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# Comparison of outcomes in infected cardiovascular implantable electronic devices between complete, partial, and failed lead removal: an ESC-EHRA-EORP ELECTRa (European Lead Extraction ConTrolled) registry

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**Aims** The present study sought to determine predictors for success and outcomes of patients who underwent cardiac implantable electronic devices (CIED) extraction indicated for systemic or local CIED related infection in particular where complete lead removal could not be achieved.

**Methods and results** ESC-EORP ELECTRa (European Lead Extraction ConTRolled Registry) is a European prospective lead extraction registry. Out of the total cohort, 1865/3510 (52.5%) patients underwent removal due to CIED related infection. Predictors and outcomes of failure were analysed. Complete removal was achieved in 1743 (93.5%) patients, partial (<4 cm of lead left) in 88 (4.7%), and failed (>4 cm of lead left) in 32 (1.8%) patients. Removal success was unrelated to type of CIED infection (pocket or systemic). Predictors for failure were older leads and older patients [odds ratio (OR) 1.14 (1.08–1.19), $P < 0.0001$ and OR 2.68 (1.22–5.91), $P = 0.0146$, respectively]. In analysis by lead, predictors for failure were: pacemaker vs. defibrillator removal and failure to engage the locking stylet all the way to the tip [OR 0.20 (0.04–0.95), $P = 0.03$ and OR 0.32 (0.13–0.74), $P = 0.008$, respectively]. Significantly higher complication rates were noted in the failure group (40.6% vs. 15.9 for partial and 8.7% for success groups, $P < 0.0001$).

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Failure to remove a lead was a strong predictor for in hospital mortality [hazard ratio of 2.05 (1.01–4.16), $P = 0.046$].

**Conclusion** A total of 6.5% of infected CIED patients failed attempted extraction. Only were >4 cm of lead remained resulted in higher procedural complications and mortality rates.

**Keywords** Lead extraction • Cardiac implantable electronic devices • Infection • Registry



### What's new?

- Complete lead removal failed in 6.5% of infected cardiac implantable electronic devices patients.
- Baseline demographic variables including infectious status did not predict extraction failure.
- Failure to remove >4 cm of the lead but not partial failure, was associated with increased risk for procedural complications and higher mortality rates.

## Introduction

Over the past decade, there has been a dramatic increase in the number of cardiac implantable electronic devices (CIED),[1,2] and an exponential rise in transvenous lead extraction (TLE) procedures exceeding the increase in implantation rates.[3–7]

Current CIED guidelines recommend complete removal of all hardware, regardless of location of infection for patients with established CIED infection.[4] Complete removal is required because infection relapse rates due to retained hardware are high according to several small series, with no information on characteristics of the initial infection and the predictors/prognosis of retained material.[4,7]

Despite the evolvement in extraction techniques from simple traction to extraction with powered sheaths (mechanical or laser), TLE remains a technically challenging procedure which is still associated with small but inherent risks and procedural mortality.[8] Furthermore, complete removal of all retained hardware cannot always be achieved. To date, predictors of incomplete lead extraction of infected CIED systems and the outcomes of these patients have not been extensively studied.

ELECTRa (European Lead Extraction ConTRolled Registry) is an ESC-EHRA-EORP European prospective lead extraction registry. The present study sought to determine predictors for success and outcomes of patients who underwent CIED extraction because of an infectious indication and where complete lead removal could not be achieved.

## Methods

### Patients

This study is based on the ESC-EHRA-EORP ELECTRa registry.[9] In brief, from 1 November 2012 to 31 May 2014, 116 European centres across all regions of the European continent were invited to participate, of which 73 from 19 countries participated in the study. A total of 3555 consecutive patients were enrolled, 3510 (98.7%) underwent TLE. For the purpose of the present study, 1865/3510 patients (52.5%) who underwent extraction for infectious reasons were included. All subjects provided written informed consent prior to the extraction procedure. No specific protocol or recommendations regarding technique were made for the TLE procedure. The executive committee in collaboration with the EURObservational Research Program (EORP) provided the study design, protocol, and the scientific leadership of the registry under the responsibility of the EHRA Scientific Initiatives Committee (SIC). For the purpose of the present study, only patients who underwent extraction for infectious reasons were included (1865 patients, 52.5% of the total cohort).

### Study design, definitions, and data management

In general, during removal procedures a stepwise approach is used. Simple traction is applied on the lead from the pocket, either with or without introduction of a locking stylet into the lead lumen. When removal by simple traction is not successful, a mechanical or powered sheaths was used. Each step of the procedure was documented in the case report form.

*Success or failure* was defined by the radiological findings and not clinical. Patients were divided into three groups depending on the outcome of the extraction procedure:

(1) 'Complete success' was classified as the removal of the entire lead system.
(2) 'Partial success' was defined as when most of the lead was removed, leaving at the most 4 cm of coil and/or insulation and/or lead tip.
(3) 'Failure' was definite if more than ≥4 mm tip remained.

If a patient had more than one lead removed, he/she was classified according to the worst outcome of any of the leads. For example, if a patient had three leads removed, one successful, one partial, and one failed, it was defined as a failed procedure.

Complications were divided into major and minor:

(1) Major complications included: sepsis, multiorgan failure, tamponade, major vessel laceration, life-threatening arrhythmia, heart failure, acute myocardial infarction, acute massive valvular regurgitation, or any need for emergency surgery.
(2) Minor complications included pericardial effusion not requiring pericardiocentesis or surgical intervention, hemothorax not requiring a chest tube, haematoma at the surgical site requiring reoperation for drainage, arm swelling or thrombosis of implant veins resulting in medical intervention, vascular repair near the implant site or venous entry site, haemodynamically significant air embolism, migrated lead fragment without sequelae, blood transfusion related to blood loss during surgery, pneumothorax requiring a chest tube, and pulmonary embolism not requiring surgical intervention.

High volume and low volume centres were defined as >30 and <30 extraction procedures/year.

### Statistical analysis

Univariate analyses were applied to both continuous and categorical variables, and the results were summarized according to the three groups. Continuous variables were reported as median and interquartile range. Among-group comparisons were made using a non-parametric test (Kruskal–Wallis test). Categorical variables were reported as percentages (without missing values if applicable). Among-group comparisons were made using a $\chi^2$ test or the Fisher's exact test (if any expected cell count was less than five).

Multivariate logistic regressions including variables considered of relevant clinical interest (except variables with a high number of missing data) were performed to determine predictor factors on failure outcomes. Mortality was studied through a multivariate Cox regression and survival at discharge according to the three groups was illustrated thanks to the Kaplan–Meier method and a log-rank test.

A two-sided *P*-value of 0.05 was considered as statistically significant. All the statistical analyses and graphs were performed using SAS statistical software version 9.4 (SAS Institute, Inc., Cary, NC, USA).

## Results

### Patients and leads characteristics

Lead extraction for infectious reasons was performed in 1865 (52.5% of the total registry) patients. Complete procedural information was available for 1863 (99.9%) patients who constituted the present study cohort. Complete removal of all leads was achieved in 1743 (93.5%) patients, partial removal in 88 (4.7%) and in 32 (1.8%) the procedure was concluded as failure. There were no key differences between these three patient groups. Baseline clinical patient characteristics are outlined in *Table 1*.

Baseline CIED characteristics are outlined in *Table 2*. Patients with partial success or failure had significantly more pacemakers (PMs) than in the complete success group (76.1% and 78.1% vs. 57.9%, respectively, $P < 0.0001$), while the opposite was observed for implantable cardiac defibrillators (ICDs) (23.9% and 21.9% vs. 38.6%, respectively, $P = 0.0001$).

The rate of lead removal failure was related to the type of device implanted or the primary indication for their CIED; in patients implanted with PM due to sinus node dysfunction complete lead removal was successful in 38.6%, partially successful in 26.9%, and failed in 16% ($P = 0.0128$). The opposite trend was observed in patients with devices for complete atrioventricular block (AVB); 53.8% success, 59.7% partially successful, and 76% in the failure group, ($P = 0.0627$) (*Table 2*). This was not observed in patient undergoing ICD removal.

The unsuccessful groups (partial and complete failure) had more previous complications with their CIED (≈59% vs. 38% respectively, $P < 0.0001$) with no difference in respect to the type of complication (i.e. infectious or not, *Table 2*). Specifically, they had more system revisions and generator replacements compared with the success group (*Table 2*). The failure group had higher rates of previous attempts for extraction as well as a trend towards more damage to leads during the previous procedure (previous attempts/lead damage: 25%/87.5% in failure group, 9.1%/75% in partial success group, and 5%/52.3% in the success group, $P < 0.0001$ and $P = 0.087$, respectively).

Several lead characteristics were more prevalent in the unsuccessful groups such as unipolar PM leads, left insertion vein site and more passive lead fixations (Supplementary material online, *Table S1*). Finally, the median time from lead implant to extraction was significantly longer in the failure group (12.5 years vs. 11 years for the partial group vs. 5 years for the success group, $P < 0.0001$).

### Infectious reason for removal

The median time from first symptoms of CIED infection to the extraction procedure (days) was significantly longer in patients with failed extraction (81 days vs. 56 days in the partial group vs. 41 days in the success group, $P = 0.0366$) (*Table 3*). Interestingly, success rates between patients presenting with local CIED infection and systemic CIED infection were identical (≈62% and ≈36%, respectively) (*Table 3*). Type of bacteria in cases of positive cultures also did not differ between groups (*Table 3*). Additionally, there was no correlation between success of extraction and time from initiation of antibiotic treatment to the procedure (≈10 days, *Table 3*).

### Lead removal procedure

No difference was observed in success rates whether the procedure was performed by electrophysiologist or cardiac surgeon and if performed in the catheter laboratory or operative room (Supplementary material online, *Table S2*). Similarly, there were no differences between high-volume and low-volume centres in terms of success rates.

*Table 4* summarizes the lead removal approach and tools used. In 60% of the patients, the lead could not be removed by traction alone and a sheath or other tools were needed. However, in cases were successful complete removal failed the operators needed to use sheaths in 75% and 78% of the cases [for partial lead removal and failed lead removal, respectively (*Table 4*)]. The most common approach was superior left (≈68% for the partial and failure groups and 80% for the success group, $P = 0.0016$). However, in cases of failure or partial success most operators opted to convert to femoral approach rather than a jugular approach using a wide variety of tools (snares, lasso, pigtail, ablation catheters, and etc.) (*Table 4*). Patients were referred to surgical extraction in 31/48 (65%) of the cases of failure, while none were referred for surgery in cases of partial failure. Almost all patients with complete success and majority of partial success were considered by operator to have clinical success as opposed to the minority in the failure group (99.9% and 86.4% vs. 27.1%, respectively, $P < 0.0001$).

### Outcomes during hospitalization

No difference was observed between groups in the median length of hospitalization (days) (7 days for success group vs. 8 days for partial success group vs. 9 days for failure group, $P = 0.169$) (*Table 5*). However, significantly higher major and minor complication rates were noted in the failure group (40.6% vs. 15.9% for partial and 8.7% for success groups, $P < 0.0001$) (*Table 5*). Half of the patients were reimplanted during the same hospitalization regardless of the success of the procedure, mostly with the same type of device prior to extraction (≈68%) (*Table 5*).

**Table 1** **Patient characteristics**

| Variables | Class | Statistic | Total (*N* = 1863) | Complete lead removal (*N* = 1743) | Partial lead removal (*N* = 88) | Failed lead removal (*N* = 32) | *P*-value |
|---|---|---|---|---|---|---|---|
| Age (years) | | Median (IQR) | 72.00 (62.00–79.00) | 72.00 (62.00–79.00) | 72.00 (66.00–77.50) | 67.50 (59.00–77.00) | 0.5765[b] |
| Gender | Male | *n*/*N* (%) | 1451/1863 (77.89%) | 1361/1743 (78.08%) | 68/88 (77.27%) | 22/32 (68.75%) | 0.4472[c] |
| | Female | *n*/*N* (%) | 412/1863 (22.11%) | 382/1743 (21.92%) | 20/88 (22.73%) | 10/32 (31.25%) | |
| Body mass index (kg/m$^2$) | | Median (IQR) | 26.00 (23.70–28.70) | 26.00 (23.70–28.80) | 25.70 (23.25–27.80) | 25.60 (23.00–28.40) | 0.531[b] |
| Left ventricular ejection fraction (%) | | Median (IQR) | 50.00 (35.00–60.00) | 50.00 (34.00–60.00) | 50.00 (35.00–60.00) | 60.00 (35.00–60.00) | 0.0389[b] |
| Type of centre | Low-volume centre | *n*/*N* (%) | 349/1863 (18.73%) | 328/1743 (18.82%) | 15/88 (17.05%) | 6/32 (18.75%) | 0.9171[c] |
| | High-volume centre | *n*/*N* (%) | 1514/1863 (81.27%) | 1415/1743 (81.18%) | 73/88 (82.95%) | 26/32 (81.25%) | |
| Coronary artery disease | | *n*/*N* (%) | 740/1843 (40.15%) | 709/1724 (41.13%) | 23/88 (26.14%) | 8/31 (25.81%) | 0.0051[c] |
| Valvular heart disease | | *n*/*N* (%) | 305/1858 (16.42%) | 290/1738 (16.69%) | 11/88 (12.50%) | 4/32 (12.50%) | 0.4883[c] |
| Previous sternotomy | | *n*/*N* (%) | 321/1859 (17.27%) | 304/1739 (17.48%) | 12/88 (13.64%) | 5/32 (15.63%) | 0.6286[c] |
| Congenital heart disease | | *n*/*N* (%) | 39/1857 (2.10%) | 32/1737 (1.84%) | 7/88 (7.95%) | 0/32 (0.00%) | 0.0003[c] |
| Previous repair | | *n*/*N* (%) | 29/39 (74.36%) | 22/32 (68.75%) | 7/7 (100.00%) | 0/32 (0.00%) | 0.0863[c] |
| Primary electrical disease | | *n*/*N* (%) | 546/1852 (29.48%) | 513/1733 (29.60%) | 23/87 (26.44%) | 10/32 (31.25%) | 0.7992[c] |
| Hypertension | | *n*/*N* (%) | 1097/1848 (59.36%) | 1031/1728 (59.66%) | 47/88 (53.41%) | 19/32 (59.38%) | 0.507[c] |
| Diabetes mellitus | | *n*/*N* (%) | 508/1849 (27.47%) | 481/1730 (27.80%) | 18/87 (20.69%) | 9/32 (28.13%) | 0.348[c] |
| Chronic kidney disease | | *n*/*N* (%) | 418/1853 (22.56%) | 396/1734 (22.84%) | 15/88 (17.05%) | 7/31 (22.58%) | 0.4474[c] |
| Chronic obstructive Pulmonary disease | | *n*/*N* (%) | 192/1848 (10.39%) | 180/1729 (10.41%) | 11/88 (12.50%) | 1/31 (3.23%) | 0.3446[c] |

[a]Kruskal–Wallis test.
[b]Pearson's $\chi^2$ test.

**Table 2** Cardiac implantable electronic device characteristics

| Variables | Class | Statistic | Total (*N* = 1863) | Complete Lead removal (*N* = 1743) | Partial Lead removal (*N* = 88) | Failed Lead removal (*N* = 32) | *P*-value |
|---|---|---|---|---|---|---|---|
| Implanted device is: pacemaker | | *n*/*N* (%) | 1078/1863 (57.86%) | 986/1743 (56.57%) | 67/88 (76.14%) | 25/32 (78.13%) | <0.0001[b] |
| | Single-chamber | *n*/*N* (%) | 174/1078 (16.14%) | 164/986 (16.63%) | 8/67 (11.94%) | 2/25 (8.00%) | 0.1942[b] |
| | Dual-chamber | *n*/*N* (%) | 810/1078 (75.14%) | 734/986 (74.44%) | 55/67 (82.09%) | 21/25 (84.00%) | |
| | CRT-pacemaker | *n*/*N* (%) | 86/1078 (7.98%) | 82/986 (8.32%) | 3/67 (4.48%) | 1/25 (4.00%) | |
| | Other | *n*/*N* (%) | 8/1078 (0.74%) | 6/986 (0.61%) | 1/67 (1.49%) | 1/25 (4.00%) | |
| Indication for CIED (PM) | | | | | | | |
| Sinus node disease | | *n*/*N* (%) | 403/1078 (37.38%) | 381/986 (38.64%) | 18/67 (26.87%) | 4/25 (16.00%) | 0.0128[b] |
| AV block | | *n*/*N* (%) | 590/1078 (54.73%) | 531/986 (53.85%) | 40/67 (59.70%) | 19/25 (76.00%) | 0.0627[b] |
| Carotid sinus syndrome | | *n*/*N* (%) | 23/1078 (2.13%) | 20/986 (2.03%) | 3/67 (4.48%) | 0/32 (0.00%) | 0.3072[b] |
| Heart failure | | *n*/*N* (%) | 78/1078 (7.24%) | 73/986 (7.40%) | 4/67 (5.97%) | 1/25 (4.00%) | 0.744[b] |
| Other | | *n*/*N* (%) | 46/1078 (4.27%) | 40/986 (4.06%) | 5/67 (7.46%) | 1/25 (4.00%) | 0.4094[b] |
| Implanted device is: ICD | | *n*/*N* (%) | 780/1863 (41.87%) | 752/1743 (43.14%) | 21/88 (23.86%) | 7/32 (21.88%) | 0.0001[b] |
| | Single-chamber | *n*/*N* (%) | 153/780 (19.62%) | 151/752 (20.08%) | 1/21 (4.76%) | 1/7 (14.29%) | 0.5121[b] |
| | Dual-chamber | *n*/*N* (%) | 241/780 (30.90%) | 234/752 (31.12%) | 5/21 (23.81%) | 2/7 (28.57%) | |
| | CRT-D | *n*/*N* (%) | 384/780 (49.23%) | 365/752 (48.54%) | 15/21 (71.43%) | 4/7 (57.14%) | |
| | Other | *n*/*N* (%) | 2/780 (0.26%) | 2/752 (0.27%) | 0/88 (0.00%) | 0/32 (0.00%) | |
| Indication for CIED (ICD) | | | | | | | |
| Sinus node disease | | *n*/*N* (%) | 35/780 (4.49%) | 33/752 (4.39%) | 1/21 (4.76%) | 1/7 (14.29%) | 0.4518[b] |
| AV block | | *n*/*N* (%) | 77/780 (9.87%) | 75/752 (9.97%) | 2/21 (9.52%) | 0/32 (0.00%) | 0.6776[b] |
| Heart failure | | *n*/*N* (%) | 528/780 (67.69%) | 507/752 (67.42%) | 16/21 (76.19%) | 5/7 (71.43%) | 0.6826[b] |
| Other | | *n*/*N* (%) | 239/780 (30.64%) | 231/752 (30.72%) | 7/21 (33.33%) | 1/7 (14.29%) | 0.6203[b] |
| Prevention of sudden death (ICD) | Primary | *n*/*N* (%) | 552/780 (70.77%) | 530/752 (70.48%) | 16/21 (76.19%) | 6/7 (85.71%) | 0.5813[b] |
| | Secondary | *n*/*N* (%) | 228/780 (29.23%) | 222/752 (29.52%) | 5/21 (23.81%) | 1/7 (14.29%) | |
| Previous complications to CIED | | *n*/*N* (%) | 735/1863 (39.45%) | 664/1743 (38.10%) | 52/88 (59.09%) | 19/32 (59.38%) | <0.0001[b] |
| Infection | | *n*/*N* (%) | 463/735 (62.99%) | 420/664 (63.25%) | 30/52 (57.69%) | 13/19 (68.42%) | 0.642[b] |
| Malfunction | | *n*/*N* (%) | 276/735 (37.55%) | 245/664 (36.90%) | 24/52 (46.15%) | 7/19 (36.84%) | 0.4135[b] |
| Chronic pain | | *n*/*N* (%) | 22/735 (2.99%) | 21/664 (3.16%) | 0/88 (0.00%) | 1/19 (5.26%) | 0.3665[b] |
| Venous thrombosis | | *n*/*N* (%) | 15/735 (2.04%) | 15/664 (2.26%) | 0/88 (0.00%) | 0/32 (0.00%) | 0.441[b] |
| Other | | *n*/*N* (%) | 37/735 (5.03%) | 34/664 (5.12%) | 2/52 (3.85%) | 1/19 (5.26%) | 0.9203[b] |
| Number of previous system revisions | | Median (IQR) | 0.00 (0.00–1.00) | 0.00 (0.00–1.00) | 1.00 (0.00–1.00) | 1.00 (0.00–2.00) | 0.0012[c] |
| Number of generator replacements | | Median (IQR) | 1.00 (0.00–1.00) | 1.00 (0.00–1.00) | 1.00 (1.00–2.00) | 1.00 (1.00–2.00) | <0.0001[c] |
| 1 generator replacement | | *n*/*N* (%) | 721/1863 (38.70%) | 669/1743 (38.38%) | 38/88 (43.18%) | 14/32 (43.75%) | 0.5589[b] |
| 2 generators replacement | | *n*/*N* (%) | 201/1863 (10.79%) | 169/1743 (9.70%) | 25/88 (28.41%) | 7/32 (21.88%) | <0.0001[b] |
| CIED upgrades | | *n*/*N* (%) | 266/1863 (14.28%) | 249/1743 (14.29%) | 12/88 (13.64%) | 5/32 (15.63%) | 0.9621[b] |
| Previous attempt of lead extraction | | *n*/*N* (%) | 104/1863 (5.58%) | 88/1743 (5.05%) | 8/88 (9.09%) | 8/32 (25.00%) | <0.0001[b] |
| Outcome of the previous extraction | Lead damaged | *n*/*N* (%) | 59/104 (56.73%) | 46/88 (52.27%) | 6/8 (75.00%) | 7/8 (87.50%) | 0.0869[b] |

*Continued*

**Table 2** *Continued*

| Variables | Class | Statistic | Total (*N* = 1863) | Complete Lead removal (*N* = 1743) | Partial Lead removal (*N* = 88) | Failed Lead removal (*N* = 32) | *P*-value |
|---|---|---|---|---|---|---|---|
| | Lead not damaged | *n*/*N* (%) | 45/104 (43.27%) | 42/88 (47.73%) | 2/8 (25.00%) | 1/8 (12.50%) | |
| Which way? | Manual | *n*/*N* (%) | 73/104 (70.19%) | 64/88 (72.73%) | 5/8 (62.50%) | 4/8 (50.00%) | 0.3578[b] |
| | With tools | *n*/*N* (%) | 31/104 (29.81%) | 24/88 (27.27%) | 3/8 (37.50%) | 4/8 (50.00%) | |
| Standard stylet | | *n*/*N* (%) | 6/31 (19.35%) | 5/24 (20.83%) | 1/3 (33.33%) | 0/32 (0.00%) | 0.5043[b] |
| Locking stylet | | *n*/*N* (%) | 10/31 (32.26%) | 5/24 (20.83%) | 1/3 (33.33%) | 4/4 (100.00%) | 0.0073[b] |
| Mechanical sheath | | *n*/*N* (%) | 8/31 (25.81%) | 7/24 (29.17%) | 0/88 (0.00%) | 1/4 (25.00%) | 0.5525[b] |
| Laser sheath | | *n*/*N* (%) | 4/31 (12.90%) | 2/24 (8.33%) | 0/88 (0.00%) | 2/4 (50.00%) | 0.0553[b] |
| Lasso or Snare | | *n*/*N* (%) | 4/31 (12.90%) | 2/24 (8.33%) | 0/88 (0.00%) | 2/4 (50.00%) | 0.0553[b] |
| Basket | | *n*/*N* (%) | 0/31 (0.00%) | 0/24 (0.00%) | 0/3 (0.00%) | 0/4 (0.00%) | |
| Other | | *n*/*N* (%) | 6/31 (19.35%) | 5/24 (20.83%) | 1/3 (33.33%) | 0/32 (0.00%) | 0.5043[b] |

[a]Pearson's $\chi^2$ test.
[b]Kruskal–Wallis test.

**Table 3** **Infection characteristics**

| Variables | Class | Statistic | Total (*N* = 1863) | Complete lead removal (*N* = 1743) | Partial lead removal (*N* = 88) | Failed lead removal (*N* = 32) | *P*-value |
|---|---|---|---|---|---|---|---|
| Time from first symptoms of infection to removal (days) | | Median (IQR) | 42.00 (18.00–105.00) | 41.00 (18.00–103.00) | 56.00 (20.00–127.00) | 81.00 (25.00–215.00) | 0.0366[b] |
| Local CIED infections | | *n*/*N* (%) | 1169/1863 (62.75%) | 1095/1743 (62.82%) | 57/88 (64.77%) | 17/32 (53.13%) | 0.4901[c] |
| Systemic CIED infections | | *n*/*N* (%) | 679/1863 (36.45%) | 635/1743 (36.43%) | 29/88 (32.95%) | 15/32 (46.88%) | 0.3742[c] |
| Positive culture | | *n*/*N* (%) | 871/1615 (53.93%) | 821/1507 (54.48%) | 34/77 (44.16%) | 16/31 (51.61%) | 0.2008[c] |
| CoNS | | *n*/*N* (%) | 325/871 (37.31%) | 306/821 (37.27%) | 12/34 (35.29%) | 7/16 (43.75%) | 0.8422[c] |
| Ms-SA | | *n*/*N* (%) | 254/871 (29.16%) | 239/821 (29.11%) | 10/34 (29.41%) | 5/16 (31.25%) | 0.9822[c] |
| Mr-SA | | *n*/*N* (%) | 90/871 (10.33%) | 85/821 (10.35%) | 4/34 (11.76%) | 1/16 (6.25%) | 0.8338[c] |
| Gram- | | *n*/*N* (%) | 108/871 (12.40%) | 101/821 (12.30%) | 4/34 (11.76%) | 3/16 (18.75%) | 0.7357[c] |
| Other gram+ | | *n*/*N* (%) | 136/871 (15.61%) | 127/821 (15.47%) | 7/34 (20.59%) | 2/16 (12.50%) | 0.6806[c] |
| Fungal | | *n*/*N* (%) | 13/871 (1.49%) | 13/821 (1.58%) | 0/88 (0.00%) | 0/32 (0.00%) | 0.669[c] |
| Polymicrobial | | *n*/*N* (%) | 13/871 (1.49%) | 12/821 (1.46%) | 1/34 (2.94%) | 0/32 (0.00%) | 0.6931[c] |
| Antibiotic treatment pre-operatively | | *n*/*N* (%) | 1489/1863 (79.92%) | 1394/1743 (79.98%) | 69/88 (78.41%) | 26/32 (81.25%) | 0.9212[c] |
| Time since start appropriate treatment (days) | | Median (IQR) | 10.00 (5.00–20.00) | 10.00 (5.00–20.00) | 14.00 (7.00–21.00) | 7.00 (5.00–18.00) | 0.2308[b] |

[a]Kruskal–Wallis test.
[b]Pearson's $\chi^2$ test.

**Table 4** Lead removal approaches and tools

| Variables | Class | Statistic | Total (*N* = 4186) | Complete lead removal (*N* = 4028) | Partial lead removal (*N* = 110) | Failed lead removal (*N* = 48) | *P*-value |
|---|---|---|---|---|---|---|---|
| Approach for TLE: | | *n*/*N* (%) | 777/4186 (18.56%) | 740/4028 (18.37%) | 25/110 (22.73%) | 12/48 (25.00%) | 0.2624[b] |
| Superior right | | | | | | | |
| Superior left | | *n*/*N* (%) | 3332/4186 (79.60%) | 3224/4028 (80.04%) | 75/110 (68.18%) | 33/48 (68.75%) | 0.0016[b] |
| Femoral | | *n*/*N* (%) | 158/4186 (3.77%) | 134/4028 (3.33%) | 18/110 (16.36%) | 6/48 (12.50%) | <0.0001[b] |
| Stylet used | | *n*/*N* (%) | 3533/4119 (85.77%) | 3404/3963 (85.89%) | 91/109 (83.49%) | 38/47 (80.85%) | 0.4847[b] |
| Locking stylet engagement to tip | | *n*/*N* (%) | 1700/4119 (41.27%) | 1636/3963 (41.28%) | 49/109 (44.95%) | 15/47 (31.91%) | 0.3154[b] |
| Sheath used | | *n*/*N* (%) | 2506/4185 (59.88%) | 2386/4028 (59.24%) | 83/110 (75.45%) | 37/47 (78.72%) | <0.0001[b] |
| Total number of sheaths used | | Median (IQR) | 1.00 (1.00–2.00) | 1.00 (1.00–2.00) | 1.00 (1.00–2.00) | 2.00 (1.00–3.00) | <0.0001[c] |
| Sheath time | | Median (IQR) | 6.00 (3.00–15.00) | 6.00 (2.50–12.00) | 10.00 (3.00–21.50) | 20.00 (10.00–30.00) | <0.0001[c] |
| Lead alternative approach | Yes, Femoral | *n*/*N* (%) | 196/4185 (4.68%) | 154/4028 (3.82%) | 33/110 (30.00%) | 9/47 (19.15%) | <0.0001[b] |
| | Yes, Jugular | *n*/*N* (%) | 31/4185 (0.74%) | 28/4028 (0.70%) | 3/110 (2.73%) | 0/47 (0.00%) | |
| | Yes, Jugular and Femoral | *n*/*N* (%) | 16/4185 (0.38%) | 13/4028 (0.32%) | 1/110 (0.91%) | 2/47 (4.26%) | |
| | Yes, Other | *n*/*N* (%) | 22/4185 (0.53%) | 10/4028 (0.25%) | 5/110 (4.55%) | 7/47 (14.89%) | |
| Other tools used | | *n*/*N* (%) | 358/4185 (8.55%) | 294/4028 (7.30%) | 48/110 (43.64%) | 16/47 (34.04%) | <0.0001[b] |
| Lasso | | *n*/*N* (%) | 174/358 (48.60%) | 148/294 (50.34%) | 22/48 (45.83%) | 4/16 (25.00%) | 0.1306[b] |
| Snare | | *n*/*N* (%) | 170/358 (47.49%) | 134/294 (45.58%) | 26/48 (54.17%) | 10/16 (62.50%) | 0.2548[b] |
| Pigtail | | *n*/*N* (%) | 36/358 (10.06%) | 30/294 (10.20%) | 4/48 (8.33%) | 2/16 (12.50%) | 0.8735[b] |
| EP catheter | | *n*/*N* (%) | 36/358 (10.06%) | 24/294 (8.16%) | 10/48 (20.83%) | 2/16 (12.50%) | 0.0243[b] |
| Deflectable wires | | *n*/*N* (%) | 22/358 (6.15%) | 17/294 (5.78%) | 3/48 (6.25%) | 2/16 (12.50%) | 0.552[b] |
| Basket | | *n*/*N* (%) | 16/358 (4.47%) | 12/294 (4.08%) | 3/48 (6.25%) | 1/16 (6.25%) | 0.7487[b] |
| Catchers | | *n*/*N* (%) | 17/358 (4.75%) | 12/294 (4.08%) | 5/48 (10.42%) | 0/16 (0.00%) | 0.1056[b] |
| Other | | *n*/*N* (%) | 7/358 (1.96%) | 5/294 (1.70%) | 2/48 (4.17%) | 0/16 (0.00%) | 0.4397[b] |
| Solution in case of partial extraction | Lead abandonment | *n*/*N* (%) | 104/110 (94.55%) | 0/459 (0.00%) | 104/110 (94.55%) | 0/28 (0.00%) | – |
| | Surgical extraction | *n*/*N* (%) | 6/110 (5.45%) | 0/459 (0.00%) | 6/110 (5.45%) | 0/28 (0.00%) | |
| Solution in case of failure | Lead abandonment | *n*/*N* (%) | 17/48 (35.42%) | 0/459 (0.00%) | 0/110 (0.00%) | 17/48 (35.42%) | – |
| | Surgical extraction | *n*/*N* (%) | 31/48 (64.58%) | 0/459 (0.00%) | 0/110 (0.00%) | 31/48 (64.58%) | |
| Assumed clinical success | | *n*/*N* (%) | 4130/4186 (98.66%) | 4022/4028 (99.85%) | 95/110 (86.36%) | 13/48 (27.08%) | <0.0001[b] |

[a]Pearson's $\chi^2$ test.
[b]Kruskal–Wallis test.

**Table 5** **Outcomes during hospitalization/reimplantation**

| Variable | Class | Statistic | Total (*N* = 1863) | Complete lead removal (*N* = 1743) | Partial lead removal (*N* = 88) | Failed lead removal (*N* = 32) | *P*-value |
|---|---|---|---|---|---|---|---|
| Duration of hospital stay related to TLE (days) | | Median (IQR) | 7.00 (4.00–13.00) | 7.00 (3.00–13.00) | 8.00 (4.00–15.00) | 9.00 (5.00–20.00) | 0.1668[b] |
| Complications | | *n*/*N* (%) | 178/1863 (9.55%) | 151/1743 (8.66%) | 14/88 (15.91%) | 13/32 (40.63%) | <0.0001[c] |
| Major | | *n*/*N* (%) | 67/1863 (3.60%) | 56/1743 (3.21%) | 4/88 (4.55%) | 7/32 (21.88%) | <0.0001[c] |
| Major complication type | Major complications Intra-procedure | *n*/*N* (%) | 18/67 (26.87%) | 15/56 (26.79%) | 0/88 (0.00%) | 3/7 (42.86%) | 0.3041[c] |
| | Major complications post-procedure | *n*/*N* (%) | 49/67 (73.13%) | 41/56 (73.21%) | 4/4 (100.00%) | 4/7 (57.14%) | |
| Intraoperative mortality | | *n*/*N* (%) | 5/1863 (0.27%) | 4/1743 (0.23%) | 0/88 (0.00%) | 1/32 (3.13%) | 0.0064[c] |
| Minor | | *n*/*N* (%) | 113/1863 (6.07%) | 98/1743 (5.62%) | 9/88 (10.23%) | 6/32 (18.75%) | 0.0021[c] |
| Minor complication type | Intra-procedural | *n*/*N* (%) | 19/113 (16.81%) | 16/98 (16.33%) | 3/9 (33.33%) | 0/32 (0.00%) | 0.4631[c] |
| | Post-procedural | *n*/*N* (%) | 90/113 (79.65%) | 78/98 (79.59%) | 6/9 (66.67%) | 6/6 (100.00%) | |
| | Intra- and post-procedural | *n*/*N* (%) | 4/113 (3.54%) | 4/98 (4.08%) | 0/88 (0.00%) | 0/32 (0.00%) | |
| CIED implanted during hospital stay | | *n*/*N* (%) | 913/1863 (49.01%) | 852/1743 (48.88%) | 44/88 (50.00%) | 17/32 (53.13%) | 0.8768[c] |
| Type of reimplanted CIED | Single chamber pacemaker | *n*/*N* (%) | 200/913 (21.91%) | 183/852 (21.48%) | 11/44 (25.00%) | 6/17 (35.29%) | 0.1955[c] |
| | Dual chamber pacemaker | *n*/*N* (%) | 339/913 (37.13%) | 310/852 (36.38%) | 21/44 (47.73%) | 8/17 (47.06%) | |
| | CRT-Pacemaker | *n*/*N* (%) | 56/913 (6.13%) | 51/852 (5.99%) | 3/44 (6.82%) | 2/17 (11.76%) | |
| | Dual chamber ICD | *n*/*N* (%) | 86/913 (9.42%) | 84/852 (9.86%) | 1/44 (2.27%) | 1/17 (5.88%) | |
| | Single chamber ICD | *n*/*N* (%) | 66/913 (7.23%) | 65/852 (7.63%) | 1/44 (2.27%) | 0/32 (0.00%) | |
| | CRT-Defibrillator | *n*/*N* (%) | 166/913 (18.18%) | 159/852 (18.66%) | 7/44 (15.91%) | 0/32 (0.00%) | |
| Update | Same type | *n*/*N* (%) | 628/913 (68.78%) | 588/852 (69.01%) | 29/44 (65.91%) | 11/17 (64.71%) | 0.9497[c] |
| | Upgrade | *n*/*N* (%) | 79/913 (8.65%) | 72/852 (8.45%) | 5/44 (11.36%) | 2/17 (11.76%) | |
| | Downgrade | *n*/*N* (%) | 206/913 (22.56%) | 192/852 (22.54%) | 10/44 (22.73%) | 4/17 (23.53%) | |

[a]Kruskal–Wallis test.
[b]Pearson's $\chi^2$ test.

**Table 6 Predictors for failed lead removal: multivariate analysis on lead level**

| Covariables | Reference level | Class level | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|---|
| Gender | Male | Female | 1.14 (0.49–2.62) | 0.7649 |
| Age (class) | ≥65 years | <65 years | 2.68 (1.22–5.91) | 0.0146 |
| Diabetes mellitus | No | Yes | 1.38 (0.57–3.31) | 0.8961 |
| Chronic kidney disease | No | Yes | 1.37 (0.54–3.48) | 0.054 |
| Systemic infections | No | Yes | 1.43 (0.68–3.01) | 0.349 |
| Type of centre | Low-volume centre | High-volume centre | 0.77 (0.30–2.00) | 0.5938 |
| Type of device | Pacemaker | Defibrillator | 0.58 (0.21–1.60) | 0.9739 |
| | | No generator | 0.00 (0.00 to >99.99) | 0.9711 |
| Number of previous system revisions | Continuous variable | | 0.99 (0.94–1.05) | 0.8593 |
| Number of leads in heart | Continuous variable | | 1.32 (0.89–1.96) | 0.1726 |
| Oldest lead dwelling time (years) | Continuous variable | | 1.14 (1.08–1.19) | <0.0001 |
| Right-side lead removed | No | Yes | 1.10 (0.48–2.53) | 0.8208 |

Multivariate logistic regression with 'radiological failed lead removal' as the outcome.
The variables cited in the shell tables which were subparts of other variables or had more than 20% of missing data has not been considered in this model: «For ICD (single/dual coil)», «max sheath size used», and «max (total number of sheaths used)».
«Unknown» class levels were integrated in the model to have the largest size of population analysed but there were not displayed in the following result tables.
Number of events/number of subjects analysed in this model: 32/1848 (98.7% of the total infected population analysed).

## Predictors for failure

Multivariate analysis of patient and device characteristics (with <20% missing data) revealed that the longer lead implant duration (years) and the older the patients age (≥65 years), the higher the likelihood for failed extraction per patient [odds ratio (OR) 1.14 (1.08–1.19), $P < 0.0001$ and OR 2.68 (1.22–5.91), $P = 0.0146$, respectively] (*Table 6*). Analysis performed by lead failure (number of failed events 43 out of a total of 4077 leads extracted, *Table 7*), added PM vs. ICD removal and failure to engage the locking stylet all the way to the tip as predictors to failed extractions [OR 0.20 (0.04–0.95), $P = 0.03$ and OR 0.32 (0.13–0.74), $P = 0.008$, respectively].

Similar to failure, predictors for incomplete removal or failure by patient—related analysis, were the longer (years) the leads were implanted and the number of leads [OR 1.11 (1.08–1.15), $P < 0.0001$ and OR 1.54 (1.23–1.93), $P = 0.0001$, respectively] (*Table 8*). Analysis on lead level (number of unsuccessful events 151 out of a total of 4077 leads extracted, *Table 9*), revealed similar predictors: the longer time (years) the leads were implanted [OR 1.10 (1.06–1.13), $P < 0.0001$], whether a sheath was used [OR 2.29 (1.26–4.16), $P = 0.007$] and whether other tools were needed [OR 3.02 (1.43–6.42), $P = 0.004$]. Left ventricular (LV) leads were also predictive of failure [2.69 (0.72–10.05), $P = 0.01$]. On the other hand, extraction of double coil leads, and active fixations were protective [OR 0.21 (0.07–0.68), $P = 0.01$ and OR 0.73 (0.46–1.14), $P = 0.009$, respectively, *Table 9*].

## Mortality

There were five intraoperative mortality cases. Four of them occurred in complete lead removal group and all were a result of mechanical complications (*Table 5*). Four deaths were secondary to cardiac tamponade and one due to hemothorax.

During hospitalization 42 patients (2.3%) died. Of these, 4 (12.5%) were from the failure group, 3 (3.4%) from the partial group, and 35 (2%) from the success group. The log-rank *P*-value comparing all three groups is equal to 0.003 (*Figure 1*).

Multivariate analysis on the whole ELECTRA registry revealed that systemic infection had a hazard ratio of 2.05 (1.01–4.16) ($P = 0.046$) for mortality.

# Discussion

The ESC-EHRA-EORP ELECTRa registry is the first large prospective controlled registry on consecutive TLE procedures conducted by an independent scientific society [European Heart Rhythm Association (EHRA)/European Society of Cardiology (ESC)] in Europe.[9] One of their observations was that CIED infection was the most common [52.8% of all cases (19.3% systemic)] indication for TLE. Additionally, the study concluded that infection was one of the predictors of all-cause mortality during the TLE hospitalization with an OR of 4.93 (95% confidence interval 2.72–8.93, $P < 0.0001$).[9] The only guideline Class I indication for lead extraction is infection;[10] however, in this large European registry almost half of the extraction procedures were performed for non-infectious reasons. In a large USA based study, infection was the indication in only 13% of the total extraction procedures.[11]

In the present study, which included 1863 patients from the ELECTRa registry[9] who underwent TLE because of infection, complete removal of hardware was achieved in 93.5% of the patients, however, in 6.5% total removal was not achieved thus theoretically leaving the patient at risk because of indwelling leads. Specifically, infected leads that are not completely removed pose a challenge because of the likelihood for remaining infection. Another concern is reimplantation during an active infection, especially in the setting of incomplete TLE.

**Table 7 Predictors for failed lead removal: multivariate analysis on lead level**

| Covariables | Reference level | Class level | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|---|
| Gender | Male | Female | 1.15 (0.51–2.59) | 0.736 |
| Age (class) | ≥65 years | <65 years | 3.44 (1.61–7.38) | 0.0015 |
| Diabetes mellitus | No | Yes | 0.89 (0.36–2.17) | 0.9466 |
| Chronic kidney disease | No | Yes | 1.74 (0.72–4.20) | 0.9523 |
| Systemic infections | No | Yes | 1.23 (0.60–2.51) | 0.5732 |
| Type of device | Pacemaker | Defibrillator | 0.20 (0.04–0.95) | 0.0308 |
| | | No generator | 0.00 (0.00 to >99.99) | 0.9508 |
| Number of previous system revisions | Continuous variable | | 0.99 (0.94–1.04) | 0.6699 |
| Lead type (any lead) | PM leads | Double coil | 3.72 (0.59–23.54) | 0.3896 |
| | | LV leads | 2.70 (0.25–29.31) | 0.8081 |
| | | Single coil | 2.08 (0.21–20.41) | 0.973 |
| Insertion vein | Axillary | Cephalic | 634.19 (0.00 to >99.99) | 0.9736 |
| | | External jugular | 3639.49 (0.00 to >99.99) | 0.9159 |
| | | Femoral | 3.11 (0.00 to >99.99) | 0.9734 |
| | | Internal jugular | 9611.99 (0.00 to >99.99) | 0.8838 |
| | | Not applicable | 1279.17 (0.00 to >99.99) | 0.9504 |
| | | Subclavian | 1813.74 (0.00 to >99.99) | 0.9388 |
| Lead tip location | Right atrium | CS or branches | 2.59 (0.24–28.22) | 0.8959 |
| | | Free floating | 0.00 (0.00 to >99.99) | 0.9373 |
| | | Left atrium | 0.00 (0.00 to >99.99) | 0.9737 |
| | | Left ventricle | 9.61 (0.79 to >99.99) | 0.8577 |
| | | Other | 0.00 (0.00 to >99.99) | 0.915 |
| | | Right ventricle | 2.20 (0.94–5.16) | 0.9006 |
| Fixation type | Passive | Active | 1.69 (0.70–4.05) | 0.2923 |
| Time from date of lead implant to extraction procedure (years) | Continuous variable | | 1.13 (1.06–1.19) | <0.0001 |
| Approach for TLE: | No | Yes | 5.96 (0.63–56.61) | 0.1199 |
| Superior right | | | | |
| Superior left | No | Yes | 6.49 (0.67–63.06) | 0.1072 |
| Femoral | No | Yes | 1.61 (0.39–6.71) | 0.5104 |
| Stylet used | No | Yes | 0.86 (0.21–3.51) | 0.8346 |
| Locking stylet engagement to tip | No | Yes | 0.32 (0.13–0.74) | 0.0079 |
| Sheath used | No | Yes | 2.88 (0.87–9.49) | 0.0827 |
| Lead alternative approach | No | Femoral | 5.70 (0.88–36.88) | 0.6958 |
| | | Jugular | 1.10 (0.06–21.49) | 0.1452 |
| | | Other | 75.40 (13.37 to >99.99) | <0.0001 |
| Other tools used | No | Yes | 1.04 (0.18–6.01) | 0.9628 |

The variables cited in the shell tables which were subparts of other variables or had more than 20% of missing data has not been considered in this model: «type of stylet used», «sheath type used», «total number of sheaths», and «sheath time».
Number of events/number of subjects analysed in this model: 43/4077 (97.4% of the total infected leads analysed).

Interestingly, even with only partial radiological success most operators still concluded the procedure as complete clinical success. This is in contrast to guidelines, were only complete removal should be counted as clinical success in patients with infection.[4]

## Patients and leads characteristics

The present study did not find major differences in basic patient characteristics between the complete, partial, and failure groups, emphasizing that success was not dependent on the clinical status of the patient. Interestingly, infected PMs removal was more often unsuccessful as opposed to infected ICDs. Moreover, PMs implanted because of AVB tended to have a worse procedural outcome than PMs implanted because of sinus node dysfunction. One might speculate that patients implanted for AVB are more pacer dependent which tends to complicate the extraction procedure or that patients with sinus node dysfunction were younger than those with AVB. Of note, these differences were not observed in the ICD group. Success vs. failure rates were not different regarding PM indications on top of existing ICD indication.

**Table 8 Predictors for failed or partial lead removal: multivariate analysis on patients level**

| Covariables | Reference level | Class level | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|---|
| Gender | Male | Female | 0.96 (0.60–1.53) | 0.8564 |
| Age (class) | ≥65 years | <65 years | 1.02 (0.65–1.59) | 0.9355 |
| Diabetes mellitus | No | Yes | 0.95 (0.59–1.53) | 0.8678 |
| Chronic kidney disease | No | Yes | 0.79 (0.47–1.32) | 0.5059 |
| Systemic infections | No | Yes | 1.13 (0.74–1.71) | 0.5727 |
| Type of centre | Low-volume centre | High-volume centre | 0.92 (0.54–1.55) | 0.7417 |
| Type of device | Pacemaker | Defibrillator | 0.50 (0.30–0.84) | 0.9717 |
| Type of device | Pacemaker | No generator | 0.00 (0.00 to >99.99) | 0.9682 |
| Number of previous system revisions | Continuous variable | | 0.98 (0.94–1.03) | 0.4901 |
| Number of leads in heart | Continuous variable | | 1.54 (1.23–1.93) | 0.0001 |
| Oldest lead dwelling time (years) | Continuous variable | | 1.11 (1.08–1.15) | <0.0001 |
| Right-side lead removed | No | Yes | 0.90 (0.58–1.41) | 0.6612 |

Multivariate logistic regression with 'radiological failed or partial lead removal' as the outcome.
The variables cited in the shell tables which were subparts of other variables or had more than 20% of missing data has not been considered in this model: «for ICD (single/dual coil)», «max sheath size used», and «max (total number of sheaths used)».
Number of events/number of subjects analysed in this model: 119/1848 (98.7% of the total infected population analysed).

**Table 9 Predictors for failed or partial lead removal: multivariate analysis on leads level**

| Covariables | Reference level | Class level | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|---|
| Gender | Male | Female | 1.02 (0.66–1.59) | 0.9224 |
| Age (class) | ≥65 years | <65 years | 1.37 (0.91–2.07) | 0.1277 |
| Diabetes mellitus | No | Yes | 0.88 (0.56–1.39) | 0.185 |
| Chronic kidney disease | No | Yes | 0.66 (0.39–1.09) | 0.9171 |
| Systemic infections | No | Yes | 0.88 (0.59–1.30) | 0.5162 |
| Type of device | Pacemaker | Defibrillator | 0.92 (0.53–1.60) | 0.9459 |
| | | No generator | 0.00 (0.00 to >99.99) | 0.9451 |
| Number of previous system revisions | Continuous variable | | 0.97 (0.92–1.03) | 0.3034 |
| Lead type (any lead) | PM leads | Double coil | 0.21 (0.07–0.68) | 0.0105 |
| | | LV leads | 2.69 (0.72–10.05) | 0.0135 |
| | | Single coil | 0.42 (0.12–1.46) | 0.2967 |
| Insertion vein | Axillary | Cephalic | 2.20 (0.27–18.21) | 0.556 |
| | | External jugular | 1.65 (0.05–54.18) | 0.6789 |
| | | Femoral | 6.33 (0.20 to >99.99) | 0.507 |
| | | Internal jugular | 8.29 (0.69–99.90) | 0.114 |
| | | Not applicable | 2.87 (0.31–26.87) | 0.9476 |
| | | Subclavian | 2.31 (0.29–18.55) | 0.615 |
| Lead tip location | Right atrium | CS or branches | 0.52 (0.14–1.89) | 0.9507 |
| | | Free floating | 0.00 (0.00 to >99.99) | 0.9357 |
| | | Left atrium | 0.00 (0.00 to >99.99) | 0.9726 |
| | | Left ventricle | 1.10 (0.20–5.97) | 0.9322 |
| | | Other | 0.63 (0.07–5.54) | 0.9459 |
| | | Right ventricle | 1.35 (0.88–2.06) | 0.9271 |
| Fixation type | Passive | Active | 0.73 (0.46–1.14) | 0.0094 |
| Time from date of lead implant to extraction procedure (years) | Continuous variable | | 1.10 (1.06–1.13) | <0.0001 |
| Approach for TLE: Superior right | No | Yes | 0.76 (0.22–2.59) | 0.6605 |

*Continued*

**Table 9** *Continued*

| Covariables | Reference level | Class level | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|---|
| Superior left | No | Yes | 0.99 (0.29–3.35) | 0.9856 |
| Femoral | No | Yes | 0.74 (0.33–1.67) | 0.4741 |
| Stylet used | No | Yes | 0.65 (0.31–1.36) | 0.2556 |
| Locking stylet engagement to tip | No | Yes | 0.76 (0.50–1.15) | 0.1915 |
| Sheath used | No | Yes | 2.29 (1.26–4.16) | 0.0069 |
| Lead alternative approach | No | Femoral | 3.60 (1.64–7.92) | 0.6244 |
| | | Jugular | 1.32 (0.35–4.91) | 0.0668 |
| | | Other | 20.35 (6.48–63.87) | <0.0001 |
| Other tools used | No | Yes | 3.02 (1.43–6.42) | 0.0039 |

Multivariate logistic regression with 'radiological failed or partial lead removal' as the outcome.
The variables cited in the shell tables which were subparts of other variables or had more than 20% of missing data has not been considered in this model: «type of stylet used», «sheath type used », «total number of sheaths », and «sheath time».
Number of events/number of subjects analysed in this model: 151/4077 (97.4% of the total infected leads analysed).

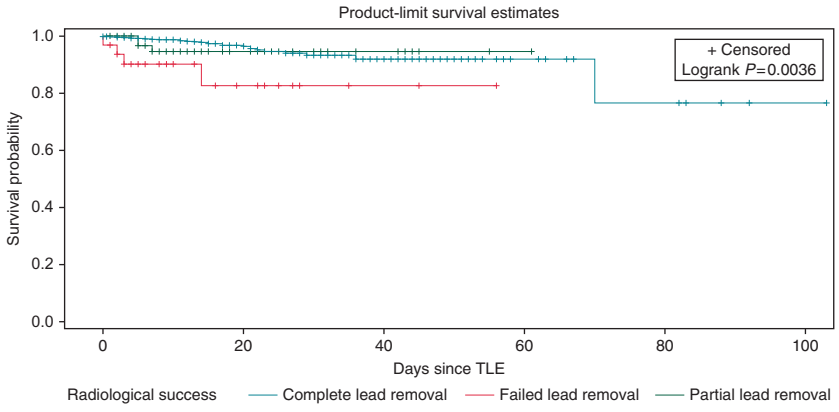


**Figure 1** Kaplan–Meier curve of survival free from death at discharge in the 1863 infected patients by lead removal radiological success/partial failure/failure category. TLE, transvenous lead extraction.

The finding that patients with previous complications, additional system revisions, and generator replacements were less successful in extraction are logical. Furthermore, this group had statistically greater previous attempts for extraction as well as a trend towards more damaged leads. These observations support the notion that generator replacements are associated with a notable complication risk, particularly in those with adding leads during the replacement procedure.[12] Our study also emphasizes that the longer the lead is in the heart, it is less likely to be completely removed.

## Infectious reason for extraction

The present study found that extraction procedure success was independent of the type of infection (pocket or systemic), type of bacteria, or length of antibiotic treatment prior to removal. This is in contrast to the notion of many extractors that systemic infection and prolonged indwelling infection are associated with easier removal of the leads. Nevertheless, complete removal was related to the time that passed from infection diagnosis to the procedure, stressing that extraction should be performed as soon as possible. This has been shown by others to reduce mortality.[13]

## Lead extraction procedure and outcomes

The most common approach in our study for extraction was from the left superior. When failing to extract the whole lead, most opted for the femoral approach and not jugular approach. This observation suggests that perhaps during the laser era, operators are used to left superior approach and not jugular. Therefore, when left superior approach failed, they were more confidant to extract from the femoral

vein rather than from the jugular vein with regular mechanical sheaths.

We did not find differences in success rates if procedure was performed by electrophysiologist or surgeon and if in catheter laboratory or operating room. However, one must be careful in interpretation of these results as they are probably biased by the fact the more challenging cases might be performed by surgeon or in hybrid room. Secondly, our study did not look into complications rates between electrophysiologist vs. surgeon or catheter laboratory vs. hybrid room.

Our study also showed that there were no differences between high- and low-volume centres in term of successful removal. Although not the scope of our study, data from the ELECTRA registry[9] has shown that all cause in-hospital major complications and deaths were significantly lower in high-volume centres vs. low-volume centres, although those related to the procedure did not reach statistical significance.

Not surprisingly, attempts to extract remnant leads resulted in significantly more major and minor complications, however, without prolonging hospital stay duration. The median hospital stay duration was 7 (range 4–13). This is longer than previously reported[14] most probably since our patient population was treated for infection as well. The overall rate of major complications in our study was 3.6%, comparable to what is reported in the literature.[11,14] However, in cases of failure to remove a lead, complication rates were extremely high (23%), suggesting that persisting to extract the entire lead once it tears apart, needs to be weighed against its risk of complications.

Although reimplantation during an active infection is not advised, in our patient population 50% with incomplete or failure to remove all hardware were reimplanted during the same hospitalization.

## Predictors for failure

Predictors for failure were older leads and older patients. The latter finding as an independent risk factor is counterintuitive as younger patients tend to develop more fibrosis and theoretically should be more challenging to extract. On lead level, it seems that the stronger the lead is there is less chance that it will tear apart. Thus passive leads, single coil vs. dual coil, lack of locking stylet engagement to the tip are all predictors of failure to remove the lead. In most studies removal of LV leads were found to comparable or even better than other leads.[15] Our study shows that failure rates were similar to other leads but incomplete removal rates were higher than other leads. This is due perhaps to the fact that laser activation or other tools are usually not used within the coronary sinus thus making the leads more vulnerable to tear.

## Mortality

There were five intraoperative mortality cases. The reason for death was noted by the operator as tamponade in four and by hemothorax in one. It is of note that cardiac tamponade is *per se* not deadly if corrective measures can be applied rapidly but is still the most feared complication. We do not know what preventive measures were taken or how were the operating teams composed and how rapid was the response in each of the cases. Failure to remove a lead was a strong predictor for in hospital mortality. It remains unclear if the reason for death was the remnant lead serving as a reason for non-resolving infection or due to the fact that this group had significantly more major complications during surgery. In contrast, mortality of those with retained leads <4 cm was similar to those who underwent successful extraction. Thus, one may conclude that even in infected leads the risk benefit ratio would lean towards not insisting on total lead removal when left with remnants less than 4 cm. Even when left with remnants >4 cm, one should take in account the extreme high procedural complication rate in this group when insisting to extract all the lead.

# Conclusions

Lead extraction failed in 6.5% of infected CIED patients, leaving them at risk for continuous spreading of the infection. However, only failure where >4 cm of lead remained resulted in higher procedural complications and mortality rates. Partial removal with lead fragments <4 cm had the same outcome as complete radiological success, indicating this may be an acceptable procedural outcome. Further technological improvement for extraction should be pursued.

# Supplementary material

Supplementary material is available at *Europace* online.


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# Intra-atrial re-entrant tachycardia around atretic tricuspid annulus

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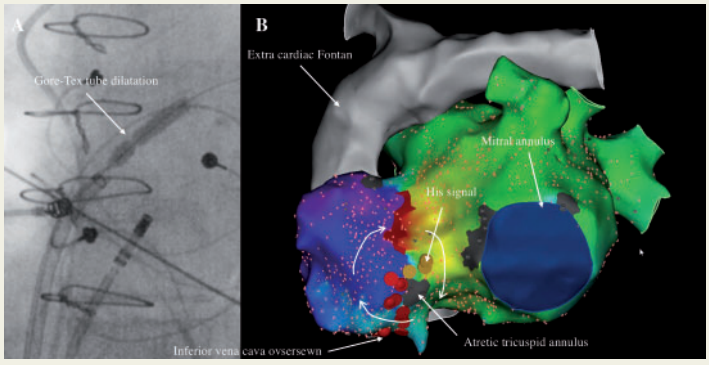


A 47-year-old woman with tricuspid atresia and extra-cardiac Fontan palliation who developed symptomatic atrial arrhythmia was referred for catheter ablation. The clinical arrhythmia was easily inducible with a stable tachycardia cycle length of 260 ms. Trans-Gore-Tex tube puncture was performed, and multiple dilatations up to a 6-mm cutting balloon were required to allow the introduction of a steerable sheath (Agilis NxT$^{TM}$, Abbott) (*Panel A*). Bi-atrial activation and entrainment mapping using a high-density mapping catheter (Pentaray, Biosense) revealed a macro intra-atrial re-entrant tachycardia around the atretic tricuspid annulus identified by a small scar area near to the His signal (*Panel B*, propagation map video is provided in Supplementary material online). We performed a linear ablation between the atretic tricuspid annulus and the scar where the inferior vena cava was oversewn. The arrhythmia slowed then terminated during the second radiofrequency application. The conduction block was confirmed by activation mapping, and no further atrial arrhythmia was inducible. In patients with extra-cardiac conduits, the isthmus between the atrioventricular valve annulus and the oversewn inferior vena cava is often involved. In this case, despite the absence of tricuspid valve due to tricuspid atresia, the arrhythmia circuit rotated around the atretic annulus identified by a small scar area.

Supplementary material is available at *Europace* online.

The full-length version of this report can be viewed at: https://www.escardio.org/Education/E-Learning/Clinical-cases/Electrophysiology.