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DATA ARTICLE

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Japanese Lead EXtraction (J-LEX) registry: Annual report 2019

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Abstract

Along with the incremental cases of cardiac implantable electronic devices implantation or upgrade, the lead-related complications are also in rise year after year. The most common and serious lead-related complication is infection that needs a transvenous lead extraction (TLE) as the first-line therapy. TLE is also performed for abandoned leads in case of lead failure or device upgrade, and for lead-related trouble such as pain, vessel stenosis or occlusion, too many leads, tricuspid valve regurgitation, and difficulty of radiation therapy. This registration has been performed by the Japanese Heart Rhythm Society and started in July 2018. The first reported data of the Japanese Lead Extraction (J-LEX) from July 2018 to December 2019 were underestimated since the number of patients and hospitals increased gradually because of the approval process of each hospital's IRB. The TLE procedure was attempted to 1253 leads among 661 patients. Complete removal was achieved in 96.7% of the target leads and the clinical success was obtained in 98.9% of the patients. Perioperative complications were observed in 4.1% of the patients. The annual J-LEX report reflects a real-world TLE medicine in Japan and demonstrates that the clinical outcome is similar to former reports from high-volume centers in North America and European countries.

KEY WORDS
complicationimplantable cardioverter-defibrillatorlead extractionpacemakerprospective nationwide registry

Along with the incremental cases of cardiac implantable electronic devices implantation or upgrade, the lead-related complications are also in rise year after year. The most common and serious lead-related complication is infection. The first-line treatment of device infection is a transvenous lead extraction (TLE), which has grown to be a standard procedure in Japan.[1] TLE is also performed for abandoned leads in case of lead failure or device upgrade, and for lead-related trouble such as pain, vessel stenosis or occlusion, too many leads, tricuspid valve regurgitation, and difficulty of radiation therapy.[2]

Several registries of TLE have been reported, but they consisted of voluntary registration mainly from high-volume centers in North America[3] and European countries.[4] Accordingly, we conducted a nationwide, mandatory, multi-center, prospective, observational registry in Japan. This registration has been performed by the Japanese Heart Rhythm Society in collaboration with the National Cerebral and Cardiovascular Center using a Research Electronic Data Capture system. This study has been conducted according to the methods of the previously published design paper,[5] under the approval from the Institutional Review Board (IRB) of NCVC (M29-146, February 23, 2018), along with the IRBs of all participating hospitals.

Since the start of the Japanese Lead Extraction (J-LEX) registry in July 2018, the number of patients and hospitals increased gradually because of the approval process of each hospital's IRB as shown in Figure 1. The TLE procedure was attempted to 1253 leads among 661 patients. The average age of the registered patients were 70.9 years and were mostly male (68.4%) (Figure 2A). The body mass index (BMI) was smaller than previous reports from western countries.[3,4] Comorbidity of ischemic heart disease was rare. The age distribution demonstrated that 62.6% of the subjects were more than 70 years (Figure 2B). The TLE procedure was performed in hybrid operating room (HBOR) in 50.5%, in standard operating room with a C-arm fluoroscope in 26.3%, and in catheter laboratory in 23.2% (Figure 3A). The method of anesthesia was mainly general anesthesia in 72.0% (Figure 3B). The indication of TLE was infection in 62.8% (Figure 3C). The average number of extracted leads per patient was 1.9 (Figure 3D). The type of extracted lead was pacemaker lead in 78.6%, implantable cardioverter-defibrillator lead in 15.4%, and cardiac resynchronization left ventricular lead in 5.8% (Table 1A). Multiple lead extraction techniques were used in most patients and the laser sheath plus a locking stylet was the most common (Table 1B). "Complete removal" that means all parts of the lead(s) were extracted was achieved in 96.7% of the target leads, and "clinical success" that means complete removal or partial removal (retention of the small lead material less than 4 cm) without a negative impact of clinical goal was obtained in 98.9% of the patients (Table 1C). Perioperative complications were observed in 4.1% of the patients (Table 1D).

The 2019 annual J-LEX report presented here reflects a real-world TLE medicine in Japan because it is a nationwide prospective mandatory registry of TLE and demonstrates that the clinical outcome is acceptable and not inferior to former reports from high-volume centers in North America and European countries.

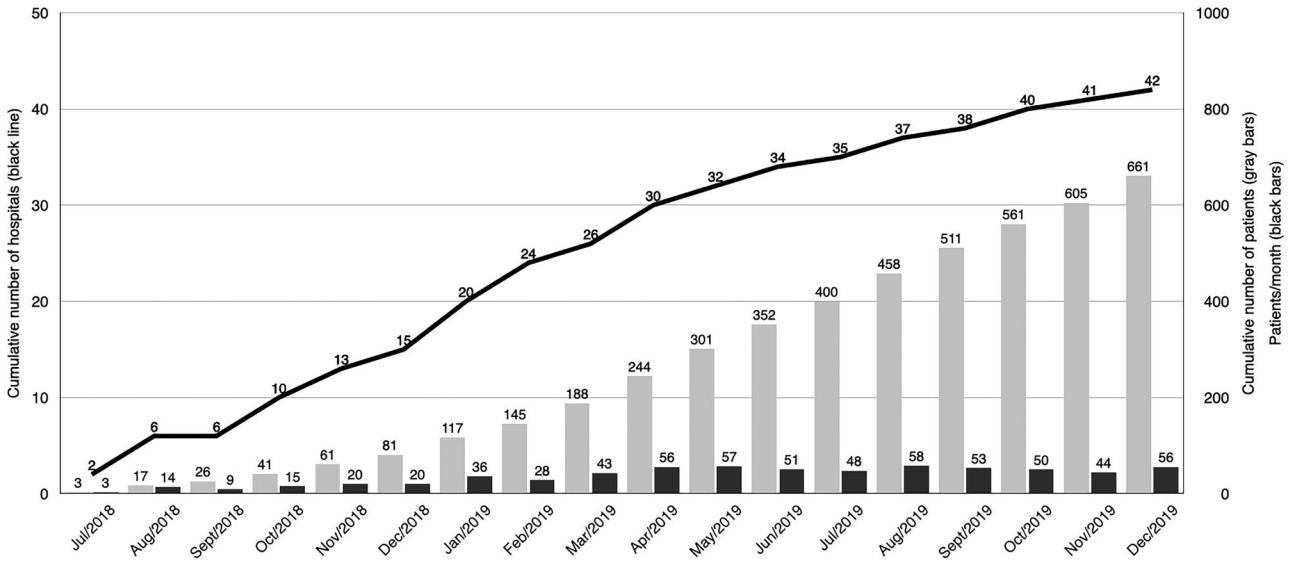


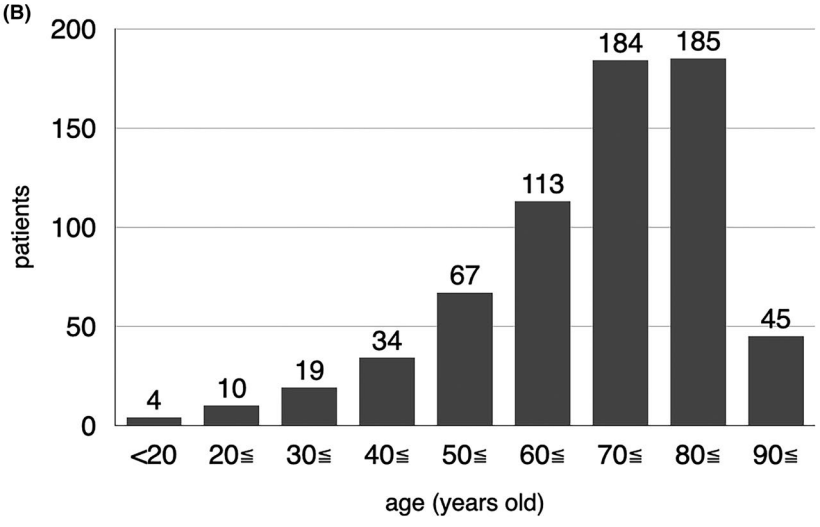
FIGURE 1 Monthly registered patient from January 2018 to December 2019 (black bars), cumulative number of patients (gray bars) and hospitals participating in the J-LEX registry (black line)

FIGURE 2 (A) Patient characteristics of the registered patients ($n = 661$). (B) Age distribution of patients. BMI; body mass index

(A)

Patient characteristics (n=661)	
Age, mean year ± SD	70.9 + 15.4
Gender, male, n (%)	452 (68.4)
BMI, mean ± SD	22.6 + 3.8
Number of former TLE procedure, n (%)	
None	634 (95.9)
1≤	27 (4.1)
Comorbidity, n (%)	
Ischemic heart disease	130 (19.7)
Non-ischemic heart disease	256 (38.7)
Hypertension	307 (46.4)
Diabetes mellitus	174 (26.3)
Hemodialysis	36 (5.5)
History of open heart surgery	93 (14.1)

(B)



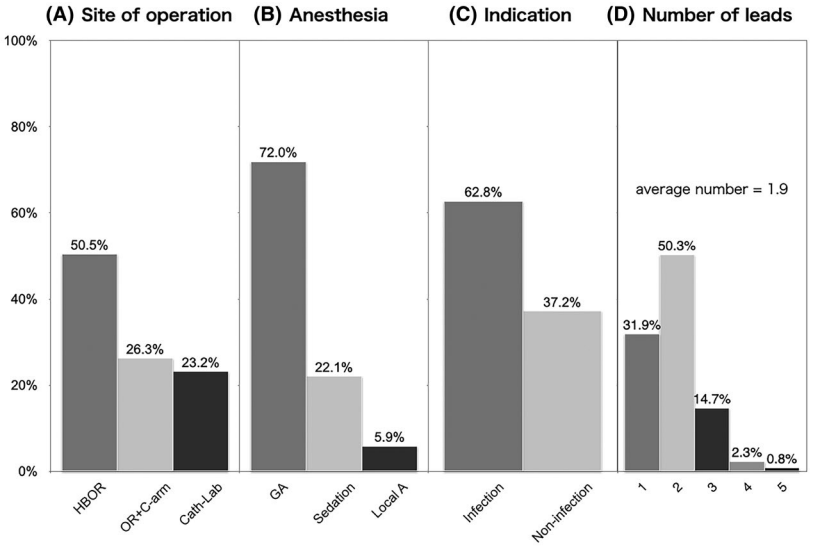


FIGURE 3 Site of lead extraction operation (A), a method of anesthesia (B), indication of lead extraction (C), and number of target leads for transvenous lead extraction (D). Cath-lab; catheter laboratory, GA; general anesthesia, HBOR; hybrid operating room

TABLE 1 (A) Extracted leads. (B) Methods of lead extraction. Multiple methods were used in selected patients. The surgical-only lead extraction was excluded from the registry. (C) Outcome of extraction. "Partial removal" means the retention of the small lead material less than 4 cm that did not negatively impact the clinical goals. (D) Complications per patient. "Cardiac tamponade" means pericardial effusion that negatively affected hemodynamics

(A) Extracted leads	*n*	%
Pacemaker, unipolar	22	1.8
Pacemaker, bipolar	942	75.2
Pacemaker, VDD	20	1.6
ICD, single coil	85	6.8
ICD, dual coil	108	8.6
ICD, patch	0	0.0
ICD, only coil	0	0.0
LV, unipolar	4	0.3
LV, bipolar	25	2.0
LV, quadripolar	44	3.5
LV, active fixation	1	0.1
Other	1	0.1
Unknown	1	0.1
(B) Methods of lead extraction	***n***	**%**
Simple traction	280	22.4
Locking stylet	955	76.2
Mechanical sheath	229	18.3
Laser sheath	887	70.8
Rotational mechanical sheath	255	20.4
Other power sheath	5	0.4
Snare	150	12.0
Surgical (open chest)	10	1.0
Surgical (open heart)	12	1.0
(C) Outcome of lead extraction	***n***	**%**
Per lead		
Complete removal	1211	96.7
Partial removal	34	2.7
Unsuccess	6	0.5
Suspended by complication	2	0.2
Per patient		
Clinical success	654	98.9
Complete success	623	94.2
Partial success	31	4.7
Failure	7	1.1
(D) Complications	***n***	**%**
Perioperative complication	24	4.1
Pericardial effusion	2	0.3
Cardiac tamponade	7	1.1
No intervention	0	0.0
Pericardiocentesis	3	0.5
Surgical repair	4	0.6
Hemothorax	1	0.2
No intervention	0	0.0
Intervention	1	0.2
Other bleeding	12	1.9
No BTF	3	0.5
BTF	9	1.4
AV fistula	1	0.2
Pulmonary embolism	0	0.0
No intervention	0	0.0
Intervention	0	0.0
Other	3	0.5
Perioperative death	0	0.0
In-hospital death	6	1.0
Cardiac	2	0.3
Non-cardiac	4	0.6

Abbreviation: AV fistula; atrioventricular fistula, BTF; blood transfusion, ICD; implantable cardioverter-defibrillator, LV; left ventricle.

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CONFLICT OF INTEREST

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