Initial experience with transvenous lead extraction in patients with left ventricular assist devices

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INTRODUCTION

Left ventricular assist devices (LVADs) are an essential treatment for patients with advanced heart failure. Many of these patients may have previously received an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy with a defibrillator before LVAD implantation. Combining electrical and mechanical support has been shown to significantly benefit heart failure management [1]. However, a common complication with both devices is the risk of infection, including lead-dependent infective endocarditis (LDIE), making patients with LVADs and cardiac implantable electronic devices (CIEDs) particularly vulnerable to infections in one or both devices [2]. Additionally, the presence of a cardioverter-defibrillator lead increases the risk of CIED dysfunction [3, 4]. The increasing prevalence of patients with both LVADs and CIEDs has led to a corresponding rise in the need for transvenous lead extraction (TLE) procedures, driven by a range of clinical indications. Currently, data on TLE procedures in patients with LVADs are limited.

Our study aims to evaluate the effectiveness and safety of TLE procedures in patients with LVADs using mechanical extraction systems from the perspective of a reference center.

METHODS

A prospective analysis was conducted, including all patients with LVADs who underwent TLE between October 2011 and December 2023. The Research and Ethics Committee of Jagiellonian University approved the study protocol (KBET/259/B/2011), and written informed consent was obtained from all patients for the use of their anonymized data in this study. The study protocol adhered to the Declaration of Helsinki and followed Good Clinical Practice guidelines. Patients with endocardial leads implanted less than one year prior to the procedure were excluded from the analysis.

Data were collected from a prospectively maintained database, which included records of device implantation, follow-up visits at device and cardiology clinics, medical information from the index admissions for TLE, and data on 30-day post-procedure complications as well as one-year follow-up after TLE. We analyzed data related to the age of extracted leads, fluoroscopy time, extraction techniques, effectiveness of TLE, complete/incomplete lead removal for each targeted lead, and complications occurring intra-operatively and within 30 days post-operatively. The effectiveness of TLE procedures was defined based on current HRS and EHRA consensus guidelines [5, 6]. A detailed description of the TLE procedure has been provided in our previous study [7].

Statistical analysis

Continuous variables were presented as median and interquartile range (IQR) or minimum and maximum values. Categorical variables were presented as counts and percentages.

Table 1. Baseline clinical and procedural characteristics

Patient	1	2	3	4	5	6	7	8	9
Gender	M	M	F	M	M	M	M	M	M
Age, years	53.0	62.8	62.3	50.2	67.9	62.8	64.9	50.9	63.6
Pacing system	ICD-VR	ICD-VR	CRT-D	ICD-VR	ICD-DR	ICD-VR	ICD-VR	CRT-D	CRT-D
Prevention of SCD	Primary	Primary	Primary	Primary	Primary	Secondary	Secondary	Primary	Primary
Etiology of CM	Ischemic	Non-ischemic	Ischemic	Ischemic	Ischemic	Ischemic	Ischemic	Ischemic	Non-ischemic
Diabetes mellitus	No	No	No	Yes	No	Yes	Yes	Yes	Yes
Creatinine clearance, ml/min/1.73 m^2	44	49	67	77	44	31	59	78	43
BMI, kg/m^2	30.08	29.05	22.76	22.84	31.71	25.83	25.43	36.93	26.08
LVAD type	HW	HM3	HW2	HW2	HW2	HW2	HM3	HM3	HM3
LVAD indication	DT	DT	DT	DT	DT	DT	DT	DT	DT
Indication for TLE	PI	Lead dysfunction	LDIE	LDIE	Lead dysfunction	LDIE	PI	High defibrillation threshold	LDIE
Time from LVAD implant to CIED removal, months	28.3	1.0	0.9	37.1	53.6	24.6	51.9	6.9	62.6
Number of extracted leads, n	1	1	3	1	2	1	1	2	4
Oldest extracted lead, years	4.1	7.0	4.7	3.7	11.4	9.5	11.8	5.0	10.8
Sum of age of extracted leads, years	4.1	7.0	14.0	3.7	12.8	9.5	11.8	10.0	37.5
Tools	TS	TS	TS, Evo	TS	TS, Evo	TS, Evo	TS, Evo	TS	Evo
Total fluoroscopy time during extraction of all leads, min	4.67	2.27	6.16	1.00	23.88	5.92	5.00	1.15	12.65
Results of TLE procedure	FS	FS	FS	FS	FS	FS	FS	FS	FS
Major complications	None	None	None	None	None	None	None	None	None
Minor complications	None	None	None	None	None	None	None	None	None
30-day complications after the procedure	None	None	None	None	None	None	None	None	None
Follow-up duration, months	76.9	75.3	63.8	43.4	39.7	39.4	37.2	22.0	10.5
1-year follow-up after TLE	Dead	Alive	Alive	Dead	Alive	Dead	Dead	Alive	NA
Survival after TLE, months	7.1	42.0	still alive	0.7	30.2	3.4	7.8	still alive	4.0

Abbreviations: BMI, body mass index; CM, cardiomyopathy; CRT-D, cardiac resynchronization therapy with defibrillator; DT, destination therapy; FS, full success; Evo, Evolution mechanical system; F, female; HW, HeartWare; HW2, HeartWare2; HM3, HeartMate 3; ICD-DR, dual chamber implantable cardioverter-defibrillator; ICD-VR, single chamber implantable cardioverter-defibrillator; LDIE, lead-dependent infective endocarditis; LVAD, left ventricular assist device; M, male; NA, not applicable; PI, pocket infection; SCD, sudden cardiac death; TS, telescopic sheaths

RESULTS AND DISCUSSION

The study included 9 patients who met the inclusion criteria, one of whom was female, with a median (IQR) age of 62.8 (53.0–63.6) years, ranging from 50.2 to 67.9 years. All patients had CIEDs with high-voltage therapy, with 6 patients having an ICD and 3 having cardiac resynchronization therapy with a defibrillator. All CIEDs were implanted on the left side of the chest, for primary prevention in 7 patients (78%) and secondary prevention in 2 patients (22%). TLE was performed due to LDIE in 4 patients, pocket infection in 2 patients, and non-infectious indications in 3 patients. Among those with non-infectious indications, 2 required TLE due to an increased ICD lead threshold, while one underwent TLE due to a high defibrillation threshold with ineffective defibrillation. A total of 16 leads were extracted: 9 ICD leads, 5 pacing leads, and 2 left ventricular leads, with a median (IQR) lead dwell time of 4.4 (4.2–4.8) years. Most of the leads were over 4 years old. The median (IQR) fluoroscopy time was 2.75 (1.21–4.83) minutes per lead. No major or minor complications occurred during the procedure or within the 30-day post-procedure period (Table 1). All patients with infectious indications for TLE received appropriate antibiotic therapy.

The overall median (IQR) follow-up duration after the TLE procedure was 3.3 (3.1–5.3) years (Table 1). During the one-year follow-up, 5 patients (55.6%) died — 3 with LDIE and 2 with pocket infections. Notably, only one patient with LDIE and all patients with non-infectious indications for TLE survived the one-year follow-up period (Table 1).

Guidelines for managing CIED infections recommend the immediate extraction of all leads and devices as a class I indication [5]. However, there are no data on the management of non-infectious indications for TLE in this patient group. To perform TLE in patients with both LVADs and CIEDs for non-infectious indications remains controversial. While it increases the risk of complications, including infection, it may not offer the same therapeutic benefits as in patients without LVADs. In our study, despite the absence of TLE-related complications and a 100% procedural success rate, 5 patients (83.3%) who underwent TLE for infectious indications died within the 12-month follow-up. In contrast,

Black-Maier et al. reported a lower one-year mortality rate of 22% in a similar patient group [8].

In contrast, Krishnamoorthy et al. [9] reported an 83.3% (5 out of 6) mortality rate due to early recurrence of bloodstream infections within one year of the procedure in patients with CIED- and LVAD-associated infections, which aligns with our findings. Notably, among patients with non-infectious indications for TLE, there were no deaths or CIED reinfections during the 12-month follow-up.

Our initial experience suggests that TLE in patients with LVADs is both safe and effective. However, patients undergoing TLE for infectious indications face a high 12-month mortality rate, despite satisfactory procedural outcomes. In contrast, TLE in patients with LVADs for non-infectious indications is not associated with an increased risk of infection at the 12-month follow-up. Nonetheless, the risks, benefits, and optimal management strategies for TLE in this patient population warrant careful consideration and further research.

Article information

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