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Mortality after transvenous lead extraction: A risk prediction model for sustainable care delivery

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Abstract

Background and Aims: Transvenous lead extraction (TLE) has become a pivotal part of a comprehensive lead management strategy, dealing with a continuously increasing demand. Nonetheless, the literature about the long-term impact of TLE on survivals is still lacking. Given these knowledge gaps, the aim of our study was to analyse very long-term mortality in patients undergoing TLE in public health perspective.

Methods: This prospective, single-centre, observational study enrolled consecutive patients with cardiac implantable electronic device (CIED) who underwent TLE, from January 2005 to January 2021. The main goal was to establish the independent predictors of very long-term mortality after TLE. We also aimed at assessing procedural and hospitalization-related costs.

Results: We enrolled 435 patients (mean age 70 ± 12 years, with mean lead dwelling time 6.8 ± 16.7 years), with prevalent infective indication to TLE (92%). Initial success of TLE was achieved in 98% of population. After a median follow-up of 4.5 years (range: 1 month–15.5 years), 150 of the 435 enrolled patients (34%) died. At multivariate analysis, death was predicted by: age (≥77 years, OR: 2.55, CI: 1.8–3.6, $p < 0.001$), chronic kidney disease (CKD) defined as severe reduction of estimated glomerular filtration rate (eGFR <30 mL/min/1.73 m^2, OR: 1.75, CI: 1.24–2.4, $p = 0.001$) and systolic dysfunction assessed before TLE defined as left ventricular ejection fraction (LVEF) <40%, OR: 1.78, CI 1.26–2.5, $p = 0.001$. Mean extraction cost was €5011 per patient without reimplantation and €6336 per patient with reimplantation respectively.

Conclusions: Our study identified three predictors of long-term mortality in a high-risk cohort of patients with a cardiac device infection, undergoing successful

Maria Lucia Narducci and Eleonora Ruscio contributed equally to this study.

TLE. The future development of a mortality risk score before might impact on public health strategy.

KEYWORDS

chronic renal disease, elderly, long-term outcomes, mortality risk, personalized medicine, public health, sustainability, systolic dysfunction, transvenous lead extraction

1 | BACKGROUND

As a result of growing life expectancy and broadening indication, there has been a significant increase in the proportion of cardiac implantable electronic device (CIED) with consequent increase of infection rate, prevalence of comorbid and frail recipients, lead dysfunction, system revisions and upgrade.[1–3] Thus, transvenous lead extraction (TLE) has become a pivotal part of a comprehensive lead management strategy,[4] dealing with a continuously increasing demand.[5] Nonetheless, literature about the long-term follow-up of patients undergoing TLE is still lacking. In particular, short-term safety and efficacy of TLE have been extensively investigated,[2,6,7] while reports on very long-term outcomes after TLE are still limited and particularly focused on infection-related predictors of mortality.[8–15] Moreover, there is evidence in the scientific literature of substantial costs associated with extraction and reimplantation procedures.[16] Given these knowledge gaps, the aim of our study was to provide a careful analysis of very long-term mortality from a single high-volume tertiary referral centre for TLE, in a public health perspective, with regard to the sustainability of TLE procedure and clinical follow-up. In addition to that, we evaluated and reported the costs of CIED extraction and reimplantation in a long term follow-up perspective.

2 | METHODS AND MATERIALS

2.1 | Study design and patient population

This prospective, single-centre, observational study consecutively enrolled 451 patients with indication for TLE, according with 2018 EHRA expert consensus statement.[5] Patients were admitted from spoke centres to our TLE hub centre, from January 2005 to January 2021. Exclusion criteria were as follows: age <18 years, pregnancy and life expectancy <6 months.

The enrolment started at the time of TLE. All the population was followed-up for early (before discharge) and long-term (after discharge) mortality. Institutional Ethics Committee approval (prot. 202/18, study ID 1846) was taken and a written informed consent was obtained from each participant.

2.2 | Data collection and data management

Thorough information about the patients' history, clinical and echocardiographic data, intracardiac device data, extraction indication, comorbidities, procedural success, hospitalization length, early (before discharge) and long-term follow-up (after discharge) mortality data were collected on case report forms.

Major complications were defined as hemopericardium requiring cardiac surgery, haemothorax requiring cardiac surgery and pericardial tamponade requiring drainage. Minor complications were defined as tricuspid valve damage, pericardial effusion not requiring drainage, haematoma, femoral venous thrombosis and surgical site haematoma.

Particularly, chronic kidney disease was defined according with NICE UK-KDIGO US guideline[17]; reduced LVEF is defined as ≤40%, as recently reported on the Universal Definition and Classification of Heart failure.[18] The consistency and accuracy of the data have been audited by health data management. Direct medical costs associated with the procedure and the hospitalization were derived from the Diagnosis Related Group (DRG) reimbursements our Institution received from Region Lazio in Italy.

2.3 | Transvenous lead extraction

All patients with indication for TLE of CIED were treated in the hybrid room or electrophysiology laboratory, according to current guidelines.[2,5,19] Definitions for TLE procedures and outcomes were derived from EHRA expert consensus statement.[5]

The following TLE techniques were used in a stepwise manner: simple manual traction, mechanical dilators and powered tools (laser and hand-powered sheaths).

Pacemaker-dependent patients received a percutaneous active fixation lead, which was placed in the right ventricle and connected to an external pacemaker. After

extraction, all patients received 24-h intensive care unit (ICU) monitoring for occurring complications and were secondarily transferred to Arrhythmology Unit, until the discharge. Patients come from spoke centres were back transferred to the source centre after achieving clinical stabilization. Early mortality and related causes were evaluated before discharge.

2.4 | Follow-up and outcome

All patients were followed at regular intervals (every 12 months) for complete clinical evaluation, reassessment of reimplantation indication and device interrogation. Mortality data were collected using the "Regione Lazio SISMED portal" and Death Records by hub and spoke centres, in order to determine the cause of death.

2.5 | Statistical analysis

Continuous variables were expressed as mean ± SD. Categorical data were expressed as frequencies and percentages. Two-sided *p*-values <0.05 were considered statistically significant.

To assess long-term predictors of mortality after TLE, the Cox proportional hazards regression model was used. The statistical models were adjusted for typical risk factors and potential baseline confounders including sex, age, type of the extracted device, indication for the extraction, major and minor complications, procedural failure and cardiovascular risk factors.

Statistical analysis was performed using SPSS Version 23.0.0 (Statistical Package for Social Sciences Inc.) and STATA 17.0 software (Stata Corporation).

3 | RESULTS

3.1 | General population findings

We enrolled 451 patients, with 16 patients (3%) lost to follow-up and consequently a total population of 435 patients. Table 1 showed the main baseline characteristics of our cohort (435 patients, mean age was 70 ± 12, male prevalence: 77%), with evidence of systolic dysfunction (mean left ventricular ejection fraction LVEF: 44% ± 13%) and high rates of comorbidities (14% of patients affected by coexisting hypertension, diabetes mellitus and severe chronic renal disease, 86% of patients affected by two of these risk factors).The source hospital in 269 patients (62% of population) was our hub centre, whereas 38% of patients were referred from spoke centres to our hub in order

TABLE 1 Baseline characteristics of patients included in the study.

Clinical characteristics all population (*n* = 435)	
Age, years, mean ± SD	70 ± 12
Male, *n* (%)	337 (77)
Lead dwelling time, months, mean ± SD	81.7 ± 201.2
Total leads extracted, *n*	929
Source hospital (FPG), *n* (%)	269 (62)
TLE room (EP room/hybrid room)	282/153 (65/35)
TLE indication (infection/malfunctioning), *n* (%)	396/39 (92/8)
Procedural success rate *n* (%)	426/435 (98%)
Major complications *n* (%)	8/435 (1.8%)
Minor complications *n* (%)	36/435 (8.3%)
LVEF, %, mean ± SD	44 ± 13
Chronic kidney disease[a], *n* (%)	166 (38)
Diabetes mellitus, *n* (%)	136 (31)
Hypertension	328 (78)
Type of infection	
Definite endocarditis, *n* (%)	201 (46)
Sepsis/bacteraemia only, *n* (%)	174 (40)
Endocarditis + sepsis/bacteraemia, *n* (%)	81 (19)
Pocket infection only, *n* (%)	295 (68)
Pocket infection + sepsis/bacteraemia, *n* (%)	100 (23)
Device extracted	
PM, *n* (%) 211 (49)	
ICD, *n* (%) 224 (51)	
Type of device	
Bicameral, *n* (%)	222 (51)
Biventricular, *n* (%)	122 (28)
Monocameral, *n* (%)	91 (21)
Reimplanted patients, *n* (%)	313 (72)
Reimplanted with an ICD *n* (%)	162 (52%)
Therapy	
ACEi/sartans, *n* (%)	261 (60)
Beta-blockers, *n* (%)	300 (69)
ASA, *n* (%)	177 (41)
Statin, *n* (%)	197 (45)
AADs, *n* (%)	82 (19)
Diuretics, *n* (%)	238 (55)
Antibiotics iv[b]	338 (78)
Extraction costs analysis	
Extraction hospitalization length, days, mean ± SD	27 ± 21
Cost (euros) per patient	5989 ± 7751
• Without reimplantation (*n* = 122, 28%)	5011 ± 6535
• With reimplantation (*n* = 313, 72%)	6336 ± 8108

Abbreviations: AADs, antiarrhythmic drugs; ACEi, Angiotensin-converting enzyme inhibitors; DRG, diagnosis-related group; EP room, Electrophysiology room; FPG, Foundation Policlinico Gemelli; LVEF, left ventricular ejection fraction.

[a]Chronic kidney disease defined as eGFR <30 mL/min.

[b]Empirical intravenous (IV) antibiotics administration before TLE.

to perform TLE. Noteworthy, on a total of 929 extracted leads, the mean lead dwelling time was 6.8 ± 16.7 years. The majority of extracted devices were bicameral (51%). Three hundred ninety-six patients (92%) presented with an infective indication to TLE, whereas the remaining 39 patients (8%) underwent TLE due to a malfunctioning cause. In particular, the most frequent indications to TLE were pocket infection (68%) and definite CIED endocarditis (46%). Complete procedural success rate was reached in 98% of patients. Furthermore, 313 patients (72%) were reimplanted before discharge, with 162 patients receiving an ICD (52%) (Table 1).

3.2 | Follow-up: mortality outcomes, long-term predictors

The median follow-up time was 54 months (4.5 years). We found that 182 out of the 435 total enrolled patients died, with a global mortality rate of 41%. In particular, early mortality (first 30 post-operative days) rate accounted for 32 patients (7%) and long-term mortality rate for 150 patients (34%) of the total population. With regard to early mortality causes, the most frequent was sepsis (accounting for 16 patients, 50% of deaths), followed by cardiovascular nonarrhythmic causes (10 patients, 31% of deaths, including ischaemia, pulmonary embolism and heart failure), intra-procedural complications (two patients, 6%), noncardiovascular events (three patients, 9%) and arrhythmic cause (one patient, 3%). The most frequent cause of long-term mortality was represented by multiple chronic diseases (94 patients out of 150 deaths, 62%); secondly, nonarrhythmic cardiovascular causes accounted for 36 patients (24% of deaths), sepsis for six patients (4%) (Figure 1). Procedural success was 98% and rates of major and minor complications were 1.8% and 8.3% respectively. Early mortality (before discharge) did not differ between patients undergoing extraction for infection and malfunction. We reimplanted a new device in 313 patients (72%), with 11 patients upgraded from pacemaker to ICD group and six patients downgraded from ICD to PM. Patients reimplanted with an ICD were 162/313 (52%). There were no differences of survival at follow-up between PM versus ICD recipients. Device reimplantation was not a predictor of long-term mortality at follow-up (PM reimplantation OR = 0.93, CI 0.63–1.37, p ns, ICD reimplantation: OR = 1.2, CI 0.85–1.73, p ns).

At follow-up, only a minority[4] of patients had reinfection of the reimplanted cardiac device. They all underwent another successful extraction procedure and one died of pneumonia 2 months later. Moreover, after dividing our population in three consecutive 5-year period cohorts, we did not find significant baseline clinical differences from 2005 to 2010, from 2011 to 2015 and from 2015 to 2021. The mean hospitalization length did not change between groups when dividing the overall population in the three aforementioned cohorts.

At univariate analysis, as showed in Table 2, long-term mortality predictors were as follows: chronic kidney disease defined as severe reduction of eGFR (<30 mL/min/1.73m^2), elderly, referral from spoke centres, diabetes, left ventricular (LV) systolic dysfunction defined as LVEF ≤40%, infective indication to TLE, sepsis at admission, number of extracted leads, intravenous antibiotic therapy and diuretics. At multivariate analysis, long-term mortality independent predictors were represented by advanced age, severe chronic kidney disease and reduced LVEF (Table 3, Figure 2).

Kaplan–Meier curves summarized the different survival on the basis of three independent predictors of long-term mortality (Figures 3A–C). At 54 months of follow-up, elderly patients with severe chronic kidney disease and patients with LV systolic dysfunction had a higher mortality rate compared to younger, patients with normal or mild chronic kidney disease and patients with LVEF >40% (Figure 3A–C). Particularly, Kaplan–Meier analysis demonstrated a cumulative mortality rate of 83% in patients with age ≥77 years, 68% in patients with severe chronic kidney disease and 73% in those with LV systolic dysfunction at 90 days from discharge.

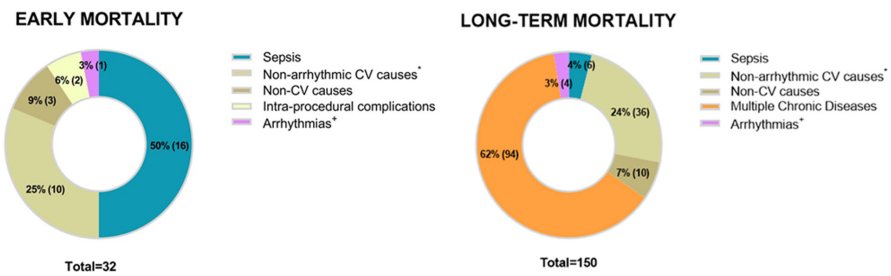

FIGURE 1 Early and long-term mortality pie charts (n = 435 patients). *Nonarrhythmic cardiovascular (CV) causes: ischaemia, pulmonary embolism and heart failure. +Arrhythmias: ventricular tachycardia, ventricular fibrillation and pulseless electrical activity.

TABLE 2 Univariate analysis of long-term mortality predictors.

Univariate analysis			
	OR	**IC 95%**	***p*-Value**
Chronic kidney disease[a]	2.67	1.77–4.02	<0.001
Age (>77 years)	2.56	1.70–3.86	<0.001
Diabetes mellitus	1.55	1.02–2.36	0.040
LVEF (%)	0.98	0.96–0.99	0.006
Major bleeding	3.25	1.32–8.03	0.011
Infective indication	4.72	1.64–13.62	0.004
Number of extracted leads (>3)	1.46	1.12–1.90	0.005
Antibiotics iv[b]	2.38	1.39–4.07	0.002
Diuretics iv[c]	1.67	1.11–2.51	0.013
PM reimplantation	0.93	0.63–1.37	ns
ICD reimplantation	1.2	0.85–1.73	ns

Abbreviations: ICD, Implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; PM, pacemaker.

[a]Chronic kidney disease defined as eGFR <30 mL/min.

[b]Empirical intravenous (IV) antibiotics administration before TLE.

[c]Intravenous diuretics as surrogate index of heart failure.

TABLE 3 Multivariate analysis of long-term mortality predictors.

Multivariate analysis			
	OR	**IC 95%**	***p*-Value**
Chronic kidney disease[a]	1.75	1.24–2.4	0.001
Age (>77 years)	2.55	1.8–3.6	<0.001
LVEF (%)	1.78	1.26–2.5	0.001
Major bleeding	0.91	0.5–1.64	ns
Diabetes mellitus	1.15	0.70–1.87	ns
Infective indication to TLE	2.66	0.69–10.15	ns
Number of extracted leads (>3)	1.11	0.81–1.52	ns
Antibiotics iv[b]	1.53	0.81–2.89	ns
Diuretics iv[c]	1.47	1.03–2.09	<0.005

Abbreviations: LVEF, left ventricular ejection fraction; ns, not significant.

[a]Chronic kidney disease defined as eGFR <30 mL/min.

[b]Empirical intravenous (IV) antibiotics administration before transvenous lead extraction (TLE).

[c]Intravenous diuretics as surrogate index of heart failure.

3.3 | TLE procedure cost description

In relation to the direct medical costs associated with the clinical activities, the mean costs were €5989 ± €7751 per TLE procedure. Patients undergoing reimplantation showed, obviously, notably higher costs per patient (€6336 ± €8108) compared to patients who did not receive another implantable device (€5011 ± €6535). Table 4 specifies healthcare costs relative to the various phases of the hospital stay (intervention, reimplantation, intensive care unit stay, cardiology ward stay and outpatient visits). Cost per year lived was 1331 ± 1772 € per patient, a value that however does not take into account costs associated with medical assistance after TLE, such as subsequent hospitalizations and follow-up visits. Total costs amounted to €2,606,215, over the period of the study, of which €1,983,168 for patients with reimplantation and €611,342 for patients without reimplantation.

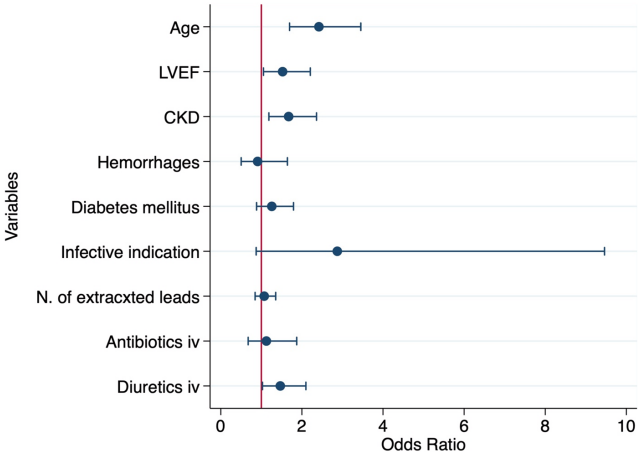

FIGURE 2 Forest plot of predictors at multivariate analysis.

4 | DISCUSSION

This observational single-centre prospective cohort study with 435 patients undergoing TLE showed a high long-term mortality, also after a complete resolution of CIED infection. With a very long-mortality rate of 34%, this first analysis on the cause of death data after TLE, supported the notion that the survival continues to be burdened by multiple chronic diseases progression, beyond the clinical resolution of infection.

In the last two decades, numerous reports of single and multi-centres experiences outlined mainly positive short-term results, paving the way for guidelines definition.[7] The largest 'real-word' prospective registry confirmed both 'acute' safety and efficacy of TLE, with a complete clinical success of 96.7% and all cause in-hospital deaths of 1.2% in high volume centres.[2] Nonetheless, evidences on long-term mortality after TLE are still scarce, as described by recent studies focused on 'CIED infection'-related predictors of long-term outcomes after TLE.[8–15]

Our results showed how patients undergoing a successful TLE, especially for an infective cause, remain at high-risk of death at median follow-up of 54 months due to progression of underlying multiple chronic diseases.

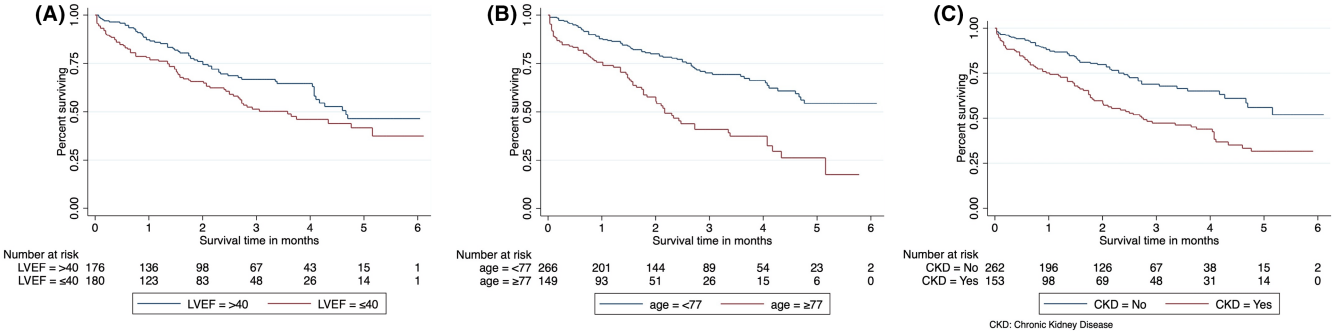

FIGURE 3 (A) Survival curve for independent predictors significant at multivariate analysis: Left ventricular ejection fraction (LVEF≤ or >40%). (B) Survival curve for independent predictors significant at multivariate analysis: Age (< or ≥77 years). (C) Survival curve for independent predictors significant at multivariate analysis: chronic kidney disease (defined as eGFR <30 mL/min/1.73 m^2).

TABLE 4 Mean costs associated with extraction and reimplantation procedures per patient.

	Cost (€)
Transvenous lead extraction	1882
Reimplantation	1325
Intensive care unit stay per day	648
Cardiology ward stay per day	91
Outpatient visits per visit	63

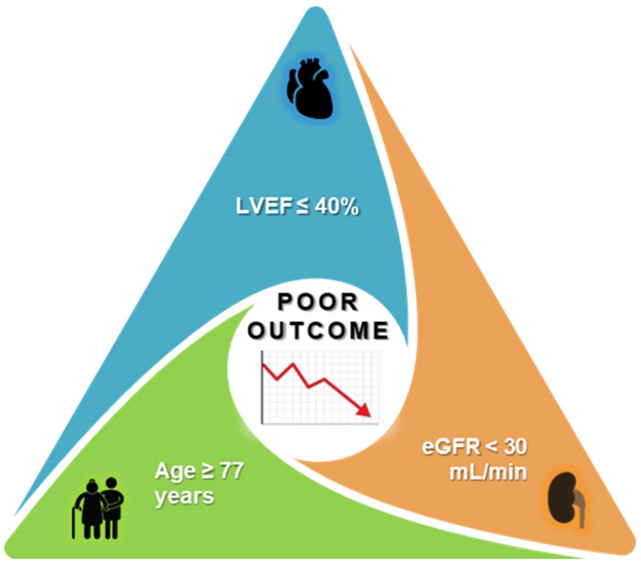

FIGURE 4 Independent baseline predictors of long-term mortality risk after TLE.

Conversely, the infective cause is the leading cause of death before discharge. However, it should be noted that, after the initial phase of short- and medium-term follow-up in which mortality may be due to septic relapses or complications such as valvular insufficiencies or heart failure, the mortality of the population could be similar to that of an equivalent group of patients.

Moreover, we observed a relatively short-time interval to death after discharge in elderly subjects, in patients with severe CKD and systolic LV dysfunction.

More in detail, our population is high-risk population with high rates of comorbidities and 92% of patients with evidence of infection as TLE indication: as formerly stated, infective indication itself represents a mortality risk enhancer as showed By Mehta et al.[11] Nonetheless, clear evidence regarding mortality rates for untreated patients supports the indication TLE in case of CIED-related infections.[20]

With particular regard to long-term predictors, the postprocedural risk conveyed by age confirms previous findings[12] as also the risk conferred by chronic kidney disease strongly supported by the literature, mainly with regard to short-term follow-up.[10,12,15,21]

Conversely, long-term data on systolic LV dysfunction after TLE remained unclear. According to Metha et al,[11] our results showed LV systolic dysfunction as an independent long-term predictor of death at multivariate analysis in patients undergoing TLE with CIED infection as indication. Recently, Nishii et al demonstrated that the survival rate after TLE was not significantly different between patients with LVEF ≤35% and those with LVEF >35% at 30 days and 1 year after TLE. Nevertheless, patients with systolic LV dysfunction were more likely to require additional haemodynamic support and temporary cardiac resynchronization therapy pacing after TLE and brain natriuretic peptide levels as marker of heart failure represented a significant predictor for 1-year mortality.[22]

With regard to lead-related data, number of extracted leads or dwelling time were not significant predictors of mortality in our cohort, but the impact of leads on long-term mortality was more noticeable in the noninfection group of patients undergoing TLE than in CIED infection group.[11]

As important limitation of our study focused on tertiary care centre data set, referral bias could have affected the clinical data, thereby limiting the generalization of our results to other populations.

Our findings suggest the urgent need for a risk score including age at explant, CKD and reduced LVEF, in larger populations undergoing TLE to better define not only the risk/benefit analysis of lead extraction and related follow-up by the multidisciplinary team but also the cost-effectiveness of this entire clinical pathway (Figure 4). In particular, risk stratification allows a coherent segmentation that divides patients into groups with relative service needs is a relevant foundation for effective, equitable and sustainable care delivery consistent with a public health perspective. This main clinical implication is strongly reinforced by the analysis of the costs related to the TLE procedure which showed a significant economic impact for the National Health Service with particular regard for reimplanted patients. A 'risk prediction model' should help optimizing clinical management since hospital admission, moving towards personalized, patient-centred medicine. Given the goal of improving outcomes, these assumptions also imply value-based care considerations in a global health perspective and economic sustainability. Given the current lack of such a risk prediction model, there is the need for individualized care and shared decision making, with a multidisciplinary approach that takes into consideration all the aspects previously discussed, such as expected procedural success, need for reimplantation, patient's clinical assistance after the event and, last but not least, the associated costs.

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CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author.

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