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RESEARCH ARTICLE

A retrospective review of elevated lead impedances in impedance-dependent magnetic resonance-conditional spinal cord stimulation devices

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Abstract

Objectives: Advances in Spinal cord stimulation (SCS) device technology in recent years have led to the development of SCS systems that are magnetic resonance imaging (MRI)-conditional, most of which are dependent on normal lead impedances. The objective of this study was to retrospectively analyze the rate of elevated lead impedance in these devices to determine the rate of failure of MR-conditional modes.

Materials and Methods: This was a single-center, retrospective, chart-based review conducted during a five-year period. Patients were included if they had been implanted with an impedance-dependent MR-conditional SCS and had a documented impedance check at least 6 months after implantation. A Kaplan–Meier survival analysis was performed to map the survival of MR-conditionality over time.

Results: There were 363 cases included between 2015 and 2020, which corresponded to a total of 602 SCS leads. Nevro was the most common manufacturer (67.8%), followed by Boston Scientific (22.3%) and Abbott (9.9%). The average overall follow-up time was 2.25 years. Overall, 67 (18.5%) of patients had lead impedances over 10,000 Ω at follow-up with a total of 186 electrode contacts (3.9%). Leads most commonly had either one (40%), two (22%) or three (12%) electrode contacts out of range. Risk of failure of lead impedances increased by 35.4% with each successive year to a peak of 43% of all leads by year 5. Mean overall survival time of normal lead impedances was 4.77 years (CI 4.40–5.13). There was no statistically significant difference in mean overall survival time between Abbott ($M = 4.0$ years, SD = 1.25), Boston Scientific ($M = 4.64$ years, SD = 1.75) and Nevro ($M = 4.80$ years, SD = 3.28), χ^2 (2, $N = 358$) = 1.511, $p = 0.47$; however, Abbott leads had a greater total number of failed impedance contacts (50/568, 8.8%), in comparison to Nevro (124/3064, 4.0%), χ^2 (1, $N = 3630$) = 23.76, $p < 0.00001$, at a similar follow-up time.

Conclusion: This retrospective study identified elevated impedances in 18.5% of MR-conditional SCS devices at an average of 2.25 years follow-up resulting in loss of MR-conditionality and a mean overall lead survival time of 4.77 years for normal lead impedance.

KEYWORDS
hardware complications, lead impedances, magnetic resonance conditionality, magnetic resonance imaging, patient safety, spinal cord stimulation

INTRODUCTION

Spinal cord stimulation (SCS) is used to reduce the intensity of neuropathic pain that does not respond to conventional neuropathic analgesics and topical therapies.[1] SCS is delivered by implanting a medical device which typically consists of an implantable pulse generator (IPG) and cylindrical or paddle epidural leads and may also include anchors and extensions. Historically, SCS implantation was a contra-indication to magnetic resonance imaging (MRI) due to the electrical conductivity of SCS devices and the strong static and pulsed electromagnetic fields and spatial gradient present within an MRI scanner.[2] These fields can induce rotational forces (torque) on medical devices and translational forces to align the object with the electromagnetic field which can cause acceleration of the object (missile effect), resulting in tissue damage.[3,4] Moreover, current induction and radiofrequency-induced currents may cause device malfunction or heating, which can result in thermal injury, alteration in stimulation settings or unintended stimulation.[5] Protocols had been developed to permit MRI scanning of these early devices, including using transmit/receive coils for isolated scanning of certain body regions; however, these protocols were not FDA-approved.[2,6] As greater than 80% of patients requiring an MRI within 5 years of SCS implantation, many MRI-unsafe SCS devices need to be explanted for this reason.[7] SCS explant to facilitate MRI has been reported to account for 9%–12% of all explants.[8,9]

Medical devices can be sorted into three MRI categories depending on their electrical conductivity; MRI-safe, MRI-conditional and MRI-unsafe.[10–12] Devices that are MRI-safe do not post any risk in all MRI environments and are typically composed of materials that are nonconducting and nonmagnetic. MRI-conditional devices pose no threat in MRI environments under certain specified conditions; these devices may require interrogation and configuration and amendments may be needed to the magnetic field strength, spatial gradient, time rate of change, radiofrequency field and specific absorption rate (SAR). MRI-unsafe devices contain ferromagnetic materials that are known to be hazardous in all MRI environments.

Advances in SCS device technology and safety in recent years have led to the development of SCS systems that are MRI-conditional.[13] This has been achieved by changing the electrical conductivity of the IPG and the leads so that the specific absorption rate (SAR) is decreased or dissipated. Most MR-conditional SCS devices are dependent on a fully intact lead-IPG system with normal lead impedances (impedance-dependent MR-conditional) (Table 1).[13] Impedance refers to the ratio of voltage to current in an electrical circuit and can give information on the structural integrity of system components. High impedances in one of the electrode contacts could indicate a lead fracture which leads to failure of MR-conditional modes.[14] Other SCS devices do not require normal lead impedances to facilitate MRI due to the unique insulation of the leads (non-impedance-dependent MR-conditional) (Table 1). Lead impedances may fail over time affecting the ability to perform MRI in impedance-dependent MR-conditional SCS devices. A recent retrospective review of 327 patients implanted with a 10 kHz SCS device reported elevated impedances in 4.0% at a mean follow-up time of 7.8 months (±8.1 months).[15] Aside from this study and a case series of three patients, elevated SCS lead impedances affecting MRI conditionality have been neglected within the literature and the rate of lead impedance failure over time or across different manufacturers is unknown.[16]

The objective of this study was to retrospectively analyze the rate of lead impedance failure in impedance-dependent MR-conditional SCS devices over time and across different manufacturers to determine the rate of failure of MR-conditional modes of SCS.

MATERIALS AND METHODS

This was a single-center, retrospective, chart-based review conducted during a five-year period between January 1, 2015, and December 31, 2019, with a follow-up to July 2022. The electronic health records including outpatient consultation letters and neurostimulation programming notes for all patients implanted with an impedance-dependent MRI-conditional SCS devices were retrospectively reviewed. Patients were included if they had been implanted with an impedance-dependent MR-conditional SCS and had a documented impedance check at least 6 months after implantation. We recorded the device type, number of leads, whether impedances were within range and the number of lead contact impedances that were out-of-range (>10,000 Ω). The time to lead impedance failure or most recent follow-up with a fully intact system was recorded. Patients were excluded if lead impedances were not documented, if they were lost to follow-up, or if the device was explanted without documentation of lead impedances. A Kaplan–Meier survival analysis was performed to map the survival of MR-conditionality over time. Survival times were compared between manufacturers and also for SCS devices with one and two leads. A sample size calculation was performed using a log-rank test of exponential survival for lead survival rates across manufacturers with nQuery, Version 9, Sample Size and Power Calculation (Statistical Solutions).

We only included impedance-dependent MR-conditional SCS devices which depend on a fully intact IPG-lead system with no disconnections or fracture and lead impedances <10 kΩ (Table 1). We did not include any Medtronic SureScan systems in the study, as these

TABLE 1 List of SCS devices categorized by MR-conditionality.

Impedance-dependent MR-conditional SCS devices	
Nevro®	SENZA® (IPG1000, IPG1500)
	SENZA II® (IPG2000)
	SENZA Omnia™ (IPG2500)
Boston Scientific®	Precision Montage MRI (SC-1200)
	Wavewriter Alpha (SC-1232, SC-1216)
	Wavewriter Alpha Prime (SC-1416, SC-1432)
	Precision Spectra (SC-1132)
	Spectra Wavewriter (SC-1160)
Abbott®	Proclaim™ DRG (3664)
	Proclaim™ XR recharge-free SCS (3660, 3662)
	Proclaim™ Elite recharge-free SCS (3660, 3662)
	Prodigy™ MRI SCS (3772)
Saluda Medical®	Evoke® system[a]
Impedance-independent MR-conditional SCS devices	
Medtronic® SureScan	Intellis™ with AdaptiveStim™ SureScan MRI (model 97,715)
	RestoreSensor™ SureScan MRI (model 97,714)
	RestoreUltra™ SureScan MRI (model 97,712)
	PrimeAdvanced™ SureScan MRI (model 97,702)
	RestoreAdvanced™ SureScan MRI (model 97,713)
MRI-unsafe SCS devices	
Boston Scientific®	Precision®
	Precision Novi® (SC-1140)
Medtronic®	X-trel®
	I-trel®
	Matrix® systems (early)
Abbott/St. Jude®	Eon®
	Genesis®
	Axium®
	Renew®

Abbreviations: MRI, magnetic resonance imaging; SCS, spinal cord stimulator.
[a]Saluda Medical Evoke® has CE approval but not FDA approval for MRI conditionality.

are not dependent on lead impedances for MRI conditionality. We also did not include any MRI-unsafe devices.

Statistical analysis was performed using SPSS, version 28 (IBM). Unless stated otherwise, data are presented using mean and standard deviation. A Student's *t*-test or analysis of variance test was used to compare continuous variables (follow-up time, time to impedance failure). The chi-square test of independence was performed for categorical variables (number of leads, number of impedances out of range). A log-rank test was used to compare survival rates between manufacturers and number of leads. Binary logistic regression was employed to investigate time as a risk factor for loss of normal lead impedance. Statistical significance was set at $p < 0.05$. The study was registered with the hospital audit committee and formal ethics committee approval was not required.

RESULTS

There were 363 cases included between 2015 and 2020, which corresponded to a total of 602 SCS leads and 4816 electrode contacts (Table 2). Nevro was the most common manufacturer ($n = 246$, 67.8%), followed by Boston Scientific ($n = 81$, 22.3%) and Abbott ($n = 36$, 9.9%). Nevro had a greater proportion of single-lead SCS devices (44.3%), compared to Boston Scientific (17.3%) and Abbott (2.8%), χ^2 (2, $N = 358$) = 76.66, $p < 0.00001$.

The average follow-up time at the last recorded impedance check was 2.25 years (SD = 1.49) (Table 2). Follow-up time was significantly shorter for Boston Scientific ($M = 1.68$ years), compared to Nevro ($M = 2.4$ years) and Abbott ($M = 2.5$ years), $f(360) = 8.011$, $p = 0.0004$, with no significant difference between Nevro and Abbott, $t(325) = -0.40$, $p = 0.35$.

Overall, at an average of 2.25 years follow-up, 67 (18.5%) of patients had leads with impedances over 10,000 Ω, corresponding to a total of 186 electrode contacts (3.8%) (Table 2). Leads most commonly had either 1 (40.2%), 2 (22.4%) or 3 (11.9%) electrode contacts out-of-range (Figure 1). The annual rate of lead impedance failure is shown in Figure 2. For year 1, 9.3% of patients had lead impedance failure. This figure increased each successive year, to a peak of 42.9% at year 5. Binary logistic regression analysis revealed the odds of lead impedance failure increased by 35.4% with each successive year (OR, 1.354, CI = 1.137–1.611, $p < 0.001$). A Kaplan–Meier survival analysis for normal lead impedance calculated the mean lead survival time as 4.77 years (95% CI, 4.40–5.13) (Figure 3). There was no difference in average survival for normal lead impedance comparing those with one lead ($M = 4.53$ years) and two leads ($M = 4.84$ years), χ^2 (1, $N = 358$) = 0.444, $p = 0.505$ (Figure 4).

There were differences observed in lead impedance failure rates among manufacturers; however, some of these differences were due to different follow-up times. As patients with Boston Scientific leads were only followed up to an average of 1.68 years, these patients could not be compared with Nevro and Abbott, whose average follow-up was much longer at an average of 2.4 and 2.5 years, respectively. At this follow-up timeframe, only 6.2% of patients with Boston Scientific leads had impedances that were out-of-range, compared to 21.1% of Nevro and 27.8% of Abbott leads; however, a Kaplan–Meier survival analysis revealed no statistically significant difference in predicted mean lead survival time between Abbott ($M = 3.93$ years, 95% CI = 3.48–4.36), Boston Scientific ($M = 4.65$ years, SD = 4.26–5.05) and Nevro ($M = 4.79$ years, 95% CI = 4.38–5.20), χ^2 (2, $N = 358$) = 1.462, $p = 0.326$. Comparing Nevro and Abbott, whose follow-up times were similar, no statistical difference was noted in the proportion of patients with out-of-range lead impedances, χ^2 (1, $N = 287$) = 0.8071, $p = 0.369$, however, Abbott leads had a greater total number of failed impedance contacts (50/568, 8.8%), in comparison to Nevro (124/3064, 4.0%), χ^2 (1, $N = 3630$) = 23.76, $p < 0.00001$.

The average time to detection of first impedance failure was 2.75 years (SD 1.57 years); Boston Scientific had a shorter time to detection of lead impedance failure ($n = 5$, $M = 1.89$ years), compared to Nevro ($n = 52$, $M = 2.73$ years) and Abbott ($n = 10$, $M = 3.34$ years), but

TABLE 2 Baseline characteristics, follow-up, loss of lead normal lead impedance and predicted lead survival across manufacturers.

	Total	Nevro	Boston scientific	Abbott	Statistical comparison
SCS included, *n* (%)	363 (100)	246 (67.8)	81 (22.3)	36 (9.9)	
Total electrode contacts	4816 (100)	3064 (63.6)	1184 (24.6)	568 (11.8)	
One lead	124 (34.2)	109 (44.3)	14 (17.3)	1 (2.8)	$p < 0.00001$
Two leads	239 (65.8)	137 (55.7)	67 (82.7)	35 (97.2)	
Average follow-up, years (SD)	2.25 (1.49)	2.40 (1.58)	1.68 (1.05)	2.5 (1.38)	$p = 0.004$
Patients with impedances > 10 kΩ, *n* (%)	67 (18.5)	52[a] (21.1)	5 (6.2)	10[a] (27.8)	$p = 0.368$
Electrode contact impedances 10 kΩ, *n* (%)	186 (3.9)	124[a] (4.0)	12 (1.0)	50[a] (8.8)	$p < 0.00001$[a]
Time to first impedance 10 kΩ, years (SD)	2.75 (1.57)	2.73[a] (1.66)	1.89 (0.87)	3.34[a] (1.18)	$p = 0.325$[a]
Predicted lead survival, years (95% CI)	4.77 (4.40–5.13)	4.79 (4.38–5.20)	4.65 (4.26–5.05)	3.93 (3.48–4.36)	$p = 0.326$

Abbreviations: CI, confidence interval; SCS, spinal cord stimulator; SD, standard deviation.

[a]Comparison only performed between Nevro and Abbott as Boston Scientific had statistically shorter follow-up time.

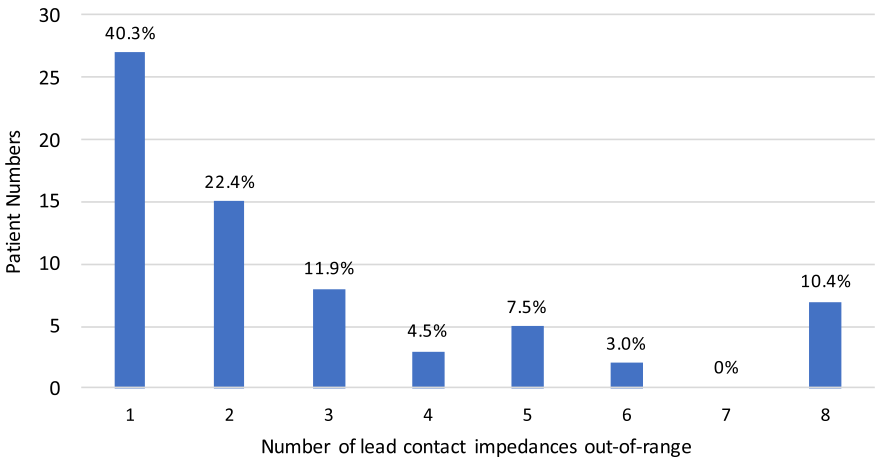

FIGURE 1 Leads with elevated impedances at follow-up ($n = 67$).

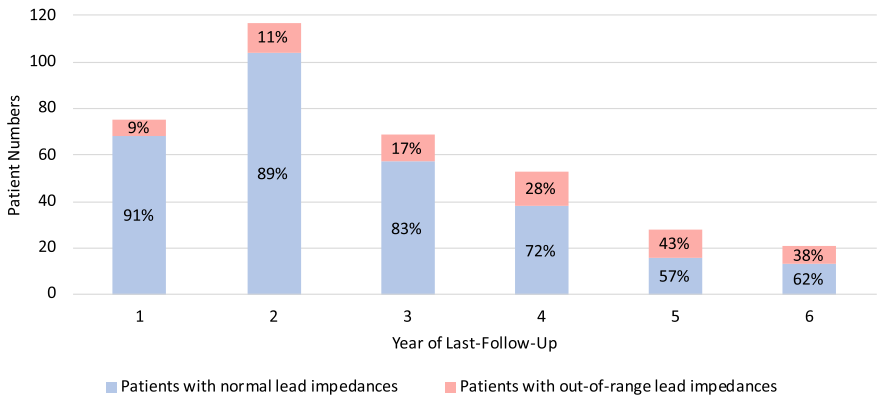

FIGURE 2 Loss of lead impedances over time in patients with magnetic resonance imaging-conditional spinal cord stimulator.

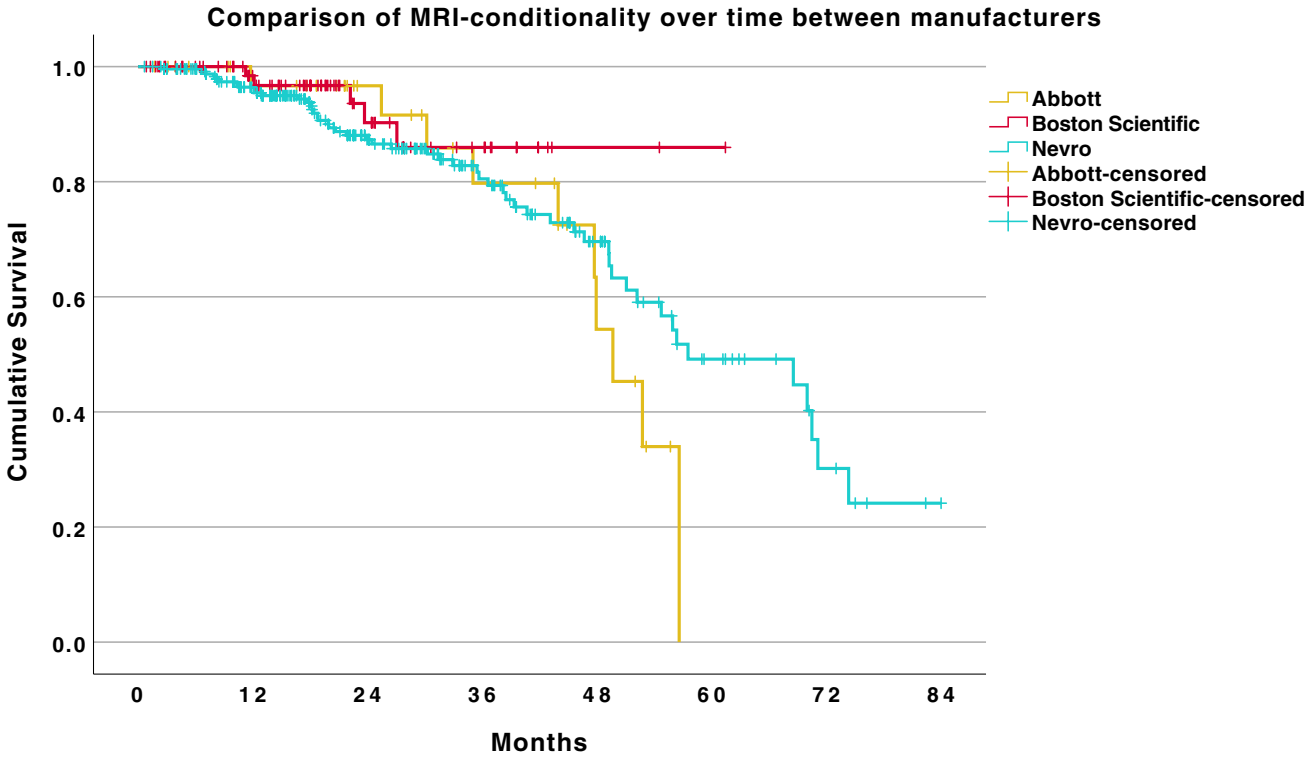

FIGURE 3 Kaplan–Meier survival analysis comparing survival of magnetic resonance imaging conditionality over time between manufacturers.

Boston Scientific had a shorter follow-up time (Table 2). There was no statistical difference in time to detection of lead impedance failure between Nevro and Abbott, $t(1, N=287)=0.99312$, $p=0.325$.

DISCUSSION

This retrospective study highlights the substantial failure rate of impedance-dependent MR-conditional SCS devices over time due to high lead impedance. The odds of failure of lead impedances increased by 35.4% with each successive year from 9.3% of all patients in the first year to a peak of 42.9% by year 5. There was an average survival time of normal lead impedance of 4.77 years (CI 4.40–5.13), with no statistical difference between manufacturers studied (Nevro, Boston Scientific and Abbott) or between number of leads; however, a higher total number of failed impedance contacts were noted with Abbott leads in comparison to Nevro.

This has significant clinical implications for treatment planning and patient consent. With the advent of MRI-conditional labeling, many patients who were previously reluctant to undergo SCS implantation due to this restriction or who required disease surveillance with MRI were afforded the option of pursuing SCS with MR-conditional devices. The loss of MR-conditionality over time for these patients can result in failure to obtain timely imaging, treatment delay and device explant, with the associated risks of re-operation. A recent case

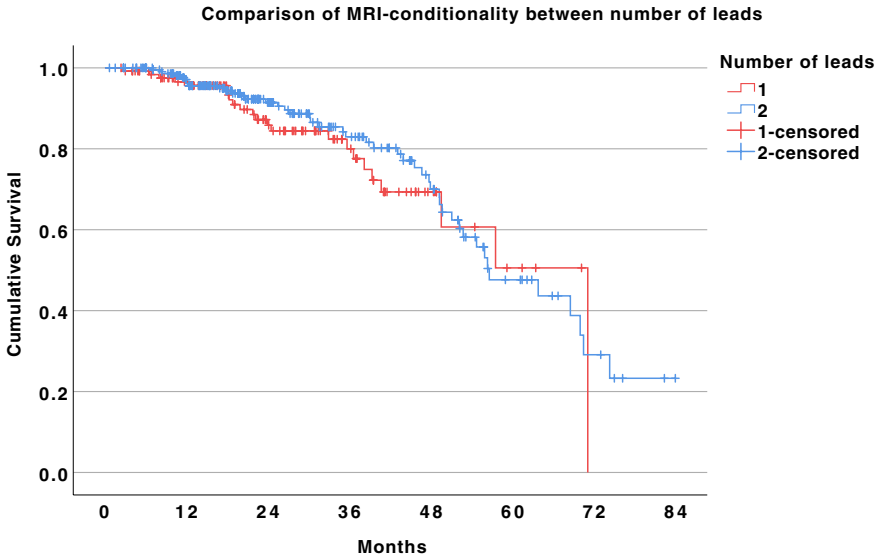

FIGURE 4 Kaplan–Meier survival analysis comparing survival of magnetic resonance imaging conditionality between one and two leads.

series described three cases where high lead impedances precluded timely MRI in impedance-dependent MR-conditional SCS systems, with these patients instead undergoing alternative imaging with computerized tomography (CT).[16] Two of these cases had the SCS explanted in order to facilitate MRI, with one undergoing re-implantation after MRI. The issue is of particular concern where urgent MRI is required, such as in suspected cerebrovascular accident or acute disc herniation, or in cases where multiple MRIs may be required over a period of time for disease surveillance in cancer or multiple sclerosis. Lack of clarity over imaging protocols can result in treatment delays and possible patient harm. Advice on impedance testing varies across manufacturers and the effects of the MR environment may vary depending on the device.[16] There are different safe impedance thresholds quoted for Nevro (>10 kΩ) and Boston (>4.5 kΩ) but no specific advice on impedances mentioned for other devices. Further safety studies on impedance thresholds in SCS would help physicians with contingency planning and deciding whether it is safe to proceed with MRI. Possible failure of SCS MR-conditionality should be incorporated into patient consent prior to implant.

The only retrospective review of lead impedance failure was published recently and reported elevated impedances in 4.0% of 327 patients implanted with a 10 kHz SCS device.[15] They did not detect specific surgical or patient risk factors for elevated impedances post-operatively. Interestingly, they did not detect a difference with time on the rate of impedance failure; however, mean follow-up time was only 7.8 months (±8.1 months). In comparison, mean follow-up time in our study was 2.25 years, with many patients followed up for longer than 5 years, and we observed a 35.4% increased risk of lead impedance failure for each successive year (OR, 1.354, CI = 1.137–1.611, $p < 0.001$). Our study also included SCS devices from different manufacturers; while we did not detect a significant difference in predicted lead survival rates across manufacturers and we were only able to make valid comparisons between two manufacturers due to differences in follow-up times, we did observe a higher incidence in the total number of failed impedance contacts with Abbott devices (50/568, 8.8%), in comparison to Nevro (124/3064, 4.0%), at a similar follow-up times.

It has been postulated that lead design may be a factor in elevated lead impedances.[17] Boston Scientific and Nevro possess a similar design with eight concentrically arranged lumens (multi-lumen concentric leads) to accommodate individual cable leads around a centrally located stylet; in comparison, Abbott and Medtronic have a single large lumen and a non-concentric arrangement of cable leads and an off-center stylet lumen.[17] The higher observed incidence of total failed impedance contacts with Abbott devices may indicate that this lead design may be more prone to lead impedance failure, however, there were significantly greater numbers of patients with multi-lumen concentric leads from Nevro ($n = 246$) and Boston Scientific ($n = 81$), in comparison to non-concentric leads from Abbott ($n = 36$), and further prospective studies with greater patient numbers are required to correctly establish the failure rate of lead impedance over time, to identify risk factors for elevated lead impedance and to compare different lead designs.

There are multiple possible reasons for the development of high lead impedances over time. High lead impedances may represent underlying lead fracture or microfracture, the incidence of which is quoted as 5.9%–10.2%.[18,19] The usual site of lead fracture is reported as distal to the fixation point at the deep fascia where the lead enters the epidural space, which would be expected to lead to elevated lead impedances throughout the lead.[19] However, in our study, lead impedances

were out of range in the whole lead in only 10.4% of cases; with elevated lead impedances more common in one (40.3%), two (22.4%) or three (11.9%) lead contacts. It is likely therefore, that lead fracture was the underlying cause in only a minority of cases of elevated lead impedance. Lead migration can result in misalignment of electrode poles, with resulting circuit changes which can result in higher lead impedance. Other factors include epidural fibrosis, tissue impedance, vertebral level of electrodes, time since implant, patient age and previous spinal surgery.[16,20,21] Mean lead impedance has been shown to rise over time, possibly due to the development of fibrotic tissue around lead electrodes.[21] The vertebral level of electrodes can affect impedance due to CSF volume and crowding of the thecal sac at higher vertebral levels with lower thoracic regions associated with higher impedance compared to mid-cervical leads by approximately 200 Ω.[20] Further research should be done into the causes of high impedance in light of the high prevalence of elevated lead impedances detected in this study and its impact on the MR-conditionality of impedance-dependent SCS devices. Improving SCS lead design to prevent the development of this problem should be prioritized.[16]

Limitations

This was a single-center retrospective study with limitations inherent to this study design. Participants were only included if they had a documented impedance check after SCS implant. This was not performed in all cases and there may be confounding factors that resulted in an impedance check. For example, patient may only have had an impedance check if there were problems with the SCS device such as charging issues or loss of efficacy, which may indicate a problem with lead impedances. Therefore, the true incidence of elevated lead impedances is unknown and should be monitored in a prospective study. The Kaplan–Meier survival analysis contained censored data as participants were followed up at different time points. Survival analysis is limited to the longest survival time if censored and estimation of survival data is most accurate when most patients are still included within the study. Survival analysis should therefore be interpreted with caution. Comparison of lead survival data across manufacturers is limited by the significantly greater sample size in the Nevro group ($n=246$) in comparison to Boston Scientific ($n=81$) and Abbott ($n=36$), the relatively lengthy follow-up period required due to the median observed survival time of 4.7 years, and the relatively small observed survival differences (hazard ratio of 0.863 comparing Nevro and Abbott median lead survival). At a maximum follow-up of 84 months, a sample size per group of 855 would be required in order to ensure that the study was adequately powered to detect a statistical difference in average lead survival times. Such large patient numbers and long follow-up times would require use of national registry data in order to correctly elucidate differences in lead survival rates.

CONCLUSION

This retrospective study identified elevated impedances in 18.5% of MR-conditional SCS devices at an average of 2.25 years follow-up resulting in loss of MR-conditionality and a mean overall lead survival time of 4.77 years for normal lead impedance. Risk of failure of lead impedances increased by 35.4% with each successive year to a peak of 43% of all leads by year 5. If future MRI is likely, patients and clinicians should consider implanting impedance-independent MR-conditional systems and possible failure of MR-conditionality should be routinely incorporated into patient consent prior to implant. Further prospective studies should be done to investigate the true incidence for elevated lead impedances and to identify possible risk factors and mitigation strategies.

AUTHOR CONTRIBUTIONS

Cormac Francis Mullins, Stephany Harris and David Pang designed and conducted the study, including patient recruitment, data collection and data analysis. Cormac Francis Mullins prepared the manuscript draft with important intellectual input from Stephany Harris and David Pang. Cormac Francis Mullins, Stephany Harris and David Pang had complete access to the study data. All authors approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to restrictions that could compromise the privacy of research participants.

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