RESEARCH ARTICLE

Magnetic resonance imaging scans in patients with dorsal root ganglion stimulation

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Abstract
Objective: Patients fitted with a neurostimulator face a greater need to undergo magnetic resonance imaging (MRI) scans. Given the lack of literature in this regard, this study aims to review our experience with MRI examinations on patients implanted with a dorsal root ganglion stimulation (DRG-S) system and their potential adverse events.

Materials and Methods: We conducted a retrospective analysis of the prospective treatment documentation gathered from November 2011 to October 2020. We identified 259 MRI registrations for patients with an implanted neurostimulation system; the MRI examinations were performed using a 1.5 Tesla MRI system in accordance with a structured scheme.

Results: Among the 259 MRI registrations identified in this study, 28 corresponded to patients with an implanted DRG-S system. In 2 cases, no MRI scan was performed, and thus, only 26 MRI examinations were evaluated in detail. The DRG-S device was approved for the requested MRI scans in only 2 of these 26 cases (7.7%). In addition, 2 minor adverse events (syncopal episode and connection problem) were identified, and only the second problem (3.8%) was related to neurostimulator operation.

Conclusions: Necessary MRI examinations in patients with DRG-S systems are rarely covered by the European CE/US Food and Drug Administration (CE/FDA) approval. Although the manufacturer recommendations are against the use of MRI in patients with implanted DRG-S in certain conditions, we performed these scans without causing injury to the patient or damaging the device. Given that data on safety are limited, MRIs should be conducted study related. We provide recommendations for the procedure that should be followed when an MRI is needed urgently.

KEYWORDS
dorsal root ganglion stimulation, implantable neurostimulators, implantable stimulation electrodes, magnetic resonance imaging, patient safety
INTRODUCTION

Dorsal root ganglion stimulation (DRG-S) systems were launched in Europe after CE approval in November 2011. The US Food and Drug Administration (FDA) approved the DRG-S system in February 2016. In practice, DRG-S has become a widely established clinical routine; in Germany, 219 implantable pulse generator (IPG) devices for DRG-S were implanted in patients in 2017. In Europe, DRG-S systems are CE-approved for the treatment of chronic neuropathic pain, regardless of its origin, and there are no anatomic limitations. In the United States, the DRG-S system is approved by the FDA for the treatment of complex regional pain syndrome (CRPS) type I or II of the trunk and lower extremities; the implantation of leads above vertebrae level T10 is not recommended. This is reflected in different manufacturer’s reference numbers for the same lead in Europe and in the United States of America.

Magnetic resonance imaging (MRI) has become a standard diagnostic method since its development in the late 1970s. Since then, subsequent developments in both MRI devices and image processing techniques have improved MRI image quality. Currently, it is the primary diagnostic technique used to identify several diseases, like low back pain or internal derangement of the knee. The number of MRI examinations conducted worldwide is steadily increasing owing to its excellent contrast and image quality when visualizing soft and bone tissues; in Germany, 143.4 MRI examinations were performed per 1000 citizens in 2016. Furthermore, the need for MRI examinations in patients with neurostimulators is significant; in particular, 82–84% of patients with spinal cord stimulation (SCS) systems are expected to undergo at least one MRI examination within 5 years of neurostimulator implantation.

Despite the high number of MRI examinations conducted on patients in Germany, there are no reports investigating MRI examinations in patients with implanted DRG-S systems.

This lack of literature can be attributed to the fact that all 3 major magnetic and radiofrequency (RF) fields of the MRI environment pose risks for patients with a neurostimulator, including the induction of a current, undesired stimulation, device heating, tissue alterations caused by a shift in magnetic forces, or damage to the implanted neurostimulator. Further, metal in the implants cause image degradation (erasures, artifacts, etc.). Unlike SCS, which is the closest system to a DRG-S, the dorsal root ganglion (DRG) is characterized by a thin surrounding layer of cerebrospinal fluid and it can access small fiber nerves that are more susceptible to injury. The RF energy can cause overstimulation or motor stimulation, and it can interfere with RF wireless communication technologies, such as Bluetooth. The major concern with MRI and DRG-S is thermal injury to the DRG and the IPG malfunction.

Key Points

- The CE/FDA certifications rarely cover necessary MRI scans in patients with DRG-S.
- Despite lack of approval, we were able to perform MRI scans without harming the patients.
- Manufacturers are encouraged to adapt future devices to meet clinical requirements for MRI scanning.

Given these concerns, there is significant uncertainty regarding the safety of MRI scans in patients with a neurostimulator according to a published case report of a patient with deep brain stimulation suffering from severe brain damage after an MRI scan.

There are currently 2 CE-/FDA-approved systems for DRG-S that can be implanted: Axium IPG (Spinal Modulation, Inc.), which is not designed for MRI compatibility and is no longer available, and Proclaim DRG IPG (Abbott Laboratories), whose MRI mode protects the Bluetooth unit and the stimulation electronics of the IPG from damage during imaging. Manufacturer recommendations on MRI examinations that are part of the approval for these devices (hereinafter referred to as MRI approval) limit the MRI scans to 1.5-Tesla (T) MRI scanners with a cylindrical-bore magnet and horizontal field orientation operated under the normal operating mode and with combined RF transmit-receive coils. The extensions and leads besides the 50-cm standard or SlimTip leads are restricted. The examined body regions are limited to the head and extremities except the hip and the shoulder. The position of the FDA-approved leads is limited to spinal level T10-S2, whereas the CE-approved version is limited to C6-S2. Further, there are limits for the gradient slew rate (≤200 T/m/s per axis), spatial field gradient (≤30 T/m), and active scanning time (≤30 min per session).

The objective of this study was to review our experiences of MRI examinations for patients with implanted DRG-S systems.

MATERIALS AND METHODS

Ethical statement

Prior to the study, we obtained professional advice from the appropriate ethics committee. After ensuring that our study was not subject to the restrictions of the German Act on Medical Devices, the Medical Association of Thuringia approved our study under No. 64752/2019/28 on May 7, 2019. The extended period of investigation was approved by the same ethics committee on November 18, 2020.
Implantation procedure

The DRG-S systems were implanted independently of this study as per the clinical requirements. As our department is in Europe, we only used CE-approved devices. We used 50-cm SlimTip leads (Spinal Modulation, Inc.; hereinafter referred to as ST leads) in most cases. An exception to this was a 90-cm SlimTip lead used in a single case. The leads were anchored in the typical manner using S-shaped epidural loops; we formed subcutaneous strain relief loops at the lead insertion site and at the IPG site.

The IPG was selected between the Axium IPG (Spinal Modulation, Inc.; hereinafter referred to as IPG A) and Proclaim DRG IPG (Abbott Laboratories; hereinafter referred to as IPG P), based on device availability. All IPGs were implanted to the upper buttock or the abdomen, the exception is one case where the IPG was implanted subclavicularly.

Selection of study participants and data acquisition

We obtained the study data from the database of our hospital information system (HIS) for the period ranging from the foundation of our department in November 2011 to October 2020. We included all requests for MRI examinations with the slightest indication of the presence of a neurostimulator. We reviewed patient charts for the entire case histories for all selected records. Relevant data from patients with neurostimulators were extracted from all available treatment documentation.

Structured MRI examinations

MRI examinations were performed independently of this study as part of the usual medical procedures in accordance with a structured scheme based on the suggestions by De Andres. The patients received an appointment for an MRI scan after sending a request; however, we rejected requests from patients who had inconclusive indications, and therefore did not require an MRI examination. On the day of the examination, a pain physician (neuromodulation specialist) reconfirmed the necessity of the MRI scan while considering possible diagnostic alternatives (such as sonography, X-ray imaging, and computerized tomography). With a positive assessment of the benefit–risk balance, the patient was informed about the risks, termination criteria, and, where applicable, the lack of general approval for the planned MRI examination. After the patient and physician signed the informed consent form, we performed a thorough check of the system, including the impedances of every single contact of leads and battery level. The appearance of postoperative cutaneous scars was documented as the original state in the event of a complication.

The settings of the implanted devices were adjusted for the MRI scan based on the device model and results of the final system check. Whenever applicable, the MRI mode of the IPG was initiated. However, if this mode was not available or could not be started, we created a new "lowest settings program" with the following settings intended to prevent harm to patients in case the MRI environment switches the IPG on unintentionally during the MRI scan.

- The anode and cathode were placed only on functional contacts.
- Pulse width of 50 µs.
- Maximum pulse amplitude of 50 µA.
- Magnet mode was set to "Turn Stimulation Off Only" for preventing the stimulation to be turned on by the built-in magnet switch.

Subsequently, the stimulation was switched off for the time of the MRI examination.

All MRI scans were performed by a radiologist using 2 different 1.5-T MRI scanners: the Achieva system (Philips, Amsterdam, The Netherlands) used originally was replaced in January 2020 by an Ingenia Ambition system (Philips). The built-in transmit coil was used for all examinations. We selected the receive-only coils (built-in Sense Spine, 4-channel Sense Shoulder, 8-channel Sense Knee, dStream posterior, and dStream HeadNeck, all Philips) and settings for the examinations based on the indication, clinical necessities, availability, and operating instructions of the neurostimulator. The radiographer informed the neuromodulation specialist about any unexpected observations or occurrences during the MRI examination.

Immediately after the MRI scan, a neuromodulation specialist examined all patients again. A complete system check was repeated, and the patients were asked if they experienced any abnormalities during the MRI procedure. All patients with one exception were looked after in our follow-up consultation no later than 12 months after the MRI.

Technical MRI parameters

The corresponding MRI examination data were exported from our Picture Archiving and Communication System in the Digital Imaging and Communications in Medicine (DICOM) format. Then, we extracted the specific absorption rate (SAR), slew rate, and active scanning time from the DICOM headers using a script. Then, all data in this file were manually checked, and the calculated sequences without separate scanning time information were excluded.
We used the maximum value for SAR in our analysis because SARs represent 6-minute average data; further, we used the maximum value for the slew rate. Finally, we summed together the active scanning times for each patient.

Statistical analysis

We used different versions (2010 32-bit and 365 64-bit) of a commercial spreadsheet software (Microsoft Excel, Microsoft, Inc.) with the latest updates for data acquisition and processing. After consultation with a statistician, it was confirmed that the statistical tests would not be suitable for our analysis.

RESULTS

Selection of study participants

The search for MRI requests performed on our hospital’s information database delivered a total of 1245 results, of which 259 requests were made by patients fitted with a neurostimulator system. In addition, 28 of these 259 cases were related to a DRG-S system, and these were further evaluated (Figure 1).

In 2 of the 28 cases, no MRI examination was performed. In one of these 2 cases, the MRI examination was canceled because there was no pain indication caused by the significant pain relief after periradicular infiltration therapy; in the other case, the revision surgery of the DRG-S system was required because of 2 defective leads. The MRI examination was subsequently conducted a few weeks after the revision surgery. Finally, only 26 MRI examinations were considered during this subgroup analysis.

Patient characteristics

The 26 MRI examinations considered in our study were performed on 14 patients (4 men and 10 women) with a median age of 52.5 years (range: 31—76 years). Two leads (median value; range: 1–3) were implanted between C6 and S1. Extension implantation was required in 2 cases. In 4 MRI examinations, IPG A was present; IPG P was present in 21 cases; and no IPG presence was observed in one MRI examination. Indications for DRG-S include CRPS type I \( (n=1) \), CRPS type II \( (n=4) \), nerve injury (Budapest criteria not fulfilled, \( n=6 \)), arthrofibrosis of the knee joint \( (n=2) \), and post-zoster neuralgia \( (n=1) \).

The MRI examinations were performed after a median time interval of 25 months (range: 0–61 months) from...
the date of IPG implantation. One patient underwent 9 MRI examinations because of oncologic consultations, whereas 4 patients underwent 2 MRI examinations; all other patients only underwent a single MRI scan. The MRI examinations covered the trunk (spine, abdomen, shoulder, and pelvis), the skull, and the upper and lower extremities. The details are summarized in Figure 2 and in Table 1.

MRI examination without IPG

In one case, only 2 ST leads were implanted at the time of the MRI examination. Despite the lack of approval, the MRI scan was necessary to rule out an epidural bleeding or abscess after the application of the leads. Prior to the MRI scan, a computerized tomography scan was performed, which yielded an image with unsuitable quality because of artifacts. Finally, we confirmed that the patient suffered from meningitis. This MRI examination was conducted without any issues after performing the individual benefit–risk assessment.

MRI examinations with IPG A

The IPG A is not approved for MRI examinations. However, we performed 4 MRI scans in patients with this system. Three examinations were performed without any problems; however, in one case, the examination was prematurely terminated because of a syncopal episode. We found no evidence that the DRG-S system caused this episode. The female patient only reported a slight feeling of fear, and no pain, paresthesia, or feeling of heat was indicated. She described that the environment and noise moved increasingly further away and she remembered waking up when she was moved onto the bed. At that moment, she reported that she felt no pain or heat. Further, the physical examination did not reveal any evidence of damage from the MRI examination with the neurostimulator. We immediately checked the DRG-S system following this and found no changes or new defects compared with its status before the scan.

MRI examinations with IPG P

IPG P is approved for MRI scans of the head, upper extremities (except shoulder), and lower extremities (except hip). For 20 out of 21 cases considered in this study, the entire combination of implanted IPG and leads was classified as MR conditional, which implies MRI examinations are safe with defined restrictions. The MRI mode was initiated without encountering any problems in 19 cases. A defective contact inhibited the MRI mode initiation in one case. However, the DRG-S system was labeled for the MRI scan of the requested organ system in only 2 cases of knee scans (7.7%). These details are summarized in Table 1 and Figure 2.

In one case involving a male patient, we identified a temporary issue with the connection of the patient controller with the IPG after MRI examination. This issue was resolved by connecting the IPG to the physician controller. All other MRI examinations were performed without any adverse events.

Technical MRI parameters

On average, 8.0 ± 1.8 (range: 4–12) MRI sequences were scanned per MRI examination. A total of 16 examinations were performed in the normal mode (SAR ≤ 2 W/kg), whereas 8 examinations were performed using the controlled mode 1 (SAR ≤ 4 W/kg). The low SAR mode (SAR ≤ 0.7 W/kg) was used during 2 examinations. The average slew rate equaled 71.3 ± 21.4 T/m/s, and it never exceeded the limit of 200 T/m/s prescribed in the clinician’s manual. Further, the average total active-scanning time equaled 20.7 ± 9.2 min. In 4 cases, the scanning-time limit of 30 min was exceeded because of the need for complex examinations with time-consuming sequences. All examinations were performed using the body RF transmit coil. The receive-only shoulder, knee, head, and built-in spine coils were used for the MRI scans of the shoulder, knee joint, skull, and all other body parts, respectively.

Follow-up

All 26 patients received a system check immediately after the MRI examination. We observed no abnormalities; battery voltages were documented in 24 cases and were equal to the system check before the MRI; in 2 cases, the battery voltage was observed but not documented, and there were no premature IPG replacements caused by battery exhaustion.

A total of 25 patients (96.2%) were regularly cared for in our follow-up consultation. The follow-up was conducted no later than 12 months after the MRI. We observed no possibly MRI-related technical problems, and the battery voltage was in the expected range based on the power consumption in all cases.

DISCUSSION

To the best of our knowledge and after reviewing the existing literature, this retrospective monocenter study appears to be the first to investigate MRI examinations in patients implanted with a DRG-S system. The MRI scan patient-safety data obtained using SCS systems—the most closely related technology—remain limited; the rate of adverse events varies between
0 and 70%. Some authors suggest the explantation of the neurostimulator\textsuperscript{40–44} or the replacement of the non-MRI-approved system with an MRI conditional system.\textsuperscript{31} The significant uncertainty in dealing with the MRI examinations of patients fitted with DRG-S systems is also reflected in the timing of the MRI examinations. Despite being granted approval in 2011, we performed the first examination in May 2014, and the second examination was not performed until August 2016.

The IPG A has no longer been available for a couple of years; however, there are many patients implanted with this device. The MRI approval of the IPG P devices sets several limitations on MRI examinations for these patients.\textsuperscript{14,15} The manuals prescribe combined RF transmit-/receive coils, which were not available to us. Therefore, all MRI scans were performed off-label. In addition, we used the controlled mode 1 for 8 examinations, which was advised against. This was done for 2 reasons: (1) the controlled mode 1 (SAR $\leq 4$ W/kg) was the hospital standard used with the Achieva MRI scanner system, and not everyone was aware about this limitation; and (2) in some cases, we made a conscious decision to achieve acceptable scanning times for complex examinations with time-consuming sequences.

Besides these MRI-technical aspects, only 2 examinations of the knee joint out of 26 cases (7.7%) were possible within the approval. The reasons for this include the lack of approval for using IPG A ($n = 4$), absence of an IPG ($n = 1$), lead issues ($n = 2$), implanted extensions ($n = 2$), and restrictions on the examined body parts ($n = 17$).

Our data show that off-label MRI examinations are possible with both IPG A and IPG P devices in patients with DRG-S. Two adverse events were recorded in the 26 MRI examinations considered in our study. First, in the case of one patient who experienced a syncopal episode, we assume hyperventilation under anxiety as the cause because the patient described fear as the only symptom. We could not identify any evidence that interference between the DRG-S system and the MRI environment (e.g., device heating or undesired stimulation) caused this event. Second, a connection problem between the patient controller and the IPG was observed; the lack of a meaningful explanation implies this adverse event was presumably caused by the MRI examination with the neurostimulator. This problem was resolved by reprogramming the device with the clinician programmer without sequelae. This single event corresponds to an implant-specific complication rate of 3.8%. Interestingly, even the 5 exceptional MRI scans performed (1) using a 90-cm lead and an extant 50-cm lead not connected with the IPG, (2) with a defective contact, (3) without any IPG, and (4) 2 cases with implanted extensions were completed without any complications. Further, the use of the controlled mode 1 for MRI examination had no negative effect. This is consistent with our experience of using the SCS systems.

The rare coverage of CE/FDA approval demonstrates the lack of correspondence to the clinical needs of patients. Manufacturers are encouraged to adapt their devices to clinical requirements including full-body MRI conditionality regardless of the position of the leads on the spine in the normal mode (SAR $\leq 2$ W/kg). Because 3 T MRI scanners are becoming increasingly widespread, compatibility with them is desirable in the future.

The indication for MRI examinations should be made critically and with noninvasive alternatives, such as sonography, X-ray imaging, or computerized tomography, which should be preferred when these diagnostic modalities are suitable. In contrast, invasive methods, such as myelography or arthroscopy, are not justified because of their advanced procedural complications.\textsuperscript{45–48} Further, the procedures may be associated with pain and restrictions in everyday life, and this aspect must be considered when weighing the benefits and risks. In our opinion, it is not justified to explant...
MRI WITH DORSAL ROOT GANGLION STIMULATION

A well-functioning system for the sole purpose of MRI examinations and follow it with reimplantation, because the ACCURATE study reported a rate of severe adverse events of 10.5% and a recently published Danish study reported a complication rate of 58% for DRG-S systems, caused by defective or migrated leads. An exemplary case is presented in Figure 3.

It is evident that patient safety must be the focus of any procedure. Therefore, the patient must be fully informed about termination criteria (heating, new pain, paresthesia, and involuntary movement) before an MRI examination. According to De Andres’ recommendations for the SCS systems, the MRI examination should be performed only on awake patients without any sedation. If possible, the IPG should be set to the MRI mode. Moreover, these MRI examinations should be performed in specialized centers that have experience in conducting both neuremodulation and MRI examinations. The pain physician and radiologist must collaborate, and a medical physicist should be involved if available. Further, the local law must be observed. In Germany and many other countries, off-label use is permitted if the benefit outweighs the risks as per the risk–benefit analysis that considers possible alternatives. We need to provide information to the patient detailing the facts of the off-label use, and the procedure and risk information related to the intended MRI scan and alternatives. Then, we need to obtain patient consent before the MRI examination.

The most important limitations of our study are that it is retrospective, with a monocentric design, and it considers a small number of cases / patients for DRG-S.

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**TABLE 1** Summarized presentation of the demographic data of the examined patients including the scan parameters of MRIs

| Patient characteristics | No IPG | Axiom | Proclaim DRG |
|-------------------------|--------|-------|--------------|
| Number of patients      | 1      | 3     | 11           |
| Age                     | 42     | Median: 49 | Median: 60  |
|                         |       | Range: 40–51 | Range: 31–76 |
| Sex                     | Male (n = 1) | Male (n = 1) | Male (n = 3) |
|                         | Female (n = 2) | Female (n = 8) |
| DRG-S system characteristics | | |
| Number of leads         | 2      | 2 (n = 4) | 1 (n = 2) |
|                         |       | 2 (n = 4) | 2 (n = 17) |
|                         |       | 2 (n = 2) | 3 (n = 2) |
| Location of leads       | Lumbar spine (n = 1) | Lumbar spine (n = 4) | Lumbar spine (n = 19) |
|                         |       | Lumbar spine (n = 1) | Lumbar spine (n = 5) |
|                         |       | Wrist (n = 1) | Thoracic spine (n = 1) |
| Extensions              | N/A    | None   | n = 2 |
| MRI                     |        |       | |
| Number of MRI scans     | 1      | 4     | 21 |
| Examined body regions   | Lumbar spine (n = 1) | Knee (n = 2) | Abdomen (n = 8) |
|                         |       | Lumbar spine (n = 1) | Knee (n = 3) |
|                         |       | Wrist (n = 1) | Lumbar spine (n = 5) |
| DRG-S located in examined area | n = 1 | n = 1 | n = 15 |
| MRI system              | Achieva (n = 1) | Achieva (n = 4) | Achieva (n = 13) |
|                         |       | Ingenia (n = 0) | Ingenia (n = 8) |
| MRI modes               | Normal mode (n = 0) | Normal mode (n = 2) | Normal mode (n = 14) |
|                         | Controlled mode 1 (n = 1) | Controlled mode 1 (n = 2) | Controlled mode 1 (n = 5) |
| Number of sequences     | 7      | 6.8 ± 2.2 | 8.3 ± 1.7 |
|                         |       | Range: 4–9 | Range: 5–12 |
| Active scanning time [mm:ss] | 20:47 | 16:21 ± 07:28 | 21:30 ± 09:37 |
|                         |       | Range: 10:32–17:18 | Range: 07:55–14:34 |
| Scanning time limit exceeded | n = 0 | n = 0 | n = 4 |

Arithmetic means ±SE and the range are given.
Abbreviations: DRG, dorsal root ganglion; DRG-S, dorsal root ganglion stimulation; IPG, implantable pulse generator; MRI, magnetic resonance imaging; N/A, not applicable.
Given the importance of both MRI and DRG-S, further investigations or registries would be most welcome.

**CONCLUSIONS**

To the best of our knowledge, this study was the first involving a series of MRI examinations performed on patients fitted with DRG-S devices. The CE/FDA certification rarely cover these necessary examinations.

Although manufacturers’ recommendations are against the use of MRI in patients implanted with DRG-S in certain conditions, our institution performed these scans in 26 cases without injury to the patients or the devices. Owing to the limited data available for safety, we recommend performing MRI examinations in these patients only as part of a study. In the event an MRI is urgently needed, we recommend the following steps:

1. The examination should be performed using a 1.5 T MRI scanner.
2. The examination should be performed on an awake and cooperative patient.
3. The scan should be immediately terminated if new pain, paresthesia, or involuntary movements occur.
4. The therapy system should be in a technically fully functional condition before the examination.
5. The MRI mode of the device should be activated, if applicable.

In life-threatening scenarios, an MRI scan with a defective system or absent IPG (leads only) can be considered if there are no alternative imaging options and there is no time for device revision surgery left.

Finally, IPG device manufacturers are encouraged to adapt the MRI approvals of future (and if possible current) devices to clinical requirements.

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**CONFLICT OF INTEREST**

Prof. Kretzschmar and Mr. Reining were involved in studies at St. Jude Medical/Abbott Laboratories as the Principal Investigator and Co-Investigator, respectively. Prof. Boettcher, Prof. Winkler, and Prof. Meixensberger declare no conflicts of interest.

**DATA AVAILABILITY STATEMENT**

All data can be reviewed in our hospital information system upon request.

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**FIGURE 3** Exemplary case. A 49-year-old women implanted with a DRG-S system (IPG A with leads at L3 and L4 level) was referred to by the attending orthopedist for MRI examination of her right knee joint for the diagnosis of a clinically suspected bone infection. She suffered from persistent pain after conversion osteotomy. The white blood cell count and CRP were slightly increased, whereas X-ray and computerized tomography were normal. Shown MRI images were obtained using proton-density-weighted sequences in frontal and sagittal orientations. The scan revealed a previously unknown longitudinal tear in the inner meniscus, which explains the symptoms. DRG-S, dorsal root ganglion stimulation; IPG A, implantable pulse generator Axium; MRI, magnetic resonance imaging.
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