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Article

Perioperative Predictors of Early Spinal Cord Stimulator Removal: A Machine Learning-Assisted Retrospective Cohort Study

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Abstract: Background: Spinal cord stimulators can offer an effective treatment in chronic pain refractory to conventional medical management. However, with a failure rate of up to 44% and an annual explant rate of 6-9%, there is a need to better identify patients at high risk of therapeutic failure. The objective of this retrospective cohort study was to determine predictors of early SCS explant following device placement. **Methods:** The Medical Informatics Operating room Vitals and Events Repository database was queried for patients with a spinal cord stimulator and at least two years of follow up (n = 56). A multivariate logistic regression was fitted. Recursive factor elimination and bootstrap validation were used to minimize risk of overfitting. The model was used to predict risk factors for explant, odds ratio (OR), and 95% confidence interval (CI). **Results:** The final model displayed good performance with a bootstrap mean Area Under the Receiver Operating Curve of 0.91 (bootstrap CI: 0.74 – 1.0) and bootstrap mean accuracy of 82.1% (bootstrap CI: 63.0% – 97.7%). Fibromyalgia (OR: 2.38; CI: 2.34 – 2.41), hyperlipidemia (OR: 2.24; CI: 2.20 – 2.27), sleep disorder (OR: 2.10; CI: 2.07 – 2.14), obesity (OR: 1.93; CI: 1.90 – 1.95), and irritable bowel syndrome (OR: 1.63; CI: 1.61 – 1.65) displayed statistically significant increased risk of explantation. **Conclusions:** A medical history of fibromyalgia, hyperlipidemia, sleep disorders, obesity, and irritable bowel syndrome are novel risk factors for spinal cord stimulator explantation. While further prospective studies are needed, our study would suggest these factors may be worth considering in pre-operative evaluation.

Keywords: spinal cord stimulator; chronic pain management; explantation; surgical indication; degenerative spine disease

1. Introduction

Chronic pain represents a significant public health challenge, and, for some patients who fail conventional treatment options, spinal cord stimulation (SCS) offers an effective neuromodulation strategy [1]. Despite its efficacy, SCS explantation remains a persistent concern, with previous studies estimating explant rates of 6%–38% [2–5]. This not only impacts patient satisfaction but also contributes to an increased financial burden on healthcare systems.

Evidence on the incidence of and risk factors associated with SCS explantation is limited by heterogeneous patient populations, and mixed findings [3,6,7]. Moreover, while therapeutic failure, commonly defined as an inability to achieve at least 50% pain relief, has been reported in up to 44% of SCS recipients, the factors driving device removal remain poorly understood [8,9]. Notably, the rate of explantation appears to increase with time since implantation, though the trajectory of this trend and the associated patient characteristics are not well defined [4,9].

This retrospective cohort study seeks to analyze data from a large-scale electronic health record database to identify factors associated with early SCS explantation — defined as explantation for any reason besides end of battery life. Using supervised machine learning in the form of a multivariate logistic regression model, we identified predictors of early device removal and examined how patient-specific factors influence the risk of early explantation.

2. Materials and Methods

The study was designed in accordance with TRIPOD-AI guidelines for reporting clinical prediction models that use regression or machine learning methods.

2.1. Data

Data was collected from the Medical Informatics Operating room Vitals and Events Repository (MOVER) dataset, containing electronic health records (EHR) from 58,799 unique patients who underwent surgery at the University of California Irvine Medical Center (UCI) between January 2018 and July 2023 [10]. The data was compiled by the UCI investigators using original retrospective review of the HER and, where applicable, waveform matching. Patient health information (PHI) was manually removed from free text, patient age capped at 90, and dates shifted by a consistent, random number of days to comply with HIPAA Privacy Rule. A data use agreement (DUA) was completed to allow access to the data. The database is organized by patient ID, with comprehensive EHR data complete with patient demographics, medical comorbidities, surgical procedure, and operative medicines, lines, and drains, and any post-operative complications included for each patient. The UCI MOVER study team conducts maintenance on and updates of the database.

2.2. Participants

Patients included in the study were patients undergoing spinal cord stimulator placement at a single center (UCI). The treatment received was placement of a spinal cord stimulator. Inclusion criteria: adult (≥ 18 years of age), SCS procedure, and ≥ 2 years of follow up. Exclusion Criteria: < 18 years of age, < 2 years of follow up, peripheral nerve stimulator ($n = 16$) and sacral nerve stimulator ($n = 54$). Following review of the database and application of the inclusion/exclusion criteria, we were left with a study cohort of 56 unique patients with SCS placement and at least 2-years of follow up. Figure 1 illustrates the sampling process.

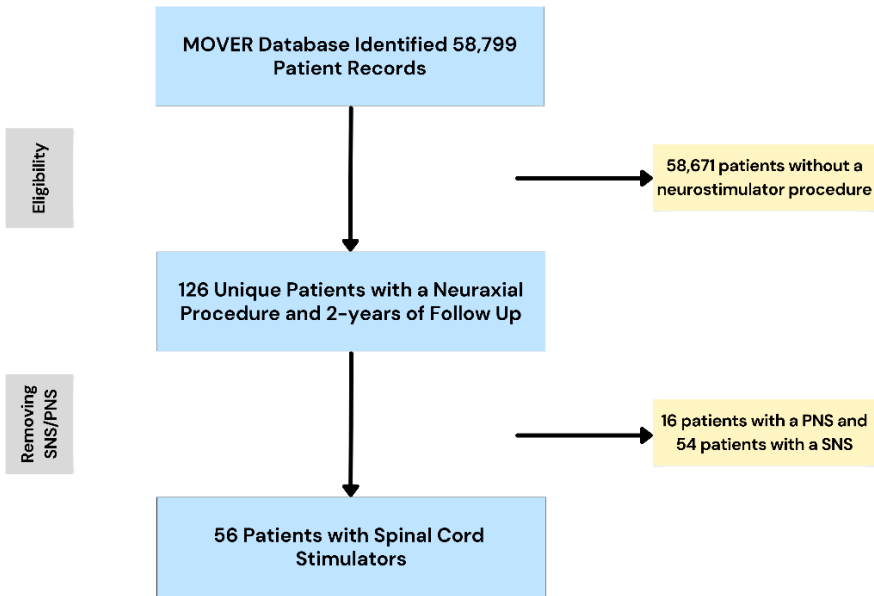


Figure 1. The MOVER database contained 58,799 patient records, including 126 unique patients with a neuraxial procedure and at least 2 years of follow up. Of these 126 patients, 56 underwent a spinal cord stimulator procedure. SNS: sacral nerve stimulator; PNS: peripheral nerve stimulator.

2.3. Data Preparation

Study variables were created using International Classification of Diseases (ICD)-9-CM codes, procedure codes/claims (ICD-9, -10, and CPT), demographic data, American Society of Anesthesiologist (ASA) score, anesthesia type, and postoperative events including hospitalizations, and intensive care unit (ICU) admissions. The included codes and/or definitions for each of the study variables can be seen in Table S1. Sex was encoded 1: female, 0: male. Medical comorbidities were encoded 1: present, 0: absent. Anesthesia type was encoded 1: monitored anesthesia care, 0: general anesthesia. ICU admission was encoded 1: yes, 0: no. LOS and ASA score was encoded as the numerical value.

2.4. Predictors

Predictors were chosen broadly based upon prior literature reports [6,11,12] and author clinical experience. We chose to error on the side of a broad inclusion of variables, as our methodology using recursive factor elimination with cross validation would remove variables offering limited predictive value in a data-driven manner.

2.5. Sample Size

All patients meeting inclusion/exclusion criteria were included. The study cohort consisted of 56 patient records.

2.6. Missing Data

Records with missing data were excluded from the study (n = 2)

2.7. Analytical Methods

Age and length of stay were reported as means \pm standard deviation (SD) and ASA score was reported as median with interquartile range (IQR). All categorical variables were reported as percentages. First, Fisher's exact test (categorical variables) and Mann-Whitney U test (numerical variables) were used to compare patient with early explantation to those without early explantation. Statistical significance was set at $p < 0.05$. Given the limited associations previously identified using basic statistical methods, we sought to use a model which could assess for interactions between variables. Data was imported into Anaconda Version 2.3.1. (Anaconda Software Distribution. Austin, TX) with following add-ons used for analysis: pandas[16], numpy [13], sklearn.model_selection[15], sklearn.linear_model[14], sklearn.metrics[14], sklearn.preprocessing[14], imblearn.over_sampling[15], matplotlib.pyplot[16], scipy.stats[17], sklearn.feature_selection[14], cross_val_score[14] and seaborn[17]. The outcome variable was defined (explantation = 1, no explantation = 0). Synthetic Minority Oversampling Technique (SMOTE) was used to address class imbalance. Data was split into training and testing using an 80:20 split, with random state used to create deterministic train-test sets. The multivariate logistic regression was fitted. To minimize the risk of overfitting, recursive factor elimination with cross validation (RFECV) was applied to identify the optimal number and combination of predictor variables (Figure 2) Bonferroni correction was performed (Bonferroni-corrected significance: 0.0014).

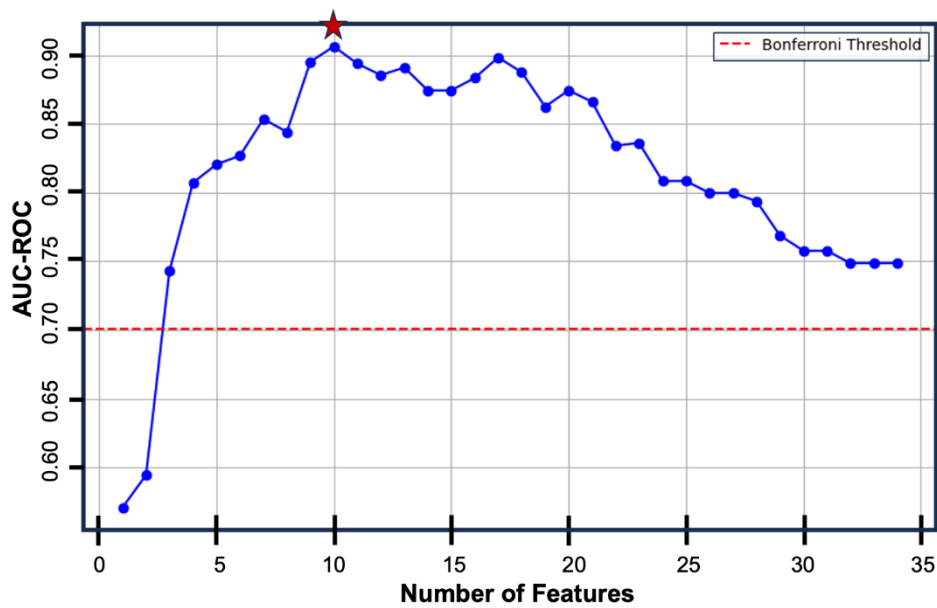


Figure 2. Line plot showing the predicted AUC-ROC at each respective number of features (blue line). The Bonferroni threshold for statistical significance is represented by the red-dotted line. Ten features resulted in the optimal predicted AUC-ROC of 0.91. The red-dotted line represents the Bonferroni threshold for statistical significance.

The multivariable logistic regression was fitted using only the ten features identified by RFECV. Performance was measured using precision, recall, f1-score, AUC-ROC, and bootstrap validation and a calibration curve was plotted (Figure 3). The model was then used to calculate odds ratios and 95% confidence intervals for each of the included variables.

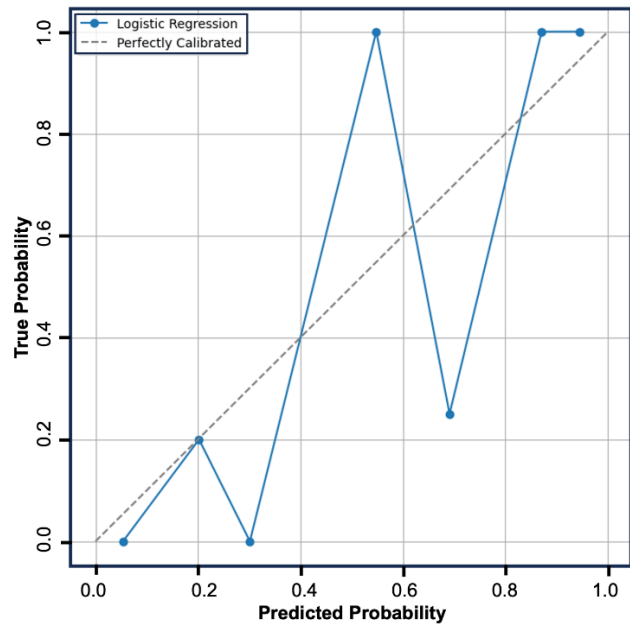


Figure 3. Calibration curve providing a visual assessment of the logistic regression model performance. The grey dotted line represents a perfectly calibrated model. The blue solid line represents the model's performance. The model displayed robust performance with an AUC: 0.91.

2.8. Class Imbalance

SMOTE was used to address class imbalances.

2.9. Fairness

To ensure model fairness, minimize risk of overfitting, and accurately assess model performance we applied recursive factor elimination with cross-validation, plotted a calibration curve, and performed bootstrap validation to identify an AUC-ROC and 95% confidence interval.

2.10. Model Output

Model output consisted of an odds ratio and 95% confidence interval. In rare outcomes, such as SCS explant, odds ratio approximates relative risk. Odds ratio and 95% confidence interval > 1.0 or < 1.0 was considered statistically significant.

3. Results

3.1. Cohort Demographics

Baseline cohort characteristics are shown in Table 1. The overall cohort was 55.4% female with an average age of 60.0 (+/- 14.2) years. The most common indications for SCS implantation were low back pain (69.6%) and failed back surgery (16.1%). The median ASA score was 3.0 (IQR: 2-3) and the cases were predominantly done under general anesthesia (78.6%) as opposed to monitored anesthesia care (MAC). The average length of stay following implantation was 0.7 (+/- 0.3) days with no statistically significant difference seen in patients with explanation compared to those without explantation. The most common medical comorbidities were hypertension (26.8%) and hyperlipidemia (25.0%), followed by sleep disorder (17.9%), arthritis (17.9%), musculoskeletal pain (17.9%), and depression (17.9%). There were no statistically significant differences in demographic or medical comorbidities between the cohorts by Fisher’s Exact Test analysis.

Table 1. Comparison of Demographic, Perioperative, and Medical Comorbidity Variables.

Variable	Overall	Explant	No Explant	P value
Number of patients	56	14	42	
Sex				
Male n (%)	25 (44.6%)	7 (50.0%)	18 (42.9%)	0.7593
Female n (%)	31 (55.4%)	7 (50.0%)	24 (57.1%)	0.7593
Age (years ± SD)	60.0 ± 14.2	62.6 ± 13.7	59.1 ± 14.5	0.2735
ASA Score (IQR)	3.0 (2-3)	3.0 (2-3)	3.0 (2-3)	0.3613
Anesthesia Type				
Monitored Anesthesia Care n (%)	12 (21.4%)	3 (21.4%)	9 (21.4%)	>0.9999
General Anesthesia n (%)	44 (78.6%)	11 (78.6%)	38 (78.6%)	>0.9999
Length of Stay (days ± SD)	0.7 ± 0.3	2.4 ± 5.5	0.6 ± 0.9	0.1632
ICU Admission n (%)	4 (7.1%)	1 (7.1%)	3 (7.1%)	>0.9999
Possible Indications for SCS *				
Failed Back Surgery n (%)	9 (16.1%)	3 (21.4%)	6 (14.3%)	0.6759
Peripheral Neuropathy n (%)	7 (12.5%)	1 (7.1%)	6 (14.3%)	0.6662
Low Back Pain n (%)	39 (69.6%)	8 (57.1%)	31 (73.8%)	0.3171
Cervical Pain n (%)	8 (14.3%)	2 (14.3%)	6 (14.3%)	>0.9999
Urinary Dysfunction n (%)	8 (14.3%)	3 (21.4%)	5 (11.9%)	0.3981
Past Medical History				
Cerebrovascular Disease	2 (3.6%)	1 (7.1%)	1 (2.4%)	0.4409
Obstructive Sleep Apnea n (%)	8 (14.3%)	3 (21.4%)	5 (11.9%)	0.3981
Sleep Disorder n (%)	10 (17.9%)	4 (28.6%)	6 (14.3%)	0.2472
Hypertension n (%)	15 (26.8%)	3 (21.4%)	12 (28.6%)	0.7364
Hyperlipidemia n (%)	14 (25.0%)	5 (35.7%)	9 (21.4%)	0.3045
Atrial Fibrillation n (%)	5 (8.9%)	0 (0.0%)	5 (11.9%)	0.3163
Diabetes Mellitus n (%)	6 (10.7%)	0 (0.0%)	6 (14.3%)	0.3195

Chronic Kidney Disease n (%)	3 (5.4%)	2 (14.3%)	1 (2.4%)	0.1510
Anxiety n (%)	7 (12.5%)	1 (7.1%)	6 (14.3%)	0.6662
Depression n (%)	10 (17.9%)	1 (7.1%)	9 (21.4%)	0.4226
Fibromyalgia n (%)	3 (5.4%)	2 (14.3%)	1 (2.4%)	0.1510
Irritable Bowel Syndrome n (%)	3 (5.4%)	2 (14.3%)	1 (2.4%)	0.1510
Obesity n (%)	8 (14.3%)	4 (28.6%)	4 (9.5%)	0.0970
Migraine n (%)	2 (3.6%)	1 (7.1%)	1 (2.4%)	0.4409
Musculoskeletal Pain n (%)	10 (17.9%)	3 (21.4%)	7 (16.7%)	0.6984
Arthritis n (%)	10 (17.9%)	5 (35.7%)	5 (11.9%)	0.0998
Malignancy n (%)	5 (8.9%)	2 (14.3%)	3 (7.1%)	0.5898
Social History				
Opioid Use n (%)	7 (12.5%)	2 (14.3%)	5 (11.9%)	>0.9999
Illicit Substance Use n (%)	1 (1.8%)	0 (0.0%)	1 (2.4%)	>0.9999
Tobacco Products n (%)	3 (5.4%)	0 (0.0%)	3 (7.1%)	0.5652

The parametric p-value is calculated by the Fisher’s Exact test for categorical variables. The non-parametric p-value is calculated by the Mann-Whitney U test for numerical values. * In patients with multiple listed indications, they were included for each of the indications.

3.2. Multivariable Logistic Regression Model

Given the limited associations identified by basic statistical analysis, we hypothesized an effective predictive model would need to be able to account for the interactions between multiple variables. To this end, we applied supervised machine learning in the form of a multivariable logistic regression model. RFE with cross validation identified 10 features: ‘Sleep Disorder’, ‘Hypertension’, ‘Hyperlipidemia’, ‘Atrial Fibrillation’, ‘Diabetes Mellitus’, ‘Depression’, ‘Fibromyalgia’, ‘Irritable Bowel Syndrome’, ‘Obesity’, and ‘Female Sex’ as the optimal combination of variables (Figure 2). The multivariable logistic regression model was fitted using these variables and performance was assessed. The model displayed robust performance with a precision: 0.76, recall: 0.76, f1-score: 0.76, bootstrap AUC-ROC mean of 0.91 (CI: 0.74 – 1.00), and bootstrap accuracy mean of 82.1% (bootstrap CI: 63.0% – 97.7%). (Figure 4).

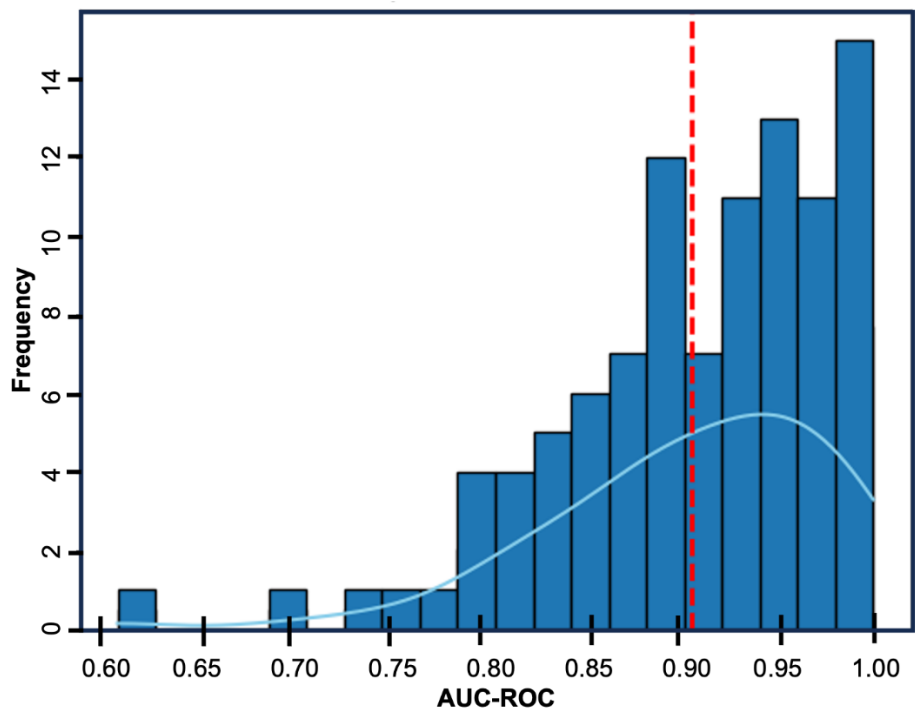


Figure 4. Bootstrap AUC-ROC distribution. The multivariable logistic regression model displayed excellent performance with an AUC-ROC mean of 0.91 (red dotted line) and a bootstrap AUC-ROC 95% confidence interval was 0.74 – 1.00. This AUC-ROC distribution suggests the risk of overfitting inherent within our small dataset was adequately addressed, with the entire 95% confidence interval falling within an acceptable range for model performance.

Amongst the assessed variables, five were predictive of increased risk of explantation. Fibromyalgia (OR: 2.38; CI: 2.34 – 2.41), hyperlipidemia (OR: 2.24; CI: 2.20 – 2.27), sleep disorder (OR: 2.10; CI: 2.07 – 2.14), obesity (OR: 1.93; CI: 1.90 – 1.95), and irritable bowel syndrome (OR: 1.63; CI: 1.61 – 1.65). Atrial fibrillation, hypertension, diabetes mellitus, depression, and female sex were included in the model, however all conferred decreased risk of explantation (Figure 5).

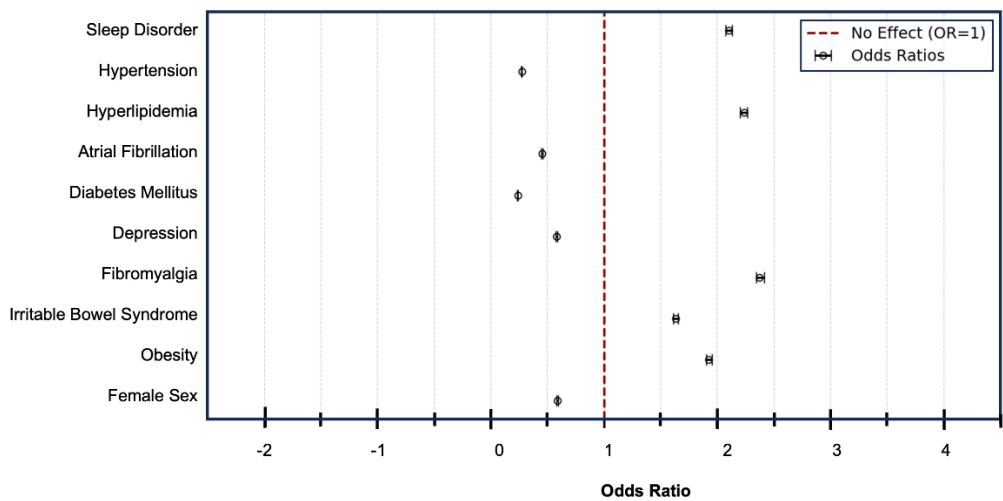


Figure 5. Forest plot illustrating the odds ratio and 95% confidence interval for the ten factors included in the multivariable logistic regression model. Fibromyalgia (OR: 2.38; CI: 2.34 – 2.41), hyperlipidemia (OR: 2.24; CI: 2.20 – 2.27), sleep disorder (OR: 2.10; CI: 2.07 – 2.14), obesity (OR: 1.93; CI: 1.90 – 1.95), and irritable bowel syndrome (OR: 1.63; CI: 1.61 – 1.65) conveyed statistically significant increased risk of early explant.

4. Discussion

SCS can offer an effective therapeutic option in patients with chronic pain refractory to conventional treatment [1]. However, early explantation remains a significant problem with explant rates of 6 – 9% [2–4]. In this single-center retrospective cohort study, we identified fibromyalgia, hyperlipidemia, sleep disorders, obesity, and irritable bowel syndrome as significant perioperative risk factors for SCS explantation. Our findings suggest certain medical comorbidities may predispose patients to suboptimal outcomes following SCS implantation and should therefore be considered in the pre-operative evaluation.

We hypothesize these associations may be secondary to the impact of central sensitization, systemic inflammation, and altered pain thresholds. Fibromyalgia is defined by a clinical syndrome consisting of widespread low-grade inflammation and myalgia. This results in central sensitization resulting in nociceptive hyperalgesia [18]. We hypothesize that a similar pathophysiology may be contributing to the poor outcomes in patients with irritable bowel syndrome. There is a significant interplay between the gut and central nervous system, termed the gut-brain axis [19]. Chronic visceral pain, as is often seen in irritable bowel syndrome, can also be long lasting and challenging to treat [19].

The deleterious impact of obesity and hyperlipidemia may be explained by the effect of lipid dysregulation on somatosensory fibers. Previous work has implicated lipid dysregulation within small fiber neuropathy [20], with obese patients showing small fiber damage on confocal microscopy [21]. Importantly, small fiber damage can be reversed by treatment of obesity with bariatric surgery

[21]. Lipid dysregulation, as is seen in hyperlipidemia and obesity, thereby may be contributing to small fiber damage and increased nociceptive sensitivity.

The association between sleep and pain is well established. In patients with sleep-disordered breathing, there is a state of chronic hypoxia resulting in oxidative stress and increased levels of inflammatory mediators [22]. Increase levels of inflammatory mediators such as Interleukin-6 and Tumor Necrosis Factor-alpha have been shown to correlate with increased levels of patient reported pain [23,24]. As such, we hypothesize sleep disorders may be resulting in increased nociceptive sensitivity and decreased pain tolerance, resulting in poor response to SCS therapy.

Interestingly, atrial fibrillation, hypertension, diabetes mellitus, depression, and female sex were included in the model, however all conferred decreased risk of explantation. We suspect this may be a result of more robust preoperative evaluation in patients with these conditions, resulting in only ideal candidates undergoing the procedure. Psychological screening is often a part of the SCS pre-operative evaluation [25]. Cardiac screening is routinely considered in the perioperative evaluation for elective surgery [26]. As a result, we hypothesize patients who received the procedure will have gone through necessary screening and therefore be more likely to have well-controlled psychiatric comorbidities and/or cardiac comorbidities. Diabetic neuropathy is an appropriate indication for SCS [27], which may explain the favorable relationship with diabetes mellitus. Female sex has previously been associated with small increased risk of SCS explant [28]. While basic statistics noted no differences between the cohorts in gender distribution between patients with explant or no explant, the multivariable logistic regression noted female sex to convey decreased risk. Certain comorbidities conveying increased risk of explant, such as fibromyalgia [29], are more common in women. As such, we hypothesize that it may be the prevalence of these comorbidities which is conveying the increases risk.

We are not the first to attempt to identify factors associated with SCS explantation. A previous retrospective study using univariate logistic regression identified comorbid depression, pre or post operative opioid use, cannabis use, tobacco use, and comorbid coagulopathy as risk factors for explantation [3]. Another study did a similar univariate regression analysis noting an association between any psychiatric comorbidity and increased risk of any complication, infection, lead displacement, surgical pain, explant, and 1 year readmission rates [30]. Unlike the previous study, the authors followed up this analysis with a multivariate logistic regression, noting an increased risk of any complication, reoperation, or readmission with each additional psychiatric comorbidity. A smaller study of 253 patients in a private health insurance database applied a bivariate analysis approach, identifying younger age, tobacco use, and the presence of other mental health disorders, defined as any mental health diagnosis except depression or anxiety, as risk factors for explantation [6]. A fourth study, using local and national registries in Sweden, identified the use of 10 kHz versus tonic waveform and age 60 years or older as risk factors, while higher education and being employed were associated with a good outcome [8].

While our results are promising, with an AUC_ROC of 0.91, the associations should be interpreted with caution. The use of a claims base dataset limits the ability to capture patient-reported outcomes, granular clinical reasoning, and device specific factors such as SCS programming [31]. Furthermore, while many steps were taken to minimize the risk of overfitting, the small sample size (n=56) and retrospective design limit generalizability. To counteract the potential implications of overfitting, bootstrap validation assessment was done, with even the low end of the 95% confidence interval displaying acceptable performance (AUC-ROC: 0.74). While we chose two-years follow up as the cut-off, we find it important to note prior work has noted no time effect on the incidence of SCS explantation, infection, or lead/generator dysfunction [32]. It is expected that a certain portion of patients were lost to follow up, with prior literature showing approximately 19% of SCS patients will be lost to follow up; however, the most common reason for loss to follow up in previous study was improvement in pain (58% of patients), suggesting these patients are most likely to represent a favorable rather than adverse outcome [33].

5. Conclusions

SCS remains a valuable therapeutic option compared to conventional medical management [34]. With ongoing efforts to expand SCS indications and utilization [30], it remains important to identify those patients most likely to benefit and those at high risk for explant. In this single-center retrospective cohort study, we pilot a novel analysis technique using a multivariate logistic regression combined with recursive factor elimination, identifying five possible novel risk factors for SCS explanation. Further prospective study is needed to validate these findings.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org, Table S1: Data collection sheet describing how each variable was defined, relevant ICD-9 codes, and relevant CPT codes.

Author Contributions: Conceptualization, Y.C.M.; Methodology, Y.C.M., Pe.J.M.; Formal Analysis, Pe.J.M, Pa.J.M.; Resources, Y.C.M.; Data Curation, Y.C.M., Pe.J.M, Pa.J.M.; Writing – Original Draft Preparation, Y.C.M., Pe.J.M., Pa.J.M., S.V.J.; Writing – Review & Editing, Y.C.M, Pe.J.M., S.V.J.; Validation, S.V.J.; Visualization, Y.C.M., Pe.J.M, Pa.J.M; Supervision, Y.C.M.

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Institutional Review Board Statement: The study was evaluated by the Saint Louis University Institutional Review Board (IRB) and determined to be exempt from review.

Informed Consent Statement: Patient consent was waived because data within the MOVER database was de-identified in accordance with HIPPA Privacy Rule.

Data Availability Statement: The data that supports the findings of this study is openly available in the MOVER database at <https://mover.ics.uci.edu/index.html>, reference [10]. Analytical code is available on request.

Conflicts of Interest: S.V.J. is an owner and treasurer of the Scientific Research Group, PLLC. Pe.J.M, Pa.J.M., and Y.C.M declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Abbreviations

The following abbreviations are used in this manuscript:

ASA	American Society of Anesthesiologists
AUC-ROC	Area Under the Curve – Receiver Operating Characteristic
CI	Confidence Interval
CPT	Current Procedural Terminology
EHR	Electronic Health Record
HIPAA	Health Insurance Portability and Accountability Act
ICD	International Classification of Diseases
ICU	Intensive Care Unit
IQR	Interquartile Range
LOS	Length of Stay
MAC	Monitored Anesthesia Care
MOVER	Medical Informatics Operating room Vitals and Events Repository
OR	Odds Ratio
PHI	Protected Health Information
PNS	Peripheral Nerve Stimulator
RFECV	Recursive Feature Elimination with Cross-Validation
SCS	Spinal Cord Stimulator / Spinal Cord Stimulation
SD	Standard Deviation
SMOTE	Synthetic Minority Oversampling Technique
SNS	Sacral Nerve Stimulator

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