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ORIGINAL ARTICLE

Ten-year study of late electrotherapy complications. Single-centre analysis of indications and safety of transvenous leads extraction

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Abstract

Background: An increase in the number of cardiac implantable electronic device (CIED) implantations is associated with a higher frequency of electrotherapy complications.

Aim: The aim of the study was to determine the risk factors for late electrotherapy complications and to evaluate the effectiveness of transvenous lead extraction (TLE) and survival after TLE.

Methods: We analysed the clinical data of 225 patients with electrotherapy complications referred for TLE in a single centre in the years 2006 to 2015. Indications for TLE, risk factors for infectious complications, effectiveness of TLE, and survival after the procedure were assessed.

Results: In the study group, non-infectious indications for TLE predominated (78.2%). Analysis of risk for infectious complications demonstrated the important role of chronic renal failure (hazard ratio [HR] 1.842, $p = 0.034$) and a greater number of CIED-related procedures (HR 4.768, $p < 0.001$). High effectiveness of TLE and significantly higher long-term mortality of patients with infectious complications compared with the remainder (50% vs. 20%, $p < 0.05$) were documented.

Conclusions: The study demonstrated a high rate of patients with non-infectious complications referred for TLE and very high effectiveness of the procedure. The worse long-term survival of patients with infectious complications, as well as increased risk for such complications due to the greater number of prior procedures, should prompt the consideration of early referral for TLE in the case of lead dysfunctions.

Key words: late complications of electrotherapy, local pocket infection, lead-related infective endocarditis, transvenous lead extraction

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INTRODUCTION

The rise in the number of cardiac implantable electronic device (CIED) implantations: pacemakers (PMs), implantable cardioverter-defibrillators (ICDs), and cardiac resynchronisation therapy (CRT) devices, resulting from broader indications for implantation and a change in patient profile, is associated with an increased incidence of complications of electrotherapy [1–5]. Particularly important are the late complications, appearing a few, or even over a dozen years, after implantation, because it is difficult to predict the risk factors for their occurrence, as well as to establish a single mode of action. The most commonly used method of treatment of such complications is complete removal of the system, i.e. transvenous lead extraction (TLE). The Heart Rhythm Society (HRS) guidelines from 2009 [1] concerning indications for TLE, and their updated version from 2017 [6], do not solve all the problems

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related to this field, often recommending the individualisation of therapy, especially in patients without symptoms of infection. It is therefore necessary to conduct further studies to clarify the indications for TLE due to non-infectious causes and clearly define their place in electrotherapy.

METHODS

Retrospective analysis of the clinical data of 225 patients (36% women) hospitalised in the Regional Cardiology Centre in the years 2006 to 2015 due to complications associated with PM/ICD/CRT was conducted. All patients undewent TLE, and all the procedures were performed by an experienced operator in a single Reference Centre. TLE was performed using polypropylene Byrd dilators (Cook® Medical, Leechburg, PA, USA) or rarely with the use of mechanical catheters (Evolution, Cook; TighRail Spectranetix). In the TLE centre, catheters using laser energy or electrosurgical dissection sheaths were not used. In the study group, 176 (78.2%) patients with non-infectious indications for TLE were identified, and there were 49 (21.8%) patients with infectious complications. Non-infectious indications included various types of lead dysfunction: breaking of the lead, dislocations (loops of the leads), late dry perforations of the exit block type with disorders of pacing, sensing, and resistance (P/S/R), symptomatic venous obstructions as well as the need for elective replacement of Sprint Fidelis leads, and prophylactic extractions of abandoned, redundant leads. Infections related to the presence of PM/ICD/CRT were divided into pocket infection (PI), lead-related infective endocarditis (LRIE), and PI coexisting with LRIE.

The phenomenon of intracardiac abrasion of a lead was defined as macroscopically visible damage of external insulation located only in its intracardiac part, usually in the first 15 to 20 cm from the tip. The presence of abrasion was confirmed on microscopic examinations [7, 8] carried out by researchers from the TLE centre to which study patients were referred.

Concepts such as TLE, total and clinical success of the procedure, major and minor complications, local PI, and LRIE were defined according to the 2017 TLE HRS guidelines [6] and the 2015 European Society of Cardiology guidelines [9].

In particular groups and subgroups of patients, the potential clinical factors and procedural complications of electrotherapy were evaluated. On the basis of univariate and multivariate analyses, risk factors for infectious complications were identified. The effectiveness of procedures, the occurrence of major and minor complications, and long-term survival after TLE were also assessed.

Survival status and date of death were obtained from the Ministry of Internal Affairs until 2014. In the years 2014 and 2015 these data were complemented by the National Health Fund. The survival observation was completed in all patients after TLE. The authors have an official permit to obtain these data.

The study was approved by the local Bioethics Committee (decision number 02/2012).

Statistical analysis

The examined data are presented for all patients and for subgroups of patients classified according to the type of detected infectious complications. Continuous variables are presented as mean ± standard deviation and were compared using Student t test. Categorical data are presented as absolute numbers and percentages and were compared using the χ^2 test with Yates correction. If the p-value was less than 0.05, the odds ratio with 95% confidence interval was calculated. Calculation of Cox proportional hazards regression analysis (uni- and multivariate) was applied to identify the variables associated with infective system dysfunction and prognosis after TLE. Multivariate regression analysis included the data that obtained a p-value of < 0.1 in univariate analysis. Survival analysis based on Kaplan-Meier curves and log-rank tests was used to assess the death-free survival after TLE depending on the type of detected infectious complications. Differences between the groups were considered statistically significant at $p < 0.05$. If the p-value ranged between 0.05 and 0.1 (estimated to the third decimal place), the value of $p \geq 0.1$ was determined as non-statistical. Statistical analysis was performed with 10.0 Statistica software (StatSoft Inc., Tulsa, OK, USA).

RESULTS

The study included 225 patients (36.9% patients with ICD, 3.9% with CRT) in whom a total of 313 leads were removed. Among them, 176 (78.2%) patients were referred for TLE due to non-infectious indications, and 49 (21.8%) patients due to causes related to infection (Fig. 1A). In patients with infectious complications, the causes for referral for TLE were isolated PI in 16 (32.7%) patients, PI with LRIE in 23 (46.9%) patients, and isolated LRIE in 10 (20.4%) patients (Fig. 1B).

Non-infective causes for qualification for TLE were divided into classes in accordance with the HRS guidelines [1, 3]. The presented classification distinguishes primary and lower-level indications. The most common type of indication for TLE was the removal of superfluous non-functional leads — it was present in 79.5% of patients and constituted a primary indication in 52.8% of cases. Another indication was the presence of leads that pose a potential threat to the patient, it was identified in 54.5% of patients and classified as a primary indication in 29.5% of them. Among the primary indications, an important one was the need for the removal of an excess of functional leads, demonstrated by 6.3% of patients. A very important indication of the lower-level was the need for the recapture of venous access, identified in 15.9% of patients. Other types of indications included interference with an active pacing system or with anti-cancer therapy, chronic pain at the site of device insertion, reces-

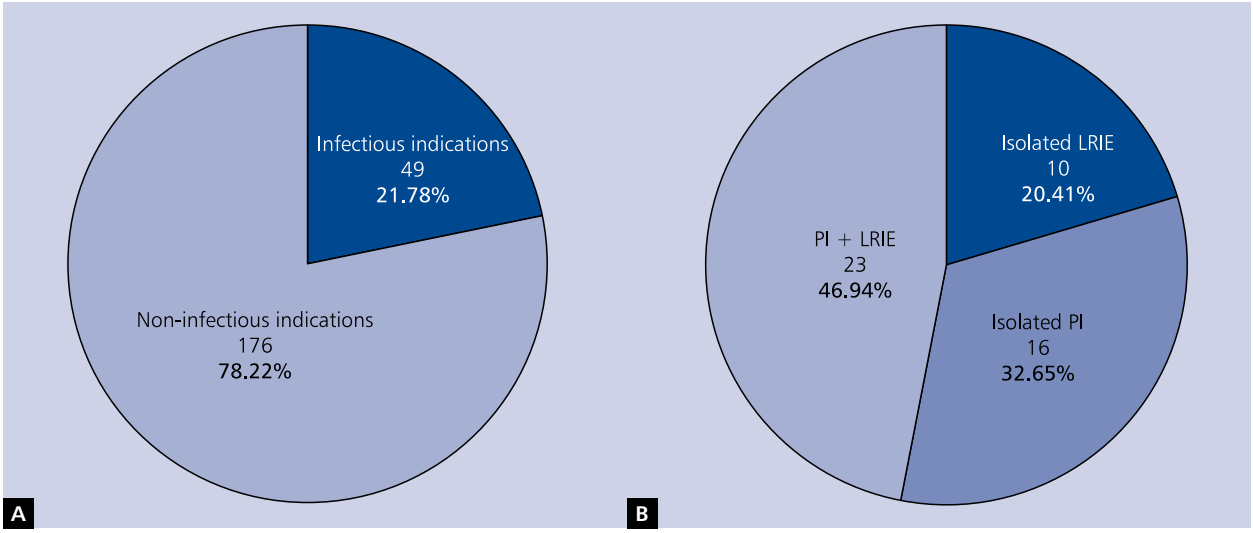

Figure 1. Analysis of indications for transvenous leads extraction. **A.** Classification of complications throughout the entire studied group (n = 225); **B.** Type of infectious complications (n = 49); LRIE — lead-related infective endocarditis; PI — pocket infections

sion of pacing indication, recalled leads, and missed tip location (Table 1).

Analysis of clinical factors potentially affecting the development of electrotherapy complications showed a higher incidence of chronic renal failure (CRF) in patients with LRIE. Other clinical parameters were comparable between subjects in different groups and subgroups (Table 2).

Comparison of factors related to implantable devices showed more frequent presence of abandoned, non-functional leads in patients with infectious complications (especially in patients with LRIE), including systems implanted on both sides of the chest, and a greater number of implanted leads in this group of patients. In patients referred for TLE due to infection, significantly more previous CIED-related procedures were also observed, with a clearly shorter time interval since the last procedure preceding TLE, and the largest number of early reinterventions in patients with PI. The study showed no significant difference between the type of the implanted system and the dwell time of the leads removed in infectious and non-infectious groups (Table 2).

Major TLE complications were observed in one (0.4%) patient, and minor complications in three (1.3%) patients. In the studied population no periprocedural death occurred (Table 2).

Assessment of the risk for infectious complications

Based on univariate analysis, a higher incidence of infectious complications in patients with CRF was observed, with a greater number of implanted leads (in particular non-functional, abandoned ones), older leads (with a higher sum of the lead dwell time), and more frequent history of prior CIED-related procedures, in particular performed in a shorter span of time before TLE (Table 3).

Multivariate analysis confirmed the effect of CRF and a greater number of procedures preceding TLE on the development of infectious complications (Table 4).

Among the parameters potentially affecting the development of isolated pocket infection, based on univariate analysis, the importance of the number of leads and the number of procedures prior to TLE, especially early reinterventions, was highlighted (Table 5).

Analysis of factors potentially affecting the development of PI coexisting with LRIE revealed significant effects of CRF, the number of implanted leads, especially non-functional ones, and the number of prior procedures, especially those performed a short time before TLE (Table 6).

Among the factors potentially affecting the development of isolated LRIE, univariate analysis demonstrated the importance of the number of leads, especially abandoned ones, the impact of lead dwell time (the sum of dwell time of all the leads), and the number of procedures preceding TLE, in particular those performed a short time before TLE (Table 7).

Evaluation of the effectiveness and safety of TLE

Total procedural success was observed in 96.9% of patients undergoing TLE, and clinical success was observed in 99.6% of patients. In the whole population there was no periprocedural death. A major complication occurred in one patient — pericardial tamponade controlled by drainage of the pericardium. Minor complications were observed in three (1.3%) patients and included significant tricuspid regurgitation associated with the rupture of the chordae tendineae during TLE (two

Table 1. Classification of non-infectious indications for transvenous leads extraction (TLE) according to the Heart Rhythm Society (HRS) guidelines

Indication for TLE	Specific indication/lead-related CIED problem	HRS class	Primary indication for TLE			Lower-level indication (1 out of 3 possible indications)		
			Number of patients	Percentages	Percentages	Number of patients	Percentages	Percentages
Need for recapture of venous access	Bilateral subclavian or VCS occlusion precluding implantation requiring transvenous lead or contraindicated utilisation of contralateral side (AV fistula, vascular access port, mastectomy)	I	0	0.0	3.4	0	0.0	15.9
	VCS syndrome with limited evidence of symptoms	I	0	0.0		0	0.0	
	Ipsilateral venous occlusion precluding implantation requiring transvenous lead with no contraindication for the use of contralateral side	IIa	6	3.4		28	15.9	
Need for saving venous flow	Implantation that would require > 4 leads in SV or > 5 in VCS	IIa	0	0.0		0	0.0	
Interferences or potential interferences	Interference with an active CIED system	I	0	0.0	1.7	0	0.0	1.7
	Interference with breast cancer therapy	I	3	1.7		3	1.7	
Chronic pain	Chronic pain at device insertion site	I	1	0.6	0.6	1	0.6	0.6
Immediate or potential threat to the patient	Life-threatening arrhythmias secondary to the retained lead or lead fragment	I	0	0.0	29.5	0	0.0	54.5
	Leads that may pose an immediate threat to the patient if left in place	I	1	0.6		1	0.6	
Potentially dangerous/ /threatening leads	Leads that may pose a potential future threat to the patient if left in place	IIb	1	0.6		21	11.9	
	Lead in conflict with tricuspid valve	IIb	3	1.7		10	5.7	
	Perforation dysfunction	IIb	47	26.7		64	36.4	
Excess of functional leads	Change of pacing mode, upgrading, downgrading	IIb	11	6.3	6.3	11	6.3	8.5
	Excess of functional leads, prevention of abandonment	IIb	0	0.0		4	2.3	
Superfluous non-functional leads	Non-functional — damaged	IIb	48	27.3	52.8	53	30.1	79.5
	Non-functional — exit entry block	IIb	31	17.6		33	18.8	
	Non-functional — dislodgement	IIb	10	5.7		12	6.8	
	Non-functional — extracardiac pacing	IIb	2	1.1		3	1.7	
	Non-functional — permanent AF	IIb	1	0.6		10	5.7	
	Change of pacing mode, upgrading, downgrading	IIb	1	0.6		13	7.4	
	Non-functional — excess of leads	IIb	0	0.0		16	9.1	
Other indications	Recession of pacing indication	IIb	1	0.6	5.7	1	0.6	7.4
	Recalled leads	IIb	9	5.1		11	6.3	
	Missed tip location (out of standard position)	III	0	0.0		1	0.6	

Data are shown as number or percentage. AF — atrial fibrillation; AV — arteriovenous; CIED — cardiovascular implantable electronic devices; SV — subclavian vein; VCS — vena cava superior

Table 2. Clinical characteristics of patients with complications of electrotherapy

Variables	The whole study group	Non-infectious complications	Infectious complications	Isolated pocket infections	Lead-related infective endocarditis with pocket infection	Isolated lead-related infective endocarditis
Number of patients	225	176 (78.2)	49 (21.8)	16 (7.1)	23 (10.2)	10 (4.4)
Age [years]	66.27 ± 11.73	66.15 ± 11.51	66.69 ± 12.62	69.69 ± 8.86	65.22 ± 13.41	65.30 ± 15.97
Male sex	144 (64.00)	109 (61.93)	35 (71.3)	11 (68.75)	16 (69.57)	8 (80.00)
LVEF [%]	40.32 ± 11.17	40.18 ± 11.29	40.85 ± 10.80	37.86 ± 12.51	43.04 ± 9.74	40.00 ± 10.54
NYHA class	1.79 ± 0.70	1.78 ± 0.68	1.82 ± 0.78	2.00 ± 0.73	1.57 ± 0.79	2.10 ± 0.74
Permanent atrial fibrillation	62 (27.56)	47 (26.70)	15 (30.61)	6 (37.50)	7 (30.43)	2 (20.00)
Antiplatelet therapy	117 (52.00)	90 (51.14)	27 (55.10)	10 (62.50)	11 (47.83)	6 (60.00)
Anticoagulation therapy	76 (33.78)	62 (35.23)	14 (28.57)	5 (31.25)	7 (30.43)	2 (20.00)
Diabetes mellitus	46 (24.44)	35 (19.89)	11 (22.45)	3 (18.75)	6 (26.09)	2 (20.00)
Creatinine level [mg/dL]	1.15 ± 0.61	1.11 ± 0.57	1.31 ± 0.72	1.08 ± 0.33	1.40 ± 0.86*	1.47 ± 0.79
Creatinine ≥ 2 mg/dL	8 (3.56)	4 (2.27)	4 (8.16)	0 (0.00)	2 (8.70)	2 (20.00)*
Pacemakers	133 (59.11)	101 (57.39)	32 (65.30)	9 (56.25)	15 (65.28)	8 (80.00)
ICD (DDD or VVI)	83 (36.89)	67 (38.07)	16 (32.65)	7 (43.75)	7 (30.43)	2 (20.00)
Defibrillation lead	91 (40.44)	74 (42.04)	17 (34.69)	7 (43.75)	8 (34.78)	2 (20.00)
CRT-D	8 (3.55)	7 (3.98)	1 (2.04)	0 (0.00)	1 (4.35)	0 (0.00)
CRT-P	1 (0.44)	1 (0.56)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
CS lead	9 (4.00)	8 (0.45)	1 (2.04)	0 (0.00)	1 (4.35)	0 (0.00)
Number of leads before TLE	1.78 ± 0.63	1.74 ± 0.60	1.90 ± 0.71	1.81 ± 0.66	2.00 ± 0.85	1.80±0.42
Number of active fixation leads	1.68 ± 0.54	1.68 ± 0.55	1.67 ± 0.52	1.63 ± 0.50	1.65 ± 0.57	1.80 ± 0.42
Number of passive fixation leads	0.10 ± 0.37	0.06 ± 0.29	0.22 ± 0.55**	0.19 ± 0.54	0.35 ± 0.65***	0 (0.00)
Presence of abandoned leads	17 (7.55)	9 (5.11)	8 (16.33)**	2 (12.50)	6 (26.09)***	0 (0.00)
Number of extracted leads	313	227	86	27	41	18
Number of extracted leads per patient	1.40 ± 0.57	1.30 ± 0.54	1.76 ± 0.56***	1.69 ± 0.60**	1.78 ± 0.60***	1.80 ± 0.42
Mean lead dwell time [years]	5.35 ± 4.01	5.27 ± 4.07	5.61 ± 3.84	5.79 ± 2.46	5.20 ± 3.68	6.25 ± 5.86
Dwell time of the oldest lead in patient [years]	5.56 ± 4.34	5.47 ± 4.26	6.32 ± 4,60	6.65 ± 3.30	6.10 ± 4.97	6.29 ± 5.83
Intracardiac lead abrasion	30 (13.33)	25 (14.20)	5 (10.20)	1 (6.25)	1 (4.35)	3 (30.00)
Number of previous CIED-related procedures	1.38 ± 0.72	1.23 ± 0.53	1.94 ± 1.01***	2.31 ± 1.20***	1.91 ± 0.95***	1.40 ± 0.52
Time from previous procedure to TLE [months]	42.34 ± 32.25	47.36 ± 32.09	24.33 ± 26.02***	25.63 ± 32.24**	21.87 ± 23.49***	27.90 ± 22.30*

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Table 2. (cont.) Clinical characteristics of patients with complications of electrotherapy

Variables	The whole study group	Non-infectious complications	Infectious complications	Isolated pocket infections	Lead-related infective endocarditis with pocket infection	Isolated lead-related infective endocarditis
Early reintervention (two months before TLE)	12 (5.33)	5 (2.84)	7 (14.28)**	4 (25.00)***	3 (13.04)*	0 (0.00)
Leads in both side of thorax	3 (1.33)	0 (0.00)	3 (6.12)***	1 (6.25)***	2 (8.69)***	0 (0.00)
Previous upgrading	18 (8.00)	14 (7.95)	4 (8.16)	1 (6.25)	2 (8.69)	1 (10.00)
Upgrading with lead abandonment	8 (3.55)	5 (2.84)	3 (6.12)	1 (6.25)	2 (8.69)	0 (0.00)
Loops of leads irritating tricuspid valve	11 (4.89)	9 (5.11)	2 (4.08)	0 (0.00)	0 (0.00)	2 (20.00)
Full procedural success [%]	96.9	96.7	98.0	98.8	97.9	98.3
Clinical success [%]	99.6	99.4	100.0	100.0	100.0	100.0
Major complications	1 (0.44)	1 (0.57)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Minor complications	3 (1.33)	2 (1.13)	1 (2.04)	0 (0.00)	0 (0.00)	1* (10.00)
Procedure-related death	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

Data are shown as number (percentage) or mean ± standard deviation. *p < 0.05; **p < 0.01; ***p < 0.001. CIED — cardiovascular implantable electronic devices; CRT-D — cardiac resynchronisation therapy defibrillator; CRT-P — cardiac resynchronisation therapy pacemaker; CS — coronary sinus; ICD — implantable cardioverter defibrillator; LVEF — left ventricular ejection fraction; NYHA — New York Heart Association; TLE — transvenous leads extraction

patients) and air embolism (one patient). The effectiveness of treatment in patients with infectious and non-infectious complications was comparatively high (Table 1).

Analysis of survival after TLE

Rating long-term survival after TLE (mean follow-up period of 3.0 ± 2.14 years in the whole studied group) showed significantly higher mortality among patients with infectious complications. During a five-year observation period, the mortality rate in this group was about 50%, compared with about 20% in the non-infectious group ($p < 0.05$; Fig. 2).

DISCUSSION

Complications of electrotherapy are a relatively new problem in modern cardiology, and so there are few studies on the methods of action in a variety of clinical situations, while therapeutic standards are based on the short duration of patient observation. In the present study, in the group of patients referred for TLE in the years 2006–2015, a very low percentage of infectious complications (21.9%) representing an absolute indication for TLE was demonstrated. This rate is highly variable depending on the centre and the study population. In most TLE centres the percentage of infectious indications is 40% to 60% [10–12], but it may even reach the level of 70% to 80% [13, 14]. In recent years, however, there have been studies showing significantly more frequent referral for TLE due to non-infectious causes. Based on the analysis of data from the National Cardiovascular Data Registry from the period of 2010 to 2012, it was determined that the percentage of infectious indications in this population was only 15% [15]. The existence of such a large discrepancy may be due to steadily increasing awareness of the complications of electrotherapy, which may result in their frequent recognition at an early stage, leading to the prevention of the development of infectious complications. This concept has been confirmed in the current study; the important factors in the risk of infections associated with PM/ICD/CRT were the number of CIED-related procedures preceding TLE, and a greater number of implanted leads, especially superfluous and abandoned ones in patients with LRIE. Such results have been reported in studies based on large populations of patients undergoing TLE [16, 17].

Detailed analysis of non-infectious complications in the current population showed that the dominant indication for TLE was the presence of unnecessary, abandoned leads (52.8% of primary indications, 79.5% of all indications) and extraction of potentially threatening leads (29.5% and 54.5%, respectively). This type of indication is most often identified as class IIb in the HRS guidelines [6]. In clinical practice this means special consideration of the risk-benefit balance of the procedure. The spectrum of non-infective indications, especially the percentage of extraction of functional and non-functional leads, illustrates how frequently our doctors consider lots of patients with long life perspectives with abandoned leads in terms of problems far in the future.

Table 3. Univariate analysis of the risk of infectious complications in the studied population

All study patients (n = 225)	HR	95% CI	p
Male sex	1.537	0.767–3.077	0.223
Age during implantation	0.998	0.972–1.024	0.865
Age during TLE	1.004	0.977–1.031	0.796
LVEF	1.057	0.786–1.421	0.714
NYHA class	1.067	0.680–1.675	0.777
Diabetes mellitus	1.166	0.540–2.520	0.694
Creatinine level	1.570	0.934–2.640	0.087
Atrial fibrillation	1.211	0.603–2.431	0.589
Anticoagulation therapy	0.735	0.367–1.476	0.385
Antiplatelet therapy	1.173	0.619–2.222	0.623
Number of leads	1.462	0.888–2.408	0.133
Number of active leads	0.972	0.538–1.755	0.923
Presence of abandoned leads	3.621	1.309–10.014	0.013
Number of abandoned leads in a patient	2.621	1.231–5.581	0.012
Number of extracted leads in a patient	3.667	2.078–6.472	0.000
ICD lead	0.732	0.377–1.422	0.355
CS lead	0.429	0.051–3.610	0.433
CRT-D system	0.503	0.060–4.238	0.525
Intracardiac lead abrasion	0.686	0.247–1.909	0.468
Dwell time of oldest lead	1.043	0.974–1.118	0.226
Mean lead dwell time	1.020	0.945–1.102	0.606
Sum of lead dwell time	1.039	1.004–1.075	0.029
Number of procedures before TLE	3.436	2.115–5.583	0.000
Time from the latest procedure before TLE	0.970	0.956–0.984	0.000
Early reintervention (within two months before TLE)	5.700	1.712–18.977	0.004
Previous system upgrading	1.029	0.317–3.332	0.962
Upgrading with lead abandonment	2.230	0.510–9.758	0.284
Loop of leads irritating tricuspid valve	0.790	0.163–3.813	0.768

HR — hazard ratio; CI — confidence interval; other abbreviations — see Table 2

Table 4. Multivariate analysis of the risk of infectious complications in patients with implanted pacemaker/ICD/CRT

All study patients (n = 225)	HR	95% CI	p
Creatinine level	1.842	1.049–3.248	0.034
Sum of lead dwell time	0.961	0.909–1.016	0.162
Number of previous procedures	4.768	2.253–10.093	0.000
Presence of abandoned leads	1.111	0.039–31.881	0.951
Number of abandoned leads in a patient	1.135	0.094–13.753	0.920
Early reintervention (within two months before TLE)	3.270	0.687–15.558	0.134

Abbreviations — see Tables 2 and 3

Table 5. Univariate analysis of the risk of isolated pocket infection (presentation only of significant factors)

Isolated pocket infection (n = 16)	HR	95% CI	p
Number of leads in a patient	2.621	1.235–5.563	0.012
Sum of lead dwell time	1.039	0.992–1.089	0.105
Number of previous procedures before TLE	4.070	2.176–7.609	0.000
Early reintervention (within two months before TLE)	11.400	2.678–48.522	0.001

Abbreviations — see Tables 2 and 3

Table 6. Univariate analysis of the risk of local pocket infection with coexisting lead-related infective endocarditis (PI + LRIE) — presentation only of significant factors

PI + LRIE (n = 23)	HR	95%	p
Creatinine level	1.795	1.007–3.200	0.046
Presence of abandoned leads	4.123	1.350–12.595	0.012
Number of abandoned leads in a patient	2.823	1.22–6.492	0.014
Number of extracted leads in a patient	3.745	1.980–7.084	0.000
Sum of lead dwell time	1.033	0.995–1.073	0.087
Number of procedures before TLE	2.840	1.675–4.814	0.000
Time from the latest procedure before TLE	0.967	0.950–0.984	0.000

Abbreviations — see Tables 2 and 3

Table 7. Univariate analysis of the risk of isolated lead-related infective endocarditis (LRIE) — presentation only of significant factors

Isolated LRIE (n = 10)	HR	95%	p
Presence of abandoned leads	3.621	1.309–10.014	0.013
Number of abandoned leads in a patient	2.621	1.231–5.581	0.012
Number of extracted leads in a patient	2.652	1.091–6.448	0.031
Sum of lead dwell time	1.039	1.004–1.075	0.029
Number of procedures before TLE	3.436	2.115–5.583	0.000
Time from the latest procedure before TLE	0.970	0.956–0.984	0.000
Early reintervention (within two months before TLE)	5.700	1.712–18.977	0.004

Abbreviations — see Tables 2 and 3

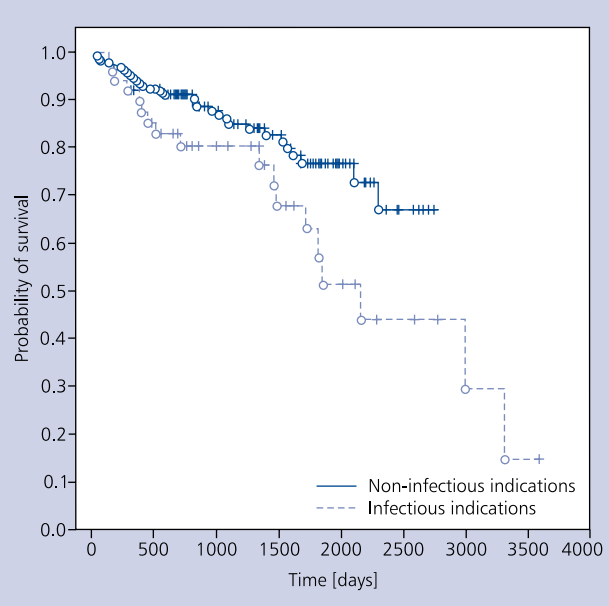

Figure 2. Kaplan-Meier survival curves of patients with complications of electrotherapy. Survival in the whole group of patients after transvenous lead extraction depending on aetiology: $p < 0.05$

The present study confirmed the high effectiveness and safety of TLE. According to reports evaluating TLE procedures in various populations, the overall procedural success ranged from 91%, in cases where the application of laser energy predominated [18] to 96%–98% in centres that preferred Byrd dilators and mechanical catheters [12, 19, 20]. The rate of major complications in these studies ranged from 0.3% to 3.4% and was higher when laser techniques were used [12, 18–20]. As stated in the present study, an overall procedural success rate of 96.9%, a clinical success rate of 99.6% with a major complication rate of 0.4%, and the absence of periprocedural deaths support the very high effectiveness and safety of TLE procedures in a population with predominantly non-infectious indications.

The present study also confirmed, similarly to other studies, a relatively high (30%–50%) long-term mortality in the population of patients undergoing TLE. The factors most frequently identified as increasing mortality in long-term follow-up are age, diabetes, renal insufficiency, and infectious complications [13, 21–23]. In most reports, beneficial direct effects of TLE procedures are emphasised, especially in patients referred for the procedure due to infection, although the long-term survival of this population is low [24, 25]. The

present study confirmed a significantly higher five-year mortality among patients with infectious complications. This observation may also result from the more unfavourable clinical profile of this group, not only from the presence of infection.

The main limitation of the study is the small study population, the lack of a thorough follow-up of patients after TLE procedures, and especially the lack of data on the direct cause of death in the long-term follow-up and its relationship to infectious complications.

In conclusion, a 10-year analysis of long-term complications associated with the presence of PM/ICD/CRT showed that thorough diagnosis and effective treatment of non-infectious adverse events may prevent the development of the most dangerous infectious complications. In the present study, confirmed high effectiveness and safety of procedures performed in an experienced centre should prompt an early, preventive referral for TLE. Such action is very important in light of the high long-term mortality among patients with infectious complications.

Conflict of interest: *none declared*

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WHAT IS NEW?

The current study presents a modern approach to the problem of complications observed in patients with cardiac implantable electronic devices. A thorough diagnosis of lead dysfunction and early referral for transvenous lead extraction may contribute to a reduction in infectious complications. In the present study, a very high effectiveness and safety of procedures performed by an experienced operator were demonstrated and there was a significantly higher survival rate of patients undergoing transvenous lead extraction due to non-infectious causes. Documenting the benefits of the procedure should bring measurable clinical effects in the form of a reduction in the number of the most dangerous infectious complications and improved survival of patients with electrotherapy complications.