In-Hospital Complications Associated With Reoperations of Implantable Cardioverter Defibrillators

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Repeat implantable cardioverter defibrillator (ICD) procedures are increasing and may be associated with higher risks for complications. To provide more information for clinical decision making, especially in light of recent defibrillator advisories, we examined a large national cohort to characterize repeat ICD procedural outcomes. Using data from the National Cardiovascular Data Registry (ICD Registry), we compared patient characteristics, reasons for ICD implantation, and associated in-hospital adverse events among 92,751 patients receiving their first device and 81,748 patients who underwent repeat procedures with (n = 31,057) and without (n = 50,691) lead involvement. Hierarchical multivariable logistic regression was used to determine the predictors of in-hospital complications. Complication rates were higher in those who underwent repeat ICD procedures with lead involvement (lead implantation or revision), compared with patients who underwent initial implants (3.2% vs 2.6%, p <0.001) or versus those with pocket-only (e.g., generator change only) procedures (3.2% vs 0.6%, p <0.001). There were significantly more in-hospital deaths, lead dislodgements, and infections requiring antibiotics in the lead involvement cohort. Compared with those who had a pocket-only procedure, the multivariable adjusted odds ratio of any complication were increased at 4.20 (95% confidence interval: 3.66 to 4.82, p <0.001) in patients who underwent repeat procedures with lead involvement excluding lead extraction or 7.11 (95% confidence interval: 5.96 to 8.48, p <0.001) in procedures involving lead extractions. In conclusion, repeat ICD procedures, when involving the addition or revision of a lead with or without concurrent lead extraction, are associated with higher complication rates compared with initial implants and with those who underwent pocket-only procedures. **(Am J Cardiol 2014;114:419−426)**

There are few studies comparing the complication rates specifically related to the indication for a repeat implantable cardioverter defibrillator (ICD) procedure.[1−5] The implantable cardiac pulse generator replacement registry (REPLACE) reported a difference in complication rates between patients who underwent repeat pocket procedures with and without lead implantation or revision. Furthermore, studies examining lead revision and extraction outcomes because of lead advisory recalls have found an increased rate of procedure-related complications.[6−10] It is important for both patients and implanting physicians to be aware of the causes of device reimplantation and their potential adverse effects. The National Cardiovascular Data Registry (NCDR) offers an opportunity to study the causes and complications of repeat ICD procedures across a large population. This study seeks to define the characteristics of patients who underwent ICD reimplantation procedures, the distribution of specific indications for reimplantation, and important predictors of in-hospital complications.

Methods

Data and cross-sectional analyses were provided by the NCDR ICD Registry. Participating hospitals are required to submit periprocedural data on all Medicare patients receiving primary prevention devices. In addition, >80% of hospitals in the United States routinely submit standardized data on all patients. All procedures performed between April 1, 2010 and June 30, 2011 including single-chamber, dual-chamber, and cardiac resynchronization therapy (CRT) ICDs were screened for patients who underwent reimplant procedures. Patients requiring a thoracotomy were excluded.

Three separate groups consisting of patients who underwent initial ICD implant, repeat procedures with lead revision or replacement, and generator replacement only were analyzed. Initial implants consisted of procedures in patients

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See page 425 for disclosure information.

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Table 1
Baseline characteristics

Description	Implant Status			p-Values	
	Initial Implant	Reoperation With Lead Involvement	Repeat Pocket Procedure	Initial vs All Repeat Procedures	Reoperation With Lead Involvement vs Pocket-Only Procedure
	n = 92751	n = 31057	n = 50691		
Age >70 years	34598 (37.3%)	16509 (53.2%)	27232 (53.7%)	<0.001	0.116
Female	26327 (28.4%)	7608 (24.5%)	13633 (26.9%)	<0.001	<0.001
White	75953 (81.9%)	27284 (87.9%)	44905 (88.6%)	<0.001	0.002
Heart failure	72193 (77.8%)	26377 (84.9%)	38889 (76.7%)	<0.001	<0.001
NYHA functional classification				<0.001	<0.001
I	13356 (14.4%)	3632 (11.7%)	10850 (21.4%)		
II	32676 (35.2%)	8013 (25.8%)	20896 (41.2%)		
III	43305 (46.7%)	18136 (58.4%)	17769 (35.1%)		
IV	3046 (3.3%)	1160 (3.7%)	914 (1.8%)		
Nonischemic cardiomyopathy	32854 (35.4%)	10402 (33.5%)	15323 (30.2%)	<0.001	<0.001
Coronary heart disease	55900 (60.3%)	19684 (63.4%)	32793 (64.7%)	<0.001	<0.001
Prior myocardial infarction	45866 (49.5%)	15507 (49.9%)	26692 (52.7%)	<0.001	<0.001
Prior percutaneous coronary intervention	30071 (32.4%)	10115 (32.6%)	16310 (32.2%)	0.679	0.215
Prior coronary bypass	27346 (29.5%)	11536 (37.1%)	18718 (36.9%)	<0.001	0.512
Primary valvular heart disease	10712 (11.6%)	4899 (15.8%)	5735 (11.3%)	<0.001	<0.001
Cerebrovascular disease	13822 (14.9%)	5481 (17.7%)	8392 (16.6%)	<0.001	<0.001
Chronic lung disease	20228 (21.8%)	6926 (22.3%)	10404 (20.5%)	0.002	<0.001
Diabetes mellitus	35692 (38.5%)	11924 (38.4%)	18241 (36.0%)	<0.001	<0.001
Sleep apnea	10540 (11.4%)	4176 (13.5%)	5854 (11.6%)	<0.001	<0.001
Dialysis	3018 (3.2%)	734 (2.4%)	1022 (2.0%)	<0.001	<0.001
Hypertension	73027 (78.7%)	24274 (78.2%)	38809 (76.6%)	<0.001	<0.001
Syncope	15318 (16.5%)	5232 (16.9%)	7644 (15.1%)	<0.001	<0.001
Family history of sudden death	3749 (4.0%)	1087 (3.5%)	1891 (3.7%)	<0.001	0.089
Atrial fibrillation/flutter	26575 (28.7%)	15330 (49.4%)	20608 (40.7%)	<0.001	<0.001
Ventricular tachycardia	28922 (31.2%)	13730 (44.2%)	24457 (48.3%)	<0.001	<0.001
Cardiac arrest	9939 (10.7%)	3176 (10.2%)	5578 (11.0%)	0.978	<0.001
Previous implantable cardioverter defibrillator	0	20180 (65.0%)	50691 (100.0%)	<0.001	<0.001
Permanent pacemaker	0	13151 (42.3%)	6185 (12.2%)	<0.001	<0.001
Implantable cardioverter defibrillator indication					<0.001
Primary prevention	74657 (80.5%)	22820 (73.5%)	36124 (71.3%)	<0.001	<0.001
Secondary prevention	18094 (19.5%)	8237 (26.5%)	14567 (28.7%)	<0.001	<0.001
Final device type				<0.001	<0.001
Single chamber	21779 (23.5%)	2497 (8.0%)	8340 (16.5%)		
Dual chamber	40026 (43.2%)	8202 (26.4%)	20015 (39.5%)		
Cardiac resynchronization therapy defibrillator	30725 (33.1%)	20320 (65.4%)	22241 (43.9%)		
Left ventricular ejection fraction				<0.001	<0.001
≤30%	65550 (70.7%)	19329 (62.2%)	20081 (39.6%)		
31%–40%	15731 (17.0%)	5363 (17.3%)	8481 (16.7%)		
>40%	9982 (10.8%)	3692 (11.9%)	11290 (22.3%)		
QRS duration—121–140 ms	13469 (14.5%)	3273 (10.5%)	4290 (8.5%)	<0.001	<0.001
Cardiac rhythm—paced	1185 (1.3%)	16007 (51.5%)	27107 (53.5%)	<0.001	<0.001
Abnormal intraventricular conduction	45124 (48.7%)	20531 (66.1%)	27190 (53.6%)	<0.001	<0.001
Left bundle branch block	23341 (25.2%)	7583 (24.5%)	8216 (16.3%)	<0.001	<0.001
Right bundle branch block	9576 (10.4%)	2685 (8.7%)	3456 (6.9%)	<0.001	<0.001
Left anterior fascicular block	4640 (5.0%)	978 (3.2%)	1304 (2.6%)	<0.001	<0.001
Left posterior fascicular block	789 (0.85%)	192 (0.6%)	252 (0.5%)	<0.001	<0.001
Ventricular paced rhythm	516 (0.6%)	8554 (27.7%)	13321 (26.4%)	<0.001	<0.001
Systolic blood pressure <100 mm Hg	5040 (5.4%)	1943 (6.3%)	2305 (4.6%)	0.028	<0.001
Creatinine >2.0 mg/dl	7281 (7.9%)	2767 (8.9%)	3677 (7.3%)	0.418	<0.001
Mean BNP (pg/ml)	992.4	946.3	593	<0.001	<0.001
Aldosterone receptor blocker or angiotensin-converting enzyme use	69668 (75.1%)	21806 (70.2%)	34813 (68.7%)	<0.001	<0.001
Antiarrhythmic use	14282 (15.4%)	7926 (25.5%)	11153 (22.0%)	<0.001	<0.001
Beta blocker use	81472 (87.8%)	26920 (86.7%)	43085 (85.0%)	<0.001	<0.001
Statin use	60918 (65.7%)	20530 (66.1%)	33879 (66.8%)	<0.001	<0.001
Device manufacturer				<0.001	<0.001
Biotronik	4695 (5.1%)	1019 (3.3%)	1192 (2.4%)		

Table 1
(*continued*)

Description	Implant Status			p-Values	
	Initial Implant	Reoperation With Lead Involvement	Repeat Pocket Procedure	Initial vs All Repeat Procedures	Reoperation With Lead Involvement vs Pocket-Only Procedure
	n = 92751	n = 31057	n = 50691		
Boston Scientific	20576 (22.2%)	6376 (20.5%)	15853 (31.3%)		
Cameron health	169 (0.2%)	19 (0.1%)	2 (0.0%)		
ELA medical	506 (0.6%)	112 (0.4%)	109 (0.2%)		
Guidant	328 (0.4%)	85 (0.3%)	494 (1.0%)		
Medtronic	38873 (41.9%)	16128 (51.9%)	23987 (47.3%)		
St Jude medical	27604 (29.8%)	7318 (23.6%)	9054 (17.9%)		
No specialized electrophysiology training	5970 (6.4%)	1602 (5.2%)	3009 (5.9%)	<0.001	<0.001

Table 2
Reasons for reimplantation

Reasons for Reimplantation	Reoperation With Lead Involvement	Pocket Procedure	p-Values
	n = 31057	n = 50691	
Upgrade from pacemaker to implantable cardioverter defibrillator	10879 (35.0%)	0	<0.001
End of expected battery life	8715 (28.1%)	48502 (95.7%)	<0.001
Replaced at time of lead revision	3995 (12.9%)	635 (1.3%)	<0.001
Any implantable cardioverter defibrillator upgrade	9853 (31.7%)	1546 (3.1%)	<0.001
Infection	1701 (5.5%)	181 (0.4%)	<0.001
Under manufacturer advisory/recall	490 (1.6%)	297 (0.6%)	<0.001
Faulty connector/header	93 (0.3%)	66 (0.1%)	<0.001
Device relocation	334 (1.1%)	214 (0.4%)	<0.001
Malfunction	990 (3.2%)	495 (1.0%)	<0.001

with no previous pacemaker or ICD. A reoperation procedure with lead implantation or revision consisted of any reoperation procedure involving the implantation of a new lead, such as an upgrade from a previous pacemaker to an ICD requiring a defibrillation lead; upgrade of an ICD to a dual chamber ICD or CRT defibrillator; lead replacement or revision with or without lead extraction; device infection in which the leads are manipulated or replaced; or a malfunction because of a problem with atrial pacing, right ventricular pacing, left ventricular pacing, or lead-related defibrillation function. A reoperation with pocket-only procedure was defined as any reoperation procedure without involvement of a lead, such as a generator change only, a pocket revision, or a procedure to move the generator.

The primary outcome was in-hospital major adverse event during and after device procedure until the end of the hospital stay. These events included cardiac arrest, cardiac perforation, cardiac valve injury, conduction block, hematoma requiring reoperation, evacuation or transfusion, hemothorax, lead dislodgement, myocardial infarction, pericardial tamponade, set screw problem, pneumothorax, transient ischemic attack or stroke, urgent cardiac surgery, drug reaction, coronary venous dissection, infection requiring antibiotics, peripheral embolus, peripheral nerve injury, and venous obstruction. All complications occurred during the hospital stay for the given ICD procedure. Patients could have >1 complication recorded; multiple complications were not considered separately.

Statistical analyses were performed at the NCDR Analysis Center at Yale University. Baseline patient characteristics were compared using independent *t* tests, analysis of variance, and chi-square tests. Wilcoxon rank sum tests and Kruskal-Wallis tests were used when normality assumptions of continuous variables were violated. Tests comparing characteristics of patients who underwent reimplantation procedures and initial ICD implantation were also performed. Total number of in-hospital complications associated with reimplantation was tabulated according to the subgroups categorized based on the reason for ICD procedure, and simple proportions were calculated. To examine potential predictors of in-hospital complications in patients who underwent reimplantation, univariate hierarchical logistic regression models based on the baseline patient variables adjusting for clustering on center were first fitted. A similar multivariable hierarchical logistic regression model adjusting for clustering was developed by including all variables significant at the univariate level. Each variable was evaluated for significance and confounding. Variables no longer significantly contributing to the overall model and that did not produce confounding of other variables were dropped from the model. Variables having the highest p-values were evaluated first, and this step was performed iteratively until all variables in the model met the inclusion criteria of $p < 0.05$. Before modeling, categorical variable missing data were assumed to represent a "no" response. Continuous variable missing data were imputed with the

Table 3
Incidence of in-hospital complications in patients undergoing reoperation procedures

Complication	Initial Implant	Reoperation With Lead Involvement	Pocket Procedure	p-Value	
	n = 92571	n = 31057	n = 50691	Initial vs All Repeat Procedures	Reoperation With Lead Involvement vs Pocket-Only Procedure
All events	2382 (2.6%)	994 (3.2%)	302 (0.6%)	<0.001	<0.001
Discharge status—dead	318 (0.34%)	109 (0.35%)	52 (0.1%)	<0.001	<0.001
Cardiac arrest	243 (0.26%)	83 (0.27%)	40 (0.08%)	<0.001	<0.001
Cardiac perforation	67 (0.07%)	22 (0.07%)	2 (0.0%)	<0.001	<0.001
Cardiac valve injury	1 (0.0%)	0	0	NA	NA
Conduction block	38 (0.04%)	5 (0.02%)	1 (0.0%)	<0.001	0.032
Hematoma requiring reoperation, evacuation or transfusion	264 (0.28%)	201 (0.65%)	86 (0.17%)	0.014	<0.001
Hemothorax	24 (0.03%)	21 (0.07%)	5 (0.01%)	0.465	<0.001
Lead dislodgement	869 (0.94%)	349 (1.12%)	29 (0.06%)	<0.001	<0.001
Myocardial infarction	27 (0.03%)	4 (0.01%)	2 (0.0%)	0.001	0.209
Pericardial tamponade	92 (0.1%)	22 (0.07%)	2 (0.0%)	<0.001	<0.001
Set screw problem	33 (0.04%)	17 (0.05%)	5 (0.01%)	0.309	<0.001
Pneumothorax	299 (0.32%)	112 (0.36%)	27 (0.05%)	<0.001	<0.001
Transient ischemic attack or stroke	47 (0.05%)	22 (0.07%)	7 (0.01%)	0.129	<0.001
Urgent cardiac surgery	22 (0.02%)	5 (0.02%)	2 (0.0%)	0.014	0.113
Drug reaction	55 (0.06%)	19 (0.06%)	17 (0.03%)	0.164	0.068
Coronary venous dissection	128 (0.14%)	42 (0.14%)	11 (0.02%)	<0.001	<0.001
Infection requiring antibiotics	85 (0.09%)	44 (0.14%)	16 (0.03%)	0.187	<0.001
Peripheral embolus	12 (0.01%)	10 (0.03%)	0	<0.001	<0.001
Peripheral nerve injury	1 (0.0%)	1 (0.0%)	1 (0.0%)	NA	NA
Venous obstruction	25 (0.03%)	28 (0.09%)	8 (0.02%)	0.057	<0.001

median. SAS v9.2 was used for the analyses (SAS Institute, Cary, N C).

Results

Our analysis included 174,499 patient hospital visits. This included 92,751 initial ICD implants, 31,057 patients who underwent repeat procedures involving lead revision or replacement, and 50,691 patients who underwent generator-only procedures. A comparison of patient characteristics between patients with initial ICD implantation, repeat procedures involving lead replacement or revision, and repeat procedures involving the generator only are listed in Table 1. Compared with new ICD implants, patients who underwent repeat procedures were older and more likely to be men; they had more atrial and ventricular arrhythmias and were more likely to have dual chamber or CRT devices with underlying paced cardiac rhythms. Compared with those who had pocket-only procedures, those who underwent repeat procedures involving lead implantation or revision had more heart failure with a lower ejection fraction, valvular heart disease, atrial arrhythmias, and cardiovascular co-morbidities.

End of expected battery life was the major reason for reimplantation in the pocket-only cohort (95.7%), compared with 28.1% in the lead implantation or revision cohort (Table 2). Thirty-five percentage of the lead-related reimplant group was referred for an upgrade from a pacemaker to an ICD. Other reasons for a reimplantation with lead involvement included lead dislodgement or other reasons for lead revision (12.9%), infection (5.5%), device malfunction (3.2%), and advisory or recall (1.6%).

The incidence of adverse events in those patients who underwent initial ICD implantation was 2.6%. Overall, adverse event rates were significantly higher in patients who underwent reimplantation with lead manipulation (3.2%), compared with those with pocket-only procedures (0.6%) and initial implantation. There were significantly more patient deaths, cardiac events, hematomas, lead dislodgements, pneumothoraces, infections, and venous issues in the reimplant cohort with lead involvement compared with those without lead involvement and with initial implants (Table 3 and Figure 1). Complications with pocket-only reimplantation procedures were significantly lower compared with reimplant procedures requiring a lead implantation or revision and compared with initial ICD implants. For every 100 patients who underwent lead reimplantation or revision instead of a pocket-only procedure, there would be an increase of 2.6 major adverse events.

Repeat procedures with lead implantation or revision with or without lead extraction, upgrading to an ICD, lack of prophylactic antibiotics, heart failure, dual chamber and CRT device implantation, and cardiovascular co-morbidities were all associated with worse outcomes (Table 4). After adjusting for baseline characteristics and medical co-morbidities, multivariable analysis revealed more than fourfold greater odds of an adverse in-hospital complication for patients who underwent a repeat procedure requiring lead implantation or revision without lead extraction. Those patients who underwent lead extraction during a reoperation procedure had more than a sevenfold increase in adverse in-

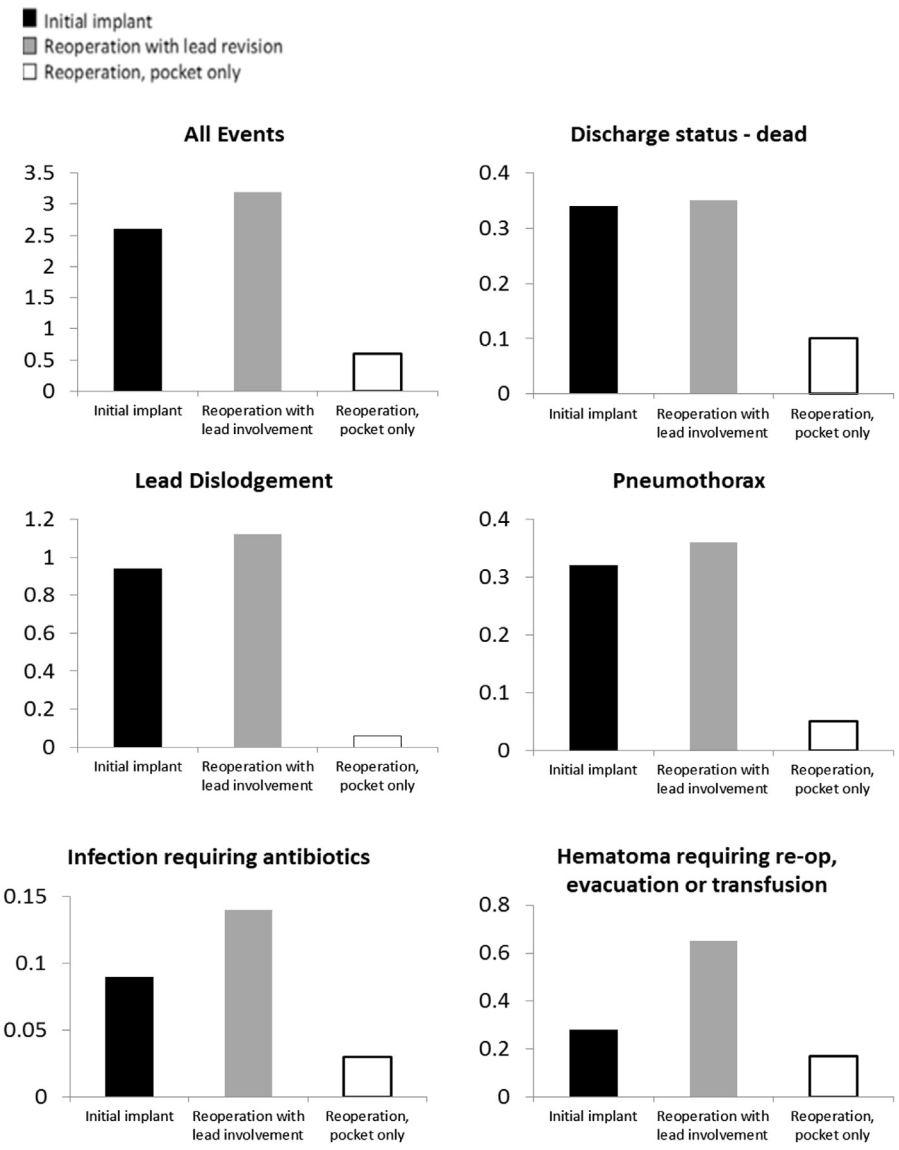

Figure 1. Selected in-hospital adverse outcomes comparing initial ICD implantation to reimplantation procedures stratified by lead implantation or revision and pocket-only procedures. Y-axis represents percentage of all patients with specific complication. p-Values for all variables comparing initial versus all repeat procedures are <0.001 except for infection requiring antibiotics ($p = 0.187$) and hematoma requiring reoperation, evacuation, or transfusion ($p = 0.014$). p-Values for all variables comparing reoperation with lead involvement versus pocket-only procedures are <0.001.

hospital complications. Furthermore, there were increased risks of adverse events in patients not receiving prophylactic antibiotics, for those not receiving a single-chamber ICD, female patients, and for patients with cardiovascular risk factors (Table 4).

Discussion

Our study investigated the epidemiology, risk factors, and complications of repeat ICD implantation with and without lead revision in a large contemporary multicenter registry cohort. A significant finding was the higher overall incidence of major complications in the cohort that underwent a reoperation procedure requiring lead implantation or revision (3.2%), compared with those with pocket-only reimplants (0.6%). The most striking differences included a higher rate of death, cardiac arrest, hematoma, lead dislodgement, and lung damage in the repeat procedure cohort with lead involvement. Although undergoing a reimplantation procedure with lead revision and extraction was the most predictive of adverse events, those patients who underwent lead revision or reimplantation without lead extraction also had significantly increased in-hospital complications. Multivariable analysis also revealed that lack of prophylactic antibiotics, device implants other than a single-chamber device, and female gender also predicted worse outcomes. As expected, patients with significant kidney, heart, lung, and cerebrovascular disease also fared poorly. Reoperation involving lead revision when compared with initial implantation was also associated with a higher risk of overall complications (3.2% vs 2.6%), most notably lead dislodgements, hematomas, and infections. Although the

Table 4
Univariate and multivariate predictors of in-hospital complications in patients undergoing reoperation

Predictor	Univariate Analysis		Multivariable Analysis	
	Odds Ratio	95% CI, p-Value	Odds Ratio	95% CI, p-Value
Reimplant with lead implantation or revision, with extraction	8.45	7.07−10.1, <0.001	7.11	5.96−8.48, <0.001
Reimplant with lead implantation or revision, without extraction	5.95	5.22−6.77, <0.001	4.20	3.66−4.82, <0.001
Upgrade from pacemaker to implantable cardioverter defibrillator	2.94	2.62−3.30, <0.001		
Prophylactic antibiotics not given for medical reason	2.64	1.77−3.93, <0.001	1.78	1.21−2.63, 0.003
NYHA III or IV	2.53	2.26−2.83, <0.001		
Final device type: not a single chamber	2.4	1.93−3.00, <0.001	1.46	1.18−1.81, 0.001
Previous pacemaker	2.36	2.12−2.63, <0.001		
Currently on dialysis	2.1	1.63−2.72, <0.001	1.43	1.11−1.85, 0.006
Heart failure	1.88	1.60−2.20, <0.001		
Creatinine >2 mg/dl	1.82	1.56−2.12, <0.001		
Primary valvular heart disease	1.76	1.54−2.01, <0.001		
Prophylactic antibiotics not given, unclear reason	1.54	1.07−2.22, 0.021		
Systolic blood pressure <100	1.53	1.26−1.86, <0.001		
Chronic lung disease	1.47	1.30−1.65, <0.001	1.26	1.12−1.41, <0.001
Atrial fibrillation/flutter	1.34	1.21−1.49, <0.001		
Cerebrovascular disease	1.29	1.13−1.47, <0.001	1.14	1.00−1.29, 0.045
Routine warfarin therapy prior to procedure	1.27	1.14−1.41, <0.001		
Nonischemic dilated cardiomyopathy	1.27	1.14−1.42, <0.001	1.24	1.10−1.39, <0.001
Syncope	1.24	1.09−1.42, 0.002		
Hypertension	1.23	1.07−1.40, 0.003		
Sleep apnea	1.18	1.01−1.39, 0.040		
Female	1.18	1.05−1.32, 0.005	1.14	1.01−1.28, 0.019
Age >70 years	1.16	1.04−1.28, 0.007		
Diabetes mellitus	1.12	1.01−1.25, 0.031		
Prior percutaneous coronary intervention	1.07	0.96−1.20, 0.213	1.14	1.02−1.28, 0.026
Family history of sudden cardiac death	1.01	0.76−1.33, 0.947		
Ventricular tachycardia	0.95	0.86−1.06, 0.372		
Coronary artery disease	0.94	0.84−1.05, 0.249		

precise causes for increased complications are not known from this study, we suspect longer procedural times, need for more anesthesia, the more invasive nature of the procedure, and a requirement for venous access are contributing to worse outcomes when undergoing repeat procedures involving some type of lead manipulation.

Up to a quarter of patients in the primary implantation group and 70.2% in the reoperation group were not on angiotensin-converting enzyme inhibitors or aldosterone receptor blockers and 13% of patients in both groups were not on β blocker therapy at the time of implant. Although it is not possible to discern the reason for low compliance with these standard heart failure medications including ongoing heart failure, intolerance, or inadequate reporting to the NCDR, it is worth noting that some patients referred for implantation may have undergone primary or upgraded device implantation before receiving optimal medical therapy.

Our study offers some comparisons with recent studies investigating device reimplantation procedures. The Ontario ICD database investigators found a short-term 4.3% complication rate in 1,081 patients who underwent reimplantation procedures after a 45-day follow-up period. Although cohorts were not stratified by lead revision or no-lead revision, there was a substantial increase in risk associated with an upgrade to a CRT device. The overall major infection rate of 1.7% found by Krahn et al[3] was higher than the rate of 0.14% in-hospital infections requiring antibiotics found in our study, but the follow-up periods differed. Significant hematomas were similar in both studies. Predictors of poor outcome in the Canadian study included anginal class, number of previous pocket procedures, operator volume, and antiarrhythmic therapy. In our study, patients with a history of percutaneous coronary intervention, previous pocket procedures, and atrial fibrillation fared worse.

The REPLACE registry reported an increased risk in 713 patients who underwent an ICD or pacemaker reimplantation procedure with a lead addition versus 1,031 patients who underwent generator-only replacement. Patients were followed up to 6 months after procedure. ICDs were associated with more complications than pacemakers, and CRT devices had overall worse outcomes than any other device. Overall complications were increased in the lead addition cohort (15.3%) compared with the pocket-only procedure arm (4.0%).[4] Although these studies provide some data regarding repeat procedures and complication rates with longer follow-up than our study, the number of patients studied was relatively less. Our study provides further corroborating evidence in a substantially larger national cohort that patients who underwent repeat operations with lead implantation or revision have increased complications.

The large NCDR cohort allows for a characterization of the reasons why patients return for repeat ICD procedures. The most common reason for repeat procedures requiring lead implantation or revision was upgrading from

a pacemaker to an ICD or more complex ICD system requiring additional leads. Notably, a total of 787 patients, or 2.2% of all device reimplants, were performed because of a device recall or advisory. Previously published data suggest that failed or recalled generators are becoming more common.[5,6] Gould et al[9] studied ICD advisory reoperations up to 1 year and reported a 9.1% complication rate, with 5.9% of those patients requiring another procedure because of device malfunction. The number of previous pocket procedures was a strong predictor of worse outcomes. The Canadian Hearth Rhythm Society survey study looking into Sprint Fidelis lead recall reoperations reported a 14.5% complication rate for patients who underwent lead revisions.[7] The risk of complications more than doubled when extracting a lead at the time of revision (18.9%) versus abandoning the old lead (8.6%), similar to the findings in our study. The Lead Extraction in the Contemporary Setting study retrospectively reviewed adverse outcomes related to consecutive laser lead extractions and found an overall in-hospital mortality of 1.86% in those patients. Infection markedly increased the risk of death in patients with concomitant lead extraction, with in-hospital mortality as high as 12.4% in patients with endocarditis and renal failure.[11] Our large cohort study confirms that the addition of lead extraction further increases the reoperation procedural risk above a pocket-only procedure (Table 4).

More recently, there is growing evidence that the Riata ICD lead has a clinically meaningful failure rate.[12,13] Whether to address lead revision or replacement on finding a damaged but functional lead poses a complicated clinical dilemma. In a small single-center cohort study, up to 1/3 of Riata leads had externalized cables on fluoroscopy investigation within a few years of implant.[14] Furthermore, it has been suggested that Riata lead failures may lead to increased mortality.[12] These potential risks should be weighed against the increased risk of serious complications found in our study associated with repeat procedures involving lead manipulation.

Repeat procedures with lead involvement may increase risks of adverse events and add to health-care costs. According to data collected from ICD implants covered by Medicare, the average cost per hospital admission for an ICD is 42,184 dollars with a median length of stay of 2 days. Those patients experiencing a complication related to the implant have an average increase of 7,251 dollars per hospital stay with an increase in length of stay by 3.4 days. Specifically, device infection increased cost by 18,477 dollars with an incremental length of stay increase of 9.6 days. Pneumothoraces, mechanical complications associated with lead or pocket revision, and hematomas increased cost by 5,000 to 6,000 dollars with an increased hospital stay of 1 to 3 days.[15]

Notably, female gender portended a worse outcome in both reoperation groups. Previously reported data suggest that women who underwent ICD procedures had more heart failure, worse functional class, more often had nonischemic cardiomyopathy, and more often underwent biventricular device implantation, which may explain our results as well.[16]

Physicians are facing complex decisions in an era of lead advisories, recalls, device infections, and upgrades to advanced devices. This study and others suggest that there can be significant risks to revision or addition of leads during a reimplantation procedure. Our data suggest that for every 38 patients who underwent lead revision, there would be 1 major complication. The higher complication rates associated with repeat ICD procedures involving lead implantation or revision should be considered when counseling patients being evaluated for an upgrade from a dual chamber ICD to a CRT defibrillator.

Although this study helps to elucidate the risks of lead-associated procedures, including those at the time of generator replacement, it does not specifically address the benefits that physicians and patients may be seeking by undertaking such a procedure. Although our findings may help in the process of shared decision making with regard to procedural planning, ultimately, the individual choice to undergo a lead-related procedure at the time of a generator replacement will depend on a discussion of risks and benefits between patients and their physicians.

One major limitation of studying this large registry population is the lack of outpatient follow-up data. It is difficult to make direct comparisons with other published studies with long-term follow-up, and data analysis is often difficult given the limitation of a 1-time data entry sheet at the time of the procedure. The observed low in-hospital complication rate recorded for generator-only procedures may falsely estimate the overall complication rate as it does not include out of hospital adverse events nor does it specifically include return hospital visits. However, this limitation applies to all subgroups studied and, therefore, fairly underestimates our results. In addition, data coding as part of the NCDR may be imperfect, resulting in the possibility of uncontrolled confounding and bias. However, most data are entered by specialists in the coding process with data quality assurance protocols, thereby decreasing the chances of improper data recording.[17] Furthermore, random errors in data entry and the resulting misclassifications would bias our results toward no association between procedure type and complication rates. Lastly, we did not collect data on procedural technique and postprocedural care that may affect outcomes such as procedural time, use of arm slings, or differing approaches to venous access. However, postprocedural care and procedural technique cannot explain our results as the same operators and centers were involved for each procedure studied. Any bias introduced by differences in periprocedural care would apply to all subgroups studied.

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