Is MRI Safe in Patients with Implanted Cardiac Devices?


Study Overview

Objective. To assess the risks associated with magnetic resonance imaging (MRI) in patients with a pacemaker or implantable cardioverter-defibrillator (ICD) that is “non–MRI-conditional.”

Design. Prospective cohort study using the multicenter MagnaSafe Registry.

Setting and participants. Patients were included in the registry if they were 18 years of age or older and had a non–MRI-conditional pacemaker or ICD generator, from any manufacturer, that was implanted after 2001, with leads from any manufacturer, and if the patient’s physician determined that nonthoracic MRI at 1.5 tesla was clinically indicated. Exclusion criteria included an abandoned or inactive lead that could not be interrogated, an MRI-conditional pacemaker, a device implanted in a nonthoracic location, or a device with a battery that was near the end of its battery life. In addition, pacing-dependent patients with an ICD were also excluded.

Main outcome measures. The primary outcomes of the study were death, generator or lead failure requiring immediate replacement, loss of capture (for pacing-dependent patients with pacemakers), new-onset arrhythmia, and partial or full generator electrical reset. The secondary outcomes were changes in device settings including: a battery voltage decrease of 0.04V or more, a pacing lead threshold increase of 0.5V or more, a P-wave amplitude decrease of 50% or more, an R-wave amplitude decrease of 25% or more and of 50% or more, a pacing lead impedance change of 50 ohms or more, and a high-voltage (shock) lead impedance change of 3 ohms or more.

Main results. Between April 2009 and April 2014, clinically indicated nonthoracic MRI was performed in a total of 1000 pacemaker cases (818 patients) and 500 ICD cases (428 patients) across 19 centers in the United States. The majority (75%) of the MRI examinations were performed on the brain or the spine. The mean time patients spent within the magnetic field was 44 minutes. Four patients reported symptoms of generator-site discomfort; one patient with an ICD was removed from the scanner when a sensation of heating was described at the site of the generator implanted and did not complete the examination.

Regarding primary outcomes, no deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI. One ICD device was left in the active
mode for anti-tachycardia therapy (a protocol violation) and the generator could not be interrogated after MRI and required immediate replacement. Four patients had atrial fibrillation and 2 patients had atrial flutter during or immediately after the MRI. All 6 patients returned to sinus rhythm within 49 hours after MRI. No ventricular arrhythmias were noted. There were also 6 cases of partial generator electrical reset with no clinical significance.

Regarding secondary outcomes, a decrease of 50% or more in P-wave amplitude was detected in 0.9% of pacemaker leads and in 0.3% of ICD leads; a decrease of 25% or more in R-wave amplitude was detected in 3.9% of pacemaker leads and in 1.5% of ICD leads, and a decrease of 50% or more in R-wave amplitude was detected in no pacemaker leads and in 0.2% of ICD leads. An increase in pacing lead threshold of 0.5 V or more was detected in 0.7% of pacemaker leads and in 0.8% of ICD leads. A pacing lead impedance change of 50 ohms or more was noted in 3.3% of pacemakers and in 4.2% of ICDs.

**Conclusion.** Device or lead failure did not occur in any patient with a non–MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla when patients were appropriately screened and had the cardiac device reprogrammed in accordance with the protocol. Substantial changes in device settings were infrequent and did not result in clinical adverse events.

**Commentary**

It is estimated that 2 million people in the United States and an additional 6 million worldwide have an implanted non–MRI-conditional cardiac pacemaker or ICD [1]. At least half of patients with such devices are predicted to have a clinical indication for MRI during their lifetime after device implantation [2]. The use of MRI poses concerns due to the potential for magnetic field–induced cardiac lead heating, which could result in myocardial thermal injury and detrimental changes in pacing properties [3,4].

In this study, Russo and colleagues assessed the risks for patients with a non-MRI-conditional pacemaker or ICD receiving an MRI scan using a pre-scanning protocol. If the patient was asymptomatic and had an intrinsic heart rate of at least 40 beats per minute, the device was programmed to a no-pacing mode (ODO or OVO). Symptomatic patients or those with an intrinsic heart rate of less than 40 beats per minute were determined to be pacing-dependent, and the device was reprogrammed to an asynchronous pacing mode (DOO or VOO). All bradycardia and tachycardia therapies were inactivated before the MRI. Based on this standardized protocol, no major adverse outcomes occurred. All pacemaker or ICD device were reprogrammed in accordance with the pre-specified protocol except one case where the ICD device was left in the active mode for anti-tachycardia therapy (a protocol violation) and the generator could not be interrogated after MRI and required immediate replacement. In addition to patient safety, the authors also measure the functionality of the devices pre-MRI and post-MRI. One of these measurements were battery voltage changes, a small decrease was noted for both pacemakers and ICDs as expected. The radiofrequency energy generated during MRI scanning creates a temporary decrease in battery voltage, which had resolved in all pacemaker cases although some ICD voltage decreases of 0.04 V or more had not resolved by the end of the 6 month post-MRI follow-up.

Several limitations exist. The study registry included devices and leads from different manufacturers, but did not report outcomes by manufacturer. While overall it appears to be safe to conduct an MRI study for patients who have non–MRI-conditional devices, this study did not provide enough information for patients younger than 18 years of age, patients who required repeat MRI studies, MRI examinations of the thorax, or higher MRI field strengths—the newer 3 tesla high-resolution MRI machines.

**Applications for Clinical Practice**

This multicenter prospective cohort study provides strong evidence that patients with a non–MRI-conditional pacemaker or defibrillator can receive nonthoracic MRI studies at 1.5 tesla when a straight pre-scanning device interrogation is performed per the standardized protocol. —Ka Ming Gordon Ngai, MD, MPH

**References**

Communicating Prognostic Information in Oncology


Study Overview

Objective. To assess the prevalence and determinants of patient–oncologist discordance in opinion of prognosis, and evaluate how often patients are aware of this discordance.

Design. Cross-sectional study.

Setting and participants. The study included 236 adult patients with advanced cancer and their 38 oncologists at academic and community oncology practices in Rochester, New York, and Sacramento, California. Inpatients and those already enrolled in hospice were excluded.

Main outcome measures. Patients and their oncologists independently reported their ratings of 2-year survival probability on a postindex visit multiple-choice questionnaire (response options included 100%, about 90%, about 75%, about 50%, about 25%, about 10%, and 0%). Prognostic discordance was defined as a more than 1 category difference between the patient and physician prognostic ratings. All patients were asked to report how they believed their oncologist would rate their 2-year survival probability. Those who correctly perceived their oncologist’s rating of their prognosis (within 1 category) were defined as knowing their oncologist’s opinion, and the rest were defined as not knowing their oncologist’s opinion. This distinction was used to categorize patients whose self-rating of their prognosis was discordant from their oncologist’s rating as either knowingly discordant or unknowingly discordant. Patient characteristics including age, sex, race/ethnicity, education, income, aggressiveness of cancer, self-efficacy with health care communication, recall of prognostic discussion with the oncologist, and end-of-life treatment preferences were evaluated as potential determinants of prognostic discordance.

Main results. 68% of patients rated their 2-year survival probability discordantly from their oncologists. Among these, 96% rated their prognosis more optimistically than their oncologists, and 89% were unaware that their opinions differed from that of their oncologists. Prognostic discordance was more common among nonwhite compared to white patients (95% versus 65%, \( P = 0.03 \)). The prevalence of prognostic discordance did not significantly differ based on the other patient characteristics studied. Among patients whose prognostic ratings were discordant from their oncologist’s, 99% reported that they wanted to be involved in treatment decision making, and 70% were interested in involving palliative care when the end of life became near.

Conclusion. Patient–oncologist discordance about prognosis was common, particularly among nonwhite patients. In cases of prognostic discordance, patients rarely knew that their opinion differed from that of their oncologist, suggesting a lack of successful communication of prognostic information.

Commentary

Prior studies have noted that patients with advanced cancer perceive prognosis more optimistically than their physicians [1–3]. In a large national prospective observational study, the majority of patients receiving chemotherapy for metastatic (stage IV) lung or colorectal cancer inaccurately believed that chemotherapy was likely to be curative, potentially compromising their ability to make informed treatment decisions [4]. In the present study by Gramling et al, the authors confirm the observation that patients are more optimistic about prognosis than their oncologists, and furthermore demonstrate that most patients are unaware of the discrepancy, suggesting a failure of communication. As in prior studies, racial disparity in prognostic understanding was observed, with nonwhite patients being more likely to have overly optimistic views of their prognosis [4,5]. While the perceived 2-year survival probability is a somewhat arbitrary measure of prognostic opinion, it provides a useful representation of how one views the expected trajectory of disease. A high perceived likelihood of 2-year survival implies a view that long-term disease control can be achieved, whereas a low perceived likelihood of 2-year survival implies acknowledgement of terminal illness. This
study effectively contrasts patient and physician opinions of 2-year survival probability, but it does not discriminate among clinically relevant differences in opinions within the 0–2 year prognostic range. For example, a patient whose oncologist believes his prognosis is < 6 months may be an inappropriate candidate for hospice, but the patient may be unprepared to make the transition to hospice if he believes his prognosis is closer to a year or more. While the patient and oncologist may agree that 2-year survival is unlikely, they may have differing beliefs about the appropriateness of certain interventions based on their discrepant short-term prognostic views. Additional studies looking at perceived probabilities of short-term survival may be helpful in assessing patients' readiness to transition to symptom-focused care when medically appropriate.

The authors designate 7 categories of 2-year survival probability (100%, about 90%, about 75%, about 50%, about 25%, about 10%, and 0%). The differences in percentage between prognostic categories are not evenly distributed, and therefore definition of discordance is non-uniform. The smaller percentage difference at the highest and lowest ends of the scale may result in overestimation of discordance at these extremes. For example, a patient rating her 2-year survival probability at 100% would be defined as having a discordant viewpoint from an oncologist rating her 2-year survival at 75% (as would be realistic for a diagnosis such as metastatic colon cancer). Given the imprecise nature of prognostication, the views of the patient and oncologist in this example are arguably similar, and perhaps should not be categorized as discordant.

As noted, patients already enrolled in hospice were excluded from the study, thus omitting a key group of patients whose prognostic views are more likely to be concordant with their physicians’ views. This group may be better captured in a prospective study of prognostic discordance among newly diagnosed advanced cancer patients after initial oncology consultation, allowing for inclusion of those who make an early transition to hospice.

**Applications for Clinical Practice**

Although clinicians tend to overestimate prognosis, their predictions correlate with outcomes in advanced cancer [6], and may therefore provide a useful framework for patients to understand the likely course of their disease. However, physicians often avoid explicit discussion of prognosis by shrouding prognostic information in discussions of radiographic findings, and quickly transitioning to discussion of treatment options [7]. Patients and families rarely inquire about prognosis, further limiting disclosure of prognostic information [7,8]. Even when prognostic information is explicitly stated, patients may misinterpret the information [4], potentially adversely affecting their ability to participate in shared decision making.

Some useful approaches for successfully communicating prognostic information may include asking patients what information they wish to hear before it is disclosed, providing prognostic data for patients with similar disease states while acknowledging individual variability, clearly defining the intent of proposed therapy (ie, curative versus noncurative), and asking the patient to restate information in order to assess understanding. Early involvement of palliative care specialists may help reinforce understanding about prognosis and goals of therapy, facilitate advance care planning, and reduce aggressive interventions at the end of life [2]. Ongoing research is directed at identifying effective interventions to improve communication between patients with advanced cancer and their oncologists [9].

—Irene M. Hutchins, MD, Scripps Cancer Center, La Jolla, CA

**References**