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PREOPERATIVE MAGNETIC RESONANCE IMAGING DOES MODIFY SPINAL CORD STIMULATOR TRIAL PROGRESSION AND PLANNING

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Introduction

Spinal cord stimulator (SCS) implantation is utilized to treat persistent chronic cervical, lumbar, and limb pain (1). Both during the SCS implantation and the preceding percutaneous trial, leads are placed into the epidural space. However, placing leads in the epidural space poses a risk of neurological injury and infrequent catastrophic spinal cord injury (SCI). In the United States, percutaneous SCS implantation is associated with a 2.35% SCI incidence (2). To limit the risk of neurologic injury, the Neural Stimulation Appropriateness Consensus Committee (NACC) recommends preprocedural MRI imaging of the location of planned needle entry and lead placement to identify relevant spinal anatomical considerations that may modify placement (3).

Preoperative MRIs to assess the areas of needle entry and lead placement are associated with increased healthcare economic cost and preauthorization burden. A previous retrospective study of 160 individuals that underwent paddle lead placement demonstrated that advanced imaging modified treatment in 22% of patients (4). However, a large-scale study has not been performed for percutaneous epidural lead placement, and only case reports or small case series have been identified on the clinical value of preprocedural MRIs.

The purpose of this study is to analyze the ability of preoperative MRI imaging to modify cervical and thoracic SCS percutaneous epidural lead placement. In addition, specific patient characteristics were examined to identify at-risk populations to assist in limiting the need for preoperative MRI screening.

Materials and Methods

Following IRB approval, a retrospective review of patients from a single center was conducted for patients who were being considered for an SCS trial between September 2013 and July 2023 and had preprocedural MRIs. Trial information and patient demographics were identified. If progression to an SCS trial did not occur or the trial technique were modified, the reason was identified, including whether preprocedural MRI interpretation influenced

trial progression. All MRIs were reviewed to document stenosis at potential lead entry sites or areas of lead placement.

Logistic regression was used to identify demographic variables that were most associated with moderate/severe cervical, thoracic, and lumbar stenosis (CSS, TSS, and LSS, respectively), which were selected since these degrees of stenoses are more likely to change practice than are mild stenoses. First, simple logistic regression identified all variables that explained a substantial (<0.25) amount of variation, and then these variables were used in multiple logistic regression models where only significant (<0.05) variables were retained.

Relative risks (RR) were used to infer the risk associated with particular outcomes: moderate/severe stenosis by age group; preoperative MRI influencing cervical (C) versus thoracic/lumbar (T/L) trial; and moderate/severe stenosis at an entry zone for T/L versus C trial. All statistical analyses were conducted using R software version 4.0.3 (R Core Team, Vienna, Austria).

Results/Case Report

The sample identified 343 patients who were considered for an SCS trial and had preprocedural MRIs. Preoperative MRIs influenced SCS treatment for 7% (n = 25) of total patients. For these 25 patients, 60% (n = 15) had the trial technique altered, and 40% (n= 10) did not progress to trial due to an MRI finding that would not allow for safe lead placement (Figure 1a). For the 15 patients that progressed to trial, the MRI findings resulted in 53% having only one lead placed, 33% having an alteration in the lead entry zone, and 13% having only one lead placed and a change in final lead cranial direction placement.

For C cases, the preprocedural MRIs were more likely to influence SCS trial progression and technique (Figure 1b) in comparison to T/L cases (21% versus 5%, respectively; RR = 4.5, 95% CI 2.2 – 9.4, $p < 0.001$). For the 12 C cases that were modified based on MRI findings, none were due to entry zone stenosis, and 92% were due to concerns for lead placement. For the 13 T/L cases that were modified based on MRI findings, 38% were due to entry zone stenosis, and 31% were due to concerns for lead placement.

Logistic regression revealed Age Group to be significantly ($p \leq 0.02$) associated with moderate/severe CSS and LSS, while only Age was found to be significantly ($p \leq 0.04$) associated with moderate/severe TSS (Table 3). Moderate/severe CSS was significantly associated with patients ≥60 years old, while moderate/severe LSS was significantly ($p \leq 0.01$) associated with patients older than 40 years. Overall, older patients (≥50 years) were 10% (RR = 1.10, 95% CI 1.06 – 1.14, $p \leq 0.02$) and 50% (RR = 1.50, 95% CI 1.34 – 1.67, $p < 0.001$) more likely to be associated with moderate/severe CSS and LSS, respectively, as compared to younger patients (<50 years).

For potential entry zones (Table 2) for lead placement, T/L cases were more likely to have an area of entry zone moderate/severe stenosis identified in comparison to C cases (RR = 15.7 (95% CI 2.2 – 110.4, $p < 0.001$). Twenty-seven percent (77/285) of the possible T/L SCS cases had an area of moderate to severe stenosis at potential entry zone (T11-L3). In these 77 cases, 91% of the identified moderate to severe stenosis were between L1-L3.

Discussion

This is the first large-scale study examining the influence of preprocedural MRIs on SCS percutaneous

lead trial progression. We demonstrated that the preprocedural MRIs did influence SCS trial progression with 7% of total cases being affected by radiographic findings. C cases were 4.5 times more likely to have a trial influenced by the preprocedural MRI in comparison to T/L cases. Age group was the only condition identified as a risk factor for moderate/severe stenosis in the cervical and lumbar areas, while Age was the only significant risk factor for moderate/severe stenosis in the thoracic area. In addition, physicians that are performing T/L SCS cases and considering lead entry between L1-L3 should check preprocedural MRIs to avoid areas of moderate to severe stenosis at those levels. Since limited patient characteristics were inclusive and associated with a greater risk of stenosis, all patient populations should be considered for preprocedural MRI to identify spinal pathology that may alter SCS percutaneous trials progression.

References

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Disclosures

No

Tables / Images

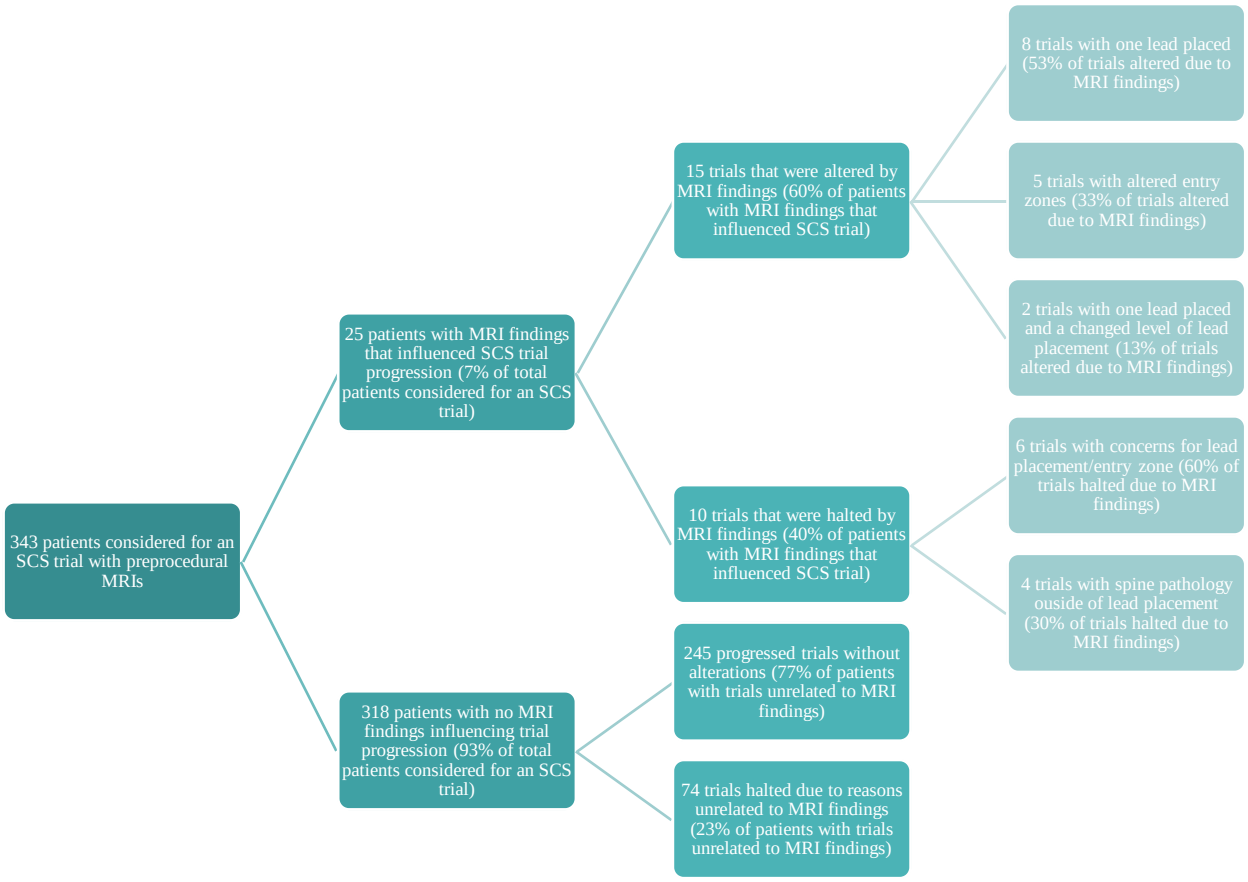

Figure 1a: Branching flow diagram of individuals considered for an SCS trial that underwent preprocedural MRIs.

Table 1: Characteristics of patients who considered an SCS trial.

Patient Characteristics	Outcomes (N = 343)
Demographics	
Age, mean ± SD (years), range	62.3 ± 13.5, 20-88
Age Group, n (%)	
1 (<40)	23 (6.7)
2 (40-49)	32 (9.3)
3 (50-59)	80 (23.3)
4 (>59)	208 (60.6)
Race, n (%)	
Black	5 (1.5)
White	338 (98.5)
Sex, n (%)	
Female	169 (49.3)
Male	174 (50.7)
Body Mass Index, mean ± SD (kg/m^2)	30.3 ± 5.8
BMI Group[a]	
1 (<18.5), n (%)	1 (0.3)
2 (18.5 - 24.9), n (%)	57 (16.6)
3, n (%)	118 (34.4)
4, n (%)	167 (48.7)
Obesity, n (%)	
Yes	167 (48.7)
No	176 (51.3)
Hypertension, n (%)	
Yes	179 (52.2)
No	164 (47.8)
Diabetes, n (%)	
Yes	77 (22.4)
Diabetes Mellitus 1	5 (1.5)
Diabetes Mellitus 2	72 (21.0)
No	266 (77.6)
Osteoarthritis, n (%)	
Yes	110 (32.1)
No	233 (67.9)
Smoking, n (%)	
Current	57 (16.6)
Previous	87 (25.4)
Never	199 (58.0)
Prior Lumbar Surgeries, n (%)	
Yes	208 (60.6)
No	135 (39.4)

Complex Regional Pain Syndrome (CRPS), n (%)	
Yes	51 (14.9)
Lower Extremity CRPS	14 (4.1)
Upper Extremity CRPS	37 (10.8)
No	292 (85.1)
Number of Leads Used in Trial, n (% of patients progressed to trial)	Outcomes (N = 259)
1 Lead Trials	36 (13.9)
1 Lead Due to MRI Findings	11 (4.2)
1 Lead Due to Reasons Unrelated to MRI Findings	25 (9.7)
2 Lead Trials	223 (86.1)

Note: Some percentages may be slightly off from 100% due to rounding error. The subcategories under “Yes” for “Diabetes”: “Diabetes Mellitus 1” and “Diabetes Mellitus 2” should add up to the percentage for “Yes,” not 100%. “Yes” and “No” should add up to 100%. The subcategories under “Yes” for “Complex Regional Pain Syndrome (CRPS)”: “Lower Extremity CRPS” and “Upper Extremity CRPS” should add up to the percentage for “Yes,” not 100%. “Yes” and “No” should add up to 100%. The subcategories under “1 Lead Trials” for “Number of Leads Used in Trial”: “1 Lead Due to MRI Findings” and “1 Lead Due to Reasons Unrelated to MRI Findings” should add up to the percentage for “1 Lead Trials,” not 100%. “1 Lead Trials” and “2 Lead Trials” should add up to 100%.

a: BMI Groups were designated from the Centers for Disease Control’s groupings for “underweight,” “healthy weight,” “overweight,” and “obese” for Groups 1, 2, 3, and 4, respectively.

Table 2: Stenosis level information about patients who considered an SCS trial.

MRI-Identified Spinal Stenosis		
Spine Stenosis, n (%)		Outcomes (N = 343)
Yes		225 (65.6)
No		118 (34.4)
Stenosis-Related Characteristics by Trial Type		
Trial Type	**Stenosis Type**	
Cervical	CSS, n (%)	Outcomes (N = 58)
	Yes	26 (44.8)
	Mild	15 (25.9)
	Moderate	6 (10.3)
	Severe	5 (8.6)
	No	30 (51.7)
	N/A[a]	2 (3.4)
Thoracic/Lumbar	LSS, n (%)	Outcomes (N = 285)
	Yes	176 (61.8)
	Mild	67 (23.5)
	Moderate	71 (24.9)
	Severe	38 (13.3)
	No	104 (36.5)
	N/A[b]	5 (1.8)
Cervical and Thoracic/Lumbar	TSS, n (%)	Outcomes (N = 343)
	Yes	85 (24.8)
	Mild	63 (18.4)
	Moderate	20 (5.8)
	Severe	2 (0.6)
	No	258 (75.2)
	N/A[c]	0 (0.0)
Stenosis-Related Characteristics at Entry Zones by Trial Type		
Trial Type	**Stenosis at Entry Zone**	
Cervical	C7-T1, n (%)	Outcomes (N = 58)
	Yes	2 (3.4)
	Mild	1 (1.7)
	Moderate	0 (0.0)
	Severe	1 (1.7)
	No	54 (93.1)
	N/A[a]	2 (3.4)
	T1-T2, n (%)	
	Yes	1 (1.7)
	Mild	1 (1.7)
	Moderate	0 (0.0)

	Severe	0 (0.0)
	No	57 (98.3)
	N/A[d]	0 (0.0)
	T2-T3, n (%)	
	Yes	2 (3.4)
	Mild	2 (3.4)
	Moderate	0 (0.0)
	Severe	0 (0.0)
	No	56 (96.6)
	N/A[d]	0 (0.0)
	T3-T4, n (%)	
	Yes	2 (3.4)
	Mild	2 (3.4)
	Moderate	0 (0.0)
	Severe	0 (0.0)
	No	56 (96.6)
	N/A[d]	0 (0.0)
Thoracic/Lumbar	T11-T12, n (%)	Outcomes (N = 285)
	Yes	18 (6.3)
	Mild	15 (5.3)
	Moderate	3 (1.1)
	Severe	0 (0.0)
	No	267 (93.7)
	N/A[e]	0 (0.0)
	T12-L1, n (%)	
	Yes	18 (6.3)
	Mild	14 (4.9)
	Moderate	4 (1.4)
	Severe	0 (0.0)
	No	267 (93.7)
	N/A[e]	0 (0.0)
	L1-L2, n (%)	
	Yes	67 (23.5)
	Mild	41 (14.4)
	Moderate	18 (6.3)
	Severe	8 (2.8)
	No	213 (74.7)
	N/A[b]	5 (1.8)
	L2-L3, n (%)	
	Yes	95 (33.3)
	Mild	51 (17.9)
	Moderate	31 (10.9)
	Severe	13 (4.6)

No	185 (64.9)
N/A[b]	5 (1.8)

Note: Some percentages may be slightly off from 100% due to rounding error. The percentages under the columns for “Mild,” “Moderate,” and “Severe” should add up to the corresponding “Yes” column percentages, not 100%. The “Yes” and corresponding “No” and “N/A” columns should add up to 100%.

a: N/A refers to the number of patients considered for a cervical trial who did not have a preoperative cervical MRI.

b: N/A refers to the number of patients considered for a thoracic/lumbar trial who did not have a preoperative lumbar MRI.

c: N/A refers to the number of patients considered for either a cervical or thoracic/lumbar trial who did not have a preoperative thoracic MRI.

d: N/A refers to the patients considered for a cervical trial who did not have a preoperative thoracic MRI.

e: N/A refers to the patients considered for a thoracic/lumbar trial who did not have a preoperative thoracic MRI.

Table 3: Logistic Regression Analyses

Logistic Regression for Significant Demographic Variables			
Response	**Demographic[a]**	**Coefficient[b] (95% CI)**	**p-value[c]**
Moderate/Severe CSS	**Age Group**	0.96 (0.27, 1.94)	0.02
	DM2	-0.76 (-2.22, 0.34)	0.23
	Osteoarthritis	0.65 (-0.17, 1.46)	0.11
Moderate/Severe TSS	**Age**	0.04 (0.003, 0.08)	0.04
	BMI Group	0.38 (-0.22, 1.07)	0.24
Moderate/Severe LSS	**Age Group**	1.15 (0.75, 1.61)	<0.001
	BMI Group	0.24 (-0.07, 0.55)	0.14
	DM2	0.78 (0.24, 1.31)	<0.01
	Hypertension	0.55 (0.09, 1.02)	0.02
	Sex	-0.31 (-0.77, 0.15)	0.19
	Current Smoker	-0.78 (-1.52, -0.11)	0.03
Logistic Regression Analyses for Significant Age Groups			
Response	**Demographic**	**Coefficient (95% CI)**	**p-value[d]**
Moderate/Severe CSS	Age Group 4	1.07 (0.14, 2.19)	0.04
Moderate/Severe LSS	Age Group 2	-1.61 (-3.05, -0.55)	<0.01
Moderate/Severe LSS	Age Group 3	-0.78 (-1.41, -0.20)	0.01
Moderate/Severe LSS	Age Group 4	1.54 (1.00, 2.12)	<0.001

Abbreviations: DM2, Diabetes Mellitus Type 2

a: Simple logistic regressions for each demographic; only demographics found to be significant ($\alpha = 0.25$) are listed. Bolded demographics were the only significant ($\alpha = 0.05$) variables in multiple logistic regression models.

b: Risk of having moderate/severe stenosis associated with a demographic was calculated by raising ten to the power of the coefficient of regression

c: Multiple logistic regressions for demographics found to be significant ($\alpha = 0.25$) in the simple logistic regression for each type of stenosis; only demographics found to be significant ($\alpha = 0.05$) in the final multiple regression models are shown

d: Simple logistic regressions for each Age Group; only Age Groups found to be significant ($\alpha = 0.05$) are shown