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Magnetic Resonance Imaging of Cochlear Implant Recipients

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Objective: Determine the diagnostic usefulness of postimplantation 1.5 T magnetic resonance imaging (MRI) and review magnet-related MRI complications.
Study Design: Retrospective chart review with additional review of MRIs.
Setting: Tertiary care children's hospital.
Patients: Twelve patients who underwent MRI after receiving a cochlear implant (CI).
Intervention: One or more episodes of 1.5 T MRI with CI in place.
Main Outcome Measures: Occurrence of magnet-related complications; whether imaging was clinically useful.
Results: The 12 patients underwent 23 episodes of MRI, including 13 episodes in 11 patients (18 ears) during which a magnet was present and 17 studies were obtained. Complications related to the magnet occurred during 4 of the 13 imaging episodes (30.8%), all during body or spine studies. Magnet torsion with reversal of polarity occurred in three devices; reduced magnet strength in one; and displacement of the magnet from its housing in one. One patient required surgical magnet replacement, whereas other headpiece retention problems were resolved without surgery. All studies but one brain with bilateral magnets were clinically useful.
Conclusions: CI patients who undergo MRI with a magnet in situ may experience complications, especially when imaged below the head. Most complications may be resolved without surgery. Diagnostic usefulness of non-cranial MRI is not likely to be limited by presence of the magnet, while a magnet may prevent clinically useful brain imaging. Obtaining MRI with the magnet in situ avoids the cost and risks associated with multiple surgeries to remove and replace the magnet or the entire implant. **Key Words:** Cochlear implant—Magnetic resonance imaging—Magnet-related MRI complications.

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All cochlear implant (CI) systems contain an internal magnet within the implanted device as well as a magnet within the externally worn headpiece transmitter. The magnets play a crucial role in maintaining the externally worn transmitter in proximity of the internal antenna, thus enabling communication between the external speech processor and the internal receiver-stimulator. Coupling of the externally worn transmitter to the internal device, and, therefore, consistent device use and hearing, is very difficult without effective magnetic retention.

Only one CI manufacturer (Med-El, Innsbruck, Austria) currently has device models that have conditional approval by the Food and Drug Administration (FDA) for use in 1.5 T magnetic resonance imaging (MRI) with the magnet in situ (1). However, most CI patients have received a device with a surgically removable and replaceable magnet that is conditionally FDA approved for use in 1.5 T MRI only after the magnet has been surgically removed. Some older models do not have a removable magnet and have no FDA approval for use in MRI. For these patients, only explantation of the implanted device would permit MRI to be done in a manner consistent with FDA guidelines. Re-implantation of a new CI would be necessary to return hearing to these patients. Significant cost, risk of complication, and a period of auditory deprivation occur in this situation.

Many medical centers in the United States do not conduct MRI of CI patients unless done in compliance with FDA guidelines. To avoid the additional surgeries necessary to remove and replace the magnet, patients and/or their physicians may forego MRI when it would otherwise be recommended. This situation could result in delayed or misdiagnosis in situations where MRI is crucial to medical decision making.

In contrast to the United States, MRI with the magnet in place is performed more frequently in other countries. This difference exists because sale of medical implants in the European Union and countries that follow their commercial conformity guidelines requires manufacturers to affix a CE marking, or logo, that signifies that their device meets legislated safety and health requirements (2). The manufacturers have declared that 1.5 T MRI of a device with a removable magnet in situ is safe if

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N.M.Y. serves on the advisory boards of the 3 device manufacturers listed in the article. The other authors disclose no conflicts of interest.

guidelines, including use of a compression head wrap, are followed.

It has been the practice at our tertiary care children's hospital to obtain 1.5 T MRI without magnet removal when useful clinical information is likely to be obtained. Informed consent is obtained that includes counseling the patient or parent of a minor CI recipient about off-label use of MRI and the potential risks to the device as well as the possibility of surgery to address magnet-related complications. The purpose of this study was twofold: 1) review MRI complications related to the presence of the magnet; and 2) determine whether the diagnostic goals of MRI were achieved in our patients with and without the magnet(s) in situ.

MATERIALS AND METHODS

Following Institutional Review Board approval for the project, a records search of 991 cochlear implant patients implanted between 1991 and 2014 was performed to identify those who underwent 1.5 T MRI postimplantation at our medical center. The medical records of those having undergone MRI were further reviewed and information extracted, including age at CI, time between most recent implantation and MRI, age at MRI, type and number of MRI studies obtained during each episode of imaging, the model and manufacturer of each implanted device and whether a device with or without magnet was in place unilaterally or bilaterally during imaging, the use of a compression head wrap during imaging, whether imaging was done with or without sedation/general anesthesia, and whether device-related complications occurred. The MRIs of these patients were reviewed for the presence of artifact related to the CI(s) and whether artifact impacted the diagnostic utility of the study.

Patients

Twelve patients, six males and six females, underwent 1.5 T MRI after having received a cochlear implant. Table 1 details their characteristics. Average age at initial implantation was 4.8 years (range, 1.1–13). The mean age at time of initial MRI episode was 10.6 years (range, 1.8–24.2). For patients undergoing MRI with a magnet in situ, the mean time between the most recent implantation and MRI episode was 6.2 years (0.4–13). This group of patients included three different CI device models from two different manufacturers. Five of the patients had bilateral implants with magnets in situ during an episode of MRI.

RESULTS

A total of 23 episodes of 1.5 T MRI were completed during which 27 MRI studies were obtained (See Table 2). Eleven patients (16 implanted ears) underwent 13 episodes of MRI with a magnet in situ in which 17 studies of brain, body, or spine were obtained. With the exception of two unilaterally implanted patients (# 8, 10), all had been implanted with a device model designed to permit magnet removal and replacement. Of these 13 episodes of MRI with the magnet in situ, seven involved imaging of the body and/or spine only, four brain only, and two brain plus spine. Two patients (# 3, 11) underwent 10 MRI studies of the brain alone without a magnet in situ. They had a removable magnet model with a spacer substituted for the magnet. Patient #3 was initially implanted without a magnet as serial MRI was anticipated based upon the need to follow a brain lesion identified by MRI before implantation. He later also had imaging with bilateral magnets in situ. Patient #11 was diagnosed with a brain tumor postimplantation based upon computer tomography and underwent magnet removal before serial MRIs.

All CI patients undergoing MRI with a magnet in situ received a compression head wrap just before entry into the MRI room. One patient (#10), age 19, who underwent a cardiac study, did not receive sedation or anesthesia.

TABLE 1. *Characteristics of 12 cochlear implant subjects undergoing 1.5 T MRI postimplantation*

Patient	Sex (M/F)	Age 1st CI (yrs)	Time to MRI (yrs)[a]	Age 1st Post-CI MRI	Device Model	Ear(s) Implanted at Time of MRI(s)
1	Female	1.1	4.4	6.3	Nucleus 24 (CA)	Bilateral
2	Male	13.0	5.2	18.0	HiRes 90K (AB)	Right
3	Male	1.4	0.4[b]	1.4[b]	Nucleus 24 (CA)	Left
			0.6[c]	4.3[c]		Bilateral[d]
4	Female	12.3	12.0	24.2	Nucleus 24 (CA)	Right
5	Female	2.2	9.8	11.9	Nucleus 24 (CA)	Left
6	Male	2.8	1.2	11.6	Nucleus 24 (CA)	Bilateral
7	Female	2.4	6.3	11.5	Nucleus 24 (CA)	Bilateral
8	Male	10.6	8.8	19.3	Clarion (AB)[e]	Right
9	Male	2.8	0.3[b]	3.2	HiRes 90K (AB)	Bilateral
10	Male	6.3	13.0	19.3	Clarion (AB)[e]	Right
11	Female	2.4	1.5	3.8	Nucleus 24 (CA)	Right
12	Female	7.7	1.3	9.1	HiRes 90K (AB)	Right

AB indicates Advanced Bionics (Valencia, CA, U.S.A.); CA, Cochlear Americas (Denver, CO, U.S.A.).
[a]Years from most recent CI to first MRI.
[b]No magnet in situ.
[c]First MRI with magnet in situ.
[d]During third episode of MRI.
[e]Model with ceramic case and non-removal magnet.

TABLE 2. *1.5 T MRI studies of cochlear implant patients and magnet-related complications*

Patient	MRI Episode	MRI Study	Presence of Magnet (unilateral/bilateral)	Complications
1	1	Spine (total)	Yes, bilateral	None
2	1	Brain	Yes, unilateral	None
	2	Brain; spine (total)	Yes, unilateral	None
	3	Brain	Yes, unilateral	None
3	1–2	Brain	No	None
	3	Brain	Yes, bilateral	None
4	1	Brain	Yes, unilateral	None
5	1	Abdomen; pelvis	Yes, unilateral	None
6	1	Knee	Yes, bilateral	None
7	1	Pelvis; spine (lumbar)	Yes, bilateral	Unilateral displacement
8	1	Knee	Yes, unilateral[a]	None
9	1	Pelvis	Yes, bilateral	Bilateral polarity reversal
10	1	Heart flow	Yes, unilateral[a]	Partial de-magnetization
11	1–8	Brain	No	None
12	1	Brain; spine (total)	Yes, unilateral	Polarity reversal

[a]Model with ceramic case and non-removal magnet.

The other patients received sedation or general anesthesia for each episode of imaging. There was no correlation between length of time between implantation and MRI and the occurrence of complications.

Complications related to the in situ magnet (Table 2) occurred in five implanted ears in four patients (# 7, 9, 10, 12). All complications occurred during MRI episodes that included a body or spine study. Two patients (# 9, 12) experienced 180-degree magnet rotation, resulting in reversal of polarity that interfered with headpiece retention. This complication occurred bilaterally in patient #9. Reversal of magnet polarity was easily and successfully managed by reversing the polarity of the external magnets to re-attain effective coupling of the headpiece transmitter with the internal device. One bilaterally implanted patient (#7) experienced displacement of the magnet from one device after MRI of the pelvis and lumbar spine. Discomfort and swelling of the soft tissue overlying the portion of the device containing the magnet was noted after MRI. A radiograph revealed 90-degree rotation of the magnet (Fig. 1). This magnet spontaneously completed 180 degrees of rotation and palpation revealed mobility consistent with displacement from its housing. Displacement was managed by surgical replacement of the magnet, which lay outside of the silastic housing but beneath the scar tissue that encapsulated the device. One patient (#10) with a non-removable magnet experienced immediate reduction of magnet strength, which interfered with retention of the headpiece transmitter. This complication was successfully addressed by increasing the strength of the magnets within the externally worn headpiece transmitter.

All body and spine studies yielded useful clinical information (Table 3). Artifact affected images of the upper cervical spine only. Significant artifact was present in all 16 brain studies, including patients #2 and #11 who had multiple studies of the brain without a magnet in situ (Table 3). However, all brain MRIs of unilaterally implanted patients, with and without a magnet in situ, were clinically useful. For example, brain MRI in CI patient #2 (Fig. 2) was adequate to differentiate brain tumor from vascular malformation, a distinction that could not be made by computed tomography. Despite significant artifact, the information obtained enabled the neurosurgeon to proceed with surgical biopsy and monitoring of the tumor. Additional surgery and problems with headpiece retention for consistent hearing were avoided during this patient's remaining year of life. The

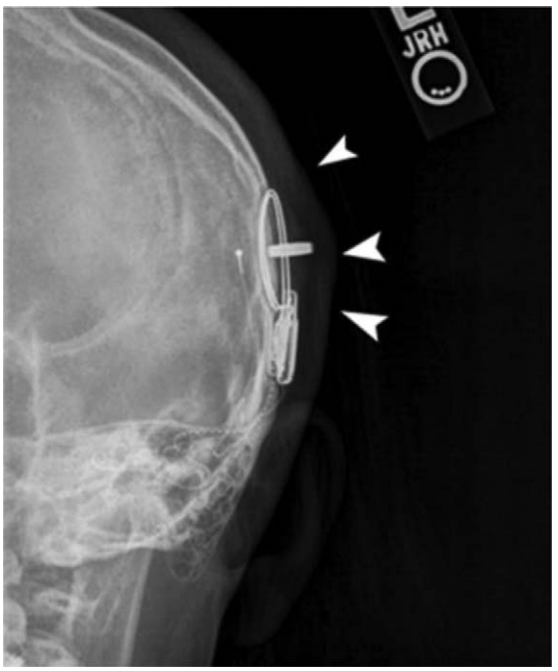

FIG. 1. AP skull film demonstrating 90-degree rotation of the internal magnet. There is associated protrusion of the scalp tissues (*arrowheads*).

TABLE 3. *Presence of artifact and clinical utility of 1.5 T MRI*

Patient	MRI Episode	MRI Study	Presence of Magnet and Device (unilateral/bilateral)	Artifact	Clinically Useful
1	1	Spine (total)	Yes, bilateral	Yes (upper cervical area)	Yes
2	1	Brain	Yes, unilateral	Yes	Yes
	2	Brain	Yes, unilateral	Yes	Yes
		Spine (total)		No	Yes
	3	Brain	Yes, unilateral	Yes	Yes
3	1–2	Brain	No, unilateral	Yes	Yes
	3	Brain	Yes, bilateral	Yes	No
4	1	Brain	Yes, unilateral	Yes	Yes
5	1	Abdomen	Yes, unilateral	No	Yes
		Pelvis		No	Yes
6	1	Knee	Yes, bilateral	No	Yes
7	1	Pelvis	Yes, bilateral	No	Yes
		Spine (lumbar)		No	Yes
8	1	Knee	Yes, unilateral	No	Yes
9	1	Pelvis	Yes, bilateral	No	Yes
10	1	Heart flow	Yes, unilateral	No	Yes
11	1–8	Brain	No	Yes	Yes
12	1	Brain	Yes, unilateral	Yes	Yes
		Spine (total)		No	Yes

one patient (#3) who underwent brain imaging with bilateral implants with magnets in situ had non-diagnostic imaging due to more extensive artifact.

DISCUSSION

Diagnostic imaging studies of all types have become more common since the 1990s. MRI was initially primarily used for neuroimaging. Its usage has increased annually by 10% in the United States (3). This increase has been driven by many factors including wide spread availability, advances in technology and broader application to musculoskeletal and body imaging to diagnose and manage disease. In addition, concern about minimizing exposure to ionizing radiation has shifted clinical practice away from computer tomography (4). During the same time period, use of MRI has been growing, so has the number of individuals receiving CIs. More than 300,000 people world-wide have received a CI, including more than 38,000 children in the United States alone (5). This situation has created increased access problems for CI patients and can prove challenging to physicians who rely upon MRI to diagnose and treat certain conditions.

Until 2013, no CI systems were FDA approved for use in 1.5 T MRI. Med-El Corporation (Innsbruck, Austria) received conditional FDA approval for MRI with magnet in situ for three models (Pulsar, Sonata, and Concert) with use of a compression bandage (6). These models do not have removable magnets. However, their design does eliminate the problem of magnet displacement during 1.5 T MRI. In 2015, a new model by the same manufacturer with a removable magnet received

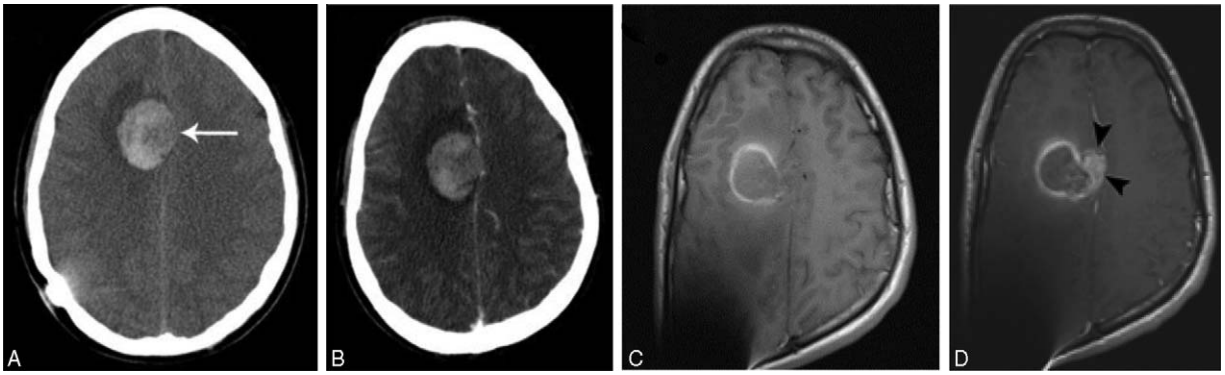

FIG. 2. CT and MRI images of patient with right cochlear implant and new onset of seizure. *A*, Axial pre-contrast CT shows a hyperdense hemorrhagic paramidline lesion (*white arrow*). *B*, Post-contrast CT is essentially noncontributory as areas of enhancement cannot be distinguished from high density blood products. *C*, Pre-contrast T1-weighted fast spin echo MR images show some high signal associated with blood products. Note the susceptibility artifact posteriorly from a right implant. *D*, Post-contrast T1-weighted fast spin echo MR images demonstrate an enhancing mass along medial margin (*black arrowheads*). Biopsy revealed a malignant melanocytic lesion.

conditional FDA approval for MRI up to 3 T without previous magnet removal (1). However, the vast majority of CI patients have not been implanted with devices FDA conditionally approved for 1.5 T MRI with magnet in situ.

To follow FDA guidelines, most CI patients in the United States must first undergo surgery to remove the internal magnet. A spacer provided by the manufacturer is typically substituted for the magnet. It is common practice to replace the magnet subsequent to MRI in patients for whom serial MRI is not expected. If not replaced, headpiece transmitter retention must be achieved by other methods that are typically less than satisfactory for consistent device use and uninterrupted hearing. The need to undergo additional surgery to remove and replace the magnet may create hesitancy on the part of patients to undergo an MRI or physicians to order the study. This situation may delay diagnosis or treatment if MRI is not done or if less satisfactory information is obtained from alternative diagnostic procedures.

The need to remove the magnet or the device also results in added cost and risk of surgical complications such as infection or damage to the silastic sleeve housing the magnet. For example, recipient #3 in our series experienced tearing of the silastic sleeve when the magnet was removed at time of initial implant surgery. This child was ultimately reimplanted with a new device to ensure consistent device use. In situations where the magnet is not removable, or cannot be replaced, the entire implant will need to be replaced to meet FDA guidelines. Significant cost is associated with re-implantation. We estimate that if we had followed FDA guidelines, an additional 29 surgeries on 15 devices (11 patients) would have been necessary. These surgeries would have included two device explantations with subsequent reimplantation of a new device in the two CI patients with non-removable magnets. This approach would have resulted in considerable expense and likely a considerable period of auditory deprivation.

Gubbels and McMenomey (7) conducted cadaver studies of the impact of 1.5 T on CI devices with a removable magnet in situ. They found that displacement of the magnet occurred 87% of the time and that this rate was reduced to zero when a compression bandage was applied. This study attempted to duplicate the forces on the magnet in adults undergoing brain MRI. Their study did not examine whether compression dressing would be adequate to contain the magnet in other circumstances, including extracranial MRI.

Table 4 summarizes published literature in which CI patients experienced magnet-related complications during 1.5 T MRI. With the exception of a single case report (8), all authors reported that a compression bandage was used. All complications occurred in adults, with the exception of one child (9). Displacement of the magnet was reported in 16 patients (9–13). These patients' MRIs included a spine study in three of the four patients for whom the type of study was reported (9–11). In one series, two displacements occurred in the same patient and device during two separate episodes of brain imaging (12). One medical center reported 12 magnet displacements, but did not provide information about the types of MRI studies being performed when complications occurred (13). This is the only series in which a magnet extrusion through the skin was reported and in which management of complications related to the magnet required device explantation. Reversal of polarity was reported in a number of series as well (8,11,14,15). All five polarity reversals reported in the literature occurred during an MRI episode that included imaging of the body or spine, similar to the three polarity reversals in our series. Canting of the magnet in three patients

TABLE 4. *Magnet-related complications in patients with magnet in situ during 1.5 T MRI*

Author	Complication	MRI Study	Series Size (n)	Management
Deneuve et al. (9)	Displacement[a] (n = 1)	Brain and spine	1	Magnet removal without replacement
Crane et al. (14)	Reverse polarity[b] (n = 2)	Body	16	Reversal of headpiece magnets
Jeon et al. (15)	Reverse polarity	Lumbar spine	1	Reversal of head piece magnet
Broomfield et al. (10)	Displacement[c] (n = 1)	Brain and cervical spine	1	Removal of magnets bilaterally in anticipation of need for serial MRIs
Kong et al. (8)	Reverse polarity	Lumbar spine	1	Reversal of head piece magnet
Hassepass et al. (13)	Displacement[d] (n = 12)	Not reported	12	Magnet replacement in nine, explant of two due to infection, including patient with magnet extrusion through the skin
Kim et al. (11)	Displacement (n = 1)	Lumbar spine	16	Surgical reinsertion
	Reversal of polarity (n = 1)	Knee and lumbar spine		Not reported
Carlson et al. (12)	Displacement[e] (n = 1)	Brain	16	Surgical magnet replacement
	Canting (n = 3)	Brain		Reseated with external manual pressure
		Brain		
		Brain		

[a]Device with history of magnet removal and replacement.
[b]Occurred bilaterally in one patient.
[c]Unilateral displacement in bilaterally implanted patient.
[d]Two patients with additional complications of displacement: one with extrusion though skin and infection and a second with infection.
[e]Occurred in same device after each of two brain MRIs.

undergoing brain MRI was reported in one series (12). This problem was successfully managed with gentle external pressure applied to rotate the magnet into its sleeve. None of the authors reported any demagnetization like we found in one patient.

A common problem reported in the literature was significant discomfort in CI patients who underwent MRI without sedation or general anesthesia (8,10,11,12,14,15). This complication was not addressed in our study as all but one of our patients were sedated or anesthetized.

A number of studies have reported that MRI of adequate diagnostic utility may be achieved in CI and auditory brainstem implant patients with the magnet in situ (12,14,16,17). Several authors have commented on the lack of artifact seen in body or spine imaging (11,14). Our experience in this series of pediatric CI patients was similar.

Previous literature has attributed magnet complications in part to the type and quality of the compression bandage or to weakness of the silastic retaining the magnet and scar tissue encapsulating the device. However, other variables not previously considered include the forces due to MRI that vary depending upon many factors including type of imaging sequences, position of the body within the gantry and on the MRI table, and the speed of table movement within the gantry. Although it may initially appear counterintuitive, some forces on an in situ CI magnet are more likely to be stronger when body or spine images are being acquired than when the brain is the area of study. During MRI, the region to be scanned is positioned at the isocenter of the MRI where the static magnetic field has highest uniformity. The MRI table moves the patient into the MRI bore to a degree that depends upon patient length and the area to be imaged. The spatial static magnetic field gradients (i.e., the changing rate of static magnetic field along with the spatial distance) can induce the greatest translational forces of attraction and repulsion on the CI magnet when it is positioned near the entrance to the MRI opening (18,19). Constant in and out movement and speed of movement of the table within the MRI gantry causes faster change of the spatial magnet field, resulting in higher polarity-changing forces on the CI magnet. Echo planar imaging sequences, such as diffusion-weighted imaging, may rely on rapid time varying magnetic field (i.e., gradient field), which may induce voltage and also reduce magnetic strength of the CI magnet. During body imaging, it is more likely that a patient's device will be positioned for longer periods near the entrance to the MRI bore where the spatial static and time-varying magnetic field gradients are higher, although that will depend upon the site being imaged, the length of the patient, and whether the patient remains fully supine on the table.

With the exception of the upper cervical region, artifact related to the presence of the CI magnet is not expected. When the brain is imaged, artifact will be present without a magnet in situ, and will be greater if the magnet is present. When a magnet is in situ, whether the study will be clinically useful depends upon the area of interest and the type of sequences required. Echo planar imaging such as diffusion-weighted imaging will not, in our experience, yield useful images (see Fig. 3).

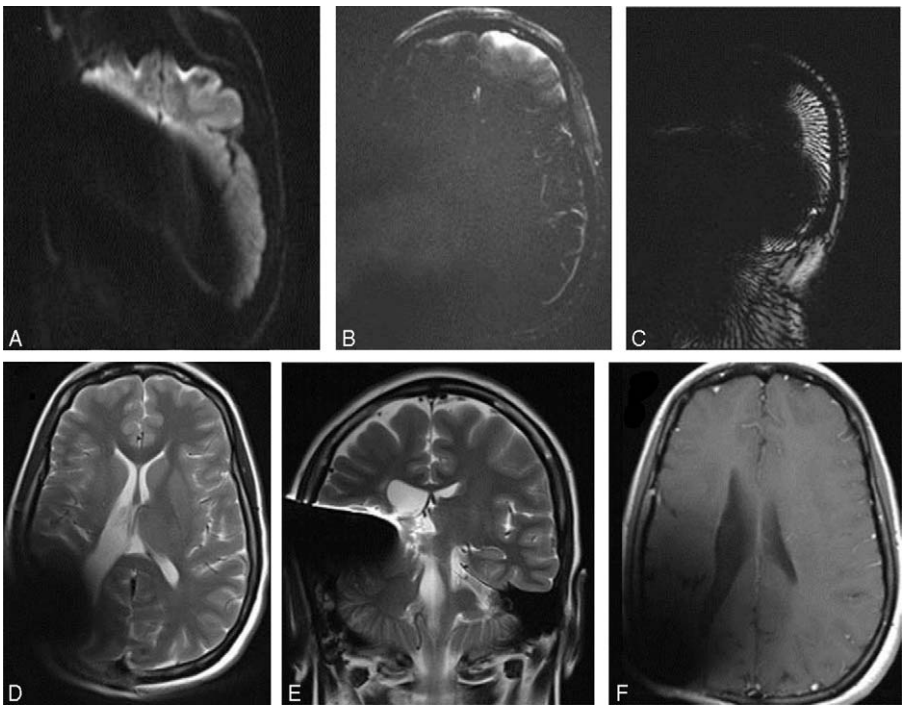

FIG. 3. Brain imaging with a CI magnet in situ (implanted right ear). Diffusion-weighted echo-planer images (*A*), hemorrhage sensitive sequences such as gradient recalled echo (*B*), and susceptibility weighted imaging (*C*) are generally non-diagnostic. In comparison, T2-weighted (*D* and *E*) and T1-weighted (*F*) fast spin echo images often are more useful due to more localized artifact.

T1 and T2 imaging are more likely to provide adequate image quality when the area of interest is relatively distant from the magnet. Whether magnet removal will be necessary to obtain useful brain images will depend upon the specifics of each situation.

CONCLUSION

Cochlear implant patients undergoing body or spine MRI with a removable magnet in situ are at higher risk to experience magnet-related complications than patients undergoing brain imaging alone. The vast majority of complications reported in the literature, and in our series, are relatively minor and were resolved non-surgically. The problem of polarity reversal due to magnet rotation may be resolved without surgery if the magnet remains within its sleeve. De-magnetization of a non-removable magnet is rare and in our series the resultant headpiece retention difficulty was rectified non-surgically. MRI artifact is not likely to affect clinical usefulness of body or spine imaging but may significantly impact brain imaging depending upon the area of interest and type of sequences required. In light of the steady increase in use of MRI to diagnose and manage a broad range of conditions, the issue of obtaining safe and useful MRI in CI patients is of growing importance. Surgical removal of the magnet or device to meet FDA guidelines not only results in significant expense but may deter some patients and their physicians from pursuing MRI. In some CI patients, this situation might lead to delay in diagnosis and compromised medical management.

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