Disparities in Care Among Patients With Cardiac Implantable Electronic Devices Undergoing MRI

Joseph J. Cavallo, MD[a], *Yapei Zhang*[b], *Lawrence H. Staib, PhD*[c], *Rachel Lampert, MD*[d], *Jeffrey C. Weinreb, MD*[a]

Abstract

Importance: Abundant data now demonstrate safe use of MRI for patients with non-MR conditional cardiac implantable electronic devices (CIEDs). However, CMS does not currently reimburse these examinations.

Objective: Determine whether differences in reimbursement between commercial insurance carriers and CMS are impacting the completion rates of MRI examinations ordered in patients with non-MR conditional CIEDs.

Methods: This study retrospectively examined patients with non-MR conditional CIEDs for whom an MRI was ordered between January 1, 2015, and August 31, 2016. Completion rates of MRI in patients with Medicare or Medicaid insurance were compared with those in patients with commercial insurance. Before November 7, 2015, all patients with non-MR conditional CIEDs underwent MRI examinations at no charge to the patient regardless of insurance. After that date, outpatients with only Medicare or Medicaid insurance coverage received an Advanced Beneficiary Notice that informed them that they would have to pay out of pocket for the entire cost of their MRI examinations.

Results: Of 143 MRI examinations ordered, 127 met inclusion criteria for analysis. In the post-Advanced Beneficiary Notice period, outpatients with commercial insurance were significantly more likely to complete their MRI examinations (19 of 22 patients, 86%) when compared with patients with Medicare or Medicaid insurance (1 of 36 patients, 3%; $P < .0001$). No significant difference was observed in the inpatient setting.

Conclusions: Due to CMS coverage policies based on now outdated concepts about MRI safety, patients with non-MR conditional CIEDs and Medicare or Medicaid insurance are undergoing significantly fewer appropriate diagnostic MRI examinations than patients with commercial insurance.

Key Words: CIED, MRI, insurance, SAFETY

J Am Coll Radiol 2017;14:1566-1571.

INTRODUCTION

MRI is a widely used and irreplaceable diagnostic tool for a wide range of clinical conditions. There are more than 12,500 MRI scanners in the United States [1], and in 2016 an estimated 39 million MRI procedures were performed [2]. The use of cardiac implantable electronic devices (CIEDs), including both pacemakers (PMs) and implantable cardioverter defibrillators (ICDs), has also become commonplace and continues to rise. Over 3 million patients in the United States have CIEDs, and approximately 400,000 are implanted each year [3]. Many of these patients are elderly, and it is estimated that 50% to 75% will develop a medical condition requiring an MRI examination after cardiac device implantation [4]. However, due to concerns

[a]Department of Diagnostic Radiology and Biomedical Imaging, Yale School of Medicine, New Haven, Connecticut.

[b]Yale School of Medicine, New Haven, Connecticut.

[c]Department of Biomedical Engineering, Radiology and Biomedical Imaging & Electrical Engineering, Yale University, New Haven, Connecticut.

[d]Department of Internal Medicine (Cardiology/Electrophysiology), Yale School of Medicine, New Haven, Connecticut.

Corresponding author and reprints: Joseph J. Cavallo, MD, Department of Diagnostic Radiology and Biomedical Imaging, 333 Cedar St, TE 2-224, New Haven, CT 06520-8042; e-mail: Joseph.Cavallo@yale.edu.

The data on which this manuscript is based were presented at the 2016 Radiology Society of North America (RSNA) meeting in Chicago, Illinois. Dr Lampert reports grants and personal fees from Medtronic, Inc, as well as grants from St Jude Medical (Abbott) and Boston Scientific, all of which are outside the submitted work. Dr Weinreb reports personal fees from Bracco, Guerbet, and Bayer HealthCare, all of which are outside the submitted work. The authors have no conflicts of interest related to the material discussed in this article.

1546-1440/17/$36.00 ■ http://dx.doi.org/10.1016/j.jacr.2017.07.014

about the potential adverse effects of MRI on CIED function and detrimental consequences for the patient, including fatalities [5], MRI for patients with CIEDs has traditionally been considered nearly absolutely contraindicated.

Over the past decade, manufacturers have addressed the presumed incompatibility of MRI and CIEDs by developing CIEDs specifically designed with MRI safety in mind. Using terminology developed by ASTM International [6], the US FDA categorizes these CIEDs as "MR conditional"; they were first approved for the US market in 2011 (PMs) [7] and 2015 (ICDs) [8]. All other CIEDs are termed "non-MR conditional."

Although non-MR conditional CIEDs are not FDA approved for use with MRI, increasing evidence, including the multicenter MagnaSafe registry of 1,500 patients, has shown that non-MR conditional CIEDs can be safely and effectively used in an MRI environment when performed with the appropriate protocols [9-12]. There is a growing consensus that the low risk of performing MRI on patients with non-MR conditional CIEDs may be acceptable when weighed against the potential benefits as described in various professional society recommendation statements [13-15]. Furthermore, MRI in this patient population was shown to affect patient outcome or add diagnostic value in 88% of cases [16]. Provision of this service has thus become more common at an increasing number of institutions [17,18].

Programs for MRI on patients with devices require dedicated protocols. At our institution, this includes the following: (1) The ordering clinician and a subspecialty radiologist must agree that the indication is appropriate and that there is no acceptable alternative examination. (2) The cardiac electrophysiology service confirms inclusion and exclusion criteria consistent with the MagnaSafe protocol [12]. (3) Patients must sign a standard informed consent document, "MRI in the presence of a non-conditional PM/ICD." (4) On the day of the MRI examination, the patient's device is programmed to a nondemand mode, they are placed on continuous telemetry, and vitals are monitored. (5) At completion, the device is reprogrammed to original settings and interrogated to document-appropriate device function.

CMS has a long-standing policy, described in the National Coverage Determinations manual [19], that prohibits reimbursement for any medical device that is not FDA approved. Despite both MRI and CIEDs having documented patient benefit and independent FDA approval, the FDA had never approved their combined use, citing inadequate evidence for safety and efficacy. Based on this policy, a 2009 decision memo [20] by CMS declared that MRI would not be reimbursed when performed on patients with CIEDs. It should be noted that this original memo predates the manufacture and sale of MR conditional CIEDs.

Subsequent revisions to this decision were made in February [21] and July 2011 [22]. Currently, MRI examinations of patients with non-MR conditional CIEDs are only reimbursed by CMS when performed as part of an approved clinical study meeting Coverage with Evidence Development Criteria. Commercial insurance providers currently do reimburse MRI examinations performed on patients with non-MR conditional CIEDs as indicated. As a result, there has been a variable reimbursement landscape at our institution for MRI examinations on patients with CIEDs, as follows:

- Before May 24, 2012: Institutional policy prohibited MRI of any patient with a CIED.
- May 24, 2012, to January 8, 2015: Yale participated in the MagnaSafe Registry [23]. Examinations were reimbursed by CMS based on Coverage with Evidence Development criteria [21].
- January 9, 2015, to November 6, 2015: After closure of the MagnaSafe registry, our institution continued to perform MRI scans on patients with non-MR conditional CIEDs in an insurance-blind manner, absorbing the cost of each MRI without billing CMS or the patient.
- November 7, 2015, to present: A new payment policy was instituted that requires that outpatients with only Medicare or Medicaid insurance sign an Advanced Beneficiary Notice (ABN) and agree to pay out of pocket for the MRI examination. Patients are informed of the need for the ABN after the MRI is ordered and before it is scheduled.

The purpose of this study was to determine if there were disparities in completion rates of clinically indicated and ordered MRI examinations for patients with non-MR conditional CIEDS as a result of differences in insurance coverage.

METHODS

Utilization was compared retrospectively between those with Medicare or Medicaid insurance and those with commercial insurance after the institution of the ABN based on the current CMS National Coverage Determinations manual. Because all patients received MRIs without cost regardless of insurance before this change,