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CLINICAL RESEARCH

Mechanical extraction of implantable cardioverter-defibrillator leads with a dwell time of more than 10 years: insights from a single high-volume centre

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Aims

To analyze and compare the effectiveness and safety of transvenous lead extraction (TLE) of implantable cardioverter-defibrillator (ICD) leads with a dwell time of >10 years (Group A) vs. younger leads (Group B) using mechanical extraction systems.

Methods and results

Between October 2011 and July 2022, we performed TLE in 318 patients. Forty-six (14.4%) extracted ICD leads in 46 (14.5%) patients that had been implanted for >10 years. The median dwell time of all extracted ICD leads was 5.9 years. Cardiovascular implantable electronic device-related infection was an indication for TLE in 31.8% of patients. Complete ICD leads removal and complete procedural success in both groups were similar (95.7% in Group A vs. 99.6% in Group B, $P = 0.056$% and 95.6% in Group A vs. 99.6% in Group B, $P = 0.056$, respectively). We did not find a significant difference between major and minor complication rates in both groups (6.5% in Group A vs. 1.5% in Group B and 2.2% in Group A vs. 1.8% in Group B, $P = 0.082$, respectively). One death associated with the TLE procedure was recorded in Group B.

Conclusion

The TLE procedures involving the extraction of old ICD leads were effective and safe. The outcomes of ICD lead removal with a dwell time of >10 years did not differ significantly compared with younger ICD leads. However, extraction of older ICD leads required more frequent necessity for utilizing multiple extraction tools, more experience and versatility of the operator, and increased surgery costs.

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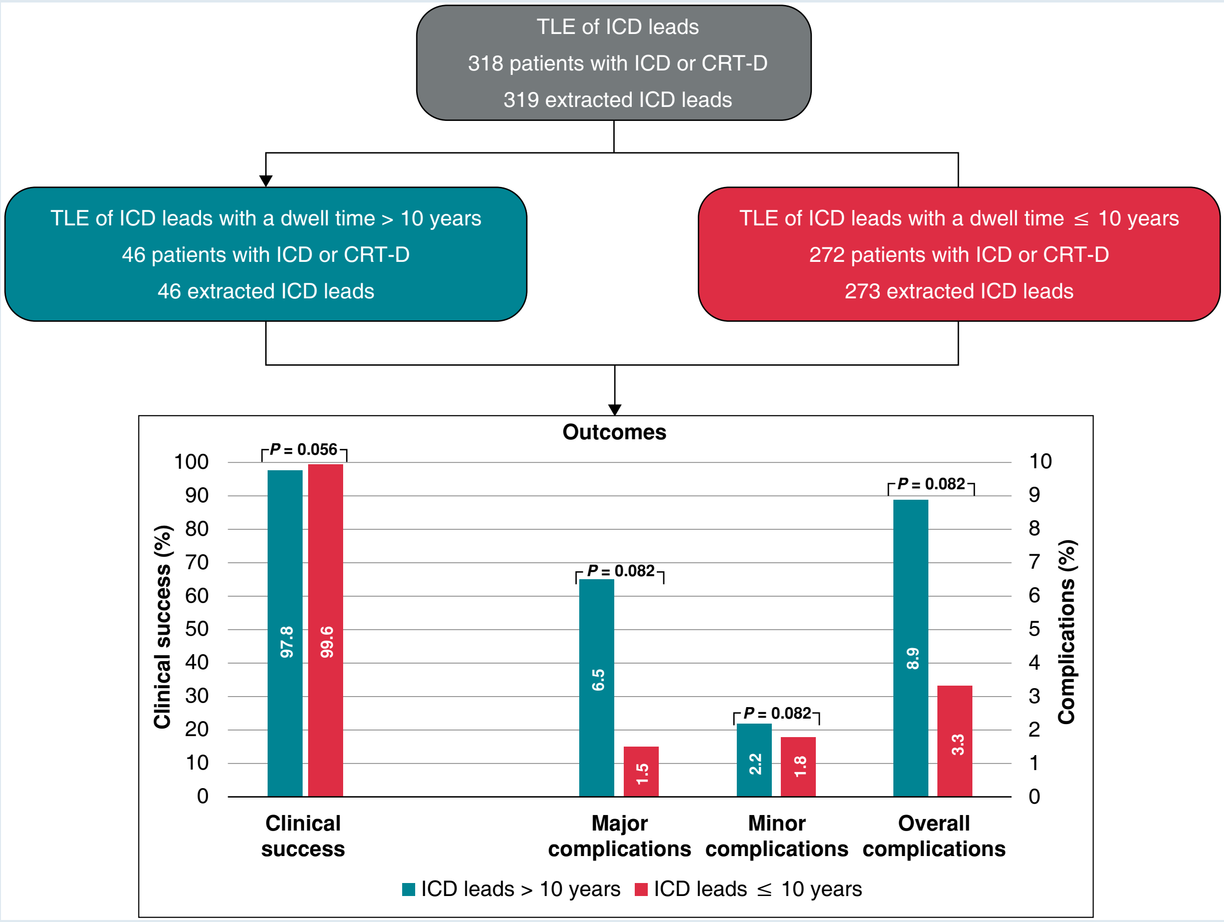
Graphical Abstract



Keywords cardiac implantable electronic devices • complications • effectiveness • implantable cardioverter-defibrillator • lead • safety • transvenous lead extraction

What's new?

(1) This study evaluates at the effectiveness and safety of transvenous lead extraction of implantable cardioverter-defibrillator leads with a dwell time of >10 years vs. younger leads.
(2) The outcomes of ICD lead removal with a dwell time of >10 years did not differ significantly compared with younger ICD leads.
(3) Extraction of older ICD leads required more frequent necessity for utilizing multiple extraction tools, more experience and versatility of the operator, and increased procedural costs.

Introduction

According to the current guidelines, indications for implantable cardioverter-defibrillator (ICD) therapy have been widened over the last few years. On the other hand, the increasing number of CIEDs has been associated with a higher incidence of CIED-related complications.[1,2] First, ICD leads have been shown to malfunction more frequently than pacing leads.[3] Also, the annual rate of ICD lead defects that requires intervention increases with time and reaches 20% in 10-year-old leads.[4]

Transvenous lead extraction (TLE) is an integral part of the management of patients with cardiac implantable electronic devices (CIED) who develop device-related complications or need a system upgrade.[5] Lead dwell time is inversely related to TLE success and impacts the risk of periprocedural complications. Brunner *et al*. observed that the combined age of the extracted leads was associated with major complications, cardiovascular injury, and 30-day all-cause mortality in a univariable analysis.[6] In addition, a prospective multicentre European ELECTRa registry of TLE procedures showed that lead dwell time of >10 years was among the factors associated with major procedural complications and death, as well as clinical failure.[7] The authors of that study calculated that a lead dwell time of >10 years was associated with an ~3.5-fold higher risk of major complication and death and a 4-fold higher risk of clinical failure of the procedure.

In contrast, Maciąg *et al*.[8] observed no major complications during the removal of leads older than 10 years and concluded that the TLE of these leads is feasible and safe. Furthermore, our previous study on pacemaker leads showed that the extraction of leads over 20 years was comparably safe and effective to the extraction of younger leads.

We noted, however, that procedures on older leads required frequent utilization of advanced tools, a femoral approach, and longer fluoroscopy time.[9] To this end, Pecha *et al*. in an analysis based on 154 patients showed that TLE of leads aged over 10 years was safe and effective when performed in specialized centres and with the use of multiple tools and techniques. Leads that could not be extracted entirely had statistically significant longer lead dwell time.[10]

The procedural effectiveness and safety of extracting more than 10-year-old ICD leads are unknown. The lack of direct comparison of extraction ICD leads younger and older than 10 years prompted us to review the outcomes from our high-volume centre for lead extraction.

Combining multiple extraction tools might enhance the procedural success rate in complex cases, including very old leads.

Methods

The study aimed to assess the effectiveness and safety of TLE of ICD leads younger and older than 10 years using mechanical extraction systems. A prospective analysis of the records consisted of all patients with ICD or CRT-D who underwent TLE of ICD leads from October 2011 to July 2022. The Research and Ethics Committee of Jagiellonian University approved the study protocol (KBET/259/B/2011). Furthermore, written informed consent was obtained from all patients for using their anonymous data in the present study. The study protocol conformed with the Declaration of Helsinki and complied with the principles of Good Clinical Practice guidelines.

Patients whose ICD leads had been implanted for <1 year before the procedure were excluded from the analysis. The population was divided into two groups: in Group A at least one removed ICD lead was >10-years-old, and in Group B, all removed ICD leads were younger than 10 years. Of note, the dwell time of removed pacing leads did not influence group allocation.

Data were collected from a prospectively maintained database comprising records of device implantation, follow-up at the device and general cardiology clinics, medical information obtained during the index admissions for TLE, and data on 30-day complications after the procedure.

The following variables were collected and compared between the two groups: demographic data (age, sex), body mass index (BMI), the New York Heart Association (NYHA) Functional Classification, left ventricular ejection fraction (LVEF), indications for ICD implantation (primary or secondary prevention), comorbidities including diabetes mellitus and coronary artery disease, laboratory studies [haemoglobin concentration, creatinine level, estimated glomerular filtration rate (eGFR)], previous cardiac surgery, types of implanted CIED, number of CIED-related procedures before TLE (implantation, reimplantation, device upgrade), indications for TLE. The CKD-EPI equation was used to calculate eGFR. Lead extraction was performed due to lead-dependent infective endocarditis (LDIE), isolated local infection (LI), or non-infectious indications. LDIE was diagnosed based on Modified Duke Leads Criteria, LI based on local inflammatory signs limited to the device pocket, such as erythema, excessive warming, fluid in the device pocket, swelling, leakage of fluid from the device pocket, erosion of the skin, and fistula. When both LDIE and LI were present, LDIE was used as an indication for TLE.

Both groups were compared in terms of proportions of passive-fixation leads, non-functional/abandoned leads, age of extracted leads, age of the oldest extracted lead, cumulative age of all extracted leads, number of extracted leads, fluoroscopy time, extraction techniques used during TLE, the effectiveness of TLE, complete/incomplete lead removal for each lead targeted, and complications occurring during the intra-operative and 30-day post-operative period.

The effectiveness of TLE procedures was defined according to the current HRS and EHRA consensus:[5,11]

- complete procedural success: Removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure-related death;
- clinical success: Removal of all targeted leads and lead material from the vascular space or retention of a small portion of the lead that does not negatively impact the outcome goals of the procedure. A retained lead fragment may be the tip of the lead or a small part of the lead (conductor coil, insulation, or the latter two combined) when the residual lead part does not increase the risk of perforation, embolic events, the perpetuation of infection or cause any undesired outcome;
- failure of the procedure: Inability to achieve complete procedural or clinical success or the development of any permanently disabling complication or procedure-related death.
- For each lead removed, the efficiency according to the EHRA consensus was determined:[11]
- complete lead removal—lead explant or extraction with the removal of all targeted lead material,
- incomplete lead removal—lead explant or extraction where part of the lead remains in the patient's body (vascular or extra-vascular).

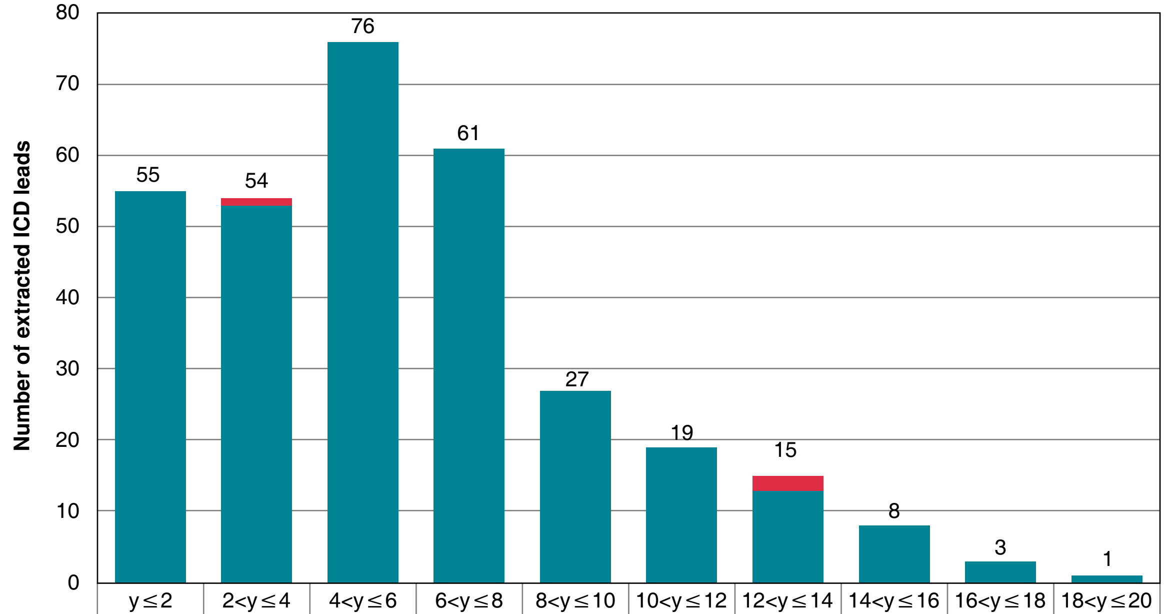
We recorded complications occurring in the intra-operative and 30-day post-operative periods and classified them into two types as per HRS and EHRA consensus:[5,11]

- major complication: Any of the outcomes related to the procedure which is life-threatening or results in death. In addition, any unexpected event that causes persistent or significant disability or any event that requires substantial surgical intervention to prevent any of the outcomes listed above;
- minor complication: Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy the complications and does not limit the patient's function persistently or significantly, nor does it threaten life or cause death.

TLE procedure

The description of the TLE procedure has been presented previously.[12] The patient preparation for the TLE procedure consisted of the following tests: laboratory tests, chest X-ray, transthoracic echocardiography in all patients, transesophageal echocardiography in the majority of patients, pre-operative device assessment and evaluation of pacemaker dependency. Before the operation, ipsilateral venography was performed in patients without contraindications to contrast medium. In non-infectious patients, antibiotic prophylaxis was routinely administered, whereas antimicrobial therapy was continued in infectious cases.

All the procedures were performed in the hybrid operating room with on-site cardiothoracic surgical standby, under general anaesthesia or intravenous sedation. Continuous invasive monitoring of blood pressure, blood saturation, and ECG was used during the procedure. Most of the patients were additionally monitored with TOE without complications. Our centre does not provide the usage of ICE. All patients were prepared for a possible emergency sternotomy with a heart-lung machine on standby. In pacemaker-dependent patients, we placed a temporary pacing wire via the femoral vein. Implant vein was used as the primary access site. While extracting the leads, we used a stepwise approach. Simple traction was the first extraction technique used in the active-fixation and relatively young leads. In the next step, we utilized non-powered extraction tools. Standard stylets were used to stiffen the leads. If the lead lumen allowed the stylet insertion to its tip, we used the locking stylets (Liberator Beacon Tip Locking Stylet, Cook Medical or Lead Locking Device, Spectranetics) since December 2013. Finally, we utilized telescoping dilators (Cook Medical). Powered extraction tools (cutting sheath system—Evolution, Cook Medical) were usually applied when previously used non-powered extraction tools failed. Where a subclavian approach failed or was impossible, a femoral approach was performed. In these cases, a variety of snares were used, predominantly the Needle's Eye (Cook Medical, USA). In the analyzed population, the authors did not use internal transjugular approach. Laser techniques, electrosurgical sheaths and intracardiac echocardiography imaging (ICE) were not used. Pacemaker-dependent patients who required delayed permanent system reimplantation due to device-related infection were bridged between TLE and reimplant with a temporary active-fixation lead implanted on the ipsilateral side of the chest and connected to the externalized permanent pacemaker generator. Furthermore, in patients



	y≤2	2<y≤4	4<y≤6	6<y≤8	8<y≤10	10<y≤12	12<y≤14	14<y≤16	16<y≤18	18<y≤20
Failure	0	1	0	0	0	0	2	0	0	0
Success	55	53	76	61	27	19	13	8	3	1

Lead dewll time (years)

Figure 1 Outcomes of transvenous ICD leads extraction according to leads dwell time in 2-year intervals (y years).

at a very high risk of sudden cardiac death, we implanted a temporary external ICD as a bridge to ICD reimplantation.

Statistical analysis

The analysis was performed using IBM SPSS Statistics Version 28.0 software (IBM Corp, Armonk, New York, United States). Continuous variables were expressed as mean ± standard deviation (SD) and additionally as median (Me) and interquartile range (Q1–Q3). Shapiro–Wilk W test was used to assess the normality of continuous variables. Comparisons of two groups of categorical variables were performed with Student's *t*-tests of unpaired samples. In case of non-normality or small sample sizes, the Mann–Whitney *U* test was used. The categorical variables were presented as counts and percentages and compared with chi-square or Fisher's exact test. Logistic regression was performed to identify predictive factors for use of powered sheaths for TLE and clinical failure of the procedure. All statistical tests were two-tailed, and a *P*-value < 0.05 was considered statistically significant.

Results

The study population comprised 318 patients aged 63.2 ± 13.5 (range: 22.5–86.8) years, including 61 (19.2%) women. TLE was performed due to LDIE (61 patients), LI (40 patients), and non-infectious indications (217 patients). There were 240 patients with ICD and 78 with CRT-D in the analyzed group. In total, 505 leads were extracted with a mean lead dwell time of 5.7 ± 3.8 years. There were 319 ICD leads with a mean dwell time of 5.9 ± 3.7 years.

Group A had 46 patients and group B 272 patients.

The majority of extracted ICD leads were up to 8-year-old. However, four removed ICD leads were older than 16 years (*Figure 1*). The oldest extracted ICD lead was 19.4-year-old. The clinical characteristics of patients in both groups are presented in *Table 1*.

Patients in group A were significantly younger than those in group B. They had fewer comorbidities such as coronary artery disease, peripheral artery disease, hypertension, heart failure, and chronic kidney disease.

In group A, CIEDs were more often implanted as part of secondary SCD prevention (76.1% vs. 34.9%, *P* < 0.001), and in this group, there was a higher proportion of ICD compared with group B (89.1% vs. 73.2%, *P* = 0.025). However, both groups were similar in terms of the percentage of women, the rate of infectious indications, the incidence of diabetes mellitus, previous cardiac surgery, dyslipidemia, atrial fibrillation, and chronic obstructive pulmonary disease. In addition, CRP level, haemoglobin, and BMI index were similarly distributed (*Table 1*).

Patients with older ICD leads (group A) had significantly more previous device-related interventions compared with patients with younger ICD leads (2.7 vs. 1.5, *P* < 0.001).

A comparison of extracted leads and results of TLE procedures in both groups is presented in *Table 2*.

We extracted 46 ICD leads with a dwell time of >10 years, and 273 ICD leads with a dwell time shorter than 10 years, including 23 Medtronic (Medtronic, Minneapolis, MN, USA) Sprint Fidelis ICD leads and 1 St. Jude Medical/Abbott (Abbott, Sylmar, CA, USA) Durata ST ICD lead. Concerning other types of leads, in Group A there were 20 pacing leads removed, including one left ventricular lead. In contrast, in Group B, there were 166 pacing leads removed, including 38 left ventricular leads. In 23 patients with Sprint Fidelis ICD leads median (Q1–Q3) lead dwell time was 6.6 years (5.8–8.0), including two leads with a dwell time of >10 years.

The median dwell time of all extracted leads, median dwell time of only ICD leads, age of the oldest extracted lead, and a sum of the dwell time of all extracted leads were significantly higher in group A compared with group B (*P* < 0.001).

Table 1 Clinical characteristics of patients, type of implanted devices and indications for TLE in both groups of patients

Parameter	All patients ($n = 318$)	Group A ($n = 46$)	Group B ($n = 272$)	*P*-value
Age of pts (years) (mean ± SD; Me; Q1–Q3)	63.2 ± 13.5; 65.0; 56.1–72.8	58.1 ± 14.4; 61.7; 49.8–67.7	64.1 ± 13.2; 66.1; 57.2–73.6	**$P = 0.008$**
Female, *n* (%)	61 (19.2)	13 (28.3)	48 (17.6)	$P = 0.105$
LVEF (%) (mean ± SD; Me; Q1–Q3)	34.2 ± 14.5; 30.0; 23.0–43.5	43.0 ± 16.1; 41.0; 30.0–60.0	32.7 ± 13.7; 30.0; 22.5–40.0	**$P < 0.001$**
NYHA Class III or IV, *n* (%)	126 (39.6)	10 (21.7)	116 (42.6)	**$P = 0.009$**
Secondary prevention, *n* (%)	130 (40.9)	35 (76.1)	95 (34.9)	**$P < 0.001$**
BMI (kg/m^2) (mean ± SD; Me; Q1–Q3)	27.8 ± 5.1; 27.4; 24.2–30.5	27.4 ± 3.7; 26.3; 25.1–29.8	27.9 ± 5.3; 27.4; 23.9–30.6	$P = 0.722$
Hb (g/dL) (mean ± SD; Me; Q1–Q3)	13.5 ± 1.9; 13.8; 12.4–14.9	13.9 ± 1.5; 13.8; 12.9–15.0	13.4 ± 2.0; 13.7; 12.3–15.0	$P = 0.296$
CRP (mg/L) (mean ± SD; Me; Q1–Q3)	21.6 ± 49.4; 2.8; 1.0–13.0	10.2 ± 20.7; 2.0; 1.0–7.6	23.5 ± 52.5; 3.0; 1.0–13.7	$P = 0.197$
Creatinine (umol/L) [mean ± SD; Me; Q1–Q3]	108.3 ± 59.2; 97.0; 79.7–117.2	92.9 ± 32.7; 87.5; 68.7–113.7	110.9 ± 62.3; 98.0; 81.0–119.0	**$P = 0.020$**
eGFR (mL/min/1.73 m2) (mean ± SD; Me; Q1–Q3)	69.1 ± 24.9; 70.0; 51.9–87.2	78.6 ± 24.1; 81.0; 58.7–97.2	67.5 ± 24.7; 68.0; 50.0–85.0	**$P = 0.003$**
Diabetes mellitus, *n* (%)	108 (34.0)	12 (26.1)	96 (35.3)	$P = 0.243$
Coronary artery disease, *n* (%)	210 (66.0)	23 (50.0)	187 (68.7)	**$P = 0.018$**
Previous cardiac surgery, *n* (%)	64 (20.1)	5 (10.9)	59 (21.7)	$P = 0.112$
Peripheral artery disease, *n* (%)	210 (66.0)	24 (52.2)	186 (68.4)	**$P = 0.043$**
Dyslipidemia, *n* (%)	273 (85.8)	37 (80.4)	236 (86.8)	$P = 0.360$
Hypertension, *n* (%)	213 (67.0)	25 (54.3)	188 (69.1)	$P = 0.062$
Atrial fibrillation, *n* (%)	139 (43.7)	21 (45.7)	118 (43.4)	$P = 0.873$
Chronic obstructive pulmonary disease, *n* (%)	34 (10.7)	2 (4.3)	32 (11.8)	$P = 0.195$
Implanted device				
ICD, *n* (%)	240 (75.5)	41 (89.1)[a]	199 (73.2)[b]	**$P = 0.025$**
CRT-D, *n* (%)	78 (24.5)	5 (10.9)	73 (26.8)[c]	
Indications for TLE				
LDIE, *n* (%)	61 (19.2)	5 (10.9)	56 (20.6)	$P = 0.153$
LI, *n* (%)	40 (12.6)	4 (8.7)	36 (13.2)	
Non-infectious indications, *n* (%)	217 (68.2)	37 (80.4)	180 (66.2)	
Number of previously performed procedures	1.7 ± 0.9; 1.0; 1.0–2.0	2.7 ± 0.9; 2.0; 2.0–3.0	1.5 ± 0.8; 1.0; 1.0–2.0	**$P < 0.001$**

bold values - statistically significant value.
[a]in one patient—abandoned ventricular lead in ipsilateral of the chest and in two patients DDD pacing system in contralateral of the chest.
[b]- in one patient—the lack of pacing system, remaining ICD lead after generator removal, in two patients additionally subcutaneous defibrillator leads due to high defibrillation threshold, in one patient DDD pacing system in contralateral of the chest, in three patients VVI pacing system in contralateral of the chest (two patients) and in ipsilateral of the chest (one patient)
[c]– in two patients—the lack of pacing system, remaining fragment of ICD lead after heart transplant, in 1 patient VDD pacing system in contralateral of the chest.
LVEF, left ventricular ejection fraction, NYHA, New York Heart Association, BMI, body mass index, Hb, haemoglobin, CRP, C-reactive protein, eGFR, estimated glomerular filtration rate, ICD, implantable cardioverter-defibrillator, CRT-D, cardiac resynchronization therapy defibrillator, TLE, transvenous lead extraction, LDIE, lead-dependent infective endocarditis, LI, local infection, Me, median, Q1, first quartile, Q3, third quartile.

In group A, there were significantly more ICD leads with passive-fixation and dual-coil ICD leads compared with group B (60.9% vs. 2.2%, $P < 0.001$% and 41.3% vs. 21.2%, $P = 0.005$).

In both groups, the percentage of abandoned leads and patients with three or more leads removed were similar—*Table 2*.

We observed a comparable number of extracted all targeted leads per procedure in both groups.

The extraction efficacy of all targeted leads in the whole population was high (99.2%) and similar between groups A and B (97.0% vs. 99.5%, $P = 0.085$). Considering only ICD leads, the extraction efficacy was still high (99.1%). However, we observed a more frequent incomplete lead removal in group A with a trend towards significance (95.7% vs. 99.6%, $P = 0.056$).

All targeted leads in group A required more advanced extraction tools than those in group B ($P < 0.001$), similar to when comparing only ICD leads ($P < 0.001$)—*Table 2*. *Figure 1* shows transvenous ICD leads extraction outcomes according to lead dwell time.

In group A, no lead was extracted using simple traction. Removal of leads in group A was associated with significantly longer fluoroscopy time compared with group B ($P < 0.001$). A similar result was noted when comparing only ICD leads ($P < 0.001$)—*Table 2*.

The effectiveness of TLE in the present cohort was high. Complete procedural success between groups was similar. However, we observed a trend towards less frequent complete success in group A (95.6% vs. 99.6%, $P = 0.056$). Overall clinical success was archived in 45 patients (97.8%) in group A and 271 patients (99.6%) in group B and was similar between both groups ($P = 0.269$).

Failure of the procedure occurred in one patient in group A and one in group B—*Table 2*.

In group A—during extraction of a nearly 13-year-old dysfunctional dual-coil ICD passive-fixation lead, its distal coil remained in the myocardium despite various retrieval techniques.

In group B—failure occurred in one patient as an intra-operative death.

Table 2 Comparison of extracted leads and results of tle procedures in both groups

Parameter	All patients ($n = 318$)	Group A ($n = 46$)	Group B ($n = 272$)	P-value
No of all extracted leads[a]	505	66	439	—
Medtronic, *n* (%)	326 (64.5)	38 (57.6)	288 (65.6)	—
Biotronik, *n* (%)	94 (18.6)	22 (33.3)	72 (16.4)	—
St Jude Medical/Abbott, *n* (%)	64 (12.7)	5 (7.6)	59 (13.4)	—
Other, *n* (%)	21 (4.2)	1 (1.5)	20 (4.6)	—
No of extracted ICD leads[b]	319	46	273	—
Medtronic, *n* (%)	209 (65.5)	28 (60.9)	181 (66.3)	—
Biotronik, *n* (%)	60 (18.8)	14 (30.4)	46 (16.9)	—
St Jude Medical/Abbott, *n* (%)	42 (13.2)	4 (8.7)	38 (13.9)	—
Other, *n* (%)	8 (2.5)	0 (0.0)	8 (2.9)	—
Passive-fixation of ICD leads, *n* (%)[b]	34 (10.7)	28 (60.9)	6 (2.2)	**$P < 0.001$**
Dual-coil of ICD leads, *n* (%)[b]	77 (24.1)	19 (41.3)	58 (21.2)	**$P = 0.005$**
Age of extracted lead (years) (mean ± SD; Me; Q1–Q3)[a]	5.7 ± 3.8; 5.2; 2.7–7.7	12.4 ± 2.7; 12.1; 10.8–13.8	4.7 ± 2.8; 4.7; 2.3–6.6	**$P < 0.001$**
Age of extracted ICD lead (years) (mean ± SD; Me; Q1–Q3)[b]	5.9 ± 3.7; 5.4; 3.0–7.9	12.9 ± 2.1; 12.4; 11.1–14.2	4.7 ± 2.5; 4.7; 2.4–6.5	**$P < 0.001$**
Oldest extracted lead (years) (mean ± SD; Me; Q1–Q3)[a]	6.2 ± 4.0; 5.6; 3.2–8.2	13.2 ± 2.4; 13.0; 11.1–14.7	5.1 ± 2.9; 4.8; 2.7–7.0	**$P < 0.001$**
Sum of age of extracted leads (years) (mean ± SD; Me; Q1–Q3)[a]	9.1 ± 6.7; 7.3; 4.1–12.9	17.9 ± 7.0; 15.4; 11.9–22.1	7.6 ± 5.4; 6.3; 3.5–10.4	**$P < 0.001$**
Patients with one abandoned lead, *n* (%)[a]	9 (2.8)	1 (2.2)	8 (2.9)	$P > 0.99$
Patients with two or more abandoned leads, *n* (%)[a]	0 (0.0)	0 (0.0)	0 (0.0)	$P > 0.99$
Patients with 3 or more extracted leads, *n* (%)[a]	40 (12.6)	2 (4.3)	38 (14.0)	$P = 0.090$
Number extracted leads per procedure (1) [mean ± SD; Me; Q1–Q3] [a]	1.6 ± 0.7; 1.0; 1.0–2.0	1.4 ± 0.6; 1.0; 1.0–2.0	1.6 ± 0.7 1.0; 1.0–2.0	$P = 0.168$
Leads:				
Complete lead removal (all leads), *n* (%)[a]	501 (99.2)	64 (97.0)	437 (99.5)	$P = 0.085$
Incomplete lead removal (all leads), *n* (%)[a]	4 (0.8)	2 (3.0)	2 (0.5)	
Complete ICD lead removal, *n* (%)[b]	316 (99.1)	44 (95.7)	272 (99.6)	$P = 0.056$
Incomplete ICD lead removal, *n* (%)[b]	3 (0.9)	2 (4.3)	1 (0.4)	
Finally effective techniques:				
Simple traction, *n* (%)[a]	98 (19.4)	0 (0.0)	98 (22.3)	**$P < 0.001$**
Telescopic sheaths, *n* (%)[a]	359 (71.1)	49 (74.3)	310 (70.6)	
Evolution mechanical system, *n* (%)[a]	35 (6.9)	16 (24.2)	19 (4.3)	
Femoral access, *n* (%)[a]	13 (2.6)	1 (1.5)	12 (2.8)	
Simple traction (only ICD leads), *n* (%)[b]	36 (11.3)	0 (0.0)	36 (13.2)	**$P < 0.001$**
Telescopic sheaths (only ICD leads), *n* (%)[b]	241 (75.5)	31 (67.4)	210 (76.9)	
Evolution mechanical system (only ICD leads), *n* (%)[b]	30 (9.4)	14 (30.4)	16 (5.9)	
Femoral access (only ICD leads), *n* (%)[b]	12 (3.8)	1 (2.2)	11 (4.0)	
Fluoroscopy time during ICD lead removal (min) [mean ± SD; Me; Q1–Q3] [b]	2.8 ± 4.1; 1.6; 0.8–3.0	6.1 ± 8.4; 3.3; 2.0–8.2	2.2 ± 2.8; 1.4; 0.8–2.6	**$P < 0.001$**
Total fluoroscopy time during all leads removal (min) [mean ± SD; Me; Q1–Q3][a]	3.7 ± 5.2; 2.0; 1.0–4.3	7.4 ± 8.5; 4.4; 2.4–9.5	3.0 ± 4.0; 1.8; 1.0–3.6	**$P < 0.001$**
Procedures:				
Complete success, *n* (%)	315 (99.1)	44 (95.6)	271 (99.6)	$P = 0.056$
Clinical success (excluding complete success), *n* (%)	1 (0.3)	1 (2.2)	0 (0.0)	
Failure, *n* (%)	2 (0.6)	1 (2.2)	1 (0.4)	
Complications:				
No complications, *n* (%)	305 (95.9)	42 (91.3)	263 (96.7)	$P = 0.082$
Minor complications, *n* (%)	6 (1.9)	1 (2.2)	5 (1.8)	
Major complications, *n* (%)	7 (2.2)	3 (6.5)	4 (1.5)	

Continued

Table 2 ***Continued***

Parameter	All patients (*n* = 318)	Group A (*n* = 46)	Group B (*n* = 272)	*P*-value
Deaths:				
Intra-operative period procedure-related, *n* (%)	1 (0.3)	0 (0.0)	1 (0.4)	$P > 0.99$
During 30-day post-operative period procedure-related, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)	$P > 0.99$
During 30-day post-operative period non-procedure-related, *n* (%)	14 (4.4)	1 (2.2)	13 (4.8)	$P = 0.701$

[a]including all leads: pacing and ICD leads, not including subcutaneous ICD leads.
[b]only ICD leads, not including subcutaneous ICD leads.
ICD—implantable cardioverter-defibrillator, Me—median, Q1—first quartile, Q3—third quartile.

Table 3 Predictors Of use of powered sheaths of transvenous lead extraction

Variable	Odds ratio (95% CI)	*P*-value
Female sex	1.612 (0.681–3.819)	0.278
Age of pts (years)	0.978 (0.948–1.009)	0.167
LVEF (%)	1.000 (0.974–1.026)	0.982
NYHA Class III or IV	0.627 (0.295–1.333)	0.225
Secondary prevention	2.021 (0.871–4.692)	0.102
BMI (kg/m^2)	0.969 (0.905–1.039)	0.381
Chronic kidney disease	0.865 (0.354–2.111)	0.749
Diabetes mellitus	0.877 (0.401–1.917)	0.743
Previous cardiac surgery	1.009 (0.394–2.482)	0.986
Hypertension	1.195 (0.546–2.613)	0.656
Atrial fibrillation	1.183 (0.550–2.547)	0.667
CRT-D	0.735 (0.322–1.680)	0.466
One or more abandoned leads	4.128 (3.876–12.983)	0.042
Dwell time of the oldest extracted lead (years)[a]	2.041 (1.550–2.687)	<0.001
Sum of age of extracted leads (years)[a]	1.531 (1.275–1.839)	<0.001
Number extracted leads (1)[a]	0.812 (0.497–1.326)	0.405
Passive-fixation of ICD lead[b]	6.264 (4.142–9.768)	<0.001
Dual-coil of ICD lead[b]	2.207 (0.745–6.536)	0.153

[a]including all leads: pacing and ICD leads, not including subcutaneous ICD leads.
[b]only ICD leads, not including subcutaneous ICD leads.

Table 4 Predictors Of clinical failure of transvenous lead extraction

Variable	Odds ratio (95% CI)	*P*-value
Female sex	4.267 (0.263–9.190)	0.307
Age of pts (years)	0.960 (0.845–1.092)	0.536
LVEF (%)	1.224 (0.951–1.575)	0.117
NYHA Class III or IV	1.012 (0.783–1.535)	0.782
Secondary prevention	0.984 (0.892–1.106)	0.088
BMI (kg/m^2)	0.970 (0.775–1.245)	0.810
Chronic kidney disease	0.878 (0.764–1.1.842)	0.464
Diabetes mellitus	0.512 (0.032–8.265)	0.637
Previous cardiac surgery	1.010 (0.766–1.524)	0.476
Hypertension	0.972 (0.886–1.124)	0.112
Atrial fibrillation	0.775 (0.048–12.506)	0.858
CRT-D	0.998 (0.793–1.577)	0.419
One or more abandoned leads	6.121 (0.184–14.426)	0.809
Dwell time of the oldest extracted lead (years)[a]	0.877 (0.662–1.162)	0.361
Sum of age of extracted leads (years)[a]	0.982 (0.811–1.189)	0.851
Number extracted leads (1)[a]	1.211 (0.157–9.357)	0.854
Passive-fixation of ICD lead[b]	0.117 (0.007–1.908)	0.132
Dual-coil of ICD lead[b]	0.317 (0.020–5.124)	0.418
Use of Evolution mechanical system	0.211 (0.018–9.122)	0.635
Femoral access	1.512 (0.864–2.126)	0.770

[a]including all leads: pacing and ICD leads, not including subcutaneous ICD leads.
[b]only ICD leads, not including subcutaneous ICD leads.

The safety in both groups was comparable—*Table 2*.

The study population had six (1.9%) minor complications and seven (2.2%) major complications.

In group A there were three major complications (three cardiac tamponades requiring surgical intervention) and one minor complication (worsening tricuspid valve function after the TLE procedure).

In group B, there were five minor (two pneumothoraces and three pocket haematomas requiring surgical intervention) and four major complications (one intra-operative death, one haemorrhage to the pleural cavity requiring drainage, and two cardiac tamponades managed surgically).

We observed a trend toward the more frequent occurrence of minor and major complications in group A (2.2% vs. 1.8% and 6.5% vs. 1.5%, $P = 0.082$). However, the difference was not statistically significant.

TLE of the Sprint Fidelis ICD lead was performed with a 100% success. There were no major procedural complications or deaths.

Logistic regression analysis (*Table 3*) demonstrated that the presence of one or more abandoned leads [odds ratio (OR): 4.128; 95% confidence interval (CI): 3.876–12.983; $P = 0.042$], the dwelling time of the oldest extracted lead (OR: 2.041 per a year; 95% CI: 1.550–2.687; $P < 0.001$), total age of age of extracted leads (OR: 1.531 per a year; 95% CI: 1.275–1.839; $P < 0.001$) and presence of passive-fixation ICD lead (OR: 6.264; 95% CI: 4.142–9.768; $P < 0.001$) were associated with a use of powered sheaths for TLE procedure. In the next logistic

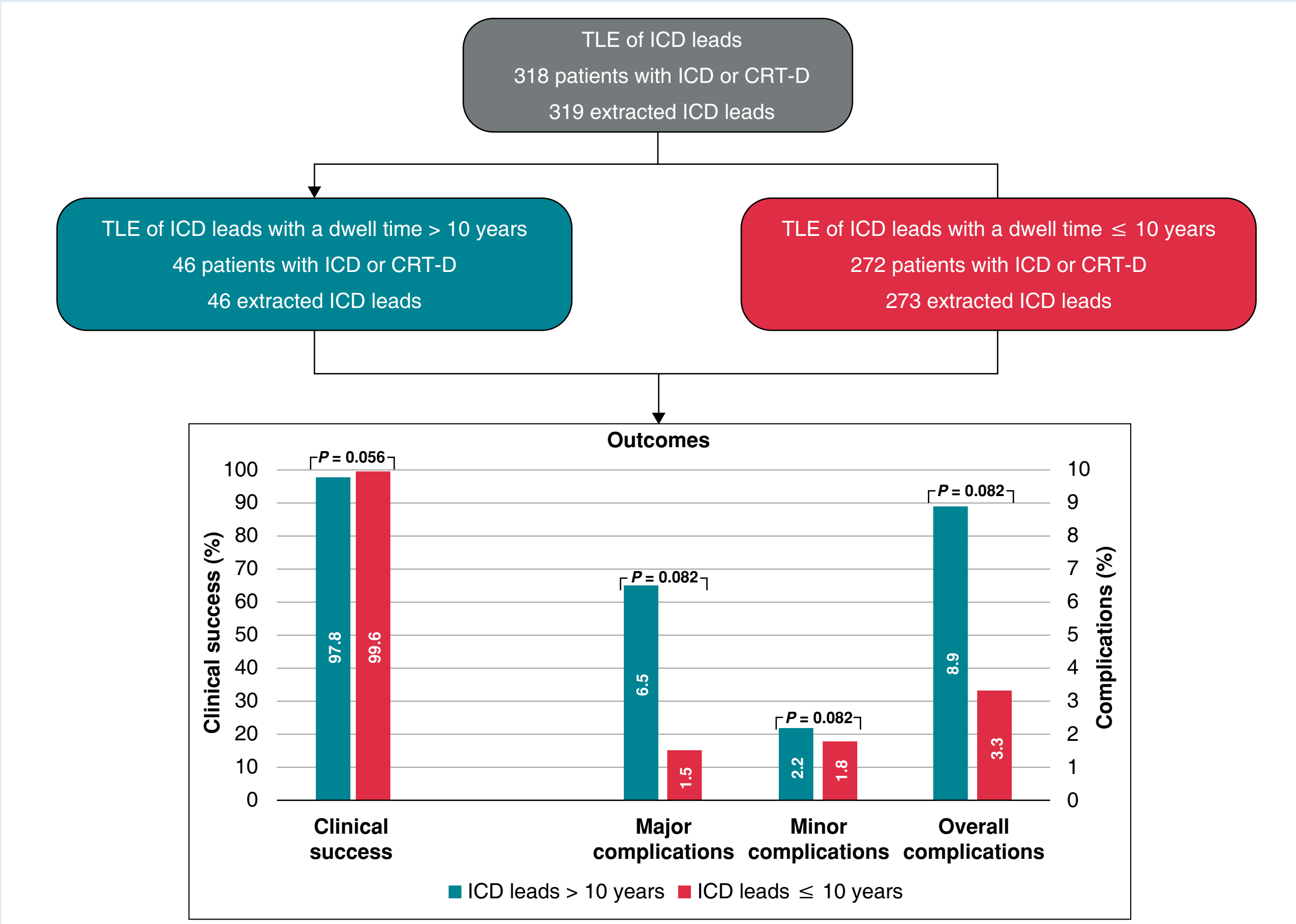


Figure 2 Study population characteristics, procedures, and outcomes.

regression analysis (*Table 4*), it was not possible to identify the factors associated with a higher risk of clinical failure. It is most likely related to the small amount of clinical failure in our group. A summary of the results is provided in *Figure 2*. Total mortality within 30 days (including intra-operative) was 4.4% (14 patients), and there was no significant difference between groups (1 patient—2.2% in group A vs. 13 patients—4.8% in group B, $P = 0.701$).

Both groups' dominant cause of death was severe heart failure or sepsis due to LDIE (one patient in group A and ten in group B). Additionally, one patents in group B died during the TLE procedure, and two died due to thromboembolic events.

Discussion

In the available literature, there are few studies on the safety and effectiveness of TLE procedures on ICD leads older than 10 years. In our study cohort, the median lead dwell time of leads older than 10 years was 12.4 years. Most of the leads were extracted due to non-infectious indications, similar to reports from other lead extraction centres and registries. The observed low rate of TLE due to infection is consistent with our strategy to rigorously treat pacing-related complications.[3,9,12,13] This approach aligns with the current expert consensus statement.[5] However, in other studies, especially those concerning older electrodes, the dominant indication was infectious complications.[8,10,14]

Our study shows a gradual move towards using single-coil ICD leads rather than dual-coil leads over the study period, in accordance with the results from a meta-analysis including 18 studies.[15] The ALTITUDE Study demonstrated that single-coil lead implantations increased from 1.9% to 55.2% between 2004 and 2014.[16] Furthermore, this observation is supported by a higher number of prior device-related interventions in group A (mostly ICD generator change) compared with group B (2.0 vs. 1.0, $P < 0.001$).

The removal efficiency of ICD leads older than 10 years in our cohort was high and amounted to 95.7%. Similar results were reported by Pecha *et al.*[10] in a group of 154 patients. Other authors also report a similar percentage of complete lead removal in leads older than 10 years.[8,14] Our experience shows that the TLE of the old leads was generally more complex, often requiring the utilization of multiple extraction tools and techniques.[10,14]

In our previous study, we demonstrated that extraction of dual-coil ICD leads required more advanced tools and longer fluoroscopy time.[12] Pecha *et al.* showed that extraction of dual-coil ICD leads was associated with longer laser treatment times.[17] Additionally, as proved by The GermAn Laser Lead Extraction RegistrY: GALLERY a lead dwell time ≥10 years was identified as an independent risk factor for procedural failure during laser lead extraction.[18]

As observed by Nir Levi *et al.* in lead fixation mechanism impacts outcome of TLE: data from the European Lead Extraction ConTRolled Registry: older age of ICD leads, a higher percentage of passive-fixation leads, and dual-coil ICD leads contributed to longer fluoroscopy time during extraction of ICD leads in group A compared with group B (3.3 min vs. 1.4 min, $P < 0.001$).[19]

Additionally, in our study with 23 Sprint Fidelis leads, we observed complete procedural success in all cases with no major complications or procedure-related deaths regardless of the method of extraction. Similar results on group 349 Sprint Fidelis leads are reported by Maytin *et al.*[20]

Our research shows that when TLE is done in a high-volume centre and by experienced operators, extracting ICD leads over 10-years-old is effective and safe. In our study, complete procedural success was high and amounted to 95.6%. However, we note a higher procedural failure rate in the older leads than in younger ones (2.2% vs. 0.4%, $P = 0.056$). In other studies evaluating the extraction of old ICD leads, the results were comparable with ours.[10,14]

The major perioperative complication rate in the entire cohort was 2.2%. There was a trend toward more frequent complications in the group of patients with ICD leads older than 10 years compared with younger ones (6.5% vs. 1.5%). Several previous publications have shown a significant influence of the age of extracted leads on the efficacy and safety of TLE procedures. For example, in the study of Segreti *et al*. success rate resulted a bit lower, especially in the presence of abandoned leads with long implantation time.[21] In the prospective multicentre European ELECTRa registry of TLE procedures, a lead dwell time of >10 years was associated with about a 3.5-fold higher risk of major complications and death and a fourfold higher risk of clinical failure.[7] Additionally, another author of the Electra registry demonstrated that the risk factors of cardiac avulsion or tear with tamponade were: extraction of a Riata lead, female sex, mean lead dwelling time of more than 10 years, extraction of three or more leads, or placement of multiple sheaths. Additionally, occlusion or critical stenosis of superior venous access and mean lead dwelling time of >10 years were independent predictors of vascular avulsion or tearing.[22] As proved by the ELECTRA registry, ICD lead Dwell time over 10 years is associated with higher risk of major complication of TLE procedure.[23] Similarly, in the analyzed population only a trend towards higher amount of major complication is visible, but without statistical significance.

In the group of nearly three thousand TLE procedures and over five thousand extracted leads, the combined age of extracted leads was associated with an increased risk of major complications and all-cause 30-day mortality.[6] In addition, Epstein *et al*. in a multicentre retrospective study involving nine high-volume centres (385 patients with single-coil ICD lead and 1791 patients with dual-coil ICD lead), indicated the presence of superior vena cava coil was associated with significantly higher complication rates.[24] In our study, a significantly higher percentage of dual-coil ICD leads was observed in the group with older ICD leads, which could have influenced the trend to a higher percentage of minor and major complications.

All-cause mortality in our patients within 30 days of TLE was 4.4% and was similar between groups. There was no death related to the procedure during the 30-day post-operative period in the group of patients with ICD electrodes older than 10 years. In the prospective FRAGILE registry (French Attitude reGistry in case of ICD LEad replacement), the authors compared two approaches in case of ICD lead replacement; extraction or capping and abandonment.[25] In this registry, there was no statistical difference between both groups concerning early and 2 years complications. However, the decision on ICD lead replacement in non-infectious TLE indications depended on the patient's age, comorbidities, and lead dwelling time. We think that taking into account the possible late consequences of abandoned leads and the results from our study show high clinical success and low complication rates. Therefore, we believe it is reasonable to perform lead extractions of very old ICD leads in experienced centres.[10] However, the frequent utilization of multiple extraction tools requires more experience and versatility of the operator and increases procedural costs.

Study limitations

The primary study limitation was a relatively small sample of patients with ICD leads with more than 10 years of dwell time and single-centre experience. We did not compare mechanical dilator sheaths or evolution systems and other techniques currently used for TLE because the authors used only mechanical systems, the authors did not utilize internal transjugular approach. During TLE procedure: laser techniques, electrosurgical sheaths and ICE were not used. Furthermore, the follow-up was limited to a 30-day post-procedural period. This study presents outcomes of high-volume centres and operators with expertise in mechanical extraction systems, and therefore our results may not be widely applicable to less experienced centres. Additional studies with a larger sample size are needed in order to clarify the role of lead dwell time as a predictor of outcomes in lead extraction.

Future directions

Further research involving more patients is needed. Moreover, outcomes beyond 30-day post-TLE are warranted. Finally, other extraction techniques, i.e. laser, could be explored in terms of efficacy and safety compared with mechanical techniques.

Conclusions

The TLE procedures involving the extraction of old ICD leads were effective and safe. In addition, the outcomes of ICD lead removal with a dwell time of >10 years did not differ significantly compared with younger ICD leads. However, extraction of older ICD leads required more frequent necessity for utilizing multiple extraction tools, more experience and versatility of the operator, and increased surgery costs.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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