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Lead Burden as a Factor for Higher Complication Rate in Patients With Implantable Cardiac Devices

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Purpose	Lead revisions have increased over the last decade. Patients who do not undergo lead extraction face an increased lead burden. Consequences of increased lead burden have not been fully defined. We sought to characterize the complication rate and outcomes in patients with sterile redundant leads.
Methods	We retrospectively reviewed 242 consecutive patients [mean age 74 ± 12 years; 66.9% male] who underwent lead revision that resulted in an abandoned lead from January 2005 to June 2010. Patients were placed in a cohort based on number of leads after last recorded procedure (Group A: ≤2 [n=58]; Group B: 3–4 [n=168]; Group C: ≥5 [n=16]). Prespecified inhospital and long-term follow-up events were compared. Mortality rates were obtained from Social Security Death Index. Median follow-up was 2 years.
Results	Baseline age, gender and race demographics were similar among the three groups. Increasing lead burden was associated with more adverse periprocedural events (A: 3.4%, B: 10.1%, C: 25.0%; P=0.031) and long-term device-related events (A: 1.7%, B: 13.0%, C: 18.8%; P=0.031). Device-related readmissions increased in frequency as lead burden increased (A: 3.5%, B: 18.5%, C: 37.5%; P=0.002). Combined periprocedural and late events also increased with more redundant leads (A: 5.2%, B: 23.2%, C: 44.0%; P=0.001). Major events were infrequent (3.3%). There was no procedure-related mortality. Long-term all-cause mortality was not significantly different (A: 17.2%, B: 23.8%, C: 25.0%; P=0.567).
Conclusions	Greater lead burden was associated with increased number of periprocedural and long-term minor events. It did not significantly impact major events or mortality. (<i>J Patient-Centered Res Rev.</i> 2015;2:17-24.)
Keywords	abandoned leads, implantable cardioverter-defibrillator, pacemaker, lead revision, complications, mortality

The use of cardiac rhythm management devices has increased dramatically over the last decade, with more than 486,000 new devices implanted from 2006 to 2009.¹ The established success of these devices in multiple clinical trials, particularly in the setting of cardiomyopathy, has expanded the indications for device therapy and increased the number of patients who qualify for them.² With the success of medical and device therapy in the treatment of cardiovascular disease, patients are living long enough to benefit from increasingly sophisticated device upgrades (e.g.

biventricular pacing and defibrillation capability), which require the introduction of additional leads. Many patients now outlive the functional life of their implanted hardware and require replacement of nonfunctioning leads. Once a device has been replaced or upgraded, a decision has to be made as to whether existing leads should be extracted or revised (i.e. capped and secured, leaving an abandoned lead in place). Lead extraction is defined as removal of the lead, regardless of the duration of the implant, using specialized equipment not included in a typical implant package.³ Lead extraction may require emergent cardiac surgery and carries a mortality risk of 0.4–0.8%.⁴ Due to the extremely high rate of mortality and morbidity associated with device and/or lead infection, extraction of infected leads as the optimal management strategy is not debated. However, only 60% of leads extracted are

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in response to infection, and 40% of extracted leads are sterile and merely superfluous.⁵

Extraction of sterile redundant leads is controversial. Arguments for extracting these leads are based on maintaining future central venous access options and to prevent potential complications, including venous thrombosis, lead migration, infection, lead-lead interaction, tricuspid regurgitation and venous or cardiac chamber perforation. However, the frequency of these complications is not well-defined in the literature. Moreover, the efficacy of intervening to prevent these complications is not well-documented. The purpose of this study was to characterize complication rates and potential outcomes in patients with sterile redundant leads.

METHODS

After institutional review board approval, we retrospectively reviewed 242 consecutive patients (mean age 74 ± 12 years; 66.9% male) who underwent a lead revision procedure that resulted in an abandoned lead from January 2005 to June 2010 at our facility. This patient population represented 3.75% of the total patient population that underwent device implantation at our facility during the study period (N=6,451). Our main inclusion criterion was that a patient underwent any lead revision procedure resulting in at least one abandoned lead. Patients who had a lead removed either by manual traction during device revision/upgrade or through a lead extraction procedure for a sterile redundant lead, leaving no superfluous leads, were excluded. Patients with implantable cardioverter-defibrillator (ICD) leads and/or pacemaker leads were included. Patients were placed in one of three cohorts based on total number of functional and abandoned leads present after their last recorded device-related procedure (Group A: ≤ 2 leads [n=58]; Group B: 3 or 4 leads [n=168]; Group C: ≥ 5 leads [n=16]).

The groups were compared based on age, gender and comorbidities (Table 1). Indications for device upgrade and lead abandonment were reviewed in the medical record (Table 1). The cohorts were compared to determine whether number of leads (escalating level of lead burden) affected prespecified endpoints in regard to outcomes. Because actual individual events were infrequent, we compared outcomes that were prespecified: inhospital and periprocedural

events, device-related readmissions and long-term follow-up events. Inhospital and periprocedural events associated with the abandonment of a lead included pneumothorax, bleeding/hematoma, spontaneous unstable procedural arrhythmias requiring treatment, central venous or cardiac perforation, failure to place a new lead, failure to attain adequate defibrillation thresholds requiring additional intervention, venous thrombosis requiring change of strategy for new lead implantation (i.e. venoplasty, tunneling, contralateral access) and death. Long-term events (after 30 days of procedure) included late bleeding, cardiac or central venous perforation, venous thrombosis, inappropriate ICD shock, atrial arrhythmia, device-related infection and death. Device-related readmissions were documented through analysis of the medical record. Mortality rates were obtained from the Social Security Death Index. Overall median follow-up was 2.0 years (with interquartile range of 1.1–3.5).

Statistical Analysis

Continuous variables are summarized as medians with interquartile range. Discrete variables are described as counts with percentages. Differences among the three study groups (≤ 2 , 3–4 and ≥ 5 leads) were tested using Kruskal-Wallis test or Wilcoxon rank-sum test for continuous variables and chi-square/Fisher's exact tests with 95% confidence levels (two-tailed) for discrete variables.

RESULTS

During the study period, 242 patients met the inclusion criteria (3.75% of the total number of patients receiving cardiac rhythm management device implants or lead revision at our facility). The study population included 162 men and 80 women (mean age 74 years); 75.2% of patients (n=182) were older than 65 years. There was no significant difference among the groups with regard to gender or mean age. There was a statistically significant difference in the number of patients older than 65, as Group A (patients with ≤ 2 leads) had fewer of these patients compared with the other two groups (A: 58.6%, B: 80.4%, C: 81.3%; $P=0.004$). At baseline, patients in each group had similar rates of coronary artery disease, diabetes, atrial arrhythmia and dialysis. Hypertension (A: 37.9%, B: 60.0%, C: 68.0%; $P=0.007$) and prior congestive heart failure (A: 62.1%, B: 78.0%, C: 87.5%; $P=0.027$) were

Table 1. Baseline patient characteristics and indications for original lead revision and abandonment

Variable	Overall (N=242)	Body surface area, m ²			P
		≤2 (n=58, 24.0%)	3 or 4 (n=168, 69.4%)	≥5 (n=16, 6.6%)	
Demographics					
Mean age, years (IQR)	74 (65-79)	70 (60-82)	74 (67-79)	75 (68-80)	0.636
Age older than 65	182 (75.2%)	34 (58.6%)	135 (80.4%)	13 (81.3%)	0.004
Gender					
Male	162 (66.9%)	32 (55.2%)	118 (70.2%)	12 (75.0%)	0.085
Female	80 (33.1%)	26 (44.8%)	50 (29.8%)	4 (25.0%)	
Race					
White	229 (94.6%)	55 (94.8%)	158 (94.1%)	16 (100%)	0.599
Other	13 (5.4%)	3 (5.2%)	10 (6.0%)	0	
Comorbidities					
Hypertension	134 (55.4%)	22 (37.9%)	101 (60.1%)	11 (68.8%)	0.007
Coronary artery disease	141 (58.3%)	28 (48.3%)	105 (62.5%)	8 (50.0%)	0.131
CABG	68 (28.1%)	13 (22.4%)	51 (30.4%)	4 (25.0%)	0.490
Cerebrovascular accident	22 (9.1%)	7 (12.1%)	14 (8.3%)	1 (6.3%)	0.639
Dialysis	4 (1.7%)	1 (1.7%)	3 (1.8%)	0	1.000
AF/AFL	118 (48.8%)	32 (55.2%)	78 (46.4%)	8 (50.0%)	0.514
Congestive heart failure	181 (74.8%)	36 (62.1%)	131 (78.0%)	14 (87.5%)	0.027
Mean LVEF, % (IQR)	30 (20-40)	35 (25-50)	30 (20-35)	25 (15-35)	0.002
Median follow-up, years (IQR)	2.0 (1.1-3.5)	1.7 (0.9-3.1)	2.0 (1.2-3.6)	1.7 (1.0-3.9)	0.423
Device Type					
Pacemaker	127 (52.5%)	24 (41.4%)	95 (56.6%)	8 (50.0%)	<0.001
Defibrillator	72 (29.8%)	33 (56.9%)	35 (20.8%)	4 (25.0%)	
Biventricular	5 (2.1%)	0	5 (3.0%)	0	
Biventricular-ICD	38 (15.7%)	1 (1.7%)	33 (19.6%)	4 (25.0%)	
Atrial lead	168 (69.4%)	21 (36.2%)	133 (79.2%)	14 (87.5%)	<0.001
Indication for lead revision					
Device malfunction	21 (8.7%)	18 (31.0%)	3 (1.8%)	0	<0.001
Lead malfunction	115 (47.5%)	35 (60.3%)	76 (45.2%)	4 (25.0%)	0.024
Lead recall	13 (5.4%)	2 (3.5%)	11 (6.6%)	0	0.409
Pain	4 (1.7%)	2 (3.5%)	2 (1.2%)	0	0.440
Venous occlusion	1 (0.4%)	0	0	1 (6.3%)	0.066

Values are presented as counts (percentages), except where noted otherwise.

AF/AFL, atrial fibrillation/atrial flutter; CABG, coronary artery bypass graft; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction.

more prevalent with escalating number of leads. As lead burden increased, mean left ventricular ejection fraction (LVEF) also was significantly lower (A: 35%, B: 30%, C: 25%; P=0.002). The differences with regard to congestive heart failure and reduced LVEF were to be expected, as patients with advanced left ventricular dysfunction are more often candidates for upgrade to ICD and biventricular devices. This was demonstrated

by the higher number of biventricular ICD devices in Group B (19.6%) and Group C (25.0%) vs. Group A (1.7%), P<0.001. The difference in number of biventricular ICD devices between Group B and Group C was not statistically significant (P=0.856). The same contrast was found regarding the presence of atrial lead (A: 36.2%, B: 79.2%, C: 87.5%; P<0.001; whereas P=0.744 for B vs. C). Indications for lead revision

also differed, with more device or lead malfunctions associated with Group A (Table 1).

Adverse Events

Our study population had 49 total periprocedural or long-term events over the study period, a 20.2% event incidence (49 events/242 patients). Combined periprocedural and late events occurred more frequently with increasing lead burden (A: 5.2% [n=3], B: 23.2% [n=39], C: 44.0% [n=7]; P=0.001) (Figure 1). Major events were rare, occurring in 3.3% of patients (8 events/242 patients). Major events were defined as subsequent infection post-lead abandonment (n=6), cardiac or central venous perforation (n=2), and/or death related to abandoned lead (n=0).

Periprocedural and Inhospital Events

Slightly less than half of the total events (23/49) occurred during the lead revision periprocedural/inhospital period. As lead burden increased, the periprocedural/inhospital event rate increased (A: 3.4% [n=2], B: 10.1% [n=17], C: 25% [n=4]; P=0.031) (Figure 2). These complications (Table 2) included pneumothorax (A: 0% [n=0], B: 0.6% [n=1], C: 6.3% [n=1]; P=0.185), hematoma (A: 0% [n=0], B: 1.2% [n=2], C: 0% [n=0]; P=1.000), spontaneous procedural

arrhythmias requiring treatment (A: 0% [n=0], B: 0.6% [n=1], C: 6.3% [n=1]; P=0.185) and cardiac or central venous perforation (A: 0% [n=0], B: 1.2% [n=2], C: 0% [n=0]; P=1.000). Three patients with redundant leads had coronary sinus lead implantation failures (A: 0% [n=0], B: 1.8% [n=3], C: 0% [n=0]; P=0.651). One patient required additional intervention to attain adequate defibrillation thresholds (A: 0% [n=0], B: 0.6% [n=1], C: 0% [n=0]; P=1.000). Eleven patients (A: 3.4% [n=2], B: 4.2% [n=7], C: 12.5% [n=2]; P=0.280) undergoing device upgrade required a redundant lead-related procedural adjustment such as tunneling, use of a different access site or venoplasty for an occluded vessel. There was no procedure-related or inhospital mortality in any group.

Long-Term Events

There was a 10.7% incidence of events (26 events/242 patients) during long-term follow-up (Table 3). Infection occurred in 6 patients (A: 0% [n=0], B: 3.6% [n=6], C: 0% [n=0]; P=0.452). There were 5 late bleeding episodes (A: 0% [n=0], B: 3.0% [n=5], C: 0% [n=0]; P=0.527). Symptomatic venous thrombosis occurred in 3 patients (A: 1.7% [n=1], B: 1.2% [n=2], C: 0% [n=0]; P=1.000). Four patients had inappropriate ICD shock (A: 0% [n=0], B:

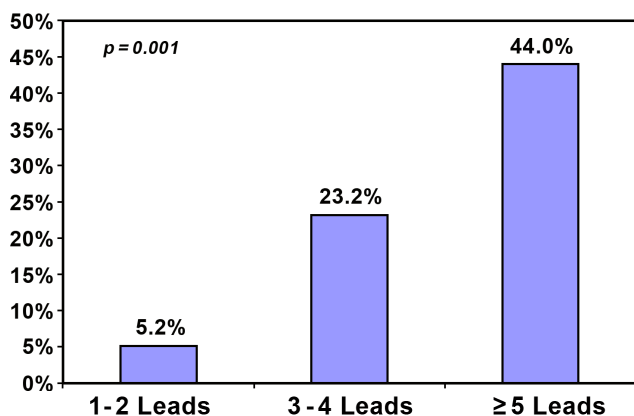


Figure 1. Combined periprocedural and late event rates. Periprocedural events were defined as vein occlusions requiring change in strategy for lead placement, pneumothorax, cardiac or central venous perforation, failure to place new lead, high defibrillation thresholds requiring additional intervention and hematoma. Late events were defined as infection, bleeding, inappropriate implantable cardioverter-defibrillator shock, new atrial arrhythmia and venous thrombosis.

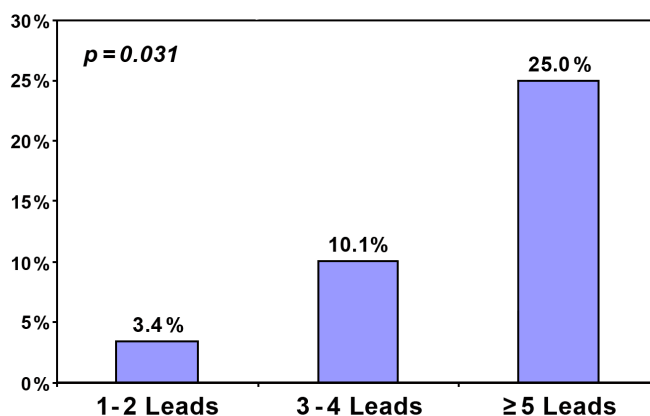


Figure 2. Rates of periprocedural events, defined as vein occlusions requiring change in strategy for lead placement, pneumothorax, cardiac or central venous perforation, failure to place new lead, high defibrillation thresholds requiring additional intervention and hematoma.

Table 2. Periprocedural events

Variable	Overall (N=242)	Number of leads			P
		≤2 (n=58)	3 or 4 (n=168)	≥5 (n=16)	
Vein occlusion requiring procedural adjustment	11 (4.5%)	2 (3.4%)	7 (12.1%)	2 (12.5%)	0.280
Pneumothorax	2 (0.8%)	0	1 (0.6%)	1 (6.3%)	0.185
Central venous or cardiac perforation	2 (0.8%)	0	2 (1.2%)	0	0.185
Lead placement failure	3 (1.2%)	0	3 (1.8%)	0	0.651
Hematoma	2 (0.8%)	0	2 (1.2%)	0	1.000
Spontaneous procedural unstable arrhythmia requiring treatment	2 (0.8%)	0	1 (0.6%)	1 (6.3%)	1.000
Failure to attain adequate defibrillation threshold requiring additional intervention	1 (0.4%)	0	1 (0.6%)	0	1.000
Total events	23 (9.5%)	2 (3.4%)	17 (10.1%)	4 (25.0%)	0.031

Values are presented as counts (percentages).

Table 3. Distribution of late events

Variable	Overall (N=242)	Number of leads			P
		≤2 (n=58)	3 or 4 (n=168)	≥5 (n=16)	
Infection	6 (2.5%)	0	6 (3.6%)	0	0.452
Late bleeding	5 (2.0%)	0	5 (3.0%)	0	0.527
Inappropriate ICD shock	4 (1.7%)	0	3 (1.8%)	1 (6.3%)	0.188
New atrial arrhythmia	8 (3.3%)	0	6 (3.6%)	2 (12.5%)	0.045
Venous occlusion	3 (1.2%)	1 (1.7%)	2 (1.2%)	0	1.000
Total events	26 (10.7%)	1 (1.7%)	22 (13.1%)	3 (18.8%)	0.031

Values are presented as counts (percentages). ICD, implantable cardioverter-defibrillator.

1.8% [n=3], C: 6.3% [n=1]; P=0.188). New atrial arrhythmia presented in 8 patients (A: 0% [n=0], B: 3.6% [n=6], C: 12.5% [n=2]; P=0.045). There was no clinically apparent cardiac or central venous perforation. Combined long-term device-related events significantly increased with greater lead burden (A: 1.7% [n=1], B: 13.0% [n=22], C: 18.8% [n=3]; P=0.031) (Figure 3).

Device-Related Readmission

Patients with increased lead burden had significantly increased frequency of device-related unplanned readmission (A: 3.5%, B: 18.5%, C: 37.5%; P=0.002) (Figure 4). Cause for admission included infection

(occurring after a lead was abandoned), new arrhythmia and inappropriate ICD therapies.

All-Cause Mortality

There were 54 deaths during the follow-up period. No deaths were secondary to device-related issues. Long-term all-cause mortality was not significantly different among the groups (A: 17.2%, B: 23.8%, C: 25.0%; P=0.567) (Figure 5).

DISCUSSION

The management of infected cardiac rhythm devices is straightforward, with lead extraction being the preferred strategy due to the significantly higher

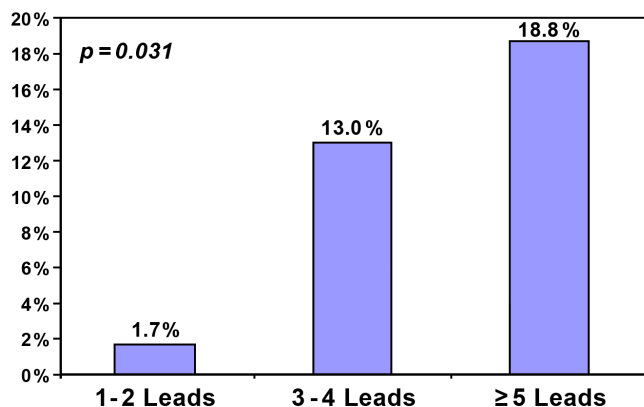


Figure 3. Rates of late events, defined as infection, bleeding, inappropriate implantable cardioverter-defibrillator shock, new atrial arrhythmia and venous thrombosis.

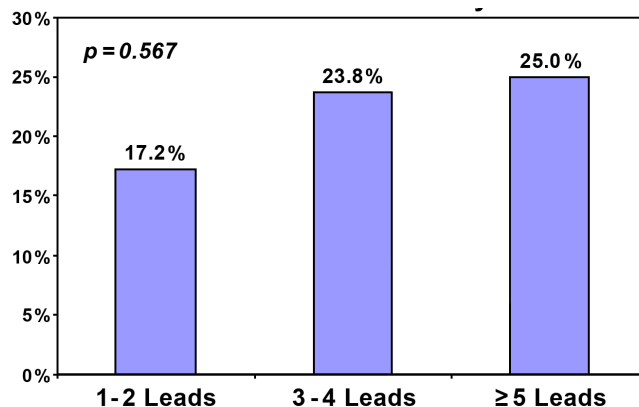


Figure 5. Overall all-cause mortality (obtained from Social Security Death Index).

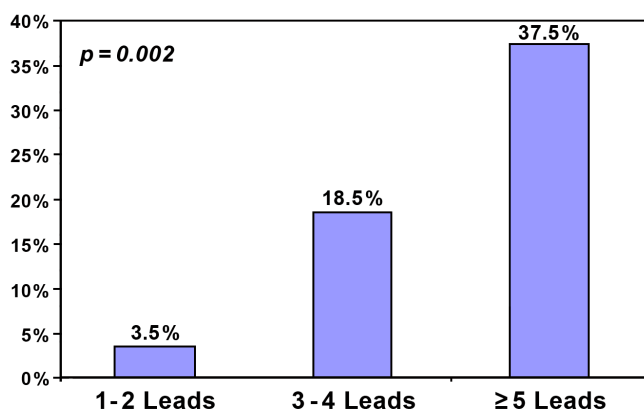


Figure 4. Device-related readmissions. Admissions included patients with infections (occurring after a lead was abandoned), new arrhythmia and inappropriate implantable cardioverter-defibrillator therapies.

mortality rate with medical therapy alone.^{6,7} However, whether to leave sterile pacemaker and ICD leads in place remains controversial. This retrospective study of a single institutional experience had an approximate event rate of 20.2% (3.3% major event rate) over 2-year median follow-up, with no difference in mortality among the groups based on lead burden. Most studies in the literature have reported a low complication rate relating to the continued presence of sterile nonfunctioning leads. An observational study that followed 433 patients with abandoned pacemaker leads over a 21-year period showed a 5.5% complication rate.⁸ Another retrospective study that examined patients with retained infected and noninfected leads

showed a 42% (22/53 patients) major complication rate with retained infected leads, but a 3% (2/66) major complication rate in sterile leads abandoned because of electrical failure.⁷ A study of 152 patients with retained pacemaker leads and mean follow-up of 47.6 months recorded one major event, an infection resulting in death during the attempted extraction procedure.⁹ However, a single-center European retrospective study of 60 patients with nonfunctioning sterile pacemaker leads reported a complication rate of 20% over long-term follow-up,¹⁰ similar to our institutional experience. Our study differed from previous investigations in that it included both patients with ICD and pacemaker leads. In the earlier studies, device therapy was mainly indicated for bradyarrhythmias, as the efficacy of ICD was not proven at that point; thus, most lead systems were pacemakers. One recent study addressed 101 abandoned leads in 78 ICD patients and confirmed the safety of these abandoned leads.¹¹ However, it did not address outcomes in patients with higher lead burden at a given time.

Arguments for more aggressive use of lead extraction are based on prevention of future complications, such as infection, lead-lead interaction, tricuspid regurgitation and venous thrombosis, and preservation of venous access to simplify future procedures. While our study did not show an overall significant number of individual events related to infection, lead interaction or venous thrombosis, nor did it attempt to measure frequency of tricuspid regurgitation, it did show a greater number of combined periprocedural complications associated with

increased number of leads. Patients undergoing repeat procedures such as generator change or device upgrade were more likely to experience minor complications such as hematoma and pneumothorax, but these patients had no significant increase in mortality or major morbidity rates. However, lead extraction may have been a better option in the 11 patients (A: 2, B: 7, C: 2) needing procedural adjustments (e.g. tunneling of a vein, use of an alternate access site, venoplasty of an occluded vessel) during device upgrade related to a redundant lead. If a lead is removed and then replaced by a new lead in the same vein, the contralateral vein is preserved for potential future access. However, there is no evidence that extraction of a lead, with the concomitant insult to the endothelium, will not lead to a greater likelihood of thrombosis in that vein postextraction.

There was a 10.7% incidence rate of events that occurred outside of elective periprocedural periods; incidents included device-related infection (n=6), late bleeding (n=5), symptomatic venous thrombosis (n=3), inappropriate ICD shocks (n=4) and new atrial arrhythmias (n=8). Other than venous thrombosis, it is unclear whether these late events were directly related to the presence of a redundant lead. Some of the long-term complications seen in other studies, such as lead migration, erosion and perforation, were perhaps not seen in our study because all abandoned leads were capped and secured, which was not always the strategy used in older studies. This study is limited in its assessment of long-term follow-up because our median follow-up was 2 years, significantly less than the 20-year follow-up of prior studies.

It is essential to mention that Group C (≥ 5 leads) had higher baseline comorbidities (older population, history of hypertension, more congestive heart failure and lower left ventricular function). Therefore, some of the periprocedural and late events could be caused by these comorbidities rather than the lead burden itself. In terms of periprocedural events, vein occlusion requiring procedural adjustment, pneumothorax and spontaneous procedural arrhythmia requiring treatment were the three factors showing higher events in Group C. Theoretically, vein occlusion was most likely due to the lead burden; pneumothorax could be related to the lead burden, vein occlusion or possibly older age; and spontaneous arrhythmia requiring treatment could

be due to presence of hypertension, heart failure or left ventricular dysfunction in addition to lead burden. The two main factors driving the higher rate of late events in Group C were inappropriate ICD shocks and new atrial arrhythmia. Both of them could be related to lead burden, but also to the cardiac condition of patients (e.g. hypertension, congestive heart failure, lower LVEF). The presence of more new atrial arrhythmia in Group C compared to Group B was not related to atrial leads, as there was no statistical difference between these two groups regarding the presence of atrial lead. Further studies of larger number of patients with more than 5 leads are necessary to evaluate these findings, although this could be difficult to achieve through a single institution.

Whether lead extraction and its 0.4–0.8% risk for death or emergent cardiac surgery is a better option than lead abandonment is uncertain. Optimal management strategy will likely vary from patient to patient and facility to facility. The only modifiable risk factor for complications from lead extraction is operator experience.¹² Centers with limited operator experience will likely prefer an observation strategy. Another aim in the argument for extracting leads is to maintain long-term venous access. Young patients who will likely require several future procedures and be exposed to superfluous leads for longer periods of time may benefit from lead extraction strategy. Patients with venous access issues also may benefit from a lead extraction strategy.

CONCLUSIONS

The results of this study show that complications associated with redundant sterile leads are not necessarily rare, but that major complications and mortality related to superfluous leads are not common. However, patients who undergo additional electrophysiologic procedures are subjected to increased minor complications and access issues during future lead implantations. A lead management strategy of abandonment and observation is likely the best alternative for patients with four or fewer leads who will not require more than one future procedure. On the other hand, in patients with a long life expectancy who are likely to require multiple repeat procedures, have access issues or have more than four leads, a better strategy than abandoning the lead needs to be strongly considered.

Patient-Friendly Recap

- Physicians will often recommend a pacemaker or cardiac defibrillator to manage serious heart rhythm disorders.
- Due to recent advances in technology, the number of these device implantations has dramatically increased.
- Flexible wires called “leads” are used to connect these devices to the heart, and typically run through a vein.
- Some patients undergo multiple implant procedures over the course of their lives, and old leads, while sterile, cease to be used with the new devices.
- The authors report that removing these unused leads may not be necessary. However, leaving old leads in place can lead to minor complications or limit access to needed veins for future procedures.

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Conflicts of Interest

None.

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