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ORIGINAL PAPER

Transvenous Lead Extraction of Cardiac Implantable Electronic Devices: Reimplant Strategy and Outcomes in a Single-Center Experience

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ABSTRACT

Cardiac implantable electronic devices are now widely used worldwide and the numbers are increasing exponentially. Subsequently, long-term complications have increased. Transvenous lead-extraction (TLE) is the gold standard for removing infected devices, treating systemic device-related infections including endocarditis, and removing devices for other non-infectious complications. Most patients still require device therapy after TLE for several indications, including lifesaving defibrillation or pacing in pacemaker-dependent patients. The decision to reimplant is challenging, particularly when the primary cause for device removal

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includes device-related infections and patients frequently are pacemaker dependent. We aim to present our strategy for reimplanting after performing TLE in 88 consecutive patients. We performed transvenous removal of 150 pacemaker and defibrillator leads, of which 74% for local or systemic infection. We report a 99.3% clinical success after TLE. Out of 88 patients who had undergone TLE and after reanalysing the device indication, 67 patients (76%) still had indication for device removal, but three of them refused to undergo reimplant and 58 were re-implanted. Of the re-implanted patients, 58.6% were implanted on the contra-lateral side, 38% on the ipsilateral side and two patients who had been previously implanted with ICD were reimplanted with a subcutaneous implantable cardioverter defibrillator (S-ICD). Up to 34.4% of patients were re-implanted during the same TLE procedure, which was performed for device up-grade in patients with venous occlusion, 24% were implanted during the same hospital admission for TLE but not during TLE, and 41.3% were discharged and reimplanted afterwards. With this strategy for reimplantation, we report no re-infections and no device-removal-related arrhythmic major events or deaths during one-year follow-up. In conclusion, most patients still require device therapy after TLE. In patients with previous infection of the device, the reimplantation strategy should be carefully analyzed to prevent infection relapse and limit the consequences of the absence of the device.

Keywords: transvenous lead extraction, pacemakers, defibrillators, reimplant, reinfection.

INTRODUCTION

Cardiac implantable electronic devices (CIEDs) play a major role in treating cardiovascular diseases. Over the last 30 years, a sharp rise in the use of cardiac devices can be easily observed in our daily practice. They have led to a reduction in death from arrhythmic disease as well as cardiomyopathies and ischemic heart disease. (1). Annually, over one million CIEDs are implanted and reports estimate a number of 4.5 million active devices (2-4). Long-term complications of CIED implants have also increased with a longer life expectancy; infection, lead failure, intravascular occlusion of the implanted lead route and device upgrade have become the most frequent complications that require medical and surgical attention (5-12). Local or systemic infection related to the CIED, the most life-threatening long-term complication of CIED implant, almost always requires culture-specific antimicrobial intravenous (IV) therapy and complete device removal (13, 14). Transvenous lead extraction (TLE) is now the gold standard for removing the infected hardware and capsulectomy, followed by culture-targeted (when detected) antibiotic IV therapy (15-21). Every year, about 10.000–15.000 of TLEs are being performed worldwide, and the numbers are increasing (22). Transvenous lead extraction has been proven to be highly successful and to have low complication rates (23, 24).

However, many TLE-treated patients still have an indication for device therapy or device upgrade. This is a challenging issue, particularly when the primary cause for device removal includes device-related infections, which may present as local pocket infection (Figure 1) or systemic infection, including cardiac-device-related endocarditis (CIED-IE) and sepsis. Pacemaker-dependent patients, cardiac resynchronization therapy (CRT) patients, and secondary-prevention-high-arrhythmic risk patients relying on an implantable cardioverter defibrillator (ICD) are exposed in the absence of the device, and a careful approach with a thorough strategy should be planned. Early reimplant may lead to infection relapse in a more aggressive and antibiotic-resistant manner. Several papers have suggested various types of approaches, including temporary pacing for pacemaker-dependent patients and reimplant to the contra-lateral side, or the use of a different plane such as sub-pectoral muscle implant, and different re-implant waiting times with referral to the device-removal indication in the first place (25, 26). However, there is no international consensus on the optimal timing and site of the reimplant as the strategy may widely vary and could be influenced by several aspects such as the reason for removal, indication of the first implant, and patient's comorbi-

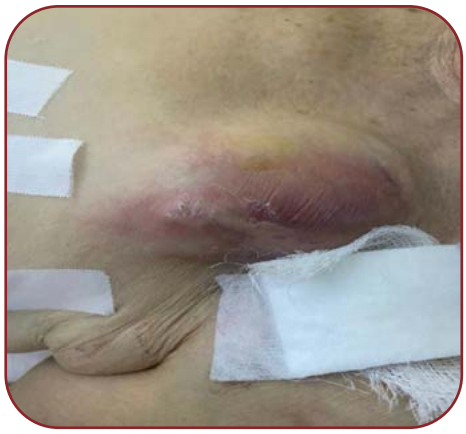

FIGURE 1. Fluctuance and swelling clinically indicating pocket-infection (adapted from Dardari *et al*)

dities and will. Some patients may no longer have an indication for the device. In contrast, others could have had a relative indication from the beginning, which does not necessarily mandate the device therapy (such as chronotropic incompetence or unexplained syncope, which was proven to be non-arrhythmic after all). Also, non-responders to cardiac resynchronization therapy (CRT) and sudden cardiac death (CSD) primary prevention patients who never benefited from the device are subject to a meticulous approach before deciding to reimplant.

We aim to present the results of the re-implant strategy used by us after performing TLE in our center. ❑

MATERIALS AND METHODS

All patients referred to our center for TLE between 2018 and 2022 were included in the present retrospective study. Informed consent was obtained from all participants. We collected the relevant demographic, medical and procedural data of the current study. Medical data included comorbidities and general health data. Procedure data included the type of device and leads, duration of implant, number of procedures before TLE (e.g., box-change or device upgrades) and indication for TLE. The success and procedure-related complication rates, including death, were retained. Infection types were defined according to the 2018 EHRA expert consensus statement for TLE (27). An advanced diagnostic approach was applied to confirm the infection and infectious complications, followed by a meticulous follow-up to closely monitor di-

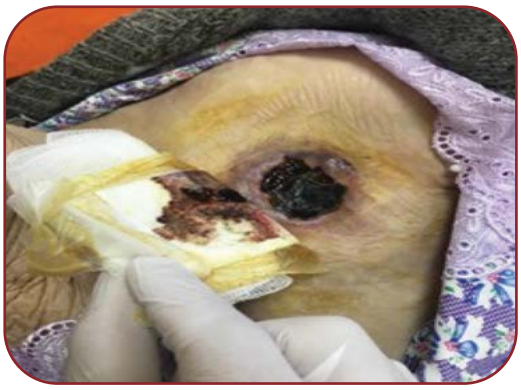

FIGURE 2. Skin necrosis in an infected wound (adapted from Dardari *et al*)

sease evolution after TLE. Transthoracic echography was performed in all patients, followed by transesophageal echography in those with systemic infection. General blood work and specific blood cultures were obtained. When patients presented with fever, another set of blood cultures was collected during the fever spike for microbiological analysis aimed at providing a targeted antimicrobial treatment. Patients with infected wounds (Figure 2) were subject to local wound cultures. All materials removed from patients with any device-related systemic infection were also sent for microbiological analysis (lead tip, vegetation on the leads, etc.)

Indication for reimplantation was reevaluated in all patients, and the decision and course of reimplanting were taken individually.

RESULTS

In our study we included 88 procedures and performed transvenous removal of 150 pacemaker and ICD leads. The mean age of patients undergoing a TLE procedure was 66.16 years. The oldest patient was 98 and the youngest 18. The average lead age was 6.92 ± 4.47 years, with a minimum of one year and maximum of 26. Lead dwell time was over five years in 52.8% of patients, and 15.8% had lead dwell time more than 10 since the first implant; 73.9% were referred to TLE for infection, out of which 31.8% for infective endocarditis/sepsis and 42% for device pocket-infection. Transvenous lead extraction for abandoned and/or dysfunctional leads was performed in 15.9% of patients, while venous thrombosis was responsible for TLE in 10.2% of subjects. Patient characteristics and comorbidities are shown in Table 1. Device and

TABLE 1. Patient characteristics

Patient age, years, mean (SD)	66.16 (16.00)	
Implant age, years, mean (SD)	6.92 (4.47)	
LV ejection fraction, %, mean (SD)	43.8% (14.06)	
Creatinine, mg/dL, mean (SD)	1.00 (0.46)	
	n	**%**
Total patients	**88**	**100**
Males	59	67.0%
Other co-morbidities		
Hypertension	55	65.5%
Ischaemic heart disease	21	25%
Type 2 diabetes	23	27.4%
Renal failure	13	14.7%
Hyperlipidemia	10	11.9%
Atrial fibrillation	36	42.9%
Anemia	52	63.4%
TLE indication		
Infection	65	74%
Device related endocarditis	28	31.8%
Infected pocket	37	42%
Other (no infection)	23	26%
Vein thrombosis	9	10.2%
Abandoned OR dysfunctional	14	15.9%

TABLE 2. Device characteristics

Type	n	%
Single chamber pacemaker	12	13.6
Dual chamber pacemaker	32	36.4
CRT-P	7	8.0
Single chamber ICD	15	17.0
Dual chamber ICD	7	8.0
CRT-D	15	17
Total	88	100.0

CRT: cardiac resynchronization therapy;
P: without defibrillation support;
D: with defibrillation support;
ICD: implantable cardioverter defibrillator.

TABLE 3. Lead characteristics

Lead dwell time (mean, years)	6.92 ± 4.47 (1–26)	
>5	46	52.8%
>10	14	15.8%
Number of leads extracted per case		
Mean	2 (1–4)	
1	31	38.2%
2	34	42%
3	14	17.3%
4	2	2.5%
	n	**%**
Pacing lead	102	68
Single-coil defibrillation	25	16.6
Dual-coil defibrillation	7	4.6
Coronary sinus	16	10.6
Fixation type		
Active	139	92.6
Passive	11	7.3

lead characteristics are described in Tables 2 and 3.

The success rate for device and lead removal was as high as 99.3%, with 6% needing partial extraction, but the goal of TLE was achieved. Minor complications were reported in 6.8% of all procedures, including atrial and ventricular arrhythmias and atrio-ventricular conduction disturbance, pocket hematoma in two cases and one case of pericardial effusion which did not require further medical intervention. There were no major complications or procedural deaths in our study. A 30-day mortality rate of 3.4% was reported, with one patient dying from heart failure, another one from complicated sepsis and a third one from an undetermined cause the second day following the procedure.

All patients had their indication for reimplantation re-evaluated. A total of 67 patients (76%) still had indication for device removal, with three of them refusing to undergo reimplant and 58 being re-implanted. Of the reimplanted patients, 58.6% were implanted on the contra-lateral side, 38% on the ipsilateral side and two patients previously implanted with ICD were reimplanted with a S-ICD (Figure 3). Up to 34.4% of subjects were reimplanted during the same TLE procedure, 24% were implanted during the same hospital admission for TLE but not during TLE, and 41.3% were discharged and reimplanted distantly. Our strategy for reimplant resulted in zero reinfections during a 12-month follow-up. ❑

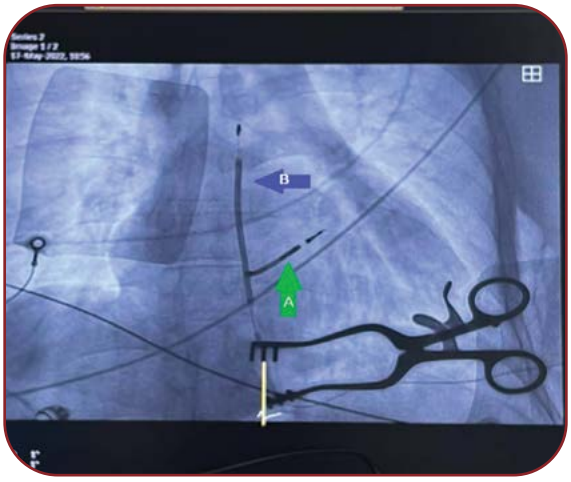

FIGURE 3. (A) Residual coil after incomplete TLE for removing a sing coil defibrillator lead for device related endocarditis; (B) subcutaneous ICD reimplantation after one year; the new lead can be observed in a left parasternal position (adapted from Dardari *et al*)

DISCUSSION

The decision for reimplant is complex and should consider several factors, including the patient's choice. There is still no international consensus for the best strategy in different clinical scenarios in our day-to-day practice. Reinfection is a major issue. One large study on 496 patients reported a 9,5% reinfection rate in subjects with TLE indication rates similar to those found in our study, with a time-to-reinfection ranging from 45 to 214 days and a median of 103 days (28).

While reimplant was done during the TLE procedure and at the same site in non-infectious TLE patients, mainly including subjects with indications for device upgrade and concomitant venous route occlusion, reimplant for those with infection was done distantly. The waiting period took into account the need for permanent pacing, implantation was done after a couple of days in patients with pacemaker-dependency and after 2-4 weeks in those who were not relying on pacing for survival. We always favored reimplant on the contra-lateral side, except when the duration to reimplant exceeded six months.

Patients with systemic infections, including IE, were reimplanted only after normalization of imagistic studies and biological infection markers, as well as lack of bacterial growth on two blood cultures collected in two different days.

Waiting periods for patients with systemic infection varied between 30 and 90 days, depending on the need of pacing for survival. Temporary pacing was initiated for pacemaker-dependent patients through a peripheral route (usually internal jugular vein) using an active fixation lead and an external re-sterilized generator over the skin.

We believe that the approach chosen by us could pave the way for future investigations, which might help to establish an international consensus regarding the most appropriate approach for this issue. In fact, a similar approach regarding this issue was reported by Elshazly *et al* (29). Further studies are needed to confirm the optimal strategy. ❑

CONCLUSION

The decision for reimplantation should be reconsidered in all patients after undergoing TLE. Reimplant procedure was indicated in 76% of the patients previously referred for TLE in our study. A meticulous strategy regarding the timing and site of device reimplantation should be followed in order to limit the risk of infection relapse without compromising the patient's clinical status. We report no infection relapse using this approach during a one-year follow-up. ❑

Conflicts of interest: none declared.
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