INTRODUCTION

Since the introduction of cochlear implants (CI) by Dr. William House in 1961, the use and number of CI recipients has grown exponentially. As of 2012, the number of CI recipients is estimated to exceed over 300 thousand without signs of slowing down. Similarly, we have seen a rapid increase in the use of advanced imaging modalities. Diagnostic magnetic resonance imaging (MRI) is considered the imaging modality of choice for a myriad of medical issues because of its improved visualization and spatial resolution using high powered magnetic fields. Together, we have seen a rapid increase in the number of patients with CIs who require diagnostic MRI, which has generated significant concern and discussion over MRI safety.3–5

Historically, MRIs were strongly contraindicated for patients with implantable metal medical devices such as CIs and pacemakers. MRI is a safety concern because of its tremendously powerful magnetic fields, strong radio frequency excitation, and rapidly switching gradient fields used to generate state of the art images. Metallic implants are a significant concern because of their interaction with the complex MR environment, which can introduce significant force, voltage, heat, image artifact, demagnetization, and potential device malfunction.5–8 With the rise in CI recipients requiring diagnostic MRI, the U.S. Food and Drug Administration (FDA) assigned MR conditional designation to most CI systems up to 1.5 tesla (T), and MED-EL Synchrony (MED-EL, Innsbruck, Austria) up to 3.0 T, with and without magnet removal with proper head splint securement.9–11

The path that CI MRI safety has taken from one of complete contraindication to MR conditional safety recommendations has been quick and without any robust scientific data. With the ever-increasing rise in CI recipients undergoing diagnostic MRI over the last decade, patient MRI safety has emerged into the limelight. With a recent rise in MRI-related CI complications at the authors’ own institution, it necessitated a review of the existing literature and implementation of new MRI safety measures. Interestingly, the initial small cadaveric and patient series showed minimal to no issues with MRI safety for CI and auditory brainstem implants (ABI).6,7,12 However, despite these initial findings, there has been a...
plethora of case reports and additional patient series that describe a relatively high frequency of MRI-related CI complications.\textsuperscript{3,4,13–20}

Herein, we summarize the MRI safety and image quality in our series of 18 patients with CI or ABI who collectively have undergone a total of 62 postimplantation MRI scans. Our review offers a unique perspective compared to the literature on the variety of CI manufacturers used at our institution.\textsuperscript{3,4} Furthermore, we aim to raise awareness about our growing concern for CI and MRI safety. We may have a false sense CI and MRI safety, and we need to continue to advocate for improvement and advancement to achieve the best for our CI patients.

MATERIALS AND METHODS

Approval was obtained by our institutional review board. A retrospective chart review was performed for patients who underwent cochlear implantation and diagnostic MRI. Each patient was evaluated and treated at a tertiary academic medical center between January 2006 and April 2018. One hundred and eighty-eight patients were initially identified. Patient were subsequently excluded from analysis if they did not have CI prior to MRI, if follow-up was not performed at the author’s primary institution, or if they had incomplete information within the electronic medical records. Data collected included age of first CI placement, sex, CI manufacturing device, age at time of first MRI, number of MRIs, details on MRI performed (indication, magnetic strength, image type), whether FDA head wrap was placed prior to MRI, and any complications during or after MRI. We included pain as a complication if it precluded completion of the MRI, whereas pain with successful completion of the MRI was not considered a complication. Once data was collected, head MRIs following CI placement were retrospectively analyzed by the senior author neuroradiologist (L.N.L) for image quality (adequate, obscured, or unusable). Other MRI series were excluded from retrospective review with the assumption that CI would not cause any artifact.

RESULTS

We identified a total of 18 patients who met inclusion criteria (Table I). A total of 15 CI patients underwent MRI with a magnet in place for a total of 24 scans. Two patients underwent MRI with magnet removed prior to diagnostic MRI for a total of 29 scans. Finally, one patient had an ABI with magnet in place for a total of nine diagnostic MRI scans. The median age of first CI placement was 61; 11 (61%) were male; and seven (39%) were female. The median age of first MRI after CI implantation was 62. The two most common indications for MRI were neurofibromatosis type II (NF2) and back pain/radioulectropathoma type II (NF2) surveillance. CI recipients who required MRI of the head were reviewed by the senior author neuroradiologist (L.N.L) for quality of images. Only one MRI of the head was slightly obscured because the arachnoid cyst of interest was situated along the midline at the pituitary. Otherwise, all other MRIs of the head were adequate in evaluating the contralateral skull base lesions of interest. For evaluation of the ipsilateral skull base, the internal auditory canal (IAC) of two patients were completely obscured by the magnet artifact, the internal auditory canal (IACs) of two patients were adequately visualized with the magnet in place, and the IAC of one patient was adequately visualized without the magnet in place. We did not observe any difference in artifact between the different CI manufacturers (Fig. 3). As expected, removal of the magnet did minimize ipsilateral artifact (Fig. 3).

DISCUSSION

The results of our patient series show that MRI safety in CI recipients is a significant issue, occurring in approximately one-third of CI recipients undergoing diagnostic MRIs. Our findings are in accordance with two of the largest series published within the literature. Kim et al. retrospectively reviewed CI recipients and found five of 18 CI patients (28%) and five of 30 MRI scans (17%) had complications while undergoing MRI despite a head wrap. All five had significant pain limiting ability to complete their MRI, one of which had magnet displacement, one with magnet polarity reversal, and one necessitating the OR for magnet removal.\textsuperscript{20} In a separate series, Carlson
<table>
<thead>
<tr>
<th>Age of First CI Placement</th>
<th>Sex</th>
<th>Device</th>
<th>Age First MRI</th>
<th>Indication for MRI</th>
<th>Scan Type</th>
<th>MRI Strength</th>
<th>No. of MRI</th>
<th>Method</th>
<th>Head Wrap*</th>
<th>Complications</th>
<th>Image Quality</th>
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<tr>
<td>73</td>
<td>F</td>
<td>AB HiRes Ultra</td>
<td>73</td>
<td>Pituitary arachnoid cyst</td>
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<td>45</td>
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<td>F</td>
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<td>34</td>
<td>Breast mass</td>
<td>Breast</td>
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<td>1</td>
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<td>61</td>
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<td>MED-EL Pulsar</td>
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<td>35</td>
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<td>9</td>
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<td>Adequate</td>
<td></td>
</tr>
</tbody>
</table>

*Respective manufacturer provided implant bandage and splint kit for MRI applied according to manufacturer instructions.

AB = Advanced Bionics; CI = Cochlear Corporation; F = female; M = male; NF2 = Neurofibromatosis Type 2; OR = operating room; T = tesla.
et al. retrospectively reported that four of 16 patients (25%) undergoing total 34 MRI scans had complications: one patient with two separate episodes of magnet polarity reversal, three with canting of the magnet, and two with significant pain requiring trip to the OR for magnet removal. In addition, they reported that up to 15% of patients may experience internal magnet movement despite tight head wrap. As the number of CI recipients continues to grow alongside the ever-increasing access to advanced imaging modalities, CI and MRI safety is an inevitable concern. In our opinion, patient complication rates in our series and in the literature ranging from 15% to 30% are unacceptable.

MRI uses precise control over electromagnetic fields, typically ranging from 1.5 to 3.0 T in strength (clinically approved up to 7 T). The main magnetic field in MRI is formed by a strong electric current within a superconducting coil and thus is always active. This magnetic field, along with strong switching gradient systems and radiofrequency coils, is used to manipulate various molecular properties of human tissues to generate images. Cochlear implants and other metal implantable devices interactions with strong electromagnetic fields raise four significant safety principles: induction of voltage across the metal implant, force and torque on the metal implant, heating of the implant, and artifact generated from the metal implant on the formed diagnostic image. For the sake of this discussion, CIs and ABIs are most influenced by force and artifact compared to cardiac pacemakers in which the voltage generated is potentially lethal and of

![Fig. 1. Lateral X-ray of the head demonstrating magnet displacement posteriorly of CI after 1.5 tesla MRI of the spine. Patient required a separate trip to the operating room to reposition the magnet. (A) Placement of CI before MRI. (B) Posterior displacement following MRI. CI = cochlear implant; MRI = magnetic resonance imaging.](image1)

![Fig. 2. X-rays in two patients with magnet canting following 1.5 T MRI. (A) Patient CI magnet placement prior to MRI. (B) Patient CI magnet canting following 1.5 T MRI (same patient from Fig. 1). (C) Magnification of patient in (A) and (B) demonstrates magnet is completely separated from the main CI receiver. (D) X-ray in second patient with CI magnet canting following 1.5 T MRI. (E) Magnification of same patient in (D). CI = cochlear implant; MRI = magnetic resonance imaging; T = tesla.](image2)
Fig. 4. Schematic of the typical electromagnetic fields surrounding 1.5 T MRI machine from the magnetic isocenter. Patient is placed supine outside the MRI suite to minimize interaction of the strong electromagnetic flux with the cochlear implant. Patients are then brought into the MRI suite laying down and must remain supine. Following MRI completion, patients remain supine and are taken out of the scanner room and then allowed to move into a sitting position. Magnetic field diagram ©GE Healthcare, used by permission. G = Gauss; MRI = magnetic resonance imaging; T = tesla.

Fig. 3. MRI of three CI recipient patients with three different CI manufacturers, including Advanced Bionic Ultra (Valencia, CA), with magnet (A, D), MED-EL Synchrony (Innsbruck, Austria) with magnet (B, E), and Cochlear Corporation Nucleus 512 (Sydney, Australia) with magnet removal (C, D). MRI artifact comparison with magnet in place (A, B, D, E) compared to without magnet in place (C, F). (A) Axial 3D T1 post- and (D) coronal T1 post-MRI in a patient for postoperative monitoring of an arachnoid cyst within the pituitary. (B) Axial 3D T1 post- and (E) coronal T1 post-MRI in a NF2 patient with a left vestibular schwannoma. (C) Axial 3D T1 post- and (F) coronal T1 post-MRI in an NF2 patient with a left vestibular schwannoma. 3D = three dimensional; CI = cochlear implant; MRI = magnetic resonance imaging; T = tesla; NF2 = Neurofibromatosis type 2; T1 = T1 relaxation time.
primary concern. When designing MRI safety protocols, it is paramount that each of these factors is considered to minimize patient morbidity.

Electric voltage is induced whenever an electrically conducting material (i.e., CI + electrode) passes through a magnetic flux. A voltage is generated during three MRI scenarios. Voltage can be generated whenever a patient moves toward the MR scanner; the magnetic flux goes from essentially zero to its maximum $B_0$ value. A voltage can also be generated whenever a CI is inside or moving around the MR scanner or during MR image acquisition as a result of the rapid switching gradient fields that generate proton spin and their relaxation. A third example, and most significant to MRI CI safety, is the force that is generated and induced from the interacting magnetic moment (i.e., magnet inside the CI) with the surrounding magnetic fields and the respective closed generated eddy currents. A linear force is exerted on the CI whenever a patient moves in and out of the MR scanner and during active image acquisition. A second rotational force, or torque, is generated whenever the CI magnet is not parallel to the magnetic field. This occurs most notably when patients go from a seated to a supine position near the bore of the magnet, where a patient can pass through multiple closed three-dimensional magnetic fields during this motion.

Magnetic resonance imaging safety protocols for patient handling and MR image acquisition are rarely described in the literature. To our knowledge, only one series provides an in-depth description. Taking the aforementioned safety principles and in partnership with our radiology department, we have adopted a similar protocol described by Carlson et al. On the day of the MRI, patients must first visit with our audiologist to ensure proper securement and placement of the manufacturer-approved head wrap. Patients are then placed supine outside the MRI room, away from the strongest electromagnet effects. While remaining supine, patients are slowly brought into the room and docked into the MRI scanner. To minimize any torque on the CI, patients must remain in supine position. Once the MRI is completed and the patients are taken out of the scanner room, they are allowed to move into a sitting position again (Fig. 4).

In our series, we found that the head splint wrap is insufficient in preventing MRI-related complications. Four of five patients who experienced MRI-related complications had the wrap in place; eight had recorded use; and nine were not recorded in the electronic medical record and were noted as “unknown” (Table I). There are multiple patient series and case reports of CI MRI-related complications with the head wrap in place. Prior to the introduction of the head wrap, the first studies that pioneered MRI safety and approval were done in CI systems in which the magnets were embedded within the device. These studies clearly demonstrated that the magnetic fields induced a significant torque and caused CIs to move; however, they showed that adult skulls could withstand these forces and are safe in up to 1.5 T MRI. These studies were complemented with two patient series on 30 and 11 patients showing no issues or adverse events.

To address the significant artifact generated, a new generation of CIs came to market with a removable magnet. Interestingly, this coincided with some of the first reports of magnet dislocation. The introduction of the head wrap was an educated methodology to address magnet dislocation. A cadaveric study demonstrated that four of 16 implants moved with 1.5 T without a compressive head wrap, compared to 0 of 16 with a compressive head wrap in place. Two subsequent patient series showed no complications in up to 1.5 T MRI. Crane et al. had no complications in 22 1.5 T MRI studies in 16 CI recipients, and Walton et al. reported no complications with magnet displacement in 76 1.5 T MRI studies in 13 NP2 patients. Despite these findings, starting in 2008 there has been a myriad of case reports and patient series that have demonstrated CI magnet displacement. In a retrospective review of 1,706 CI, Hassepas et al. found that 1.5 T MRI is the primary cause of magnet dislocation requiring revision surgery. In addition to magnet displacement, pain and discomfort are significant issues that are often overlooked in CI MRI safety. Kim et al. reported that five of 18 CI recipients had significant pain and discomfort that precluded them from completing the MRI, whereas only one of these patients had magnet dislocation. Carlson et al. reported two of 16 patients had significant pain that required magnet removal before MRI could be completed. In our review, we had two patients who experienced significant pain that precluded them from completing their MRI. Although some authors have found this issue can be solved with light sedation, pain is still a significant concern for MRI safety moving forward.

Our series offers a diversity of CI manufacturers, including MED-EL, Cochlear, and Advanced Bionics. Unfortunately, the majority of the literature on MRI safety is limited to Cochlear. Only one other series reports on a large diversity of CI manufacturers similar to ours; their review included Cochlear, Clarion (Advanced Bionics), and MED-EL. In our review, we found MED-EL to be associated with the least number of complications. Most significantly, we found that the Synchrony model ($n = 6$, total 9 MRI scans) had no adverse events. Of the MED-EL implants not including Synchrony, we observed one of six patients to have complications, and two of four Cochlear CIs had MRI-related complications. Both Advanced Bionics CIs had MRI-related complications, and two of four Cochlear CIs had MRI-related complications. The Synchrony model (MED-EL) is unique, and in our opinion represents a vital step forward in MRI safety. The Synchrony model (MED-EL) features a freely rotating and self-aligning diamagnetic magnet that ultimately minimizes torque pressure and demagnetization. Similar industry-driven technical innovations will be paramount as we address patient MRI safety in the future.

Finally, because ordering providers must be mindful of the necessity of an MRI in CI recipients. Benefits of diagnostic MRI must clearly outweigh the CI-related risks. Two of the five complications had an MRI of the spine ordered for back pain and radiculopathy. Interestingly, both MRIs were completed, and no further interventional management was taken. Unbeknown to most
providers, an MRI of the spine will put more torque and force on the magnet compared to an MRI of the head due to patient positioning within the magnetic fields. Providers often assume that CIs are MRI safe with the “approved” head wrap, but in fact we have found this not always true.

Despite the 15% to 30% rate of complications, we must acknowledge the advancement we have made over the last couple of decades for CI patients undergoing MRI. Historically, every patient prior to MRI was taken to the OR for magnet removal and replacement. These additional procedures add pain, risk of contamination and device infection, and interval of nonuse while the incision heals. With this in mind, we as providers who are familiar with CI MRI safety will counsel patient on the risks benefits of keeping the magnet in place during MRI in order to avoid a separate OR procedure. Although the risk profile is a significant improvement, in our opinion the literature on CI MRI safety has ushered a false sense of safety that the head wrap is sufficient when in reality it may not be as safe as we would like to think. Furthermore, the fact we did not observe any complications with the model featuring a freely rotating magnet should be part of the counseling session with patients when choosing their respective CI if MRIs are anticipated in the future. As the number of CI recipients continues to grow and the advancement in MRI technology moves toward more powerful magnets, we cannot settle for better. We need to continue to raise awareness and push industry innovation to achieve the best for our patients.

Limitations of this study include those inherent with any retrospective study and small sample size. We cannot comment on the consistency on patient handling and MR image acquisition safety because until recently our institution did not have an official CI MRI safety protocol in place. Furthermore, we did not attempt to manually reduce the canted magnet back into place prior to the OR, as proposed by Carlson et al.4 Both these factors may attribute to larger number of complications and CI magnet displacement compared to other studies. Nonetheless, we advocate that all intuitions revisit their MRI safety protocols with the aforementioned MR safety principles to maximize CI patient safety. In order to draw stronger conclusions, MRI safety protocols will need to be standardized across multiple institutions, and larger prospective studies are needed with a diverse number of CI systems.

CONCLUSION

Our series and review demonstrate that CI recipients MRI-related complications are occurring at an unacceptable rate and are a significant issue that can no longer be ignored. We review a diverse number of CI manufacturers, and our findings are in agreement with recent literature. In our series, we found that CI MRI-related complications are occurring in up to one-third of patients. We hope our findings raise awareness that we may have a false sense of CI MRI safety and instigate discussion and action on CI and MRI safety. We believe the MED-EL Synchrony system is an enormous step in the right direction for patient safety, and our findings support this. We as physicians and providers can help address MRI safety through three primary measurable actions: 1) We can first revisit our respective institutions MRI CI patient protocols to maximize safety; 2) we must advocate for continued industry technology innovation for our auditory implant systems to improve safety, such as the freely rotating magnet; and 3) we as providers must continue to spread awareness and make sure other providers are cognizant that the benefits of diagnostic MRI truly outweigh the CI-related risks.

BIBLIOGRAPHY


