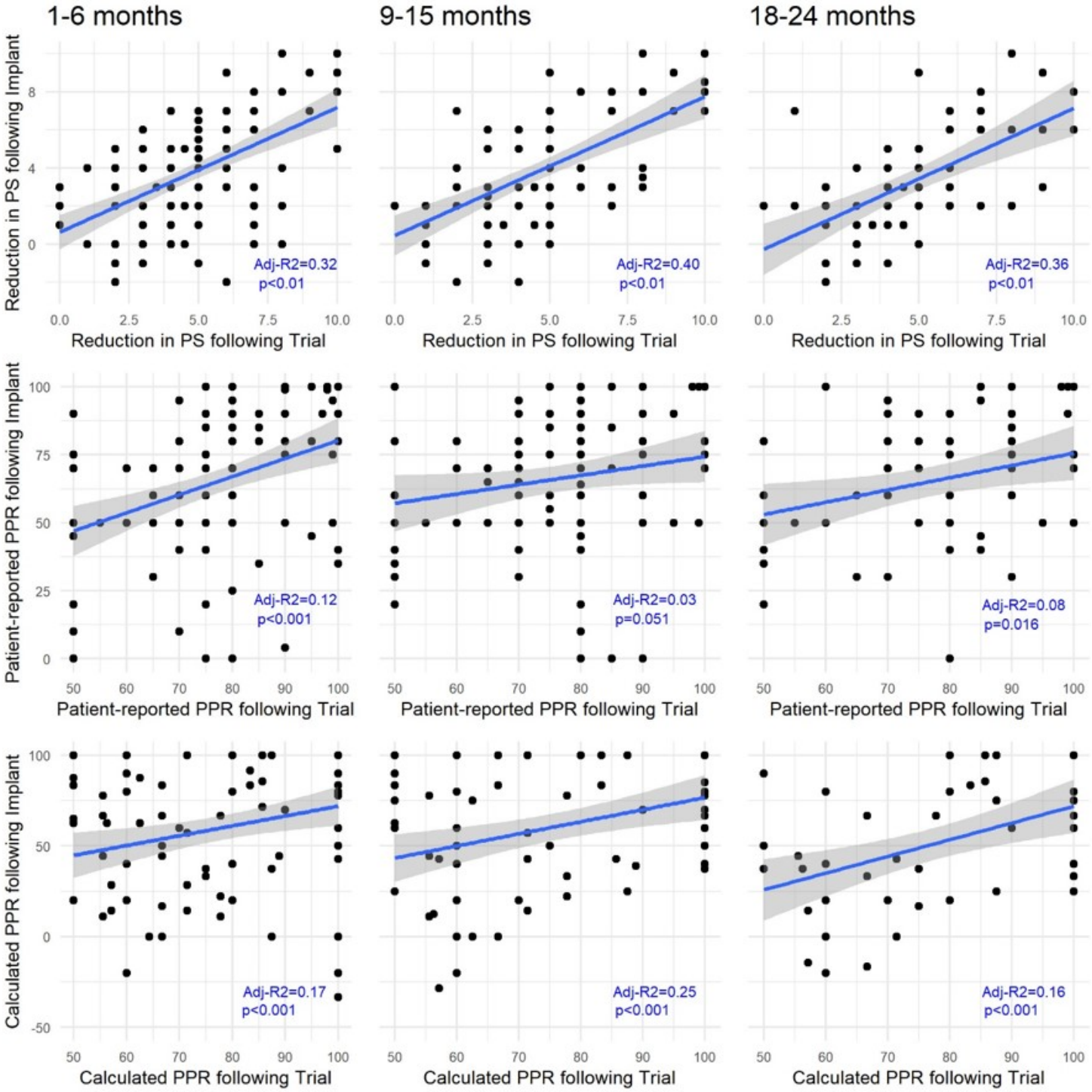

Figure 1: Linear regression of post-implant compared to post-trial pain assessment values by reduction in pain score (ΔPS), patient-reported percent pain reduction (PR-PPR), and calculated percent pain reduction (C-PPR) for each follow-up period.

Table 1: Patient-reported Characteristics

Characteristics	Outcomes (N = 123)
Age, mean ± SD (years)	62.1 ± 13.5
Sex, n (%)	
Male	58 (47)
Female	65 (53)
Body Mass Index, mean ± SD (lbs.)	30.1 ± 5.5
Smoking, n (%)	
Current	13 (11)
Former	36 (29)
Never	74 (60)
Depressive Disorder, n (%)	
Yes	25 (20)
No	98 (80)
Anxiety Disorder, n (%)	
Yes	33 (27)
No	90 (73)
Prior Lumbar Surgeries, n (%)	
Yes	33 (27)
No	90 (73)
Prior Cervical Surgeries, n (%)	
Yes	25 (20)
No	98 (80)
Alcohol Use, n (%)	
Yes	67 (54)
No	56 (46)
Serotonin-norepinephrine reuptake inhibitor, n (%)	
Yes	31 (25)
No	92 (75)
Tricyclic Antidepressant, n (%)	
Yes	4 (3)
No	119 (97)
Anticonvulsants, n (%)	
Yes	64 (52)
No	59 (48)
Milligram Morphine Equivalent, n (%)	
<5	55 (45)
$5 \leq x < 90$	61 (50)
≥ 90	7 (6)
Trial Duration, mean ± SD (days)	4.5 ± 1.0
SCS Pain Scores	
Prior to trial	
PS, mean ± SD	6.9 ± 1.7
End of Trial	
ΔPS, mean ± SD	4.7 ± 2.4
PR-PPR, mean ± SD	77.2 ± 14.0
C-PPR, mean ± SD	67.0 ± 26.8
1–6-Month	
ΔPS, mean ± SD	3.7 ± 2.8
PR-PPR, mean ± SD	64.6 ± 26.9
C-PPR, mean ± SD	53.0 ± 37.1
9–15-Month	
ΔPS, mean ± SD	3.8 ± 3.0
PR-PPR, mean ± SD	66.6 ± 24.5
C-PPR, mean ± SD	53.2 ± 39.8
18–24-Month	
ΔPS, mean ± SD	3.3 ± 2.9
PR-PPR, mean ± SD	65.8 ± 23.0
C-PPR, mean ± SD	45.2 ± 37.2

Table 2: Analysis of Linear Regression Slopes

Pain Assessment	1–6-Month	9–15-Month	18–24-Month
ΔPS	0.65 (0.48, 0.83)	0.79 (0.59, 0.98)	0.74 (0.49, 0.99)
PR-PPR	0.67 (0.36, 0.97)	0.34 (-0.002, 0.69)	0.45 (0.09, 0.82)
C-PPR	0.55 (0.34, 0.76)	0.72 (0.48, 0.97)	0.59 (0.26, 0.92)

Slopes (95% confidence intervals [CIs]) from linear regression of post-implant compared to post-trial pain assessment values for pain assessment in reduction in pain score (ΔPR), patient-reported pain reduction (PR-PPR), and calculated percent pain reduction (C-PPR) for each

Table 3: Bi-directional, Stepwise Multiple Regression Analysis

Pain Assessment	Follow-up Period	Covariate	Coefficient	Standard Error	P-value
ΔPS	1–6-month	Duration of pain	1.35	0.69	0.054
	9–15-month	Age*	0.02	0.02	0.214
	18–24-month	Age	0.03	0.02	0.214
PR-PPR	1–6-month	Alcohol use	6.87	4.28	0.111
	9–15-month	Opioid use	-11.99	4.30	0.006
	18–24-month	Opioid use	-9.19	4.54	0.048
C-PPR	1–6-month	Duration of pain	18.83	10.14	0.066
	9–15-month	Opioid use	-14.06	6.19	0.025
	18–24-month	Age*	0.40	0.35	0.257

Effects of patient characteristics on regression of post-implant compared to post-trial values for pain assessment by reduction in pain score (ΔPS), patient-reported percent pain relief (PR-PPR), and calculated percent pain relief (C-PPR) for each follow-up period. * Denotes no covariate was identified by AIC to be included in the model, but Age was most correlated (r=0.28 and 0.24, respectively) and thus included.