Utilization and Likelihood of Radiologic Diagnostic Imaging in Patients With Implantable Cardiac Defibrillators

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Purpose: To examine imaging utilization in a matched cohort of patients with and without implantable cardioverter defibrillators (ICD) and to project magnetic resonance imaging (MRI) utilization over a 10-year period.

Materials and Methods: The Truven Health MarketScan Commercial claims and Medicare Supplemental health insurance claims data were used to identify patients with continuous health plan enrollment in 2009–2012. Patients with ICDs were identified using ICD-9 and CPT codes, and matched to patients with the same demographic and comorbidity profile, but no record of device implantation. Diagnostic imaging utilization was compared across the matched cohorts, in total, by imaging categories, and in subpopulations of stroke, back pain, and joint pain. MRI use in the nonimplant group over the 4-year period was extrapolated out to 10 years for ICD-indicated patients.

Results: A cohort of 18,770 matched patients were identified; average age 65.5 ± 13.38 and 21.9% female. ICD patients had significantly less MRI imaging (0.23 ± 0.70 SD vs. 0.00 ± 0.08 SD, P < 0.0001) than nonimplant patients. Among patients with records of stroke/transient ischemic attack (TIA) (ICD 5%, nonimplant 4%) and accompanying diagnostic imaging, 44% of nonimplant patients underwent MRI vs. 1% of ICD patients (P < 0.0001). Forecast models estimated that 53% to 64% of ICD-eligible patients may require an MRI within 10 years.

Conclusion: MRI utilization is lower in ICD patients compared to nonimplant patients, yet the burden of incident stroke/TIA, back, and joint pain suggests an unmet need for MR-conditional devices.

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Over the past decade the use of magnetic resonance imaging (MRI) has witnessed a sharp increase as the modality of choice for diagnosing a spectrum of conditions. For joint pain and lower back pain, MRI is cited as an appropriate diagnostic method by the American College of Radiology. For stroke, an MRI method known as diffusion-weighted imaging (DWI), has emerged as a sensitive and specific technique. In these conditions and others, such as cardiomyopathy, MRI has emerged as a preferred imaging modality because it provides excellent spatial resolution without exposing patients to ionizing radiation, iodinated contrast agents, and risks of invasive procedures.

The use of MRI technology is expected to grow in tandem with the expanding number of cardiovascular patients, and the increasing number of cardiovascular indications for MRI. At the same time, there is a corresponding rise in the volume of patients receiving implantable cardioverter defibrillators (ICDs), with an estimated 2.9 million implanted between 1993–2009 in the U.S. In 2013, the National ICD Registry published a report on the latest entries into its database, including the number of ICDs implanted in the U.S. for quarters 2–4 in 2010 and all of 2011. According to the report, there were ~263,000 ICD procedures over the time period, translating to 12,500 per month.
The importance of MRI in the growing population of ICD recipients is underscored by the ongoing concerns regarding its safety. MRI scanners utilize static and gradient magnetic fields and radiofrequency energy that can disable or reset ICD electronics, result in inappropriate therapies or inhibit needed therapy, exert force upon the generator, or heat ICD components. The U.S. Food and Drug Administration (FDA), in a statement updated in 2014, advises caution and summarizes possible hazards of ICD interaction with MRI. Also in 2014, the Canadian Heart Rhythm Society and Canadian Association of Radiologists published a Consensus Statement summarizing potential risks in scanning patients with non-MR conditional devices. The Statement notes that scanning of these patients is not endorsed by Health Canada, and should be avoided unless there is a compelling medical need.

Studies have shown that MRI examination can safely be performed on modern ICD recipients if safety protocols are followed. Yet, despite the growing evidence, the safety concerns continue, and the impact of ICD implantation on diagnostic imaging utilization has not been clearly defined.

The purpose of this study was to examine imaging utilization in a matched cohort of patients with and without ICDs and to project MRI utilization over a 10-year period.

Materials and Methods
The methodology compares utilization of imaging in the ICD and nonimplant cohorts to illustrate the gap in volume of imaging linked to restrictions in its use in patients with ICDs. The study also compares utilization in subsets of the cohorts, including stroke, back pain, and joint pain. Four calendar years of MRI utilization in the nonimplant cohort was utilized to forecast the potential utilization for MRI over a 10-year time horizon.

Data Source
This study used data from the Truven Health MarketScan Commercial Claims and Medicare Supplemental Research Databases, which contain Health Insurance Portability and Accountability Act (HIPAA)-compliant, individual-level, deidentified, healthcare claims information from employers, health plans, hospitals, Medicare, and Medicaid programs. Research using MarketScan data has been widely published in peer-reviewed journals, including the field of imaging. A protocol describing the study objectives, criteria for patient selection, data elements of interest, and statistical methods was submitted to the New England Institutional Review Board (NEIRB) and deemed exempt from review (NEIRB #13–343).

Patient Selection and Identification
Patient-level data were extracted from the Truven Health MarketScan Research Databases for the years 2009–2012. Two cohorts were defined: 1) patients having a record of an ICD implant: “ICD implant cohort”; 2) patients without a record of a cardiac device or other implantable device that is contraindicated for MRI: “nonimplant cohort.” The following inclusion/exclusion criteria were then applied to each cohort:

1. ICD Implant Cohort: Patients with continuous health plan enrollment in the calendar year 2012 who had a record of an ICD implant for that entire calendar year were identified (Appendix A, implant codes). (Note: patients had to have a record of an implant prior to the start of the calendar year 2012 and could not have a record of an explant [Appendix B] anytime during that year).
2. Nonimplant Cohort: Patients with continuous health plan enrollment in 2009–2012 without a record of any cardiac or contraindicated MRI implant or related monitoring codes (Appendix A–C) during the entire 4-year time period were identified.

Variables of Interest
The main outcome measure analyzed was yearly (2012) diagnostic imaging utilization which was organized into the following six categories: 1) computed tomography (CT) and computed tomography angiography (CTA); 2) MRI and magnetic resonance angiogram (MRA); 3) ultrasound, echo, Doppler, and duplex; 4) X-ray and fluoroscopy; 5) nuclear; and 6) other. Diagnostic imaging utilization was then measured two different ways: i) by the number of procedures overall and across each category, and ii) by the number of actual patients having a procedure within each category.

The main independent variable for this analysis was whether a patient was in the ICD cohort or the nonimplant cohort. Explanatory variables included patient demographics (age, gender, and type of plan) and patient comorbidities (diabetes, hypertension, chronic pulmonary obstruction disease [COPD], etc.). See Appendix D for a complete listing of all comorbidities and their corresponding diagnostic codes.

Three additional variables were created to further subdivide the population. This included patients with a diagnosis code on record for the year 2012 for the following diseases: acute stroke, back pain, and joint pain. For the calendar year 2012, patients with ICD-9 diagnosis codes for stroke or transient ischemic attack (TIA) had their diagnostic imaging utilization summarized within ±3 days of the stroke/TIA event. Patients with ICD-9 diagnosis codes for back pain or joint pain had their diagnostic imaging utilization summarized within 3 days before and 30 days after their first diagnosis on record.

Statistical Analysis
All data were imported and maintained in SAS data files. Tabulation of summary statistics, graphical presentations, and data analyses were performed using SAS v. 9.2. (SAS Institute, Cary, NC).

Once all variables were created, patients in the ICD implant cohort were matched 1:1 using a combination of direct (age, gender, type of plan) and propensity score matching (comorbidity conditions) to patients in the nonimplant cohort. A full list of comorbid conditions used for the propensity score are listed in Appendix D. Propensity score matching, or conditional probability of assignment to a particular treatment given a set of observed characteristics, has been shown to balance the number of confounders among matched cohorts. The propensity score was calculated from a logistic regression model as the probability that a patient was assigned...
to a particular treatment given the patient’s comorbid conditions. From this model, individual propensity scores were calculated for each patient as a measure of the likelihood that the patient would have been in the ICD cohort versus the nonimplant cohort. An SAS macro from the Mayo Clinic (gmatch) was used to create a greedy match based on the propensity score.23,24 This method utilizes random selection of treatment subjects and chooses the nearest matching nonimplant subject. Once matched, the pairs will not be broken, even for a more optimal match.

**Propensity Score Logit Model:**

\[ p_i = \frac{e^{\left(\beta_0 + \beta_1 X_{1i} + \cdots + \beta_p X_{pi}\right)}}{1 + e^{\left(\beta_0 + \beta_1 X_{1i} + \cdots + \beta_p X_{pi}\right)}} \]

Where \( p_i \) is the likelihood of ICD implant for the \( i \)-th patient (\( i = 1, \ldots, n \)) and \( X_{1i}, \ldots, X_{pi} \) are covariate characteristics for the \( i \)-th patient.

Diagnostic imaging utilization was compared across the matched cohorts, in total, by imaging category (MRI, CT scan, X-ray, etc.), and for MRI by body area for the calendar year 2012. The same comparison was carried out for the following three subpopulations of interest: acute stroke/TIA, back pain, and joint pain.

**Predicting the Probability of MRI Utilization: 10-Year Time Horizon**

In an effort to further understand MRI utilization, the non-implant matched cohort was used to measure the percent of patients with ICDs who needed an MRI over the 4-year period (2009-2012). This survival data were then fitted with exponential functions to forecast a range of best fit scenarios, as measured by the coefficient of determination, out to 10 years.

**Results**

A total of 97,150,333 patients from the Truven Health MarketScan Research Databases were identified as meeting the initial inclusion criteria. For the 1) ICD Implant Cohort, a total of 12,615 patients had continuous health plan enrollment in the calendar year 2012 and a record of an ICD implant for that entire calendar year. For the 2) Nonimplant Cohort, a total of 13,112,933 patients had continuous health plan enrollment in 2009–2012 without a record of any cardiac or contraindicated MRI implant or related monitoring codes during the entire 4-year time period. After 1:1 matching, the final sample was a total of 18,770 with 9,385 patients in each cohort. See Fig. 1 for the complete attrition diagram.

Patient demographics and comorbid conditions in the matched cohorts are shown in Tables 1 and 2. Since direct matching was used for age, gender, and type of plan, distributions were virtually equal across cohorts. Over 70% in each cohort were 60 years of age or older and ~78% male. Medicare and commercial insurance were distributed fairly equally, with ~53% being Medicare and 47% commercial. The highest concentration of patients by region occurred in the north central (30%) and south (34%). All standardized differences for demographics and comorbid conditions were <0.01, except for region.

After matching, ICD patients had significantly less imaging per patient compared to the nonimplant cohort (4.3 6.10 SD vs. 5.6 7.87 SD, \( P < 0.0001 \)). ICD patients had significantly less MRI (0.23 0.70 SD vs. 0.00 0.08 SD, \( P < 0.0001 \)) than the nonimplant cohort.
| TABLE 1. Patient Demographics After Matching |
|---------------------------------------------|
|                                             |
| **Total**                                   | **ICD** | **Nonimplant** | **Standardized difference** |
| **N** | **%** | **N** | **%** | **N** | **%** |                                  |
|-------|-------|-------|-------|-------|-------|----------------------------------|
| Total |       |       |       |       |       | 18,770 | 100.0 | 9,385 | 100.0 | 9,385 | 100.0 |
| Age in January 2012                         |        |       |       |       |       |        |       |       |       |        |        |
| <18   | 128   | 0.7   | 65    | 0.7   | 63    | 0.7   |       |       |       | 0.0066 |        |
| 18–29 | 188   | 1.0   | 94    | 1.0   | 94    | 1.0   |       |       |       |        |        |
| 30–39 | 323   | 1.7   | 165   | 1.8   | 158   | 1.7   |       |       |       |        |        |
| 40–49 | 1,247 | 6.6   | 636   | 6.8   | 611   | 6.5   |       |       |       |        |        |
| 50–59 | 3,667 | 19.5  | 1,866 | 19.9  | 1,801 | 19.2  |       |       |       |        |        |
| 60–69 | 5,512 | 29.4  | 2,750 | 29.3  | 2,762 | 29.4  |       |       |       |        |        |
| 70–79 | 4,787 | 25.5  | 2,362 | 25.2  | 2,425 | 25.8  |       |       |       |        |        |
| 80+   | 2,918 | 15.6  | 1,447 | 15.4  | 1,471 | 15.7  |       |       |       |        |        |
| Gender |       |       |       |       |       |        |       |       |       |        |        |
| Male  | 14,654 | 78.1  | 7,327 | 78.1  | 7,327 | 78.1  |       |       |       | 0.0000  |        |
| Female | 4,116 | 21.9  | 2,058 | 21.9  | 2,058 | 21.9  |       |       |       |        |        |
| Commercial or Medicare in January 2012      |        |       |       |       |       |        |       |       |       |        |        |
| Commercial | 8,797 | 46.9  | 4,365 | 46.5  | 4,432 | 47.2  |       |       |       | 0.0143  |        |
| Medicare | 9,973 | 53.1  | 5,020 | 53.5  | 4,953 | 52.8  |       |       |       |        |        |
| Insurance plan in January 2012              |        |       |       |       |       |        |       |       |       |        |        |
| Missing/unknown | 538 | 2.9  | 381 | 4.1 | 157 | 1.7 |       |       |       | 0.0836 |        |
| Comprehensive | 5,574 | 29.7  | 2,787 | 29.7 | 2,787 | 29.7 |       |       |       |        |        |
| EPO  | 196   | 1.0   | 108   | 1.2   | 88    | 0.9   |       |       |       |        |        |
| HMO   | 2,185 | 11.6  | 966   | 10.3  | 1,219 | 13.0  |       |       |       |        |        |
| POS   | 1,084 | 5.8   | 522   | 5.6   | 562   | 6.0   |       |       |       |        |        |
| PPO   | 8,568 | 45.7  | 4,301 | 45.8  | 4,267 | 45.5  |       |       |       |        |        |
| POS with Capitation | 24 | 0.1 | 12 | 0.1 | 12 | 0.1 |       |       |       |        |        |
| CDHP  | 437   | 2.3   | 218   | 2.3   | 219   | 2.3   |       |       |       |        |        |
| HDHP  | 164   | 0.9   | 90    | 1.0   | 74    | 0.8   |       |       |       |        |        |
| Region in January 2012                      |        |       |       |       |       |        |       |       |       |        |        |
| Northeast region | 3,271 | 17.4  | 1,636 | 17.4 | 1,635 | 17.4 |       |       |       | 0.1849 |        |
| North central region | 5,647 | 30.1  | 2,883 | 30.7 | 2,764 | 29.5 |       |       |       |        |        |
| South region | 6,507 | 34.7  | 3,330 | 35.5 | 3,177 | 33.9 |       |       |       |        |        |
| West region | 3,176 | 16.9  | 1,386 | 14.8 | 1,790 | 19.1 |       |       |       |        |        |
| Unknown region | 169 | 0.9  | 90 | 1.6 | 19 | 0.2 |       |       |       |        |        |

CDHP: Consumer Driven Health Plans; EPO: Exclusive Provider Organization; HDHP: High Deductible Health Plan; HMO: Health Maintenance Organization; ICD: implantable cardioverter defibrillator; POS: Point Of Service; PPO: Preferred Provider Organization.
| Condition                          | Total         | ICD          | Nonimplant   | Standardized difference |
|-----------------------------------|---------------|--------------|--------------|--------------------------|
| All patients                      | 18,770 100.0 | 9,385 100.0  | 9,385 100.0  |                          |
| Rheumatoid arthritis              | 262 1.4      | 136 1.5      | 126 1.3      | 0.0091                   |
| Psoriatic arthritis               | 41 0.2       | 22 0.2       | 19 0.2       | 0.0068                   |
| Ankylosing spondylitis            | 15 0.1       | 5 0.1        | 10 0.1       | 0.0189                   |
| Skin cancer                       | 964 5.1      | 529 5.6      | 435 4.6      | 0.0454                   |
| Colon cancer                      | 105 0.6      | 63 0.7       | 42 0.5       | 0.0300                   |
| Lung, bronchus, or trachea        | 150 0.8      | 82 0.9       | 68 0.7       | 0.0168                   |
| GERD                              | 1,623 8.7    | 814 8.7      | 809 8.6      | 0.0019                   |
| Gastritis                         | 618 3.3      | 312 3.3      | 306 3.3      | 0.0036                   |
| Gastric ulcer                     | 81 0.4       | 51 0.5       | 30 0.3       | 0.0341                   |
| Crohn's disease                   | 79 0.4       | 37 0.4       | 42 0.5       | 0.0082                   |
| Ulcerative colitis                | 68 0.4       | 37 0.4       | 31 0.3       | 0.0106                   |
| Diverticulitis                    | 158 0.8      | 79 0.8       | 79 0.8       | 0.0000                   |
| Kidney stones                     | 451 2.4      | 240 2.6      | 211 2.3      | 0.0202                   |
| Cystitis                          | 229 1.2      | 126 1.3      | 103 1.1      | 0.0223                   |
| Depressive disorders              | 1,581 8.4    | 750 8.0      | 831 8.9      | 0.0311                   |
| Neurotic disorders                | 1,124 6.0    | 500 5.3      | 624 6.7      | 0.0557                   |
| Heart failure                     | 7,986 42.6   | 4,109 43.8   | 3,877 41.3   | 0.0500                   |
| MI (any)                          | 2,570 13.7   | 1,347 14.4   | 1,223 13.0   | 0.0384                   |
| Angina                            | 1,286 6.9    | 654 7.0      | 632 6.7      | 0.0093                   |
| Other coronary artery Disease     | 11,545 61.5  | 5,794 61.7   | 5,751 61.3   | 0.0094                   |
| Stroke                            | 547 2.9      | 309 3.3      | 238 2.5      | 0.0450                   |
| TIA                               | 430 2.3      | 226 2.4      | 204 2.2      | 0.0157                   |
| Cardiac dysrhythmias              | 11,687 62.3  | 5,793 61.7   | 5,894 62.8   | 0.0222                   |
| Sleep apnea                       | 2,417 12.9   | 1,152 12.3   | 1,265 13.5   | 0.0360                   |
| Hypertension                      | 12,373 65.9  | 6,208 66.2   | 6,165 65.7   | 0.0097                   |
| Irritable bowel disease           | 152 0.8      | 58 0.6       | 94 1.0       | 0.0428                   |
| Lumbar disk disease               | 969 5.2      | 465 5.0      | 504 5.4      | 0.0188                   |
| Osteoporosis                      | 371 2.0      | 192 2.1      | 179 1.9      | 0.0100                   |
| Osteoarthritis                    | 3,206 17.1   | 1,639 17.5   | 1,567 16.7   | 0.0204                   |
| Parkinson's disease               | 137 0.7      | 79 0.8       | 58 0.6       | 0.0263                   |
| Multiple sclerosis                | 51 0.3       | 19 0.2       | 32 0.3       | 0.0266                   |
| Migraine                          | 181 1.0      | 69 0.7       | 112 1.2      | 0.0469                   |
| Obstructive chronic bronchitis    | 784 4.2      | 457 4.9      | 327 3.5      | 0.0693                   |
| Emphysema                         | 355 1.9      | 199 2.1      | 156 1.7      | 0.0336                   |
| Chronic obstructive asthma        | 201 1.1      | 114 1.2      | 87 0.9       | 0.0280                   |
| Bronchiectasis                    | 64 0.3       | 42 0.5       | 22 0.2       | 0.0366                   |
When evaluating the breakdown of procedures by imaging modality, there was a lower utilization of all imaging among ICD patients, with the most marked differences in MRI/MRA (2,121 nonimplant vs. 37 ICD), X-ray and fluoroscopy (25,956 nonimplant vs. 19,577 ICD), and ultrasound (16,543 nonimplant vs. 13,692 ICD) (Fig. 2A). These differences were similar in the patient-level analysis (Fig. 2B). Among those patients of each 9,385 cohort, who had an MRI, the most frequently occurring MRI was of the brain (29% nonimplant vs. 30% ICD). Table 3 shows the number and percent of MRIs for each cohort by body area.

| Extrinsic allergic alveolitis | 6 | 0.0 | 4 | 0.0 | 2 | 0.0 | 0.0119 |
|-------------------------------|---|-----|---|-----|---|-----|--------|
| Chronic airway obstruction NEC | 2,268 | 12.1 | 1,262 | 13.5 | 1,006 | 10.7 | 0.0838 |
| Eczema (dermatitis) | 580 | 3.1 | 291 | 3.1 | 289 | 3.1 | 0.0012 |
| Sebaceous gland diseases | 546 | 2.9 | 284 | 3.0 | 262 | 2.8 | 0.0139 |
| Diabetes | 6,410 | 34.2 | 3,245 | 34.6 | 3,165 | 33.7 | 0.0180 |
| Hyperlipidemia | 10,667 | 56.8 | 5,276 | 56.2 | 5,391 | 57.4 | 0.0247 |
| Hypothyroidism | 2,079 | 11.1 | 991 | 10.6 | 1,088 | 11.6 | 0.0329 |
| Anticoagulants usage | 4,170 | 22.2 | 2,126 | 22.7 | 2,044 | 21.8 | 0.0210 |
| Atrial fibrillation | 5,996 | 31.9 | 2,760 | 29.4 | 3,236 | 34.5 | −0.1089 |
| Hypertrophic cardiomyopathy | 382 | 2.0 | 357 | 3.8 | 25 | 0.3 | 0.2525 |
| Sarcoidosis | 87 | 0.5 | 72 | 0.8 | 15 | 0.2 | 0.0895 |

**TABLE 3. MRI/MRA Scans by Body Area**

| Location | Total | ICD | Nonimplant | Standardized difference |
|----------|-------|-----|------------|-------------------------|
| Abdomen | 2 | 5% | 112 | 5% | 0.2525 |
| Brain | 11 | 30% | 607 | 29% | 0.1089 |
| Cardiac, breast, & chest | 1 | 3% | 91 | 4% | 0.2525 |
| Head | 0 | 0% | 132 | 6% | 0.2525 |
| Lower extremities | 6 | 16% | 274 | 13% | 0.2525 |
| Neck | 0 | 0% | 87 | 4% | 0.2525 |
| Other | 0 | 0% | 37 | 2% | 0.2525 |
| Pelvis | 0 | 0% | 58 | 3% | 0.2525 |
| Spine - chest | 2 | 5% | 77 | 4% | 0.2525 |
| Spine - lumbar | 9 | 24% | 326 | 15% | 0.2525 |
| Spine - neck | 2 | 5% | 187 | 9% | 0.2525 |
| Upper extremities | 4 | 11% | 135 | 6% | 0.2525 |

*Includes two instances of the same subcategory of MRI on the same day, causing that MRI to only be counted once previously.

MRA: magnetic resonance angiogram; MRI: magnetic resonance imaging.
Table 4 depicts the overall differences in imaging utilization between ICD and nonimplant patients across the three subpopulations: stroke/TIA, back pain, and joint pain. Among patients with records of stroke/TIA (ICD 5%, nonimplant 4%) and accompanying diagnostic imaging, 44% of nonimplant patients underwent MRI vs. 1% of ICD patients (P < 0.0001) (Fig. 3A) and nonimplant patients had more imaging tests overall (4.1 ± 2.47 SD vs. 3.2 ± 2.16 SD, P < 0.0001). Among patients with records of back pain and accompanying diagnostic imaging, 22% of nonimplant patients underwent MRI vs. 0.7% of ICD patients (P < 0.0001) (Fig. 3B), and nonimplant patients had more imaging tests overall (2.5 ± 2.80 SD vs. 2.0 ± 2.04 SD, P = 0.0003). By comparison, patients with records of back pain and ICDs underwent a statistically significantly larger volume of CT and CTA (32%) as compared to the nonimplant cohort (21%) (P = 0.0011).

Among patients with records of joint pain and accompanying diagnostic imaging, 17% of nonimplant patients underwent MRI vs. 0.1% of ICD patients (P < 0.0001) (Fig. 3C), and nonimplant patients had more imaging tests overall (2.5 ± 2.77 SD vs. 2.1 ± 1.89 SD, P < 0.0001). Similar to the back pain subgroup, patients with joint pain records and ICDs underwent CT and CTA more often (19%) than patients with joint pain in the nonimplant cohort (16%). The difference, however, was not statistically significant.

The proportion of nonimplant patients who received an MRI or MRA at 1, 2, 3, and 4 years and projected to 10 years are shown in Fig. 4. These ICD-indicated patients had a projected MRI or MRA utilization of between 53% and 64% within 10 years.

| Subpopulation | Category          | ICD  | Nonimplant | P-value |
|---------------|-------------------|------|------------|---------|
| Stroke/TIA    | Total patients (% of total) | 442 (5%) | 379 (4%) |         |
|               | Total with imaging | 304  | 285        |         |
|               | CT & CTA          | 228  | 204        | 0.8916  |
|               | MRI & MRA         | 3    | 125        | <.0001  |
|               | Nuclear           | 11   | 5          | 0.2274  |
|               | Other             | 0    | 1          | 0.2804  |
|               | Ultrasound/Echo/Doppler/Duplex | 209  | 206        | 0.0165  |
|               | X-Ray & Fluoroscopy | 184  | 194        | 0.0003  |
| Back pain     | Total patients (% of total) | 1,552 (17%) | 1,681 (18%) |       |
|               | Total with imaging | 869  | 930        |         |
|               | CT & CTA          | 274  | 198        | 0.0011  |
|               | MRI & MRA         | 6    | 203        | <.0001  |
|               | Nuclear           | 49   | 72         | 0.0850  |
|               | Other             | 0    | 1          | 0.3175  |
|               | Ultrasound/echo/Doppler/duplex | 235  | 270        | 0.0626  |
|               | X-ray & fluoroscopy | 694  | 744        | 0.0501  |
| Joint pain    | Total patients (% of total) | 2,073 (22%) | 2,355 (25%) |       |
|               | Total with imaging | 1,456 | 1,668      |         |
|               | CT & CTA          | 273  | 270        | 0.1649  |
|               | MRI & MRA         | 2    | 315        | <.0001  |
|               | Nuclear           | 102  | 117        | 0.8886  |
|               | Other             | 1    | 2          | 0.6339  |
|               | Ultrasound/echo/Doppler/duplex | 403  | 500        | 0.0193  |
|               | X-ray & fluoroscopy | 1,280 | 1,472      | 0.0009  |

CT: computed tomography; CTA: computed tomography angiography; MRI: magnetic resonance imaging; MRA: magnetic resonance angiogram.
Discussion

These findings of minimal utilization of MRIs among ICD patients suggest continued reluctance to perform MRIs in those patients and an unmet need for MRIs, yet this practice conflicts with the current trend toward greater use of complex imaging. The volume of patients with ICDs is growing, and for much of the last decade Medicare Part B spending on complex scanning methods, including MRI, rose an average 17% per year. This indicates a spending pattern that is nearly twice that of spending on ultrasound, radiography, and other standard imaging procedures. MRI volume flattened somewhat mid-decade, following implementation of the Deficit Reduction Act in 2007, but the overall trajectory is upward. According to a recent report from the Medicare Payment Advisory Committee, the number of brain MRIs per 1000 Medicare beneficiaries rose to 75 in 2012, up from 44 in 2000. Likewise, the number of "other" MRIs jumped to 129 per 1000 in 2012, versus 58 in 2000.

Further evidence of the growing role of MRIs comes from Appropriateness Criteria from the American College of Radiology, which are evidenced-based guidelines designed to help imaging decision-making. The Appropriateness Criteria consistently rank MRI as an appropriate diagnostic tool for a wide range of musculoskeletal, neurologic, cardiac, and other conditions. In the case of low back pain, for example, MRI is highly rated as a preferred modality, ranking an "8" out of a possible "9" for patients with a suspicion of cancer, infection, or immunosuppression, or in patients with low-velocity trauma, osteoporosis, focal and/or progressive deficit, prolonged symptom duration, or greater than 70 years of age. By comparison, for this same indication, use of a CT scan is rated "6," which suggests this approach "may be appropriate." Similarly, for pain in the hip joint, an MRI without contrast is rated a "9" for patients who are radiograph negative, equivocal, or nondiagnostic, and have suspected osseous or surrounding soft-tissue abnormality, excluding osteoid osteoma. A CT scan for this indication is rated "2," which translates as "usually not appropriate."

Given the evidenced-based importance of MRI as a valued diagnostic tool, its minimal use in ICD patients is a concern. Our study revealed this same pattern of sharply different MRI/MRA utilization among the three matched subpopulations of interest: acute stroke/TIA, back pain, and joint pain.

At the time of this analysis, MR-conditional ICDs were not available in the U.S., but our finding of an unmet need for imaging in patients with ICDs is similar to results from a European study where conditional ICDs have been available for a few years. A study of 51 European Heart Rhythm Association centers by Marinskis et al focused on MRIs in patients with ICDs, and 65.8% reported never performing MRI on non-MR-conditional ICD recipients.

Our results indicate that despite the growing literature regarding the safety of MRI in the setting of implanted legacy ICDs, widespread adaptation of safety protocols has not occurred. In the course of evaluating a protocol for safely imaging ICD patients, a prospective study conducted 555 MRIs in 438 patients. They found devices of three patients reverted to back-up programming mode and decreases in right ventricular (RV) sensing, as well as atrial, right and left ventricular lead impedances. Interrogations at 6 months showed decreased RV sensing, decreased RV lead

FIGURE 3: A: Percentage of patients with stroke/TIA event by radiology type. B: Percentage of patients with back pain by radiology type. C: Percentage of patients with joint pain by radiology type. ICD: implantable cardioverter defibrillator; CT: computed tomography; CTA: computed tomography angiography; MRI: magnetic resonance imaging; MRA: magnetic resonance angiogram.
impedance, increased RV capture threshold, and decreased battery voltage. It is important to note that none of the reported changes required device revision or reprogramming. The MagnaSafe Registry reported on 500 patients with an ICD who have had a nonthoracic MRI. They report that no deaths, generator or lead failures, loss of capture, or ventricular arrhythmias occurred and found that one or more clinically relevant device parameter changes occurred in 29% of ICD patients. The generator of one ICD was later replaced due to inappropriate activation of tachytherapy during the MRI. The hesitation to adopt such safety protocols is partially attributable to the current lack of an FDA-approved MR-conditional ICD and Medicare coverage restrictions regarding MRI scans in patients with ICDs. It is possible that with additional safety data the U.S. FDA and CMS will review and revise their MRI coverage policy; however, substantial safety data will understandably be needed.

An important outcome of our study is that more than half, 53%–64%, of ICD-indicated patients are projected to require MRI within a decade, a result that is consistent with previous research. Kalin and Stanton reported that the combination of greater MRI use and more patients with ICDs coupled with expanded Medicare coverage leads to a projected range from 50% to 75% of ICD patients needing an MRI over the lifetime of the device.

This study adds to the literature, as it had sizeable cohorts to highlight the nominal use of MRIs in patients with ICDs, reflecting ongoing safety concerns. Moreover, this research indicates the need for MR-conditional protocols that will increase the likelihood that MRIs can be performed safely in individuals implanted with these devices. Currently, there is a growing body of research on careful use of MRIs in patients implanted with ICDs. Van der Graaf et al describe the status of MRI and implantable electronic devices, including ICDs, and report on four ongoing clinical trials studying MR-conditional pacing devices. The European Society of Cardiology (ESC) on cardiac pacing and cardiac resynchronization therapy (CRT) recently published guidelines that suggest that MRI can be safely performed in patients with ICDs if strict safety conditions are met. These guidelines represent a major shift in the previously accepted standard that patients with a pacemaker or ICD should not undergo MRI.

There are several important limitations to consider. First, although data sources were large and contemporary, variables were based on medical claims designed for billing purposes, and unidentified confounders may be present, which could affect the precision of the prediction model. Second, we are unable to ascertain indication for imaging, which could help generate precise estimates of likelihood of need or MRI based on comorbidities, or clarify conditions or indications in which non-MRI alternatives could be suitable. Third, findings may not be generalizable to other countries or non-fee for service healthcare systems, which may have lower rates of imaging utilization. Finally, patient outcomes related to receiving MRI versus not could not be determined from this claims analysis.

In conclusion, MRI utilization is lower in ICD patients compared to nonimplant patients, and disparities are seen in access to MRI among the three subgroups of interest. One in 25 ICD patients would have qualified for imaging for a recorded stroke/TIA, yet less than 1% received MRI for this indication. We project that ~53%–64% of ICD patients are likely to need an MRI over a 10-year time horizon, highlighting the importance of MR-conditional ICDs for this patient population.

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APPENDIX A: IMPLANT CODE COMBINATIONS

| CPT Code          | Explant Type |
|-------------------|--------------|
| # 00.50           | CRT-P        |
| # 00.50, 33208, 33225 | CRT-P      |
| # 00.50, 33225    | CRT-P        |
| # 00.50, 33207, 33225 | CRT-P      |
| # 37.72, 37.83, 33208, 33225 | CRT-P |
| # 00.50, 33208    | CRT-P        |
| # 33208, 33225    | CRT-P        |
| # 00.50, 33207, 33208, 33225 | CRT-P  |
| # 33207, 33225    | CRT-P        |
| # 37.72, 37.83, 33208 | CRT-P      |
| # 37.72, 37.83, 33208 | CRT-P      |
| # 37.72, 37.83, 33208 | CRT-P      |
| # 37.72, 37.80, 33208 | CRT-P      |
| # 33208           | Pacemaker    |
| # 37.72, 37.83, 33208 | Pacemaker  |
| # 37.72, 37.80, 33208 | Pacemaker  |
| # 37.80,37.83, 33208 | Pacemaker  |
| # 33208           | Pacemaker    |
| # 37.72, 33208    | Pacemaker    |
| # 37.72, 37.83, 33207, 33208 | Pacemaker |
| Code Combination  | Implant Type |
| # 37.70, 37.83, 33208 | Pacemaker  |
APPENDIX A: Continued

| CPT Code                  | Explant Type   |
|--------------------------|----------------|
| # 37.72, 37.80, 37.83    | Pacemaker      |
| # 37.72, 37.80, 37.83, 33208 | Pacemaker    |
| # 37.73, 37.80           | Pacemaker      |
| # 37.73, 37.82, 33206, 33207 | Pacemaker  |
| # 37.73, 37.82, 33208    | Pacemaker      |
| # 37.80, 33206           | Pacemaker      |
| # 37.80, 33207           | Pacemaker      |
| # 37.82, 37.83, 33208    | Pacemaker      |
| # 37.83, 33207           | Pacemaker      |
| # 37.70, 37.82           | Pacemaker      |
| # 33206                  | Pacemaker      |
| # 37.73, 37.81           | Pacemaker      |
| # 3781,33206             | Pacemaker      |
| # 37.73, 37.82           | Pacemaker      |
| # 37.73, 37.82, 33206    | Pacemaker      |
| # 37.73, 37.81, 33206    | Pacemaker      |
| # 37.71, 37.81           | Pacemaker      |
| # 37.71, 37.82           | Pacemaker      |

Code Combination | Implant Type
----------------|----------------|
# 37.71, 37.82, 33207 | Pacemaker  |
# 37.71, 37.81, 33207 | Pacemaker  |
# 33207             | Pacemaker   |
# 37.81, 37.82, 33207 | Pacemaker  |
# 37.71, 37.81, 33207, 33208 | Pacemaker  |
# 37.71, 37.80       | Pacemaker   |
# 37.70, 37.81, 33207 | Pacemaker  |
# 00.51             | CRT-D       |
# 00.51, 33225       | CRT-D       |
# 00.51, 33249       | CRT-D       |
# 00.51, 33249, 33225 | CRT-D   |
# 33249, 33225       | CRT-D       |
# 33249             | CRT-D       |
# 37.94             | CRT-D       |
# 37.94, 33249       | CRT-D       |
# 37.94, 37.95       | CRT-D       |
# 37.94, 37.95, 33249 | CRT-D  |
# 37.94, 37.95, 37.96, 33249 | CRT-D |

APPENDIX B: EXPLANT CODES

| Code Combination | Implant Type |
|------------------|--------------|
# 37.94, 37.96, 33249 | ICD         |
# 37.95, 33249      | ICD         |

APPENDIX C: INTERROGATION AND EVALUATION CODES

| CPT Code | Interrogation Code Description |
|----------|--------------------------------|
# 93279   | Pm Device Progr Eval Sngl      |
# 93280   | Pm Device Progr Eval Dual      |
# 93281   | Pm Device Progr Eval Multi     |
# 93282   | Icd Device Prog Eval 1 Sngl    |
# 93283   | Icd Device Progr Eval Dual     |
# 93284   | Icd Device Prog Eval Mult      |
# 93285   | Ilr Device Eval Progr          |
# 93288   | Pm Device Eval In Person       |
| CPT Code | Interrogation Code Description |
|----------|-------------------------------|
| # 93289 | Icd Device Interrogate        |
| # 93290 | Icm Device Eval               |
| # 93291 | Ilr Device Interrogate        |
| # 93293 | Pm Phone R-Strip Device Eval  |
| # 93294 | Pm Device Interrogate Remote  |
| # 93295 | Icd Device Interrogate Remote |
| # 93296 | Pm/Icd Remote Tech Serv       |
| # 93297 | Icm Device Interrogat Remote  |
| # 93298 | Ilr Device Interrogat Remote  |
| # 93299 | Icm/Ilr Remote Tech Serv      |

| Condition | ICD9 Code |
|-----------|-----------|
| Angina    | 411.1, 413.x |
| Ankylosing Spondylitis | 720.0 |
| Atrial Fibrillation | 427.31 |
| Back Pain | 724.xx, 847.xx |
| Bronchiectasis | 494.x |
| Cardiac Dysrhythmias | 427.xx |

APPENDIX D: COMORBID CONDITION CODES AND ANTICOAGULATION SPECIFICATION

| Condition | ICD9 Code |
|-----------|-----------|
| Chronic Airway Obstruction NEC | 496 |
| Chronic Obstructive Asthma | 493.2x |
| Colon Cancer | 153.x |
| Crohn's Disease | 555.xx |
| Cystitis | 595.xx |
| Depressive Disorders | 311, 300.4, 309.0, 309.1, 309.28, 298.0, 296.2x, 296.3x, 296.5x, 296.6x, 296.8x (except 296.81) |
| Diabetes | 249.xx, 250.xx |
| Diverticulitis | 562.11, 562.13 |
| Eczema (Dermatitis) | 692.9 |
| Emphysema | 492.x |
| Extrinsic Allergic Alveolitis | 495.x |
| Gastric Ulcer | 531.xx |
| Gastritis | 535.xx (except 535.6x) |
| GERD | 530.81 |
| Heart Failure | 398.91, 402.x1, 404.x1, 404.x3, 428.xx |
| Hyperlipidemia | 272.0, 272.1, 272.2, 272.4, 272.9 |
| Hypertension | 401.x, 402.xx, 404.xx, 405.xx |
| Hypothyroidism | 243, 244.x |
| Hypertrophic Cardiomyopathy | 425.11, 425.18 |
| Irritable Bowel Disease | 564.1 |
| Joint Pain | 716.xx, 718.xx, 719.xx |
| Kidney Stones | 592.x |
| Lumbar Disk Disease | 722.10, 722.73, 722.52, 722.93 |
| Lung, Bronchus, or Trachea | 162.x |
| MI (any) | 410.xx, 412, 411.0 |
| Migraine | 346.xx |
| Multiple Sclerosis | 340 |
| Neurotic Disorders | 300.xx (without 300.4) + 309.81 |
| Obstructive Chronic Bronchitis | 491.2x |
APPENDIX D: Continued

| Condition                  | ICD9 Code            |
|----------------------------|----------------------|
| Osteoarthritis             | 721.x, 715.xx        |
| Osteoporosis               | 733.0x               |
| Other Coronary Artery      | 411.81, 411.89, 414.0x, 414.2, 414.3, 414.4, 414.8, 414.9, 429.2, V45.81, V45.82 |
| Disease                    |                      |
| Parkinson's disease        | 332.x                |
| Psoriatic Arthritis        | 696.0                |
| Rheumatoid Arthritis       | 714.0                |
| Sarcoidosis                | 135                  |
| Sebaceous Gland Diseases   | 706.x                |
| Skin Cancer                | 176.0, 209.31–209.36, 172.x, 173.x |
| Sleep Apnea                | 327.2x, 780.51, 780.53, 780.57 |
| Stroke                     | 430, 431, 432.x, 433.x1, 434.x1, 997.02 |
| TIA                        | 435.x                |
| Ulcerative Colitis         | 556.xx               |
| Anticoagulation (included any of these) | Anisindione, Antithrombin III Human, Antithrombin, Recombinant, Apixaban, Ardeparin Sodium, Argatroban, Bivalirudin, Citric Acid/Dextrose/Na Cit/Na Phos, Citric Acid/Dextrose/Sodium Citrate, Dabigatran Etxetil Us, Dalteparin Sodium, Danaparoid Sodium, Desirudin, Dextrose/Heparin Sodium, Dicumarol, Enoxaparin Sodium, Fondaparinux Sodium, Heparin, Heparin Calcium, Heparin Sodium, Heparin/Dihydroergotamine, Lepirudin, Phenprocoumon, Rivaroxaban, Sodium Citrate, Tinzaparin Sodium, Warfarin Potassium, Warfarin Sodium |

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