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Magnetic Resonance Imaging in Patients with Spinal Neurostimulation Systems

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Background: **The safety of performing magnetic resonance imaging (MRI) in patients with spinal cord stimulation (SCS) systems needs to be documented. A prospective *in vivo* study in patients with SCS, exploring the changes produced by MRI and the associated side effects, was performed.**

Methods: **After ethics committee approval and patient consent, 31 consecutive patients with SCS at different spinal levels requiring a scheduled MRI evaluation were studied during an 18-month period. All MRIs were performed with a 1.5-T clinical use magnet and a specific absorption rate of no more than 0.9 W/kg. Frequency tables were used for the descriptive study, whereas comparative evaluations were made with the chi-square test for qualitative variables and single-factor analysis of variance for quantitative variables.**

Results: **The mean patient age was 49 ± 9.5 yr; 67.7% were women (n = 21), and 32.3% were men (n = 10). None of the patients experienced hemodynamic, respiratory, or neurologic alterations. Reported changes were as follows: increased temperature in the generator's area (n = 2, 6.5%); increased in the intensity of the stimulation (n = 1, 3.2%); impedance greater than 4,000 Ω on several of the electrodes in the leads (n = 1, 3.2%); telemetry not possible (n = 2, 6.5%). Radiologic evaluation after MRI revealed no spatial displacements of the SCS leads in any case.**

Conclusion: **Under the conditions of the described protocol, MRI in patients with SCS systems resulted in few complications. None of the recorded problems were serious, and in no case were patients harmed or the systems reprogrammed. Maximum patient satisfaction was reported in all cases.**

THE clinical use of magnetic resonance imaging (MRI) for the diagnosis of cerebral, musculoskeletal, cardiovascular, and other disorders has increased in the past decade. This is particularly relevant in patients with chronic pain who may require MRI for the diagnosis of a new medical condition, or for the evaluation of progression of disease.

Although the potential benefits of MRI are numerous, there are intrinsic hazards to the MRI environment that must be considered in patients with spinal cord stimulators (SCS). These hazards are the result of one or a combination of the three main components that make up the MRI environment: a strong static magnetic field, including its associated spatial gradient; pulsed gradient magnetic fields; and pulsed radiofrequency fields. For a properly operating system, the hazards associated with direct interactions of these fields and the body of the patient is negligible. The safety concerns arise on the interactions of these fields with medical devices placed within the patients.** The effects of MRI on the different implantable devices and systems, including SCS, are dependent on the physical mechanisms of action of such fields,[1] *i.e.*, the static magnetic field, the static magnetic field spatial gradient, the gradient magnetic field, and the radiofrequency field. When interacting with the implanted medical device, these fields can induce a rotational force (torque) on the device, resulting in the tearing of surrounding tissues. Moreover, rotation to align the object with the field, translation force exerted on the device, and acceleration of the object into the bore of the magnet (the so-called missile effect) may also result in tissue damage. In addition, current induction due to the rate of change of the magnetic flux density over time (T/s), may result in device malfunction or failure, and radiofrequency-induced currents may cause device heating and patient burns (thermal and electrical). Less concerning, but yet important, are the effects of the medical device on the operation of the MRI scanner, resulting in poor-quality images due to excessive electromagnetic emission. In the presence of an implanted pulse generator (IPG) or lead in or near the imaging field of view, image degradation (distortion, artifacts, *etc.*) is to be expected.

The use of implantable medical devices for internal bone fixation, pacemakers, arterial clips, stents, permanent venous accesses, and so forth is growing at a tremendous rate, thus giving rise to the need for specific research to ensure MRI safety or compatibility with such devices.[1–4] In this context, and based on the existing experience, patients with certain implanted devices, such as many types of intracranial aneurysm clips, should not be subjected to an MRI study, because the torque and displacement forces exerted on the device can result in the tearing of surrounding tissues. Based on these concerns, a number of specialists working in this field have created a Cooperative Group as a consortium of experts in the fields of MRI safety. Biomedical engi-

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** US Food and Drug Administration, Center for Devices and Radiological Health: FDA Public Health Notification: A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems. February 27, 1997. Available at: http://www.fda.gov/cdrh/ode/primerf6.html. Accessed May 25, 2006.

neers, radiologists, and neurosurgeons have joined to perform systematic assessments of MRI safety for when performing MRI studies in patients with deep brain stimulation implants. This group has produced several scientific articles addressing the safety factors of deep brain stimulation and MRI.[3,5–9]

Recent studies have been conducted *in vivo*[1,3,10–12] to identify those implantable devices that pose a risk of injuring patients during MRI explorations. This information is of crucial importance, because most MRI facilities do not perform explorations on patients with implanted metal objects, due to the lack of available safety information. Some centers routinely scan patients with neuromodulation devices based on the premise that there have been no problems among those patients scanned in the past. In other centers, MRI examination of patients with spinal cord stimulation and cardiac pacemakers is strictly prohibited, although the evidence in the published literature is scant and inconclusive to support such restrictions. Indeed, some published studies suggest that MRI can be safely used in selected circumstances.[11,13] Nevertheless, the US Food and Drug Administration has recently issued a warning regarding the use of MRI in patients with neurostimulation systems.†† Likewise, some manufacturers have included the following statement in their patient management guidelines for clinicians: "Each system is contraindicated for those patients who will be exposed to magnetic resonance imaging."‡‡ §§ ||||

Despite these recommendations, studies in patients have yielded different results, and have led to contrasting guidelines or recommendations for their use.[3]

Based on this contradictory situation, the current study addresses the safety of performing MRI in patients with implanted SCS by using a joint MRI technique and SCS programming protocol. To this end, a prospective *in vivo* study in patients with SCS at different spinal levels was performed to evaluate the changes produced in these devices by MRI and the morbidity associated with the application of a strict protocol in these patients.

Materials and Methods

A study protocol was defined by consensus between the Department of Radiology and the Multidisciplinary Pain Management Department (Valencia University General Hospital, Valencia, Spain).

The protocol and the study design were submitted to the institutional review board of our institution, and after obtaining approval, the study was started. Written informed consent was obtained from each of the participating patients. During the study's inclusion interview, the patients were instructed to report any abnormal sensation during the diagnostic MRI exploration and were fully briefed on the study.

Eligible patients were required to be scheduled for an elective MRI and to have a SCS system implanted. The SCS technology consists of three implantable components: a lead (a small wire), an extension cable, and an IPG. The lead is a small, insulated wire that has a set of four or eight electrodes at one end and the connecting connection at the other end. The extension cable connects the IPG to the lead. The IPG is the power source for the spinal cord stimulator and is usually placed anteriorly in the lateral wall of the abdomen, or posteriorly at the level of the lumbar or gluteal region. The IPG generates low-voltage electrical impulses which amplitude and frequency can be programmed *via* an external programmer. In this study, we included patients with leads implanted at the cervical or lumbar epidural spaces with both single and double four-electrode leads and an Itrel III® or Synergy® (Medtronic, Inc., Minneapolis, MN) IPG. All patients were required to have posteroanterior and lateral projection radiologic control views of the system for the assessment of possible displacement of any of the SCS system components, before and after the MRI study. A radiologist not participating in the study evaluated these x-rays and gave a report. Patients with established neurologic deficits or those who did not accept the conditions of the study protocol were excluded.

All MRI explorations were conducted using the GE Signa Horizon LX® 1.5 T (GE Healthcare, Waukesha, WI; n = 19) and Magnetom Sonata® 1.5 T (Siemens Medical Solutions, Erlangen, Germany; n = 12) systems. For this protocol, we considered the information supplied by the study of Baker *et al.*[14] in relation to magnetic field interactions at 1.5 and 3 T for IPG used for implantable neurostimulation systems.

Magnetic resonance imaging uses radiofrequency pulses and a strong magnetic field, so that all the protons in the atoms of the patient's body can be aligned to a magnetic field. Then, radio waves are directed at the protons—*i.e.*, the nuclei of hydrogen atoms—to excite the protons. Once the radio waves are stopped, excited atoms emit radio signals received by an antenna (*i.e.*, a surface coil in the MRI machine), which are then measured and processed to form an image using a computer. The specific absorption rate (SAR) is a measurement of the absorption of electromagnetic energy in the body (measured in W/kg), and its calculation may vary accord-

†† US Food and Drug Administration, Center for Devices and Radiological Health: FDA Public Health Notification: MRI-Caused Injuries in Patients with Implanted Neurological Stimulators. May 10, 2005. Available at: http://www.fda.gov/cdrh/safety/neurostim.html. Accessed May 25, 2006.

‡‡ ANS Medical: Implantable Therapies for Chronic Pain & Neurological Disorders. Available at: www.ans-medical.com/patient/safetyinformation.cfm. Accessed May 25, 2006.

§§ Medtronic: Spinal Cord Stimulation: Patient Management Guidelines for Clinicians. Available at: www.medtronic.com/neuro/paintherapies/pain_treatment_ladder/pdf/1_patient_management.pdf. Accessed May 25, 2006.

|||| Advanced Bionics Precision: Patient System Handbook. Available at: www.controlyourpain.com/printables/precisionsystemmanual.pdf. Accessed May 25, 2006.

ing to the model of MRI system involved (a combination of hardware and software-related factors). In every case, the use of a standard technique ensuring the lowest SAR possible was implemented for our study by the Radiology Department. The radiofrequency deposited at the time of execution of the sequence is the one that produces the warming of the poles of the lead. In our protocol, the mean total body SAR was required not to exceed 0.9 W/kg during the execution of each sequence.

The time rate of change of magnetic field (dB/dt) is the rate of change of the magnetic flux density with time (T/s). Induced currents due to dB/dt have the potential adverse effect of producing device malfunction or failure. Current Food and Drug Administration guidelines limit the dB/dt to levels that do not result in painful peripheral nerve stimulation. According to Bourland *et al.*,[15] the dB/dt intensity to induce a sensation that the subject described as uncomfortable was approximately 50% above the sensation threshold. The sequences are usually optimized by the machine to execute more rapidly the gradients when the field of view and the slice are greater. The rapid changes in the gradients cause warming and stimulation; for this reason, they must be programmed so that the amplifiers of the gradients have a limited power (ramp-up to maximum set to low level, *e.g.*, 20 T/m/s or less). In our protocol, we use the type of sequences that has very low dB/dt, because they are the sequences "Whisper" in the Magnetom Sonata®. The Signa Horizon LX® system has the capability of having an automatic configuration of the dB/dt for every sequence, without needing special adjustments or manual configuration to be made by the technician or operator. We never used sequences of the steady state free precession, or echo planar imaging type, in which a nonzero steady state develops for both components of magnetization (transverse and longitudinal), and also if the radiofrequency pulses are close enough to each other, the magnetic resonance signal will never completely decay, implying that the spins in the transverse plane never completely dephase. The rapid changes in the gradients with these sequences cause warming and stimulation that depend on the orientation of the scan.

In the pre-MRI phase, in addition to demographic and affiliation data, information on the type of implanted generator and its location, along with the model of the lead(s), and programming mode was collected.

Regardless of the IPG model (Itrel III® or Synergy®) or the number (single or dual) and model of leads used, the SCS systems were reprogrammed by means of a systematized standard protocol before MRI. Telemetry was performed, with pre-MRI recording of all parameters, including estimated battery life. Then, programming counters were reset to 0, voltage was set to 0 V, the poles in each of the leads were programmed to 0 = N, 1 = N, 2 = (+), and 3 = (−), and the operating mode was set to OFF. Due to specific system requirements, not all lead poles could be deactivated. Therefore, we decided to assign the cathode (−) to the most caudal electrode and the anode (+) to the one above it. All of these settings are in agreement with the published manufacturer recommendations and guidelines for neurostimulation systems used for deep brain stimulation.[9]

To ensure that the device did not suffer long-term damage, we consulted with the manufacturer of the equipment, who suggested testing the impedance of the entire circuit, to confirm that the lead is working and connected properly, and also to guarantee the integrity of the stimulation system. According to Meadows *et al.*,## two types of impedance measurements were made: monopolar, where the impedance between each implanted electrode was measured with respect to the IPG; and bipolar, where the impedance was measured between adjacent electrodes on the same lead. For quality control, we used the value of 13% variation from contact-to-contact in single electrode, and 17% on dual parallel SCS leads.[16]

The procedure was performed in fully awake patients. In no case was sedation provided to facilitate the complete and total collaboration of the patient during the procedure.

Once in the room of the magnet, we brought the patient to the table for the examination. The patient was placed on site using the antennae adapted for the specific planned study, and introduced very slowly inside the magnet. We use this approach because our systems use very high magnetic gradients (GEH 33 mT/m and Siemens 40 mT/m) that can produce sudden movements in the metallic objects. This fact is related with spatial change in the magnetic field, and it could happen rapidly while we introduce the patient inside the magnetic field (variation of almost 0 to 1.5 T in a short distance).

During the MRI, visual contact was kept with patients at all times, and they were equipped with an alarm handheld device. In addition, the speaker system allowed direct communication between staff members of the Multidisciplinary Pain Management Department, who were present throughout the exploration, and the patients. Any sensations perceived by the patient as being abnormal (heating, displacement, discharges, paresthesias, *etc.*) during the procedure were recorded. Likewise, although the radiologic technique used was standard, particular caution was exercised if the neurostimulator was in the anatomical region of the scanned area.

In the post-MRI phase, telemetry was performed, and recording of all the system parameters was done. The data were printed, and the system was subsequently reprogrammed using the same parameters as before the

Meadows P, Varga C, Oakley J, Krames E, Bradley K: Impedance effects in spinal cord stimulation: Contact impedance variability. Available at: www.ifess.org/cdrom_target/Vienna04/Session10/Bradley.pdf. Accessed May 25, 2006.

Table 1. MRI Exploration Zone

Region	n	%	GE Signa Horizon LX 1.5 T, n	Siemens Magnetom Sonata 1.5 T, n
Cervical	8	25.8	5	3
Cervical–thoracic	2	6.5	2	0
Thoracic	1	3.2	1	0
Lumbar	9	29.0	6	3
Brain	11	35.5	6	5

MRI = magnetic resonance imaging.

exploration. Information collected for analysis included abnormal sensations (paresthesias, increased temperature, and burning sensations) during the procedure, duration and location of these sensations, complications affecting patient safety from potential activation of the system, with the degree and type of stimulation perceived by the patient, and neurologic injuries. Evaluations of the changes in telemetry and patient stimulation patterns after reprogramming were conducted to assess changes in the perception of stimulation occurring after MRI. Posteroanterior and lateral radiologic views of the system were carried out to assess possible displacement of any of the SCS system components.

In view of the controversy of MRI in patients with implantable medical devices, special interest was focused on the recording of patient satisfaction throughout the application of the study protocol, and particularly during the exploration. Satisfaction was measured on a scale from 0 to 5, where 0 = completely dissatisfied and 5 = completely satisfied.

A control visit was scheduled 3 months after the procedure to assess possible alterations/damage in the neurostimulation systems and/or neurologic sequelae. At this visit, the patients were questioned about sensory or motor alterations, paresthesias, and changes in the characteristics of stimulation and/or perception in this time period. Alterations in the stimulation system were also documented, including circuit integrity (electrode impedance), programming, or battery consumption.

The data were recorded in a database, Microsoft Access 2003 (Microsoft Corp., Redmond, WA), and the results were analyzed using the SPSS 11.0 statistical package (SPSS Inc., Chicago, IL). Frequency tables were used for the descriptive study, whereas comparative evaluations were made with the chi-square test for qualitative variables and single-factor analysis of variance for quantitative variables. Significance was established at $P < 0.05$.

Results

Thirty-one explorations were performed during the 18-month study period. The mean patient age was 49 ± 9.5 yr; 67.7% were women (n = 21), and 32.3% were men (n = 10). The most commonly used IPG was the Synergy® system (n = 21, 67.7%) with dual quadrapolar leads (n = 18, 58.1%), followed by the Itrel III® (n = 10, 32.3%) with a single quadrapolar lead (n = 13, 41.9%). The localization of the leads was lumbar in 14 cases (45.2%), cervical in 10 cases (32.3%), and both cervical and lumbar in 7 cases (22.6%).

In all cases, the SAR was less than 0.9 W/kg, and the previously established protocol for conducting the exploration was followed in all cases. The most frequently evaluated region was the brain, followed by the lumbar spinal area (table 1).

Specific technical details of the examinations performed at the spine (appendix 1) as well as at the brain (appendix 2) are displayed divided according to the MRI system used.

In our patients, the receiver coils that we used for spine examination were the USCTL coil (GE Signa Horizon LX®), and the SPINE coil (Magnetom Sonata®). For brain studies, we use the standard of the system because these coils are specifically designed for localized body regions (head transmit coil) and provide improved signal-to-noise ratios by limiting the spatial extent of the excitation or reception.

There were seven events recorded during the MRIs (22.8%): Five patients reported the same pattern of stimulation, as that felt before turning the generators off while imaging was being conducted during the MRI examination. Because the IPG was turned off during the whole MRI exploration, the quantity of induced current was significant.

Two patients reported increased temperature in the area where the generators were implanted (6.5%), but there were no burns in the surrounding skin or later malfunction of the system. These events were not related to the IPG mass, because in one case a patient with an Itrel III® generator was affected, whereas in the other case a Synergy® system was involved. None of the patients experienced hemodynamic, respiratory, or neurologic problems requiring any type of supportive measures on the part of the Pain Management Department physician present during the exploration or termination of the procedure.

Patient evaluation after MRI revealed changes in the programming or electrical conditions of the system in four cases (12.9%). One patient (3.2%) reported an increased in the intensity of the stimulation and required a decreased in the programmed amplitude. One patient (3.2%) exhibited

Table 2. Correlation between Complications and SCS Settings

Complication	IPG Type	Electrode Type	Lead Location	IPG Location	MRI
On reprogramming channel 2, current intermittent in channel 1	Synergy®	Pisces Quad	Lumbar	Left midaxillary line	Cervical
Impedance > 4,000 in several electrodes	Synergy®	Pisces Quad	Lumbar	Left midaxillary line	Cerebral
Telemetry not possible	Itrel III®	Pisces Quad-Plus	Lumbar	Left midaxillary line	Lumbar
Telemetry not possible	Itrel III®	Pisces Quad-Plus	Lumbar	Left midaxillary line	Lumbar

IPG = implanted pulse generator; MRI = magnetic resonance imaging.

impedance greater than 4,000 Ω on several of the poles in the leads. The electrical impedance of contact arrays in SCS was studied between any two contacts using the software command included in the hardware (N'Vision Programmer; Medtronic, Inc.). This change did not have clinical implications because those electrodes were not used for stimulation purposes in this patient.

In two patients, it was not possible to perform telemetry and reprogramming; therefore, the generators had to be changed (6.5%). We consider this event the result of total battery exhaustion, because the charge was known to be low before the performance of the MRI.

In none of the remaining cases was system reprogramming or change in the demographic data stored by the generator observed.

Radiologic evaluation of the baseline *versus* the post-MRI situation revealed no displacements of the SCS system, electrode, or IPG in any case.

Patient satisfaction was high: 4.90 ± 0.396 (mean ± SD).

The 3-month interval assessment revealed no complications or changes in either the patients or their neurostimulation system.

The statistical analysis revealed no significant differences between the incidence of the described events and any of the study parameters. Therefore, the demographic variables, generator parameters, number and location of the electrodes, and IPG variables did not influence the occurrence of untoward events (table 2).

According our results, the area to be studied by the MRI did not exert an influence on the recorded events. Nevertheless, it must stated that the type of coil used could influence the warming of the leads/electrodes. For example, if the IPG or the lead is out of the region of exploration, as it is in the case of the head, certainly there would be no problem with warming due to radiofrequency, or it would be minimal in this case. Considering the number of patients included in the study and the possible combinations of body parts scanned, coil, device type, position of tip of the lead, and so forth, the statistical power to find any correlations between events and MRI study parameters was limited. Consequently, these initial results must be interpreted with caution.

Discussion

Magnetic resonance imaging studies in patients with neurostimulation systems are currently contraindicated by the manufacturers of such neurostimulation systems and by organizations such as the US Food and Drug Administration.** †† However, because of the increasing demand for MRI explorations in patients with implanted neurostimulation systems, many authors have designed strategies to offer a measure of safety when performing such imaging studies. These strategies involve the patient (information, capacity to report complications), the MRI system (tesla and SAR specifications), and the neurostimulation system (programming and preradiologic and postradiologic exploration adjustments).[3] Moreover, the presence of a healthcare provider with expertise in programming the system (ideally from a pain management department) during the exploratory procedure adds a measure of safety.[17]

Our explorations have been conducted in patients with SCS systems, closely adhering to the recommendation that the SAR rating should be no more than 0.9 W/kg (and always using the lowest possible value), informing the patient, and programming the system according to an established standard protocol to ensure maximum patient safety. Interactions between the magnetic fields and SCS system can cause torsion or displacement of the components in the latter.[10] The risk of such movements is proportional to the magnetic field intensity and spatial gradient involved, the mass and shape of the implanted system, and its magnetic susceptibility. The implanted electrodes, the extensions, and the IPG contain no ferromagnetic materials and are therefore not susceptible to such field effects. The fact that no displacements of any of the system components were recorded in our study further corroborates this fact. Moreover, there have been studies involving devices for deep brain stimulation (Activa®; Medtronic, Inc.) with magnetic fields of intensity 1.5 T where the magnetic forces to which the systems are exposed have been shown to be less than the force of gravity.[18] Displacements may be mitigated by tissue fibrosis after implantation of the device, thereby anchoring the latter to the surrounding tissues, as is the case with defibrillating pacemakers, which resist displacement and torsion forces of 16–19 g/cm.[19]

Perhaps the most feared physical effect associated with MRI exploration in patients with a SCS is heating of the generator and/or tip of the lead and the electrodes[2,3,6,18–20] generated by the variable magnetic fields

and pulsed radiofrequency fields which are elicited by MRI signals. This may result in heat-induced lesions, such as burns at the location of the implanted components. This is particularly serious in the case of the leads, because serious spinal cord injury may result. Heating is poorly tolerated in the central nervous system, with irreversible lesions occurring at temperatures in the range of 45°C.[3] The rate at which radiofrequency energy is deposited in tissue is indicated by the SAR. Current Food and Drug Administration guidelines limit SAR whole body exposure to 4.0 W/kg for patients with normal thermoregulatory function and to 1.5 W/kg for all patients, regardless of their physical condition. The duty cycle of the radiofrequency pulse during MRI exploration is restricted based on this SAR limit.** The quantity of induced current depends on many factors, but the certain thing is that the induction will be greater if the sequences have a higher dB/dt value, and it will be independent from the SAR.

In studies of the Activa® system, no clinically significant temperature increments were recorded in the system.[12] Safety is also warranted by the fact that the use of SAR less than 1.4 W/kg has produced no significant thermal changes at the leads where the maximum temperature is reached at the lead tip.[18] The latter is considered to be the critical element in relation to such heating effects, because the small mass of the tip makes it susceptible to larger temperature increments (up to 2.1°C).[20] Other authors[6,21] have reported greater temperature elevations associated with loops in the generator pouch secondary to tangling of the extension, or with electrode loops, thus becoming factors to be considered when implanting a system in a patient who will potentially need an MRI in the future. In the current study, we observed only two cases of slight heating of the generator. These effects were not serious and caused no patient injuries, and follow-up evaluation suggested no thermal lesions in the zone of the generator or in any other component of the SCS system.

Another factor to be considered is the possibility of structural damage or inappropriate activation of the implanted system, inevitably resulting in patient morbidity.[12,19] The magnetic fields could not only change the on–off setting of the implanted device, as in systems such as the Itrel II® (Medtronic, Inc.), but it could also modify the programming of the generator. In our study, there were no recorded instances of a change in the programming of the device, but there were five patients who reported feeling stimulating sensations in the same areas affected by the stimulation pattern before the study. We believe that these stimulating sensations were related to radiofrequency pulses and/or the magnetic field, but not due to activation of the IPG during the MRI, because the programming encounters in the memory revealed no programming changes during the execution of the study. This is in line with observations by other authors.[11,18]

There have been reports of neuromodulation system damage due to voltage induction.[17,19] In the case of the electrodes and extensions, a circuit break may result, whereas at the generator level, the programming may be modified, or the generator serial number may be erased.[18,19] At 1.5 T, MRI systems exert lesser effects on the implanted system,[14,18] although a decrease in the battery life may result.[18] The energy consumption of an implanted pulse generator for neurostimulation, and thus its battery life, is related to the stimulation current, the stimulation pulse width, and the load impedance at the stimulator output. According to Aló *et al.*,[22] the tissue impedance is 36% lower in the cervical region compared with the lower thoracic region. Our findings indicate that the impedance of SCS arrays can vary by gross vertebral level and time since implantation during trial stimulation. This is in line with our two cases where telemetry could not be performed after MRI, which could be attributable to total battery exhaustion, because the charge was known to be low before MRI. However, in the rest of the cases, we recorded no changes in the estimated service life of the battery *versus* baseline. We also considered the possibility that the inability to reprogram the system may have been due to limitations in the software used to analyze it, but the interrogation system was checked by the manufacturer and found to be in perfect working condition.

The application of our protocol, based on safety criteria previously established by different authors, in relation both to the MRI technique[12] and to programming of the neurostimulation system,[3,6] has shown low patient morbidity. Only untoward events were recorded, with no neurologic lesions over the short or middle term. There was no direct damage to the neurostimulation system, and the patients expressed great satisfaction with the protocol.

The limitations of this study are related to the variety of technology currently available for SCS, because this study only tested the described Medtronic products. Neurostimulators are currently driven using different power sources including lithium-ion batteries as primary cells, and rechargeable cells. Likewise, important differences exist in the functioning of the IPG among the currently marketed systems: Medtronic uses a constant voltage, Advanced Neuromodulation Systems uses a constant current, and Advanced Bionics uses a fractionated constant current in their new rechargeable IPGs. Moreover, the Medtronic system and the Advanced Neuromodulation Systems device have one energy source for all electrodes, whereas the Advanced Bionics system has independent energy sources for each electrode. In addition, the leads are very different among the systems. From a stimulation selectivity standpoint, the key differences between lead types can be broken down into

several categories: number of contacts, intercontact center-to-center spacing, contact length, contact width, contact shape, intraspinal lead shape, and for paddle designs with multiple columns, the relative orientation of the contacts among columns. In the percutaneous leads, the contacts are cylindrical, most commonly 3 mm in length, and made of platinum–iridium alloys. The lead itself consists of an isodiametric polyurethane body containing wires that connect the epidural contacts to a proximal connector, for connection to the stimulator electronics.[20] For these reasons, we caution that specific studies are also needed for the Advanced Neuromodulation Systems and Advanced Bionics system, as well as the Medtronic rechargeable system. Moreover, we suggest that the results of the study should not be extrapolated to patients who have been implanted with octapolar leads, because the magnetic fields may have a different effect on these leads.

Based on our results, we conclude that MRI systems operating at 1.5 T may be used in patients with SCS in both the single and double electrode mode, with an Itrel III® or Synergy® IPG at both the cervical and lumbar levels. The MRI must be carried under specific well-controlled conditions, including collaboration between the Radiology and Pain Management Departments to ensure application of a mutually approved protocol. In fact, since the implementation of this protocol, our hospital has become the center of reference for the performance of MRIs in all the patients with SCS systems, and also implanted spinal infusion devices.

Finally, our results emphasize the fact that MRI examinations may be performed in patients with SCS devices under specific, well-controlled conditions. More comprehensive research is needed to provide information on other neurostimulation systems, positioning schemes, other MRI systems, and other imaging scenarios. Considering the complexity of the problem, we stress that all centers that scan patients with neuromodulation devices must create an appropriate environment for safe MRI performance.

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Appendix 1: Data of the Type of Coils and the Type of Pulse Sequences Used for Spine Scan

	PS	TR	TE	FA	ETL	FOV	THK	MAT	NEX
GE Signa Horizon LX 1.5 T									
Cervical spine									
Sagittal T2W	FRFSE	3,400	116		33	24	3	256 × 224	4
Sagittal STIR	FIR	4,200	35; TI: 140		24	24	3	256 × 192	5
Sagittal T1	SE	550	15			24	3	256 × 224	3
Axial GRE T2	GrE	360	15	20		24	3	256 × 192	3
Siemens Magnetom Sonata 1.5 T									
Cervical spine									
Sagittal T2W	TSE	3,520	101		17	240	3	512 × 333	2
Sagittal STIR	TIR	3,890	68; TI: 140		13	240	3	256 × 192	3
Sagittal T1	SE	500	14			240	3	384 × 320	3
Axial GRE T2	Medic	896	27	30		200	2.5	256 × 192	3
GE Signa Horizon LX 1.5 T									
Thoracic spine									
Sagittal T2W	FRFSE	3,800	102		21	36	3.5	384 × 256	4
Sagittal STIR	FIR	3,000	50; TI: 150		6	36	3.5	256 × 160	3
Sagittal T1	SE	500	15			35	3.5	320 × 256	4
Axial T2W	FRFSE	3,800	90		21	16	4	256 × 224	4
GE Signa Horizon LX 1.5 T									
Lumbar spine									
Sagittal T2W	FRFSE	3,300	114		33	32	4	256 × 224	4
Sagittal STIR	FIR	4,500	35; TI: 150		16	32	4	256 × 160	3
Sagittal T1	SI	400	15			32	4	320 × 256	4
Axial T2W	FRFSE	4,000	113		15	24	3	256 × 192	3
Siemens Magnetom Sonata 1.5 T									
Lumbar spine									
Sagittal T2W	FSE	3,520	101		17	300	4	512 × 333	2
Sagittal STIR	TIR	4,000	70; TI: 140		13	300	4	320 × 240	3
Sagittal T1	SE	500	14			300	4	512 × 256	3
Axial T2W	FSE	5,680	97		17	200	4	384 × 280	2

ETL = echo train length; FA = flip angle; FIR = fast inversion recovery; FLAIR = fluid attenuated with inversion recovery; FLASH = fast low angle shot; FOV = field of view; FRFSE = fast recovery fast spin echo; FSE = fast spin echo; GRE = gradient echo; MAT = matrix; NEX = number of excitations; PS = pulse sequence; SE = spin echo; STIR = short time inversion recovery; TE = echo time; THK = thickness; TIR = turbo inversion recovery; TR = repetition time; TSE = turbo spin echo.

Appendix 2: Data of the Type of Coils and the Type of Pulse Sequences Used for Brain Scan

	PS	TR	TE	FA	ETL	FOV	THK	MAT	NEX
GE Signa Horizon LX 1.5 T									
Brain									
Axial T2W	FSE	4,000	120		16	24	5	320 × 256	3
Axial FLAIR	FIR	8,000	120; TI: 2,000		16	24	5	256 × 224	1
Sagittal T1	FIR	2,000	24; TI: 750		6	24	5	256 × 224	2
Coronal T1W	SE	500	15			24	5	256 × 224	2
Axial GRE T2	GrE	550	18	15		24	5	256 × 192	1
Siemens Magnetom Sonata 1.5 T									
Brain									
Axial T2W	TSE	3,850	97		15	24	5	384 × 256	2
Axial FLAIR	TIR	9,000	107; TI: 2,500		21	24	5	256 × 192	1
Sagittal T1	TIR	2,540	10; TI: 750		5	24	5	256 × 256	1
Coronal T1W	SE	500	14			24	5	256 × 200	2
Axial GRE T2	FLASH	686	26	20		24	5	256 × 192	1

ETL = echo train length; FA = flip angle; FIR = fast inversion recovery; FLAIR = fluid attenuated with inversion recovery; FLASH = fast low angle shot; FOV = field of view; FRFSE = fast recovery fast spin echo; FSE = fast spin echo; GRE = gradient echo; MAT = matrix; NEX = number of excitations; PS = pulse sequence; SE = spin echo; STIR = short time inversion recovery; TE = echo time; THK = thickness; TIR = turbo inversion recovery; TR = repetition time; TSE = turbo spin echo.