Experience of cardiac implantable electronic device lead removal from a South African tertiary referral centre

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Abstract

Background: The rate of cardiac implantable electronic device (CIED) implantation in low- and middle-income countries is increasing. Patients receiving these devices are frequently older and with multiple co-morbidities, which may later lead to complications requiring CIED removal. CIED removals are associated with life-threatening complications. However, high success rates are reported in high-income countries. The purpose of this study was to report on the experience of CIED removal in a resource-constrained setting.

Methods: In this retrospective study, we included consecutive adult patients admitted to Groote Schuur Hospital and the University of Cape Town Private Academic Hospital for CIED removal from 1 January 2008 to 31 December 2019.

Results: During the study period, 53 patients underwent CIED removal (26 extractions and 27 explants). The patients had a mean (standard deviation) age of 59.1 (16.0) years. A history of systemic hypertension was present in 50.9% of patients, diabetes mellitus in 30.2% and dilated cardiomyopathy in 47.2%. Complete heart block was the leading indication for CIED implantation (37.7%), and device infection was the leading indication for removal (69.2%). CIEDs were removed after a median (interquantile range) of 243 (53–831) days. There were 40 leads extracted and 35 explants. Lead extractions were performed in the cardiac catheterisation laboratory under general anaesthesia via a percutaneous transvenous superior approach. There was one major and one minor complication related to lead extraction.

Conclusion: CIED infections were the primary indication for CIED removal in a tertiary referral centre in South Africa. Despite being a low-volume centre, we report a high percutaneous transvenous extraction success rate with low complication rate; results which are comparable to high-volume centres.

Keywords: cardiac implantable electronic device removal, pacemaker lead removal, explant and extraction

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Cardiac implantable electronic devices (CIEDs) are a well-established lifesaving technology for the treatment of bradycardias, heart failure and ventricular arrhythmias in susceptible patients. Currently, it is estimated that up to 1.4 million CIEDs are implanted globally every year. As the population ages, the rate of CIED implantation also increases. Approximately 70% of CIED recipients are older than 65 years of age, often with co-morbidities that may necessitate implantation of more complex CIEDs. The number of CIED implantations is increasing in low- and middle-income countries. For example, in South Africa there were 54 per million population new pacemaker implants in 2005, which increased to 132 new implants per million population in 2013.

At present the main indications for CIED removal include CIED infection and lead or pacemaker generator malfunction. Percutaneous transvenous lead extraction is now preferred over surgical lead extraction due to its high success rates and low risk of complications. However, percutaneous transvenous lead extraction is associated with a small risk of major complications, including cardiac avulsion, vascular tears and death. In high-volume extraction centres, the reported clinical success rates of lead extraction are more than 95%, with low complication rates. The purpose of this study was to report the experience (indications and outcomes) of lead removal (extraction and explant) from a tertiary South African referral centre.

Methods

We conducted a retrospective review of all patients who underwent percutaneous transvenous CIED lead removal at Groote Schuur Hospital (GSH) and the University of Cape
Town Private Academic Hospital (UCTPAH) between 1 January 2008 and 31 December 2019. This study was approved by the University of Cape Town Human Research Ethics Committee (HREC number: 591/2019).

All lead extractions and explants were performed in the cardiac catheterisation laboratory. The extractions were performed under general anaesthesia, with a transoesophageal echocardiogram in situ to exclude large vegetations and for monitoring of potential complications. The extraction team consisted of a cardiac electrophysiologist, a cardiothoracic surgeon, a cardiac anaesthetist, a clinical cardiology fellow, a scrub nurse and auxiliary catheterisation laboratory staff.

The extractions were all performed via a percutaneous transvenous superior approach. A standard infraclavicular incision was used to extract the pacemaker generator. A stepwise procedure was followed: if the lead could not be removed using a standard stylet and gentle traction, a locking stylet was used to remove the lead. If the locking stylet failed to free the lead with gentle traction, a mechanical extraction sheath (Cook Medical 9–13 French, 40.6 cm Evolution RL controlled-rotation dilator) was used. Occasionally an additional mechanical extraction sheath (Cook Medical 9–11 French, 13.6 cm Evolution Shortie mechanical dilator sheath) was required to free the proximal extent of the lead. Once the lead was successfully extracted, haemostasis of the axillary and subclavian veins was secured using a figure-of-eight suture. In all cases of device infection, an extensive pocket capsulotomy was performed, followed by wound closure with interrupted nylon sutures.

Definitions published in the 2009 and 2017 Heart Rhythm Society (HRS) expert consensus statement on cardiovascular implantable electronic device lead management and extraction and the 2018 European Heart Rhythm Association (EHRA) consensus expert consensus statement on lead extraction were used to define patient outcomes.7,8,36

A lead-removal procedure is defined as removal of a pacing or ICD lead using any technique.14 Lead explant is defined as lead removal using simple traction techniques (no locking stylets, telescoping sheaths or femoral extraction tools) or leads implanted for less than one-year duration.6,7 Lead extraction is defined as the removal of at least one lead that has been implanted for more than one year, or a lead, regardless of duration of implant, requiring the assistance of specialised equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than the implant vein.7,36

Major complications/serious adverse events are defined as any of the outcomes related to the procedure that are life-threatening or result in death (cardiac or non-cardiac).7,8 Minor complications are defined as any undesired event related to the procedure that requires medical intervention or minor procedural intervention and does not persistently or significantly limit the patient’s function, nor does it threaten life or cause death.7,36

Complete procedural success is defined as a lead-extraction procedure with 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.7,36 Clinical success is defined as lead extraction procedures with removal of all targeted leads and lead material from the vascular space or retention of a small portion of the lead (≤ 0.4 cm) that does not negatively impact on the outcome goals of the procedure.7,36

**Statistical analysis**

Statistical analyses were performed using SPSS Statistics for Macintosh version 24.0 (IBM, USA). Normally distributed continuous variables are reported as means [standard deviations (SD)], and as medians [interquartile ranges (IQR)] when skewed. Discrete data are presented as numbers and percentages. The mortality difference between the extraction group and the explant group was assessed using the chi-squared test; the Kaplan–Meier and log rank tests were used to assess the cumulative survival difference. A p-value ≤ 0.05 represents a statistically significant difference.

**Results**

A total of 53 patients underwent percutaneous transvenous CIED (lead/s and generator) removal at GSH and UCTPAH between 1 January 2008 and 31 December 2019. Twenty-six (49%) patients required CIED lead extractions and 27 (51%) had their CIED leads explanted.

The baseline characteristics of the patients and the details of their CIEDs are presented in Table 1. The mean age of the patients was 59.1 (16.0) years, 50.9% were male, 50.9% had systolic hypertension, 30.2% had diabetes mellitus and 47.2% had cardiomyopathy. The leading indication for CIED implantation was complete heart block (37.7%). The most common CIED removed was a single-chamber permanent pacemaker (35.8%). The main indication for CIED removal was device infection (69.2%) (Fig. 1A, B). The majority of infected CIEDs removed were for culture-negative endocarditis (Fig. 2) and all patients who had CIED infection had received multiple courses of antibiotics prior to referral.

A total of 75 leads was removed (40 extractions and 35 explants) (Table 2). The CIEDs were removed after a median (IQR) of 243 (53–831) days since the primary implantation. Extraction occurred after a median (IQR) of 359–2546 days from the date of CIED implantation. For CIED extractions, a

### Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Removal (extraction and explant) (n = 53)</th>
<th>Extraction (n = 26)</th>
<th>Explant (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, n (SD), years</td>
<td>59.1 (16.0)</td>
<td>57.8 (16.3)</td>
<td>60.2 (15.9)</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>27 (50.9)</td>
<td>17 (65.4)</td>
<td>10 (37)</td>
</tr>
<tr>
<td>Systemic hypertension, n (%)</td>
<td>27 (50.9)</td>
<td>10 (38.5)</td>
<td>17 (63.0)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>16 (30.2)</td>
<td>7 (26.9)</td>
<td>9 (33.3)</td>
</tr>
<tr>
<td>Dyslipidaemia, n (%)</td>
<td>16 (30.2)</td>
<td>10 (38.5)</td>
<td>6 (22.2)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>15 (28.3)</td>
<td>9 (34.6)</td>
<td>6 (22.2)</td>
</tr>
<tr>
<td>Chronic kidney disease, n (%)</td>
<td>8 (15.1)</td>
<td>6 (23.1)</td>
<td>2 (7.4)</td>
</tr>
<tr>
<td>Cardiomyopathy, n (%)</td>
<td>25 (47.2)</td>
<td>14 (53.8)</td>
<td>11 (40.7)</td>
</tr>
<tr>
<td>Atrial fibrillation, n (%)</td>
<td>11 (20.8)</td>
<td>6 (23.1)</td>
<td>5 (18.5)</td>
</tr>
<tr>
<td>Chronic obstructive airway disease, n (%)</td>
<td>4 (7.5)</td>
<td>2 (7.7)</td>
<td>2 (7.4)</td>
</tr>
<tr>
<td>Single-chamber permanent pacemaker</td>
<td>19 (35.8)</td>
<td>5 (19.2)</td>
<td>14 (51.9)</td>
</tr>
<tr>
<td>Dual-chamber permanent pacemaker</td>
<td>9 (17.0)</td>
<td>7 (26.9)</td>
<td>2 (7.4)</td>
</tr>
<tr>
<td>CRT-P</td>
<td>8 (15.1)</td>
<td>5 (19.2)</td>
<td>3 (11.1)</td>
</tr>
<tr>
<td>CRT-D</td>
<td>4 (7.5)</td>
<td>3 (11.5)</td>
<td>1 (3.7)</td>
</tr>
<tr>
<td>Dual-chamber ICD</td>
<td>2 (3.8)</td>
<td>1 (3.8)</td>
<td>1 (3.7)</td>
</tr>
<tr>
<td>Single-chamber ICD</td>
<td>11 (20.8)</td>
<td>5 (19.2)</td>
<td>6 (22.2)</td>
</tr>
<tr>
<td>CRT-P, cardiac resynchronisation therapy pacemaker</td>
<td>CRT-D, cardiac resynchronisation therapy defibrillator, ICD, implantable cardioverter defibrillator</td>
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</tr>
</tbody>
</table>
locking stylet was required in 92.3% and a mechanical extraction sheath was used in 73.1% of patients.

Extraction-related complete procedural success was achieved in 84.6% and clinical success was achieved in 96.2% of patients. One patient who had a lead extraction died a few hours post lead extraction (mortality rate 3.8%). She had a successful extraction of four leads (two atrial, one right ventricle and one coronary sinus) for CIED infection. She had unexplained ventricular fibrillation and cardiac arrest the morning after the procedure. There were no other major complications.

Minor complications occurred in one patient (3.8%). This was due to a small lead fragment (< 1 cm) that embolised in the lung without complications and could not be retrieved with a snare. The overall one-year mortality rate after lead removal was 19.1% (19.2% in the extraction group vs 14.8% in the explant group) ($p = 0.764$). There was no difference in survival rate between patients who had their CIEDs extracted versus explanted (Fig. 3).

Discussion

The key findings of this study are: (1) CIED-related infection was the leading indication for CIED removal (extraction or explant) at a tertiary referral centre in South Africa; (2) percutaneous tranvenous lead extraction using a locking stylet with or without mechanical extraction sheaths had a high procedural and clinical success rate; (3) percutaneous lead removal was associated with a low risk of major and minor complications and low mortality rate, which is comparable with high-volume centres in Europe and North America; and (4) the overall one-year mortality rate remained high, similar to previous reports.

The implantation rates of CIEDs are increasing globally and in low- to middle-income countries such as South Africa.9,10,18 The

![Table 2. Lead-removal procedure details and outcomes](image)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Removal (extraction and explant)</th>
<th>Extraction (n = 26)</th>
<th>Explant (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days since primary implantation median (IQR)</td>
<td>243 (53–831)</td>
<td>831</td>
<td>57</td>
</tr>
<tr>
<td>Total number of removed leads, mean (SD)</td>
<td>75</td>
<td>40</td>
<td>35</td>
</tr>
<tr>
<td>Number of removed leads per patient</td>
<td>1.42 (0.69)</td>
<td>1.54 (0.76)</td>
<td>1.3 (0.61)</td>
</tr>
<tr>
<td>Locking stylet, n (%)</td>
<td>24 (45.3)</td>
<td>24 (92.3)</td>
<td>0</td>
</tr>
<tr>
<td>Extraction sheath, n (%)</td>
<td>19 (35.8)</td>
<td>19 (73.1)</td>
<td>0</td>
</tr>
<tr>
<td>Straight stylet, n (%)</td>
<td>27 (50.9)</td>
<td>26 (100)</td>
<td>25 (92.6)</td>
</tr>
<tr>
<td>Procedural success, n (%)</td>
<td>49 (92.5)</td>
<td>22 (84.6)</td>
<td>27 (100)</td>
</tr>
<tr>
<td>Clinical success, n (%)</td>
<td>53 (100)</td>
<td>25 (96.2)</td>
<td>27 (100)</td>
</tr>
<tr>
<td>Major complications, n (%)</td>
<td>1 (1.9)</td>
<td>1 (3.8)</td>
<td>0</td>
</tr>
<tr>
<td>Minor complications, n (%)</td>
<td>1 (1.9)</td>
<td>1 (3.8)</td>
<td>0</td>
</tr>
<tr>
<td>In-hospital mortality, n (%)</td>
<td>1 (1.9)</td>
<td>1 (3.8)</td>
<td>0</td>
</tr>
</tbody>
</table>

*There was one death, which was recorded as a major complication.
# One minor complication was a lead-fragment embolism to the lung without complications.

![Fig. 2. Pie chart depicting the frequency of causative microorganisms for CIED infection leading to CIED removal.](image)

![Fig. 3. Kaplan–Meier curves depicting the cumulative survival difference between the extraction and explant group.](image)

"Fig. 1. A. Bar chart depicting indications for CIED removal. B. Bar chart depicting indications for CIED extraction."
rates of CIED removal, particularly for CIED infection, have also been on the rise. The findings of this study are consistent with the current international standard of extraction procedural success rate of more than 80%, clinical success rate of more than 95% and major complication rate of less than 5%. Additionally, in a multicentre study from European countries, infections were the indication for lead extraction in 52.9% of cases. Additionally, in a multicentre study from 13 sites in the USA and Canada that included 1 449 consecutive patients who underwent laser-assisted lead extraction, infections were the indication for extraction in 56%. This probably reflects our current practice of rarely removing redundant or non-functional leads. As our experience with lead extraction grows, removal of non-infected leads is likely to contribute more to the indications for lead extraction.

In our study, CIED infection was the main indication for lead extraction (69.2% of lead extractions, 69.8% of CIED removals). The incidence of infections as the primary indication for lead extraction was almost 20% higher than that from high-income countries. For example, in the European Lead Extraction ConTRolled Registry (ELECTRa), out of 3 555 patients who underwent lead extractions at 73 centres from 19 European countries, infections were the indication for lead extraction in 52.9% of cases. Additionally, in a multicentre study from 13 sites in the USA and Canada that included 1 449 consecutive patients who underwent laser-assisted lead extraction, infections were the indication for extraction in 56%. This probably reflects our current practice of rarely removing redundant or non-functional leads. As our experience with lead extraction grows, removal of non-infected leads is likely to contribute more to the indications for lead extraction.

In this study we present data from a tertiary referral centre serving both public and private patients in the Western Cape province of South Africa. The very low number of patients (26 patients referred for lead extraction procedures over 11 years) referred for extraction raises two points of potential concern:

- The finding of a relatively low number of patients who underwent lead extraction suggests a lack of referral as Groote Schuur Hospital was the only public hospital performing lead extractions over this period in the Western Cape province. This is concerning as patients with CIED are probably inappropriately managed with antibiotics and not referred for lead extraction, which is the only treatment for CIED infection. Non-removal of an infected CIED is associated with a seven-fold increase in 30-day mortality and a three-fold increase in one-year mortality. Furthermore, early removal of infected CIEDs has been associated with reduced in-hospital mortality. In a study by Viganego and colleagues, patients who had their infected CIEDs extracted within three days versus later than three days of hospitalisation had a lower in-hospital mortality rate irrespective of antibiotic use ($p = 0.001$). The rates of CIED implantation in South Africa are increasing, therefore we expect the rates of CIED infections and extractions or explant to increase in parallel.

- Maintaining competency and procedural skills can be difficult in low-volume centres. Lead-extraction procedural outcomes are reported to be better in high-volume centres. In the ELECTRa study, rates of extraction-related major complications and death were significantly lower in high-volume centres (defined as centres performing more than 30 extraction procedures per year) when compared to low-volume centres (less than 30 extraction procedures per year).

Furthermore, for maintenance and transfer of skills, knowledge and competence in lead extraction, guidance documents recommend a minimum of 20 extraction procedures on an annual basis. Lead extractions should ideally be conducted in a few highly specialised public and private referral centres in South Africa.

The major limitations of this study are its retrospective nature and small sample size. Data on baseline cardiac function as measured by echocardiography were not available and the duration of symptoms prior to referral for lead extraction and explant was also not available.

**Conclusion**

CIED infections were the primary indication for CIED removal in a tertiary referral centre in South Africa. Despite being a low-volume centre, we report a high percutaneous transvenous extraction success rate with low complication rate, results which are comparable to high-volume centres. The low number of patients referred for CIED removal probably reflects poor management of device infection at the primary healthcare level.

**References**


