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ORIGINAL ARTICLE

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Study Design of the Nationwide Japanese Lead Extraction (J-LEX) Registry: Protocol for a Prospective, Multicenter, Open Registry

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Abstract

Background: Transvenous lead extractions (TLEs) in Japan have grown to become the standard therapy since the approval of the laser extraction system in 2008. However, little is known about the current indications, methods, success rate, and acute complications in the real-world setting.

Methods: The Japanese Lead EXtraction (J-LEX) registry is a nationwide, multicenter, observational registry, performed by the Japanese Heart Rhythm Society (JHRS) in collaboration with the National Cerebral and Cardiovascular Center. This study is a nationwide registry ordered by the JHRS and its data are collected prospectively using the Research Electronic Data Capture (REDCap) system. The acute success rate at discharge and complications associated with TLEs will be collected in all cases. Based on the provided information, the annual incidence and predictive factors for the outcomes will be investigated by the Event Assessment Committee (EAC). This registry started in July 2018 and the number of participating medical institutions will be more than 50 hospitals and the target number of procedures will be 500-1000 per year. We will also compare the results with other registries in foreign countries.

Result: The results of this study are currently under investigation.

Conclusion: The J-LEX registry will provide real-world data regarding the results and complications of TLEs for the various types of indications, methods, and performing hospitals in Japan.

KEYWORDS
cardiac implantable electronic device, complication, J-LEX, lead extraction, REDCap

1 | INTRODUCTION

The use of cardiac implantable electronic devices (CIEDs) has become more popular in recent years not only for bradyarrhythmias but also for life-threatening ventricular arrhythmias or advanced heart failure. Along with incremental cases of CIED implantations/up-grades, lead-related complications are also rising year by year. The most common and serious lead-related complication is an infection. Device infections may occur after a new device implantation with an incidence of 0.5%–2% and device exchanges or up-grades with that of 1%–3%.[1-6] The only curative treatment of device infections is a lead extraction (LE) which has grown to be the standard procedure in Japan.[7-10] Less invasive transvenous LEs (TLEs) may also be performed for abandoned leads in the case of a lead failure or device up-grade, and for lead-related troubles such as pain, vessel stenosis or occlusions, too many leads, tricuspid valve regurgitation, or difficulty with chest radiation therapy.[11-14] Although TLE complications seem to be acceptable, some major complications such as a cardiac tamponade and hemothorax sometimes occur and lead to a catastrophic outcome. Therefore, a careful assessment of the risk of an LE or whether or not to leave the lead should be required before the procedure.

Excimer laser sheaths were approved by the Ministry of Health and Labour Welfare (MHLW), Japan in 2008, mechanical dilator sheaths in 2015, and controlled-rotation dilator sheaths in 2018.[12] The number of TLE cases and centers has increased accordingly with all these TLE medical tools became approved in Japan. There are several preceding LE registries in North America[15,16] and European countries,[17] and the majority have collected data from selected centers to reveal the current status of LEs. However, such data from selected institutions does not always reflect the clinical practice in the real world. Accordingly, the Japanese Heart Rhythm Society (JHRS) and National Cerebral and Cardiovascular Center (NCVC) conducted a nationwide, multicenter registry in Japan, named the Japanese Lead Extraction (J-LEX) registry in 2018. In contrast to the preceding registries, this is a prospective nationwide multicenter registry designed to collect the clinical variables and short-term outcome data, aiming to register all TLE cases performed in Japan.

2 | METHODS

2.1 | Objectives

This study is a nationwide registry, controlled by the JHRS, in collaboration with the NCVC. The objectives of this registry are to observe and describe the developments in the TLE procedures in Japan and to provide reliable information on the indications, methods, success rate, complications, and 30 day prognosis.

2.2 | Study population

A total of 500-1000 patients per year from more than 50 hospitals will be investigated. The inclusion criteria are patients who undergo TLEs with or without LE tools such as a mechanical dilator sheath (Byrd Dilator Sheath Sets; Cook Medical, USA), controlled-rotation dilator sheath (Evolution; Cook Medical, USA), excimer laser sheath (GlideLight; Philips, Netherland), lead locking device (LLD; Philips, Netherland, and/or Liberator; Cook Medical, USA), snare (Needle's Eye Snare; Cook Medical, USA and/or Goose Neck Snares; Medtronic, USA, and/or Lassos; Osypka, Germany), or others. The method and result of TLEs will be recorded for each of the extracted leads. Patients who receive an open-chest surgical extraction alone will be excluded from the registry; however, hybrid procedures with open-chest and transvenous techniques will be included.

2.3 | Data acquisition and analysis

The data are collected prospectively using the REDcap system. After approval of the local institutional review board (IRB) committee of the participating institutions, the physician will register the TLE cases online into the J-LEX system. We will collect the data on the patients, lead characteristics, medical history, details of the LE procedure, lead characteristics, and outcomes. The data management will be performed by the J-LEX secretariat at the NCVC. All of the compiled data will remain anonymous, even to the registry coordinators, without any identifying information of the patients. Based on the provided information, the annual incidence and predictive factors of the outcomes will be investigated by the Event Assessment Committee (EAC). All results of the J-LEX, including the number of cases performed, methods, outcomes, and complications, will be published and/or reported at the respective scientific meetings.

2.4 | Study schedule

This study started in July 2018 and is now recruiting participating medical institutions.

2.5 | Ethics

This study is registered in the Umin Clinical Trial Registry (UMIN000036078) and ClinicalTrials.gov (NCT04345627). This study is being conducted in accordance with the Declaration of Helsinki and Ethical Guidelines for Clinical Studies issued by the MHLW, Japan, and has received approval from the IRB of NCVC, Japan (M29-146, February 23, 2018), along with the IRBs of all participating institutions. All participants will provide a written informed consent and the subjects may withdraw their consent at any time.

3 | RESULTS

Figure 1 demonstrates the number of the monthly accumulated participating centers and the registered TLE cases during the first 20 months since the beginning of this registry. Figure 2 shows the geographic distribution of the participating institutions as of March 2020. The detailed analyses of this study are currently under investigation and will be published elsewhere in the near future.

4 | DISCUSSION

The use of CIEDs has recently increased.[18-21] With the expanded CIED use and indications, CIED-related infections, lead revisions, and system upgrades have also increased globally. As a result, opportunities for lead extractions have become a usual practice in our CIED management scenario.

In Japan, TLE tools and excimer laser sheaths were first approved by the MHLW, Japan in 2008.[7-10,12] The number of TLEs during the first 3 years was only 98 performed in 9 certified hospitals, and now, more than 600 transvenous lead extractions were performed in more than 50 hospitals in 2019, resulting in more than 4,000 cases over the past decade. In spite of the expansion of patients and hospitals, the current status of TLEs in Japan, including the indications, methods, clinical outcomes, complications, and prognoses, has remained unclear. The J-LEX is designed as a prospective Japanese nationwide multicenter registry to collect the clinical variables and perioperative outcome data. The amount of data and variety of aspects covered by this registry will give new insights into the CIED practice in Japan as well as the world. Additionally, since the J-LEX is not a voluntary, but a mandatory registration controlled by the JHRS, precise, accurate, and reliable data will be collected. Therefore, comparative investigations between infectious indications and non-infectious indications, pacemaker leads and shock leads, high-volume centers and low-volume centers, etc, can be fulfilled in the real world.

The registry items for each case in the J-LEX are not complicated but are rather simple since the basic concept of this registry is to gather all the TLE cases in Japan; however, we can collect detailed lead extraction data in all cases during the period the J-LEX will be carried out. We believe that this nationwide Japanese

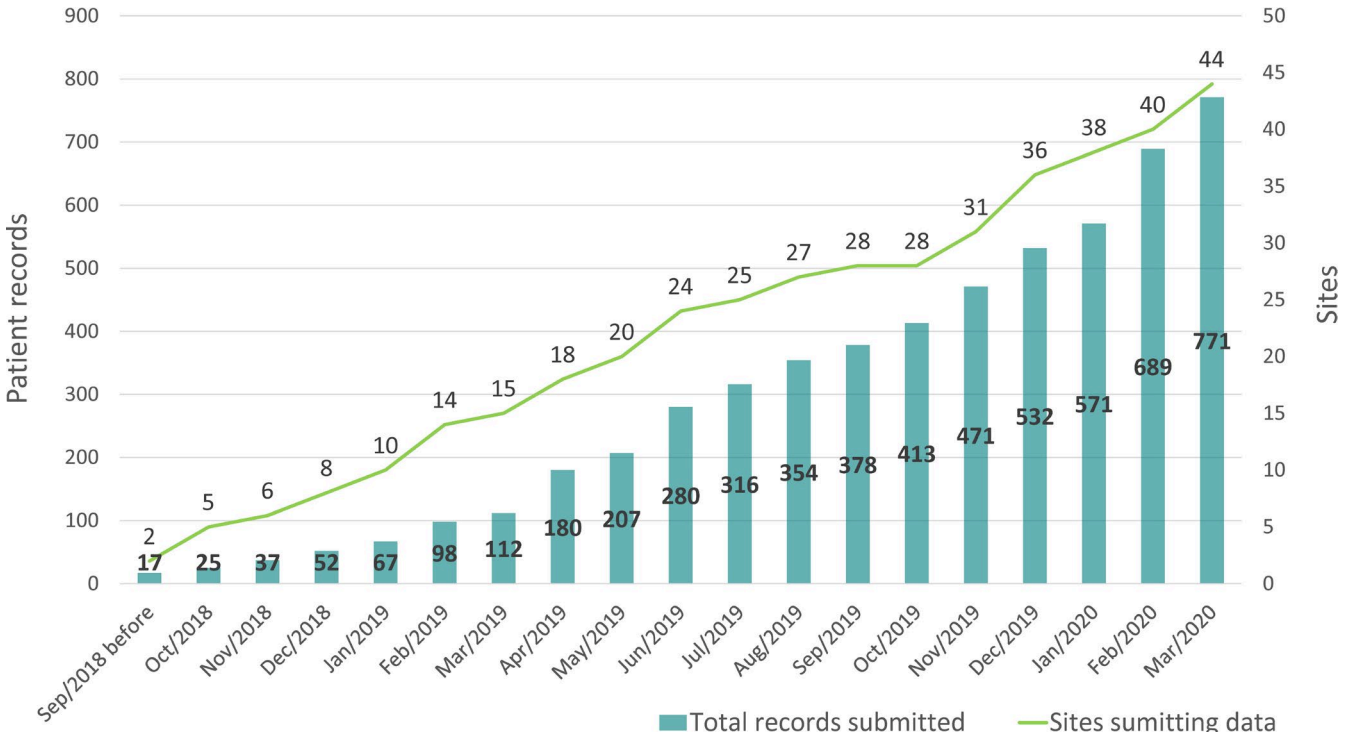

FIGURE 1 Number of patients and participating institutions. The patients were enrolled from July 2018 to March 2020. The left and right vertical axes indicate the total number of patients enrolled (blight green line) and total number of participating institutions (green bars), respectively

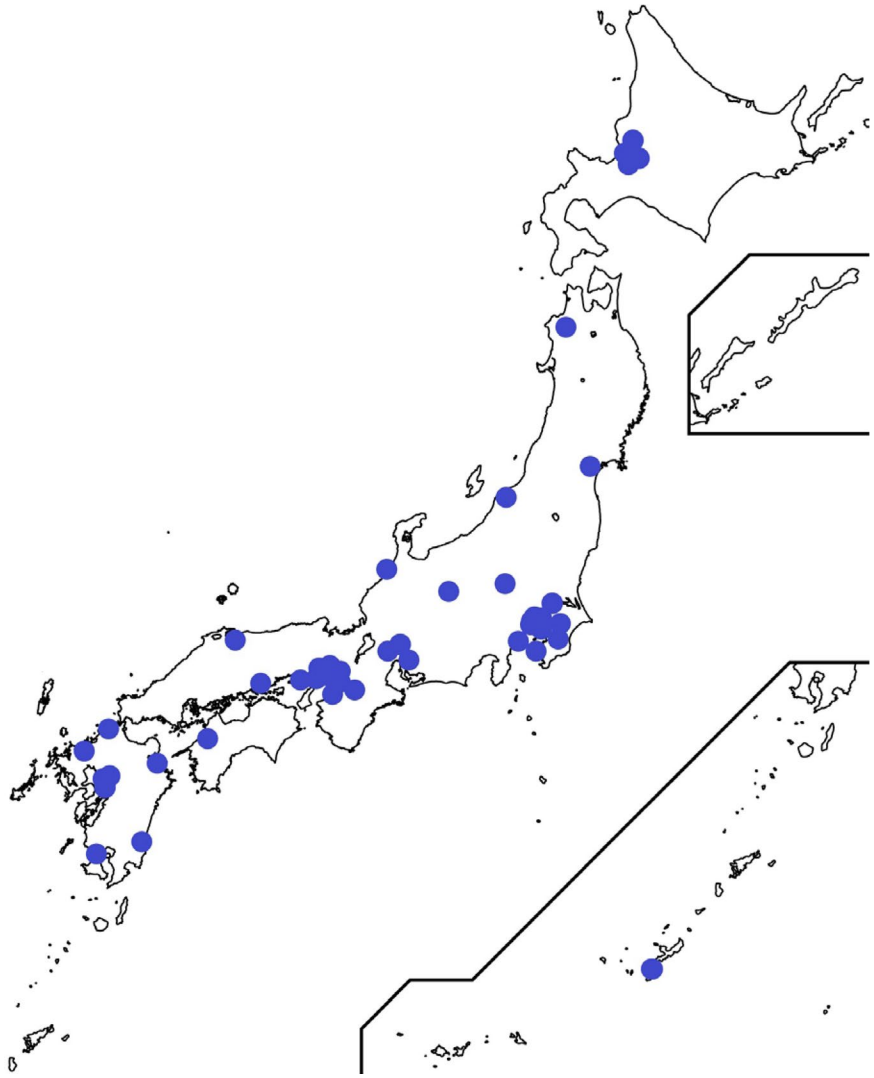

FIGURE 2 Geographic distribution of the participating institutions in J-LEX

data collection regarding TLEs will give us extremely important information.

5 | CONCLUSION

The J-LEX registry will provide real-world data regarding the results and complications of the TLEs according to the various types of indications, methods, and performing hospitals in Japan.

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CONFLICT OF INTEREST

Morio Shoda: Speaker honorarium from Medtronic Japan, and financial endowments to our clinical research division from Biotronik Japan, Medtronic Japan, Boston Scientific Japan, and Abbott Japan. Kengo Kusano: Speaker honoraria from DAIICHI SANKYO COMPANY, Ltd., Japan, Bristol-Myers Squibb, Biotronik Japan, and Medtronic Japan, and research grants from Medtronic Japan and EP-CRSU Co., Ltd. Masahiko Goya: Speaker hororarium from Japan Lifeline, Medtronic Japan, Johnson and Johnson, and Bayer. Nobuhiro Nishii: Speaker honoraria from Medtronic Japan, Boston Scientific Japan, and financial endowments to our clinical research division from Medtronic Japan. Akihiko Nogami: Speaker honoraria from Abbott and Daiichi-Sankyo; an endowment from Medtronic and DVX.

DISCLOSURE

IRB approved at February 23, 2018 (M29-146, National Cerebral and Cardiovascular Center, Japan).

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REFERENCES

1. Cabell CH, Heidenreich PA, Chu VH, Moore CM, Stryjewski ME, Corey GR, et al. Increasing rates of cardiac device infections among Medicare beneficiaries: 1990–1999. Am Heart J. 2004;147:582–6.
2. Deshmukh A, Patel N, Noseworthy PA, Patel AA, Patel N, Arora S, et al. Trends in use and adverse outcomes associated with transvenous lead removal in the United States. Circulation. 2015;132:2363–71.
3. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT, et al. 16-year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States 1993 to 2008. J Am Coll Cardiol. 2011;58:1001–6.
4. Johansen JB, Jorgensen OD, Moller M, Arnsbo P, Mortensen PT, Nielsen JC. Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients. Eur Heart J. 2011;32:991–8.
5. Maytin M, Wilkoff BL, Brunner M, Cronin E, Love CJ, Grazia Bongiorni M, et al. Multicenter experience with extraction of the Riata/Riata ST ICD lead. Heart Rhythm. 2014;11:1613–8.
6. Uslan DZ, Sohail MR, St Sauver JL, Friedman PA, Hayes DL, Stoner SM, et al. Permanent pacemaker and implantable cardioverter defibrillator infection: a population-based study. Arch Intern Med. 2007;167:669–75.
7. Okamura H. Lead extraction using a laser system: techniques, efficacy, and limitations. J Arrhythm. 2016;32:279–82.
8. Okada A, Shoda M, Tabata H, Shoin W, Kobayashi H, Okano T, et al. Single-center experience with percutaneous lead extraction of cardiac implantable electric devices. J Cardiol. 2018;71:192–6.
9. Nishii N, Morimoto Y, Miyoshi A, Tsukuda S, Miyamoto M, Kawada S, et al. Prognosis after lead extraction in patients with cardiac implantable electronic devices infection: comparison of lead-related infective endocarditis with pocket infection in a Japanese single-center experience. J. Arrhythmia. 2019;35:654–63.
10. Yagishita A, Goya M, Sekigawa M, Yamamoto T, Akiyoshi K, Maeda S, et al. Transvenous excimer laser-assisted lead extraction of cardiac implantable electrical devices in the Japanese elderly population. J Cardiol. 2020;75:410–4.
11. Amelot M, Foucault A, Scanu P, Gomes S, Champ-Rigot L, Pellissier A, et al. Comparison of outcomes in patients with abandoned versus extracted implantable cardioverter defibrillator leads. Arch Cardiovasc Dis. 2011;104:572–7.
12. Higuchi S, Shoda M, Saito S, Kanai M, Kataoka S, Yazaki K, et al. Safety and efficacy of transvenous lead extractions for noninfectious superfluous leads in a Japanese population: a single-center experience. Pacing Clin Electrophysiol. 2019;42:1517–23.
13. Imai K. Lead extraction in a non-infectious situation – it's becoming a major cause gradually. J Cardiol. 2018;72:314–5.
14. Rijal S, Shah RU, Saba S. Extracting versus abandoning sterile pacemaker and defibrillator leads. Am J Cardiol. 2015;115:1107–10.
15. Wilkoff BL, Byrd CL, Love CJ, Hayes DL, Sellers TD, Schaerf R, et al. Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. J Am Coll Cardiol. 1999;33:1671–6.
16. Wazni O, Epstein LM, Carrillo RG, Love C, Adler SW, Riggio DW, et al. Lead extraction in the contemporary setting: the LExICon study: an observational retrospective study of consecutive laser lead extractions. J Am Coll Cardiol. 2010;55:579–86.
17. 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.
18. Hammill SC, Kremers MS, Kadish AH, Stevenson LW, Heidenreich PA, Lindsay BD, et al. Review of the ICD Registry's third year, expansion to include lead data and pediatric ICD procedures, and role for measuring performance. Heart Rhythm. 2009;6:1397–401.
19. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm. 2017;14:e503–e551.
20. Bongiorni MG, Burri H, Deharo JC, Starck C, Kennergren C, Saghy L, et al. EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS. Europace. 2018;2018(20):1217.
21. Sood N, Martin DT, Lampert R, Curtis JP, Parzynski C, Clancy J. Incidence and predictors of perioperative complications with transvenous lead extractions: real-world experience with national cardiovascular data registry. Circ Arrhythm Electrophysiol. 2018;11:e004768.

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