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Sex differences in long-term outcomes following transvenous lead extraction

Gianmarco Arabia MD, PhD[1] | Mohamed Aboelhassan MD[2] | Emiliano Calvi MD[1] | Manuel Cerini MD[1] | Maria Giulia Bellicini MD[1] | Luca Bontempi MD[3] | Daniele Giacopelli PhD[4] | Amr Nawar MD[5] | Abdallah Raweh MD[6] | Mohamed Magdy M. Abbas MD[7] | Antonio Curnis MD[1]

[1]Cardiology Department, Spedali Civili Hospital, University of Brescia, Brescia, Italy

[2]Cardiology Department, Assiut University Heart Hospital, Assiut University, Asyut, Egypt

[3]Unit of Cardiology, Cardiac Electrophysiology and Electrostimulation Laboratory, "Bolognini" Hospital of Seriate, ASST Bergamo Est, Bergamo, Italy

[4]Clinical Unit, Biotronik Italia, Cologno Monzese, Italy

[5]Critical Care Department, Cairo University, Giza, Egypt

[6]Cardiology Unit, Catholic University of the Sacred Heart, Rome, Italy

[7]Cardiology Department, Al Qassimi Hospital, Emirates Health Services, Sharjah, United Arab Emirates

Correspondence

Gianmarco Arabia, MD, PhD, Cardiology Department, Spedali Civili Hospital, University of Brescia, Piazzale Spedali Civili 1, Brescia 25123, Italy.
Email: gianmarcoarabia@gmail.com

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Abstract

Introduction: Transvenous lead extraction (TLE) is generally considered a safe procedure, albeit not without risks. While gender-based disparities have been noted in short-term outcomes following TLE, a notable gap exists in understanding the long-term consequences of this procedure. The objective of this analysis was to investigate sex differences in both acute and long-term outcomes among patients who underwent TLE at a tertiary referral center.

Methods: In this retrospective cohort study, consecutive patients who underwent TLE between January 2014 and January 2016 were enrolled. The primary outcome comprised a composite of all-cause mortality and need for repeated TLE procedures. Secondary outcomes included fluoroscopy time, lead extraction techniques, success rates, and major and minor complications. Results were compared between female and male cohorts.

Results: The study population comprised 191 patients (median age, 70 years), 29 (15.2%) being women and 162 men (84.8%). Study groups had similar baseline characteristics. Complete procedural success was achieved in 189 out of 191 patients (99.0%), with no significant difference observed between the two groups ($p = .17$). No major complications were reported in the total cohort. However, there was a significantly higher incidence of minor complications in women compared to men (17.2% vs. 2.5%, $p < .01$). Following a median follow-up of 6.5 years, the incidence of the primary composite outcome occurred similarly between the study groups (log-rank $p = .68$).

Conclusion: Women who underwent TLE exhibited a significantly higher incidence of minor acute intra- and peri-procedural complications than men. However, no differences in long-term outcomes between genders were observed.

Gianmarco Arabia and Mohamed Aboelhassan share the first coauthorship.

KEYWORDS
cardiac implantable electronic device, lead removal, sex disparities, transvenous lead extraction, women

1 | INTRODUCTION

The number of cardiac implantable electronic device (CIED) implantations has increased over recent years[1] with a consequent increase in rates of complications necessitating transvenous lead extraction (TLE). This procedure is generally acknowledged as safe and effective, particularly when conducted in specialized centers.

Women have been identified as predictors of peri-procedural complications in the context of CIED implantation.[2] Similarly, a gender-based disparity has been observed during TLE procedures in short-term follow-up.[3–5] However, a gap exists in the available body of knowledge regarding long-term outcomes following this procedure.[6]

The objective of this analysis was to explore sex differences in baseline characteristics and acute and long-term outcomes of patients who underwent TLE at a tertiary referral center.

2 | METHODS

2.1 | Study population

A retrospective cohort study was conducted, enrolling consecutive patients with CIEDs who underwent TLE for all causes and subsequently received device reimplantation between January 2014 and January 2016. Clinical, demographic, CIED-related, and TLE procedure related data were retrospectively extracted from electronic medical records.

All TLE procedures were performed by two experienced electrophysiologists at the Spedali Civili di Brescia, Italy, which is a high-volume center (>30 TLE procedures per year) in accordance with Heart Rhythm Society (HRS) guidelines.[7] All patients provided informed consent. The study was conducted in compliance with the principles of the Helsinki Declaration on human research and received approval from local institutional committees.

2.2 | Definitions

Clinical success of the procedure and major and minor complications were defined according to the 2017 HRS[7] and 2018 European Heart Rhythm Association (EHRA) guidelines.[8] Complete procedural success was defined as removal of all targeted leads. Major complications, according to the EHRA guidelines, were identified as those resulting in death, requiring urgent/emergency surgical intervention, or causing permanent disability. All other complications attributed to the extraction procedure were classified as minor.

2.3 | TLE procedure

Indications for TLE were categorized into infective, lead dysfunction, venous access issues, device upgrade, or other rare indications. A preoperative risk assessment was done for all patients using the LED index and MB score, both predicting complex procedures requiring advanced extraction tools.[9,10]

All procedures were performed in the electrophysiological laboratory with available cardiac surgery support. A standard stepwise approach was adopted, progressing from simple to more complex strategies. Once the device pocket was opened, the leads were detached and prepared for extraction by removing the anchors, severing the proximal portion, and retracting any active fixation mechanism if present. At the beginning of each case, two gentle manual traction attempts were made: the first with a regular stylet insertion, followed by a second attempt using a locking stylet. If initial traction indicated the presence of more than minor fibrosis but the fibrous adhesions were not deemed substantial enough to necessitate the immediate use of powered tools, a telescoping dilator sheath could be advanced over the lead to attempt detachment of fibrous adhesions. Should these initial measures prove ineffective, more advanced techniques were employed, primarily involving the use of powered sheaths. Either mechanical or laser sheaths were available at our sites and used at the discretion of the operating physician. In case of failure with the superior approach, a femoral approach was considered as a bailout strategy.

Blood culture and pocket culture tests were assessed to guide the antibiotic regimen and the optimal timing for reimplantation, in accordance with the 2023 ESC guidelines for endocarditis.[11] Transesophageal echocardiography (TEE) was performed in all patients with CIED-related infections to evaluate the presence of vegetations. The decision and scheduling for CIED reimplantation were collaboratively determined by electrophysiologists and infectious disease specialists. Generally, patients with infections underwent reimplantation after confirming negative blood cultures and ensuring no persistent intracardiac infectious remnants were observed on TEE. Pacing-dependent patients received temporary pacing before the reimplantation of the new device. Alternatively, a concurrent surgical approach was adopted, involving the placement of epicardial pacing leads. For patients with noninfective indications for TLE, transvenous device reimplantation was typically carried out during the same extraction procedure.

2.4 | Follow-up

Following the standard practice of the enrolling center, patients underwent postdischarge evaluations through outpatient visits at 1, 6, and 12 months, followed by subsequent assessments every 6 or 12 months to check the reimplanted device. During these follow-ups, the patient's clinical condition was evaluated, and any adverse events related to the extraction procedure were evaluated. Information on patients who did not undergo subsequent follow-up at the enrollment institution was gathered through surveys or via consultation with their primary care physician or the designated reference institution (if follow-up occurred elsewhere). The analysis considered data available as of June 30, 2022.

2.5 | Outcomes definition

The primary outcome was a composite of all-cause mortality and repeated TLE procedure. Secondary outcomes included fluoroscopy time, lead extraction technique, success rates, and major and minor complications. Results were compared between women and men.

2.6 | Statistical analysis

Data analysis was conducted using the STATA software, version 17.0 (StatCorp LP). All tests were two-tailed, and a p-value of <.05 was considered statistically significant. Continuous variables were presented as median [interquartile range, IQR] and compared between groups using the Mann–Whitney U test. Binary and categorical variables were expressed as absolute (relative) frequencies and analyzed with Pearson's $\chi 2$ test or Fisher's exact test, as appropriate. Long-term outcomes were compared between groups using the log-rank test. Results were displayed with Kaplan–Meier survival curves. As a sensitivity analysis, we also conducted a propensity score-based matching with the nearest-neighbor method without replacement to control for potential cofounders (Supporting Information S1: Table S1).

3 | RESULTS

The study population included 191 CIED patients who underwent TLE between January 2014 and January 2016 at our institution, with 29 (15.2%) being women and 162 (84.8%) men. Study groups had similar baseline characteristics, with a few exceptions. As compared to men, women had a lower body mass index and a lower prevalence of diabetes (6.9% vs. 24.1%, $p = .04$) and ischemic heart disease (24.1% vs. 43.8%, $p = .05$). There were no differences in terms of age, indication for TLE, and characteristics of the implanted system (Table 1). The risk of procedure difficulty, as assessed by LED and MB scores, was also similar between study groups ($p = .58$ and $p = .90$, respectively).

Complete procedural success was achieved in 189 out of 191 patients (99.0%), with no significant difference observed between the two groups ($p = .17$). Procedural characteristics are detailed in Table 2. The median fluoroscopy time was 9.5 min (IQR, 4.0–15.0) in women and 8 min (IQR, 3.0–15.0) in men, showing no significant difference ($p = .57$). Similar extraction tools were used across both groups. Overall, procedures were completed using manual traction with unpowered extraction sheaths in 72 patients (73.7%), powered mechanical sheaths in 95 patients (49.7%), and laser sheaths in 95 patients (49.7%). However, the use of snare through femoral approach was more frequent in women ($n = 4$, 13.8%) compared to men ($n = 3$, 1.9%) ($p = .01$).

In the overall population, there were nine minor complications (4.7%) and no major complications. These minor complications included transient hypotension ($n = 7$, 3.7%), pericardial effusion not requiring invasive intervention ($n = 2$, 1.0%), and sustained ventricular tachycardia requiring electrical cardioversion ($n = 2$, 1.0%). Notably, there was a significantly higher incidence of minor complications in women compared to men (17.2% vs. 2.5%, $p < .01$) (Table 2).

After a median follow-up of 6.5 years (IQR, 5.4–7.1), the incidence of the primary composite outcome (all-cause death or repeated TLE) occurred similarly between the study groups (log-rank $p = .68$, Figure 1). All-cause death occurred in 5 women (17.2%) and 33 men (20.4%) ($p = .70$), with the most frequent reason of death being noncardiac (20/38, 52.6%). The rate of repeated TLE was also not significantly different between groups (3.4% vs. 6.2%, $p = .52$). Kaplan–Meier survival curves for the primary endpoint components are depicted in Figure 2. Sensitivity analysis performed using propensity score-matched groups yielded consistent results (Supporting Information S1: Figure S1).

4 | DISCUSSION

The present study included 191 patients undergoing TLE, with women accounting for 15% of the cohort. The acute minor complication rate was 4.7%, and no major complications were observed. The median follow-up was 6.5 years, revealing a mortality rate of 37.6%. The main findings indicate that women exhibited a significantly higher incidence of minor acute intra- and peri-procedural complications. Nevertheless, there are no distinct differences in worse long-term outcomes between genders.

In the early study conducted by Byrd et al. (involved 1684 TLE patients, with major and minor complications observed in 1.9% and 1.4%, respectively), female sex emerged as the only predictor of complications in a multivariate model.[12] Similarly, Deshmukh et al., in a nationwide database study including 91 890 TLE patients, identified female gender as an independent predictor of complications [hazard ratio 1.19 (1.12–1.26), $p < .001$].[13] Bongiorni et al., including 3510 TLE patients, reported a major complication rate of 1.7%, with female gender being one of the predictors of major complications, including deaths.[14] In a study by Sood et al., involving 11 304 TLE patients,

TABLE 1 Characteristics of study cohort at transvenous lead extraction.

Variable	All (*n* = 191)	Women (*n* = 29)	Men (*n* = 162)	*P*-value
Age (years)	70 (61–77)	74 (65–78)	70 (61–77)	.22
BMI (Kg/m^2)	25.8 (23.0–27.7)	23.0 (21.4–26.2)	26.1 (23.7–27.8)	< .01
Creatinine (mg/dL)	1.60 (1.34–1.80)	1.55 (1.50–1.70)	1.60 (1.30–1.80)	.90
Medical history (*n*,%)				
Atrial fibrillation	65 (34.0%)	10 (34.5%)	55 (33.9%)	.96
Chronic kidney disease	57 (29.8%)	6 (20.7%)	51 (31.5%)	.24
Diabetes	41 (21.5%)	2 (6.9%)	39 (24.1%)	.04
CABG	25 (13.1%)	2 (6.9%)	23 (14.2%)	.28
Valvular prosthesis	13 (6.8%)	2 (6.9%)	11 (6.8%)	.98
Cardiomyopathy (*n*,%)				
Ischemic	78 (40.8%)	7 (24.1%)	71 (43.8%)	.05
Dilated idiopathic	40 (20.9%)	7 (24.1%)	33 (20.4%)	.65
Congenital	10 (5.2%)	2 (6.9%)	8 (4.9%)	.66
Device type (*n*, %)				.62
PM	65 (34.0%)	15 (51.7%)	50 (30.9%)	
CRT-P	9 (4.7%)	3 (10.3%)	6 (3.7%)	
ICD	55 (28.6%)	6 (20.7%)	49 (30.2%)	
CRT-D	62 (32.3%)	5 (17.2%)	57 (35.2%)	
Indication for lead removal (*n*, %)				.52
Infection	96 (50.3%)	13 (44.8%)	83 (51.2%)	
Lead dysfunction	69 (36.1%)	12 (41.4%)	59 (36.4%)	
Device upgrade	18 (9.4%)	2 (6.9%)	16 (9.9%)	
Thrombosis/stenosis	4 (2.1%)	2 (6.9%)	4 (2.4%)	
Leads to be extracted (*n*)	2 (1–3)	2 (1–3)	2 (1–3)	.81
Oldest targeted lead (years)	6.9 (3.7–9.3)	6.8 (2.6–10.3)	6.9 (3.8–9.2)	.84
Previous pocket revision (*n*, %)	49 (25.8%)	10 (34.5%)	39 (24.2%)	.25
Infection exams (*n*, %)				
Presence of vegetation	54 (28.3%)	8 (27.6%)	46 (28.4%)	.84
Positive pocket cultures	25 (13.1%)	4 (13.8%)	21 (13.0%)	.71
Positive blood cultures	26 (13.6%)	5 (17.2%)	21 (13.0%)	.24
LED index	9 (6–12)	9 (3–13)	9 (6–12)	.58
MB score	4 (2–4)	4 (2–4)	4 (2–4)	.90

Note: Data are shown as median (interquartile range) or as number (% of nonmissing data).

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CRT-P/D, cardiac resynchronization therapy pacemaker/defibrillator; ICD, implantable cardioverter defibrillator; PMpacemaker.

where the incidence of major complications was 2.3%, female gender emerged as one of the independent predictors of complications in both pacing and high-voltage TLE for both univariate (odds ratio 1.35, *p*-value = .02) and multivariate analysis (adjusted odds ratio 1.46, *p*-value < .01).[15] Similarly, in a study by Kutarski et al. enrolling 2049 TLE patients (major complication rate was 1.8%), female gender was identified as a risk factor for major complications and cardiac tamponade.[16]

More recently, the ELECTRa study observed a higher rate of major complications (1.96% vs. 0.71%, $p = .0025$) and lower procedural success (98.14% vs. 99.21%, $p = .0098$) among women.[4] Another analysis from the registry demonstrated that women were

TABLE 2 Procedural characteristics.

Variable	All (*n* = 191)	Women (*n* = 29)	Men (*n* = 162)	*P*-value
Procedure characteristics				
Fluoroscopy time (minutes)	8.0 (3.0–15.0)	9.5 (4.0–15.0)	8.0 (3.0–15.0)	.57
Extraction techniques (*n*, %)[a]				
Manual traction	72 (37.7%)	9 (31.0%)	63 (38.9%)	.42
Mechanical sheath	95 (49.7%)	14 (48.3%)	81 (50.0%)	.87
Laser sheath	95 (49.7%)	16 (55.2%)	79 (48.8%)	.53
Snares via femoral route	7 (3.7%)	4 (13.8%)	3 (1.9%)	.01
Outcome (*n*, %)				.17
Complete procedural success	189 (99.0%)	28 (96.6%)	161 (99.4%)	
Partial procedural success	2 (1.0%)	1 (3.5%)	1 (0.6%)	
Unsuccessful procedure	0 (0%)	0 (0%)	0 (0%)	
Concomitant CIED reimplant (n, %)	94 (49.7%)	16 (59.3%)	78 (48.2%)	.29
Use of temporary pacemaker (n, %)	62 (33.2%)	8 (30.8%)	54 (33.5%)	.78
Major complications (n,%)	0 (0%)	0 (0%)	0 (0%)	-
Minor complications (n,%)	9 (4.7%)	5 (17.2%)	4 (2.5%)	< .01
Hypotension	7 (3.7%)	4 (13.8%)	3 (1.9%)	-
Pericardial effusion	2 (1.0%)	1 (3.5%)	1 (0.6%)	-
Sustained ventricular tachycardia	2 (1.0%)	2 (6.9%)	0 (0%)	-

Abbreviation: CIED, cardiac implantable electronic device.

[a]Percentages do not add up to 100% because more than one technique was successfully used to achieve the extraction of a lead in a single procedure.

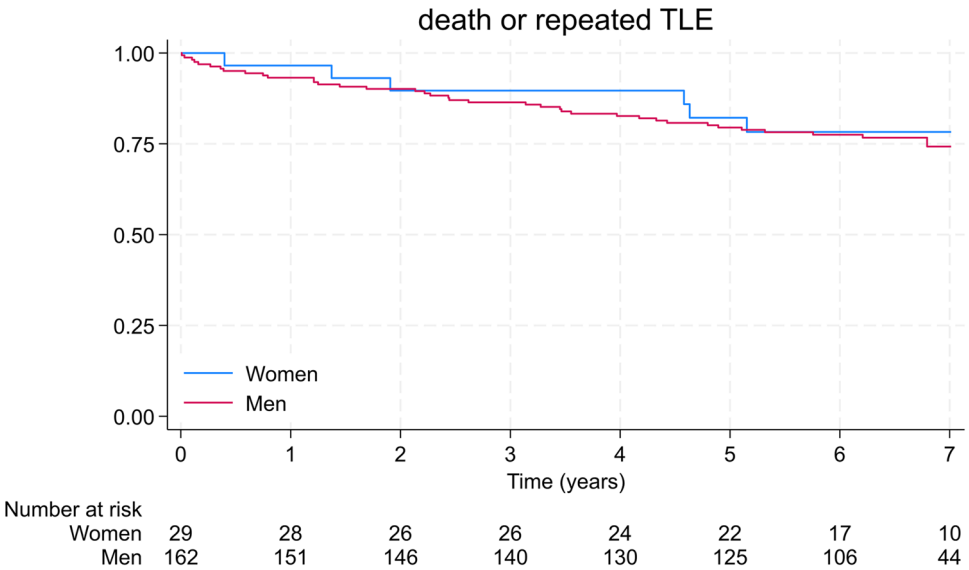

FIGURE 1 Kaplan–Meier survival curve for death or repeated transvenous lead extraction (TLE) in women and men.

at greater risk of major cardiac and vascular complications following TLE.[17] In our study, complete procedural success was achieved at a rate of 99%. This was accomplished using comparable extraction tools in both groups that had comparable preprocedural MB and LED scores (both dedicated for prediction of difficulty and need of advanced TLE tools). However, the use of snare through femoral approach, employed as a bailout technique, was significantly more frequent in women. This could suggest a higher prevalence of

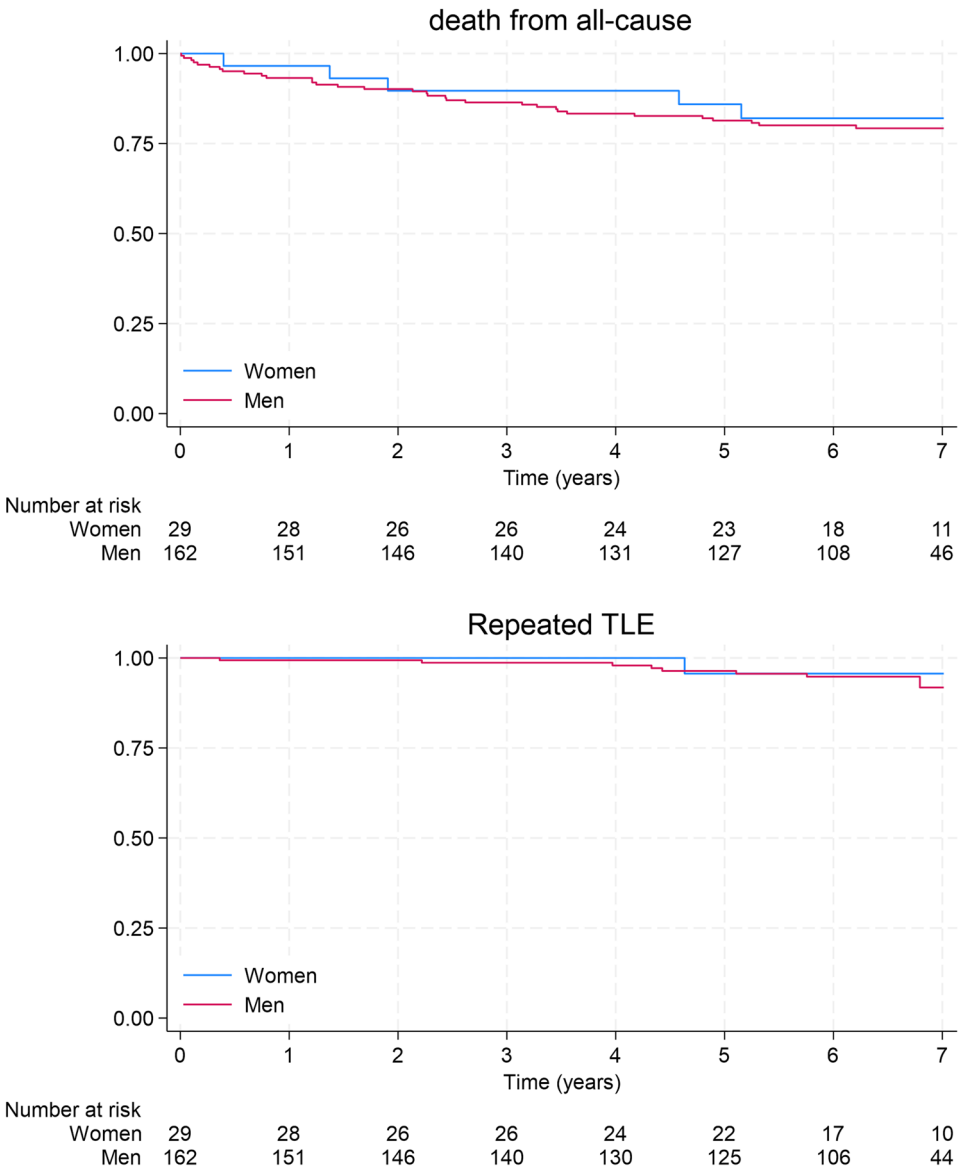

FIGURE 2 Kaplan–Meier survival curve for death from all-cause (above panel) and repeated transvenous lead extraction (TLE) (below panel) in women and men.

extensive adhesions in women compared to men, causing higher rates of failure with the superior approach.

On the other hand, some other studies did not observe an elevated risk of TLE-related complications in women. Brunner et al. included 2999 TLE procedures and found no significant sex differences in acute complications or 30-day all-cause mortality.[18] Similarly, a retrospective study of more than 1000 TLE procedures by Maytin et al. showed no significant adjusted risk based on male sex [hazard ratio 0.94 (0.64–1.39), $p = .77$].[19]

The reason for an association between female sex and procedure-related complications is a matter of debate. Various hypotheses have been proposed, including anatomical factors such as smaller vessels, thinner myocardial/venous walls, and more extensive lead adhesions in women.[20] Moreover, lenient decision-making in lead failure management, with a tendency toward abandonment rather than TLE, could contribute to increased lead dwell time and subsequently increased procedural risk.[21,22] Another factor to consider is that, despite a higher incidence of CIED-related infections in men, women have a greater risk of worse clinical course of infection and mortality.[23–26]

It is important, however, to elucidate that the observed increased risk of procedural complication in women is not associated with worse long-term outcomes. In the present study, despite the observed higher incidence of minor acute intra- and peri-procedural complications in female patients undergoing TLE, there were no significant differences in worse long-term outcomes. The follow-up period extended up to 6.5 years, and female patients did not exhibit adverse effects in terms of the primary endpoints, which included a composite of death from any cause and repeated TLE, as well as individual outcomes such as all-cause deaths and repeated TLE.

This suggests that while there may be heightened procedural complexities for women, it does not necessarily translate into poorer long-term prognosis.

Prior studies specifically evaluating long-term mortality, such as those by Deharo et al. [$n = 197$, hazard ratio 0.78 (0.41–1.47), $p = .439$] and Habib et al. [$n = 415$, hazard ratio 1.06 (0.74–1.50), $p = .76$], showed no difference in long-term mortality based on sex.[27,28] However, in a recent larger-scale notional database study conducted by Khalil et al., which included 71 754 TLE patients, female patients were associated with higher in-hospital complication and a higher 30-day readmission rate.[3] In a study recently conducted by Mehta et al. with a mean follow-up of 66 months, women undergoing TLE demonstrated more favorable long-term outcomes than men, with lower long-term mortality.[29]

The findings from the current study align with other research, reinforcing the robust evidence of an increased risk of complications in women during TLE. This emphasizes the importance of considering gender-specific factors in preprocedural risk stratifications. This may help in decision-making regarding choice of appropriate TLE tools, field, and center with the aim of mitigating the risk of complications. Importantly, despite the elevated procedural complexities for women, the study underscores that worse long-term outcomes are not higher in this group. Consequently, advocating for equal decisions in lead failure management for both genders is a prudent approach.

The results of this study are mainly limited by its retrospective design, which does not allow to consider any other unmeasured significant confounders. Despite the strength of a lengthy follow-up period, the sample size in our study was relatively small, with women comprising only a minority of our cohort (approximately 15%). This underrepresentation of women may suggest an underlying sex disparity in the clinical practice for this procedure. Additionally, the limited available statistical power restricted a thorough exploration of how various types of cardiomyopathy and age differences between genders might impact long-term outcomes. Given these limitations, further validation of our research through larger multicenter analyses is warranted.

5 | CONCLUSIONS

In this retrospective cohort study evaluating 191 patients who underwent TLE at a tertiary referral center, women exhibited a significantly higher incidence of minor acute intra- and peri-procedural complications compared to men. However, despite these heightened procedural complexities, there were no discernible differences in long-term outcomes between genders during a median follow-up of 6.5 years. These findings emphasize the importance of gender-specific considerations in TLE procedures for risk stratification and decision-making, ensuring optimal patient outcomes from both short- and long-term perspectives.

DATA AVAILABILITY STATEMENT

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

ORCID

Mohamed Aboelhassan http://orcid.org/0000-0002-8196-8878
Manuel Cerini http://orcid.org/0000-0002-8081-0577
Daniele Giacopelli http://orcid.org/0000-0003-1584-7944

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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