Discontinuation of cardiac implantable electronic device therapy after transvenous lead extraction

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DOI: 10.33963/v.kp.97655

Received: May 30, 2023

Accepted: September 19, 2023

Early publication date: November 30, 2023

ABSTRACT

Background: Patients with cardiac implantable electronic devices (CIEDs) may no longer be eligible for continued therapy.

Aims: The study aimed to assess the circumstances under which CIED reimplantation may not be necessary after transvenous lead extraction (TLE).

Methods: A retrospective analysis of 3646 TLE procedures was performed with assessment of indications for device reimplantation.

Results: Reimplantation was not performed immediately after TLE in 169 (4.6%) and, in long-term follow-up, in 146 (4.0%) of patients. No further need for CIED reimplantation was mostly associated with establishment of stable sinus rhythm (2.4%), conversion of sinus node dysfunction to chronic atrial fibrillation (AF; 1.4%), or improvement in left ventricular ejection fraction (LVEF) (0.9%). Independent prognostic factors were in the pacing groups: LVEF (odds ratio [OR], 1.03; 95% confidence interval [CI], 1.01–1.05; P <0.001), AF (OR, 3.8; 95% CI, 2.4–15.7; P <0.001), patients' age during first CIED implantation (OR, 0.97; 95% C, 0.96–0.98; P <0.001), and New York Heart Association (NYHA) class (OR, 0.616; 95% CI, 0.43–0.86; P <0.01); in the cardioverter-defibrillator group: LVEF (OR, 1.06; 95% CI, 1.04–1.09; P <001). Non-reimplanted patients had more complex procedures and more frequent complications, but survival after TLE was better in this group of patients.

Conclusions: Reassessment of the need for continuation of CIED therapy should be considered in all patients following lead extraction and also before planned device replacement as TLE delay increases implant duration, complexity, and procedural risk. The predictors of non-reimplantation are a younger age during the first CIED implantation, lower NYHA class, presence of AF, and higher LVEF in pacemaker carriers, and, in the defibrillator group, only higher LVEF. A decision not to reimplant does not negatively affect the long-term prognosis.

Key words: implantable electronic device, long-term prognosis, loss of indications for pacing, superfluous CIED, unnecessary cardiac transvenous lead extraction

INTRODUCTION

Transvenous lead extraction (TLE) is an inherent part of lead management strategy [1–3]. Indications for lead removal are well-known and generally accepted [1–3]. The TLE guidelines recommend or even mandate reassessment of indications for cardiac implantable electronic device (CIED) therapy continuation before a new implantation [1–3]. Also, the practical guidelines on the CIED implantation technique endorsed by the Heart Rhythm Society recommend reviewing

WHAT'S NEW?

To the best of our knowledge, this is the first report discussing the problem of loss of indications for cardiac device therapy in such a large study population. We have demonstrated that reassessment of the need to continue therapy with cardiac implantable electronic devices (CIEDs) should be considered in all patients referred for transvenous lead extraction for both infectious and non-infectious indications. The present study documents for the first time that the loss of the indications for CIED therapy has no effect on long-term survival. The study also indicates that a significant delay in the decision to remove the unnecessary system is associated with greater procedure complexity and higher risk of major complications. Considering the increase in lead removal difficulty from decade to decade, it seems better to remove unnecessary CIEDs earlier than put off removal to a future time.

the justification for continuing electrotherapy before any generator replacement due to battery deployment [4]. It is a widely known fact that about 15%–35% of CIED patients do not meet the criteria for continuation of cardiac pacing following device removal [5–10]. This applies to patients with infectious [5–7], non-infectious [13–15], and mixed indications [8–12] for lead extraction The guidelines for CIED implantation [4] and lead extraction [1–3] address the issue of CIED therapy discontinuation; however, most patients no longer needing device therapy receive a new CIED, which puts off device removal to a future time. The present study aimed to identify the reasons for resigning from reimplantation and the need for new CIED implantation during long-term follow-up as well as to assess long-term survival in such patients. An additional goal was examination of complexity and outcome of redundant system removal.

METHODS

Study population

We performed retrospective analysis of data from 3646 subsequent patients undergoing lead extraction procedures (described in our previous reports [16–20]) in three high-volume centers in the years 2006–2021. Indications for TLE and lead extraction techniques were described previously [16–20]. Definitions of TLE efficacy and technical and procedural complications are provided in the supplementary materials.

Detailed inclusion criteria

The study population was divided into five groups based on the reimplantation decision.

Group 1. **Patients with unnecessary pacemaker, normal sinus rate (NSR).** A pacemaker was deemed unnecessary when there was an extremely low percentage (<1%) or absence of any pacing in pacemaker memory, stable normal sinus rhythm, and normal atrioventricular (AV) conduction over a long period (pacemaker memory). In borderline cases, pacemakers were programmed to VVI with a rate of 35 bpm for 6 months (minimum pacing rate test). In case of doubt on the doctor's or patients' side, pacing was switched off (impulse amplitude 0.1 V and duration 0.1 ms) for the next 6 months ("switch off test"). This time-consuming, "conventional" approach was used in 79 patients. In the remaining 7 patients, possible influences of the autonomic nervous system on heart rhythm were evaluated and cardiac neuroablation was performed before device removal.

Group 2. Patients with an unnecessary pacemaker, permanent atrial fibrillation (AF), normal heart rate (NHR). A pacemaker was unnecessary in this group when we observed an extremely low percentage (<1%) or absence of ventricular pacing in pacemaker memory, stable AF with normal AV conduction (NHR) over a long period (pacemaker memory). In doubtful (non-infective) cases, the pacemaker was programmed to VVI with a rate of 35 bpm for 6 months. This time-consuming, "conventional" approach ("minimum ventricular pacing output test" and "switch off ventricular pacing test") was used in 34 patients. In patients with CIED-related infection, the system was removed, and Holter monitoring on 2 or 3 occasions was performed to reassess the need for permanent pacing.

Group 3. **Patients with unnecessary implantable cardioverter-defibrillator (ICD)/cardiac resynchronization therapy (CRT), improved left ventricular ejection fraction (LVEF), NHR.** Indications for CIED reimplantation were lost in the case of improvement in LVEF > 40%, no ventricular arrhythmia in device memory, no indications for pacing in ICD patients, and no indications for pacing and narrow QRS complexes in CRT-dual (CRT-D) patients (transient arrhythmias or significant impairment of left ventricular contractility were probably caused by an inflammatory process in these cases).

The decision made by patients and their physicians resulted in resignation from ICD or CRT reimplantation.

Group 4. All non-reimplanted patients from groups 1, 2, and 3 were taken together for general comparisons with the controls.

Group 5. A control group of patients in whom leads or entire devices were removed for infectious or non-infectious indications, and a new CIED (A [atrial], V [ventricular], D [dual], CRT-P [cardiac resynchronization therapy-pacing] — in 2448 [70.4%], ICD — in 78 [22.4%], and CRT-D — in 251 [7.2%]) was implanted immediately or after infection treatment.

The patient's and his/her doctor's consent to discontinue pacemaker/ICD-CRT-D therapy was mandatory.

Analysis of non-reimplantation by type of CIED and multivariate analysis of prognostic factors for discontinua-

tion of indications for CIED, as well as analysis of the risk of death in the non-reimplantation group and information on reimplantation during long-term follow-up are presented in supplementary materials.

Dataset and statistical methods

Due to non-Gaussian distribution, all continuous variables were presented as medians and interquartile ranges (IQR). The categorical variables were presented as numbers and percentages. The patients were divided into 5 groups. The significance of differences between groups (1, 2, 3, 4 vs. 5) was determined using the nonparametric χ^2 test with Yates' correction or the unpaired Mann-Whitney U test, as appropriate. The Bonferroni correction was applied, assuming a *P*-value of <0.0125 as statistically significant. The uni- and multivariable logistic regression were used to determine prognostic factors for the loss of indications for CIED reimplantation. In the multivariable model, data that achieved *P* <0.05 under univariable analysis were included. Analysis was performed in the two subgroups divided depending on the kind of CIED: conventional pacemakers and cardioverter defibrillator groups. The parameters that reached *P* <0.05 under multivariable regression analysis were presented.

The Cox regression model was used to determine the impact of not meeting any longer the criteria for device implantation on long-term survival following TLE. Clinical and CIED-related data were analyzed. In the multivariable model, the data that achieved *P* <0.05 under univariable analysis were included. The parameters that reached *P* <0.05 under multivariable regression analysis were presented.

To present the relationship between no longer meeting the reimplantation criteria and mortality, Kaplan-Meier survival curves were plotted, whose course was assessed using the log-rank test. Kaplan-Meier log-rank survival analysis and Cox regression survival analysis considered the time from last TLE to the end of the follow-up period and were performed on the basis of data from 3464 patients. A *P*-value less than 0.05 was considered statistically significant. Statistical analysis was performed with Statistica version 13.3 (TIBCO Software Inc.).

Approval of the Bioethics Committee

All patients gave their informed written consent to undergo TLE, and we used anonymous data from their medical records. The telephone follow-up was approved by the Bioethics Committee at the Regional Chamber of Physicians in Lublin no. 288/2018/KB/VII. The study was carried out in accordance with the ethical standards of the 1964 Declaration of Helsinki.

RESULTS

The study group consisted of 3646 patients (61.6% men), aged 5–96 years, the median age: 69.0 (60.0–77.0), who underwent lead extraction between 2006 and 2021. Indications for TLE included infectious (17% of patients) and non-infectious complications, such as dysfunction or dislocation of the leads, need to upgrade the system, and loss of indications for device therapy (Table 1).

Patients from group 1 were the youngest age group at first CIED implantation (37.1 years), and most often had unknown underlying heart disease. In 23.3% of patients, the main indication for system removal was infection.

Patients from the second group were characterized by the oldest age at TLE (72 years) and there were many women in this group (54%). In 32.0% of patients, the main indication for system removal was infection.

Group 3 (33 patients) was relatively young, both during system implantation and extraction (45.7 and 52.8 years, respectively); they rarely had ischemic heart disease (IHD) (24.2%), more frequently had normal LVEF (over 50% in 50% of patients), and a low score according to the Charlson co-morbidity index.

The best general health status was observed in patients from groups 1 and 3; it was significantly better than in the control group. Group 2, in spite of older age, presented, indeed, better LVEF than controls (Table 1).

A decision to discontinue CIED therapy was made in 169 (4.6%) patients of the entire analyzed population (group 4), and it was made significantly more often in patients with pacemaker (136 patients, 5.3%) than in patients with ICD (28 [3.5%]) or CRT-D5 (1.9%) (Supplementary material, *Table S1*).

Independent prognostic factors for loss of indications for CIED reimplantation in the group of patients with pacemakers were: higher LVEF (odds ratio [OR], 1.03; *P* <0.001), presence of AF (OR, 3.8; *P* <0.001), older age (by one year) during first CIED implantation (OR, 0.97; *P* <0.001), and higher New York Heart Association (NYHA) class (OR, 0.61; *P* <0.01). The only predictive parameter for loss of indications for ICD/CRT-D reimplantation was an increase in LVEF (OR, 1.06; *P* <0.001) (Supplementary material, *Table S2*).

Implant duration was significantly longer in groups 1 and 2 than in the control group (Table 2). The oldest leads were extracted from patients from group 1. That resulted in a higher risk of major TLE complications, which was predicted using the SAFeTY-TLE calculator in the groups with unnecessary pacemakers. In about 50% of all non-reimplanted patients, verification of indications took place during the third or next CIED-related procedure, which explains long or very long implant duration and subsequent slightly worse TLE effectiveness and increased complication rates. Procedure duration was longer in all patients with redundant CIEDs compared to the control group. Procedure difficulty and complexity (expressed as the number of technical problems, mutual lead-to-lead connections, with strong scars or breaks of extracted lead) were significantly more frequent in patients from group 1. Its resulted from the longest implant duration and youngest patient's age. The necessity to utilize second-line tools (Evolution or TightRail, metal sheath, lasso catheter/snare) confirms

Table 1. Clinical characteristics of the study patients

	Unnecessary pacemaker, χNSR	Unnecessary pacemaker, AF, NHR	Unnecessary ICD/CRT, improvement in EF, NHR	All non-reimplanted patients	Control group Removal of necessary CIED with immediate or delayed reimplantation
Group number	1	2	3	4	5
	χ^2 test/ /Mann-Whitney "U" test 1 vs. 5	χ^2 test/ /Mann-Whitney "U" test 2 vs. 5	χ^2 test/ /Mann-Whitney "U" test 3 vs. 5	χ^2 test/ /Mann-Whitney "U" test 4 vs. 5	
Number of patients, (%)	N = 86 (2.4%)	N = 50 (1.4%)	N = 33 (0.9%)	N = 169 (4.6%)	N = 3477 (95.4%)
Patient age during TLE, years	50.5 (35.5–64.5) *P* <0.001	72.0 (65.0–77.0) *P* = 0.03	53.0 (36.0–67.0) *P* <0.001	60.5 (41.0–71.0) *P* <0.001	69.0 (60.0–77.0)
Patient age at first implantation, years	37.1 (20.5–49.5) *P* <0.001	62.0 (55.0–68.0) *P* = 0.27	45.0 (33.0–61.0) *P* <0.001	46.5 (29.6–61.0) *P* <0.001	61.0 (51.0–70.0)
Sex, female	35 (40.7) *P* = 0.65	27 (54.0) *P* = 0.02	8 (24.2) *P* = 0.02	70 (41.4) *P* = 0.46	1331 (38.3)
Underlying heart disease: ischemic heart disease	11 (12.8) *P* <0.001	36 (72.0) *P* = 0.04	8 (24.2) *P* <0.001	55 (32.5) *P* <0.001	1974 (56.8)
Underlying heart disease: valvular heart diseases, cardiomyopathies, post inflammatory	4 (4.7) *P* = 0.01	3 (6.0) *P* = 0.09	18 (54.6) *P* <0.001	25 (14.8) *P* = 0.7	553 (15.9)
Underlying heart disease: conduit, unknown, channelopathies, neurocardiogenic, surgical, post ablation	71 (82.6) *P* <0.001	11 (22.0) *P* = 0.51	7 (21.2) *P* = 0.55	89 (52.7) *P* <0.001	947 (27.2)
NYHA class III & IV	2 (2.3) P <0.001	4 (8.0) *P* = 0.2	0 (0.0) *P* = 0.03	6 (3.6) *P* <0.001	541 (15.6)
Congestive heart failure (symptomatic presently)	0 (0.0) *P* <0.001	9 (18.0) *P* = 1.0	4 (12.1) *P* = 0.44	13 (7.7) *P* <0.001	659 (19.0)
LVEF average, %	62.0 (60.0–65.0) *P* <0.001	55.0 (45.0–60.0) *P* = 0.11	52.0 (45.0–60.0) *P* = 0.04	60.0 (54.0–65.0) *P* <0.001	53.0 (35.0–60.0)
Charlson comorbidity index, points	1 (0–3) *P* <0.001	4 (3–6) *P* = 0.58	1 (0–3) *P* <0.01	2 (0–4) *P* <0.001	4 (3–6)
Main indications for TLE — (primary / predominant)					
Infective endocarditis with or without pocket infection	14 (16.3) *P* = 0.26	10 (20.0) *P* = 0.87	5 (15.2) *P* = 0.47	29 (17.2) *P* = 0.17	764 (21.5)
Local (isolated) pocket infection	6 (7.0) *P* = 0.45	6 (12.0) *P* = 0.79	3 (9.1) *P* = 0.98	15 (8.9) *P* = 0.78	342 (9.8)
Mechanical lead damage (electric failure)	16 (18.6) *P* = 0.09	3 (6.0) *P* < 0.001	11 (33.3) *P* = 0.57	30 (17.8) *P* < 0.01	953 (27.4)
Lead dysfunction (exit/entry block, dislodgement, perforation, extracardiac pacing)	8 (9.3) *P* = 0.046	3 (6.0) *P* = 0.12	1 (3.0) *P* = 0.06	12 (7.1) *P* < 0.01	808 (23.2)
Other non-infective indications[a]	42 (48.8) *P* <0.001	28 (56.0) *P* <0.001	13 (39.4) *P* <0.01	83 (49.1) *P* <0.001	610 (17.5)

Continuous variables are presented as medians and first and third quartiles (IQR). Categorical variables are presented as numbers and percentages
[a]Other non-infective indications: no longer meeting indications for pacing/ICD, change of pacing mode, abandoned lead/prevention of abandonment, threatening lead (loops, free ending, left heart, LDTVD) and other rare indications: MRI indication, cancer, painful pocket, and regained venous access (symptomatic occlusion, superior vena cava syndrome, lead replacement/upgrading)

Abbreviations: CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LDTVD, lead-derived tricuspid valve defect; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; NYHA, New York Heart Association; TLE, transvenous lead extraction

the most difficult, and most complicated lead extraction in the group of patients with superfluous pacemakers and NSR (Table 2).

After TLE, the median follow-up of the whole study group was 1584 days. Occurrence of any major complications, necessity for urgent rescue cardiac surgery, tricuspid valve damage during TLE, partial radiographic success (lead remnants), and lack of complete procedural success were significantly more frequent in group 1. However, there were no procedure-related deaths (intra or post-procedural) in the non-reimplanted groups of patients. Analysis showed that periprocedural and 30-day mortality was similar and that there was no death in the non-reimplanted groups in this period. However, mortality rates during all-time follow-up at > 1 year and ≥3 years following TLE were significantly higher in reimplanted patients (Table 3, Figure 1).

In non-reimplanted patients, 19 died during follow-up. In the subgroup with removed ICD systems, there were two deaths up to 3 years and one death at >3 years, whereas in the subgroup with removed CRT-D systems, no patient died (Supplementary material, *Table S3*).

The mortality rate during long-term follow-up was significantly lower in non-reimplanted patients (11.2% vs. 33.7%,). The risk factors for death were infections, older age, low LVEF, IHD, and congestive heart failure.

Regression analysis confirmed that the risk of death during follow-up increased with patient age (by 5.0% for each year), infectious indications (by 49.4%), higher NYHA

Table 2. Risk factors for major complications and procedure complexity related to the device, history of pacing, and the procedure itself

	Unnecessary pacemaker, NSR	Unnecessary pacemaker, AF, NHR	Unnecessary ICD/CRT, improvement in LVEF, NHR	All non-reimplanted patients	Control group Removal of necessary CIED with immediate or delayed reimplantation
Group number	1	2	3	4	5
	χ^2 test/ /Mann-Whitney "U" test 1 vs. 5	χ^2 test/ /Mann-Whitney "U" test 2 vs.5	χ^2 test/ /Mann-Whitney "U" test 3 vs.5	χ^2 test/ /Mann-Whitney "U" test 4 vs.5	
Number of patients, %	N = 86 (2.4%)	N = 50 (1.4%)	N = 33 (0.9%)	N = 169 (4.6%)	N = 3477 (95.4%)
Types of CIED systems					
PM (A,V,D)	86 (100.0)	50 (100.0)	0 (0.00)	136 (80.5)	2448 (70.4)
ICD (V,D)	0 (0.00)	0 (0.00)	28 (84.9)	28 (16.57)	778 (22.4)
CRT-D	0 (0.00)	0 (0.00)	5 (15.2)	5 (3.0)	251 (7.2)
Number of procedures before lead extraction, n	2 (1–2) $P = 0.08$	1 (1–2) $P = 0.21$	2 (1–2) $P = 0.29$	2 (1–2) $P = 0.94$	2 (1–2)
Time since last CIED procedure (any), months	75.0 (34.5–115.5) $P < 0.001$	72.0 (34.0–93.0) $P < 0.001$	42.0 (13.0–76.0) $P = 1.0$	67.0 (33.0–97.0) $P = 0.001$	38.0 (16.0–70.0)
TLE-related potential risk factors for major complications and procedure complexity					
Oldest extracted lead per patient, months	135.0 (82.4–213.6) $P < 0.001$	125.0 (79.0–157.0) $P < 0.01$	85.0 (42.0–132) $P = 0.37$	122.0 (74.5–185.5) $P < 0.001$	84.0 (43.0–22.9)
Cumulative dwell times of extracted leads per patient, years	18.1 (10.3–31.6) $P < 0.001$	19.0 (12.5–28.0) $P < 0.001$	10.1 (4.33–14.2) $P = 0.32$	16.4 (9.9–28.0) $P = 0.001$	9.25 (4.7–18.0)
SAFeTY-TLE probability ~~score~~ of MC risk, %	1.3 (0.4–3.2) $P < 0.001$	1.8 (0.5–3.7) $P = 0.06$	0.33 (0.2–0.6) $P = 0.07$	1.2 (0.4–2.6) $P = 0.001$	0.5 (0.3–1.8)
TLE complexity					
Procedure duration (sheath-to-sheath time), minutes	11.5 (8.0–25.0) $P < 0.001$	11.0 (8.0–19.0) $P = 0.04$	9.0 (4.0–18.0) $P = 0.55$	11.0 (8.0–21.0) $P < 0.001$	9.0 (4.0–12.0)
Average time of single lead extraction (sheath-to-sheath / number of extracted leads), minutes	6.5 (4.0–15.0) $P < 0.001$	5.0 (4.0–10.0) $P < 0.59$	5.0 (4.0–12.0) $P = 0.04$	6.0 (4.0–12.5) $P < 0.001$	4.5 (4.0–9.0)
Unexpected procedure difficulties during TLE (any) [18]	28 (32.6) $P < 0.01$	9 (18.0) $P = 0.9$	6 (18.2) $P = 0.8$	43 (25.4) $P = 0.21$	687 (19.8)
Lead-to-lead binding	11 (12.8) $P = 0.03$	5 (10.0) $P = 0.45$	1 (3.0) $P = 0.68$	17 (10.1) $P = 0.08$	220 (6.3)
Break of extracted lead	13 (15.1) $P < 0.01$	3 (6.0) $P = 0.81$	1 (3.3) $P = 0.76$	17 (10.1) $P = 0.03$	201 (5.8)
Two or unexpected procedure difficulties [18]	13 (15.12) $P = 0.001$	3 (6.00) $P = 0.724$	2 (6.1) $P = 0.88$	18 (10.7) $P < 0.001$	139 (4.0)
Use of additional tools					
Evolution (old and new) or TightRail	6 (6.98) $P = 0.001$	0 (0.00) $P = 0.849$	1 (3.0) $P = 0.93$	7 (4.1) $P < 0.01$	46 (1.3)
Use of advanced tools (metal sheaths, lasso-basket catheters/snares)	22 (24.2) $P < 0.001$	6 (10.7) $P = 0.79$	3 (8.82) $P = 0.59$	21 (12.4) $P = 0.94$	409 (11.9)

Continuous variables are presented as medians and first and third quartiles (IQR). Categorical variables are presented as numbers and percentages

Abbreviations: AF, atrial fibrillation; CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MC, major complications; NHR, normal heart rate; NSR, normal sinus rate; PM, pacemaker; SAFeTY-TLE, score of major complications; TLE, transvenous lead extraction

class (by 31.8% per one class), presence of diabetes (by 32.6%), renal dysfunction (by 85.2%), presence of CRT before TLE (by 9.4%). The loss of indications for electrotherapy lowered the risk of death by 35.0% (Supplementary material, *Table S4*).

Long-term telephone follow-up was performed for this analysis. In 86.4% of cases, a new system was not implanted, 4.7% received a new device, and we lost contact with 8.9% (all survived) (Supplementary material, *Table S5*).

DISCUSSION

In clinical practice, it may appear that sometimes, after many years, in various clinical situations, some patients with CIEDs no longer meet the treatment criteria. Device therapy is no longer needed after lead extraction for various reasons [5–15]. Moreover, the guidelines for lead extraction strongly recommend detailed reassessment of indications for a new CIED implantation [1–3]. Discontinuation of CIED therapy was described in 19.3%–45.0% of patients with infectious indications [5–7], 14.0%–38.8% of patients with non-infectious indications for TLE [13–15], and 14.8%–35.0% with mixed reasons [8–12]. However, most reports show a high rate of discharge of patients who did not receive a new device with a recommendation to continue antibiotic therapy and follow-up [5–12]. In our study, we analyzed the reasons for the decision to resign from reimplantation in patients

Table 3. TLE major complications, outcomes and long-term mortality following lead extraction

	Unnecessary pacemaker, NSR	Unnecessary pacemaker, AF, NHR	Unnecessary ICD/CRT, improvement in EF, NHR	All non-reimplanted patients	Control group Removal of necessary CIED with immediate or delayed reimplantation
Group numer	1	2	3	4	5
	χ2 test / Mann-Whitney "U" test 1 vs. 5	χ2 test / Mann-Whitney "U" test 2 vs. 5	χ2 test / Mann-Whitney "U" test 3 vs. 5	χ2 test / Mann-Whitney "U" test 4 vs. 5	
Number of patients, %	N = 86 (2.4%)	N = 50 (1.4%)	N = 33 (0.9%)	N = 169 (4.6%)	N = 3477 (95.4%)
Major complications (any)	9 (10.5) *P* <0.001	1 (2.0) *P* = 0.67	1 (3.0) *P* = 0.2	11 (6.5) *P* <0.001	62 (1.8)
Hemopericardium	8 (9.3) *P* <0.001	1 (2.0) *P* = 0.42	1 (3.0) *P* = 0.81	10 (59.2) *P* <0.001	37 (1.1)
Tricuspid valve damage during TLE (severe)	3 (3.5) *P* <0.01	0 (0.0) *P* = 0.54	0 (0.0) *P* = 0.39	3 (1.8) *P* = 0.1	17 (0.5)
Rescue cardiac surgery	9 (10.5) *P* <0.001	1 (2.0) *P* = 0.96	1 (3.0) *P* = 0.73	11 (6.5) *P* <0.001	32 (0.9)
Procedure-related death (intra-, post-procedural)	0 (0.0) *P* = 0.89	0 (0.0) *P* = 0.59	0 (0.0) *P* = 0.39	0 (0.0) *P* = 0.74	6 (0.2)
Partial radiographic success (a tip or <4 cm lead fragment remained)	9 (10.5) *P* <0.01	1 (2.0) *P* = 0.81	1 (3.0) *P* = 0.78	11 (6.5) *P* = 0.09	132 (3.8)
Complete procedural success	75 (87.2) *P* <0.001	49 (98.0) *P* = 0.6	32 (97.0) *P* = 1.0	156 (92.3) *P* = 0.09	3318 (95.4)
Survival after TLE during 1584 (718.0–2823) (1–5519) days of follow-up. Log-rank *P* for all models: *P* <0.001					
Length of the follow-up: survivors, days	1689 (752.0–2330)	1761 (1185–2494)	1213 (850.0–1629)	1577 (784.0–2389)	1913 (961.0–3145)
Length of the follow-up: death, days	595.0 (158.0–1116)	1228 (595.0–2592)	1081 (702.0–1894)	1081 (585.0–2147)	1112 (374.0–2072)
1-month mortality after TLE 1–30 days	0 (0.0) *P* = 0.45	0 (0.0) *P* = 0.74	0 (0.0) *P* = 0.97	0 (0.0) *P* = 0.18	56 (1.6)
Alive during all follow-up	81 (94.2) *P* <0.001	39 (78.0) *P* = 0.11	30 (90.9) *P* <0.01	150 (88.8) *P* <0.001	2304 (66.3)
Death during all follow-up	5 (95.8) *P* <0.001	11 (22.0) *P* = 0.11	3 (9.1) *P* <0.01	19 (11.2) *P* <0.001	1173 (33.7)

Continuous variables are presented as medians and first and third quartiles (IQR). Categorical variables are presented as numbers and percentages

Abbreviations: AF, atrial fibrillation; EF, ejection fraction; CIED, cardiac implantable electronic device; CRT, cardiac resynchronization ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NHR, normal heart rhythm; NSR, normal sinus rate; TLE, transvenous lead

undergoing TLE mainly for non-infectious indications. The overall percentage of patients who did not undergo CIED reimplantation after transvenous lead extraction was only 4.64% (4.00% during long-term follow-up). The patients did not undergo subsequent device reimplantation mainly because of the return of stable NSR and normal AV conduction in 2.36% of patients, conversion of sinus node dysfunction (SND) to permanent AF with NHR in 1.37%, a significant improvement in LVEF, and no ventricular arrhythmia during long-term follow-up in 0.91% of patients. There are many potentially reversible causes of SND or AV conduction disturbances over a long or very long period [21–23]. Especially in young patients, sinus arrest or paroxysmal AV block may be a sign of different forms of neurocardiogenic syncope (vagal reflex only) without heart disease [24–27]. Reports of various forms of neurocardiogenic syncope do not present a long-term natural history of the disorder [27–30]. Our personal observations seem to indicate that in patients with neurocardiogenic syncope and pacemakers, the severity of vagal reflex decreases over time and the percentage of atrial or ventricular pacing becomes low. Considering potential lead-related complications (infectious or lead dysfunction) that can occur over the next decades, and difficulties with extraction of very old leads, we decided to remove unnecessary CIEDs without reimplantation in patients with higher life expectancy (most patients in group 1). Such decisions were based on device memory analysis and the results of the "minimum pacing output test" and "switch off test" with Holter monitoring. We believe that it is better to remove unnecessary CIEDs in the case of battery exhaustion than to reimplant the device and put off removal to a future time.

The most important aspect of the decision to resign from CIED reimplantation after TLE is assessment of rhythm stability and, above all, long-term survival. There are several reports on long-term survival among non-reimplanted patients [9–12, 14], and nobody has demonstrated a relationship between death and lack of CIED. In our study, the rates of periprocedural and 30-day mortality were similar, and there were no deaths in non-reimplanted patients in this period, but mortality at >1 year and ≥3 years following lead extraction was, paradoxically, higher among

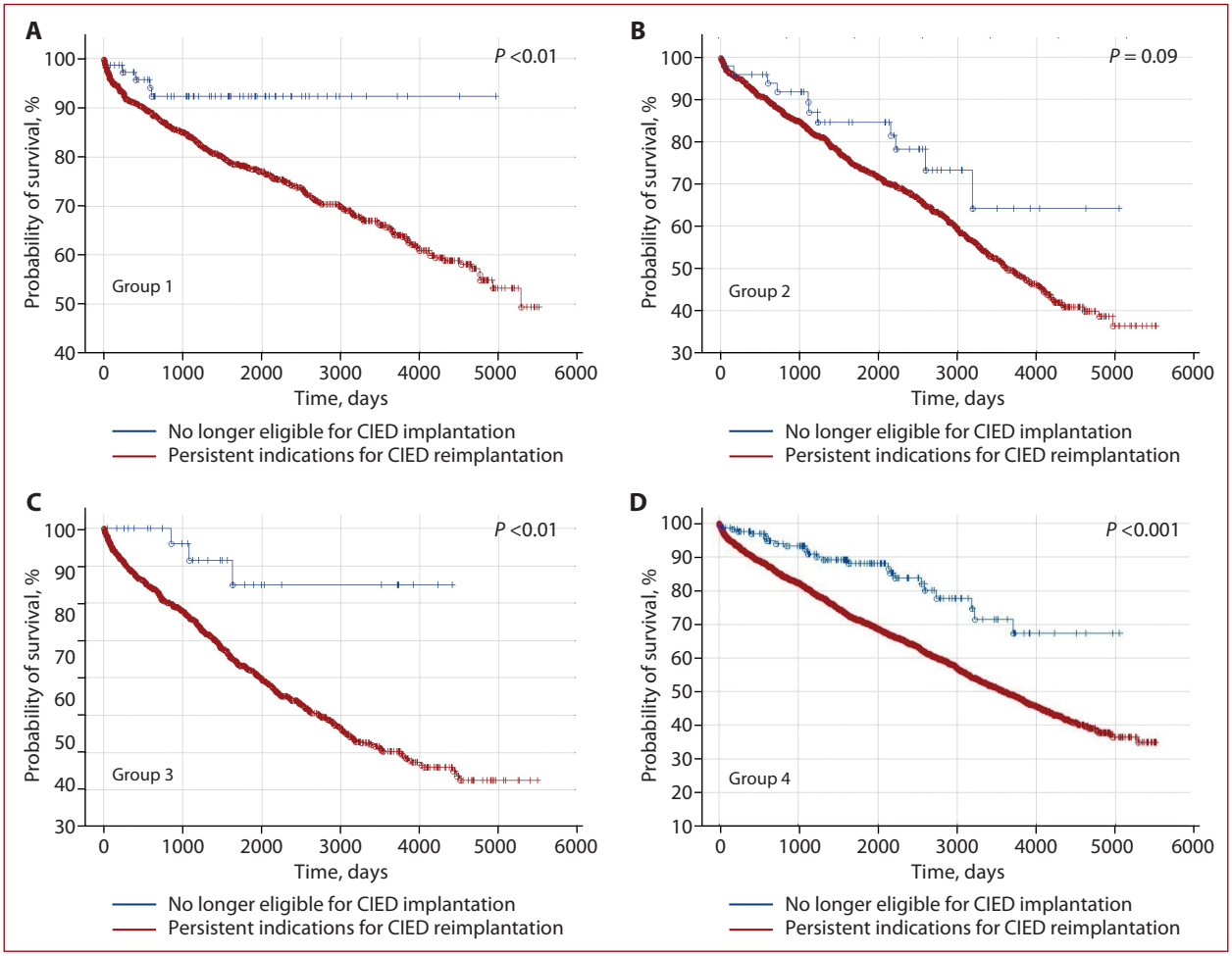

Figure 1. Survival after transvenous lead extraction according to continuation or discontinuation of cardiac implantable electronic device therapy for different reasons

reimplanted patients. This can be accounted for by the fact that risk factors for mortality during follow-up were mainly infection, older age, IHD, lower LVEF, and congestive heart failure, while patients from groups without reimplantation were often younger and had fewer comorbidities.

The issue of discontinued ICD therapy is less known. Pediatric guidelines recommend reconsideration of indications for ICD for each CIED-related intervention [31]. The authors of the guidelines refer to the extensive study by Kini et al. [32], which showed that approximately 25% of patients receiving ICDs as primary prevention may no longer meet the indications for an ICD at the time of generator replacement. In other reports, a thorough analysis of non-implanted ICD patients is omitted [33] or patients with pacemaker and ICD are discussed as one group. Döring showed that more than one-third of patients undergoing TLE do not need reimplantation due to loss of indications [5]. Al-Hijji [14] pointed out that 14% of patients who had device extraction did not undergo reimplantation mainly because they no longer met CIED indications. The high mortality in these patients is related to device complications and comorbid conditions, whereas mortality (as reported by Döring) associated with arrhythmia is rare. Little is known about discontinuing CRT in responders as this therapy should be continued for as long as possible [34]. Recently, a report by D'Angelo et al. [35] was published, in which the authors indicate that mortality among non-reimplanted patients (with CRT and ICD systems removed, which constituted about 70% of the group) was even lower than in patients who received CIEDs again as indicated immediately after TLE or after recovery.

Study limitations

In many cases, especially in young patients, it was very difficult to establish the underlying heart disease and causes of rhythm disturbances. We showed that Holter findings of sinus node dysfunction or recurrent AV conduction disturbances may disappear within the service life of the device, but we cannot be sure about regression of, for example, vasovagal syndrome or another form of neurocardiogenic syncope and differentiate it retrospectively from inflammatory or drug-induced arrhythmia.

CONCLUSIONS

In the presented TLE population CIED reimplantation was not necessary, due to the disappearance of indications in

4.6% of patients during short-term follow-up. In about 70% of them, a decision was made during TLE performed due to infective or non-infective indications, but in 30 %, the decision was taken when patients were referred for TLE due to battery depletion and with intention not to reimplant their device. The most important predictive parameters for discontinuation of CIED therapy are younger age of patients during first CIED implantation, lower NYHA class, an increase in LVEF, and occurrence of AF (pacemaker group). Patients in whom indications for device therapy have disappeared had better general and cardiac status health (excluding patients with permanent AF) and had longer implant duration (excluding ICD/CET carriers). These factors affects procedure complicity, effectiveness, and complications, but not short, mid, and long-term mortality, which is strongly dependent on infective indications for TLE and general health status.

In about 50% of all non-reimplanted patients, verification of the necessity for continuation of CIED therapy takes place during the third or next CIED-related procedure, which explains long or very long implant duration and subsequent slightly worse TLE effectiveness and increased complication rates. Therefore, such verification should be performed in all CIED carriers, not only after lead extraction but before planned unit replacement due to battery depletion.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

Conflict of interest: None declared.

Funding: None.

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