

Effectiveness and safety of transvenous extraction of single- versus dual-coil implantable cardioverter-defibrillator leads at single-center experience

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Abstract

The available literature lacks data concerning direct comparison of the effectiveness and safety of single- versus dual-coil implantable cardioverter-defibrillator (ICD) leads transvenous extraction. Certainly, additional shocking coil in superior vena cava adds to the amount of metal in the vascular system. Adhesions developing around the superior vena cava coil add to the difficulty of extraction of ICD lead if lead removal is required. The aim of the study was to assess the effectiveness and safety of single- and dual-coil ICD leads transvenous extraction using mechanical systems. We performed transvenous lead extraction (TLE) of 197 ICD leads in 196 patients. There were 46 (23.3%) dual-coil leads removed from 46 (23.5%) patients. Cardiovascular implantable electronic device-related infection was an indication for TLE in 25.0% of patients. The following extracting techniques were used: manual direct traction, mechanical telescopic sheaths, controlled-rotation mechanical sheaths, and femoral approach. Complete ICD lead removal and complete procedural success in both groups were similar (99.3% in single-coil vs 97.8% in dual-coil, $P = .41$ and 99.3% in single-coil vs 97.8% in dual-coil, $P = 0.41$, respectively). We did not find significant difference between major and minor complication rates in both groups (2.0% in single-coil vs 4.3% in dual-coil, and 0.7% in single-coil vs 0.0% in dual-coil, $P = .58$, respectively). There was 1 death associated with the TLE procedure of single-coil lead.

This study shows that extraction of dual-coil leads seems to be comparably safe and effective to extraction of single-coil leads. On the other hand, it requires longer fluoroscopy time and frequent utilization of advanced tools.

Abbreviations: BMI = body mass index, BOB = bridge occlusion balloon, CIED = cardiovascular implantable electronic devices, CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration, CRP = C reactive protein, CRT-D = cardiac resynchronization therapy defibrillator, CT = computed tomography, DC = dual-coil, DCL = dual-coil lead, eGFR = estimated glomerular filtration rate, EHRA = European Heart Rhythm Association, ESC = European Society of Cardiology, HRS = Heart Rhythm Society, ICD = implantable cardioverter-defibrillator, IVC = inferior vena cava, LDIE = lead-dependent infective endocarditis, LI = local infection, LVEF = left ventricular ejection fraction, NYHA = New York Heart Association, SC = single-coil, SCL = single-coil lead, SVC = superior vena cava, TLE = transvenous lead extraction, TOE = transoesophageal echocardiography, TTE = transthoracic echocardiography.

Keywords: cardiovascular implantable electronic devices, dual-coil lead, effectiveness, implantable cardioverter-defibrillator, safety, single-coil lead, transvenous lead extraction

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1. Introduction

Transvenous lead extraction (TLE) is an integral part of management of patients with cardiovascular implantable electronic devices (CIED).^[1,2] According to the current guidelines, indications for implantable cardioverter-defibrillator (ICD) therapy have been widened over the last few years.^[3,4] Importantly, ICD leads are prone to damage in long-term follow-up.^[5,6] Kleemann et al demonstrated an increasing annual rate of failure among ICD leads during long-term follow-up, which reached 20% in 10-year-old ICD leads.^[7] Increasing number of ICD lead implantations and significant risk of lead failure have resulted in growing need for TLE procedures involving ICD leads. Despite the accumulated evidence showing that single-coil (SC) leads are comparable to dual-coil (DC) leads in terms of efficacy of defibrillation and overall safety,^[8–10] until recently DC leads have been regarded as the standard of care and implanted more frequently than SC leads.^[10,11]

The available literature lacks data concerning direct comparison of both types of ICD leads in terms of extraction efficacy and safety. The currently available data have demonstrated conflicting results. Certainly, additional shocking coil in superior vena cava (SVC) adds to the amount of metal in the vascular system. Adhesions developing around the SVC coil add to the difficulty of extraction of ICD lead if lead removal is required.^[12,13] Bontempi et al identified patient and lead characteristics (number of leads, presence of double coil lead and absence of vegetation) which influenced the difficulty of TLE procedure.^[14] Epstein et al in a multicenter retrospective study involving 9 high-volume centers (385 patients with SC and 1791 patients with DC) indicated that the presence of SVC coil was associated with significantly higher complication rates. Furthermore, authors observed that the procedures involving removal of DC ICD leads were about 2.6 times more difficult as compared to extraction of SC/ICD leads.^[12]

Furthermore, Pecha et al in a report on laser ICD lead extraction concluded that removal of DC ICD leads was associated with longer laser treatment times but without statistically significant differences in complication and procedural success rates.^[15] Brunner et al in the group of nearly 3000 TLE procedures with over 5000 extracted leads did not find significantly increased risk of complications related to DC lead removal. Of note, in the univariate analysis, the DC leads were more prevalent in the group of patients in whom complications occurred; however, the difference was not statistically significant (29.8% vs 43.8%, $P = .086$).^[16] Additionally, authors of European Lead Extraction ConTRolled, prospective multicenter European registry of TLE procedures, did not observe association between DC lead removal and major cardiac and vascular complications during TLE.^[17]

The above-mentioned results and the lack of direct comparison of extraction of DC and SC leads prompted us to analyze the outcomes from university reference center for lead extraction.

2. Methods

The aim of the study was to assess the effectiveness and safety of TLE of SC and DC ICD leads using mechanical systems.

A prospective analysis of the records consisted of all patients with ICD or cardiac resynchronization therapy defibrillator (CRT-D), who underwent TLE of SC or DC ICD leads from October 2011 to December 2018. Patients whose ICD leads had been implanted for less than 1 year before the procedure were excluded from the analysis. The population was divided into 2 groups: group single-coil lead (SCL) – during the procedure at least 1 lead had SC and group dual-coil lead (DCL) – at least 1 lead had DC. Cases with both types of lead targeted for TLE were excluded from analysis. Data were collected from the medical documentation issued at the time of device implant, during follow-up at outpatient clinics and medical information collected during TLE procedure and within 30-days post TLE procedure.

The selected groups of patients (SCL and DCL) were compared by assessing demographic data (age, sex), body mass index (BMI), the New York Heart Association (NYHA) Functional Classification and left ventricular ejection fraction (LVEF), indications for ICD implantation (primary or secondary prevention), comorbidities including diabetes mellitus and coronary artery disease, laboratory studies (hemoglobin concentration, creatinine level, estimated glomerular filtration rate [eGFR]), types of implanted CIED, number of CIED-related procedures before TLE (implantation, reimplantation, device upgrade), indications for TLE. Chronic Kidney Disease

Epidemiology Collaboration equation was used to calculate eGFR. Indications for TLE were divided into 3 categories: lead-dependent infective endocarditis (LDIE), isolated local infection (LI) and noninfectious indications. LDIE was diagnosed on the basis of Modified Duke Leads Criteria, while LI was diagnosed on the basis of local inflammatory signs which were limited to device pocket: erythema, excessive warming, fluid in the device pocket, swelling, leakage of fluid from the device pocket, erosion of the skin and fistula. When both LDIE and LI were present, LDIE was used as an indication for TLE.

Lead dislodgement was defined as any lead displacement, including lead penetration into the myocardium or through the myocardium into the pericardial cavity – termed cardiac perforation. Lead dislocation was documented on chest X-ray, fluoroscopy screening, echocardiography examination, and cardiac computed tomography (CT) angiogram. Lead perforation was diagnosed when the lead tip passed through the myocardium and extended into the pericardial cavity by at least 5 mm with or without pericardial effusion.^[6]

In addition, both groups were analyzed and compared in terms of percentage of passive fixation leads, percentage of nonfunctional/abandoned leads, age of extracted leads, age of the oldest extracted lead, cumulative age of all extracted leads, number of extracted leads, fluoroscopy time, techniques used during TLE, effectiveness of TLE, complete/incomplete lead removal for each lead removed, complications occurring during intraoperative, and 30-day postoperative period.

The effectiveness of TLE procedures was divided into 3 categories according to current Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) consensus^[1,2,18]:

- complete procedural success: removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure-related death;
- clinical success: removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead, which does not negatively impact the outcome goals of the procedure. This may be the tip of the lead or a small part of the lead (conductor coil, insulation, or the latter 2 combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome;
- failure of the procedure: inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure-related death.

For each electrode removed, the efficiency according to the EHRA consensus was determined^[18]:

- complete lead removal – lead explant or extraction with removal of all targeted lead material,
- incomplete lead removal – lead explant or extraction where part of the lead remains in the patient's body (vascular or extravascular).

We recorded complications occurring in intraoperative and 30-day postoperative period and classified as 2 types in accordance with HRS and EHRA consensus^[1,2,18]:

- major complication: any of the outcomes related to the procedure which is life threatening or results in death. In addition, any unexpected event that causes persistent or significant disability, or any event that requires significant surgical intervention to prevent any of outcomes listed above;

- minor complication: any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy the complications, and does not limit persistently or significantly the patient's function, nor does it threaten life or cause death.

The institutional ethics committee approved the study protocol, and written informed consent was obtained from all patients for the use of their anonymous data in the present publication. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

The study complied with the principles of the Good Clinical Practice guidelines and was approved by the Jagiellonian University Ethics Committee – No: KBET/259/B/2011.

2.1. TLE procedure

The description of TLE procedure has been presented previously.^[19] The patient preparation for TLE procedure consisted of the following tests: laboratory tests, chest X-ray, TTE in all patients, transoesophageal echocardiography (TOE) in majority of patients, preoperative device assessment, and evaluation of pacemaker dependency. Before the operation ipsilateral venography was performed in patients without contraindications to contrast medium. In noninfectious patients the antibiotic prophylaxis was routinely administered, whereas in infectious cases the antimicrobial therapy was continued.

All the procedures were performed in hybrid operating room with on-site cardiothoracic surgical standby, under general anesthesia or intravenous sedation. During the procedure continuous invasive monitoring of blood pressure, blood saturation and electrocardiogram was used. Most of the patients were additionally monitored with TOE. In pacemaker-dependent patients a temporary pacing wire was inserted from the femoral vein. The primary access site used by the operators was the implant vein. While extracting the lead we used a stepwise approach. Simple traction was the first extraction technique used in active fixation and relatively young leads. At the next step we utilized nonpowered extraction tools. Standard stylets were used to stiffen the leads. If the lumen of the lead allowed the insertion of the stylet to its tip, the locking stylets (Liberator Beacon Tip Locking Stylet, Cook Medical or Lead Locking Device, Spectranetics) were used from December 2013. We utilized telescoping dilators (Cook Medical, Bloomington, IN). Powered extraction tools (cutting sheath system – Evolution, Cook Medical) were usually applied when previously used nonpowered extraction tools failed. In case of leads which were completely in the cardiovascular system either before the procedure or as a result of lead fracture during the procedure, the femoral approach was utilized. Laser techniques and electrosurgical sheaths were not used. Pacemaker-dependent patients who underwent TLE due to infectious indications were bridged to reimplantation with a temporary active-fixation lead implanted on the ipsilateral side of the chest and connected to the externalized permanent pacemaker generator.^[20] Furthermore, in patients at a very high risk of sudden cardiac death we implanted a temporary external ICD as a bridge to ICD reimplantation.^[21]

2.2. Statistical analysis

The analysis was performed using StatSoft Statistica version 13.1 (StatSoft, Tulsa, OK). Continuous variables were expressed as mean \pm standard deviation and additionally as median and

interquartile range. Shapiro–Wilk *W* test was used to assess the normality of continuous variables. Comparisons of 2 groups of categorical variables were performed with Student *t* tests of unpaired samples, and in cases of non-normality or small sample sizes, the Mann–Whitney *U* test was used. The categorical variables were presented as the number of observations in each category and the percentage of observations in that category. Categorical variables were compared with Chi-square tests. The 2×2 contingency tables were analyzed using the Chi-square test, Chi-square test with Yates continuity correction, or Fisher exact test.

All statistical tests were 2-tailed and a *P*-value $<.05$ was considered statistically significant.

3. Results

The study population consisted of 196 patients at the age of 62.7 ± 14.3 (range, 22.5–87.6) years, 44 (22.4%) were female. One patient was excluded in whom due to infective complications (LDIE) an active DC lead and a nonfunctional SC were extracted. The leads were extracted due to various indications (29 pts due to LDIE, 20 pts due to LI, 147 patients due to noninfectious indications). In analyzed group there were 150 patients with ICD and 46 with CRT-D. In total 311 leads were extracted with lead dwell time of 5.5 ± 3.6 years. There were 197 ICD leads with dwell time of 5.6 ± 3.5 years. Clinical characteristics of patients in SCL and DCL groups were presented in Table 1. Both groups were similar in terms of age at the extraction, percentage of women, ratio of secondary to primary prevention of sudden cardiac death indication, type of the device, the rate of infectious indications, incidence of diabetes mellitus, coronary artery disease, peripheral artery disease, dyslipidemia, hypertension, atrial fibrillation, and chronic obstructive pulmonary disease. Moreover, both groups had comparable LVEF and percentage of patients in NYHA class III and IV. Additionally, creatinine level, C-reactive protein, eGFR, hemoglobin and BMI index were similarly distributed (Table 1).

Patients with DC ICD leads had significantly more previous device-related interventions compared with patients with SC ICD leads (1.9 vs 1.6, $P=.03$).

Comparison of extracted leads and results of TLE procedures in both groups were presented in Table 2. We extracted 151 ICD leads in SCL group and 46 ICD leads in DCL group. Concerning other types of leads, in SCL group there were 82 pacing leads removed including 14 left ventricular leads, whereas in DCL group there were 32 pacing leads removed including 6 left ventricular leads. The mean dwell time of all extracted leads, mean dwell time of only ICD leads, age of the oldest extracted lead and sum of the dwell time of all extracted leads were significantly higher in DCL group compared to SCL group ($P<.001$). In SCL group there were significantly less leads with passive fixation compared to DCL group (9.3% vs 26.1%, $P<.01$). In both groups the percentage of abandoned leads and the percentage of patients in whom 3 or more leads were removed were similar – Table 2. We observed comparable number of extracted leads per procedure (1.6 vs 1.7, $P=.27$) and complete procedural success (99.1% vs 98.7%, $P>.99$) in both groups. Considering only ICD leads, the extraction efficacy was still not significantly different (99.3% vs 97.8%, $P=0.41$).

Incomplete ICD lead removal occurred in 1 lead in each group. In SCL group over 13% of ICD leads were removed with simple traction, on contrary to DCL group in which 2 (4.4%) leads were

Table 1
Clinical characteristics of patients and type of implanted devices and leads in both groups of patients.

Parameter	All patients (n = 196)	SCL group (n = 150)	DCL group (n = 46)	P value
Age of pts, yr [mean ± SD; Me; IQR]	62.7 ± 14.3; 63.9; 18.8	62.5 ± 14.8; 64.5; 20.7	63.4 ± 12.7; 62.9; 14.9	<i>P</i> = .97
Female, n (%)	44 (22.4)	37 (24.7)	7 (15.2)	<i>P</i> = .18
LVEF, (%) [mean ± SD; Me; IQR]	34.6 ± 14.8; 30.0; 22.5	34.8 ± 15.1; 30.0; 23.0	34.0 ± 13.9; 31.0; 22.0	<i>P</i> = .91
NYHA class III or IV, n (%)	79 (40.3)	60 (40.0)	19 (41.3)	<i>P</i> = .87
Secondary prevention, n (%)	83 (42.3)	60 (40.0)	23 (50.0)	<i>P</i> = .23
BMI, kg/m ² [mean ± SD; Me; IQR]	27.9 ± 6.8; 27.3; 6.6	27.6 ± 7.1; 27.1; 6.3	28.7 ± 5.9; 28.0; 6.8	<i>P</i> = .16
Hb, g/dL [mean ± SD; Me; IQR]	13.7 ± 1.9; 14.0; 2.4	13.6 ± 1.9; 13.9; 2.5	14.0 ± 1.6; 14.1; 2.9	<i>P</i> = .31
CRP, mg/L [mean ± SD; Me; IQR]	19.8 ± 52.8; 2.7; 7.5	20.3 ± 56.3; 2.7; 7.0	18.4 ± 39.8; 2.5; 9.0	<i>P</i> = .90
Creatinine, umol/L [mean ± SD; Me; IQR]	106.7 ± 53.8; 97.0; 40.0	107.8 ± 58.8; 96.0; 40.0	102.8 ± 33.0; 100.0; 38.0	<i>P</i> = .64
eGFR, mL/min/1.73 m ² [mean ± SD; Me; IQR]	69.1 ± 25.4; 71.1; 39.0	69.1 ± 26.1; 72.0; 42.0	69.1 ± 23.3; 62.7; 35.0	<i>P</i> = .96
Diabetes mellitus, n (%)	66 (33.7)	50 (33.3)	16 (34.8)	<i>P</i> = .87
Coronary artery disease, n (%)	129 (65.8)	100 (66.7)	29 (63.0)	<i>P</i> = .65
Peripheral artery disease, n (%)	116 (59.2)	90 (60.0)	26 (56.5)	<i>P</i> = .67
Dyslipidemia, n (%)	158 (80.6)	121 (80.7)	37 (80.4)	<i>P</i> = .97
Hypertension, n (%)	122 (62.4)	91 (60.7)	31 (67.4)	<i>P</i> = .41
Atrial fibrillation, n (%)	83 (42.3)	58 (38.7)	24 (54.3)	<i>P</i> = .10
Chronic obstructive pulmonary disease, n (%)	24 (12.2)	21 (14.0)	3 (6.5)	<i>P</i> = .27
Implanted device				
ICD, n (%)	150 (76.5)	113 (75.3)	37 (80.4)	<i>P</i> = .47
CRT-D, n (%)	46 (23.5)*	37 (24.7)*	9 (19.6)	
Indications for TLE				
LDIE, n (%)	29 (14.8)	22 (14.7)	7 (15.2)	<i>P</i> = .98
LI, n (%)	20 (10.2)	15 (10.0)	5 (10.9)	
Noninfectious indications, n (%)	147 (75.0)	113 (75.3)	34 (73.9)	
Number of previously performed procedures, 1 [mean ± SD; Me; IQR]	1.7 ± 0.9; 1.0; 1.0	1.6 ± 0.9; 1.0; 1.0	1.9 ± 0.7; 2.0; 1.0	<i>P</i> = .03

BMI = body mass index, CRP = C-reactive protein, CRT-D = cardiac resynchronization therapy defibrillator, DCL = dual-coil lead, eGFR = estimated glomerular filtration rate, Hb = hemoglobin, ICD = implantable cardioverter-defibrillator, LDIE = lead-dependent infective endocarditis, LI = local infection, LVEF = left ventricular ejection fraction, NYHA = New York Heart Association, SCL = single-coil lead, TLE = transvenous lead extraction.

* In 1 patient – the lack of pacing system, remaining fragment of ICD lead after heart transplant.

extracted with that method (4.4%). Extraction of leads in DCL group required more often use of evolution mechanical system. Femoral access was not performed in DCL group in contrast to SCL group. Fluoroscopic screening time during DC leads extraction was significantly longer than in SCL group (3.9 minutes vs 2.0 minutes, *P* < .01).

The effectiveness of TLE in present cohort was high and comparable in both groups (*P* = .41). Complete procedural success was achieved in 194 pts (99.0%), and failure in 2 pts (1.0%). Among patients with SC ICD leads complete procedural success was achieved in 99.3% of patients. Failure occurred in 1 patient as an intraoperative death. In DCL group occurred 1 procedural failure – during extraction of nearly 13-year-old dysfunctional DC ICD passive-fixation lead its distal coil remained in myocardium in spite of performing various retrieval techniques. In the whole study population there was 1 (0.5%) minor complication and 5 (2.6%) major complications.

All targeted leads in group DCL required more advanced extraction tools compared to leads in SCL group (*P* < .01). Similar result was noted for comparison of only ICD leads (*P* = .02) – Table 2. In the SCL group, statistically significantly more leads were removed with a simple traction. The success rate of simple traction technique was higher in patients with a device-related infection. Infectious indications were present in 25% of study population. A total of 54 pacing and SC ICD leads were extracted with a simple traction: 23 (42.6%) leads of the infected devices (LDIE and LI) and 31 leads in patients with non-infectious indications (*P* = .02). That association was no longer significant when only ICD leads were analyzed. Of 21 SC ICD

leads removed with a simple traction, 8 (38.1%) were extracted due to device infection (*P* = .30).

The safety in both groups was comparable – Table 2. In SCL group 3 major complications were identified (intraoperative death, hemorrhage to pleural cavity requiring drainage and cardiac tamponade managed surgically) and 1 minor complication (pneumothorax). Intraoperative death in a patient in SCL group occurred in a 70-year-old woman with a single-chamber ICD who was referred for TLE due to 3.6-year-old SC ICD lead dysfunction and total occlusion of ipsilateral venous access. An upgrade to CRT-D was planned as she presented with heart failure in NYHA class III and LVEF of less than 15%. Lead was extracted with green telescopic sheath, Cook Medical (inner diameter of the innermost sheath – 10 Fr) from ipsilateral subclavian vein access. A massive hemorrhage from SVC occurred as a result of vessel injury caused by telescopic sheaths. Despite an immediate intervention of a cardiothoracic surgeon the patient died during the procedure. The Bridge Occlusion Balloon (BOB) (Bridge; Spectranetics Corporation, Colorado Springs, CO) was not used as it was unavailable on the market at the time. Hemorrhage to the pleural cavity requiring drainage occurred during extraction of 7.1-year-old dysfunctional SC ICD lead in a 26-year-old patient with a dual-chamber ICD and with a history of surgical correction of Tetralogy of Fallot. Ipsilateral venography showed subclavian vein patency and the presence of a loop created by ICD lead inside subclavian vein. During the extraction of ICD lead with green dilator sheath the left subclavian vein and left pleura were damaged.^[22]

Table 2
Comparison of extracted leads and results of TLE procedures in both groups.

Parameter	All patients (n = 196)	SCL group (n = 150)	DCL group (n = 46)	P value
No of all extracted leads	311	233	78	–
No of extracted ICD leads	197	151	46	–
Passive fixation of ICD leads, n (%)	26 (13.2)	14 (9.3)	12 (26.1)	<i>P</i> < .01
Age of extracted lead, yr [mean ± SD; Me; IQR]*	5.5 ± 3.6; 4.9; 4.5	5.1 ± 3.6; 4.5; 4.1	6.9 ± 3.5; 7.0; 4.4	<i>P</i> < .001
Age of extracted ICD lead, yr [mean ± SD; Me; IQR]†	5.6 ± 3.5; 5.1; 4.1	5.1 ± 3.4; 4.6; 3.8	7.1 ± 3.5; 7.0; 4.4	<i>P</i> < .001
Oldest extracted lead, yr [mean ± SD; Me; IQR]*	5.9 ± 3.8; 5.2; 4.3	5.4 ± 3.8; 4.7; 3.8	7.6 ± 3.6; 7.5; 4.9	<i>P</i> < .001
Sum of age of extracted leads, yr [mean ± SD; Me; IQR]*	8.8 ± 6.5; 7.0; 8.0	7.9 ± 6.2; 6.4; 6.7	11.7 ± 6.9; 9.9; 10.3	<i>P</i> < .001
Patients with 1 abandoned lead, n (%)	5 (2.6)	4 (2.7)*	1 (2.2)	<i>P</i> = .73
Patients with 2 or more abandoned leads, n (%)	0 (0.0)*	0 (0.0)*	0 (0.0)*	<i>P</i> > .99
Patients with 3 or more extracted leads, n (%)	21 (10.7)	15 (10.0)	6 (13.0)	<i>P</i> = .76
Extracted leads per procedure, 1 [mean ± SD; Me; IQR]	1.6 ± 0.7; 1.0; 1.0	1.6 ± 0.7; 1.0; 1.0	1.7 ± 0.8 2.0; 1.0	<i>P</i> = .27
Leads:				
Complete lead removal (all leads), n (%)	308 (99.0)	231 (99.1)	77 (98.7)	<i>P</i> > .99
Incomplete lead removal (all leads), n (%)	3 (1.0)	2 (0.9)	1 (1.3)	
Complete lead removal (ICD leads), n (%)	195 (99.0)	150 (99.3)	45 (97.8)	<i>P</i> = .41
Incomplete lead removal (ICD leads), n (%)	2 (1.0)	1 (0.7)	1 (2.2)	
Finally effective techniques:				
Simple traction, n (%)	61 (19.6)	54 (23.2)	7 (9.0)	<i>P</i> < .01
Telescopic sheaths, n (%)	236 (75.9)	168 (72.1)	68 (87.2)	
Evolution mechanical system, n (%)	5 (1.6)	2 (0.9)	3 (3.8)	
Femoral access, n (%)	9 (2.9)	9 (3.8)	0 (0.0)	
Simple traction (only ICD leads), n (%)	23 (11.7)	21 (13.9)	2 (4.4)	<i>P</i> = .02
Telescopic sheaths (only ICD leads), n (%)	161 (81.7)	120 (79.5)	41 (89.1)	
Evolution mechanical system (only ICD leads), n (%)	5 (2.5)	2 (1.3)	3 (6.5)	
Femoral access (only ICD leads), n (%)	8 (4.1)	8 (5.3)	0 (0.0)	
Fluoroscopy time during ICD lead removal, min [mean ± SD; Me; IQR]	2.5 ± 4.2; 1.3; 1.7	2.0 ± 2.4; 1.2; 1.8	3.9 ± 7.5; 1.5; 2.3	<i>P</i> < .01
Total fluoroscopy time during all leads removal, min [mean ± SD; Me; IQR]	3.4 ± 5.3; 1.9; 3.0	2.8 ± 3.4; 1.8; 2.7	5.2 ± 8.9; 2.3; 2.9	<i>P</i> = .02
Procedures:				
Complete success, n (%)	194 (99.0)	149 (99.3)	45 (97.8)	<i>P</i> = .41
Clinical success, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	
Failure, n (%)	2 (1.0)	1 (0.7)	1 (2.2)	
Complications:				
No complications, n (%)	190 (96.9)	146 (97.3)	44 (95.7)	<i>P</i> = .58
Minor complications, n (%)	1 (0.5)	1 (0.7)	0 (0.0)	
Major complications, n (%)	5 (2.6)	3 (2.0)	2 (4.3)	
Deaths:				
Intraoperative period procedure-related, n (%)	1 (0.5)	1 (0.7)	0 (0.0)	<i>P</i> > .99
During 30-d postoperative period procedure-related, n (%)	7 (3.6)	4 (2.7)	3 (6.5)	<i>P</i> = 0.36

DCL = dual-coil lead, ICD = implantable cardioverter-defibrillator, SCL = single-coil lead.

* Including all leads: pacing and ICD leads.

† Only ICD leads.

Cardiac tamponade requiring surgical intervention occurred in a 41-year-old woman with hypertrophic cardiomyopathy and a dual-chamber ICD in a secondary prevention of sudden cardiac death. The indication for an extraction was SC ICD lead dysfunction of 11.7-year-old lead. Green, white, and orange telescopic sheaths (inner diameter of the innermost sheaths – 10 Fr, 11.5 Fr, and 13 Fr) were used to extract ICD lead.

In DCL group there were 2 major complications (cardiac tamponades requiring surgical intervention). During extraction of DC ICD leads with telescopic sheaths the free wall of the right ventricle was damaged and caused tamponade. Both complications were caused by a lead tip penetration into the myocardium without lead perforation in TTE and cardiac CT angiogram. Additional information on major complication in both groups was presented in Table 3.

We observed a trend towards more frequent occurrence of major complications in DCL group (4.3% vs 2.0%, *P* = .58); however, the difference was not statistically significant.

Total mortality within 30-day period was 3.6% (7 patients) and there was no significant difference between groups (2.7% in SCL group vs 6.5% in DCL group, *P* = .36) – Table 2. Among patients who died, 4 had LDIE (1 in SCL group and 3 in DCL group; all died due to severe heart failure or sepsis). The remainder were in SC group and were referred to TLE due to noninfectious indications (1 patient died during TLE procedure and 2 died due to thromboembolic events).

4. Discussion

In our study cohort noninfectious indications were present in 75% of patients. The observed low rate of TLE due to infection is consistent with our strategy to rigorously treat pacing-related complications and has been shown in our previous reports.^[6,19,23] The qualification for TLE procedure was based on careful consideration involving patient whether to abandon or remove a lead and/or CIED.^[6] This process has been in line with

Table 3
Major complications in both groups.

ICD lead type	Gender	Age, yr	Left ventricular ejection fraction (%)	BMI, kg/m ²	Implanted device	Prevention of sudden cardiac death	Age of extracted ICD lead, yr	ICD lead fixation	Fluoroscopy time during ICD lead extraction, min	Utilized tools (maximum inner diameter of the innermost sheath), Fr	Complication
SCL	F	70	15	22.1	ICD-VR	Secondary	3.6	Active	2.67	Telescopic sheath (10)	Intraoperative death secondary to superior vena cava tear
SCL	M	26	60	22.0	ICD-DR	Secondary	7.1	Passive	0.67	Telescopic sheath (10)	Haemorrhage to pleural cavity
SCL	F	41	58	29.7	ICD-DR	Secondary	11.7	Passive	2.67	Telescopic sheath (13)	Cardiac tamponade
DCL	M	46	50	27.1	ICD-VR	Secondary	2.9	Active	0.67	Telescopic sheath (13)	Cardiac tamponade
DCL	M	58	30	30.4	ICD-VR	Primary	4.5	Active	3.00	Telescopic sheath (13.0)	Cardiac tamponade

BMI=body mass index, DCL=dual-coil lead, F=female, ICD=implantable cardioverter-defibrillator, ICD-DR=dual-chamber implantable cardioverter-defibrillator, ICD-VR=single-chamber implantable cardioverter-defibrillator, M=male, SCL=single coil lead.

the current expert consensus statement.^[2] The tendency towards higher frequency of noninfectious indications for TLE has been noted previously in other centers in Poland.^[24] In present population SC ICD leads were in the majority of extracted leads (76.6%). It is in contrast to previous studies in which DC ICD leads were usually in the majority.^[8,12,16,25] In our cohort prevailed SC leads which are currently considered as the leads of first choice for routine new left-sided ICD implants. However, DC ICD leads were implanted more frequently in the initial period of ICD implantations which is showing gradual move towards SC ICD leads. This observation is in accordance with the results from meta-analysis including 18 studies.^[26] Noteworthy, data from ALTITUDE Study demonstrated that SC lead implantations increased from 1.9% to 55.2% between 2004 and 2014.^[27] Moreover, in Israeli ICD Database, a prospective registry of all patients referred for implantation or replacement of ICD or CRT-D for primary and secondary prevention, percentage of DC ICD leads implantations has been gradually decreasing.^[11] In our cohort DC ICD leads were more frequently with passive fixation and had long dwell-time which may be explained by an earlier time of implantation of these ICD systems. Furthermore, this observation is supported by a higher number of prior device-related interventions in DCL group (mostly ICD generator change) compared to SCL group (1.9 vs 1.6, $P=.03$). Older age of ICD leads and higher percentage of passive fixation leads contributed to longer fluoroscopic screening time during extraction of DC leads compared to SC leads (3.9 minutes vs 2.0 minutes, $P=0.021$). Similar results have been obtained by other researchers. Pecha et al showed that extraction of DC ICD leads was associated with longer laser treatment times.^[15] Additionally, Bontempi et al demonstrated that among nonindependent factors increasing the fluoroscopy time was a presence of DC lead.^[14]

Present study showed that the extraction of DC ICD leads required more frequent use of mechanical systems compared to simple traction. Similar conclusions were drawn by Bongiorno et al who observed that longer lead dwell time, passive fixation, and DC construction predicted a more challenging extraction procedure.^[28] The association between the presence of DC ICD lead and the difficulty of extraction has been mentioned in other reports.^[12,13] Pacing and ICD leads were more frequently removed with a simple traction in SCL group compared to DCL group which may be explained by the lack of additional coil in SVC; however, longer dwell time of leads in DCL leads might need to be factored in as well. Authors observed a trend toward

higher success rate of simple traction in SCL group in infectious indications. In our study population the infectious indications were in the minority; therefore, that association might be incidental. Consequently, it warrants further research as the evidence in the current literature is insufficient.

Major perioperative complication rate in our study was 2.6%. In a recently published registry of 11,304 TLE procedures (8632 high-voltage lead extraction and 2942 pacing lead extraction procedures) performed in 762 centers, authors reported 2.4% incidence of major perioperative complications during ICD lead extraction,^[25] which is comparable to our outcomes. One intraprocedural death occurred as a result of SVC injury caused by telescopic sheaths. Injury to the SVC, though uncommon, is a serious and potentially fatal complication of TLE and occurs in approximately 0.5% of procedures.^[29] The BOB can enable hemodynamic stability through control of hemorrhage by occluding the SVC in the minutes required for full open access to the chest.^[30] According to Brunner et al, situations that may be considered higher risk and warrant staging BOB on the wire and placement in the inferior vena cava (IVC) may include the following: female patients, low BMI (<25 kg/m²), low LVEF, ICD leads, DC ICD leads, multiple indwelling leads (≥ 4), combined age of leads over 10 (sum of every implanted lead multiplied by its implant duration), difficult case with multiple extraction tools already used, after familiarity or competency practice placement.^[30] In our opinion, we would have considered staging BOB on the wire and placement in the IVC in such a case.

In present study the effectiveness and safety of TLE extraction of DC and SC leads were comparable; however, there was a trend towards more frequent complications in patients with DC leads (4.3% vs 2.0%, $P=.58$). It concurs with the previous report by Brunner et al.^[16]

Epstein et al noted a higher rate of TLE complications in 1791 patients with DC leads compared to 385 patients with SC ICD leads.^[12] Importantly, in the report by Epstein et al DC leads had much shorter mean dwell time compared to our group of DC leads (38.2 months vs 85.2 months).

Sood et al did not find association between DC ICD lead construction and the risk of major TLE complication; however, did find a 4% increased relative risk of major complication per 10 mm² increase in proximal surface coil area.^[25] Authors thought this was as a surrogate marker of increased risk for perioperative complications associated with DC leads.

The increased risk of TLE in the group of DC ICD leads might have been caused by a longer dwelling time of those leads. Brunner

et al in the group of nearly 3000 TLE procedures and over 5000 extracted leads considered in univariate analysis the presence of DC ICD lead as a risk factor for major complications, major cardiovascular injury and all-cause mortality within 30 days of TLE. However, in a multivariate analysis this parameter was no longer associated with increased risk of complications or all-cause mortality within 30 days of TLE, whereas the cumulative age of all leads extracted affected significantly those outcomes.^[16]

All-cause mortality in our patients within 30 days of TLE was 3.6% (2.7% in SCL group and 6.5% in DC L group, $P=.36$). Noteworthy, we observed a trend towards higher mortality within 30 days of TLE among patients with DC ICD leads. Other authors also noted higher mortality rate in patients with DC ICD leads within 30 days after extraction.^[31] Literature has not provided a conclusive explanation of this phenomenon to date. We have assumed that tendency towards higher mortality rate in patients with DC ICD leads within 30 days following TLE might have been related to the complications of LDIE.

Consistently with the report by Sunderland et al. we showed that given the increased risk and complexity of extracting DC ICD leads, centers should strongly consider SC leads as the lead of the first choice for routine new left-sided ICD implants.^[26]

4.1. Study limitations

The main study limitation was a relatively small sample of patients with DC ICD leads and single-center experience. No comparison was made between mechanical dilator sheaths or Evolution system and other techniques currently used for TLE because the authors used only the mechanical systems. Furthermore, the follow-up was limited to 30-day post-procedural period. This study presents outcomes of high volume center and operators with expertise in mechanical extraction systems and; therefore, our results may not be widely applicable to less experienced centers.

4.2. Future directions

Further research involving more patients is needed. Moreover, outcomes beyond 30-day post TLE are warranted. Finally, other extraction techniques, that is, laser could be explored in terms of efficacy and safety and compared to mechanical techniques.

5. Conclusions

The TLE procedures involving extraction of SC and DC ICD leads were effective and safe. The outcomes of DC ICD leads removal did not differ significantly compared to SC ICD leads, although extraction of DC ICD leads required more advanced tools and longer fluoroscopy time.

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