Cardiovascular implantable electronic device lead removal in a resource-constrained setting: A single-center experience from India

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ABSTRACT

Background: Data from large-volume centers in developed countries, using dedicated tools, show a high success rate with a good safety record for the percutaneous lead removal procedure. However, there are constraints to replicate the results in a resource-poor setting and there is limited data from India.

Methods: We retrospectively analyzed lead removal procedures performed in our institution from 2008 to 2019.

Results: Seventy-five patients underwent percutaneous removal of 138 leads. Of these, 44 procedures and 80 leads qualified as extraction with a median dwell time of 52.1 (IQR 28.2–117.2) months. Overall, 33/44 (75.0%) procedures were successful and 65/80 (81.2%) leads were successfully extracted. Manual traction was successful in the extraction of 44/57 (77.2%) leads. All leads implanted less than 2.7 years could be removed with manual traction alone. Specialized tools were used in 23 leads and 21 (91.3%) of those could be successfully extracted. Inability to use dedicated tools was an independent predictor of procedural failure (adjusted OR 14.0; 95% CI 1.8–110.2; p-value 0.012). Right-sided implant (adjusted OR 12.6; 95% CI 1.3–119.5; p-value 0.027) was also independently associated with failure. There was 1 death (1.3%) and minor complications occurred in 6 (8.0%) patients.

Conclusions: In a resource-limited setting, percutaneous lead extraction of predominantly pacemaker leads by manual traction methods achieved success in extracting about three-fourths of the leads. Inability to use specialized tools was the main factor limiting success. The complication rate was low.

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1. Introduction

The growing number of cardiovascular implantable electronic device (CIED) implantations has seen a concomitant increase in the indications for their removal. Percutaneous lead extraction, as opposed to surgical removal, has become the standard of care for the management of infected or dysfunctional CIED systems. In developed countries, large-volume centers with specialized lead extraction programs have evolved. Data from these centers, using dedicated tools, show a high success rate with a good safety record for the procedure [1,2]. Despite all the technical advances, percutaneous lead extraction remains a challenging and risky procedure. Data about lead management strategies from resource-constrained settings is limited. Given the prohibitive cost associated with these dedicated tools, reserving them for selected cases may be reasonable in countries like India. We report a single-center experience of non-laser assisted percutaneous lead removal procedures.

2. Methods

2.1. Study population

We retrospectively analyzed 75 lead removal procedures performed in our institution from 2008 to 2019. Patient data, device details, and follow-up data were collected from electronic medical records. Procedure details were collected from the detailed procedural notes written by the operator.

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Peer review under responsibility of Indian Heart Rhythm Society.

https://doi.org/10.1016/j.ipej.2019.12.002

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2.2. Lead removal procedure

All patients had pre-procedure blood group typing and cross-matching done. When feasible, antiplatelet drugs and anticoagulants were stopped before the procedure. In cases where they could not be stopped safely, antiplatelets were continued through the procedure. Anticoagulants were stopped 2–3 days before the procedure and bridged with heparin or the procedure was done once the international normalized ratio (INR) was less than 2.0 without using heparin. Pacing-dependent patients who were not expected to receive immediate reimplantation were placed on a transapical ventricular active-fixation lead connected to an external pulse generator. The choice to operate in the operating room (OR) or electrophysiology (EP) lab was at the discretion of the explanting physician. Regardless of the place of the procedure, thoracic-surgeons were always available on standby. Local anesthesia was used for leads with short dwell time while general anesthesia was used to extract longer dwelling leads.

A stepwise approach was used as described previously [3–7]. To summarize, after unscrewing and separating the device from the leads, manual lead traction with the aid of an implantation stylet was used in various combinations according to the choice of the operator - (a) lead locking stylets (Liberator® Cook Medical, Bloomington, Indiana, USA, or LLD®, Spectranetics), (b) snaring device (Needle’s Eye Snare®, Amplatz, Plymouth, Minnesota, USA) was inserted through a 6F catheter via the femoral route and lead retrieval was attempted. This snare, though not specifically designed for lead extraction, was used as an extension of manual traction for removal of retained lead fragments.

When available and not constrained by cost, the following types of dedicated extraction tools were used in various combinations according to the choice of the operator - (a) lead locking stylets (Liberator®, Cook Medical, Bloomington, Indiana, USA, or LLD®, Spectranetics), (b) snaring device (Needle’s Eye Snare®, Amplatz, Plymouth, Minnesota, USA), (c) telescoping sheaths (SlightRail®, Spectranetics), and (d) rotating mechanical dilator sheaths (Evolution®, Cook Medical, or TightRail™, Spectranetics).

Several procedural caveats apply while performing the extraction with dedicated tools. A skin incision directly over the site of lead’s entrance into the vascular system and dissecting as close as possible to that site helped transmit the coxial traction. The LLD was passed till the lead tip or to distal-most point possible to achieve effective traction. When manual traction with the lead stylet or LLD did not help, more advanced tools were used. It was made sure that the traction on the LLD was coaxial and controlled so as to ensure that the LLD did not retract. Continuous repeated application of the rotational cutting sheath mechanism was seldom required and waiting between applications while delivering forward counter pressure was more effective.

2.3. Reimplantation

When infection was the indication for CIED removal and there was no evidence of bacteremia, reimplantation was at the discretion of the physician depending on the adequacy of wound healing and urgency of reimplantation. In the case of endocarditis, at least 2 weeks of antibiotic therapy was administered and the blood cultures were negative before reimplantation.

In infected cases, implantation of a new CIED system was always advised. However, if the patient could not afford a new device and the old device had adequate battery life, it was reused. The leads were never reused. Exploited pulse generators were screened for any significant external damage and interrogated. Devices were washed with a detergent solution to remove particulate debris.

They were packed as a double barrier package using commercially available sterilization pouches (Tyvek®, DuPont, Midland, Michigan, USA) and sterilized at least twice with either ethylene oxide (prior to 2017; EO-FCT, Andersen sterilizers, Haw River, North Carolina, USA) or low temperature hydrogen peroxide plasma sterilization (from 2017; STERRAD®, ASP [a Johnson & Johnson company], Irvine, California, USA). The last sterilization was done not more than 24 h before reimplantation. A separate consent explicitly stating the implantation of a refurbished device and the potentially higher risks, was taken.

2.4. Definitions

The terms related to lead removal have been defined previously in the expert consensus statements on lead extraction [7–9]. In brief, a procedure was called ‘lead explantation’ when all the removed leads were implanted for less than one year and no special tools (other than implantation stylets) were used. A procedure was defined as ‘lead extraction’ when at least one lead was implanted for more than one year or the procedure required the assistance of specialized equipment designed for lead removal. ‘Complete success’ refers to the removal of all targeted leads and lead material without permanently disabling complications/procedure-related death. ‘Clinical success’ was the removal of all targeted leads with retention of a small portion of the lead (<4 cm) that does not negatively impact the outcome goals. The procedure was considered a ‘failure’ when neither complete nor clinical success could be achieved or a permanently disabling complication/procedure-related death ensued. In addition, for the purpose of this study, we defined ‘manual lead removal’ as removal of leads with traction or using snares not typically designed for lead extraction.

2.5. Statistical analysis

Continuous variables were expressed as mean ± standard deviation and in case of skewed distribution, median with interquartile range (IQR) was used. Categorical variables were expressed as frequency and percentage. Means were compared with Student’s t-test and categorical variables were compared with the Chi-square test. Non-parametric tests (Mann-Whitney U test and Fisher’s exact test) were used when a variable had skewed distribution. Multi-variable analysis was done using binary logistic regression by selecting variables with p-value < 0.200 on univariate analysis or if the variable was thought to be clinically relevant. Penalized logistic regression was used when the odds ratio could not be estimated due to empty cells or cells with low frequency, because of failure of the maximum likelihood estimate to converge. The point estimates were reported as odds ratio (OR) and 95% confidence interval (CI). A p-value of <0.05 was considered statistically significant. Statistical analysis was done with SPSS® software (Ver. 21.0, IBM, USA) and SAS® (Ver. 9.2, SAS Institute, USA).

3. Results

3.1. Patient characteristics

A total of 86 patients required CIED removal during the study period. Eleven patients underwent direct surgical removal due to other indications for surgery or the treating physician considered percutaneous removal very risky. Most of the surgical referrals were before the ready availability of extraction tools. The remaining 75 patients underwent percutaneous removal of 138 leads (average 1.8 leads per procedure). Majority of the leads (63.0%) were implanted elsewhere and referred to our institution for extraction.

The most common reason for device removal was infection in
68/75 (90.7%) patients. The baseline patient characteristics are summarized in Table 1 and the infection characteristics in Table 2. Most infections were confined to the pocket with only 4/68 (5.9%) having endocarditis. Cultures were negative in 29/68 (42.6%) of the cases. Coagulase-negative Staphylococcus aureus (CONS) was the most common organism (22.0%), followed by Pseudomonas aeruginosa (10.3%), Staphylococcus aureus (7.4%), other gram-negative bacilli (7.4%), atypical mycobacteria (2.9%), Candida species (2.9%), and others (4.4%).

3.2. Lead and procedure characteristics

Removal of 138 leads was attempted. Six of the 138 (4.3%) were ICD leads and 68 (49.3%) were passive fixation leads. Seven leads (5.1%) were cut during earlier attempts at extraction before referral to our institution. The median dwell time was 22.1 (IQR 4.5–61.3) months. Eighty leads and 44 procedures qualified as extraction. Seventy of the 75 procedures (93.3%) were performed in the EP lab.

Manual traction (including use of a goose-neck snare in 3 cases) was successful in 16/25 (64.0%) of the extraction procedures. On complete success was achieved in 33/44 (75.0%) extraction procedures. Leads and 44 procedures that qualified as ‘lead extractions’. Complete success was achieved in 33/44 (75.0%) extraction procedures. When analyzed according to leads, 65/80 (81.2%) could be extracted successfully.

3.3. Outcomes

Overall, 64/75 (85.3%) lead removal procedures were successful and 123/138 (89.1%) leads were removed. Analysis was done to 80 leads and 44 procedures that qualified as ‘lead extractions’. Complete success was achieved in 33/44 (75.0%) extraction procedures. When analyzed according to leads, 65/80 (81.2%) could be extracted successfully.

Multivariable analysis was performed only for pacing leads, as the ICD leads were few as compared to pacing leads and technical challenges of ICD implantation are different. Multivariable analysis was performed for predicting procedural failure by adding the following variables to the model - the inability to use dedicated tools, presence of passive fixation leads, right-sided implants, and dwell-time of the oldest lead (Table 4). After adjustment for other variables (Table 4), inability to use dedicated tools was the only significant predictor of procedural failure (adjusted OR 14.00; 95% CI 1.78–110.25; p-value 0.012).

Lead wise univariate analysis for the 75 pacing leads is summarized in Table 5. Multivariable analysis for predicting failure of lead extraction was performed by adding the following variables to the model – the inability to use dedicated tools, passive fixation leads, right-sided implants, and dwell-time. On multivariable analysis (Table 5), right-sided implants (adjusted OR 12.65; 95% CI 1.34–119.49; p-value 0.027), use of manual traction (adjusted OR 17.89; 95% CI 1.82–176.07; p-value 0.013), and dwell-time (adjusted OR 1.02; 95% CI 1.00–1.03; p-value 0.024) were significant.

3.4. Complications

Complications occurred in 7 (9.3%) patients. Six of them were minor complications not resulting in death or permanent disability - 4 patients had bleeding requiring a blood transfusion, 1 patient developed sepsis post-procedure and recovered with antibiotic therapy, and 1 patient developed deep vein thrombosis of the distal lower limb veins. No deaths occurred during the procedure, but one patient died due to massive pulmonary embolism 1 week after failed extraction. Twenty-seven patients (36.0%) did not have long-term (>1 month) follow-up. Of the remaining, none of the patients had a complication after a median follow-up of 21.4 months (IQR 7.1 to 53.4).

3.5. Reimplantation

Fifty-five patients underwent reimplantation. Eighteen patients with infected devices underwent reimplantation of their own old device after resterilization. Two patients were lost to follow-up. There was no recurrence of infection in the remaining 16 patients after a median follow-up of 15.7 months (IQR 7.0–39.7 months).

4. Discussion

Many previous studies from large-volume centers in the developed countries have shown that percutaneous lead extraction has high success with low complication rates [1,2,10–12]. The high efficacy is in part due to access to dedicated extraction tools. Although there are a growing number of CIED implants in developing countries and an accompanying increase in the indications for their removal, data about the methods used and outcomes is lacking. We report a single-center experience in lead removal from India, highlighting the issues unique to the resource-constrained setting.

The key findings of the current study are (a) removal of CIED leads using manual traction and improvised snares was successful in extraction of 77.2% of the leads and 64.0% of the extraction procedures with good safety, (b) all leads with dwell time less than 33 months could be removed with manual traction alone. Dedicated tools were used for extraction of 23 leads - traction tools (LLD and/or dedicated snares) in 9 and cutting sheaths (telescopic and/or rotational cutting sheaths) in 14 leads. When procedures with the use of dedicated tools were analyzed, 17/19 (89.5%) of the procedures were successful and 21/23 (91.3%) of the leads could be successfully extracted.

Table 1
Baseline characteristics.

| Number of patients | 75 |
|--------------------|----|
| Number of leads    | 138|
| Age, yrs           | 62.6 ± 13.4 |
| Male               | 55 (73.3) |
| Device type        |     |
| Pacemaker          | 66 (88.0) |
| ICD                | 3 (4.0)  |
| CRT - P            | 3 (4.0)  |
| CRT - D            | 3 (4.0)  |
| Indication for implantation |     |
| Sinus node dysfunction | 21 (28.0) |
| AV block           | 42 (56.0) |
| LV dysfunction/heart failure | 5 (6.7) |
| Others             | 7 (9.3)  |
| Comorbid conditions |     |
| Diabetes           | 24 (32.0) |
| Hypertension       | 36 (48.0) |
| Ischemic heart disease | 9 (12.0) |
| Chronic kidney disease | 5 (6.7) |
| Left ventricular dysfunction | 10 (13.3) |
| Prosthetic valves  | 2 (2.7)  |
| Prior CABG         | 2 (2.7)  |
| Medications        |     |
| Any antithrombotic drugs | 18 (24.0) |
| Antiplatelets      | 17 (22.7) |
| Anticoagulants     | 3 (4.0)  |
| Last procedure     |     |
| Initial implant    | 60 (80.0) |
| Device change/revision/upgrade | 15 (20.0) |
| Reason for device removal |     |
| Infection/erosion  | 68 (90.7) |
| Lead dysfunction   | 6 (8.0)  |
| Device upgrade     | 1 (1.3)  |

Note: Values are mean ± standard deviation or frequency (%).
Table 2
Infection characteristics (n = 68).

| Type of infection       | Total leads removed (n = 138) | p-value  |
|-------------------------|-------------------------------|----------|
| Pocket infection/erosion| 64 (94.1)                     |          |
| Infective endocarditis  | 4 (5.9)                       |          |

Organisms

- Coagulase negative staphylococcus aureus: 15 (22.0)
- Staphylococcus aureus: 5 (7.4)
- Enterococcus spp.: 2 (2.9)
- Gram-negative enteric bacilli: 5 (7.4)
- Pseudomonas aeruginosa: 7 (10.3)
- Atypical mycobacteria: 2 (2.9)
- Candida spp.: 2 (2.9)
- Others: 1 (1.5)
- Culture-negative: 29 (42.6)

Note: Values are frequency (%).

Table 3
Lead and procedure characteristics.

| Total leads removed (n = 138) | Extraction (n = 80) | p-value  |
|-------------------------------|---------------------|----------|
| Lead type                     |                     |          |
| Atrial pacing leads           | 50 (36.2)           |          |
| Ventricular pacing leads      | 75 (54.3)           |          |
| VDD pacing leads              | 1 (0.7)             |          |
| Coronary sinus leads          | 6 (4.3)             |          |
| Single coil ICD leads         | 2 (1.4)             |          |
| Dual coil ICD leads           | 4 (2.9)             |          |
| Lead fixation                 |                     |          |
| Active                        | 70 (50.7)           |          |
| Passive                       | 68 (49.3)           |          |
| Vascular access for the leads |                     |          |
| Subclavian/axillary           | 125 (90.6)          |          |
| Cephalic                      | 13 (9.4)            |          |
| Cut leads                     | 7 (5.1)             |          |
| Side of the implant           |                     |          |
| Left side                     | 79 (57.2)           |          |
| Right side                    | 59 (42.8)           |          |
| Dwelling time, months         | 22.1 (4.5–61.3)     |          |
| Place of explantation         |                     |          |
| Electrophysiology lab         | 128 (92.8)          |          |
| Operating room                | 10 (7.2)            |          |
| Technique of explantation     |                     |          |
| Manual traction only          | 115 (83.3)          |          |
| Traction tools (Lead locking device and/or snare) | 9 (6.5) |          |
| Cutting sheaths               | 14 (10.1)           |          |
| Successful removal            |                     |          |
| Success                       | 123 (89.1)          |          |
| Total removal                 | 121 (87.7)          |          |
| Partial removal (<4 cm remnant left) | 2 (1.4) |          |

Note: Values are frequency (%) or median (25th percentile – 75th percentile).

- Not applicable or not analyzed.
- * Comparison between explantation and extraction groups.
Table 4
Predictors of failure of pacemaker extraction procedures (n = 39) a.

|                        | Failure (n = 11) | Success (n = 28) | p-value | Univariate OR (95% CI) p-value | Adjusted OR (95% CI) p-value |
|------------------------|-----------------|-----------------|---------|-------------------------------|-----------------------------|
| **Age, years**          |                 |                 |         |                               |                             |
| 41.1 ± 18.0            | 65.8 ± 11.6     | 0.338           |         |                               |                             |
| **Male sex**           | 9 (81.9)        | 21 (75.0)       | 1.000   |                               |                             |
| **Comorbid conditions**|                 |                 |         |                               |                             |
| Diabetes mellitus      | 2 (18.2)        | 12 (42.9)       | 0.266   |                               |                             |
| Hypertension           | 6 (54.5)        | 14 (50.0)       | 0.798   |                               |                             |
| Chronic kidney disease | 0 (0)           | 2 (7.1)         | 0.918   |                               |                             |
| Ischemic heart disease | 1 (9.1)         | 4 (14.3)        | 1.000   |                               |                             |
| Prior open heart surgery| 1 (9.1)        | 1 (3.6)         | 0.490   |                               |                             |
| Left ventricular dysfunction b | 0 (0)    | 5 (17.9)        | 0.644   |                               |                             |
| **Procedure characteristics** |         |                 |         |                               |                             |
| Procedure in the EP lab| 11 (100.0)      | 25 (89.3)       | 0.644   |                               |                             |
| Use of manual traction only (unable to use special tools) | 9 (81.8) | 14 (50.0) | 0.086 | 4.50 (0.82–24.68) b | 0.083 b 14.00 (1.78–110.25) 0.012 |
| **Device characteristics** |         |                 |         |                               |                             |
| Presence of passive leads b | 11 (100.0) | 18 (64.3)       | 0.059   | 13.00 (0.60–280.53) 0.101 | 6.57 (0.22–199.54) 0.280 |
| Presence of cut lead   | 3 (27.3)        | 3 (10.7)        | 0.323   |                               |                             |
| Right-sided implants   | 10 (90.9)       | 13 (46.4)       | 0.014   | 11.54 (1.30–102.65) 0.028 | 7.05 (0.74–67.20) 0.090 |
| Dwell time of the oldest lead, months | 117.2 (80.3–173.8) | 41.4 (21.9–95.8) | 0.003 1.02 (1.00–1.03) | 0.022 1.01 (1.00–1.02) | 0.210 |

Note: Values are mean ± standard deviation, frequency (%) or median (25th percentile - 75th percentile).

- Not applicable or not included in multivariable model.
  a ICD leads were not included in multivariable analysis.
  b Penalized simple logistic regression was performed.
  c Penalized multiple logistic regression was performed.

Guidelines from professional societies recommend transvenous extraction to be performed in centers with high volumes where thoracic surgery back-up is available and by operators with adequate experience [8,9]. However, such centers are very few in the developing world. The first step towards the evolution of such centers would be reporting of outcomes and sharing data towards establishing a registry. There is no standardized approach or recommendation for the selection of extraction tool or technique of extraction. The available tools are, in most cases, prohibitively expensive. So, there is a need for adapting improvised techniques to a resource-constrained setting and reporting such techniques.

4.1. Limitations

Being a retrospective single-center study with a relatively small sample size, there are limitations to its generalizability. Nevertheless, to our knowledge, this is the first case series about percutaneous lead removal from India. Inability to use specialized tools in all patients significantly decreases the success rate. However, this is the real scenario in most cases in India. The number of ICD leads in this series is small - reflecting the overall lower number of ICDs implanted.

5. Conclusions

In a resource-limited setting, percutaneous lead extraction of
predominantly pacemaker leads, by manual traction methods achieved success in extracting three-fourths of the leads and all leads implanted less than 2.7 years could be removed with manual traction alone. The complications of lead removal were low. Inability to use specialized tools due to financial constraints was the main factor responsible for failure and it would be wise to plan a lead extraction of a right-sided implants, cut leads and leads with long dwell times with dedicated tools available at hand.

Declaration of competing interest

The authors declare no conflict of interest for this study.

Acknowledgments

The authors thank Ms. Rintu Tisho James and Ms. Suganya for their assistance in collecting patient follow-up data.

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