学位論文

Transvenous lead extraction versus surgical lead extraction or conservative treatment for cardiac implantable electronic device infections: Propensity score-weighted analyses of a nationwide claim-based database
（植込み型心臓電気デバイス感染に対する経静脈的リード抜去術と外科的リード抜去術または保存的加療との比較）

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Transvenous lead extraction versus surgical lead extraction or conservative treatment for cardiac implantable electronic device infections: Propensity score-weighted analyses of a nationwide claim-based database

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Keywords

pacemaker, implantable cardioverter defibrillator, cardiovascular infection, device removal, excimer laser

Abbreviations

ASD = absolute standardized difference

CI = confidence interval

CIED = cardiac implantable electronic device

DPC = diagnosis procedure combination/per diem payment system

ICD-10 = international classification of diseases, tenth revision

IPW = inverse probability weighting

IQR = interquartile range

MRSA = methicillin-resistant *Staphylococcus aureus*

OR = odds ratio

TLE = transvenous lead extraction

Abstract

Introduction: Infection is one of the most important complications associated with cardiac implantable electronic device (CIED) therapy. The number of reports comparing the outcomes of transvenous lead extraction (TLE), surgical lead extraction, and conservative treatment for CIED infections using a real-world database is limited. This study investigated the association between the treatment strategies for CIED infections and their outcomes.

Methods: We performed a retrospective analysis of 3,605 patients with CIED infections admitted to 681 hospitals using a nationwide claim-based database collected between April 2012 and March 2018.

Results: We divided the 3,605 patients into TLE (n = 938 [26%]), surgical lead extraction (n = 182 [5.0%]), and conservative treatment (n = 2,485 [69%]) groups. TLE was performed more frequently in younger patients and at larger hospitals (p for trend < 0.001). The rate of TLE increased during the study period, whereas that of surgical lead extraction decreased (p for trend < 0.001). TLE was associated with lower in-hospital mortality (vs. surgical lead extraction: odds ratio [OR], 0.20; 95% CI, 0.06–0.70; vs. conservative treatment: OR, 0.45; 95% CI: 0.22–0.94) and lower 30-day readmission rates (vs. surgical lead extraction: OR, 0.18; 95% CI: 0.06–0.56; vs. conservative treatment: OR, 0.06; 95% CI, 0.03–0.13) in propensity score-weighted analyses.

Conclusions: Only 26% of patients with CIED infections received TLE. TLE was associated with significantly lower in-hospital mortality and 30-day recurrence rates than surgical lead extraction and conservative treatment, suggesting that TLE should be more widely recommended as a first-line treatment for CIED infections.

1. Introduction

Cardiac implantable electronic devices (CIEDs) are increasingly used as the population ages and the treatment of arrhythmias and heart failure progresses. Infection is one of the most important complications associated with CIED therapy, and the rate of CIED infections is increasing [1,2]. There are three treatment strategies for CIED infections: (1) transvenous lead extraction (TLE), (2) surgical lead extraction, and (3) conservative treatment without lead extraction. Although TLE is less invasive than surgical lead extraction, it has the risk of fatal complications such as cardiac avulsion or vascular tear. In contrast, conservative treatment has a low risk of complications related to surgery, and several reports demonstrated its efficacy [5,6]. However, there is limited data for comparing their outcomes because of the small number of cases [7,8].

TLE has been performed in Japan since 2010, when excimer laser sheaths became available. Because it has not been long since the widespread implementation of TLE, the frequency rates of surgical lead extraction and conservative treatment could be higher in Japan than in Western countries. Therefore, we compared the outcomes of TLE with those of surgical lead extraction and conservative treatment for CIED infections by analyzing data from a nationwide hospitalization database in Japan.

2. Methods

2.1. Data Source

We conducted a multicenter retrospective observational study using the Japanese Registry of All Cardiac and Vascular Diseases diagnosis procedure combination/per diem payment system (JROAD-DPC). More than 60% of admissions in cardiovascular departments in the Japanese Circulation Society-certified cardiology training facilities in Japan are included in the database. The JROAD-DPC database consists of the following information for each patient discharged: age; sex; height; weight; primary diagnoses/comorbidities/conditions arising after admission based on the International Classification of Diseases, 10th revision (ICD-10) codes; the Charlson comorbidity index, drugs; diagnostic and therapeutic procedures; and discharge status. The diagnoses in this database comprised six categories: main diagnosis; admission-precipitating diagnosis; most resource-consuming diagnosis; second-most resource-consuming diagnosis; comorbidities; and conditions arising after admission. In addition to ICD-10 codes, detailed diagnosis names were listed, ensuring the determination of conditions that cannot be identified using ICD-10 codes alone.

This research was approved by the Institutional Review Board of the National Cerebral and Cardiovascular Center (approval number: R19066). The requirement for individual informed consent was waived because information specific to individuals was not included in the database.

2.2. Study Population

We initially identified 4,361 hospitalization records from 681 hospitals between April 2012 and March 2018 using the ICD-10 codes of T82.7 or T82.8 in any of the "main diagnosis," "admission-precipitating diagnosis," and "most resource-consuming diagnosis." Additionally, the diagnoses recorded in the texts were carefully reviewed to exclude vague diagnoses other than CIED infections. Records with the following criteria were excluded: patients under 20 years old (n = 29), incomplete data (n = 163), and readmission (n = 564). Details of records with incomplete data were as follows: records without height data (n = 139), records without weight data (n = 11), records without medical costs data (n= 9), and records without age data (n = 4). A total of 3,605 hospitalization records were included in the analysis.

2.3. Definition

Patients were divided into the TLE, surgical lead extraction, and conservative treatment groups. Procedure codes used to identify treatment methods and ICD-10 codes used to identify comorbidities are summarized in Supplemental Table 1. If a hospitalization record had both procedure codes for TLE and surgical lead extraction, we assigned it to the TLE group. It was because, in such cases, TLE would have been performed first and switched to surgical lead extraction if TLE was unsuccessful or a fatal complication occurred. Hospitalization records without procedure codes for TLE or surgical lead extraction were assigned to the conservative treatment group; for this group, we identified whether local wound surgery was performed or not using procedure codes shown in Supplemental Table 1. We categorized hospitals into three sizes: more than 500 beds, 100 to 500 beds, and less than 100 beds.

2.4. Outcomes

The outcomes of this study were in-hospital mortality, readmission because of CIED infections within 30 days of discharge, length of hospital stay, and medical costs. We excluded patients who died during the initial hospitalization from the 30-day readmission analysis. We also excluded patients discharged during the fiscal year's last month (i.e., March) from the 30-day readmission analysis to ensure a 30-day follow-up after discharge. Based on the average exchange rate during the study period, 106.7 Japanese Yen was converted to 1 US dollar.

2.5. Statistical Analysis

Categorical data are given as frequency (percentage). Continuous variables were expressed as medians and interquartile ranges (IQRs). The Mann–Whitney U test was performed to compare the two groups. The chi-square test was used to compare categorical variables. The Cochran-Armitage test was used to analyze the trend. Inverse probability weighting (IPW) was used to adjust for confounding factors. The propensity score for each patient was calculated using a logistic regression analysis with the following variables: age, sex, Charlson comorbidity index score, sepsis, and infective endocarditis. We performed a mixed-effects logistic regression or linear regression analysis using the institutes as random intercepts weighted by stabilized inverse propensity scores to estimate the average treatment effect of TLE [9]. If the absolute standardized differences (ASDs) were less than 0.10, we considered the two groups balanced. All statistical comparisons were two-sided, and $p < 0.05$ was considered significant. All statistical analyses were performed using STATA 17.0 (StataCorp LP, College Station, TX, USA).

3. Results

There were 938 patients (26%) in the TLE group, 182 patients (5.0%) in the surgical lead extraction group, and 2,485 patients (69%) in the conservative treatment group (Figure 1). The median age was 77 (69–84) years. Thirty-three percent were female. Patient characteristics in each group are shown in Table 1. The intervals from admission to the first TLE or surgical lead extraction were not significantly different between the TLE and surgical lead extraction groups (median, 6 [3–9] vs. 5 [2–11] days; p = 0.32). One hundred four patients underwent both TLE and surgical lead extraction. Five of the 104 (4.8%) patients underwent TLE first and surgical lead extraction the next day or later. The remaining 99 patients (95%) underwent TLE and surgical lead extraction on the same day. In the conservative treatment group, 1,015 of 2,485 (41%) patients underwent local wound surgery, and the remaining 59% were treated non-surgically. Antibiotic treatment is detailed in Table 1.

Of the younger patients under 60 years old, 31% underwent TLE, thus showing a significant decreasing trend with increasing age (p for trend < 0.001) (Figure 2A). Only 14% of patients aged 90 or older underwent TLE. There was a significant trend between the hospital size and the proportion of patients who underwent TLE (p for trend < 0.001) (Figure 2B). Thirty-six percent of the patients who were admitted to hospitals with 500 or more beds and 12% who were admitted to hospitals with fewer than 500 beds underwent TLE. The rate of TLE significantly increased over time (p for trend < 0.001); conversely, that of surgical lead extraction significantly decreased (p for trend < 0.001) (Figure 2C). The rate of TLE increased from 12% in 2012 to 36% in 2017.

3.1. Outcomes

Outcomes are shown in Table 1. The in-hospital mortality rate was highest in the surgical lead extraction group at 6.0%, and the 30-day readmission rate was highest in the conservative treatment group at 9.4%. The in-hospital mortality and 30-day readmission rates were lowest in the TLE group at 1.0% and 0.8%, respectively.

3.2. TLE vs. Surgical Lead Extraction or Conservative Treatment

The TLE and surgical lead extraction groups and the TLE and conservative treatment groups were each balanced in the propensity score-weighted analyses (Supplemental Figure 1). TLE was significantly associated with lower in-hospital mortality and 30-day readmission rates than surgical lead extraction and conservative treatment (Table 2). The hospital stay for TLE was significantly shorter than that for surgical lead extraction and significantly longer than that for conservative treatment. The medical costs for TLE were significantly lower than those for surgical lead extraction and significantly higher than those for conservative treatment (Table 2).

4. Discussion

Using a nationwide, claim-based retrospective database between 2012 and 2018, we investigated patient characteristics, trends, and clinical outcomes of treatments for CIED infections during the early adoption period of TLE in Japan. TLE was more frequently performed for younger patients and at larger hospitals. The proportion of patients who underwent TLE increased over the years, whereas that of surgical lead extraction decreased. We demonstrated that in-hospital mortality and 30-day readmission rates were lower in patients who underwent TLE than those who underwent surgical lead extraction or conservative treatment. The medical costs required for TLE were more than those for conservative treatment but less than those for surgical lead extraction.

4.1. TLE vs. Surgical Lead Extraction

Few reports compared the outcomes of TLE and surgical lead extraction for CIED infections. In this study, 182 patients underwent surgical lead extraction. Even after adjusting for confounding factors, they had a significantly higher in-hospital mortality rate than those who underwent TLE. Although it is difficult in a clinical setting to refer all patients for TLE and to treat infections according to American and European guidelines, our results suggest that TLE is preferable to conservative treatment of infection or cardiac surgery in all patients, except in exceptional cases such as lack of patient consent, extremely high risk of TLE, or special conditions requiring surgical lead extraction. Surgical lead extraction is recommended for cases with lead vegetations larger than 2.5 cm [4]. Recently, debulking large lead vegetations using a vacuum catheter system has been attempted [10]. The indication for surgical lead extraction might change in the future. Further studies are warranted to determine whether the current status of surgical lead extraction selection is appropriate.

4.2. TLE vs. Conservative Treatment

This study, including 2,485 conservatively treated patients, was the largest in any similar studies reported, and it was the first study to adjust for patient characteristics using a large cohort. Most previous studies included fewer than 40 patients who received conservative treatment for CIED infections and assessed their outcomes [7,8].

The in-hospital mortality rate of the conservative treatment group was 2.0% in this study. This rate was lower than the previously reported rates of 8.4% to 23% [7,8]. The severity of CIED infections can differ greatly among patients. A previous cohort study showed that removing the leads improved survival in patients with CIED-related endocarditis [11]. In our analysis, less than 5% of patients in the conservative treatment group had CIED-related endocarditis. Our results suggest that many patients have mild symptoms associated with CIED infections in the real world and that the mortality rates for such patients are relatively low, in contrast to those reported by previous studies of more patients with CIED-related endocarditis

[7,8].

It should be noted that although the in-hospital mortality of patients with CIED infections treated conservatively was lower than that reported in previous studies, TLE was significantly associated with reduced mortality and recurrence. Guidelines recommend that TLE be performed even in patients with mild symptoms due to CIED infections. However, a recent survey indicated that there is still a knowledge gap between physicians who do and do not perform TLE in treating CIED infections [12]. During the survey, approximately 10% of cardiologists and 40% of non-cardiologist physicians chose partial device removal for CIED pocket infections [12].

Moreover, a low utilization of TLE for severe CIED infections complicated by infective endocarditis has recently been reported [13]. In this report, patients who underwent TLE had a better prognosis than those who did not. Our cohort had a lower number of patients with infective endocarditis. Nevertheless, TLE improved the prognosis, suggesting that TLE should be performed as a first-line treatment for all patients with CIED infection, not just those with severe cases.

4.3. Limitations

There were several limitations to this study. First, it was an observational study analyzing data that were not collected for this study. The database did not include several important factors such as vital signs, patient frailty, type of CIED, and factors related to the difficulty of TLE (e.g., lead dwelling time and the number of leads). Second, only the readmissions to the same hospital were identified in the database; therefore, the readmission rates might be underestimated. Third, although we used robust statistical methods to account for differences between groups, we cannot rule out the possibility of residual confounding factors. Finally, bias might have occurred because we conducted a complete case analysis.

5. Conclusions

In a nationwide Japanese hospitalization database, only 26% of patients with CIED infections received TLE. Although the rate of TLE increased during the study period, TLE tended to be performed for younger patients and at larger hospitals. TLE was preferred for treating CIED infections compared with surgical lead extraction and conservative treatment using propensity score-weighted analyses, suggesting that TLE should be more widely recommended as a first-line treatment for CIED infections.

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Figure Legends

Figure 1. Study flowchart

Records of the initial hospitalizations for cardiac implantable electronic device (CIED) infections were analyzed for in-hospital mortality, length of hospital stay, and medical costs by dividing patients into transvenous lead extraction, surgical lead extraction, and conservative treatment groups. Thirty-day readmission was analyzed after excluding patients who died during the initial hospitalization and those discharged in the last month of the fiscal year.

Figure 2. Relationships between treatment strategies and patient age, hospital size, and hospitalization year

As the patients' age increased, the proportion of transvenous lead extraction (TLE) decreased (p for trend < 0.001). (B) The proportion of TLE was higher at high-volume hospitals (p for trend < 0.001). (C) The rate of TLE increased during the study period (p for trend < 0.001), and that of surgical lead extraction decreased (p for trend < 0.001).

Figure 1

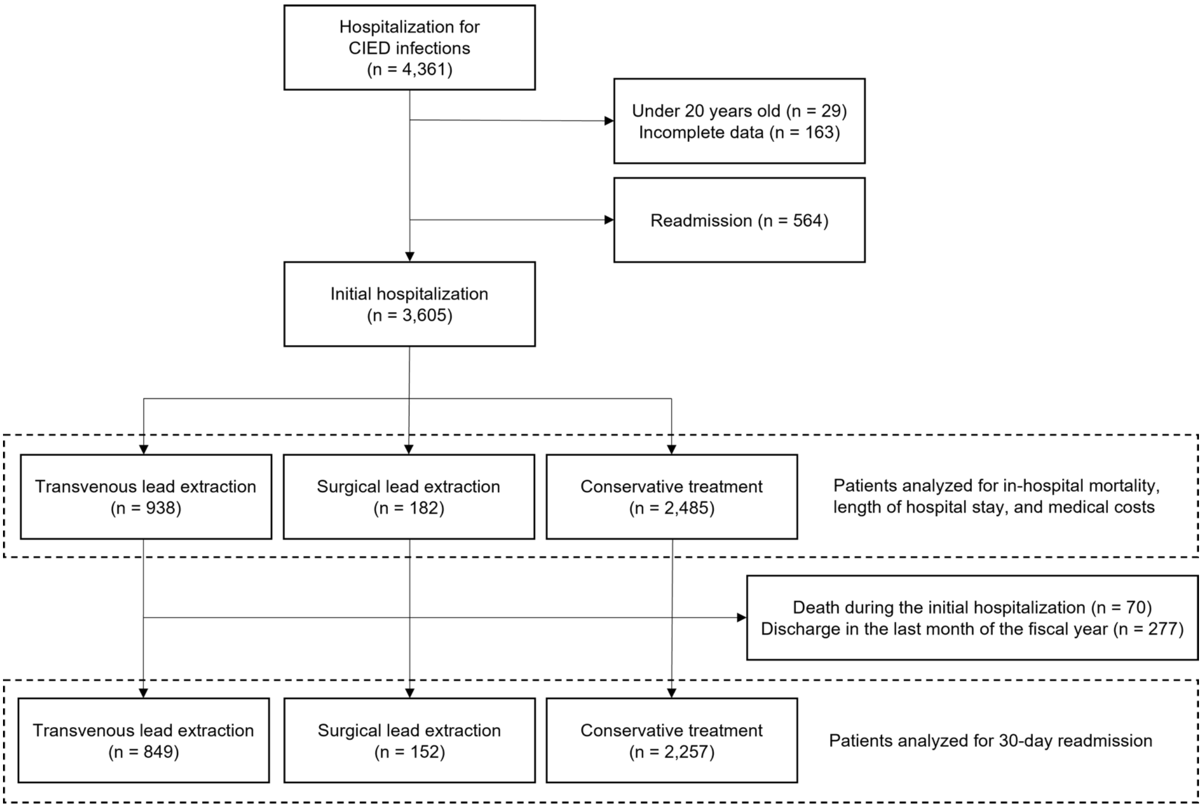


Figure 2

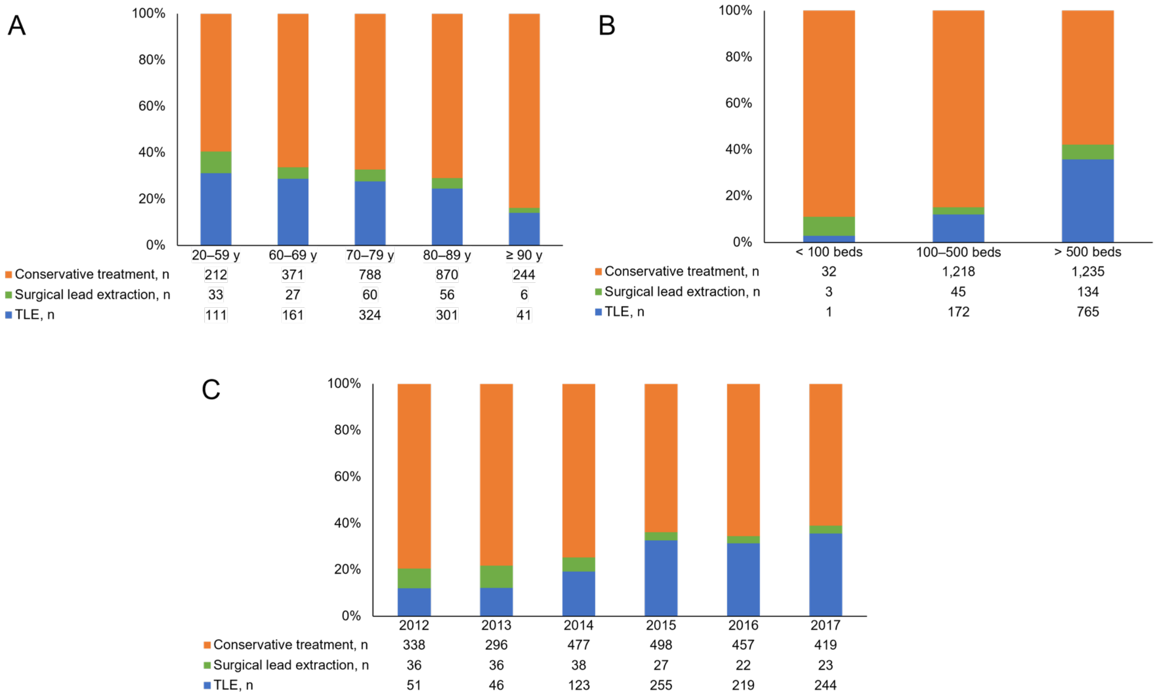


Table 1. Patient characteristics and outcomes

	TLE N = 938	Surgical lead extraction N = 182	Conservative treatment N = 2,485
Age, years	76 (68–82)	75 (64–82)	78 (70–85)
Female	258 (28)	58 (32)	871 (35)
Body mass index, kg/m^2	22.5 (20.3–24.6)	22.4 (19.2–24.4)	22.0 (19.4–24.5)
Congestive heart failure	351 (37)	65 (36)	843 (34)
Myocardial infarction	43 (4.6)	9 (4.9)	86 (3.5)
Renal disease	50 (5.3)	23 (13)	161 (6.5)
Diabetes mellitus	168 (18)	42 (23)	525 (21)
Liver disease	16 (1.7)	4 (2.2)	57 (2.3)
Chronic pulmonary disease	25 (2.7)	6 (3.3)	71 (2.9)
Cerebral vascular disease	27 (2.9)	4 (2.2)	134 (5.4)
Dementia	21 (2.2)	4 (2.2)	96 (3.9)
Cancer	14 (1.5)	7 (3.8)	93 (3.7)
Charlson comorbidity index score			
0	368 (39)	70 (39)	928 (37)
1	356 (38)	51 (28)	839 (34)
≥ 2	214 (23)	61 (33)	718 (29)
Sepsis	56 (6.0)	28 (16)	58 (2.3)
Infective endocarditis	66 (7.0)	34 (19)	103 (4.1)
Antibiotic treatment			
Antibacterial drugs	938 (100)	182 (100)	2,339 (94)
Anti-MRSA drugs†	348 (37)	94 (52)	661 (27)
Antifungal drugs	8 (0.9)	12 (6.6)	18 (0.7)
In-hospital outcomes			
In-hospital death	9 (1.0)	11 (6.0)	50 (2.0)
Length of hospital stay, days	29 (19–49)	39 (23–57)	17 (10–29)
Medical costs, US dollar	29,876 (18,580–39,984)	43,137(24,176–59,864)	7,583 (3,581–17,373)
Readmission‡	N = 858	N = 163	N = 2,307
30-day readmission	7 (0.8)	7 (4.6)	212 (9.4)

IQR = interquartile range; MRSA = methicillin-resistant *Staphylococcus aureus*; TLE = transvenous lead extraction.
†Anti-MRSA drugs included vancomycin, teicoplanin, daptomycin, and linezolid.
‡Patients who died during the initial hospitalization (n = 70) and those discharged in the last month of the fiscal year (n = 277) were excluded from the 30-day readmission analysis.

Table 2. Associations between treatment strategies and outcomes

	TLE vs. Surgical lead extraction			TLE vs. Conservative treatment		
	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value
In-hospital mortality	0.20	0.06–0.70	0.01	0.45	0.22–0.94	0.03
30-day readmission‡	0.18	0.06–0.56	0.003	0.06	0.03–0.13	< 0.001
	Coefficient	95% CI	p-value	Coefficient	95% CI	p-value
Length of hospital stay, days	−12.1	−18.6– −5.7	< 0.001	10.8	8.1–13.5	< 0.001
Medical costs, US dollar	−10,620	−16,139– −5,102	< 0.001	21,218	18,785–23,652	< 0.001

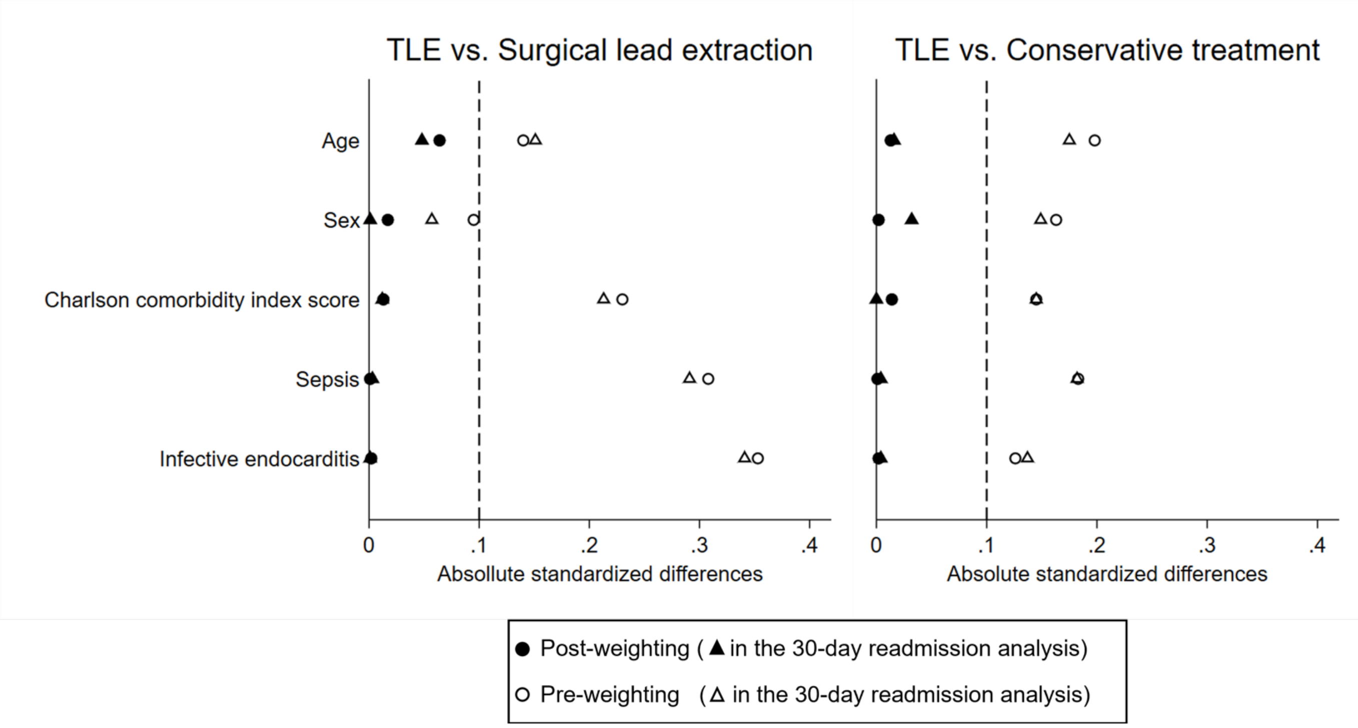
CI = confidence interval; TLE = transvenous lead extraction.
†Mixed-effects analyses using the institutes as random intercepts were performed. Also, inverse probability weighting was performed to adjust the following variables: age, sex, Charlson comorbidity index score, sepsis, and infective endocarditis.
‡Patients who died during the initial hospitalization (n = 70) and those discharged in the last month of the fiscal year (n = 277) were excluded from the 30-day readmission analysis.

Supplemental Table 1. Definition of procedures and comorbidities

Procedures or equipment	Claim codes in the DPC† system
Transvenous lead extraction	
Transvenous lead extraction by excimer laser	K599-5
Excimer laser sheaths	710010608
Lead locking devices	710010963
Snare catheters	710010964
Surgical lead extraction	
Surgery with cardiopulmonary bypass	K601
Intracardiac foreign body removal	K542
Local wound surgery	
Wound surgery	K000, K001
Debridement	K002
Pacemaker implantation or replacement	K597, K598
Implantable cardioverter-defibrillator implantation or replacement	K599
Comorbidities	**ICD-10 codes**
Congestive heart failure	I09.9, I11.0, I13.0, I13.2, I25.5, I42.0, I42.5–I42.9, I43.x, I50.x, P29.0
Myocardial infarction	I21.x, I22.x, I25.2
Renal disease	I12.0, I13.1, N03.2–N03.7, N05.2–N05.7, N18.x, N19.x, N25.0, Z49.0–Z49.2, Z94.0, Z99.2
Diabetes mellitus	E10.x, E11.0, E11.x, E12.x, E13.x, E14.x
Liver disease	B18.x, I85.0, I85.9, I86.4, I98.2, K70.0–K70.4, K70.9, K71.1, K71.3–K71.5, K71.7, K72.1, K72.9, K73.x, K74.x, K76.0, K76.2-K76.9, Z94.4
Chronic pulmonary disease	I27.8, I27.9, J40.x–J47.x, J60.x–J67.x, J68.4, J70.1, J70.3
Cerebral vascular disease	G45.x, G46.x, H34.0, I60.x–I69.x
Dementia	F00.x–F03.x, F05.1, G30.x, G31.1
Cancer	C00.x–C26.x, C30.x–C34.x, C37.x–C41.x, C43.x, C45.x–C58.x, C60.x–C76.x, C81.x–C85.x, C88.x, C90.x–C97.x
Sepsis	I33.0
Infective endocarditis	A40.x, A41.0–A41.5, A41.8, A41.9, B37.7

ICD-10 = international classification of diseases, tenth revision; DPC = diagnosis procedure combination/per diem payment system.
†The DPC is a system used for claiming medical costs in Japan.

Supplemental Figure 1. Absolute standardized differences before and after inverse probability weighting



Inverse probability weighting (IPW) was performed to balance the following variables: age, sex, Charlson comorbidity index score, sepsis, and infective endocarditis. The circle markers indicate the absolute standardized differences (ASDs) in the in-hospital mortality, length of hospital stay, and medical costs analyses. The triangle markers indicate the ASDs in the 30-day readmission analyses. The transvenous lead extraction (TLE) and surgical lead extraction groups and the TLE and conservative treatment groups were balanced by IPW.