



DATA ARTICLE

The Japanese lead extraction registry (J-LEX): Annual report 2020

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Abstract

The Japanese Heart Rhythm Society established a nationwide, mandatory, multi-center, prospective, observational registry of transvenous lead extraction (TLE) named the Japanese lead extraction registry (J-LEX) in 2018. We have published the first annual report of J-LEX with 661 cases from 42 hospitals. The second annual report of J-LEX in 2020 enrolled increased numbers of 785 cases from 75 hospitals. TLE procedure was attempted on patients with an average age of 71.7 years old, male in 72.5% in the hybrid operating room in 57.9%, and in standard OR with a C-arm fluoroscope in 18.7%. The indication of TLE was an infection in 62.8% and the guideline classification was class-I in 67.4% and class-IIa in 23.8%. The average implantation duration of target leads was 7.9 years. Complete removal was achieved in 96.6% of the target leads and clinical success in 98.1% of the patients. Perioperative complications were observed in 7.1% of the patients. One patient died during a TLE operation and the other three patients died in-hospital (cardiac death in one patient and non-cardiac in two patients). Although the annual J-LEX report in 2020 demonstrated an increased number of TLE procedures despite the first pandemic year of coronavirus

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disease-2019 (COVID-19), perioperative complications increased a little in comparison with J-LEX 2019.

KEYWORDS

complication, implantable cardioverter defibrillator, lead extraction, pacemaker, registry

The Japanese Heart Rhythm Society established a nationwide, mandatory, multi-center, prospective, observational registry of transvenous lead extraction (TLE) named the Japanese lead extraction registry (J-LEX) in 2018. This registration has been conducted according to the methods of the previously published design paper,¹ under the approval from the Institutional Review Board (IRB) of the National Cardiovascular Center (M29-146, February 23, 2018), along with the IRBs of all participating hospitals. We have published the first annual report of J-LEX with 661 cases from 42 hospitals.² The second annual report of J-LEX in 2020 enrolled increased numbers of 785 cases from 75 hospitals despite the coronavirus disease-2019 (COVID-19) pandemic year (Figure 1). TLE procedure was attempted on the patients from January to December in 2020 with an average age of 71.7 years old, male in 72.5%, and body mass index (BMI) smaller than previous reports from western countries^{3,4} (Figure 2). The TLE procedure was performed in a hybrid operating room (HBOR) in 57.9%, in the standard operating room with a C-arm fluoroscope in 18.7%, and in a catheter laboratory in 23.4% (Figure 3A). The method of anesthesia was mainly general anesthesia in 75.7% (Figure 3B). The indication of TLE was an infection in 62.8% and the guideline classification⁵ was class-I in 67.4%, class-IIa in 23.8%, and class-IIb in 8.8% (Figure 3C). The average number of extracted leads per patient was 1.9 (Figure 3D). The type of extracted lead

was pacemaker lead in 80.3%, implantable cardioverter-defibrillator lead in 14.8%, and cardiac resynchronization left ventricular lead in 4.7% (Table 1A). The average implantation duration of target leads was 7.9 ± 7.0 years (Table 1B). Multiple methods of lead extraction were used in many cases: laser sheaths (GlideLight, Philips) were used for 67.5% of leads, rotational mechanical sheaths (Evolution RL, Cook Medical) for 26.2% of leads, and mechanical sheaths (Cook Medical) for 16.6% of leads. Also, snaring techniques were used for 15.2% of the leads. Complete removal means all parts of the lead(s) were extracted was achieved in 96.6% of the target leads and clinical success means complete removal or partial removal (retention of the small lead material less than 4 cm) without a negative impact on clinical goal was obtained in 98.1% of the patients (Table 1E). Perioperative complications were observed in 7.1% of the patients (Table 1D). Open surgical procedures were performed for lead remnants, infected vegetations, or bleeding complications for 28 leads. One patient died during a TLE operation and the other three patients died in-hospital (cardiac death in one patient and non-cardiac in two patients).

Although the annual J-LEX report in 2020 demonstrated an increased number of TLE procedures despite the first pandemic year of COVID-19 and acceptable clinical outcomes, perioperative complications increased a little in comparison with J-LEX 2019.

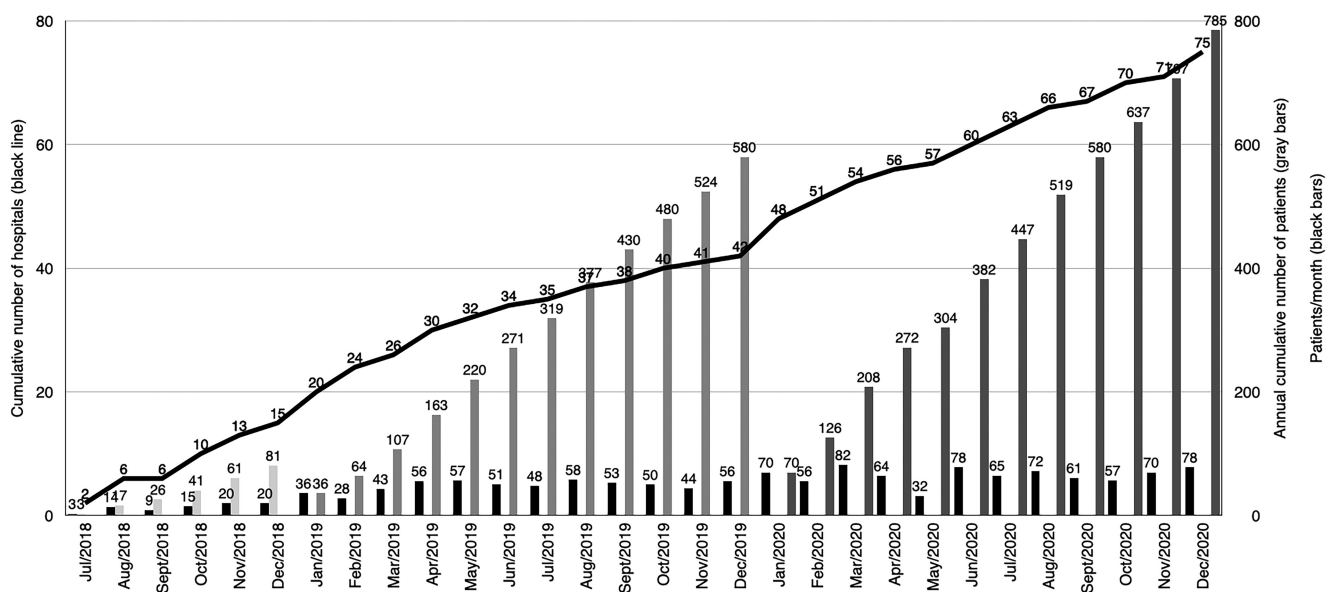


FIGURE 1 Monthly registered patients from January 2018 to December 2020 (black bars), the annual cumulative number of patients (2020; dark gray bars, 2019; gray bars, 2018; light gray bars), and cumulative number of hospitals participating in the J-LEX registry (black line)

(A)

Patient characteristics (n = 785)	
Age, mean year ± SD	71.7 + 14.8
Gender, male, n (%)	569 (72.5)
BMI, mean ± SD	22.7 + 3.8
Number of former TLE procedure, n (%)	
None	754 (96.0)
1≤	31 (4.0)
Comorbidity, n (%)	
Ischemic heart disease	163 (20.8)
Non-ischemic heart disease	263 (33.5)
Hypertension	367 (46.8)
Diabetes mellitus	215 (27.4)
Hemodialysis	45 (5.7)
History of open heart surgery	112 (14.3)

(B)

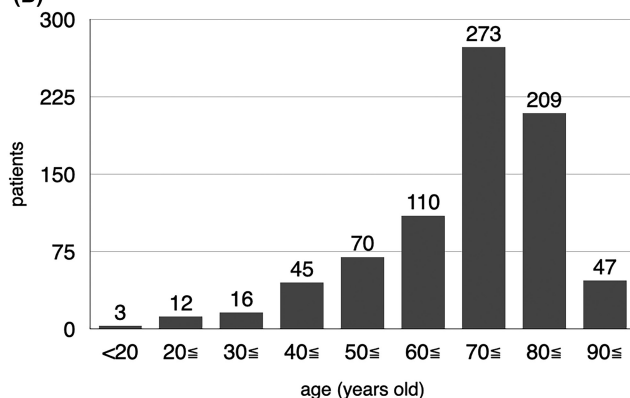


FIGURE 2 (A) Patient characteristics of the registered patients (n = 785). (B) Age distribution of patients. BMI, body mass index

TABLE 1 (A) Extracted leads. (B) Implantation duration of the extracted leads. (C) Lead status. (D) Methods of lead extraction. Multiple methods were used in selected patients and the surgical-only lead extraction was excluded from the registry. (E) Outcome of extraction “per lead” and “per patient.” The definitions of “success” were shown in the main document. (F) Complications per patient. “Cardiac tamponade” meant pericardial effusion, that negatively affected hemodynamics

(A) Extracted leads (n = 1511)

	n	%
Pacemaker, unipolar	33	2.2
Pacemaker, bipolar	1167	77.2
Pacemaker, VDD	14	0.9
ICD, single coil	116	7.7
ICD, dual coil	103	6.8
ICD, patch	0	0.0
ICD, only coil	4	0.3
LV, unipolar	3	0.2
LV, bipolar	17	1.1
LV, quadripolar	52	3.4
LV, active fixation	0	0.0
Other	2	0.1
Unknown	0	0.0

(B) Lead age (n = 1472)

7.9 ± 7.0 years

(C) Lead status (n = 1511)

	n	%
Non-recall, function	1214	80.3
Non-recall, non-function	269	17.8

(Continues)

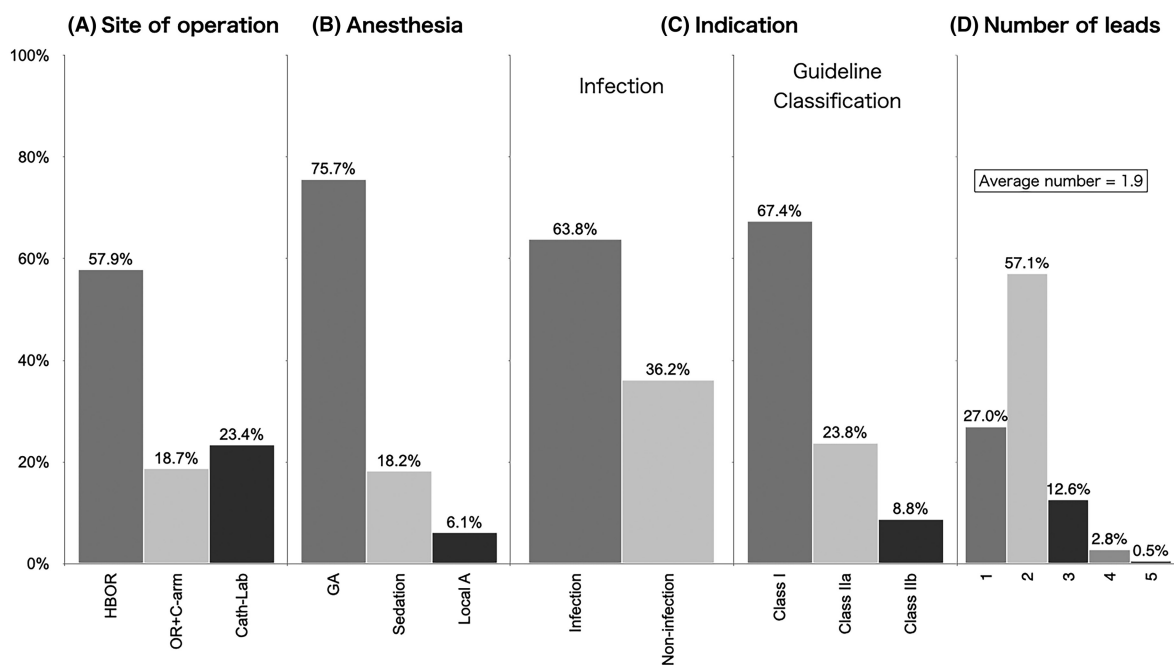


FIGURE 3 Site of lead extraction operation (A), a method of anesthesia (B), indication of lead extraction (C), and the number of target leads for transvenous lead extraction (D). Cath-lab; catheter laboratory, GA; general anesthesia, HBOR; hybrid operating room

TABLE 1 (Continued)

Recall, function	8	0.5
Recall, non-function	20	1.3
(D) Methods of lead extraction (n = 1511)		
	n	%
Simple traction	395	26.1
Locking stylet	1122	74.3
Mechanical sheath	250	16.6
Laser sheath	1020	67.5
Rotational mechanical sheath	396	26.2
Other power sheath	9	0.6
Snare	230	15.2
Surgical (open chest)	4	0.3
Surgical (open heart)	24	1.6
(E) Outcome of lead extraction		
Per lead (n = 1511)	n	%
Complete removal	1460	96.6
Partial removal	33	2.2
Unsuccess	17	1.1
Suspended by complication	1	0.1
Per patient (n = 785)	n	%
Clinical success	770	98.1
Complete success	738	94.0
Partial success	32	4.1
Failure	14	1.8
Unknown	1	0.1
(F) Complications (n = 785)		
	n	%
Perioperative complication	55	7.0
Pericardial effusion	8	1.0
Cardiac tamponade	13	1.7
No intervention	0	0.0
Pericardiocentesis	3	0.4
Surgical repair	10	1.3
Hemothorax	3	0.4
No intervention	0	0.0
Intervention	3	0.4
Other bleeding	20	2.6
No BTF	7	0.9
BTF	13	1.7
AV fistula	0	0.0
Pulmonary embolism	1	0.1
No intervention	1	0.1
Intervention	0	0.0
Other	10	1.3
Perioperative death	1	0.1
In-hospital death	3	0.4
Cardiac	1	0.1
Non-cardiac	2	0.3

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

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REFERENCES

- Shoda M, Kusano K, Goya M, Nishii N, Imai K, Okamoto Y, et al. Study Design of the Nationwide Japanese Lead Extraction (J-LEX) registry: protocol for a prospective, multicenter, open registry. *J Arrhythm*. 2020;36:849–53.
- Shoda M, Kusano K, Goya M, Nishii N, Imai K, Okamoto Y, et al.; J-LEX registry investigators. Japanese Lead Extraction (J-LEX) registry: annual report 2019. *J Arrhythm*. doi:<https://doi.org/10.1002/joa3.12678>.
- Wazni O, Epstein LM, Carrillo RG, Love C, Adler SW, Riggio DW, et al. Lead extraction in the contemporary setting: the LEXCon study: an observational retrospective study of consecutive laser lead extractions. *J Am Coll Cardiol*. 2010;55:579–86.
- Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA, et al. The European Lead extraction ConTRolled (ELECTRa) study: a European heart rhythm association (EHRA) registry of transvenous lead extraction outcomes. *Eur Heart J*. 2017;38:2995–3005.
- Nogami A, Kurita T, Abe H, Ando K, Ishikawa T, Imai K, et al. Guideline on non-pharmacotherapy of cardiac arrhythmias. *J Arrhythm*. 2019;2021(37):709–870.

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