ORIGINAL ARTICLE

Indications for transvenous lead extraction and its procedural and early outcomes in elderly patients: a single-center experience

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KEY WORDS

cardiovascular implantable electronic devices, effectiveness, elderly, safety, transvenous lead extraction

ABSTRACT

INTRODUCTION Due to the prolonged survival of patients with cardiovascular implantable electronic devices, leads often need to be removed in elderly individuals.

OBJECTIVES We aimed to analyze indications for transvenous lead extraction (TLE), procedure effectiveness and safety, as well as 30-day follow-up in younger patients (≤80 years) and octogenarians (>80 years).

PATIENTS AND METHODS This prospective study included 667 patients who underwent TLE: 90 octogenarians (13.5%) at a mean age of 83.8 (range, 80.4–93) years and 577 younger patients (86.5%) at a mean age of 64.2 (range, 18.9–79.9) years.

RESULTS Octogenarians had a greater number of comorbidities, fewer implantable cardioverter-defibrillators implanted, and more frequently had infection as an indication for TLE, as compared with younger patients (33.3% vs 17.1%; $P < 0.001$). In octogenarians, 138 leads were extracted, as compared with 894 leads in younger patients. Octogenarians and younger patients had similar rates of complete lead removal (98.6% and 97.1%, respectively; $P = 0.48$), total procedural success (97.8% and 96%, respectively; $P = 0.7$), major complications (0% and 1.6%, respectively; $P = 0.45$), and minor complications (2.2% and 1.6%, respectively; $P = 0.45$). There was 1 death associated with TLE in younger patients. Non–procedure-related deaths within 30 days after TLE were more frequent in octogenarians than in younger patients (5.6% vs 1.9%; $P = 0.04$).

CONCLUSIONS We showed that TLE in patients older than 80 years seems to be as effective as in younger patients; however, it is associated with significantly higher non–procedure-related 30-day mortality.

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INTRODUCTION Transvenous lead extraction (TLE) is the cornerstone in the management of cardiovascular implantable electronic device (CIED)–related adverse events.[1-3] Due to the prolonged survival of patients with CIEDs, leads need to be frequently removed in elderly individuals. Population aging and a growing rate of older persons with multiple chronic comorbidities pose new challenges for clinical practice.[4] Elderly patients, compared with younger ones, may have worse outcomes of TLE due to frailty, higher morbidity, and risks related with general anesthesia.

The current literature data show mostly unanimously that octogenarians and younger patients do not differ in terms of TLE outcomes[5-7]; however, the issue remains controversial. Williams et al[8] demonstrated that the overall rate of adverse events was higher in octogenarians. Furthermore, according to the prospective multicenter ELECTRa (European Lead Extraction ConTRolled) study on TLE procedures, the age above

WHAT'S NEW?

Our study evaluated indications for transvenous lead extraction (TLE), its effectiveness, safety, and 30-day follow-up in patients at the age of 80 years or younger and those older than 80 years. Compared with younger patients, the octogenarians had more comorbidities and more frequently underwent TLE due to infection. The TLE procedure is effective, and its outcomes are similar to those obtained in patients at a younger age. The adverse event and procedural success rates were similar for octogenarians and younger patients. The key difference was the increased all-cause mortality in octogenarians within the 30-day follow-up after TLE, which was linked to higher morbidity. In this subgroup of patients, potential benefits of complex TLE for indications other than infection should be carefully weighed against the high risk of unfavorable short-term outcome.

68 years is one of the predictors of increased all-cause mortality during hospitalization.[9] Additionally, Kennergren et al[10] reported that in a low number of patients with class II indications for TLE, leads were not extracted because of advanced patient age. Brunner et al[11] observed that patients over the age of 65 years experienced major adverse events and major cardiovascular injury, which was the first report stating that patients older than 65 years had higher 30-day mortality following TLE.

Conflicting evidence prompted us to conduct a prospective single-center study on the relationship between patients' age and outcome of TLE, with a particular focus on the relation between 30-day mortality and risk factors.

PATIENTS AND METHODS We aimed to assess indications for TLE, procedure effectiveness and safety, as well as all-cause mortality within 30 days after the procedure in patients younger and older than 80 years.

We performed a prospective analysis (a case--control study) of the records of all patients who underwent TLE from October 2011 to April 2019. The study protocol was approved by the Research and Ethics Committee of Jagiellonian University (KBET/259/B/2011). Written informed consent was obtained from all patients for the use of their anonymous data in this article. The study protocol conformed with the 1975 Declaration of Helsinki and complied with the principles of Good Clinical Practice guidelines.

Patients with pacemakers or implantable cardioverter-defibrillator (ICD) leads implanted later than 1 year before TLE were excluded from the analysis.

The population was divided into 2 groups based on age at the time of the procedure: the group of younger patients included those at 80 years of age and younger, and the group of octogenarians, those over 80 years of age.

Transvenous lead extraction was performed only in patients expected to survive at least 12 months. Octogenarians who were incapable of giving consent for TLE (due to brain damage, dementia, etc) were managed conservatively. On the other hand, in the case of an infectious indication for TLE, such patients were routinely referred to the regional court for a ruling.

Data were collected from records taken at the time of device implantation, records from follow--up visits at outpatient cardiology clinics, and medical information obtained during index admissions for TLE and 30 days after the procedure.

The study groups were compared with regard to demographic characteristics (age, sex), body mass index (BMI), New York Heart Association (NYHA) functional class, left ventricular ejection fraction (LVEF), comorbidities defined by the Charlson Comorbidity Index (CCI), laboratory tests (hemoglobin, creatinine, and estimated glomerular filtration rate [eGFR]), type of the implanted CIED, number of CIED-related procedures before TLE (implantation, box change, device upgrade), and indications for TLE.

The CCI score was determined based on 19 diseases weighted according to their association with mortality.[12] The 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 indications other than infection. The Modified Duke Leads Criteria were used to diagnose LDIE, whereas LI was diagnosed based on signs of local inflammation restricted to the device pocket: erythema, warmth, pain, swelling, wound dehiscence, purulent discharge, skin erosion, or sinus formation. When both LDIE and LI were present, LDIE was considered the primary indication for TLE.

In addition, both groups were analyzed and compared for the following characteristics: percentage of unipolar leads, percentage of passive fixation leads, percentage of nonfunctional or abandoned leads, age of extracted leads, age of the oldest extracted lead, total age of all extracted leads (a sum of extracted lead dwell times per procedure [years]), number of extracted leads during TLE, fluoroscopy time during TLE, techniques used during TLE, effectiveness of TLE, complete or incomplete lead removal for each lead removed, complications during the intraoperative and 30--day postoperative period.

The effectiveness of TLE was divided into 3 categories (complete success, clinical success, and failure) according to the current consensus of the Heart Rhythm Society and the European Heart Rhythm Association (EHRA).[1-3] We used the following definitions: 1) complete procedural success—removal of all targeted leads and all lead material from the vascular space, without any permanently disabling complications or procedure--related death; 2) 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 procedure outcome; it may be a tip or a small part of the lead (a conductor coil, insulation, or the combination of both) when the residual part neither increases the risk of perforation, embolic events, or nonresolving infection nor causes any undesired outcome; and 3) failure of the procedure—inability to achieve either complete procedural or clinical success, developing any permanently disabling adverse event, or procedure-related death.[1-3] For each removed lead, the efficacy (complete or incomplete) was determined according to the EHRA consensus.[3] A complete lead removal was defined as lead explantation or extraction with removal of all targeted lead material, whereas an incomplete lead removal referred to lead explantation or extraction where a part of the lead remained in the patient's body (in the vascular or extravascular space).[3] We recorded adverse events that occurred during the intraoperative period and within 30 days after the procedure and classified them into 2 types in accordance with the Heart Rhythm Society and EHRA consensus.[1-3]

Transvenous lead extraction The description of TLE was presented elsewhere.[13] Pacemaker-dependent patients who underwent TLE due to infection were bridged to reimplantation with a temporary active fixation lead implanted on the ipsilateral side of the chest and connected to an external permanent pacemaker generator.[14] Furthermore, in patients at a very high risk of sudden cardiac death, we implanted a temporary external ICD as a bridge to the ICD reimplantation.[15]

Statistical analysis The analysis was performed using the Statistica software, version 13.1 (StatSoft, Tulsa, Oklahoma, United States). Continuous variables were expressed as mean (SD) or median and interquartile range (IQR). The Shapiro–Wilk test was used to assess normality of data distribution. Two groups of continuous variables were compared with the *t* test of unpaired samples, and in the case of data distribution other than normal or a small sample size, the Mann–Whitney test was applied. Categorical variables were presented as the number and percentage of observations in each category. Those data were compared with the χ^2 test, χ^2 test with the Yates continuity correction, or Fisher exact test, as appropriate. Univariable and multivariable logistic regression was performed to determine the independent predictors of 30-day mortality. Odds ratios (ORs) with 95% CIs were used to present the impact of independent variables on 30-day mortality. Predictors with a *P* value of less than 0.1 in the univariable analysis were selected for the multivariable logistic regression analysis. All statistical tests were 2-tailed and a *P* value of less than 0.05 was considered significant.

RESULTS We identified 667 patients at a mean (SD) age of 66.9 (13.4) years (range, 18.9–93 years), including 240 women (36%). Transvenous lead extraction was performed due to LDIE (67 patients [10%]), LI (62 patients [9.3%]), and for indications other than infection (538 patients [80.7%]). Both LDIE and LI coexisted in 21 patients (3.1%). There were 90 octogenarians (13.5%) at a mean (SD) age of 83.8 (2.8) years (range, 80.4–93 years), and 577 younger patients at a mean (SD) age of 64.2 (12.5) years (range, 18.9–79.9 years).

The clinical characteristics of both groups are shown in TABLE 1. The female sex was more prevalent in octogenarians compared with the younger group (44.4% vs 34.7%; $P = 0.07$). Octogenarians had higher mean values of LVEF and creatinine as well as a lower NYHA class. They also had significantly lower BMI, hemoglobin levels, and eGFR (TABLE 1). Both groups differed with regard to the type of implanted devices. The percentage of patients with pacemakers was higher in octogenarians, whereas the percentage of those on cardiac resynchronization therapy and with ICDs was higher in the younger group ($P < 0.001$) (TABLE 1).

Octogenarians twice more often had a device-related infection (LDIE and / or LI) than younger patients (33.3% vs 17.1%; $P < 0.001$) (TABLE 1). The groups did not differ in terms of the prevalence of diabetes, coronary artery disease, and the number of previously performed device-related procedures (TABLE 1). Overall morbidity measured with the CCI was higher in octogenarians than in younger patients (2.4 vs 2; $P = 0.02$).

The total number of extracted leads in both groups was 1032 (138 leads in octogenarians and 894 leads in the younger group). The comparison of extracted leads and results of TLE in both study groups are shown in TABLE 2. The percentage of extracted ICD leads was higher in younger patients than in octogenarians (21.7% vs 11.6%; $P = 0.006$).

The groups had a similar percentage of unipolar pacing leads, passive fixation leads, abandoned leads, and patients with 3 or more extracted leads, as well as a similar number of extracted leads at the index procedure (TABLE 2). Additionally, the mean age of extracted leads, age of extracted pacing and ICD leads, oldest extracted leads, and the total age of all extracted leads were comparable between the groups (TABLE 2).

Complete lead removal rates were similar in octogenarians and younger patients (98.6% and 97.1%, respectively; $P = 0.48$). We did not observe any differences between the groups in the use of extraction tools ($P = 0.43$). The time of a single permanent pacemaker (PPM) or ICD lead extraction was longer in younger patients compared with octogenarians; however, the difference did not reach significance ($P = 0.08$). The fluoroscopy time of PPM or ICD lead extraction and the fluoroscopy time of ICD lead extraction were longer in the younger group compared with octogenarians (TABLE 2). The fluoroscopy time of PPM lead extraction was comparable between groups (TABLE 2).

The effectiveness of procedures in the whole population was high and similar in both groups ($P = 0.7$). Complete procedural success was

TABLE 1 Clinical characteristics of patients as well as the type of implanted devices and leads in the study groups

Variable		All patients (n = 667)	Octogenarians (n = 90)	Younger patients (n = 577)	*P* value
Age, y		66.9 (13.4); 68.3; 17.6	83.8 (2.8); 83.3; 4.2	64.2 (12.5); 66.2; 16.4	–
Female sex, n (%)		240 (36)	40 (44.4)	200 (34.7)	0.07
LVEF, %		43.6 (16.1); 45; 28	48.9 (12.8); 50; 20	42.8 (16.5); 45; 28	0.001
NYHA class III or IV, n (%)		169 (25.3)	15 (16.7)	154 (26.7)	0.04
BMI, kg/m^2		27.9 (4.8); 27.5; 6.1	26.4 (3.6); 26.4; 4.6	28.1 (4.9); 27.7; 6.2	0.001
Hemoglobin, g/dl		13.6 (1.7); 13.8; 2.2	13.1 (1.8); 13.4; 2.6	13.7 (1.7); 13.9; 2.2	0.004
Creatinine, µmol/l		100.9 (53.8); 91; 35	105.7 (32.6); 98.5; 35	100.2 (56.4); 89; 32	0.001
eGFR, ml/min/1.73 m^2		68.1 (22.2); 69; 32	54.5 (16.6); 52.1; 25	70.3 (22.2); 71; 32	<0.001
Diabetes mellitus, n (%)		221 (33.1)	34 (37.8)	187 (32.4)	0.31
Coronary artery disease, n (%)		367 (55)	57 (63.3)	310 (53.7)	0.09
Charlson Comorbidity Index		2.1 (1.7); 2; 2	2.4 (1.6); 2; 3	2 (1.7); 2; 2	0.02
Previous TLE procedures, n		1.6 (0.9); 1; 1	1.6 (0.8); 1; 1	1.7 (0.9); 1; 1	>0.99
Implanted device, n (%)	Pacemaker	408 (61.2)[a]	73 (81.1)	335 (58.1)[a]	<0.001
	ICD	177 (26.5)[b]	12 (13.3)	165 (28.6)[b]	
	CRT-P	11 (1.7)	0	11 (1.9)	
	CRT-D	71 (10.6)[c]	5 (5.6)	66 (11.4)[c]	
Indications for TLE, n (%)	LDIE	67 (10)	12 (13.3)	55 (9.5)	<0.001
	LI	62 (9.3)	18 (20)	44 (7.6)	
	Other than infection	538 (80.7)	60 (66.7)	478 (82.9)	

Data are presented as mean (SD) and median; IQR unless otherwise indicated.

a In 2 patients: in 1 patient—no pacing system, remaining 2 leads after the removal of a dual-chamber pacemaker due to a device-pocket infection; in 1 patient—no pacing system, a remaining VDD lead after pacemaker removal due to an indication other than infection

b In 1 patient: no pacing system, a remaining ICD lead after unsuccessful lead removal in another center

c In 1 patient: no pacing system, a remaining fragment of an ICD lead after heart transplant

Abbreviations: BMI, body mass index; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter--defibrillator; IQR, interquartile range; LDIE, lead-dependent infective endocarditis; LI, local infection; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; TLE, transvenous lead extraction

achieved in 642 patients (96.3%); clinical success, in 15 (2.2%); and failure, in 10 (1.5%). In octogenarians, complete success was achieved in 88 patients (97.8%), while in the younger group, in 554 patients (96%) of patients.

In the entire study group, there were 11 (1.5%) minor and 9 (1.3%) major complications. The safety of TLE was similar in both groups (*P* = 0.45). In octogenarians, 2 minor and no major complications were reported. In the younger group, minor and major complications occurred in the equal percentage of patients, namely, 1.6% (9 patients).

All-cause mortality within 30 days after TLE was 2.4% (16 patients) and a significant difference was found between groups (5.6% in octogenarians vs 1.9% in the younger group; *P* = 0.04) (TABLE 2). Among patients who died, 11 had LDIE (3 octogenarians and 8 younger patients; all died of severe heart failure or sepsis while being on antibiotic therapy). One patient died due to adverse events after a fall that resulted in hemorrhage to the pleural cavity (in octogenarians, after TLE due to LI).

Four deceased patients had indications for TLE other than infection. Three patients in the younger group died of the following causes: 1 patient during TLE, 1 of heart failure after cardiac surgery, and 1 of thromboembolic events. One octogenarian died of thromboembolic events.

The association between selected factors and 30-day all-cause mortality following TLE is presented in TABLE 3. Factors entered into the univariable analysis of the 30-day mortality included: the octogenarian vs younger group status, sex, LVEF, BMI, LDIE as an indication for TLE, hemoglobin levels, CCI, number of extracted leads at the index procedure, total age of all extracted leads, presence of a dual-coil ICD lead extracted, total fluoroscopy time during all lead extractions, and presence of major adverse events of TLE.

The univariable analysis showed that the octogenarian status (OR, 3.027), lower LVEF (OR, 1.035 per 1%), LDIE as an indication for TLE (OR, 23.375), lower hemoglobin levels (OR, 2.024 per 1 g/dl), higher CCI (OR, 2.274 per 1 point), and the number of extracted leads at the index procedure (OR, 4.583 per 1 lead) were

TABLE 2 Extracted leads and results of transvenous lead extraction in both study groups

Variable	All patients (n = 667)	Octogenarians (n = 90)	Younger patients (n = 577)	*P* value
Extracted leads, total n	1032	138	894	–
Extracted ICD leads, n (%)	210 (20.3)	16 (11.6)	194 (21.7)	0.006
Unipolar pacing leads, n (%)	70 (8.5)	5 (4.1)	65 (9.3)	0.07
Passive fixation leads[a], n (%)	315 (30.5)	34 (24.6)	281 (31.4)	0.11
Age of an extracted lead, y	7.5 (5.8); 6; 6.2	7.2 (5.2); 6.6; 5.1	7.6 (5.9); 6; 6.3	0.47
Age of an extracted pacing lead, y	8 (6.1); 6.5; 6.8	7.5 (5.3); 6.9; 5.2	8.1 (6.3); 6.4; 7.2	0.26
Age of an extracted ICD lead, y	5.5 (3.4); 5; 4.3	4.6 (2.3); 4.6; 3.5	5.6 (3.5); 5.1; 4.4	0.45
Oldest extracted lead, y	7.9 (6.2); 6.1; 6.4	7.5 (5.5); 6.6; 5.2	8 (6.3); 6; 6.7	0.94
Total age of extracted leads, y	11.6 (10.2); 8.3; 10.9	11 (9.3); 7.6; 10.3	11.7 (10.4); 8.4; 11	0.34
Patients with 1 abandoned lead, n (%)	26 (3.9)	5 (5.6)	21 (3.6)	0.56
Patients with 2 abandoned leads, n (%)	4 (0.6)	1 (1.1)	3 (0.5)	0.44
Patients with 3 or more extracted leads, n (%)	37 (5.5)	3 (3.3)	34 (5.9)	0.46
Extracted leads at the index procedure, n	1.5 (0.6); 1; 1	1.5 (0.6); 1.5; 1	1.5 (0.6); 1; 1	0.98
Lead removal, n (%)				
Complete lead removal	1004 (97.3)	136 (98.6)	868 (97.1)	0.48
Incomplete lead removal	28 (2.7)	2 (1.4)	26 (2.9)	
Techniques finally used				
Simple traction, n (%)	233 (22.6)	38 (27.5)	195 (21.8)	0.43
Telescopic sheaths, n (%)	754 (73.1)	93 (67.4)	661 (74)	
Evolution mechanical system, n (%)	22 (2.1)	3 (2.2)	19 (2.1)	
Femoral access, n (%)	23 (2.2)	4 (2.9)	19 (2.1)	
Fluoroscopy time during single pacing or ICD lead removal[a], min	2.1 (3.6); 1.1; 1.8	1.8 (2.8); 1; 1.5	2.2 (3.7); 1.1; 1.8	0.08
Fluoroscopy time during single pacing lead removal[a], min	2 (3.4); 1; 1.8	1.9 (2.9); 1; 1.6	2.1 (3.5); 1; 1.8	0.36
Fluoroscopy time during single ICD lead removal, min	2.4 (4.1); 1.3; 1.7	1.2 (1.2); 1; 1.6	2.5 (4.3); 1.3; 1.9	0.049
Total fluoroscopy time during all lead removal procedures, min	3.3 (5.2); 1.7; 2.7	2.8 (5); 1.1; 2.5	3.4 (5.2); 1.8; 2.8	0.02
Procedure outcome, n (%)				
Complete success	642 (96.3)	88 (97.8)	554 (96)	0.7
Clinical success	15 (2.2)	1 (1.1)	14 (2.4)	
Failure	10 (1.5)	1 (1.1)	9 (1.6)	
Complications, n (%)				
None	648 (97.2)	88 (97.8)	559 (96.8)	0.45
Minor	11 (1.5)	2 (2.2)	9 (1.6)	
Major	9 (1.3)	0	9 (1.6)	
Deaths, n (%)				
In the intraoperative period, procedure-related	1 (0.15)	0	1 (0.2)	>0.99
Postoperatively within 30 days after TLE, procedure-related	0	0	0	>0.99
Postoperatively within 30 days after TLE, non–procedure-related	16 (2.4)	5 (5.6)	11 (1.9)	0.04

Data are presented as mean (SD) and median; IQR unless otherwise indicated.

a Including left ventricular leads

Abbreviations: see TABLE 1

significant predictors of 30-day mortality. In the multivariable analysis, only lower hemoglobin levels (OR, 1.642 per 1 g/dl), higher CCI (OR, 1.836 per 1 point), and the number of extracted leads at the index procedure (OR, 3.441 per 1 lead) remained significant. The results of the statistical analysis are presented in TABLE 3. Octogenarians and younger patients with LDIE as an indication for TLE had similar 30-day all-cause mortality (60% and 72.7%, respectively; *P* = 0.94).

DISCUSSION The current state of knowledge regarding safety, effectiveness, and particularly survival after TLE in elderly patients is still limited. In our study cohort, indications for TLE other than infection were present in 80.7% of patients. The observed low rate of TLE due to infection results from our strategy to rigorously treat pacing-related adverse events and is consistent with our previous report.[16] The decision whether or not to perform TLE was based on

TABLE 3 Predictors of all-cause mortality within 30 days after transvenous lead extraction

Variable	Univariable analysis			Multivariable analysis		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Octogenarians vs younger patients	3.027	1.026–8.926	0.045	3.058	0.758–12.339	0.12
Female sex	1.069	0.384–2.979	0.9	–	–	–
LVEF, 1% decrease	1.035	1.002–1.068	0.04	1	0.950–1.053	0.99
BMI, 1-kg/m² decrease	1.071	0.955–1.2	0.24	–	–	–
LDIE as an indication for TLE	23.375	7.843–69.668	<0.001	3.307	0.843–12.966	0.09
Hemoglobin, 1-g/dl decrease	2.024	1.572–2.604	<0.001	1.642	1.178–2.278	0.003
CCI, 1-point increase	2.274	1.614–3.203	<0.001	1.836	1.193–2.827	0.006
Number of extracted leads at the index procedure, 1-lead increase	4.583	2.171–9.672	<0.001	3.441	1.330–8.903	0.01
Total age of extracted leads, 1-year increase	0.989	0.938–1.044	0.7	–	–	–
Dual-coil ICD lead extraction	3.035	0.835–11.034	0.09	1.979	0.308–12.73	0.47
Total fluoroscopy time during all lead extractions, 1-minute increase	0.92	0.77–1.1	0.36	–	–	–
Major complications of TLE	5.358	0.63–45.588	0.12	–	–	–

Abbreviations: CCI, Charlson Comorbidity Index; OR, odds ratio; others, see **TABLE 1**

a careful consideration of the pros and cons of lead abandonment and extraction, in line with patient preferences.[17] This process was in line with the current expert consensus statement.[2]

The tendency toward a higher frequency of noninfectious indications for TLE was previously noted in other Polish centers.[18,19] Our results, like the previous publication from Poland,[6] show that patients over 80 years were referred for TLE due to infection more frequently than younger patients, who underwent TLE predominantly due to noninfectious causes. On the contrary, Rodriguez et al[7] reported that the number of infectious indications for TLE was similarly distributed in young and elderly patients.[7] As suggested by Kennergren et al,[10] it may indicate that elderly patients are less likely to be offered TLE due to noninfectious indications and may be treated conservatively.[10]

Regarding the prevalence of LI in our study, this type of device-related infection dominated among octogenarians, whereas other investigators observed no significant difference between both groups.[5,6] In our study, a higher prevalence of women in octogenarians compared with the younger group did not reach significance, presumably due to a low number of octogenarians. It has been reported previously that women prevail in the elderly population.[5-7] As expected, the longer life expectancy in women compared with men is a likely explanation. In line with other studies, octogenarians were in better cardiovascular condition reflected by the NYHA class and LVEF as well as had fewer ICDs implanted than younger patients.[5,7]

Octogenarians in our study had significantly lower hemoglobin levels and higher morbidity assessed by the CCI, which is in agreement with previous reports.[5,7,8] Similarly to the data published by other Polish authors, a significantly higher number of ICD leads were extracted in younger patients.[6] Our data are in line with the studies by Kutarski et al[6] and Williams et al[8] with regard to a similar age of extracted leads in both groups. On the other hand, the literature provides conflicting results with a shorter lead dwell time in elderly patients compared with younger ones (29 months vs 42 months; $P = 0.03$) shown by Pelargonio et al[5] as opposed to a longer lead dwell time (59.6 months vs 38.6 months; $P = 0.04$) reported by Rodrigez et al.[7]

The total fluoroscopy time during extraction of all leads was longer in younger patients than in octogenarians. In our opinion, it was related to longer fluoroscopy time during ICD lead extraction in the younger group compared with octogenarians (2.5 min vs 1.2 min; $P = 0.049$) and a higher prevalence of ICD leads in the younger group (21.7% vs 11.6%; $P = 0.006$). As reported in the literature, removing ICD leads, particularly the dual-coil ones, increases fluoroscopy time and requires more advanced equipment.[13] The fluoroscopy time only during the PPM lead extraction was similar in both groups. As shown in our previous study, the older age of leads is also a major predictor of long fluoroscopy during TLE,[17] whereas in the current study, we observed a similar age of extracted leads in both groups. No reports concerning fluoroscopy time in a population divided by age can be found in the available literature.

As observed in the previous trials, both younger and older patients required similar lead extraction techniques.[5,7,8]

The complete procedural success rates were 97.8% in octogenarians and 96% in younger patients, which is in line with the findings of other authors: Pelargonio et al[5] reported 97% and 96%, respectively ($P = 0.39$), and Kutarski et al,[6] 97.4% and 94.6%, respectively ($P = 0.14$). Lower rates of complete procedural success were reported by

Williams et al[8]: 91.7% in elderly patients vs 91.3% in younger ones. Bongiorni et al[9] noted complete clinical and radiological success rates in 96.7% of older patients and 95.7% of younger ones. The findings from the ELECTRa registry and the study by Bongiorni et al[9] are in agreement with our results. Importantly, the ELECTRa registry has not been analyzed in terms of complete clinical and radiological success in a population divided by age.

The percentage of major and minor complications was similar in octogenarians and younger patients, amounting to 1.3% and 1.5%, respectively ($P = 0.45$). Pelargonio et al[5] reported the rates of 1.1% for major (2% in elderly patients and 0.9% in younger ones) and 3.1% for minor complications (4% in elderly patients and 2.9% in younger ones). Kutarski et al[6] observed major complications in 1.56% of elderly patients and 1.51% of younger ones ($P = 0.79$), and minor complications, in 1% of elderly patients and 1.88% of younger ones ($P = 0.6$). Furthermore, Rodriguez et al[7] demonstrated no significant difference in the rate of minor ($P = 0.65$) and major ($P = 0.56$) complications between elderly and younger patients. On the contrary, Williams et al[8] reported a higher rate of complications in elderly patients compared with younger ones ($P = 0.01$). In the multivariate logistic regression analysis, they showed that the octogenarian status was associated with a 6.45-fold higher OR of complications (major and minor). In the prospective multicenter ELECTRa registry, the procedure-related major and minor complication rates were 1.7% and 5%, respectively. In general, the complication rates are comparable to our results in terms of major complications and markedly higher for minor complications.[9] Importantly, the subanalysis of the ELECTRa registry with regard to patients' age has not been conducted so far.

We reported 1 case of procedure-related death in the entire study population (0.15%), which occurred in a woman from the younger group (0.2%). No procedure-related deaths were recorded in octogenarians. Similar results were shown by Rodrigez et al,[7] with 1 death in the nonoctogenarian group. A slightly larger number of periprocedural deaths was noted by Pelargonio et al[5]; however, the mortality rate was comparable between younger and older patients (0.7% vs 1.3%; $P = 0.45$). No intraprocedural deaths occurred in the groups of younger and elderly patients in the study by Williams et al.[8] Moreover, Kutarski et al[6] reported 4 cases of death (0.31%) in the periprocedural period in 1252 patients undergoing TLE.[6] Additionally, the procedure-related mortality in our study is in line with another large prospective analysis on TLE. In the ELECTRa registry, there were 17 procedure-related deaths (0.5%; 1% in low-volume centers and 0.4% in high-volume centers).[9] Brunner et al[11] reported a total of 11 procedure-related deaths (0.4%), including 6 intra- and 5 postoperative ones. In a recently published registry of 11 304 TLE procedures (8632 high-voltage and 2942 pacing lead extractions), performed in 762 centers, the authors reported a mortality rate of 0.12% during TLE,[20] which is comparable with our findings.

Similarly to the reports of other authors, all-cause mortality within 30 days after TLE was 2.4% in our study. Gould et al[21] reported a 30-day all-cause mortality rate of 2.3% in 925 patients, Williams et al,[8] a rate of 2.5% (10 patients in 406 procedures), and Brunner et al[22] showed an even lower rate of 2.2%. Of note, the latter analysis included patients with a mean lead dwell time of 4.7 years, whereas in our study the lead dwell time was markedly longer and amounted to 6.5 years. On the other hand, Deckx et al[23] showed higher mortality (3.4%) within 1 month after the procedure.

We noted that octogenarians had higher 30-day all-cause mortality than the younger group. One in 20 octogenarians did not survive 1 month after TLE due to various causes. In the univariable analysis, the risk factors for all-cause 30-day mortality, apart from the octogenarian status, were reduced LVEF, LDIE as an indication for TLE, low hemoglobin levels, higher CCI, and the number of extracted leads at the index procedure. In the multivariable analysis, the independent risk factors for increased 30-day all-cause mortality were low hemoglobin levels, higher CCI, and the number of extracted leads at the index procedure. Williams et al[9] did not demonstrate higher 30-day all-cause mortality in elderly patients; however, all cases of death occurred in patients undergoing extraction of infected devices and were attributable to overwhelming sepsis.[9] Previous studies also showed that sepsis (systemic infection) accounted for the majority of deaths within 30 days after TLE.[21-23] In our study, the multivariable analysis showed only a trend toward a higher 30-day mortality rate in patients with LDIE in octogenarians. The stronger association of LDIE with mortality in this group in the univariable as compared with multivariable analysis (OR, 23.375; $P < 0.001$ vs OR = 3.307; $P = 0.09$) showed the modifying effect of multimorbidity.

Gould et al[21] and Brunner et al[22] demonstrated that the age of patients at the index TLE procedure was associated with a higher risk of periprocedural death in the univariable analysis. Interestingly, the ELECTRa registry analysis showed that the age above 68 years was one of the predictors of increased all-cause mortality during hospitalization (OR, 2.42; $P = 0.008$).[9]

In agreement with our results, in the study by Brunner et al,[22] reduced LVEF in the univariable analysis was a predictor of periprocedural death; however, in the multivariable analysis, it tended to be related to higher mortality (OR, 1.7; $P = 0.148$). Anemia proved to be independently associated with increased mortality, which corresponds with previous reports. Brunner et al[22] showed a 3-fold increase of mortality in patients with low hemoglobin levels.

Furthermore, Deckx et al[23] noted a trend toward higher mortality in patients with anemia (OR, 2.024; P = 0.082). Several authors established that impaired renal function was associated with increased 30-day mortality.[8,21,23] However, in our study, the CCI was associated with 30-day survival. The index reflects the morbidity status and adds 2 points for moderate to severe renal disease. In the analysis of acute coronary syndrome in 30 711 patients from 69 Swiss hospitals (AMIS Plus—National Registry of Acute Myocardial Infarction in Switzerland), Radovanovic et al[24] concluded that the CCI seems to be an appropriate prognostic indicator for in-hospital and 1-year outcomes.

Brunner et al[11,22] noted in the multivariable analysis that the extraction of a dual-coil ICD lead was a predictor of all-cause mortality within 30 days of TLE. Our study showed that the extraction of a dual-coil ICD lead also tended to be related to higher mortality (OR, 3.035; P = 0.09) in the univariable analysis. In line with these findings, our previous analysis showed that the extraction of dual-coil ICD leads was as safe and effective as the extraction of a single-coil ICD lead, but it required longer fluoroscopy time and frequent use of advanced tools.[13] Importantly, the number of extracted leads at the index procedure was associated with an increased all-cause mortality rate within 30 days after TLE both in univariable and multivariable analyses.

A higher morbidity status of octogenarians may explain higher 30-day mortality in this group compared with the younger group. The elderly age is a well-known predictor of both in-hospital and outpatient mortality. In patients who underwent primary percutaneous coronary intervention for ST-segment elevation myocardial infarction, Ipek et al[25] showed that octogenarians had a 10.6-fold higher risk of in-hospital mortality compared with younger patients. Additionally, after the adjustment for all potential risk factors, the age of 80 years and older was associated with in-hospital mortality (OR, 8.37; 95% CI, 2.33–30.03; P = 0.001). Other investigators have also demonstrated a significant association between age and 30-day mortality after ST-segment elevation myocardial infarction.[26]

Uncertain outcomes following TLE in elderly patients, in particular in those undergoing the procedure due to noninfectious indications, remain unclear. As shown in our study, octogenarians with multiple comorbidities, anemia, and certain predictors of high procedural risk, such as a large number of targeted leads, appear to be less likely to benefit from TLE. On the other hand, octogenarians in good overall condition and without major adverse events who were referred for single lead extraction are likely to have favorable short-term outcomes. Nonetheless, the dilemma which subset of patients should not be referred for TLE due to poor postprocedural 30-day prognosis still needs to be explored in further multicenter studies.

Study limitations We acknowledge that our study has several important limitations. First, we analyzed a relatively small sample of octogenarians and conducted the study in a single center. Second, no comparison was made between mechanical systems (dilator sheaths and the Evolution system) and other techniques currently used for TLE, as we used mechanical systems only. Third, the follow-up was limited to a 30-day postprocedural period.

Conclusions In conclusion, the octogenarians in our study, compared with younger patients, had more comorbidities and underwent TLE more frequently due to infection. We showed that TLE is effective and safe, and the outcomes are similar to those obtained in patients at a younger age.

The adverse event and procedural success rates were similar for octogenarians and younger patients. We observed a higher 30-day all-cause mortality within 30 days after TLE in octogenarians, which was associated with higher morbidity and lower hemoglobin levels. In this subgroup of patients, the potential benefits of the procedure should be considered against the high risk of unfavorable short-term outcomes following complex TLE for indications other than infection.

ARTICLE INFORMATION

CONTRIBUTION STATEMENT AZ conceived the concept and design of the study, collected data, performed statistical analysis, interpreted data, and wrote the manuscript. KB, MD, RP, MU, KH, MK, RM, and JL collected data and critically revised the article for important intellectual content. BM collected and interpreted data, critically revised the article for important intellectual content, and approved its final version for submission. All authors approved the final version of the article.

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