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Indications, procedural and early results of transvenous lead extraction in elderly patients: single-centre experience

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Short title: TLE in elderly patients.

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“What’s new?”

Our study evaluated the indications, effectiveness, safety and 30-day follow-up of transvenous lead extraction (TLE) in patients younger and older than 80 years old. The octogenarians had more comorbidities than the younger group and had TLE more frequently due to infectious indications compared to young patients. TLE procedure is effective and safe and the outcomes are similar to those obtained in patients with younger age. The complication rates and the procedural success rates were similar for octogenarians and younger patients. The fundamental difference is the increased all-cause mortality of octogenarians in 30-day follow-up after TLE, what was linked to higher morbidity status and lower Hb. This subgroup of patients requires cautious weighting of potential benefits against the high risk of unfavorable short-term following complex TLE for non-infectious indications.
Abstract:

Introduction:

Due to prolonged survival of patients with cardiovascular implantable electronic devices, there is often a need to remove the leads in elderly patients.

Objectives:

To analyze the indications, effectiveness, safety and 30-day follow-up of transvenous lead extraction (TLE) in patients younger (YP) and older than 80 years old (EP).

Patients and Methods:

This prospective study included 667 patients, who underwent TLE. There were 90 (13.5%) EP with mean age of 83.8, range 80.4–93 years and 577 YP with mean age of 64.2, range 18.9–79.9 years.

Results:

EP had a greater number of comorbidities, had less ICD systems and had more frequently infectious indications for TLE than YP (33.3% vs 17.1%, P <0.001).

A hundred and thirty-eight leads were extracted in EP and 894 in YP. Complete lead removal and complete procedural success in both groups were similar (98.6% in EP vs 97.1% in YP, P = 0.48 and 97.8% in EP vs 96.0% in YP, P = 0.70, respectively). We did not find significant difference between major and minor complication rates in both groups (0.0% in EP vs 1.6% in YP, and 2.2% in EP vs 1.6% in YP, P=0.45, respectively). There was one death associated with TLE procedure in YP. Non-procedure-related deaths within 30 days after the procedure were more frequent in EP compared to YP (5.6% vs 1.9%, P = 0.04).

Conclusion:

This study shows that TLE in EP seems to be comparably safe and effective as in younger patients, however it is associated with significantly higher non-procedure-related 30-day mortality.
Key Words: cardiovascular implantable electronic devices; effectiveness; elderly; safety; transvenous lead extraction
Introduction:

Transvenous lead extraction (TLE) is the cornerstone in management of CIED related complications [1-3]. Due to prolonged survival of patients with CIED, frequently there is need to remove leads in elderly patients. An aging population and a growing proportion of older persons with multiple chronic comorbidities pose new challenges for clinical practice [4]. Elderly patients may have worse outcomes of TLE compared to younger patients due to frailty, higher morbidity and risks related to general anaesthesia.

In the available literature the data has mostly unanimously showed lack of difference between octogenarians and younger patients in terms of TLE results [5-7], however there remain some controversies. Williams et al. indicated that overall rate of complications was higher in octogenarians [8]. Furthermore, prospective multi-centre European ELECTRa registry of TLE procedures showed that one of predictors of increased all-cause mortality during hospitalization is age >68 years [9]. Additionally, Kennergren et al. reported that a low number of patients with Class II indications for TLE were not extracted because of advanced age [10]. Brunner et al. observed that patients at age over 65 years influenced major complications and major cardiovascular injury. It has been the first reported observation that patients over 65 years old had higher 30-day mortality following transvenous lead extraction [11].

In the light of the conflicting evidence we were prompted to conduct a prospective single-centre analysis on the relationship between patients' age and outcome of TLE with particular focus on relation between 30-day mortality and risk factors.

Patients and methods

We aimed to analyse the indications, effectiveness, safety and all-cause mortality within 30 days after TLE in patients younger and older than 80 years old.
We performed a prospective analysis (case-control study) of the records of all patients who underwent TLE from October 2011 to April 2019. The study protocol was approved by Research and Ethics Committee of Jagiellonian University: decision no. KBET/259/B/2011. 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 and complied with the principles of the Good Clinical Practice guidelines.

Patients with pacemaker or implantable cardioverter-defibrillator leads implanted less than one year before TLE were excluded from the analysis.

The population was divided into 2 groups based on age at the time of the procedure: group YP (young patients) comprised patients younger than 80 years old and group EP (elderly patients) included patients over 80 years old.

Transvenous lead extraction was performed only in patients expected to survive at least 12 months. Elderly patients with who lacked capacity to consent for the TLE due to brain damage, dementia etc. were managed conservatively. On the other hand, in case of infectious indication such patients were routinely referred to the Court of Protection for a ruling.

Data were collected from the patients’ notes created at the time of device implant, records from follow-up appointments at outpatient cardiology clinics and medical information from the index admission for TLE procedure and 30 days after TLE procedure.

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

The CCI takes into account the presence of 19 diseases weighted on the basis of their association with mortality [12]. CKD-EPI equation was used to calculate eGFR. Indications for TLE were divided into three categories: lead-dependent infective endocarditis (LDIE), isolated local infection (LI) and non-infectious indications. LDIE was diagnosed on the basis of Modified Duke Leads Criteria, whereas LI was diagnosed on the basis of local inflammatory signs confined to device pocket: erythema, warmth, pain, swelling, wound dehiscence, purulent discharge, skin erosion or sinus formation. When both LDIE and LI were present, LDIE was used as the primary indication for TLE.

In addition, both groups were analyzed and compared in terms of percentage of unipolar leads, percentage of passive fixation leads, percentage of non-functional/abandoned leads, age of extracted leads, age of the oldest extracted lead, combined age of extracted leads (sum of extracted leads dwell time per procedure [years]), number of extracted leads during TLE, fluoroscopy time during TLE, techniques used during TLE, effectiveness of TLE, complete/incomplete lead removal for each lead removed, complications occurring during intra-operative and 30-day post-operative period.

The effectiveness of TLE procedures was divided into 3 categories (complete success, clinical success or failure) according to current HRS and EHRA consensus [1-3]. 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 [1-3]. For each lead removed, the efficacy (complete or incomplete) according to the EHRA consensus was determined [3]. Complete lead removal was defined as lead explant or extraction with removal of all targeted lead material, whereas incomplete lead removal refers to lead explant or extraction where part of the lead remains in the patient’s body (vascular or extravascular) [3]. We recorded complications occurring during intra-operative and within 30-day post-operative period and classified as two types in accordance with HRS and EHRA consensus [1-3].

**TLE procedure:**

The description of TLE procedure has been presented previously [13]. 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 externalised 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 ICD reimplantation [15].

**Statistical analysis**

The analysis was performed using StatSoft Statistica version 13.1 (StatSoft, Tulsa, Oklahoma, USA). Continuous variables are expressed as mean (SD) and additionally as median and interquartile range (IQR). Shapiro–Wilk W test was used to assess the continuous variables normality. Comparisons of two groups of continuous variables were performed with Student’s t-tests of unpaired samples, and in case of non-normality or small sample size, the U Mann–Whitney test was used. The categorical variables were presented as the number of
observations in each category and the percentage of observations in this category. Categorical variables were compared with Chi-square tests, Chi-square test with Yates continuity correction, or Fisher’s exact test as appropriate. Uni- and multivariable logistic regression was performed to determine independent predictors of 30-day mortality. Odds ratios (OR) with 95% confidence interval (95% CI) were used to present the impact of independent variables on 30-day mortality. Predictors with univariable analysis of $P < 0.1$ were selected for multivariable logistic regression analysis. All statistical tests were 2-tailed and a $p$-value $< 0.05$ was considered statistically significant.

**Results**

We identified 667 patients at mean (SD) age of 66.9 (13.4), range, 18.9–93.0 years, including 240 (36.0%) women. TLE was performed due to LDIE (67 patients), LI (62 patients) and non-infectious indications (538 patients). LDIE and LI coexisted in 21 patients. There were 90 (13.5%) patients in EP group at mean age of 83.8, range, 80.4–93 and 577 in YP group at mean age 64.2, range 18.9–79.9.

Clinical characteristics of patients in EP group and patients in YP group are shown in Table 1. Female patients were more prevalent in EP group compared to YP group (44.4% vs 34.7%, $P = 0.07$). Elderly patients had on average higher LVEF, creatinine and lower NYHA class. BMI, Hb, and eGFR were statistically significantly lower in senior group – Table 1. Both groups significantly differed in terms of type of implanted devices. Proportion of patients with pacemakers was higher in EP group, whereas proportion of patients with cardiac resynchronisation therapy and implantable cardioverter defibrillators was higher in YP group ($P < 0.001$) – Table 1.

Patients with device infection (LDIE and/or LI) were twice more prevalent in seniors compared to younger patients (33.3% vs 17.1%, $P < 0.001$) – Table 1. Study groups did not differ in terms of prevalence of diabetes, coronary artery disease and number of previously
performed device-related procedures (Table 1). Overall morbidity measured with CCI was statistically significantly higher in EP group relative to YP group (2.4 vs 2.0, P = 0.02).

The total number of extracted leads in both groups amounted to 1032 (138 leads in EP group and 894 leads in YP group). Comparison of extracted leads and results of TLE procedures in both groups are shown in Table 2. In YP group the percentage of ICD extracted leads was higher than in EP group (21.7% vs 11.6%, P = 0.006).

In both groups there was similar proportion of unipolar pacing leads, passive fixation, abandoned leads, patients in whom three or more leads were extracted and number of extracted leads at index procedure – Table 2. Additionally, mean age of extracted leads, age of extracted pacing and ICD leads, oldest extracted leads, combined age of all extracted leads was comparable in both groups (Table 2).

Complete lead removal rates in both groups were similarly high (98.6% vs 97.1%, P = 0.48). We did not observe differences between the groups in the use of extraction tools (P = 0.43).

The time of a single PPM or ICD lead extraction was longer in YP group compared to EP group, however the difference did not reach statistical significance (P = 0.08). Fluoroscopy time of PPM/ICD lead extraction and fluoroscopy time of ICD lead extraction were longer in YP group compared to EP group – Table 2. Fluoroscopy time of PPM lead extraction was comparable in both groups - Table 2.

The effectiveness of procedures in the whole population was high and comparable in both groups (P = 0.70). Complete procedural success was achieved in 642 patients (96.3%), clinical success in 15 patients (2.2%) and failure occurred in 10 patients (1.5%). In EP group complete success was achieved in 97.8%, while in YP group in 96.0% of patients.

In the entire study group, there were eleven (1.5%) minor complications and nine (1.3%) major complications. The safety of TLE procedures in both groups was similar (P = 0.45). In EP group, there were two minor complications and no major complications.
In YP group minor and major complications occurred at an equal percentage 1.6%.

All-cause mortality within 30 days after TLE was 2.4% (16 patients) and there was a statistically significant difference between both groups (5.6% in EP group vs 1.9% in YP group, \( P = 0.04 \)) – Table 2. Among patients who died, eleven had LDIE (3 in EP group and 8 in YP group; all died due to severe heart failure or sepsis whilst being on antibiotic therapy). One patient died due to complications after a fall and resultant hemorrhage to pleural cavity (in EP group, after TLE due to LI).

Four deceased patients had non-infectious indication for TLE. Three patients in YP group died due to the following reasons: one patient died during TLE procedure, one due to heart failure after cardiac surgery, and one due to thromboembolic events. One patient in EP group died due to thromboembolic events.

The association between selected factors and 30-day all-cause mortality following TLE is presented in Table 3. Factors entered into univariable analysis for 30-day mortality included: EP vs YP group, gender, LVEF, BMI, LDIE indication for TLE, Hb, CCI, number of extracted leads at index procedure, combined age of extracted leads, presence of dual-coil ICD lead extracted, total fluoroscopy time during all leads extracted, presence of major complication of TLE.

Univariable analysis showed that EP group (OR 3.027), lower LVEF (OR 1.035 per 1%), LDIE indication for TLE (OR 23.375), lower Hb (OR 2.024 per 1g/dL), higher CCI (OR 2.274 per 1 point) and number of extracted leads at index procedure (OR 4.583 per 1 lead), were statistically significant predictors of 30-day mortality. On multivariable analysis, only lower Hb (OR 1.642 per 1g/dL), higher CCI (OR 1.836 per 1 point) and number of extracted leads at index procedure (OR 3.441 per 1 lead), remained statistically significant. The results of the statistical analysis are presented in Table 3. Patients with LDIE indication for TLE had
similar 30-day all-cause mortality in both analyzed groups (60.0% in EP vs 72.7% in YP; P = 0.94).

**Discussion**

The current state of knowledge regarding safety, effectiveness and especially survival after TLE in elderly patients is not yet conclusive. In our study cohort non-infectious indications in whole group were present in 80.7% of the patients. Observed low rate of TLE due to infection results from our strategy to rigorously treat pacing-related complications and is consistent with our previous reports [16]. The decision whether or not to perform TLE procedure was based on careful consideration with patient to pros and cons of lead abandonment and lead extraction [17]. This process was in line with the current expert consensus statement [2]. The tendency towards higher frequency of non-infectious indications for TLE was noted previously in other centers in Poland [18, 19]. Our results, like the previous publication from Poland [6], show that patients over 80 years old were referred for TLE more frequently due to infectious indications as compared to younger patients who underwent TLE predominantly due to non-infectious reasons. On the contrary, Rodriguez et. al. reported that the proportion of infectious indications was similarly distributed in young and elderly patients [7]. As suggested by Kennergren et al., it may indicate that elderly patients are less likely to be offered TLE due to non-infectious indications and may be treated conservatively [10].

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

Elderly patients had significantly lower Hb and higher morbidity status assessed by CCI, which is in agreement with previous reports [5, 7, 8]. Similarly to the experience of other Polish authors, there were statistically significantly more ICD leads extracted in YP [6]. Our data concurs with Kutarski et al. and Williams at al. with regard to the similar age of extracted lead in both groups [6, 8]. On the other hand, literature provides discrepant results with shorter lead dwell time in EP compared to YP (29 vs 42 months, \(P = 0.03\)) shown by Pelargonio et al. [5] as opposed to longer lead dwell time (59.6 months vs 38.6 months, \(P = 0.04\)) reported by Rodriguez et al. [7].

Total fluoroscopy time during all leads extraction was significantly longer in YP group compared to EP group (\(P = 0.02\)). In our opinion it was related to longer fluoroscopy during ICD lead extraction in YP relative to EP (2.5 min vs 1.2 min, \(P = 0.049\)) and higher prevalence of ICD leads in YP group (21.7% vs 11.6%; \(P = 0.006\)). As is known, removing ICD leads, especially dual-coil ones, increases fluoroscopy time and the use of more advanced equipment [13]. The fluoroscopy time during only PPM leads was similar in both groups. As our previous study shows, the older age of the leads is also a major predictor of long fluoroscopy during TLE [17], while in the current study we observed similar age of extracted lead in both groups. There are no reports concerning fluoroscopy time in age wise divided population in available literature.

As observed in previous trials both groups required utilization of similar extraction techniques [5, 7, 8].

Complete procedural success amounted to 97.8% in EP and 96.0% in YP and was in line with other authors’ observations: Pelargonio et al. achieved 97% and 96%, \((P = 0.39)\) [5] and
Kutarski et al. 97.4% and 94.6% (P = 0.14), respectively [6]. Lower rates of complete procedural success were reported by Williams et al. - 91.7% in EP vs 91.3% in YP [8]. Bongiorni et al. noted complete clinical and radiological success rates of 96.7% and 95.7%, respectively. Findings from ELECTRa registry and study by Bongiorni et al. are in agreement with our results [9]. Importantly, ELECTRa registry has not been analyzed in terms complete clinical and radiological success in age wise divided population.

Major and minor complications amounted to 1.3% and 1.5% and were similar in EP group and YP group (P = 0.45). Pelargonio et al. reported 1.1% rate of major (2.0% in EP group and 0.9% in YP group) and 3.1% rate of minor complications (4.0% in EP group and 2.9% in YP group) [5], Kutarski et al. observed major complications in 1.56% of patients in EP group vs 1.51% in YP group, P = 0.79, and minor complications in 1.0% of patients in EP group vs 1.88% in YP group, P = 0.60 [6]. Furthermore, Rodriguez et al. demonstrated that there was no statistically significant difference in the proportion of minor (P = 0.65) and major (P = 0.56) complications between EP group and YP group [7]. On the contrary, Williams et al. reported higher rate of complications in EP group relative to YP group (P = 0.01) [8]. In multivariate logistic regression analysis they demonstrated that octogenarian status was associated with 6.45-fold higher odds ratio of a complications (major and minor). In a prospective multi-centre European ELECTRa registry procedure-related major and minor complications rates were 1.7% and 5.0%. In general, the adverse events rates are comparable to our results in terms of major complications and markedly higher in terms of minor complications [9]. Importantly, the subanalysis of ELECTRa registry with regard to patients’ age has not been conducted.

There was one procedure-related death in the entire population (0.15% of total population) and occurred in a female patient in YP group (0.2% pts of YP group). We did not observe any procedure-related deaths in EP group. Similar results were shown by Rodriguez et al. with one
death in the nonoctogenarian group [7]. Slightly larger number of peri-procedural deaths was noted by Pelargonio et al., however the incidence of deaths was comparable in YP and EP groups (0.7% vs 1.3%, P = 0.45) [5]. No intra-procedural deaths occurred in EP and YP groups in the study by Williams et al. [8]. Moreover, Kutarski et al. reported 4 deaths (0.31%) in the peri-procedural period among 1,252 patients undergoing TLE [6]. Additionally, the procedure-related mortality is in line with other large prospective analysis on TLE. In ELECTRa registry there were 17 (0.5%) procedure-related deaths (1.0% in low volume centers and 0.4% in high volume centers) [9]. Brunner et al. reported a total of 11 (0.4%) procedure-related deaths, including 6 intra-operative and 5 post-operative [11]. In a recently published registry of 11,304 TLE procedures (8,632 high-voltage lead extraction and 2,942 pacing lead extraction procedures) performed in 762 centres authors reported 0.12% deaths during TLE procedure [20], which is comparable to our outcomes. Similarly to the reports of other authors, our all-cause mortality within 30 days after TLE was 2.4%. Gould et al. in the group of 925 patients reported 2.3% 30-day all-cause mortality [21], Williams et al. demonstrated 2.5% 30-day all-cause mortality (10 patients in 406 procedures) [8], and Brunner et al. showed even lower rate of 2.2% [22]. Noteworthy, the latter analysis included patients with a mean lead dwell time of 4.7 years, whereas our patients’ lead dwell time period was markedly longer and amounted to 6.5 years. On the other hand, higher mortality (3.4%) within 1 month of a procedure showed Deckx et al. [23]. It was noted that EP had higher 30-day all-cause mortality than younger patients. One in twenty octagenarians did not survive one month after TLE for various indications. In univariable analysis the risk factors for all-cause 30-day mortality apart from EP status were reduced LVEF, LDIE indication for TLE, low Hb, higher CCI and the number of extracted leads at index procedure. In multivariable analysis the independent risk factors for
increased 30-day all-cause mortality were low Hb, higher CCI and number of extracted leads at index procedure.

Williams et al. did not demonstrate higher 30-day all-cause mortality in EP group, however all deaths occurred in patients undergoing extraction of infected systems 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 present study the multivariable analysis showed only a trend towards greater 30-day mortality in EP patients with LDIE. The stronger association of LDIE with mortality among EP in univariable analysis compared to multivariable analysis (OR = 23.375, P <0.001 vs OR = 3.307, P = 0.09) is showing the modifying effect of multimorbidity.

Gould et al. and Brunner et al. indicated that the age of patients at index TLE was associated in univariable analysis with a higher risk of peri-procedural death [21, 22]. Interestingly, ELECTRa registry analysis showed that among the predictors of increased all-cause mortality during hospitalization was age > 68 years (OR 2.42; P = 0.008) [9]. In agreement with our results, Brunner et al. demonstrated that reduced LVEF in univariable analysis was a predictor of peri-procedural death, however in multivariable analysis it tended to be related with a higher mortality, but this was not statistically significant (OR 1.7; P = 0.148) [22]. The parameter that proved to be independently associated with increase in mortality was anaemia, which is in agreement with previous reports. Brunner et al. showed 3-fold increase of mortality in patients with low Hb [22]. Furthermore, Deckx et al. noted a trend toward a higher mortality in patients with anaemia, but this was not significant (OR 2.024; P = 0.082) [23]. Several authors established that renal impairment was associated with an increased risk of 30-day mortality [8, 21, 23]. However, in present study CCI proved to be associated with 30-day survival and the index reflects morbidity status and adds two points for moderate to severe renal disease. The analysis on acute coronary syndrome in 30,711
patients from 69 Swiss hospitals (AMIS Plus registry) Radovanovic et al. concluded, that CCI seems to be an appropriate prognostic indicator for in-hospital and 1-year outcomes [24]. Brunner et al. noted in multivariable analysis that extraction of a dual-coil ICD lead was a predictor for all-cause mortality within 30 days of TLE [11, 22]. Present study showed that extraction of a dual-coil ICD lead also tended to be related to a higher mortality, but this was not significant (OR 3.035; P = 0.09) in univariable analysis. In keeping with the above-mentioned findings our previous analysis showed that extraction of dual-coil ICD leads appeared to be comparably safe and effective to extraction of single-coil ICD, but required longer fluoroscopy time and frequent utilization of advanced tools [13]. Importantly, number of extracted leads at index procedure was associated with increased rate of all-cause mortality within 30 days of TLE both in univariable and multivariable analysis. Regarding the higher 30-day mortality in EP group compared to YP group we presume that the likely explanation of this phenomenon is a higher morbidity status of the elderly patients. Elderly age is a well-known predictor of both in-hospital and outpatient mortality. Ipek et al. showed in patients who underwent primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (STEMI) that octogenarians had 10.6-fold higher in-hospital mortality risk compared to younger patients [25]. Additionally, after adjustment for all potential risk factors, age ≥80 years was significantly associated with in-hospital mortality (OR 8.37, 95% CI 2.33–30.03, P = 0.001). Other investigators have also demonstrated significant association between age and 30-day mortality after STEMI [26]. Uncertainty of the outcome following TLE in elderly patients, in particular for non-infectious indications, remains without definite answer. Based on the present study, those who appear to be less likely to derive benefit from TLE are elderly patients with multiple comorbidities, anaemia and certain factors for high procedural risk such as large number of targeted leads. On the other hand, elderly patients in good overall condition and without major comorbidities
referred for single lead extraction are likely to have favourable short-term outcomes.

Nonetheless, the dilemma what subset of patients should not be referred for TLE due to poor post-procedural 30-day prognosis still warrants exploration in further multicentre studies.

We acknowledge several important limitations of our study: 1. The main study limitation is a relatively small sample of elderly patients and single-centre set-up. 2. No comparison was made between mechanical systems (dilator sheaths and Evolution system) and other techniques currently used for TLE because the authors used exclusively mechanical systems. 3. The follow-up was limited to 30-day post-procedural period.

In conclusion, the octogenarians had more comorbidities than the younger group and had TLE more frequently due to infectious indications compared to young patients. TLE procedure is effective and safe and the outcomes are similar to those obtained in patients with younger age. The complication rates and the procedural success rates were similar for octogenarians and younger patients. We observed higher 30-day all-cause mortality within 30 days of TLE in elderly patients what was linked to higher morbidity status and lower Hb. This subgroup of patients requires cautious weighting of potential benefits against the high risk of unfavorable short-term following complex TLE for non-infectious indications.
Contribution Statement:

AZ: the conception and design of the study, acquisition of data, statistical analysis, interpretation of data, writing the manuscript. KB, MD, RP, MU, KH, MK, RM, and JL: acquisition of data, revising article critically for important intellectual content. BM: acquisition of data, data interpretation and revising article critically for important intellectual content; final approval of the version to be submitted.

All authors have approved the final article.

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

| Variable                        | All patients (n=667) | EP group (n=90) | YP group (n=577) | P value |
|---------------------------------|----------------------|-----------------|------------------|---------|
| Age of pts., years              | 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                          | 240 (36.0) | 40 (44.4) | 200 (34.7) | 0.07    |
| LVEF, %                         | 43.6 (16.1); 45.0; 28.0 | 48.9 (12.8); 50.0; 20.0 | 42.8 (16.5); 45.0; 28.0 | 0.001   |
| NYHA class III or IV            | 169 (25.3) | 15 (16.7) | 154 (26.7) | 0.04    |
| BMI, kg/m²                      | 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   |
| Hb, 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, umol/l              | 100.9 (53.8); 91.0; 35.0 | 105.7 (32.6); 98.5; 35.0 | 100.2 (56.4); 89.0; 32.0 | 0.001   |
| eGFR, ml/min/1.73m²             | 68.1 (22.2); 69.0; 32.0 | 54.5 (16.6); 52.1; 25.0 | 70.3 (22.2); 71.0; 32.0 | <0.001  |
| Diabetes mellitus               | 221 (33.1) | 34 (37.8) | 187 (32.4) | 0.31    |
| Coronary artery disease         | 367 (55.0) | 57 (63.3) | 310 (53.7) | 0.09    |
| Charlson Comorbidity Index      | 2.1 (1.7); 2.0; 2.0 | 2.4 (1.6); 2.0; 3.0 | 2.0 (1.7); 2.0; 2.0 | 0.02    |

**Implanted device:**


|                  | Pacemaker | ICD       | CRT-P | CRT-D |
|------------------|-----------|-----------|-------|-------|
|                  | 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 (0.0)   | 11 (1.9)            |
| CRT-D            | 71 (10.6)\(^c\) | 5 (5.6)   | 66 (11.4)\(^c\)    |

**Indications for TLE:**

|                  | LDIE       | LI        | Non-infectious indications | Number of previously performed procedures |
|------------------|------------|-----------|----------------------------|-------------------------------------------|
|                  | 67 (10.0)  | 12 (13.3) | 60 (66.7)                  | 1.6 (0.9); 1.0; 1.0; 1.0                  |
|                  | 12 (13.3)  | 18 (20.0) | 478 (82.9)                 | 1.7 (0.9); 1.0; 1.0; 1.0                  |
|                  | 55 (9.5)   | 44 (7.6)  | 478 (82.9)                 | 1.7 (0.9); 1.0; 1.0; 1.0                  |

Data are presented as number (percentage) or mean (SD); median; IQR.

Abbreviations: BMI, body mass index; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; eGFR, estimated glomerular filtration rate; EP, elderly patients; Hb, hemoglobin; LDIE, lead-dependent infective endocarditis; LI, local infection; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; TLE, transvenous lead extraction; YP, young patients.

\(^a\) - 2 patients: in 1 patient – the lack of pacing system, remaining 2 leads after DDD pacemaker removal due to device pocket infection, in 1 patient - the lack of pacing system, remaining VDD lead after pacemaker removal due to non-infectious indication

\(^b\) - in 1 patient – the lack of pacing system, remaining ICD lead after unsuccessful lead removal in another centre

\(^c\) - in 1 patient – the lack of pacing system, remaining fragment of ICD lead after heart transplant
Table 2. Comparison of extracted leads and results of TLE procedures in both groups

| Variable                              | All patients (n=667) | EP group (n=90) | YP group (n=577) | P value |
|---------------------------------------|----------------------|-----------------|------------------|---------|
| Total number of extracted leads       | 1032                 | 138             | 894              |         |
| Number of extracted ICD leads         | 210 (20.3)           | 16 (11.6)       | 194 (21.7)       | **0.006**|
| Unipolar pacing leads                 | 70 (8.5)             | 5 (4.1)         | 65 (9.3)         | 0.07    |
| Passive fixation leads a              | 315 (30.5)           | 34 (24.6)       | 281 (31.4)       | 0.11    |
| Age of extracted lead (years)         | 7.5 (5.8); 6.0; 6.2 | 7.2 (5.2); 6.6; 5.1 | 7.6 (5.9); 6.0; 6.3 | 0.47    |
| Age of extracted pacing lead, years   | 8.0 (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 extracted ICD lead, years      | 5.5 (3.4); 5.0; 4.3 | 4.6 (2.3); 4.6; 3.5 | 5.6 (3.5); 5.1; 4.4 | 0.45    |
| Oldest extracted lead, years          | 7.9 (6.2); 6.1; 6.4 | 7.5 (5.5); 6.6; 5.2 | 8.0 (6.3); 6.0; 6.7 | 0.94    |
| Combined age of extracted leads, years| 11.6 (10.2); 8.3; 10.9 | 11.0 (9.3); 7.6; 10.3 | 11.7 (10.4); 8.4; 11.0 | 0.34    |
| Patients with one abandoned lead       | 26 (3.9)             | 5 (5.6)         | 21 (3.6)         | 0.56    |
| Patients with two abandoned leads      | 4 (0.6)              | 1 (1.1)         | 3 (0.5)          | 0.44    |
| Patients with 3 or more extracted     | 37 (5.5)             | 3 (3.3)         | 34 (5.9)         | 0.46    |
| leads                                 |                      |                 |                  |         |
| Number of extracted leads at index    | 1.5 (0.6); 1.0; 1.0  | 1.5 (0.6); 1.5; 1.0 | 1.5 (0.6); 1.0; 1.0 | 0.98    |
| procedure                             |                      |                 |                  |         |
| Leads:                                |                      |                 |                  |         |
| 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) |
|-------------------------|---------|--------|---------|

**Finally used techniques:**

| Technique                        | 233 (22.6) | 38 (27.5) | 195 (21.8) |
|----------------------------------|------------|----------|------------|
| Simple traction                  | 754 (73.1) | 93 (67.4) | 661 (74.0) |
| Telescopic sheaths               | 22 (2.1)   | 3 (2.2)  | 19 (2.1)   |
| Femoral access                   | 23 (2.2)   | 4 (2.9)  | 19 (2.1)   |

**Evolution mechanical system**

| Fluoroscopy time during single pacing or ICD lead removal, min a | 2.1 (3.6); 1.1; 1.8; 2.2 (3.7); 1.0; 1.5; 1.1; 1.8 |
|------------------------------------------------------------------|---------------------------------------------------|
| Fluoroscopy time during single pacing lead removal, min a       | 2.0 (3.4); 1.0; 1.8; 1.9 (2.9); 1.0; 1.6; 2.1 (3.5); 1.0; 1.8 |
| Fluoroscopy time during single ICD lead removal, min            | 2.4 (4.1); 1.3; 1.7; 1.2 (1.2); 1.0; 1.6; 2.5 (4.3); 1.3; 1.9 |

**Total fluoroscopy time during all leads removal, min**

| 3.3 (5.2); 1.7; 2.7; 2.8 (5.0); 1.1; 2.5; 1.8; 2.8 |

**Procedures:**

| Complete success | 642 (96.3) | 88 (97.8) | 554 (96.0) |
| Clinical success | 15 (2.2)   | 1 (1.1)   | 14 (2.4)   |
| Failure          | 10 (1.5)   | 1 (1.1)   | 9 (1.6)    |

**Complications:**

| No complications | 648 (97.2) | 88 (97.8) | 559 (96.8) |
| Minor complications | 11 (1.5) | 2 (2.2) | 9 (1.6) |
| Major complications | 9 (1.3) | 0 (0.0) | 9 (1.6) |

**Deaths:**
| Intra-operative period, procedure-related | 1 (0.15) | 0 (0.0) | 1 (0.2) | 1.00 |
|----------------------------------------|----------|---------|---------|------|
| Post-operatively within 30 days after TLE, procedure-related | 0 (0.0) | 0 (0.0) | 0 (0.0) | 1.00 |
| Post-operatively within 30 days after TLE, non-procedure-related | 16 (2.4) | 5 (5.6) | 11 (1.9) | **0.04** |

Data are presented as number (percentage) or mean (SD); median; IQR.

Abbreviations: EP, elderly patients; ICD, implantable cardioverter-defibrillator; TLE, transvenous lead extraction; YP, young patients.

a - including LV leads
Table 3. Predictors of all-cause mortality within 30 days after TLE

| Variable                                      | Univariable |            |          | Multivariable |            |          |
|-----------------------------------------------|-------------|------------|----------|---------------|------------|----------|
|                                               | OR          | 95% CI     | P value  | OR            | 95% CI     | P value  |
| EP group vs YP group                          | 3.027       | 1.026-8.926| **0.045**| 3.058         | 0.758-12.339| 0.12     |
| Female sex                                    | 1.069       | 0.384-2.979| 0.90     |               |            |          |
| LVEF, 1% decrease                            | 1.035       | 1.002-1.068| **0.04** | 1.000         | 0.950-1.053| 0.99     |
| BMI, 1 kg/m2 decrease                        | 1.071       | 0.955-1.200| 0.24     |               |            |          |
| LDIE indication for TLE                       | 23.375      | 7.843-69.668| **<0.001**| 3.307         | 0.843-12.966| 0.09     |
| Hb, 1 g/dL decrease                          | 2.024       | 1.572-2.604| **<0.001**| 1.642         | 1.178-2.278| **0.003**|
| Charlson Comorbidity Index, 1 point increase  | 2.274       | 1.614-3.203| **<0.001**| 1.836         | 1.193-2.827| **0.006**|
| Number of extracted leads at index procedure, 1 lead increase | 4.583       | 2.171-9.672| **<0.001**| 3.441         | 1.330-8.903| **0.01** |
| Combined age of extracted leads, 1 year increase | 0.989       | 0.938-1.044| 0.70     |               |            |          |
| Dual-coil ICD lead extraction                 | 3.035       | 0.835-11.034| 0.09     | 1.979         | 0.308-12.730| 0.47     |
| Total fluoroscopy time during all leads extraction, 1 min increase |  |  |  |
|---|---|---|---|
| 0.920 | 0.770-1.100 | 0.36 |  |

| Major complication of TLE |  |  |  |
|---|---|---|---|
| 5.358 | 0.630-45.588 | 0.12 |  |

Abbreviations: BMI, body mass index; CI, confidence interval; EP, elderly patients; Hb, hemoglobin; ICD, implantable cardioverter-defibrillator; LDIE, lead-dependent infective endocarditis; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; OR, odds ratio; TLE, transvenous lead extraction; YP, young patients.