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[1–3] as the modality of choice for diagnosing a spectrum of conditions.[4] For joint pain and lower back pain, MRI is cited as an appropriate diagnostic method by the American College of Radiology.[5] For stroke, an MRI method known as diffusion-weighted imaging (DWI), has emerged as a sensitive and specific technique.[6–8] In these conditions and others, such as cardiomyopathy,[9–12] 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.[13]

The use of MRI technology is expected to grow in tandem with the expanding number of cardiovascular patients,[13] and the increasing number of cardiovascular indications for MRI.[5,11] At the same time, there is a corresponding rise in the volume of patients receiving implantable cardioverter defibrillators (ICDs),[13,14] with an estimated 2.9 million implanted between 1993–2009 in the U.S..[15] 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.[16]

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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[11,12] that can disable or reset ICD electronics, result in inappropriate therapies or inhibit needed therapy, exert force upon the generator, or heat ICD components.[14] 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.[17] 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.[18]

Studies have shown that MRI examination can safely be performed on modern ICD recipients if safety protocols are followed.[19,20] 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.[21,22] 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 imagining 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 (comorbid 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

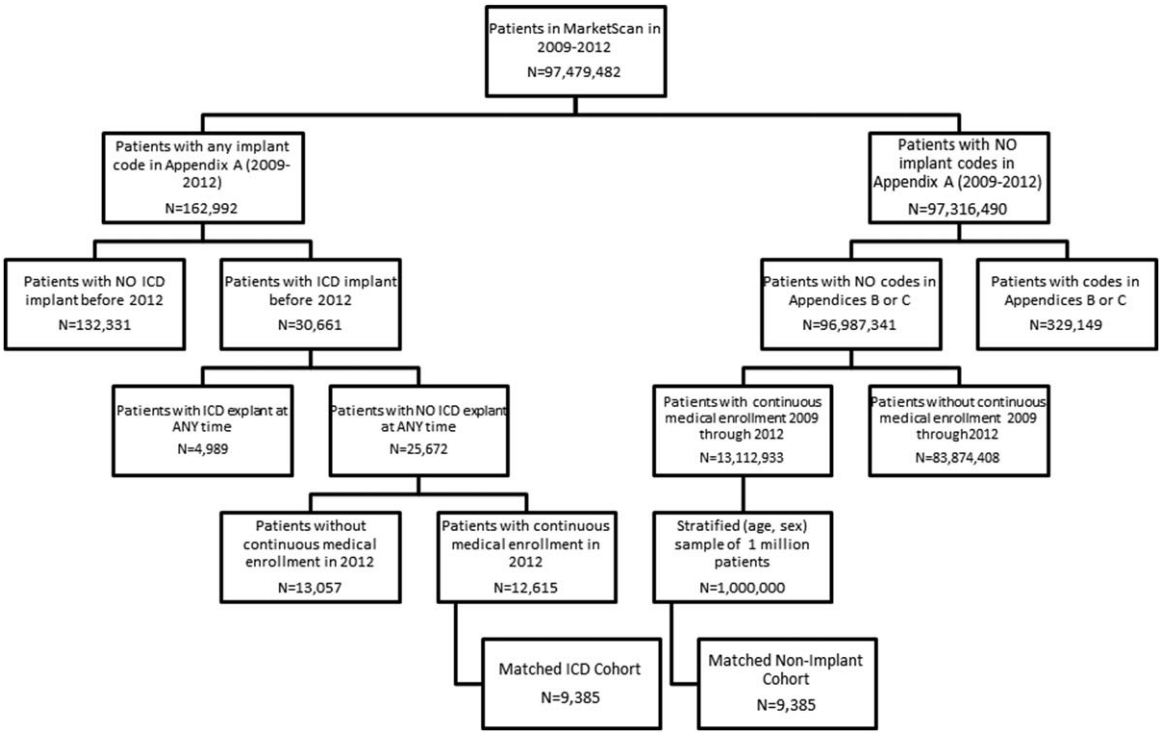

FIGURE 1: Patient attrition diagram. ICD: implantable cardioverter defibrillator.

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 $X_{1i}\ldots X_{ip}$ 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 nonimplant 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		Cohort				Standardized difference
			ICD		Nonimplant		
	N	%	*N*	%	*N*	%	
Total *N*	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	150	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.

TABLE 2. Comorbid Conditions After Matching

	Total		Cohort				Standardized difference
			ICD		Nonimplant		
	N	%	*N*	%	*N*	%	
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

TABLE 2: Continued

	Total		Cohort				Standardized difference
			ICD		Nonimplant		
	N	%	*N*	%	*N*	%	
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 cardiomypathy	382	2.0	357	3.8	25	0.3	0.2525
Sarcoidosis	87	0.5	72	0.8	15	0.2	0.0895

GERD: gastroesophageal reflux disease; MI: myocardial infarction; NEC: not elsewhere classified; TIA: transient ischemic attack.

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 9385 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.

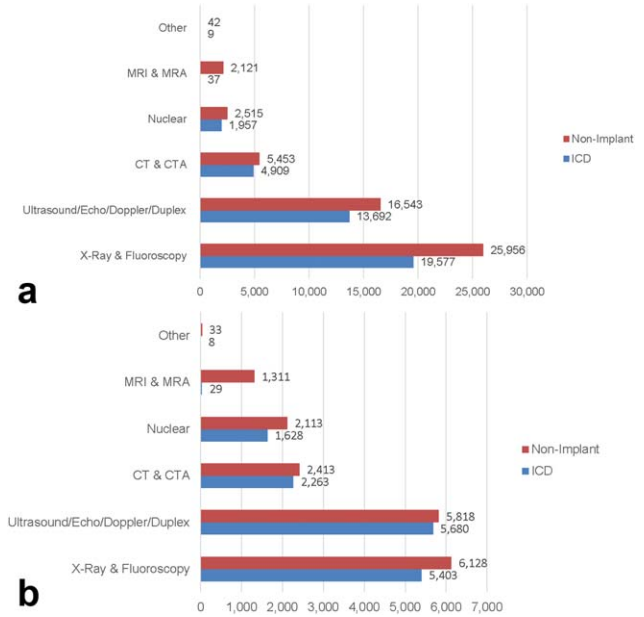

FIGURE 2: A: Total number of procedures for each cohort by radiology category. B: Number of patients for each cohort by radiology category. ICD: implantable cardioverter defibrillator; CT: computed tomography; CTA: computed tomography angiography; MRI: magnetic resonance imaging; MRA: magnetic resonance angiogram.

TABLE 3. MRI/MRA Scans by Body Area

Location	ICD		Nonimplant	
Total	**37**		**2123[a]**	
	N	%	N	%
Abdomen	2	5%	112	5%
Brain	11	30%	607	29%
Cardiac, breast, & chest	1	3%	91	4%
Head	0	0%	132	6%
Lower extremities	6	16%	274	13%
Neck	0	0%	87	4%
Other	0	0%	37	2%
Pelvis	0	0%	58	3%
Spine - chest	2	5%	77	4%
Spine - lumbar	9	24%	326	15%
Spine - neck	2	5%	187	9%
Upper extremities	4	11%	135	6%

[a]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. Subgroup Radiology

Subpopulation	Category	ICD		Nonimplant		
		Number of patients	Number of procedures	Number of patients	Number of procedures	*P*-value
Stroke/TIA	Total patients (% of total)	442 (5%)		379 (4%)		
	Total with imaging	304	962	285	1,160	
	CT & CTA	228	339	204	294	0.8916
	MRI & MRA	3	3	125	184	<.0001
	Nuclear	11	11	5	5	0.2274
	Other	0	0	1	1	0.2804
	Ultrasound/Echo/Doppler/Duplex	209	334	206	349	0.0165
	X-Ray & Fluoroscopy	184	275	194	327	0.0003
Back pain	Total patients (% of total)	1,552 (17%)		1,681 (18%)		
	Total with imaging	869	1,776	930	2,284	
	CT & CTA	274	349	198	262	0.0011
	MRI & MRA	6	6	203	235	<.0001
	Nuclear	49	51	72	76	0.0850
	Other	0	0	1	1	0.3175
	Ultrasound/echo/Doppler/duplex	235	324	270	422	0.0626
	X-ray & fluoroscopy	694	1,046	744	1,288	0.0501
Joint pain	Total patients (% of total)	2,073 (22%)		2,355 (25%)		
	Total with imaging	1,456	3,005	1,668	4,142	
	CT & CTA	273	347	270	347	0.1649
	MRI & MRA	2	2	277	315	<.0001
	Nuclear	102	105	109	117	0.8886
	Other	1	1	2	2	0.6339
	Ultrasound/echo/Doppler/duplex	403	568	500	764	0.0193
	X-ray & fluoroscopy	1,280	1,982	1,472	2,597	0.0009

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

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.

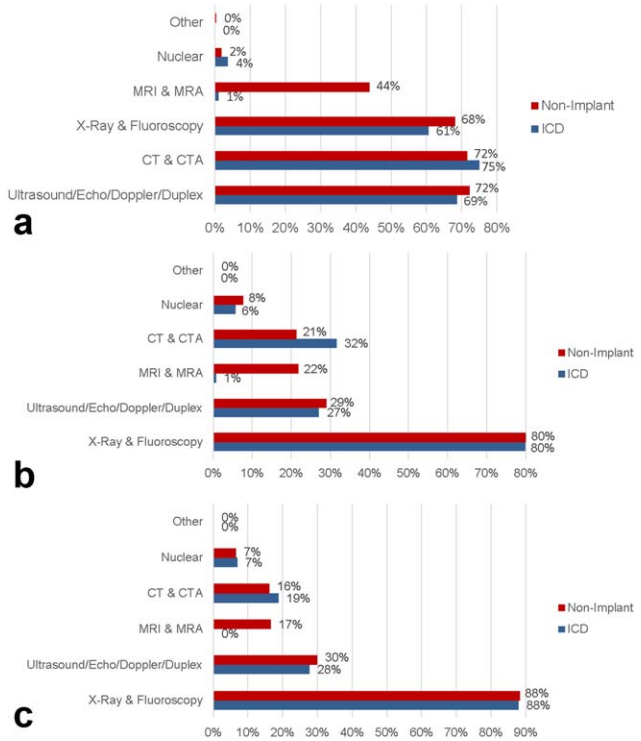

FIGURE 3: A: Percentage of patients with stroke/TIA event by radiology type. B: Percentage of patients with back pain by radiology type. C: Percentage of patients with joint pain by radiology type. ICD: implantable cardioverter defibrillator; CT: computed tomography; CTA: computed tomography angiography; MRI: magnetic resonance imaging; MRA: magnetic resonance angiogram.

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.[2] MRI volume flattened somewhat mid-decade,[25] following implementation of the Deficit Reduction Act in 2007,[26] but the overall trajectory is upward.[1] 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.[5] 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[27] 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,[19] 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

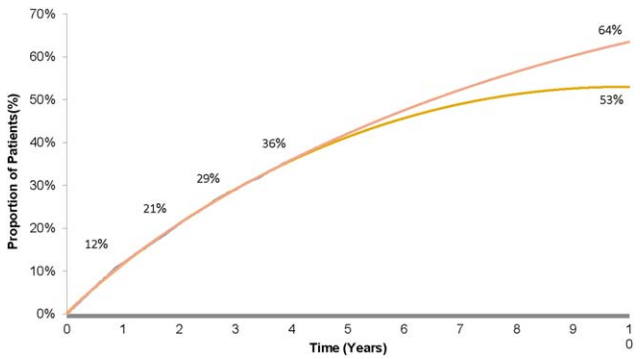

FIGURE 4: MRI/MRA use by ICD-indicated patients and projected utilization to 10 years. The black line represents the proportion of ICD-indicated patients who received an MRI or MRA at 1, 2, 3, and 4 years. The lines extending after year 4 show two projections, which are high and low estimates of utilization. MRI: magnetic resonance imaging; MRA: magnetic resonance angiogram; ICD: implantable cardioverter defibrillator.

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.[19] 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.[28] 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.[4] Kalin and Stanton[4] 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.[13] Moreover, this research indicates the need for MR-conditionally safe ICDs and appropriate 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.[11,19,29] Van der Graaf et al[29] 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.[30] These guidelines represent a major shift in the previously accepted standard that patients with a pacemaker or ICD should not undergo MRI.[29]

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, 33225	CRT-P
# 37.83, 33208, 33225	CRT-P
# 37.72, 37.83	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
# 37.72, 37.83, 33207, 33225	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	ICD
# 37.94	ICD
# 37.94, 33249	ICD
# 37.94, 37.95	ICD
# 37.94, 37.95, 33249	ICD
# 37.94, 37.95, 37.96, 33249	ICD

APPENDIX A: Continued

Code Combination	Implant Type
# 37.94, 37.96, 33249	ICD
# 37.95, 33249	ICD
Code Combination	Implant Type
# 37.95, 37.96	ICD
# 37.96, 33249	ICD
# 33282	Reveal

APPENDIX B: EXPLANT CODES

CPT Code	Explant Type
# 37.79	ICD or CRT-D
# 37.89	PM
# 33227	PM
# 33233	PM
# 33234	PM
# 33235	PM
# 33236	PM
# 33237	PM
# 33238	ICD or PM
# 33241	ICD
# 33244	ICD
# 33284	ILR

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 Progr Eval Mult
# 93285	Ilr Device Eval Progr
# 93288	Pm Device Eval In Person

APPENDIX C: Continued

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 Interrogat Remote
# 93296	Pm/Icd Remote Tech Serv
# 93297	Icm Device Interrogat Remote
# 93298	Ilr Device Interrogat Remote
# 93299	Icm/Ilr Remote Tech Serv
CPT Code	Interrogation Code Description
# 93287	ICD Evaluation Peri-procedural
# 93741	ICD Evaluation (pre-2009)
# 93742	ICD Evaluation (pre-2009)
# 93743	ICD Evaluation (pre-2009)
# 93744	ICD Evaluation (pre-2009)
# 93286	PM Evaluation Peri-procedural
# 93731	PM Remote Evaluation (pre-2009)
# 93732	PM Remote Evaluation (pre-2009)
# 93733	PM Remote Evaluation (pre-2009)
# 93734	PM Remote Evaluation (pre-2009)
# 93735	PM Remote Evaluation (pre-2009)
# 93736	PM Remote Evaluation (pre-2009)
# 93724	PM Electronic Analysis
# 93641	PM EP Evaluation
# 93642	PM EP Evaluation

APPENDIX D: COMORBID CONDITION CODES AND ANTICOAGULATION SPECIFICATION

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: Continued

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 Cardiomypathy	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 Disease	411.81, 411.89, 414.0x, 414.2, 414.3, 414.4, 414.8, 414.9, 429.2, V45.81, V45.82
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 Etexilate Mesylate, 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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