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VARIABLES ASSOCIATED WITH NONRESPONDERS TO HIGH-FREQUENCY (10KHZ) SPINAL CORD STIMULATION.

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Introduction

Chronic low back pain (CLBP) remains the leading cause of disability worldwide with an astonishing economic impact due to its excessive prevalence, high recurrence rate, and variable treatment effectiveness resultant from diverse anatomical etiologies and complex symptoms. Spinal cord stimulation (SCS) has been historically used for CLBP for over twenty years, and its use continues to grow as therapeutic indications expand. Optimal patient selection remains one of the most important factors for SCS success. However, despite increased utilization and the existence of general indications, predicting which patients will benefit from neuromodulation remains one of the main challenges for this therapy. Therefore, this study aimed to identify variables that may correlate with nonresponders to high-frequency (10kHz) SCS to distinguish the subset of patients less likely to benefit from this intervention.

Materials and Methods

This was a retrospective single-center observational study of patients who underwent 10kHz SCS implant. Subjects were divided into two cohorts: responders and nonresponders. In accordance with other published studies, our study defined nonresponders as those subjects who had less than 50% self-reported pain relief at the last follow-up visit compared to baseline measured by the numeric rating scale (NRS), while responders had greater than or equal to 50% improvement. Demographic data collected at baseline for analysis included age, gender, BMI, presence of diabetes, psychiatric illness, smoking history, alcohol history, and history of spinal surgery. Outcome measures collected at baseline for analysis were numeric rating scale (NRS) for pain, Oswestry Disability Index (ODI) for disability and function, Morphine milliequivalents (MME) for opioid dose utilization, Pain Catastrophizing Scale (PCS) for cognitive response to chronic pain magnification, Tampa Scale for Kinesiophobia Scale (TSK) for fear-avoidance behavior and Patient-Reported Outcomes Measurement Information System (PROMIS) domains for function, anxiety, depression, fatigue, sleep, social role and pain interference. Statistical analysis was performed for all continuous and categorical variables between the two groups to calculate statistically significant differences. IRB approval was obtained from the institution.

Results/Case Report

The study population comprised of 237 patients , of which 67.51% were responders and 32.49% were nonresponders. Table 1 and 2 illustrates demographic data and variables stratified by nonresponders and responders. Our results suggested a statistically significant difference between responders and nonresponders with high levels of kinesiophobia, greater disability, and higher pain intensity at baseline in the nonresponder group compared to the responder group. We further explored the relationship of pain catastrophizing behavior at baseline, and there was no statistically significant difference between the two groups; however, nonresponders had a higher PCS median and mean average. When utilizing a clinically relevant level of catastrophizing cut off (PCS >30) between the two groups, our results suggested a statistically significant association with higher median and mean in the nonresponders.

Likewise, we examined the preoperatively TSK score to evaluate the relationship of kinesiophobia with SCS efficacy which demonstrated a statistically significant difference at baseline between the groups.
We further investigated this association and utilized the cut off score ≥37, which is known to indicate clinically relevant levels of kinesiophobia in chronic pain and established a subset cohort within both groups. Notably, within this subset cohort, all nonresponders had moderate (41.17%) and severe (58.82%) kinesiophobia at baseline, with more subjects displaying clinically relevant pain catastrophizing (53.84%), greater severe disability (58.33%), stronger pain intensity (mean average 6.24) and more opioid use (48.84 MME/day) at baseline, in contrast to the responder group. Table 3 summarizes descriptive statistics comparing variables at baseline between nonresponder and responder groups, stratified by clinically relevant levels of kinesiophobia (TSK>37).

There was a significantly greater mean baseline ODI in nonresponders versus responders but no statistically significant difference in ODI categories was observed among the two groups. Although there was no statistically significant difference in MME at baseline between the two groups, a few data points are noteworthy. Nonresponders were taking more opioids at baseline, totaling 66.23% of subjects and with a mean average of 50.68 MME. In those using any opioids at baseline, 37.25% of nonresponders had an MME ≥50 at baseline with a mean average of 91.84 MME. Conversely, 62.89% of responders with preoperative opioid use had a mean of 51.05 MME. Among responders with baseline opioid use, 41% were taking ≥50MME with an 87.78 MME mean average. In patients with no baseline opioid use prior to implant, , 33.76% were nonresponders and 37.10% were responders.

A few variables deemed potentially relevant, such as age, gender, history of spinal surgery, diabetes, alcohol use, tobacco use, psychiatric illness and opioid utilization at baseline were not statistically significant.

Discussion

Our study is the first in the neuromodulation literature to raise awareness to the association between clinically relevant high levels of kinesiophobia preoperative associated with nonresponders to 10 kHz SCS therapy. Our study also found a statistically significant difference of higher clinically meaningful pain catastrophizing behavior at baseline in the nonresponders compared to the responders group. Nonresponders to 10kHz SCS therapy also had a statistically significant difference of greater pain intensity and disability scores compared to the responders group at baseline.

Collectively, our findings indicate a clinically relevant association of high levels of kinesiophobia, greater disability, severe pain intensity and pain catastrophizing, as subtle indicators, and possible predictive factors to nonresponders to 10 kHz SCS. As such, it may be appropriate to utilize preoperative screening tools for these factors to help optimize patient selection and predict a patient’s response to neuromodulation. Furthermore, if risk factors are present, it might be prudent to consider a pre-rehabilitation program with pain neuroscience patient education prior to SCS therapy to address these modifiable risk factors and potentially enhance outcomes in neuromodulation.

References

References upon request (list has 147 studies).

Disclosures

Yes

Tables / Images

Table 1. Baseline demographics and independent variables of nonresponders and responders.

Independent variables	Category	Total**	Non-responders N(%)	Responders N(%)	P-value
Gender	Male	100	31(40.3)	69(43.1)	0.68
	Female	137	46(59.7)	91(56.9)	
Alcohol use	No	132	45(58.4)	87(54.4)	0.55
	Yes	105	32(41.6)	73(45.6)	
Tobacco use	No	144	44(57.1)	100(62.5)	0.42
	Yes	93	33(42.9)	60(37.5)	
Diabetes	No	162	52(67.5)	110(68.8)	0.85
	Yes	75	25(32.5)	50(31.3)	
Psych illness	No	114	41(53.2)	73(45.6)	0.27
	Yes	123	36(46.8)	87(54.4)	
History of spine surgery	No	121	42(54.5)	79(49.4)	0.45
	Yes	116	35(45.5)	81(50.6)	
Morphine milligram equivalents (MME)	≤ 50	183	61(79.2)	122(76.7)	0.66
	> 50	53	16(20.8)	37(23.3)	

**total number of subjects/counts for each individual variable measured.

Table 2. Baseline demographics and discrete variables divided by nonresponders and responders.

Variable	Total**	Non-responders Mean (Std. Dev)	Responders Mean (Std. Dev)	P-value (2 sided)
Age	237	61.99 (13.56)	63.58 (14.31)	0.41
Body mass index (BMI)	237	31.29 (6.88)	31.61 (7.09)	0.74
Oswestry Disability Index (ODI)	210	47.94 (13.27)	43.64 (15.22)	0.03*
Morphine milligram equivalents (MME)	236	33.57 (44.19)	32.11 (41.20)	0.80
Numeric Rating Scale (NRS)	237	6.29 (1.90)	5.58 (1.97)	< 0.01*
Physical Function Score	42	22.29 (4.90)	22.72 (4.71)	0.78
Anxiety Score	42	11.88 (6.15)	11.08 (4.44)	0.64
Depression Score	42	13.35 (6.52)	11.76 (5.05)	0.40
Fatigue Score	42	20.06 (6.00)	18.08 (5.51)	0.28
Sleep Disturbance Score	42	21.18 (6.00)	17.48 (5.82)	0.06
Social Role Score	42	24.06 (5.74)	21.76 (5.87)	0.21
Pain Interference Score	42	24.76 (5.02)	24.36 (5.05)	0.79
Pain Catastrophizing Scale (PCS)	39	28.35 (13.60)	22.14 (13.61)	0.15
PCS > 30		45.33 (3.39)	38.43 (6.11)	0.03*
Tampa Scale for Kinesiophobia (TSK)	40	44.76 (8.97)	38.83 (7.13)	0.03*

*denotes statistically significant finding

**total number of subjects/counts for each individual variable measured.

Table 3. Descriptive statistics comparing variables at baseline between nonresponder and responder groups, stratified by clinically relevant levels of kinesiophobia (TSK>37).

Variable at baseline	Nonresponders (%)	Responders (%)
Clinically relevant kinesiophobia (TSK >37)	76.47%	56.52%
Mild kinesiophobia	0%	30.43%
Moderate kinesiophobia	41.17%	43.47%
Severe kinesiophobia	58.82%	26.08%
PCS mean average	31.53	22.33
Clinically relevant pain catastrophizing	53.84%	36.36%
ODI mean average	42.00	41.00
ODI Minimal disability	8.33%	8.33%
ODI Moderate disability	25%	41.66%
ODI Severe disability	58.33%	33.33%
ODI Crippling back pain	8.33%	16.66%
NRS mean average	6.24	4.13
MME mean average	48.84	43.38